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The implementation of care regulations in residential disability services in Ireland

Thesis presented by

Paul Dunbar, BSocSc, MA

ORCID: 0000-0002-7325-3653

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School of Public Health, University College Cork, Ireland

Head of School/Department: Prof Ella Arensman

Supervisor(s): Prof John Browne, University College Cork, Ireland

Dr Laura Keyes (O'Connor),

(1) Health Information and Quality Authority, Ireland

(2) University of Limerick, Ireland

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Declaration

This is to certify that the work I am submitting is my own and has not been submitted for another degree, either at University College Cork or elsewhere. All external references and sources are clearly acknowledged and identified within the contents. I have read and understood the regulations of University College Cork concerning plagiarism and intellectual property.

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Publications

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Thesis abstract

Background

Governments seek to monitor quality and safeguard citizens through regulation of various industries. Regulation is common feature of health and social care systems worldwide. Despite its prevalence as an intervention, there is relatively little attention paid to regulation with respect to its implementation in health and social care services i.e. how is compliance achieved? The aim of this thesis is to investigate how care regulations are implemented in health and social care services, including the processes and strategies that support the implementation process.

Methods

We adopted a multiple-methods approach to this research, albeit that the majority of the work was qualitative in nature. An overarching approach for the original research components of this thesis was to adopt an implementation science approach and regard regulation as an intervention. Firstly, a systematic review was undertaken to identify determinants of regulatory compliance in health and social care services. Secondly, an analysis of compliance data and inspection reports relating to residential disability services in Ireland was conducted to determine the level of non-compliance with regulations and to identify causes of non-compliance. Thirdly, a qualitative interview study was undertaken to describe how managers of residential disability services in Ireland engage with the implementation of care regulations. This study examined managers' perspectives on regulation, the strategies, structures, and processes they use to implement it, and key factors shaping their approaches. Finally, a qualitative focus group study was carried out with inspectors of residential disability services in Ireland. This study sought to describe how inspectors worked to implement the regulation of residential care for people with disabilities in Ireland, focusing on their views about the regulatory system, the strategies they use to improve compliance and deal with poor performance, and the challenges they face in implementing these strategies.

Results

The systematic review found a large amount of studies (n=157), describing a wide range of determinants of regulatory compliance. The majority of studies were quantitative, located in the United States and focused on nursing homes. The analysis of compliance data and inspection reports showed that non-compliance with regulations was common in residential disability services in Ireland. Eight themes describing causes of non-compliance were identified, with the 'insufficient resources' theme appearing most frequently, followed by 'governance and management failings'. In the interview study with managers of residential disability services, five themes were identified. Managers sought to foster a positive culture towards regulation in order to support implementation. They had instituted a range of structural and process measures to promote compliance and had used various strategies to manage their relationship with inspectors and other external stakeholders. In the focus group study, four themes were identified. Inspectors used skill and strategy to support implementation in the services they regulated. Notwithstanding this, they encountered legislative and bureaucratic barriers that inhibited their capacity to regulate effectively.

Conclusion

This thesis has contributed to knowledge in the field of regulation of health and social care services by regarding regulation as an intervention and adopting an implementation science approach. Further research on the implementation of regulations and the effectiveness of regulation is merited given the prevalence of regulation as a quality improvement intervention in health and social care services.

CHAPTER 1: Regulation as a tool to address healthcare quality

1.1 Introduction

This thesis is concerned with the implementation of social care regulations in residential disability services in Ireland. This introductory chapter seeks to provide an overview of the problem by describing efforts to address healthcare quality variation; regulation as a tool to address quality concerns; the various theoretical approaches used to understand regulation; and the problem of implementing regulatory requirements i.e. achieving compliance.

I begin by firstly charting the emergence of medicine as a discipline and efforts towards standardisation and quality improvement. I then describe what is meant by regulation and outline some of the key works by authors in this field of study. What follows is an exploration of how regulation has been applied in a healthcare context and then I make the argument for treating regulation as a problem of implementation.

1.2 The emergence of healing as a discipline and efforts towards standardisation

While most modern nations have a regulatory framework governing the provision of health and social care, this is a relatively new phenomenon. Healing and medicine have been studied and practiced for thousands of years, spawning a huge range of disciplines and specialties.(1) In ancient civilisations, such as in Egypt, India, China and Greece, those practicing healing and medicine were just as likely to also be priests, magicians or philosophers.(2) The emergence of schools for medicine in the 9th Century in places such as Italy, and latterly China, were a catalyst for institutionalising and standardising medical practice.(3) The 18th Century was a transformative period for medicine as the influences of the enlightenment were brought to bear and medical practitioners devised interventions for public health crises such as plague epidemics.(4) Medicine was further institutionalised with the establishment of societies — tantamount to governing bodies — such as the Société Royale de Médecine in Paris in 1730, the British Medical Association in 1832 and the American Medical Association in 1847.(5)

As described above, medical practitioners operated relatively freely for centuries, unbound by any formalised codes of conduct or limits on their activities i.e. unregulated. However, by the 18th and 19th Centuries, many nations began to institute more formal, legal arrangements to govern the profession. For example, the Medical Act of 1858 in the United Kingdom defined the distinct occupational category of 'medical practitioner', whilst also establishing the General Medical Council with responsibility for monitoring training standards and registering practitioners.(6) Other types of medical practitioners were also subject to government oversight e.g. the Midwives Act of 1901 in Tasmania.(7) Thus, the landscape of medicine and health care in the 19th and 20th Centuries was one where individual professions (doctors, nurses, dentists, surgeons) increasingly came together under the umbrella of their respective professional bodies in a self-regulatory fashion.(8, 9)

At the same time, Governments — given their increasing role in the funding and provision of health and social care — began to take an interest in the operations, costs and quality of such services. For example, the Commissioners in Lunacy were given responsibility for reporting to parliament on the conditions in asylums for "lunatics and idiots" in England and Wales in 1845;(10) in 1877, the National Medical Board in Sweden assumed overall authority for hospitals and appointed chief provincial medical officers to carry out inspections.(11) There were also examples of where professional bodies undertook inspections to monitor standards in health and social care services, such as when the American College of Surgeons initiated a hospital standardization program in 1917, accompanied by a set of minimum standards.(12)

The trend toward increasing standardisation, supervision and regulation evolved throughout the course of the 20th Century, albeit in somewhat different forms. In the United States, accreditation (voluntary evaluation of quality by independent, not-for-profit organisations) was the predominant form of external evaluation of hospitals, chiefly by the Joint Commission on Accreditation of Healthcare Organizations.(13) In Ireland, Government departments (e.g. Department of Local Government and Public Health) assumed responsibility for inspections of facilities like county hospitals and 'mother and baby homes'.(14) In the United Kingdom, the Nursing Homes Registration Act (1927) required providers of private nursing homes to be registered and empowered local authorities to carry out inspections.(15)

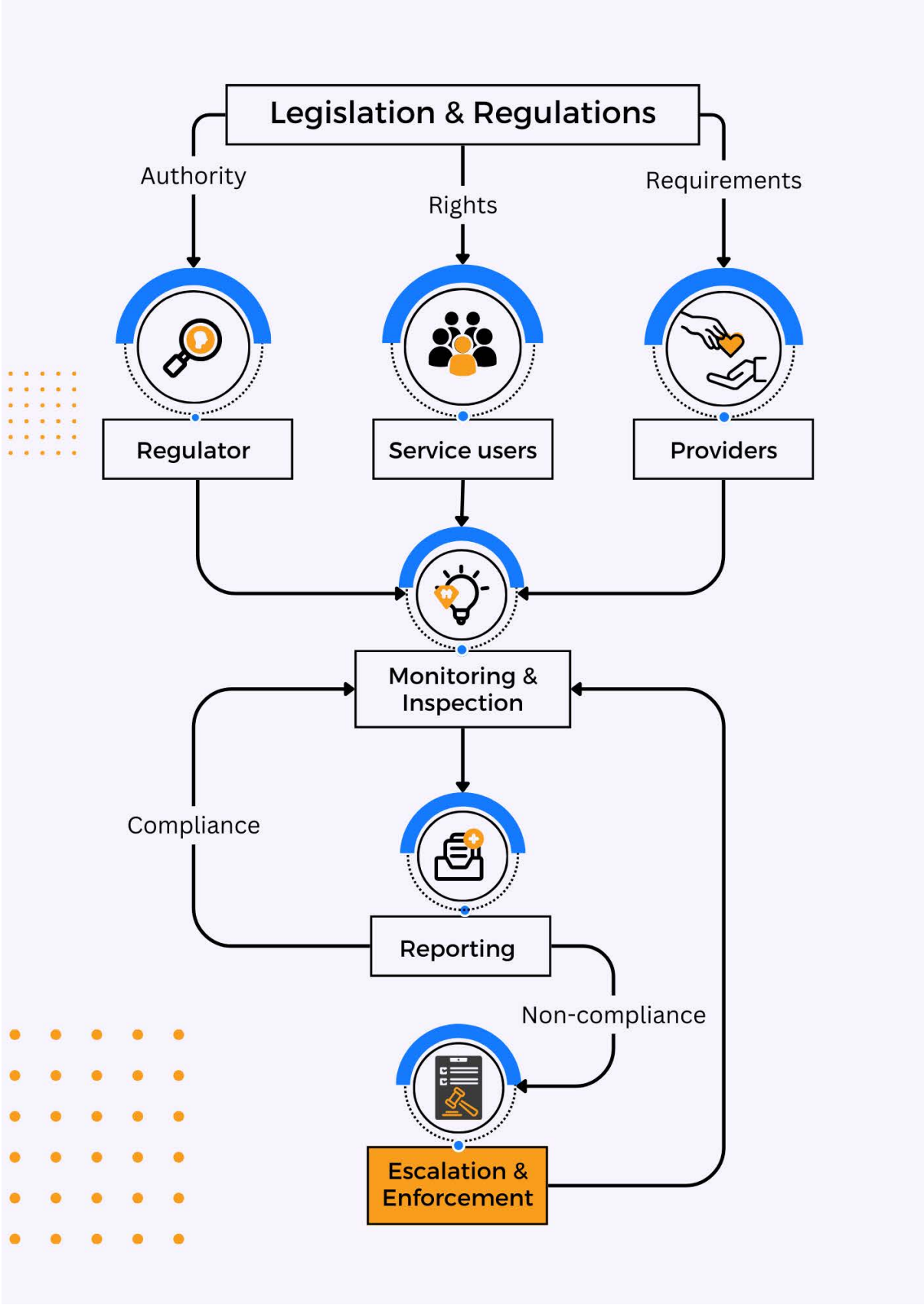
The 20th Century also saw a dramatic increase in the level of state funding globally for healthcare. Expressed as a percentage of gross domestic product (GDP), spending on health by governments has increased at least ten-fold between 1900 and the early part of the 21st Century.(16) Consequently, it is understandable that the demand for efficiency, value for money and quality in healthcare has risen in tandem with the increased level of public spending.

Concerns about quality are central to the argument for regulation of health and social care services. Variation in the quality of health and social care services is a persistent issue(17) and regulation is commonly one tool deployed to remedy such issues. Furthermore, the introduction of regulation — or the reform of existing regulation — is often a state's response to a public crisis concerning quality and safety. For example, in Ireland, an undercover investigation in 2005 by the national broadcaster exposed abuse of elderly residents by staff in Leas Cross Nursing Home.(18) The resulting public outcry led the Irish Government to establish the Health Information and Quality Authority to regulate nursing homes.(19) In the United Kingdom, public scandals such as those concerning the serial killer Dr Harold Shipman, Winterbourne View hospital, and Mid-Staffordshire Hospital resulted in changes to the regulator and the broader regulatory framework.(20) A 2021 report by the Royal Commission into Aged Care Quality and Safety in Australia reported a range of unsafe care practices and recommended reform of the regulatory framework.(21) As set out above, the introduction of regulation (or its reform) is often a reactive measure by governments rather than a proactive initiative. Nevertheless, regulation of health and social care has become the norm in most healthcare systems worldwide.(22)

1.3 What is regulation?

This section will discuss regulation as a whole i.e. its use as an intervention across multiple industries or disciplines. Various dictionary definitions of regulation use words like 'rules', 'authority', 'control', 'order' and 'behaviour'. One can conceptualise regulations as rules or standards that individuals or organisations are required to abide by or comply with (Figure 1). Regulation is the activity or process whereby regulations are upheld and enforced.

Figure 1 – Description of regulation



While many might subconsciously equate regulation as an expression of authority by a state or government, it can be more broadly understood as an overarching term for "all mechanisms of social control, by whomsoever exercised".[23] In this light, we can see that a professional body that registers solicitors or electricians is a regulator: in order to practice as a solicitor or electrician one must be appropriately registered and act in compliance with the rules and norms established by the trade or profession. So, in general, regulation entails a set of rules that organisations are required to comply with and that are monitored by an authority (regulator).

In a heavily regulated environment, regulators expect or require regulated organisations to behave in a certain way. Some of these behaviours might be specific and explicitly set out. For example, in the case of nuclear safety, facility construction specifications and maintenance schedules may be subject to exacting specifications.[24] Other behaviours are more nebulous and allow the regulated organisation a certain degree of flexibility in how they demonstrate compliance. For example, in the case of education, there may be room for interpretation with respect to school governance arrangements or the range of available supports for pupils.[25] Failure to comply with regulations can result in a series of escalated enforcement actions depending on the level of assessed risk.[26] Consistently poor compliance levels can cause reputational damage,[27, 28] lead to restrictive conditions on an organisation's operations, orders to cease operations or criminal charges.[29]

1.4 Regulation as a power struggle

Regulation is often conceptualised in terms of a power struggle between regulator and regulated organisations. The regulator (i.e. the state) seeks to control behaviours in a given industry by monitoring compliance with a set of regulations or standards, and sanctioning those that are not compliant. The regulated organisation (i.e. private enterprise or other civil bodies) pursues its goals within the confines of the regulatory environment, attempting to avoid sanctions whilst maximising profits or outputs.[30] The regulated organisation may also seek to influence or change the way regulation works.[31] The regulatory interaction can generally be described as a cyclical process whereby the regulator seeks to influence the behaviour of the regulated organisation: "In various ways…regulators communicate behavioural expectations to regulatees; they call on them to choose or reject one of the options

available for the performance of a particular task. Therefore, compliance can be understood as behaviour fitting these behavioural expectations".[32]

The conceptualisation of regulation as a power struggle has influenced the research literature. Consequently, we observe studies that seek to understand regulator and regulated organisation behaviour in this light. For example, there is a substantial literature[32-37] on the manner of interactions between regulator and regulated organisation: the various strategies adopted by regulators to maximise compliance and the means by which regulated organisations seek to be compliant. The strategies of regulators can be split into two broad categories, each at the opposite end of a spectrum: compliance and deterrence.[33, 34] Regulators adopting a compliance strategy will identify non-compliances and then deliberate with the regulated organisation as to how these will be remedied. The regulator and its staff become a type of consultancy for the regulated organisation, identifying issues and proposing or negotiating solutions.[33] A deterrence strategy, on the other hand, enters into formal enforcement measures much more quickly: "central to this approach is a preoccupation with the application of punishment for harm done".[34] This strategy, therefore, relies on the idea that punishment deters future non-compliance.

Similarly, regulated organisations form views about the type of regulator they encounter. Kagan and Scholz (1984) constructed three dispositions which regulated organisations ascribe to an inspector or regulator: police-like; negotiator-like; and consultant-like.[37] The police-like approach connotes a strict adherence to the requirements of the law and indifference to excuses or explanations for non-compliance. A negotiator-like approach seeks to be understanding, cooperative and enter into compromises. A consultant-like approach offers ideas and solutions to identified non-compliances and provides a lot of information to contextualise compliance ratings.[37]

Non-compliant organisations have been categorised according to three motivational postures: amoral calculator; political citizen; and organisationally incompetent.[37] The amoral calculator justifies non-compliance in the pursuit of economic interests; the political citizen is generally compliant but may be non-compliant on a point of principle where the law is adjudged to be unreasonable; the organizationally incompetent become non-compliant through ignorance or a lack of understanding.[37]

Drawing on survey data from regulated organisation subject to environmental and taxation regulation, the authors of a Danish study suggest five types of encounter behaviour: co-operators, accommodators, game players, protesters, and fighters. Co-operators are supportive of the goals of regulation and broadly accept the regulator's findings. Similarly, accommodators tend to readily engage with the regulator and yield to any demands on them. Game players exhibit a high level of engagement with regulators but make efforts to shape encounters to their own advantage. The final two, protestors and fighters, represent more adversarial approaches, both showing high levels of opposition but diverging somewhat in the level of engagement with regulators.[38]

1.5 The literature on the regulation of health and social care

It is necessary to draw attention to an important distinction with respect to how regulation works in health and social care. There are essentially two forms: individual and organisational. The regulation of individual is concerned with monitoring the qualifications, practices and conduct of individual health and social care professionals (e.g. physicians, nurses, social workers).[39] The regulation of organisations (e.g. hospitals, primary care centres, nursing homes) typically involves monitoring services to ensure a certain standard of quality and safety and to promote the wellbeing of service users.[40] For clarity, this thesis is concerned only with the regulation of organisations.

There is very little literature that describes the implementation of regulation in the context of health and social care services and organisations. In their analysis of nursing home inspection teams in Australia, Braithwaite and Makkai posit three approaches adopted by inspection teams confronted with non-compliance: reintegrative shaming; stigmatising; and tolerant and understanding.[35] Each of the three draw on theories from the field of criminology. Reintegrative shaming involves the expression of disapproval whilst maintaining a respectful demeanour; disapproval of the 'evil' deed without labelling the person or organisation as evil. The stigmatising approach also expresses disapproval but does so in a disrespectful or humiliating manner. Finally, the tolerant and understanding approach does not convey disapproval and seeks to coax the regulated organisation into compliance in a non-judgmental manner.[35]

In a study of nursing homes across several jurisdictions, Braithwaite (1993) employed a criminological construct, that of Merton's typology[41] of modes of adaptation.[33] The typology describes five modes of behaviour in response to a regulator: conformity, innovation, ritualism, retreatism and rebellion. Conformity and rebellion are self-explanatory and can be seen as being at opposite ends of a spectrum. Innovation, contrary to what one might expect, refers to "achieving regulatory goals but by other than the institutionally approved means".[33] Retreatism is found where a key figure (e.g. an owner or manager) in an organisation is dysfunctional or becomes exhausted by the pressures of management and causes the organisation to disengage from the regulatory process. Lastly, ritualism describes the type of behaviour that Braithwaite encountered most commonly in his study. It is considered a more subtle form of resistance where the regulated organisation gives the appearance of compliance or commits to changes that will pacify the regulator. Critically, the regulated organisation does this knowing that the regulator will either neglect to confirm the changes have been implemented or will accept written assurances of same. The following is an instructive example from Braithwaite's study:

> Our favorite example of ritualism is of an Australian director of nursing who did not want to oppose an inspection team who "made a big heap out of ethnic diet" under an Australian standard that requires sensitivity to cultural preferences for different types of food: "So we bought ethnic diet books - a ragout, goulash is a stew - give it a foreign name and they'll be happy".[33]

Other researchers have sought to explore various aspects of regulation in a health and social care context, for example: the inter-rater reliability of inspectors' assessments of hospitals;[42] the conduct of announced versus unannounced inspections in nursing homes;[43] the impact of regulation and inspections on quality in nursing homes[44] and in hospitals.[45]

In an analysis of healthcare regulation in the USA and UK, Walshe (2003) argued that, despite decades of regulation, quality issues persisted in both country's healthcare systems.[46] There are multiple potential reasons why a health or social care service might fail to comply with regulatory requirements. As referenced earlier, non-compliance may arise out of a principled stand taken by a regulated

organisation, or one that judges non-compliance more cost effective than compliance.[37] It may be that it is simply extremely difficult to be fully compliant with all of the regulations all of the time. A healthcare organisation may have to comply with a wide range of regulations (often involving multiple regulators) that govern care quality, worker safety, privacy and data protection, corporate responsibility, and environmental health.[47] It might also be the case that regulatory compliance is only one of several considerations for service managers (e.g. performance targets, budget control, personnel management), and it may not be the highest priority.[48]

Notwithstanding the above, non-compliance may also be explained by a failure to take appropriate action to be compliant i.e. a problem of implementation: "The rationale behind regulation can sometimes be very basic, while it occasionally is so complicated that organizations need a system for acquiring knowledge to interpret and implement (which requires resources)…it is unrealistic to expect every healthcare organization and its practitioners to understand and implement complex legislation without any pre-knowledge or assistance".[49]

When considering compliance in health and social care services the focus tends to fall, understandably, on the regulated organisation. However, it is important not to lose sight of the role of regulator in the production of compliance. Regulation of health and social care is often criticised but it is also the case that the various procedures involved in regulation, chiefly inspections, have rarely been properly evaluated.[50, 51] Therefore, I argue that there is a gap in knowledge with respect to the implementation of regulations in health and social care services, as well as a gap concerning what regulators can do better to support compliance.

1.6 Overarching thesis aim

The overarching aim of this thesis is to develop a greater understanding of implementation issues when organisations, and regulators, work to ensure compliance with regulations in health and social care services. This will be pursued through an implementation science approach and will consider the role of the regulated organisation as well as the regulator. Regarding regulation as an intervention means that compliance is the outcome of interest.

My intention is to take a 360-degree perspective on the problem. That is, I am interested in the learning about implementation issues from the regulated organisation's perspective and from the regulator's perspective. Staff and management working in regulated organisations will have valuable insights into the challenges (e.g. structural and process issues) of implementing regulations, the manner in which the regulator assesses the implementation outcome (i.e. compliance), and the impact regulation has on the quality of their services and the lives of their service users. Equally, inspectors working for the regulator will have perspectives on what enables or inhibits them in carrying out their roles and duties. Their regular engagement at the interface of regulation (i.e. the inspection) and interaction with a regulated organisation's staff and management means they will have an understanding of the implementation issues in those organisations.

The setting chosen to address the research aim is residential disability services in Ireland. Regulation of residential disability services in Ireland was introduced in 2013 after persistent calls for intervention due to concerns about quality and safety.[52] Given that the inspection of social care services is under-researched, and the relatively recent introduction of regulation to this sector, I regard this as a suitable setting to address the various research questions in this thesis. While residents of these services play no role in the implementation of regulations, it is my intention to seek their input, and those of families/carers for residents, to inform the research design and data collection approach.

CHAPTER 2: The development of disability services in Ireland and the introduction of regulation

2.1 Introduction

This chapter provides background information to the development of health and social care for people with disabilities in Ireland. I discuss how regulation was introduced for residential disability services and offer an overview of how the sector is organised at present in Ireland. I then focus on compliance levels for residential disability services before proceeding to outline the thesis aim, objectives, study design, theoretical framework and research context.

2.2 A history of the provision of health and social care for people with disabilities in Ireland

The provision of social care in Ireland began primarily in workhouses, poorhouses and asylums in the 1800s.[53, 54] These facilities took in people who were ill, destitute or suffering from a mental illness or disability.[54] The progression towards more specialised institutional care was marked by the opening of the Stewart Institution in 1869 which provided education and training to children with a learning or intellectual disability.[55] The first half of the 20th Century saw people with intellectual disabilities being accommodated in 'mental hospitals' and 'county homes'.[56, 57] Organisations set up to provide services for people with physical and sensory disabilities also emerged during this period. For example, the National Council for the Blind in Ireland; National Association for the Deaf; Cork Polio and General Aftercare Association; National Association for Cerebral Palsy.[56]

Up until the 1950s, social care was largely provided by voluntary agencies that had a religious — primarily Catholic — ethos. This changed markedly with the introduction of the Health Act (1953).[58] Section 65 of this act facilitated state financial support for organisations providing or proposing to provide a health service which was 'similar or ancillary' to a service being provided by the health authorities.[58] This was the first formal mechanism through which voluntary and religious organisations could avail of state funding to provide a health or social care service. Critically, Section 65 allowed providers to self-regulate and contained no stipulations as to the quality or oversight of such services: "the act included no

requirements for the supervision of services by health authorities or a system of formal contract for service delivery".[59]

While religious organisations comprised the majority of providers, this period also saw the emergence of 'Parents and Friends Associations'. These were lay organisations that started out as fundraising initiatives and advocacy groups but increasingly became involved in service delivery.[56]

The predominant model of care for people with disabilities in the mid-20th Century followed an institutional, congregated style where large numbers of people were accommodated in open wards and dormitories in one building or centre. A series of reports[53, 60, 61] in the latter half of the 20th Century emphasised support — and a growing body of evidence — for a move away from congregated settings towards a community-based model of residential care. Despite this, a shift in policy to support people to leave congregated settings to live in accommodation in the community did not materialise until the publication of the Health Service Executive's (state body in Ireland with responsibility for the health service) *'Time to move on'* policy in 2011.[62]

2.3 The introduction of regulation for residential disability services in Ireland

As outlined above, in the early part of the 20th Century most residential services for people with disabilities were provided through a combination of state and voluntary agencies. Voluntary agencies received funding for the provision of services from the state. There was little formal regulation or independent scrutiny of the services being provided. This was noted in a 1927 report submitted to the Oireachtas that made the following recommendation:

> "Approved institutions ... should be visited and reported on by the Inspector of Mental Hospitals. The Minister should be empowered to make regulations as to the good management of such institutions; the instruction and employment of patients in suitable occupations; the admission, transfer to other public institutions or discharge of patients; the absence on leave of patients and as to such other matters as may be necessary to ensure that the institutions are well managed and the patients properly maintained and cared for".[63]

Almost 70 years later, a report by the Commission on the Status of People with Disabilities in 1996 made the following recommendation:

> "The rights of people living in residential centres must be protected. They should have a Charter of Rights. They should have their own income. There should be an Ombudsman for residential centres. Standards in residential centres should be checked by the relevant authorities".(64)

Little changed in the subsequent period in terms of independent oversight or scrutiny of residential services for people with disabilities. The Irish Human Rights Commission, at the request of concerned parents, carried out an enquiry into a residential service in Galway.(65) The enquiry report, published in 2010, contains some useful information on the level of oversight and inspection in the social care sector in the preceding years. Of note, the report found that between the years 1989 and 2010 there had been two occasions when officials from the Western Health Board visited the centre. There had been no independent inspections during that period. Moreover, the Department of Health confirmed to the Irish Human Rights Commission that there was no statutory provision relating to the safety and welfare of people living in such services.(65)

The government established the Social Services Inspectorate (SSI) in 1999 under the auspices of the Department of Health and Children. The SSI was focused on inspecting children's services, including services for children with a disability, until it was placed on a statutory footing and subsumed into the Health Information and Quality Authority (HIQA) in May 2007.(66) HIQA published the draft *National Quality Standards: Residential Services for People with Disabilities* in 2009.(67) The expectation was that these standards — applicable only in adult services — would be placed on a statutory footing and that residential centres would need to meet these standards. However, the 2010 Irish Human Rights Commission enquiry report noted that:

> "during the course of the enquiry it was clear that independent inspections by HIQA were expected to commence from 2008/2009 following finalisation of its National Standards. However, in May 2009, it was announced that the standards would not be placed on a statutory

> footing and that independent inspections would not occur… due to cutbacks in health spending".[65]

HIQA published a revised set of standards in May 2013, the *National Standards for Residential Services for Children and Adults with Disabilities*.[68] Following commencement of regulations by the Minister for Health on 1 November 2013, HIQA became the state regulator for residential centres for adults and children with disabilities.

2.4 The regulatory framework for residential disability services in Ireland

The regulatory framework for social care in Ireland is founded on the Health Act 2007 which is the key piece of legislation.[66] The legislation that sets out the regulatory framework for social care in Ireland specifies the role of chief inspector within HIQA whose broad function it is to assess compliance with specified regulations.[69]

The Health Act 2007 defines the types of services that are to be subject to regulation, known as designated centres. In the case of disability services, designated centres are defined as follows:

> "designated centre means an institution—
>
> > (*a*) at which residential services are provided by the Executive, the Agency, a service provider under this Act or a person that is not a service provider but who receives assistance under section 39 of the Health Act 2004—
> >
> > > (ii) to persons with disabilities, in relation to their disabilities".[66]

Designated centres are required to register with the chief inspector and must be in a position to demonstrate compliance with the regulations, as well as satisfying other administrative criteria, in order to be granted registration. Registration is valid for three years at which point a designated centre must renew their registration.[66] All registered designated centres are subject to inspection and monitoring. The Health Act 2007 does not stipulate the frequency with which inspections should take place.[66]

The chief inspector has a range of inspection powers under the Health Act 2007 such as the right to enter premises where care is provided, review documentation, access computer systems and interview residents, staff and management. The chief inspector may also appoint inspectors of social services and delegate the aforementioned inspection powers accordingly.(66) The chief inspector in HIQA has adopted a risk-based approach to regulation meaning that inspection activity is proportionate to the level of risk assigned to a designated centre.(70)

The Health Act 2007 facilitates the Minister for Health to set regulations for how care should be provided in designated centres. These regulations, commenced in November 2013, were still in use at the time of writing.(69) There are 34 pages in the regulations and they begin by setting out definitions for things such as a personal plan, person in charge, restrictive procedure and communication. The majority of the regulations are short statements, typically no longer than one sentence, that stipulate what is required of designated centres and the person legally responsible for compliance. For example, the following is a regulation pertaining to staffing:

> "The registered provider shall ensure that the number, qualifications and skill mix of staff is appropriate to the number and assessed needs of the residents, the statement of purpose and the size and layout of the designated centre".(69)

The registered provider — the legal entity that owns and operates the designated centre — is responsible for compliance with the above regulation. In other regulations, it is the person in charge that is responsible for compliance, as is the case with staff rostering:

> "The person in charge shall ensure that there is a planned and actual staff rota, showing staff on duty during the day and night and that it is properly maintained".(69)

The above examples neatly illustrate the distinction in operational responsibilities created by the regulations i.e. the registered provider is responsible for ensuring that adequate numbers of staff are employed to meet residents' needs; the person in charge must ensure that those staff are rostered accordingly. The full list of regulations is available in Appendix 1.

Inspectors typically spend one day on an inspection, having prepared in advance what regulations they will assess based on the designated centre's previous inspections.[70] During the course of inspections, inspectors will speak with residents, staff and management. They will observe care practices and tour the facilities and accommodation. They will also review samples of documentation such as *inter alia* residents' personal plans, fire safety records, healthcare records and activity logs.[70] Inspectors record their observations and findings in an inspection notebook and then draft an inspection report. The inspection report details the findings and also provides a compliance judgment for each of the regulations assessed on the inspection.[70] There are three possible judgments that an inspector can select for each regulation:

> "Compliant means the provider and or the person in charge is in full compliance with the relevant regulation; Substantially compliant means that the provider or person in charge has generally met the requirements of the regulation but some action is required to be fully compliant…; A judgment of not compliant means the provider or person in charge has failed to comply with a regulation and that considerable action is required to reach compliance".[70]

Each designated centre is afforded the opportunity to develop a compliance plan that addresses the identified issues in an inspection. The compliance plan is submitted prior to the publication of the inspection report and it is also published as part of the inspection report.[70]

Failure to adequately address non-compliances, or persistent non-compliances, may result in the initiation of escalation and enforcement measures. The chief inspector has a range of powers available under the Health Act 2007 and these powers can be seen along a continuum of mild to severe.[70] At the mild end of the scale, a registered provider can be asked to develop a 'provider assurance report' detailing how they propose to address specific failings in their service. This can be sometimes be accompanied by a cautionary provider meeting, a warning provider meeting and/or a warning letter. At the more severe end of the scale, the chief inspector has powers to prosecute registered providers or place restrictions on a designated centre's registration (e.g. reduce bed numbers or prevent new admissions). As a last resort, the chief inspector can apply to the

court to cancel the registration of a designated centre, effectively removing the registered provider and placing the national health service in temporary charge.[70]

2.5 An overview of residential disability services in Ireland

At the time of writing (April 2025), according to the publicly-available register on the HIQA website, there were 1673 designated centres, with a total bed capacity of 9289, giving a mean bed number per centre nationally of 5.5. The largest centre had 31 beds and there were 103 centres that had one bed.[71] The majority of centres (1505, 90.0%) provided services to adults, 130 (7.7%) were for children (i.e. under 18) and the remainder 38 (2.3%) were mixed where both adults and children were accommodated.[71]

No up-to-date information is published on the types of services provided in designated centres because the register does not contain this information. However, a database published in 2020 contained a range of information obtained from each designated centre's statement of purpose, a document required by the regulations.[72] These data, listing 1287 centres, show that the majority provided services for people with intellectual disabilities and/or autism spectrum disorder, with more than 1242 (96.5%) listing this in their statement of purpose. The remaining 45 (3.5%) provided services to people with a range of needs including acquired brain injury, sensory disabilities, physical disabilities, neurological and medical needs.[72]

There were 87 registered providers according to the register at the time of writing. The largest registered provider operated 200 designated centres and there were 18 that operated only one centre.[71] The mean number of designated centres per registered provider nationally was 18.8. Registered providers are a mix of voluntary (not-for-profit), statutory and private (for-profit) providers. The statutory provider, the Health Service Executive, was responsible for the operation of 174 (10.6%) of designated centres. Of the remainder, the register does not designate whether a registered provider is for-profit or not-for-profit. A 2024 publication by HIQA stated that 26 registered providers were designated as operating on a for-profit basis at the end of 2023.[73]

2.6 Challenges of implementing care regulations in residential disability services in Ireland

As referenced earlier, regulation was introduced for residential disability services in Ireland in 2013.[69] The chief inspector in HIQA publishes a yearly report that summarises findings from the previous calendar year. Successive reports in the early years of regulation described persistent non-compliance with regulations, albeit to varying degrees across the country and among registered providers.[74-78] A 2019 report published by the chief inspector in HIQA sought to summarise the findings of the first five years of regulation.[79] The report acknowledged a mostly positive response to the introduction of regulation, and an improvement in quality as a consequence of regulation:

> "The majority of providers and staff responded positively, taking significant steps to comply with the regulations and to improve the quality of their services. This has resulted in positive outcomes for people with disabilities living in these centres... Regulation has increased awareness of what life is like in residential care for people with disabilities and has driven sustained improvements to the quality of life and experiences of many people living in these centres around Ireland.[79]

Nonetheless, the regulator had areas of concern. These included poor governance arrangements among some registered providers, outdated premises, poor safeguarding practices and the failure to uphold residents' rights.[79] For example, the foreword by the chief inspector observed that, in 2018, around one-third of centres had failed to meet the regulations pertaining to safeguarding. In summary, while progress had been made in terms of quality, non-compliance persisted.

A subsequent report, published in 2024, described the regulator's findings for 2023.[73] For all regulations assessed in that year, 69% were found fully compliant, with 19% substantially compliant and 12% not compliant. The level of non-compliance varied among regulations. For example, the healthcare regulation had a not compliant level of 2.8% whilst the governance and management regulation was found not compliant 24.9% of times assessed.[73] Clearly, despite regulation being in place for more than 10 years, there remained a substantial level of non-compliance with regulations.

In summation, I argue that residential disability services in Ireland are an ideal context within which to investigate the implementation of regulations. People that live in these services are often vulnerable. Their vulnerability is compounded by communication challenges and cognitive difficulties that mean self-advocacy is not an available option. There is clear evidence that people with disabilities have been subject to abuse,[80] experience poorer support for independent living,[81] and are subject to high rates of restrictive practices[82] while living in health and social care services. All of this serves to underscore the importance of the regulator as an advocate for the rights of people with disabilities living in residential care. Therefore, the implementation of regulations in these settings has a real bearing on the health, safety, wellbeing and prosperity of a sizeable portion of the population, and represents a perfect test case for the study I am undertaking.

CHAPTER 3: Methods

3.1 Thesis aims and objectives

The preceding sections have charted the emergence of medicine and healthcare, some of the predominant theories in the field of regulation and compliance, and an overview of the historical development of residential disability services in Ireland. While regulation is usually a state intervention to improve quality, as shown above, quality issues persist. Moreover, little is known about the challenges of effectively implementing regulatory requirements. Therefore, the aim of this thesis is as follows:

- To identify the implementation challenges with respect to care quality regulations in residential disability services in Ireland.

The following are the objectives to achieve the overarching thesis aim:

- To systematically review and synthesise, using the Consolidated Framework for Implementation Research (CFIR),[83] the available quantitative, qualitative and mixed-methods evidence concerning determinants of compliance in health and social care services with a view to identifying knowledge gaps.
- To identify and critically reflect on the frequency and causes of non-compliance with care quality regulations in residential disability services in Ireland through analysis of inspection reports and regulatory data on compliance.
- To examine, utilising Normalisation Process Theory,[84] how health and social care managers engage with the implementation of statutory regulations in residential disability services in Ireland, focusing on managers' perspectives on regulation; the strategies, structures, and processes they use to implement it; and key factors shaping these approaches, such as resource availability and attitudes toward the regulatory regime.
- To critically explore and examine how health and social care inspectors in Ireland implement the regulation of residential care for people with disability, with a particular focus on their views about the regulatory system, the strategies they use to improve compliance and deal with poor performance, and the challenges they face in implementing these strategies.

- To provide, based on the learning from the above objectives, a range of policy and practice recommendations for relevant stakeholders, geared towards improving the implementation of regulatory requirements in residential disability services in Ireland.

3.2 Research paradigm

The approach adopted for the research in this thesis was a critical realist paradigm. The critical realist philosophical framework uses both positivist (quantitative) and constructivist (qualitative) approaches to address questions related to complex phenomena in the social science world.[85, 86] The critical realist "search for causation helps researchers to explain social events and suggest practical policy recommendations to address social problems".[87] I consider this the most appropriate paradigm for this research given that the problems of regulation and quality in health and social care services are inherently social events and social problems. As described earlier, regulation is a complex intervention and health and social care systems are also complex. Thus, in order to understand how and why things do and do not work i.e. regulating health and social care to produce quality improvements, critical realism offers a means to understand "the mechanisms that drive social reality even when they are not directly observable".[88]

This paradigm also provides space to critically reflect on the claims made by participants in the studies i.e. managers of disability services and inspectors. Moreover, it also provides space for the author to acknowledge their role in the production of knowledge. As a current employee of the regulator for social care in Ireland, there must be a recognition that my values, dispositions and biases (conscious or unconscious) are influenced by this role and, consequently, they have the potential to seep into the knowledge producing process. As such, the research process is also a 'social event' and researchers should be cognisant of how this can impact on their outputs.

3.3 Study design

A sequential, multi-method approach was employed for this thesis, entailing both qualitative and quantitative studies.[89] The qualitative and quantitative designs chosen in this thesis represented the best means by which to address the individual study's research questions. Moreover, due to the lack of data, both internationally

and in Ireland, it would not have been possible to properly address the research questions using only quantitative methods. Overall, this thesis relies more heavily on qualitative study designs, with quantitative methods featuring mostly in the study in Chapter 6.

3.4 Theoretical framework

A novel feature of this thesis was the application of implementation science theories and methods to the field of regulation of social care. While implementation science has been a feature of the healthcare improvement literature for more than a decade, it appears that there has been no substantive research on how care quality regulations are implemented or embedded into day-to-day work by practitioners. Regulation certainly bears consideration as an innovation or intervention that can be studied in an implementation science context. Regulation typically entails the prescription of certain standards or regulations (e.g. care quality, documentation, provision of information, fiduciary responsibilities) in organisations; these are effectively interventions, both at the macro and micro level. The performance of organisations against these standards or regulations is then assessed by external persons (inspectors) who can gather evidence and make judgments on whether compliance has been achieved. There then typically follows on ongoing process of monitoring, assessment, improvement, and escalation or enforcement where judged appropriate by the regulator. The above description follows a similar process as found in many implementation processes. Two theoretical frameworks from the field of implementation science underpinned this thesis: the Consolidated Framework for Implementation Research (CFIR)[83] and Normalisation Process Theory (NPT).[84]

The CFIR is a framework developed by drawing together a range of existing theories relevant to implementation science to produce an "overarching typology–a list of constructs to promote theory development and verification about what works where and why across multiple contexts".[83] The original CFIR contained five domains (intervention characteristics; outer setting; inner setting; characteristics of individuals; and process) and 37 constructs.[83] An update in 2022 saw revisions to existing domains and constructs, as well as the addition, removal and relocation of certain constructs.[90] There appears to be no application of CFIR to a regulatory context in the literature.

NPT was developed and formulated between 1998 and 2008, first published in 2009 as a means to explain how new technologies, methods or practices are understood and embedded in everyday practice.[84] NPT has four core constructs: coherence (i.e. making sense of a practice); cognitive participation (i.e. building a local community of practice); collective action (i.e. operational implementation work) and reflexive monitoring (i.e. appraising impact), each with four sub-constructs. The NPT was updated in 2022 with the development of a coding manual following a context-mechanism-outcome configuration.[91] NPT was previously used as a framework for a study on the regulation of medical revalidation in the United Kingdom.[92]

Both the CFIR and NPT were used throughout the various studies in this thesis. They informed the study design of the studies in Chapters 5 and 7. They were also used as aids in data collection and data extraction.

In addition, this thesis also draws on an inductive-deductive analytical framework.[93] This approach is of value with respect to research that seeks to investigate "layered and complex problems which might necessitate both a more open and inductive approach to theme generation and yet at the same time would also benefit from the theoretical rigor offered by the deductive application of themes derived from an existing framework".[93] The existing frameworks in this case are the aforementioned CFIR and NPT. An inductive-deductive analytical framework was used in the study in Chapter 7.

While not explicitly used as methodological frameworks in any of the studies in this thesis, there were several important theories related to regulation that helped inform the broad approach and study designs. The compliance/deterrence model of regulation holds that the style and strategy used by regulators can be plotted along a spectrum.[37] Compliance, at one end of the spectrum, means that regulators look to advise and persuade regulated organisations in order to encourage compliance with regulations. At the other end of the spectrum, regulators with a deterrence style are intolerant of non-compliance and quick to use sanctions to prevent further non-compliance.[37] Building on this conceptualisation, other prominent authors in the field of regulation introduced new ideas such as those of responsive regulation and risk-based regulation.[94] Responsive regulation is akin to a hybrid compliance/deterrence model, where the regulator takes account of the attitudes and behaviours of regulated organisations and adjusts its own style and behaviours

accordingly. Risk-based regulation focuses regulatory attention on the areas of highest risk in a regulated sector, reducing the need for regulatory activity in well-performing organisations.[95]

Other leading researchers in the field of regulation have sought to characterise the behaviour of regulated organisations, and this literature was also useful for the development of our studies. For example, there is a body of work in the field of criminology that categorises organisations as amoral calculators (focused on circumventing regulatory requirements to maximise profit), political citizens (objecting to regulatory requirements on a point of principle) or organisationally incompetent (poorly managed organisations incapable of implementing requirements).[37] In a similar vein, Braithwaite (1993) identified five types of behaviours in nursing home operators: conformity (unquestioning acceptance of requirements), innovation (keen to identify workarounds that will circumvent requirements), ritualism (apparent compliance with the letter of the law but not the spirit), retreatism (complete withdrawal from engagement with the regulator) and rebellion (open defiance of the regulator).[33]

3.5 Research context

The student responsible for this thesis was a full-time employee of the Health Information and Quality Authority (HIQA) throughout the entire course of the PhD study. HIQA funded and effectively commissioned the research to improve its understanding of the various barriers and facilitators surrounding the implementation of regulations in social care services. As the regulator for health and social care services in Ireland, HIQA has a remit to monitor and inspect a range of different services e.g. public and private hospitals, nursing homes, children's foster care services, children's residential centres, residential services for people with disabilities and accommodation provided to international protection applicants (asylum seekers). HIQA is a relatively young organisation, having been established in 2007.[96] It commenced the regulation of nursing homes in 2009 and of residential disability services in 2013.[75]

In commissioning this research, HIQA, as the key knowledge user, was interested to learn about how care quality regulations — as opposed to voluntary national standards — were implemented by services. As described above, the regulations are legally binding and failure to comply can result in enforcement action. Despite this,

services routinely fail to comply with regulations.[97-100] Conducting research on what underlines this non-compliance can improve understanding of barriers and facilitators to compliance and can also inform regulatory policy and practice.

The thesis author took several steps to guard against the introduction of any bias during the course of the research. Firstly, a continuous process of journaling was undertaken throughout the course of the PhD. This offered an opportunity to reflect on the trajectory of the research and its findings, as well as interactions with various study participants (i.e. PPIE participants, mangers and inspectors of disability services). Interactions with study participants were conducted to a high level of ethical standard and the author was fully transparent about their role as a PhD student and current employee of the regulator. In addition, the PhD supervisors played a key role by regularly discussing the potential for bias at supervision meetings and requiring the author to reflect on how bias may influence the interactions with study participants and the research findings.

3.6 Public-patient involvement and engagement (PPIE)

Contributions to aid in the development of the questions for the interviews (Chapter 7) and focus group (Chapter 8) components were sought from current residents of residential disability services in Ireland, as well as carers for people living in these services. We recruited PPIE contributors through a national disability advocacy organization, Inclusion Ireland, and a south of Ireland-based disability service provider [name withheld to protect the anonymity of the provider and the participants]. The contributors were two residents and two relatives of people living in residential care facilities for people with disabilities (RCF-D). Discussions with the residents took place in person on two occasions in 2023, while conversations with the relatives were conducted by phone. The contributors were two residents of a RCF-D and two relatives of people living in RCF-D. PD met the residents in person on two occasions during 2023. Telephone discussions were conducted with the relatives. The PPIE component of this research received ethical approval from the Social Research Ethics Committee of University College Cork (2023-011).

CHAPTER 4: Determinants of regulatory compliance in health and social care services: a systematic review protocol

The following chapter was published in the HRB Open Research Journal:

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Authors

Paul Dunbar[1], Dr Laura O'Connor[2], Prof John P Browne[3]

Author details

[1] Health Information and Quality Authority, Unit 1301, City Gate, Mahon, Cork, Ireland T12 Y2XT. pdunbar@hiqa.ie (corresponding author)

[2] Health Information and Quality Authority, Unit 1301, City Gate, Mahon, Cork, Ireland T12 Y2XT. loconnor@hiqa.ie

[3] School of Public Health, University College Cork, Ireland j.browne@ucc.ie

4.1 Abstract

Background

The delivery of high quality health and social care services is a fundamental goal for health systems worldwide. Identifying the determinants of quality is a complex task as there are a myriad of variables to choose from. Researchers in this field have assessed a range of organisational and environmental factors (for example: staff composition, facility ownership, facility size) for an association with various quality metrics. Less attention has been paid to the determinants of compliance with quality regulation. Identifying the determinants of compliance has the potential to improve regulatory processes and can inform quality improvement initiatives undertaken by service providers and policy makers. This protocol describes a systematic review

which will review literature from a wide range of study designs and sources to develop an overview of the determinants of regulatory compliance in health and social care services.

Methods

A wide range of study designs and grey literature will be sought for this review. Searches will be conducted using PubMed, MEDLINE, PsycInfo, SocINDEX and CINAHL databases. The studies included in the review will be subject to quality appraisal with reference to the collection of tools available from the Joanna Briggs Institute. Data extraction will be informed by the Consolidated Framework for Implementation Research (CFIR). A narrative synthesis will be conducted on the barriers, facilitators and factors associated with compliance, with reference to the concepts mapped onto the CFIR. GRADE-CERQual will be used to grade the overall body of evidence.

Conclusion

The findings of this review will be useful to regulators to inform regulatory policy and practice. Service providers and policy makers may also use the findings to inform quality improvement initiatives aimed at improving compliance and quality across a range of health and social care services.

4.2 Introduction

The delivery of high quality health and social care services is a fundamental goal for health systems worldwide. Quality is a nebulous term that can be difficult to define. In health and social care, the following have been proffered — by the European Commission and the Institute of Medicine — as definitions of quality: “health care that is effective, safe and responds to the needs and preference of patients”;[(101)] “Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge”.[(102)]

Quality of care is often conceptualised with reference to Donabedian’s framework: structure, process and outcome.[(103)] Donabedian "defined structure as the environment in which healthcare is provided, process as the method by which healthcare is provided and outcome as the consequence of the healthcare provided".[(104)] To use social care as an example: the number of staff working in a

centre would represent structure; the frequency with which a person has an assessment of need would represent process; and the degree to which a person has autonomy to make decisions about their care would be an outcome.

Quality of care in health and social care settings is variable. Variation in quality may be the result of a structural component as demonstrated in a study that assessed the effect of changes to staffing levels on the prevalence of pressure sores in nursing homes.[105] It may be process-related as found in a prospective evaluation of simulated emergency department triage which found a high degree of variability in the processes of triage and measurement of vital signs.[106] Outcomes are also subject to variation such as found in an analysis of in-hospital mortality in non-cardiac surgical patients across Europe, which found that mortality varied across the countries studied.[107]

Regulation is one response to variability in quality: authorities establish a set of norms or standards to benchmark quality and then assess the extent to which organisations and individuals meet these standards. Failure to comply with regulations may lead to sanctions such as intensified surveillance, or even revocation of license to operate (typically through a registration or licensing system). Regulation is a common feature in a wide range of sectors: finance, environment, transport and healthcare. Selznick (1984) offers a useful definition of regulation where it is described as: “sustained and focused control exercised by a public agency over activities which are valued by a community”.[108]

Regulations in health and social care are wide-ranging but typically cover aspects such as, hygiene, governance and management, documentation/records, care practices, staffing, training.[69, 109-111] As with components of quality, regulations can also be conceived of as falling into the categories of structure, process and outcome. By way of example, in the context of staffing and patient experience: a regulation specifying the staffing ratio represents structure; a regulation specifying the supervision or development of staff in the humanity of care represents process; and a measure of patient experience represents the outcome.

Compliance, in a regulatory context, can be understood as “behavior fitting expectations communicated to regulatees regarding how the former should or should not behave in a given domain”.[112] Compliance is generally articulated by a regulator along a continuum of ‘compliant’ to ‘not compliant’. For example, the Care

Quality Commission (CQC), regulator for health and adult social care in England, has four levels of compliance: outstanding, good, requires improvement, inadequate.[113] These ratings are determined according to the professional judgment of a CQC inspector and assessed at the level of individual care components; services also receive an overall rating.

Determining the level of compliance with a specific regulation requires varying degrees of effort and evidence gathering on behalf of an inspector. Evidence can be generated from speaking with residents and staff, reviewing documentation and records, and observing practices as they happen. For example, assessing compliance with a structural requirement, such as a requirement that a person in charge should have "a minimum of 3 years' experience in a management or supervisory role in the area of health or social care",[69] is a relatively straight-forward task of identifying the appropriate documentation. Judging whether a service has admitted residents in "a competent, equitable, timely, and respectful manner",[114] requires the inspector to undertake several tasks: speak with recently-admitted residents or their representatives, review admission records, speak with staff involved in admitting new residents. Assessing compliance in a regulation which specifies an outcome, such as one that seeks to "ensure respect for the personal privacy of each person in care",[115] requires the inspector to speak with residents and staff, review documentation and observe care practices on-site.

As with quality, compliance with regulations is also variable. This is evidenced in a number of reports by regulators in the health and social care sectors.[116-118] Various factors have been assessed for their association with compliance in health and social care settings such as: ownership, facility size, patient feedback, staff levels and competencies, availability of amenities, location, presence of an ombudsman and patient/resident characteristics.[119-126] In the case of some of the above, there is a danger of a type of circular reasoning because it may be a factor that is regulated. For example, if there is a regulation requiring managers to have a certain qualification, then it is difficult to construe this as a determinant because it is a pre-requisite for compliance.

Describing the reasons and potential explanations for the variability in compliance with regulations is the key focus for this systematic review. The authors have found no such review to date and this represents a gap in knowledge. Our review will use

the Consolidated Framework for Implementation Research (CFIR) to categorise the determinants of compliance described in the literature.

The CFIR is an overarching typology used in implementation science.[83] The CFIR was developed by including "constructs from a synthesis of existing theories" and is concerned more with what works where and why as opposed to simply 'what works'.[83] There are five domains within the CFIR: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation. Each of these have multiple constructs within each domain.

The CFIR may be applied to regulation by mapping any barriers, facilitators or factors associated with levels of compliance. In this sense, regulation is perceived as the intervention and compliance is the outcome. By way of example, the points below illustrate how regulation and compliance can, hypothetically, be mapped onto the constructs within the five CFIR domains:

- intervention characteristics: do regulatees regard regulations as being evidence-based?
- outer setting: are there incentives/disincentives that encourage the regulatee to comply?
- inner setting: what resources (e.g. staffing) are available to the regulatee to achieve compliance?
- characteristics of the individuals: what knowledge and beliefs do senior managers in regulatees have towards the regulator?
- process of implementation: do inspectors act as external change agents to foster compliance?

Beyond mapping the barriers, facilitators or factors associated with levels of compliance, our review will use theory to aid interpretation. It is not possible at this juncture to be definitive in what theories will be applicable, as this will be informed by the nature and design of the studies included for the systematic review. As such, the following sections will describe some potential theories that may serve to elucidate the material that is mapped on to the CFIR domains and constructs.

Various theories have been posited in the context of regulation and on the means by which regulators seek to ensure compliance.[36, 127, 128] The disposition or *modus*

operandi of a regulator can be conceptualised as being plotted along a spectrum. At one end are those that are intolerant of any form of non-compliance and quick to deploy punitive measures. At the other end of the spectrum there is a greater acceptance that compliance can fluctuate and the regulator will adopt a more consultative approach which seeks to coax providers into compliance.[36, 127, 128]

Other theories look to characterise the disposition of regulatees and their attitude towards compliance.[33, 34, 128] Non-compliant organisations may be 'political citizens', generally agreeing with the goals of regulation but objecting to the prescriptions of the regulator in terms of how this is to be achieved. Or, they may simply be 'organisationally incompetent' and fail to understand or manage the demands of the regulations or the regulator.[36] Some organisations may fully subscribe to the goals of regulation and be 'model citizens' that strive to meet or exceed the standards that have been set. Others pay 'lip service' to these goals and do the minimum to satisfy the regulator, giving the appearance of compliance.[33]

The regulator can also be interpreted by organisational actors as being either an ally, threat or obstacle.[129] The regulator being perceived as a threat can mean the threat is at the level of an individual (their job or esteem) or at the level of the organisation (profits or reputation). As an ally, the regulator is perceived as competent and regarded as encouraging an organisation into compliance, offering advice and support to achieve common goals.[129] The regulator as obstacle is seen as lacking authoritative technical expertise in the particular field or where "compliance requirements…are inadequately connected to the underlying regulatory goals".[129]

As set out above, compliance is not only influenced by structural or organisational factors such as the size of a facility or who owns it. It is also an outcome of the nature of engagement between regulator and regulatee and contingent on their respective dispositions towards compliance. Normalisation process theory (NPT) represents a theory within which to understand these relationships and contingencies. NPT facilitates "systematic exploration of why some processes lead to a practice becoming successfully (or not) embedded (i.e. normalised) and sustained, by attempting to understand the intervention in relation to the work that people do".[130] NPT facilitates an exploration of what factors are associated with the successful integration and alignment of an organisation's goals with those of regulation. Such an approach has been adopted elsewhere[130] but the author has found no studies that

have used NPT as a theory to aid understanding of regulatory compliance in organisations. NPT may be particularly useful in the fifth CFIR domain: process.

The findings of this review will be of benefit to regulators as they may inform changes to regulatory policy and practice. In addition, service providers and policy makers may use the findings to develop quality improvement initiatives to improve rates of compliance and, ultimately, provide a better quality service.

Research question: What are the determinants of regulatory compliance in health and social care services?

The protocol will describe the:

- process for a comprehensive search for relevant articles
- eligibility criteria for the inclusion of such articles
- method for screening articles for inclusion
- appraisal method for assessing the quality of individual studies
- approach to data extraction, synthesis and appraisal of the overall body of evidence.

4.3 Protocol

4.3.1 Criteria for inclusion

The phenomena of interest are the determinants of regulatory compliance in health and social care services. There are no limits on the articles for inclusion in terms of publication date or language. Articles — either qualitative, quantitative or mixed-methods — will be included if they:

- Describe factors or characteristics that are related to regulatory compliance. Specifically, this refers to regulations that are mandated by government or other state authorities. A wide range of constructs will be considered for inclusion including, but not limited to, the following: service characteristics (size, location, model of care, ownership); organisational characteristics (culture, management/governance structure, maturity); service user characteristics (age, disability type, disease/illness); nature of engagement (punitive, adversarial, collaborative).

- Discuss barriers or facilitators to regulatory compliance for health and social care services.
- Are focused on quality of care in health and social care services and use regulatory compliance as an outcome measure.

Studies will be excluded if they:

- Analyse regulatory compliance in a field other than in a health or social care setting or service.
- Analyse compliance with clinical guidelines or other evidence-based methods for managing care that are not underpinned by the potential for regulatory sanction where there is a failure to comply.
- Use an outcome measure that is not equivalent to regulatory compliance in accordance with the definitions set out above. For example: adherence to voluntary standards or codes of conduct; where failure to comply does not result in regulatory sanctions of enforcement; compliance concerning individuals as opposed to organisations as is the case with regulations for specific health care professionals.

4.3.2 Types of study to be included

There will be no specific limitations on the types of study considered for inclusion. Given the nature of the research question and the topic under review, it is anticipated that the studies will generally fall into the categories of: cross-sectional designs for quantitative studies; and ethnographic or focus group/interview designs for qualitative studies. Preliminary searches have found studies that use compliance data from regulators coupled with cross-sectional data on services which are sourced either directly through surveys or via national repositories such as the Centers for Medicare and Medicaid Services (CMS) in the USA.

4.3.3 Search methodology

The CIMO (Context, Intervention, Mechanisms, Outcome) framework for developing a search strategy will be used for this systematic review (see Table 1). The search terms in the framework are set out in Table 2 below.

Table 1 – Context, Intervention, Mechanisms, Outcome (CIMO) framework for this systematic review

Context
Any health or social care service (e.g. hospital, nursing home, residential disability service) which is regulated as an organisation. This excludes services that are provided by individual professionals such as dentists or general practitioners.
Intervention(s)
Regulation is the intervention. The term 'regulation' may differ in a given context but it is generally taken to mean a process of external evaluation by an independent or statutory agency which is underpinned by enforcement powers.
Mechanism
Factors influencing, or determinants of, compliance; barriers and facilitators to compliance; nature of engagement between regulator and regulatee.
Outcome
Main outcome: regulatory compliance. **Additional outcome(s):** Other measures that are consistent with compliance will be included (e.g. in the USA, equivalent terms for non-compliance may be a 'deficiency' or 'violation').

Table 2 – Key search terms

Context	"healthcare system*" OR "health care system*" OR "care system*" OR "social care" OR "healthcare service*" OR "health care service*" OR "social care service*" OR "hospital*" OR "health care setting*" OR "healthcare setting*" OR "social care setting" OR "residential facilit*" OR "care facility*" OR "nursing home*" OR

	“residential care” OR “long-term care” OR “long term care” OR “disabilit*” OR “disability service” OR “care home” OR “aged care” OR “aged-care” OR “mental health service” OR “mental health centre” OR “mental health facilit*” OR “psychiatric service” OR “psychiatric centre” OR “psychiatric facilit*” OR “addiction service” OR “addiction centre” OR “addiction facilit*” OR “drug-treatment centre” OR “drug-treatment service” OR “drug-treatment facilit*” OR “drug treatment centre” OR “drug treatment service” OR “drug-treatment facilit*” OR “homecare” OR “home care” OR “domiciliary” OR “primary care” OR “community care” OR “respite care” OR “specialist care” OR “live-in care” OR “live in care” OR “homeless service*” OR “homeless shelter*”
Intervention	“regulation” OR “regulator*” OR “inspect*” OR “enforcement” OR “licens*” OR “certification” OR “withdrawal”
Mechanisms	“factor*” OR “barrier*” OR “facilitator*” OR “enabler*” OR “determinant*” OR “characteristic*” OR “indicator*” OR “association*” OR “relationship*” OR “cause*” OR “engagement” OR “attitude*” OR “predictor*”
Outcome	“compliance” OR “non-compliance” OR “violat*” OR “deficienc*” OR “sanction*” OR “citation*” OR “failure*” OR “failing*”

4.3.4 Information sources

Searches will be carried out on the following databases: PubMed, MEDLINE, PsycINFO, CINAHL and SocINDEX. In addition, the bibliographies of the included full-text articles will be hand searched for relevant articles. Forward citation searching will also be carried out to identify other potential material for inclusion. The search terms for one electronic database (PubMed) are provided in Table 2.

Searches will also be conducted on established grey literature databases including OpenGrey System for Information on Grey Literature in Europe and OpenSIGLE. Targeted searches will also be carried out on websites of regulatory organisations and Government agencies/departments involved in health and social care regulation, identified by referring to the Organisation for Economic Development and Cooperation's (OECD) resources on regulatory policy internationally.[131]

4.3.5 Software

The software used for screening articles is the online tool Covidence[132] and the bibliography manager is EndNote 20 published by Clarivate.[133]

4.3.6 Screening

All references returned by the search terms from each information source will be imported into Covidence. Duplicate references will be removed. Two researchers will independently screen the titles and abstracts of each of the retrieved articles against the inclusion/exclusion criteria using Covidence. Any disagreements on inclusion/exclusion will be resolved, in the first instance, by discussion. Any disagreements not resolved by discussion will be adjudicated on by a third author. Full-text review and bibliography searches will be performed by PD. The search strategy and study selection process will be reported in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement.[134] A PRISMA flow diagram will be generated.

4.3.7 Quality appraisal

As referenced above, a wide range of study designs will be considered for inclusion in the systematic review. Preliminary searches have found studies that are entirely quantitative or qualitative as well as mixed-methods. Quality appraisal tools will be selected dependent on the type of study. As such, the suite of appraisal tools made available by the Joanna Briggs Institute will be used.[135] Grey literature will be appraised for quality with reference to Tyndall's checklist which assesses the following aspects: authority, accuracy, coverage, objectivity, date and significance (AACODS).[136]

Two reviewers will independently assess the quality of articles selected for data extraction. Any disagreements on quality appraisal will be resolved by consensus or, if necessary, a third author will be consulted for final decision.

4.3.8 Data extraction

Two reviewers will independently carry out data extraction of all articles deemed eligible for inclusion, using a data extraction table (Appendix 2). The data to be extracted includes general information (title, author(s), publication date) as well as specific data under each of the CFIR domains. The data extraction template has been piloted and refined using studies retrieved during preliminary searches. The extracted data will be compared to ensure agreement and identify any discrepancies; disagreements will be resolved by discussion. Any disagreements not resolved by discussion will be referred to a third author for arbitration or, where appropriate, through contact with the study authors.

4.3.9 Data synthesis

Due to the wide range and heterogeneity of the studies that will be returned through the search strategy, a narrative synthesis will be performed. Narrative synthesis uses text and illustrations to describe, compare and combine heterogeneous qualitative findings and quantitative results.[137] This approach places the focus on the interpretive synthesis of the narrative aspects of research findings, as opposed to any attempt to synthesise findings in a quantitative manner, such as in a meta-analysis.

The extracted data will first be tabulated in accordance with the CFIR and its respective domains and constructs. The data will then be summarised in narrative form, incorporating elements of *Popay et al.*'s methodology of narrative synthesis,[138] and in line with the CFIR domains and constructs in addition. Overall confidence in the evidence will be appraised with reference to GRADE-CERQual.[139]

4.3.10 Dissemination of information

The systematic review will be submitted to an academic journal on completion. Conference abstracts arising out of the systematic review will also be submitted to appropriate conferences for presentation. The findings of the systematic review will be circulated and presented to regulation staff in the Health Information and Quality Authority, Ireland. Review findings will be circulated to other regulators in Europe through the Supervision and regulation Innovation Network for Care (SINC).

4.3.11 Study status

Database searches using the search terms outlined in Table 2 have commenced.

4.3.12 Strengths and limitations

To the best of the author's knowledge, this review will be the first to systematically assess the determinants of regulatory compliance. In addition, the methodological approach (including a wide range of study designs; synthesising the data using narrative synthesis with reference to the CFIR) allows for a comprehensive exploration of what factors are associated with the successful integration of regulatory requirements with an organisation's goals. The use of GRADE-CERQual in appraising the quality of the overall body of evidence will aid knowledge users in establishing which determinants are appropriate for inclusion in any quality improvement initiatives.

In terms of limitations, it is possible that some relevant studies may not be retrieved due to the multiplicity of terms used in the literature to refer to regulation and compliance. This has been ameliorated with reference to resources from a range of countries to ensure that equivalent words and phrases are used in the search terms.

4.4 Conclusion

This protocol describes the methodological approach for searching, synthesising and quality appraisal of the available literature to answer the research question, what are the determinants of regulatory compliance in health and social care services? The findings of the systematic review will be of interest to organisations working in a regulatory capacity across diverse fields and may also inform quality improvement initiatives for service providers and policy makers in the health and social care sector.

4.5 Data availability

Underlying data

No data are associated with this article.

CHAPTER 5: Determinants of regulatory compliance in health and social care services: a systematic review using the Consolidated Framework for Implementation Research.

The following chapter was published in the PLOS one Journal:

Dunbar P, Keyes LM, Browne JP. Determinants of regulatory compliance in health and social care services: a systematic review using the Consolidated Framework for Implementation Research. Plos one. 2023 Apr 13;18(4):e0278007.

Authors

Paul Dunbar[1], Dr Laura Keyes[2], Prof John P Browne[3]

Author details

[1] Health Information and Quality Authority, Unit 1301, City Gate, Mahon, Cork, Ireland T12 Y2XT. pdunbar@hiqa.ie (corresponding author)

[2] Health Information and Quality Authority, Unit 1301, City Gate, Mahon, Cork, Ireland T12 Y2XT. loconnor@hiqa.ie

[3] School of Public Health, University College Cork, Ireland j.browne@ucc.ie

5.1 Abstract

Background

The delivery of high quality care is a fundamental goal for health systems worldwide. One policy tool to ensure quality is the regulation of services by an independent public authority. This systematic review seeks to identify determinants of compliance with such regulation in health and social care services.

Methods

Searches were carried out on five electronic databases and grey literature sources. Quantitative, qualitative and mixed methods studies were eligible for inclusion. Titles and abstracts were screened by two reviewers independently. Determinants were identified from the included studies, extracted and allocated to constructs in the

Consolidated Framework for Implementation Research (CFIR). The quality of included studies was appraised by two reviewers independently. The results were synthesised in a narrative review using the constructs of the CFIR as grouping themes.

Results

The search yielded 7,500 articles for screening, of which 157 were included. Most studies were quantitative designs in nursing home settings and were conducted in the United States. Determinants were largely structural in nature and allocated most frequently to the inner and outer setting domains of the CFIR. The following structural characteristics and compliance were found to be positively associated: smaller facilities (measured by bed capacity); higher nurse-staffing levels; and lower staff turnover. A facility's geographic location and compliance was also associated. It was difficult to make findings in respect of process determinants as qualitative studies were sparse, limiting investigation of the processes underlying regulatory compliance.

Conclusion

The literature in this field has focused to date on structural attributes of compliant providers, perhaps because these are easier to measure, and has neglected more complex processes around the implementation of regulatory standards. A number of gaps, particularly in terms of qualitative work, are evident in the literature and further research in this area is needed to provide a clearer picture.

5.2 Introduction

The delivery of high quality care is a fundamental goal for health systems worldwide. Quality is variable, due to structural issues such as insufficient staffing levels,[140] or process issues like poor cleaning practices,[141] and can cause differences in outcome across health and social care providers such as high complication rates and poor patient experience.[107]

Governments commonly introduce regulation to monitor the quality of goods and services. Regulated organisations/individuals must comply with prescribed standards. In health and social care, regulatory bodies typically license or authorise providers, and/or directly regulate the structures and processes of care through inspection, feedback or sanctions.[142]

Regulation can be defined as: “sustained and focused control exercised by a public agency over activities which are valued by a community”.[143] The scope of regulation in health and social care differs depending on the setting and country. Principally, regulation centres on structural, process and outcome-related aspects of services. For example, in nursing homes (NH) in the United States, regulations cover *inter alia* resident rights, nursing services, infection control, physical environment and resident assessment.[144]

There are important differences in how countries regulate health and social care. In one model the regulator is a publicly-funded, independent organisation which is aligned to a government ministry e.g. Healthcare Improvement Scotland.[145] There are also examples of regulatory authorities that are incorporated into government ministries e.g. Ministry of Long-Term Care (Ontario).[146]

In both examples above, the regulator has statutory powers of inspection and enforcement. A third approach is found in countries such as Australia where mandatory accreditation is performed by third-party organisations.[147] While having no statutory powers their role is akin to a regulator because any decision to not accredit can result in State sanctions.[148] This is distinct from other models of voluntary accreditation.[149]

Regulatory compliance can be understood as “behavior fitting expectations communicated to regulatees regarding how the former should or should not behave in a given domain”.[112] This conceptualisation of compliance is markedly different to adhering to clinical guidelines or voluntary codes of practice. A feature of regulatory compliance is the mandatory requirement to comply with standards and rectify deficits.

There is a substantial literature on the structures (e.g. public/private ownership, facility size and staffing levels/competencies[120, 122, 150, 151]) and processes (e.g. disposition towards regulation, normalisation of compliance within day-to-day operations[33, 152]) which determine compliance by health and social care organisations. This literature, not yet synthesised, is a distinct subset of the broader literature on determinants of quality because of the context and focus of regulation. Unlike most quality assessment initiatives, regulation involves consequences for the regulatee, and therefore introduces different motivations around implementation.

Regulators and regulatees would prefer that all interactions produced findings of compliance. Understanding the determinants of compliance is one way to increase this likelihood. Regulation can be regarded as a complex intervention and compliance equates to successful implementation. This allows for the use of implementation science concepts to better understand why some organisations fail to comply: "implementation science enables questions to be asked about whether, and if so how, an intervention can make a difference to a patient's life or to the practice of a health care delivery team".[153] The success of an innovation is contingent on a range of factors. For example, the attitudes and beliefs of staff towards an innovation can influence its implementation.[154]

Several tools/frameworks have been developed in the field of implementation science. The Consolidated Framework for Implementation Research (CFIR) is one such framework.[83] The CFIR was developed by drawing together disparate existing theories on implementation to produce an "overarching typology–a list of constructs to promote theory development and verification about what works where and why across multiple contexts".[83] The CFIR has been used previously as a framework for structuring and synthesising the results of systematic reviews.[155]

There is a body of work critiquing the effectiveness of regulation (e.g. improving system performance[156]), but given that regulation exists, and that there is much effort put into compliance, it is legitimate to investigate this practice on its own terms. There has been no previous synthesis of the extensive literature which makes use of regulatory compliance as an outcome measure in health and social care settings. Moreover, little is known about the processes by which health and social care services manage regulatory encounters and how this impacts on compliance. Thus, the aim of this systematic review is to identify and describe determinants of regulatory compliance in health and social care services, and the broader phenomenon of attempting compliance. The focus of the review is on the regulation of organisations as there are existing evidence syntheses on the regulation of individual professionals.[157, 158]

5.3 Methods

We performed a systematic review of studies that used qualitative, quantitative or mixed-methods approaches to identify determinants of compliance in health and social care services. We take regulation to mean any form of evaluation of quality

and safety which is underpinned by sanctioning powers. Any literature focusing on the regulation of individual professionals (e.g. nurses) or on occupational health and safety (e.g. working hours) were outside scope. Determinants were anything associated with compliance and could be aspects of the organisation or the environment in which it is situated. Determinants may also be barriers or facilitators to successful implementation of regulatory requirements. In quantitative studies the outcome of interest was regulatory compliance and in qualitative studies this was also the phenomenon of interest. We interpreted regulatory compliance as any formal approval of the performance of a health or social care provider by the relevant regulator or accrediting agency. The review follows a published protocol which was not registered.[159] The methods applied are summarised in brief with additions to/deviations from the original protocol outlined.

5.3.1 Criteria for inclusion

The phenomena of interest were determinants of regulatory compliance in health and social care services.

Articles — either qualitative, quantitative or mixed-methods — were included if they:

- Described factors or characteristics that were related to regulatory compliance. Specifically, this refers to regulations that are mandated by government or other state authorities. A wide range of constructs were considered for inclusion including, but not limited to, the following: service characteristics (size, location, model of care, ownership); organisational characteristics (culture, management/governance structure, maturity); service user characteristics (age, disability type, disease/illness); nature of regulatory engagement (punitive, adversarial, collaborative).
- Discussed barriers or facilitators to regulatory compliance for health and social care services.
- Were focused on quality of care in health and social care services and used regulatory compliance as an outcome measure.

Studies were excluded if they:

- Analysed regulatory compliance in a field other than in a health or social care setting.
- Analysed compliance with clinical guidelines or other evidence-based methods for managing care that were not underpinned by the potential for regulatory sanction where there was a failure to comply.
- Used an outcome measure that was not equivalent to regulatory compliance in accordance with the definitions set out above. For example: adherence to voluntary standards or codes of conduct; where failure to comply does not result in regulatory sanctions of enforcement; compliance concerning individuals as opposed to organisations as is the case with regulations for specific health care professionals.

A search strategy using the CIMO (Context, Intervention, Mechanism, Outcome) framework was devised (Appendix 3). Searches were carried out on 22nd July 2022 on PubMed, MEDLINE, PsycINFO, CINAHL, SocINDEX and OpenGrey. Targeted web searches were conducted. The reference lists of any systematic reviews identified were searched for relevant material. In deviating from the protocol, we included the term 'accreditation' in the search terms to identify studies where accreditation was mandatory i.e. *de facto* regulation. There were no time or language restrictions. The reference lists of all included articles were hand-searched for additional relevant material. Forward citation searching of included articles was also conducted.

5.3.2 Screening and full-text review

All articles were imported into Covidence[132] and the title/abstract screened by two reviewers independently. Full-text review was carried out by PD.

5.3.3 Data extraction

Data extraction was performed by PD. LMK independently performed data extraction on 10% of articles for crosscheck purposes. For all studies, the following data were extracted: full reference, study type, publication type, country, study aim(s), population/setting (Appendix 2). The extraction of results data differed depending on the study design. For example, in studies reporting quantitative results, the variable name and its direction of association with compliance were extracted whereas for qualitative studies whole sentences or phrases were extracted.

Determinants expressed as composites (e.g. Medicaid occupancy multiplied by Medicaid rate) were omitted. We focused on determinants of overall compliance measures. Where not available, determinants of compliance with specific regulations were reported. We excluded variables acting as measures of quality (e.g. proportion of patients/residents with pressure sores; proportion of patients/residents subject to physical restraint), because of the likelihood of circular reasoning: in theory, quality is an outcome, rather than a determinant of compliance.

In qualitative and mixed-methods studies, anything mentioned as influential with respect to compliance activity, either negative or positive, was extracted for synthesis.

5.3.4 Analysis

We counted studies where a determinant was estimated and recorded the association with compliance in each case. In quantitative studies, associations with compliance were recorded as 'positive/negative/null' for continuous or ordinal variables, 'different/null' for nominal variables ('different' denoting that one or more categories in the variable was positively or negatively associated with compliance). In qualitative studies, the role of the relevant factor in influencing engagement with the regulatory process was noted.

Determinants were then coded to the most appropriate CFIR construct through an iterative and deliberative process among all three authors. PD first coded each determinant to the most appropriate CFIR construct (e.g. determinants related to facility size were coded to the structural characteristics construct in the inner setting domain), with reference to established definitions.[83] These data were then discussed jointly by PD and LMK in order to ensure that determinants were placed in the most appropriate construct. This process resulted in some determinants being moved to alternative constructs and also the creation of a category of 'other' within each domain. This was necessary due to the significant number of determinants that had no appropriate match in the CFIR (e.g. the survey tools used by inspectors had no equivalent match for a construct in the intervention characteristics domain).

PD, LMK and JPB subsequently discussed all coding with a particular emphasis on whether the determinant had relevance in the specific context of implementing regulations. For example, a determinant relating to the level of public/state funding made available for services was originally coded to the available resources construct

in the inner setting domain. On reflection, we determined that this was not appropriate as the funding was not specifically related to implementing regulations. As such, this determinant was moved to 'other' in the inner setting domain. This process continued until all three authors agreed on the coding of each determinant. The analysis was also consistent with the application of the CFIR to post-implementation evaluation of innovations, where determinants are linked to outcomes i.e. compliance.[83]

5.3.5 Quality appraisal

Quality appraisal of quantitative and qualitative studies used the Joanna Briggs Institute tools[135]; for mixed-methods studies we used the Mixed-Methods Appraisal Tool (MMAT).[160] All grey literature were PhD theses and were appraised using the most appropriate Joanna Briggs Institute tool.[135] PD and FB (see acknowledgments) carried out quality appraisal independently and subsequently compared findings. Any disagreements were resolved by PD and FB jointly reviewing the respective studies and arriving at a consensus.

5.4 Results

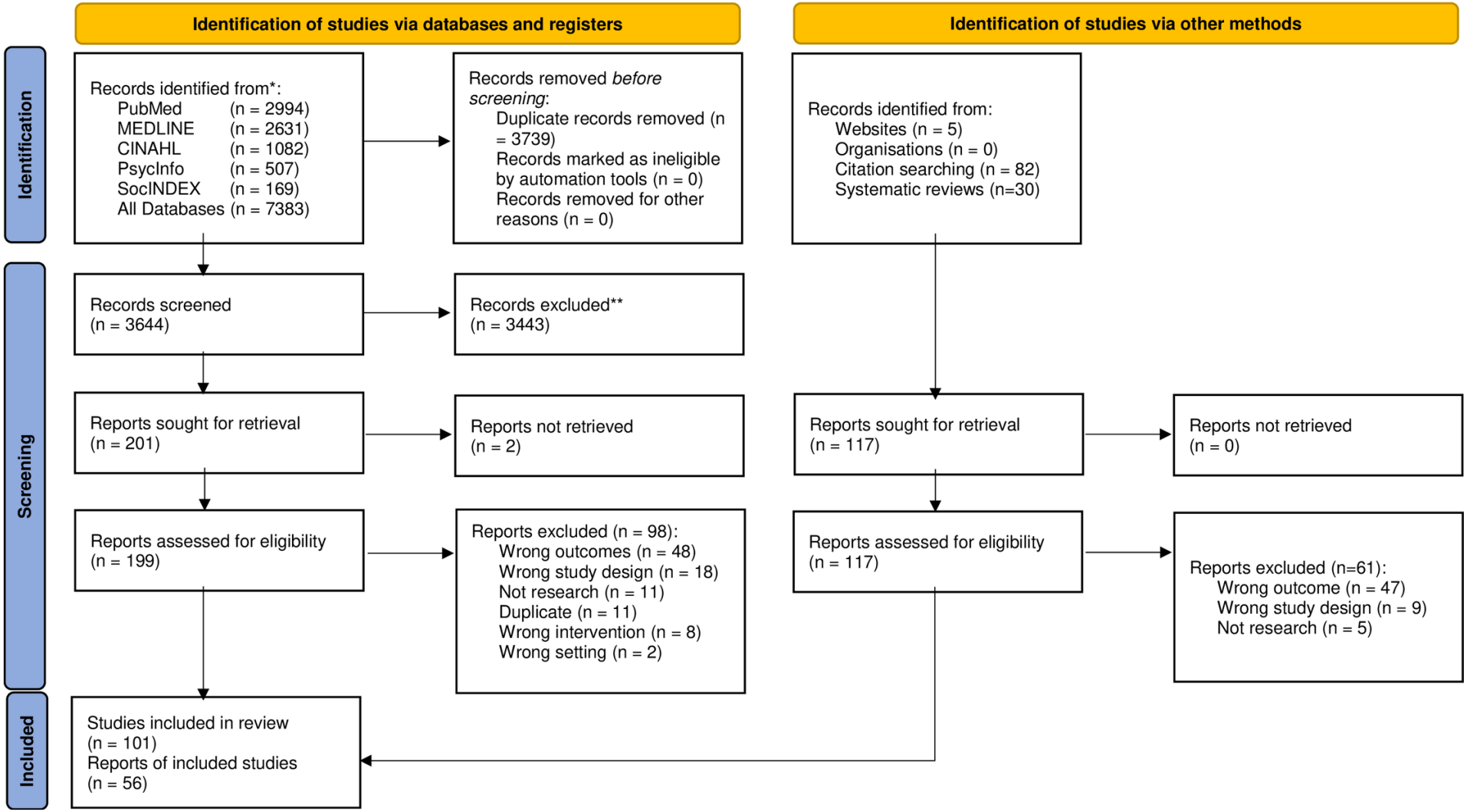
7,500 records were retrieved: 7,383 from electronic database searches and 117 from targeted web searches, reference searches and forward citation searching. Of the 7,383, 3,739 duplicates were removed. Title/abstract of 3,644 were screened, 3,443 did not meet inclusion criteria, leaving 201 for full-text review. All but two studies were retrieved, leaving 199 for full-text review. Upon full-text review, 98 were excluded leaving 101.

Of the 117 found by other means (i.e. targeted web searches, reference searches and forward citation searching), 61 were ineligible, leaving 56. The total number of studies in the review was 157 (See Figure 2 for PRISMA flow diagram, Appendix 4 for PRISMA checklist and Appendix 5 for full list of included studies). Characteristics of included studies are set out in Table 3. The full dataset of all extracted data in the systematic review is available from the following repository: https://doi.org/10.1371/journal.pone.0278007.s006

Table 3 – Characteristics of studies included in the systematic review

Publication type	**n (%)**
Journal Article	137 (87.3)
Thesis	19 (12.1)
Book Section	1 (0.6)
Study setting	**n (%)**
Nursing Homes	143 (91.1)
Hospitals	7 (4.4)
Nursing/Care Homes	2 (1.3)
Assisted-living facilities	2 (1.3)
Nursing Home/Assisted-Living Facilities	2 (1.3)
Pharmacies	1 (0.6)
Study design	**n (%)**
Quantitative	
Cross-sectional/Observational	140 (89.2)
Longitudinal	3 (1.9)
RCT	2 (1.3)
Experimental	2 (1.3)
Qualitative	
Case study	4 (2.5)
Ethnography	1 (0.6)
Focus groups	1 (0.6)
Mixed methods	4 (2.5)
Country	**n (%)**
USA	140 (89.2)
Australia	9 (5.7)
Europe	
United Kingdom	3 (1.9)
Denmark	1 (0.6)
Portugal	1 (0.6)
Netherlands	1 (0.6)
China	1 (0.6)
Saudi Arabia	1 (0.6)

Figure 2 – PRISMA 2020 flow diagram: Determinants of regulatory compliance in health and social care services: a systematic review using the Consolidated Framework for Implementation Research



Search parameters were configured to identify studies that specifically focused on compliance as an outcome. It is possible there is a body of literature on regulatees' perspectives on regulation that were not included as there was no attempt to link these perspectives to compliance.

5.4.1 Quality appraisal

Quantitative studies

There were mixed findings in terms of the quality of quantitative studies (Appendix 6). Most followed best practice in terms of defining their samples, identifying and controlling for confounding factors, and using appropriate statistical methods. However, there were limitations evident in the use of self-reported measures (e.g. measurements of culture) and therefore it was not possible to be assured that these were objective.

Qualitative and mixed methods studies

Most qualitative and mixed methods studies were of good quality (Appendix 6). There was generally a congruence between the methods employed by the researchers and their objectives, data collection methods, analysis and interpretation of results. Common weaknesses in these studies tended to be a lack of reflexivity or the absence of a statement locating the authors culturally and theoretically in the research.

5.4.2 Mapping findings to the CFIR

We coded findings to all five CFIR domains. We coded findings to 19 of the 39 CFIR constructs, in addition to coding findings to an additional construct for 'other' in each of the five domains.

5.4.3 Intervention characteristics

This domain covers "aspects of an intervention that may impact implementation success, including its perceived internal or external origin, evidence quality and strength, relative advantage, adaptability, trialability, complexity, design quality and presentation, and cost".[161] We coded nothing to four of the eight constructs in this domain: intervention source; trialability; design quality and packaging; cost. In total, 16 studies featured in this domain, see Table 4.

Table 4 – Determinants coded to the intervention characteristics domain

Construct	Determinant
Intervention Source	No studies
Evidence Strength & Quality	"The sentiment seemed to be shared among others in the room, who laughed and nodded, and agreed that there was a tangible disconnect between their delivery of clinical care and the ratings and scores representing their care to the public" "As one nurse manager put it in a meeting," … it's not about the clinical management of sepsis, it's about fully reporting the "cookbook" steps of the goal" "clinicians repeatedly defined metric compliance as distinct to their clinical practice or scientific expertise"[152]
Relative Advantage	"Rather than containing the worst aspects of corporate activity in this sector, regulation may serve to obscure what might be widespread routine forms of injurious activity through a veil of bureaucratic compliance"[162]
	"During the discussion one of the participants (E8) mentioned that there are an estimated 3,000 non-licensed nursing homes in Portugal. "An inspection with a global closing order of all the illegal nursing homes would create an unsolvable problem: what would become of all the elderly who live there nowadays, who are roughly 25,000 to 30,000 people? There are simply not enough beds for so many people" (E8). Therefore, as mentioned by E5: "Unfortunately there is a lot of covering-up and impunity in Portugal"[163]
Adaptability	"A mandate that requires clinicians to timestamp and document secondary tasks, just to ensure metric compliance, historically is not typical for ED workflow"[152]
Trialability	No studies
Complexity	"An internist involved in quality assurance, explained that clinicians and administrators agreed SEP-1 was so complex it would need its own meeting" "His explanation echoes accounts from research at other hospitals, which confirm unprecedented complexity contributing to SEP-1's difficulty"[152]
Design Quality & Packaging	No studies
Cost	No studies
Other	Disapproving inspection teams[35] Inspection team characteristics[164-168]

	Inspection survey tool[169, 170] Inspection team: cooperative[36] Inspection team: deterrence[36] Inspection team: persuasion and education[36] Inspection team viewed intervention as necessary[36] Inspection type[171] Perceived persuasive approach by regulator[172] Perceived punishment approach by regulator[172] Re-integrating inspection teams[35] Stigmatizing inspection teams[35] Tolerant inspection teams[35] Unannounced inspections[173]

5.4.3.1 Evidence strength & quality

Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the innovation will have desired outcomes.

Hospital staff expressed scepticism that a regulatory rating reflected their own perception of quality: "The sentiment seemed to be shared among others in the room, who…agreed that there was a tangible disconnect between their delivery of clinical care and the ratings and scores representing their care to the public".[152]

5.4.3.2 Relative advantage

Stakeholders' perception of the advantage of implementing the innovation versus an alternative solution.

In this instance, regulatory standards were the innovation to be implemented. Findings were coded here if they were concerned with advantages (or disadvantages) derived from complying. NH inspectors noted that enforcing closure of unauthorised NH would mean loss of bed capacity, thereby questioning the logic of implementing that solution.[163] The inspectors reasoned that turning a blind eye was somehow more desirable than the closure of thousands of beds.[163] In a participant observation study, regulators provided "a veil" of compliance to care providers who then leveraged this to attract service users.[162] Managers "reproved workers not on the basis of whether tasks had been completed, but according to whether files reflected

regulatory standards".[162] Thus, management perceived the advantage of good documentation — even going as far as to falsify records — in order to achieve compliance.[162]

5.4.3.3 Adaptability

The degree to which an innovation can be adapted, tailored, refined, or reinvented to meet local needs.

This construct refers to how regulatory measures can be adapted to fit with existing work practices. In a qualitative study, the requirement for clinicians to document secondary tasks to ensure compliance was reported to be difficult to adapt to a hospital's workflow.[152] Thus, it was challenging to comply because it created additional work or necessitated a work-around.

5.4.3.4 Complexity

Perceived difficulty of the innovation, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.

A regulatory measure related to sepsis treatment procedures presented "unprecedented complexity"; study participants suggested it was so complex it required its own quality assurance meeting.[152]

5.4.3.5 Other

Findings were placed in this section where they could not be coded to an appropriate construct but were considered relevant to this domain.

A study on attitudes to regulation reported that physicians who perceived a persuasive approach by regulators tended to be more compliant, as compared with a punishment approach.[172] Disapproving and re-integrating (i.e. respectful disapproval and then terminating disapproval through forgiveness upon improvement) inspection teams and compliance were positively associated whereas tolerant and stigmatizing teams were negatively associated.[35] Inspection teams that viewed intervention as necessary were positively associated with compliance, compared to three other types (cooperative; deterrence; persuasion & education) where there was a null association.[36]

Inspection team characteristics (e.g. office base, team composition) and compliance was reported to be associated in all five studies that investigated these determinants.[164-168] The number of inspectors on a team was reported to have a null

association with compliance.[174] Two studies investigated various tools used for inspection and both had an association with compliance.[169, 170] The type of inspection (e.g. inspections that mandated interviews with service users) was reported to be associated with compliance[171] whereas unannounced inspections were reported to have a null association when compared with announced.[173]

5.4.4 Outer setting

The outer setting domain is defined as "external influences on intervention implementation including patient needs and resources, cosmopolitanism or the level at which the implementing organization is networked with other organizations, peer pressure, and external policies and incentives".[161] Seventy-two studies were featured in the 'peer pressure' and 'external policy and incentives' constructs, as well as in 'other'. No determinants were coded to two of four constructs in this domain: 'cosmopolitanism' or 'needs and resources of those served by the organisation', see Table 5.

Table 5 – Determinants coded to the outer setting domain

Construct	Determinant
Needs & Resources of Those Served by the Organization	No studies
Cosmopolitanism	No studies
Peer pressure	Higher competition[120, 151, 175-192] Higher excess bed capacity in county[151, 193] Higher service demand[191] Nursing homes per population[193] Proportion of chains in region[184, 194, 195] Proportion of for-profit facilities[195] Proportion of hospital-based facilities[184, 195] Transparency (publication of star-rating)[182]
External Policy & Incentives	Higher state focus on infection prevention[196] Minimum staffing standard[197-199] More stringent nursing home administrator licensing criteria[195] Ombudsman available[200-202]

	State-level mandatory overtime laws[175] States with certificate of need law[203]
Other	Ageing advocacy group influence[195] Democratic party controlled legislature (USA)[195] Governor's institutional power[195] Higher local income[176, 179, 181, 188, 189, 191, 192, 195] Higher local unemployment[204] Higher mean age of service users[180, 195, 205] Higher population density[166, 175, 180, 191, 205-216] Higher proportion of African-American service users[120, 181, 205, 217, 218] Higher proportion of African-Americans residents in county[181] Higher proportion of Asian service users[181] Higher proportion of female service users[174, 180] Higher proportion of George W. Bush supporters in county[203] Higher proportion of Hispanic service users[120, 181, 218] Higher proportion of Hispanic residents in county[181] Higher proportion of married service users[174] Higher proportion of other non-White service users[120] Higher proportion of service users with dementia[122, 176, 178, 179, 183, 187, 188, 191, 192, 219-221] Higher proportion of service users with a disability[151, 174, 211] Higher proportion of service users with intellectual disability[178, 179, 183, 187, 188, 192, 221] Higher proportion of service users with incontinence needs[122, 183, 211, 219, 220, 222-226] Higher proportion of service users with mental illness[122, 176, 178, 179, 183, 186-188, 191, 192, 211, 219, 221-225, 227-231] Higher proportion of service users with obstructive bowel syndrome[211] Higher proportion of service users with high/complex care needs[122, 151, 175, 176, 178-181, 183, 187-193, 201, 211, 215, 219-226, 228, 232-239]

	Higher proportion of veterans[240] Higher proportion of White residents[180, 205, 241] Higher public funding[176-179, 184, 186-189, 192-195] Higher rate of religiosity[203] Individualistic state[203] Higher legislative professionalism[195] Nursing home industry influence[195] Moralistic state[195] State with Democratic Governor (USA)[184, 195]

5.4.4.1 Peer pressure

Mimetic or competitive pressure to implement an innovation, typically because most or other key peer or competing organizations have already implemented or are in a bid for a competitive edge.

Market pressure was frequently studied and we mapped related determinants to this construct. This may occur in two ways: pressure to have better compliance rates than competitors in order to attract more clients; or pressure to match or exceed the compliance levels of peer organisations (e.g. a chain of hospitals owned by one corporation). Of 20 studies investigating competition, four reported high competition was positively associated with compliance,[151, 186-188] four had a negative association,[189-192] 11 reported a null association;[120, 175-184] one had a u-shaped finding where higher competition and monopoly were both positively associated whereas moderate competition was negatively associated.[185]

Other studies investigated NH markets in a region. A higher proportion of chain NHs in a state and compliance was negatively associated in two studies,[184, 194] a third reported a null association.[195] The proportion of for-profit[195] and/or hospital-based NHs[184, 195] and compliance had a null association. The number of NHs in a county per population and compliance had a null association.[193] Additional findings related to this construct included: publication of quality ratings, which we construed as increasing competitive pressure within local markets (null[182]), excess bed capacity in a county (positive[193]; null[151]) and higher service demand (positive[191]).

5.4.4.2 External policy and incentives

A broad construct that includes external strategies to spread innovations including policy and regulations (governmental or other central entity), external mandates, recommendations and guidelines, pay-for-performance, collaboratives, and public or benchmark reporting.

We interpreted this construct as relating to the regulatory environment, either via funding, legislative measures or quality improvement initiatives from external sources. In American states that had legislation/policies governing quality issues (e.g. minimum staffing standards[197-199] or infection control initiatives[196]) a 'spillover' effect was observed: service providers were more compliant with other regulations compared with states that had no such legislation/policies. Other findings included: presence of an ombudsman (positive[200]; null[201, 202]); stricter licensing criteria for NH managers (null[195]); mandatory overtime laws (negative[175]); and states with 'certificate of need' laws (positive[203]).

5.4.4.3 Other

Findings were placed in this section where they could not be coded to an appropriate construct but were still considered relevant to this domain.

Most of the material listed below relates to service user needs or the characteristics of a given population. We coded measures of service user case-mix to the 'outer setting' domain because, although case-mix is treated within the 'inner setting', it is a measure of the broader population being served.

In the context of people using services, 43 studies investigated the proportion of service users with needs that may require more care (e.g. dementia, incontinence, mental ill health).[122, 151, 174-176, 178-181, 183, 186-193, 201, 211, 215, 219-239, 242] In general, higher proportions of such service users and compliance was negatively associated. For example, a higher proportion of service users with higher or more complex care needs (typically measured by case mix or activities of daily living scores) and compliance was reported to be positively associated in five studies,[122, 187, 219, 222, 226] negatively in 18 studies,[122, 151, 175, 176, 178, 189, 191, 211, 219-222, 225, 228, 233, 234, 237, 242] with 21 reporting a null association[179-181, 183, 188, 190, 192, 193, 201, 211, 215, 221-223, 225, 226, 232, 235, 236, 238, 239] (some studies investigated multiple different measures of care needs and reported different associations with compliance. Therefore, these studies appear across more than one of the above categories).

Higher mean age of service users and compliance was negatively associated in two[195, 205] of three studies. Studies also investigated service user ethnicity: higher proportion of white service users (positive[205]; null[180]); higher proportion of Asian service users (positive[181]); higher proportion of black service users (negative[205, 217]; null[120, 181, 218]); higher proportion of Hispanic service users (null[181, 218]; positive[120]); higher proportion of other non-white service users (positive[120]). Studies also reported on proportion of female service users (positive[174]; null[180]), proportion of married service users (positive[174]), and proportion of service users that were war veterans (negative[240]).

Other studies measured characteristics of the broader population served by a provider. Higher population density and compliance was positively associated in five studies [191, 205, 213, 214, 216], negatively in one,[215] with ten finding a null association.[166, 175, 180, 206-212] Other material featuring in this construct were the proportion of elderly in the population (positive[179, 189, 203], negative[178, 184, 187, 192], null[176, 188]); higher per-capita/household income (positive[178, 195]; negative[175, 187]; null[176, 179, 181, 188, 189, 191, 192]) higher unemployment rates (positive[204]); higher rates of religiosity (positive[203]); higher proportions of African-Americans in a county (positive[181]); and higher proportions of Hispanics in a county (positive[181]).

Higher levels of public/state funding for services and compliance was positively associated in six studies,[176, 179, 186, 187, 189, 243] negatively in one study[192] and seven studies reported no association.[177, 178, 184, 188, 193-195]

Three studies from the United States examined political context such as having a Democratic party Governor (negative[184]; null[195]); a higher level of legislative professionalism;[195] the proportion of people that supported George W. Bush (positive[203]); having a Democratic-controlled legislature (negative[195]); or states designated as individualistic (positive[203]) or moralistic (null[203]). The presence of lobbying groups and compliance was reported to have a null association.[195]

5.4.5 Inner setting

The majority of studies (n=132) included at least one determinant coded to this domain (see Table 6). We coded no determinants to five out of 12 constructs: implementation climate – organisational incentives and rewards; implementation climate – goals and feedback; readiness for implementation; readiness for

implementation – available resources; readiness for implementation – access to knowledge and information.

Table 6 – Determinants coded to the inner setting domain

Construct	Determinant
Structural Characteristics	Continuing care retirement community[200, 221, 222] County medical care facility[235] Facility certification status[166] Facility certification type[207, 216] Facility provides skilled/specialist services[166, 191, 200, 209, 211, 220, 221, 224, 239, 244-246] For-profit facility[120, 151, 163, 165, 166, 174, 176-181, 183, 186-194, 200, 201, 203, 205, 209-216, 219-222, 224, 232, 233, 235, 237, 242, 244-252] Geographic location[120, 170, 174, 183, 190, 193, 208, 214, 216, 221, 223, 235, 246, 253, 254] Government-owned nursing home without a shared owner in hospital referral region[222] Higher number of years of facility in operation[174, 182, 222, 239, 244] Hospital-based facility[122, 151, 166, 190, 191, 200, 203, 207, 220, 222, 224, 233, 235, 255] Hospital participating in a clinical surgery registry[234] Larger size facility [120, 122, 151, 164-167, 174-176, 178-181, 183, 186-193, 200, 201, 203, 206, 207, 209-212, 214-216, 220-226, 234, 235, 237, 242, 243, 245-247, 249-253, 255-257] Level-1 trauma centre[234] Major teaching hospital[234] Model of ownership[191, 206, 207, 221, 225, 226, 236, 252, 255, 258, 259] Number of years organisation has engaged with accreditation[250] Nursing home co-location[256] Nursing home located near psychiatric hospital[231] Nursing home participating in community nursing home programme[240] Nursing home with shared owner of another nursing home in hospital referral region[222]

	Nursing home with specialist registration[239] Revenue source[207] Safety-net hospital status[234] "social workers and admission coordinators [in poorly-performing nursing homes as measured by compliance] were instructed to fill beds with Medicare residents before accepting Medicaid residents"[260]
Networks & Communications	Chain membership[120, 176, 178-181, 183, 187-192, 203, 205, 209, 211, 219, 221-225, 233, 235, 237, 242, 245, 251, 252, 261] Higher facility consultation with families[181, 205, 219, 245] Higher facility consultation with residents[200, 219, 245] Higher staff meeting frequency[262, 263] Higher use of information technology[210, 253, 263-265] Notification method for residents with potential infection[262] Nursing home has resident/family council[222] Nursing home is associated with other compliant facilities[266] Nursing homes that use a satisfaction survey[267] Process standardisation across chain[223] "In the historically high-performing nursing homes (NH1 and NH2), administrative and direct care staff used multiple modes of communication to care for residents and their families"[260] "In both homes, the flow of information, both hierarchically and laterally, was important to meeting resident needs quickly and thoroughly"[260] "In the low-performing nursing homes (NH3 and NH4), the conflicting message regarding the organizational mission, that is, the explicit (resident care) versus the implicit (economic viability and regulatory compliance), fragmented and confused staff"[260] "Problem resolution resulted in the creation of new forms, additional steps, problem intensification, and communication breakdown within and across disciplines and departments"[260]
Culture	Changing from non-profit to for-profit facility[268] Higher culture change focus[269, 270]

	Higher focus on reducing hospitalisation[262] Higher focus on patient-centred care[232, 237, 271, 272] Nursing home strategic focus[273] Organisational disposition towards regulation[36, 266]
Implementation Climate	
Tension for Change	More strict enforcement[182, 222, 244, 274-277] "participants expressed an awareness of the pressure they feel to reduce the overall reported rate to fulfill regulatory requirements and maintain or improve their star rating via the CMS public-reporting system to denote nursing home care quality"[278]
Compatibility	"The powerplan was stressed as the key to correct documentation and thereby improved compliance with the metric"[152] "a coordinated, and inevitably, standardized approach to treating sepsis based on both policy requirements and clinical expertise. They also produce the documentation necessary for meeting and reporting on regulatory sepsis metrics"[152]
Relative Priority	Provider concern about regulatory enforcement[174]
Organizational Incentives & Rewards	No studies
Goals & Feedback	No studies
Learning Climate	"Staff across and within all disciplines [in high-performing nursing homes as measured by compliance] were involved in problem solving and decision making; staff were reminded that decision making and creativity improved with multiple perspectives"[260]
Readiness for Implementation	No studies
Leadership Engagement	Accredited facility[234, 247, 279-281] Higher ownership turnover[213] Receipt of a quality award[282] "In the high-performing homes, the leadership behaviors of the NHA and the DON created a clear, explicit, and coherent mission, a strong sense of purpose, for the organization….The importance of leadership relationship behaviors and the congruence of the stated and lived mission of the home were

	strikingly different between high- and low-performing homes"[260]
Available Resources	No studies
Access to Knowledge & Information	No studies
Other	**Staffing** Higher administrative staffing[122, 183] Higher agency/contract staff levels[175, 272, 283, 284] Higher degree of nursing centralisation in a nursing home[166] Higher food-service staffing[285] Higher housekeeping staffing[122, 285] Higher infection control professional quality[263] Higher job satisfaction[286] Higher level of certified medication aide staffing[287] Higher level of staff training[220, 223, 239, 245, 262] Higher level of trainee nurse aides[287] Higher licensed practitioner/vocational nurse staffing[122, 176, 178-180, 183, 186-190, 192, 206, 210, 211, 222, 224, 237, 243, 252, 272, 285, 287] Higher nurse aide absenteeism[261] Higher nurse aide staffing[122, 150, 164, 166, 176, 178-180, 183, 186-190, 192, 210, 211, 222, 224, 237, 243, 252, 255, 256, 272, 285, 287, 288] Higher ratings for work effectiveness and practice environments in nursing homes[237, 249] Higher ratio of registered nurses as against other nurse and care staff [165, 186, 188, 226, 238, 242, 272, 289] Higher registered nurse staffing[122, 150, 165, 178-180, 183, 187, 188, 190, 192, 195, 222, 224, 225, 236-238, 242, 243, 251, 252, 256, 272, 283, 285, 287, 288, 290] Higher social services director caseload level[213] Higher specialist staffing[122, 164, 166, 186, 220, 245, 285, 291] Higher staff turnover[165, 181, 183, 205, 226, 262, 263, 272, 283, 289, 292-298] Higher staff workload[213, 262]

	Higher total nursing staff [165, 166, 176, 186, 189, 190, 201, 210, 212, 234, 236, 255, 287, 290, 293] Higher total staffing[181, 220, 223, 245, 251, 283] Nursing home meeting minimum staffing standard[189, 290] "Administrative leadership behaviors that fostered staff appreciation included routine practices such as having adequate staffing levels and resources to do the job (e.g., resident lifts); helping out on the floor by making beds, passing meal trays, and assisting residents when needed"[260] **Financial** Facilities that provided finances training, meetings or expert consultation related to infection control[262] Higher facility costs[193, 205, 211, 226, 235, 259, 299-302] Higher facility income[181, 193, 239, 301] Higher facility market share[303] Higher facility profitability[120, 180, 226, 304, 305] Higher staff salary levels[257] Higher proportion of private payers[191, 226, 245] Higher proportions of publicly-funded service-users[120, 122, 151, 165, 166, 175-181, 183, 186-188, 190, 191, 193, 195, 205, 206, 209, 211, 215, 216, 219-221, 224, 226, 233, 235, 236, 238, 239, 242, 243, 245] **Admissions** Accepts Medicaid admissions[165, 200, 209, 212, 244] Accepts Medicare admissions[200, 233] Higher admission rate[211, 225] Hospitals accepting critical access or rural referrals[215] Higher occupancy levels[151, 175, 176, 178-180, 183, 184, 186-190, 192-194, 211, 219-222, 224, 235, 239, 242, 248, 255, 283] **Ownership** Recently-acquired nursing homes[222, 306] Poor quality nursing homes that were acquired by a chain[306] Higher quality of acquiring nursing home chain[306] **Infection control**

	Additional job responsibilities for infection control staff[262] Participation in infection control collaborative[262, 263] Types of resources used to determine and treat infection[262] **Chains** Physical plant standardisation across a nursing home chain[223]

5.4.5.1 Structural characteristics

The social architecture, age, maturity, and size of an organization.

We construed this construct as including a wide range of organisational characteristics such as size, location, for-profit status and services provided.

Of the 15 studies that evaluated geographic location (comparing cities or regions), 14 reported compliance differed depending on location;[120, 170, 174, 183, 190, 193, 208, 214, 216, 221, 223, 235, 246, 254] one[253] reported a null association.

For-profit service providers and compliance were negatively associated in 29 studies,[120, 151, 163, 174, 177, 181, 186, 189-191, 194, 201, 203, 205, 209, 213-216, 219-222, 233, 242, 244, 245, 248, 252] positively associated in seven, [179, 187, 192, 210, 224, 246, 250] with a null association in 17 studies.[165, 166, 176, 178, 180, 183, 188, 193, 200, 211, 212, 232, 235, 237, 247, 249, 251] Aligned to the profit motive, in a qualitative study, staff in poorly-performing NHs (as measured by compliance) were instructed to prioritise the admission of people that attracted higher fees.[260]

Larger facilities and compliance were negatively associated in 40 studies;[120, 122, 151, 164-167, 175, 179-181, 183, 186, 187, 189-191, 193, 203, 206, 209, 211, 212, 215, 220-225, 235, 242, 243, 245, 246, 249, 251, 253, 256, 257] three reported a positive association[188, 192, 200] and 16 a null association[174, 176, 178, 201, 207, 209, 210, 214, 216, 226, 234, 237, 247, 250, 252, 255] (one study [209] reported larger size NHs had a null association whereas larger size assisted-living facilities had a negative association, thereby represented in both columns). The longer a service was in operation was reported to be associated with poorer compliance in four of five studies.[174, 182, 222, 239, 244] Hospital-based NHs and compliance were positively associated in five studies,[151, 191, 220, 222, 224] negatively in one,[203] and there was no association in eight studies.[122, 166, 190, 200, 207, 233, 235, 255]

There was no consistent association with compliance for facilities that provided a range of skilled/specialist services (positive[191, 200, 209, 211, 220, 245]; negative[191, 220, 221, 239, 244-246]; null [166, 191, 221, 224]). Assisted-living facilities with a nursing licence and compliance were negatively associated;[209] those with a mental health care licence positively associated;[209] and those providing memory care services had a null association.[209] Various models of facility ownership (e.g. publicly owned, voluntary organisation or private corporation) and compliance were reported to be associated in five studies that investigated this determinant,[207, 225, 252, 258, 259] whereas six reported a null association.[191, 206, 221, 236, 255, 257]

Among other findings were: continuing care retirement communities (positive[221, 222]; null[200]); location beside a psychiatric hospital (negative[231]); county medical care facilities (null[235]); participation in a community NH program (negative[240]); teaching hospital status (negative[234]; null[215]); NH location (in the context of being co-located with various other types of services) was associated with compliance[256]; revenue source (null[207]); facility certification type was associated with compliance in one study[207] with a null association reported in another;[216] facilities in the United States designated as safety-net hospitals (i.e. serve all populations regardless of insurance status) (negative[234]); hospitals designated as level-1 trauma centres (negative[234]); hospitals participating in a clinical surgery registry (negative[234]); facility certification status (null[166]); facility proximity to a psychiatric hospital (negative[231]); nursing home shared ownership status (a form of public-private ownership) (positive[222]); and more organisational experience with the accreditation process (positive[250]).

5.4.5.2 Networks and communications

The nature and quality of webs of social networks, and the nature and quality of formal and informal communications within an organization.

Chain facilities and compliance had a negative association in 14 studies,[120, 187-189, 191, 203, 209, 219, 224, 233, 242, 245, 251, 261] eight reported a positive association[176, 179, 192, 205, 222, 223, 225, 252] and nine a null association.[178, 180, 181, 183, 190, 211, 221, 235, 237] NHs that had a history of compliance were found to have effective communication practices, both hierarchically and laterally in a qualitative study: “administrative and direct care staff used multiple modes of communication to care for residents and their families”.[260] In contrast, poorly-performing nursing homes “confused staff” with

conflicting messages regarding the service's organisational mission and tension between providing resident care and ensuring economic viability.[260]

A range of other factors were found to have no clear association with compliance: higher consultation with families (positive[205, 245]; negative[205]; null[181, 219]); higher consultation with NH residents (positive[245]; negative[219]; null[200]); NHs with family/resident councils (negative[222]); NHs that used a satisfaction survey (positive[267]); higher use of information technology (positive[210, 265]; null[253, 263, 264]); higher staff meeting frequency (negative[263]; null[262]); administrative/clinical standardisation across a nursing home chain (null[223]); facility methods for communicating potential IC issues (null[262]); maintaining a list of service users with infection (null[262]); and association with other compliant facilities (null[266]).

5.4.5.3 Culture

Norms, values, and basic assumptions of a given organisation.

In the context of our research question we interpreted this construct to refer to institutional culture with an obvious relevance to regulatory compliance. A study of motivational postures towards regulation reported that facilities adopting a posture of disengagement and compliance were negatively associated whereas those with a culture of resistance to regulation were positively associated with compliance [36]. The authors surmised that this seemingly incongruous finding may be explained by an interaction with the inspectors' regulatory style.[36] Two further determinants in this study were reported as having a null association with compliance: a culture of capture (high degree of cooperation with regulators) and of managerial accommodation (where management were cooperative and accepted responsibility for implementation).[36] A similar study measured the perspectives of senior managers in NHs in terms of whether they 'believed in the standards' or exhibited a 'subculture of resistance''; both were positively associated with compliance.[266]

Organisations with a higher patient-centred culture and compliance were positively associated in three studies,[232, 237, 272] with a fourth reporting a null association.[271] NHs that had a "culture change" focus and compliance were positively associated in two studies.[269, 270] One study investigated whether a NH's culture of cooperation with a regulator was associated with compliance (null[266]).

Other factors included a culture that focused on reducing hospitalisation for residents (negative[262]) and culture change brought on by converting from a non-profit to for-profit facility (negative[307]). The strategic focus of a NH (e.g. attracting clients through higher quality/lower costs) was associated with compliance.[273]

5.4.5.4 Implementation climate – Tension for change

The degree to which stakeholders perceive the current situation as intolerable or needing change.

We interpreted this construct as including studies that investigated organisational drivers for improved compliance or the urgency with which changes in compliance levels were considered necessary by organisations. A qualitative study on efforts to reduce anti-psychotic medication in NHs reported staff felt pressure to fulfil regulatory requirements and improve their publicly-reported quality level.[278] There were mixed findings on the stringency of regulators: three studies[182, 244, 276] reported stricter enforcement and compliance was positively associated, four negatively,[222, 244, 274, 275] and one[277] reported a null association (one study[244] reported determinants in the positive and negative categories).

5.4.5.5 Implementation climate – Compatibility

The degree of tangible fit between meaning and values attached to the innovation by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the innovation fits with existing workflows and systems.

We took compatibility to mean the degree to which a regulatory measure fits with pre-existing practices in an organisation. One qualitative study featured here, where the author reported compliance was improved because the regulatory metric was compatible with the electronic health record system enabling "a coordinated…standardized approach to treating sepsis based on both policy requirements and clinical expertise. They also produce the documentation necessary for meeting and reporting on regulatory sepsis metrics".[152]

5.4.5.6 Implementation climate – Relative priority

Individuals' shared perception of the importance of the implementation within the organization.

This construct relates the implementation of regulations to how important a goal it is for those charged with achieving compliance. One study investigated a range of issues relating to an organisation's perception of regulation, their estimation of the likelihood of non-compliance being detected, and the perceived severity of regulatory sanctions.[174] The perceived severity of withholding a funding increase and compliance was negatively associated; the remaining factors in this study (e.g. probability of: prosecution/state detection/withdrawal of licence) had a null association.[174]

5.4.5.7 Implementation climate – Learning climate

A climate in which: 1. Leaders express their own fallibility and need for team members' assistance and input; 2. Team members feel that they are essential, valued, and knowledgeable partners in the change process; 3. Individuals feel psychologically safe to try new methods; and 4. There is sufficient time and space for reflective thinking and evaluation.

The authors of one qualitative study on high- and low-performing nursing homes (as measured by compliance levels) reported that high-performing nursing homes were characterised by management who actively encouraged staff participation in decision-making.[260]

5.4.5.8 Readiness for implementation – Leadership engagement

Commitment, involvement, and accountability of leaders and managers with the implementation of the innovation.

Organisations where management submit to an external quality assessment (e.g. voluntary accreditation) were more likely to be compliant in all four studies that investigated this.[279-282] A fifth study investigated hospital accreditation by the Joint Commission (negative[234]) and the Commission on Cancer (null[234]). The authors of a qualitative study reported a difference in leadership behaviours when comparing high- and low-performing NHs: "the leadership behaviours of the NHA [Nursing Home Administrator] and the DON [Director of Nursing] created a clear, explicit, and coherent mission, a strong sense of purpose, for the organisation. The importance of leadership relationship behaviours and the congruence of the stated and lived mission of the home were strikingly different between high- and low-performing homes".[260]

5.4.5.9 Other

Findings were placed in this section where they could not be coded to an appropriate construct but were still considered relevant to this domain. For example, while many studies may have investigated whether staffing levels were associated with compliance, they did not investigate staffing that were specifically dedicated to implementing regulations or achieving compliance.

5.4.5.10 Other: staffing

Of the 29 studies examining registered nurse staffing, 19 reported higher levels of this staff grade and compliance were positively associated,[122, 165, 178-180, 187, 188, 190, 222, 224, 237, 242, 243, 252, 272, 285, 287, 288, 290] nine reported a null association[150, 183, 192, 195, 225, 238, 251, 256, 283] and one reported a negative association.[236] Likewise, total nurse staffing levels (all grades of nurse staff) and compliance were positively associated in eleven studies,[165, 176, 186, 189, 210, 212, 236, 255, 287, 290, 293] with two finding a negative association[190, 212] and three a null association.[166, 201, 234] The results were similar for nurse aides/care assistants: 15 studies reported higher levels these staff and compliance were positively associated,[122, 164, 166, 176, 178, 180, 188-190, 222, 224, 255, 256, 272, 285, 287] nine reported a null association[150, 183, 192, 210, 211, 237, 243, 252, 288] and three reported a negative association.[179, 186, 187] A higher ratio of registered nurses as against other nurse and care staff and compliance was positively associated in four studies[226, 238, 242, 272] with a null association in a further four.[165, 186, 188, 289] Higher levels of licensed practitioner/vocational nurses and compliance were positively associated in five,[176, 178, 179, 196, 285] negatively in five,[186-189, 206] and a null association reported in 13.[122, 180, 183, 190, 192, 210, 211, 222, 237, 243, 252, 272, 287]

Higher specialist staff levels (e.g. dietary professionals) and compliance were positively associated in five studies,[122, 164, 220, 285, 291] negatively in one;[245] and null in two.[166, 186] NHs meeting state criteria for minimum staffing and compliance were positively associated in two studies.[189, 290]

Among other staffing-related determinants were the following: higher total staffing levels (positive[220, 245]; null[181, 223, 251, 283]); higher proportion of trained staff (positive[220, 262]; negative[245]; null[223, 239]); higher agency/contract staff levels (negative[175, 272, 284]; null[283]); higher administrative staff levels (positive[122]; null[183]); higher housekeeping staff levels (null[122, 285]); higher food-service staff levels (null[285]); higher infection control professional quality (measured by

certification level and training attainment)(null[263]); higher levels of trainee nurse aides (null[287]); and higher levels of certified medication aide staffing (null[287]).

In a qualitative study, the authors found high-performing nursing homes (as measured by compliance levels) had leaders who made adequate resources available to allow staff do their job.[260] Higher staff workload was associated with poorer compliance in two studies.[213, 262]

Of the 19 studies that assessed staff turnover, 16 reported high staff turnover and compliance was negatively associated[181, 183, 205, 248, 262, 272, 283, 289, 292-298, 308] and three reported no association[226, 262, 263] (one study[262] had two measures of turnover with different associations and is counted in both the negative and null columns). Higher job satisfaction and compliance had a null association in one study;[286] nurse-aide absenteeism and compliance was negatively associated.[261] Two studies found higher ratings for work effectiveness and practice environments in NHs and compliance were positively associated.[237, 249] The degree of nursing centralisation in a NH and compliance had a null association.[166] A higher social services director caseload level and compliance was negatively associated.[213]

5.4.5.11 Other: financial

The majority of studies listed in this section were literature from the United States. Higher costs (most of which were expressed as costs per patient day in a NH context) and compliance were negatively associated in six studies,[193, 205, 211, 259, 300, 302] four reported a null association,[226, 235, 300, 301] and one a positive association[299] (one study[300] had cost determinants in both the negative and null categories). Services with higher proportions of publicly-funded service-users and compliance also tended to be negatively associated (six positive[120, 176, 191, 205, 219, 238]; 21 negative[122, 151, 164, 177, 178, 181, 186, 187, 193, 206, 209, 219-221, 224, 226, 233, 239, 242, 243, 245]; 16 null[120, 165, 166, 175, 179-181, 183, 188, 190, 195, 211, 215, 216, 235, 236]) (some studies investigated multiple different types of public funding and reported different associations with compliance. Therefore, these studies appear across more than one of the above categories). Three studies investigated the proportion of private-payers (positive[191]; negative[245];null [257]). Staff salary levels and compliance had a null association.[226]

Four studies investigated facility profit level/margin (positive[180, 304]; negative[120]; null[226]). One study reported a u-shaped finding where average financial performance was positively associated with compliance whereas both high and poor

financial performance were negatively associated.[305] Higher facility income and compliance was positively associated in two studies,[181, 239] with two reporting a null association.[193, 301] Facilities that provided finances to attend infection control training and compliance were positively associated,[262] whereas there was a null association when providing funding for infection control meetings or access to expert consultation on infection control.[262] Higher facility market share and compliance was reported to be positively associated.[303]

5.4.5.12 Other: admissions

NHs or assisted-living facilities accepting Medicaid (a public health insurance program in the United States for people on low incomes) admissions and compliance were positively associated in three studies,[165, 200, 212] a fourth reported a negative association,[244] and a fifth a null association.[209] NHs accepting Medicare (a health insurance program in the United States generally for those over 65 or with specific conditions) admissions and compliance were positively associated in two studies.[200, 233] NH admission rate and compliance had a null association in two studies.[211, 225] Hospitals accepting critical access or rural referrals and compliance had a null association.[215] Higher occupancy levels and compliance had no consistent direction of association in 28 studies (eight positive[151, 187, 188, 192, 222, 235, 248, 283]; nine negative[175, 184, 186, 189, 190, 194, 220, 224, 242]; 11 null[176, 178-180, 183, 193, 211, 219, 221, 239, 255]).

5.4.5.13 Other: ownership

Recently-acquired NHs and compliance were reported to have a negative[306] and null[222] association. Compliance was reported to improve in poor quality NHs that were acquired by a chain.[306] Where a NH was acquired by a chain, higher quality chains were positively associated with compliance.[306]

5.4.5.14 Other: infection control

Participation in an infection control collaborative focused on reducing MRSA and compliance was positively associated;[262] while other infection control collaborations had a null association.[262, 263] The types of resources used to determine and treat infection and compliance had a null association.[262] A study of additional job responsibilities for infection control staff reported that being Director/Assistant Director of Nursing and compliance was negatively associated, all other roles were reported as having a null association.[262]

5.4.5.15 Other: chains

Physical plant standardisation across a nursing home chain and compliance was positively associated.[223]

5.4.6 Characteristics of individuals

This domain reflects how "individuals' beliefs, knowledge, self-efficacy, and personal attributes" may impact the implementation of regulations. We found no determinants that could be coded to two of the five constructs in this domain: knowledge and beliefs about the innovation, and individual stage of change. In total, seven studies – the lowest for any domain – investigated a determinant coded to this domain (see Table 7).

Table 7 – Determinants coded to the characteristics of individuals domain

Construct	Determinant
Knowledge & Beliefs about the Innovation	No studies
Self-efficacy	Blocked legitimate opportunities to comply[266]
Individual Stage of Change	No studies
Individual Identification with Organization	Higher job commitment[261, 266, 286]
Other Personal Attributes	Directors of nursing having a higher emotional connection with inspectors[266] Higher level of task expectation (a measure of staff familiarity and clarity with their roles)[232]
Other	Higher staff empowerment[213] Ranking of infection control activities in order of how time-consuming each were[262] Senior managers' perception of what is important in job knowledge[309]

5.4.6.1 Self-efficacy

Individual belief in their own capabilities to execute courses of action to achieve implementation goals.

Studies were included in this construct if they examined perceptions of capacity to implement regulations and its relationship to successful compliance. When nursing home managers felt that legitimate means of achieving compliance were blocked by owners, this was negatively associated with compliance.[266]

5.4.6.2 Individual identification with organisation

A broad construct related to how individuals perceive the organization, and their relationship and degree of commitment with that organization.

Higher job commitment and compliance was positively associated in two studies[261, 286] and had a null association in a third.[266]

5.4.6.3 Other personal attributes

A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style.

Any studies which reported on miscellaneous personal attributes and their association with compliance were coded here. Directors of nursing having a higher emotional connection with inspectors and compliance was positively associated.[266] A higher level of task expectation (a measure of staff familiarity and clarity with their roles) and compliance was negatively associated.[232]

5.4.6.4 Other

Findings were placed in this section where they could not be coded to an appropriate construct but were still considered relevant to this domain.

The degree to which staff felt empowered to do their job and compliance was positively associated.[213] A study of infection control attitudes among NH staff asked respondents to rank a range of activities in order of how time-consuming each were. The ranking of vaccination (negative[262]) and infection control policy development (positive[262]) as highly-time consuming and compliance was associated, the remainder having a null association. Senior managers' perception of what is important in job knowledge (e.g. leadership; resident care; human resources) and compliance had a null association.[309]

5.4.7 Process

The process domain refers to "stages of implementation such as planning, executing, reflecting and evaluating, and the presence of key intervention stakeholders and influencers including opinion leaders, stakeholder engagement, and project

champions".[161] No studies were coded to six of the 10 constructs within the domain: planning; engaging – opinion leaders; engaging – formally appointed internal implementation leaders; engaging – champions; engaging – external change agents; engaging – innovation participants. In total, 17 studies investigated a determinant coded here (see Table 8).

Table 8 – Determinants coded to the process domain

Construct	Determinant
Planning	No studies
Engaging	
Opinion Leaders	No studies
Formally Appointed Internal Implementation Leaders	No studies
Champions	No studies
External Change Agents	No studies
Key Stakeholders	Physician represented on the infection control committees[262] "Administrative personnel made decisions without involving the staff or residents affected by the change…Administration handed down a solution, without input…the social work department director was distressed when she was not included in the problem solving and resolution of a survey deficiency"[260]
Innovation Participants	No studies
Executing	"The data analysis for this study revealed challenges from different non-clinical departments regarding pushing person centered care policies but showed little to no negative impact on annual state survey results. Most participants responded that the department had great annual survey results after achieving Eden Alternative certification"[310] "One physician explained that she orders blood cultures on every patient of hers that comes through the emergency room because the sepsis metric requires that immediate cultures are documented"[152] "The dynamics described in this article reveal that the formal aspects of caring—those enacted by regulatory authorities— are

	superseded by material conditions, which can lead standards to be enacted discursively but practically inactivated…What is uncovered in this study is that compliance with various standards becomes feigned by the corporation just as policing is performed by the so-called independent regulators…In the case of social care, it may be that the primary intention of regulation is to give credence to the overall system and the accumulation of private enterprises that takes place by establishing the appearance of regulatory effort coupled with an illusion of corporate compliance"[162] "Participants recognized that there were many potential benefits of antipsychotic medication reduction with four primary themes: (d) Improvement in the facility Quality Indicator score (regulatory compliance)"[278]
Reflecting & Evaluating	"Clinicians felt inundated with pressure and performance evaluations that tracked their compliance with the sepsis metric"[152]
Other	Availability of corporate training across a nursing home chain[223] Facility has a mechanism for providing hand hygiene feedback to staff[262] Formal staff teams[237] Hand hygiene product used in facility[262] Higher degree of managerial control[174, 266] Higher level of consensus leadership by Directors of Nursing[261] Higher levels of antibiotic prescribing in nursing homes[262] Higher levels of management autonomy[174] Higher quality senior managers[205, 232, 239, 247, 262] Higher scores on hand hygiene audits[311] Methods to determine service user infection[262] More time spent on infection control activities[262] Providing quality indicator outcome information to nursing home managers[312] Self-managed staff teams[237] Training methods used for infection control[262]

5.4.7.1 Engaging – Key stakeholders

Individuals from within the organization that are directly impacted by the innovation, e.g., staff responsible for making referrals to a new program or using a new work process.

In this construct, compliance can be influenced by how key individuals in an organisation are affected, or consulted with, during the ongoing process of implementing regulations. In a qualitative study, the compliance of NHs was poor where management were reported to make decisions without involving other staff and residents: "Administration handed down a solution, without input…the social work department director was distressed when she was not included in the problem solving and resolution of a survey deficiency".[260] Including physicians on infection control committees and compliance was positively associated.[262]

5.4.7.2 Executing

Carrying out or accomplishing the implementation according to plan.

We regarded this construct quite broadly and included determinants that described how an organisation carried out its functions and which could reasonably be argued to have some bearing on the implementation of regulations.

Four qualitative studies feature in this construct. One author argued that the execution of regulation is a façade that masks poor quality care; a form of performative compliance in which both the regulator and regulatee are complicit in providing false public assurance.[162] A second qualitative study described how a physician developed a work-around for a metric: "ordering blood tests ahead of a confirmed sepsis diagnosis to ensure she doesn't fail the metric later if the patient becomes septic".[152] Compliance was also achieved as a consequence of implementing another intervention such as a reduction in anti-psychotic medication or the implementation of a more person-centred care model in NHs.[278, 310]

5.4.7.3 Reflecting and evaluating

Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.

Studies that investigated how the provision of feedback or information on the implementation of regulations impacted the process of implementation were coded

here. The author of a qualitative study reported clinicians felt overburdened with performance evaluations, ultimately developing work-arounds and "gaming the system" in order to worry less about meeting the metric.[152]

5.4.7.4 Other

Findings were placed in this section where they could not be coded to an appropriate construct but were still considered relevant to this domain.

A higher level of consensus leadership by Directors of Nursing and compliance was positively associated.[261] The availability of corporate training across a NH chain and compliance had a null association.[223] A higher degree of managerial control and compliance had positive[266] and null[174] associations in two different quantitative studies whereas higher levels of management autonomy and compliance were positively associated.[174] Having higher quality senior managers (as measured by educational attainment or years of experience) and compliance was positively associated in three studies,[205, 232, 239] with two finding a null association.[247, 262]

A study of infection control practices reported that, of five methods to determine resident infection, only one (using Centers for Disease Control definitions[313]) was positively associated with compliance, the remainder having a null association.[262] In the same study, whether a NH had a mechanism for providing hand hygiene feedback to staff, as well as the type of hand hygiene product used, and compliance, had null associations.[262] Training methods used for infection control, video-based training, face-to-face training and handouts/flyers and compliance all had null associations.[262] The time spent on infection control activities and compliance had a null association.[262]

Self-managed staff teams and compliance were positively associated[237] whereas more formal staff teams had a null association.[237] Higher levels of antibiotic prescribing in nursing homes and compliance were negatively associated.[262] Higher scores on hand hygiene audits and compliance had a null association.[311] The provision of quality indicator outcome information to NH managers and compliance had a null association.[312]

5.5 Discussion

The evidence base indicates that the following structural characteristics were positively associated with regulatory compliance: smaller facilities (as measured by

bed capacity); higher nurse staffing levels; lower staff turnover. A facility's geographic location was also strongly associated with compliance (Table 9). There was a paucity of evidence on the processes associated with successful implementation of regulations.

Table 9 – Determinants of regulatory compliance where evidence is most consistent

Domain	Construct	Determinant	Associated*	Negative	Null	Positive
Inner setting	Other	Higher staff turnover		16	3	0
Inner setting	Structural characteristics	Geographic location of facility	13		1	
Inner setting	Structural characteristics	Larger size facility (bed number)		40	16	3
Inner setting	Other	Higher total nursing staff		2	3	11
Inner setting	Other	Higher registered nurse staffing		1	9	19

* Denotes a nominal variable where a significant association was reported for one or more of those variables (e.g. federal states in Australia)

The evidence presented in this review was predominantly quantitative (n=147, 94%), conducted in the United States (n=140, 90%) and focused on NHs (n=143, 91%). The observed focus on the structural attributes of compliant providers may be because these attributes were easier to measure and were available for quantitative analysis via routinely-collected data e.g. the Online Survey, Certification, And Reporting (OSCAR) database.[314]

We find no other systematic review that has specifically focused on determinants of regulatory compliance in health and social care services. There are some reviews that used regulatory compliance as one of several outcome measures to evaluate associations between a specific structural or organisational characteristic (e.g. for-profit status[315] or service size[125]) and quality). However, these studies were primarily interested in regulatory compliance as a proxy measure for quality while our review sought to identify structural or process determinants of compliance.

The processes that determined successful implementation of regulations (e.g. leadership engagement to ensure readiness for inspection) were much harder to map to routinely available data and were therefore harder to study. There were some CFIR constructs in the 'process' domain, which encompasses various stages of the implementation of an intervention such as 'planning', 'engaging – innovation participants' and 'reflecting & evaluating', to which we coded very few/no determinants. For example, we found no studies that investigated how organisations engaged in planning prior to the introduction of regulations.

We also coded few determinants to the 'characteristics of individuals' domain. Many of this domain's constructs deal with the views, opinions and perceptions of individuals towards an intervention. Such constructs, by their nature, lend themselves to qualitative research in contrast to routinely available quantitative data. Therefore, our review reveals a clear gap in the evidence base and opportunities for future qualitative or mixed-methods studies on successful engagement with the regulatory process.

5.5.1 Facility characteristics

Our finding on facility size is in agreement with a similar review which investigated NH size and its relationship to quality.[125] Some have posited that staff attention and resources in larger facilities are directed towards health and quality of care outcomes at the expense of quality of life outcomes.[316] Larger facilities may also perform poorly with regard to broad quality measures (i.e. regulatory compliance) but better on individual quality indicators.[125, 317] Size may also interact with other facility characteristics that may impact on quality e.g. larger hospitals tend to be located in urban areas.[318] Facility size was also associated with staff turnover, where larger NHs have higher turnover, which may impact on quality.[319] We also found that high staff turnover was associated with compliance (see below).

Other studies have shown that for-profit facilities were associated with poorer compliance;[315] our findings are that 55% of studies reported a negative association. One explanation for the poorer performance may be that expenditures are minimised thereby resulting in fewer resources being directed towards care activities, which could in turn impact on compliance.[315] Not-for-profit facilities may be in a position to 'cherry-pick' clients (preferring people with minimal care needs and/or greater resources) whereas for-profit facilities may be more reliant on low-income clients

with greater needs, thereby impacting on quality outcomes.[203] Higher process quality (e.g. leadership, training) in not-for-profit facilities may also be a mechanism through which higher quality is achieved.[232]

Health service chains (mostly in the NH sector) have been the subject of considerable research with respect to quality, generally reporting a negative association.[320-322] We did not replicate this finding: 45% of studies in our review also reported a negative association but 26% reported a positive association and 29% a null association. Chain ownership accounts for varying proportions of the market across jurisdictions (e.g. in 2014, 64% of NHs were owned/operated by chains in the United Kingdom whereas the figure was 17% in Sweden and Canada).[320] One possible explanatory mechanism is the association between chain status and lower rates of nurse staffing.[151, 323] potentially impacting on a facility's compliance capability. The pursuit of corporate interests may also diminish resources,[324] thereby affecting compliance. Some have cautioned that the literature on chain facilities tends to treat all chains equally, whereas there may be important differences in terms of chain size and ownership.[324]

The association between occupancy levels and quality is also a facility characteristic subject to much research.[325-328] High occupancy levels (typically regarded as >90%) and overcrowding in hospitals have been associated with higher mortality,[326, 329] and higher incidence of healthcare associated infections.[330] We found no clear association between occupancy and compliance. This is surprising as lower occupancy has been associated with poorer financial performance in nursing homes[331] and higher use of antipsychotic medication,[328] which one might expect to also impact compliance. Given most studies in our review were set in NHs, it may be that NH compliance levels are less sensitive to occupancy compared to hospitals.

5.5.2 Staffing

We find high staff turnover to be strongly associated with poorer compliance. A circular relationship may be evident here: poor quality care precipitates staff dissatisfaction and vice versa.[319] The high costs related to staff turnover[332] may impact on an organisation's compliance levels. High turnover rates have also been associated with poor implementation of evidence-based practices,[333] thereby providing another potential causal mechanism for poorer compliance.

There was robust evidence that higher nurse staffing levels are associated with higher compliance. This finding is concordant with previous studies investigating nurse staffing levels and quality in hospitals[334-337] and NHs,[328, 338, 339] albeit that some report inconclusive findings.[340] Some studies draw a distinction with respect to nurse type, finding registered nurses had a greater impact on quality when compared with licensed vocational nurses,[328, 335, 336] a finding replicated in our review. Higher nurse staffing levels may be associated with quality when measures were nurse-sensitive outcomes (e.g. cardiac arrest, unplanned extubation).[334] Lower nurse staffing levels may result in frontline care being provided by less-qualified staff which impacts on quality.[336] Higher levels of registered nurse staffing have been associated with lower antipsychotic medication use in NHs,[328] which is also often a quality measure subject to regulation in these settings.[341, 342] Potential interaction effects with other staff-related measures (e.g. turnover, agency staff) have led some to argue that simply measuring nurse staffing levels is insufficient in terms of explaining the relationship to quality.[343]

5.5.3 Demographics

We find that the geographic location of a facility was strongly associated with compliance. Most studies that investigated this were interested in multiple other factors and were usually at national-level; the geographic location may have been different cities or states in America or Australia (as distinct from urban/rural or population density). It is likely that location was interacting with multiple other variables producing this association. One obvious explanation is inconsistent regulation, for which there is evidence across a range of industries.[42, 344-346] The level of public funding available across regions can also differ substantially, thereby impacting the resources available for compliance.[347, 348] Geographic location is associated with health service availability,[349] medically underserved populations[350] and NH use of antipsychotic medication,[328] each of which may have implications for compliance.

Our findings indicate no clear association of service-users with more complex or resource-intensive needs, or populations with a more challenging profile (e.g. older, sicker or poorer) and compliance. This is somewhat surprising as there is evidence to suggest these populations have generally poorer access to quality healthcare. For example, facilities in severely-deprived neighbourhoods have lower staffing

levels.[351] Moreover, greater resourcing is required for service users with higher acuity,[352] which one might argue limits the resources available for compliance.

We found some evidence relevant to the processes by which implementation of regulations becomes 'normalised' within organisations. For example, the degree to which regulatory requirements were compatible with existing work practices was important.[152] Some studies in our review reported that habitually producing good documentation to substantiate regulatory compliance was also important (albeit that this was geared more towards 'gaming the system' as opposed to achieving the goals of regulation).[152, 162] The above findings were echoed in studies relying on normalisation process theory (NPT) to evaluate implementation efforts. For example, in a study using NPT to evaluate the implementation of a regulatory intervention for individual doctors, the authors discussed how successful implementation was influenced by compatibility with existing practices and good documentation/record-keeping.[92] The process of interaction between regulator and regulatee also appears to influence the compliance outcome.[35, 36, 266]

There was a very limited literature investigating behaviours of regulatory staff and their responses to varying levels of compliance. However, there was evidence that regulation was sometimes implemented poorly by regulators, thereby giving a false measure of compliance. For example, by inspectors effectively turning a blind eye,[163] services finding workarounds,[152] or the entire system of regulation representing a performative means by which to draw a veil over poor care practices.[162] There are two relevant issues here. Firstly, there are multiple examples in a range of industries where a public scandal erupts, implicating the regulator.[353-355] Poor implementation of regulations by a regulator (through mechanisms such as regulatory capture or incompetence) can have potentially serious consequences for the public good. Secondly, the circumvention of regulatory prescriptions (e.g. by workarounds or misleading documentation) is similar in nature to 'ritualism'.[33] Here, organisations engage in a subtle rejection of regulatory goals by 'playing the game' typified in the following example: "an Australian director of nursing…did not want to oppose an inspection team who 'made a big heap out of ethnic diet' under an Australian standard that requires sensitivity to cultural preferences for different types of food: 'So we bought ethnic diet books…give it a foreign name and they'll be

happy'".[33] This is compliance in name only and can mean that regulatory goals such as safety or person-centred care are not met.

There is an extensive literature on compliance theory which seeks to explicate compliance at the level of individuals, organisations and nation states across various regulated contexts such as tax,[356, 357] transport[358, 359] and environmental protection.[360, 361] There are four conceptual themes that seek to explain compliance: "motives, organizational capacities and characteristics, regulation and enforcement, and social and economic environments (or institutions)".[362] Motives include the pursuit of material (e.g. profit or limiting costs), emotional (fear of admonishment, anger) or normative (to act appropriately, do the right thing) goals.[112] Organisational capacity refers to the differences between organisations in terms of economic resources, knowledge and expertise.[362] Regulation and enforcement draws attention to the various strategies and styles adopted by regulators and how these influence compliance behaviour.[362] Finally, compliance can be affected by the wider environment (e.g. political, economic or social) such as when a regulator leverages public pressure through 'naming and shaming'.[363]

There are two broad empirical approaches evident in the literature on compliance theory: objectivist and interpretive.[362] Objectivist efforts at explaining compliance test theories by regarding compliance as the dependent variable and seeking associations with specific independent variables. The interpretive school is more concerned with how compliance is socially constructed and contested: "The research task shifts from mapping 'compliance' and 'noncompliance'…to describing and understanding a whole range of organizational perceptions of, and behavioural responses to, regulation".[362]

Within the literature on compliance theory (which we searched separately), we found very few studies that sought to describe determinants of compliance in organisations within whole industries (e.g. banking or manufacturing). Rather, studies tended to focus on individual organisations[364] or were ethnographies that described how organisations/people engaged with regulation.[365] One review of financial regulation sought to identify organisational determinants of compliance.[366] The only statistically significant finding related to ownership structure: firms with a high separation of ownership from control (the degree to which board and shareholder

power are separated) and family-owned firms were associated with higher compliance.[366]

The lack of wide-ranging reviews make it difficult to situate our study within the wider literature on compliance theory. Some reflection on our findings in the light of the four conceptual themes and two empirical approaches outlined above may be useful. The studies in our review were located mostly within the organisational capacities and characteristics conceptual theme. These were largely objectivist in nature and identified variables that may be associated with compliance (e.g. staff levels, local demographics). There were only small numbers of studies that could be described as relevant for each of the other themes: motives; regulation and enforcement; and environment. Thus, the interpretive approach (which often relies on qualitative means of enquiry[362]) was largely absent from our review, representing a significant gap in the literature.

Our findings, particularly those that are supported by findings of other reviews, have important implications. Several modifiable organisational characteristics such as facility size and nurse staffing levels merit attention by policy makers, particularly in the context of NH design.

The inequity highlighted in the finding of poorer compliance for service users with higher needs and less resources (although not reaching our >60% threshold) is another reminder of the importance of the socio-economic determinants of health.[367] This represents a real challenge for regulators because while these populations deserve parity in terms of care quality, regulatory sanctions could potentially further diminish quality by diverting time/resources away from care. Regulators may need to be cognisant of this issue, especially during times of economic uncertainty and pressure on public spending.[368]

The design of regulatory interventions and their subsequent implementation could be informed by the application of implementation science. For example, regulatory impact analysis — an increasingly common process undertaken prior to the introduction of regulation[369] — could potentially benefit from identifying implementation barriers or facilitators.

There was an expectation on behalf of the authors that a larger number of qualitative studies would be found. There is an extensive field of qualitative enquiry on the

implementation of other aspects of quality in health and social care such as clinical guidelines,[370, 371] quality improvement initiatives,[372, 373] patient feedback,[374, 375] and professional regulation.[376] Moreover, the regulation and compliance literature is replete with qualitative studies of organisational responses to regulation, yet very few examine organisations working in health and social care.[362] The relative absence of studies on the implementation of regulatory standards and how this is linked to compliance is therefore puzzling and represents a gap in the literature. It may be the case that regulators are seen as a "remote disembodied agent" due to infrequent contact with managers and frontline staff, therefore being overlooked as a potential field of enquiry in implementation science.[377]

Multiple avenues for future research arise from our findings. Firstly, the causal mechanisms for some determinants of compliance warrant deeper investigation across a range of contexts and settings. For example, while we find that larger facilities were associated with poorer compliance, some studies have found a positive association of quality and size.[328, 378] It may be that associations between facility size and quality differ depending on the quality measure assessed and further research may be able to address this matter.

Secondly, the 'regulatory character' of one setting/context can differ significantly to another: "findings from any one study need to be assessed in light of the particular jurisdiction and regulatory regime in question".[379] Therefore, given the extensive body of research from the United States and in NHs, research focused on other countries and other settings could prove instructive.

Thirdly, the heavy focus on objectivist approaches could be complemented by more interpretive and qualitative research. For example, one may wish to understand how the behaviour of organisations (and individuals within those organisations) during regulatory encounters impacts on the compliance outcome, building on contemporary work in other settings.[380]

Finally, there may be merit in exploring the utility of various implementation strategies that could potentially address barriers to regulatory compliance. For example, certain Expert Recommendations for Implementing Change (ERIC) strategies have been identified as most appropriate for addressing specific CFIR constructs.[381] Consideration of various implementation strategies could also inform a regulator's approach to inspection and enforcement practices.

5.5.4 Strengths and limitations

A strength of this review is the application of a systematic, wide-ranging search that offered the best opportunity of identifying relevant literature. A published protocol guided the process and provided methodological rigour.[159] The authors are not aware of any other systematic review which focused specifically on regulatory compliance in health and social care services. In addition, the conceptualisation of regulation as an intervention, thereby facilitating use of the CFIR and implementation science more generally, is novel.

The ability to draw generalisable conclusions in this review is limited by the preponderance of literature focusing on NHs in the United States. Other settings like hospitals, and other jurisdictions, are relatively absent in the literature. A further weakness in the evidence base is the reliance on observational designs which means causal inferences have to be tentative. We also draw attention to the mixed quality of the included studies as a limitation. Many studies relied on self-reported measures which could not be objectively verified. For example, many studies involving nursing homes relied on staffing levels as reported in the OSCAR database, which has been shown to be inconsistent when compared with other data sources.[382]

A further limitation of our review is the heterogeneity of regulations used across the included studies. The heterogeneity is found both among studies (e.g. where one may focus specifically on infection control and another may cover a broad basket of regulations) and also in the diversity of regulatory frameworks across jurisdictions. It is likely that determinants vary in their importance depending on the specific regulation in question and the nature (e.g. timeliness, use of sanctions) of the regulatory relationship. This limits our ability to generalise about the importance of different determinants of compliance.

We considered a number of framework options for structuring our review. While we considered other options such as Normalisation Process Theory[383] and the Practical Robust Implementation and Sustainability Model (PRISM),[384] we ultimately chose to use the CFIR as it provided a comprehensive framework that encompassed both organisational and individual-level implementation features.

One might question whether regulation was a good fit for study under implementation science and the CFIR. Regulation can hardly be regarded as an ‘innovation’ — it is not new. Moreover, the ‘ongoing’ nature of regulation makes it

different to other, more common, interventions which are perhaps time-limited[385, 386] or intended to be introduced and then subsumed (normalised) by an organisation.[387, 388] We encountered some coding difficulties with the CFIR, which perhaps reflects that initial implementation of an intervention and continuous quality assurance (i.e. regulation) are distinct. For example, organisations are required to implement and sustain regulatory standards on an ongoing basis, and have that monitored by a third-party (the regulator) at often random intervals. Such an intervention feature (i.e. sustainability and external evaluation) has no natural home within the CFIR. Nevertheless, we were satisfied that the CFIR provided a useful framework within which to evaluate regulation as an intervention.

There has been an acknowledgment that the CFIR has a blind spot in terms of implementation sustainability,[389] indeed a revision to CFIR was recently published.[90] Discussions on CFIR utilisation in various contexts have also highlighted a need to differentiate between innovation and implementation outcomes.[389] In this review we regarded compliance as an implementation outcome i.e. the degree to which organisations successfully implemented regulations. Similarly, we regarded determinants as constituting implementation determinants which predicted or explained actual implementation outcomes. Authors using the CFIR are encouraged to reflect on three questions which we have addressed in Appendix 7.

5.6 Conclusion

This review sought to identify and describe determinants of regulatory compliance. The multiplicity of determinants identified illustrates how regulatory compliance is a complex and context-specific phenomenon. There were some structural characteristics of organisations that showed an association with compliance. It is difficult to draw conclusive causal relationships and further research should attempt to better understand these mechanisms.

Regarding regulation as an intervention and using the CFIR as a framework offered some useful insights into the structures and processes that produce compliance. The uneven distribution of determinants across the five CFIR domains demonstrates that the literature included in this review tends to draw on objectivist approaches.

There were only a small number of studies in this review that were qualitative and could be described as using an interpretive approach to understand compliance determinants. While such studies exist in other fields of regulation and compliance research, they are relatively absent in the context of health and social care and represent a gap in the literature.

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CHAPTER 6: Non-compliance with residential disability care regulations in Ireland: a retrospective analysis of frequency and causes.

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Authors

Paul Dunbar[1], Prof John P Browne[2], Dr Laura M Keyes[3],

Author details

[1] Health Information and Quality Authority, Unit 1301, City Gate, Mahon, Cork, Ireland T12 Y2XT. pdunbar@hiqa.ie (corresponding author)

[2] School of Public Health, University College Cork, Ireland j.browne@ucc.ie

[3] Centre for Implementation Research, University of Limerick, Ireland laura.keyes@ul.ie

6.1 Abstract

Background

Non-compliance with care regulations is common but underlying causes are poorly understood.

Methods

We used inspection data to calculate the frequency of non-compliance in residential disability services (RDS) in Ireland and characterised the non-compliance using thematic analysis.

Results

The median level of non-compliance across all centres was 27% (interquartile range 13% to 46%). Of the 1263 centres inspected 13 (1%) were compliant and 100 (8%) were non-compliant with all regulations inspected. Eight themes were identified in a sub-sample of non-compliant inspections. The theme ‘insufficient resources’ appeared most frequently, second was ‘governance and management failings’. The theme ‘poor documentation quality’ had the broadest explanatory reach, linked to non-compliance in 72% of regulations.

Conclusion

Non-compliance with regulations is common in Irish RDS. Themes describing non-compliance provide insight to service providers and regulators to develop quality improvement initiatives. Interventions focusing on resources, documentation quality and governance are most likely to stimulate broad-based improvement across all regulations.

6.2 Introduction

The statutory regulation of health and social care services is commonly used to assure quality, increase accountability and identify opportunities for improvement. Regulation can be defined as: "sustained and focused control exercised by a public agency over activities that are valued by a community".[143] Governments typically empower an independent authority to regulate and inspect service providers. There are also models of mandatory accreditation that are largely equivalent to regulation.[149, 390] In the health and social care field a wide range of regulations related to structures (e.g. the physical environment) and processes (e.g. infection control procedures) are assessed in different jurisdictions.

Regulatory compliance is the degree to which an organisation adheres to the prescriptions of the regulator: "behavior fitting expectations communicated to regulatees regarding how the former [regulatees] should or should not behave in a given situation".[112] Non-compliance provokes some form of response from the regulator and can lead to an escalating set of sanctions including, in rare circumstances, the withdrawal of licenses to operate.[391]

Non-compliance with health and social care regulations is common as evidenced in a range of contexts: 22% of adult social care services in England received ratings of 'requires improvement' or 'inadequate' with respect to regulations pertaining to governance[392]; non-compliance with certain personal and clinical care standards in Australian residential care settings was as high as 44% between April and June of 2022[393]; nursing home inspectors in the USA make an average of between six and seven findings of non-compliance (deficiencies) per standard inspection.[394] An improved understanding of the reasons for non-compliance may assist service providers and regulators in identifying opportunities to improve compliance. It

would be particularly useful to know which causes have the broadest reach across regulations as addressing such root causes could have a large impact on overall compliance and quality of care.

While inspection reports are routinely published, we have found no research (by means of a preliminary systematic search) that uses this potentially rich source of information to identify the most common reasons for non-compliance.[395, 396]

Residential disability services provide care to a vulnerable population. Mortality rates for people with disabilities living in residential care facilities are lower than those for the general population.[397, 398] There is a high prevalence of abuse of people with intellectual disabilities when compared with the general population.[80] Communication difficulties can often represent a barrier between people with disabilities and health and social care professionals, making it difficult to identify healthcare needs and preferences.[399] From a service provider perspective, social care is challenged in many jurisdictions by a funding crisis that has concomitant impacts on quality.[400-402] It is therefore particularly important to improve compliance in the residential disability sector given the unique vulnerabilities of the population coupled with the challenges that exist in service provision.

This study answer three questions. First, what is the frequency of non-compliance with health and social care regulations at residential centres for people with disabilities in Ireland? Second, what are the causes of non-compliance as stated in inspection reports? Third, which causes of non-compliance have the broadest impact across regulations?

6.3 Methods

6.3.1 Study design

This was a descriptive, qualitative study using document analysis. The document analysis was conducted in accordance with the seven-phase process outlined by Moilanen. First, determining the purpose, data and study design; second, determining the selection strategy; third, selecting or developing an extraction matrix; fourth, pilot testing; fifth, collecting and analysing data; sixth, credibility of the study; seventh, research ethics.[403] Thematic analysis was conducted as a part of the fifth step.

We identified inspection reports for providers of residential care for people with disabilities [hereafter referred to as 'centres'] published by the health and social care regulator in Ireland [hereafter referred to as 'the regulator'] as potentially suitable for addressing the research questions. Inspections of centres in Ireland are typically carried out by one inspector over one to two days. Inspectors do not assess all regulations during an inspection. In advance of an inspection inspectors will choose what to assess from a total of 32 regulations. During the course of an inspection, inspectors will speak with residents and staff as well as carers or relatives of residents should they make themselves available. They will also observe care, assess the physical environment and review documentation.[70]

There were 1329 inspections carried out by the regulator in 2022, 70% of which were unannounced.[99] The frequency of a centre's inspections can be higher where poor levels of compliance are identified. In 2022, 145 centres were inspected twice and 23 were inspected 3 or more times.[99] The regulator publishes most inspection reports within four months of the inspection (some are withheld in the interests of

protecting people's identity, see section on ethical approval) after a process of quality assurance and allowing centre a right of reply to the findings.[70]

6.3.2 Population

All centres in Ireland that were inspected by the regulator between 1st January 2019 and 31st October 2022 inclusive, were included. There were 1401 centres operating in Ireland as of 31st December 2021 (the most recently-published data by the regulator for the sample period), these included the following service types: adults (n=1270; 90.7%), children (n=94; 6.7%), mixed i.e., all age groups (n=37; 2.6%).[98]

6.3.3 Data

Access to compliance data was approved by the regulator via a letter from the Chief Inspector of Social Services. In addition, PD was legally authorised to access this data as a current employee of the regulator and their status as an authorised person. PD obtained the data by accessing the regulator's IT system (PRISM), selecting the necessary variables through an 'advanced find' search and exporting the resulting data to an Excel spreadsheet.[404]

These data included the inspection reference number (alphanumeric), inspector's name (character), centre name (character), centre identification number (alphanumeric), inspection type (categorical: risk inspections [conducted due to significant concerns about quality and safety of a service]/thematic inspections [focused solely on infection control practices]/new applicant inspections [assessments of centres prior to admitting residents]/regular inspections [wide-ranging assessments that were carried out twice per three year period for each centre]) and service type (categorical: adults/children/mixed).

Compliance judgments for each regulation that was assessed by the inspector on the day(s) of inspection were included. There were three possible judgments: compliant,

substantially compliant, and not compliant. The regulatory judgments are described by the regulator as follows: “Compliant means the provider and or the person in charge is in full compliance with the relevant regulation. Substantially compliant means that the provider or person in charge has generally met the requirements of the regulation but some action is required to be fully compliant. A judgment of not compliant means the provider or person in charge has failed to comply with a regulation and that considerable action is required to reach compliance”.[70]

We used published and unpublished inspection reports as a data source. Inspection reports were authored by inspectors and contained descriptions of their findings on the day of inspection. Reports follow a template with three main sections: section 1, what residents told inspectors and what inspectors observed; section 2, capacity and capability (the governance arrangements and resources available to a centre to carry on the service); section 3, quality and safety. Section 1 contains descriptions of interactions with residents and inspector observations on how care was provided. There are no regulatory judgments in this section. In section 2, the inspector(s) write a narrative describing the centre’s capacity and capability for providing the service, referencing issues such as governance arrangements, training, complaints and the management of incidents. At the end of section 2, the reports contain a list each of the regulations assessed in the capacity and capability category as well as the regulatory judgment (compliant/substantially compliant/not compliant) for each, along with text as supporting evidence for the judgment. In section 3, the inspector(s) describe in narrative form their findings with respect to quality and safety (e.g. quality of life, activities, fire safety, safeguarding) and the report lists each of the regulations assessed in the quality and safety category, along with the regulatory judgment and the supporting evidence for each. During the period covered

by this study there were 32 regulations that could feature in inspection reports[69] (Appendix 1 contains a full list of regulations). The 32 regulations contain multiple sub regulations, as demonstrated for regulation 10 (communication) below:

"*Communication*

10. (1) The registered provider shall ensure that each resident is assisted and supported at all times to communicate in accordance with the residents' needs and wishes.

(2) The person in charge shall ensure that staff are aware of any particular or individual communication supports required by each resident as outlined in his or her personal plan.

(3) The registered provider shall ensure that—

(*a*) each resident has access to a telephone and appropriate media, such as television, radio, newspapers and internet;

(*b*) where required, residents are facilitated to access assistive technology and aids and appliances to promote their full capabilities; and

(*c*) where required residents are supported to use assistive technology and aids and appliances." [69]

Some regulations are worded in a manner that seeks to provide support to people relative to their specific needs whereas others are more prescriptive in terms of the facilities that should be provided to people (e.g. a telephone).

All inspection reports described the evidence identified by the inspector to support each compliance judgment. The evidence supporting judgments of 'not compliant' and 'substantially compliant' were the data of interest for this study. While 'substantially compliant' could be read as a positive finding, we opted to include

data pertaining to these judgments because, as per the description above, they referred to some element of the regulation not being satisfactorily met.

6.3.4 Sample

The time period for the sample (1st January 2019 to 31st October 2022) was chosen because the regulator changed the way regulations were assessed during the course of 2018. Any inspections conducted prior to this used different compliance judgments. The end date for the sample was the last full month available prior to commencing data extraction.

There are four inspection types: monitoring inspections which are conducted routinely regardless of the level of risk in a service; risk inspections which are carried out on foot of concerns around the quality and safety of a service; new applicant inspections that take place prior to a service commencing operations; and thematic inspections which focus on a specific aspect of care. We selected monitoring inspections for our analysis (n=1917). We did this because of the nature of the other inspection types. Risk inspections could have biased the sample as they are conducted due to specific quality concerns. Thematic inspections only covered infection control during the study period. New applicant inspections only assess the likelihood of future compliance.

To ensure a centre was represented only once in the sample we retained the most recent inspection reports for each centre. This sample contained inspection reports for 1263 centres, one report per centre.

A thematic analysis was conducted of causes of non-compliance on a sub-sample of 35 inspection reports. The sub-sample was identified by first excluding all reports with 100% ‘compliant’ judgments (n=777) as they contained no relevant data i.e., information on non-compliances. We then randomly sampled the remaining 1140

inspection reports. Each included inspection was allocated a random number in MS Excel[404] through the random number generator function which produced the seed for the sample. Inspections were then sorted in ascending order by the seed. We selected the first 25 inspections on the list and this constituted the first tranche of reports in the sub-sample. To ensure an inspector was only represented once in the sub-sample we retained their numerically first inspection and deleted any subsequent ones. We then replaced a deleted inspection with the next inspection on the list by an inspector that did not appear in the initial 25.

6.3.5 Analysis

Data were imported into R Studio (Version 2023.03.0, RStudio PBC).[405] We calculated the frequency each regulation was assessed and the non-compliance percentage for each regulation ((total number of judgments of 'not compliant' and 'substantially compliant'/total number of judgments) * 100) in the sample (n=1263).

We calculated the mean non-compliance percentage for all centres by first calculating the non-compliance percentage for each individual centre. This was done by summing the number of judgments of 'not compliant' and 'substantially compliant' in each inspection and dividing the result by the total number of regulations assessed in the inspection: ((number of judgments of 'not compliant' and 'substantially compliant'/total number of judgments) * 100). We used this to calculate the mean non-compliance percentage for all centres.

We calculated the number of centres that were fully compliant (i.e. were found to be in compliance with all regulations that were assessed on an inspection) and centres that were fully non-compliant (i.e. no regulations assessed during the inspection were found to be compliant).

Descriptive statistics (n (%) or median (IQR) as appropriate) for centre type; publication status; bed number; year of inspection; overall non-compliance percentage; number of fully compliant and fully non-compliant centres for all inspection reports in the sample and sub-sample were calculated.

We adopted a thematic analysis approach to identify reasons for non-compliance using the first tranche of 25 inspection reports in the sub-sample. Two researchers (PD and LMK) piloted a data extraction process for three inspection reports. The focus of data extraction was on phrases or sentences that supported compliance judgements made by the inspector. We included the number of the regulation that was associated with the extracted text. Subsequent to the pilot we amended the data extraction form to specify which section in the report the extracted data came from.

Two researchers (PD and LMK) independently coded an initial five reports. Coding was performed inductively where each researcher assigned codes to the text using NVivo.[406] There were occasions in reports where a non-compliance was referenced in more than one section. Similarly, there were instances where several issues that contributed to a single instance of non-compliance were listed e.g. multiple rooms in a premises that required cleaning. In such cases, to avoid counting multiple instances of the same reasons for non-compliance and increasing the frequency count for that code, we only coded one piece of text relevant to a reason for non-compliance per report. However, the same piece of text was placed in multiple codes where appropriate. For example, the following text “one resident had no plan in place to guide how they should be supported with their mental health diagnosis” could be placed in a code related to ‘documentation’ as well as ‘guidance for staff’.

Upon completion of coding the initial five reports, codebooks were generated through NVivo[406] where PD and LMK then met to compare and agree coding and

interpretation of the data, and devise any additional codes for inclusion. Disagreements were resolved through consensus or through discussion with the third author (JB). The codebook was subsequently revised and PD coded the remaining data independently.

PD reviewed the codes to group them into sub-themes and parent themes that characterised the reasons for non-compliance. Once completed, PD reviewed all sub-themes and parent themes to identify similarities and determine whether any could be combined or collapsed. We proceeded to add five inspection reports to the sub-sample until saturation was reached i.e. no new themes were identified.

We then determined the frequency effect size (FES) and intensity effect size (IES) for each parent theme and sub-theme by adapting an approach to meta-summary as described by Sandelowski (2007).[407] The FES represents how prevalent each theme and sub-theme was in the sample of inspection reports and the IES represents the quantity of data coded to a theme and sub-theme as a proportion of all coded data. The FES was calculated by dividing the number of reports that included a theme by the total number of reports in the sample. The IES was calculated by dividing the total number of texts ('texts' refers to words or phrases which were coded during thematic analysis) included in a theme and sub-theme by the total number of texts. We reported our thematic analysis findings under each parent theme in order of highest FES.

We mapped the parent themes back to the regulations by identifying which regulation was being referred to in each individual piece of text, calculating the frequency and percent contribution of themes to each regulation and tabulating these data as a heat map.

6.3.6 Data management

Inspection reports contained no personally identifiable information (PII) relating to residents as this is the policy of the regulator.[408] As such, there was no PII contained in these data apart from the name of the person in charge of the centre which is publicly available. All data pertaining to this research were stored on a secure online platform. Files used for the analysis were only accessible by the first author and shared with the other authors as necessary.

6.3.7 Researcher characteristics

The lead author, PD, is a full-time employee of the Health Information and Quality Authority (HIQA), which is the regulator for health and social care in Ireland. PD is engaged in a PhD that is funded by HIQA and this study comprises part of the PhD research. PD is a male with over 10 years of experience working in a regulatory capacity. There is a potential for the experience of working in a regulatory capacity to influence the means by which documents were analysed in this study and in the interpretation of data. To guard against this, document analysis involved the input of the other authors and the potential for bias or assumptions to be introduced into the interpretation of data was openly discussed among the authors at all stages of the research.

6.4 Results

1263 inspections were included in our study that took place between 1st January 2019 and 31st October 2022 inclusive. These included 19,173 individual assessments of regulations. All of the possible 32 regulations were featured (Figure 3). There were inspection reports for 1,147 (91.8%) adult centres, 87 (6.9%) children's centres and 29 (2.3%) mixed centres. Unpublished reports accounted for 150 (11.9%) of the total sample. The median (IQR) bed number in centres was 5.0 (4.0, 8.0). There were 256 (20.3%) inspections in 2019, 79 (6.3%) in 2020, 403 (31.9%) in 2021 and 525

(41.6%) in 2022. The median centre-level non-compliance was 27% (13%, 46%). Thirteen centres (1%) in the overall sample had an inspection where all regulations assessed were judged compliant; 100 centres (8.1%) failed to comply with any regulations. The characteristics of the sub-sample were broadly similar to the overall sample (Table 10).

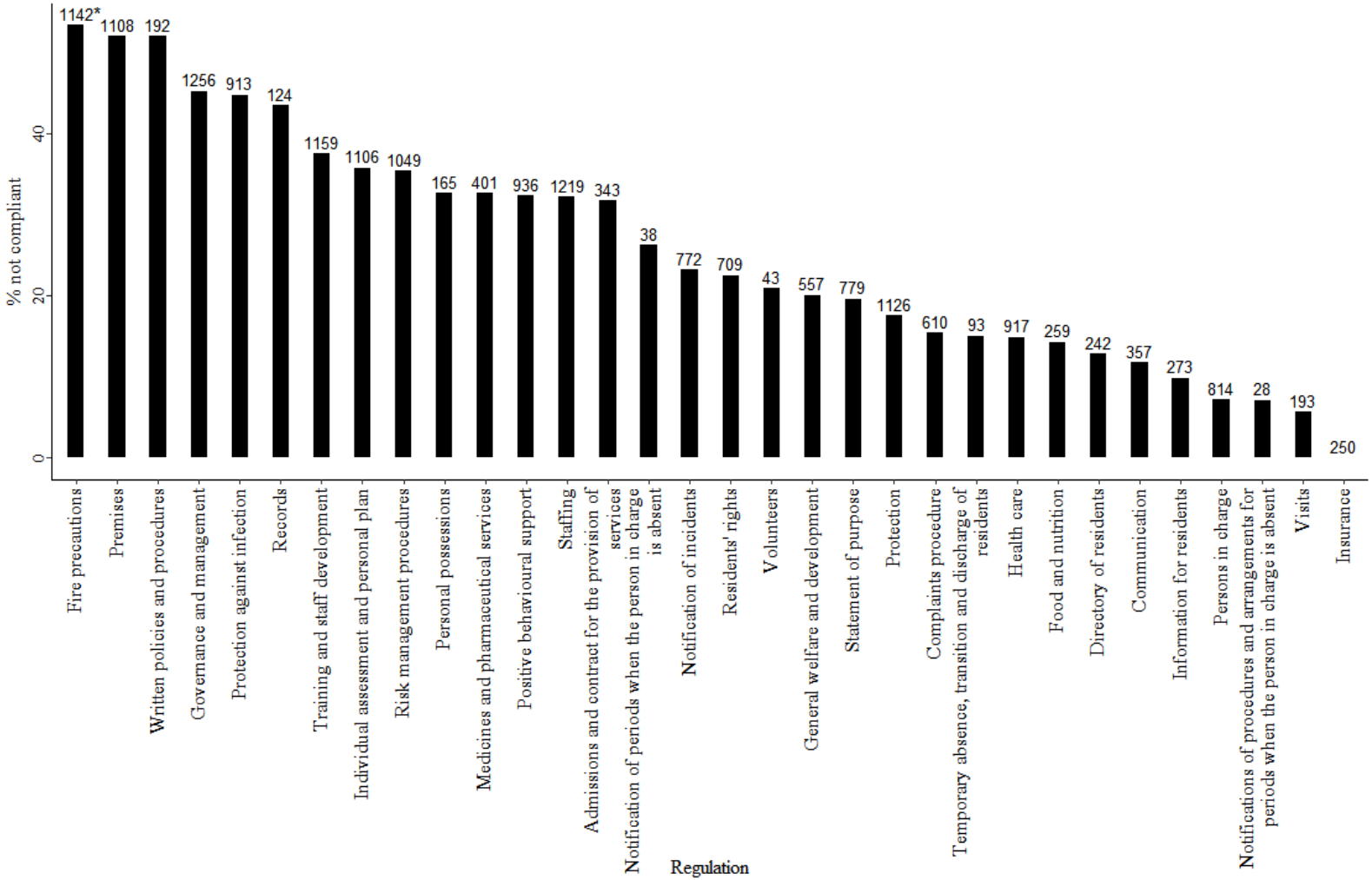
Table 10 – Characteristics of inspection reports and residential disability centres overall and in sub-sample

Characteristic	**Total**, n = 1263[1]	**Sub-sample**, n = 35[1]
Service type		
Adults	1147 (90.8%)	32 (91.4%)
Children	87 (6.9%)	2 (5.7%)
Mixed	29 (2.3%)	1 (2.9%)
Publication status		
Report not published	150 (11.9%)	3 (8.6%)
Report published	1113 (88.1%)	32 (91.4%)
Beds	5.0 (4.0, 8.0)	6.0 (4.0, 8.0)
Year of inspection		
2019	256 (20.3%)	9 (25.7%)
2020	79 (6.3%)	1 (2.9%)
2021	403 (31.9%)	10 (28.6%)
2022	525 (41.6%)	15 (42.9%)
Non-compliance percentage	27 (13, 46)	32 (14, 50)
Fully compliant centres	13 (1.0%)	n/a
Fully non-compliant centres	100 (8.1%)	n/a

[1]n (%); Median (IQR)

"Governance and management" was the most frequently assessed regulation (n=1256, 99.4%), followed by "staffing" (n=1192, 96.5%) and "training and staff development" (n=1133, 91.8%). The regulation with the highest percentage of non-compliance (not compliant + substantially compliant judgments) was "fire precautions" (53.4%), followed by "written policies and procedures" (52.1%) and "premises" (52.1%). "Insurance", was found fully compliant in all inspections where it was assessed (n=250).

Figure 3 – Non-compliance percentage of all regulations from most recent regular inspection of residential disability centres conducted between 1st Jan 2019 – 31st Oct 2022 (total number of individual assessment: n=19173)



* The number at the end of each bar represents the number of occasions the regulation was assessed.

Eight parent themes describing reasons for non-compliance were identified. In order of FES these were: insufficient resources, governance and management failings, poor documentation quality, non-person-centred care, weak processes, inadequate safety, staffing-related concerns and poor care management (Table 11).

Table 11 – Parent themes and sub-themes and FES and IES resulting from thematic analysis of text describing non-compliant regulations in a sample of inspection reports (n=35) of inspections conducted between 1st January 2019 and 31st October 2022 in residential care facilities for people with disability

Theme/sub-theme	**FES*** **(n=35)**		**IES**** **(n=385)**	
	n	%	n	%
Insufficient resources	27	77.1	65	16.9
Quality of physical premises	22	62.9	49	12.7
Other resources	10	28.6	16	4.2
Governance and management failings	23	65.7	57	14.8
General governance issues	16	45.7	21	5.5
Reporting failures	10	28.6	14	3.6
Quality improvement issues	8	22.9	8	2.1
Inadequate management supervision	7	20.0	11	2.9
Incompatibility of residents	3	8.6	3	0.8
Poor documentation quality	23	65.7	77	20.0
Failure to review/update a plan or document	16	45.7	21	5.5
Planning documents or information not available, not comprehensive or poor quality	16	45.7	32	8.3
Record keeping failures	14	40.0	19	4.9
Contract of care issues	4	11.4	5	1.3
Non-person-centred care	21	60.0	66	17.1
Non person-centred care	16	45.7	31	8.1
Unmet resident need	12	34.3	21	5.5
Information unavailable for residents	7	20.0	7	1.8
Lack of privacy	6	17.1	7	1.8
Weak processes	20	57.1	40	10.4
Risk management problems	14	40.0	20	5.2
Cleaning required improvement	9	25.7	10	2.6
Infection control practices	8	22.9	10	2.6
Inadequate safety	17	48.6	40	10.4
Fire safety concerns	15	42.9	31	8.1
Safeguarding concerns	6	17.1	9	2.3
Staffing-related concerns	16	45.7	27	7.0
Staff training unavailable or not provided	14	40.0	23	6.0
Uninformed staff	4	11.4	4	1.0
Poor care management	9	25.7	13	3.4
Care not provided as per plan	6	17.1	8	2.1
Behaviour management issues	3	8.6	5	1.3

* FES = Frequency effect size

** IES = Intensity effect size

6.4.1 Insufficient resources

This parent theme refers to the physical and human resources available to the centre to provide a service. For clarity, the reference to resources in the title does not necessarily relate to financial resources. There were 27 inspection reports containing instances of this parent theme.

6.4.1.1 Quality of physical premises

Twenty-two inspection reports contained references to the quality of the physical premises where care was provided. The codes included in this sub-theme outlined problems related to *inter alia* the suitability of the premises for meeting the needs of residents; refurbishment requirements; worn surfaces and fabrics; accessibility difficulties and general maintenance or repairs. The code that most frequently appeared in this sub-theme was 'fixtures, fittings or surfaces in need of repair', for example: "*damaged seals on a floor and other bathroom fittings and a damaged mirror*"; "*large furnishings required repair or replacement*"; "*internal window sills in one house were water damaged*". 'Painting or decorating required' was the second most frequent code: "*chipped and worn paintwork was noted around both buildings*"; "*A number of rooms, including residents' bedrooms required painting*".

6.4.1.2 Other resources

This sub-theme contained instances of where an inspection report described issues related to an identified lack of physical and human resources within the premises. Resources sometimes referred to relatively minor items such as clinical waste bins but also included inadequate staff levels to meet the assessed needs of residents, for example: "*staff had told the inspector that recent staffing levels negatively impacted on their ability to support residents in activities both in the centre and in their local community, especially at the weekends*"; "*the provider had not consistently allocated sufficient staff to the centre to support residents' assessed needs*".

6.4.2 Governance and management failings

This parent theme refers to instances where the practices and structures relating to governance contributed to non-compliance; this theme was identified in 23 inspection reports.

6.4.2.1 General governance issues

This sub-theme contained instances of where services had failed with regard to routine governance matters. For example, codes included ‘no training needs analysis’, ‘no observational audits of hand hygiene’ and ‘failure to adhere to statement of purpose’. There were other examples where inspection reports described concerns with governance due to inaction or a failure to implement commitments that were previously made to the regulator: “*improvements identified as required in relation to the premises at the time of the last inspection, had not yet been undertaken*”; “*A protective measure, stated by the registered provider to be in place, related to staff supervision. This protective measure was not in place on the day of inspection and only related to days that the person in charge was present in the house*”. The code that appeared most frequently in this sub-theme related to a service’s failure to act on the findings of their own audits, for example: “*The person in charge had identified that there remained an ongoing issue with the heating of the centre and temperature of water, as the controls were not contained within the building. There was no time bound plan to address this, and some areas of the centre were uncomfortably warm during the inspection*”.

6.4.2.2 Reporting failures

Centre staff are responsible for reporting various incidents to relevant authorities. Ten inspection reports described failings in this responsibility. Primarily, these related to a failure to notify the regulator of certain prescribed incidents within the required timeframe e.g. “*The use of some restrictive practices, including chemical*

and physical restraints, had not been notified to the Chief Inspector"; "*13 notifications in relation to safeguarding were submitted retrospectively following inspection*". There were a smaller number of incidents relating to failures on behalf of staff to report certain incidents to management: "*incidents were reported by staff when they encountered the person in charge rather than when the alleged event happened*"; "*staff had failed to record or report these behaviours as they felt it was unnecessary*".

6.4.2.3 Quality improvement issues

Eight inspection reports contained findings related to how quality improvement in services was not managed effectively. For example, in some cases audits were conducted that did not result in actions for quality improvement: "*While the registered provider had in place a recent annual review of the quality and safety of the service provided to residents, there was no improvement plan identified in relation to notifiable incidents*". Inspectors also occasionally found fault with the quality of audit practice: "*the inspector found that audits did not comprehensively reflect the known risks in the centre. Furthermore, there was no comprehensive plan in place to address these risks. It was not established therefore that these audits were being used as a tool to drive service improvement*".

6.4.2.4 Inadequate management supervision

There were examples in seven inspection reports of failures related to management supervision of the service and of staff. On occasion it was found that staff were not in receipt of supervision, support or development: "*Records reflected that each staff member had been met once in the last twelve months and not every two months as per the providers [sic] policy*"; "*effective arrangements were not in place to support, develop and performance manage all members of the staff team*". There were some also instances of senior management not having sufficient time to carry out their

duties: "*The clinical nurse manager worked full-time hours in the centre, however approximately two-thirds of their shifts were spent as one of the two nurses directly supporting the residents throughout the day, with a limited portion of hours protected for attending to management duties*".

6.4.2.5 Incompatibility of residents

Three reports contained references to interpersonal difficulties between residents which were impacting on the wellbeing of all who lived in the centre. We determined this to be a governance and management issue as the service providers were aware of the difficulties but had not acted promptly: "*The provider had failed to address the compatibility of residents in the centre. The inspector met five residents and two spoke of their worry, concern, avoiding contact with the resident experiencing unstable mental health and the limitations this had on their living environment*".

6.4.3 Poor documentation quality

Instances of documents being insufficiently detailed, poor record-keeping or not properly reviewed were reflected in this parent theme. This parent theme was identified in 23 inspection reports.

6.4.3.1 Failure to review/update a plan or document

Sixteen reports contained examples of where plans or documents were available but had not been reviewed or updated in an appropriate manner. This included occasions where it was mandatory to review a document: "*not all of the policies and procedures required to be maintained, as identified in Schedule 5 of the regulations, had been reviewed within the last three years as is required*"; or where it would be deemed necessary to support residents' care and support needs: "*associated risk*

assessments and safety plans required reviewing to ensure that they included measures that were in line with the behaviour support plan".

6.4.3.2 Planning documents or information not available, not comprehensive or poor quality

This sub-theme captured instances where inspectors found fault with various documents and information that were important for guiding care and support within a service. Some examples of the types of documentation that were found to be of poor quality or not comprehensive included assessments of need, personal plans, behaviour support plans and medication plans. Inspectors also found documentation and information to have been unavailable: *"there was no procedure or guidance available to lone working staff around the supervision and care of residents"*; or due to not being of the required quality: *"While dietary care plans were on file, these had not been completed in consultation with multidisciplinary professionals such as dietitians or by staff with specific training or knowledge in the relevant areas"*.

6.4.3.3 Record-keeping failures

There were 14 instances where inspection reports outlined failures in the maintenance of records. Among the codes included in this sub-theme were poor record upkeep; poor recording of fire safety precautions taken; poor record-keeping relating to restrictive practice use. In some cases, it was found that important information was not being recorded: "*while the residents reported peer-on-peer related issues, they were not being recorded*"; "*the inspector found that a number of specific behavioural incidents were not being satisfactory logged or recorded*".

6.4.3.4 Contract of care issues

Four inspection reports detailed issues related to residents' contracts of care. Some contracts were not signed by the resident or their representative, were generic in

nature, or did not detail all charges for services. For example: "*the agreements did not include details of the fees to be charged*".

6.4.4 Non-person-centred care

This parent theme included instances where the care provided to people living in centres did not adequately take account of their individual needs and preferences; non-person-centred care was identified in 21 inspection reports.

6.4.4.1 General non-person-centred care

This sub-theme encompassed a wide range of practices that were considered to reflect care that did not meet the needs of individuals using services. Some of the codes related to failures by services to support residents in living a fulfilling life (e.g. poor access to activities; unresponsive to resident needs/preferences; lack of progress on personal goals) whilst others were related to the nature of the premises (e.g. premises required age-appropriate facilities for children; garden not accessible to wheelchair users; lack of suitable storage for residents). Some inspection reports relayed concerns as expressed by residents. For example, one report contained a reference to a resident telling an inspector that they had no remote control for their television, another described a resident expressing a wish to move to accommodation with fewer service users.

6.4.4.2 Unmet resident need

Twelve inspection reports noted that residents had needs that were either partially or fully unmet by the service, in part linked to insufficient staffing levels: "*On other occasions it was noted that residents were asked to leave the vicinity during an incident where a resident was engaging in behaviours of concern. As there was only one staff member present, there was limited support for all residents during this time*"; "*Staff spoken with told inspector [sic] that the current staffing levels had*

affected residents' ability to access the community and attend activities". There were some codes which appeared in this sub-theme as well as in non-person-centred care above because it clearly reflected an unmet need in addition to a failure to provide care in a person-centred manner. For example, the following text was placed in the 'unmet responsive to resident preferences' code in both sub-themes: "*a review of daily notes indicated that some residents have limited opportunities to engage in activities that were in line with their interests, capacities and needs*".

6.4.4.3 Information unavailable for residents

Seven inspection reports contained findings where information on fees and services were not provided in contracts of care as required. In addition to contracts, there were failings found in terms of how information was presented ("*some of the information displayed was too high on the wall for the children to see*") and with information not being made available ("*the resident did not have access to information about their payments or financial affairs*"). There was text in this sub-theme that also appeared in the contracts of care sub-theme above. For example, the failure to include details on additional charges was regarded as a shortcoming in the content of the contract and also a lack of information available to the resident.

6.4.4.4 Lack of privacy

This sub-theme reflected two distinct aspects of resident privacy. The first related to being facilitated to have a private space such as one's own bedroom: "*One area for improvement noted on the walkabout of the centre was the practice and use of viewing panels on residents bedroom doors…The inspector was not assured that these checks were required in response to the assessed needs of residents*"; "*the inspector saw that one resident had recently expressed a wish to have their own bedroom. There was no comprehensive, time-bound plan in place to support this resident to have their own room and to uphold their right to privacy*". Secondly,

there were failures in terms of keeping personal information private: "*Inspectors observed personal information regarding residents were being stored in communal areas*"; "*residents [sic] files were left in the kitchen area on an open shelved unit and one residents feeding support plan was taped to the kitchen table*".

6.4.5 Weak processes

This parent theme refers to instances where processes in a centre (e.g. cleaning routines or ongoing risk management) contributed to non-compliances. There were 20 inspection reports that contained instances of weak processes.

6.4.5.1 Risk management problems

Fourteen inspection reports detailed examples of where services had failed to identify risks (e.g. "*a number of risks had not been identified within the designated centre's risk register, including the risk of injury to residents due to sloping roofs in residents' bedrooms*"); failed to carry out risk assessments for identified risks (e.g. "*not all identified risks to residents had corresponding risk assessments*"); and had not reviewed risk assessments appropriately (e.g. "*risk assessments and safety plans required reviewing to ensure that they included measures that were in line with the behaviour support plan*"). Some inspection reports also described occasions where the risk assessment processes required improvement, for example, in the context of risk rating: "*some risk assessments required review as the ratings were not reflective of the risks posed by hazards in this centre*".

6.4.5.2 Cleaning required improvement

Nine reports noted that cleaning processes were inadequate. One of these reports described mould in areas. Others identified stains on carpets and toilets. Areas of general uncleanliness were also found: "*shared shower spaces which were not clean and thick dust or cobwebs in some corners and ceilings around the house*".

6.4.5.3 Infection control practices

The processes supporting infection control were found to be insufficient in eight reports. The most frequent issue related to worn or damaged surfaces that could not be adequately cleaned and thereby presented an infection control risk. In addition, there were examples of where services had operated outside of national guidance for managing COVID-19 (e.g. "*the inspector saw that the provider's written guidance and procedures for managing cases of COVID-19 had not been updated in line with the most recent public health guidance*"; "*staff practices regarding wearing of PPE [Personal Protective Equipment] at the start of the inspection did not reflect the most up-to-date guidance*".

6.4.6 Inadequate safety

This parent theme contained examples of where safety precautions were insufficient to ensure the wellbeing of people living in centres. Inadequate safety was noted in 17 reports.

6.4.6.1 Fire safety concerns

Fifteen reports contained instances where fire safety contributed to non-compliances. There were seven reports in which issues with fire doors (doors with a technical specification to withstand fire for a certain number of minutes) were identified. Fire doors were sometimes not in places they should have been (e.g. "*considerable areas of the centre did not have fire doors fitted*"), or they were being held open inappropriately (e.g. "*it was observed that a resident's bin was placed in front of their bedroom door, which may prevent the door from closing in the event of a fire*"). Other findings related to fire safety included: personal emergency evacuation plans (personalised plans for managing the evacuation of individuals) were not sufficiently comprehensive or not available in accordance with the service's fire plan; fire

equipment in need of repair/review; inadequate fire containment measures; and fire drills not being comprehensive.

6.4.6.2 Safeguarding concerns

Safeguarding is the practice of protecting a person from harm or neglect whilst also promoting their individual wellbeing.[409] Six inspection reports contained examples of where safeguarding investigations were not carried out: "*an allegation of abuse raised in May 2020 had not been resolved. While the provider had put steps in place to begin the investigation it had not commenced at the time of this inspection*"; safeguarding plans not put in place: "*safeguarding plans had not been updated or put in place following incidents*"; residents leaving a centre unsupervised: "*three incidents had occurred in recent months which resulted in the resident leaving the centre without staff support*"; and residents not being protected against the behaviours of concern of other residents: "*residents were not safeguarded against the effects of behaviours of concern in the centre*".

6.4.7 Staffing-related concerns

This parent theme referred to instances where staff did not have the capacity to carry out their duties, due to being uninformed on people's needs or not having access to training; there were 16 such instances in inspection reports.

6.4.7.1 Staff training unavailable or not provided

Fourteen inspection reports noted issues with mandatory training (e.g. fire safety) and with service-specific training (e.g. management of dysphagia). For example, "*there were some gaps in staff being in receipt of training in mandatory areas and also in relation to training to support residents in relation to specific assessed needs*". In some instances, the inspector noted reasons for the lack of training of staff such as the unavailability of in-person training programmes due to COVID-19

restrictions and the inaccessibility of online training due to a cyber-attack on the computer systems of the Irish national health service.

6.4.7.2 Uninformed staff

Inspectors drew attention to staff not having the required knowledge or guidance to carry out their duties or meet the needs of residents in four reports. For example, "*staff were unaware of specific sensory and tactile responses to be employed in the event that a resident was upset and required a behavioural support intervention. These therapeutic interventions were clearly documented in the resident's behaviour support plan but the inspector did not see evidence that staff could identify and alleviate the cause of a resident's behaviour*". One report noted excessive use of relief/agency staff which impacted on continuity of care and created extra work for regular staff.

6.4.8 Poor care management

This parent theme contained examples of where the care of persons living in a service was not managed in accordance with their identified needs and preferences. There were nine reports that contained such instances.

6.4.8.1 Care not provided as per plan

The types of plans referred to in this sub-theme included 'personal plans' which provide an overall assessment of a person's needs and how these are to be met, as well as plans to address specific care needs such as behaviour support plans or a percutaneous endoscopic gastronomy (PEG) feed plan. Six inspection reports described occasions where the care provided was not in accordance with such plans. For example, "*one resident had a protocol in place for the use of a psychotropic medication as needed (PRN). The protocol in place advised staff to monitor the resident for the presentation of three of six identified behaviours before*

administering this PRN. Progress notes suggested that at times, the resident only presented with one or two of these behaviours when staff had adminstered [sic] the PRN".

6.4.8.2 Behaviour management issues

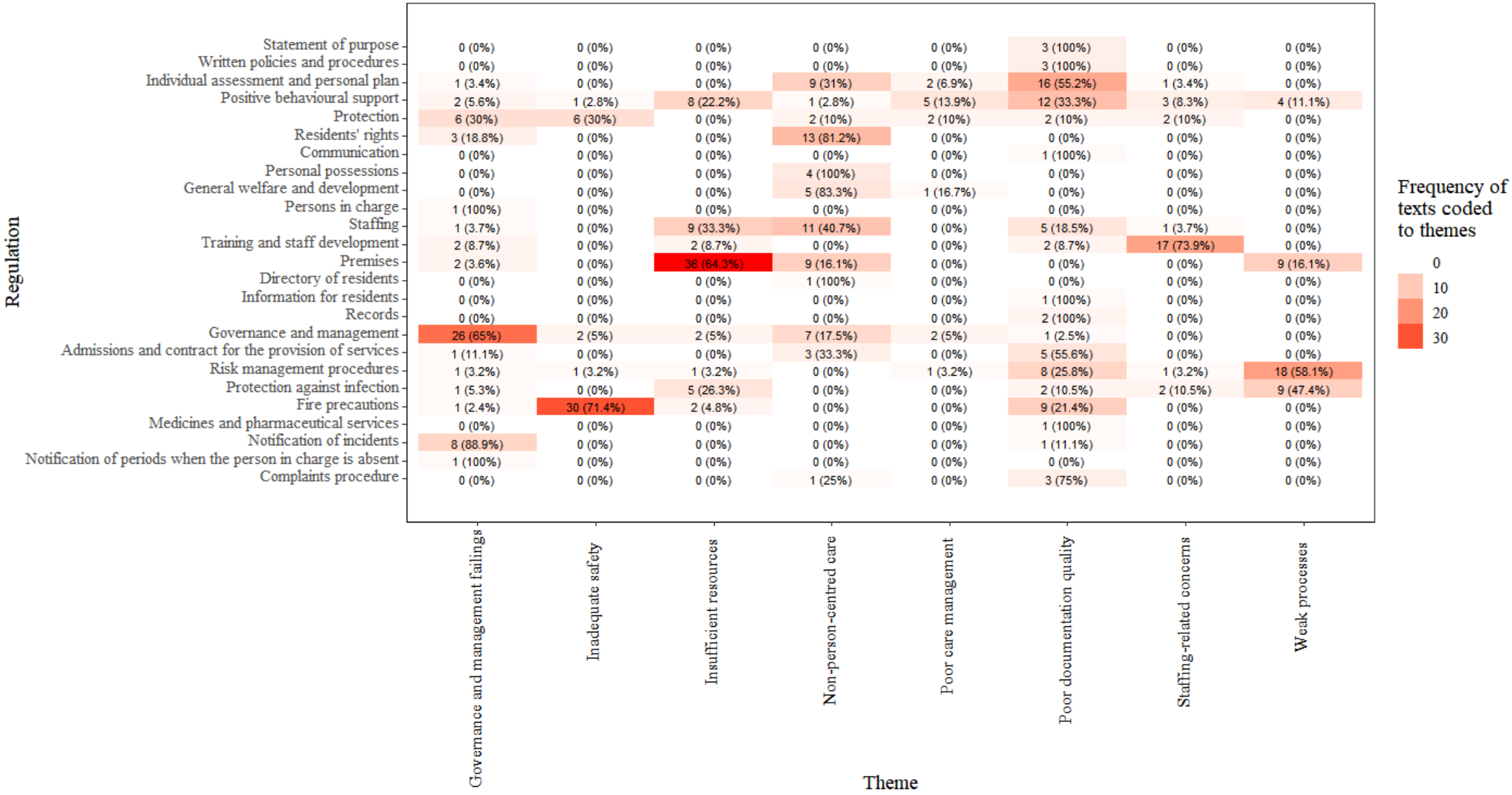
The management of residents' behavioural support needs was found to be an issue in three inspection reports. In some instances these issues were impacting on the wellbeing of other residents: "*the behaviours of a small number of residents were sometimes difficult for staff to manage in a group living environment and this had the potential to have a negative impact on other residents*".

6.4.9 Mapping of themes to regulations

Of the 32 regulations, 25 were featured in the sub-sample i.e. were found to be 'not compliant' or 'substantially compliant' in at least one inspection report (Figure 4). The theme of 'poor documentation quality' was linked to 18 of the 25 regulations, followed by 'governance and management failings' (n=15 regulations) and 'non-person-centred care' (n=12 regulations). The theme that was linked to the least number of regulations was 'weak processes' (n=4 regulations).

One regulation (positive behavioural support) was linked to all eight themes indicating that it was the area with the greatest variety of potential causes of non-compliance. Seven themes were identified as causes of non-compliance for the 'risk management procedures' regulation and six themes were linked to the 'governance and management' and 'protection' regulations. There were six regulations that appeared only once in the data and, by default, where only one theme appeared (communication; persons in charge; directory of residents; information for residents; medicines and pharmaceutical services; Notification of periods when the person in charge is absent).

Figure 4 – Heat map representing the frequency of texts coded to themes, including the percent contribution of themes to non-compliant regulations, in a sample of inspections of residential disability centres (n=35) conducted between 1st Jan 2019 – 31st Oct 2022



6.5 Discussion

Our findings show that non-compliance with social care regulations in residential disability services in Ireland is widespread. Only 1% of centres in our sample managed to be fully compliant. At the other end of the spectrum, over 8% of centres failed to comply with all of the regulations assessed during inspection. The median non-compliance percentage of centres nationally was 27%. This suggests that compliance with regulations in this sector is challenging and that only a very small number of centres were able to satisfactorily meeting all of the regulatory requirements.

It is difficult to compare our findings with similar care settings in other countries. For example, the Care Quality Commission (CQC) in England publish annual, national-level data on compliance levels but do not include data specific to residential disability services.[410] Moreover, the compliance descriptors differ to those used in Ireland (inadequate, requires improvement, good, outstanding). For reference, the CQC rated 83% of adult social care services as good or outstanding.[410] We could not identify any other publicly-available data on compliance levels in services similar to residential disability services in other countries.

Three regulations were found non-compliant more than half the time they were assessed: fire precautions; written policies and procedures; and premises. One potential explanation for the high level of non-compliance with these regulations may be found in their content and complexity. For example, the premises regulation contains seven subsections which specify requirements with a wide range of matters related to the physical infrastructure of centres such as design, outdoor areas, equipment and accessibility. Similarly, the fire precautions regulation has five

subsections which cover firefighting equipment, staff training, fire drills and evacuation. This is in contrast with regulations such as insurance which has two subsections that require centres to have insurance against injury to residents and loss or damage to property — matters which are relatively simple to arrange. This regulation was found to be fully compliant in our sample.

A systematic review focusing on standards in healthcare settings identified several barriers in terms of implementation which may prove instructive due to their similarity with regulations.[411] Two themes are consistent with our findings: services have a lack of training, support tools and consistent monitoring processes; services have poor access to resources and funding. One outcome of insufficient funding identified in the review was the poor maintenance of infrastructure and equipment;[411] this outcome also featured prominently in our findings although our study was not designed to investigate whether this was a consequence of poor funding.

In exploring the causes of non-compliance, the theme that appeared most frequently was ‘insufficient resources’. A focus on remedying these matters — many of which appear to be financial or staffing matters — could contribute to significant improvements in compliance levels. Many reports drew attention to relatively minor maintenance or refurbishment works such as painting, the presence of mould, furniture repair or flooring problems. However, the inspection reports did not provide any additional explanation as to why these failings occurred. One might expect issues that were clearly visible and obvious to be identified and remedied on an ongoing basis by centre management. Indeed, there is a subsection in the governance and management regulation that requires centre providers to make unannounced visits to their centres every six months and prepare a report on the

quality and safety of the service. One might conclude that the failure to address basic repair and maintenance issues is symptomatic of a lack of financial or staff resources to address such issues; or, a failure of governance and oversight.

However, not all resource-related issues can be remedied easily in residential care. It is difficult for service providers in Ireland to independently increase their available resources as the vast majority of residential disability centres are state-funded.[99] In 2019 the regulator in Ireland called attention to poor quality premises as a key challenge for service providers nationally and stated that state funding for new infrastructure would be required.[79] This underlines the need for a national strategy in Ireland focused on improving the quality of physical infrastructure in centres as well as identifying future reforms necessary to achieve a highly-person-centred approach to care for what will be a vulnerable, ageing population.[412]

The theme of ‘Governance and management failures’ featured prominently in the sub-sample of inspection reports. Material in this theme made reference to management in centres not acting on known issues, not supervising staff appropriately or not reporting matters as required. The regulation for governance and management was also frequently found not compliant, the fourth highest of the 32 regulations. It would seem logical to suggest that a centre that is not well managed will not only fail to meet governance and management regulations but also fail multiple other regulations. Therefore, improvements in governance and management — potentially through personnel with more management expertise or stronger accountability practices — may lead to concomitant compliance improvements across a broad range of regulations.

There are examples in the literature that can inform quality improvement approaches for governance. A systematic review of interventions to strengthen professional governance in nursing in a broad range of healthcare settings identified two broad approaches: enhancing structural empowerment and reinforcing leadership and teamwork.[413] The former included interventions such as the creation of nursing councils or expanding staff involvement in budgeting decisions. Interventions in the latter category included mentoring programmes and succession planning frameworks. Eight of the 12 studies included in the review reported positive results in terms of improvements to governance, albeit with some caution regarding the methodological quality of the included studies.[413]

Policy options to improve leadership in managers of Australian nursing homes was the subject of a systematic review published in 2010.[414] The authors identified a range of options such as *inter alia* higher middle-manager qualification requirements; development of a leadership and management qualities framework; establishment of a minimum dataset for data on managers containing information on diversity, qualifications, remuneration and turnover.[414]

'Poor documentation quality' was the theme with the third highest FES in our study. Some of the sub-themes (i.e. 'failure to review/update a plan or document', 'planning documents or information not available, not comprehensive or poor quality') suggest that non-compliances were commonly found with care plan documentation. The accuracy and coherence of care plan documentation was also found to be poor in a study conducted in long-term care settings in the Netherlands.[415] The authors suggested that investments in resources such as more time for staff to attend to documentation and more structured (electronic) care plans had the potential to improve documentation quality.[415] Further, a systematic review

evaluating the introduction of electronic nursing documentation found evidence that they can reduce documentation errors.[416] These studies illustrate possible means by which service providers can undertake quality improvement initiatives aimed at reducing non-compliances related to documentation.

When the themes were mapped back to the regulations we observed a difference across regulations with respect to how many themes contribute to findings of non-compliance. Of the 25 regulations in the sub-sample, 'poor documentation quality' was a factor in 18 (72%); 'governance and management failings' was a factor in 15 (60%). This suggests that improvements in both these themes could lead to broad-based improvement across all regulations. Conversely, there were some themes that appeared as factors in a relatively small number of regulations e.g. 'weak processes' (n=4) and 'inadequate safety' (n=5). To take inadequate safety as an example, this may mean that improvements in this regard would only impact a narrower range of regulations that are related to safety e.g. fire precautions or safeguarding.

Similar inferences can be drawn with respect to individual regulations. For example, there were 16 instances of non-compliance with the residents' rights regulation but it was linked to only two themes, with one (non-person-centred care) accounting for 81.3% of its total. There were others such as positive behavioural support that featured all themes and where there was a broad spread in terms of each theme's percent contribution (ranging from 2.8% for 'inadequate safety' to 33.3% for 'poor documentation quality'). This suggests that there are some regulations that are quite narrow in terms of ways they can be found non-compliant and others which are more wide-ranging. The amount of content in each regulation, and its complexity, may also play a role in this regard.

There may be additional factors contributing to non-compliance that were not observable by our study. For example, how does the relationship between the regulatee and inspector influence the outcome of an inspection? Some recent research in the field of regulation has sought to investigate the interaction between inspector and regulatee to examine how this impacts on levels of compliance.[380, 417] The wider context within which social care is structured and resourced may also have a bearing on levels of compliance with regulations. Many countries are in the midst of a crisis in social care, characterised by inadequate funding levels, staff shortages and demographic challenges.[400-402, 418, 419]

6.5.1 Strengths and limitations

This is the first study to characterise non-compliance in a health or social care setting using thematic analysis. This type of analysis is sparse in the literature on regulatory compliance in health and social care services.[420] We used a structured approach to document analysis as described in Moilanen et al. (2022).[403] We also adapted a method to measuring frequency and intensity effect sizes in our analysis, more commonly used in meta summaries,[407] which makes it somewhat novel. This allowed for a description of themes and regulations that highlighted their relative importance in terms of understanding non-compliance.

There were a number of limitations to our study. Some regulations did not appear in the sub-sample for the thematic analysis and several others were featured only once. It is possible that some additional themes may have emerged from assessing non-compliances related to these regulations. Nevertheless, the regulations that did feature in the sample are reflective of those most frequently-assessed and we are satisfied that the parent themes and sub-themes identified are representative of the broader problems found in centres.

Our findings rely on evidence described in inspection reports which, by their nature, constitute first order constructs. For example, an inspection report may include the following observation as evidence of non-compliance: “There was evidence of mould and condensation in the bedroom window of one resident”. Here, the mould was the cause of the inspector’s concern and the reason for the judgment of non-compliance. However, there may be several contributory factors at play here, ones that are not explicitly stated in the report. These may include poor cleaning practices, inadequate ventilation, or old/outdated premises. In turn, such contributory factors might have root causes such as poor staff culture or a lack of financial resources. Therefore, while we identify themes that represent reasons for non-compliance, these themes may themselves have deeper root causes which this study was not designed to identify. Nonetheless, we consider the findings of our study useful as they identify high-level failures that can be leveraged in further research to identify potential root causes.

A further potential limitation is observed in the somewhat circular nature of the relationship between themes and regulations. For example, the theme with the highest frequency in the governance and management regulation was ‘governance and management failings’. This is perhaps to be expected because the inspection reports, as described in the limitation above, do not provide any details which might identify deeper root causes for non-compliances. Nevertheless, we hold the view that mapping the themes to the regulations was a useful exercise as it demonstrated how some regulations can be failed in a multiplicity of ways and how certain themes of non-compliance, are found in the majority of regulations.

6.6 Conclusion

Non-compliance with social care regulations by centres in Ireland is commonplace. Interventions focusing on resources, governance and documentation quality represent areas for targeted improvements which may lead to higher overall levels of compliance. We describe non-compliance at the level of individual regulations where three (fire precautions, premises and written policies and procedures) were found non-compliant in more than half of the occasions they were assessed. The content and complexity of some regulations compared to others may go some way to explaining the observed differences in levels of non-compliance across regulations. Eight themes were identified in the text describing non-compliance in inspection reports. Some of the themes (e.g. 'insufficient resources') appeared frequently in inspection reports and were also featured more widely when mapped back to individual regulations. There may be deeper underlying causes that explain how these themes manifest. The themes describing non-compliance may provide insights to service providers and regulators in the development of quality improvement initiatives. Further quantitative studies on resource availability or qualitative research exploring non-compliance with individuals tasked with compliance in residential disability services (e.g. service managers or inspectors) may help elucidate these underlying causes.

6.6.1 Ethical approval

The Social Research Ethics Committee of University College Cork, Ireland, provided ethical approval for this research (2023-011). Ethical approval was sought in order to access the inspection reports that were not published by the regulator. Non-publication of inspection reports is typically done to protect the identity and privacy of people living in a centre. For example, where a centre has only one

resident, making that inspection report (which may contain sensitive information such as their healthcare or safeguarding needs) publicly available would compromise that person's privacy and dignity. Unpublished reports accounted for 150 (11.9%) of the total sample.

6.6.2 Data availability

The data that support the findings of this study are available on request from the corresponding author, and can be shared by way of a data sharing agreement. The data are not publicly available due to privacy or ethical restrictions.

6.6.3 Competing interests

PD is a current employee of the Health Information and Quality Authority, the regulator for health and social care in Ireland. LK is a former employee of the same organisation. Nevertheless the authors are of the view that does not represent a conflict of interest.

6.6.4 Funding statement

This study comprises part of a PhD being undertaken by PD. Funding for the PhD is provided by the Health Information and Quality Authority, Ireland. PD is also participating in the Structured Population health, Policy and Health-services Research Education (SPHeRE) programme which is funded by the Health Research Board, Ireland (SPHeRE/2018/1).

CHAPTER 7: Implementing quality and safety regulations in residential disability services: A qualitative interview study

The following chapter has been accepted by the BMJ Quality and Safety Journal and, at time of writing, was being prepared for publication:

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Authors

Paul Dunbar[1], Dr Laura M Keyes[2], Prof John P Browne[3]

Author details

[1] Health Information and Quality Authority, Unit 1301, City Gate, Mahon, Cork, Ireland T12 Y2XT. pdunbar@hiqa.ie (corresponding author)

[2] Centre for Implementation Research, University of Limerick, Ireland laura.keyes@ul.ie

[3] School of Public Health, University College Cork, Ireland j.browne@ucc.ie

7.1 Abstract

Background

Regulation plays a central role in health and social care systems, particularly in ensuring quality, safety, and accountability. However, there is limited understanding of how organisations effectively implement and adhere to these regulatory requirements. In particular, little is known about how providers of residential care facilities for people with disabilities (RCF-D) navigate and apply statutory care regulations.

Methods

We conducted semi-structured interviews with managers of RCF-D. Participant recruitment followed a purposive maximum variation sampling approach. Nineteen participants were interviewed, representing 22 RCF-D and 16 provider organisations. Interview data were analysed using a mixed deductive-inductive approach.

Results

Most managers were supportive of regulatory goals, creating a more favourable environment for successful implementation. By making sense of regulatory requirements and sharing insights across their organisations, managers facilitated smoother implementation. Crucially, building strong internal and external networks played a pivotal role in driving success. Collaborative relationships with inspectors, centred on a shared commitment to improving residents' lives, further strengthened the implementation process.

Conclusion

Managers of RCF-D devised a range of strategies to manage compliance, balancing regulatory demands with problem-solving and relationship-building. These efforts were supported by a collaborative approach to working with inspectors, which fostered a shared commitment to improving residents' lives. Our findings offer practical guidance for organizations seeking to improve regulatory compliance through effective relationship management and resource alignment. Future research could investigate how framing regulation as an adaptive intervention could further enhance implementation and sustain compliance.

What is already known on this topic

- *Regulation plays a central role in ensuring the quality, safety and accountability of health and social care systems worldwide, but little is known of how organisations implement regulatory requirements.*

What this study adds

- *This study reports the perspectives of managers of residential disability services and describes the strategies they use to comply with quality and safety regulations.*

How this study might affect research, practice or policy

- *This study conceptualises regulation as an intervention and the authors argue that regulation should be subject to research from an implementation science perspective to better understand how regulatory practices are implemented, adapted, and sustained.*
- *Our findings describe a range of themes that can inform the practice of service providers in managing regulatory engagements and achieving compliance.*
- *The findings may also be of interest to regulators in terms of how best to manage relationships with regulatees.*

7.2 Background

Regulation has been defined as: “sustained and focused control exercised by a public agency over activities which are valued by a community”.[143] Regulation is typically the responsibility of an independent authority, overseen by government.

In health and social care, regulation of individual professionals such as doctors and nurses has been intensively studied,[92, 421-423] but there is less insight into how organisations such as hospitals and residential care facilities respond to regulation.

The implementation of regulations has been studied across diverse disciplines such as economics, political science, public administration, and health organization studies. How individuals respond to regulation and the processes through which regulations are integrated into everyday practice, have been examined. Studies have identified key strategies used to support implementation, including instituting internal compliance systems[424], appointing compliance officers[425], and fostering a ‘culture of compliance’.[426] However, implementation does not always follow a linear path. Those responsible for regulatory adherence may engage with it in different ways, such as aligning with requirements, adapting them to local contexts, or resisting them altogether. Some studies have categorized these responses as amoral calculators,[36] conformists,[33] or game players,[38] illustrating the varying degrees of engagement with regulation in practice.

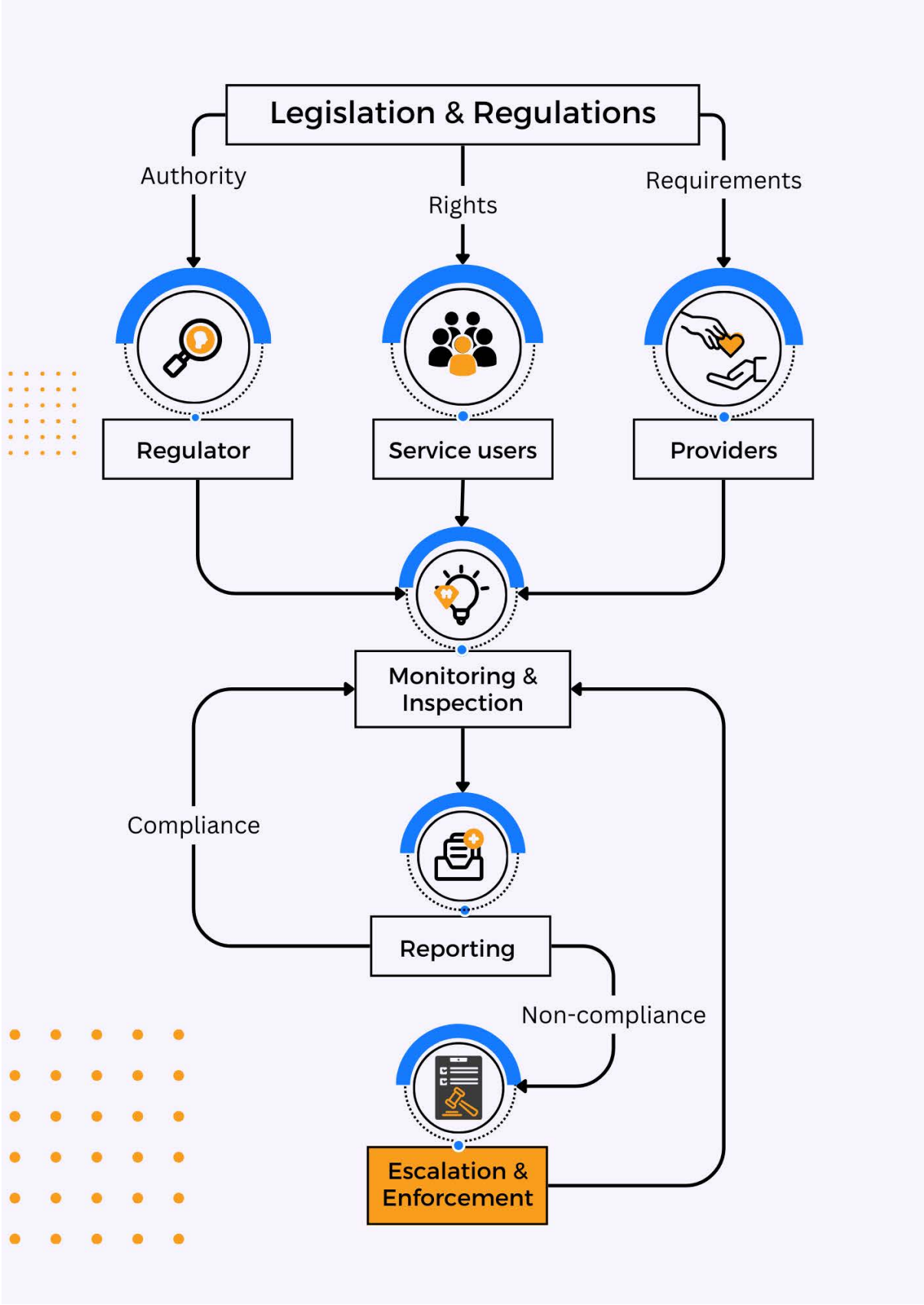
Our study focused on residential care for people with disability. Residents in such services are vulnerable because of communication problems, cognitive difficulties and physical restrictions. People with disabilities have been subject to abuse,[80] experienced poorer support for privacy and independent living[81], and high rates of restrictive practices[82] while living in residential care. The high stakes, and highly regulated nature of this context, makes it a rich source for insight into successful practices in achieving regulatory compliance.

The focus of this study — the intervention — is regulation (Figure 1). This differs from accreditation, another common form of external evaluation. There are several key differences. Accreditation can be voluntary or mandatory, depending on the country; regulation is always mandatory.[427] Accreditation assessments usually occur at a specified frequency (e.g. every three years) whereas regulatory inspections can occur at any time, be contingent on the perceived level of risk, and can occur

without prior warning.[428] Accreditation agencies do not usually possess legal powers of enforcement or sanction whereas regulators have both assessment/evaluation and enforcement powers.[149] These differences and the significance of the consequences associated with regulatory non-compliance mean that implementation strategies are likely to be different in regulated bodies compared with accredited bodies.

The study aim was to describe how residential disability service managers in Ireland engage with implementation of statutory regulations. We examine managers' perspectives on regulation, the strategies, structures, and processes they use to implement it, and key factors shaping these approaches, such as resource availability and attitudes toward the regulatory regime. Additionally, the study considers how managers perceive the impact of regulation on service quality.

Figure 1 – Description of regulation



7.3 Methods

We conducted semi-structured interviews with senior managers of residential care facilities for people with disabilities (RCF-D) in Ireland.

7.3.1 Setting

Approximately 95% of RCF-D in Ireland provide care for people with an intellectual/learning disability.[72] In August 2024, there were 88 providers of RCF-D in Ireland, operating 1,622 RCF-D centres; total beds nationally was 9,177.[71] Voluntary (not-for-profit) providers accounted for 1,150 (70.9%) of RCF-D. 301 (18.6%) were operated by private (for-profit) providers and 171 facilities (10.5%), were state-run.

Regulation for RCF-D in Ireland was introduced in 2013 providing residents of RCF-D with certain rights (e.g. individualised personal plan, respect for privacy and dignity). The regulator mandates at least two inspections of RCF-D in each three-year registration period. Data from 2023 showed 61% of inspections were unannounced while 30% were announced and 9% short-notice announced.[100]

Inspectors choose what regulations to assess based on an RCF-D's compliance history and profile. The inspector can choose to focus on regulations that were not in compliance previously, or those not recently assessed. A centre's profile (i.e. number of beds, type of care provided, premises age) may influence an inspector's choice of regulations. Inspectors judge each regulation as compliant, substantially compliant or not compliant.[70]

7.3.2 Participants and recruitment

Two categories of manager were sought: Persons in Charge (PICs) and Persons Participating in Management (PPIMs). PICs are responsible for day-to-day running of services. PPIMs are more senior than PICs and "is the person holding senior operational management decision-making responsibilities" for a service.[429] This study aimed to explore both organisation-level approaches to implementation, and views and experiences of individual managers. PICs were recruited to provide individual-level material and PPIMs to provide organisation-level insight.

Service providers (n=88) were contacted requesting permission to approach people for interview; 32 (36.4%) agreed to participate. PICs and PPIMs in participating

organisations (n=524) were emailed an information sheet and invited to interview. Respondents (n=40) were selected using a purposive maximum variation sampling approach[430] to produce diversity. Our primary characteristic for maximum variation was provider size: small/medium/large/statutory (statutory was included post-hoc because the single statutory provider was also large, which would result in their proportional over-representation). We sought to recruit two participants from each of the four groups to capture potentially divergent views i.e. eight PICs and eight PPIMs. Our secondary characteristic was participants that represented urban/rural centres and different provider compliance levels to ensure participants varied from each other as much as possible. This sampling approach was applied to PICs and PPIMs separately. Participants were invited until we had satisfied maximum variation as described above. All participants signed consent forms and reviewed transcripts for comment.

7.3.3 Public-Patient Involvement and Engagement (PPIE)

PPIE contributors were recruited through a national disability advocacy organisation and a local disability service provider. The contributors were two residents of a RCF-D and two relatives of people living in RCF-D. PD met the residents in person on two occasions during 2023. Telephone discussions were conducted with the relatives. PPIE contributions informed development of the interview topic guide.

7.3.4 Data collection

The topic guide (Appendix 8) was informed by Normalisation Process Theory (NPT).[84] We chose NPT over other frameworks because the implementation of regulations is a constant process that requires fundamental change to a wide range of practices. The fundamental requirement for implementation is therefore 'normalisation', which implies that everyday work practices become aligned with regulations. We considered using the Consolidated Framework for Implementation Research[90], but felt this framework was too broad for our study aims and would have diluted the focus on implementation practices.

All interviews were conducted by PD (see Appendix 9 for interviewer personal characteristics) using Microsoft Teams, transcripts and video were collected.[431] Automated transcripts produced by Microsoft Teams were edited and verified by PD. Two pilot interviews were conducted and minor changes were made to the prompts

before being finalised. The first phase of interviews covered PICs with PPIMS in the second phase. The topic guide for the second phase was amended by editing prompts for three questions.

7.3.5 Analysis

Eight PICs were required for phase one to align with the purposive maximum variation sampling approach; we ultimately recruited 11. We used a mixed deductive-inductive approach to analysis using NVivo software.[406] Deductive analysis started with an NPT coding manual[91] to explore the data and identify text relevant to implementation. Two researchers (PD and LK) reviewed three transcripts independently and coded data to the most appropriate NPT construct. PD and LK then met to review coding and resolve inconsistencies. PD coded the remaining data.

Inductive analysis used the deductive thematic structure as a starting point and was also informed by NPT.[432] Two researchers independently coded the data. PD and LK met to refine the coding framework. Codes were grouped into new higher-order sub-themes and parent themes. PD then coded remaining data independently. All three authors then discussed the codes, sub-themes and parent themes. This was an iterative process involving the clear delineation of themes, re-allocating certain codes to alternative sub-themes and agreement on theme names.

Once phase one interviews were completed, all authors were satisfied that the sample size was adequate and represented sufficient 'information power'.[433] The concept of information power is contingent on the unique characteristics of a study and entails a stepwise approach as opposed to determining a sample size from the outset.[433] The criteria used for determining information power are: study aim (narrow or broad); sample specificity (dense or sparse); use of established theory (yes or no); quality of dialogue (strong or weak); and analysis strategy (case or cross-case). For example, a study with a narrow aim using an established theory requires fewer participants to reach information power than the inverse. All authors were involved in the determination of information power and each had access to the interview transcripts to assess the quality of dialogue. On recruitment of eight PPIMs for phase two, we analysed the data as above. We again assessed these data and were satisfied that information power had been achieved.

Findings are reported in accordance with the Consolidated Criteria for Reporting Qualitative Research (COREQ) qualitative research reporting guidelines (Appendix 10).[434]

Results are reported under parent and sub-theme headings, with quotes used to support observations as well as a table containing strategies to improve regulatory compliance.

7.3.6 Ethical approval

This study received ethical approval from the Social Research Ethics Committee in University College Cork, Ireland (2023-228).

The PPIE component of this research received ethical approval from the Social Research Ethics Committee of University College Cork, Ireland (2023-011).

7.4 Results

Interviewee characteristics are available in Table 13. Interview length was 32 to 74 minutes, with a mean of 53 minutes. Findings are presented under five parent themes: managing organisational culture; putting the right structures and resources in place; putting the right processes in place; dealing with the outside world; and managing the relationship with the regulator (Table 12). The complete dataset for the thematic analysis is available in Appendix 11.

Table 12 – Themes identified from qualitative analysis, and related strategies for improving regulatory compliance

Parent theme	**Sub-theme**	**Strategies for improving regulatory compliance**	**Examples**
Managing organisational culture	Views about the regulatory process and regulator	Emphasise that the organisation and regulator have a shared goal of ensuring high quality care to foster a positive culture towards regulation	"I think a lot of services now have risen to the standard that's been created [by regulation]…and it just becomes a normal part of practice".
	Overall strategic approach adopted by regulatee	Embed regulatory compliance in the organisation's overall ethos and strategy	"nobody's house, I know my house certainly isn't in pristine, 100% condition all the time, you know? You'll say 'we need to do this', but there's a period of time and it's acceptable to wait that period of time".
Putting the right structures and resources in place	Implementing governance structures	Institute formal internal oversight structures to monitor implementation of regulations	"we now have a rights commission, restrictive practice team with two independents on it. I drove that for the

			last year or so and it's working really well".
	Managing human resources	Hire competent staff and train them to provide person-centred care in line with regulatory requirements	"Their [quality and compliance managers] role is more, they have an in-depth knowledge of the regulations and HIQA and the inspectors, etc…they have an in-depth knowledge of the process".
	Resourcing services to enable compliance	Secure adequate financial resources to provide the required level of service and ensure that funders are aware of any shortcomings	"[the nature of the non-compliant findings] was speech and language, it was psychology and so on… we might have to find money in the interim and just go ahead and get something so that we're compliant".
Putting the right processes in place	Clear assignment of responsibility for making compliance happen	Establish clear lines of accountability for implementing regulatory requirements and involve staff in tasks to deliver and maintain compliance	"you're trying to reach compliance across so many different regulations…It's a huge amount for one person…we all work together, but it's a huge amount to be responsible for it as a PIC".

	Communication processes that support compliance	Disseminate learning from previous local inspection reports, and reports from other facilities, throughout your organisation	"you're trying to learn from colleague's inspections and…raise the standard before you get inspected".
	Monitoring processes that support compliance	Continuously monitor and record implementation practices that are supported by internal auditing and self-assessment	"[inspectors] have to be able to make a judgment on how the service is within probably 6 or 7 hours…the better the files are…the more relaxed they are about how things are running here".
Dealing with the outside world	Accessing external resources	Ensure that external services are available to support service user needs and build relationships with the providers of such services	"sometimes the barrier to my centre being compliant is actually an external problem: how do you get MDT input if it's not being provided by the [national health service]?".
	Structural or environmental factors that influence the implementation process	Identify and adequately prepare for any relevant changes to policy or legislation that may impact on your organisation's capacity for compliance	"We have significant level of resources going in and responding to need. But it is becoming somewhat untenable. And the ADMA [Assisted Decision-Making (Capacity) Act] piece is adding to that.

			And the new safeguarding policy is going to add to it as well".
Managing the relationship with the regulator	Effectively responding to findings of non-compliance	Devise responses to non-compliance that are prompt, effective and centred on improving the lives of service users	"I often have my own ideas around how something should be implemented. And I've no problem, respectfully, with an inspector going back and forth".
	Relationship between service management and inspector/regulator	Build and maintain positive relationships with inspectors — and with the regulator generally — that is underpinned by openness and transparency	"[the inspector] spoke about how HIQA are…looking to be allies in the process of improving health outcomes for people's lives rather than be something that's feared".

7.4.1 Managing organisational culture

Interviewees influenced, and were influenced by, the prevailing culture within their organisation regarding regulation. Managers often had to interpret or challenge the fit of regulations within their organisational culture, echoing the NPT sub-construct of differentiation, as they assessed whether regulatory changes aligned with existing practices. The sub-construct of internalisation also had relevance for this theme as managers identified the positive contribution regulation had made to services. Efforts by managers to foster a positive attitude towards regulation among staff is consistent with the NPT sub-construct, enrolment.

7.4.1.1 Views about the regulatory process and the regulator

Interviewees expressed positive and negative opinions on regulation. These opinions had evolved as engagement with regulation increased over time. Many interviewees spoke about regulation in positive terms, arguing that it established a baseline that became normalised.

Most interviewees acknowledged other benefits like increased staffing, improved physical premises and support for a person-centred ethos. Management positivity towards regulation meant they were well disposed to embedding regulatory requirements throughout their services. This might indicate positive interactions with the regulator, impressions of benefits for residents, or it may reflect that regulation is mandatory and positive engagement makes sense.

Some interviewees had negative views about regulation, specifically the burdens of implementation, the apparent incongruence of some requirements and increased costs. Interviewees sometimes struggled to make sense of the regulations in the early years of regulation. Moreover, the 'human' character of RCF-D led some to question whether application of specific prescriptions was appropriate. Notwithstanding, there was an acknowledgment that regulations had to have a certain rigidity:

> "the unique needs of each individual doesn't always fit into the boxes I suppose…how do you create regulation without it being black and white?".

This negativity meant implementation was sometimes de-prioritised due to perceived negative effects. Ultimately, these perspectives (both positive and negative) had a bearing on managers' strategic approach to implementation.

7.4.1.2 Overall strategic approach adopted by regulatee

The organisational culture regarding regulation informed the strategic approach to implementation. Some interviewees felt their organisation's culture aligned with regulatory requirements and implementation of regulations did not require significant changes to common work practices.

However, some interviewees felt regulations were sometimes unnecessary or conflicted with the interests of residents. For these regulations, managers tolerated low-level non-compliance, in the expectation that it would not trigger sanctions. This suggests managers had developed a sense of where the boundaries lay, and tailored implementation to ensure they did not venture into serious non-compliance.

There were multiple instances where managers surmised that full implementation of regulations was neither achievable nor in service's best interests. This was due to a perverse incentive where findings of non-compliance acted as leverage for resources. In this scenario, managers felt they were not empowered or resourced to facilitate full implementation, and wished for inspectors to know this:

> "I'd always be delighted to get that in a HIQA report because I know that that would be what I needed if I couldn't get anything else done in that regard".

This indicates managers acted as advocates for their services, regularly requesting additional resources. Requests were strengthened when supported by inspection findings, thus incentivising managers to game the system by pursuing non-compliances.

7.4.2 Putting the right structures and resources in place

This theme reflects the work managers did to plan and operationalize regulatory requirements. In line with the coherence construct in NPT, this involved activities that helped staff understand and enact the intervention.

7.4.2.1 Implementing governance structures

Governance structures in organisations evolved to take account of regulatory requirements. These structures provided a means for managers to work together to understand what regulations required of them. Once established, the structures provided a means to monitor implementation and oversee audits that had a bearing

on compliance. So, while a positive culture towards regulation was important, there remained a requirement to formulate governance structures to ensure compliance.

7.4.2.2 Managing human resources

The recruitment of staff was not merely an exercise in increasing resident:staff ratios or diversifying the skill mix; interviewees also spoke about how their organisations hired managers with experience of regulated environments.

Some interviewees voiced frustration with recruitment and retention of staff challenges, impacting on implementation capacity. Some felt staff did not act with management to implement regulations. This created a culture where managers felt they were solely accountable for implementation. However, managers were clear that participation by all staff in implementation was necessary and if they were left isolated, the service would struggle to be compliant.

7.4.2.3 Resourcing services to enable compliance

The implementation effort was contingent on securing adequate resources (e.g. premises maintenance access to healthcare) to achieve compliance. This was a consideration for those managing ongoing compliance and those addressing non-compliance. While there was evidence of efforts to provide adequate resources within organisations, this was typically in response to specific findings of non-compliance.

For managers that regularly advocated for additional resources, inspectors were often seen as allies, lending weight to their case. This suggests the regulator's power made them active participants in the implementation process. Furthermore, it indicates some managers saw the regulator as an advocate for increased resources, and not merely a detached evaluator of quality.

7.4.3 Putting the right processes in place

Regulatory prescriptions become embedded and normalised through processes founded on the structures described above. These processes facilitate the implementation effort through unambiguous understanding of responsibilities, effective communication, training and continuous monitoring. The sub-themes outlined below map onto the NPT constructs of coherence and collective action where managers have understood what is required and worked to devise processes to support implementation.

7.4.3.1 Clear assignment of responsibility for compliance

Managers played a central role in implementation. They delegated tasks to support compliance and escalated matters where appropriate. They also keenly felt the responsibility for achieving compliance despite the collaborative effort.

Interviewees also described strategies used to ensure staff were aware of their responsibilities for compliance. Sometimes, this meant requiring something was done because the regulator required it, rather than for the benefit of residents. This suggests some managers thought that regulation was something foisted on them. Equally, it demonstrates the regulator had a sufficient level of authority to command the buy-in of all in support of the implementation process.

7.4.3.2 Communication processes that support compliance

Internal communication processes were important, such as focusing on the requirements of a specific regulation at staff meetings. Managers viewed such processes as important for ensuring staff had a consistent conception of what successful implementation looked like. Published inspection reports were useful for managers that wanted to learn how other RCF-D operated, and this learning was shared across organisations.

There were regular communications (e.g. information sessions and webinars) from the regulator to aid implementation. Guidance documents were a key resource for understanding what was required for compliance. This indicates the regulator felt a sense of duty to educate regulatees and be transparent about what successful implementation looked like. This is evidence of a cooperative relationship, geared towards supporting implementation. Regulatory guidance was not always viewed positively as some noted the large volume of documentation required an excessive amount of time to consume.

7.4.3.3 Monitoring processes that support compliance

Monitoring processes were required to measure and evidence compliance. Audits were a feature of monitoring processes, where managers assessed aspects of services to identify potential non-compliances. Actions arising from audits required tracking to ensure they were addressed. Implementation of regulations, therefore, required constant vigilance and attention. Successful embedding of regulatory requirements

could not be taken for granted; it was a burdensome and resource intensive undertaking requiring a sustained effort.

Continuously monitoring documentation quality was also important for implementation. Interviewees recognised inspectors were on-site for a short period of time and documentation was a key source of evidence. Thus, it was not enough that tasks were done, they needed to be documented.

Thus, good quality documentation made assessing compliance easier for inspectors and served to build cooperative and trusting relationships with them. Nevertheless, some felt regulation required an excessive focus on documentation, detracting from care opportunities and reducing appetite for implementation.

Some interviewees felt the competencies of frontline staff required continuous monitoring to ensure they understood and supported the regulations. Encouraging a collective effort and fostering legitimacy for the regulations was seen as a key driver of successful implementation. Managers were often champions for regulations, convincing staff of the positive aspects of compliance and securing ongoing support for implementation.

7.4.4 Dealing with the outside world

The successful implementation of regulations was not simply a matter of monitoring a service's processes and practices. It also meant building networks and relationships that supported implementation or aided in navigating a complex milieu of overlapping legislation, policy and guidelines. This theme is relevant for NPT's collective action construct where people work together to enact interventions and the degree to which they are supported by their organisations to do so.

7.4.4.1 Accessing external resources

There were regulatory requirements that some argued were entirely outside their organisation's sphere of influence. A recurring theme was the difficulty with access to community-based healthcare services. Long waiting lists meant that many were non-compliant with the 'healthcare' regulation.

Some managers felt unsupported by other state agencies in the implementation effort. Some pooled resources to collectively source services. This demonstrates

managers' willingness to establish networks outside their own organisations to support implementation.

7.4.4.2 Structural or environmental factors that influence the implementation process

Managers in large organisations that engaged with multiple regulators felt this was an advantage. It was reasoned that the requirements in a wide range of regulations served to raise standards throughout the organisation. New policy and legislative developments also changed the context within which services operated. These required time and effort to understand and complicated the implementation environment for managers.

7.4.5 Managing the relationship with the regulator

Interviewees spoke about the importance of good relationships with inspectors and the regulator. Some found it beneficial to work collaboratively with inspectors, mapping to NPT's collective action construct. Others challenged findings of non-compliance — echoing the NPT sub-construct of legitimacy — but not always in an adversarial manner.

7.4.5.1 Relationship between service management and inspector/regulator

Many interviewees spoke about how the nature of the relationship with the inspector affected their ability to implement regulations. Most inspectors were said to have a collaborative approach and were willing to work alongside services to deliver benefits for residents. In contrast, some interviewees spoke about less supportive relationships with inspectors.

Having knowledge of an inspector's professional background enabled some to target improvements to impress the inspector. Therefore, compliance was sometimes 'gamed' by over-compensating in an inspector's area of interest. This suggests that, for some managers, demonstrating a high level of competence in key areas was more important than full implementation as it improved their standing with inspectors. It also demonstrates the importance of experience and having well-developed relationships so the manager can anticipate the preferences of inspectors.

7.4.5.2 Effectively responding to findings of non-compliance

There were different approaches for addressing findings of non-compliance. For some, they unquestioningly accepted inspection findings. For others, their

relationship with the inspector allowed space for issues to be discussed and negotiated.

Compliance could be contested, particularly where there was a good inspector-manager relationship. Some interviewees said their organisations were fully supportive of them challenging inspectors' findings, particularly where it benefit residents.

The relationship with the inspector was also strengthened if managers could devise a clear plan to address identified issues. Some interviewees felt this disposition demonstrated their commitment to implementation and respect for the inspector's professionalism.

7.4.6 Differences in individual and organisational-level responses

We observed some differences with respect to interviewees' individual views and views that reflect their organisation's perspective. This was evident when comparing responses of PICs and PPIMs. PICs focused mostly on their individual perspective, explaining how they approached implementation as managers, their strategies and their challenges. Some PICs felt caught in the middle: required by the inspector to take action but sometimes not empowered by their organisation to do so:

> "the PICs are the ones rolled out for the inspection and we are responsible for so much".

PPIMs tended to speak more from an organisational perspective. This is understandable due to their position i.e. overseeing quality in multiple RCF-D. This often meant their engagement with implementation was only required when non-compliance arose. Equally, their engagement was often not with individual inspectors but with more senior managers in the regulator. As such, their role was to represent (and defend) their organisation.

7.5 Discussion

Managers of RCF-D implement care regulations by establishing a range of structures and processes informed by overall organisational culture. Their implementation effort is also influenced by how they deal with the world outside their organisations and how they manage the relationship with the regulator.

While there are a small number of studies in other sectors, most of these do not focus specifically on the implementation of regulations, which is a critical aspect of improving regulatory compliance and service delivery. Our findings contribute new insights into how managers navigate regulatory requirements in this context and offer alignment with constructs in NPT, thereby advancing both theoretical and practical understanding in a previously underexplored area.

Our findings can be situated within a broader literature concerned with implementation processes for interventions closely related to regulation, such as accreditation. A large narrative review of healthcare accreditation literature in 2012 presented results that concur to some extent with our findings.[435] For example, financial support and macro-economic factors were seen as key system-level levers, akin to our finding with respect to resourcing.[436, 437] Similarly, good quality documentation was an important enabler for implementation of accreditation, a finding reflected in our study. In contrast to our findings, while the authors identified organisational change mechanisms arising out of the accreditation process, these mechanisms did not include a legal imperative for change in the same manner as regulation.

Overall, interviewees welcomed regulation. While many acknowledged troublesome aspects — burdensome record-keeping, increased costs — most saw it as a net benefit. Interviewees saw alignment between regulations and their commitment to providing good quality care. Interviewees often regarded inspectors as allies rather than adversaries. Inspection findings were used by PICs to make the case to their organisations for additional resources. The generally positive disposition of interviewees toward regulation may also be attributable to the approach of inspectors, often characterised in terms such as helpful, educational and collaborative. While positive working relationships may be beneficial for both parties, this could heighten the risk of regulatory capture where the regulator begins to act in the interests of the regulatee rather than the service user.[438]

The interviewees in our study provided some critiques of regulation. For example, inspectors were seen as often differing in their interpretation of what represented compliance. There is an inherent difficulty in asking inspectors — who have different professional backgrounds and biases — to consistently judge compliance

across a wide range of care practices. Such inconsistency has been reported in other settings.[42, 439]

Interviewees were critical of regulation, for example arguing some regulations were an administrative burden and did not link to a resident's wellbeing Some interviewees felt inspectors resorted to identifying non-compliances with menial regulations when they found no faults elsewhere, leading to resentment.

Our findings are situated in the wider context of societies that demand higher quality health and social care services and the full realisation of human rights for people with disabilities.[440] This is a substantial challenge to service providers operating with constrained funding and competing for staff in labour markets. Consequently, regulators walk a tightrope: overly-punitive regulation could reduce capacity in services, whilst a laissez-faire approach might mean poorer quality; both outcomes are sub-optimal for people with disabilities. The collaborative approach identified in our findings may be a fruitful means by which to improve quality.

The lack of previous literature on implementation of regulations in health and social care services is surprising. There is no shortage of literature on the implementation of other interventions such as clinical practice guidelines[441-443] or evidence-based practice.[444-446] We argue that regulatory requirements should receive as much attention as other interventions given their potential to leverage improvements in quality and safety. The sparse literature may be a consequence of not considering regulation to be an 'intervention' in the traditional sense. This appears to be a missed opportunity as regulation bears many of the hallmarks of an intervention in the implementation science understanding: a quality improvement initiative; a set of prescriptions for how things should be done (regulations); and an evaluation of the success of the implementation (inspections).

7.5.1 Limitations

One limitation of our study is it is based only on interviews. Nevertheless, interviews facilitated deep exploration of the subject matter. A second limitation is we only gathered views of managers of RCF-D. While our population is appropriate for our main phenomena of interest this meant we could not explore related phenomena such as the impact of implementation strategies on non-management staff and residents/carers. Another limitation is our partial insight into organisation-level

approaches to implementation; this would require further research to address. Another potential limitation is that the interviewer's role as a current employee of the regulator may have influenced interviewee's responses. To guard against this the interviewer was fully transparent about this with interviewees.

7.6 Conclusion

Our work draws attention to an often-overlooked aspect of health and social care management: compliance with regulatory requirements. Managers offered useful insights on how they interpret and understand regulations, how they structure and resource services to achieve compliance, and how they manage relationships with funders and inspectors. Framing regulation as an intervention provides a useful means by which to better understand how organisations succeed (and fail) in implementing regulatory prescriptions. Our findings may be of benefit to organisations that struggle to achieve compliance and for regulators that wish to better understand the various tactics and approaches adopted by regulatees.

Table 13 – Characteristics of interviewees

Participant ID	Job title	No of centres managed (max occupancy) *	Service-user population**	Geographic location of centre***	Provider organisation classification****	Provider organisation compliance measure*****
PIC1	Person in Charge	2 (5-9)	(1) Adults (male and female) with mild, moderate, severe or profound learning disability	Independent urban town	Medium-Voluntary	75.8
			(2) Adults (male and female) with mild, moderate, severe or profound learning disability	Independent urban town		
PIC2	Person in Charge	1 (10-20)	Short-term respite for people with a neurological condition	City	Small-Voluntary	100
PIC3	Person in Charge	1 (5-9)	Respite service for children aged 4 to 18 with significant physical disability, associated complex medical needs and those with life-limiting conditions	Rural area with high urban influence	Small-Voluntary	90
PIC4	Person in Charge	1 (5-9)	Adults (male and female) with acquired brain injury	City	Large-Voluntary	94.8
PIC5	Person in Charge	2 (10-20)	(1) Adults (male and female) with intellectual disability, autism spectrum disorder or acquired brain injury	Rural area with high urban influence	Medium-For profit	97.9

			(2) Adults (male and female) with intellectual disability, physical disability, autism spectrum disorder or acquired brain injury	Satellite urban town		
PIC6	Person in Charge	1 (5-9)	Adults (male and female) with mild or moderate intellectual disability	City	Medium-Voluntary	92.6
PIC7	Person in Charge	1 (10-20)	Adults (male and female) with intellectual disability	Satellite urban town	Small-Voluntary	83.3
PIC8	Person in Charge	1 (21-50)	Adults (male and female) with physical disability or neurological condition, in addition to secondary disabilities such as learning disability, mental health difficulties or medical complications like diabetes	Rural area with moderate urban influence	Large-Voluntary	92.2
PIC9	Person in Charge	1 (1-4)	Adults (male and female) with intellectual disability	City	Large-Voluntary	89.9
PIC10	Person in Charge	1 (5-10)	Adults (male and female) with intellectual disability or autism spectrum disorder	Highly rural/remote areas	Large-Public	91.7
PIC11	Person in Charge	2 (10-20)	(1) Adults (male and female) with intellectual disability	Satellite urban town	Large-Public	91.7
			(2) Adults (male and female) with intellectual disability	Satellite urban town		
PPIM1	Area Director	n/a	Provides services to people with intellectual disability and/or autism spectrum disorder	n/a	Large-Voluntary	94.6

PPIM2	Service Manager	n/a	Provides services to young people with a visual impairment who may also have an additional disability e.g. learning, hearing or physical and have complex needs as a result of social, cultural, economic or emotional factors.	n/a	Small-Voluntary	64.9
PPIM3	Regional Manager	n/a	Provides services to people who need support across the areas of mental health, disability, aftercare, elderly, transitional and mainstream social care.	n/a	Medium-For profit	87.8
PPIM4	Service Manager	n/a	Provides services to people with intellectual disabilities	n/a	Large-Voluntary	88.9
PPIM5	Social Care Manager	n/a	Provides care to people with a wide range of disabilities	n/a	Large-Public	91.7
PPIM6	Director of Nursing	n/a	Provides care to people with a wide range of disabilities	n/a	Large-Public	91.7
PPIM7	Service Manager	n/a	Provides services to adults with intellectual disability	n/a	Medium-Voluntary	87.0
PPIM8	Service Manager	n/a	Provides services to adults and children with intellectual disability and other disabilities	n/a	Medium-For profit	89.2

* Bed numbers are placed in a range to ensure the anonymity of the centre and service provider.

** Describes the characteristics of individual centres in the case of persons in charge; and characteristics of the service provider organisation in the case of persons participating in management.

*** Urban/rural designation obtained through search of Central Statistics Office interactive map of Urban and Rural Life in Ireland 2019.[447]

**** The provider organisation classification variable is comprised of the size of the provider organisation and its designation as voluntary, for-profit or public. Provider size categories are as follows: small (1 service); medium (2-10 services); large (>10 services). There is only one public provider and it is classified as large.

***** The mean level of compliance for each provider was calculated as follows: a compliance score for each inspection from 1/1/2018 to 29/2/2024 was calculated by dividing the number of regulations found compliant by the total number of regulations assessed. The results were grouped by provider and the mean was calculated, thereby giving the mean level of compliance. National provider mean compliance from 1/1/18-29/2/24 was 87.3%.

CHAPTER 8: Improving the quality of residential care for people with disabilities — what is the experience of inspectors when implementing care quality regulations in Ireland?

This chapter has been submitted to the Journal of Health Services Research and Policy and is currently under review.

Authors

Paul Dunbar[1], Dr Laura M Keyes[2], Prof John P Browne[3]

Author details

[1] Health Information and Quality Authority, Unit 1301, City Gate, Mahon, Cork, Ireland T12 Y2XT. pdunbar@hiqa.ie (corresponding author)

[2] Centre for Implementation Research, University of Limerick, Ireland laura.keyes@ul.ie

[3] School of Public Health, University College Cork, Ireland j.browne@ucc.ie

8.1 Abstract

Background

Regulation by an independent state authority is a common means by which governments seek to safeguard service users and ensure good quality health and social care services. Inspectors play a key role in this process as they work at the interface between regulator and regulate. Our aim was to investigate the role played by inspectors in the implementation of care regulations in residential disability services in Ireland.

Methods

We conducted focus groups with inspection staff working for the regulator social care in Ireland. Participant recruitment was facilitated with the permission of the

regulator. Nineteen people participated over five focus group sessions that took place online. Thematic analysis was carried out on the interview data.

Results

Four parent themes were identified: overall views on the regulatory system; the important of skill and strategy for the role of inspector; impediments to effective regulation and inspection; and, positive effects of regulation. While not directly responsible for implementing regulations in services, inspectors played a role by calling attention to poor practices, apportioning accountability at the appropriate level in regulated organisations, and behaving in a consultant-like fashion in support of managers. There were barriers that complicated and inhibited their work such as resource constraints and bureaucracy. Their observation of improvements in service quality led them to conclude that regulation was an effective intervention, despite some flaws.

Conclusion

Inspectors had a clear sense of the part they play in terms of aiding the implementation effort in services. They shared the goals of managers: trying to improve the quality of services and the lives of those that use services. While there were barriers that impacted on the effectiveness of their work, most inspectors regarded regulation as a positive intervention and had first-hand experience of its impact.

8.2 Background

Governments often establish regulatory frameworks to protect a public good. Regulation can have many targets such as domestic energy pricing,[448] urban air emissions,[449] banking and financial services,[450] and the quality and safety of hospitals.[451] In each of these cases, the principal goal is to oversee the activities of industries that could potentially harm individuals, groups or the environment if left unregulated.

Regulators can approach their role in different ways. The deterrence or command and control model regards regulators as akin to police forces, preventing prohibited behaviour and meting out punishments in the form of public admonishments, fines or facility closures.[452] Alternatively, regulators can adopt a co-operative model where they work alongside regulatees to help them meet regulatory standards.[453] Responsive regulation represents a third form where regulators tailor their approach towards policing or co-operation depending on the capacity, track-record and perceived motivations of regulated organisations.[454]

Much regulatory activity is conducted by individual inspectors who visit sites, gather information, assess compliance levels and draft inspection reports.[455] Inspector roles are usually filled by people who have qualifications and experience relevant to the industry they are regulating. For example, workplace safety inspectors tend to have qualifications and experience in occupational health or health and safety,[456] and school inspectors tend to be current or former school principals or senior teachers.[457]

Inspectors play a key role in the regulatory framework. They are often the most common point of contact for regulated organisations, which has led to their characterisation as ‘street-level bureaucrats’.[455] Street-level bureaucrats are defined as “public service workers who interact directly with citizens in the course of their job, and who have substantial discretion in the execution of their work”.[458] In essence, they are front-line workers that represent the state and are tasked with implementing the policy and laws of the state.[459] There is a significant body of research on the role of inspectors, covering such aspects as leniency among school inspectors,[439] informal socialisation (day-to-day contact with colleagues or clients)

of veterinary inspectors,[460] training of environmental health inspectors,[461] and discretion among labour inspectors.[462] However, almost none of this research has been carried out in health and social care regulation. Only two studies have been conducted to date, both in Norway. The first found that inspectors customised their practice and strategies to promote improvement in services. For example, this could mean communicating by a different method or adjusting the amount of time made available to a service to remedy an issue.[463] The second found that inspection teams had different expectations around how healthcare providers should prepare for announced inspections.[464]

This very limited evidence base means we have almost no insight on how health and social care inspectors go about their work, what they think of regulation, the strategies they use to improve compliance and deal with poor performance, and the challenges they face in implementing these strategies. An improved understanding of these phenomena would be useful to the regulatory community, to service providers and could ultimately benefit service users if good practice can be identified and disseminated.

We chose residential disability services in Ireland as the setting for this study. We made this decision for a number of reasons. Firstly, regulation of residential disability services in Ireland was introduced in 2013 amid long-standing concerns about quality and safety.[52] As such, given the relatively-recent introduction of regulation to this setting, prospective participants will have witnessed the impact of regulation as well as issues that arose in the early stages of implementation. Secondly, residential care tends to be subject to wide-ranging regulatory requirements due to the nature of the services i.e. they are, in effect, a person's home as opposed to a facility where people are treated for an illness on a short-term basis. Therefore, regulations governing residential care are diverse and comprehensive. For example, long-term care homes in Ontario must comply with as many as 400 rules describing the management of everything from elevators, lighting, care plans, social activities and volunteers.[465, 466] A third reason for our choice of study setting is the vulnerability of services users in residential disability services compared with other health and social care services. The prevalence of abuse is high in comparison to the general population, albeit that it

is difficult to determine precise rates due to differences across countries with respect to definitions and measurement techniques.[80] Communication difficulties compound this vulnerability, meaning that people with disabilities living in residential care are often reliant on others to advocate on their behalf.[467] It is also frequently the case that regulation is introduced (or reformed) as a result of public scandals concerning quality of care in these settings.[468]

This study uses qualitative methods to examine how health and social care inspectors in Ireland implement the regulation of residential care for people with disability, with a particular focus on their views about the regulatory system, the strategies they use to improve compliance and deal with poor performance, and the challenges they face in implementing these strategies.

8.3 Methods

8.3.1 Setting and participants

Regulation of residential disability services in Ireland commenced in late 2013. There are 32 regulations (each with varying numbers of sub-regulations) that prescribe how residential disability services should be operated (Appendix 1). Inspectors have the right to access centres, review documentation, access computer systems and interview residents, staff and management.[66]

At the time of commencing the study there were 38 inspectors and seven regional managers engaged in the inspection and regulation of 1640 RCF-D in Ireland. Inspectors of RCF-D in HIQA were organised into seven teams that operated within a given geographical area. As of November 2024, each team had either five or six inspectors and was led by a regional manager.

The regulator for health and social care in Ireland has adopted a risk-based approach to regulation. This means that the scheduling of inspections is dependent on the level of risk ascribed to centres: lower risk centres are subject to less frequent inspections and *vice versa*. The level of risk is determined by a range of factors such as a centre's compliance history and the receipt of solicited or unsolicited information.[70]

Inspections typically take place over one day and are conducted by a single inspector. There are three types of inspections: monitoring (routine) inspections; targeted (risk)

inspections; and thematic (focused on a particular aspect of care) inspections.[70] Inspections can be either announced, unannounced or short-term announced (48 hours notice). Data for 2024 shows that almost two-thirds of inspections were unannounced.[73]

An inspector prepares for an inspection by reviewing previous reports and assessing solicited and unsolicited information. This determines how many, and which, of the 32 regulations are to be assessed in an inspection. Evidence is gathered during inspection by speaking with residents, staff and management; observing care; reviewing documentation and evaluating the physical premises. The gathered evidence is then used to judge the level of compliance which can be: compliant; substantially compliant or not compliant. These judgments, along with the evidence to support them, is contained in a report that is made publicly available.[70]

We sought inspectors and regional managers as participants for this study in the form of focus groups. We felt focus groups offered the best mode of data collection as all participants were familiar with each other as colleagues and, in sharing their experiences, would have contributed to a rich discussion to address the research question.

Engagement with participants via focus groups was approved in advance by the regulator. Each inspector and regional manager was sent an information sheet and consent form by email. Participation was voluntary and prospective participants were assured of anonymity and confidentiality. While PD was an employee of the regulator at the time of the focus groups, it was made clear to participants that the research was being conducted as part of a PhD programme with a university in Ireland.

8.3.2 Consent

All who agreed to participate in the focus groups were asked to complete a consent form.

8.3.3 Scheduling, data collection and data management

We decided to keep regional managers and inspectors separate in focus group sessions. This was to ensure that both groups could speak freely about their

experiences or operational matters. Therefore, one date was scheduled for the regional manager focus group. Focus groups were conducted online using Microsoft Teams[431] and were facilitated by PD. There was no requirement for a note-taker or second facilitator because we utilised the automatic transcription feature in Microsoft Teams.[431] Data collection was guided by a focus group topic guide (Appendix 12). The topic guide was informed by a study we conducted previously with managers of residential disability services.[469] Questions in the topic guide were also devised as part of the Public-Patient Involvement and Engagement with current service users of residential disability services in Ireland, and carers for current service users. The topic guide included general, over-arching questions (e.g. what are your overall thoughts on the current system of regulation and inspection that is in place for residential disability services in Ireland?) and more specific ones (e.g. do you feel you have access to enough information to allow you to effectively assess the quality of a service?) which were targeted at addressing the research aim.

The automatically produced transcripts were reviewed and edited by PD for accuracy, with reference to the video recording to correct any errors. Participants were provided with a transcript of their session and given an opportunity to correct any inaccuracies. Once digitised, any hard-copy data (i.e. consent forms, focus group notes) were destroyed. Microsoft Teams videos were deleted once the transcripts were agreed.

Participant data was pseudonymised by assigning a code as a participant ID (e.g. Insp1, Insp2 etc.). All subsequent references to a person's contributions used the participant ID. All personally identifiable information (PII) used for the purposes of communicating with participants was retained on a spreadsheet on a secure online platform.

In accordance with the consent sheet, participants had a right to request their data be removed from the study if they so wished. This was accommodated up to four weeks after the participant's involvement, upon which data linkages were broken. Upon removal of consent, a participant's data was destroyed by the author. Where such a request was received, the person's contributions were removed from the transcript by replacing any relevant text with [Withdrew consent to participate] beside their participant ID. No participant made a request to withdraw.

All digitised data was uploaded to a secure online platform. Data will be retained for 10 years as per university requirements and then destroyed by the author. Access for others on the research team was facilitated by the author through the sharing facility on the secure online platform. Other individuals on the team retained the shared data securely on their secure online platform account and destroyed it once the study was published. Findings are reported in accordance with the Standards for Reporting Qualitative Research (Appendix 13).[470]

8.3.4 Analysis

All transcripts were imported into NVivo.[406] Transcripts were analysed using thematic analysis in a stepwise manner as described by Braun and Clarke.[432] In the first stage, PD read through all transcript data for familiarisation. Secondly, PD assigned codes to sections of text that were concerned with material relevant to the research questions. This meant identifying places in the focus group where participants spoke about their general views of the regulatory system, strategies used to address non-compliance, and challenges experienced when implementing those strategies. The third phase entailed identifying themes in the data where codes were grouped together into sub-themes, and the sub-themes then grouped into parent themes. This was then followed by the review process where PD, JB and LK jointly evaluated the data in each theme and agreed on the final list of parent themes and sub-themes.

8.3.5 Public-Patient Involvement and Engagement (PPIE)

The development of this study was informed by input from people currently living in residential disability services and families or carers of people living in services. The author met in-person with current residents of on two occasions throughout the course of 2023. Telephone discussions were also conducted with families/carers of people living in services. The contributions of these people were used to inform the development of the focus group topic guides. The PPIE component of this research received ethical approval from the Social Research Ethics Committee of University College Cork (2023-011).

8.3.6 Ethical approval

The author obtained ethical approval for this study from the University College Cork Social Research Ethics Committee (2024-075).

8.4 Results

Twenty-two participants attended the focus groups over five sessions. There were four participants in the focus group for regional managers, representing 57% of all regional managers. There were 18 inspectors in the remaining four focus groups, a participation rate of 47%. Inspector focus groups had either four or five participants (Table 14). The focus groups took between 57 and 75 minutes to complete.

Table 14 – Characteristics of focus group participants

Session	Role	Sex	Background	No. of years experience as an inspector
1	Inspector	F	Social care	5
1	Inspector	M	Social care	9
1	Inspector	F	Speech and Language Therapy	5
1	Inspector	F	Psychology	7
2	Inspector	F	Nursing (ID); Nursing (General)	6
2	Inspector	F	Nursing (ID)	1
2	Inspector	F	Nursing (ID)	8
2	Inspector	F	Nursing (ID)	8
3	Inspector	F	Social care	5
3	Inspector	M	Social care	5
3	Inspector	F	Social worker	6
3	Inspector	F	Nursing (ID); Legal	15
3	Inspector	F	Psychology	5
4	Regional Manager	F	Social care; Psychology	11
4	Regional Manager	M	Social care; Social worker	11
4	Regional Manager	F	Social care; Nursing (Paediatric)	15
4	Regional Manager	M	Social care	11
5	Inspector	F	Nursing (ID)	9
5	Inspector	F	Nursing (ID); Nursing (General)	9
5	Inspector	M	Social care; Quality and Safety	3
5	Inspector	F	Nursing (ID)	2
5	Inspector	F	Speech and Language Therapy	3

Four themes were identified in the thematic analysis: overall views on the regulatory system; the importance of skill and strategy for the role of inspector; impediments to effective inspection and regulation; and positive effect of regulation. Our findings are presented under theme and sub-theme headings. A summary and overview of the findings with specific reference to the research questions (Table 15) is presented after the themes are described. The complete dataset for the thematic analysis is available in Appendix 14.

8.4.1 Overall views on the regulatory system

Participants expressed a wide range of general views on the system of regulation and the challenges faced by service providers in complying with regulations. This theme has two sub-themes: general views about service providers and general views about regulation.

8.4.1.1 General views about service providers

Discussions during focus groups often touched on the role of service providers, the characteristics of good (and poor) providers, and the challenges they faced. A recurring theme in all focus groups was the critical importance of strong and effective governance arrangements in service provider organisations. Participants observed that service providers with strong leaders, clear lines of accountability, and a consistent management presence in RCF-D tended to have higher levels of compliance. The role of Person in Charge (PIC) — person designated as the manager of the RCF-D — was seen as critical, because their influence was key to setting standards and influencing culture.

In general, there was a certain amount of empathy for the challenges faced by service providers. In part, this was due to inspectors identifying with the struggles of management and staff because they themselves were in those roles previously. The challenges were sometimes issues that were beyond the effective control of RCF-D, such as labour shortages or insufficient state funding. In such circumstances, inspectors were sometimes conflicted: their role required them to objectively assess compliance but they could not always adequately apportion accountability for the root causes of non-compliance.

8.4.1.2 General views about regulation

There were a range of perspectives expressed by participants with respect to how regulation functions and the nature of the role of the inspector. One perspective shared by many participants was that inspections (i.e. ‘boots on the ground’) were the best means of assessing compliance when compared with other methods such as desktop reviews or self-assessments. Moreover, inspectors enjoyed the direct engagement with residents in RCF-D. This engagement, coupled with the sense of

achievement on seeing improvements in centres as a result of inspection findings, contributed to job satisfaction among inspectors.

Nevertheless, it was acknowledged that inspections were an imperfect means by which to gauge quality. For example, when inspections were announced (which was sometimes necessary to accommodate residents that did not wish to be present), it was difficult to build a true picture of what life was like for residents because the RCF-D had time to prepare. It was also acknowledged that, regardless of whether an inspection was announced, it was only possible to assess quality at a specific point in time:

> "one day, you're there for 8 hours…[staff are] on high alert the whole time. I don't know, do we ever really get a true picture?". [Insp2]

This suggests there is a latent anxiety for anyone in the role of inspector where, despite their best efforts, one can never be fully assured that their findings are an accurate reflection of quality.

Some participants welcome the evolution in the practices of the regulator in the past decade, despite the fact that the regulatory framework, from a legal perspective, had barely changed. For example, certain issues (e.g. safeguarding, restrictive practices) were targeted by the regulator for quality improvement initiatives through the development of 'thematic' inspections. In addition, a greater emphasis has been placed on representing the 'voice of the resident' in inspection reports, and on amplifying the importance of regulations concerning residents' rights. This indicates a certain malleability in the regulatory framework, where the regulator had a degree of autonomy in how it carried out its role.

8.4.2 The importance of skill and strategy for the role of inspector

Participants spoke about the various skills that are required of inspectors to fulfil their role. These ranged from practical skills such as how to access or analyse information, to soft skills like knowing what kind of probing questions to ask on inspection. When dealing with findings of non-compliance, participants described a range of strategic considerations that were central to performing their role as an inspector. This theme has four sub-themes: the inspector skills required for effective implementation;

compiling evidence to make judgments; walking the tightrope between assistance and sanctions; and correctly identifying accountability for compliance.

8.4.2.1 The inspector skills required for effective implementation

Inspectors are typically professionals that have a knowledge of the field they are regulating (predominantly nurses or social care workers in the case of this study), but do not necessarily know how to regulate, they receive on-the-job training and learn from others. A key skill required of inspectors was the ability to ask questions that would elicit useful information. This meant delving deeper into identified issues to search for the root cause. For example, if there was an issue with sufficient staffing, was this because of a failure to properly assess needs, a lack of resources, or poor management planning?

Participants observed that maintaining focus during inspections was also an important skill. This could mean ensuring that highly consequential regulations (e.g. fire safety, medication management) were properly assessed, or guarding against an excessive focus on documentation and ignoring other forms of evidence such as interviews or observations. Some inspectors described using the assessment of certain regulations to build a clearer picture of what residents' life was like. For example, the 'general welfare and development' regulation was broad and allowed inspectors to assess how residents were being supported to live a fulfilling life. This, in turn, provided useful evidence for the assessment of other regulations such as 'residents' right' or 'personal plans'. This illustrates the autonomy of inspectors in choosing what to assess and indicates a degree of discretion that allows them to explore key aspects of care from a range of perspectives.

Another key skill described by participants was the allocation of non-compliances to regulations that would deliver the most impact for residents. There was an awareness among participants that some regulations were more consequential for residents than others:

> "you put a non-compliant in Regulation 21 [Records], how is that going to impact residents? Whereas if you put it in somewhere like safeguarding

> or rights, it's more likely to bring about improvement for residents". [Insp6]

This suggests that inspectors were not simply satisfied with identifying issues (justifying their existence), but sought means by which they could positively impact on the quality of services.

8.4.2.2 Compiling evidence to make judgments

Accessing and properly compiling evidence was also seen as an important skill for inspectors. In the first instance, obtaining the correct information was a challenge. In the face of endless amounts of documentation and records, inspectors had to determine what was key for them to be able to make a judgment on compliance. Secondly, once the correct information was to hand, a skilled inspector would then have to ensure it was sufficiently strong, and substantiated by other evidence, for their judgment to withstand any challenge:

> "it can be quite some time to get through [all the information] before you actually make that decision, because sometimes you're…wondering, 'do I actually have enough now to call this…compliant or not compliant?'." [Isnp1]

Compiling evidence was sometimes complicated by the bureaucracy of the RCF-D, both in terms of the volume and complexity of their documentation systems. In order to circumvent these barriers, inspectors looked to spend as much time engaging with residents as possible. Speaking with residents, asking them about their daily lives and whether they enjoyed living in the RCF-D often provided useful lines of enquiry that could then be supplemented with documentary or observational evidence. While this was an effective strategy with residents that could communicate, it was more difficult in services where residents had communication difficulties and complex needs.

8.4.2.3 Walking the tightrope between assistance and sanctions

Some participants spoke about the need to be strategic and use discretion in how one approaches an issue with a service provider. Context was important and inspectors had to consider a range of factors when deciding if, or to what extent, escalation or enforcement measures were warranted. For example, if a RCF-D had an elderly

population, you may not expect to see the same level (or type) of activities that one would expect in a service with younger people. This required the use of discretion on behalf of inspectors who were aware that a 'one size fits all' approach was not always appropriate.

Nevertheless, discretion had its limits and inspectors were acutely aware that, ultimately, their job was to protect residents and promote their wellbeing:

> "the regulations are black and white…you can't just say, 'well, look, they've made a good effort'. You can reflect it in the report and you can reflect it to a certain level…But if they're not compliant, they're not compliant". [Insp4]

Inspectors were also conscious that their relationships with RCF-D management and staff could be affected by any sense that they were not being fair or proportionate. This meant there was a fine line to be treaded: take account of the particular issues facing a RCF-D, but guard against being overly permissive to the point that your effectiveness as an inspector is diminished.

8.4.2.4 Correctly identifying accountability for compliance

Strategy was also important for how an inspector ensured the correct person was made accountable for non-compliance. While the PIC was often the most senior point of contact in a RCF-D during an inspection, it was not always the case that they should be held accountable for all non-compliances. Some participants had a certain level of sympathy for persons in charge as they were sometimes caught in the middle: accountable for compliance yet persistently struggling to secure resources from their organisation to facilitate compliance. Some participants were of the view that the focus of regulation and the locus of accountability should shift more towards provider organisations rather than individual RCF-D.

8.4.3 Impediments to effective regulation and inspection

Participants encountered a range of barriers to the effective conduct of their duties. These barriers were sometimes external issues like gaps in the regulatory framework, or internal issues such as bureaucracy or resource constraints. This theme has three

sub-themes: flaws and gaps in the regulatory framework; impact of resource constraints on oversight and compliance; and internal bureaucratic processes.

8.4.3.1 Flaws and gaps in the regulatory framework

The quality of the text of the regulations was an issue discussed at all focus groups. Some felt the regulations had blind spots; others felt the wording of some regulations rendered them all but impossible to assess or enforce. In addition to concerns around specific wording, inspectors also found that it was difficult to properly apply the regulations to what was a diverse range of settings and clients groups. These observations led many to conclude that the regulations required review in order to bring them into line with current practice and to address gaps and blind spots. These observations also suggest there may have been issues with the evidence-base underpinning the regulations, or their drafting by government.

Some components of the legislative framework also limited the inspector's capacity to inspect, such as the legal requirement for centres to renew their registration every three years. The burden imposed on inspectors by the re-registration process meant their attention was drawn away from everyday regulatory activities.

8.4.3.2 Impact of resource constraints on oversight and compliance

Resource constraints in the regulator, in the form of a shortage of inspectors, was limiting capacity to effectively regulate. These constraints meant that inspectors were expected to monitor a larger number of centres. The inevitable outcome of this was less-frequent inspections. As a consequence, there was a downstream effect on compliance, what participants referred to as 'regulatory drift' or 'regulatory slippage':

> "we're not going out as often, which means if there are issues with the provider and they're not being identified, if the provider isn't self identifying, we're not going out there that often to identify it. Which means there could be an ongoing issue for longer than needed regarding some aspects of care and support because no external person may be going in and having a quick eye on whatever it might be". [Insp11]

Infrequent inspections meant inspectors felt they needed to carry out more comprehensive inspections when they did visit because they could not be certain when they would visit again.

8.4.3.3 Internal bureaucratic processes

The regulator's processes and business rules also featured as an impediment to the work of inspectors. These included duplication of work, time-consuming administrative tasks and inefficient work practices. For example, some business rules limited the number of inspectors that could conduct an inspection (typically limited to one person for one day) and limited the duration of inspections (generally no longer than eight hours). These rules limited inspectors' autonomy and constrained their capacity to inspect.

Most participants referenced the amount of administrative work they had to carry out. For example, inspectors played a role in processing or approving changes to RCF-D management and the renewal of registration, and this was seen as detracting from the real work of inspecting or regulating. There were also issues with the regulator's information technology infrastructure that meant accessing and processing information was time-consuming and cumbersome. In summary, participants felt their time could be substantially freed up to do more inspecting if the regulator's internal processes were better designed and resourced.

8.4.4 Positive effects of regulation

There was a general consensus across all participants that regulation has had a positive impact on the quality of residential disability services in Ireland. The perceived positive impact of regulation gave inspectors the sense that they were agents of change in a process of quality improvement, and that regulation had also played a role in changing culture in services.

8.4.4.1 Regulation has improved the quality of services

Given the relatively recent introduction of regulation (2013), many participants were in a position to offer opinions on what services were like prior to its introduction, especially because many had worked in services. While there were some that expressed a view that some of the regulations had negative unintended consequences

(e.g. creating an institutionalised setting by requiring a full suite of fire safety measures in residential houses), the overwhelming sentiment was that the introduction of regulation had been a positive development for people using services.

Participants recounted many stories of observing the transformation of people's lives through the implementation of the regulations, such as improvements in the physical environment, moving away from institutionalised settings, a greater emphasis on person-centred care, and enhanced safeguarding. These observations suggest that inspectors fully subscribed to the goals of regulation and were, therefore, more likely to be enthusiastic proponents of regulation as an intervention that improves quality.

8.4.4.2 Inspectors as agents of change

Many participants viewed their role as agents of change, performing an external assessment of quality and then monitoring the service so that it addressed the identified failings. While appearing counterintuitive, managers of RCF-D would often welcome negative findings because they were currency for improved resources:

> "[persons in charge] will ask you, 'are you putting that in the report?' Because they will use that then to support things like business cases and applications for funding and things like that". [Insp2]

It is interesting that, in such circumstances, inspectors and persons in charge were closely aligned and functioned almost like allies who had a shared goal of improving service quality. Participants also spoke in positive terms about escalation and enforcement measures as these were seen to have the desired effect i.e. prompt remedial action by the RCF-D to improve compliance.

8.4.4.3 The role of regulations in culture change

It was not just the presence of inspectors that brought about change; participants also felt the mere fact of the existence of the regulations acted to promote a change in culture across the sector. This suggests that the 'spirit' of the regulations had acted to change the culture in RCF-D. Regulation was also seen as giving a voice to people using services, reflecting their views in inspection reports and facilitating them to self-advocate.

Table 15 – Overview of key findings in relation to each research question

Research question	Overview of findings
What are inspectors' views about the regulatory system?	• Regulation has served to improve quality in residential disability services in Ireland and inspectors had first-hand experience of changes in the sector • Inspections remain the most important means by which to judge compliance, albeit that they only reflect a point in time • Direct engagement with residents is key to gathering evidence • The regulator had the capacity to be flexible in its interpretation of the regulations • The legislative framework had gaps and blind spots that impacted on inspectors' ability to effectively regulate quality • Some inefficient processes and resource constraints with regard to the regulator impacted on inspectors' ability to regulate effectively.
What strategies do inspectors use to improve compliance and address non-compliance?	• Inspectors look to gather multiple sources of evidence (e.g. interviews, documents, observations) to make judgments on compliance • Making findings of non-compliance in areas of care that will have the greatest impact on residents' safety and wellbeing • Honing in on specific regulations (e.g. those focusing on 'residents' rights' or

	'general welfare and development') in order to build a picture of what life is like for residents in a centre • Engaging and speaking with residents directly (as opposed to reviewing documentation or observing staff) in order to gather evidence to support judgments • Discretion is used and context taken into account where possible, often with a view to establishing and maintaining a positive relationship with centre management • Where necessary, inspectors seek to allocate responsibility for non-compliances to senior managers within organisations, to prompt action at the appropriate level of accountability.
What are the challenges of implementing these strategies?	• The manner in which some centres organise and manage documentation can make it difficult to access key information • The regulator's business rules (e.g. 8 hour limit for inspection days) can sometimes limit capacity for engagement with residents and evidence gathering • Resource constraints within the regulator (e.g. inspector shortage) led to higher caseloads and less-frequent inspections, impacting on inspectors' capacity to visit centres • Announcing inspections (sometimes necessary to meet residents' needs) meant

	it was difficult to form an accurate view of residents' daily lives • Direct engagement with residents was sometimes compromised where those residents had communication challenges • The use of discretion by inspectors was only feasible in circumstances where residents' wellbeing would not be unduly affected.

8.5 Discussion

The inspector role requires skill and the use of strategy to drive implementation of regulations in services. Legislative flaws, resource constraints and bureaucracy sometimes inhibits their work. Inspectors have a clear sense of the effectiveness of regulation and observed many instances of improvements in service quality because of their interventions.

We found there was only a limited literature comparable to our study. There is a broad literature on the role of inspectors in the process of implementing regulatory requirements. However, the literature is mostly from fields other than health and social care e.g. schools,[471] chemical facilities,[472] organic food.[473] Moreover, the literature on inspectors in a health or social care context does not deal specifically with implementation issues e.g. expectations of health care provider inspection preparation,[464] reliability of hospital inspector assessments,[42] challenge of identifying abuse in nursing homes.[474]

Our study underscores the central role played by inspectors in the regulatory process, and also their impact on the implementation effort in services they regulate. The skills and strategies they rely on for their work draws comparisons to 'street-level bureaucrats'.[455] A key feature of the street-level bureaucrat is the use of discretion and this is a subject that arose in our study. Discretion for inspectors was represented in the autonomy available to them to select what regulations to assess for each

inspection. It also arose in circumstances where inspectors took individual service's circumstances and resident profile into account when assessing compliance. This means they had discretion to perceive compliance as context-specific rather than a binary determination. Notwithstanding this, the exercise of discretion had its limits. While inspectors could empathise with the predicament of service managers that may be challenged by resource issues, their discretion did not go beyond a point that would negatively impact on residents of services.

Direct engagement with service users was important for inspectors in our study. Residents' perspectives were an important aid for generating lines of enquiry and compiling evidence to make judgments. It is noteworthy that inspectors in our study are distinct from other types of inspectors i.e. they engage with the producers *and* consumers of services in their regulatory work. For example, an inspector for nuclear safety may visit a nuclear power plant to review the various facilities, assess safety systems and speak with management and technical staff.(475) Food safety inspectors may visit a production facility to take samples, observe food handling practices and speak with staff and management.(476) In both examples, the inspectors are somewhat removed from the people they are ultimately safeguarding: people that can be affected by a nuclear accident or food consumers. Having direct contact with the consumers of regulated services may influence the inspectors' behaviour as they have access to first-hand evidence regarding the negative consequences of non-compliance. Equally, being able to observe the positive impact of regulation on the lives of residents (e.g. improved staffing levels or more person-centred care) served to instil in inspectors a sense that they had influence and were agents of change.

Our findings show that inspectors of residential disability services in Ireland viewed themselves as playing a part (agents of change) in driving quality improvement in these services, rather than being dispassionate surveyors of care. They were aware — through observation over time — that their inspection reports were affecting change in services. Moreover, they were aware that service providers used inspection reports to advocate for increased resources from the state. Inspectors were also strategic in how they framed non-compliances in reports and ensured that accountability rested at the appropriate level in a service provider. These observations place the inspectors in

our study firmly in the consultant-like regulatory style.[127] Rather than being intolerant of non-compliance and quick to sanction (police-like), or pleading and persuading service providers to take action to the benefit of service-users (persuasive-like), the inspectors in our study were keen to act in commune with managers. There was clearly a sense of a shared purpose or goal: to improve the lives of people with disabilities living in residential care. Inspectors evidently also saw this goal in managers of services, for example, where they empathised with the plight of managers that were struggling to provide a good quality service in the face of limited resources. So, while implementation of regulations was ultimately the responsibility of service managers, inspectors recognised they had a role to play in supporting services to achieve compliance. They did this by providing advice and support to managers and by drawing attention to resourcing issues that managers were unable to resolve within their organisations.

While regulation is a common intervention deployed by governments to monitor quality and protect service users in health and social care, it is not without its critics. Some take issue with the burden created by regulation that detracts from the work of providing care.[477] Others, justifiably, point to a catalogue of failure where service users have been subjected to abuse, neglect or poor care standards despite the presence of a regulator and regular inspections.[18, 353, 478, 479] Regulators, equally justifiably, can argue they cannot be everywhere all of the time, and that service providers are ultimately responsible for the quality of care they provide in services.[480] Notwithstanding the above point, there is a still a pressing need to properly evaluate the effectiveness of regulation.[50] There are several questions one could pose in relation to regulation that are worthy of consideration. For example: is regulation effective for improving quality? How often should inspections happen? What qualifications or skills should inspectors possess? What other data could support regulators to properly evaluate quality? What role should service users play in the regulatory process? Despite the prevalence of regulation in health systems globally, these questions are presently under-researched.

What do our findings say about how regulation is operationalised and how it could be made better? While our findings are situated in Ireland, there is potential for them to

be generalisable to other countries that have a similar regulatory model. Our findings suggest there is merit in developing education or training programmes that teach professionals how to regulate. Many inspectors in our study explained how they developed important regulatory skills by conducting inspections and learning from more experienced inspectors. A formalised qualification in regulation or inspecting may further strengthen and refine one's ability to inspect. Equally, a regular evaluation or review of regulations should be built into a regulatory framework. This would ensure flaws or gaps are addressed and that regulators are equipped to deal with new developments in care practices. The consultant-like approach of inspectors in our study is shown to be effective in terms of eliciting action from regulated organisations. However, this may be due to local factors such as resource allocation, service provider types and the relatively recent introduction of regulation (2013) to the sector. Further research on the optimum regulatory style based on the characteristics of the sector to be regulated may provide useful insights for how the effectiveness of regulation could be improved.

8.5.1 Limitations

Our study is limited by the reliance solely on focus group data. While direct observation of inspection activity may have been a useful additional data source, this was not feasible because only inspectors have the legal authority to enter and inspect residential disability services in Ireland. Another potential limitation is the first author's position as a current employee of the regulator. This meant many of the participants in the focus groups were personally known to the first author. This may have influenced their responses and the degree to which they felt comfortable to speak openly about their work. To guard against this, participants were assured that all of the focus group transcripts would be pseudonymised and would not be shared with any other person working for the regulator. In addition, the first author, as focus group facilitator, acknowledged their dual role as both researcher and employee of the regulator, and assured all participants that they were free to express their opinions on any matters related to the research questions.

8.5.2 Conclusion

Our study underscores the importance of the role of inspector in quality assurance in health and social care services. The inspector identifies and documents poor practice for the purpose of safeguarding service users and promoting their rights. In addition, they also play a role in supporting managers to implement regulatory requirements. This is achieved through acting in a consultative and educational fashion and reflects a sense of shared purpose among inspector and those they are inspecting. It may be unsurprising to learn that inspectors are supportive of regulation. Notwithstanding this, the ability to witness changes in services — and the lives of residents of those services — over time, as a consequence of regulation, strengthens inspectors' belief in the effectiveness of regulation as an intervention. However, barriers in the form of limited resources and overly-bureaucratic processes can inhibit this effectiveness. Our findings may be informative for regulatory agencies that wish to support the compliance effort in the organisations they regulate. The findings also suggest there may be opportunities for additional research on how inspectors play a role in the implementation of innovations or interventions.

CHAPTER 9: Discussion

Despite regulation's prevalence as an intervention to monitor the quality of health and social care services, its implementation is understudied. This thesis attempts to address this gap by: identifying, by way of systematic review, the determinants of the implementation outcome (i.e. compliance); investigating the causes of non-compliance as recorded in inspection reports from the regulator for health and social care services in Ireland; describing how health and social care managers engage with the implementation of statutory regulations in residential disability services in Ireland; and examining how health and social care inspectors in Ireland implement the regulation of residential disability services. This discussion summarises the findings from each of the studies undertaken as part of this research (i.e. chapters 5 to 8) and then proceeds to situate and interpret those findings in terms of the theoretical framework and research paradigm for this thesis.

9.1 Summary of findings

In Chapter 5, we sought to identify determinants of regulatory compliance by way of a systematic review. We identified 157 studies for inclusion, most were: quantitative designs (n=147, 94%); focused on nursing home settings (n=143, 91%); and carried out in the United States (n=140, 90%). On mapping the findings to the CFIR, most determinants were coded to the 'Inner Setting' and 'Outer Setting' domains.

While a meta-analysis was not methodologically feasible, we identified five determinants of compliance that had a strong association (greater than 60% of studies reported a negative or positive association) with compliance, all of which were coded to the 'Inner Setting' domain of the CFIR. Those with a negative association with compliance were higher staff turnover and larger facilities. Those with a positive association were higher total nursing staff and higher registered nurse staffing levels. A facility's geographic location was also associated with compliance but was simply reported as being 'associated' due to it being a nominal variable.

In general, the studies included in the review used regulatory compliance as a proxy measure for facility quality i.e. most were not specifically interested in how

regulations were implemented. The determinants assessed in these studies tended to be variables that were easily measured, such as staffing levels, funding, for-profit status or resident demographics. A typical example of this type of study is one by Kamimura et al (2007) entitled 'Do corporate chains affect quality of care in nursing homes? The role of corporate standardization'.[223] Here, the authors investigated whether corporate chain nursing homes were higher or lower quality compared with non-chain nursing homes; regulatory compliance was the outcome measure used. There were relatively few studies that sought to investigate the effect of more difficult to measure variables (e.g. leadership engagement, preparedness) on implementation. Moreover, there were only a small number of qualitative studies that touched on implementation issues.

Some of our findings were in agreement with other reviews. For example, our finding that larger facilities tended to have lower compliance rates when compared to smaller facilities was replicated in another review.[125] A potential causal mechanism here is that staff attention in larger facilities is directed towards health and quality of care outcomes, at the expense of quality of life outcomes.[316] Moreover, there may be an interaction effect between facility size and other important characteristics such as urban location[318] or staff turnover.[319]

Staffing-related determinants were also prominent in our findings. We found higher total nurse staffing levels and higher total registered nurse staffing levels to be associated with higher compliance. The finding related to nursing staff is consistent with other studies, both in hospital[334-337] and nursing home settings.[328, 338, 339] It is possible that nurse staffing is associated with higher quality when the outcome measures were nurse-sensitive outcomes.[334] Equally, lower nurse staffing levels can mean care is provided by less-qualified staff, thereby impacting quality.[336] Higher staff turnover was also associated with lower compliance in our findings, possibly indicating a circular relationship i.e. poor quality care precipitates staff dissatisfaction and vice versa.[319]

Demographics (both relating to facilities and service users) were also shown to be associated with compliance. For geographic location, there may be an interaction effect with other variables e.g. variation in the measurement of compliance by

regulators,[42, 344-346] or differing levels of state funding for facilities.[347, 348] While some studies have found an association between service user characteristics and quality,[351] this was not replicated in our study with respect to compliance.

Most of the determinants identified in our study can be regarded as structural issues (e.g. staffing, funding, location). We found relatively few studies that investigated process issues. Among the process-related determinants were the degree to which regulatory requirements were compatible with current work practices[152] and ensuring good quality documentation.[152, 162] These findings are broadly consistent with other studies on processes, for example one that evaluated implementation using Normalisation Process Theory (NPT).[92]

To summarise the key findings in Chapter 5, a large number of determinants were identified in our study, underscoring the fact that regulatory compliance is complex and context-specific. It is difficult to conclusively identify causal relationships due to the observational nature of the majority of included studies. The use of CFIR was beneficial as it guided us in drawing insights into structures and processes that produced compliance. The small number of qualitative studies represents a knowledge gap that could be addressed by further research.

In Chapter 6, having learned about the wide range of determinants identified in the systematic review, we sought to sharpen our focus. We did this by using data describing non-compliances from inspection reports of residential disability services in Ireland. This was done to develop a greater understanding of the causes (as stated in inspection reports) for non-compliance in our study setting, and also to measure the level of non-compliance nationally. Data from 1263 reports published between 1st January 2019 and 31st October 2022 were included. Thirteen centres (1%) in the sample were found to have complied with all regulations assessed; 100 centres (8.1%) failed to be compliant with any regulations.

A sub-sample of 35 inspection reports was used to carry out a thematic analysis with a view to describing the reasons for non-compliance. Eight themes were identified: insufficient resources, governance and management failings, poor documentation

quality, non-person-centred care, weak processes, inadequate safety, staffing-related concerns and poor care management.

It is difficult to compare the compliance levels reported in our study with other studies, primarily due to a scarcity of similar studies and different methodological and measurement approaches. The regulations found to be non-compliant most frequently (i.e. fire precautions; written policies and procedures; and premises) may be a consequence of their content and complexity. That is, there are multiple sub-regulations in these regulations compared to others (e.g. the premises regulation has seven sub-regulations whereas the regulation pertaining to insurance has only two).

A key finding in this study was the frequency with which the theme of 'insufficient resources' appeared in inspection reports. This included issues related to staffing or financial capacity to comply with regulations. For example, non-compliances with premises maintenance issues (painting, furniture repair, mould) were frequent, suggesting increased funding for maintenance would remedy these matters. The theme of 'governance and management failures' was also prominent in our findings, where inspectors found fault with the way centres were supervised or with governance structures.

On mapping the identified themes back on to the regulations, we surmised that improvements made with respect to documentation quality and governance arrangements could deliver broad-based improvements across all regulations. This is because these issues were fundamental to compliance in a range of areas.

Our study did not investigate other aspects of the regulatory process that may offer insight into implementation issues. This was due, in part, to the nature of inspection reports i.e. their purpose is to describe compliance levels and the evidence for same, rather than to offer underlying causes for compliance/non-compliance. Inspection reports also did not contain any information on another important aspect of the regulatory process: the nature of the relationship between the inspector and staff/management in the regulated organisation.

The learning from the above study informed our thinking on the subsequent studies. To further address the aim of the thesis and to address the gap identified above, we

turned our attention to the managers of care facilities that are regulated. In Chapter 7, our aim was to describe how health and social care managers engaged with the implementation of care regulations, focusing on residential disability services in Ireland. Of particular interest were the overall strategic approaches to the implementation of regulations as adopted by managers, the structures and processes used to implement regulations, and important determinants of these implementation strategies such as resource availability and attitudes to the regulatory regime.

We recruited 19 participants to take part in one-to-one interviews, all of whom played a key role in the management of residential disability services in Ireland and were responsible for regulatory compliance within their organisations. The data collection and subsequent analysis were informed by NPT.[91] Our deductive-inductive analysis produced five parent themes and twelve sub-themes. In summary, we found managers implemented care regulations by instituting various structures and processes, each of which were informed by the prevailing organisational culture with respect to regulation. The implementation effort was also contingent on how they managed relationships i.e. with the world outside their organisation (e.g. other health services, families of residents) and with the inspector/regulator.

The themes can be aligned with many of the constructs and sub-constructs of NPT. We observed how managers worked within their organisations to understand regulatory requirements and then put measures in place to ensure compliance i.e. *coherence.* We also identified examples of *internalisation* where managers perceived of regulation as a positive intervention that improved quality; and *differentiation,* where managers determined that some regulatory requirements were compatible with current ways of working. Managers sought to build relationships, internally and externally, that supported the implementation effort, which represented a form of *collective action.* There were also instances of *reflexive monitoring* where managers witnessed, over time, improvements in their services as a consequence of being regulated, thus supporting the implementation effort and representing a positive feedback loop.[84]

Among the other key findings in this study was the generally positive attitude managers had towards regulation as an intervention. While there were some who

pointed to the burdens it imposed in terms of documentation and increased costs, most were of the view it had served to improve quality and change culture in services. Many managers also formed the view, which is somewhat counterintuitive, that inspectors were allies and behaved in a collegial and helpful manner. This underscores their shared purpose of ensuring the residents being cared for in services had a good quality of life.

We found only a limited number of similar studies to ours and concluded that this was an understudied area in health services research. While managers played a key role in the implementation of regulations, we were keen to understand how the implementation effort appeared from the other side i.e. the regulator. This led us to turn our attention to inspectors for the final study in this thesis.

In Chapter 8, we sought the views of inspectors working in the regulation of residential disability services in Ireland. Our aim was to examine how inspectors worked to implement the regulations, with a particular focus on their views about the regulatory system, the strategies they used to improve compliance and deal with poor performance, and the challenges they faced in implementing these strategies. This was a qualitative study with a focus group design. There were 22 participants in five focus groups. The focus groups were conducted online; four of the sessions were comprised of inspectors of residential disability services in Ireland; the fifth group was held for regional managers of inspection teams. Thematic analysis was conducted on these data.

We identified four parent themes in our analysis: overall views on the regulatory system; the importance of skill and strategy for the role of inspector; impediments to effective regulation and inspection; and, positive effects of regulation. While inspectors were not legally responsible for the implementation of regulations (the legal responsibility rests with the service provider and the person in charge of the service), they did perceive their role as important for the implementation process and for improving quality. They used various skills and strategies to focus their inspection findings on issues that would have the most impact for the lives of residents. They also sought to apportion accountability for non-compliances at the appropriate level in an organisation, thereby stimulating action at an organisational

level. While there were elements of the regulatory framework that represented barriers to their work (e.g. resource constraints and bureaucratic processes), inspectors regarded regulation as an effective intervention and had first-hand knowledge of its impact within services through regular and repeat inspections.

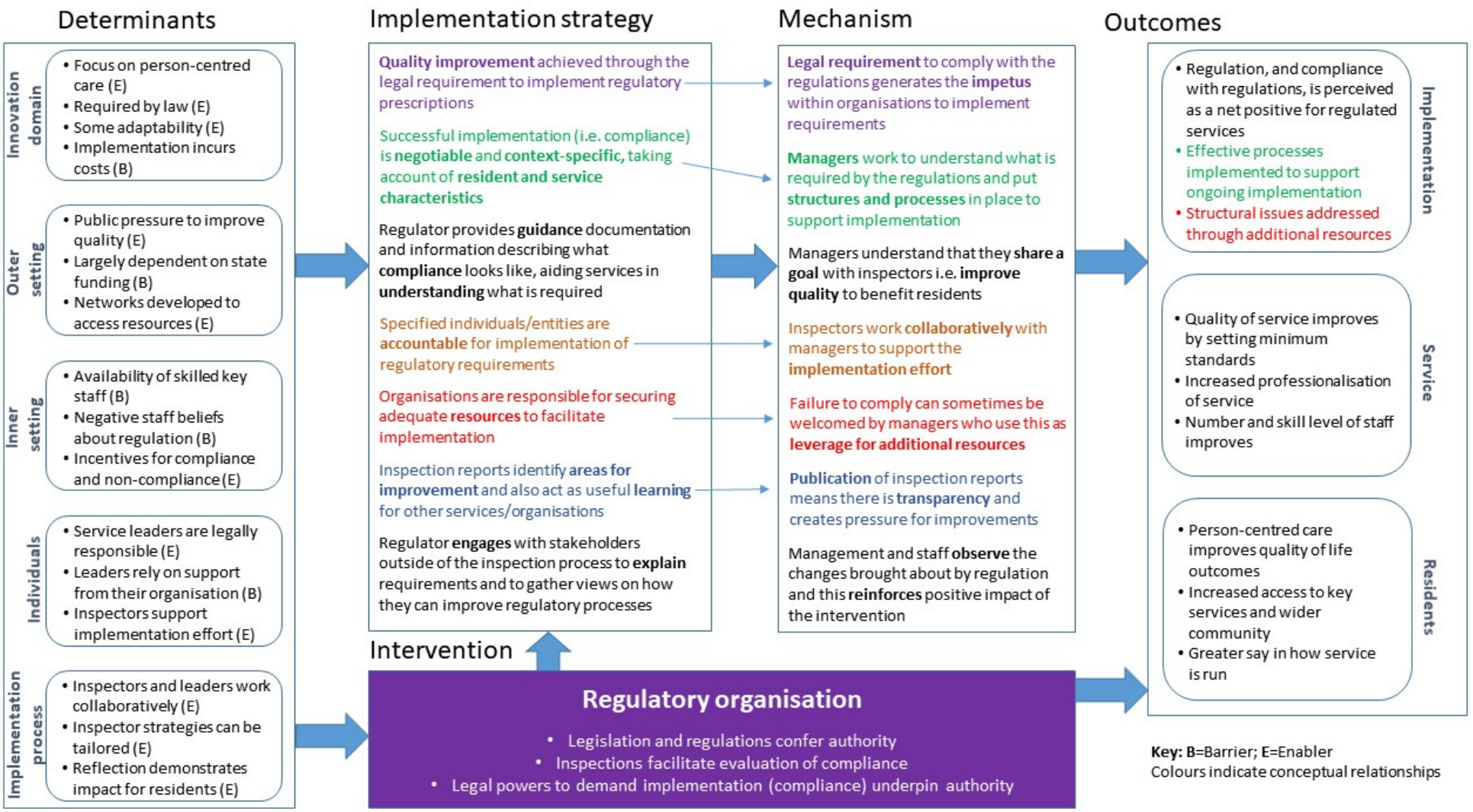
The findings described in Chapter 8 show how the role of inspector is aligned with that of the 'street-level bureaucrat'.[458] This is particularly the case in terms of their use of discretion. Inspectors spoke about how they had autonomy to choose which regulations to assess in advance of each inspection. They also were able to take specific contexts into account (e.g. resident profile) when weighing evidence to make judgments. This meant that compliance was sometimes context-specific and inspectors allowed a certain degree of flexibility in their dealings with regulated organisations. The discretion employed by inspectors also placed them in the category of 'consultant-like' regulatory style. This meant they engaged collaboratively with regulated organisations to demonstrate how compliance could be achieved and quality enhanced.

9.2 Interpretation

This thesis is underpinned by a conceptualisation of regulation as an intervention (Figure 5 represents a regulatory organisation using the Implementation Research Logic Model[481]). This allows for the application of implementation science theoretical frameworks and methods to understanding how regulatory requirements are incorporated and embedded — both by regulated services and by regulators — and the outcome (compliance) is produced. This outcome is not simply a bureaucratic exercise in performance measurement. Compliance with regulations is targeted towards producing good outcomes for the people that use services. In the context of this study, it is the state's expectation that, through regulation, people with disabilities living in residential care facilities will have a better quality of life as a result of compliant services.

It is important to address the question of whether regulation can indeed be regarded as something that should be investigated using an implementation science lens. The

Figure 5 – Regulatory agency conceptualised as an intervention using the Implementation Research Logic Model



definition, as put forward in the first issue of the journal by the same name, states implementation science is: “the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practice into routine practice and, hence, to improve the quality and effectiveness of health services”.[482] Clearly, regulation is more akin to evidence-based practice than a research finding.

There are two approaches one can take to the idea that regulation represents evidence-based practice. Firstly, one could argue that regulation has been shown to be an effective intervention to improve quality and safety in a wide range of fields. However, the evidence for this proposition with respect to health and social care services is limited, as was noted in a recent editorial in the British Medical Journal editorial.[50] The second approach requires one to examine individual regulatory requirements and assess whether these represent evidence-based practice. The following are examples of regulations for positive behavioural support in effect in three different jurisdictions:

Ireland

The person in charge shall ensure that, where a resident’s behaviour necessitates intervention under this Regulation—

(*a*) every effort is made to identify and alleviate the cause of the resident’s challenging behaviour;
(*b*) all alternative measures are considered before a restrictive procedure is used; and
(*c*) the least restrictive procedure, for the shortest duration necessary, is used.[69]

Australia

In developing and reviewing a behaviour support plan for a person with disability, the specialist behaviour support provider must take all reasonable steps to:

(a) reduce and eliminate the need for the use of regulated restrictive practices in relation to the person with disability; and

(b) take into account any previous behaviour support assessments and other assessments; and

(c) make changes within the environment of the person with disability that may reduce or remove the need for the use of regulated restrictive practices; and

(d) consult with the person with disability; and

(e) consult with the person with disability's family, carers, guardian or other relevant person; and

(f) consult with the registered NDIS provider who may use the regulated restrictive practice and other relevant specialists.[483]

California

The facility administrator shall assign a qualified behavior modification professional to each client. Each client shall receive a minimum of 6 hours per month of direct time for behavior assessments and intervention methods by a qualified behavior modification professional. Time utilized will be documented in the client file.[484]

Positive behavioural support is an evidence-based intervention for people that present with responsive behaviours or behaviours that challenge.[485] This is but one example among many of where regulatory requirements represent evidence-based practice.

Notwithstanding the above, there are likely many regulatory requirements in health and social care services that do not have an evidence-base. One reason for this is some regulatory requirements are founded on an aspiration to underpin people's basic human rights or rights under law. This is evident in the regulations for RCF-D in Ireland concerning things like privacy and dignity, personal possessions, protection from abuse and access to advocacy services (See Appendix 1). A second reason is that some regulatory requirements are based on established practices that cannot ethically be subject to research e.g. fire exits or visitation rights.

Returning to the original point, as set out above, there are regulatory requirements in health and social care services that are evidence-based. This alone is a sufficiently

strong argument for considering regulation as an intervention in an implementation science context: the intent or goal of regulation is to set clear requirements that services must implement in order to provide a good quality service. This touches on the second component of the definition for implementation science i.e. the incorporation of interventions into routine practice with a view to realising improvements. There can be little argument that regulation also fits this definition. Regulators routinely visit and inspect facilities. However, for the majority of the time facilities are operating, there is no inspector looking over their shoulder; they are required to implement regulatory requirements on an ongoing basis. Should an inspector visit, the facility is expected to demonstrate compliance through their actions, their evidence, their environment and their records. The ongoing nature of this implementation effort adds credence to the argument that regulation is an intervention that can be studied from an implementation science perspective.

This thesis draws on two theoretical frameworks from implementation science: the Consolidated Framework for Implementation Research (CFIR)[83] and Normalisation Process Theory (NPT).[84] The CFIR was used to categorise determinants of compliance in the systematic review (Chapter 5) and also structured the results. Use of the CFIR in this fashion facilitated a key conclusion of the review: there was a substantial literature focused on quantitative assessment of structural determinants of compliance (e.g. staffing, for-profit status, size). Conversely, there was a paucity of qualitative literature investigating process-related determinants. The uneven distribution of determinants across the CFIR underscores the fact that most of the included studies were objectivist in nature. It was evident, therefore, that the research undertaken as part of this thesis, particularly Chapters 7 and 8, were addressing a legitimate research gap.

The document analysis (Chapter 6), while not explicitly relying on a theoretical framework, provides some useful points with respect to the implementation of regulations: the complexity of implementation and interdependence i.e. how one aspect of care provision can have knock-on effects on multiple other aspects. On complexity, there is a marked variance in the level of detail and specificity among the regulations in place for RCF-D in Ireland. The regulation on fire safety has 250

words whereas the regulation for insurance has just 44.[69] Clearly, it will be more difficult to properly implement a regulation that is detailed and specific compared with one that has relatively few prescriptions. On interdependence, there were a small number of themes (e.g. governance and management failures, poor documentation quality) that contributed to non-compliance across a broad range of regulations. This indicates that certain aspects of service provision were key to effective implementation across a range of areas. Similarly, improvements in these key aspects have the potential to deliver improvements across the board.

NPT featured strongly in the interviews in Chapter 7. Several NPT constructs were evident when mapped against that study's themes. Managers were shown to make efforts to understand what regulation required of them and work within their organisations to devise the means by which these requirements could be implemented (*Coherence*). Managers encouraged staff to embrace regulation and established networks to aid the implementation process (*Cognitive participation*). Structures and processes were established and refined to support the implementation effort and staff were expected to take responsibility for compliance (*Collection action*). Finally, over time, managers and staff could see some positive outcomes from regulation (e.g. change in culture, increased state resources), and this served to shore up support for the intervention (*Reflexive monitoring*). The alignment of NPT constructs with the themes support the view that regulation can be regarded as an intervention and is worthy of further research.[84]

In Chapter 8, we showed that inspectors perceived themselves as key agents of change. Whilst the CFIR and NPT address the central role played by individuals and leaders in implementation, this is often from the perspective of internal rather than external actors (the CFIR has an 'External change agents' construct but, as shown in Chapter 5, there were few studies that engaged with this from an implementation perspective). The findings in Chapter 8 illustrate how inspectors play an active role in the implementation effort. While they are not responsible for implementing individual regulatory requirements, they can support the implementation effort by calling attention to resource shortfalls or by apportioning accountability for non-compliances at the appropriate level within an organisation. The collaborative

approach observed by inspectors in this study may also be interpreted as them co-producing successful implementation by guiding and supporting managers.

The research paradigm for this thesis is a critical realist epistemology.[87] This calls for researchers to reflect on the observations and claims of all study participants i.e. managers of residential disability services, inspectors, the author, and the Public-Patient Involvement and Engagement (PPIE) participants. Moreover, it requires a critique of regulation as a phenomenon, including the key institutions that operate it i.e. the state and the regulator.

As shown in Chapters 7 and 8, managers played a central role in implementation. An interesting finding was managers' broad-based welcome and acceptance of regulation. The majority held the view that regulation had, since its introduction in 2013, served to improve quality in services, enhance the lives of residents and change culture to a more person-centred approach to care. One could argue this was simply managers telling the interviewer — a current employee of the regulator — what they wanted to hear. In a world where services fear the regulator and are reluctant to challenge inspectors out of concern that this would lead to punitive measures, a claim such as this could perhaps be countenanced. However, as evidenced in this thesis, managers and inspectors described a collaborative approach to regulation, where there was a shared goal of improving the quality of life of residents. Moreover, there was no shortage of criticism of regulation and inspectors in the interviews. I am confident, therefore, that managers were candid in their interviews and felt free to speak openly about their opinions on regulation and the regulator.

Managers of residential disability services embracing regulation appears counterintuitive to the view of regulation that describes it as a nuisance, burdensome, ineffective, excessive or stifling. Taking a wider lens, this reflects a classical political argument. Those on the left argue that regulation is a necessary state intervention to safeguard a public good or protect vulnerable members of society.[486] Those on the right make the case that regulation reflects an overly-intrusive state that shackles the free market, increases costs and limits innovation.[486] There are a number of possible reasons why the positivity towards regulation is observed in this thesis. Firstly, politically, Ireland is a broadly centrist country. Elections over the past number of

decades have produced coalition governments incorporating one of the large centre-left or centre-right parties with a range of smaller liberal, social democrat or green parties.[487] This political climate has been generally receptive to regulation and views it as a modernising force across a range of sectors.[488] Several high-profile scandals (abuse in Leas Cross nursing home,[489] the financial crash of 2008,[490] the blood contamination scandal,[491] and defective concrete blocks[492]) may also have crystallised a view among the general public in Ireland that regulation is a necessary state intervention.

A second reason for the positivity may be found in the nature of organisations that provide residential disability services in Ireland: the vast majority are owned and operated by voluntary providers.[73, 100] The state effectively outsources disability care provision to these organisations and provides the majority of funding for their operations.[493] The not-for-profit ethos of these organisations may influence their disposition towards regulation i.e. they are not concerned about how regulatory requirements will impact on profit. However, they may be concerned with how their services can be expected to meet regulatory requirements if they are under-resourced or if staff require upskilling. In this framing, the regulator (and the inspector) do not represent a feared arm of the state; they are seen as potential allies. The legal authority of the regulator means their inspection reports and their enforcement capacity gives them power to call attention to poor quality and demand remedial action. This forces the hand of the state: provide adequate funding for services or face disruption and capacity issues if services are forced to cease operations. This provides a clear rationale for why residential disability services managers in Ireland are, in general, positively disposed to regulation.

The observations of inspectors of residential disability services in Ireland were described and thematically analysed in Chapter 8. Just as with managers of residential disability services, inspectors may also have had reason to be circumspect in focus group settings. They were fully aware the research was being conducted by an employee of the regulator. That, coupled with the presence of other inspectors in the focus group, may have caused them to be circumspect in expressing their views.[494] Nevertheless, the views and opinions contained in the various themes in

Chapter 8 allay any fears that inspectors were not candid. Inspectors were open about the challenges of working within a flawed regulatory framework. Moreover, they were openly critical of the impact of resource constraints and bureaucracy on their ability to effectively regulate services.

While inspectors voiced several criticisms of the regulatory framework and of the regulator, they were generally positive about regulation as an intervention. One might argue that such a finding is akin to the inverse of the 'turkeys voting for Christmas' idiom. However, inspectors' support for regulation was not based on some kind of self-interest. Rather, it was founded on a belief that the introduction of regulation for residential disability services in 2013 had delivered tangible improvements in quality. Inspectors had personally observed these improvements and some were in a position to construct a 'before and after' picture due to previous roles working in residential disability services. This not only gave inspectors a positive perspective on the effectiveness of regulation, it also underscored the criticality of their role in quality improvement. Therefore, inspectors viewed themselves as agents of change and were proud of the work they did.

Inspectors' positivity towards regulation may also be a consequence of the relatively good standing of the health and social care regulator in Ireland. The Health Information and Quality Authority (HIQA) is a relatively new regulator, established in 2007.[100] While it has been the subject of criticism from various quarters,[495, 496] HIQA has thus far avoided a major scandal that could tarnish its reputation. The Care Quality Commission (CQC) in England is a useful counterpoint. As a regulator in the area of health and social care, the CQC (and its predecessors the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Commission) has been criticised for high-profile public scandals that took place in services they were regulating.[497] More recently, the CQC has been branded not fit for purpose due to significant failings.[498] Morale among inspectors was observed to be low in 2010, a finding also replicated in 2024.[499] This point is made to draw attention to the fact that an inspector's opinion of their value can be influenced by the public perception of their employer just as much as it can by the power they wield as agents of change. In short, while HIQA inspectors are currently positive about the

effectiveness of regulation, the emergence of a scandal could significantly damage this perspective.

The preceding section discussed the relatively positive public perception of HIQA as a regulator in Ireland. However, this raises another important point worthy of critical reflection: the author's role as a current employee of HIQA. It is fair to argue that the author's interpretation of HIQA's public perception is biased or influenced by their role as an employee of the regulator. Bias could also have entered the knowledge production process, for example in the development of themes or the direction of conversation in focus groups and interviews.[500] This potential bias was acknowledged at several stages in the production of this research and was also regularly discussed at PhD supervision meetings. So, while the potential for bias exists — as it does in virtually all research undertakings — every effort was made to guard against this affecting the research outputs. This means the author was transparent about their role with all study participants, rigorous methodological approaches were used and the PhD supervisors regularly drew attention to the potential for bias.

This thesis concerns a wide range of stakeholders: inspectors and the regulator, service providers and their management and staff, the state. Perhaps the most important stakeholders are the residents living in disability services. Their care and welfare is central to the existence of regulation in the first instance. However, residents of disability services did not feature as study participants for this research. The principal reason for this is that the focus was on implementation of regulations, a matter that residents have no input or control over. The responsibility for implementation rests with service providers, with the regulator playing a role in monitoring the quality of implementation. It is for this reason that study participants were drawn from residential disability services management and inspectors working for the regulator in Ireland. Nevertheless, this is not to argue that residents of disability services should be excluded from the research process. The Public-Patient Involvement and Engagement (PPIE) component of this thesis sought the views of current residents of, and carers of people living in, residential disability services. The PPIE process allowed these important voices to shape the research design and

identify any gaps in the topics and questions that were to be directed to study participants.

The PPIE process was not without its challenges. The recruitment of PPIE participants was facilitated through a gatekeeper organisation: Inclusion Ireland, a non-governmental organisation advocating for the rights of people with disabilities in Ireland. The gatekeeper route represented the best chance of recruiting PPIE participants. Gatekeepers could circulate the information personally and also explain the PPIE process to potential recruits. The use of gatekeepers can be problematic as it distances the researcher from the participants and can also result in the introduction of biases.[501]

Both of the resident participants in the PPIE process had an intellectual disability, reflecting the broader population of residential disability services in Ireland.[100] While both participants communicated verbally, there were challenges in terms of comprehension of the subject matter. This was despite efforts by the residents' keyworkers to explain the PPIE process and questions in advance, and the presence of those keyworkers during the first PPIE meeting. Despite these challenges, the PPIE process was worthwhile and done with a view to being inclusive research.[502]

Turning the critical focus to the phenomenon of regulation, this research has touched on a wide range of perspectives that are features of various debates on regulation. Despite its prevalence as a government intervention, regulation's effectiveness remains disputed. A cursory search for literature across a range of fields returns evidence to support positive[51, 503-505] and negative[506-508] perspectives on regulation. The lack of agreement on effectiveness is likely a consequence of the scale and complexity of the intervention; is it even possible to evaluate the effectiveness of something that has so many variables, dependencies and human actors? Nonetheless, the failure to establish an evidence-base for regulation will always leave it open to criticism, and represents a real gap in the knowledge base concerning quality improvement in health and social care.

Regulation of health and social care services is largely reliant on inspections. This is where the real work takes place: care is observed, interviews are conducted,

documents are reviewed and evidence is compiled. This is distinct from other forms of regulation that can draw on real-time data for monitoring purposes.[509] Therefore, the health and social care regulator is at an immediate disadvantage compared to some other regulators. The labour intensive means by which they assess compliance places limits on their capacity to inspect. Moreover, the complexity of health and social care services, coupled with the voluminous documentation, means it is only realistic to take samples of data to inform regulatory judgments. It is simply not possible to exhaustively assess a health and social care service in this manner. So, there is a trade-off for the state: ensure sufficient oversight of services to protect vulnerable people yet do so in a manner that is cost-effective and not overly intrusive in people's homes.

There are not many palatable alternatives to regular, on-site inspections. Advances in technology make it possible to comprehensively monitor a premises via closed-circuit television. However, this prospect is dystopian in the extreme and represents a digital form of Bentham's *Panopticon*, a circular prison built around a central watch tower where people are constantly under surveillance.[510] In a similar vein, stationing an inspector permanently in a health and social care service to monitor quality is equally unpalatable, not to mention prohibitively expensive. There is, therefore, an acceptance that inspections are episodic and infrequent. The frequency and thoroughness of inspections is contingent on a range of different factors e.g. the number of inspectors (which is correlated to the budget made available to the regulator by the state and the pool of qualified candidates), the number of facilities, the number of inspectors per inspection, the complexity of facilities, the number of regulations and the distribution of non-compliance across facilities. Taking this into account, most health and social care regulators opt for an inspection frequency of 12-24 months.[70, 511, 512]

There are sources of information from a regulatory perspective other than inspectors e.g. residents, staff, families. Regulators often leverage these sources to provide valuable information, typically via confidential reporting of complaints or concerns[513] or via formal surveys of residents and their families.[514] While such sources of information can be a useful complement to inspection data, their utility is

dependent on the profile of people using services. Receiving information from people that have communication or cognitive difficulties is challenging. In addition, where care services are stretched or difficult to access, people may be reluctant to complain for fear of losing a service. As such, inspections, however imperfect, continue to be the primary means by which health and social care regulators gather data about the services they regulate.

Despite all of the arguments against regulation (i.e. the lack of evidence for effectiveness, the cost, the administrative burden and its inconsistent application), it remains a key intervention used by governments globally. The essential principle underpinning regulation in health and social care is difficult to argue against: people have a right to high quality, safe services and the state will facilitate independent monitoring to observe that is achieved.

The findings outlined in this thesis paint a broadly positive picture of regulation as an intervention in the case of residential disability services in Ireland. Managers of residential disability services have mostly embraced regulation and have observed positive changes since its introduction in 2013. Equally, inspectors have a positive perception of their effectiveness in improving the lives of people with disabilities living in residential care. The regulations have not only set out the specific details of what service providers must do. They have also served to change the culture in services to one that is more person-centred. As referenced elsewhere in this thesis, the positive sentiments towards regulation could be a consequence of its relatively recent introduction for residential disability services in Ireland. The quality of care pre and post introduction of regulation plays a significant role in what informs people's perspective. However, a public scandal that implicates the regulator could swiftly damage this positive outlook.

Certainly, there are implementation challenges. That much is clear from Chapter 6 where most services find it difficult to comply with *all* regulations. Chapters 7 and 8 make clear that the implementation challenges are not only those imposed by insufficient resources. There are also issues around the quality of governance, overly bureaucratic processes and gaps in the legislative framework. The following section outlines some implications arising out of the findings of this thesis.

9.3 Implications

9.3.1 Implications for policy and practice

The introduction of regulations to any sector is an act of government but the practicalities of how regulations are designed and introduced differs considerably across countries.[515] For example, regulatory impact assessments (RIAs) are used to varying degrees to evaluate the impact of proposed regulations and to prepare organisations for regulation. There is no evidence that a RIA was undertaken in Ireland in advance of the introduction of regulation for residential disability services. The Organisation for Economic Cooperation and Development (OECD) has consistently called attention to the importance of the preparatory phase that supports the introduction of regulations: "The quality of both the regulatory environment and regulatory outcomes is strongly dependent on the quality of processes for designing regulations. When developing interventions, whether policies, laws, regulations or other types of 'rule', governments do not always fully consider their likely effects".[515] A standardised method of developing, consulting on, implementing and periodic review for any new regulations would prepare all stakeholders for the approaching changes. It would also highlight resource needs for organisations to be compliant.

Governments should give consideration as to how best they can equip a regulator to perform its duties. This means giving the regulator the appropriate tools and legislative powers to realise its goals. It also means resourcing the regulator to ensure that inspections are commensurate with the level of risk in any given sector. There may also be merit in establishing a statutory minimum frequency for inspections that could act as a benchmark for resourcing of inspection teams.

An interesting finding of this thesis is that inspectors seek to apportion accountability for failings at the appropriate level of management within an organisation. There are two entities accountable for implementation of regulations in residential disability services in Ireland: the person in charge and the registered provider. The person in charge is the manager responsible for the day-to-day operations of a service. The registered provider is the organisation that owns or operates services. Whenever an inspector makes a finding of non-compliance, one of the above are responsible for

remedying the matter(s). However, as shown in the findings in this thesis, inadequate resources are often cited as reasons for non-compliance. Residential disability services in Ireland receive the majority of their funding from the state.(493) Therefore, if the claims of lack of resources are taken at face value, this means one of two things: governance at the registered provider is poor which renders it incapable of distributing resources effectively; or, the state has not provided sufficient funding to enable compliance with regulations.

It is beyond the scope of this research to determine which of the above is true. It is likely both claims have validity. The key point here is the regulator has power to take action against a registered provider but not against the state. This means that poorly performing registered providers — those exhibiting poor governance or an inability to effectively distribute resources — can be held accountable and can be sanctioned by the regulator. However, the state, which could be accused of under-resourcing services — especially in times of austerity of where the development and introduction of regulations was sub optimal — is beyond the reach of the regulator.

This poses the question: how independent should a regulator be in order to effectively fulfil its goal? The answer to this question requires one to reflect on the nature of the industry being regulated. In the case of private industry such as food services or manufacturing, an independent regulator represents little threat to a government because the industry is privately resourced. However, in the case of services that receive state resources such as health care or education, a genuinely independent regulator may begin to pose awkward questions for governments that may be under-resourcing those services.

There are examples of regulators that are independent and empowered or permitted to hold governments or elected officials to account. This is the norm in the context of central banks and other similar regulators in the financial sphere.(516) Such candour is not the norm for regulators of health and social care services. This is not to criticise these regulators but rather to draw attention to their limitations with respect to apportioning blame for non-compliance with regulations. This is typified in Chapter 6 where inspection reports describe non-compliances but do not venture an opinion on the underlying causes of the failings; that is not their concern.

It is possible that under-resourcing is a contributory factor to non-compliance. It is equally possible that the inspector, and the regulator more broadly, are aware of and can privately acknowledge this fact. However, they are not empowered to do so publicly. This does not mean that such regulators are toothless. If they have enforcement powers that allow them to shut down services, this represents a means by which the state can be held to account. Where services are threatened with closure, it is the responsibility of the state to intervene or run the risk of reduced service capacity. The implication of the above discussion is that regulators should be cognisant of their capacity to hold all relevant parties to account when the goal of regulation is threatened. Where the regulatory framework prohibits them from apportioning blame on the state or elected officials, there is still scope to be strategic in how they use the powers that are available to them to maximise their effectiveness.

Inspectors play a critical role in the regulatory process. As street-level bureaucrats, they work at the interface of state and the general public, striving to implement policy in a range of sectors.(458) Inspectors are required to interact with and build relationships with people; identify, access and synthesise information; weigh evidence and make judgments on complex matters; and understand the point at which persuasion has failed and enforcement is required. Despite the fact that many inspectors are professionals and highly qualified in the context of the services they are regulating, little attention is paid to the skills they need to be effective regulators. In the absence of any formal education pathway that equips inspectors with the skills necessary to be effective regulators, regulatory organisations must rely on in-house training. Thus, it would appear there is a gap with respect to the educational needs of inspectors.

As shown in Chapter 6, there is potential learning for regulators and service providers in systematically evaluating inspection reports and compliance data. This could be done to identify trends and patterns in data that would identify barriers to the successful implementation of regulations. It may be possible to design interventions (e.g. improvements to governance arrangements or documentation quality) that deliver broad-based improvements across a range of areas.

It is worth discussing the generally collaborative approach adopted by the regulator with respect to residential disability services in Ireland. While there is no material made available by the regulator to formally state they adopt a collaborative approach, the findings in Chapters 7 and 8 support this view. Managers of residential disability services are broadly appreciative of this approach and acknowledge that it aids them in their implementation efforts. Nevertheless, there are dangers to such an approach. A close relationship between inspectors and those they regulate can lead to capture. This means the inspector begins to identify and side with those they are regulating rather than those they are supposed to protect.(517)

It could be argued that some of the language observed in Chapters 7 and 8 (e.g. 'allies') is evidence of an unhealthy relationship from a regulatory perspective. However, in these studies we also observed a shared goal among inspectors and managers of improving the lives of residents of residential disability services. There is no reason to doubt that this is a genuinely held shared goal. The fact that most residential disability services in Ireland are operated on a not-for-profit basis is also important in this context. This means that managers have nothing to gain by short-circuiting regulations or gaming compliance. They would not benefit materially in terms of profits or bonuses in the same manner as might happen in other industries. Indeed, our findings show that managers often welcome the identification of non-compliances as this represents currency in their argument for more resources. As such, the argument over whether a regulator should behave in a collaborative or punitive manner may require consideration of the fundamental goals and principles held by the organisations to be regulated. Ergo, a profit-maximising organisation or sector could be regulated differently to one that is voluntary or not-for-profit.

Finally, this thesis makes the case that regulators (HIQA in this case) behave as an active implementation intervention within the health and social care system. HIQA functions through a set of mechanisms — inspection, monitoring, and enforcement — which shape organisational behaviour and influence compliance outcomes. By conceptualising HIQA as an intervention, it is possible to identify both enabling and constraining mechanisms. On the enabling side, HIQA can drive cultural change, promote governance reforms, and act as a catalyst for quality improvement. On the

constraining side, bureaucratic processes and legislative rigidity may limit inspectors' capacity to respond flexibly to local contexts.

Framing HIQA as an intervention highlights the need to consider how regulatory practices can be optimised using implementation science principles. For example, CFIR constructs such as leadership engagement, available resources, and external policy incentives provide explanatory power for understanding compliance variability. Similarly, NPT highlights how coherence, collective action, and reflexive monitoring influence whether regulation is embedded as routine practice within services. In this way, HIQA can be developed and evaluated as a structured implementation intervention rather than solely as a compliance mechanism.

Framing HIQA as an implementation intervention highlights the need to analyse its impact across various outcome levels, moving beyond simple compliance metrics. The effectiveness of any intervention is best understood by examining its ripple effects, from the immediate adoption of new practices to the long-term benefits for the end user. This multi-level approach provides a more comprehensive picture of success.

At the most immediate level, we look at implementation outcomes. These outcomes are focused on the process of putting the intervention into practice. Key measures here include acceptability, or the perception that the intervention is agreeable and satisfactory among stakeholders, and fidelity, which assesses the degree to which the intervention is delivered as intended. For HIQA, this would involve evaluating how well its regulatory practices are accepted by service providers and whether its inspection protocols are applied consistently and accurately. In addition, feasibility—the extent to which the intervention can be successfully used within a specific setting—is critical. If HIQA's processes are too costly or burdensome, they may be less likely to be adopted. For example, a new digital reporting system might be introduced, but its success hinges on its usability and whether it integrates smoothly with existing workflows.

Moving up a level, service outcomes evaluate the direct effects on the services themselves. This includes measures like the quality of care provided, improvements

in staff training, or the implementation of evidence-based care. HIQA's intervention might lead to a service provider's adoption of better risk management strategies, a reduction in medication errors, or improved communication among staff. These outcomes directly reflect changes in the operational and structural elements of the service as a result of the regulatory influence. For instance, an inspection report might highlight a gap in infection control protocols, leading the service to implement new policies and training, thereby improving the overall safety of the environment.

Ultimately, the most important measures are the service user outcomes. These are the direct impacts on the individuals receiving care. This level of analysis focuses on what truly matters: improved health, increased satisfaction, and a better quality of life for residents using services. For example, a successful HIQA intervention could lead to improvement in residents' autonomy, living conditions and employment or educational opportunities. This level of analysis connects regulatory action directly to tangible benefits for the people the system is designed to benefit. Without considering this final layer, the true purpose and impact of the regulatory intervention is likely to be missed.

9.3.2 Implications for future research

As shown in Chapter 5, the vast majority of studies included in the systematic review examining determinants of compliance (i.e. the implementation outcome) were observational in nature. It is, therefore, difficult to draw any strong conclusions with respect to causal relationships. Throughout this thesis, there has been discussion of the importance of resources for implementation of regulations. Moreover, we have seen the role played by key individuals in the implementation effort. This is not to discount the important of organisation-level approaches to implementation, a limitation acknowledged in Chapter 7. Further research that seeks to better understand the causal mechanisms underlying successful implementation of regulations (i.e. compliance) would be useful for policy-makers, regulators and service providers.

As argued in Chapter 8, there is a pressing need to evaluate the effectiveness of regulation as an intervention to improve quality and safety in health and social care services.[50] This is no mean feat. The complexity of regulatory interventions and the

ethical and practical difficulty of performing experiments to prove its efficacy (e.g. a randomised controlled trial where one group is regulated while another is not) leads one to conclude that only observational studies or natural experiments are a possibility. There likely also needs to be an acknowledgement that no two inspectors — regardless of the level of training, coaching or supervision they receive — will arrive at the exact same conclusions when presented with identical evidence.[42] Rather, research on how this inconsistency can be minimised could be useful for regulators. In addition, as shown in Chapter 8, the role played by inspectors in the implementation effort is worthy of further research. Such an endeavour could have relevance across a wide range of regulated sectors.

As argued throughout this thesis, regulation represents an intervention that is worthy of study from an implementation science perspective. As shown in the results of the systematic review in Chapter 5 and elsewhere in this thesis, there are only a limited number of studies that have pursued this approach. Moreover, there is a dearth of qualitative inquiry with respect to how regulatory requirements are implemented and compliance achieved. As I have argued, many individual regulatory requirements are evidence-based. Therefore, it is reasonable to study them to identify strategies, structures and processes that can support successful implementation.

Further research could also make a contribution to improving the evidence base and quality of regulations and regulatory frameworks more generally.[518] A stronger evidence base for certain regulatory requirements should offer the best opportunity for optimising the care, support and outcomes of people that use health and social care services.

9.4 Strengths and limitations

A key strength of the research undertaken for this research was the novel conceptualisation of regulation as an intervention. This facilitated the application of implementation science approaches to help understand what is a complex intervention involving multiple actors. In a related point, this thesis is strengthened through the use of established theoretical frameworks such the CFIR and NPT. The individual studies in the thesis were also conducted in a rigorous and transparent

manner under the supervision of experienced academics. This was done to ensure the findings are as objective as possible and represent a true picture of the reality of the regulatory process.

Another strength lies in the reflection on implementation of regulations from both sides of the equation i.e. the regulated organisation and the regulator. This was done to ensure that equal weight and value was given to both perspectives to facilitate a critical reflection on regulation as an intervention.

As shown in Chapter 5, there is a substantial gap in the literature with respect to qualitative research on the implementation of regulations. The studies contained in this thesis make a contribution to addressing this gap and may also identify avenues for future research.

While there are differences in how nations institute regulatory frameworks, there is a broad similarity with respect to how this is done in the context of health and social care services. That is, external evaluators (inspectors) conduct inspections of facilities to gather evidence and write reports that are made publicly available. As such, I argue the findings in this thesis, while set in residential disability services in Ireland, are generalisable to similar settings in other countries. Therefore, the findings are potentially useful to regulators, service providers and policy makers more widely than Ireland.

No research is without its limitations. As has been acknowledged throughout this thesis, the author's role as a current employee of the regulator for health and social care in Ireland raises the question of bias. Moreover, the funding of the PhD research by the regulator represents another potential bias. Notwithstanding this, the regulator had no input into the study aims, designs or publication decisions. While satisfied that every measure was taken to limit bias, both personally and on the part of the PhD supervisors, the presence of bias in the results and interpretation of the findings cannot be discounted.

A further limitation is found in the data collection methods for Chapters 7 and 8, which relied on interviews and focus groups respectively. There may have been additional data sources that could have complemented these studies. For example,

direct observation of inspections of residential disability services could have allowed for certain claims to be corroborated or challenged. Direct observation of meetings between regulated organisations and senior regulator management to address matters of non-compliance may also have produced useful data. However, in both cases, there were legal and ethical barriers to conducting such fieldwork e.g. only persons authorised by the Chief Inspector of Social Services in HIQA are allowed to enter residential disability services for the purposes of inspection. Furthermore, engagement with policy makers or those responsible for introducing regulation of residential disability services in Ireland may also have provided useful insights.

While I earlier argued that the findings of this research may be generalisable to regulatory contexts outside of Ireland, there are also limits to this claim. Given that residential disability services in Ireland are funded primarily by the state and are voluntary, not-for-profit in nature, it is likely the case that the findings are not generalisable outside of this context.

9.5 Recommendations

An objective of this thesis was to formulate policy and practice changes arising out of the learning described in each of the chapters. While some of these changes have been mentioned throughout the preceding material, they are stated in this section for ease of reference.

Government/policy-makers

- Consider the adoption of a standardised process when formulating a regulatory framework. This should include a detailed regulatory impact assessment and stakeholder engagement component. Such a standardised process can lead to greater clarity on a range of important factors such as projected costs, evidence-base for regulatory requirements and preparation of regulated organisations and the regulator.

- Explore the merit in legislating for minimum inspection frequency for different types of services/organisations and then benchmarking the regulator's resources accordingly.
- Clearly delineate the scope and breadth of a regulator's reach. For example, is it appropriate that a regulator can evaluate whether a publicly-funded service has sufficient funding available to meet statutory regulations? Should a regulator have a role in regulating the commissioning practices for health and social care services?

Regulatory organisations

- Explore the options for developing or providing inspection staff with a formal education programme that equips them with the skills necessary to be an effective inspector.
- Assess compliance trends at a higher level (i.e. over time and by provider) to identify potential areas for broad-based improvement in regulated organisations.
- Identify inspector engagement strategies that take account of the characteristics of different services and organisations. For example, do some services/organisations respond better to a collaborative and educational approach from inspectors?
- Remove administrative and process barriers that impinge on inspectors' core work of assessing compliance and promoting quality improvement in regulated organisations.
- Devise means to reduce inconsistency among inspectors in so far as is practicable.

Researchers

- Explore methods to establish an evidence-base on the effectiveness of regulation as an intervention to achieve stated goals (e.g. improve quality, ensure safety)
- Identify means by which to further explore the merit in conceptualising regulation as an intervention in an implementation science context. This may include considering the views of service users, staff, funders, policy makers and regulatory organisations.

9.6 Conclusion

Although regulation is a common intervention deployed by governments to improve the quality of health and social care services, it has received relatively little attention from a research perspective. Moreover, the attention it has received has been confined to quantitative enquiry that was not necessarily concerned with how regulatory requirements are implemented. This thesis has sought to address this gap by identifying the structures, processes and strategies that regulated organisations rely on to achieve compliance and that regulators use to drive successful implementation.

While the findings outlined in this thesis paint a broadly positive picture of the effectiveness of regulation as a quality improvement intervention, implementation challenges exist. Service providers sometimes struggle to understand regulatory requirements and can be frustrated by inconsistent judgments on the part of the regulator. They are also subject to resources constraints that limit their capacity to comply. Inspectors see themselves as agents of change yet experience legislative and bureaucratic barriers that inhibit their effectiveness. Addressing these gaps and barriers has the potential to improve the lives of the people that regulation is intended to empower and protect.

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Appendices

Appendix 1 – Full list of care and support regulations in place for residential disability services in Ireland at time of publication

STATUTORY INSTRUMENTS.

S.I. No. 367 of 2013

HEALTH ACT 2007 (CARE AND SUPPORT OF RESIDENTS IN DESIGNATED CENTRES FOR PERSONS (CHILDREN AND ADULTS) WITH DISABILITIES) REGULATIONS 2013

S.I. No. 367 of 2013

HEALTH ACT 2007 (CARE AND SUPPORT OF RESIDENTS IN DESIGNATED CENTRES FOR PERSONS (CHILDREN AND ADULTS) WITH DISABILITIES) REGULATIONS 2013

I, JAMES REILLY, Minister for Health, in exercise of the powers conferred on me by sections 98 and 101 of the Health Act 2007 (No. 23 of 2007) (as adapted by the Health and Children (Alteration of Name of Department and Title of Minister) Order 2011 (S.I. No. 219 of 2011), hereby make the following regulations:

PART 1

Preliminary

Citation and commencement

1. (1) These Regulations may be cited as the Health Act 2007 (Care and Support of Residents in Designated Centres for Persons (Children and Adults) with Disabilities) Regulations 2013.

(2) These Regulations come into operation on 1 November, 2013.

Definitions

2. In these Regulations—

"abuse" means mistreatment of any kind and includes the physical, financial or material, psychological, sexual or discriminatory mistreatment or neglect of a resident;

"Act" means the Health Act 2007 (No. 23 of 2007) as amended;

"advocacy" means a process of empowerment of the person which takes many forms and includes taking action to help communicate wants, secure rights, rep- resent interests or obtain services needed;

"Authority" means the Health Information and Quality Authority;

"Certificate of Registration" means the certificate issued in respect of a designated centre by the chief inspector under the Health Act 2007 (Registration of Designated Centres for Persons (Children and Adults) with Disabilities) Regulations 2013 (S.I. No. 366 of 2013);

"chief inspector" means the Chief Inspector of Social Services as defined in section 40 of the Act;

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 1*st November,* 2013.

"child" means a person under the age of 18 years other than a person who is or has been married;

"communication" means the exchange of information between one person and another that may be written or spoken and may be facilitated through another person or by the use of aids, appliances or assistive technology;

"designated centre" means an institution to which paragraph (*a*)(ii) of the definition of "designated centre" in section 2(1) of the Act applies;

"Executive" means the Health Service Executive;

"person in charge" means the person appointed as the person in charge of a designated centre pursuant to Regulation 14 and named in the Certificate of Registration issued in respect of the designated centre;

"personal plan" means a plan prepared in accordance with Regulation 5(4);

"personal property and possessions" means the belongings, personal effects and monies that a resident brings into a designated centre and includes

(a) items purchased by or on behalf of the resident, and

(b) items and monies received by the

resident, while residing in the designated centre;

"record" means any record required to be kept or retained in accordance with Regulation 21;

"representative", in relation to a resident, means a person acting on behalf of that resident for the purpose of representing the will and preferences of the resident and may include a child's HSE Child and Family Social Worker, a carer of the resident or a person involved in promoting the health, welfare or wellbeing of the resident;

"resident" means an adult or a child being provided with residential services;

"resident's guide" means the written guide produced in accordance with Regulation 20;

"restrictive procedure" means the intentional restriction of a person's voluntary movement or behaviour;

"staff" means persons employed by the registered provider and includes persons placed in employment with the registered provider concerned by an employment agency used by that registered provider but does not include—

(a) persons who provide professional services to the designated centre and to whom the registered provider pays fees for such services, or

(b) volunteers;

"standards" means standards set by the Authority under section 8 of the Act and approved by the Minister under section 10 of the Act;

"statement of purpose" means the written statement compiled in accordance with Regulation 3.

PART 2

Maintenance, Care, Support and Well-being of Persons Resident in a Designated Centre

Statement of purpose

3. (1) The registered provider shall prepare in writing a statement of purpose containing the information set out in Schedule 1.

(2) The registered provider shall review and, where necessary, revise the statement of purpose at intervals of not less than one year.

(3) The registered provider shall make a copy of the statement of purpose available to residents and their representatives.

Written policies and procedures

4. (1) The registered provider shall prepare in writing and adopt and implement policies and procedures on the matters set out in Schedule 5.

(2) The registered provider shall make the written policies and procedures referred to in paragraph (1) available to staff.

(3) The registered provider shall review the policies and procedures referred to in paragraph (1) as often as the chief inspector may require but in any event at intervals not exceeding 3 years and, where necessary, review and update them in accordance with best practice.

Individualised assessment and personal plan

5. (1) The person in charge shall ensure that a comprehensive assessment, by an appropriate health care professional, of the health, personal and social care needs of each resident is carried out—

(a) prior to admission to the designated centre; and

(b) subsequently as required to reflect changes in need and circumstances, but no less frequently than on an annual basis.

(2) The registered provider shall ensure, insofar as is reasonably practicable, that arrangements are in place to meet the needs of each resident, as assessed in accordance with paragraph (1).

(3) The person in charge shall ensure that the designated centre is suitable for the purposes of meeting the needs of each resident, as assessed in accordance with paragraph (1).

(4) The person in charge shall, no later than 28 days after the resident is admitted to the designated centre, prepare a personal plan for the resident which—

(a) reflects the resident's needs, as assessed in accordance with para- graph (1);

(b) outlines the supports required to maximise the resident's personal development in accordance with his or her wishes; and

(c) is developed through a person centred approach with the maximum participation of each resident, and where appropriate his or her representative, in accordance with the resident's wishes, age and the nature of his or her disability.

(5) The person in charge shall make the personal plan available, in an accessible format, to the resident and, where appropriate, his or her representative.

(6) The person in charge shall ensure that the personal plan is the subject of a review, carried out annually or more frequently if there is a change in needs or circumstances, which review shall—

(a) be multidisciplinary;

(b) be conducted in a manner that ensures the maximum participation of each resident, and where appropriate his or her representative, in accordance with the resident's wishes, age and the nature of his or her disability;

(c) assess the effectiveness of the plan; and

(d) take into account changes in circumstances and new developments.

(7) The recommendations arising out of a review carried out pursuant to paragraph (6) shall be recorded and shall include—

(a) any proposed changes to the personal plan;

(b) the rationale for any such proposed changes; and

(c) the names of those responsible for pursuing objectives in the plan within agreed timescales.

(8) The person in charge shall ensure that the personal plan is amended in accordance with any changes recommended following a review carried out pursuant to paragraph (6).

Health care

6. (1) The registered provider shall provide appropriate health care for each resident, having regard to that resident's personal plan.

(2) The person in charge shall ensure that—

(a) a medical practitioner of the resident's choice or acceptable to the resident is made available to the resident;

(b) where medical treatment is recommended and agreed by the resident, such treatment is facilitated;

(c) the resident's right to refuse medical treatment shall be respected. Such refusal shall be documented and the matter brought to the attention of the resident's medical practitioner;

(d) when a resident requires services provided by allied health professionals, access to such services is provided by the registered provider or by arrangement with the Executive; and

(e) residents are supported to access appropriate health information both within the residential service and as available within the wider community.

(3) The person in charge shall ensure that residents receive support at times of illness and at the end of their lives which meets their physical, emotional, social and spiritual needs and respects their dignity, autonomy, rights and wishes.

Positive behavioural support

7. (1) The person in charge shall ensure that staff have up to date knowledge and skills, appropriate to their role, to respond to behaviour that is challenging and to support residents to manage their behaviour.

(2) The person in charge shall ensure that staff receive training in the management of behaviour that is challenging including de-escalation and intervention techniques.

(3) The registered provider shall ensure that where required, therapeutic interventions are implemented with the informed consent of each resident, or his or her representative, and are reviewed as part of the personal planning process.

(4) The registered provider shall ensure that, where restrictive procedures including physical, chemical or environmental restraint are used, such procedures are applied in accordance with national policy and evidence based practice.

(5) The person in charge shall ensure that, where a resident's behaviour necessitates intervention under this Regulation—

(a) every effort is made to identify and alleviate the cause of the resident's challenging behaviour;

(b) all alternative measures are considered before a restrictive procedure is used; and

(c) the least restrictive procedure, for the shortest duration necessary, is used.

Protection

8. (1) The registered provider shall ensure that each resident is assisted and supported to develop the knowledge, self-awareness, understanding and skills needed for self-care and protection.

(2) The registered provider shall protect residents from all forms of abuse.

(3) The person in charge shall initiate and put in place an investigation in relation to any incident, allegation or suspicion of abuse and take appropriate action where a resident is harmed or suffers abuse.

(4) Where the person in charge is the subject of an incident, allegation or suspicion of abuse, the registered provider shall investigate the matter or nominate a third party who is suitable to investigate the matter.

(5) The registered provider shall ensure that where there has been an incident, allegation or suspicion of abuse or neglect in relation to a child the requirements of national guidance for the protection and welfare of children and any relevant statutory requirements are complied with.

(6) The person in charge shall have safeguarding measures in place to ensure that staff providing personal intimate care to residents who require such assistance do so in line with the resident's personal plan and in a manner that respects the resident's dignity and bodily integrity.

(7) The person in charge shall ensure that all staff receive appropriate training in relation to safeguarding residents and the prevention, detection and response to abuse.

(8) The person in charge shall ensure that where children are resident, staff receive training in relevant government guidance for the protection and welfare of children.

Residents' rights

9. (1) The registered provider shall ensure that the designated centre is operated in a manner that respects the age, gender, sexual orientation, disability, family status, civil status, race, religious beliefs and ethnic and cultural back- ground of each resident.

(2) The registered provider shall ensure that each resident, in accordance with his or her wishes, age and the nature of his or her disability—

(a) participates in and consents, with supports where necessary, to decisions about his or her care and support;

(b) has the freedom to exercise choice and control in his or her daily life;

(c) can exercise his or her civil, political and legal rights;

(d) has access to advocacy services and information about his or her rights; and

(e) is consulted and participates in the organisation of the designated centre.

(3) The registered provider shall ensure that each resident's privacy and dignity is respected in relation to, but not limited to, his or her personal and living space, personal communications, relationships, intimate and personal care, professional consultations and personal information.

Communication

10. (1) The registered provider shall ensure that each resident is assisted and supported at all times to communicate in accordance with the residents' needs and wishes.

(2) The person in charge shall ensure that staff are aware of any particular or individual communication supports required by each resident as outlined in his or her personal plan.

(3) The registered provider shall ensure that—

(a) each resident has access to a telephone and appropriate media, such as television, radio, newspapers and internet;

(b) where required, residents are facilitated to access assistive technology and aids and appliances to promote their full capabilities; and

(c) where required residents are supported to use assistive technology and aids and appliances.

Visits

11. (1) The registered provider shall facilitate each resident to receive visitors in accordance with the resident's wishes.

(2) The person in charge shall ensure that, as far as reasonably practicable, residents are free to receive visitors without restriction, unless—

(a) in the opinion of the person in charge, a visit would pose a risk to the resident concerned or to another resident, or

(b) where the resident has requested the restriction of visits; or

(c) in the case of a child, where the family/guardian or social worker has so requested; or

(d) a Court order has required the restriction of visits.

(3) The person in charge shall ensure that having regard to the number of residents and needs of each resident:

(a) suitable communal facilities are available to receive visitors, and,

(b) a suitable private area, which is not the resident's room, is available to a resident in which to receive a visitor if required.

Personal possessions

12. (1) The person in charge shall ensure that, as far as reasonably practicable, each resident has access to and retains control of personal property and possessions and, where necessary, support is provided to manage their financial affairs.

(2) The person in charge shall ensure that, as far as reasonably practicable, residents can bring their own furniture and furnishings into the rooms they occupy.

(3) The person in charge shall ensure that—

(a) each resident uses and retains control over his or her clothes;

(b) each resident is supported to manage his or her laundry in accordance with his or her needs and wishes;

(c) where necessary, each resident's linen and clothes are laundered regularly and returned to that resident; and

(d) each resident has adequate space to store and maintain his or her clothes and personal property and possessions.

(4) The registered provider shall ensure that he or she, or any staff member, shall not pay money belonging to any resident into an account held in a financial institution unless—

(a) the consent of the person has been obtained; and

(b) the account is in the name of the resident to which the money belongs; and

(c) the account is not used by the registered provider in connection with the carrying on or management of the designated centre.

General welfare and development

13. (1) The registered provider shall provide each resident with appropriate care and support in accordance with evidence-based practice, having regard to the nature and extent of the resident's disability and assessed needs and his or her wishes.

(2) The registered provider shall provide the following for residents:

(a) access to facilities for occupation and recreation;

(b) opportunities to participate in activities in accordance with their interests, capacities and developmental needs; and

(c) supports to develop and maintain personal relationships and links with the wider community in accordance with their wishes.

(3) The registered provider shall ensure that, where children are accommodated in the designated centre, each child has—

(a) opportunities for play;

(b) age-appropriate opportunities to be alone; and

(c) opportunities to develop life skills and help preparing for adulthood.

(4) The person in charge shall ensure that—

(a) residents are supported to access opportunities for education, training and employment;

(b) where residents are in transition between services, continuity of education, training and employment is maintained;

(c) when children enter residential services their assessment includes appropriate education attainment targets; and

(d) children approaching school-leaving age are supported to participate in third level education or relevant training programmes as appropriate to their abilities and interests.

PART 3

Staff

Person in charge

14. (1) The registered provider shall appoint a person in charge of the designated centre.

(2) The post of person in charge shall be full-time and shall require the qualifications, skills and experience necessary to manage the designated centre, having regard to the size of the designated centre, the statement of purpose, and the number and needs of the residents.

(3) A person who is appointed as person in charge on or after the day which is 3 years after the day on which these Regulations come into operation shall have—

(a) a minimum of 3 years' experience in a management or supervisory role in the area of health or social care; and

(b) an appropriate qualification in health or social care management at an appropriate level.

(4) A person may be appointed as person in charge of more than one designated centre if the chief inspector is satisfied that he or she can ensure the

effective governance, operational management and administration of the designated centres concerned.

(5) The registered provider shall ensure that he or she has obtained, in respect of the person in charge, the information and documents specified in Schedule 2.

Staffing

15. (1) The registered provider shall ensure that the number, qualifications and skill mix of staff is appropriate to the number and assessed needs of the residents, the statement of purpose and the size and layout of the designated centre.

(2) The registered provider shall ensure that where nursing care is required, subject to the statement of purpose and the assessed needs of residents, it is provided.

(3) The registered provider shall ensure that residents receive continuity of care and support, particularly in circumstances where staff are employed on a less than full-time basis.

(4) The person in charge shall ensure that there is a planned and actual staff rota, showing staff on duty during the day and night and that it is properly maintained.

(5) The person in charge shall ensure that he or she has obtained in respect of all staff the information and documents specified in Schedule 2.

Training and staff development

16. (1) The person in charge shall ensure that—

(a) staff have access to appropriate training, including refresher training, as part of a continuous professional development programme;

(b) staff are appropriately supervised; and

(c) staff are informed of the Act and any regulations and standards made under it.

(2) The person in charge shall ensure that copies of the following are made available to staff:

(a) the Act and any regulations made under it;

(b) standards set by the Authority under section 8 of the Act and approved by the Minister under section 10 of the Act; and

(c) relevant guidance issued from time to time by statutory and professional bodies.

PART 4

Premises

Premisesssss

17. (1) The registered provider shall ensure the premises of the designated centre are—

(a) designed and laid out to meet the aims and objectives of the service and the number and needs of residents;

(b) of sound construction and kept in a good state of repair externally and internally; and

(c) clean and suitably decorated.

(2) The registered provider shall ensure that where the designated centre accommodates adults and children, sleeping accommodation is provided separately and decorated in an age-appropriate manner.

(3) The registered provider shall ensure that where children are accommodated in the designated centre appropriate outdoor recreational areas are provided which have age-appropriate play and recreational facilities.

(4) The registered provider shall ensure that such equipment and facilities as may be required for use by residents and staff shall be provided and maintained in good working order. Equipment and facilities shall be serviced and maintained regularly, and any repairs or replacements shall be carried out as quickly as possible so as to minimise disruption and inconvenience to residents.

(5) The registered provider shall ensure that the premises of the designated centre are equipped, where required, with assistive technology, aids and appliances to support and promote the full capabilities and independence of residents.

(6) The registered provider shall ensure that the designated centre adheres to best practice in achieving and promoting accessibility. He, or she, regularly reviews its accessibility with reference to the statement of purpose and carries out any required alterations to the premises of the designated centre to ensure it is accessible to all.

(7) The registered provider shall make provision for the matters set out in Schedule 6.

PART 5

Food and Nutrition

Food and

nutrition

18. (1) The person in charge shall, so far as reasonable and practicable, ensure that—

(a) residents are supported to buy, prepare and cook their own meals if they so wish; and

(b) there is adequate provision for residents to store food in hygienic conditions.

(2) The person in charge shall ensure that each resident is provided with adequate quantities of food and drink which—

(a) are properly and safely prepared, cooked and served;

(b) are wholesome and nutritious;

(c) offers choice at mealtimes; and

(d) are consistent with each resident's individual dietary needs and preferences.

(3) The person in charge shall ensure that where residents require assistance with eating or drinking, that there is a sufficient number of trained staff present when meals and refreshments are served to offer assistance in an appropriate manner.

(4) The person in charge shall ensure that residents have access to meals, refreshments and snacks at all reasonable times as required.

PART 6

Information and Records

Directory of residents

19. (1) The registered provider shall establish and maintain a directory of residents in the designated centre.

(2) The directory established under paragraph (1) shall be made available, when requested, to the chief inspector.

(3) The directory shall include the information specified in paragraph (3) of Schedule 3.

Information for residents

20. (1) The registered provider shall prepare a guide in respect of the designated centre and ensure that a copy is provided to each resident.

(2) The guide prepared under paragraph (1) shall include—

(a) a summary of the services and facilities provided;

(b) the terms and conditions relating to residency;

(c) arrangements for resident involvement in the running of the centre;

(d) how to access any inspection reports on the centre;

(e) the procedure respecting complaints; and

(f) arrangements for visits.

Records

21. (1) The registered provider shall ensure that—

(a) records of the information and documents in relation to staff specified in Schedule 2;

(b) records in relation to each resident as specified in Schedule 3; and

(c) the additional records specified in Schedule 4

are maintained and are available for inspection by the chief inspector.

(2) Records kept in accordance with this section and set out in Schedule 2 shall be retained for a period of not less than 7 years after the staff member has ceased to be employed in the designated centre.

(3) Records kept in accordance with this section and set out in Schedule 3 shall be retained for a period of not less than 7 years after the resident has ceased to reside in the designated centre.

(4) Records kept in accordance with this section and set out in paragraphs (6), (11), (12), (13), and (14) of Schedule 4, shall be retained for a period of not less than 4 years from the date of their making.

(5) Records kept in accordance with this section and set out in paragraphs (7), (8), (9), and (10) of Schedule 4, shall be retained for a period of not less than 7 years from the date of their making.

(6) Notwithstanding paragraphs (3) and (5) of this regulation, records related to children in care shall be kept in perpetuity and transferred to the Executive not later than 7 years from the date on which the child ceased to reside in the designated centre.

Insurance

22. (1) The registered provider shall effect a contract of insurance against injury to residents.

(2) The registered provider may insure against other risks in the designated centre, including loss or damage to property and where such insurance is effected the residents shall be advised accordingly.

PART 7

Management and Control of Operations

Governance and management

23. (1) The registered provider shall ensure that—

(a) the designated centre is resourced to ensure the effective delivery of care and support in accordance with the statement of purpose;

(b) there is a clearly defined management structure in the designated centre that identifies the lines of authority and accountability, specifies roles, and details responsibilities for all areas of service provision;

(c) management systems are in place in the designated centre to ensure that the service provided is safe, appropriate to residents' needs, consistent and effectively monitored;

(d) there is an annual review of the quality and safety of care and support in the designated centre and that such care and support is in accordance with standards;

(e) that the review referred to in subparagraph (*d*) shall provide for consultation with residents and their representatives; and

(f) that a copy of the review referred to in subparagraph (*d*) is made available to residents and, if requested, to the chief inspector.

(2) The registered provider, or a person nominated by the registered provider, shall carry out an unannounced visit to the designated centre at least once every six months or more frequently as determined by the chief inspector and shall—

(a) prepare a written report on the safety and quality of care and support provided in the centre and put a plan in place to address any concerns regarding the standard of care and support; and

(b) maintain a copy of the report made under subparagraph (*a*) and make it available on request to residents and their representatives and the chief inspector.

(3) The registered provider shall ensure that effective arrangements are in place to—

(a) support, develop and performance manage all members of the work- force to exercise their personal and professional responsibility for the quality and safety of the services that they are delivering; and

(b) facilitate staff to raise concerns about the quality and safety of the care and support provided to residents.

Admissions and contract for the provision of services

24. (1) The registered provider shall ensure that—

(a) each application for admission to the designated centre is determined on the basis of transparent criteria in accordance with the statement of purpose; and

(b) admission policies and practices take account of the need to protect residents from abuse by their peers.

(2) The person in charge shall ensure that each prospective resident and his or her family or representative are provided with an opportunity to visit the designated centre, as far as is reasonably practicable, before admission of the prospective resident to the designated centre.

(3) The registered provider shall, on admission, agree in writing with each resident, or their representative where the resident is not capable of giving con- sent, the terms on which that resident shall reside in the designated centre.

(4) The agreement referred to in paragraph (3) shall—

(a) include the support, care and welfare of the resident in the designated centre and details of the services to be provided for that resident and, where appropriate, the fees to be charged; and

(b) provide for, and be consistent with, the resident's needs as assessed in accordance with Regulation 5(1) and the statement of purpose.

Temporary absence, transition and discharge of residents

25. (1) The person in charge shall ensure that, where a resident is temporarily absent from the designated centre, relevant information about the resident is provided to the person taking responsibility for the care, support and wellbeing of the resident at the receiving designated centre, hospital or other place.

(2) When a resident returns from another designated centre, hospital or other place, the person in charge of the designated centre from which the resident was temporarily absent shall take all reasonable actions to ensure that all relevant information about the resident is obtained from the person responsible for the care, support and wellbeing of the resident at the other designated centre, hospital or other place.

(3) The person in charge shall ensure that residents receive support as they transition between residential services or leave residential services through:

(a) the provision of information on the services and supports available; and

(b) where appropriate, the provision of training in the life-skills required for the new living arrangement.

(4) The person in charge shall ensure that the discharge of a resident from the designated centre—

(a) is determined on the basis of transparent criteria in accordance with the statement of purpose;

(b) take place in a planned and safe manner;

(c) is in accordance with the resident's needs as assessed in accordance with Regulation 5(1) and the resident's personal plans;

(d) is discussed, planned for and agreed with the resident and, where appropriate, with the resident's representative; and

(e) is in accordance with the terms and conditions of the agreement referred to in Regulation 24(3).

Risk management procedures

26. (1) The registered provider shall ensure that the risk management policy, referred to in paragraph 16 of Schedule 5, includes the following:

(a) hazard identification and assessment of risks throughout the designated centre;

(b) the measures and actions in place to control the risks identified;

(c) the measures and actions in place to control the following specified risks:

(i) the unexpected absence of any resident,

(ii) accidental injury to residents, visitors or staff,

(iii) aggression and violence, and

(iv) self-harm;

(d) arrangements for the identification, recording and investigation of, and learning from, serious incidents or adverse events involving residents; and

(e) arrangements to ensure that risk control measures are proportional to the risk identified, and that any adverse impact such measures might have on the resident's quality of life have been considered.

(2) The registered provider shall ensure that there are systems in place in the designated centre for the assessment, management and ongoing review of risk, including a system for responding to emergencies.

(3) The registered provider shall ensure that all vehicles used to transport residents, where these are provided by the registered provider, are roadworthy,

regularly serviced, insured, equipped with appropriate safety equipment and driven by persons who are properly licensed and trained.

Protection against infection

27. The registered provider shall ensure that residents who may be at risk of a healthcare associated infection are protected by adopting procedures consistent with the standards for the prevention and control of healthcare associated infections published by the Authority.

Fire precautions

28. (1) The registered provider shall ensure that effective fire safety management systems are in place.

(2) The registered provider shall—

(a) take adequate precautions against the risk of fire in the designated centre, and, in that regard, provide suitable fire fighting equipment, building services, bedding and furnishings;

(b) make adequate arrangements for—

(i) maintaining of all fire equipment, means of escape, building fabric and building services,

(ii) reviewing fire precautions, and

(iii) testing fire equipment; and

(c) provide adequate means of escape, including emergency lighting.

(3) The registered provider shall make adequate arrangements for—

(a) detecting, containing and extinguishing fires;

(b) giving warning of fires;

(c) calling the fire service; and

(d) evacuating, where necessary in the event of fire, all persons in the designated centre and bringing them to safe locations.

(4) The registered provider shall—

(a) make arrangements for staff to receive suitable training in fire prevention, emergency procedures, building layout and escape routes, location of fire alarm call points and first aid fire fighting equipment, fire control techniques and arrangements for the evacuation of residents; and

(b) ensure, by means of fire safety management and fire drills at suitable intervals, that staff and, in so far as is reasonably practicable, residents, are aware of the procedure to be followed in the case of fire.

(5) The person in charge shall ensure that the procedures to be followed in the event of fire are displayed in a prominent place and/or are readily available as appropriate in the designated centre.

Medicines and pharmaceutical services

29. (1) The registered provider shall ensure that a pharmacist of the resident's choice, in so far as is practicable, or a pharmacist acceptable to the resident, is made available to each resident.

(2) The person in charge shall facilitate a pharmacist made available under paragraph (1) in meeting his or her obligations to the resident under any relevant legislation or guidance issued by the Pharmaceutical Society of Ireland. The person in charge shall provide appropriate support for the resident if required, in his/her dealings with the pharmacist.

(3) The person in charge shall ensure that, where a pharmacist provides a record of a medication-related intervention in respect of a resident, such record is kept in a safe and accessible place in the designated centre.

(4) The person in charge shall ensure that the designated centre has appropriate and suitable practices relating to the ordering, receipt, prescribing, storing, disposal and administration of medicines to ensure that—

(a) any medicine that is kept in the designated centre is stored securely;

(b) medicine which is prescribed is administered as prescribed to the resident for whom it is prescribed and to no other resident;

(c) out of date or returned medicines are stored in a secure manner that is segregated from other medicinal products, and are disposed of and not further used as medicinal products in accordance with any relevant national legislation or guidance; and

(d) storage and disposal of out of date, or unused, controlled drugs shall be in accordance with the relevant provisions in the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988), as amended.

(5) The person in charge shall ensure that following a risk assessment and assessment of capacity, each resident is encouraged to take responsibility for his or her own medication, in accordance with his or her wishes and preferences and in line with his or her age and the nature of his or her disability.

Volunteers

30. The person in charge shall ensure that volunteers with the designated centre—

(a) have their roles and responsibilities set out in writing;

(b) receive supervision and support; and

(c) provide a vetting disclosure in accordance with the National Vetting Bureau (Children and Vulnerable Persons) Act 2012 (No. 47 of 2012).

PART 8

Notification ofIncidents

Notification of incidents

31. (1) The person in charge shall give the chief inspector notice in writing within 3 working days of the following adverse incidents occurring in the designated centre:

(a) the unexpected death of any resident, including the death of any resident following transfer to hospital from the designated centre;

(b) an outbreak of any notifiable disease as identified and published by the Health Protection Surveillance Centre;

(c) any fire, any loss of power, heating or water, and any incident where an unplanned evacuation of the centre took place;

(d) any serious injury to a resident which requires immediate medical or hospital treatment;

(e) any unexplained absence of a resident from the designated centre;

(f) any allegation, suspected or confirmed, of abuse of any resident;

(g) any allegation of misconduct by the registered provider or by staff; and

(h) any occasion where the registered provider becomes aware that a member of staff is the subject of review by a professional body;

(2) In the case of an unexpected death notified to the chief inspector pursuant to paragraph (1)(*a*) the person in charge shall also ensure that written notice is provided to the chief inspector setting out the cause of the death when same has been established.

(3) The person in charge shall ensure that a written report is provided to the chief inspector at the end of each quarter of each calendar year in relation to and of the following incidents occurring in the designated centre:

(a) any occasion on which a restrictive procedure including physical, chemical or environmental restraint was used;

(b) any occasion on which the fire alarm equipment was operated other than for the purpose of fire practice, drill or test of equipment;

(c) where there is a recurring pattern of theft or burglary;

(d) any injury to a resident not required to be notified under paragraph (1)(*d*);

(e) any deaths, including cause of death, not required to be notified under paragraph (1)(*a*); and

(f) any other adverse incident the chief inspector may prescribe.

(4) Where no incidents which require to be notified under (1), (2) or (3) have taken place, the registered provider shall notify the chief inspector of this fact on a six monthly basis.

(5) This regulation is without prejudice to the reporting requirements as set out in the Authority's Guidance for the Health Service Executive for the Review of Serious Incidents including Deaths of Children in Care and any other relevant guidance.

PART 9

Notification of Absence of Person in Charge and Procedures and Arrangements for such Absence

Notification of periods when person in charge is absent

32. (1) Where the person in charge proposes to be absent from the designated centre for a continuous period of 28 days or more, the registered provider shall give notice in writing to the chief inspector of the proposed absence.

(2) Except in the case of an emergency, the notice referred to in paragraph (1) shall be given no later than one month before the proposed absence commences or within such shorter period as may be agreed with the chief inspector and the notice shall specify—

(a) the length or expected length of the absence; and

(b) the expected dates of departure and return.

(3) Where the person in charge is absent from the designated centre as a result of an emergency or unanticipated event, the registered provider shall, as soon as it becomes apparent that the absence concerned will be for a period of 28 days or more, give notice in writing to the chief inspector of the absence, including the information referred to in paragraph (2).

(4) Where an absence referred to in paragraph (3) has occurred, the registered provider shall notify the chief inspector of the return to duty of the person in charge not later than 3 working days after the date of his or her return.

Notification of procedures and arrangements for periods when person in charge is absent

33. (1) Where the registered provider gives notice of the absence of the person in charge from the designated centre under Regulation 32, he or she shall give notice in writing to the chief inspector of the procedures and arrangements that will be in place for the management of the designated centre during the said absence.

(2) The notice referred to in paragraph (1) shall specify—

(a) the arrangements which have been or were made for the running of the designated centre during the absence of the person in charge;

(b) the arrangements that have been, or are proposed to be, made for appointing another person in charge to manage the designated centre during that absence, including the proposed date by which the appointment is to be made; and

(c) the name, contact details and qualifications of the person who was or will be responsible for the designated centre during the absence.

PART 10

Complaints Procedures

Complaints procedure

34. (1) The registered provider shall provide an effective complaints procedure for residents which is in an accessible and age-appropriate format and includes an appeals procedure, and shall—

(a) ensure that the procedure is appropriate to the needs of residents in line with each resident's age and the nature of his or her disability;

(b) make each resident and their family aware of the complaints procedure as soon as is practicable after admission;

(c) ensure the resident has access to advocacy services for the purposes of making a complaint; and

(d) display a copy of the complaints procedure in a prominent position in the designated centre.

(2) The registered provider shall ensure that—

(a) a person who is not involved in the matters the subject of complaint is nominated to deal with complaints by or on behalf of residents;

(b) all complaints are investigated promptly;

(c) complainants are assisted to understand the complaints procedure;

(d) the complainant is informed promptly of the outcome of his or her complaint and details of the appeals process;

(e) any measures required for improvement in response to a complaint are put in place; and

(f) the nominated person maintains a record of all complaints including details of any investigation into a complaint, outcome of a complaint,

any action taken on foot of a complaint and whether or not the resident was satisfied.

(3) The registered provider shall nominate a person, other than the person nominated in paragraph 2(*a*), to be available to residents to ensure that:

(a) all complaints are appropriately responded to; and

(b) the person nominated under paragraph (2)(*a*) maintains the records specified under paragraph (2)(*f*).

(4) The registered provider shall ensure that any resident who has made a complaint is not adversely affected by reason of the complaint having been made.

SCHEDULE 1

Information to be Included in the Statement of Purpose

Registration details

1. The information set out in the Certificate of Registration.

Services and facilities provided in the designated centre

2. Information regarding the following:

   (a) the specific care and support needs that the designated centre is intended to meet;

   (b) the facilities which are to be provided by the registered provider to meet those care and support needs;

   (c) the services which are to be provided by the registered provider to meet those care and support needs; and

   (d) criteria used for admission to the designated centre, including the designated centre's policy and procedures (if any) for emergency admissions.

3. The number, age range and gender of the residents for whom it is intended that accommodation should be provided.

4. A description (either in narrative form or a floor plan) of the rooms in the designated centre including their size and primary function.

5. Any separate facilities for day care.

Management and staffing

6. The total staffing complement, in full-time equivalents, for the designated centre with the management and staffing complements as required in Regulations 14 and 15.

7. The organisational structure of the designated centre.

Residents' wellbeing and safety

8. The arrangements made for dealing with reviews and development of a resident's personal plan.

9. Details of any specific therapeutic techniques used in the designated centre and arrangements made for their supervision.

10. The arrangements made for respecting the privacy and dignity of residents.

11. The arrangements for residents to engage in social activities, hobbies and leisure interests.

12. The arrangements for residents to access education, training and employment.

13. The arrangements made for consultation with, and participation of, residents in the operation of the designated centre.

14. The arrangements made for residents to attend religious services of their choice.

15. The arrangements made for contact between residents and their relatives, friends, representatives and the local community. These arrangements also include contact between a child in care and his/her HSE Child and Family Social Worker.

16. The arrangements made for dealing with complaints.

17. The fire precautions and associated emergency procedures in the designated centre.

Regulations 14, 15, 21

SCHEDULE 2

Information and Documents to be Obtained in respect of Staff, Currently and Previously Employed at the Designated Centre

1. A record of all persons, currently and previously, employed at the designated centre, including in respect of each person so employed:

   a) full name, address and date of birth of each person;

   b) evidence of the person's identity, including a recent photograph;

   c) the dates on which he or she commenced and ceased employment (if relevant);

   d) a vetting disclosure in accordance with the National Vetting Bureau (Children and Vulnerable Persons) Act 2012;

   e) details and documentary evidence of any relevant qualifications or accredited training of the person;

   f) relevant current registration status with professional bodies in respect of nursing and other health and social care professionals employed in the designated centre;

   g) a full employment history, together with a satisfactory history of any gaps in employment;

   h) details of any previous experience (if any) of carrying on the business of a designated centre;

   i) two written references including a reference from a person's most recent employer (if any). Where a format has been specified by the chief inspector the references should be in that format;

   j) the position the person holds, or held, at the designated centre, the work the person performs/performed and the number of hours the person the person is or was employed each week; and

   k) correspondence, reports, records of disciplinary action and any other records in relation to his or her employment.

SCHEDULE 3

Records to be Kept in Designated Centre in respect of Each Resident

1. The assessment of the resident's need under Regulation 5(1) and his or her personal plan.

2. A recent photograph of the resident.

3. A record of the following matters in respect of each resident in the directory of residents established under Regulation 19(1):

   (a) the name, address, date of birth, sex, and marital status of the resident;

   (b) the name, address and telephone number of the resident's next of kin or representative;

   (c) the name, address and telephone number of the resident's general practitioner and of any officer of the Executive whose duty it is to supervise the welfare of the resident;

   (d) the date on which the resident first came to reside in the designated centre;

   (e) the name and address of any authority, organisation or other body, which arranged the resident's admission to the designated centre;

   (f) the medical, nursing and psychiatric (where appropriate) condition of the resident at the time of admission;

   (g) all nursing or medical care provided to the resident, including a record of the resident's condition and any treatment or other intervention.

   (h) where residents have not chosen to take personal responsibility for his/her own medication, each drug and medicine administered to the resident, giving the date of the prescription, the dosage, the name of the drug or medicine, the method of administration, signed and dated by a medical practitioner or the nurse or staff member administering the drug or medicine in accordance with any relevant professional guidelines;

   (i) any decision by the resident not to receive certain medical treatments and a record of any occasion where the resident refused treatment;

   (j) on-going medical assessment, treatment and care provided by the resident's medical practitioner where that information is available;

   (k) any medication errors or adverse reactions in relation to the resident;

   (l) all referrals and follow-up appointments in respect of the resident;

(m) any occasion on which restrictive procedures, including physical, chemical or environmental restraint, were used in respect of the resident, the reason for its use, the interventions tried to manage the behaviour, the nature of the restrictive procedure and its duration;

(n) any incident in the designated centre in which the resident suffers abuse or harm, including the nature, date and time of the incident, whether medical treatment was required, the names of the persons who were respectively in charge of the designated centre and supervising the resident and the names and contact details of any witnesses;

(o) details of any specialist communication needs and methods of communication that may be appropriate in respect of the resident;

(p) all money or other valuables deposited by the resident for safekeeping or received on the resident's behalf, including—

(i) the date on which the money or valuables were deposited or received, the date on which any money or valuables were returned to the resident or used, at the request of the resident, on his or her behalf; and

(ii) a written acknowledgement of the return of the money or valuables; and

(q) a record of furniture brought by the resident into the room occupied by him or her.

4. A copy of correspondence to or from the designated centre relating to each resident.

Regulation 21

SCHEDULE 4

Other Records to be Kept in respect of the Designated Centre

General Records

1. A copy of the current statement of purpose.

2. A copy of the current resident's guide.

3. A copy of all inspection reports.

Charges

4. A record of the designated centre's charges to residents, including any extra amounts payable for additional services not covered by those charges, and the amounts paid by or in respect of each resident.

Food

5. Where the registered provider provides food, records of the food provided for residents in sufficient detail to enable any person inspecting the record to determine whether the diet is satisfactory, in relation to nutrition and other- wise, and of any special diets prepared for individual residents.

Complaints

6. A record of all complaints made by residents or representatives or relatives of residents or by persons working at the designated centre about the operation of the designated centre, and the action taken by the registered provider in respect of any such complaint.

Residents

7. If the resident was discharged from the designated centre, the date on which he or she was discharged.

8. If the resident was transferred to another designated centre or to a hospital, the name of the designated centre or hospital and the date on which the resident was transferred.

9. Any dates during which the resident was not residing at the centre.

Notifications under Regulation 31

10. A record of any of the following incidents occurring in the designated centre:

    (a) the death of any resident, including the death of any resident following transfer to hospital from the designated centre and the date, time,

circumstances and medical cause of death when established;

(b) an outbreak of any notifiable disease as identified and published by the Health Protection Surveillance Centre.

(c) any serious injury to a resident which requires hospital treatment;

(d) any unexplained absence of a resident from the designated centre;

(e) any allegation, suspected or confirmed of abuse of any resident;

(f) any allegation of misconduct by the registered provider or any person who works in the designated centre;

(g) any occasion where the registered provider became aware that a member of staff is the subject of review by a professional body;

(h) any occasion on which a restrictive procedure including physical, chemical or environmental restraint was used;

(i) any fire, or loss of power, heating or water;

(j) any incident where an unplanned evacuation of the designated centre took place;

(k) any occasion on which the fire alarm equipment was operated other than for the purpose of fire practice, drill or test of equipment;

(l) a recurring pattern of theft or burglary; and

(m) any other adverse incident, as directed by the chief inspector.

11. A copy of the duty roster of persons working at the designated centre, and a record of whether the roster was actually worked.

12. A record of attendance at staff training and development

Fire Safety

13. A record of each fire practice, drill or test of fire equipment (including fire alarm equipment) conducted in the designated centre and of any action taken to remedy any defects found in the fire equipment.

14. A record of the number, type and maintenance record of fire-fighting equipment.

Regulation 4

SCHEDULE 5

Policies and Procedures to be Maintained in Respect of the Designated Centre

1. The prevention, detection and response to abuse, including reporting of concerns and/or allegations of abuse to statutory agencies.

2. Admissions, including transfers, discharge and the temporary absence of residents.

3. Incidents where a resident goes missing.

4. Provision of personal intimate care.

5. Provision of behavioural support.

6. The use of restrictive procedures and physical, chemical and environmental restraint.

7. Residents' personal property, personal finances and possessions.

8. Communication with residents.

9. Visitors.

10. Recruitment, selection and Garda vetting of staff.

11. Staff training and development.

12. Monitoring and documentation of nutritional intake.

13. Provision of information to residents.

14. The creation of, access to, retention of, maintenance of and destruction of records.

15. Health and safety, including food safety, of residents, staff and visitors.

16. Risk management and emergency planning.

17. Medication management.

18. The handling and investigation of complaints from any person about any aspects of service, care, support and treatment provided in, or on behalf of a designated centre.

19. Education policy which complies with relevant legislation in respect of the education needs of children with disabilities (in centres where children reside).

20. Access to education, training and development.

21. CCTV (in designated centres where CCTV systems are in use).

Regulation 17

SCHEDULE 6

Matters to be Provided for in Premises of Designated Centre

1. Adequate private and communal accommodation for residents, including adequate social, recreational, dining and private accommodation.

2. Rooms of a suitable size and layout suitable for the needs of residents.

3. Adequate space and suitable storage facilities, insofar as is reasonably practicable, for the personal use of residents.

4. Communal space for residents suitable for social, cultural and religious activities appropriate to the circumstances of residents.

5. Suitable storage.

6. Ventilation, heating and lighting suitable for residents in all parts of the designated centre which are used by residents.

7. A separate kitchen area with suitable and sufficient cooking facilities, kitchen equipment and tableware.

8. Baths, showers and toilets of a sufficient number and standard suitable to meet the needs of residents.

9. Suitable arrangements for the safe disposal of general and clinical waste where required.

10. Adequate facilities, insofar as is reasonably practicable, for residents to launder their own clothes if they so wish.

L.S.

GIVEN under my Official Seal, 29 October 2013.

JAMES REILLY,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations set down requirements in relation to the maintenance, care, support, and well being of residents, the staff employed at such centres, the premises of such centres, the food served to residents, the information and records to be kept, the management and control of operations, the notification of incidents and complaints.

These Regulations are made under sections 98 and 101 of the Health Act 2007.

These Regulations may be cited as the Health Act 2007 (Care and Support of Residents in Designated Centres for Persons (Children and Adults) with Disabilities) Regulations 2013.

BAILE ÁTHA CLIATH

ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR

Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,

52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2
(Teil: 01 - 6476834 nó 1890 213434; Fax: 01 - 6476843)

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Appendix 2 – Data extraction table for systematic review

General	Researcher	
	Date of extraction	
	Record number	
	Author(s)	
	Title	
	Citation	
	Publication type	
	Country of origin	
	Year of publication	
Study characteristics	Aim/objectives	
	Study design	
	Unit of analysis	
	Inclusion/exclusion criteria	
	Intervention	
CFIR Domains and Constructs		
I. INTERVENTION CHARACTERISTICS		
A	Intervention Source	
B	Evidence Strength & Quality	
C	Relative Advantage	
D	Adaptability	
E	Trialability	
F	Complexity	
G	Design Quality & Packaging	
H	Cost	

II. OUTER SETTING		
A	Needs & Resources of Those Served by the Organization	
B	Cosmopolitanism	
C	Peer Pressure	
D	External Policy & Incentives	
III. INNER SETTING		
A	Structural Characteristics	
B	Networks & Communications	
C	Culture	
D	Implementation Climate	
1	Tension for Change	
2	Compatibility	
3	Relative Priority	
4	Organizational Incentives & Rewards	
5	Goals & Feedback	
6	Learning Climate	
E	Readiness for Implementation	
1	Leadership Engagement	
2	Available Resources	
3	Access to Knowledge & Information	
IV. CHARACTERISTICS OF INDIVIDUALS		
A	Knowledge & Beliefs about the Innovation	
B	Self-efficacy	
C	Individual Stage of Change	
D	Individual Identification with Organization	

E	Other Personal Attributes	
V. PROCESS		
A	Planning	
B	Engaging	
1	Opinion Leaders	
2	Formally Appointed Internal Implementation Leaders	
3	Champions	
4	External Change Agents	
5	Key Stakeholders	
6	Innovation Participants	
C	Executing	
D	Reflecting & Evaluating	

Appendix 3 – Search terms used on electronic databases

Context	"healthcare system*" OR "health care system*" OR "care system*" OR "social care" OR "healthcare service*" OR "health care service*" OR "social care service*" OR "hospital*" OR "health care setting*" OR "healthcare setting*" OR "social care setting" OR "residential facilit*" OR "care facility*" OR "nursing home*" OR "residential care" OR "long-term care" OR "long term care" OR "disabilit*" OR "disability service" OR "care home" OR "aged care" OR "aged-care" OR "mental health service" OR "mental health centre" OR "mental health facilit*" OR "psychiatric service" OR "psychiatric centre" OR "psychiatric facilit*" OR "addiction service" OR "addiction centre" OR "addiction facilit*" OR "drug-treatment centre" OR "drug-treatment service" OR "drug-treatment facilit*" OR "drug treatment centre" OR "drug treatment service" OR "drug-treatment facilit*" OR "homecare" OR "home care" OR "domiciliary" OR "primary care" OR "community care" OR "respite care" OR "specialist care" OR "live-in care" OR "live in care" OR "homeless service*" OR "homeless shelter*"
Intervention	"regulation" OR "regulator*" OR "inspect*" OR "enforcement" OR "licens*" OR "certification" OR "withdrawal" OR "accredit*"
Mechanisms	"factor*" OR "barrier*" OR "facilitator*" OR "enabler*" OR "determinant*" OR "characteristic*" OR "indicator*" OR "association*" OR "relationship*" OR "cause*" OR "engagement" OR "attitude*" OR "predictor*"
Outcome	"compliance" OR "non-compliance" OR "violat*" OR "deficienc*" OR "sanction*" OR "citation*" OR "failure*" OR "failing*"

Appendix 4 – PRISMA 2020 checklist from systematic review in Chapter 5

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	94
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	14
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	92-94
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	94-98
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	100-111
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	112-116
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	113
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	121-122
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	124-137
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	107-109
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	104-108
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	150-155
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	126-137
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	139-148
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	143-145
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	226-228

Section and Topic	Item #	Checklist item	Location where item is reported
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	143-147
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	n/a
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	n/a
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	n/a
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	n/a
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	175-208
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	210-211
Study characteristics	17	Cite each included study and present its characteristics.	164-165
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	214
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	n/a
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	n/a
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	229-674
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	n/a
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	n/a
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	n/a
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	n/a
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	703-772
	23b	Discuss any limitations of the evidence included in the review.	882-885
	23c	Discuss any limitations of the review processes used.	886-896
	23d	Discuss implications of the results for practice, policy, and future research.	861-874
OTHER INFORMATION			

Section and Topic	Item #	Checklist item	Location where item is reported
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	110
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	110
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	116-117
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	922-925
Competing interests	26	Declare any competing interests of review authors.	927-929
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	931

Appendix 5 – List of included studies in systematic review in Chapter 5

Title	Authors	Year	Country	Type	Publication name	Setting
A longitudinal study of the relationship between nurse staffing and quality of care in nursing homes	Kim, H.	2006	USA	Thesis	n/a	Nursing Homes
A national-level analysis of the relationship between nursing home satisfaction and quality	Nadash, P. et al	2019	USA	Journal Article	Research on Aging	Nursing Homes
A panel data analysis of the relationships of nursing home staffing levels and standards to regulatory deficiencies	Hongsoo, K. et al	2009	USA	Journal Article	The Journals of Gerontology Series B: Psychological Sciences and Social Sciences	Nursing Homes
A report of information technology and health deficiencies in U.S. nursing homes	Alexander, G. L.; Madsen, R. W.	2017	USA	Journal Article	Journal of Patient Safety	Nursing Homes
Abuse and neglect in nursing homes: The role of serious mental illness	Jester, D. J. et al	2022	USA	Journal Article	The Gerontologist	Nursing Homes
Administrative deficiency citations and quality of care in nursing homes	Castle, N. G.; Longest, B. B.	2006	USA	Journal Article	Health Services Management Research	Nursing Homes
Administrator turnover and quality of care in nursing homes	Castle, N. G.	2001	USA	Journal Article	The Gerontologist	Nursing Homes
An examination of special focus facility nursing homes	Castle, N. G.; Engberg, J. B.	2010	USA	Journal Article	The Gerontologist	Nursing Homes
An examination of strategic group membership and technology in the nursing home industry	Laberge, A.	2009	USA	Thesis	n/a	Nursing Homes
An exploratory study of boarding home sanctions and compliance in Washington State	Graf Schaffner, M. L.	2011	USA	Journal Article	Nursing Outlook	Nursing/Care Homes

Analysis of the relationships between nursing home administrator's types of learning and nursing home effectiveness	Loescher, S. C.	1994	USA	Thesis	n/a	Nursing Homes
Analyzing the effect of complaints, investigation of allegations, and deficiency citations on the quality of care in united states nursing homes (2007 – 2012)	Hansen, K. E.	2015	USA	Thesis	n/a	Nursing Homes
Are nursing home survey deficiencies higher in facilities with greater staff turnover	Lerner, N. B. et al	2014	USA	Journal Article	Journal of the American Medical Directors Association	Nursing Homes
Are patients with serious mental illness more likely to be admitted to nursing homes with more deficiencies in care?	Li, Y. et al	2011	USA	Journal Article	Medical Care	Nursing Homes
Association between nursing home staff turnover and infection control citations	Loomer, L. et al	2022	USA	Journal Article	Health Services Research	Nursing Homes
Building policy and service theory from nursing home inspection results: Qualitative Comparative Analysis	Bell, E. et al	2013	USA	Journal Article	International Journal on Disability and Human Development	Nursing Homes
Care deficiencies and super-organization of American nursing homes in hospital referral region	Pittman, T.	2020	USA	Journal Article	Frontiers in Public Health	Nursing Homes
Characteristics of community nursing homes serving per diem veterans, 1999 to 2002	Johnson, C. E. et al	2007	USA	Journal Article	Medical Care Research and Review	Nursing Homes
Citations and compliance with the Nursing Home Reform Act of 1987	Castle, N. G.	2001	USA	Journal Article	Journal of Health & Social Policy	Nursing Homes
Civil money penalty enforcement actions for quality deficiencies in nursing homes	Wang, X. et al	2020	USA	Journal Article	The Gerontologist	Nursing Homes

CMS mega-rule update and the status of pharmacy-related deficiencies in nursing homes	Wesson, K. W.	2020	USA	Journal Article	Journal of Applied Gerontology	Nursing Homes
Community presence and nursing home quality of care: the ombudsman as a complementary role	Cherry, R. L.	1993	USA	Journal Article	Journal of Health and Social Behavior	Nursing Homes
Comparing public quality ratings for accredited and nonaccredited nursing homes	Williams, S. C. et al	2017	USA	Journal Article	Journal of the American Medical Directors Association	Nursing Homes
Comparing quality of care in non-profit and for-profit nursing homes: a process perspective	Chesteen, S. et al	2005	USA	Journal Article	Journal of Operations Management	Nursing Homes
Correlation between administrator turnover and survey results	Christensen, C.; Beaver, S.	1996	USA	Journal Article	The Journal of Long Term Care Administration	Nursing Homes
Cost-effective adjustments to nursing home staffing to improve quality	Bowblis, J. R.; Roberts, A. R.	2020	USA	Journal Article	Medical Care Research and Review	Nursing Homes
Criminological theories and regulatory compliance	Makkai, T.; Braithwaite, J.	1991	Australia	Journal Article	Criminology	Nursing Homes
Cross-subsidization in nursing homes: Explaining rate differentials among payer types	Troyer, J. L.	2002	USA	Journal Article	Southern Economic Journal	Nursing Homes
Culture change and nursing home quality of care	Grabowski, D. C. et al	2014	USA	Journal Article	The Gerontologist	Nursing Homes
Deficiency citations for physical restraint use in nursing homes	Castle, N. G.	2000	USA	Journal Article	The Journals of Gerontology Series B: Psychological Sciences and Social Sciences	Nursing Homes

Determinants of non-prescription antibiotic dispensing in Chinese community pharmacies from socio-ecological and health system perspectives	Wang, X. et al	2020	China	Journal Article	Social Science & Medicine	Pharmacies
Dietary service staffing impact nutritional quality in nursing homes	Smith, K. M. et al	2019	USA	Journal Article	Journal of Applied Gerontology	Nursing Homes
Disentangling quality and safety indicator data: a longitudinal, comparative study of hand hygiene compliance and accreditation outcomes in 96 Australian hospitals	Mumford, V. et al	2014	Australia	Journal Article	BMJ Open	Hospitals
Do corporate chains affect quality of care in nursing homes? The role of corporate standardization	Kamimura, A. et al	2007	USA	Journal Article	Health Care Management Review	Nursing Homes
Do high rates of OSCAR deficiencies prompt improved nursing facility processes and outcomes?	Klopfenstein, K. et al	2011	USA	Journal Article	Journal of Aging & Social Policy	Nursing Homes
Do mandatory overtime laws improve quality? Staffing decisions and operational flexibility of nursing homes	Lu, S. F.; Lu, L. X.	2017	USA	Journal Article	Management Science	Nursing Homes
Do recipients of an association-sponsored quality award program experience better quality outcomes compared with other nursing facilities across the United States?	Castle, N. G. et al	2018	USA	Journal Article	Journal of Applied Gerontology	Nursing Homes
Does competition improve service quality? The case of nursing homes where public and private payers coexist	Lu, S. F. et al	2021	USA	Journal Article	Management Science	Nursing Homes
Does investor ownership of nursing homes compromise the quality of care?	Harrington, C. et al	2001	USA	Journal Article	American Journal of Public Health	Nursing Homes
Does litigation increase or decrease health care quality?: a national study of negligence claims against nursing homes	Stevenson, D. G. et al	2013	USA	Journal Article	Medical Care	Nursing Homes

Does the public sector outperform the nonprofit and for-profit sectors? Evidence from a national panel study on nursing home quality and access	Amirkhanyan, A. A. et al	2008	USA	Journal Article	Journal of Policy Analysis and Management: The Journal of the Association for Public Policy Analysis and Management	Nursing Homes
Effects of Medicare payment changes on nursing home staffing and deficiencies	Konetzka, R. T. et al	2004	USA	Journal Article	Health Services Research	Nursing Homes
Effects of nursing practice environments on quality outcomes in nursing homes	Flynn, L. et al	2010	USA	Journal Article	Journal of the American Geriatrics Society	Nursing Homes
Effects of state minimum staffing standards on nursing home staffing and quality of care	Park, J.; Stearns, S. C.	2009	USA	Journal Article	Health Services Research	Nursing Homes
Elderly Hispanics more likely to reside in poor-quality nursing homes	Fennell, M. L. et al	2010	USA	Journal Article	Health Affairs	Nursing Homes
Excess demand, the percentage of Medicaid patients, and the quality of nursing home care	Nyman, J. A.	1988	USA	Journal Article	Journal of Human Resources	Nursing Homes
Exploring the challenges non-clinical departments encounter during eden alternative implementation	George, K.	2019	USA	Thesis	n/a	Nursing Homes
Exploring the influence of the regulatory survey process on nursing home administrator job satisfaction and job seeking	Holecek, T. et al	2010	USA	Journal Article	Journal of Applied Gerontology	Nursing Homes
Factors affecting compliance with national accreditation essential safety standards in the Kingdom of Saudi Arabia	Althumairi, A. et al	2022	Saudi Arabia	Journal Article	Scientific Reports	Hospitals
Factors that influence an administrator's perception of what they consider important in job knowledge and how those perceptions impact quality of care	Fabbri, M. A.	2006	USA	Thesis	n/a	Nursing Homes

Failing the metric but saving lives: The protocolization of sepsis treatment through quality measurement	Winslow, R.	2020	USA	Journal Article	Social Science & Medicine	Hospitals
Government regulation and the quality of healthcare - Evidence from minimum staffing legislation for nursing homes	Matsudaira, J. D.	2014	USA	Journal Article	Journal of Human Resources	Nursing Homes
Hand hygiene deficiency citations in nursing homes	Castle, N. G. et al	2014	USA	Journal Article	Journal of Applied Gerontology	Nursing Homes
Hidden owners, hidden profits, and poor nursing home care	Harrington, C. et al	2015	USA	Journal Article	International Journal of Health Services	Nursing Homes
High-performing and low-performing nursing homes: a view from complexity science	Forbes-Thompson, S. et al	2007	USA	Journal Article	Health Care Management Review	Nursing Homes
Hospital characteristics associated with penalties in the centers for Medicare & Medicaid Services Hospital-Acquired Condition Reduction Program	Rajaram, R. et al	2015	USA	Journal Article	Journal of the American Medical Association	Hospitals
Impact of voluntary accreditation on deficiency citations in U.S. nursing homes	Wagner, L. M. et al	2012	USA	Journal Article	The Gerontologist	Nursing Homes
Implementation of an emergency power rule: Compliance of Florida nursing homes and assisted living facilities	June J. W. et al	2022	USA	Journal Article	Disaster Medicine and Public Health Preparedness	Nursing Home/Assisted-Living Facilities
Infection control citations in nursing homes: Compliance and geographic variability	Jester, D. J. et al	2021	USA	Journal Article	Journal of the American Medical Directors Association	Nursing Homes
Infection prevention and control programs in US nursing homes: results of a national survey	Herzig, C. T. et al	2016	USA	Journal Article	Journal of the American Medical Directors Association	Nursing Homes

Influence of administrator and facility characteristics on nursing home performance	Singh, D. A.	1994	USA	Thesis	n/a	Nursing Homes
Institutional form and the nursing home industry: Ownership effects on costs and quality	Holmes, J. S.	1992	USA	Thesis	n/a	Nursing Homes
Intended and unintended consequences of minimum staffing standards for nursing homes	Chen, M. M.; Grabowski, D. C.	2015	USA	Journal Article	Health Economics	Nursing Homes
Iowa nursing home characteristics associated with reported abuse	Jogerst, G. J. et al	2006	USA	Journal Article	Journal of the American Medical Directors Association	Nursing Homes
Is nurse aide retention associated with nursing home quality?	Kennedy, K. A.	2021	USA	Thesis	n/a	Nursing Homes
Is the quality of nursing homes countercyclical? Evidence from 2001 through 2015	Huang, S. S.; Bowblis, J. R.	2019	USA	Journal Article	The Gerontologist	Nursing Homes
Joint commission accreditation and quality measures in US nursing homes	Wagner, L. M. et al	2012	USA	Journal Article	Policy, Politics, & Nursing Practice	Nursing Homes
Long-term care standards: enforcement and compliance	Christianson, J. B.	1979	USA	Journal Article	Journal of Health Politics, Policy and Law	Nursing Homes
Medicare's prospective payment system for skilled nursing facilities: Effects on staffing and quality of care	White, C.	2005	USA	Journal Article	INQUIRY: The Journal of Health Care Organization, Provision, and Financing	Nursing Homes
Mental health care deficiency citations in nursing homes and caregiver staffing	Castle, N. G.; Myers, S.	2006	USA	Journal Article	Administration and Policy in Mental Health and Mental Health Services Research	Nursing Homes

Nurse aide retention in nursing homes	Castle, N. G. et al	2020	USA	Journal Article	The Gerontologist	Nursing Homes
Nurse staffing and deficiencies in the largest for-profit nursing home chains and chains owned by private equity companies	Harrington, C. et al	2012	USA	Journal Article	Health Services Research	Nursing Homes
Nurse staffing and deficiency of care for inappropriate psychotropic medication use in nursing home residents with dementia	Yoon, J. M. et al	2022	USA	Journal Article	Journal of Nursing Scholarship	Nursing Homes
Nurse staffing and quality of care in nursing facilities	Johnson-Pawlson, J.; Infeld, D. L.	1996	USA	Journal Article	Journal of Gerontological Nursing	Nursing Homes
Nurse staffing levels and quality of care in Northeastern Pennsylvania nursing homes	Akinci, F.; Krolikowski, D.	2005	USA	Journal Article	Applied Nursing Research	Nursing Homes
Nursing home administrator turnover and quality of care: A quantitative study	Harvey, D.	2014	USA	Thesis	n/a	Nursing Homes
Nursing home deficiencies: An exploratory study of interstate variations in regulatory activity	Kelly, C. M. et al	2008	USA	Journal Article	Journal of Aging & Social Policy	Nursing Homes
Nursing home deficiency citations for abuse	Castle, N. G.	2011	USA	Journal Article	Journal of Applied Gerontology	Nursing Homes
Nursing home deficiency citations for infection control	Castle, N. G. et al	2011	USA	Journal Article	American Journal of Infection Control	Nursing Homes
Nursing home deficiency citations for medication use	Castle, N. G.; Engberg, J. B.	2007	USA	Journal Article	Journal of Applied Gerontology	Nursing Homes
Nursing home deficiency citations for physical restraints and restrictive side rails	Wagner, L. M. et al	2008	USA	Journal Article	Western Journal of Nursing Research	Nursing Homes
Nursing home deficiency citations for safety	Castle, N. G. et al	2010	USA	Journal Article	Journal of Aging & Social Policy	Nursing Homes

Nursing home director of nursing leadership style and director of nursing-sensitive survey deficiencies	McKinney, S. H. et al	2016	USA	Journal Article	Health Care Management Review	Nursing Homes
Nursing home environment and organizational performance: Association with deficiency citations	Temkin-Greener, H. et al	2010	USA	Journal Article	Medical Care	Nursing Homes
Nursing home infection control program characteristics, CMS citations, and implementation of antibiotic stewardship policies: A national study	Stone, P. W. et al	2018	USA	Journal Article	INQUIRY: The Journal of Health Care Organization, Provision, and Financing	Nursing Homes
Nursing home profit margins and citations for infection prevention and control	Sharma, H.; Xu, L.	2021	USA	Journal Article	Journal of the American Medical Directors Association	Nursing Homes
Nursing home quality and financial performance: Does the racial composition of residents matter?	Chisholm, L. et al	2013	USA	Journal Article	Health Services Research	Nursing Homes
Nursing home quality and financial performance: Is there a business case for quality?	Weech-Maldonado, R. et al	2019	USA	Journal Article	INQUIRY: The Journal of Health Care Organization, Provision, and Financing	Nursing Homes
Nursing home safety: does financial performance matter?	Oetjen, R. M. et al	2011	USA	Journal Article	Journal of Health Care Finance	Nursing Homes
Nursing home staffing and its relationship to deficiencies	Harrington, C. et al	2000	USA	Journal Article	The Journals of Gerontology Series B: Psychological Sciences and Social Sciences	Nursing Homes
Nursing home survey deficiencies for physical restraint use	Graber, D. R.; Sloane, P. D.	1995	USA	Journal Article	Medical Care	Nursing Homes

Nursing home work environment characteristics: Associated outcomes in psychosocial care	Bonifas, R. P.	2008	USA	Journal Article	Health Care Financing Review	Nursing Homes
Nursing homes in states with infection control training or infection reporting have reduced infection control deficiency citations	Cohen, C. C. et al	2015	USA	Journal Article	Infection Control & Hospital Epidemiology	Nursing Homes
Nursing homes with persistent deficiency citations for physical restraint use	Castle, N. G.	2002	USA	Journal Article	Medical Care	Nursing Homes
Nursing staff availability and other facility characteristics in relation to assisted living care deficiencies	Trinkoff, A. M. et al	2019	USA	Journal Article	Journal of Nursing Regulation	Assisted-living facilities
Organizational and environmental effects on voluntary and involuntary turnover	Donoghue, C.; Castle, N. G.	2007	USA	Journal Article	Health Care Management Review	Nursing Homes
Organizational correlates of the risk-adjusted pressure ulcer prevalence and subsequent survey deficiency citation in California nursing homes	Dellefield, M. E.	2006	USA	Journal Article	Research in Nursing & Health	Nursing Homes
Outcomes of health information technology utilization in nursing homes: Do implementation processes matter?	Hamann, D. J.; Bezboruah, K. C.	2020	USA	Journal Article	Health Informatics Journal	Nursing Homes
Ownership conversions and nursing home performance	Grabowski, D. C.; Stevenson, D. G.	2008	USA	Journal Article	Health Services Research	Nursing Homes
Performative compliance and the state–corporate structuring of neglect in a residential care home for older people	Greener, J.	2019	UK	Journal Article	Critical Criminology	Nursing Homes
Physician compliance with quality and patient safety regulations: The role of perceived enforcement approaches and commitment	Weske, U. et al	2019	Netherlands	Journal Article	Health Services Management Research	Hospitals
Predictors of quality in rural nursing homes using standard and novel methods	Towsley, G. L. et al	2013	USA	Journal Article	Research in Gerontological Nursing	Nursing Homes

Predictors of quality of care in California nursing homes	Dellefield, M. E.	1999	USA	Thesis	n/a	Nursing Homes
Providing outcomes information to nursing homes: can it improve quality of care?	Castle, N. G.	2003	USA	Journal Article	The Gerontologist	Nursing Homes
Public, private, nonprofit ownership and the response to asymmetric information: The case of nursing homes	Weisbrod, B. A.; Schlesinger, M.	1986	USA	Book Section	The Economics of Nonprofit Institutions: Studies in Structure and Policy	Nursing Homes
Quality care and financial viability of rural nursing homes	Towsley, G. L.	2007	USA	Thesis	n/a	Nursing Homes
Quality concerns in nursing homes that serve large proportions of residents with serious mental illness	Jester, D. J. et al	2020	USA	Journal Article	The Gerontologist	Nursing Homes
Quality failures in residential aged care in Australia: The relationship between structural factors and regulation imposed sanctions	Baldwin, R. et al	2015	Australia	Journal Article	Australasian Journal on Ageing	Nursing Homes
Quality indicator survey versus traditional survey in New York State: a comparison of results from annual nursing home surveys	Delaney, C. M. et al	2018	USA	Journal Article	Journal of Aging & Social Policy	Nursing Homes
Quality of care and California nursing homes: The effects of staffing, organizational, resident and market characteristics	Collier, E. J.	2008	USA	Thesis	n/a	Nursing Homes
Quality of care in nursing homes: An analysis of relationships among profit, quality, and ownership	O'Neill, C. et al	2003	USA	Journal Article	Medical Care	Nursing Homes
Quality of care: Impact of nursing home characteristics	Lee, H. Y.	2009	USA	Thesis	n/a	Nursing Homes
Quality procedures and complaints: nursing homes in Portugal	Gil, A. P.	2019	Portugal	Journal Article	The Journal of Adult Protection	Nursing Homes

Reducing antipsychotic medication use in nursing homes: A qualitative study of nursing staff perceptions	Simmons, S. F. et al	2018	USA	Journal Article	The Gerontologist	Nursing Homes
Reforming nursing home quality regulation: Impact on cited deficiencies and nursing home outcomes	Spector, W. D.; Drugovich, M. L.	1989	USA	Journal Article	Medical Care	Nursing Homes
Registered nurse staffing and OBRA deficiencies in Nevada nursing facilities	Moseley, C. B.; Jones, L.	2003	USA	Journal Article	Journal of Gerontological Nursing	Nursing Homes
Registered nurse staffing mix and quality of care in nursing homes: A longitudinal analysis	Kim, H. et al	2009	USA	Journal Article	The Gerontologist	Nursing Homes
Regulatory styles, motivational postures and nursing home compliance	Braithwaite, V. et al	1994	Australia	Journal Article	Law & Policy	Nursing Homes
Reintegrative shaming and compliance with regulatory standards	Makkai, T.; Braithwaite, J.	1994	Australia	Journal Article	Criminology	Nursing Homes
Relationship between nurse staffing and quality of care in Louisiana nursing homes	Kercado, V.	2016	USA	Thesis	n/a	Nursing Homes
Relationship between quality of care and negligence litigation in nursing homes	Studdert, D. M. et al	2011	USA	Journal Article	New England Journal of Medicine	Nursing Homes
Relationship of facility characteristics and presence of an Ombudsman to Missouri long-term care facility state inspection report results	Cox, C. C. et al	2011	USA	Journal Article	Journal of Elder Abuse & Neglect	Nursing Homes
Relationship of ownership and size to quality in Wisconsin nursing homes	Riportella-Muller, R.; Slesinger, D. P.	1982	USA	Journal Article	The Gerontologist	Nursing Homes
Reliability of the nursing home survey process: A simultaneous survey approach	Lee, R. H. et al	2006	USA	Journal Article	The Gerontologist	Nursing Homes
Revisiting the relationship between nurse staffing and quality of care in nursing homes: An instrumental variables approach	Lin, H.	2014	USa	Journal Article	Journal of Health Economics	Nursing Homes

Serious mental illness and nursing home quality of care	Rahman, M. et al	2013	USA	Journal Article	Health Services Research	Nursing Homes
Staff turnover and quality of care in nursing homes	Castle, N. G.; Engberg, J. B.	2005	USA	Journal Article	Medical Care	Nursing Homes
Staffing-related deficiency citations in nursing homes	McDonald, S. M. et al	2013	USA	Journal Article	Journal of Aging & Social Policy	Nursing Homes
State nursing home enforcement systems	Harrington, C. et al	2004	USA	Journal Article	Journal of Health Politics, Policy and Law	Nursing Homes
Testing an expected utility model of corporate deterrence	Braithwaite, J; Makkai, T.	1991	Australia	Journal Article	Law & Society Rev.	Nursing Homes
The admission of blacks to high-deficiency nursing homes	Grabowski, D. C.	2004	USA	Journal Article	Medical Care	Nursing Homes
The association between hospital characteristics and emergency medical treatment and Labor Act citation events	Terp, S. et al	2020	USA	Journal Article	Medical Care	Hospitals
The association between staff retention and English care home quality	Allan, S.; Vadean, F.	2021	UK	Journal Article	Journal of Aging & Social Policy	Nursing/Care Homes
The contribution of electronic health records to risk management through accreditation of residential aged care homes in Australia	Yu, P. et al	2020	Australia	Journal Article	BMC Medical Informatics and Decision Making	Nursing Homes
The effects of ownership and ownership change on nursing home industry costs	Holmes, J. S.	1996	USA	Journal Article	Health Services Research	Nursing Homes
The impact of Electronic Health Records on risk management of information systems in Australian residential aged care homes	Jiang, T. et al	2016	Australia	Journal Article	Journal of Medical Systems	Nursing Homes
The impact of nurse turnover on quality of care and mortality in nursing homes: Evidence from the great recession	Antwi, Y. A.; Bowblis J. R.	2018	USA	Journal Article	American Journal of Health Economics	Nursing Homes

The influence of consistent assignment on nursing home deficiency citations	Castle, N. G.	2011	USA	Journal Article	The Gerontologist	Nursing Homes
The influence of nurse staffing levels on quality of care in nursing homes	Hyer, K. et al	2011	USA	Journal Article	The Gerontologist	Nursing Homes
The influence of nursing home characteristics and task environment on complaints and survey performance	Graber, D. R.	1993	USA	Thesis	n/a	Nursing Homes
The influence of registered nurse staffing on the quality of nursing home care	Munroe, D. J.	1990	USA	Journal Article	Research in Nursing & Health	Nursing Homes
The quality indicator survey: Background, implementation, and widespread change	Lin, M. K.; Kramer, A. M.	2013	USA	Journal Article	Journal of Aging & Social Policy	Nursing Homes
The quality of care in residential care facilities for the elderly	Flores, C.	2007	USA	Thesis	n/a	Nursing Home/Assisted-Living Facilities
The regulation and enforcement of federal nursing home standards, 1991-1997	Harrington, C; Carrillo, H.	1999	USA	Journal Article	Medical Care Research and Review	Nursing Homes
The regulation of US nursing homes: An examination of state and federal tools and their effect on providers' performance	Hawks, B. A.	2018	USA	Thesis	n/a	Nursing Homes
The relationship between nursing staff levels, skill mix, and deficiencies in Maryland nursing homes	Lerner, N. B.	2013	USA	Journal Article	The Health Care Manager	Nursing Homes
The relationship between volunteer long-term care ombudsmen and regulatory nursing home actions	Nelson, H. W. et al	1995	USA	Journal Article	The Gerontologist	Nursing Homes
The rise of human service chains: antecedents to acquisitions and their effects on the quality of care in US nursing homes	Banaszak-Holl, J. et al	2002	USA	Journal Article	Managerial and Decision Economics	Nursing Homes
The role of sanctions in Australia's residential aged care quality assurance system	Ellis, J. M.; Howe, A.	2010	Australia	Journal Article	International Journal for Quality in Health Care	Nursing Homes

The role of the not-for-profit firm in the mixed industry: Three empirical analyses of the long-term care and hospital industries	Ballou, J. P.	2000	USA	Thesis	n/a	Nursing Homes
The social worker in interdisciplinary care planning	Vongxaiburana, E. et al	2011	USA	Journal Article	Clinical Gerontologist	Nursing Homes
The use of contract licensed nursing staff in U.S. nursing homes	Bourbonniere, M. et al	2006	USA	Journal Article	Medical Care Research and Review	Nursing Homes
Unannounced versus announced hospital surveys: a nationwide cluster-randomized controlled trial	Ehlers, L. H. et al	2017	Denmark	Journal Article	International Journal for Quality in Health Care	Hospitals
Using deficiency data to measure quality in assisted living communities: A Florida statewide study	June J. W. et al	2020	USA	Journal Article	Journal of Aging & Social Policy	Assisted-living facilities
Voluntary and involuntary nursing home staff turnover	Donoghue, C.; Castle, N. G.	2006	USA	Journal Article	Research on Aging	Nursing Homes
Who are the innovators? Nursing homes implementing culture change	Grabowski, D. C. et al	2014	USA	Journal Article	The Gerontologist	Nursing Homes
Why are some care homes better than others? An empirical study of the factors associated with quality of care for older people in residential homes in Surrey, England	Gage, H. et al	2009	UK	Journal Article	Health & Social Care in the Community	Nursing Homes

Appendix 6 – Quality appraisal of studies included in the systematic review – Chapter 5

The file detailing the quality appraisal is available at the following address: https://doi.org/10.1371/journal.pone.0278007.s004

Appendix 7 – Author reflections on using the Consolidated Framework for Implementation Research (CFIR)

Authors using the CFIR are encouraged to reflect on three questions: (1) coherence of terminology, (2) whether use of the CFIR promotes comparison across studies, and (3) whether use stimulates new theoretical development.[1]

To address question 1, we found the terminology of the CFIR to be broadly coherent despite overlap across some constructs. For example, network-related determinants could be coded to either the 'cosmopolitanism' or 'networks & communications' constructs. Similarly, we encountered determinants that could have been coded to both the 'culture' and 'knowledge and beliefs about the innovation' constructs.

We also found a significant number of determinants for which there was no appropriate construct. We coded these as 'other' within the most appropriate domain. Any decision to code a determinant as 'other' was principally done because the studies did not make any explicit link with the implementation of regulations. For example, some determinants related to costs or finances were coded as 'other' because they could not be linked to costs associated with implementing regulations. This is not a criticism of the CFIR but more a feature of the literature in this review.

We would also concur with the previously identified gap in the CFIR around implementation sustainability. The implementation of regulations and the ongoing process by which compliance is measured means that the process does not simply cease at the point of 'reflecting and evaluating'. As a final point to address question 1, our review found many determinants that related to people's medical conditions or care needs. We could not code such determinants to this construct because it was limited to how well an organisation *accurately knew and prioritised* the needs of these service users, as opposed to those people's actual or potential needs. This was also an observation made by authors of another study using the CFIR.[2]

On question 2, cross-comparison was not a possibility due to the nature of our study and the lack of any similar studies in this field using the CFIR. However, there may be merit in utilising the CFIR across jurisdictions or across distinct service types to compare findings on determinants of regulatory compliance.

On question 3, the process of deciding on the coding of individual determinants raised some useful discussion among the authors. We ultimately decided on coding a

large number of determinants to ‘other’ in each of the five domains. These were primarily related to externalities, determinants over which an organisation had little or no control, or were entirely unrelated to implementing regulations, but may have had a bearing on that organisation’s ability to successfully implement regulations (e.g. staffing, population density, political climate). This prompted discussions among the authors as to whether there was a suitable place in the CFIR to address phenomena that are extraneous to organisations and also to the implementation process, but nevertheless influence the success of an innovation. Indeed, a similar observation was made in another study that used the CFIR.[3]

1. Kirk MA, Kelley C, Yankey N, Birken SA, Abadie B, Damschroder L. A systematic review of the use of the Consolidated Framework for Implementation Research. Implementation Science. 2016; 11(1): 72. Available from: https://doi.org/10.1186/s13012-016-0437-z.

2. Safaeinili N, Brown-Johnson C, Shaw JG, Mahoney M, Winget M. CFIR simplified: Pragmatic application of and adaptations to the Consolidated Framework for Implementation Research (CFIR) for evaluation of a patient-centered care transformation within a learning health system. Learning health systems. 2020; 4(1): e10201. Available from: https://onlinelibrary.wiley.com/doi/pdf/10.1002/lrh2.10201.

3. Warner G, Kervin E, Pesut B, Urquhart R, Duggleby W, Hill T. How do inner and outer settings affect implementation of a community-based innovation for older adults with a serious illness: a qualitative study. BMC health services research. 2021; 21(1): 1-13.

Appendix 8 – Interview topic guide – Chapter 7

NPT component	Questions to stakeholders	Possible prompts
(1) Coherence (i.e., meaning and sense making by participants)	• Do you think regulation of disability services has a clear purpose and goal? • Do you think that staff and management working in services have a shared sense of the purpose and goal of regulation?	Does the regulator/inspector explain why certain things are required? Is there ever any conflict between management and front-line staff regarding the implementation of regulations?
(2) Cognitive participation (i.e., commitment and engagement by participants)	• How would you characterise your organisation's commitment to compliance with regulations? • How would you characterise the relationship you have with the inspector of your service(s)?	Is it embedded in everyday work or does it only matter when inspections occur? How is it embedded in everyday work? Do inspectors adopt different approaches?
(3) Collective action (i.e., the work participants do to make the intervention function)	• What impact do the regulations have on the day-to-day operations in a centre? • What happens in the aftermath of findings of non-compliance?	Can you give an example of an impact? Does it influence staff levels and skill mix? Is it burdensome? How does it affect residents? Who is responsible for action? If there is an established procedure, can you describe it?

(4) Reflexive monitoring (i.e., participants reflect on or appraise the intervention)	• Regulation has been in place for 10 years, what changes are evident in the sector as a result? • What changes would you make to the current system of regulation to improve it, and why?	Are residents receiving a better service? Has resourcing improved to meet the heightened demand for quality? Who should benefit from any changes? Changes/additions to the text of the regulations?

Closing question: Was there anything you did need have an opportunity to discuss that you would like to raise before we conclude?

NOTE: Text in red denotes prompts removed after phase one of interviews; text in blue denotes prompts added.

Appendix 9 – Interviewer personal characteristics – Chapter 7

PD, a male employed full-time by PD, conducted all of the interviews. He was a fifth-year PhD scholar with a degree in Social Science and masters in Sociology at the time of the interviews. PD had some limited experience in carrying out semi-structured interviews, primarily during data collection for a master's thesis and as an employee of a non-governmental organisation conducting interviews with migrants for a range of research projects.

As a current employee of PD, PD was conscious of certain biases or assumptions that may have influenced his views or perspectives while interacting with participants. For example, knowledge of what may have been anecdotally described within PD as 'good' or 'bad' RCF-D or provider organisations. To guard against this potential bias, prior to the interviews, PD did not access any PD regulatory information pertaining to the RCF-D or RPs. Moreover, all questions asked at interview were open-ended and general to all RCF-D — there were no questions about specific incidents or events which may have been reported in the public domain.

During the course of recruitment and data collection there may also have been concerns on the part of participants with respect to the delineation between the role of PD as a researcher and his role as an employee of PD. For example, the degree to which participants could be candid during interview could potentially be affected by apprehension that information could be shared and used for regulatory purposes. A number of measures were put in place to address concerns such as these. All communications were from PD's university email address and used university branding to make clear that this was a research project conducted under the auspices of the university. PD was fully transparent about his role as a current employee of PD and this information was included in the information sheet and stated during the introduction to all interviews. The information sheet also made clear that participants' data would be anonymised and no data would be shared with the regulator (the only exception being where a protected disclosure was made or information that indicated there is a serious risk to residents or staff in services).

Appendix 10 – Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist – Chapter 7

Note: the page numbers reported in the table below reflect those from the manuscript as submitted to the journal.

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

No. Item	Guide questions/description	Reported on Page #
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Inter viewer/facilitator	Which author/s conducted the interview or focus group?	1 (Supplementary file 1)
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	1 (Supplementary file 1)
3. Occupation	What was their occupation at the time of the study?	1 (Supplementary file 1)
4. Gender	Was the researcher male or female?	1 (Supplementary file 1)
5. Experience and training	What experience or training did the researcher have?	1 (Supplementary file 1)
Relationship with participants		
6. Relationship established	Was a relationship established	3

	prior to study commencement?	
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	1 (Information sheet)
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	1 (Information sheet)
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	2-4
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	3
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	3
12. Sample size	How many participants were in the study?	4
13. Non-participation	How many people refused to participate or dropped out? Reasons?	n/a
Setting		

14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	3
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	3
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	3
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	3
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	n/a
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	3
20. Field notes	Were field notes made during and/or after the interview or focus group?	n/a
21. Duration	What was the duration of the interviews or focus group?	4
22. Data saturation	Was data saturation discussed?	4
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	3
Domain 3: analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	4
25. Description of the coding tree	Did authors provide a description of the coding tree?	4

26. Derivation of themes	Were themes identified in advance or derived from the data?	4
27. Software	What software, if applicable, was used to manage the data?	4
28. Participant checking	Did participants provide feedback on the findings?	n/a
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	6-10
30. Data and findings consistent	Was there consistency between the data presented and the findings?	10
31. Clarity of major themes	Were major themes clearly presented in the findings?	5-10
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	n/a

Appendix 11 – Dataset for thematic analysis – Chapter 7

Coded text	Participant	NPT Construct	Sub-theme 3	Sub-theme 2	Sub-theme 1	Parent Theme
[Redacted - provider name] was different. And I missed that peer group bit where there is that universal learning. So I'm the, you know, the last inspection that I heard about was my own one and the next one will be my own one.	PIC3	Collective action		Sharing inspection findings across the organisation	Communication processes that support compliance	Putting the right processes in place
[redacted organisation name] had all these guides and all these tools that we were trying to interpret the Health Act. So I suppose that all the stuff that people created to help us interpret the Health Act was nearly too much.	PIC3	Individual specification		Support documents and tools made available by regulator	Communication processes that support compliance	Putting the right processes in place
[the inspection] is a very stressful event for me, particularly because my name is on that report and I feel like I'm the linchpin and all, as the person in charge, you are that linchpin.	PIC3	Relational restructuring		Over-reliance on PIC for compliance	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

A daily focus like whatever…It [the regulations] would certainly come into every conversation in terms of how we manage stuff with HIQA in terms of ICMs [Integrated Case Management].	PPIM4	Interactional workability		Regulations are a feature in discussions on managing care	Communication processes that support compliance	Putting the right processes in place
a lot of people with disabilities have, they've no control over anything in their lives. You know, they don't have control over what time they get up in the morning, because that depends on when the carers are available to come in. So when they're here, you know, they may, they may take 2 hours and they may not take 2 hours at home, but that's because they have control.	PIC2	Communal specification	Perceiving regulation as a force for good	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
a lot of services would use a HIQA inspector to be your advocate to get the funding that you require. And you can manipulate an inspection to get that	PIC11	Normative restructuring	Management seeking funding by drawing inspector's	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

			attention to non-compliances			
A lot of the other, kind of, pieces around regulation appear to be nearly self perpetuating. Umm. So there's a lot of spend on regulation, maybe for regulation's sake. Sometimes that's what it can feel like and…So it's harder to see that translate into day-to-day practice	PIC7	Individual appraisal		Perception that regulation does not translate into improved standards	Views about the regulatory process and the regulator	Managing organisational culture
access to a vehicle, access to an activation plan, a day service, all those things are all grown through the regulations	PPIM5	Individual appraisal		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
All we ask is that if there's something that you're not happy with, you tell your PIC and you tell your manager before any inspection. Don't be delaying on it. Don't have it that the inspector is	PIC11	Collective action		Open communication between staff and management	Communication processes that support compliance	Putting the right processes in place

the first person that's ever been told about it						
an example would be if a resident wanted to have another friend over, another resident. Like, our residents visit each other in the houses all the time, for dinner and things like that. But if somebody wants you to say to his friend, you know, 'do you wanna stay over tonight?' You know? 'No problem. There's a room for you down, down the corridor there'. Like you would in your own home, Paul, if a friend came to visit from anywhere in the country or even in the city. You can't do that [in a regulated centre]. And that's a restraint.	PIC6	Individual appraisal		Impact of regulations on residents	Views about the regulatory process and the regulator	Managing organisational culture
an inspector wanted us to do a daily diary of everything that happens with each resident. And we argued against that because we have	PIC6	Individual appraisal		Organisational support for challenging findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

weekly, you know, minutes of meetings and diaries. So we go over, and we have residents' meetings with the residents talking about their life. But a daily diary? It's much more going into, kind of, a nursing home type environment						
And basically we, as a nursing staff, were non-compliant for giving medication without a rationale. Now I found that very unfair considering I have a part…We did understand that the medication was being given and we did query the rationale, but we could only go so far. And it was an external mental health team and the GP who were responsible. They said they're not under HIQA and they're not answerable to HIQA. So	PIC10	Outer setting		Reliance on third parties for compliance	Accessing external resources	Dealing with the outside world

it left us in a position that we were never going to be compliant.						
And certainly, an informal mention I think some of HIQA inspectors have been doing that recently. I think it's really refreshing to see them talk about 'look, there's something wrong there, I don't want to see it in three years time when I come back to inspect'.	PPIM4	Activation		Use of informal findings by inspectors	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
And even though I don't like to think that back in 2005 I would have been abusive towards somebody. I think by the nature of my actions I would have. I would have been in control of people's lives and I would have restricted them unknowns to myself. That as time has gone on, you can see you can see it differently.	PIC3	Individual appraisal		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

and he [the inspector] had said, what do you think I'll find? And we had identified two challenges. One was staffing and... because we have a primarily nurse-led team. And getting nurses is a really big challenge. And the second one was we had a child here who was very challenging for behaviours. And we're a medical context or...challenging behaviours wouldn't be our normal part....It wouldn't be somebody that... challenging behaviours wouldn't be our normal profile of patients here.	PIC3	Collective action		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
And I feel that if I was a patient or a client that, if my service was HIQA compliant, then I would experience the service as being responsive to my needs and openly communicating with me and umm helping me make choices and	PIC3	Individual appraisal		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

feeling that I have a voice in my service.						
And I find that more so in the last two or three years, as I've built the rapport with the inspector, I think I've been involved with three various different inspectors for our area. So initially my very first one I was terrified. The first thing is 'God, will I get through the interview process as being a PIC?'	PPIM5	Enrolment		Fearing the inspector/regulator	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
And I found that the HIQA inspections after that tended to be, I don't know if acrimonious is the right word to describe the first couple, but, you know, less intense. More, kind of, supportive, umm, from the inspector's point of view.	PIC1	Enrolment		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

And I have been part of plans where there was a disagreement about something [how to respond to findings of non-compliance]. And so the service manager would have made a decision, say to...We had one around fire where there was a disagreement about whether or not a [fire-rated] door needed to go in somewhere. And so the service manager's action was to bring in somebody independent, but an authority on fire. And take direction from them...it's just...the service felt strongly about it. I think it was happening maybe in a number of locations and so they [the provider organisation], sort of, took a bit of a stand and there was a compromise [with the regulator] in the end	PIC9	Adaptive execution		Negotiating compliance with the inspector/regulator	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

And I have been part of plans where there was a disagreement about something [how to respond to findings of non-compliance]. And so the service manager would have made a decision, say to...We had one around fire where there was a disagreement about whether or not a [fire-rated] door needed to go in somewhere. And so the service manager's action was to bring in somebody independent, but an authority on fire. And take direction from them...it's just...the service felt strongly about it. I think it was happening maybe in a number of locations and so they [the provider organisation], sort of, took a bit of a stand and there was a compromise [with the regulator] in the end	PIC9	Relational restructuring		Organisational support for challenging findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

And I remember distinctly he [the inspector] took me into the Health Act. And then into the regulation. And then we looked at the risk assessment itself and he said this is…and I remember it really kind of opening up the whole Health Act itself. And what it means in reality and how it can, how our control is...How we're managing risk all the time and how that can massively impact the experience of the person that we're keeping safe. But we're also controlling them. We're also having an impact on their lives that we need to acknowledge and examine and determine whether or not that's worth the control that we're putting in. And that for me was a big change in how I saw the regulations	PIC3	Individual specification		Educational approach by inspector	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

And I suppose it [regulation], kind of, sped up de-congregation.	PPIM4	Internalisation	Perceiving regulation as a force for good	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
And I suppose then we went into regulation I think we were potentially a bit underprepared for what was going on. I don't think we initially accepted the feedback as proactively as possibly we should have back in the early days.	PPIM4	Reframing organisational logics	Degree by which regulation is welcomed by an organisation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture
And I think sometimes and I don't mean this the way it sounds, but lack of knowledge. Sometimes you know if, like, you know, if somebody's not, maybe a nurse, or if they're not, you know, maybe their thing is not clinical.	PIC2	Legitimation	Lack of knowledge on part of the inspector	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
And I would have spent a year working in [redacted] and [redacted] down there. Like doing relief and stuff and hours around the place. And the standards in relation to the quality of life of the	PPIM4	Individual appraisal	Inconsistency among inspection findings	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

residents within the [redacted] and within those two organisations were miles apart. We were miles ahead in what we were doing and what we were like, you know, how proactive we were around ensuring rights, ensuring quality in terms of training. And I was, kind of shocked…and then you're, kind of, going to HIQA inspections and you're seeing certain areas where they're doing better.						
And if, you know, you...I just feel you should be able to write down 'this resident, like, has requested bedside rails for this reason'. And, you know, rather than have to go in and check them and all that... when they have them at home all the time. And then it can put you to it because, like, they have to be checked, the bedside rails. If you know they have to be	PIC2	Adaptive execution	Regulations in conflict	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

monitored, right? And documented. Yet that person will say to you, I don't want to be checked at night when you come in the door. Like, and, everybody has their own room. 'When you come in the door, you're waking me up at night'. And then I have to turn around and say, 'OK, well, if you don't want to be woken at night, can you…You can't have the bedside rails'. So then they have to ring you because they have to turn. They need help to turn or whatever, you know?						
And I'm sitting there going 'I have 4 retirees in the next five or six weeks. How are they going to be replaced?' People have been here 19 years and I want them replaced with somebody who's gonna be here for 19 years. I don't want somebody that's gonna come in and	PPIM5	Activation		Challenges in recruiting/retaining staff	Managing human resources	Putting the right structures and resources in place

work next week and go and work in another unit the following Tuesday, you know? It's no good.						
And look, I remember, like you get the call and, you know, ‘there's an inspection, they’re at the door’, and you shit yourself like. Uh, probably where now, it's ‘oh, it’s such and such’ like you'll, I won’t to name the inspector. It's really not…and you literally give her a call. ‘Yeah. Look, I'll be down in 10 minutes.’ ‘Yeah. Yeah. No, you're grand, I’m just talking to such and such like’. It's completely different, really is.	PIC1	Relational restructuring	Perceiving the inspector/regulator as ally	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
And maybe put some demands on the community as well to be accommodating and, umm, to be accessible to a different group of people. And to start communicating with our local shop and bringing people into the local shop. And helping them get to know a	PIC3	Interactional workability		Management engaging with families/communities to support compliance	Overall strategic approach adopted by regulatee	Managing organisational culture

hairdresser in the area they, [we would say] 'look, he doesn't do well with waiting so'. And then [them saying] 'right, you come in, [redacted] would be ready for, you know, in a second'. And then being prepared and that access to the community piece, I think that that's huge as well that we there's a demand to access the community. If I can go to my local hairdresser, then anyone in my care should be able to go to their local hairdresser and we should be able to help them be accommodated according to what they need.						
and most of the time if…if you were able to say why you were doing something, do you know, that you could stand by and say: 'well, that's actually done because...' or 'it's done that way because...' you know, whatever for	PIC2	Relational integration		Flexibility of the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

that resident. 'It's what works best' or, do you know? And that most of the time, you know, that was alright with an inspector.						
And my memory of sitting around that table was HIQA was very, kind of, understanding and very helpful and I think that's been my overriding experience of HIQA.	PIC3	Activation		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
And she wanted more information on our, you know, on our fire procedure. She said it wasn't something she was very familiar, you know? It wasn't her thing and that she would ask the fire people.	PIC2	Skill-set workability	Lack of knowledge on part of the inspector	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
And so I a lot of the staff that were here had no experience of, of an inspection, you know, and were quite nervous, you know, and apprehensive about it. And you know, 'what If the inspector talks to me?'. And I said it, they're only here to make sure that the resident	PIC2	Communal appraisal		Fearing the inspector/regulator	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

is getting the best care that they can, I said.						
And so now all residents that come in that have a history of seizure, whether it was ten years ago or 10 days ago, must have buccal midaz with them. And and we keep it here. And that's whether they're self medicating, or whether we're medicating for them. And the inspector said ‘And what about when they go out in the bus?’ And I looked at her. I said 'ohh my God'. Never thought of the bus like. The seizure, when they're not, you know, never thought of it, that was them. That was a non-compliance	PIC2	Intervention performance		Inspector identifying issues that service overlooked	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
And so she [quality manager] would review like all our documentation, to make sure that we're compliant.	PIC2	Contextual integration		Effective monitoring of service by management	Monitoring processes that support compliance	Putting the right processes in place

And so I suppose we're very lucky in that sense.						
And so the barrier at that stage was a resource barrier. It was a resistance to investing in another. It was investing in another residential service. The gentleman eventually moved into an apartment where he lived on his own and had the support of a staff.	PIC3	Contextual integration		Organisational resistance to releasing funds for compliance	Resourcing services to enable compliance	Putting the right structures and resources in place
And so we [as an organisation] would be confident in the way, you know, we have responded [to the introduction of regulation]. And I think we've done well because other organisations similar to us, like [redacted], some of them have been shut down as a result of difficulties with you know, getting, adapting to the HIQA approach.	PIC6	Reframing organisational logics	Degree by which regulation is welcomed by an organisation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture

And so we had one inspector who, you know, when I went through everything said ‘Yes, OK, you've done everything, and that resident isn't following, you know, the direction’. And then I got a non compliance with a different inspector because, you know, I wasn't doing enough. And I said, but what…I cannot make somebody eat if somebody decides, even if they had dementia, you can't make somebody eat like.	PIC2	Individual specification	Inconsistency among inspectors	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
And so we've got to know him [the inspector] that, like, he...If there's something that’s coming up that he will say it to me, you give me an opportunity to respond to it and stuff like that.	PIC5	Relational restructuring		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
And that comes back and then I print that out and goes on the audit folder and we start working away at the actions.	PIC1	Interactional workability		Management monitor progress of actions to remedy non-compliances	Monitoring processes that support compliance	Putting the right processes in place

And that's the education piece for me with them that I'm defending the regulations and I'm defending the human rights and educating staff to see when we could potentially be breaching those.	PIC3	Relational restructuring		PIC as monitor and educator for staff	Monitoring processes that support compliance	Putting the right processes in place
And the most important about [having regulations in place] was accountability towards the residents that live there, and their families. It gave families a clearer picture of what's going on within their services.	PPIM4	Internalisation	Perceiving regulation as a force for good	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
And the person-centred planning was, you know, that wasn't there in 2012 and it's there now, you know, it was a nursing care plan that was put in place. And now it's a care plan that's actually done with the residents.	PIC5	Intervention performance		Impact of regulations on residents	Views about the regulatory process and the regulator	Managing organisational culture
And then he spoke about how HIQA are, kind of, looking at, looking to kind of be allies in the	PIC1	Activation		Collaborative approach by the inspector/regulator	**Relationship between service**	Managing the relationship with the regulator

process of improving health outcomes for people's lives rather than be something that's feared.					**management and inspector/regulator**	
And then I suppose that staff had a standard to work from. So whereas previously you were, kind of, accountable to yourself and the person you're working with, now you're accountable to an outside agency.	PPIM4	Reconfiguration	Added accountability due to presence of regulator	Regulation increases accountability	Views about the regulatory process and the regulator	Managing organisational culture
And then if they do identify something that you haven't considered of a more serious nature and you're reflective with them….'Shit, yeah, you're right'.	PIC1	Systematisation		Organisational acceptance of findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator
And then it's the next morning and we'd settle down and we'd start our action plan from the information that we got from the inspectors.	PPIM7	Interactional workability		Senior management engagement with inspection and compliance processes	Overall strategic approach adopted by regulatee	Managing organisational culture
And then we had a second inspection some months later, but my own organisation, at that time, kind of, held me responsible for the	PIC3	Relational restructuring		Over-reliance on PIC for compliance	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

failure in the inspection and it became...I was the problem after that.						
And then we had, we had an inspection where the actual inspection went...where the content of the inspection was grand, but the outcome really is that 'you can't have these four people being here'. And that, you know, even though we were managing it well it wasn't safe for one person. And there was too much managing going on in the sense that there was so much that had to happen to keep keep one person safe from the other. That was just really untenable that they stay living together. And that was a massive piece of conflict between HIQA and the governance. And we fell down on governance because...so we had that one inspection where the issues were	PIC3	Normative restructuring		Inspector identifying issues that service overlooked	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

highlighted in the safeguarding issues.						
And then when you saw inspection reports from your service, but also from other services, it was a way to see actually the ways we can do things better.	PIC11	Systematisation		Improving compliance by learning from other inspection reports	Communication processes that support compliance	Putting the right processes in place
And there have been inspections where we didn't get a lucky break at all and our service was presented in a completely, you know, the service didn't resemble anything to what we read [in the inspection report] afterwards. And I think that's down to the relationship that you form with the inspector from the moment that they walk in the door.	PIC8	Collective action		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

And there's one lady on the board who also worked with me in [redacted] many years ago and she's now on our board. So she was bringing a lot of information and guidance and that. But I think she was the only person really who had significant designated centre experience and what it meant and what needed to be in place.	PIC3	Contextual integration		Employing managers with expertise in compliance	Managing human resources	Putting the right structures and resources in place
And we [myself and my manager] sit down together and go through the areas that need to be actioned [as a result of an inspection]. And some of it might be very simple, could be just training, you know? Somebody needs to do their fire training, renew their fire training. Or I need to put in place more MAPA [Management of actual or potential aggression] training or CPI [Crisis Prevention Institution training for the management of	PIC6	Interactional workability		Senior management engagement with inspection and compliance processes	Overall strategic approach adopted by regulatee	Managing organisational culture

disruptive or aggressive behaviours] and others might be more complex like, you know, the building work that needs to be done.						
And what we found, and I've used examples for the night staff in this change of mindset, is that if you don't allow him out [to smoke a cigarette], he's a smoker and he's addicted to tobacco, to nicotine, he wants to go out no matter what. There will be different problems arising from you not allowing him to go out. He should, he has a right. So I'm more coming from a rights perspective than a HIQA perspective. I haven't actually used the word HIQA. I have used restriction when staff are sort of kicking back or questioning it, but, you know, I	PIC4	Initiation		Adopting person-centred approach to care	Overall strategic approach adopted by regulatee	Managing organisational culture

don't use HIQA as a nasty word from that perspective.						
And you can question it [regulation], there's a little bit of workability around things as long as, again, as long as you're keeping within the regulations, you know?	PIC4	Collective action		Negotiating compliance with the inspector/regulator	Effectively responding to findings of non-compliance	Managing the relationship with the regulator
And, like, as a service, you know how to hide things if you wanted to, you know? We could have, like, yeah, you know, I don't know how to put it, but you can make things look a certain way. We all know how HIQA have gone in and done inspections in organisations and then there's a big drama few years later. But, they, at the [time of the] inspections, were fine. And, I suppose, the reality is the	PIC3	Interactional workability	Fabricating compliance	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

inspections are focused on the evidence they're seeing on the day and, you know, it can be made to look a certain way if were motivated to do it.						
another bit of a frustrating piece of HIQA is they say that you have to meet this regulation, but then they're quite non…they're never prescriptive. They can't tell us how we meet that regulation. So then that brings in a whole level of interpretation as to how one would do that. Both from HIQA I think, and actually from people on the floor.	PPIM3	Individual specification		Non-provision of guidance by inspector	Views about the regulatory process and the regulator	Managing organisational culture
as a person in charge, my job is to further interpret the regulations and educate the staff.	PIC3	Initiation		PIC as monitor and educator for staff	Monitoring processes that support compliance	Putting the right processes in place
as a whole, this organisation takes the inspection outcome very importantly as opposed to what the actual goal is.	PIC4	Coherence		Organisation committed to compliance rather	Overall strategic approach adopted by regulatee	Managing organisational culture

				than goals of regulation		
as we got to know the regulations, as we've got to know the standards better, it's interpretation, interpreting the report	PIC11	Systematisation		Time required to understand and interpret the regulations	Views about the regulatory process and the regulator	Managing organisational culture
At least you have that framework of the 2013 document [the regulations]. You're guaranteed that we're working in between, you know, medication management, their lifestyle choices, you know, all those things, financial regulation. You know, their safety, you know, their…even down to their diet and, you know, their exercising. All those kind of things, healthy living choices, you know?	PPIM5	Individual specification	Regulations are clear in their prescriptions	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

at the back of everyone's mind is now before HIQA, where we would do things and we wouldn't always record. And we wouldn't always capture accurately what's been doing and we wouldn't look at the action plans or there would be very few action plans. If truth be told, it would be ‘do this, do that’. And you'd be going there, but since HIQA's been around, I find what the audits, they are actually great. There is actions and people are actually doing the actions and that. So at all times when we're working now, we do have it in our minds and we are looking at action plans.	PIC10	Intervention performance		Regulation has resulted in improved governance structures	Views about the regulatory process and the regulator	Managing organisational culture
At the start [of regulation of residential disability services in 2013], it was when the inspector came to the house, they saw the person on the day and that was it.	PIC4	Activation		Regulator engages with stakeholders outside of inspection activity	**Communication processes that support compliance**	Putting the right processes in place

And it was this person, this stranger walking in, meeting them. I think there's been a little bit more involvement with the focus groups and engaging with residents and hearing their voices. And you have done surveys and all the rest and they have been engaging with the residents themselves.						
at the start [of regulation], it just felt like those people I knew that had worked in services for years and would have had their service users' best interests at heart, would have had a great rapport with families, great rapport with the service users. But they absolutely, like, just couldn't cope anymore. It was like somebody had turned the whole system on its head.	PPIM7	Individual appraisal		Introduction of regulation resulted in some staff leaving	Managing human resources	Putting the right structures and resources in place

at the tense part of the start of it [the introduction of regulation] ‘We are regulatory authority, not an advisory authority’. Which is 100% true. And it was a case of they said it in the manner as in ‘you shouldn't be asking me those questions. You need to go away and make sure you're competent to do your role and the first step of that is getting your information’. And we've long gone past that. You, [if] you're nervous to contact an inspector, it just means you find out the bad way during an inspection. And in the meantime the quality service that the resident is receiving potentially for that lengthy period shouldn't, may not be the standard it should be.	PIC11	Activation		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

So yes, it most certainly does help compliance						
basically, we failed our IPC inspection. But what it got us was an upgrade in the bathrooms. And so the things that we've been harping on about, you know, so the HSE opens the purse strings and the board agreed to go with it.	PPIM7	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
Because I don't think the money is there, especially for section 38 providers that we are able to just magically set up a new service or a new system or…and especially within the current climate we face. Now you're talking on resourcing later but, like, obviously in	PPIM4	Outer setting		Lack of access to housing	Accessing external resources	Dealing with the outside world

[redacted] and the lack of available properties, and rents.						
Because paperwork has become so important [in order to comply with the regulations]. And every time something happens or, you know, you're reviewing a goal for a resident, we automatically go to the paperwork before we talk to the resident almost first.	PIC11	Intervention performance		Tasks required for evidencing compliance detract from time with residents	Views about the regulatory process and the regulator	Managing organisational culture
because we're so small, we don't have the resources to provide [all of the allied health services].	PIC7	Contextual integration		Lack of access to internal resources	Resourcing services to enable compliance	Putting the right structures and resources in place
because what HIQA was saying, it has no weight anymore. It doesn't have the weight it had five years ago. It certainly doesn't in our organisation or with the people that I talk to.	PPIM3	Relational integration	Perception that regulator is losing credibility	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

before my HIQA inspection last September I had grave concerns as a new manager within this service about a certain aspect of the building. I'd flagged it many times through different formats, through the audits, through health and safety audits and through emails, etcetera, about that issue with the housing. It got done just before the inspection…that escalated it…HIQA, in that sense, is a catalyst to getting certain things done.	PIC4	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
But by coming in and giving substantially compliant on things because one person doesn't do something, washing up liquid, and another person uses a different product and you're, kind of, it, kind of, brings…It demotivates staff because they're never going to	PIC10	Enrolment	Perceiving some non-compliances as trivial	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

enjoy the experience or get a learning experience from HIQA if they coming in with a negative attitude.						
But I suppose I felt in my heart that what HIQA were making us do was the right thing and that by resisting moving that fifth person and...the reason my own management didn't want to move that fifth person was they didn't have the resources, they they didn't have a place for them to go.	PIC3	Contextual integration		Lack of access to internal resources	Resourcing services to enable compliance	Putting the right structures and resources in place
But I suppose I felt in my heart that what HIQA were making us do was the right thing and that by resisting moving that fifth person and...the reason my own management didn't want to move that fifth person was they didn't have the resources, they they didn't have a place for them to go.	PIC3	Internalisation	Perceiving regulation as a force for good	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

But in other environments that I come across, I find that [the regulation requiring resident meetings] particularly difficult to be compliant in. And we've tried to interpret it in different ways by having, you know, one to one meetings with the residents and going through, you know, choices, menu choices and activity choices and trying to get feedback from them.	PIC3	Adaptive execution		Human services need flexibility sometimes not allowed by the regulations	Views about the regulatory process and the regulator	Managing organisational culture
But it would…It can be very triggering for an inspector if they come in, you know, standard stuff is not done and should be done.	PPIM6	Relational integration		Managers ensuring that standard regulatory requirements are met	Monitoring processes that support compliance	Putting the right processes in place
But the day to day, the inspections have been challenging, they're...being told you're non-compliant. That part of it has been excruciatingly painful.	PIC3	Enrolment		Demoralising impact of findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

But then if I wanted funding to pay for something to enhance the service, it was compliant, you know? We only need to put money in places that are non-compliant	PPIM5	Contextual integration		Lack of access to internal resources	Resourcing services to enable compliance	Putting the right structures and resources in place
certain inspectors, would be very heavily fire, risk orientated or risk assessment orientated. And other inspectors, you see them light up when they're engaging with them, like can be very strict from a paperwork perspective, and they'd like to be left alone to go through all the files and all the rest of it. Whereas other inspectors would like you to talk through it.	PIC4	Interactional workability		Knowledge of inspector's focus	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
certainly in the early days, inspectors were very nursing home focused and took a very nursing home approach to social care houses, which seemed to be a bit disjointed.	PIC7	Negotiating capacity	Overly-clinical approach by the inspector	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

You had a huge amount of focus on medications and some very small details. I am, and at that time also, seemed to be very focused on what the PIC knew, you know?						
certainly in this company, we've had to go away and find resources for speech and language and occupational therapy and psychology supports that we just couldn't access in the community. And we only really got the funding because of HIQA reports that showed a deficit in our provision.	PIC7	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
certainly, in the early days, the inspectors were not accepting any questions on advice, and said “we don't do that”. And it was very, you know, comply or don't comply but “we won't be telling you how to do it, we’ll be telling you if you have or haven't”	PIC7	Relational restructuring		Non-provision of guidance by inspector	Views about the regulatory process and the regulator	Managing organisational culture

culture is not fully addressed. Culture is an ongoing process. It will take multiple, multiple years. And being involved in, in multiple changes over the years and working in different services...I don't think any of us in the management perspective were naive enough to think that you put in a fancy new building and the culture will change with us.	PIC11	Reflexive monitoring	Time required to change culture in services	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture
Do you know in the sense that...and I would find now that it's much easier for me to say and like to challenge something, you know? If an inspector says ‘Ohh I don't know about that' or 'why you're doing that’? And, you know, if I can, if I can validate why I'm doing something, I feel it's listened to.	PIC2	Relational integration		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
Do you know it's, kind of, it's top of the list. And, you know for my line manager, or for the	PIC2	Contextual integration		Organisation provides adequate	Resourcing services to enable compliance	Putting the right structures and resources in place

organisation, even the CEO or that, it's always, you know, if it's needed and it's, you know, it's essential and it's needed and it's to make us think we're compliant there's no questions it's...that's the way it is, I get it.				support for compliance		
Do you know what? I don't really consider them that way. We support people to live the lives that they want to live in as much as possible, never really thinking about the regulations, which is: the lads are just living their lives and we're just doing our best to support them and achieve the outcomes that they want to achieve.	PIC1	Normative restructuring		Adopting person-centred approach to care	Overall strategic approach adopted by regulatee	Managing organisational culture

do you think that it has like a clear purpose and goal? And if it does, what is it? PIC1 Yeah, it definitely does have. It's to improve people's outcomes. And that's what, that's what the goal is. To make sure that people have a service that they have control over, input into and they get to do the things they want to get to do. And to ensure that the structures within the organisation that the people are receiving their service from are not barriers to what people want to do with their lives. That's it. They're not a jail for me.	PIC1	Internalisation	Perception that goal of regulation is to improve care for people	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
don't get me wrong, some people weren't willing to be brought along when there was more, kind of, when there was more levels of, what's the word, I suppose,	PPIM8	Normative restructuring	Staff distrust of regulation	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

paperwork, but also record keeping and demonstrating the work we were doing. Some people, it wasn't for them, you know?						
even in the personalities of the people that have been recently employed by HIQA, it seems to be a much more open and, like, the whole…I used to feel in certain aspects it'd be like the school inspector arrived at your front door, you know? It was never something, like, you were in trouble. Whereas now I just feel it's a lot more open. And it's nice conversations and like exchanges happening between PICs and inspectors. There's like, it's definitely more of a theme. I think that's a really, really, really positive step.	PPIM4	Activation		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
Even some of the old, what's the word…some of those older staff that maybe were institutionalised,	PPIM8	Skill-set workability		Effectively convincing staff that	Clear assignment of responsibility for	Putting the right processes in place

you know, maybe it took a bit more time to bring them along with you.				compliance is also their responsibility	making compliance happen	
even though it [the provider organisation] is still small, they have put in governance structures and stuff	PIC5	Contextual integration		Implementing general governance structures	Implementing governance structures	Putting the right structures and resources in place
everybody likes to be fully compliant that you're doing your work, you're doing a good job there. He came fully compliant. But that doesn't tell the whole story because I could still have three objectives or drives or changes I want to make in the service to make it better. And through having a fully compliant, that's reducing my opportunity of achieving that [because it will harm my chances of getting extra funding]. So it's kind of a double-edged sword in a way	PPIM5	Normative restructuring	Full compliance reduces argument for improved resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

Finbarr Colfer saying to me, saying something I was at in Galway, he was saying ‘when we came in here, we had to get every service up to a certain standard really, really quick. Most services weren't near that. Services were somewhere and he says that took three or four years and…Now, it’s at a level that we, kind of, think it's fairly OK. And now it's all about trying to get them up a little bit more.’	PIC1	Negotiating capacity	Organisational preparedness for regulation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture
five years ago, I would not have shown an inspector the area that I would have a concern with. And that was the trust. That was all me not understanding the process. My naiveté, thinking of ‘God, they went out the door and they never saw this. They never saw the hole in the wall in the back there.’ Whereas nowadays I'd come back	PPIM5	Relational restructuring		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

down and say, ‘well, you know, we have a very aggressive male and he was punching holes in the wall. We're having trouble getting maintenance out to fix some da-da-da-da.						
for me, it [the introduction of regulation] improved the standards across the board. It improved the standards that I suppose every registered provider needed to meet a minimum standard.	PPIM8	Internalisation		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
from a qualitative point of view I think it [regulation] is a game changer. And I think, you know, I've seen services professionalise as the years have gone by. I don't think that that would have happened as quickly or as comprehensively without HIQA being in place.	PIC8	Individual appraisal		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

From our perspective, I suppose just the size of service that we are, highlighting the training piece. Like that's a really difficult one for us. And it's very hard to be compliant all the time.	PPIM7	Negotiating capacity		Small organisation size impacts on training provision	Resourcing services to enable compliance	Putting the right structures and resources in place
generally an inspector will be around for, kind of, a number of years, you know? Before they're moved on, in general. And they'll have, kind of, an identified number of services and locations. So I would find that we have a very positive relationship with the inspectors, our PICs, and they would know who their inspector is, their case holder for locations. They're able to make contact with them if specific issues crop up.	PPIM1	Activation		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
generally we'll try and involve the PPIM [Person Participating in Management] in the feedback session. So we had an inspection in	PIC7	Interactional workability		Senior management engagement with inspection and compliance processes	Overall strategic approach adopted by regulatee	Managing organisational culture

October and the PPIM was part of the feedback via Teams…And because, actually based in [redacted], and then really it's between the PPIM and myself as to how we then frame the response…when we get the first report and then we have to put together the compliance plan. Then we'll work on that together.						
Getting the PIC off the floor having regulation is an absolute help to you. So when you're costing something, it's very easy for me then to make the case and say 'well, actually, you know…I need somebody off the floor X number of hours per week. And, you know, you need the team lead then to do ABC and D'. And it all boils down to…it is all down to regulation.	PPIM7	Internalisation		Regulation has resulted in improved governance structures	Views about the regulatory process and the regulator	Managing organisational culture

Have built up very good relationship with the two inspectors. They've been really, really helpful. They trust that if they see a gap that needs to be identified that I will do my damndest to address it.	PIC1	Cognitive participation		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
he [the inspector] was very non-threatening, very warm and not…And he he didn't inspire defensiveness.	PIC3	Enrolment		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
he [the inspector] was very non-threatening. So. And I think because of that experience, then it was easier for me to learn and be open to hearing what he had to say afterwards.	PIC3	Enrolment		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
he [the PIC] is telling me he doesn't feel that pressure because he has the time off the floor and we have an external person who comes in to do our six monthlies and all of that, he doesn't feel that pressure.	PPIM7	Contextual integration		Sufficient time for management to attend to regulatory matters	Managing human resources	Putting the right structures and resources in place

he [the resident] is going to a holiday home at how long is he going for three months. [And the inspector will say]: 'Oh, well, that's sort of holiday home and it's not registered [as a centre where care can be provided]'. So, immediately, the Chief Inspector, the deputy Chief Inspector says 'no'.	PIC6	Negotiating capacity	Regulations in conflict	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture
HIQA and [redacted], at a managerial level, you know said, ‘we’re going to have to close you down.’ I don't know what happened there, but the money came from the Department of Health and the fire doors went in and so we would have the same here.	PIC1	Contextual integration		Use of court proceedings as an enforcement measure	Views about the regulatory process and the regulator	Managing organisational culture
HIQA and then combined with the Capacity Act and some of the other changes, I suppose, in terms of the culture around rights has really empowered us as well in terms of, you know, supporting people and	PIC9	Internalisation		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

making decisions and being able to challenge, kind of, received wisdom as the older practices						
HIQA came and helped greatly helped…they were...the inspections were the leverage to make that change happen.	PIC3	Internalisation	Perceiving regulation as a force for good	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
HIQA were quite clear in saying, 'look, the funding isn't our problem. It doesn't matter'. Erm, 'we don't care what funding issues you have, that's your problem. That's what your employed to do. You need to go back to the HSE [health authority responsible for funding], do whatever you need to do. It is not safe for these five people and we will not accept it'. And I suppose I was the bit in the middle. I was the leverage and it was excruciating. But also it...there was no doubt that it was the right thing to do.	PIC3	Relational integration		Autonomy/authority of PIC	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

his approach wasn't one of criticism. It was from a position of teaching it. He was like he reminded me of someone who, and I suppose he was there as a teacher because he was teaching his inspector, who was in training so he was in that role anyway.	PIC3	Enrolment		Educational approach by inspector	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
honestly, you wouldn't be happy for your family member to be living where we were working at the time [prior to the introduction of regulation].	PIC11	Individual appraisal		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
How do you inspect somewhere and get the human lived experience of the people who live there? And how is it more weighted towards that than it is towards the ticking of the boxes and a more balanced view?	PPIM1	Communal specification		Difficulty in measursing the human lived experience in a service	Views about the regulatory process and the regulator	Managing organisational culture

I actually found it really difficult coming out of a time [the COVID-19 pandemic] where, I suppose, both myself and teams in general would have probably never worked harder and under all manner of stresses and strains. And there was no, kind of, recognition that that had been the work. And because of the pandemic and that the inspection seems, you know, like business as usual. As if none of that had ever happened.	PIC9	Activation		Regulator did not account for difficulties of pandemic	Views about the regulatory process and the regulator	Managing organisational culture
I always kind of flip it and say if you look at it negatively, if we hadn't got those [regulations] and we're working on an ad hoc basis, what would the residents' experience be? As good as it is now? No, it wouldn't, because you'd be let down in so many areas that people wouldn't have even thought of.	PPIM5	Internalisation	Perceiving regulation as a force for good	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

I am now at that top table with the provider nominee sitting face to face with them going 'this is what I need, this is what we need as a service, because this is what the non-compliance is'.	PPIM5	Initiation		Escalation of non-compliances by manager to provider-level	Clear assignment of responsibility for making compliance happen	Putting the right processes in place
I am seeing more recently now with HIQA, that there seems to be more of the opinion-based inspection. It seems to be more veering away from the regs and towards, 'oh, I think you should do it this way', or, 'I think, oh, I've seen this done that way somewhere else'. And offering more opinion-based stuff. And for me that difference can be somewhat frustrating at times.	PPIM8	Legitimation		Lack of clarity due to differing interpretations of the regulations	Views about the regulatory process and the regulator	Managing organisational culture
I attended the roadshow last year and I attended that in [redacted]. And they're going in the right direction of trying to engage with services and build relationships	PPIM2	Enrolment	Perceiving the inspector/regulator as ally	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

with services rather than being a dictator.						
I call it professional nagging. I will seek for that bathroom to be done. It's part of my 2024 goals. I've mentioned it to senior management, so it's not a surprise that when HIQA come for another inspection or when I am due a provider LED audit at some point in this six months that yeah, I'm aware of it. I've flagged it. I've documented that that bathroom needs to be refurbished.	PIC4	Relational restructuring		Escalation of non-compliances by manager to provider-level	Clear assignment of responsibility for making compliance happen	Putting the right processes in place
I came in at a point where we had to affect major cultural change. To get the staff team to understand the meaning of person-centred care and then get them on board with it. And some people, some staff, will automatically get that and understand that this is the way we should be supporting people. Well,	PPIM2	Enrolment		Using the authority of the regulator to convince staff to implement regulations	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

there's some who would respond better to ‘HIQA said we need to do this, so this is why we're doing it’. And it is helpful, depending on…When you have a large team of people, everybody doesn't think in the same way. But, so sometimes having HIQA there in the background saying ‘HIQA said we have to do this. So we have to do it’. That gets them on board. There's always going to be people who will get on board anyway because they know what's the right thing to do and it's best practice.						
I can see that now at the minute, managing both a highly regulated registered and a non-registered service, you don't have that in the other service and you can get a lot more questions going ‘Why? Why should we? We've always done it this way’. And you can't say, well,	PPIM2	Enrolment		Using the authority of the regulator to convince staff to implement regulations	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

‘HIQA said we have to’, because we're not registered with them, you know?						
I can't remember the title of the roadshow. And and they were talking about the different guides and one of the pieces of feedback from everybody there was that there's too many guides. There's too many documents that help us in supporting us. Just too many, I think at that stage they have had about 48 guides, guidance documents and as a PIC, I feel I should have read them all. I should know them all. I don't have time to read them all	PIC3	Activation		Support documents and tools made available by regulator	Communication processes that support compliance	Putting the right processes in place
I couldn't say that there's any inspector that we have that we wouldn't have that mutually respectful relationship with. And some are certainly more approachable than others. Some	PPIM1	Activation		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

would say ‘we're here to help give us a call’. Some wouldn't, you know? It would be that more, kind of, formal relationship.						
I developed a statement of purpose there and then we had an inspection. Then, about eight months later, that didn't go too well because we were still trying to, you know, get to know the two residents, what supports they needed.	PIC1	Negotiating capacity		Human services need flexibility sometimes not allowed by the regulations	Views about the regulatory process and the regulator	Managing organisational culture
I did feel at one point that there was kind of blurred lines between what was my role and what was her role. And what her role to a…you probably know who I'm talking about. But there was blurred lines. There was an incident where I phoned her [the inspector] to let her know of something that was happening within the service and I was told ‘you're not doing that’.	PPIM2	Relational integration		Autonomy/authority of PIC	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

And there was, I wasn't sure. Was it her place to be telling me how to manage this situation? And then two weeks later, I had gone along with what she said. Two weeks later, she rang back and said 'actually, you know what? It's not my place to tell you how to manage that. You manage that yourself as a service manager'.						
I did that once when I was like, 'I'm not accepting that this is a non-compliance. So therefore there is no action'. And I got back that then we can't close the inspection process so it will get escalated to uh, whatever that thing is, when you have the meeting with all the people.	PPIM3	Legitimation		Organisational acceptance of findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator
I do acknowledge that I've seen, like, definite efforts from HIQA. And the relationship between services and HIQA has definitely	PPIM2	Normative restructuring		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

improved. It's more collaborative now than it used to be.						
I do remember a time where we were quite nervous and, you know, went along with anything HIQA would have said and would have asked of us. We are getting better and that's what I was talking about. The relationship is growing between ourselves and HIQA that we can back and forth and I now as, you know, an experienced manager…When I started off first, I would never have questioned. I would never have challenged the inspector's words. Now I would.	PPIM2	Relational integration		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
I do think as well in relation to individual inspectors, there's differences between their interpretation and their preference of how they would interpret	PPIM1	Individual specification		Lack of clarity due to differing interpretations of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

whether something has been in compliance or not.						
I do think it like fire safety, medication, all of that is good. That's stuff that needs to be regulated.	PPIM6	Internalisation	Perceiving regulation as a force for good	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
I do think regulation is really good because it ensures that we, you know, ensures a set standard.	PPIM7	Normative restructuring	Regulations are clear in their prescriptions	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture
I do think there's a big updating needed of HIQA regs to reflect real standards and quality of life for the people who live in, that live in the designated centres. Rather than just organisations who are able to adapt and tick boxing, sorry box ticking.	PPIM4	Communal appraisal		Perception that regulations do not reflect real standards	Views about the regulatory process and the regulator	Managing organisational culture
I don't know if that was a policy of HIQA or not, but there…you certainly seemed to have a new inspector every year, so there was no chance to build a relationship with the person. They just, they	PIC7	Enrolment		Lack of opportunity to build relationship with inspectors	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

came, they did their bits and they went away again.						
I don't know whether it is the fact that now we have two people [inspectors] say that are in the jobs quite a while. They know us quite well, you know? That it's just a natural thing or maybe that it's a decision that HIQA have made behind the scenes [to adopt a more collaborative role] in terms of their approach to supporting service users and services and all of that. Maybe that's been a decision behind the scenes and if it is, it's definitely working.	PPIM7	Relational restructuring		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
I don't mind debating or talking about care or care policies or care procedures with anyone. I often have my own ideas around how something should be implemented. And I've no problem, respectfully,	PPIM8	Communal specification		Negotiating compliance with the inspector/regulator	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

with an inspector going back and forth to say ‘well, actually, I think you're interpretation of this is slightly off of mine’, and I'm discussing how or why or whatever. That's fine where we can have that discussion.						
I don't think a day is enough for a HIQA inspector coming in.	PIC10	Systematisation	A one day inspection is not enough to assess compliance	Perceived legitimacy of the regulatory system	Views about the regulatory process and the regulator	Managing organisational culture
I don't think we initially accepted the feedback as proactively as possibly we should have back in the early days. And that I think that led to huge issues around the relationship between HIQA and [redacted].	PPIM4	Relational restructuring		Organisational acceptance of findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator
I enjoyed that aspect of working with HIQA, particularly on the children's side of things because for me it was straightforward. Any recommendations were very	PPIM8	Systematisation	Regulations are clear in their prescriptions	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

straightforward. You're very clear as to how you either met it or didn't meet it. And any, kind of, recommendations that were easily applied then you could go ‘OK, Yeah, I see why we don't meet it’, and then we can put a plan in place to meet it.						
I feel that person-centeredness has now moved to where they should have been at the very start of regulation at…The residents are at the forefront of everything, really making, making decisions and having a bit of control over their lives. We didn’t have that before, and so that's been really positive. That's really, really the main change. And like I remember in, when regulation came in, in [redacted], we had some staff that left. They’d say ‘no, you can't do this’, you	PIC1	Communal specification	Perceiving regulation as a force for good	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

know? Literally, like the eternal child, we're minding them. You know? I try and say 'no, we're not. We're actually supporting people live lives of their own choosing'. And so that's been the biggest thing, it's person-centredness is…you can see the sense in inspectors. They're really, really focusing on this; 'How is this person doing? Are they getting to do what they want to do, and if not, why not?'						
I feel that person-centeredness has now moved to where they should have been at the very start of regulation at…The residents are at the forefront of everything, really making, making decisions and having a bit of control over their lives. We didn't have that before, and so	PIC1	Internalisation		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

that's been really positive. That's really, really the main change.						
I feel you can bring them [inspectors] around to your way of thinking. Alright. Yeah, a lot. A lot more in a lot of cases, yeah. As in, I think there's just a lot more experience. That they understand the sector we're working in a little bit more.	PPIM4	Relational integration		Flexibility of the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
I felt, initially, you got that sense of it being quite similar to the [inspections of] older person services which had come in to play first, that there was that, kind of, more clinical…It felt like a more clinical focus to the inspections. And that has lessened off and has become more, kind of, social care focused as time has gone on.	PPIM1	Individual appraisal		Person-centered focus during inspections	Views about the regulatory process and the regulator	Managing organisational culture

I find that over the course of the year, my work with the staff is punctuated with those conversations talking about the broader human rights, the right to privacy, the right to choice, that when somebody doesn't have a voice, how do you make decisions for them?	PIC3	Activation		Adopting person-centred approach to care	Overall strategic approach adopted by regulatee	Managing organisational culture
I found that a lot of the staff would shy away from the kind of the incident logs, the kind of updating of all that, stuff like that. And to be fair, that's probably my fault so that's a bit of reflective practice for me. So I've been trying to, umm, in like over the last six months especially is trying to get them more involved in stuff like that. Like, literally today, I've had two staff doing our infection control, our own infection control audit, and to get them more involved in that	PIC1	Skill-set workability		Delegating compliance tasks to staff	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

and more understanding of how we can evidence our supports in a manner that, kind of, doesn't raise concerns when there are no concerns.						
I give the rationale to the RPR [Registered Provider Representative - an identified person that represents the provider in dealings with the regulator] for why it needs to be done. And then what we do is kind of agree, like...So something like that, like a big ticket item might be, like, that's gonna affect on the budgets and it just might be a longer time period where you might be looking at three months to do it.	PIC5	Interactional workability		Judging how much time is available to address non-compliances	Effectively responding to findings of non-compliance	Managing the relationship with the regulator
I got to know [the inspector] quite well and she had been to our houses numerous times . And I thought she had a great	PIC6	Enrolment		Inspector identifying issues that service overlooked	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

understanding and a great ability when she came in to target certain things. And, you know, we had a couple of residents who weren't necessarily getting on together. And she immediately saw that and we were, you know, happy to explain that 'well, where can we move people?' We're trying and trying and eventually we solved it, but it's, you know, it felt that she was very tuned in, very smart.						
I had a medication incident this week in the service. So the information comes in and then you're thinking like, 'OK, is this an NFO [Notifiable incident], does this require an immediate notice?' And then if it doesn't, if they come in and inspect, how are we evidencing how we're following up on that?	PPIM3	Sustainment (normalisation)		Adequately evidencing compliance	Monitoring processes that support compliance	Putting the right processes in place

I had people, one gentleman in particular. He was very much around recycling and it was his responsibility and this was what he did. But he wanted, he needed a specific bin because he brought it out and he threw it into the bin outside. So the pedal bin thing didn't work. He needed a bin that he could take off the lid so it wasn't in line. And it came up in an inspection that we didn't have the bin as per regulations. But we had identified that, recognised and put in a risk assessment around it and why we were doing it that way…to support this gentleman and his preferences. And it was mentioned in the report, but we weren't given any non-compliance around it.	PPIM1	Negotiating capacity		Negotiating compliance with the inspector/regulator	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

I have a huge issue in [redacted] at the minute. There is a kitchen which is not fit for purpose and it's gonna cost 125,000 to get it into compliance. It's the old school canteen. Metal shutters, looks brutal. I agree a million percent for this. It's not homely. It's been non-compliant for five years, I'd say. It's on a hospital grounds. It's all non-personal. We've made the rest of the house so homely and with this big monstrosity of a kitchen. So I was offered…the dilemma I was offered nearly 200,000 to take somebody off a waiting list and to house somebody in an individual care setting which they have been craving for seven years. And as I said at the start, back to the resident, I was given 200 grand to do that or fix the kitchen. And I went with the former.	PPIM5	Individual appraisal		Placing interests of residents ahead of compliance	Overall strategic approach adopted by regulatee	Managing organisational culture

So we have two residents now in a beautiful, self-contained apartment. An individual one to one care plan. Their lives…one of them was so vocal that you couldn't stay in the room with her for more than 15 minutes, and now she's not vocal at all. It's been an amazing transformation and to me, that's what gets me up in the morning. This is what drives me. My problem is the kitchen still not complaint.						
I have a risk assessment which I am going to be doing this week for an extra staff member. So if they [the provider organisation] do refuse, maybe HIQA might be able to help me on that one because we just discovered we do need one more staff.	PIC10	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

I have no problem saying to a HIQA inspector, hang on a second, you know? 'Yes, they, you know, it would be best if they rang the bell like, but we've said that to them, they have they're fully able to tell me that that is not what they want to do, that they are prepared to take the risk that they may fall, that they know that that and that's fine because that's their choice', you know?	PIC2	Relational integration		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
I have seen an increase an improvement in the quality of life of residents who are under the umbrella of HIQA. Definitely.	PIC4	Internalisation		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
I just think sometimes that's just silly because I'm non-compliant because that resident, and so who am I to please? HIQA or please the resident? The resident wants the bedside rails up but does not want to be checked at night.	PIC2	Internalisation	Regulations in conflict	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

I keep on trying to drill it into my staff but it only puts more pressure on them, you know, I always say, you know, 'if we don't have it on paper, it never happened'.	PIC8	Activation		Adequately evidencing compliance	Monitoring processes that support compliance	Putting the right processes in place
I know people who have left, because, particularly people in the PIC roll, the person in charge role have left because the stipulation that it has to be full time and has… it's gotten really…I can think of women around my own age who are mothers and stuff and want to maybe work part time and it's not an option. But they've got the qualifications and they've a lot to offer. But they've kind of said it's not worth it if I have to work full time, I'd have to do all this paperwork.	PPIM2	Normative restructuring		Requirement for full-time PIC has resulted in losing staff	Managing human resources	Putting the right structures and resources in place

I know that during our last inspection we discussed an incident which I hadn't recognised as a three day notification. I hadn’t sent it to her. But I think it was that she wasn't overly concerned because of the relationship we had and the fact that I do keep her updated on what's going on in the service. So the fact that I missed this 3 day notification, it went in the report obviously, but I knew by her she wasn't overly concerned that I was hiding something because it was, it was genuinely just an oversight, so it I think it…Yeah, it's very important to build a personal relationship with your inspector.	PPIM2	Relational integration		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

I know there was a couple of people in around that time, they left the services and they felt impacted by it [the introduction of regulation] and stuff with that because of their practice being reviewed. And, you know, that, kind of, thing where like the unit that I worked, it would have been very challenging and we would have had a lot of restrictive practices and a lot of, you know, get like PBS [positive behavioural support], some [physical] holds and stuff like that and people, kind of, felt very judged on that, you know? When some people did leave and and it felt very, you know, but other people that kind of came along with us and like anybody i've talked to since, that's been positive.	PIC5	Normative restructuring	Staff distrust of regulation	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

I like the self assessment process. I like the…Self assessment tool. So we had one for restrictive practices and we have one for the infection prevention control. I don't know if there's any others? But that little checklist that comes and, like, I found the roadshows really helpful and I found some of the webinars really helpful. That little bit of ongoing education and collaboration with HIQA	PIC3	Activation		Support documents and tools made available by regulator	Communication processes that support compliance	Putting the right processes in place
I love the fact that when people come here they really, really are given choice around everything they want to do, do you know? What time they get up at, where they have their meals, what time they have their meals, what they have for their meals, etcetera. Because when they're at home, they don't have that choice	PIC2	Internalisation		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

I mean the difficulty with the staffing is that...We can undertake to recruit people, but like, it's a constant on action plans [responses to findings of non-compliance] in the last two or three years. That we're recruiting. But, generally, by the time an inspector comes back extra hours may have been provided in a house, but we'd be still non-compliant or only substantially compliant because they're being covered by relief [staff]	PIC9	Outer setting		Challenges in recruiting/retaining staff	Managing human resources	Putting the right structures and resources in place
I preface everything I say about HIQA in terms of it's the law, you know, so they're only doing what they have to do.	PIC6	Legitimation	Legal legitimacy of regulatory system	Perceived legitimacy of the regulatory system	Views about the regulatory process and the regulator	Managing organisational culture
I really do get a strong sense that the ethos within the wider organisation naturally touches upon what's going to be in the regulations anyway. There's a	PIC8	Reframing organisational logics	Provider ethos aligned with goals of regulation	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

genuine client-focused outlook on how things should be done. And so I think that does naturally touch then on how we interact with the regulations.						
I remember at the start, HIQA inspections at the start, being very frustrated because there was a lot of inconsistencies, depending on the inspector that you got.	PPIM8	Relational integration	Inconsistency among inspectors	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
I remember back, I don't know how many years ago now, but like bringing these things to team meetings, going through a regulation at a time at a team meeting, pulling it apart, getting everyone's idea as to 'what do we do well to meet this? What do we not do? What can we improve on?' And bringing those people in as part of the process of…it's not just, say, a manager dictating this change. If you bring the people	PPIM8	Enrolment		Discussing compliance issues at staff meetings	Communication processes that support compliance	Putting the right processes in place

along with you as part of the change, you're incorporating their ideas, their thoughts, their feelings						
I remember in one particular house I have worked in in Dublin, and one of the lads there, he just didn't want to get up. He stayed up to 5:00 o'clock in the morning. And you get up at 2:00 o'clock in the day, and people were saying ‘we have to get him out. We have to do something’. And there was clinical reasons why he did that and when we explained that all to everyone, they kind of got it. This person is 32 years of age. [inaudible] 8:00 o'clock in morning or in the afternoon? That's his choice. Yeah, that was. That's hard. That can be hard for staff to just…they feel that they're failing.	PIC1	Negotiating capacity		Adopting person-centred approach to care	Overall strategic approach adopted by regulatee	Managing organisational culture

I remember one evening sitting in a house and the inspector saying ‘this is not acceptable’. You know ‘this person needs more’ or whatever. And I remember asking the inspector specifically, ‘I would really appreciate your advice’, in the nicest possible way, and you know, ‘have you any suggestions that would help us?’. And her words were, ‘with respect. That's your job, [redacted]. I'm just telling you it's wrong’. And I was just thinking like ‘if this how we're doing our business? You're in here to tell me it's wrong, but you have no idea or no sense of’. Now that has evolved a bit as well, and you learn, I suppose, to engage differently with the regulator.	PPIM6	Initiation		Non-provision of guidance by inspector	Views about the regulatory process and the regulator	Managing organisational culture
I remember when I started here, I needed to ask [the inspector] a question. And we were told you	PPIM7	Enrolment		Non-provision of guidance by inspector	Views about the regulatory process and the regulator	Managing organisational culture

[the inspectors] weren't there for, you know, they weren't there for advice. They're there to regulate.						
I should be allowed to say to the staff. ‘OK, you've done the assessment’. It's safe to use the bedrails for the resident. And they're never used without the resident requesting them. And, so the resident has requested those bed rails. We know they're safe. We know they're not going to, you know, climb out. They're not going to get entrapped or whatever, so we don't need to monitor them now because that resident has...I should be able to say that to staff that they can write down, they can document down that, you know, resident has had assessment done; safe to use bed rails with residents and with	PIC2	Adaptive execution	Regulations in conflict	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

resident’s consent and no need to monitor at night.						
I started in residential care unqualified. So I hadn't got a qualification behind me. When I started I had done a small bit of GAA coaching in the background and things like that but…Like, now to today, I suppose I wouldn't get a start in residential care, you have to be qualified.	PPIM8	Individual appraisal		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
I suppose even as an organisation, we'll say above me and top down, our organisation has said that this is where our priority lies. And on these occasions, they would say that they're happy for us to push back on those things and to, you know, make those decisions that,	PPIM1	Contextual integration		Organisational support for challenging findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

‘yes, we're not strictly in line [with the regulations], but we have a really valid rationale and reason why’.						
I suppose I'm just thinking that the 26th in Dublin Castle next week [information session hosted by the regulator for providers]. I think that's really good to get board members involved.	PPIM7	Activation		Regulator engages with stakeholders outside of inspection activity	**Communication processes that support compliance**	Putting the right processes in place
I suppose it [our organisation's attitude to compliance with regulations] has evolved a bit, but it certainly...At the beginning I would have felt that, you know, we were very proactive about it. That we tried to, kind of, embrace the regulations and there was good leadership around that.	PIC9	Enrolment	Degree by which regulation is welcomed by an organisation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture
I suppose it [regulation] has become a bit of a structure. Like, in the beginning, we very much had to get to know the regulations and	PIC3	Sustainment (normalisation)		Time required to understand and interpret the regulations	Views about the regulatory process and the regulator	Managing organisational culture

taken each regulation and interpreting it. And ‘what does it mean and what's the document that helps us evidence that?’, that was, kind of, that was the biggest learning.						
I suppose that's the thing that it brings up: we’re either trusted as service providers to provide the service or we're not, that’s what I consistently feel about HIQA.	PPIM3	Relational integration	Perception that regulator does not trust the service provider	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
I suppose the important piece then is tracking [actions to remedy non-compliance] that as well. That, you know, we don't all just sail off…so there's a live tracker for those actions.	PPIM6	Interactional workability		Management monitor progress of actions to remedy non-compliances	Monitoring processes that support compliance	Putting the right processes in place
I suppose, it's not perfect. But having worked in unregulated services for many years I can definitely it’s…overall it's been a positive thing for disability services.	PPIM2	Legitimation	Perceiving regulation as a force for good	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

I suppose, uhm, it's about making the resident the most important person and their choice. And I think sometimes with the regulations that isn't, that doesn't happen. Because, you know, there's other things come into play. Like health and safety. Like, you know, that person has dementia. They've refused to eat. I can't make them eat, but I'm non-compliant because they won't eat.	PIC2	Individual appraisal	Regulations in conflict	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture
I tend to be at all the inspections from start to finish	PIC1	Activation		Senior management engagement with inspection and compliance processes	Overall strategic approach adopted by regulatee	Managing organisational culture
I think certainly the last three or four years we've seen a much clearer pathway and a much…I think there's certainly a better relationship between frontline teams of inspectors and frontline staff.	PPIM4	Activation		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

I think HIQA are like 'I don't care how you get your funding. This is what's required'. However, we just don't have…We won't always have the ability to just pump money into something. Or the ability to make huge adaptations to a house or make huge improvements just really quickly like that.	PPIM1	Contextual integration		Lack of access to internal resources	Resourcing services to enable compliance	Putting the right structures and resources in place
I think HIQA inspections and standards need to be built into the curriculum of a third level education for social care workers, for social workers, for disability. We still encounter graduates all of the time who do not know the standards, who do not know or understand…and they are the employees of the future.	PPIM6	Outer setting		Poor standard of education for staff	Managing human resources	Putting the right structures and resources in place
I think HIQA were taking further steps and were heading towards a court-based response to that [fire safety concerns]. And then I think	PIC7	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

that's really where the HSE [Health Service Executive - state funding provider] then stepped in and provided the funds that were needed.						
I think if you're able to speak about it [compliance with regulations] in terms of the goals and show that, you know, we're essentially all on the same side in terms of raising standards. And, you know, I try to work it that compliance with HIQA isn't a separate issue. That if we're doing good work, then we're naturally also compliant.	PIC9	Communal specification		Doing good work will lead to compliance	Overall strategic approach adopted by regulatee	Managing organisational culture
I think in every example that HIQA can get in [redacted] around compatibility issues. It's not for want of staff addressing it, or trying to address it, or PICs addressing it or their service manager addressing it. Or even director of service addressing it; it comes down to	PPIM4	Contextual integration		Lack of access to external resources	Accessing external resources	Dealing with the outside world

funding. And it's only really when that report comes in and there's fear in the HSE, that suddenly something is done about it or something has to be done about it.						
I think inspectors spend so much time looking over paperwork that it takes away from spending enough time having a real deep look at the quality of impact of the service that's being provided.	PIC8	Interactional workability	Excessive focus on documentation by inspector	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
I think inspectors, when they walk in the door, you know, begin to form judgment calls on the PIC that they're meeting, especially if it's the first time that they've met them. And that's just human nature and…But it does impact then on how the rest of the inspection goes.	PIC8	Relational integration		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

I think it's HIQA learning, you know? More…understanding better what its role is and services understand better what their role is. I can think of an example. Like, the very first time I ever engaged with a HIQA inspector. And I was a support worker at the time. And she asked me about food records for the people who I was supporting. And I was…we didn't keep food records with people we supported. But I panicked and I started going...'we must keep them somewhere'. And she was like, 'you need to be keeping a record of what people are eating'. And now I'm looking back on that, it was ridiculous. And if I had just explained to her, 'no, we don't keep records because we don't need to. People are able to speak for themselves. They do their own shopping. You can see the	PPIM2	Relational integration		Time required to understand and interpret the regulations	Views about the regulatory process and the regulator	Managing organisational culture

cupboard is full of good healthy food'. But at the time she was absolutely insistent that these people were in residential care. So you had to have a record of what they eat on a daily basis. And I didn't have the confidence or, you know, the vocabulary, you know, to stand up there and say, 'no, this is what we do'. So she didn't fully understand her role. I didn't fully understand mine.						
I think it's important that there is a relationship that I do that I can pick up the phone and ring it, my inspector, and to go 'listen such and such is happening. I'm thinking of doing this, what [do you think]?', you know?	PIC4	Activation		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
I think regulation having to adhere to standards gives them…Yeah, I do. I think it just gives pride and credence. Like, so, you know, like	PPIM7	Relational integration		Perceiving regulation as having professionalised services	Views about the regulatory process and the regulator	Managing organisational culture

sometimes in the past if you were working in disability services, people would say ‘Aren't you marvellous?’ Aren't you this aren't you that? But actually there's so much more to it. And so, like, social care, I think…Well, I think from our staff team I think they really feel that they are a really professional team. That they do a really good job. That they really look out for the residents.						
I think some some regulations could be clearer. And that's the...especially when...the restriction management and the chemicals restraint, some of them, you know?	PIC5	Individual specification		Lack of clarity in regulations	Views about the regulatory process and the regulator	Managing organisational culture
I think sometimes you can get tied up in the smaller bits and sometimes I feel like that part, maybe that overview, as opposed to going into the nitty gritty, is lost a	PPIM1	Communal specification	Perceiving some non-compliances as trivial	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

little bit sometimes. So you'll see non-compliances or substantially compliant for things and you're going, but overall that's a really good service. It's the small bits. So I think it's that balance of how to inspect locations and give that sense of whether it's a really good service. But then how do you do an inspection? Because you have to inspect against something.						
I think that they [the regulations] are involved in everything that we do now. So we don't really notice them from that point of view because it's become, we've kind of, probably adopted the culture of the regulations into the centre.	PIC7	Sustainment (normalisation)		Staff provide support to residents while not consciously referring to the regulations	Overall strategic approach adopted by regulatee	Managing organisational culture
I think that was why I was employed. It was because of my experience with HIQA because I didn’t have clinical experience. I didn’t know one end of a PEG feed	PIC3	Initiation		Employing managers with expertise in compliance	Managing human resources	Putting the right structures and resources in place

from another, but that really wasn't the priority because the nursing staff who were employed here have that knowledge. They were explicit that they wanted someone who had HIQA experience, who could guide it through inspections and set up the service to be compliant						
I think that's the, I think a lot of services now have risen to the standard that's been created with that and it just becomes a normal part of practice.	PPIM4	Reconfiguration		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
I think the biggest challenge with all of that was that there wasn't ever an impact assessment aligned to the implementation or the introduction of the regulations.	PPIM6	Strategic intentions	No regulatory impact assessment	Perceived legitimacy of the regulatory system	Views about the regulatory process and the regulator	Managing organisational culture
I think the governance, it's too, what's the word now? It's too set in it's definition. I think it needs to be broken down a little bit, you know? If there was local governance or if	PPIM5	Individual specification	Perception that governance regulation is too broad	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

there was, you know, daily governance or, you know what I mean? If you could solve, subdivide that into something else, it would then make it easier for people to understand what and where the issue was.						
I think the quality of professionalism really is the target, isn't it? So the regulations and, the standards are really about trying to achieve that. But when I started my career, funnily enough, in this particular company in the 90s, what we did was completely different and there was no professionalism about it. There was no real understanding of behaviour or anything. So to see all that, kind of, come in? Like regulation has really pushed that forward quite hard and…And I	PIC7	Internalisation	Perceiving regulation as a force for good	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

think I ought to be quite accepting of that. I think that was a good thing, though it was hard, but still a good thing.						
I think the risk with HIQA is that it, and as a result of the power that it has, it's creating an alternative institution in these community homes that people's lives are getting more and more restricted and restrained	PIC6	Individual appraisal		Impact of regulations on residents	Views about the regulatory process and the regulator	Managing organisational culture
I think the very first inspection in [redacted] was in [redacted] and instantly after the inspection an email went out from [redacted], who was the manager. The experience that the inspection...was asked what they were looking for, what they needed and are we learning and after each inspection we'd have a manager...there would	PIC3	Individual specification		Sharing inspection findings across the organisation	Communication processes that support compliance	Putting the right processes in place

be a manager's meeting maybe every month every six weeks. And whatever manager went through a HIQA inspection would run through it. And go through the learnings of that process and where we fell down, what we needed to do and that kind of stuff.						
I think the very first inspection in [redacted] was in [redacted] and instantly after the inspection an email went out from [redacted], who was the manager. The experience that the inspection...was asked what they were looking for, what they needed and are we learning and after each inspection we'd have a manager...there would be a manager's meeting maybe every month every six weeks. And whatever manager went through a HIQA inspection would run through it. And go through the	PIC3	Reconfiguration		Sharing inspection findings across the organisation	Communication processes that support compliance	Putting the right processes in place

learnings of that process and where we fell down, what we needed to do and that kind of stuff.						
I think there's a huge piece around like individualised, like, we're either moving towards a human rights, individualised, person centred in, in the ethos of what it was meant to, you know, not as a tick box exercise. And that needs to be incorporated into the regulations because every…if we're to provide really, truly from that ethos, every single centre should be different.	PPIM3	Legitimation		Human services need flexibility sometimes not allowed by the regulations	Views about the regulatory process and the regulator	Managing organisational culture
I think there's certainly been acceptance when [redacted] have been, I suppose, pulled up over certain things, that I think we have a clear acceptance of why those issues have occurred or why those issues have happened.	PPIM4	Normative restructuring		Organisational acceptance of findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

I think we have normalised it and so it's just part of our expectation now. So, you know, when people are doing their standard checks and they're checking things, you know? It's all come from those regulations and from, kind of, best practice that were there before that. I don't think people are constantly thinking 'this is in the regulation.' It's just part of their practice.	PIC7	Sustainment (normalisation)		Staff provide support to residents while not consciously referring to the regulations	Overall strategic approach adopted by regulatee	Managing organisational culture
I think we were at the forefront of disability services at the time and I think that was proven by the amount community houses we were opening and the amount of social care workers we were employing. And I think we moved quicker to the social model than other service providers across…nationally.	PPIM4	Negotiating capacity	Provider ethos aligned with goals of regulation	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

I think we're treated less as nursing homes now and people employed as inspectors are more social care. I think they shouldn't be nurses. There you go. There's one great suggestion. Don't employ nurses. I'm sorry. And employ social care people who are community care people whose whose, who've had training in community life or social care.	PIC6	Skill-set workability		Adopting person-centred approach to care	Overall strategic approach adopted by regulatee	Managing organisational culture
I think when different people come in to my centres because I learn something from every inspector. Because they do come in with their own interpretation of the regulations, their own experiences,	PPIM3	Normative restructuring		Educational approach by inspector	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
I think you think about why. Why am I doing that and is that the best thing to be doing and am I supposed to?	PIC2	Reconfiguration		Regulations cause staff to reflect on why they do things a certain way	Views about the regulatory process and the regulator	Managing organisational culture

I think, sometimes inspectors forget the triangulation approach where, you know, where they're bringing people into sub compliance over minor premises issues that has no effect on the residents who are living there. I think…everyone tells us all the time around safeguarding or anything or around uh, you know, around risk, to talk about impact. I really feel that HIQA inspectors need to take a wider piece around impact. Like what is the impact of a broken tile, you know?	PPIM4	Legitimation	Perceiving some non-compliances as trivial	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
I understand that we're not colleagues with the inspectors. But I would have felt that, you know, in a broader sense, everybody was on the same side. Had the same goal. And where we needed to be challenged or confronted on things, it was done in a very positive way	PIC9	Activation	Perceiving the inspector/regulator as ally	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

and that would have continued over, I would say, seven or eight years, even with different inspectors. That would have been my sense of it.						
I was involved in getting the house ready. I've never done this before so it was very enjoyable. I met the inspector pre-registration and she identified gaps that we needed to address before we sent in our package.	PIC1	Enrolment		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
I was mentoring Special Olympics for eight or ten years. One of the residents here I brought up to Limerick. He swam in the World Games and the Irish Games. What a brilliant thing to do. But at every stage of that, I was regulated to make sure that, you know, I stayed with him, you know, he was supported. I couldn't, I was still one to one with him. He got all his, you	PPIM5	Individual appraisal		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

know, medical, physical, emotional, all those needs were met.						
I worked in disability services when there was no HIQA on board in what was then termed, you know, challenging behaviour unit. And, yeah, you know, if I'm really, really honest, you know, part of the reason why I left disability services for such a long time was because I had a deep uncomfortability with what was going on around me	PIC8	Normative restructuring	Perceiving regulation as a force for good	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
I worked in one location where there were there was quite a lot of behaviours that challenged. But the organisation had thrown absolutely everything at it. You know, there was, there was behavioural psychologists, there was clinical psychology, every type of service that you could think of was thrown	PIC8	Communal specification		Incompatibility of residents	Providing resources to meet residents' specific needs	Putting the right structures and resources in place

at that service. And we did everything bar the blatantly obvious, which was to stop, just to stop mixing people who didn't want to live together. Now I got an absolutely brilliant outcome in one inspection there, I think was nearly a clean sweep because absolutely everything that needed to be in place was in place. But the HIQA inspector never said to me: 'Why are these people living with each other?'						
I would always push the narrative for change within the service. So I'd always be delighted to get that in a HIQA report because I know that that would be what I needed if I couldn't get anything else done in that regard. And I know a lot of our PICs informally use HIQA as a tool to escalate situations. Not always	PPIM4	Internalisation	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

compatibility issues, more, certainly, premises issues. They use HIQA as a tool. So like, so they go in their first day, like 'have you seen my bathroom?' like, you know?						
I would be there for a number inspections and it was like, 'why isn't this done? Why isn't that done?' and 'you need to do this'. So, nearly telling you during the inspection what you need to do. Whereas now it will be, kind of, to talk about an issue they said, 'did you ever consider this' or 'I've seen this in another service' and then because it, jeez, that's really good. Like, they've said to us like, we've done stuff here that they haven't seen anywhere else. 'That's a really good idea', and yeah, so it's completely different. It's very helpful.	PIC1	Interactional workability		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

I would definitely feel there would have been a culture of [inspectors] trying to find something.	PPIM4	Relational integration	Inspector focused on finding faults	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
I would definitely see more of a community presence [since the introduction of regulation]. I think that's definitely… there's been a huge, obviously, move away from massive group living. I would definitely say that. I would definitely think the quality is higher if we just took it all, I think our residents live in nicer places. I think they are being looked after by better trained people. And I think there are…opportunities in the world have improved and how they engage in that, you know? Even down to trips abroad, holidays, these are all things that have, I think because the regulation has moved away from massive group	PPIM3	Internalisation		Impact of regulations on residents	Views about the regulatory process and the regulator	Managing organisational culture

living and there's some of the positives.						
I would escalate the bits that are, knowing what's in your control and what's not in your control. And the issues that you needed support from above you escalate that.	PIC11	Initiation		Escalation of non-compliances by manager to provider-level	Clear assignment of responsibility for making compliance happen	Putting the right processes in place
I would feel I've seen a change of that [the approach adodpted by inspectors] over the decade. That they certainly seemed to begin with a very authoritarian, as I said, a black and white…"You're not complying or you are complying" kind of approach. That seems to have changed recently and appears to be more cooperative and trying to support the services to, you know, to make sure, ensure	PIC7	Relational restructuring		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

compliance is there and or do better than compliance.						
I would have seen a huge increase in the budget for facilities and the improvement of facilities from pre HIQA to post HIQA. In the organisation I used to work for and subsequently this organisation, we had to go back to the funders to seek additional funding to accommodate reaching the compliance standards of HIQA, following HIQA inspections and stuff.	PIC4	Normative restructuring		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
I would have seen a huge increase in the budget for facilities and the improvement of facilities from pre HIQA to post HIQA. In the organisation I used to work for and subsequently this organisation, we had to go back to the funders to	PIC4	Internalisation		Regulation has increased the level of funding	Views about the regulatory process and the regulator	Managing organisational culture

seek additional funding to accommodate reaching the compliance standards of HIQA, following HIQA inspections and stuff.						
I would have seen a lot of really good changes in practice and I suppose the pressure that HIQA were able to bring to bear on that to, you know, encourage that change. And I think has been really useful.	PIC9	Individual appraisal	Perceiving regulation as a force for good	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
I would have worked for 17 years where we had social care workers and healthcare assistants. So there was certain levels of paperwork which I could allocate to social care workers because they were suitably qualified. And healthcare assistants would have certain levels within their role that they would be required to fill out paperwork for, but not at the level.	PIC4	Skill-set workability		Poor standard of education for staff	Managing human resources	Putting the right structures and resources in place

Now I'm in the current organisation, purely healthcare assistants and I feel that they struggle with the level of expectation of paperwork that's required from a regulatory perspective in comparison to another organisation which I worked for, who employed social care workers.						
I would have worked in the private sector and I would find it much, much easier to be compliant because we're a charity because, we're not, it's not always about money like.	PIC2	Negotiating capacity		Not-for-profit motive means more resources available for compliance	Overall strategic approach adopted by regulatee	Managing organisational culture
I would say the vast majority of inspectors would have that openness to the PIC. Communicating with them and making a call.	PPIM1	Activation		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

I would sit down and we'd have formal feedback. I would take notes, really, really decent notes. And I'd section off all that under regulation such and such. I'll be writing my actions down and so by the time…So that's fine. We agree. We say goodbye. So as the inspector is preparing the report, we're actually addressing the actions before we even get the report. The report comes back and, I would do the compliance plan.	PIC1	Interactional workability		End of inspection feedback helps to clarify issues	Views about the regulatory process and the regulator	Managing organisational culture
I wouldn't be a decision maker in that process [resourcing] at all. But it would certainly give you the teeth you need to be able to come back and say, 'well, look, this is, this is not me now. I've been escalating this for a long period of time'.	PPIM4	Relational integration		Escalation of non-compliances by manager to provider-level	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

I’ve gone to all those meetings with the PIC, make our notes and make copious notes, I suppose. And the first thing we do when the inspectors are gone would be to actually meet with the team and just, I suppose, give a snapshot and an overview.	PPIM7	Interactional workability		Sharing inspection findings across the organisation	Communication processes that support compliance	Putting the right processes in place
I'd have, I'd be able to work with them [inspectors] and be able to work with the system. I've always been able to, kind of, i've always worked quite well with the system.	PPIM4	Activation		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
if I get a fully compliant unit here, designated centre is fully compliant today, do I stop looking to enhance the residents’ life because it's fully compliant? No, I don't.	PPIM5	Differentiation		Management perceiving regulations as the minimum standard	Overall strategic approach adopted by regulatee	Managing organisational culture
if I get a non-compliant and I line that up with my request for the shower, for example, and it's non-compliant the shower, it's not	PPIM5	Initiation		Escalation of non-compliances by manager to provider-level	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

compliant. We can't get it on, well, all of a sudden I get a minor capital grant which gets that compliant because eventually they've been so annoyed by me raising this every single meeting that they turn around and say, ‘well, listen, it's still not compliant’.						
if I go through the day in terms of people's personal care, of feeling safe in their home. Of making sure that all of their needs are met. Making sure that we're not restricting them in some way. That we're supporting them well. That, like, the regulations do match up with our expressed goals, you know?	PIC9	Internalisation	Provider ethos aligned with goals of regulation	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

if I look back on my last 6-7 inspection reports, there's very little written about what's done well, you know? Or there's a lack of expansion, you know? Like you can get a non-compliance for notification of incidents if you forgot to put one thing in your quarterlies. So that reads…the same non-compliant to non-notification of incidents…a family member reading that could think that there's loads of bananas stuff and nobody's reporting it when it's not. It's 'someone said that they have 4 window restrictors instead of five window restrictors', you know?	PPIM3	Relational integration	Perceiving some non-compliances as trivial	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
If it's a really bad inspection, when I say bad inspection is there's a lot of non-compliance, if there's major non-compliances, there's repercussions. Substantially	PIC4	Relational restructuring		Over-reliance on PIC for compliance	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

[compliant]? You're all fine. You've work to do, but ultimately it's the PIC that's leading then to try and pick up after it. So I've seen many inspections, where it's the PIC that manages, and the team go 'Oh, yeah, we got an inspection. But sure we knew we were doing well'. That's the mindset of staff teams when it comes to a HIQA perspective.						
if someone is just refusing to take three milligrams of melatonin like that's their fucking choice. And me escalating that, me bringing him back to the GP, I'm actually putting pressure on him to make a decision to comply [with their medication prescription].	PPIM3	Individual appraisal	Regulations in conflict	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture
if something goes wrong and HIQA or somebody come in and they say, well, you know, 'did you risk assess that?' 'Ohh we did yeah.	PIC8	Systematisation		Adequately evidencing compliance	Monitoring processes that support compliance	Putting the right processes in place

And that wasn't a problem back then’. And they say, well, show me the risk assessment and you go and you look up, ‘Jesus, I didn't update the risk assessment.’ It's the old rule: if it's not down on a piece of paper? Didn't happen.						
if there is stuff to do with properties, again, we have our own system here that we use, a flex system. And you'll push up whatever the job is and you, like, identify on that system then where this request is coming from. So is that something that needs to be done that we've identified ourselves or is it coming from the HIQA inspection.	PPIM1	Interactional workability		Clearly distinguising between actions required for compliance and self-idenitifed issues	Monitoring processes that support compliance	Putting the right processes in place
if there's something that drastically needs changing and drastically needs changing fairly quickly, uh, I think the PIC should be well capable of escalating it to a point. It	PIC4	Relational restructuring		Escalation of non-compliances by manager to provider-level	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

shouldn't be HIQA. HIQA come after and they see that, well as a PIC, I've escalated it for the last six months and where is it at now? Well, it's at, it's at that doorstep of that senior manager. But there's evidence from me with many emails or whatever						
if there's something that isn't strictly in line with regulation, I'd be very comfortable to say, 'look, we have a really clear justification for how we're doing this particular thing'. And we'll have it written down. We'll have a document and we'll have our rationale there. And I think we feel more comfortable in having that discussion with an inspector, whereas previously we might not have even questioned it.	PPIM1	Interactional workability		Organisational support for challenging findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator
if they [inspectors] were to comment on the painting and that, it would go up to our senior	PIC10	Contextual integration		Organisation provides adequate	Resourcing services to enable compliance	Putting the right structures and resources in place

management and they would organise any painting or any external works there. They [senior management] have never refused us any improvements from a HIQA inspection.				support for compliance		
if we had a designated centre in Wexford, they have a disastrous MDT team, we would have no support whatsoever.	PPIM7	Outer setting		Reliance on third parties for compliance	Accessing external resources	Dealing with the outside world
if we had committed to an action and weren't going to meet it for some reason, I definitely found it was always better to advise them [the inspector] before they come and find it. To have those discussions.	PPIM6	Relational integration		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
if we wanted to do something in a certain way, we would have, we would push back and have a discussion [with the inspector] around it.	PPIM7	Collective action		Negotiating compliance with the inspector/regulator	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

If you [as an inspector] are coming in and pointing out cobwebs or cracks or a little bit of rust on a radiator, you know? This is, these are things we [as an orgnisation] really worry about now. And then you're missing the point of, you know, a safe home, you know, a loving, caring home. And it's very hard to measure that. You see the...it's easy to pick out the rust or the cobwebs. But it's very hard to come in and measure, you know, are our people happy?	PIC6	Legitimation	Perceiving some non-compliances as trivial	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
if you [the regulator] come and it's a fire hazard or a fire door…So look, I mean, you give a time frame. You put mitigating factors in place…if it's around evacuation times. And that may mean a significant cost of extra staff to evacuate or it may mean moving somebody or different things.	PPIM6	Interactional workability		Implementation of temporary measures to achieve compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

And then you set maybe up to three months for replacement of fire doors or windows or whatever. A system to work that out. And that's a high risk response that's needed immediately. You involve the people and everybody is very clear that the time frame we've sent back to HIQA was part of the action plan and it must be delivered on.						
If you go in with a negative attitude towards them, people would pick that up very, very quickly and you're not going to get the best outcomes out of the audit, do you know what I mean? ‘There's five gaps, [PIC1], I think you should look at these’. Brilliant, right. ‘I'll have a go at these before you're back next time’. If you were adversarial, OK, I don't know where that process will be	PIC1	Enrolment		Positive engagement with findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

then. You could have 10 big gaps and it could be more like ‘you need to do this now’. And then it just becomes a negative having audits.						
If you have the bigger stuff, like something to do with buildings or property, you know? Those bigger…staffing levels or something like that. Then obviously the PIC and myself will…and then I'll go to the regional director. So if there is, we'll say resources or staffing levels. Now, we would have the ability to put in an emergency response. So if there is something identified that absolutely needs additional staff and, or whatever, it is immediately…and can't wait, then we have…Now, I would do it in consultation with the regional director. We can implement an	PPIM1	Contextual integration		Implementation of temporary measures to achieve compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

emergency response and put in additional staff there before we've gotten approval for funding or whatever, those kind of things.						
if you take the service that I manage right now and the vast majority of staff are care assistants. And a huge number of them are absolutely stunning at what they do in their job. But I personally believe that the days of staffing sensitive social care related services with level 5 care assistants should be gone. And that really genuinely shocks me that we haven't moved into that ground and defined that for services and said ‘you've got a timeline on which to professionalise your service'.	PIC8	Negotiating capacity		Poor standard of education for staff	Managing human resources	Putting the right structures and resources in place

if you were in the residential service, it was more the institutional part of it, it's those sort of things that just weren't there. And, so, but again they were running two different ways. So the community, the [redacted] guys, definitely would have had a better start because they were already working in that way. Do you know what I mean? Their ethos was that already. So they made the change very quickly whereas the guys on campus would have had much a different time of it.	PPIM7	Negotiating capacity	Services in the community were more suitable for compliance with regulations from outset	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture
if you're writing down something all the time and documenting it [to be compliant with regulations], you're not really thinking of, how do I sit with the resident? How do I listen to the resident? How do I build, you know, a home with this resident?	PIC6	Legitimation		Tasks required for evidencing compliance detract from time with residents	Views about the regulatory process and the regulator	Managing organisational culture

if you've a recurrent theme in your HIQA audits that will absolutely guarantee and garner support, you know?	PPIM7	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
I'll give you an example. So in our last inspection, we got a non-compliance under training because the whole entire team's training was up to date except for the new starter who started five days before the inspection. Who was booked into SAM (Safe Administration of Medication) the following week and wasn't giving meds; non-compliance on training. I think that's nitpicking now.	PPIM3	Legitimation	Perceiving some non-compliances as trivial	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
I'm at the stage here now where I don't be present for a lot of inspections. There's no need for me to be there. The PICs are more than capable of doing that.	PPIM8	Skill-set workability		Autonomy/authority of PIC	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

I'm familiar with the regs on a daily basis. Like, sometimes, as I said, it can be down to the interpretation. Like, a positive behaviour support plan, like I nearly need…I seem to have that debate constantly with inspectors around, they don't need to be completed by a behavioural therapist, you know? And inspectors, they will always go 'Oh, I'm going to have to check that'. And then they check it and then they come back and go, 'OK, they don't have to be completed by a behavioural therapist'. And so sometimes there is something like that, there can be some, kind of, disagreements around.	PPIM8	Coherence	Lack of knowledge on part of the inspector	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
I'm full time office based. The DSM is almost full time office-based and if we weren't there would be an awful lot more paperwork. And that's, kind of, to	PPIM2	Skill-set workability		Adequately evidencing compliance	Monitoring processes that support compliance	Putting the right processes in place

keep the paperwork away from the support staff and the social care workers who are working directly with people. And they will all tell you that there's an awful lot more paperwork. There's an awful lot more recording of restrictive practices, risk registers.						
I'm looking at…all times when I'm managing the house I'm looking at it from my HIQA standards point of view as well. And on this occasion, yes I will. I probably...don't know if not wrong to use it, it will be a case of that I do need this staff member in the house to be compliant.	PIC10	Initiation		Reflection on service through lens of regulations	Monitoring processes that support compliance	Putting the right processes in place
I'm lucky enough. it's a nice service and it's pretty well resourced. I have time to do my job. I have…this year now, last year I didn't. This year I have. And so we	PIC1	Contextual integration		Organisation provides adequate support for compliance	Resourcing services to enable compliance	Putting the right structures and resources in place

would have a program of audits that we would complete, which for the first year ever that we've completed all the audits as we wanted to complete them, we just didn't have to staff to do it last year. We've been OK with staff this year						
I'm never thinking about the regulations, as such, when I'm like working with people one to one, if I'm on the floor, actually I'm on the floor today after this, they wouldn't even enter my mind, you know? They might later on when I might have to write up a daily or, you know, make sure that if the resident is being with their money that requires receipts to be monitored. Yeah, I might think about it then.	PIC1	Differentiation		Staff provide support to residents while not consciously referring to the regulations	Overall strategic approach adopted by regulatee	Managing organisational culture
I'm not going to run a training say…what would you say, first aid training, for example, when I've only got three people. It's a waste	PPIM7	Negotiating capacity		Small organisation size impacts on training provision	Resourcing services to enable compliance	Putting the right structures and resources in place

of resources. So it's like we're not big or small. We're at that awkward stage in between where the staff training bit is going to be, you know, it's going to be difficult to be compliant for that all of the time. And it's definitely the size of the service.						
I'm trying to think, like, even as simple as like, person-centered planning could be one. So we have to evidence that everyone has to have one. But then there has to be clear goals set and then you have to evidence how you are reviewing whether the goals are met. Like, how everyone's gonna do that is completely different. And what people think is a regular review, you know what I mean? It grows into…and I've even seen it across PICs, you know? Like I have people…I've one service who	PPIM3	Interactional workability		Lack of clarity due to differing interpretations of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

reviews the PCP goals and how they're meeting them weekly, and I have another person that does it quarterly. And then that causes tension and, you know, then we're left going, well, ‘what's best practice?’						
I'm very much in favour of HIQA as an independent body coming in. There needs to be somebody coming in and, kind of, holding those standards and auditing and judging services and locations on those standards.	PPIM1	Internalisation	Perceiving regulation as a force for good	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
I'm very open with them [other senior managers] and I say ‘we’ve three non-compliances’, they read the report anyway, but then I'll sit down and discuss with my line manager, who is now the provider nominee anyway. So I discussed with her and she said, 'well, what do we need to do?' And I tell her	PPIM5	Collective action		Senior management engagement with inspection and compliance processes	Overall strategic approach adopted by regulatee	Managing organisational culture

exactly what we need, what we need funding for, or whether we need a whole revamp						
in a positive aspect it [regulation] obviously…it safeguards the residents and goes for quality I suppose. And I suppose our histories are, you know, the history in this country around service provision is, I don't even know the word, is nightmarish.	PPIM3	Individual appraisal	Perceiving regulation as a force for good	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
In fairness to the inspectors, it's what the regulation says. I am, I suppose, on the black and white face of it, non-compliant. The young person is not getting his identified need met or whatever it is, you know? And then, like, you know, I will come under a non-compliance both in, you know, the health and care aspect depending on the discipline	PPIM3	Outer setting		Reliance on third parties for compliance	Accessing external resources	Dealing with the outside world

that's missing. Then it'll come in under support plan as well like. So you could end up with two or three non-compliances around the same issue which is what you can't access. And often what's happening is then you give back an action plan and it remains outstanding until the next inspection if…particularly if you can't get private. There's some things that are impossible even to get privately here.						
in general, it [the introduction of regulation] has had a positive effect in that standards have definitely improved in services. So depending on…I've worked in a number of organisations and some of the organisations, I suppose the, kind of, older…I would feel the older, longer established organisations, were potentially at a different kind of a level. There would have been	PPIM1	Internalisation		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

quite a lot of old school, not old school, but there would have been a lot of people without a qualification, without any formal education and, no offense, but, you know, that's, kind of, the way that services would have been established in the past. So it has improved that and the requirement for qualification and all that kind of thing.						
In looking for advice, looking for how exactly, as opposed to me reading that 80 page document, can you [the inspector] just tell me what I'm meant to do? And then, in every respect, they would have been right to say, 'would you just read the document and come back to me!' They have been, without exception, very helpful and they are a pleasure to deal with.	PIC11	Activation		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

in one service that I used to work in a HIQA inspector came in and said ‘you can't charge the residents for holidays. You simply can't’. And that whole organisation sent a communication to every service manager over multiple services, saying ‘from here on out you can't charge residents for holidays’, and that lasted 2-3 years. And the amount of holidays that were organised for persons fell and fell quite significantly.	PIC8	Internalisation	Regulations in conflict	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture
in previous decades we put all of our trust into the religious institutions and then we all got burned by that. And then we were, kind of, questioning, well, ‘how did that happen?’ And I'm wondering whether we're, as a country, we’re doing something similar? That	PIC7	Legitimation	Lack of oversight of the regulator	Perceived legitimacy of the regulatory system	Views about the regulatory process and the regulator	Managing organisational culture

we're putting all our trust into healthcare institutions now and assuming that they are always going to be perfect and squeaky clean and, you know? Does that mean that in 2, 3, 4 decades time people go well, 'how did that happen? What went wrong?' So I do think there needs to be a bit more oversight, and not just an assumption that if HIQA says something it, it has to be right.						
in previous years it [the nature of the non-compliant findings] was speech and language, it was psychology and so on. So we had to find those resources. And if we had to we might have to find money [within the organisation] in the interim and just go ahead and get something so that	PIC7	Contextual integration		Organisation provides adequate support for compliance	Resourcing services to enable compliance	Putting the right structures and resources in place

we're compliant and then try and get the money back out of the HSE [Health Service Executive - state funding provider].						
in something like that [large amounts of funding to be compliant with fire safety regulations] we would have to go to the HSE [Health Service Executive - state funding body]. And I think we're not alone there I imagine. I think a lot of these changes have come through as as a result of Grenfell Tower for the fire regulations. So they trickle down and the government gets nervous about any service provider that has a fire risk	PIC6	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
in terms of illustrating compliance, I think there's frustration probably on both sides about that, but certainly on ours.	PIC9	Collective action		Adequately evidencing compliance	Monitoring processes that support compliance	Putting the right processes in place

in terms of pushing back to HIQA, I think obviously because we've got the rapport with the two ladies, I think that helps as well.	PPIM7	Collective action		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
It [regulation] does have set structures. It has to have protection of the residents at all times. You know, that they're safe, they're healthy. All those things are promoted in order to…finances are all looked after, governed in the correct way, and all those kind of things.	PPIM5	Internalisation	Regulations are clear in their prescriptions	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture
it [the current model of regulation] creates an institutionalisation through the back door because what happens? I'm not saying this happens in our houses now, but what can…what can happen is 'ohh yes, and did that person have an active day?' 'Yes'. 'Did they, did they do this?' 'Yes'. I tick that box and 'yes, now get them to bed quick	PIC6	Intervention performance		Impact of regulations on residents	Views about the regulatory process and the regulator	Managing organisational culture

so we can fill in all the other paperwork'. And the person's life just becomes like, you know, a conveyor belt, you know?						
it [the introduction of regulation] certainly has improved the standards across the board in every aspect. Whether that's the staff coming into residential care, the rights of the young people, restrictive practices around the young people. Like for me from when I started in 2011 to now it's chalk and cheese. Like the standard of care has significantly improved across the board. And, I suppose, in pretty much every single area I would say in the regs, there has been an improvement of that. So very much for me, a positive.	PPIM8	Internalisation		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

it can be a lonely place to be because it's your name on everything and it…the buck stops with you. And I think a lot of people don't…They don't want that pressure. And I do fully understand that I'm lucky I am within an organisation that's well resourced. Others are not as well resourced as ours are. And I know a lot of other people who work as PICs and are walking away from it because it's too much.	PIC11	Contextual integration		Over-reliance on PIC for compliance	Clear assignment of responsibility for making compliance happen	Putting the right processes in place
it can be frustrating when you submit, say, when you submit, say, floor plans for the registration of the centre, you do a walk around of the centre, you have a discussion around what is an internal room versus the a corridor. The inspector tells you that that needs to be changed. It can't have that in the bedroom that needs to be X, Y and	PPIM2	Interactional workability	Inconsistency among inspectors	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

Z. And then you go, you get an architect to redo the plans, you change around, you submit it, and then the fire expert in HIQA will come back and tell you to change it back to what the original plan was, you know? So things like that can be frustrating, you know?						
it can be incredibly frustrating where your HIQA inspection, and people know where you work, and they look like, where you go and they see the number that you have to compliance with [in a published inspection report]. And you're like, those compliances are totally outside my control, that can be very frustrating	PPIM8	Contextual integration		Autonomy/authority of PIC	Clear assignment of responsibility for making compliance happen	Putting the right processes in place
it depends on what CHO you're in. We're quite well resourced at the minute in CHO [redacted] so there is SLT, there's social work, there's physio. We have a great	PPIM7	Outer setting		Reliance on third parties for compliance	Accessing external resources	Dealing with the outside world

psychologist and psychiatry support.						
it goes back to my comment about discordant regulation or policies. Where, equally you have, you know, nurse's registration and doctor's registration and they're not always commensurate with what the HIQA regulation on medication is in a social care setting. And the administration, like it's almost safer for anybody except a nurse or a doctor to administer medication with the NMBI and the IMC and all of that.	PPIM6	Individual specification		Discordance between regulator and professional regulators	Views about the regulatory process and the regulator	Managing organisational culture
it is a whole of system approach. So it's not just the registered provider, it is the head of finance, it is the head of estates. It is the primary care. Mental health. All of these services that need to be involved.	PPIM6	Collective action		Senior management engagement with inspection and compliance processes	Overall strategic approach adopted by regulatee	Managing organisational culture

it is not just a blanket ‘let's do this to satisfy HIQA’.	PPIM8	Legitimation		Organisational support for challenging findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator
it makes quite a difference to the inspection, particularly if someone you feel is being fairly aggressive and because...then that makes everyone very defensive	PIC7	Relational integration		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
It very much is person centred, but I…I'm allowed the…the flexibility to say, right, that person, we're going to need somebody extra in the morning because that person takes two people for two hours and we can only afford one person for one hour because it would impact on the other people, you know? And I would be given that flexibility. Like, nobody would question me and say, why have you got all them people on?	PIC2	Contextual integration		Autonomy/authority of PIC	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

It was a very, very tough process to go through [the initial years of regulation] and you, HIQA, was very much a regulatory authority in every way, shape and form at the time. Because, in fairness, that's what we needed.	PIC11	Internalisation	Degree by which regulation is welcomed by an organisation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture
It was great in terms of building the structure for ourselves, let's say going from…we would have a PIC who was part of the team on the floor. Like, that person is now off the floor. They've, you know, they're full to paperwork hours. You've got your, you've got your two team leads, one in each house. So it really, like, the regulation helps you to build a structure.	PPIM7	Relational restructuring		Regulation has resulted in improved governance structures	Views about the regulatory process and the regulator	Managing organisational culture
it was very, kind of, hospital looking like whereas now like the, you know, as much as possible, the houses are built like a home setting and it's, like, even the likes … we	PIC5	Individual appraisal		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

would have had caterers coming in and cooking the meals and just delivering them out and stuff. So very, very clinical, fairly hospital and and environments. Where it's...now, you know, the residents getting involved in the cooking and so forth that and I think that have changed.						
it would be very much dependent on what resource is available or how strong the HIQA report was…how strong the report came down on the, like, the registered provider in the sense, you know, as in what pressure they're under to find the solution.	PPIM4	Relational restructuring		Inspector/regulator escalating issues to provider level	Clear assignment of responsibility for making compliance happen	Putting the right processes in place
It'll be down to actually parental consent, so it could even be down to: the school placement could have been identified, and actually the parent has refused to sign the	PPIM8	Outer setting		Reliance on third parties for compliance	Accessing external resources	Dealing with the outside world

appropriate paperwork. So then we're getting a non-compliant something that isn't in our control.						
it's a very concerning feature of an inspection for an inspector where the person in charge, who should be knowing what's going on, is learning from the ‘oh geez, thanks for telling me that, I’ll look into that’.	PIC11	Relational integration		PIC is unaware of issues in their centre	Monitoring processes that support compliance	Putting the right processes in place
It's a very, very pressure-driven job. There's an emphasis really on the PIC more so even than the organisation, you know? There’s almost an uneven, you know, when it comes to get, if there's anything to be blamed for, you know? The PIC is the best person in the world when HIQA come in and you get a really, really good report. And they’re the worst person in the world when HIQA come in and you	PIC8	Relational restructuring		Over-reliance on PIC for compliance	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

get a fierce smattering of noncompliance						
It's always that kind of thing, like the school inspector. You're always on the back foot a little bit because you're the one inspected.	PPIM6	Relational restructuring		Fearing the inspector/regulator	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
It's dependent on the non-compliances, to be honest. Erm, if they're small items, ultimately I can control that and I can set a time limit of those non-compliances and I can manage that. If they are more serious it will be flagged anyway with my line manager.	PIC4	Interactional workability		Autonomy/authority of PIC	Clear assignment of responsibility for making compliance happen	Putting the right processes in place
it's giving that feedback to the staff then, that when you're nagging them in six months time and that their person-centred plan goal that is meant to be reviewed every three months, you haven't done it, 'do you remember the last inspection?	PIC11	Reconfiguration		Adequately evidencing compliance	Monitoring processes that support compliance	Putting the right processes in place

They said they couldn't find it? You took them on holidays, they had a great time, would you write it in for God's sake'.						
it's great for improving quality and, you know, keeping you on your toes and I don't mean that in a, you know, like a fear thing but just to…to have, you know, to have guidance.	PIC2	Communal specification		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
It's like, 'did you risk assess this person getting the bus', you know, 'on their own?' Of course [we did]. We're not gonna let somebody get on the bus on the road if there's a risk. But the fact that we have to have it all documented? And 'did you risk assess that that person might slip in the kitchen?' Like, hello, of course we think about the risks of a person slipping in the kitchen. But we don't have to have everything documented	PIC6	Legitimation		Adequately evidencing compliance	Monitoring processes that support compliance	Putting the right processes in place

It's not like we have to do this because HIQA said we have to do it, they're done anyway. Do you know? It's best practice and it's what's best for the resident. So that's what we'll do, which in turn makes us compliant.	PIC2	Differentiation	Quality of care by provider organisation perceived as high quality irrespective of regulation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture
It's not that we're doing something to be compliant, we are compliant because of what we're doing	PIC2	Differentiation	Quality of care by provider organisation perceived as high quality irrespective of regulation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture
it's rare for a staff member to come to me and say, you know, 'we're not achieving this [redacted - name of PIC] and that's touching on regulation such and such', you know? They're, they are conversations that would be really, really rare with a frontline member staff, if I'm honest.	PIC8	Relational restructuring		Lack of awareness of regulations among staff	Managing human resources	Putting the right structures and resources in place

It's the ones [non-compliant findings] that are a big surprise that would concern me most. And I would think there shouldn't be a massive surprise if I've done my annual reports and my six month reports and my audits, I would be hopeful	PPIM6	Activation		Effective monitoring of service by management	Monitoring processes that support compliance	Putting the right processes in place
It's touching on what I keep on saying. Quality, you know? I have a legal responsibility to run a safe service [in compliance with the regulations] that's been tempered by my ability to recruit staff.	PIC8	Outer setting		Challenges in recruiting/retaining staff	Managing human resources	Putting the right structures and resources in place
it's touching on what I was saying earlier about the qualitative rather than the quantitative, because then it [evidencing compliance] almost turns into a leaving cert [Irish secondary school national exam]. Where PICs are, you know, lining up the ducks to make sure that the [inspection] outcome is good	PIC8	Interactional workability		Adequately evidencing compliance	Monitoring processes that support compliance	Putting the right processes in place

I've attended the webinar recently on the PIC role. And that sort of thing is helpful because a lot of people are just, kind of, thrown into it. And I know there's a lot of guidance up on the website, but most people don't have time to sit down and go through that. So the webinars are quite helpful, it does help get a better understanding of the role and what's involved.	PPIM2	Individual specification		Regulator engages with stakeholders outside of inspection activity	**Communication processes that support compliance**	Putting the right processes in place
I've been given out to [by inspectors], for numerous things, even since then. And, you know, for that...nothing to do with creating a good home. And then it's, uh, in the beginning they [the inspectors] were very focused on, uh, health and safety and risk management and infection prevention control. To the extent where they were losing the focus on the resident. And [should have	PIC6	Communal specification	Perceiving some non-compliances as trivial	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

been asking] 'is the resident happy and content in their home?'						
I've been involved in, I'd say about 8-9 inspections. Probably more as a PIC. And in the vast majority of them I have found the inspection process respectful and without much to complain about.	PIC8	Activation		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
I've experienced inspections where, you know, I've gotten really, really good outcomes and there's been times where I've gotten really, really good outcomes and felt that didn't deserve them. And there’s times when I got, you know, less good outcomes and being really, really frustrated because what I felt in my heart and soul was that we were providing a	PIC8	Relational integration		Perception that inspection findings are not always a true reflection of quality of service	Views about the regulatory process and the regulator	Managing organisational culture

really, really strong client focused-service.						
I've got non-compliances for fire because someone forgot to fill out the daily check once in six months. I just think that's…then we're just now…everyone's at like…I actually find, particularly with fire, my teams are stressed out about ticking these checks rather than actually going around, you know, wondering like, do you know? If there was an actual fire, lads, you know, how are we getting out?	PPIM3	Individual appraisal	Perceiving some non-compliances as trivial	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
I've read restrictive practice registers where it's populated with stuff that, if I'm honest, I just roll my eyes to heaven and go. 'Why are we putting that down on a spreadsheet?' You know, putting a lap belt on somebody is a duty of	PIC8	Communal specification	Perceiving some non-compliances as trivial	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

care. It's not a restriction, and there's a lot of, kind of, almost navel gazing where you have disputes and chats back and forth with inspectors and they go ‘Ohh yeah, well they can't get out of the chair, so that is a restriction’. And, you know, what goes unnoticed is that, you know, they [thre residents] haven't gotten into our community in the last six weeks because we're short staffed. That to me is a real restriction, not the lap belt						
I've seen significant change between 2013 [when regulation was introduced] and now and in the practices	PIC5	Individual appraisal		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
I've seen some questions [from inspectors] of things which you, kind of, wanted [to say] 'should the person really be questioning that?'	PIC7	Legitimation	Inspector questioning decision-making	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

Because you...particularly clinical decisions, where a psychologist has said we're going to do something X, and the inspector disagrees with that. Well, it's not really their place to disagree with that.			of another professional			
I've seen the before and after pictures. So I've seen residential services without HIQA regulatory body involved, and then I've seen it after it was instigated after inspections and regulation was involved. And I, as a whole, I would say it's definitely better for the people that we support within the services.	PIC4	Internalisation		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
I've used HIQA regulatory inspections to benefit, say, property, to the upkeep of the property. To push the rights of the residents and it helps having regular inspections.	PIC4	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

I've worked in section 38 and section 39. There's pros and cons to each, but I feel like section 39, which aren't directly funded, you have more ability to be flexible with your funding and how you spend it whereas section 38 are linked directly. We have the salary scales. So you have less autonomy in your funding. So HIQA come, they're like, ‘oh, you need to have this’. And we're going ‘we don't have the funding’.	PPIM1	Contextual integration		Lack of access to external resources	Accessing external resources	Dealing with the outside world
Like I think back to [redacted] and you'd never do it…It'd never be done now. Like the dinner van would head out in the evening, like with the dinners. Like, so there was, you know, a ban-marie arriving into a house like, which was ridiculous. With a kitchen in it, you know? Kitchen and a fridge and all the rest of it.	PPIM7	Intervention performance		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

Like somebody sitting up from half five in the morning because there's not enough staff, but we just did it like we didn't. You didn't think about it or question it. Whereas now if you're doing something you question it, you say, why am I doing that?	PIC2	Individual appraisal		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
Like we would have a very clear framework of the inspectors coming to [redacted], their background, and what they are looking for.	PPIM4	Cognitive participation		Knowledge of inspector's focus	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
Like, generally, it'll be pick up the phone and so, you know, you you can do that and they [the inspectors] can do that and they pick the phone to me and we can have a chat about it. And then if there's something that they need assurance, which, then it's an email, you know?	PIC5	Collective action		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

And so, yeah, yeah, I find them very approachable to be able to talk to them.						
management wants us to be fully compliant, but also by being non-compliant or substantially compliant: in some cases it enhances your service. It allows you then to debate and discuss where we need to go with this and how we can improve the service	PPIM5	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
many services [before the introduction of regulation] were still working off the old charity model which kind of worked on the emphasis that, you know, whatever you provide is a benefit because otherwise it wouldn't be provided. And, you know, that needed to be, kind of, the boundaries needed to	PIC8	Strategic intentions	Provider ethos aligned with goals of regulation	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

be pushed out further. I think was probably more prevalent than some…in the religious ethos organisations. And that's certainly changed.						
maybe a few years ago, when we weren't working in line with regulations, and we had to introduce them if…it was a big change. And I talked about having to change the culture and become more person centred and…it was a big change for us.	PPIM2	Enrolment		Adopting person-centred approach to care	Overall strategic approach adopted by regulatee	Managing organisational culture
maybe an immediate response [to address a non-compliance] would be to provide, I don't know, four hours of one to one staff support for this person to do other things, have some personal time to enable them to do more. But, you know, he [the inspector] could come back the next time and they say, ‘well,	PPIM6	Systematisation		Addressing non-compliances in a dissatisfactory manner	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

that's not sufficient. There's still an incident here’.						
maybe one day you would have someone who would come from a nursing background and they're sole focus will be on the medication and then you might have someone who'd maybe come from health and safety background or something like that. And it's all focused on hazards within the centre and a lot was nearly dependent on the background of the inspector themselves.	PPIM8	Skill-set workability	Excessive focus by inspector on their area of expertise	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
my aim is not to reach the bar [set by compliance with regulations]. My aim is to be so far ahead of the bar that the bar doesn't reach me.	PPIM5	Initiation		Management perceiving regulations as the minimum standard	Overall strategic approach adopted by regulatee	Managing organisational culture

My biggest issue with HIQA is not around…I think that the system needs to change in terms of what they inspect…like I feel it's crazy that…i've always felt that something like health care needs or social care needs are inspected in the same way that something minor like, you know, and I'm trying to think of one of the lesser inspections… Paul Dunbar Insurance? OM11 …insurance, exactly. Or statement the purpose, you know?	PPIM4	Individual appraisal	Perceiving some non-compliances as trivial	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
my huge area of, kind of, expertise would be in ASD and behaviour management. So you'll see the private providers taking over that. And then very realistically working, like, having a really clear	PPIM4	Individual appraisal		Organisation committed to compliance rather than goals of regulation	Overall strategic approach adopted by regulatee	Managing organisational culture

concept of your regulations and working just to regulation.						
My job is to moan to make the service better and to get the resources. But if someone is coming in and saying, actually, like the fire system, it absolutely needs an overhaul or whatever. And if that's a HIQA finding and we're going to be closed. If that's, you know, if that's not rectified, there's no choice in the matter. Whereas if I'm saying it with just maybe on the back of an electrician, they just know that's what I do. That's, you know, she's here to get, to bring money into the service and all the rest of it. But when, once you put HIQA behind it and regulation, it's a different ball game because it has to be risk assessed and it has to	PPIM7	Relational restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

be…Like they, they don't want to be closed, you know what I mean?						
my next line manager would be somebody that would look at it [a non-compliance] from the financial perspective and the nuts and bolts of the practicalities of what you're asking to be done. [redacted], ‘a certain time frame, well, that's not realistic’. Or ‘there's no way we can afford to renovate the kitchen’.	PIC4	Contextual integration		Organisational resistance to releasing funds for compliance	Resourcing services to enable compliance	Putting the right structures and resources in place
My view now compared to my view in 2013 has completely changed for the better insofar as I would have seen, you know, kind of a tick box, you know? ‘Oh HIQA are coming today’, so today has to be the day. It's an announced inspection. The place is painted	PPIM5	Individual appraisal	Fabricating compliance	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

within an inch of its life. Pictures are put on walls and this is all, and it was all false. It was all show.						
No, I think it was assistance with that. It gave staff something to go off. Like, in terms of, like, it's, you know, especially in the early days. Like, when HIQA came out and you would have seen a lot of, obviously, the articles published in papers and stuff like that, it would have given staff something to be accountable for. So you're like 'we're due a HIQA inspection soon. Can everyone look at their files and folders? Can everyone update their support plans?'	PPIM4	Normative restructuring	Added accountability due to presence of regulator	Regulation increases accountability	Views about the regulatory process and the regulator	Managing organisational culture
normally yourself and the PIC then would meet up with the inspectors. They go through bits and pieces with us. I always find that's a good meeting.	PPIM7	Collective action		Senior management engagement with inspection and compliance processes	Overall strategic approach adopted by regulatee	Managing organisational culture

now a resident absconds, [since the introduction of regulation] we have risk management with behaviour specialists, with all our team there in place. Now we have notifications to HIQA. Now we have all that other layer of stuff, which is huge insofar as to protect and also is a huge learning for risk assessments…for developing care plans, developing all those things.	PPIM5	Intervention performance		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
Now there's certain areas that they [inspectors] look at, you go 'OK that's really not dramatically important stuff'. Like, the statement of purpose, you know? Or the residents' guide. I've never once had a resident knock on my office door and say, 'I'm after forgetting, what is the service you're meant to be providing me? Can I have a look at the residents'	PIC8	Individual appraisal	Perceiving some non-compliances as trivial	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

guide?' But some inspectors think things like that are really, really important and spend enough time reading through them.						
Obviously, if it's a non-compliant and if it's flagged as a serious health and safety concern, it needs to be done yesterday. I get that. But there's certain things that I would manage and I would like to put down as a realistic time frame to do it.	PIC4	Interactional workability		Judging how much time is available to address non-compliances	Effectively responding to findings of non-compliance	Managing the relationship with the regulator
Occasionally during the course of an inspection you'll get that kind of friendly bit of guidance as in 'there's a lot of replication here'. Instead, I suppose information passed on in a kind of helpful way, and that 'we don't need this'. You don't have to have a big massive	PIC11	Individual specification		Educational approach by inspector	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

white folder, or the bigger doesn't mean the better.						
OK, so you've different inspectors. And different inspectors then have different skill sets and there's different things that they're interested in. So one inspection there might be say, take medication, for example. One inspector might come along and say fully compliant in that regard. [Coughing] Sorry, just a dry cough so you'll have to ignore the cough. And the more I talk, the more I cough anyway. So. This is the, kind of, the consistency piece. So, like, you know what I mean? And then the next somebody comes and they look at the exact same policy and look at how we're doing things again. And then it's like, well ‘you	PPIM7	Relational integration	Inconsistency among inspectors	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

haven't got whatever' and then we're saying 'Jesus, like, you know? Mary, when she came the last time didn't even look at that'.						
on all the inspections up until the last one in [redacted], our CEO would have come to the feedback straight afterwards.	PPIM2	Contextual integration		Senior management engagement with inspection and compliance processes	Overall strategic approach adopted by regulatee	Managing organisational culture
once the inspector can see that you're working on it, that you haven't just ignored what they have said or, you know, kind of passed the buck on to somebody else. So each time the inspector comes, each time the inspector asks I can say 'look, this is what we've done about it', you know? I keep track of, you know, any communications with the house, with the landlord and conversations with finance	PIC1	Relational restructuring		Flexibility of the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

about it. So that they can clearly see that we're working on it.						
Once you're seen to be addressing the issue and not ignoring it and linking in with them and ringing and asking questions, you can get through to the other end.	PIC11	Activation		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
one inspection where I remember the inspector, I won't mention names, they were, it was in the [inaudible]. Immediately we looked and go, 'you know that little book you have in your shirt pocket, is there any chance we can get a copy?'. 'That is the Health Act that you should have been referring to from the start'. So it was that level of information was the big gap at the beginning	PIC1	Reframing organisational logics	Organisational preparedness for regulation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture

One of the things that I try and impress on the staff teams that I support is to think of it from the point of view…If an inspector walks in here, they have to be able to make a judgment on how the service is within probably 6 or 7 hours of looking at what's in the files here behind me. So the better the files are, the more kind of …straightforward they are. And where A points to B points to C points to D, kind of triangulation approach, the easier it is for the inspectors. The more relaxed they are about how things are running here. And rather than everyone going in and just doing bits here, there's a, kind of, there's a kind of a joined up thinking process about how we actually evidence the support frameworks within our service.	PPIM4	Interactional workability		Adequately evidencing compliance	Monitoring processes that support compliance	Putting the right processes in place

organisationally, the issues we're having [in response to the introduction of regulation] then was being able to increase management time. Like certainly, certainly the systems we created at first increased the management time without, like it was seen as additional things because there was no hours increase. We're still on the floor and being asked to do those extra things	PIC3	Skill-set workability		Insufficient time for management to attend to regulatory matters	Resourcing services to enable compliance	Putting the right structures and resources in place
organisations can sometimes become resource obsessed and say 'well, we're short staffed so that means then we've to batten down the hatches and not access to the community or not do certain activities'. When actually that's not always 100% the case. And maybe we need to have a shorter walk or a shorter...you know, make some adjustments but that we still uphold	PPIM3	Adaptive execution		Organisational resistance to releasing funds for compliance	Resourcing services to enable compliance	Putting the right structures and resources in place

the rights of the person and the choices and their their best interests.						
Our clients are, you know, the unique needs of each individual doesn't always fit into the boxes I suppose. And I suppose how do you create regulation without it being black and white? I don't know is that possible, but that's the thing.	PIC11	Negotiating capacity		Human services need flexibility sometimes not allowed by the regulations	Views about the regulatory process and the regulator	Managing organisational culture
our relationship very much is a collective relationship where you as regulators, you give us guidance. You give us a kind of a book to, kind of, guide our standards from.	PPIM2	Activation	Perceiving the inspector/regulator as ally	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
our reputation is growing and we are known as an organisation that does strive to be the best we can, not just meet the basic standards. We do strive to be genuinely	PIC11	Reframing organisational logics		Adopting person-centred approach to care	Overall strategic approach adopted by regulatee	Managing organisational culture

person-centred. And I think we're getting that reputation						
outside the inspections we have the contact details and they [inspectors] will always answer it.	PIC7	Activation		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
over the seven years I've been here, I think they [staff members] are more intuitive to the thinking, well, 'what would the clinical team want us to do?' And so it's kind of moved from just your compliance to them [asking] 'what actually, what's the best thing we can do for this person?' And, but sometimes we need to go back to the regulation to say, well, you know, that needs to be done this way. Just actually be done properly.	PIC4	Communal specification		Human services need flexibility sometimes not allowed by the regulations	Views about the regulatory process and the regulator	Managing organisational culture
over the years when I do the compliance plan, I've seen various different techniques. Where I sit down with my line manager and we	PIC1	Interactional workability		Autonomy/authority of PIC	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

work through it and that's the way it would have happened, I suppose, from the early stages of 2013 onwards. But I slowly saw that filtering where it was the PIC that managed the compliance, action plan. And then you sent it on to somebody to review and, you know, they may change a bit of wording and I've seen it go right up to the CEO of an organisation.						
Overall, it's, look, it's an imperfect system and it’s a snapshot in time on a given day and people have to accept that it’s a snapshot on time on a given day. OK, in certain….and there's other things that obviously that they [the inspectors] might see that ‘OK, you haven't done this for the last three months and’… But on the day you have to accept what you find there. I think they [the inspectors] are	PIC5	Individual specification	Perceiving the inspector/regulator as ally	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

there to help us reach a certain level and keep those standards at a certain level.						
Paperwork sometimes will be difficult for the direct support workers trying to bring them along to why you were recording it.	PIC1	Skill-set workability		Effectively convincing staff that compliance is also their responsibility	Clear assignment of responsibility for making compliance happen	Putting the right processes in place
PIC's, you know, 90% of a PIC's job is talking. Most of the time, you know, if somebody's in your office or when you're walking around you're talking to people and a lot of it goes unrecorded. And then you get really frustrated then when somebody [an inspector] comes in and says 'well, I see your last team meeting was cancelled, why was that?' And I was going 'well, you know, A, B and C happened. I was, you know, speaking to…you know? I had a lot of one to ones'.	PIC8	Systematisation		Adequately evidencing compliance	Monitoring processes that support compliance	Putting the right processes in place

And, you know, ‘well can you show me the evidence that you had those one to ones?’ ‘No, I can't, I'm really, really sorry’.						
PICs talk amongst themselves and they say, well, you know, ‘John [a fictional inspector] is really hot for A, B and C so make sure that you've got A, B and C covered'.	PIC8	Coherence		Knowledge of inspector's focus	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
regardless of HIQA, we would strive to have very high standards anyway, do you know?	PIC2	Differentiation	Quality of care by provider organisation perceived as high quality irrespective of regulation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture
resources have increased definitely because of HIQA’s intervention	PIC4	Individual appraisal		Regulation has increased the level of funding	Views about the regulatory process and the regulator	Managing organisational culture
services have almost become reliant upon HIQA as their bargaining chip to get what they've	PIC8	Normative restructuring	Using findings of non-compliance to	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

been already bloody demanding [from the state funding body] for forever and a day.			support argument for resources			
she [the inspector] would phone up, and if she needed an answer, you know about an action, or if she didn't clarify it on the day and she links in with the actual house. And so, yeah, and I feel it is important to have a good relationship because if she knows you're working in the best interest of the residents. And you can contact her if you're not sure what she's actually looking for.	PIC10	Collective action		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
she would have the coordinator's meeting first. Then they would have had the team lead meetings in the house next. And then, you know, so she had a structure to the meetings. So the information filtered down one way and then filtered back up. So they would	PPIM7	Initiation		Sharing inspection findings across the organisation	Communication processes that support compliance	Putting the right processes in place

have done really well[in inspections].						
since 2013, the stuff that we have in our documentation and our files and the way we provide our care, our …it's coming and it's directed from those regulations.	PPIM1	Sustainment (normalisation)	Regulations are clear in their prescriptions	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture
So a manager like myself is expected to continue to deliver, I'm just going to…say 200 residential placements, but fifty of them now would like to live on their own. You've no more money. But you must have them living on their own.	PPIM6	Normative restructuring		Discordance between promotion of person-centred care and available funding from state	Views about the regulatory process and the regulator	Managing organisational culture
So absolutely the good thing is there's regulation. There's awareness. There's standardisation. And, to a point, there's no doubt that that's a good thing because if you reflect back, you know…I suppose I worked for years, as I say	PPIM6	Internalisation		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

in, in disability services and mental health, where there wasn't regulation as such. There was best practice and standards to work within, but there's no doubt it has improved significantly. And it's evolving all of the time. It has raised awareness and made disability more visible all over the country, and that is a good thing in communities.						
So again, that goes back to this, so if an inspector comes in, it goes back to comply or explain. This is the reason why this person doesn't have day services, because he just doesn't want one. I have it. There you go. There's where he said it there, he said. There's where we talked about, the key working session and but that's the life he's chosen. It might not be	PIC1	Relational restructuring		Adopting person-centred approach to care	Overall strategic approach adopted by regulatee	Managing organisational culture

like you and me choose, that's his choice.						
So all our policies and procedures and programmes of care is actually written based off the regulations. So the regulations has been taken into account when writing all the policies and procedures.	PPIM8	Sustainment (normalisation)		Organisation uses regulations as basis for policies and procedures	Communication processes that support compliance	Putting the right processes in place
So as managers from, especially being a PIC during regulatory inspections, you would absolutely be hoping that your HIQA inspector would find something in relation to premises. Because, you know, that might be the only way the money would be bumped into that. And that would be seen as a resource that absolutely needed to be addressed.	PPIM4	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

So for me the regs certainly did that [improve standards] because I know that they improved the practise of myself here and the organisation that I work with. Certainly improved as a result of the regs, but also it gave very clear guidance as to what you have to have in place to meet the regs.	PPIM8	Individual specification	Regulations are clear in their prescriptions	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture
so from our, kind of, board downwards they…the governance piece. We're very keen to have high compliance and but not just, uh, kind of, we just don't want the tick box.	PIC7	Contextual integration		Organisation provides adequate support for compliance	Resourcing services to enable compliance	Putting the right structures and resources in place
So I don't know whether [redacted] got it wrong or whether the regulator wasn't putting out the right vibes because there was so much work put into having a quality team and having audits and bringing the houses up to standard and bringing the staff team up to	PPIM7	Interactional workability	Organisational preparedness for regulation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture

standard. When HIQA actually came in the door, it was a disaster. I know people that I worked with that were CNM1, CNM2s. They abdicated that role. They were back, they were back to work frontline. It does seem to be it was like chaos.						
So I really, kind of, came in and had to go back and learn it all and learned how it worked and start to read up. See what was happening in other designated centres and looking at reports and that kind of thing.	PPIM7	Individual specification		Improving compliance by learning from other inspection reports	Communication processes that support compliance	Putting the right processes in place
so I think HIQA has allowed people to use it as a means of getting something that they may not get if HIQA weren't there	PIC2	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
So I think that would have been, I think that would be a good operational management tool for us to use at that time. The threat of	PPIM4	Relational restructuring		Using the authority of the regulator to convince staff to	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

HIQA coming in for want of a better word.				implement regulations		
So if someone has come from a more medical background into HIQA, the medication one is always… Which is good in itself because medication one can be tricky. When like, I mean, if you've got three or four people on a multitude of medications changing pretty regularly, being renewed pretty regularly. Three or four admins a day and you go in…It's highly unlikely over looking at 30 or 40 different points that they're going to, you know, you're gonna tick the boxes on all of them. And so, again, in my own head, if I see this, one of the nurses, one of the HIQA…I think she would have been a senior nurse manager there.	PIC1	Individual specification		Educational approach by inspector	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

If she comes in, I know our medication is going to get a right good look at and that's fine. Do you know? That is absolutely fine.						
So if the regulations weren't there, would we be providing the service that we're providing now? No, absolutely not, because they've, they've got us to a certain level. They've got all services you would hope to a certain level. And now I think the majority of services are probably, have been at that level for probably 6-7 years. So there's a kind of a ‘this is the way the service is, this is the level we have to be at’. And I think there's a complete relaxation from myself and from staff about ‘Yeah,	PIC1	Communal appraisal		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

that's where we're at'. It's just the norm now.						
So if there was an inspection in the house and, actually, we would maintain this practice whenever there are inspections, we'd always mention it at a monthly meeting of the managers, what the feedback was. And you would go back to your house then and say, well, you know, 'how would we have gotten on under that inspection?'	PIC9	Intervention performance		Sharing inspection findings across the organisation	Communication processes that support compliance	Putting the right processes in place
So if they're living a life of their choosing, and they can do the activities they like and they get the proper care they need, then everything else kind of falls into place as well.	PIC1	Coherence		Adopting person-centred approach to care	Overall strategic approach adopted by regulatee	Managing organisational culture

So if we have a restrictive practice or something that they're not terribly happy with, but we need it, that we're able to speak to them about it and educate them on it and explain it	PIC3	Interactional workability		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
So in December an inspector called, [redacted] came did the inspection. And after that I was very much held accountable for the failure to not be compliant in relation to the safeguarding and minding of those adults. Then six months later we had the second inspection where [redacted] was the inspector and she put the pressure on my management.	PIC3	Relational restructuring		Inspector/regulator escalating issues to provider level	Clear assignment of responsibility for making compliance happen	Putting the right processes in place
So it's not particularly comfortable place to be because there's inevitably organisational resistance, 'we don't have the resources, we can't do this, we can't do that'. We're saying 'we have to, and this	PIC3	Contextual integration		Organisational resistance to releasing funds for compliance	Resourcing services to enable compliance	Putting the right structures and resources in place

is the right thing to do'. And as the PIC in the middle you're like 'oh God this is uncomfortable'.						
So like it's definitely there, you can see it in the way the inspections are done now. It's very much person-centered to the people who, if they come in, it's talking to the residents.	PIC1	Systematisation		Person-centered focus during inspections	Views about the regulatory process and the regulator	Managing organisational culture
So like this historically would have been the medical model, I don't know, like Florence Nightingale times. And you [the regulator] changed that now to more social or a biosocial model of care which kind of encompasses all facets of it you know?	PPIM5	Communal appraisal	Provider ethos aligned with goals of regulation	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
So look, you'll push back a couple of times, but definitely very, very well informed. And at the draft stage, obviously not after a report is published. That's utterly pointless, because you do get the opportunity	PPIM6	Relational restructuring		Organisational support for challenging findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

for that. It's open to interpretation. And one day an inspector could come and say ‘that was alright’. And another day somebody else could come. But again, that's very hard to push back on because it's perception and the report may not reflect all of the conversation in a feedback session.						
so one inspector might be looking at risk management and go ‘yeah, OK you've got your risk register in place, it's been reviewed every quarter’. And they might go ‘that's that, you've reached the regulation’. Another HIQA inspector might come in and do a bit more of a deep dive and go ‘yeah, you've got a risk register but, you know, from a qualitative point of view there’s not a lot of detail in there’. So you just don't know which approach is going to…you're going to be	PIC8	Individual specification		Knowledge of inspector's focus	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

presented with and it can have a huge impact [on compliance with the risk management regulation].						
so one of the things for me over the years is, actually, we've been able to take what is best practise across all the regs, all the recommendations, all the national standards and nearly apply them across the whole service as best practise, if that makes sense?	PPIM8	Reframing organisational logics		Being an organisation that engages with multiple regulators is advantageous	Structural or environmental factors that influence the implementation process	Dealing with the outside world
So that was like, you know, I think I think FedVol were involved in this. At the time they were saying 'these are community houses. Your or my houses don't have fire doors. This is not a healthcare setting. This is a community setting'.	PIC1	Communal specification		Impact of regulations on residents	Views about the regulatory process and the regulator	Managing organisational culture
So that when they [inspectors] are looking at things. And they're finding something and then they,	PIC7	Relational integration	Inspector focused on finding faults	Legitimacy of regulator's/inspector's findings	Relationship between service	Managing the relationship with the regulator

they kind of drill into it in a particular way. It's more if...you think they're trying to find out what's wrong rather than what's right					management and inspector/regulator	
So then, six months later, [redacted - inspector name] came and her feedback meeting was very different. And her feedback meeting was, to, so again, the same two managers right there. My manager and her manager. And, you see, it was, I suppose [redacted - inspector name] kind of ignored me and she was very much focused on the highest manager in the room and she's like, '[redacted - manager name], what are you doing? You need to solve this problem now'.	PIC3	Relational restructuring		Inspector/regulator escalating issues to provider level	Clear assignment of responsibility for making compliance happen	Putting the right processes in place
So there's a huge education piece for me but I feel like I'm doing what [redacted inspector name] did for me and trying to educate	PIC3	Activation		Educational approach by inspector	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

downwards and helping them make those decisions so that when when they’re in my position they’ll do the same thing.						
So they would never, ever get any kind of a negative vibe off me about a HIQA inspection. They might get ‘ohh shit, they’re coming’ or ‘they've been here today and we’ve a few bits to do’. But no, you wouldn't have that kind...Where I’ve worked before, you would have got negative vibes off people about ‘HIQA this and HIQA that’, that's actually diminished a lot.	PIC1	Enrolment	Degree by which regulation is welcomed by an organisation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture
So to me, that's huge transformation and that is working along with the inspectors who say ‘that's restriction, that's restriction. Review that, review that to set up a restrictive practice team’.	PPIM5	Activation		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

So we didn't have a, we didn't have a human rights committee in [redacted] when I came down. So I formed a human rights committee. It's the human rights and Restrictive Practices Committee or forum, it's called. HPPF, and that was something that was very much to the forefront in the last place I was and now.	PIC1	Intervention performance		Implementing governance structures for restrictive practices	Implementing governance structures	Putting the right structures and resources in place
So we have a client who we were working towards self-administering and self-storing. And, you know, that huge independence piece around doing it themselves, actually going to the GP, going to the pharmacy, coming back. Obviously there's a certain inevitable oversight and governance in that. But he lived in a shared living situation, so it's deemed, it was deemed a risk, a risk to the others. Even though	PPIM3	Internalisation	Regulations in conflict	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

there was no fucking risk, if you get me? Like who in their right mind would even let, you know, that…? So we got a non-compliance for medication management and we got it under risk because we were allowing this young person to work towards that goal. And there was never an issue. There was never an incident. Obviously that's different and then we push back a little bit. But it remained the same, but before there would have been 72 meetings around, 'how do we make this compliant?' Whereas in this organisation particularly I'm just like 'fuck 'em', that sounds terrible.						
So we have our two internal provider-led audits. Then we would have an IPC audit. Then we would have a health and safety audit, had	PIC4	Sustainment (normalisation)		Effective monitoring of service by management	Monitoring processes that support compliance	Putting the right processes in place

the HIQA inspection audit. And there were other ones, pre the announced inspection I would have had two individuals come.						
So we have, like, occupational therapy because you have therapy stuff that...And, like, the resources have been increased in that way that, like, we might have had back in 2013, but it was harder to access.	PIC5	Normative restructuring		Regulation has increased the level of funding	Views about the regulatory process and the regulator	Managing organisational culture
So we now have a rights commission, restrictive practice team with two independents on it. I drove that for the last year or so and it's working really well.	PPIM5	Normative restructuring		Implementing governance structures for restrictive practices	Implementing governance structures	Putting the right structures and resources in place

So we were going in the wrong direction by...Our solution to meeting compliance after the first inspection was going in the wrong direction. We were increasing health and safety controls. We were decreasing the quality of life and when [redacted - inspector name] came with the second inspection. What she saw and what we had done was we'd moved bedrooms. We'd put electronic locks on bedrooms so that one chap who had a significant disability, could use a thumb lock. He could put his thumb on the lock and walk into his bedroom. So someone else had a button lock. But what it meant was the person, when they got to their own bedroom door, was met with a lock. And we were walking around the house and she [the inspector]	PIC3	Coherence		Addressing non-compliances in a dissatisfactory manner	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

looked at me and she said 'this isn't the solution we were hoping for'. And I remember being really ashamed that I was showing her locks on doors. I remember that very distinctly. That it just felt so wrong that we had, you know, kind of, made it feel more like a jail or prison for those five adults. Rather than, you know, making it a better place to be.						
So we're, kind of, at that point where we're starting to get…call it more professional, do you know what I mean? That we're really starting to get a skill mix. We've an OPs manager now who's going to look after the transport, the maintenance, health and safety. So, like, we've had that sourced out to other people, but in one way, without regulation, without HIQA, we probably wouldn't have those	PPIM7	Normative restructuring		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

people on board. This would be my argument to the HSE. So it's been, it's been beneficial to us in terms of building structure in the service, does that make sense?						
So when somebody wants to come in here, they fill out a very detailed reservation form and that's to make sure and I look through that and then they're kind of given a dependency level. So it can be from…from a C would be very independent to an A3 who's totally dependent. Needs assistance with…with meals, may have communication difficulties. Do you know, needs really, really high care. So and..and we wouldn't take any, kind of, new high care that the very high end and…	PIC2	Interactional workability	Organisation is selective in admissions to ensure they can provide care as required by regulations	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

so when you're, kind of, being asked half a question [by an inspector] and you're meant to, kind of, provide a full range of answers, it's not necessarily in our, kind of, mindset to, kind of, produce 5, 6, 7 documents all at the same time. So it can be a bit tricky that way. Whereas if the inspector is, kind of, saying 'what have you got that would support this?' You know? It does help you, kind of, be a bit less defensive for one, and it can help.	PIC7	Activation		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
So yeah, I don't really think of the regulations when we're actually just supporting people as such. As you said, it's kind of just melted into the way we support people now.	PIC1	Normative restructuring		Staff provide support to residents while not consciously referring to the regulations	Overall strategic approach adopted by regulatee	Managing organisational culture

So yeah, so we would have been non-compliant in infection control a couple of times in this house because of the bathrooms. [inaudible] And the lads, one of the lad's showers, he could shower 6-7 times a day. So that, like, it's getting high traffic all the time. So we identified money this year, at the end of this year, to do the bathrooms. But no, we didn't get funding from the Department of Health or the HSE. How we funded that was because we had unfilled posts in day service, so we had money left over. So we were able to, we were able to kind of switch resources around.	PIC1	Contextual integration		Organisation provides adequate support for compliance	Resourcing services to enable compliance	Putting the right structures and resources in place
So you know, you're an inspector coming in, you think one thing and then a different inspector will have	PIC2	Individual specification	Inconsistency among inspectors	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

a different, you know, view on the same on the same thing.						
So you need to have…Let's see where we are and, whether we do it, through our own, like our two six monthlies, or our annual review. Or then to our own like residents audits, finance, infection control, you need to stop regularly to look where we are and try and bring it back in, bring everything back into line. And that's just the nature of…you just have to accept that and I accept that. I actually enjoy the auditing thing.	PIC1	Sustainment (normalisation)		Implementing general governance structures	Implementing governance structures	Putting the right structures and resources in place
So you would have someone presenting or who would have been, kind of, the GP, kind of, would have been medicating. So obviously when they come in to a regulated centre, then I start drilling	PPIM3	Outer setting		Reliance on third parties for compliance	Accessing external resources	Dealing with the outside world

down into…So why is he on anti-psychotic medication, you know? I need to know the why. What's the diagnosis? And then trying to get the answers or get that assessment is next to nigh on impossible. Again, that happened to me last week. Two years, I was told privately…for, like, full psychiatric assessment						
So you're talking to the 30 heads of services, section 38 to 39s. All the [redacted] area in the one room with two HIQA inspectors, you know? And to a lot of those people, these inspectors are faceless. I've seen them, but 10% of the room had seen an inspector, 90% had never seen one. They had read all the reports, but they've never seen one and they're never in the room where you could actually have a question and answer session.	PPIM5	Activation		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

It was brilliant. I thought it was actually the way things should be done.						
So, and they [inspectors] understand the market, the labour market is very competitive at the moment and there's just not enough workers.	PIC7			Challenges in recruiting/retaining staff	Managing human resources	Putting the right structures and resources in place
So, like, the one I said where the HIQA inspector said, ‘well, we're just shutting down this inspection now we're so concerned’. So sometimes you need an immediate response, and that's…it's a red risk or beyond. You have to take in a staff or you have to find somewhere else to live. Or you have to get in immediate extra staff because of fire hazard for evacuation. Like they're the sort of things.	PPIM6	Initiation		Implementation of temporary measures to achieve compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

some of the first inspections that I would have been involved in, I would have been relatively new to the role and I did just accept what the inspector said about certain restrictive practices. And then the inspector themselves rang me back a couple of days later, saying 'I thought about that, and do you know what? Maybe I was over zealous and maybe…'. Sorry, for context, they were saying a certain restriction had to be documented every single time during the day that it was used, which was just introducing an awful lot of unnecessary paperwork. And I didn't have the confidence to challenge it at the time. A couple of days later she ran back saying 'I was over zealous. That was too much'. And I was going, 'thank God, because it was too much.' But	PPIM2	Reconfiguration		Lacking confidence to challenge inspector's findings	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

I didn't have the confidence to say that.						
Some of them would have just FETAC 5 [a nationally-recognised certificate in care skills] and stuff like that. And just getting to know how to actually document the things.	PIC5	Skill-set workability		Poor standard of education for staff	Managing human resources	Putting the right structures and resources in place
some of those [findings of non-compliance] were more service-led issues and I think that's one of the difficulties. That the PICs are the ones rolled out for the inspection and we are responsible for so much. But we don't have authority	PIC9	Contextual integration		Autonomy/authority of PIC	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

Somebody could be out sick when the training for fire was on and there's still more…Do you send them home until they do it, or do you let them come to work and put them on the next one?	PPIM5	Interactional workability		Organisation willing to tolerate non-compliance temporarily	Overall strategic approach adopted by regulatee	Managing organisational culture
sometimes I feel they [inspectors] are zoning in and then the pressure is on staff and the person in charge to be seen to be doing social things. And sometimes we feel then, are we actually doing it because HIQA wanted or are we doing it in the best interests of the residents?	PIC10	Communal appraisal		Placing interests of residents ahead of compliance	Overall strategic approach adopted by regulatee	Managing organisational culture
sometimes the barrier to my registered centre being compliant is actually an external problem, you know? How do you get MDT input if it's not being provided by the HSE or they don't understand that regulation piece?	PPIM3	Outer setting		Reliance on third parties for compliance	Accessing external resources	Dealing with the outside world

sometimes you are non-compliant, that's fine, right. I have no issue with that. But I'll go back if we are and then we'll wait till it comes back and then we'll devise an action plan. But some of our action plans are tick box because I'm not changing it, if that makes sense? So I'm telling them we're gonna do something that I'm never gonna do.	PPIM3	Normative restructuring	Fabricating compliance	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
Sometimes you can see the good practices happening, but getting it documented can be challenging to the guys, I don't know whether maybe that's to do with their own training and stuff.	PIC5	Skill-set workability		Adequately evidencing compliance	Monitoring processes that support compliance	Putting the right processes in place
that might be unique to CHO [redacted] in that, at this moment in time, there's good MDT supports.	PPIM7	Outer setting		Reliance on third parties for compliance	Accessing external resources	Dealing with the outside world
That natural reaction is to rebel to that because that's based on ignorance because you don't actually know the whole thing. And	PPIM5	Enrolment		Organisational resistance to regulation	Overall strategic approach adopted by regulatee	Managing organisational culture

as well as that regulation and regulatory services, they take a little bit of time to bed in. There's a little bit of teething problems. There's a bit of, kind of, it's not so much a blame game or something that happened. There's kind of people who have stock and standard views of how the service runs.						
That they [the inspectors] are, like, 'I'm determined to find something'. You're like, 'OK, do you need to be? Could you not just say it's really good?' And so I suppose that, but look, at the same time I get it. I guess it's for improvement. It's for that push factor of consistently and continuously improving. That you're not going 'you're grand lads, sit there'. Because you're never grand. There's always going to be something that you can do better.	PPIM1	Individual appraisal	Inspector focused on finding faults	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

That would be one of the things like the people will only come for five days, for if they're new to try and make sure that that we can facilitate and meet their needs too, you know?	PIC2	Intervention performance	Organisation is selective in admissions to ensure they can provide care as required by regulations	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
the [compliance] issues that are within your control, you need the support of staff on the ground…and for some things that you're 100% reliant on the staff, it's getting that engagement from the very beginning.	PIC11	Collective action		Effectively convincing staff that compliance is also their responsibility	Clear assignment of responsibility for making compliance happen	Putting the right processes in place
The attitude was safety. You have to keep them safe and you do. We did that without much consideration for the experience of the person we were keeping safe. And so back in 2005 we would put an Angel Guard [transport safety device] in, a person in a car without...And we would have had	PIC3	Reframing organisational logics		Adopting person-centred approach to care	Overall strategic approach adopted by regulatee	Managing organisational culture

child locks on the car without...And only because the highest importance was safety. Health and safety was paramount. That was used to justify everything. Whereas when we started having to [because of the regulations] account for them, document them, decide them with the behaviour therapist or a psychologist or someone else, then you're sitting down, you're actually having to justify why it's absolutely necessary.						
The audits were taking place. All those things you know? There was oversight on medication management, all those very important things. Finances were being done and were being recorded, but now we had it done under a guide. I suppose the big thing for me at that stage was as PIC, the two words were ensuring	PPIM5	Intervention performance	Added accountability due to presence of regulator	Regulation increases accountability	Views about the regulatory process and the regulator	Managing organisational culture

and assuring. And knowing the difference between those two words was huge to me because now in my role as I currently have, I have to ensure that…						
the biggest change [resulting from the introduction of regulation in disability services] for me is around safeguarding. You know, we...you know, people who have an inherent vulnerability had really very little recourse before it became a requirement to notify suspected abuse. And now it's very, very clear, you know, it's reported to HIQA, it's reported to your local safeguarding team, you know? You've to build a safeguarding plan around. That, to me, that's the biggest positivity.	PIC8	Internalisation		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
the biggest thing was getting a behaviour therapist and behaviour therapy support for the staff and the	PIC3	Adaptive execution		Difficulty sourcing professional assessments	Accessing external resources	Dealing with the outside world

child. And that was probably the biggest issue where we, kinda, where I could...I couldn't get a behaviour therapist, so we had to get other support. There's experienced psychologists, and we were able to get that instead and that kind of made us compliant.						
the challenges was for...because institutionalised care being what it is, a lot of staff would have...that was the only type of care that they would have witnessed themselves. And I think the biggest challenge to start was to...what are, what is good practice and what's bad practice?	PIC11	Coherence		Adopting person-centred approach to care	Overall strategic approach adopted by regulatee	Managing organisational culture
The challenges with it [regulation] are that the act seems to be open to interpretation. And I know that is the case with a lot of legislation and precedent and you know, case law changes over the years. So what started out with, you know,	PPIM6	Cognitive participation		Lack of clarity due to differing interpretations of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

maybe what I would have thought as clear standards; if you had 14 standards. All of these have moved and merged now, without any change of the act, to a very themed, focused inspection. And that's through the interpretation of the watchdog i.e. HIQA. And I think that's probably unfair.						
the director then would really, kind of, move on [the compliance plan] and get it done within timelines. If not, then it's going back to the HIQA inspector and explaining why we haven't got it done.	PPIM4	Activation		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
the filling of paperwork I think would have impacted on the time spent with residents, which is what it should have been.	PPIM1	Legitimation		Tasks required for evidencing compliance detract from time with residents	Views about the regulatory process and the regulator	Managing organisational culture

the governance, to be fair, they didn't even try. I think they felt they had been doing it their own way for so long. They thought 'who were HIQA to come in and tell them how to do…', so. From my point of view, I've never felt too badly about HIQA because I've seen the massive changes they made in that one organisation. And, but yeah, it was down to the governance and they just didn't want to engage and just thought maybe HIQA will go away if we just ignore them for long enough.	PPIM2	Reframing organisational logics		Organisational resistance to regulation	Overall strategic approach adopted by regulatee	Managing organisational culture
The HIQA inspectors were trying to find their feet. We were trying to find our feet. We weren't butting heads as such but, you know, it was a kind of a feeling out process for the first couple of inspections.	PIC1	Coherence	Organisational preparedness for regulation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture

the individuals that we support might feel that we were doing a good job, but that doesn't translate in the inspection and that can become really difficult. And I understand and have learned more, I suppose, about, you know, how the...that doesn't always translate, I suppose, in the regulations	PIC9	Systematisation		Perception that inspection findings are not always a true reflection of quality of service	Views about the regulatory process and the regulator	Managing organisational culture
the inspector identified that the living area was quite small and quite restricted. So we had to find a way to increase that and obviously we're leasing the premises. We can't build on to it, so we did have to go to…and obviously, I go to my office manager first. We go to finance and then we went to the HSE who are leasing the premises on our behalf and we've come up with a plan to install a garden room which the HSE will be funding. Because, obviously, it's outside of	PPIM2	Adaptive execution		Flexibility of the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

our budget and we, you know, we can't get into building on extensions when it's not our property.						
the inspector was satisfied that we're using consistent agency staff and not just a series of random people, but we were making an effort to have the same people. And, you know, to try and build those relationships with the residents as best you could in that situation.	PIC7	Adaptive execution		Time required to get to know residents' needs and preferences	Providing resources to meet residents' specific needs	Putting the right structures and resources in place
the inspector’s focus always was directly with the staff at the front line and again, you know, that's right, absolutely. They're the people that are there every day so they weren't necessarily interested in meeting me	PPIM6	Interactional workability		Inspector's focus is on front-line staff rather than management	Views about the regulatory process and the regulator	Managing organisational culture

The last two years, we've had the same inspector. And it feels like we're beginning to get a, kind of, some sense of understanding of how we work. Umm, and a level of trust built into that.	PIC7	Relational integration		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
The main thing at that stage was the fire doors. So we were a community house, an ordinary house on an ordinary street, and they [the regulator] wanted to have fire doors. So our organisation at that time through FedVol [an umbrella body for voluntary provider organisations] was kind of railing back on this. We had no money to put fire doors in and we couldn't get funded. This was just after the [economic] crash, so that was, we were always	PIC1	Legitimation		Lack of access to external resources	Accessing external resources	Dealing with the outside world

non-compliant for, in around fire safety in our first few inspections because, you know, we needed to put the fire doors in.						
the majority of the inspectors that I've had dealings with have brought that [the purpose of the regulations is to improve the quality of life of residents] up	PIC4	Communal specification		Educational approach by inspector	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
the one [regulation] that I think nearly causes the most confusion sometimes is actually protection. And I think it possibly could be improved upon in the wording around it. What I find is, right, obviously when we have the protection, we have the NF06 notifications that need to be submitted. However, then under Children First, we are mandated persons under Children First. And	PPIM8	Negotiating capacity		Inconsistent mandatory reporting requirements	Views about the regulatory process and the regulator	Managing organisational culture

we deal with, kind of, thresholds of harm on Children First. And, sometimes, those two pieces just don't fully match up.						
The only frustration we would have with the regulations is that it puts a lot of that onus on the provider. Where, because we're so small, we don't have the resources to provide [all of the allied health services]. So we would prefer to see those things available within the community. Erm, but they're not.	PIC7	Negotiating capacity		Reliance on third parties for compliance	Accessing external resources	Dealing with the outside world
the only other thing then within the regs that I think sometimes can be quite difficult is education. So as providers we're not part of the education network, you know? We're a residential care provider, we're not part of the…like, Tusla can use powers to enforce school placements. We can't. Like, as a residential care provider, we've	PPIM8	Outer setting		Reliance on third parties for compliance	Accessing external resources	Dealing with the outside world

actually no power in gaining a school placement. That's actually another one that can be quite difficult for a provider to meet. Sometimes if you have a young person who hasn't got a suitable school placement, that's a Department of Education piece rather than us, because a lot of time we…you might get….say, a substantially compliant to say, 'OK, we're doing in-house schooling' or whatever, with a young person who's not in the school placement. But a lot of times that's actually out of our hands.						
the other service, which is not HIQA registered, a person transitioned from another service to ours with no records. And I'm in the process of trying to find those records of a very serious mental	PPIM2	Internalisation		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

health diagnosis that we can't find the paperwork. We can't find the reports because nothing was kept and nothing was documented properly. But if she had come from a HIQA regulated service, where all that documentation was there, it would be a much easier transition.						
the patient safety and their experience of being in care is much more of a priority than the resources of an organisation and HIQA have helped us get better resources from the HSE, from our funders.	PIC3	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
the people on the ground [care staff], get off a little bit slightly, just with a few questions. One or two questions. I think if they had to experience what a person in charge has to do and…they should be knowledgeable about the	PIC10	Skill-set workability		Reluctance of staff to take on roles with responsibility for compliance	Managing human resources	Putting the right structures and resources in place

paperwork and take accountability a bit more						
the PIC spends a lot of time, you know, trying to keep those documents [to evidence compliance] up to date and, you know, we probably would love to be spending a bit more time walking around our units talking to residents and talking to staff and, you know, experiencing the actual service on the ground. But we spend 90% of our time inside our offices, so I think I think there has to be a balancing of paperwork.	PIC8	Interactional workability		Tasks required for evidencing compliance detract from time with residents	Views about the regulatory process and the regulator	Managing organisational culture
the PIC will generally get the feedback [from the inspector], they'll take notes of the feedback. And then they will meet with myself pretty much straight away. Whether it's that day or the next morning, we'll go through the feedback line by line and we	PPIM8	Interactional workability		Senior management engagement with inspection and compliance processes	Overall strategic approach adopted by regulatee	Managing organisational culture

immediately get going on, ‘OK what do we need to do to improve?’ We don't wait for the report to come in.						
the PICs can take it very personally when they get a non-compliance. When you're trying really, really hard to provide the best service that you can provide and then you come back and you get, like, non-compliance, it's really shitty. Like you feel like ‘What the fuck was the point in doing all of that?’	PPIM3	Enrolment		Demoralising impact of findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator
the PICs get the feedback from me that it's not the big bad wolf coming to the door.	PPIM5	Activation	Perceiving the inspector/regulator as ally	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
the provider themselves had to, kind of, adjust their own thinking because they didn't want to do it [implement fire safety measures in accordance with regulatory requirements] either because they,	PIC7	Negotiating capacity	Regulations in conflict	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

kind of, felt, thought it was a hospitalisation of a person's home						
The quality of care, which is first and foremost, was really good. But I know the paperwork wasn't at the standard because there was a lot of changes in that house and stuff that, there's bits I'm seeing, you know? I, as long as it…paperwork doesn't come first. For me it's the quality of the care for the people that we're supporting.	PIC4	Differentiation		Placing interests of residents ahead of compliance	Overall strategic approach adopted by regulatee	Managing organisational culture
the reason all the paperwork is being done is because nobody trusts us, you know?	PIC6	Relational integration	Perception that regulator does not trust the service provider	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
the regulator and the government will argue that it wasn't suddenly, but I suppose we are in a country where the preparation was poor. The impact assessments weren't there. I don't think it was just staff	PPIM6	Strategic intentions	No regulatory impact assessment	Perceived legitimacy of the regulatory system	Views about the regulatory process and the regulator	Managing organisational culture

to be fair. I think a huge amount of…where you have significant involvement with family members, parents, carers; they, and still to this day, will refer to ‘this is ridiculous. Sure, he can't look after himself’, or ‘she can't look after herself’.						
the regulator comes in and they audit it and it's like, where's the risk assessment around Legionnaires? Where's that, do you know? There's all the little bits, you know? Those bits that we didn't think of. We were thinking, Oh my God, the garden looks amazing. But after doing a patio, we've got, you know, we've got the hot tub. We've got all this set up and then we were thrilled with life. And then it's like, you know, all your IPC pieces that Legionnaires piece, the risk	PPIM7	Individual specification		Inspector identifying issues that service overlooked	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

assessments. And, you know, we hadn't thought of those, you know?						
the reporting and approval of using a restrictive practice. Like we've reviewed this a few years ago here and we put in a system called a 'rights impact notification'. So we have…you have your significant event notifications. So if there's an incident you're notifying the HIQA, the HSE, the placement supervisor. But now if we're using a restrictive practice we also have that pre-approved.	PPIM8	Intervention performance		Implementing governance structures for restrictive practices	Implementing governance structures	Putting the right structures and resources in place
the residents were putting chairs in front of the doors cause they didn't want them banging. They are walking in and out… and they're…so over a number of inspections we eventually got…So	PIC1	Negotiating capacity	Regulations in conflict	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

if the inspector came in and one of the residents had the chair in the door because he walks, he paces and needs the chair keeping his door open, she would have found us sub compliant because the fire door wasn't closed.						
the resource part will come to me from all of the registered providers about ‘HIQA said ABC’. I suppose sometimes there's an element of using HIQA. There's no doubt about that, to get things done.	PPIM6	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
the service that I work for is, like you said, it's one of the larger providers. And it's also one of the older ones. And I think there was a complacency that we were, you know, we felt we were doing a great job. And there hadn't been, there wasn't much change with the times. And I do think that's really	PIC9	Reframing organisational logics	Organisational preparedness for regulation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture

been accelerated in a really positive way by inspection and regulations.						
the significant part of her inspection was sitting down with the residents and the staff together and listening and hearing how everybody knew each other and the kind of things they were doing in their life.	PIC6	Interactional workability		Person-centered focus during inspections	Views about the regulatory process and the regulator	Managing organisational culture
The solution to our non-compliance was very clear and had been clear, but our own organisation had resisted that. And once we decided, the decision was made to move him. And with...and they started identifying solutions. Then everything, we were, it was so much easier then. It was like the barrier had been our own management's resistance.	PIC3	Contextual integration		Organisational resistance to releasing funds for compliance	Resourcing services to enable compliance	Putting the right structures and resources in place

the thematic inspections give you that space because you're given the questionnaire in advance. You know what the inspector is looking for.	PPIM2	Individual specification		Focused rather than broad inspections	Views about the regulatory process and the regulator	Managing organisational culture
the thematic inspections I think are very helpful because it gives you a focus, you know? If, you know, you have an inspection coming and it could literally just be an anything, you're going to get something wrong and it's…you can work really, really hard and the inspector will look at something you just missed. And it can be very disheartening. Whereas the thematic inspections, you get everything in place. And then it's really nice to get a nice inspection.	PPIM2	Individual specification		Focused rather than broad inspections	Views about the regulatory process and the regulator	Managing organisational culture
The transitions that we went through over decongregation has been huge. There's been huge steps in it. But, without HIQA, without	PIC11	Normative restructuring		Regulation has increased the level of funding	Views about the regulatory process and the regulator	Managing organisational culture

doubt, it wouldn't have happened. The millions that were invested in it would not have occurred.						
the way the HIQA inspector…the process has, kind of, morphed into being…[whereas it was once] dictatorial and adversarial…It's gone into a like, look, there's…it's much more about advice.	PIC1	Intervention performance		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
the working relationship you now have with the two female inspectors, I'd be more confident to have the discussion and the conversation around things or just to ring up for a piece of advice.	PPIM7	Activation		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
Their [quality and compliance managers] role is more, they have an in-depth knowledge of the regulations and HIQA and the inspectors, etc. Not even the inspectors, but just they have an in-depth knowledge of the process and I would see them as advisory, as an	PIC4	Contextual integration		Employing managers with expertise in compliance	Managing human resources	Putting the right structures and resources in place

extra person to bounce something off.						
then there was a second inspection six months later and the inspector was a more senior inspector who came and she was fantastic. I remember feeling very supported by her saying this isn't a person in charge problem. This is a PPIM [Person Participating in Management]. Another accommodation needs to be found for this service user. And she kind of hauled my own management over the coals because they hadn't provided provision for that fifth person to move and to safeguard them	PIC3	Initiation		Inspector/regulator escalating issues to provider level	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

There are always challenges and different elements of non-compliance, but they're really good. But it means that there's an awful lot of people that don't get any service. So people that get a service, particularly residential, that's mandated by the act, is good in the main or there are regulatory frameworks to protect them. But the people that are waiting for a service or can’t access a service, it's really, really difficult and challenging for those people. So there's a better quality of service, but much less of it. So it has depleted service availability due to the regulations and there still isn't…services have doubled in cost	PPIM6	Individual appraisal		Perceiving regulation as having increased costs for providers	Views about the regulatory process and the regulator	Managing organisational culture

there are times where people [staff] have kind of engaged in practices that aren't in the care plan and you have to bring them back and say, 'well, that's not actually something which we've assessed that person for'. And so, ‘where is your dynamic risk assessment for that? Why did you do that?’ Or your…and if someone's out of order, then we need to bring them back and say ‘this is the care plan’. So it [the regulatory requirement to have a care plan] does work for the staffing from that point of view.	PIC7	Relational restructuring		Using the authority of the regulator to convince staff to implement regulations	Clear assignment of responsibility for making compliance happen	Putting the right processes in place
there are times where, yes, the recommendation [from the inspector] doesn't make sense or isn't in the best interests [of the residents] and we might go back with…we might go back with a factual accuracy around it, or we	PPIM8	Collective action	Fabricating compliance	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

might go back and say ‘OK, we'll commit to reviewing the policy, but actually you've apparently reviewed the policy. We're happy that this policy doesn't have to change', you know?						
there might be a piece where I'm interpreting the regs in a certain way. That we’re making a change to a policy or procedure, making a change to that. And I'm implementing something and I'm interpreting the regs in a certain way. I would often pick up the phone and ring [redacted - inspector's name] and say ‘this is my feeling on this, is this your understanding of it? Am I on the right track?’ And she'd be very helpful in things like that.	PPIM8	Activation		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
There might be some new guidance out there from HIQA. They're actually very good at providing,	PPIM8	Activation		Support documents and tools made	Communication processes that support compliance	Putting the right processes in place

kind of, guidance documents for certain things as well.				available by regulator		
there was a process then of a one to one with one nurse particularly. I was saying, 'OK, so let's talk about you in bed. What would make it OK for me to put a camera on you in bed, bearing in mind it's a massive intrusion of privacy? And yes, there's a risk you might fall out of bed. Gosh, what? There's also the the risk that you are the the the impact on you is that there's there's a gross intrusion of your privacy'. And I think it was only when I put her in the bed that she got it and realized that that's because this child has a disability and, you know, you know, we're minding him, doesn't necessarily override his right to privacy	PIC3	Initiation		PIC as monitor and educator for staff	Monitoring processes that support compliance	Putting the right processes in place

there was major work around changing the culture in the organisation [after the introduction of regulation] because it would very much been, you run a [inaudible]. You know, you just get through the day and, you know, there was people, five people going out for a drive on the bus and that was their activity for the day.	PPIM2	Negotiating capacity	Provider ethos aligned with goals of regulation	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
there was many occasions where we did A, B and C and we met in the next inspection and realized A, B and C wasn't going to ever fix the problem. It needed to be entirely different plan	PIC11	Interactional workability		Addressing non-compliances in a dissatisfactory manner	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

There was two risk assessments. One is around. What was…We thought you might throw a knife, a large kitchen knife, and then the other one was around an instance of suicidal ideation. One instance. So all I want…in my head I wanted to close it. The throwing of the knives. Eh, so I did close it, but I explained very, very succinctly in it, why it was closed and I referenced then the other one around suicide ideation and all the clinical supports that have gone in around that, like the psychiatry meetings and stuff like that. So in my head I've explained why I'm closing this. Now, if they say….'No, you need to keep...' you know? I'm not going to keep it open because it looks great. Yeah, I need to keep it...staff saying 'you	PIC1	Normative restructuring		Adequately evidencing compliance	Monitoring processes that support compliance	Putting the right processes in place

need to keep it open’. No, we're not going to keep this open because…and there's a clear link of why you're…and a trail. So that's me. That's me, in my head, I'm explaining why I'm doing this. So I'm always trying to think, I need to explain my actions here. And I'm trying to engender that sense in staff, we need to explain why we're doing this.						
there's a lot of responsibility passed to the PIC and the PIC is left in the middle with the blame from senior management and from ground floor.	PIC10	Relational restructuring		Over-reliance on PIC for compliance	Clear assignment of responsibility for making compliance happen	Putting the right processes in place
There's also a difference across inspectors. I definitely think the regs aren't open to like….Actually, it's very interesting in that medication example we got three non-compliances in a row first.	PPIM3	Individual specification	Inconsistency among inspectors	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

And then the inspector changed and we didn't. Nothing else changed.						
there's always competition for resources and when you've got 10 million left over at the end of the year, it will be swallowed up by children services, cancer and mental health or…intellectual disability adults tend to come at the end of that line. And you always would have a very good advocate fighting for a particular eh, cohort of the of the population to get that funding. HIQA took that out of the equation. It was: ‘That's what the standards are. That's what is an appropriate level of service, and that's what you have to achieve’; and that has forced our hands. That's forced in	PIC11	Normative restructuring		Regulation has increased the level of funding	Views about the regulatory process and the regulator	Managing organisational culture

decision making above our heads, and it will continue to do that.						
There's an awful lot of improvement that, obviously, in the last couple of years with everything that, improvement on the premises and stuff. And our premises that, I'm making them more homely and stuff like that	PIC5	Individual appraisal		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
there's much more recognition [as a result of the introduction of regulation], I suppose, that those individuals [residents] are what should be driving our service. And what their needs are, you know? Just doing things in a particular way because we had always done them that way. Or 'it'll be good	PIC9	Internalisation	Perception that goal of regulation is to improve care for people	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

enough'. Or, you know? That attitude has really been driven through HIQA. And I suppose just, you know, the whole, that accountability that comes with regulation that...and that it's an outside view on how things are						
there's never, there's never a clear, kind of, acceptance that the voluntary providers are really struggling financially to be able to bridge these gaps in service and bridge these gaps in vacancy levels now, which is huge.	PPIM4	Contextual integration		Lack of access to external resources	Accessing external resources	Dealing with the outside world
there's no excuse [since the introduction of regulation] for having a service that does not meet the needs of a resident. There is no, there would be no, would be no acceptance of the service that's not safe.	PIC11	Internalisation		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

There's one inspector that has been, I suppose, the most consistent across our service for the last 10 years. And I feel like we have a very good relationship with that inspector. She's someone that I would always, if I have a query around something, or something has happened, kind of, I'm teasing it out, I will often pick up the phone and say ‘can I get your view or can I get your opinion on that?’ And I've always found that very helpful in that relationship, very helpful.	PPIM8	Activation		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
there's times when I felt under huge pressure by HIQA when I felt it was unnecessary. And then there's been times when I haven't felt under pressure by HIQA when I felt it was absolutely necessary.	PIC8	Collective action	Perceiving regulator's actions as legitimate	Perceived legitimacy of the regulatory system	Views about the regulatory process and the regulator	Managing organisational culture

they [findings of non-compliance on inspection] are generally fair and certainly, in recent times, the actions [required to become compliant] would have been pretty black and white.	PIC9	Activation		Organisational acceptance of findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator
they [inspectors] don't take into account that it is an individual's home. And sometimes you are going to get some mess because we are supporting individuals to live as independently as possible and therefore we're kind of restricting that individual and saying, ‘well, we can't let them clean with a certain product’. Because if HIQA come in and it's not clean to the fullest extent, they're not looking at, it is actually an individual's home. And that mess that was found on the day could be that an individual had taken part in an activity, baking, cooking and	PIC10	Negotiating capacity	Regulations in conflict	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

wanted to clean themselves. And we're, kind of, staff are reluctant to let residents do this in-house activity in fear of HIQA coming in and saying that the place is dirty, if I'm making sense?						
they [inspectors] were looking at the cleaning schedule and they were looking at whether each staff member knew how to clean, for an example, an oven. And because one person would say they would use a washing up liquid, say or something. But another staff member would say that they were using a different product. You are getting a substantially compliant there because two staff are not cleaning the same way and I think that's kind of a bit unrealistic.	PIC10	Legitimation	Perceiving some non-compliances as trivial	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
They [residential disability services] are not nursing homes, you know? We get in trouble for	PIC6	Negotiating capacity	Regulations in conflict	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

where our mops are being kept, or where, you know, our clothes are being dried or... Like, it's a home, you know?						
They [residents' families] know what regulation is, you know? They would understand all that and obviously the access to the reports and all of that sort of thing.	PPIM7	Systematisation	Published inspection reports increase sense of accountability	Regulation increases accountability	Views about the regulatory process and the regulator	Managing organisational culture
they [staff] feel that they should be there to do things for residents and...where we're trying to say 'that's not necessarily the case though'. Residents should be doing things for residents themselves [in accordance with the regulations]. Our job is to facilitate, so we're not there to be doing all the activities and being the best friend kind of thing. So helping people make that mindset adjustment, it's quite, takes time. Yeah, it's a cultural change.	PIC7	Relational restructuring	Time required to change culture in services	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture

they definitely help us access extra resources and, because if, for example if HIQA identifies a gap in a service and we have a lot more muscle to go to the HSE and say we need funding for this resource.	PIC6	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
They went and…didn't roll over and die, such as if that's the right way for HIQA… So I always remember the two guys up there, they would say it's 'comply or explain'. So my PIC or my residential services manager says 'no, we're not doing that and we'll explain why we're not doing that'.	PIC1	Cognitive participation		Negotiating compliance with the inspector/regulator	Effectively responding to findings of non-compliance	Managing the relationship with the regulator
they were so concerned about the service that they abandoned the inspection at that time and that there were to be immediate actions that afternoon. And I remember thinking at that time 'where…'…and on top of that we	PPIM6	Contextual integration		Lack of access to internal resources	Resourcing services to enable compliance	Putting the right structures and resources in place

had a recession, we had have cuts left, right and centre. We didn't have money for ABC, so it didn't really matter what I said around ‘we need this’. The money wasn't there, and the resources weren't there.						
They're [the inspectors] a great source of, kind of, information or guidance on issues if you have that relationship. But, I suppose, like a couple other services don't have that relationship, I would always try and make sure that they build a relationship with the, with the people who are doing these inspections	PIC1	Activation		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
They're living in a residential placement and HIQA come along and they're saying, ‘well, no, you know, why didn't they see a psychiatrist?’ And the psychiatrist will say ‘they don't meet my	PPIM6	Outer setting		Reliance on third parties for compliance	Accessing external resources	Dealing with the outside world

criteria’. HIQA say ‘well, I don't care’. They're on an antidepressant and the standard is they should be seen by a consultant.						
this inspector over a number of years has a consistent approach which you build up that relationship.	PPIM8	Collective action		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
to me, this is where the regulations moved from being as a set structure, kind of, all tightening thing to a more guiding, you know, workable. And I suppose no, not really negotiable, but it…it's more flexible, kind of, way around things.	PPIM5	Normative restructuring		Flexibility of the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
ultimately the responsibility stops with the PIC, but there’s significant support around us. So it would be wrong to say that the PIC just goes and, you know, ‘we'll go fix that’. You know, [redacted], it's, you know, we've organisational systems	PIC8	Contextual integration		Organisation provides adequate support for compliance	Resourcing services to enable compliance	Putting the right structures and resources in place

where, you know, the non-compliances are put on a spreadsheet. We have meetings with other supports, you know, clinical partners, to identify what needs to be done and what role each person plays in that. And so there is…Yeah, there's significant support around that. You're not just left to your own devices.						
ultimately, it's the PIC who's working flat out in advance [of an inspection]. If, you know, it's an announced inspection, it's the PIC that is worrying about an incoming…'We're due an inspection this year'…it's always in the back of your mind.	PIC4	Initiation		Over-reliance on PIC for compliance	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

up until about 18 months ago, there was no speech and language therapist in [redacted] at all. And when there was one introduced, they weren't providing any services for ID [Intellectual Disability]. So we had to go and buy it elsewhere. And the waiting lists for other services are astronomical, you know? They're just, so we've had to go and get them, which means we then have to engage with the disabilities, HSE [Health Service Executive - state funding provider] to get the funding for that	PIC7	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
we [as an organisation] actually just want to have a really good quality service that should, because it's good quality, be compliant.	PIC7	Differentiation	Quality of care by provider organisation perceived as high quality irrespective of regulation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture

we are a flagging that there's a lot more restrictions, but it's actually...we're gaining a knowledge on what is a restriction and what isn't. And right down to CCTV, freedom of movement, all those various things. It [the recording and reporting of restrictive practices in accordance with the regulations] changes and it educates the staff team and we've given that training in restrictive practices so that people understand why we're recording it.	PIC4	Intervention performance		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
We can only work within what we're funded for, you know? So on the other side, you know, we're registered with the CRO and you have to work, you have to work within the budget that you have. You can't trade recklessly.	PPIM7	Negotiating capacity		Operating within the constraints of funding	Resourcing services to enable compliance	Putting the right structures and resources in place

We did in [redacted], we did because…So you get the first couple in the first, the first year or two of inspections, the residential service said 'No way. That's fucking wrong. That's fucking wrong'. It was like back and forth, so there's none of that anymore…very, very little. There might have been one, kind of, I might have gone 'Yeah, I don't know about that, but look, let's do it anyway'.	PIC1	Relational restructuring		Organisational acceptance of findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator
We didn't prioritise people's choice and abilities so I see that progression from 2005 when our first, in the disability field to now where it's just absolutely normal that it's patient-centred and resources isn't an excuse, staffing isn't an excuse.	PIC3	Communal appraisal		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

we do have good support with… and governance and management to our senior management. They are very supportive.	PIC10	Contextual integration		Organisation provides adequate support for compliance	Resourcing services to enable compliance	Putting the right structures and resources in place
we don't feel any negativity towards the regulations. I feel like it's anything, [nothing] kind of, silly or no, not required or anything that is within them, you know?	PIC5	Legitimation	Perceiving regulatory requirements as legitimate	Perceived legitimacy of the regulatory system	Views about the regulatory process and the regulator	Managing organisational culture
we established a rights-based approaches, committees. And I think, I suppose, it was always to come…when you got a report back to look at it in detail. Look at the [inspection] feedback and then put myself, in so far as possible, and with the staff team, as the service user and look at it from that perspective.	PPIM6	Interactional workability		Address findings of non-compliance from perspective of residents	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

We focused as a whole team for all of the areas, all of the PIC's set up focus groups, task force, traffic light system of measurement. And we focused on medication management and it started to turn. So I think what was missing was there should have been a graduated, maybe single regulation focus for everybody. When we became compliant with medication management, which inevitably…when you take one focus it filters and there are tentacles out to the others. And within the next six months, like, we had full compliance in the first inspection everywhere by default, even though our entire focus being medication management.	PPIM6	Interactional workability		Intensive focus by management on compliance with a specific regulation	Monitoring processes that support compliance	Putting the right processes in place

we had an inspection recently where it was noticed that, ah, a fire escape was through a utility area. And so the inspector rightly asked for a competent person to come in and assess this. And the competent person said, well, 'does the inspector want me to just assess that area or to assess the whole house?' So the inspector said 'the whole house'. So we said, look, 'we want to go step further, then we're going to do the other houses too. And what the competent person found was that because the plasterboard in the ceiling of the house was…I don't…Don't hold me to this now at all. But it's something like it was 10 millimetres thick instead of 12 1/2 millimetres. And there wasn't sufficient fire retardation there. And therefore, now we have night	PIC6	Negotiating capacity		Implementation of temporary measures to achieve compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

waking, night staff in all our houses to mitigate against the risk of fire, even when there's no, there's been no fire.						
we had court orders [to threaten to close us down]. We had individuals named in those court orders. And it's like anything, you, you have a carrot and you have a stick. And unfortunately a stick had to be used. And from HIQA's perspective and from our perspective it was very, very tense	PIC11	Legitimation		Use of court proceedings as an enforcement measure	Views about the regulatory process and the regulator	Managing organisational culture
we have a number of staff that's FETAC level 5 as well. There needs to be an inbuilt, endemic understanding of what regulation is and the expectation because it doesn't exist. People arrive to work in a residential centre that's	PPIM6	Negotiating capacity		Poor standard of education for staff	Managing human resources	Putting the right structures and resources in place

regulated and they don't know the standards. They don't know what act it arises from, and they don't know how an inspection process works.						
we have a quality manager who did work for HIQA as well, so would be very familiar with, you know, the processes	PIC2	Contextual integration		Employing managers with expertise in compliance	Managing human resources	Putting the right structures and resources in place
we have an external person who comes in to do our six monthlies and I think she can be harsher and harder on us than HIQA can be in it, you know what I mean?	PPIM7	Contextual integration		Effective monitoring of service by management	Monitoring processes that support compliance	Putting the right processes in place
we have monthly staff meetings. We have supervisions and quarterly with all the staff. So if there's anything that's questionable from that [regulation] perspective, I don't, you know, it's part of the role that you do A, B, C and D we can discuss it further then at staff	PIC4	Collective action		Discussing compliance issues at staff meetings	Communication processes that support compliance	Putting the right processes in place

meetings, we can instigate change as well.						
We have much better staffing than we would have had prior to HIQA coming in.	PPIM2	Internalisation		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
We have significant level of resources going in and responding to need. But it is becoming somewhat untenable. And the ADMA [Assisted Decision-Making (Capacity) Act] piece is adding to that. And the new safeguarding policy is going to add to it as well	PPIM6	Outer setting		Changing policy landscape is creating additional demand for resources	Structural or environmental factors that influence the implementation process	Dealing with the outside world
we have two regular inspectors who've been with us for the last number of years. So we've actually started to build rapport with them. So if we're not sure on something we just pick up the phone and ring and have a conversation.	PPIM7	Activation		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

we just discovered this week, we do need that extra staff for more socialisation, socialising the residents. And I do feel strongly that if we don't get this staff member, we will be non-compliant with HIQA on their next visit.	PIC10	Individual specification		Lack of access to internal resources	Resourcing services to enable compliance	Putting the right structures and resources in place
We know some people, obviously they come from home and mom and dad are used to managing finances. And then obviously they come to a service, you know, to have their home outside of home. And we're supporting the young person like the adults that they are. And, you know, you're advocating on their behalf. And so I suppose, the regulation of having HIQA behind you, and the standards and all of that, gives us the support that we need to link up parents in a really professional way and say we'll look at, you know, Johnny is	PPIM7	Relational restructuring		Impact of regulations on residents	Views about the regulatory process and the regulator	Managing organisational culture

an adult. And this is how it works. And we've got our finance assessment and, you know?						
we link in with other local services. So the service in [redacted] in [redacted], the three of us, kind of, work together in terms of MDTs. We have behavioural support between the three of us	PPIM7	Cognitive participation		Creating local networks to pool resources	Accessing external resources	Dealing with the outside world
we only had a meeting yesterday. And so, you know, a heading on our meetings would be about your compliance issues. Anything problematic? Recurring themes, you know? Anything that needs to be resolved, you know, from a HIQA perspective. Like, that's, you know, that's a heading on it	PPIM7	Activation		Discussing compliance issues at staff meetings	Communication processes that support compliance	Putting the right processes in place

we put in a system where we kept the work roster and we wrote in the changes in a different roster, so it was easy to address. And we were told in 2013 that this was amazing. This was definitely the way they wanted to do it, by the inspector at the time. And we changed our, all entire houses within our cluster, to do it that way. And I brought it to a new house. And we got all the way through a sixteen outcome compliance inspection. And we were done on that; we weren't writing on our roster. We weren’t writing on our printed, worked roster. Even though everyone understood. The staff understood the system, wanted to keep the system, you understood as a manager, the service manager understood it. It went in as a sub compliance. We had to get rid of	PPIM4	Relational restructuring	Inconsistency among inspectors	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

the system the next day that no one wanted to get rid of. So I…and it was definitely, and I contested it with my service manager, contested the feedback. And it just…we never got anywhere with it.						
We talked about it with families and we get them on board...with them helping us meet some of those non-compliances because they have a role in, you know, understanding the importance of accurate checking in medication or checking in property, personal possessions.	PIC3	Interactional workability		Management engaging with families/communities to support compliance	Overall strategic approach adopted by regulatee	Managing organisational culture
We were delighted with the garden and how it worked out. We had a great family day on the Sunday, two barbecues going. Like, there was a full house, was great fun, delighted. And then, a few weeks later, then	PPIM7	Normative restructuring		Inspector identifying issues that service overlooked	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

we had an inspection. And it was, like, not one of us thought about the actual risk assessments in relation to Legionnaires or, you know, those sorts of things. I mean, like you, how did we miss it?						
we were exceptionally badly underfunded [at the time regulation was introduced] and the resources, as in the staffing numbers, but more importantly the physical environment. It was an institution. It was 15 to 20 bed units and maybe a metre, 2 metres between beds. Never mind a wall. It was just if I snored during the night 'Paul Dunbar' did not sleep. And it was it was not a comfortable place to come in and work.	PIC11	Individual appraisal		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

we weren't always happy about having people having televisions in their bedrooms. Because we felt, 'no, you need to come down'. And even in, we were slow to bring in a dishwasher. It's because people need to wash the dishes together, you know? And build a sense of family. And look, I mean, obviously we've everything there and I've had it for years, but and that would be our ethos. So we would be slow and we adapt that. We understand now the whole person-centred ethos and we use it ourselves. And likewise with HIQA, we understand why they're doing what they're doing and we work with them.	PIC6	Communal appraisal	Provider ethos aligned with goals of regulation	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

We would be perfectly happy with our risk procedures and everything else. But within an inspection HIQA recommended that we review risk over a certain incident or whatever. So as a result, we reviewed the risk policy. But actually when we reviewed the risk policy, we made some changes because actually reviewing it alongside it with a fresh head, we'll just go 'Oh yeah, maybe we need to be clearer on this, give better direction in this'. So often times where we said we'll review a policy, we've actually reviewed it and then made some sort of changes to actually make the practise better, if that makes sense?	PPIM8	Normative restructuring	Perceiving inspections as a learning opportunity	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
we would definitely be more in a position…I'd feel more confident in terms of what I know about regulation now. And I suppose my	PPIM7	Relational restructuring		Collaborative approach by the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

working relationship with the PIC and the working relationship you now have with the two female inspectors, I'd be more confident to have the discussion						
we would have had to come to an arrangement [with the inspector] so they might know if there's a plan down the line, maybe to do things differently. Maybe somebody's moving out of 1 designated centre into another. Maybe there's an application to vary coming and the application to vary will bring more funding, and so, you know, you've got something stepped out. But I think once you got an actual plan and you've something stepped out, I think people see the action plan things. At least people know you've identified it. They know there's a plan.	PPIM7	Collective action		Assuring the inspector that there is a plan to address non-compliances	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

we would have heard the phrase 'positive risk-taking' possibly for the first time around 2013, 2014. Where we were being challenged and say, 'well, why, why aren't people going out about in the community?'. [And we would think]... 'it's because they might have an outburst, they might start slapping themselves and they might do the behaviour that they do when they're anxious'. And, they [the inspectors] are like, 'well, yeah, but you're also preventing them from going into town and having a cup of coffee, like you do'.	PIC3	Reframing organisational logics		Adopting person-centred approach to care	Overall strategic approach adopted by regulatee	Managing organisational culture
we would have laid out a plan that would have to be agreed with the director of services. And then, I would then keep the pressure on the director. That would go into an organisational, we have like an organisational spreadsheet around	PPIM4	Interactional workability		Escalation of non-compliances by manager to provider-level	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

action planning. It would come up in the supervision meeting with our director. So we push that every time around the compliance plan						
we would never say it's because to be HIQA compliant because we would have very high standards anyway if that makes sense?	PIC2	Differentiation	Quality of care by provider organisation perceived as high quality irrespective of regulation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture
we would prefer to see those things available within the community. Erm, but they're not. And then we have to go through the whole process of trying to find money to then buy in those services. So I'm not sure that the regulations are well balanced on that particular point, so I don't think that's gonna change.	PIC7	Outer setting		Lack of access to external resources	Accessing external resources	Dealing with the outside world

we’ve adopted the Health Act and when I say HIQA, I mean the Health Act. And the principles of the Health Act. And the principles of our human rights. They [the regulations] have become the angel on the shoulders at...where they’ve become unconscious. So even though we [the regulator] aren’t here every six months telling us about them and making us do them, they’ve become the shadow in the background. To where we're saying, well look, you know, very early in the process, we started looking at our services through the eyes of HIQA and through the eyes of the regulation. So we’ve kind of taken on the role ourselves so that we don’t get battered when it could come, you know? We’ve already adopted their stance so that we we’ve aligned ourselves with them.	PIC3	Sustainment (normalisation)		Reflection on service through lens of regulations	Monitoring processes that support compliance	Putting the right processes in place

we'll say, an example of properties. Like nobody's house, I know my house certainly isn't in pristine, 100% condition all the time, you know? You'll say ‘we need to do this’, but there's a period of time and it's acceptable to wait that period of time. Of course, if somebody's health or welfare is at risk, that's different. But the general kind of upkeep of a property, it isn't possible for us to just have everything done to a pristine standard 100% of the time in 18 locations, do you know, that you're trying to manage.	PPIM1	Communal appraisal		Organisation willing to tolerate non-compliance temporarily	Overall strategic approach adopted by regulatee	Managing organisational culture
we'll submit business cases for something that we can see coming down the line. It's highly unusual that you'll be provided with funding for something that you can see is going to be an issue. It's ‘we'll meet what's top of the priority list this	PPIM1	Outer setting		Lack of access to external resources	Accessing external resources	Dealing with the outside world

week, or today, probably won't be top of the priority list tomorrow'. And we can quote all the regulations we want, you know, ahead of time. But until something is an actual crisis, that's generally, unfortunately, that's the process and that's how it is.						
Well, once you put standards in place and the standards are very clear, uh, you've got something to measure against, which is what the regulatory authority was doing so, yes, I would say very clearly, yes. And those standards were very clear to us all. It's accessible to family members, to the residents, to to staff and I suppose the media	PIC11	Individual specification	Regulations are clear in their prescriptions	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

we're not a massive organisation that there's loads of layers to get through. We are working in the same office, here in head office. So pretty much at the outset of the inspection, even from the feedback, everyone will know what needs to happen. And we don't really need the report to get the ball rolling. I will be having the conversation with both the director of care, the operations manager or the general manager. And then director or the Chair of the board as to what needs to happen. So, we get the ball rolling on those things straight away, really.	PPIM8	Collective action		Senior management engagement with inspection and compliance processes	Overall strategic approach adopted by regulatee	Managing organisational culture
We're not always prepared for all those eventualities, but now we're prepared for a lot of them and we all have a processes in place to record, to learn, you know, to first of all make people safe in the first	PPIM5	Normative restructuring		Regulation has resulted in improved governance structures	Views about the regulatory process and the regulator	Managing organisational culture

instance. And then we can record it and then we can teach others and ourselves what we need to do in the future and all those kind of things as well. So that's what the main thing for me that the regulations done from pre to 13 to post 13.						
We've a situation here in the house where again, it's a resource issue. We've 2 bathrooms that are in bits and we don't have the money to get to the standard required to be compliant with infection control. We've since got the money to do that.	PIC1	Contextual integration		Lack of access to internal resources	Resourcing services to enable compliance	Putting the right structures and resources in place
we've certainly had an early experience of inspection as, kind of, a social care worker in a house with an inspector who had an obvious background. It was very, very clear and obvious background in pharmacy. And spent two hours	PPIM4	Skill-set workability	Excessive focus by inspector on their area of expertise	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

going through a medication cabinet and really missing…and five minutes going through support plans and…like, and that to me as a young social care worker was like, well, ‘is this really gonna work?’						
we've had people come, staff come on board with us and, kind of, be surprised. Pleasantly surprised at the level of staffing that we have and the level of management support. And they'll talk about management in their previous service saying they were, you know, they're constantly getting pulled to cover shifts themselves.	PPIM2	Contextual integration		Organisation provides adequate support for compliance	Resourcing services to enable compliance	Putting the right structures and resources in place
we've had two new fire [safety] policies in recent years [as a result of guidance from the regulator]. And there's a whole new set of documents each time and it's not that that's not valuable or good, of course it is. But they take a huge	PIC9	Skill-set workability		Insufficient time for management to attend to regulatory matters	Resourcing services to enable compliance	Putting the right structures and resources in place

amount of time and there's only ever going to be so many people on a team who are confident with doing that and maintaining that						
We've seen huge changes [as a result of regulation], very positive changes over the past 15 years and we've seen increased accountability for services across the board. I think we've seen increased standards for the residents who live in our designated centres.	PPIM4	Internalisation	Perceiving regulation as a force for good	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
What HIQA and what the regulation states is…I don't know the term is, but basically, we go there...you go with that. You go with that, you don't question it, and it is what it is. It's part of the Health Act. It's part of the standards of HIQA.	PIC4	Legitimation	Legal legitimacy of regulatory system	Perceived legitimacy of the regulatory system	Views about the regulatory process and the regulator	Managing organisational culture
what HIQA has done in the regulations has standardised care provision because you…these are	PPIM3	Legitimation		Human services need flexibility sometimes	Views about the regulatory process and the regulator	Managing organisational culture

the regulations. What if you fall or your care needs or your unique situation falls a little bit outside of that? How is that person-centred? Because there's no getting away from the fact that there is box ticking happening, you know? We have to do this because HIQA said.				not allowed by the regulations		
What I get out of this is behaviour specialists. Psychology. Safeguarding. And then your keyworkers, staff members, management. Maybe 8 to 10 people around the table looking at the non-compliances and addressing that compliance plan in a meaningful way. Rather than turn around and say ‘OK, so we'll open that second door down there now. And when they [the inspector] come back and see it, they'll see it's opened and they put it in the compliance plan. I've opened out that middle door.	PPIM5	Interactional workability		Addressing root cause of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator

That's not what we do. We would go deeper than that. We'd go back and say, what is the actual non-compliance? The non-compliance is that we've restricted that person going down that corridor into that kitchen and making himself his own cup of tea. But he has to go through 2 doors and he needs staff with two keys to open those doors. So that's what the issue is, and that's what the nuts and bolts of it is						
What I struggle with is preferences. So we'll say I have inspector number one comes today and they have a preference for a document or an assessment of need or the statement of purpose, you know? They have a preference of how something should be. And you'll make changes and changes will be made to come into compliance with	PPIM1	Reconfiguration	Inconsistency among inspectors	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

what they want. And then the next inspection will come and another inspector will come, and their preference will be different. And they'll want something changed because of how they want it. And so I suppose in some ways there can be an over alliance, I think, on the regulation, where it's very black and white. And then other times we would very much feel that we're meeting the regulation, but we're not meeting an inspector's preference and the letter of the law.						
what I would say is there is an awful lot more paperwork involved [because of regulation] from a staffing perspective, which I'm sure you've heard takes away potentially, I should say, would take staff away from their time with the residents	PIC4	Communal appraisal		Tasks required for evidencing compliance detract from time with residents	Views about the regulatory process and the regulator	Managing organisational culture

What I've seen more and more, particularly in the last three years, is an acceptance in management of a non-compliance because it's not in the best interests of the service user.	PPIM3	Contextual integration		Placing interests of residents ahead of compliance	Overall strategic approach adopted by regulatee	Managing organisational culture
what we did instead of relying on the HSE as a small service is we bought in supports. So when we were costing the model of support that we were providing for the guys in the houses, we put in the cost for MDT	PPIM7	Adaptive execution		Accurately costing compliance	Resourcing services to enable compliance	Putting the right structures and resources in place
what you're following is these regulations. However, these are human services. It's very hard to reduce those, kind of, human services and quality of life, to a set of standards and tick it off and that's…you're always going to have that battle when you're looking at services that involve people.	PPIM1	Negotiating capacity		Human services need flexibility sometimes not allowed by the regulations	Views about the regulatory process and the regulator	Managing organisational culture

when I started here we had two gentlemen who we could tell that they had a cycle of behaviour that lasted about five weeks and then just repeat it and repeat it. And we didn't know how to intervene into that. We didn't know how to support them in that or how to break that cycle. We didn't know how to develop their social skills or anything. We had no professionalism. I cooked, I cleaned and I drove and…So by not having those skills, their outcomes, their wellbeing didn't increase. So the professionalism [brought about by the introduction of regulation] does do that.	PIC7	Internalisation		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

when it comes to regulation, the paperwork is just the role of a PIC. And sometimes the biggest challenge is actually getting out to our house to see residents and see staff because, you know, there's just endless paper.	PIC11	Intervention performance		Tasks required for evidencing compliance detract from time with residents	Views about the regulatory process and the regulator	Managing organisational culture
when it comes to something that I'm not qualified to discuss, like fire safety, you know? If I have a competent fire person that has signed off the fire doors, met all the relevant regulations and everything else. And then I have an inspector coming in and going 'I'm not sure about the gap in that fire door like it could be a mil or two off'. And I'm like, 'well, you don't have a measuring tape. So, I don't know if you're right or wrong', you know? And it's that type of thing where I need actually, it's been signed off by competent fire person. I'm not a	PPIM8	Skill-set workability	Inspector questioning decision-making of another professional	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

competent fire person. I'm trusting that they've given me a letter to say this is correct. I don't know. I'm not an expert in that field, you know? So those bits can be a bit more frustrating.						
when it comes to, say, [inspection findings related to] IPC or premises, these are things that might already be on our maintenance log, you know?	PPIM8	Interactional workability		Effective monitoring of service by management	Monitoring processes that support compliance	Putting the right processes in place
when regulation came in first there was a huge amount of fear and this, kind of, panic stations…and up all hours of the night, kind of, throwing stuff into place	PPIM1	Negotiating capacity	Organisational preparedness for regulation	Organisational readiness for regulation	Overall strategic approach adopted by regulatee	Managing organisational culture
when we have an inspection, and if there's significant non-compliances that are identified, that gives us the strength. Then, when we're going back, we're like ‘look, this is what…’ So it does give more…it gives more power to our request	PPIM1	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

but certainly we use them all the time and						
when you have that peer to peer alleged abuse or concerns, you will fail in governance and management. Or you'll have significantly non-compliant because you're not managing that situation. You've allowed…or you're overseeing these incidents and the mitigating things you've put in place aren't, you know, they're not working.	PPIM6	Normative restructuring	Added accountability due to presence of regulator	Regulation increases accountability	Views about the regulatory process and the regulator	Managing organisational culture
when you're trying to reach compliance across so many different regulations. And there's so much detail in all of them. It's a huge amount for one person that, you know, while we all work together, but it's a huge amount to be responsible for it as a PIC.	PIC9	Collective action		Over-reliance on PIC for compliance	Clear assignment of responsibility for making compliance happen	Putting the right processes in place

whenever HIQA are reporting, I think they never, they never report — and I understand the HSE are another organisation — but I think that a lot of the pressure comes on the provider rather than the HSE in those situations. Like we never publish reports to say the lack of funding, you know?	PPIM4	Reflexive monitoring	Regulator does not identify causal factors for non-compliance outside control of providers	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
where I escalate most is because it's probably under risk. So I'll escalate it a lot from the social care risk register. Whether that's a risk of non-compliance with regulations or whether that's a risk due to IPC infection or whatever it is. I will then escalate whatever has come through that process and that's where we will get, then, decisions and actions around that.	PPIM8	Collective action		Escalation of non-compliances by manager to provider-level	Clear assignment of responsibility for making compliance happen	Putting the right processes in place
where we feel that we had done something sufficiently and then an inspection says 'no'. Or, you know,	PIC9	Relational integration		Addressing non-compliances in a	Effectively responding to	Managing the relationship with the regulator

an inspection might recognise and it, you know, a change in practice or whatever...to reach compliance but doesn't find it adequate [to meet compliance]. There is frustration.				dissatisfactory manner	findings of non-compliance	
Whereas I definitely think, when it comes to compatibility issues and people not getting on and that, a HIQA inspection definitely provides the teeth necessary to make the required change.	PPIM4	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
Whether they are neurotypical or autistic or in a wheelchair...that, but that, it’s not our job to just keep them safe. We have to keep them safe and give them a quality of life and open up the world to them.	PIC3	Internalisation	Perception that goal of regulation is to improve care for people	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
with my last employer, the issue was around the fire safety system of the house, and systems that HIQA wanted to put in place that the provider didn't think was	PIC7	Negotiating capacity	Regulations in conflict	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture

appropriate in terms of community residential dwellings.						
with our current inspector, I would have…maybe a policy of my own is just to try and be as open and honest as possible and maybe let her know in advance. Give her a call and say 'look, this…such and such is happening in the service'. Rather than her finding out when I just send in a notification and it keeps…I think she appreciates that we're open and honest with her.	PPIM2	Relational integration		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
within our organisation we have PBS (Positive Bahevioural Support) and stuff. But if we need, you know, if there's an action around speech and language therapists or OT or anything like that, would work with the OPs manager, the office director on that and just bring in whoever needs to be	PPIM2	Contextual integration		Senior management engagement with inspection and compliance processes	Overall strategic approach adopted by regulatee	Managing organisational culture

within the structure of the regulations, we also have room for manoeuvre and discussion and I find that very, very healthy.	PPIM5	Activation		Flexibility of the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
within this organisation, there's a quality and compliance person. And I have sat down following receiving my report. And where I've looked for certain things, she sort of advised to go a different route. And that's fine because I'm taking direction. They're a new organisation and new organisational structures on how they manage the completion of compliance reports.	PIC4	Contextual integration		Employing managers with expertise in compliance	Managing human resources	Putting the right structures and resources in place
within two weeks of moving there and agreement being in place the provider pulled everything. She's no longer playing for the club. She's no longer working despite numerous promises. And obviously then it was inspected against. And	PPIM4	Individual appraisal	Aspects of quality that the inspector does not assess	Perceived legitimacy of the regulatory system	Views about the regulatory process and the regulator	Managing organisational culture

sure that wouldn't come in to what the inspector can inspect against.						
would you say that you're always committed to compliance or you're always committed to the best interests of the residents? Or are both of them the same thing in your eyes? OM4 Not always the same thing. I think they are very similar, but I could say that we're fully committed to upholding the best standards of compliance that we can. But we're also, I would say our… my number one priority is to our residents and to them having the life that they want to live. To having high standards of service and care. So that's my number one and, kind of, my one and a half then is the compliance. Because I can't put	PPIM1	Communal specification		Placing interests of residents ahead of compliance	Overall strategic approach adopted by regulatee	Managing organisational culture

compliance over the best interests of our residents.						
Yeah, I definitely think the conditions which they live in, would have dramatically improved. [redacted] didn't really have those structures, but there were a lot of national places where you have people sharing bedrooms and stuff like that. So all that was, kind of, quickly wiped out, eradicated. And I think we moved into a much more kind of social care space.	PPIM4	Communal appraisal		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture
Yeah, I think definitely quality of life residents [improved as a result of regulation being introduced]. I think one thing was the huge focus on people not wanting to live	PPIM4	Internalisation		Impact of regulations on residents	Views about the regulatory process and the regulator	Managing organisational culture

together. And the only way, and I really do think the only way nationally that we can address that is through HIQA reports and HIQA inspections.						
Yeah, we kind of gave up on doing it [having resident meetings in accordance with the regulations] because there's no, there's no point unless I had my two speaking children in at the one weekend, then we could do it.	PIC3	Negotiating capacity		Human services need flexibility sometimes not allowed by the regulations	Views about the regulatory process and the regulator	Managing organisational culture
Yeah, well, it I, I would argue the point that it isn't non-compliance because it is that resident's wish and they're very, you know, they know the risks etc and, you know, and I'd be annoyed if it was non-compliant. Do you know?	PIC2	Individual appraisal	Regulations in conflict	Quality of the text of the regulations	Views about the regulatory process and the regulator	Managing organisational culture
You [as a manager overseeing several centres in the community] are very isolated. Yeah, governing those is very, very challenging	PIC11	Interactional workability		Lack of capacity of management to be present in centres	Managing human resources	Putting the right structures and resources in place

because your presence is...you're not within the same building. And you have to make a conscious effort to get into the car to drive out to the house.						
you are going through the, not only the Health Act I suppose, but occasionally you [the regulators] send out information, guidance documents which tend to be really easily understood. In fairness, there is a lot of work that goes into it to make it user-friendly. That's very, very evident and it's not every week, not every month you be using it, but in in the space of a year, you probably will be referring to three or four of those documents at some time or another for couple of seconds.	PIC11	Individual specification		Support documents and tools made available by regulator	Communication processes that support compliance	Putting the right processes in place
You can fudge an inspection. You can get through an inspection. But to sustain good inspections, you	PIC11	Adaptive execution	Fabricating compliance	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

can't bluff your way through them. You will be found out						
You can get any amount of people to cover a shift, but actually asking somebody to take on, you know, the added responsibility of working as a team, getting really invested, being part of meeting compliance is really difficult. People just want to come in and work a shift and not have responsibility beyond that.	PIC9	Relational restructuring		Reluctance of staff to take on roles with responsibility for compliance	Managing human resources	Putting the right structures and resources in place
you can't have care team members, or you can't have staff members sitting in an office writing things up all day. There needs to be a balance in demonstrating the work that we do to actively record and reporting the work we do, while also making sure that the children, young people in our care are getting the best care possible and it's about getting the balance between that.	PPIM8	Interactional workability		Effective monitoring of service by management	Monitoring processes that support compliance	Putting the right processes in place

you could advertise a PIC job. It wouldn't matter what money you'd put on it. It's like, just nobody wants it. Nobody wants to be in that position.	PPIM7	Normative restructuring		Challenges in recruiting/retaining staff	Managing human resources	Putting the right structures and resources in place
you could be singing for something as long as you wanted 10 or 12 years [ago], particularly before HIQA. So if you go back a bit further, you just would have to put up with the thing and keep going. And you were relying on staff's goodwill to, kind of, continue to respond to difficult circumstances. Now there's much more of a pathway of, you know? If somebody has the dementia diagnosis. Or if, you know, whatever, if their needs change, there is a recognition that there has to be a response [from the provider in terms of resources to become compliant].	PIC9	Internalisation		Regulation has increased the level of funding	Views about the regulatory process and the regulator	Managing organisational culture

you could see the quality of the bathroom going down. And all of a sudden the, you know, HIQA were arriving and this to us…it's a big deal because it's a non-compliance. And the only way to resolve it is actually an upgrade of the bathrooms and the upgrade of the bathrooms is also going to support his therapeutic needs because he was using the shower, but we think of it as his home environment. You come from a home where he had several baths. The baths actually, you know, he didn't have the luxury of the bath with us. So we were able to redo the bathroom. We used it to put in a proper shower, put in a nice bathroom. And it's worth it, really. Well, so the whole upgrade of those bathrooms, that was all completed just after Christmas. That wouldn't have been possible	PPIM7	Internalisation	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture

without the HIQA inspection, you know?						
You do have…there was one other…one of the other inspectors are really good around risk management and I actually learned a lot from her. I realised from her that I didn't consider risks that should have been considered. So I've completely changed my kind of outlook on risks.	PIC1	Individual specification		Educational approach by inspector	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator
you do it [comply with the regulations] because I suppose the law is the law. And so there's no wriggle room on those sorts of things.	PPIM7	Legitimation	Legal legitimacy of regulatory system	Perceived legitimacy of the regulatory system	Views about the regulatory process and the regulator	Managing organisational culture

you don't boldly roll over if compliance means that someone's outcomes are diluted a little bit. But explain why we need to do this to make sure that this person is able to do that, yeah.	PIC1	Cognitive participation		Organisational support for challenging findings of non-compliance	Effectively responding to findings of non-compliance	Managing the relationship with the regulator
You get to know what the inspector generally leans towards and it just becomes very subjective…and the opinion of the inspector and…Like, you could get fully compliant in a house like that, you know, but you know you're not fully compliant, but you're fully compliant. And what was inspected on the day or what, you know…And I get that it's a, it's a one day inspection and what they see on that day but…It can be extremely subjective. Uh, like I've seen, like I had a fully compliant in one residential property a few years ago, but I know that if another inspector came	PIC4	Relational integration	Inconsistency among inspectors	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

in that they would have definitely found other things which I didn't which weren't found.						
you have inspectors come, it depends on their background. It depends on what their, kind of, area of interest or their area of expertise is. And so I suppose that's probably one of the biggest things that I find difficult and a bit frustrating. So you have the regulations and you have some inspectors who come and they will stick to their regulations like glue and it's literally black and white, word for word. 'This is it. You do not have what this says', you know? If it says something specifically and you have the same thing, but even in a different version, they're like,	PPIM1	Interactional workability		Flexibility of the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

‘but you don't have what it says here’. And so there's a lack of flexibility with some you would see. And then there's other people who you can see that their background may be in services and they're, kind of, more knowledgeable about it.						
You have to get him [an inappropriately placed resident] out now and she actually gave us a deadline of a month	PIC3	Normative restructuring		Inspector setting deadlines for actions to address non-compliances	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
you hear the phrase, kind of, bandied during that, you know, 'HIQA don't care if you have the money to fix it, you just have to fix it anyway'. Or he [the inspector] couldn't care, you know? But I think that can be a really positive thing because it makes it very clear that if the thing has to be actioned and that is the end of it.	PIC9	Normative restructuring	Added accountability due to presence of regulator	Regulation increases accountability	Views about the regulatory process and the regulator	Managing organisational culture

You just do as you normally do, and you answer questions as, you know, that you normally...whatever you would normally do. And that's all you do, you know? And like I don't get flustered. So I think it kind of, you know, I suppose if people were going around saying 'no, she's...hey, we've common interests'.	PIC2	Enrolment	Perceiving the inspector/regulator as ally	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture
You know, if an inspector comes in and asks some really, really basic questions. It's like, you know, [they] commend you, say ‘it's brilliant, you have all of these clinicians in place’. [Instead they should ask] ‘Do the residents get on with each other? Do they like each other? Is this what they would choose if they had a choice?’ And if you can, if you can't honestly turn around and say ‘no,	PIC8	Communal specification	Aspects of quality that the inspector does not assess	Perceived legitimacy of the regulatory system	Views about the regulatory process and the regulator	Managing organisational culture

this is not what they would choose if they had a choice.' Well, that's when HIQA I think should be putting pressure on services to say, OK, now you can't, you can't stand over this anymore.						
You need to then be able to prioritise well, which is more important? Do we have a kitchen floor tiled and there's two chips in it which technically doesn't meet IPC standards? Or there might be a more pressing priority issue in a different centre, so that's where it comes to me at service manager level. And then I bring them to senior levels.	PPIM8	Collective action		Effectively prioritising spending of resources towards achieving compliance	Resourcing services to enable compliance	Putting the right structures and resources in place
you still find that reports are published and they say, you know, 'ABC, there was a smell of urine', or there was some…like, they are disproportionate. They take what they saw on the day as I said at the	PPIM6	Legitimation	Perceiving some non-compliances as trivial	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

start and that's, that… So they make a bland statement that one person, they saw them not having their money on the day. Or, you know, I do think that there's a disproportion.						
You use HIQA as a tool to guide the care within your residential, within your designated centre. And you use that as a tool against, you use it as a tool when you advocate to senior managers for funds for certain things	PIC4	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
You will certainly still see inspectors, unfortunately, bringing their own speciality into their inspection. Which I think is quite tough and it's very obvious to see.	PPIM4	Interactional workability	Excessive focus by inspector on their area of expertise	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
You will go through whatever regs it was you were looking at today. You will get your feedback and you get the report. And generally there's always some level of learning from	PPIM8	Communal appraisal	Perceiving inspections as a learning opportunity	Organisational disposition towards regulation	Views about the regulatory process and the regulator	Managing organisational culture

these reports and something that maybe you didn't think of before and you could implement it. So that was very positive.						
you would be holding all your emails that you sent to the maintenance department or you've sent to your service manager or you've sent to your…that has come back from director that we are highlighting those issues and showed them. So you're showing that it's not a frontline issue.	PPIM4	Intervention performance		Escalation of non-compliances by manager to provider-level	Clear assignment of responsibility for making compliance happen	Putting the right processes in place
you'd still anecdotally hear, you know, we do that the exact same way in their service and and HIQA thought that was that was absolutely fine. And then someone else might turn around and say no, they told us that's an absolute no, no. We got a non-compliant for that	PIC8	Relational integration	Inconsistency among inspectors	Legitimacy of regulator's/inspector's findings	Relationship between service management and inspector/regulator	Managing the relationship with the regulator

whereas another service gets a gets a compliant for it.						
your inspector is a person, is a manager and dealing with people every day. And it's people management no more than forming a relationship with the inspector.	PIC4	Cognitive participation		Quality of the relationship between inspector and management	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
Your son, your daughter, your brother, your sister; would you like them in their service today or would you like them in the service that was there 10 years ago [before the introduction of regulation]? And that's without exception there, every family member I've met and even the most, eh, scared of the change at the time...Without exception, the feedback is…I'm a man and I like to think I'm tough…It would bring a tear to your eye some of the feedback you get.	PIC11	Internalisation		Perceiving regulation as having improved quality	Views about the regulatory process and the regulator	Managing organisational culture

you're aware that inspector is going to have to be consistent across the next two inspections. You're very conscious then to get that over to the rest of the cluster or wherever the…her caseload…that this is something she will be looking out for, he'll be looking out for.	PPIM4	Interactional workability		Knowledge of inspector's focus	Relationship between service management and inspector/regulator	Managing the relationship with the regulator
you're liaising with your disability managers from the HSE [Health Service Executive - state funding body]. And to be fair to them they are quite responsive you know? That they might raise eyebrows sometimes when you go to them and say 'HIQA wants this or HIQA wants that'. But, you know, they rarely ignore it.	PIC8	Normative restructuring	Using findings of non-compliance to support argument for resources	Gaming the system	Overall strategic approach adopted by regulatee	Managing organisational culture
you're trying to learn from colleague's inspections and, you know, raise the standard before you get inspected	PIC9	Intervention performance		Sharing inspection findings across the organisation	Communication processes that support compliance	Putting the right processes in place

you've got academics who are doing all sorts of research and saying, well, 'this should be in place in the law'. And you've got, you know, politicians responding to…and as scandals that have been in the paper, you know, and that have outraged the country and there... As a result, you know, we have all these…different parts of the legal framework, from safeguarding to all the other means of maintaining a safe environment for residents. But it, what you lose in the middle of that, is the kind of soul of it where...and it just becomes too structured and you lose…you lose the flexibility	PIC6	Communal specification		Flexibility of the inspector/regulator	**Relationship between service management and inspector/regulator**	Managing the relationship with the regulator

Appendix 12 – Focus group topic guide – Chapter 8

Introduction

- Welcome all attendees and advise that the session is being recorded and transcribed.
- Remind all attendees that they are free to withdraw their consent to participate at any time now or during the course of the session. In accordance with the consent form, advise participants that they may request their data be deleted after the focus group has been completed. This can be accommodated until the point where participant identities have been pseudonmyised and data linkages broken which will occur four weeks after the date of the focus group.
- Advise that all contributions will be anonymised and data will be stored securely.
- Explain that participants will be provided with a full transcript of the session and asked to confirm that they are satisfied it reflects their contributions.
- Advise participants that the data will be used to conduct analysis which will then be included in an article which will be submitted to an academic journal. Where a participant's contribution is quoted in the article, it will be attributed to their pseudonymised participant ID.
- Invite participants to introduce themselves to the group, detailing their experience as an inspector.

Introductory questions: What are your overall thoughts on the current system of regulation and inspection that is in place for residential disability services in Ireland?

Prompts: Benefit for residents; impact on running of services; differences in approach to regulation among service providers.

Questions	**Possible prompts**
How effective are the regulations in improving the quality and safety of services?	What regulations have the biggest impact on residents' lives and what ones are inconsequential? Any real-world examples of this?
Do you feel you have access to enough information to allow you to effectively assess the quality of a service?	What information do you not currently have that would be of benefit? Are you capable of preparing sufficiently prior to conducting an inspection?

How effective are inspections at determining whether a service is providing good quality care? What are the main challenges in fulfilling your role as an inspector?	What are the challenges of gathering information during the inspection day? Do you receive appropriate training? Do you have sufficient authority?
What do you think characterises centres that are most likely to be compliant with regulations? Are there factors external to the control of service providers and the regulator that impact on the level of compliance in services? If so, what are they?	Do structural and process factors matter? How important is the service's level of engagement with regulation? Are sufficient resources available from provider organisations and/or the state to ensure compliance is achievable?
To what extent does the legislative framework enable the regulator to take prompt and effective action against poor quality services? What would you change in the regulatory system to improve the quality of services, and why?	Have you ever felt that a service was allowed to continue providing care despite concerns about quality? Are some inspection types more effective than others? Are there gaps in the regulations? Are there any regulations that contradict one another?

Wrap-up Question: Was there anything not discusses that someone thinks is relevant and would like to raise now?

Appendix 13 – Standards for Reporting Qualitative Research (SRQR) – Chapter 8

Note: the page numbers reported in the table below reflect those from the manuscript as submitted to the journal.

	Page/line no(s).
Title and abstract	
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	1
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	1
Introduction	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	2-3
Purpose or research question - Purpose of the study and specific objectives or questions	3
Methods	
Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	4
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	4, 14-15
Context - Setting/site and salient contextual factors; rationale**	3
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	4
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	5

Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	4
Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	4
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	5
Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	5
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	5
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	5

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	5-10
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	5-10

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	12-13
Limitations - Trustworthiness and limitations of findings	13

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	4, 14-15
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	n/a

*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Reference:
O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. **Standards for reporting qualitative research: a synthesis of recommendations.** *Academic Medicine*, Vol. 89, No. 9 / Sept 2014
DOI: 10.1097/ACM.0000000000000388

Appendix 14 – Dataset for thematic analysis – Chapter 8

Coded Text	Code	Sub-theme 2	Sub-theme 1	Parent theme
sometimes out an inspection, you'd find that members of the MDT maybe keep their own reports. Or the person in charge doesn't have access to it. Doesn't always happen, but there are particular places where, I guess, you know, maybe social work reports of a sensitive nature or something like that. But that might, you know, obviously affect the quality of life for the rest of the…but the person in charge may not have that. And I suppose it's hard to know how far we can go in…asking to see that, if it's, you know, files of a sensitive nature.	Contested authority to review all relevant documentation	Contested authority	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
I had an instance in a centre where there was, again a safeguarding incident, and there was an ongoing investigation and an allegation in relation to a staff member…and the provider was very reluctant to provide	Contested authority to review all relevant documentation	Contested authority	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

details around that investigation. Like, even in terms of providing the terms of reference or how long the investigation process was going to take. So we have to invoke the section 65 to get that information again. It went to a HR person who had written back and said I wasn't entitled to that information.				
I know 7…I suppose it, kind of, refers to a national policy on restrictive practises…which isn't there at the moment. So there's one regulation that says that restrictive practises will be aligned with national policy and evidence-based practise. I suppose, the evidence-based practise is, kind of, what would allow us to use it, but there's no national policy. So it's referring to something that doesn't exist. And so there's some restrictive practise that are being put in….this	PBS regulation refers to a national policy that does not exist	Gaps in legislation	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

has come from the thematic where, I suppose, we're seeing some providers have detailed processes in place that are finding things as enablers and stuff. This is quite challenging to figure out where it fits under 7.				
I definitely think there's a risk there where providers can register a whole new building, a whole new service and put it through an application to vary. And it doesn't even require you know, a site visit. And we have no oversight of that. I know we're really tracking that. I know for year end we're on track to have 100 new designated centres which is equivalent to, what 22 inspectors? But the number of houses that are coming under applications to vary and the expansion of services…I think they should be new applications or applications to register. So you're getting in all the information around the person in charge, the PPIMs.	Providers circumventing registration regulations	Gaps in legislation	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

You're looking at new statements of purpose, you're going out and assessing against that. I know we do get that information in for an application to vary but it doesn't necessarily mean that we will be going out to do a site visit on that. So I just think it's…yeah, I think there could be room for improvement with the registration regulations because it allows providers to open up new houses through applications to vary.				
we need to be, kind of, conscious providers are managing an awful lot including HIQA, from funding to premises to, I suppose, some of it, some of it falls under regulation, some of it doesn't. So at times their priority gets pulled away from, I suppose, some of it's…they may lose sight of some of the regulations. So that's where, that's where our role is to go in	Acknowledgement that providers have multiple responsibilities	Competing regulatory demands for providers	General views about service providers	Overall views on the regulatory system

and, sort of, remind them of certain aspects.				
the Health and Safety Authority are now conducting inspections in health and social care services where, you know, it's probably duplication as well. Which is another regulatory burden for them, from another regulator which is constraining as well. Particularly, do you know, where, when we might go out as a regulator and say, ‘well, actually, no, that's against the rights of people with disabilities’. Whereas you have other regulators coming in saying ‘no you have to have that in place’, like, you know?	Acknowledgement that providers have multiple responsibilities	Competing regulatory demands for providers	General views about service providers	Overall views on the regulatory system
we in the region have a very large provider that was failing and failing quite significantly that they were in a service improvement plan towards the end of 2022, start of 23.	Allowing time for providers to remedy problems	Affording providers time to comply	Walking the tightrope between assistance and sanctions	The importance of skill and strategy for the role of inspector

And it was a learning curve for us as well because, apparently, the service improvement plan can only be for six months in length of time. And then the provider needs to be afforded time to implement the SIP...because we didn't go out and do inspections for that period of time while the provider was under that service improvement plan.				
Whether it all happens within a week or…is that realistic? Especially when the provider, I suppose, they're entitled to due process and a chance to respond and fix the issue.	Allowing time for providers to remedy problems	Affording providers time to comply	Walking the tightrope between assistance and sanctions	The importance of skill and strategy for the role of inspector
the danger as a regulator is that we become too focused on the documentation, you know? I was on an inspection the other day again and saying, you know, saying to the inspectors that I was with, you know, the documentation…and I know we say this all the time…but should be the last thing we're looking at, you	Danger of focusing too much on documentation	Adopting the correct focus on inspections	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

know? That we've spoken to everybody. We've got a feel for the place, you know,? We, kind of, know how things are. And then, if you like, we're using the documentation to triangulate or to validate our judgements or whatever, that kind of thing.				
we definitely have adapted our methodologies and, you know, putting in the safeguarding thematics, you know, the thematics that we're going to be doing…our restrictive practice thematics and how we look at those kind of things and how we as an organisation are in terms of being critical of our ourselves and how we do things or how we look at things, I think we've definitely grown in terms of that.	Adaptability of the regulator	Responsive and evolving regulatory practice	General views about regulation	Overall views on the regulatory system
I do think it would be good to know when there's a change in residents in a centre. I can understand why, say for	Additional information that would be useful	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

older persons or something, you know? Because it's a very different model that would be, kind of, arduous. But for us like one or two people changing in a centre actually changes the centre altogether really.				
I remember at one stage it got to a stage that the, you know, they wouldn't get funding until you had issued an NOP to cancel and then the funding would come. And now this will be done outside HIQA, you know, this is nothing to do with HIQA as such. But that's, kind of, seems to be what was happening within the HSE. The managers had to get an NOP or if they got a warning letter, you know, that was kind of evidence that they were in trouble, you know? While they get a bad report, it was, like, ‘oh, yeah, OK, we're listening’. But until they had something to hand the HSE in terms of a letter or an NOP,	Additional resources triggered by escalation level	Escalation as currency	Inspectors as agents of change	Positive effects of regulation

something like that, then that would, kind of, put them to the top of a pile of a lot of other service providers seeking money. Which is not great because it means that we can't issue that, kind of, like a warning letter or an NOP unless there's really, really risk in the centre, do you know? It has to be risk. So like it's not the right way to be funding services.				
I had one provider that was sending us in monthly things for about a year. However, they got a new premises. The residents are in a much more appropriate space now, you know? So that's just…that's a very simple example of escalation and bringing them to that has worked in terms of safeguarding, things like that. Those immediate actions are there for good reason, but they have to be. And my experience is that they have, like, they have brought about change because	Additional resources triggered by escalation level	Positive effect of escalation	Inspectors as agents of change	Positive effects of regulation

they have to. They're legally bound and they do take that quite serious. The providers I have worked with have taken those immediate actions or warning letters or whatever as seriously as they need to.				
your lines of inquiry are so important because that'll focus on the information that you really need to look at on inspection.	Establishing clear lines of enquiry	Adopting the correct focus on inspections	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
I think you also have to be cautious of the type of inspections you're doing. So, like, obviously, you know, there's more detail in an inspection if you have a regulation…5.5 they call them, inspections, because you have an awful lot more. When I started, you had to go through….they call them 18 outcomes. So you had to go through every single regulation, right? And that, to my knowledge, is, you know, it's changed now…it's more targeted. So you're basically doing an overview	Flexibility afforded by different inspection types	Adopting the correct focus on inspections	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

if that's…and that's the 5.5. But then you could have, like, the risk inspections we used to do the 18 month inspections, they don't, they've come up with a range of different types. So each type has a different focus, if you know what I mean? So they could go in and just and…actually just doing a focused inspection of actually looking at one Reg. I've done that if there's a concern. So it just depends on the, what your focus is, what's your plan, what is the reason you're going out first of all on inspection?				
our job primarily is an inspector. And that is, it's not really to spend time, I don't think anyway, checking to see whether they have their insurance or whether they have their references and this that and the other. And to do that five times with the	Administrative burden detracts from primary job of inspecting	Administrative tasks detract from work of inspecting	Internal bureaucratic processes	Impediments to effective inspection and regulation

same provider or person within a three month period.				
I think what can be very challenging is the pure administrative side of the job for inspectors and the amount of time that takes from being able to do the inspections. So then the level of notifications, the level follow up etc that, you know, where one notification can often lead to…So I suppose it's very much, I think, the administrative burden. I don't think there's any way out of that if you know what I mean? There will always be an administrative burden, maybe it could be a bit less, but, for me, I think that's the biggest challenge.	Administrative burden on inspectors	Administrative tasks detract from work of inspecting	Internal bureaucratic processes	Impediments to effective inspection and regulation
the highly voluminous, you know, administrative burden of doing an inspection: I think I can still say that the disability pillar still moves the	Administrative burden on inspectors	Administrative tasks detract from work of inspecting	Internal bureaucratic processes	Impediments to effective inspection and regulation

most amount of work, the most inspections than any other part of our organisation and do so effectively. But that is a challenge, without a doubt.				
the administrative side, there's a lot of, I think there's, I mean, they could streamline it an awful lot more, to be honest with you	Regulatory processes are administratively burdensome	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation
If you're ticking along, doing your inspections, you know, that's very manageable but cumbersome. You're writing things down in a notebook. You're coming back. You're essentially uploading that notebook manually, you know? For want of a better way of…your narrating it, if you like. But it's…the processes are just so time consuming and hopefully a lot of that will change and become more streamlined or whatever. But there's a lot of things that could cut down on our time and enable us to do the more bread and butter stuff.	Regulatory processes are administratively burdensome	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation

I think notifications take up an awful lot of our time, certainly mine. And they are, kind of, more frequent depending on the provider that you have. Like, I think some of that could be improved because people…I think people are terrified if they don't notify us of things and therefore they over report. So you're reviewing an awful lot of information that is probably not in line with, kind of, national policy, do you know?	Administrative burden caused by provider over-reporting	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation
Notifications like, you know, changes in management, management structures, registration applications, they are, you know, the application process, renewal of registration is the most time consuming probably.	Administrative burden on inspectors	Administrative tasks detract from work of inspecting	Internal bureaucratic processes	Impediments to effective inspection and regulation
we don't need to do that, like, we don't need to do that. I don't feel we're any more or less qualified than anybody to do that. It's an admin thing.	Administrative burden on inspectors	Administrative tasks detract from work of inspecting	Internal bureaucratic processes	Impediments to effective inspection and regulation

You're reviewing the same information registration review as we review it, there's at least five people, I'd say, that review it and still there's mistakes at the end of that process. So there has to be an easier way of doing it that goes ‘right, this information is correct at the beginning’. But, throughout every process, like, something will be missed. So there's something wrong there. If five people are reviewing the same amount of information and we still get to the end of it and there's a mistake, that is extremely time consuming	Administrative inefficiency in regulator's processes	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation

[Insp18] 47:13 Do you know when you're doing compliance assessments for providers. And, like, two weeks ago you've just done or…you've done it for a renewal and you're doing the exact same people two weeks later and there's no new information in about them, but, you go ‘God, I better check everything, just in case there's something… [Insp20] 47:24 Yeah. [Insp19] 47:28 Yeah. [Insp20] 47:28 just in case I've missed…’. Yeah, you've a PPIM over, like, seven or eight or nine or ten centres. You're going, ‘oh, here we go again’.	Administrative inefficiency in regulator's processes	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation

Just, kind of, an unwritten rule really. Does, you know, fire, safeguarding, medication management. They were the three, kind of, big ones where there could have been a significant risk to the resident, life of the residents, do you know? So, like, you know, are they abused...or what…in any shape or form? Or medication, that they've been, you know, to get the wrong medicine, you could die. And they were the, kind of, the three that you're most likely will give an urgent action on. I'm not saying any of the rest of them weren't important, but they're the most immediate risks to life of the residents, kind of, those, you know, I would be worried about. Not everyone is on medication that would be that risky. But, you know, you could have someone that's on diabetes or blood pressure tablets or something like that,	Focusing on three key regulations for safety	Adopting the correct focus on inspections	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

that if they get the wrong medication, it could have a significant…thing. So like, I'd always be careful around those particular ones, do you know? The life threatening ones.				
I worked at, or regulated, a congregated setting. It's actually, you know, where every report you're writing…Oh, my God…'Their food is provided from a central kitchen'. Now, I knew that that was never going to change. Because those residents were moving out. But you're still, kind of, saying that this is an institutional practise. And so it's not compliant with the regulations. But you, kind of, have to be proportionate and know that that service provider is not going to come up with €6 million in the morning to be able to provide kitchens in each service. And also it's	Taking context into account when judging compliance	Compliance can be context-specific	Walking the tightrope between assistance and sanctions	The importance of skill and strategy for the role of inspector

unrealistic because it's a waste of resources to put all those things in there now, but in 20 years or 10 years time this place is going to be obsolete, you know? So there are sometimes where our hands are tied				
we're going to some centres and there's ageing populations, people are older, they're retired. So you wouldn't expect to see them, you know, with the same level of opportunities or outings as a younger cohort of people. Whereas I think sometimes providers have in the past still felt like, 'oh, regardless, everybody has to have these outings, these goals'…x, y and z, and it's actually like…is that really realistic or in line with the person's age, needs, interests? Whereas, before, I think they felt they had to evidence that piece like, 'Michael is going to join swimming classes at 80'. It's like, really? Does he want to do that or does	Activities for residents should take account of their age	Diverse needs of residents means complying with regulations can be context-specific	Walking the tightrope between assistance and sanctions	The importance of skill and strategy for the role of inspector

it look good, you know, is that what they expect?				
sometimes you think, ‘God, I have to do a good few regulations here now’, where I would think to do three or four and focus really good, you know, do a really good, I suppose, inspection on, you know, some key regulations. I know we have thematics and all that, but I suppose just in terms of regular monitoring inspections, I suppose, sometimes it feels like, you know, if I only come back and did 5…Not that anything was ever…but you know, I suppose it's just internal. I probably feel I have to do a good few and not just three or four.	Requirement to assess multiple regulations can detract from making detailed assessments	Adopting the correct focus on inspections	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
I think some of the regulations you could spend all day on, say 12, you know? There's a few regulations you could spend, you know, a good few	Requirement to assess multiple regulations can detract from making detailed assessments	Adopting the correct focus on inspections	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

hours on and do a really good inspection of them. But sometimes I think, maybe it's just me, but it's trying to fly through…getting through a few of them just so I have…you know. I don't know if anyone else feels the same.				
you could look at a document and you could…actually, it could put you in different zones because you could, kind of, four or five regulations on one piece of paper on one individual at the same time. And then that could lead you into a different…So, being an inspector, you have to be very, I suppose, what was the word, skilled really. It's a skill you develop in terms of what is your plan? What's your outcome? What you want to get out of it. Because you could be led in an awful lot of roads	The need to stay focused and not stray into multiple regulations	Adopting the correct focus on inspections	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

I think it is reflected in the escalation process, in that, you know, if providers are making really genuine efforts and can demonstrate that, they tend to be afforded maybe a little bit more time or maybe it's a different type of escalation, like that route that you'll go down.	Differing escalation approach when provider is making genuine efforts	Genuinely engaged providers are afforded more time to remedy problems	Walking the tightrope between assistance and sanctions	The importance of skill and strategy for the role of inspector
the impact of non compliance, you have to try and hang your hat where it's going to have the biggest impact on the positive lived experience for residents. So you put, like you say, a non compliant in Regulation 21, how is that going to impact residents? What's that going to do? Whereas if you put it in somewhere like safeguarding or rights, it's more likely to bring about improvement for residents. Regulation 23 can be used so effectively. So instead of having seven not compliant regulations and the same	Assigning non-compliances to governance issues leads to bigger impact and promotes provider attention to root causes	Being strategic in where to make a finding of non-compliance	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

compliance plan coming back, you can put it all into Regulation 23 to bring about the biggest change.				
one of the things that's quite frustrating is, I suppose, the lack of powers, we have to actually get further information. A lot of the time, you know, the justification for it is a very high bar.	Difficulty of seeking additional information from providers	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
You could have one house in a community and you can add two more houses in underneath that designated centre. And I just don't think it's something that we track. As in, even the number of new houses that are opening up in the last year, but came to apps to vary versus applications register. I don't…we have no oversight of those numbers.	Providers circumventing registration regulations	Gaps in legislation	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

the other one is the definition of a designated centre, you know? The Health Act of 2007 is really…it's quite vague on that and it can leave us in a precarious situation and make it difficult to win a case. And, as you may be aware, we're in the midst of trying that in the court with a large provider in [redacted]. That might be one of the key weaknesses that I'm thinking of.	Vague definition of designated centres mean there is potential for people that should be safegaurded by regulation to be placed outside the framework	Lack of clarity in legislation	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
There are areas where those tools need to be, from a legal perspective, certainly looked at, refined and developed. So if you were to take the case of, for example, a children's service, whereby it's funded by Tusla [state agency for child protection and welfare], not the HSE [public health provider], and you issue a notice of closure, for example, who takes over that centre?	If HSE is provider of last resort, uncertain who takes over if a HSE centre fails	Lack of clarity in legislation	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

I have a centre in, had a warning meeting there with [Deputy Chief Inspector] because this organisation, their principal social worker does all preliminary screenings and admissions to their centres. And all that information is kept outside of the PICs remit. It's kept outside. This person falls completely outside of the governance of the centre, does not do, is not a stakeholder that we can contact so that I don't even have an e-mail address for them. A lot of preliminary screenings…other, I suppose, that involve family, in particular, don't get notified to us. And we've actioned it because I suppose it came up in conversation during inspection. But, yeah, they had a lot of what, I suppose, power and control of decisions made in the centre but completely outside of the remit, the	Providers placing some professionals beyond the reach of regulation	Lack of clarity in legislation	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

governance and any oversight…or we weren't able to get any oversight of this person because they're based in a completely different location.				
But, I suppose, that there's an ongoing registration rather than every three years. There's this, kind of, big build up or bottleneck of 5.5 inspections.	Bottlenecks caused by registration cycle mean that centres near renewal of registration are prioritised for inspection	Limitations imposed by legislation	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
you need to, I suppose, be very comfortable in your role and know how to use the regulation, I suppose, to impact that relevant change in a centre.	Experienced inspectors know where to allocate a non-compliance to have an impact	Being strategic in where to make a finding of non-compliance	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
premises can be an issue. Particularly where you have, you might have a premises that's owned by the organisation, who is huge and they have a maintenance programme that's	Centrally-operated premises maintenance programs can create barriers to compliance	Bureaucracy of large providers can be a barrier to compliance	General views about service providers	Overall views on the regulatory system

centrally run or something like that. So that can be a big one as well.				
the centre might consist of more than one actual house or unit. So you might, you know, depending on which house you go to, like you will only normally…correct me if I'm wrong, but normally they'll only have the information of that particular house, you know? So you, kind of, nearly have to visit the other houses to get information. So while you go and do an inspection, you could say you had this lovely centre, but you might not just hit on the house where the problems exist at that particular time.	Dispersed nature of centres complicates information gathering	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
an experienced inspector would be able to look at practises and know the areas for improvement and then find a regulation to put it under	Experienced inspectors know where to allocate a non-compliance to have an impact	Being strategic in where to make a finding of non-compliance	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
as you get more, as you progress along the role you can box a bit more clever with the regulations and how you	Experienced inspectors know where to allocate a non-	Being strategic in where to make a	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

apply them, especially in some of the weaker regulations.	compliance to have an impact	finding of non-compliance		
I think another challenge though, as well, is the diverse nature of centres. So you also have, like you know, children's centres, and you have the respite centres and you have full time residential. I mean, people can grapple with aspects of those, you know? Because you might not have the confidence or all the experience around the children's piece and the children part of the regulations, you know? And I thought respite. Respite can be quite challenging because the regulations aren't geared towards respite services. They are having to adapt and think differently and apply the AJS. It would be, you know…so I think that could be a challenge too.	It is challenging for inspectors to be comfortable making judgments on diverse types of settings	Challenging to assess all service types	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
it's not unusual to be sitting at a desk to have files the same height as you all around you because that's the modus	Document dumping	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

operandi really is to drown in paperwork and hope you won't find that one sheet in the middle.				
I do think the information that we have and that we monitor on an ongoing way does give you a flavour for what's happening.	Information volume and availability is sufficient	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
I think we can access the information and then we have the section 65 as [Insp9] was saying. If we can't access information we can utilise that then to request more information which we can utilise if needed. I haven't had to…maybe I've utilised that maybe once or twice since I've been an inspector. It hasn't been a case that I've had to utilise it hugely.	Information volume and availability is sufficient	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
I think we have the necessary information for me. But you're not always going to have all of it. So you're always, kind of, you know, every inspection is different. You're going to have to look up a different	Information volume and availability is sufficient	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

healthcare diagnosis or what this means or what that means. And I do think we have the time to do that.				
I could go to a service that may have only had drop in staff support or, you know, sleep over and it's suddenly changed to, you know, 24 hour nursing care or high needs from 2 years previously. And unless you're getting NF03s in or NF06s, you may not be aware that the whole profile or resident group or the service provision has, you know, dramatically changed. Whole time equivalents have changed. Management, you know? It's just, I don't get a lot of information in a lot of the…where service provision has changed.	Lack of information around service changes	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
you can seek an update, a compliance plan. But a lot of the time these centres are green, they didn't need a compliance plan in the first place, you know? I don’t mean to be facetious or	Only limited information from low-risk centres in between inspections	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

whatever…but there's a reason why they're green. So, I mean, really, you've notifications, but again for those centres they could be minimal				
You might seek a PAR [Provider Assurance Report]. You might get unsolicited, but other than that, for a lot of centres that are just ticking along	Only limited information from low-risk centres in between inspections	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
I would draw mental health in there as well. Because I think that's a whole melting pot in terms of dual diagnosis in relation to disability services that sometimes isn't talked about. And, particularly, as to my earlier point, these new, more complex centres opening up whereby there's a whole gamut of mental health concerns with the individual's disability as well, which manifests as behaviour. And, again, our inspectors are going in and having to make judgments and assess that and work around the risk issues,	It is challenging for inspectors to be comfortable making judgments on diverse types of settings	Challenging to assess all service types	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

health and safety issues, in terms of actually conducting the inspection.				
And I think, [Insp20], there has been, kind of, ad hoc arrangements where case holders might meet and have, you know, update meetings. But I don't think that's really been formalised	Informal information sharing among inspectors	Collaboration among inspectors	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
there are the centres…if you go in, where the person is charge is there for a long time, work really well. A consistent resident group, all of that piece. But as soon as there's change or that's challenged, you start to see those bigger issues, I think.	Change to PIC can impact on compliance levels	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system
I myself am a bit more confident going into somewhere where I've been before or I've had an ongoing engagement with. Whereas if I've been… have somewhere on my case load that I haven't been to, it's a lot more difficult to prepare for that	Changing caseloads requires additional inspection preparation	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation

centre because you have to make doubly sure you've gone through all the reports, you've gone through all the information that's there and possibly look at the old risk profiles, whatever. So there, that background work for us when there's change in cases				
there's a lot of focus now on residents and having access to their own money and things. Whereas, like, when I first started, I was expressly told that that's not something we go near, you know? And that's shifted over time. So I can see why that's challenging then, for providers, because…but it's always been in the regs, you know?	Changing regulatory approach over time	Responsive and evolving regulatory practice	General views about regulation	Overall views on the regulatory system
we're in a very different landscape now than we were in 2013. It's a very different landscape. We're more…like when we started we were a very young organisation in terms of our interpretation of the regulations. As	Changing regulatory approach over time	Responsive and evolving regulatory practice	General views about regulation	Overall views on the regulatory system

we've grown, we've become more person-centred and we've adapted, as [Insp15] said, we've adapted our own internal methodology.				
I would say is now we're seeing different changes, different demands in, in the external environment and the internal environment in terms of ensuring that we're skilled and equipped and resourced to meet that demand on an ongoing basis for the next 10 years.	Changing regulatory approach over time	Responsive and evolving regulatory practice	General views about regulation	Overall views on the regulatory system
there's lots of changes in how we're regulating from the thematic inspections. And as with the growing focus on residents rights, and as with the voice of residents	Changing regulatory approach over time	Responsive and evolving regulatory practice	General views about regulation	Overall views on the regulatory system
with any organisation, whether you're regulated or not, you know, starts with the very top. They have really good, strong governance systems. An effective board that understands their	Ciritical importance of good governance in providers	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system

brief and an effective executive management team that understands their brief, you know, then everything else follows from that. So if we don't have good systems led by the top, good culture informed by the top, the rest of it won't fall out in a positive way.				
you wouldn't have good risk management and good safeguarding if you didn't have good governance. Because the governance is what dictates the direction of the organisation.	Ciritical importance of good governance in providers	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system
i'm thinking about a place that [Insp17] has at the moment, quite a smaller organisation, you know? That have a really strong board. They have a very ineffective CEO. But actually that ineffective CEO isn’t impacting on the rest of the organisation because the board are so strong and they're driving such a strong culture and a	Ciritical importance of good governance in providers	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system

strong presence, that it’s not impacting it. But if it had a week board, jeenie mac, the whole house of cards will just fall away.				
Exactly, yeah…it's not really across…Yeah, it's a few of us have taken the initiative, but that's it, you know?	Informal information sharing among inspectors	Collaboration among inspectors	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
it's something we've done ad hoc, like, that we would have done on our team. And now there's a shared provider between [Insp22]’s team and our team, and case holders meet up.	Informal information sharing among inspectors	Collaboration among inspectors	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
the other problem is that a lot of providers now are currently transitioning onto online systems of information gathering, and that's a challenge because it's no one-size-fits-all as we know internally. But, you know, you might be looking at one system for the notification for their record of incidents and another system	Complexity of service's IT systems	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation

for how they manage their risk and a third.				
[Town name] County Council have, in all their properties now, have put in window restrictors because that's part of the housing regulations. So they've just come in and blanket put them into everything. Now there is a letter on file but there's no risks for a lot of these residents that would need, that would require the window restrictor, only for the fact that the County Council insists on it as part of the tenancy agreement. So that's a bit of, 'Ok, I'm not going to touch that one'.	Complications when housing is provided separately to care	Third-party barriers	General views about service providers	Overall views on the regulatory system
Maybe an odd occasion where there's health and safety regulations that, you know, want them to lock away stuff. And we're saying, well, that's a restrictive practise and you have to actually, like chemicals or something like that. Or things like that. And they	Conflict between requirements of different regulators	Conflicting regulatory requirements	General views about service providers	Overall views on the regulatory system

say, well, you know, ‘I have to do it for health and safety.’ And you're telling me it's a restrictive practise.				
Medication would be, kind of, a similar one, where a good practise would be safe storage, locked storage. And then we're getting NF39 from centres for restrictive practices when the assessments have all been done and this is good practise to store someone's medication in a locked press. Yet they're saying it's a restrictive practise. And so, at times, it can be minor conflicts like that where one regulation says one thing and then we’re going in and saying ‘it's restrictive’.	Conflict between requirements of different regulators	Conflicting regulatory requirements	General views about service providers	Overall views on the regulatory system
the Health and Safety at Work Act, like, that's a huge constraint for implementing positive risk taking and a human rights based approach for them because, ultimately, one of their duties is to maintain the safety of, you	Conflict between requirements of different regulators	Conflicting regulatory requirements	General views about service providers	Overall views on the regulatory system

know, residents and particularly staff. So that's a huge impediment for providers, I think, in terms of progressing person centered care now. Which is, I suppose, what the focus of regulation is and healthcare services is.				
when we might go out as a regulator and say, 'well, actually, no, that's against the rights of people with disabilities'. Whereas you have other regulators coming in saying 'no you have to have that in place', like, you know?	Conflict between requirements of different regulators	Conflicting regulatory requirements	General views about service providers	Overall views on the regulatory system
I think in disability, we're lucky because providers tend to give you what you ask for. Not always, but I suppose they do tend to, they don't challenge it as much.	Conformity of disability service providers	Positive culture among disability providers towards regulation	General views about service providers	Overall views on the regulatory system
you see services who are actually able to maintain their staff for the long term and staff really know the residents intimately well. And those	Consistency of staffing produces better quality	Consistent staffing as a facilitator of compliance	General views about service providers	Overall views on the regulatory system

services I find tend to do very well. You've staff there from…all the residents know them well. Where if…some of the services where you could be in this year and back next year and there could be 20 different staff over the space of 18 months, completely gone. Where some services, you're repeating yourself, you're seeing staff quite regularly and they know the residents very, very well. I think that those services were able to maintain their staff, in the long run, from my own experience, generally provide a better service, generally.				
I think consistent management as well, you know? You can see, I suppose, slippage where a person in charge is changing every six to months to one year, yeah. And as [Insp11] said, policies and procedures and adherence	Management stability produces better quality	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system

to that, those policies and procedures, like good policies and procedures.				
just to build on the registration piece. And I know I've been in conversations before over the last number of years where I…discussion regarding ongoing registration. Rather than with the renewal process; every three years that you submit all the stuff, you get registered, then you're inspected and your registration doesn't, you don't have to follow, I suppose, a big admin process every three years. You're either registered or not. And when you get to the stage where you're not, we're going NOPD and closure. And other than that you're being monitored and regulated against…And we're obviously kept up to date then if there's changes in floor plans or the service being provided.	3-year renewal cycle is an administrative burden	Limitations imposed by legislation	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

I wouldn't say it's a waste of time, but it probably doesn't have to be done as frequently as every three years. I don't know. I know that's part of the law. But it is extremely cumbersome.	3-year renewal cycle is an administrative burden	Limitations imposed by legislation	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
I think that continuity of staff and the PIC…I have one provider and they're quite large and then they're actually doing well on staff and…but they will move their PICs around like it's a jigsaw puzzle. And the staff then don't feel supported. They don't feel they have that, kind of, you know, that leadership in place. And they're all good PICs. It's not…I don't why they're moving them, but they do, they move them consistently around. And then they start to move their staff around after that, because people want to poach staff to another centre. And you're reading support plans and positive guidelines…they are like 'needs consistency, staff needs, a	Continuity of care is important for resident needs	Consistent staffing as a facilitator of compliance	General views about service providers	Overall views on the regulatory system

familiar staff'…'needs…this needs a male staff'…and you're going 'this could be such a lovely service'. And then it brings your inspection somewhere else because you don't have that structure in place in the continuity for residents that you would have had previously. If…just their people stay still for a little while.				
I would say the unannounced inspections give you absolutely the best idea. The announced do not give you a really true picture of what's happening.	Contrast between announced and unannounced inspections	Announced inspections	General views about regulation	Overall views on the regulatory system
The announced give you the best case scenario.	Contrast between announced and unannounced inspections	Announced inspections	General views about regulation	Overall views on the regulatory system
I'd agree with [Insp3] that I think by being in the background, you've the best chance of getting a sense of it. But I don't think we really do get a true, true picture of what it's like in a service. Especially not in an announced inspection, you know?	Contrast between announced and unannounced inspections	Announced inspections	General views about regulation	Overall views on the regulatory system

it'll all depend on whether it's an announced inspection or unannounced. If it's announced, you can, kind of, nearly prep them ahead of the time that you're going to be looking at the actions. You'll want the evidence, your documentation. It's more difficult in an unannounced because, first of all, you don't know if that person in charge is going to even be in the centre.	Contrast between announced and unannounced inspections	Announced inspections	General views about regulation	Overall views on the regulatory system
announced inspections are much, much easier because, like that, you can contact them to say what you're going to be...	Contrast between announced and unannounced inspections	Announced inspections	General views about regulation	Overall views on the regulatory system
I always preferred just an unannounced on my door when I was a PIC. Because you're like, ‘OK, grand. We'll get it done’ Or ‘whatever isn't done we’ll, you know, it'll be in a compliance plan. It won't be anything to do with the quality of care here, because residents have a nice life. But	Contrast between announced and unannounced inspections	Announced inspections	General views about regulation	Overall views on the regulatory system

when you've got that time on the other side, it's panic stations.				
It's the unannounced. When you're going at different times of the day. You go at night time. You go, you know, those kind of things. But that you do…you're never going to get it. And he's right. You would…we would need to live there. And that's not possible. So to get some kind, you know, to get a reasonable feel of what it's like to be there	Contrast between announced and unannounced inspections	Announced inspections	General views about regulation	Overall views on the regulatory system
I do think the current system that we do in terms of the inspection activity with the unannounced and the announced is good. I think it's good to have both to give residents and families and staff an opportunity to meet with us and to know that we're coming, but also unannounced. Obviously for the reasons that are obvious, you know. that they're not prepared, I suppose.	Contrast between announced and unannounced inspections	Announced inspections	General views about regulation	Overall views on the regulatory system

I think the mix of inspections is probably a good thing. The announced because people are already free, the information is there and we can get some notice. And as well as thinking about residents and their families regarding questionnaires and having opportunities to speak to people as well. With the unannounced, you get a real sense of what the day is actually like. Even last week I was on an unannounced and this was, the place spotless. And I know that wasn't it wasn't done for me, that was just the way it was.	Contrast between announced and unannounced inspections	Announced inspections	General views about regulation	Overall views on the regulatory system
Should a [redacted] year old be…would they have the same interests? Would they have the same everything? So you're, you know, you're looking at someone's future life in this. You're either going to be subject to maybe three or four moves	Critical importance of good admission procedures	Quality of provider processes	General views about service providers	Overall views on the regulatory system

because you haven't gotten it right the first time.				
if a provider has a really strong PIC, the experience to actually say ‘no, this isn't right. This is right, this is good, this is bad. We need to promote this’. I think if we put a lot into the education towards provider or the person in charge on our end and providers as well, I think you see a much different centre and much better lived experience for residents. Like, if I find, if I go into an unannounced and the PIC isn't there, that's fine, they don't need to come, but if a staff team can then run the show for you and show you what they're doing, you're going ‘that has a strong PIC’, you know? And you can see the systems that the provider has put in place. And that the PPIM and the PIC have really good lines of communication. And things are being escalated.	Critical role of the PIC	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system

If you don't have the key people right, as in your governance and management or your person in charge, people that know what they're doing.	Critical role of the PIC	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system
if you've got a good person in charge and good staff. And good systems. Well, then you'll have a good service.	Critical role of the PIC	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system
if you have a very strong person in charge who's very human rights focused, a good manager, good support for their team, you'll definitely…you will normally find very, very good practices there. And I suppose that is filtering up, I suppose, instead of down. In that, like, you know, governance and management structures are now looking at the human rights based approach, which I think is essential. But I think any centre that has a strong PIC, regardless of the provider, will have good quality of care. So I think	Critical role of the PIC	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system

that the person in charge is the key person.				
we have a regulatory programme at the moment with a large provider that we've had a lot of escalation. And we've identified some of those factors that will help a centre to meet compliance. And the person in charge, a strong person in charge is something that's come up a lot, [Insp19]. And we have examples of that compared to other centres where there may have been changes of PICs or maybe just PICs who just haven't been as strong.	Critical role of the PIC	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system
Paul Dunbar 31:17 But that was just like an informal coordination between all of you? That yeah, it wasn't… [Insp20] 31:20	Informal information sharing among inspectors	Collaboration among inspectors	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

100%. That's just us interacting. No, no. There was no process.				
I think for the big providers there's a gap in terms of information definitely.	Information sharing across inspectors is more important for large providers	Collaboration among inspectors	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
when I started, like, nobody wants to see congregated settings. It was a big fight against, you know, de-congregating because they were saying, ‘oh, they had the swimming pools and they have the kitchen and they can't go and see their friends’. All that kind of arguments you'd hear. And then, when you speak to staff, I was going in and saying, look, you can still have that, but it's just in a different setting and it's more in the community.	Culture shift that was required around de-congregation	Process of culture change in providers	The role of regulations in culture change	Positive effects of regulation

[Insp19] 46:58 [Removing the requirement to renew registration every three years] would actually change probably take at least a third of our work… [Insp18] 47:04 Yeah. Yeah, yeah, yeah. Or when you're doing… [Insp20] 47:04 Easily, yeah. [Insp22] 47:05 Yeah. [Insp19] 47:06 …away and you could concentrate then on real quality, like, do you know?	3-year renewal cycle is an administrative burden	Limitations imposed by legislation	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
we do have a lot of information before we even step inside the door, so managing information is a big part of	Proper management of information	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

our role. It's trying to get exactly the information that you need in, in the easiest way possible.				
I probably think we have access to too much information sometimes	Volume of information an inspector can access	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
Isn't that one of the shortfalls, [Insp16], of being a systems regulator, you know? If you're going to be a systems regulator, people think, ‘well, if I demonstrate every aspect I'm in compliance, that will save me on that aspect’.	Being a systems regulator sometimes results in tick-box compliance	Limitations imposed by legislation	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
unannounced inspections, I haven't had one in about six months because we've had to prioritise the amount of renewals. It's a renewal year, it's three-year cycles, that's what we're prioritising them on.	Bottlenecks caused by registration cycle mean that centres near renewal of registration are prioritised for inspection	Limitations imposed by legislation	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
Regulation 5, yeah, personal plans and assessments and assessments of need and things like that. Yeah, it kind of does. You can fit an awful lot around	Breadth of some regulations means many issues can be assigned to them	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

someone's…how someone is cared for under that, I suppose. Yeah.				
I suppose the one issue with that is sometimes it's nearly so broad that you could probably always find something under it.	Breadth of some regulations means many issues can be assigned to them	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
in one sense, being as broad as it is, you can actually…I'm not going to say manipulate because that's not what you're doing, but you can actually place some of the issues with risk under that in its general context because it doesn't tie you down to specifics.	Breadth of some regulations means many issues can be assigned to them	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
I suppose with regulation 5 as well, there's a sub reg in that that says, you know, 'the service can meet the needs of the resident'. That's very broad as well. Like, and that's often where you can capture things like incompatibility because, you know, you're saying that, like, this service as it is can't meet the needs of one resident.	Breadth of some regulations means many issues can be assigned to them	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

if it's a congregated setting, like, straight away, your inspection is going to be a different type. If you're going into a small, you know, centre or a single unit so…That inspection is…the inspections are very important.	Different settings require flexibility in inspection type	Different inspections for different settings	General views about regulation	Overall views on the regulatory system
there has to be a bit of flexibility around our monitoring processes, you know? We have to look at them and say are these the best fit, inspections being the main thing, do you know? There has to be that flexibility around, you know, maybe individual…we do have a little bit around individual needs and things like that, but around timing of inspections, you know?	Different settings require flexibility in inspection type	Different inspections for different settings	General views about regulation	Overall views on the regulatory system
there is a very clear regulation with regards to chemical restraint and I don't feel that we use that at all within HIQA. So, I mean, I wish we did. Like, that is something I think that, you know, we say we're all about the residents, that we're about	Differential assessment of regulations	Regulator reluctant to assess certain regulations	Internal bureaucratic processes	Impediments to effective inspection and regulation

a rights-based approach to regulation and all that. And I can't reconcile that with not following up on that regulation. Especially when there is so much use of what I would have always…have been trained as a chemical restraints in services.				
‘Michael is going to join swimming classes at 80’. It's like, really? Does he want to do that or does it look good, you know, is that what they expect?	Residents' needs are diverse and activities need to account for this	Ensuring that providers don't adopt a one-size-fits-all approach to care	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
if you've a good relationship with the person in charge, they'll let you know that kind of stuff anyway	Good relationship with PIC means better information	Fostering good working relationship with provider management promotes transparency	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
I think the key really is the inspectors knowing the centres and being a case holder for a period of time. Getting good feedback from the previous inspector. Because if you go into a centre and you have been there before, you would	Knowing each centre in your caseload well	Good knowledge of centres in caseload is essential	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

nearly know, kind of, where there are difficulties or having a good chat with the person charge or the staff and, kind of, getting a feel.				
We've had such…how do you say, frequent change of caseload. There is information, soft information possibly, lost between inspectors.	Knowing each centre in your caseload well	Good knowledge of centres in caseload is essential	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
I would definitely listen to the staff and the person in charge and, you know, hear what they're telling me in terms of what the life of the…quality, you know? Because I think when you build up a relationship with them, they'll be honest, generally honest with you, you know?	Building relationships with staff and management produces honesty	Importance of building good working relationships with provider staff and management	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
I suppose you have to be very conscious that when you close the centre that there are residents are going to have a big change in their lives	Recognition that closure of a centre can have big impact on residents	Negative impacts of enforcement	Walking the tightrope between assistance and sanctions	The importance of skill and strategy for the role of inspector

it's staffing allocation, I think, where needs have changed quite dramatically, quickly, or there's maybe behaviours of concern happening. Or, you know, going back to my example I said earlier, staffing was the key issue there and getting the sanction for that staffing, a business case had been done. But, obviously, as an organisation they need to look at every centre, you know what I mean? So staffing is one you'd come up against a lot	Difficulties in staff recruitment can be a barrier to compliance	Staff recruitment challenges are a barrier to compliance	General views about service providers	Overall views on the regulatory system
trying to find information in terms of following processes. That's precision. It's a bit of a nightmare, yeah.	Difficulty finding information on regulator's processes	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation
I find that some services, at times, you can be overwhelmed by what they're actually presenting to you.	Volume of information an inspector can access	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
sometimes if you're dealing with services that are providing, I suppose, kind of, complex systems of care to residents with very complex needs,	Volume of information an inspector can access	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

sometimes the information there can be quite significant, particularly under risk and under safeguarding.				
it can be quite unsettling for some residents to have somebody they don't know in their house. And you don't want to be contributing to someone's distress or discomfort or anything like that. So you know that has to happen where it needs to be, you know, the people, you know, maybe we wouldn't spend as much time in someone's house because it would be upsetting for them or, you know, staff for supportive reasons decide to take people away or whatever.	Disruption caused to residents by inspections	Invasive nature of inspections	General views about regulation	Overall views on the regulatory system
I have 2 providers in particular who have multiple files on each resident, and when you go into those inspections, it can be quite significant.	Volume of information an inspector can access	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
I used to always think you could write the whole of the first section of the report under Reg 23	Breadth of some regulations means many issues can be assigned to them	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

documenting every interaction and all that type of thing. They all take time, you know? You've had the call and you put it in your status comments. You've had your call and you add in your call log as well so that you kind of, you know, it's three things for one process. Not that you shouldn't do that. But sometimes I just feel like you should just write it in one place, you know? Rather than, you know ,if you write it in the status comment that you called and they provided assurances….well, our clarification, say it was clarification…it depends on the level of the risk around that communication that you're having. If it's a very, you know, detailed conversation that you need to write everything down to elaborate a risk. But if it's something you just clarified, whatever it'd be, I don't see the need to write it in twice, you know?	Duplication of effort when using regulator's IT system	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation

if you're in escalation, that's when you're under major pressure because you've got this, you've a case review…let's say, a warning letter…that's more stuff. You have your take actions. This, that and the other. You're duplicating information.	Duplication of effort when using regulator's IT system	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation
So that [redacted] year old actually just bought last week, bought her new house, her forever home through the council in [redacted].	Empowering residents to live independently	Empowering residents	Regulation has improved the quality of services	Positive effects of regulation
But I think like [Insp6] was saying, maybe more focused on advocacy as well, so that residents can do what the provider's doing. Because I know it says a lot, you know, you get access to your report, you get to see the report. But in a way that residents can fully understand what that means for them and how they can use it the way the provider is using it to get what they want for residents and…have that more quality, I suppose, for residents	Encouraging residents to use inspection findings for self-advocacy	Inspection reports as a benchmark for resident self-advocacy	The role of regulations in culture change	Positive effects of regulation

to be able to be, like, well, this is what I saw through the inspection. This is what I want.				
The one provider where…my first visit would have been in 2017 and premises, and safeguarding and positive behaviour support would have been the main areas of non-compliance. So, actually, a notice a proposed decision to cancel the registration was issued at that time. There were twenty residents living across five houses. Actually, sorry, 22 residents living across the five houses. And the provider brought around a lot of change. They put new roofs on houses. They completely refurbished the houses and they have now reduced the numbers. So there is now only three people living per house. That is 15 people living in the centre and their	Enforcement action prompts a response that improves quality	Enforcement as an effective tool	Inspectors as agents of change	Positive effects of regulation

quality of life has improved significantly.				
I found a warning meeting or a NOPD. Those trigger a response. And, again, is it as quick as you'd like? Maybe not, but it does get providers to focus in on the areas for improvement.	Enforcement action prompts a response that improves quality	Enforcement as an effective tool	Inspectors as agents of change	Positive effects of regulation
there's a provider forums, there's webinars, there's resident forums. There's a lot of different avenues now that's outside of the regulatory process, which can only impact in a positive way, I think, because you're giving information all the time. But you're also engaging with a provider, getting their feedback. What can we actually do? Is there anything we can do? Obviously the regulations are there, but is there anything that's more	Engagement with residents and providers outside of inspection is a postive thing	Soft engagement with service providers	General views about service providers	Overall views on the regulatory system

helpful to you? I think that can only be positive because we can't be fully on the same page.				
the person in charge is often caught in the middle. I think we do typically tend to bring those things up to provider level. Like, it rarely gets, kind of, targeted at the person in charge so much. It's recognised that, you know, that often those types of things that we've been talking about, like they're provider level issues, you know? It's acknowledged that there isn't much that the person in charge can do about a lot of those things outside of, as [Insp3] said, kind of, looking to see within the resources we have is there maybe another avenue or whatever. But I don't think that's often, kind of, put at the the person in charge, really.	Escalating issues to provider level	Making the provider accountable for non-compliance	Correctly identifying accountability for compliance	The importance of skill and strategy for the role of inspector

I think escalation takes up a huge amount of time anyway. Umm, so I think that puts pressure on all of your work. So, I think if you have a lot of centres in escalation which tends to, kind of, happen in waves, I think. Because you might have, say, a provider who's struggling overall, and if you have a lot of, if they're running a lot of centres, well then in a region or something within…you might all be busy with a lot of that.	Escalation causing time constraints	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation
when you have a centre where everything's ticking along grand, that's very different to a centre where there's a lot of escalation, a lot of regulatory activity and stuff. It might be if you're getting a lot of notifications for them or if then it goes down the road of escalation, that takes up an enormous amount of time.	Escalation causing time constraints	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation

If you're in escalation with more than one centre, you're to the wall, do you know what I mean?	Escalation causing time constraints	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation
we take a centre into escalation, it might appear that to the outside we're not doing anything because they don't see the internal workings of, say, your escalation piece. Where, you've got your caution, your warning meeting and then your cautionary…like, you know, the optics outside may not seem that we have responded quickly. Because some of the criticism in the past would have been 'oh why did it take you this long to do this?', you know?	Escalation process may not always be evident to external persons	Visibility of escalation	General views about regulation	Overall views on the regulatory system
I know there was something on Joe Duffy, was it last year about the nursing homes? The fire…and why, you know, if it was so serious, we didn't go out, you know? We didn't close the nursing home down, you know, in that instance. So I suppose	Escalation process may not always be evident to external persons	Visibility of escalation	General views about regulation	Overall views on the regulatory system

that had made me think at the time, if we're saying there's such a serious risk and still we're, kind of, going through this process that takes a good bit of time. I know we're getting our own assurances and things like that…that the residents are safe				
having your homework done and notifications prior to going. If there's any notifications coming in of concern, you'd actually be able to identify which because you'll have an ID number, you'll be able to identify which house that particular individual is in. So you might target visiting that house rather than another house.	Adequately preparing for inspections	Inspection preparation	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
Our own inspections have changed in format as well. We're seeing more person centred care, we're reflecting that more in inspection reports. Which is a sign of us being responsive as well, I think, to the changing needs that are out there.	Evolving inspection format to improve focus on person-centred care	Responsive and evolving regulatory practice	General views about regulation	Overall views on the regulatory system

I used to spend an hour or two preparing for inspection. Now, for a big inspection, it could take up to a day. You're looking at unsolicited information, solicited information, previous reports, risk profiles, annual reviews that have come in…a lot of the trending reports that you do on PRISM are really, really useful…getting all that information together.	Adequately preparing for inspections	Inspection preparation	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
I think that was impacted at lot during COVID, where maybe persons in charge weren't in centres and the governance and management….Well, I can, you know, that's been well reported in terms of the impact, you know, on governance and management.	Experience during COVID highlighted problem of PICs not being present in centres	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system
we spent a whole day looking at bed rails, like in a whole day. It was like…I never would you have thought you would. And then, I	Following a thread to identify further non-compliances	Inspection techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

even…thinking of them like…we went to day two over that but it led us to loads of different practises that weren't being followed.				
you've such a limited time you know? You have to go in there, you have to. If you're…particularly if you don't know the centre, you have to go in. You have to, basically, relax the staff and the manager to, kind of, say, "look, I'm not in here to catch you. I just want to get an overview of what the quality of life for the service user is". So you have a bit of the introduction piece of just, kind of, setting the scene for them and what the plan of the day is and that could take an hour…like it just depends on…again the premises you're in. And then you have to, kind of, you know, decide where you're going and then pick, you know, where…you'd have picked, generally, what you're going to	Importance of time management for inspectors	Inspection techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

do and it was inspected across regulations.				
I always go through the blister packs. And I'll go through with a staff and I'll do the check in and everything and what you'll expect to see	Inspectors checking medication with assistance of service staff	Inspection techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
fear of, you know, reputation damage. That's a big one, probably more so in maybe nursing homes. But there is an element of…they don't like, like there is a fear, particularly if, you know, where the families are concerned. If there's a bad report or, you know, that kind of thing. So the reputational damage one. So if residents, if service providers are not providing a good service and there's risk and they want to open another service, there's a risk that they won't get the additional funding for	Fear of reputational damage promotes compliance	Provider incentives for compliance	General views about service providers	Overall views on the regulatory system

new services because they're not managing the service. So that's another reason why, you know, regulations and enforcement is important.				
I think it would likely be better if you were out more often. Because if you're given somebody 12 non compliances, it's overwhelming for them and they may have to really, sort of, patch stuff up rather than do a root and branch analysis and put good practises in place. So if you're out and you're giving them three non-compliances, you're more likely, I would have thought, to have sustainable improvement in the quality of life of residents by regular inspections.	Infrequent inspections due to inspector shortages leads to more non-compliances	Regulatory drift	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation
I think there would be a risk in looking at regulation, that's diagnosis specific. I think that will be…I think that would not be the way to go. I mean, ultimately, you're regulating the	Different regulations needed for different settings	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

service that's provided rather than the, you know, rather than the individual who's in that service. But I do think that those age brackets often throw up huge challenges and service type is a challenge, that it's just a common treatment.				
I think respite especially, because, you know, we do take a slightly different approach to…you know, applying the regulations in respite services. Like you don't have the same expectation for, you know, someone maybe who sees someone for two days, three days a year versus someone who lives there full time, you know? But, again, that's not really backed up anywhere if you know what I mean? Like, it's what we all do. But, you know, if you know, you wonder if a provider wanted to …you just wonder if there is a bit of a gap there for ourselves.	Different regulations needed for different settings	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

And I think it's our job then as inspectors, when we go out on inspection, like you were saying [Insp5] to make people feel relaxed and to be like, ‘look, a piece of paper isn't gonna make a great service’. It's how you, you know, how you show us what you're doing, what residents are telling us.	Interpersonal skills of inspectors	Inspection techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
I always say to providers ‘if you look after the care of the residents the regulations will look after themselves’	Focus on providing good care will result in compliance organically	Good quality care will naturally result in compliance	General views about service providers	Overall views on the regulatory system
So while you may look at documentation then it's, you know, just to substantiate what you've been told or what the residents have told you.	Looking at documentation can help substantiate other evidence	Inspection techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
if a notification came in to say there was an issue, that would give you a line of inquiry	Notifications can provide lines of enquiry	Inspection techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
Because it, you know, resources and things are dictated by the funding they receive. And I don't think that has kept	Funding to meet resident needs	Inadequate funding for providers to achieve compliance	General views about service providers	Overall views on the regulatory system

up with the needs of services or residents living in services.				
Even with regards to, say, the level of detail you'd expect with regard to their assessment, or, you know, say their goals or something like that, you know? Like, you know, a lot of people say, like, 'I'm here on holidays'. So their community access might be fantastic, actually, for those two weeks or two weekends or whatever. But it just can't be the same, you know, that they don't have the access to the same type of information.	Different regulations needed for different settings	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
in terms of compliance, just even that they are aware of the regulations and what are in the regulations and what are their responsibilities under the regulations. I know it sounds like a very basic one, but it's surprising sometimes, you know, providers or management that aren't aware of the need for an App to Vary or what kind	Good providers are aware of their responsibilities under the regulations	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system

of information comes in for, you know, a registration renewal or anything like that. So umm, I think first and foremost is being aware of the regulations and what their responsibilities are.				
I think that's a really good regulation [13] to do to, kind of, get an oversight of what people's life is like. It is not, I suppose, focused on what's on paper. It's more focused on what is the life of the person like, do you know? Are they included in society? Do they have meaningful activities… … that they like, do you know? Are their choices respected in terms of that? That's a really, really strong regulation [13] that is probably underutilised because focusing on Regulation 5 is very much about paperwork and you know what that	Regulation 13 allows inspectors to focus on how a resident is empowered to live a full life	Inspection techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

looks like. So for me, I think that is a strong regulation.				
We probably, as regulation, probably don't share, I suppose…it's like what [Insp20] is saying, we probably need to meet as, you know, case holders in specific organisations to get a better feel of what's working well in an organisation and what's not working well in some parts of it. Because, I suppose, it is about shared learning and collaboration, do you know? That we get that information. And also, I suppose, we have a duty to maybe share that with the providers. That 'you're doing it really well here', like, 'what's going on that it's not happening?'	Greater sharing of information internally would benefit inspectors	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation

guidance for the different service providers as to what they need to have, you know, to have a good quality service for residents.	Guidance for providers promotes quality	Soft engagement with service providers	General views about service providers	Overall views on the regulatory system
it's very common to drive home from an inspection and think ‘I forgot to ask for that. I should have asked for, or I meant to ask for that’. And I never did because there is just so much.	Volume of information an inspector can access	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
Some services have information coming out your ears where it's like, there's so much information there that it's, actually, there's too much information there and it's hard to actually decipher. It's hard to get to what you want. And in some services, they've so much duplication of stuff that it's just nigh on impossible to find.	Volume of information an inspector can access	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
then you can't find what you need because there's so, so, so much [documentation], yeah.	Volume of information an inspector can access	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

audits are a big piece of the governance piece. And that's what…I've been in centres where they have lots of audits, but little comes from them. And then I've been in other services where there's really focused, thorough audits that have been done with clear, I suppose, standards that lead to real action. And those services I suppose would, I suppose, have higher compliance.	High quality audits are a mark of good providers	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system
I think having access to the annual review and some of the audits, 6 monthly audits prior to red 5.5 is very, very useful. You, kind of, have a good idea of what's going on here if they're, you know, answering those questions accurately and truthfully. But they give you a very good idea of what's going on in the service, what type of service it is, what type of issues there are. And some of them do that very well, like, they give you the	High-quality self audits are instructive	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system

complaints for the previous year, the adverse incidents, the numbers, all that kind of stuff and what they achieved, you know? What they're trying to achieve and feedback from family and residents, it kind of gives you a good idea of what the service is about.				
we're going into centres…we were, back when our resources was in a better space, we were probably getting close to annual inspections. We're a little bit back from that again, but hopefully we'll get back there.	Gaps between inspections increased due to staffing constraints	Inspection staff resources	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation
In terms of resources, the centres have increased significantly over the last…the number of centres over the last 10-11 years. While resource to the regulator, for us, haven't increased that much over the last 10-11 years. Therefore, you know, currently we're not getting into centres at a frequency that we would like to get into because we don't have available resource to do	Inspector numbers not keeping pace with centre increases	Inspection staff resources	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation

that. So that obviously impacts also how we can regulate the sector, you know?				
we are really restrained by our resources. That's the big piece. I mean designated centres are expanding year on year. Numbers are increasing, yet our numbers, our own numbers aren't increasing.	Inspector numbers not keeping pace with centre increases	Inspection staff resources	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation
the fact that if you go out on leave and…as someone who took maternity leave, you're nearly apologising to your colleagues, for, you know, that's your caseload just moved to five other people for a year. There's no, there's no movement or leeway or flexibility to even to cover those short term absences, let alone having more of a long term plan to increase the numbers in line with the patterns and trends of new designated centres over the last 10 years.	Inspector leave and absences are not covered	Inspection staff resources	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation

And that's probably down to resources in the Disability Services pillar. To be honest, I'm sure most inspectors would rather have their foot across the threshold before …we're doing a recommendation to register a centre, to be honest.	Some regulatory decisions are made without physically visiting a centre due to staff constraints	Inspection staff resources	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation
there's the option of day 2, but again, that's not always feasible within other workload constraints.	Two day inspections not feasible due to staffing constraints	Inspection staff resources	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation
Why are there bigger gaps between inspections now than there would have been a couple of years ago, or pre COVID? [Insp20] 37:39 Our BPOs have been revised, so it's resourcing, yeah. [Insp19] 37:41 I thought resources, resources is. Yeah. Yeah. Resourcing.	Gaps between inspections increased due to staffing constraints	Inspection staff resources	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation

You do find centres that escalate that you do require, you know, more than one inspector or the next inspection, sometimes depending on the issues, or the risk issues or the safety issues, I suppose, to assimilate all that information.	Volume of information sometimes requires more than one inspector	Access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
what used to happen a lot for me was that, you know, you'd be there 4 minutes and ‘oh, we're heading off for the day. Everyone will be back’, you know? And that does happen an awful lot.	Staff taking residents out during inspections	Availability of residents during inspection	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
if your drive is about getting resources or your drive is about getting to the next level or your drive is whatever…the service will slip. I don't know if that's even making sense? Umm, but I think the culture can't be underestimated. If you're thinking about the right fit for the job at centre level, it's huge.	Importance of motivating factors for PICs	Motivations of PICs	General views about service providers	Overall views on the regulatory system

The only other one in getting things changed then is the family. The family are very, sometimes, they're very rigid in what they want to change. And sometimes families have done that because they have had to fight tooth and nail to get the service that they've had. And the residents are very happy.	Importance of relationship between family and provider	Provider's management of third parties	General views about service providers	Overall views on the regulatory system
we have some services where maybe the person in charge is over 7 centres and if there's a really good, say, maybe team leader or something in each of those seven centres, that's fine. If there isn't they're a disaster, you know? So it's not even necessarily about the specific role of person in charge, because I think ideally the idea was that the person in charge would be the person on the ground running the service, but for all sorts of reasons, that doesn't necessarily happen. But you do need that strong leadership management role in each centre.	Importance of strong leadership in services	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system

I think a huge part of it as well, that I'm not sure can be taught, is their attitude and the culture that they form. So are you saying you're human rights? You have a focus on human rights and you're person centred. But, actually, your practise, in the way you speak about and to people can be completely contradictory. So, like, I think if you're thinking about the centres that you walk away and you say 'wow, that was exceptional'. People are leading really good lives, you know, from speaking to the person in charge. And you can see the interaction with them and residents that you go, 'they are genuinely…'. Maybe documentation can improve a bit, but they are genuinely person centred, and that trickles down.	Importance of the culture created by a PIC	Importance of good governance for compliance	General views about service providers	Overall views on the regulatory system
if it's a case of there's something there, there's something not homely. There's something not right. Well, then you	Sensing whether a centre is homely	Inspection techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

probably by the end of the day will figure out, have a good idea of what that is. You might. But on the other hand, you could go into a centre and you'll know from the get go that it's the residents home and that's what is key there				
you have to be conscious you're in people's homes. Sometimes you're sitting at a kitchen table, like, there is no physical space for you to be. You have to be conscious of the PIC, managing that stress	Imposition and stress caused by inspection	Inspection-induced stress on management and staff	General views about service providers	Overall views on the regulatory system
There is an extraordinary amount of information available, but you need to know what to ask for.	Skill in knowing what information to ask for	Inspection techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
if residents have planned outings or if after we've arrived they've planned, the staff have planned an outing with them…And I know that's just their day-to-day life and that's perfectly acceptable. But it can be challenging sometimes, I guess, when you feel like	Lack of access to residents to gather information	Availability of residents during inspection	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

people are avoiding you just trying to get, you know, the information and to triangulate and to look at the observations and communicate with residents.				
I think the biggest risk to residents is staff having the training and expertise to administer medication. Like you have situations in some of these centres where you have, like, social care staff or…not or even, like, care assistants who've had no medical training really, do you know? And they're administering injections to insulin dependent people. They could kill them in one shot if they give the wrong dose. And while they might do this, you know, training online stuff like, there's no oversight, do you know what I mean?	Inadequate training or supervision for staff to administer medication	Capacity of staff to deliver care safely	General views about service providers	Overall views on the regulatory system
it would be a worry then, you'd have non-nursing staff and…where I was had we had really good training	Inadequate training or supervision for staff to administer medication	Capacity of staff to deliver care safely	General views about service providers	Overall views on the regulatory system

systems to be fair. But medications look so similar, you know? And the errors were occurring and then near misses.				
it was the environment, it was, you know, the house was completely tailored to someone for dementia care, and it had, kind of, triggered something in that resident as well. Somebody young moving in with them. So it caused a lot of incidents that were happening.	Inappropriate placement	Inappropriate placements are a barrier to compliance	General views about service providers	Overall views on the regulatory system
I'm saying…like you really need to look at your statement of purpose. You really need to look at who you're actually…who you think is suitable to live together and that compatibility side of when you're doing your, you know, regulation 24, someone being admitted to the centre, you know?	Inappropriate placement	Inappropriate placements are a barrier to compliance	General views about service providers	Overall views on the regulatory system
their persons in charge get bonuses based on compliance levels, you	Financial bonuses in private providers for compliance	Provider incentives for compliance	General views about service providers	Overall views on the regulatory system

know? That's not happening in publicly funded.				
If you have a for-profit provider who obviously have the reputation, they're going to want to expand their businesses. So reaching compliance, obviously, is going to go a long way for them in terms of opening up new centres, getting referrals etcetera.	Reputational enhancement is an incentive for compliance	Provider incentives for compliance	General views about service providers	Overall views on the regulatory system
Your pay isn't tied to your compliance, which it can be in some private providers, yeah.	Pay tied to compliance in private providers	Provider incentives for compliance	General views about service providers	Overall views on the regulatory system
I find that some providers when you actually call it out in a report and it is a non compliance, that's an impetus to actually make that change. They will make it. Sometimes they will work with you that way as well if they're responsive.	Including issues in reports prompts action at provider level	Making the provider accountable for non-compliance	Correctly identifying accountability for compliance	The importance of skill and strategy for the role of inspector
I think, especially as a newer inspector or a less experienced inspector, that's sometimes that it's, it's a piece that, like, it obviously takes experience to	Skill in knowing what information to ask for	Inspection techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

know I haven't been given something or I need to look for something else. And I think that's a huge challenge.				
it does take a certain level of experience to actually realise that maybe they're not providing everything straight up to you or that you do need to go looking for more things.	Skill in knowing what information to ask for	Inspection techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
that's the kind of thing as you get more skilled about it, you learn to ask the right questions if that makes sense? So, ‘somebody's out all day? Oh, that's great. And where did they go? And what…did they get off the bus?’ Do you know? That kind of thing. Yeah. So that's the, kind of, additional digging that we, kind of, gather information because it's all…when you go it sounds great…’Oh, somebody was in Dingle for the day? Oh, great. And where did you go? What did you do?’ And then you find	Skill of inspectors asking the right questions	Inspection techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

out that when they drove there, they stayed on the bus and they came back, you know?				
That would lead you down a question of, well, how many staff are with them? Was it an issue because they hadn't enough staff or was it that there was a mobility issue, you know? It does lead you in lines of inquiry why these things are happening and resource issues usually is the issue there.	Skill of inspectors asking the right questions	Inspection techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
But if you were looking at, say, their day-to-day accounts, you could pick one resident that goes out a lot, say. Or one resident doesn't go out a lot and you can see what the resident that's spending a lot…See…are they spending it on what they're actually doing? So you can, kind of, judge it against what they're telling you they're doing as activities and how they spend	Taking samples of information to gather evidence	Inspection techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

it on and do a sample. You can only sample a lot of this stuff. You just don't have time.				
I think the focus on the lived experience for residents is something that has come, kind of, to the fore. So I suppose I'm [redacted] years as an inspector now and I can really see those changes and then the human rights based approach.	Increased focus on providers on lived experience and human rights-based care	Process of culture change in providers	The role of regulations in culture change	Positive effects of regulation
if you can set yourself up in a service whereby you're present in the middle of things, watching everyday activities happening around you, you get a really good sense of what life is like in that service. Not by sitting in your office but by, you know, asking if you can sit at the kitchen table or being present.	Value of observing care on inspection	Inspection techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
focus on quality improvement initiatives as well I think is really a…good providers have have that	Indicators of good providers	Indicators of good providers	General views about service providers	Overall views on the regulatory system

focus. And clearly, you know, written policies and procedures for staff to guide their practise, and good training and supervision. I think they're, kind of, the major things that I would think of.				
Centre-specific training as well. So if you go into a centre and the assessed needs of individuals are, we'll say communication…that you have the staff training specific to the assessed needs of the residents there. And, I know…I was somewhere recently I can't think of, yeah…It was a newly diagnosed individual, a person who had required a FEDS programme. And in the absence of face to face training the person in charge had gone and got online training for the staff team in the interim while they were waiting for face to face training. And it was only a matter of weeks, but	Staff training in centres takes account of residents' needs	Indicators of good providers	General views about service providers	Overall views on the regulatory system

to ensure that everybody was…so that kind of characteristic of a person in charge, seeing what's needed, the changing, assessed needs.				
I think there should have been further escalation. And then there was and issues, kind of, rumble on and you have centres in case review for, like, years at times, you know? And quality isn't improving there and all that kind of stuff.	Ineffectiveness of escalation	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation
a lot of good providers are well resourced, there's a lot of providers who wish to be good providers who aren't resourced. Who are trying so hard, but because they don't have the resources, can't meet compliance in certain areas.	Lack of resources available to providers	Inadequate funding for providers to achieve compliance	General views about service providers	Overall views on the regulatory system
There seems to be quite a disparity between what private providers are in receipt of and what section 38 and 39 services are in receipt of. But [Insp16]	Inequity of resources available to providers	Funding model creates barriers to compliance	General views about service providers	Overall views on the regulatory system

is absolutely…we, kind of, can't comment on that…but [Insp16] is absolutely right in that, you know, that this doesn't come cheap, you know? This doesn't come cheap, absolutely.				
Your judgements may be correct, but it may appear inconsistent because I might say, well, actually, 'I'm not going to put that under Regulation 23 because everything else was so good. I'm going to put it under this regulation'. Whereas another inspector might say, 'actually, no, I'm going to put that under Regulation 23 because I think that's really important'	Inconsistency can arise from where different inspectors locate a non-compliance	Inspector inconsistency	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
I think within teams we speak a lot. But, you know, as a national team, about, 'well what are we really talking about there?'. And, you know, sometimes, I mean, there was even something circulated not too long ago now that was looking at compliance levels with different regulations and	Inconsistent thresholds for compliance among inspectors	Inspector inconsistency	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

the evidence used. And, like, sometimes, what was used as evidence, I suppose, to justify a non-compliance was the exact same as what was used to justify a substantially compliant. So, you know, I think we have a lot of work to do internally as well.				
that was a huge issue at the start of the regulations. I think there was a lot of ambiguity and lack of understanding, both…within our own team…like, it was what I would see is abuse compared to what a colleague would have said.	Inconsistent thresholds for compliance among inspectors	Inspector inconsistency	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
the issue for me is consistency across the board. I find that the information that we have is good. However, applying consistent and proportionate judgements is sometimes lacking in regulation. And I think that's probably because sometimes the disability team say, for example, we're not joined up	Inconsistent thresholds for compliance among inspectors	Inspector inconsistency	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

in terms of what's going on, exactly what [Insp20] is saying. And that, kind of, gives inconsistent views. Or providers have inconsistent views…I've often heard somebody, people saying, oh, do you know ‘that inspector likes it that way’. And ‘another inspector likes it that way’. Which is…that's actually not right.				
I think we could probably do better in terms to, kind of, get that consistency across the board. Because I think that's probably one of the problems that regulators have, there's so many of us involved in it and we all have our different little views than idiosyncrasies of how we like things done.	Inconsistent thresholds for compliance among inspectors	Inspector inconsistency	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
if you notice in a provider that where you do have unannounced inspection, but then you're an hour in the centre and they're all gone out that day and you're thinking, ‘well, the last time I	Providers taking residents out of centres during inspections to limit inspector's interaction with them	Availability of residents during inspection	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

was with one of these providers that were all gone out after about an hour as well'. Is it that, you know, it's a lot more convenient to get the residents out for the day? So that it's part of their social care plan or their activity plan. Rather than, you know, the inspector to make a judgement that they have inadequate staff or something like that. Look, I don't know really, but sometimes you do have that sort of feeling, really.				
I'm just finding that with that service that I mentioned there, it is that they have stuff coming out their ears. Whereas and I do find now that a lot of stuff is there for HIQA as opposed to being meaningful for residents.	Some documentation is solely to satisfy the regulator rather than being meaningful for residents	Excessive documentation that is no benefit for residents	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
I just think that that's their system and they overcomplicate stuff like, as in, I just can't get my head around how they…they over complicate stuff. So	Some providers produce excessive documentation	Excessive documentation that is no benefit for residents	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

therefore there's 40 documents when one would do.				
I wish we were inspecting every year in centres like they are in older persons. I think that there is, there's too big a gap between inspections and it's often then by the time we spot that maybe compliance has declined…It's almost too late. And I know that's not our responsibility. It's the provider's responsibility. But, you know, if you're going, and I'm conscious about that I'm not currently going on inspections. But, you know, you see a centre, the last inspection was 18 months ago and it was IPC. Really, you have no idea what's been going on there, you know? I know there's UROIs and notifications and stuff, but I do feel there's a big gap there and I know that in our region anyway, you know, we had a lot of centres that were kind of yellow,	Infrequent inspections due to inspector shortages leads to more non-compliances	Regulatory drift	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation

maybe even green and went into escalation after those, kind of, long periods straight off the bat, you know, and that's obviously not what you want to happen.				
I just think this kind of one day every 18 months, I just, I'd query how good our data is from that, you know?	Infrequent inspections means data on centres is poor	Inspection staff resources	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation
I've some centres that will only have one inspection in three years [due to inspection staff shortages] and that'll be the renewal inspection. They wouldn't have had an inspection any other time.	Infrequent inspections due to inspector shortages	Inspection staff resources	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation
out of those large gaps, Paul, there was regulatory slippage, regulatory drift, all those kind of terms. But this was…we're not going out as often, which means if there are issues with the provider and they're not being identified, if the provider isn't self	Infrequent inspections due to inspector shortages leads to more non-compliances	Regulatory drift	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation

identifying, we're not going out there that often to identify it. Which means there could be an ongoing issue for longer than needed regarding some aspects of care and support because no external person may be going in and having a quick eye on whatever it might be. And so that's what the real impact is, at times, there can be a poor quality of care and support, despite everyone's efforts. Maybe if we were a bit more often out there and keeping the pressure on and people know that we're coming out and reviewing their own systems. So regulatory slippage, that's what the term that we use internally on it.				
I think the frequency we're in centres, as well, is changing. Our time spent in centres. So now we're all in the position where we're pushing up on 20 plus months. They're very different	Infrequent inspections leads to uncertainty around quality	Regulatory drift	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation

inspections from the centre where you've been in the last year.				
are we perfect methodology? Perfect? No. But I would say our sharpest tool in the box is, currently, and will always be, inspection.	Inspection activity is sharpest tool in the box	Inspections are optimal means of judging compliance	General views about regulation	Overall views on the regulatory system
inspection is very precious time. And it's probably, you know, top of the scale in terms of our, you know, our procedures to know what's going on.	Inspection activity is sharpest tool in the box	Inspections are optimal means of judging compliance	General views about regulation	Overall views on the regulatory system
I suppose inspection findings are quite narrow in that way as well, because I'd imagine it'd be very different if we went on a Saturday afternoon and spoke to residents and saw what their lives were like and looked at staffing levels. Maybe…they may not be that different, but I suppose we can't be assured really from our window of inspections.	Inspection findings are only a mirror of date or time they are carried out	Inspection findings are point in time	General views about regulation	Overall views on the regulatory system
the nicest part of the job is the inspection, you know? Albeit sometimes they're not so great, often	Inspection is the nicest part of the job	Inspectors enjoy conducting inspections	General views about regulation	Overall views on the regulatory system

they are very good. But all of those things that [Insp16] is talking about is, you know, the meeting, the residents, the conversations, the chats, the talking to staff etc are actually the nicest part of the job.				
The good PICs, the good managers, you know, they have often been flagging the compatibility issue or the shared bedroom or whatever it happens to be that's having a negative impact on the residents of that centre. And they've been banging their head off the wall for years trying to do something about it and we come in and we write about it in a report. And we find them not compliant. And we're well aware, Paul, that that report is currency, do you know what I mean?	Inspection reports as currency	Negative findings are used by providers as currency for resources	Inspectors as agents of change	Positive effects of regulation
that report gives a bit of credit to the provider to go and do what needs to be done. So it's often then we go back out	Inspection reports can bring about change	Negative findings are used by providers as currency for resources	Inspectors as agents of change	Positive effects of regulation

and it has happened and staff or residents or whoever are saying, you know, ‘Jesus Christ, without that report, this would never have happened’. So I think that's another strength of regulation.				
focus on the views of the residents and the observations in the centre to me actually has enhanced the reports.	Inspection reports enhanced by inclusion of residents' views	Giving voice to residents	The role of regulations in culture change	Positive effects of regulation
Children are only referred to in the regs I think maybe a couple of times or so. So there is wide scope in regulations, but also narrow in how some of them can be applied which can be a challenge. And that can probably lead then to, like [Insp21] says, possibly inconsistencies in how it is viewed whilst trying to be proportionate.	Limited mention of children in regulations can lead to inconsistency	Inspector inconsistency	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
inspectors have got a lot better at, kind of, having a consistent…just through training, experience of what they	Training and experience improves inspector consistency	Inspector inconsistency	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

would identify as, you know, an issue in any of those areas.				
from our perspective and the provider's perspective, it is something that…there will be peaks and troughs, but we will celebrate the green shoots when we see them.	Acknowledging improvements in quality	Inspectors acknowledging good practice	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
My experience generally there seems to be openness and not much, I suppose, antagonistic interactions.	Inspectors experience mostly positive engagement	Positive culture among disability providers towards regulation	General views about service providers	Overall views on the regulatory system
some providers have taken that to the nth degree. Like, I mean, Jesus, you could write an encyclopaedia in…some services have encyclopaedias on what residents life looks like and there's no need for it.	Some providers produce excessive documentation	Excessive documentation that is no benefit for residents	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
I mean, you can run reports, yeah, there is a way of pulling it up. Like, if you're doing provider meetings for example, you know the RSOs can pull up, like, the overall levels of compliance and so on. But I certainly	Inspector's relying on regulatory support workers to access information	Administrative tasks detract from work of inspecting	Internal bureaucratic processes	Impediments to effective inspection and regulation

don't have the skills or knowledge to do it. You don't have the time either				
if you use your legislative powers, you're going to come up against scenarios where we're stepping into the unknown. But sometimes you do have to step off that cliff. And perhaps the appetite for doing that isn't always there, but ultimately, I think we use what we've got in a proportionate way to affect change.	Uncertainty of outcome when engaging in enforcement	Regulatory appetite for enforcement	Walking the tightrope between assistance and sanctions	The importance of skill and strategy for the role of inspector
I think providers appreciate when you see that really good practise when you see them supporting, promoting relationships. When you see that you call it out as well. It's not all about non-compliance, you know? So I would often say to providers ‘I wasn't intending to open 13. However, I've seen really good practise today and I'm going to open it’.	Providers appreciate calling out good practice	Inspectors acknowledging good practice	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

we used to have medication management inspectors, that if you were concerned about medication…when I inspected nursing homes years ago, we used…that there was a huge amount of issues with medication and I could ask for a medication inspector who was a pharmacist actually to come with us. So I think there should be… And support as well, both for the providers, but for the inspectors in terms of the medication one.	Lack of specialist inspectors	Inspectors expected to be experts in wide range of fields	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
if you have inspectors, and, you know, they're not, they don't have a background in, say, nursing or in medication management. It's sometimes you've…and colleagues would have said this to me. They're a bit worried about going in, making judgments on it because they're not confident themselves in it.	Some inspectors feel they lack expertise to make judgments on medication management	Inspectors expected to be experts in wide range of fields	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

I think if you, if you've been, you know, you're looking at an inspection report where four people were living and now you know that, you know, there is maybe six people living there or something, you know, you'd wonder how much of that information really still applies.	Change in residents changes profile of centre	Inspectors take resident profile into account when assessing quality	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
you might have a slew of NF06s that might be of concern. So those are the notifications around suspected or alleged safeguarding concerns. But if there's been a change in residents, they may no longer be applicable or they're, you know, those individuals may no longer be in the service when you get there.	Change in residents changes profile of centre	Inspectors take resident profile into account when assessing quality	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
One of the other gaps for me that I feel will be useful…and I don't know what others feel…is with the large national providers, you could have escalation going on in another region and be completely unaware of it, you know?	Knowledge gap for inspectors on how a provider is performing nationally	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation

It's, kind of, a by the by or whatever. And I think that can be a gap because, obviously, if someone has a NOD issued in Galway, it's not necessarily going to be the case in Dublin, but it's useful information to know because it's the same management team. So that's one area that we don't need to know all the ins and outs, but just to be mindful, ‘actually, there’s significant escalation going on with this provider in Limerick and they have a certain amount of centres in Dublin'.				
I was talking earlier on about, you know, the same set of regulations covering the two people living in the apartment to the 25 people living in the dormitory style living accommodation. And so a suite of regulations that better meets the needs of specific residents were inspecting against.	Different regulations needed for different settings	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

you're trying to make regulations fit to a service, as such, sometimes. And, like, that's...disabilities in itself is very broad. You've got very low support and very high support needs across the services.	Different regulations needed for different settings	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
And other times…it can be quite some time to get through it all before you actually make that decision, because sometimes you, kind of, sometimes you're better off not going to…sometimes it's a personal thing. Sometimes I'll, kind of, wondering, do I actually have enough now to call this a, you know, compliant or not compliant? And then I'm a little bit more on the 'Oh my God'. As you read them, some of the risks even become even more, kind of, you know, all right, I wasn't expecting that.	Challenge of ensuring you have enough evidence to make a judgment	Gathering sufficient evidence	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

what we have found, just for this centre, without naming it is, the very senior governance and management structures are weak and there's a lack of accountability, I suppose. So even when centres have non compliance and serious non compliance there can be, I would say, apathy. There's just no push because no one's ultimately responsible. Everybody's responsible, but no one really. So, you know, when actions are being identified or not being assigned to, whether it's CEO or programme manager, or PIC, they're just left open and therefore they're not being monitored either. So they're just left in the ether almost. And we'll go back and find the same thing. So it's that, kind of, monitoring and governance from that higher level. If there's weaknesses there, it will trickle down	Lack of accountability at provider level results in persistent non-compliance	Importance of good governance	General views about service providers	Overall views on the regulatory system

Even in the narrowness of the regulations and how they're applied to different types of services such as respite, which is always something that crops up. And the trickiness that can raise. Even another example would be children's services, you know? Children are only referred to in the regs I think maybe a couple of times or so. So there is wide scope in regulations, but also narrow in how some of them can be applied which can be a challenge.	Different regulations needed for different settings	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
I've gone to a few centres now and they're just closed. I could have travelled to the midlands and they're closed on a Monday. Or it's a respite service and they close for the week and there was nothing to guide you to say that the centre is closed or when they're open. So that's, that does feel like, you know, obviously the waste of a day and…moreso at your respite	Lack of clarity around opening hours of centres can result in missed inspections	Regulatory processes need improvement	Internal bureaucratic processes	Impediments to effective inspection and regulation

centres. But there is a few providers that have these funny, kind of, Monday to Friday arrangements and they're actually closed weekends.				
it's the housing piece sometimes is a challenge. And I can understand why that would be then frustrating for providers because they're like, you know, you're talking about this, but we've met that Reg and we're still slotting it in somewhere and we are doing it because we feel that, you know, it's maybe a risk to residents or improvement is required for them to get the service that they deserve and need. But it is a bit tricky. Like, it's a bit of a balancing act to the whole thing really.	Fitting findings to broad regulations because the specific ones are technically compliant	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
if it was left up to me, I'd do another 27 between now and the end of the year, but I can't.	Lack of independence for inspectors	Limitations imposed on inspectors by regulator's business rules	Internal bureaucratic processes	Impediments to effective inspection and regulation

they still present you with these big huge files and you…you're, kind of, trying to get through it to make an informed decision on whether it's compliant or not or sub compliant.	Challenge of ensuring you have enough evidence to make a judgment	Gathering sufficient evidence	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
you know they update every three months or six months and you have to put in the information that you know about the centre since the last risk profile…So depending on the notifications that are coming in or inspections, you'll often find that we use that language there because we haven't, say, we haven't been in the centre for two years or coming on, you know, 2 1/2 years. And you're trying to give them a risk profile or risk rating yellow, green…or you may say 'look, you know, it's been 20 months, 24 months since last inspection'. There may be…there is an opportunity for regulatory slippage because we don't know what we don't know,	Lack of inspection activity makes it difficult to properly assess risk	Regulatory drift	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation

really…what we're saying there is that in the absence of us being out in the centres or engaging a lot with that particular centre, something could be happening in the background that we're not aware of.				
it's people and money. That's what it's down to. They either don't have the people to do it or they don't have the money to do it. They are the most common ones and they're valid quite often, more often than not, probably more.	Lack of resources impacts ability to comply	Resource limitations affect provider capacity to comply	General views about service providers	Overall views on the regulatory system
That social model for residents does not come cheap to the providers. To get the right calibre…we talked about it, we talked about it earlier. To get the right calibre of staff. To get the right calibre people to be able to support people to have a meaningful life does not come cheap. And the providers are struggling in terms of getting the right	Lack of resources impacts ability to comply	Resource limitations affect provider capacity to comply	General views about service providers	Overall views on the regulatory system

people because they also…the funding for that, you know, is not adequate.				
I think probably funding for section 39 organisations, in particular. I suppose, they're dependent on business cases to the HSE to get funding. But, in particular, where needs maybe have changed, residents needs have changed significantly. In terms of, maybe, mobility or mental health or something like that, where they require extra staffing or an adaptation to their home or something like that. And the provider doesn't actually have the money to do it. Umm, and I suppose we're going then maybe finding them not compliant in those areas.	Lack of resources impacts ability to comply	Resource limitations affect provider capacity to comply	General views about service providers	Overall views on the regulatory system
I think funding is the biggest one. There's a couple of providers that have funded their own staffing increases down to what [Insp10] said, changing	Lack of resources impacts ability to comply	Resource limitations affect provider capacity to comply	General views about service providers	Overall views on the regulatory system

needs or…waiting for the HSE to approve or not a business case…but funding is a major piece outside of the provider's control. That, I suppose, at times, can lead to areas of non-compliance because that's what…they don't have the funds necessarily to do it and it takes inspection or a significant incident for them to, I suppose, put in the staff and fund it themselves.				
sometimes the providers just can't comply with what the…It comes back to that whole resource issue doesn't it? Like, you know, we've been in centres where we said 'this is a really bad centre and you need to move residents'. Like, that's not going to happen. They need to have money, they need to have staff. So that's a huge impediment, I suppose, sometimes, and you go back again and again and say like…	Lack of resources impacts ability to comply	Resource limitations affect provider capacity to comply	General views about service providers	Overall views on the regulatory system

[Insp20] 1:03:50 Yeah. They can't just come into compliance				
That's a really, really strong regulation [13] that is probably underutilised	Some regulations can be underutilised	Inspectors underutilise certain regulations	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
I'm thinking of one that had 32 residents and it had one person in charge and it just, it wasn't possible. She didn't have the other supports there	Lack of supports for service managers	Resource limitations affect provider capacity to comply	General views about service providers	Overall views on the regulatory system
I think we have large caseloads. I mean, I was speaking with someone in DCOP the other day and no one's over 30 on their team, you know? That's not the case across the country, don't get me wrong. But, like, you know, that's not the case in disability services.	Disabilty have large caseloads compared with nursing home inspectors	Inspection staff resources	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation

I think providers respond well with Regulation 13 as well. They seem to get a better understanding when they're actioning and looking at their processes. And, like, I would agree, like 13, it's definitely, probably underutilised and very effective.	Some regulations can be underutilised	Inspectors underutilise certain regulations	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
an inspector is such a skill. It's a learned skill. Like, you can do so much, but you have to go out and get practise at it and learn from other more experienced inspectors.	Learning from more experienced inspectors	Learning how to regulate	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
I've been able to support on inspections. I learned so much. You come back here, like, ‘oh, I never would have thought of that’ or, you know? It opened your eyes or something.	Learning from more experienced inspectors	Learning how to regulate	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
when we started, you know, the policy at the time was that we got six weeks of inspection or six weeks of induction and like, 3 or 4 of that was actually just going out with colleagues as the	Learning from more experienced inspectors	Learning how to regulate	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

support, observing for the first while. And then, you know, even when I was like, inspecting, I was lucky because I came from a disability background. I was a manager in that for years. So I, kind of, had the basis of it. But not every inspector would have that. And they do, you know…so for me, it was great to, kind of, I didn't need to learn about disability services or how they were managed or any of that. I had that. But what I didn't have was how to regulate. I need to learn the skill of regulating and I think that's the piece that benefits me from going out with others. To learn that and, kind of, get the best out of an inspection, you know?				
I think because they are regulations they have a weight to them. And the fact that there is, kind of, somebody else, you know, it's an external person	Legal weight of the regulations	Authority conferred by having regulations	General views about regulation	Overall views on the regulatory system

coming in and…So like I think that in itself is going to lead to improvement.				
I think that the regulations probably at the time gave us significant powers. And have given us a really strong framework to work within.	Legal weight of the regulations	Authority conferred by having regulations	General views about regulation	Overall views on the regulatory system
It's the only thing I have. It's the only thing like it gives you a legal status to make the, you know, going in with standards, like…I know we have the standards as well, but, like, standards don't make a provider do anything. You have to have the legislative backing to get change sometimes, because the providers are going to say to you 'I don't have the money' and then they won't do it. Whereas if it's a legal requirement that they have to come up with a plan, you know, that…the legislation is the only thing that's driven change in a lot of the service providers to get funding.	Legal weight of the regulations	Authority conferred by having regulations	General views about regulation	Overall views on the regulatory system

people forget, say, external to HIQA that: these are people we're talking about. You can't just throw people out of a nursing home today because you think it's terrible. There is a process that has to go through. You have to go through the escalation piece of it. You have to be proportionate. You have to give them the opportunity to fix what's wrong. Because these are people we're dealing with. So I don't think that it's necessarily that there is a loophole, but it may appear that way.	Legislation requires that time be afforded to remedy matters	Slow pace of escalation	Internal bureaucratic processes	Impediments to effective inspection and regulation
It doesn't happen overnight. And, I suppose, that has to allow for legalities, for them to have a right to challenge judgments. And, you know, we can't jump to a section 59. We have to use our powers proportionately. And that will go to your, you know, your NOPD. And then there's the 28 days and then you may go to an NOD. There's another 28	Legislation requires that time be afforded to remedy matters	Slow pace of escalation	Internal bureaucratic processes	Impediments to effective inspection and regulation

days. So sometimes the promptness isn't really there				
I think as well the problem is even more intensified with the increase of services you have on your dashboard with the decrease in BPO. So you're getting more services, but you're…we used to inspect 36 to 40 [per year], now it's down to 30.	Limitations imposed by business rules	Limitations imposed on inspectors by regulator's business rules	Internal bureaucratic processes	Impediments to effective inspection and regulation
I think it was 36, but most people if you went to 38 or 40, there was no, there wasn't significant…but now it's 30 and that's, like, it's quite firm and that's fine if you…if it's 30 it's 30.	Limitations imposed by business rules	Limitations imposed on inspectors by regulator's business rules	Internal bureaucratic processes	Impediments to effective inspection and regulation
the barrier really is the business barrier, I guess. It's not what you would do as an individual if you had free reign to do what you would like to do. Like, I have over 60 cases on my dash and I'm already at 27 inspections. So I've only three more to do between now and the end of the year.	Limitations imposed by business rules	Limitations imposed on inspectors by regulator's business rules	Internal bureaucratic processes	Impediments to effective inspection and regulation

the other barrier, and I say this in the most respectful way, but when you look at the introduction of, say, for example, thematic programmes, they really need to be done alongside your standard regulation and not replacing a regulatory programme. Because, as [Insp2] said, you run the risk then within a three-year cycle of only having one spin out and looked at regulation in that cycle.	Limitations imposed by business rules	Limitations imposed on inspectors by regulator's business rules	Internal bureaucratic processes	Impediments to effective inspection and regulation
When I started there was two inspectors all the time went out and that was, kind of, you know, to upscale, to keep, to support each other. To make sure that the residents got the time they deserve and the service got the time deserved with inspectors so that they actually got a fair hearing. And then it was like, ‘Oh no, we had to cut back’ and inspectors had to go away and do it in one day and do a massive centre. Like, I used to go mad	Limitations imposed by business rules	Limitations imposed on inspectors by regulator's business rules	Internal bureaucratic processes	Impediments to effective inspection and regulation

because I was, like, it was unfair on everybody, it was really unfair on everybody.				
we're, kind of, told, you know, you can't spend any more than 8 hours in a centre, you know? You have to go home. Or you can't do two days because it's, kind of, constraining other business rules or whatever.	Limitations imposed by business rules	Limitations imposed on inspectors by regulator's business rules	Internal bureaucratic processes	Impediments to effective inspection and regulation
I think sometimes we are constrained in terms of time as opposed to looking at what the service delivery is like. And then base what our inspection is going to look like based on that. As opposed to what is dictated to, I suppose, by HIQA, if that makes sense?	Limitations imposed by business rules	Limitations imposed on inspectors by regulator's business rules	Internal bureaucratic processes	Impediments to effective inspection and regulation
ultimately there's a bigger picture business plan, you know what I mean? And we're part of that plan. So we worked to an instruction or a directive or whatever. So at this point in time	Limitations imposed by business rules	Limitations imposed on inspectors by regulator's business rules	Internal bureaucratic processes	Impediments to effective inspection and regulation

right now, a lot of those green centres, not high risk ones, but those green ones are being allowed, you know, they are slipping into that 20 to 24 month period where they haven't been inspected				
We should be able to point them in the right direction, I think. And there has always been this thing of ‘you can't make recommendations’ and all the rest. So in some sense have to go the roundabout way and even say, well, you won't tell them where, what centre. But you'd say ‘there's a provider in the North East, very large who have a really good system. So would you not give them a ring and just see what they're doing’.	Limitations imposed by business rules	Limitations imposed on inspectors by regulator's business rules	Internal bureaucratic processes	Impediments to effective inspection and regulation
what I didn't have was how to regulate. I need to learn the skill of regulating and I think that's the piece that benefits me from going out with others. To learn that and, kind of, get	Learning from more experienced inspectors	Learning how to regulate	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

the best out of an inspection, you know?				
I often feel people and…maybe I'm wrong in this, that are very defensive are, kind of, hiding something, you know? But, you know, and sometimes it can be just a personal thing as well, you know? Like it's a personality type, maybe, to be a bit more confrontational or something?	Defensive and confrontational managers	Negative disposition of provider management and staff towards regulation	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
there's still an enormous amount of having to wriggle around within them to find where something might sit, and sometimes it doesn't sit anywhere at all, actually. You can't find anywhere. Even though, you know, what you're witnessing is an area that could potentially be improved upon, or, you know, is not right, but there is no way to action that because, as [Isnp1] said,	Challenge of classifying under what regulation to situate a finding	Not always obvious what regulation applies in a given situation	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

they follow complaints. Or they are notifying incidents or, you know, whatever it might be.				
I mean it is a challenge, there's no doubt about it for providers. But you also want to see evidence that they've looked at every other possible alternative. So if they can't buy a property, for example, could they rent, could they look at reconfiguration internally of their own properties?	Looking for adaptability and resourcefulness in providers	Resourcefulness of providers	General views about service providers	Overall views on the regulatory system
If they can't access health and social care professionals, have they looked privately? Have they looked at other purchase schemes? What have they done to follow up? Very often you'll see something that says, ‘oh, we couldn't do it’. And then you don't see that follow up.	Looking for adaptability and resourcefulness in providers	Resourcefulness of providers	General views about service providers	Overall views on the regulatory system

I think the frequency we're in centres, as well, is changing. Our time spent in centres. So now we're all in the position where we're pushing up on 20 plus months. They're very different inspections from the centre where you've been in the last year. And even at that, where you've been in the centre previously, you somewhat…familiarity is probably the wrong word, but, you know, the residents that you're going to meet, you know, the set up of the centre. You have an idea of what, you know, the relationships are like within that centre. How to get information quicker, their systems, all of that piece. So you can be more efficient and make the most of your time and how to spend it with residents.	Lower frequency inspections are less efficient due to lack of familiarity with centres	Inspection staff resources	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation

I suppose it's not just the regulation that is important. I think some of the regulations are very person in charge heavy, so a lot of the 'person in charge shall' rather…and areas that they may not have any control or oversight. In particular, staff files or recruitment, or even…under Regulation 5, in terms of MDT. So, you know, if there are issues, it may not be the reg that I'm looking at, but it's the one that we linking it back to the registered provider. So you're…is it 5 (3), where the 'registered provider shall'. And I think that's the only one in Regulation 5. So yeah, it's not just about the regulations also about who the person is as well. Sometimes when you really need to, kind of, push up the food chain.	Making non-compliant judgments under regulations that the provider is responsible for as opposed to PIC	Making the provider accountable for non-compliance	Correctly identifying accountability for compliance	The importance of skill and strategy for the role of inspector
I used to spend time in [redacted] and, like, the most senior manager that we would deal with at provider level: she	Manager knowledge of centres is an indicator of quality	Importance of good governance	General views about service providers	Overall views on the regulatory system

was in those centres all the time. Like she, they, the residents knew her. She knew the ins and outs. Yes, she might not have known the micro detail, but she was pretty close to it, you know? So there, you know, there was, kind of, there was no surprise that she had a good sense of what was going on everywhere				
The point I was trying, and I think didn't quite manage, to make about management /leadership presence in the centre being an indicator of compliance was that you generally know you're in trouble when there are poor findings on inspection and it comes as a surprise / shock to management, or they strongly argue it (without valid arguments) with you. Typically staff in the centre (including the PIC if they are actually based there) are very aware of what non-compliances you'll find and often are	Manager knowledge of centres is an indicator of quality	Importance of good governance	General views about service providers	Overall views on the regulatory system

appreciative when you highlight them. It being a surprise to others in management positions is a real red flag!				
it's down to being their home again. I keep coming back to that. It's the residents home and that is respected as such. I remember being in somewhere where contractors…residents were informed that contractors were going to be there. It was a social story to tell them or what they were going to be doing. Centre specific, that you know the individuals. If something is not right, they're going to sort it for them. That's, kind of, would be a good feel.	Manager knowledge of centres is an indicator of quality	Importance of good governance	General views about service providers	Overall views on the regulatory system
where you have PPIMs who also know the residents, who the residents are very familiar with, all the rest. You tend to have a little, ok, the paperwork might need a bit of whatever, but the quality of life tends to be quite good	Manager knowledge of centres is an indicator of quality	Importance of good governance	General views about service providers	Overall views on the regulatory system

because they know what the reality of the day-to-day life is for people and for the person in charge.				
on-site management is really important, ensuring that managers are there on-site because that's, you know, I suppose, we saw that over COVID but, you know, you can still go into centres where you have a manager who's been on site for two hours in the last four months, like, and hasn't identified any issues and, you know, it's left up to the person in charge. And depending, again, on their capabilities, that determine how compliant they are with the regulations.	Managers being present in centres is good for quality	Importance of good governance	General views about service providers	Overall views on the regulatory system
They’re boots on the ground. It's physical presence in the centre for those, that level of management, to even visit or drop in. You can see where that's not happening and they don't even know the residents	Managers being present in centres is good for quality	Importance of good governance	General views about service providers	Overall views on the regulatory system

my experience would be that people who are, kind of, more open and welcoming and welcoming of the process tend to achieve better compliance levels.	Managers that 'buy into' regulation have better compliance	Positive culture among disability providers towards regulation	General views about service providers	Overall views on the regulatory system
if there is a concern that sometimes they use the inspection processes to actually drive home the quality improvement piece they're trying to do themselves.	Managers using inspection process to aid their own quality improvement initiatives	Centre managers using inspection findings as leverage for their own quality improvement initiatives	General views about service providers	Overall views on the regulatory system
You're actually going to regulation 23 a lot of the time because you can't pull in for medicines.	Fitting findings to broad regulations because the specific ones are technically compliant	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
we're well aware that, you know, within the nursing home sector, each centre is subject to an inspection at least once a year. Currently, we're nowhere near that within the disability pillar. And, you know, that's always a bit of a worry.	Mismatch between frequecy of NH and disability inspections	Limitations imposed on inspectors by regulator's business rules	Internal bureaucratic processes	Impediments to effective inspection and regulation

I had an issue where two residents who were related, their family representatives refused to change their GP, even though the GP wasn't providing the services. But the healthcare, I couldn't fault the provider on healthcare because they had clinical nurse assessments. They had done everything with MDT to try and maintain the well-being. So it was under [regulation] nine that the residents didn't have access, or decisions, were not involved in decision making. That's the only fit that worked…I couldn't that…so, kind of, a juggling has to go on sometimes because even though it was healthcare, it wasn't provider's fault, if that makes sense?	Challenge of classifying under what regulation to situate a finding	Not always obvious what regulation applies in a given situation	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
some of the regulations, they are quite limited in how we regulate and you're trying to sometimes fit what you find	Challenge of classifying under what regulation to situate a finding	Not always obvious what regulation applies in a given situation	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

into the regulation as opposed to the other way around.				
they're not understanding that sometimes maybe less is more. If you do it right in one way, as in one system, and join the dots, well, then it's much easier for everybody, including yourselves, as in the providers to deliver care because you don't have 40 places to tick a box. And in some cases it is a tick box exercise.	Providers produce overly-elaborate systems to manage compliance	Overly-elaborate systems for compliance complicate the inspector's job	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
when it comes to things like feedback on inspection reports or challenging judgements, which again are all, you know, there's no issue with those. But I would find that that's more likely with those [private] providers because understandably, you know, they have a business reputation and it's a different ball game.	Private providers more likely to challenge findings due to reputational risk	Private care model means those providers are more concerned about reputation	General views about service providers	Overall views on the regulatory system

I had one as well not that long ago. Maybe it's November now, but they've made huge changes since. So I think in six months they had a centre identified and the provider had…it was looking like dementia specific, but then they had an emergency admission of a [redacted] year old living with a [redacted] year old with dementia. So obviously things have changed then with the dynamics of the house. So we were getting a lot of solicited information. So I'd completed a risk inspection and based it on [regulation] 24, your statement of purpose, as well. Because the house was tailored so specifically to dementia. And I understand that there was a huge emergency with the family but, I suppose, the provider were willing to let it go on a little bit to see if it would work out, but I mean, I don't think a [redacted] year old want to live with	Providers operating outside of their statement of purpose	Rigidity required by statement of purpose	Walking the tightrope between assistance and sanctions	The importance of skill and strategy for the role of inspector

me, let alone live with someone in their [redacted].				
I think sometimes we are blamed a lot, as regulators, about what has happened and the regulatory burden of paperwork. But I think a lot of that has been self-inflicted by providers. And I think if we could develop standards about what that should look like that would be really helpful.	Need for clarity on what level of documentation is appropriate for centres	Soft engagement with service providers	General views about service providers	Overall views on the regulatory system
more generalised language is actually often easier to work within. But then that leads to the challenges between inspectors. So it's a different…it's a double edged sword really.	Broadly-worded regulations are a double-edged sword	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
the specific reg, there's no regulations to, kind of, monitor in terms of the safety of administering medication and their understanding about, you know,	Regulation on medication management is weak	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

storing medication and, you know, all that kind of thing…and making sure. So that's a really poor one. It's a really, really poor one.				
even if you look at the medication regulation. It speaks a lot about the pharmacist and the pharmacist's role in the medication, which is an aspect of it, but it's very…there's very little, I suppose, around the systems in place around medication administration and those pieces.	Regulation on medication management is weak	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
With the appropriate health and social care qualification, obviously we don't define that, but I suppose…I don't know how I say this…you see a range of qualifications, I suppose from level 5 up to level 9 or whatever. But I suppose it's very difficult for us to find somebody unfit based on qualification unless, you know, you see something in the centre. But I suppose it's...I don't know what I'm saying, really…I guess	The vagueness of the PIC qualification regulation makes it difficult to make a finding of non-compliance	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

it's just, kind of ,one of those wishy washy ones really. Regulations that, do you know, we're not going to say it's not compliant based on the appropriate health and social care qualification. If somebody has something, I know it's up to the provider what they recruit, what qualifications they look for when they're doing recruitment. But I suppose it's just a weak enough regulation				
that's been advocated for by HIQA since…2016 was the 1st paper and then another one then in 2019. The FedVol are in the middle of putting their paper together. The NDA have done a paper. I think inclusion Ireland are currently writing their manifesto and part of that is around regulatory reform so…And DFI is the same. So I think a lot of the agencies that work	Many stakeholders advocate for review of regulatory framework	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

within this sphere are all of that mind set too.				
in terms of the regulations, I do think that there is room for review. Particularly around the human rights based approach to care and support and…some of the regulations just require an update in terms of best practise now compared to when they were developed.	Regulations need to be brought in line with a human rights-based approach to care	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
there is room for us to possibly assist with further improvements…how would you say, about further enhancements of the current regulations. To move with the times.	Regulations require review to keep pace with how care is evolving	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
Regulation 8, Regulation 9. They all need a review.	Regulations 8 and 9 require review	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
Medicines [regulation] is very weak.	Regulation on medication management is weak	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

And, medicines, 29. Yeah, very weak medicines.	Regulation on medication management is weak	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
maybe there are other regulations that need to be brought in, new regulations.	There are gaps in the regulations which means new ones should be introduced	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
there was recommendations before by the Chief Inspector to change the regulations. I don't know how far they are on that one but…every single regulation should be looked at	Every regulation should be reviewed	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
we're 10 plus years now regulating against the current regulations and they haven't been updated. So there's a definite requirement there for, I suppose, regulatory reform to ensure that it's more focused on a human rights based approach. And I think while we have adapted our own methodology internally and our processes to try and capture that human rights piece, the regulations	Regulations need to be brought in line with a human rights-based approach to care	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

need to shift and be updated and be I suppose in line with the Human Rights Convention. And also with the assisted decision making capacity act as well.				
absolutely there are updates and changes required. And I suppose, you know, an issue with the regulations, as [Insp15] already alluded to is the fact that it's, you know, one-size-fits-all, you know?	Regulations are currently akin to one-size-fits-all	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
that human rights-based piece is really, really missing. And that would focus more on the individual lives of residents and what the provider, the legal entity is doing to support those fundamental rights.	Regulations need to be brought in line with a human rights-based approach to care	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
it's back to that social model. I mean, you know, people with disabilities are not sick, you know? The vast majority of them, like the rest of the population, are not sick. And, you know, there's such a focus on, you know, on health and the medical model…absolutely,	The regulations are based on the nursing home regulations and are, therefore, focused on the health/medical model	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

you know, again, it's the hangover from the older persons regulations.				
there's less myth about the idea of HIQA coming out now. That we're a more familiar presence in centres and as a result, I guess that impact piece means, as [Insp1] said, that staff are more willing to approach you. People are more willing to have those conversations with you and there's better familiarity with regulation in terms of what you might ask or how you might approach individuals within a service.	Normalising the inspection process	Provider familiarity with regulation	General views about service providers	Overall views on the regulatory system
we are ultimately all here around quality of life of people with disabilities. That's why we come to work every day. And so it's that recognition of fairness and proportionality. If a provider thinks, OK, you know, ‘they're going to be fair and proportionate’, they're far	Providers respond better to findings that are fair and proportionate	Providers appreciate fairness	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

more likely to listen. If you're hitting them on the likes of insurance or your directory of residents and you're missing the big ticket items, you know? You need to be very, not smart, but you need to be practical, I suppose, and realistic in how you apply the regulations to actually impact and make the change that you're hoping to make				
I feel, one day, you're there for 8 hours. I just feel that…they're just on high alert the whole time. I don't know do we ever really get a true picture?	Observer effect in inspections	Inspection findings are point in time	General views about regulation	Overall views on the regulatory system
Having your evidence and be it, observed, documented, you know? And that's what always in the back of your mind, if you're going following a particular regulation, what do I need to either be fully compliant or not compliant? What evidence have you got to substantiate any finding that you	Challenge of ensuring you have enough evidence to make a judgment	Gathering sufficient evidence	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

are considering while you're out on inspection?				
sometimes when I'm making a judgement, say on a compliance plan or something, you're thinking, ‘have I sufficient, verifiable and reliable evidence to make a good judgement on this’, you know? And I suppose that's the bar. And then you're thinking, well, to get that, what would I need? And then you think, ‘gosh, I'm never going to get that’.	Challenge of ensuring you have enough evidence to make a judgment	Gathering sufficient evidence	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
Out of hours inspections. Weekend inspection, night inspections. We have, you know, we have a lot of staff on night shift who might not see you, an inspector, for five years.	Out-of-hours inspections should be more frequent	Inspection types	General views about regulation	Overall views on the regulatory system
our inspections primarily are obviously Monday to Friday, 9:00 to 5:00 for the most part. And if we do outside of those hours, it usually would be very rare, but it'd be usually to follow up on unsolicited	Out-of-hours inspections should be more frequent	Inspection types	General views about regulation	Overall views on the regulatory system

information about a concern maybe in the evenings, high risk. So I suppose inspection findings are quite narrow in that way as well, because I'd imagine it'd be very different if we went on a Saturday afternoon and spoke to residents and saw what their lives were like and looked at staffing levels. Maybe…they may not be that different, but I suppose we can't be assured really from our window of inspections.				
I do think the regulations need to be updated. More, kind of, I suppose, modernised isn't so much the well, maybe modernised, but I think, you know…There's a lot of regulations there and we're probably, you know, if you've looked at this, probably some that could be lumped in together and, I suppose, just more streamlined I guess.	Regulations require modernisation	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

Some of the regulations can be quite challenging, I suppose, in terms of improving practise, positive behavioural support is one that, kind of, jumps out. It doesn't quite cover restrictive practises in any, kind of, real…I suppose it would be quite hard to find the right way of phrasing stuff under that regulation, but it's kind of…Personal possessions would be another one	Certain specific regulations require updating	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
I would say I think the rights one is a bit weak	Regulation for residents' rights is weak	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
I would say that there's some, you know, passive resistance by staff to the inspection process, particularly in congregated settings…would be my experience really. Even though I haven't been to many congregated settings…But I think that, sort of, resistance, that passive aggression towards inspectors, you know? Not	Passive resistance in certain settings	Passive resistance to inspections	General views about service providers	Overall views on the regulatory system

wanting to change services because the services suit them rather than the changes that might enhance the lives of residents.				
I think the regulations probably do need to be amended because they probably don't fit every service type that we visit. And I think that could improve things for people with disabilities because sometimes the regulations are not, I suppose, comparable to what we would have in our own homes which is, I suppose, what designated centres are, do you know? For example, with fire compliance and issues like that. Like I think they need to be amended.	The regulations do not neatly map on to all the different service types	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
That's a great feeling when you get a report back in, and a compliance plan that maybe someone's gone into more individualised style living or, you know, house got changed to meet their needs, things like that.	Personal satisfaction when improvements impact people's lives	Job satisfaction of inspectors	General views about regulation	Overall views on the regulatory system

when you actually speak to residents, because I was involved with a lot of, two or three centres, big centres to close and de-congregate and centres close. When you meet them in the community later, they come up and they say, ‘oh, thank you so much’. They've said ‘Thank you. You drove this to get…you know, us as inspectors…’to get us to a better place’. And they recognised HIQA for doing that, do you know what I mean? That HIQA, kind of, used the regulations to, kind of, give them a better quality of life.	Personal satisfaction when improvements impact people's lives	Job satisfaction of inspectors	General views about regulation	Overall views on the regulatory system
And the person in charge, without having that support there, and it might not necessarily be line managers, but the support mechanisms within the organisation, I think it's harder for it to be consistently sustained over time.	PIC needs support from their organisation to sustain compliance	Provider support for PICs	General views about service providers	Overall views on the regulatory system
I don't get it too often where you have a person in charge who's over a load	PICs typically only manage 1-2 centres	Quality of provider governance structures	General views about service providers	Overall views on the regulatory system

of centres; don't get that too much anymore. Maybe two. But they're actually in the centre now.				
[Insp19] 52:53 Yeah, and sometimes there are really strong persons in charge in organisations who are, I suppose, their governance and management structures are more driven by processes… [Insp20] 53:11 Yeah, yeah. [Insp19] 53:12 …as opposed to a, kind of, person centred care. And that is a struggle I have found for some persons in charge whose focus is, kind of, person centred care and human rights, when they are constrained to follow the processes dictated by the governance and management structures.	PICs with a person-centred focus can sometimes be constrained by provider processes	Quality of provider processes	General views about service providers	Overall views on the regulatory system

then it goes to leaders questions. It goes to Parliament. It goes to, like, it's intense.	Political influence on admission processes	Political interference in services	General views about service providers	Overall views on the regulatory system
families then saying, ‘oh, I've had to go to our local member of government. We've had to go here. We've had to go there’.	Political influence on admission processes	Political interference in services	General views about service providers	Overall views on the regulatory system
external services like health, access to healthcare and access to financial institutions for the establishment of accounts. So it's engaging with agencies outside of their own sphere, if you like, that that's often a barrier too.	Poor access to community services is a barrier to compliance	Provider reliance on third parties can be barrier to compliance	General views about service providers	Overall views on the regulatory system
access to MDT can be one. Depends on what region you're in, areas you're in, and all the rest. Again, some private providers have their own teams, maybe if they're relying on public services, it might not be as timely. It's not too bad now. I haven't been to too bad, but it can be a little bit of an issue.	Poor access to community services is a barrier to compliance	Provider reliance on third parties can be barrier to compliance	General views about service providers	Overall views on the regulatory system

housing is probably at the moment, one of the things that's popping up, access to housing. Yeah, that's popping up quite a bit, especially in services that are trying to decongregate or maybe services who have ongoing, kind of, longstanding incompatibility, but that…it's becoming…it's coming more to the fore, umm, in recent years, you know, that they're struggling to find…maybe…they've, you know, maybe their plan, their long term plan is to separate out residents or to make…to provide residents with smaller groups or whatever, but they can't actually get the housing for it, even if they have the funding.	Poor availability of housing	Impact of external environment on service delivery	General views about service providers	Overall views on the regulatory system
when I go to places because there's such a need. There's such a demand but there isn't the properties. There isn't the houses.	Poor availability of housing	Impact of external environment on service delivery	General views about service providers	Overall views on the regulatory system

the biggest problem for that provider was governance and management, culture, staff culture, residents rights. And while there is some green shoots, it is taking time and we're now going centre by centre to that provider, trying to, I suppose, be more specific to each individual centre, but the provider had a huge body of work to do. From their overall structure, their overall oversight, their auditing, their annual review, everything. There was…we were consistently finding the same issues of non compliance with the same provider in centres that were geographically apart.	Poor governance at provider level can be identified in all of their centres	Importance of good governance	General views about service providers	Overall views on the regulatory system
I think some regulations are particularly weak and were very relevant when regulation started. But times have moved so much, they're not necessarily all reflective of policy. So the assisted decision making, for example. Rights could be a lot	Regulations require modernisation	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

stronger. There are certain regulations that are weaker than others, shall we say. And as a result, you know, it's hard to action them then sometimes because you know the assessment judgement framework… you're not always backed up. It's just the way the regulations are. But I do think there are…they need modernising				
as someone who's come from working on the ground in services, like, regulation has had a huge impact definitely on how services are run and on the quality of services out there for residents. And generally that's been a really, really positive impact.	Regulation has produced improvement in services people receive	Positive impact of regulation on quality	Regulation has improved the quality of services	Positive effects of regulation
I definitely think regulation has led to improvement for the services that people are receiving.	Regulation has produced improvement in services people receive	Positive impact of regulation on quality	Regulation has improved the quality of services	Positive effects of regulation
there's such an improvement in the standard of care for residents, you know, because of the regulations.	Standard of care has improved due to regulation	Positive impact of regulation on quality	Regulation has improved the quality of services	Positive effects of regulation

10 years into regulation, I think a lot of providers have moved along and they're, kind of, beyond meeting the regulations and they're moving towards quality improvement.	Providers have progressed in the 10 years since regulation was introduced	Positive impact of regulation on quality	Regulation has improved the quality of services	Positive effects of regulation
you can see when you go back to a centre after being there maybe once or twice and you see, like, that the individual apartment living for, for people who would have previously shared that are doing very well. And have good quality of life. You can see that when you've been to a centre a couple of times, which is great. So there is positives there.	Inspectors can observe tangible changes because of regulation	Positive impact of regulation on quality	Regulation has improved the quality of services	Positive effects of regulation
the provider brought around a lot of change. They put new rooves on houses. They completely refurbished the houses and they have now reduced the numbers. So there is now only three people living per house. That is 15 people living in the centre and their	The quality of premises has improved	Positive impact of regulation on quality	Regulation has improved the quality of services	Positive effects of regulation

quality of life has improved significantly.				
from our perspective, we see some green shoots where, like that, residents have now got their forever home where they had previously been in an institutional type settings or a congregated settings.	Inspectors can observe tangible changes because of regulation	Positive impact of regulation on quality	Regulation has improved the quality of services	Positive effects of regulation
without a doubt, you know, when I say we've all been around since commencement of it I also mean by that that we can all point to lots and lots and lots of examples of where we have taken action based on regulatory non-compliance that have brought about significant improvement in the lives of people who live in residential services, particularly from within the congregated sector, you know? A lot of issues in relation to compatibility issues or compatibility of residents living together, large groups of people living together. And I also think it is	Regulation has contributed to de-congregation	Positive impact of regulation on quality	Regulation has improved the quality of services	Positive effects of regulation

worth mentioning the doubling, pretty much, in the numbers of designated centres since the commencement of regulation. And an awful lot of them, like there's a lot of new centres, you know, but there's also an awful lot of the new centres have come from previous larger living environments, which were not suitable to meet the needs of the residents living in those environments. So I think that's, umm, a real reflection of the positive impact regulation.				
if we look at where we were when we started in 2013…like we would have had quite a few congregated settings. And, you know, the impact that regulation has had in terms of, you know, the quality of life that residents now have, it's very different to what we saw when we went into services in 2013. I mean, the quality of life for, you know, as both [Insp14] and all the	Notable improvement over 10 years of regulation	Positive impact of regulation on quality	Regulation has improved the quality of services	Positive effects of regulation

panel have said that it has been very effective in terms of…providers now know what the expectation is.				
look at the amount of change in the last 10 years. By the nature of the fact that you have a [Insp16] or [Insp14] walking through the door saying ‘show me evidence that all of your staff are Garda vetted, show me evidence that all of your staff are trained to do the job that they're doing, show me evidence that you have a roster in place that shows that there's two to one here for this person, requiring two to one support’. So all very basic, but basic needs that weren't being met always before 2013 I can tell you.	Notable improvement over 10 years of regulation	Positive impact of regulation on quality	Regulation has improved the quality of services	Positive effects of regulation
I think our role, I don't know what anybody else thinks, but there's definitely improvement in governance of providers. There's definitely	Regulation has driven higher governance standards	Positive impact of regulation on quality	Regulation has improved the quality of services	Positive effects of regulation

improvements in fire safety and premises. They're very tangible improvements. And I think a lot of that has come from the regulations and the push to focus on them.				
there has been a huge improvement in the standard of care and people…overall, the implementation of the regulations has been a positive thing.	Regulation has produced improvement in services people receive	Positive impact of regulation on quality	Regulation has improved the quality of services	Positive effects of regulation
when you look at the difference that regulation has made, obviously you guys have mostly…you've been in HIQA longer than me. But even from my experience of working in services pre-registration to recent years to current to now — and obviously some centres are still encountering huge difficulties and we're still seeing patterns of non-compliance — but I suppose compared to what was first encountered and providers' understanding of what safe services	Notable improvement over 10 years of regulation	Positive impact of regulation on quality	Regulation has improved the quality of services	Positive effects of regulation

and quality services look like, it's just been immense. So I think the impact is huge.				
I certainly know the Department of Agriculture and that…they penalise financially very, very swiftly. Like, for large sums of money to people who do not comply, you know? They throw them out for six months if you don't meet your Bord Bia requirement; you're expelled for six months. And in that period of time, you get a lesser price for your sheep or your cattle, you know? When you go to the mart to advertise your cattle it's saying 'they are not Bord Bia approved', you know? So I think, yes, we have some systems in place, but I'm sure that if we looked at other regulators and the way they're treated, we'd be seen as mice among the rats.	Potential to learn from other regulators	Reforming how regulation is done	General views about regulation	Overall views on the regulatory system

the really bad ones, section 59, the bar is there. If you can meet it, then you can go and get your court hearing. And very quickly and…you can very quickly close them down.	Power is available to close poorly-performing centres	Regulator has sufficient powers	General views about regulation	Overall views on the regulatory system
the other thing that really needs to change, and I think that we are we are starting to do this, is collaboration with providers and recognising that every single one of us are there to improve the lives of people with disabilities. There's very few people, even providers, who are not there to do that, and we can all learn from each other. And I think that's really important for people with disabilities, that that's what we're doing. We're collaborating and we are improving all of the time and that while we are there to regulate, we should be able to highlight to providers where good things are happening elsewhere.	Preference for a more collaborative approach to improving quality	Soft engagement with service providers	General views about service providers	Overall views on the regulatory system

Because that, ultimately, improves the lives of people with disabilities.				
sometimes it can be, you know, almost a ‘no, we don't give recommendations or advice’. But I do think there's a gap there. I think it probably may have improved in recent years. There's more dialogue, but it's still a bit to go.	Preference for a more collaborative approach to improving quality	Soft engagement with service providers	General views about service providers	Overall views on the regulatory system
within the disability field we have providers with, you know, 60, 70, 80, 90 designated centres. And who, you know, like who, therefore are, are subject to, a huge number of inspections on an annual, but also on a cycle, a registration cycle basis. And we're often looking at the same things in the same centres, if you know what I mean?	Preference to focus regulatory action at the provider level	Preference of directing regulatory action at level of provider	Correctly identifying accountability for compliance	The importance of skill and strategy for the role of inspector
But I think in terms of the system stuff and, you know, the oversight, the management, the surveillance, all of	Preference to focus regulatory action at the provider level	Preference of directing regulatory	Correctly identifying accountability for compliance	The importance of skill and strategy for the role of inspector

those kind of things, you know? I think there's certainly something to be said for doing, you know, perhaps regulating at the provider level as opposed to the centre level		action at level of provider		
it would be prudent on our behalf to regulate, you know, to register a provider, as [Insp14] says, rather than a service. And then it would give us more opportunity to be more proactive in terms of human rights and all that.	Preference to focus regulatory action at the provider level	Preference of directing regulatory action at level of provider	Correctly identifying accountability for compliance	The importance of skill and strategy for the role of inspector

sometimes it's about how we access that information. So just as an example. One of the things we've been doing in the pillar over the last 12, 18 months, Paul, is we've been trialling some group inspections with providers who have a number of centres and renewals are coming up and all the rest of it, I don't need to explain it to you. But I suppose what struck me on one of those that we did back in May, I think it was with a good provider was, I went in and I did a piece with the senior management, the CEO etc looking at governance and their oversight, their surveillance systems, etc. And while I was doing that, there was four or five inspectors out in four or five different designated centres, you know, commencing their inspection. And genuinely, 10 minutes into my	Preference to focus regulatory action at the provider level	Preference of directing regulatory action at level of provider	Correctly identifying accountability for compliance	The importance of skill and strategy for the role of inspector

conversation, I was pretty much sure of what the inspectors were going to find in those centres. And that's because the provider had really good auditing and oversight systems in place. They were able to tell me what the issues were in those centres and, you know, it really kind of struck me that, again, it's around using our resources as effectively as possible. And using the regulations as effectively as possible because it really struck me in terms of saying, you know, I could have almost said, well, you know, we really don't need to spend 2 days out here, do you know what I mean? I was assured very, very quickly in the process that the provider was on top of everything that was going on here. And that's the way, like, the inspections then validated that. And that's the provider piece around, sort of, seeing are they doing				

and are they aware of…there'll always be things to improve.				
as we grow and the number of centres grows and grows again and…it's back to the systems piece, you know? It's around…the good providers who we know have good processes. Who we know have a good ten year regulatory history. Who we know we can trust, etc, you know? That we go in and…to use that example I already gave, without repeating it, you know, to do	Preference to focus regulatory action at the provider level	Preference of directing regulatory action at level of provider	Correctly identifying accountability for compliance	The importance of skill and strategy for the role of inspector

the governance piece and then perhaps do a bit more…not having to go to every centre and just to go to a few centres just to validate what you're being told and that kind of thing. But I just think there are other ways we can do it, yeah.				
I think there's such a requirement for regulatory reform. The regulations for disability services were developed off the back of older persons, and there's a serious bang off that, you know? That's a common thread throughout the regulations, you know? They're not focused on the individual life and rights of residents of disability. They're very much, I feel, a group-orientated regulation. They're very much, you know, looking at the centre as opposed to, you know…perhaps the provider would be a better view in my opinion.	Preference to focus regulatory action at the provider level	Preference of directing regulatory action at level of provider	Correctly identifying accountability for compliance	The importance of skill and strategy for the role of inspector

the thematics that are coming up, including the safeguarding as well these group inspections that are happening, which is more on looking at trends in the overall provider rather than individual centres and trying to provide high level feedback in areas for improvement. Rather than, I suppose, it really is spinning out areas that I suppose we as a regulator we think a provider needs attention rather than just one centre. So I think initiatives like that are quite good to add to the quality of the inspections.	Preference to focus regulatory action at the provider level	Preference of directing regulatory action at level of provider	Correctly identifying accountability for compliance	The importance of skill and strategy for the role of inspector
I think the current system, again, I think it allows us to regulate for the best interests of residents and try and capture their voice as best we can. But I think there's better opportunities, you know, going forward in terms of that regulatory reform piece where we can capture the voice of residents even more and really have them further at	Preference to shift emphasis from systems-based regulation to more person-centred	Focus of regulator should shift from systems-based to person-centred regulation	General views about regulation	Overall views on the regulatory system

the centre of the inspection process. And obviously right now it's kind of a systems based process, and we're looking at the provider from a systems based perspective. But a shift in that I suppose might focus more on the actual voice of the resident.				
absolutely there's, I suppose, there's a lot to be said for looking at, I suppose, it's easier to be, I guess, more resident focused and talk about rights and talk about all of those things when it's a small designated centre, for example.	Preference to shift emphasis from systems-based regulation to more person-centred	Focus of regulator should shift from systems-based to person-centred regulation	General views about regulation	Overall views on the regulatory system
sometimes it's a challenge to have the triangulation of all of the information that you want to utilise in the inspection report, really. And particularly, I suppose, sometimes I think it's in the centre's that are just at the pass grade. I know this sounds a bit strange but, you know, if it's a very bad service, you	Challenge of ensuring you have enough evidence to make a judgment	Gathering sufficient evidence	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

know, to think that you need obviously need a lot of evidence, but you can make that judgement. If it's a very good service, you can make that judgement. But sometimes it's these ones that are in the middle line that sometimes you're thinking 'not really sure', you know? I need a bit further information.				
You're trying to straighten it out by talking to staff. Talk to the person in charge. What's the most relevant? What's the biggest risk? What's the biggest safeguarding?	Talking to staff to substantiate evidence	Gathering sufficient evidence	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
accessing information in that way when it's not readily put out in front of you, it is a challenge.	Challenge of accessing information on inspection	Gathering sufficient evidence	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
I could read something about a resident and then when you meet them and they come in, sometimes they're gone to day centres, you have to wait till they come in, you know, to meet them…you have a completely	Importance of meeting residents and not only reading about them	Getting information directly from residents is important	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

different image about that individual on paper, to actually what they're like in person, you know? So it's really important to do the inspections and to have time.				
I find with a lot of housing associations I'm having, you know, there's a lot of difficulty in maybe getting the upgrades, premises works, or fire works, because that is under a housing association. I've had one provider says, you know, they have the mortgage regulations which they have to adhere to because they couldn't reduce numbers in one house as well.	Premises provided by housing associations have more difficulty having words carried out	Provider reliance on third parties can be barrier to compliance	General views about service providers	Overall views on the regulatory system
The best case scenario, so like staff are prepped for you, residents are prepped for you.	Preparation afforded by announced inspections	Announced inspections	General views about regulation	Overall views on the regulatory system
They've been cleaning for days.	Preparation afforded by announced inspections	Announced inspections	General views about regulation	Overall views on the regulatory system
Everything is prepped for you, like, but which is great in one way. You	Preparation afforded by announced inspections	Announced inspections	General views about regulation	Overall views on the regulatory system

can get through, I suppose, maybe a much larger volume of information because it's already in there for you and they're, kind of, expecting you along. But it doesn't give you a true reflection of what things are like every day in that centre, I think.				
I mean announced inspections. There will always be that window dressing. They'll do the painting and they'll do the cleaning and they'll do the whatever. It's the unannounced.	Preparation afforded by announced inspections	Announced inspections	General views about regulation	Overall views on the regulatory system
if you highlight something, an area maybe that indicates non compliance or that needs to be improved and they can come back to you and say and, like, you know, demonstrate, ‘well, actually, no it's all here’, you know? That they're kind of prepared for that? But also if they can go, ‘well actually, that's a gap’. And you can see, you know, they're often the people who would say by the end of the inspection	Preparation and responsiveness of management	Importance of good governance	General views about service providers	Overall views on the regulatory system

‘I've made the phone call there and that's, you know, happening there’ or whatever, you know?				
I think that there is even that ripple effect and...like, providers are more willing now to engage in, sort of, the standards piece of it, the stretch piece. The, you know, what does a good service look like? And they're willing and they're very open to exploring themselves without…and we may have been the catalyst, but I think that they're more willing now to explore, you know, expanding a better quality of life for people. And also, sort of, the introduction of the ADMA last year, you know, in terms of…it's now their will and preference as opposed to in their best interests, which is a very interesting turn around.	Presence of regulation encourages providers to improve quality beyond the regulations	Process of culture change in providers	The role of regulations in culture change	Positive effects of regulation

your conscience is thinking ‘I can't just come out and do three or four regulations because I'm not going to be able to get out again for another two years’. So, you know, I better really get my act together and get around this centre quickly and get as much done as possible.	Pressure to conduct comprehensive inspections due to infrequency of inspections	Inspection staff resources	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation
I find that increased time, there's more issues I find. And yeah, you definitely have a lot more to review and a lot more to, kind of, I suppose, you're more eager to spend more time with residents.	Pressure to conduct comprehensive inspections due to infrequency of inspections	Inspection staff resources	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation
I think if we looked at some of the process, the admin process that we're doing and pull them back, we definitely would have the time to focus on what the actual…our job primarily is an inspector. And that is, it's not really to spend time, I don't think anyway, checking to see whether they have their	Primary focus should be engaging with residents and not checking paperwork	Administrative tasks detract from work of inspecting	Internal bureaucratic processes	Impediments to effective inspection and regulation

insurance or whether they have their references and this that and the other.				
there was one particular provider we had significant issues, all of us were finding the same thing over and over and over. We were getting nowhere. So we, sort of, said look, obviously the evidence had to be there, but we consistently were giving the message: 'this is an issue. This is an issue'. And by three of us consistently giving that message the change has been enormous, do you know? And we can now see, 'oh, [Insp20] talks to this person. [Insp18] talks to that person'. And they all actually share….and that has actually given us…a better hand is the wrong way of putting it…but it's just put us in a stronger position to actually impact real change.	Collaboration among inspectors to affect change at provider level	Regulatory techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

That was just us, kind of, saying 'listen'. And the same with managing another provider. We're doing the same thing that we're…all the case holders are just saying, 'listen, I've done an inspection, X is an issue. Have you found the same?' Sometimes it's not, like… sometimes it's centre specific. But for the bigger things it has actually made a massive difference at one of our providers.	Collaboration among inspectors to affect change at provider level	Regulatory techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
for private providers my experience would be that some of them would put a lot of money into systems, so to be able to show compliance. They'll have all these amazing systems, but then they're not putting the money into the skills and a competent workforce.	Private providers invest in systems to evidence compliance	Private providers invest in systems for compliance at the expense of skilled workforce	General views about service providers	Overall views on the regulatory system

you can see that in…that is moreso, from my perspective, in private providers, I find that they are very driven by… [Insp20] 53:33 Yeah, absolutely. Yeah, yeah. [Insp19] 53:50 …policies, procedures, governance and management structures that you might see in other public bodies as opposed to human services, if you know what I mean? And it just doesn't….yeah, a more corporate approach. Exactly. And it's not…it doesn't necessarily align with a person centred approach and persons in charge struggle with that as well	Private providers prioritise process-driven management that does not always align with person-centred care	Private providers tend to expect a more procedural approach to management	General views about service providers	Overall views on the regulatory system

Centre-specific training as well. So if you go into a centre and the assessed needs of individuals are, we'll say communication…that you have the staff training specific to the assessed needs of the residents there. And, I know…I was somewhere recently I can't think of, yeah…It was a newly diagnosed individual, a person who had required a FEDS programme. And in the absence of face to face training the person in charge had gone and got online training for the staff team in the interim while they were waiting for face to face training. And it was only a matter of weeks, but to ensure that everybody was…so that kind of characteristic of a person in charge, seeing what's needed, the changing, assessed needs.	Proactive management practices indicates good quality	Importance of good governance	General views about service providers	Overall views on the regulatory system
we're now using…how do you say using our time, more…spending time with the residents. Observing the	Importance of meeting residents and not only reading about them	Getting information directly from residents is important	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

residents, establishing what exactly their meaningful day is, rather than being written down on paper.				
I think what probably enhances the quality of life of residents is the linkage of the regulations, you know? If you link something. If people don't have garda vetting that's a huge error or omission under, I suppose, safeguarding. So…and that's the tricky bit, to be honest. And it takes a while to get that right really. Because we don't, you know, we are, you know, whatever we say, we don't kick them twice. So we don't have a second bite of the cherry, but you can still link it, but not find them compliant under the two regulations. But if you link two together, sometimes I think you can make a stronger case.	Linking non-compliances can result in greater impact	Regulatory techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

I've not noticed a big difference in terms of the calibre of people. Obviously, since COVID there's been a huge impact on social care and, you know, people not wanting to be in social care because of what it costs. You know, you get more wages being in the LIDL or whatever. And it's a hard job to do. So I'm seeing more and more that providers are struggling with the resources that they have to provide a, you know, a good service. Like, if you need a second car or you need a second person to take people out to have a social evening or something like that. They are struggling.	Providers challenged to hire staff in current labour market	Staff recruitment challenges are a barrier to compliance	General views about service providers	Overall views on the regulatory system
I find sometimes you might use one regulation to action an area under another one as opposed to the one where you would think would come up with if that makes sense?	Overlap in regulations allows flexibility	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

the other, kind of, broad regulation that a lot gets put under as [Insp1], kind of, mentioned when you're, kind of, and [Insp3] as well…when something's not right, but you can't quite fit it, is Reg 23 which is governance and management. And that's often where poor medication management practice will fall under.	Overlap in regulations allows flexibility	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
I think people are terrified if they don't notify us of things and therefore they over report. So you're reviewing an awful lot of information that is probably not in line with, kind of, national policy, do you know? For example, NF06s, there probably needs to be bigger clarity in terms of notifications for providers, because sometimes we are reviewing information that is of no…it doesn't mean anything really, I suppose, to the lives of people with disabilities.	Lack of clarity around notifiable incidents leads to over-reporting	Soft engagement with service providers	General views about service providers	Overall views on the regulatory system

And look, it's people services. You're not always going to get it right the first time anyway. But just that you actually operate within your statement of purpose and not outside of it, within your own admissions policies as well.	Providers operating outside of their statement of purpose	Rigidity required by statement of purpose	Walking the tightrope between assistance and sanctions	The importance of skill and strategy for the role of inspector
I do think we have the legislative tools to use. I think that sometimes the appetite to use them is a challenge because we don't want to be seen to be disproportionate in, in dealing with people that you have to build that working relationship with.	Using regulatory tools with caution due to concerns over proportionality	Striking a balance between building relationships and imposing sanctions	Walking the tightrope between assistance and sanctions	The importance of skill and strategy for the role of inspector
Regulation 29, which is medicines management, which is so specific in some of its sub regulations that you can't reflect what's happening under the specifics, so a little bit of more generalised language is actually often easier to work within.	Overly-specific regulations	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
you have to make a call and say, well, there's a risk somewhere else that…so…that's made more complex	Prioritising inspection activity to services of highest risk	Regulatory techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

by increase of services on your dashboard and decrease in actual inspection activity. It's made more complex.				
I had, as [Insp2] said, I think maybe a year and a half ago, 38 centres, now over 50 and I'm only doing 30 inspections now this year. So you, kind of, have to, I suppose weight up where you need to be on that dashboard. The case is not where you'd like to be, it's where you need to be and hope you get that right.	Prioritising inspection activity to services of highest risk	Regulatory techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
They find you on LinkedIn and they figure out your background and they focus on that. I've had that recently.	Providers source information on inspectors to focus on their area of expertise	Compliance techniques	General views about service providers	Overall views on the regulatory system
even in the last few years there's a shift again as all the others have said, the providers are, I suppose, taking more guidance from the regulations and they’re structuring	Providers structuring services around regulations and inspection findings	Compliance techniques	General views about service providers	Overall views on the regulatory system

their service provision based on findings and inspections.				
And sometimes, do you know, when you're actually saying innocuous things on inspection they take that as a fact like and go, do you know, '[Isnp19] likes it this way and [Insp20] likes it that way. And [Insp21] likes it that way'. So they tend to change their processes, like, to align with whatever case holder they have, which is not what we want to do.	Providers tailor their processes to the liking of the inspector	Compliance techniques	General views about service providers	Overall views on the regulatory system
I always feel much more assured if I've had significant time with residents. I always feel like, if the residents and families are really happy, they're leading good lives.	Inspectors more assured of quality if have significant time with residents	Getting information directly from residents is important	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
it's the provider who, yes, has good management systems, but who has a really strong staff support system in place that actually does the best in terms of compliance; more than once a year supervisions, you know? Lots of	Providers with good staff support systems have higher compliance	Importance of good governance	General views about service providers	Overall views on the regulatory system

on the job mentoring. Really, genuinely supportive to their staff, but strong supervision and training and focus and they tend to have the higher compliance levels.				
if they're a bit disorganised with, you know, they can take ages to get to some information. And I mean, I think nearly everybody does document lists and, you know, sort of try to assist them to get the key documents you want to see, but it can still take them a while.	Providers with poorly organised documents can slow inspections down	Quality of provider processes	General views about service providers	Overall views on the regulatory system
I think there are definitely different approaches. I suppose disability is, kind of, interesting in that compared to maybe some of the other types in that it's mainly publicly funded, you know? There are some private providers but they are in the minority. But I would see a big difference in the way the providers, private providers	Public - private funding model	Contrast between private and public providers	General views about service providers	Overall views on the regulatory system

are with regards to regulation than those that are publicly funded.				
Whereas everyone else, it's all, you know, it always tends to go back to, ‘oh, we're putting forward a business case to the HSE’, you know? There's, kind of, always that level of…where they lack control, you know? Because it, you know, resources and things are dictated by the funding they receive.	Public - private funding model	Contrast between private and public providers	General views about service providers	Overall views on the regulatory system

There's definitely a difference between a private provider and a public sector one, and that's because the public sector one, you know, obviously there's a certain pool of funding nationally, you know? And it's divvied out and it's all around the business cases, you know? The annual funding and then the business cases for additional support. And that's usually the biggest problem in terms of, you know, providing the services. Because there's a lot of changing need with residents. So while you might have got a budget and…that's one thing I used to find, you know, when a service was set up initially they would have set it up, you know, with the residents being totally mobile, you know? We're able to, you know, just the one staff would support 5 residents, and that was ideal. And then over the 10 years even, you know, whatever change in needs of	Public - private funding model	Contrast between private and public providers	General views about service providers	Overall views on the regulatory system

residents, medical conditions, blah, blah, blah, there's a need then for additional staff. Or a big one was always that it a sleep in staff at night and now it needs a waking night staff. That's a huge financial drain on any service. So, the original plan or budget that was approved, they have to go back then to the HSE and…that could take a long time. So sometimes when the inspectors identify that it does build a case for them in terms of getting additional resources. The other side, then if you have the private providers, you know, they are there to make profit, like, that's what they do. So they will assess residents and they will put a case towards whoever they're doing the service for. So they come in and they'll provide a service and they'll say, ‘right, I provide so many hours of				

support for, you know, so many residents', blah, blah, blah. And they have built that package based on profit. So if the residents needs changed a little at a later date that doesn't go down well necessarily with private providers because they still have to provide that for the term that they've agreed. But the needs have changed. So they are very reluctant.				
So you'll go in and you'll find that they wouldn't have as many social care workers or nurses as other registered providers would. There would be a lot more times where its assistant support workers and HCAs, many of them on duty and very minimal, kind of, supervision. So that would be my experience of some private providers	Public - private funding model	Contrast between private and public providers	General views about service providers	Overall views on the regulatory system

and also they wouldn't be as transparent or upfront as some of the other providers as well.				
it wouldn't be unusual to hear, like, ‘oh, will that be in the report?’. And they kind of want it in there because they think they'll get funding then to do it or, you know, things like that.	Pursuing non-compliances as leverage for funding	Escalation as currency	Inspectors as agents of change	Positive effects of regulation
often, you know, they will ask you, are you putting that in the report because they will use that then to support things like business cases and applications for funding and things like that.	Pursuing non-compliances as leverage for funding	Escalation as currency	Inspectors as agents of change	Positive effects of regulation
[Insp22] 57:13 Yeah. And sometimes they're waiting for HIQA for that leverage of non-compliance. Yeah, they'll nearly ask for it in some cases. [Insp20] 57:17 Exactly. They want your non-compliance basically.	Pursuing non-compliances as leverage for funding	Escalation as currency	Inspectors as agents of change	Positive effects of regulation

some of the private services that I would have. They potentially employ less social care workers. So those people who are qualified in social care, you can clearly see they could, they can pop up in some of these services who do employ them. So I find those services that employ a significant amount of direct support workers, they tend to…well they earn quite a lot less money than social care workers.	Qualifications of staff in private providers	Contrast between private and public providers	General views about service providers	Overall views on the regulatory system
for the assurance perspective, if you go into a centre and it's a case of the PIC is doing monthly audits, there's learning…So there's an issue after occurring, somebody didn't follow process, whatever. The PIC or the staff team have taken XYZ actions, they follow up with that staff, they make sure the staff is aware of the…information triangulates down to good oversight and good governance	Quality of provider audits can provide assurance	Quality of provider processes	General views about service providers	Overall views on the regulatory system

and that if they have an issue. And particular providers do daily checks, or they do weekly checks. But they have a timeline that if something is amiss, it's caught within a very short space of time and they act on it. And that information alone, you could delve in and do a forensic thing and find something, but it's something that probably the provider would have picked up themselves if you had…if they had been given, we'll say the week or the months that they were, you know?				
providers with clearly defined management structures. With clearly defined lines of authority and accountability who are going in and doing area specific audits, 6 monthly audits, annual reviews that are transparent. That are showing and self identifying areas for improvement, you get great assurances from that.	Quality of provider audits can provide assurance	Quality of provider processes	General views about service providers	Overall views on the regulatory system

The fact that they're identifying it themselves and putting an action in place and having a clear timeline for that.				
I'd like maybe a thematic inspection where the focus is really just spending time with the residents, as in, spending, if possible, most of the day with them. And I know we do that and I think it there was a significant improvement on that, but it still is a big bulk of paperwork needs to be done while you're on inspection as well. I'd love to spend more time just listening to the residents, hearing the residents, seeing the residents, you know? But I respect that could be difficult if you were to actually call them compliant or not compliant.	Preference to spend more time engaging with residents	Getting information directly from residents is important	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
I think people's experience of regulation also impacts the type of information that they send in. And, I	Receiving a non-compliance makes managers extra cautious in that area	Providers can over-compensate in	General views about service providers	Overall views on the regulatory system

mean, if they've gotten a non-compliance previously for not submitting an unwitnessed bruise, at provider level, a message is going to go out there 'send everything in', you know? To be fair.		reaction to non-compliances		
there's no inspection methodology nationally or internationally that's infallible.	Recognising that no inspection method is perfect	Inspection methods	General views about regulation	Overall views on the regulatory system
So then we're coming in saying there's a safeguarding issue because these two residents might not get on in a house of six. But the pressure on the provider, you know? And think of it yourself, you've got a person in their late 50s and mummy and daddy are in their 80s like you…you can see it from their point of view.	Recognition of pressure on providers to admit new residents	Pressure on social care providers	General views about service providers	Overall views on the regulatory system

the pressure…I can imagine…you'll see the back and forth between case managers, the HSE to the provider and, you know, families then saying, 'oh, I've had to go to our local member of government. We've had to go here. We've had to go there'. And…or then you've a case where someone ends up in A&E and the provider has no choice but to say 'oh we're not going to leave them in A&E', you know? And I know a lot of the private providers are now are taking a lot of people, especially children services. But my experience in the last while is children who have been left in Temple St because the parents can literally do no more….it's awful. So…you've got younger children coming in as well, so the pressure is just huge. So, like, you have to…so that's tough on them.	Recognition of pressure on providers to admit new residents	Pressure on social care providers	General views about service providers	Overall views on the regulatory system

I'm thinking of a centre I was in and they had put in multiple requests for more funding for staff because they had a huge shortage because the change, the needs of that group of residents had changed significantly. And there was a large number of residents. But at the end of the day, the residents still didn't have the staffing supports they needed to be able to leave their centre, you know? They went out for day service and that was it. So I mean, I don't think you can, you know, despite all that the provider was doing, I think other than acknowledging their efforts, but still calling out the shortcoming. I don't know what we can do outside of that really.	Acknowledging barriers while assessing as not compliant	The provider is accountable regardless of their resource needs	Walking the tightrope between assistance and sanctions	The importance of skill and strategy for the role of inspector
There are always ways to do things better, and I think that definitely there's scope for different ways of regulating, maybe, that might, you	There are different ways of regulating	Reforming how regulation is done	General views about regulation	Overall views on the regulatory system

know, in the future that might improve things further.				
we have become adept at manipulating, if you like, maybe manipulating is the wrong word. But in terms of being proactive in looking at how we would regulate a particular service against those regulations, like respite and residential, that kind of stuff.	Regulator manipulating regulations to suit settings	Regulatory techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
So just to jump in on 29, the first 3 sub regulations on medication are in relation to pharmacy and access to pharmacist and then there's one regulation, regulation 29 (4) which says there'd be appropriate and suitable practises, but this was, as [Insp12] said, when you come across this, issues with administration or prescriptions: it doesn't quite fall under any of the sub regs.	Poor quality of the regulation on medication management	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

In terms of, you know, the board, so simply when we started regulating in 2013, 2014 you would have had like a lot of family members running the board for section 39. And, you know, you would have been lacking that skill set, institutional thinking…the ability to, you know, to plan ahead in terms of business planning and foresee the changing needs of residents I think. Regulation has really driven providers to look at that element and see what actually…do we have skills in it? But also, HSE have done a lot of work with providers around the composition of boards and that has been a result of regulation. And now looking at, you know, while it might have been OK pre 2013 to have a board mainly made-up of family members and well-intended people. Actually we need the skills there because the requirements that…the regulation dictates that we	Regulation has driven higher governance standards	Regulation has driven higher standards at board level in providers	Regulation has improved the quality of services	Positive effects of regulation

need that expertise and to elevate things and at that stage it was to meet the bare minimum.				
Regulation 9 is probably a good regulation. But it's probably fairly weak in terms of actioning things I find sometimes. Because it's not really aligned to, you know, the assisted decision making act and any other pieces of legislation. The regulations are very broad, I suppose, in terms of what they say, do you know?	Regulation 9 is difficult to 'action'	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
services have progressed so much in the last 10 years. And at this point, there's been some legislative change. Services, in how their function and operate, is completely different. And then having your regulations…I think	Regulations are 10 years old and are outdated	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

is leading to somewhat of an inconsistency in regulation as well.				
I think it was two or three years ago, we sent in the piece regarding reviewing the regulations or modernising or adapting towards disability. More so as they were originally drafted based on the older person's regulations. So maybe changing to a bit more disability focused might make things a bit more straightforward in terms of our role.	Regulations are not suitable as are based on nursing home regulations	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
personal possessions refers to residents managing their finances, but again, it seems to be very much nursing home based. There's a number of residents who should have the right to have their own bank account. But it, kind of, refers to the registered provider managing the money on their behalf in accounts that are not used by the registered provider in connection with carrying out the management of	Regulations are not suitable as are based on nursing home regulations	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

the designated centre. It doesn't…again rights, kind of, fit in there where they should have their own bank account.				
the inintended consequences as well. It's while we're pushing for these designated centres we call people's homes, I think some of them have gone way beyond. The whole thing about fire. Like you walk in, you see so many fire signs and lights and green dots and walkways and arrows, and 'Oh my God!'. This is a 3 bedroomed semi-detached house. Is there a need for all that? But I respect people who want to be compliant with the legislation.	Regulations create institutional conditions	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
a lot of the issues at the moment, that we're coming across would be finances and access to finances and advocacy for the finances. And providers are pushing and they're using the reports to go back to	Regulations empower providers to advocate for residents' rights	Regulations as a benchmark	The role of regulations in culture change	Positive effects of regulation

stakeholders, namely guardians and family representatives, to try and get them across the line to have the rights of the residents there.				
I find that providers are using the regulations to empower change as well. So they'll use our judgement to go back to, maybe, their funder or to other things, or to promote a resident in a certain way to get…like I've seen huge impact.	Regulations empower providers to ask for more resources	Escalation as currency	Inspectors as agents of change	Positive effects of regulation
It's commonplace now to hear people talk about rights and human rights and individual rights as well. And also I think, you know, in relation to…I think staff are much more, I suppose, knowledgeable and empowered to actually highlight where there might be, say compatibility issues, or residents' impact on each other, or services is not good. I know when I worked in services you, kind of, weren't…now that's a long time ago.	Regulations empower staff to raise concerns	Regulations empower provider staff	The role of regulations in culture change	Positive effects of regulation

You, kind of, just went with the flow and you're kind of working in that more institutionalised model. And I find staff using the regulations are, kind of, more empowered to actually…or feel more empowered to actually call out issues themselves. They might feel more freer to discuss that with the person in charge and say, you know, we do have an issue here. And they can use regulation to support what they're actually saying and how they bring that issue about.				
It's the same set of regulations for the large congregated setting down to the, you know, the couple living in a nice apartment somewhere, you know? And it's, you know, it's our job to sort of be pragmatic in how we interpret the regulations in relation to that.	Regulator manipulating regulations to suit settings	Regulatory techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
we're a relatively young organisation and the regulations are already there	Regulations still in process of being embedded	Process of culture change in providers	The role of regulations in culture change	Positive effects of regulation

since 2014. So they're still being embedded.				
I think the regulations probably do need to be amended because they probably don't fit every service type that we visit. And I think that could improve things for people with disabilities because sometimes the regulations are not, I suppose, comparable to what we would have in our own homes which is, I suppose, what designated centres are, do you know? For example, with fire compliance and issues like that. Like I think they need to be amended.	Regulations create institutional conditions	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
Premises. Fire safety can be, I don't know, quite clear. Again, that the language is quite broad on it. The centre is ‘well maintained’ and it meets the needs of the residents. So the language allows it to be broad enough to use.	Regulations with broad language are more appropriate	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

I was out in the centre where they had, sort of, holes in the tarmac at the front of it and said it's impossible to get somebody from construction here quickly because, you know, they're so busy and getting more money in Dublin or places like that. If you're in the West of Ireland….and so there's things like that, I suppose, really. And then you're thinking, well, you know, what can I do? I can put it in the compliance plan and we've put it in the one before and their out of time…is it so serious that it's an escalation matter? Or do I just give them another bit of time, you know? And, you know, in the intervening period somebody falls and breaks their hip on their way into the centre.	Skill in determining whether an issue is critical	Regulatory techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
there's not a tolerance for it. I mean, the regulations are as [Insp4] said black and white. It's…that's the ethical or the moral challenge for you as a	Tolerance level for non-compliance	Regulatory techniques	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

person, I guess, in terms of how you sit with applying those when you know genuinely what's happening on the ground. And…but you can't let it go on for years and years and, you know, just shrug your shoulders because that's not your role.				
there's also that piece about going into 2025, you know, where regulatory drift may have happened. Like, we may be under more pressure because of a lot of those centres haven't been inspected and they may not be as compliant as they were	Infrequent inspections due to inspector shortages leads to more non-compliances	Regulatory drift	Impact of resource constraints on oversight and compliance	Impediments to effective inspection and regulation
we have powers under the Health Act, you know? We can we can issue cancellation notices. We can request additional information under sections of the Health Act, you know? We can request a compliance plan in response to inspection finding. And we can go into court under section 59, you	Regulatory framework affords all necessary powers	Inspectors have access to sufficient powers	General views about regulation	Overall views on the regulatory system

know? We actually have the strongest powers in HIQA, I think, in terms of the action that we can take as the regulator. And they've just been enhanced slightly with the recent amendments, in terms of the 14 day period and all those periods. So I think we're in good stead in my opinion.				
there's a good l range or a spectrum of tools that we can use based on severity from your, like…I mean I think the urgent actions are quite effective because you're using, you're issuing that on the day of inspection. So you're identifying that this is actually urgent and we need, kind of, a quicker response from the provider than, you know, issuing a report. Right up to, you know, cautionary warning. Restrictive conditions of registration as well for more ongoing or prolonged…usually relating to funding, but I think there's, I don't	Regulatory framework affords all necessary powers	Inspectors have access to sufficient powers	General views about regulation	Overall views on the regulatory system

think there's…Maybe we were talking about the timeliness of some of the more ‘going to court’ issues, but I don't think there's any other, maybe steps that we're missing? Or actions that we could possibly take that would be beneficial to us, I don't think.				
back to that point about us only seeing it through the lens of a six hour day or whatever it is. It's the surveillance systems, the auditing systems that the provider has in place and why they're doing them. You know what I mean?	Relying on the competence of providers to self-identify issues	Quality of provider processes	General views about service providers	Overall views on the regulatory system
they're looking on the ground to see that it's actually effective. You can have all the wonderful systems in place in the world and they're not effective. But providers that are actually auditing, as [Insp14] says, and responding and being proactive in responding…’right, we see an issue here. We know it's there. This is what	Relying on the competence of providers to self-identify issues	Quality of provider processes	General views about service providers	Overall views on the regulatory system

we're doing’. Those are the good providers.				
I was on an inspection a while back and I thought it was very interesting. The young lad was out playing football on the green with his neighbours. And I said, ‘God, this is a fantastic example of inclusion’. He's out there with the neighbours, his friends playing football, and I've got an NF06 in a few days later because there was a bruise on his leg and the form was sent in because it was unwitnessed. But highly likely he got playing football. And now you have an allegation of abuse attached to something so wonderful. And I was thinking that's just a complete unbalanced…but I understand why they done it.	Providers have a low threshold for reporting potential abuse	Over-reporting of incidents	General views about service providers	Overall views on the regulatory system

if someone was to do research in the system, like you might, say, ‘Oh my God, look at the amount of NF06s coming in!’. And then when you review and say, actually, did they meet the criteria? I suppose it's when you look at first and you've got, like, that doesn't look great. And then, say, well actually if you delve into it, maybe it's not as bad as it originally looks or sounds if that makes sense? Yeah. But I do have to say that I wasn't concerned about it at all. Actually. I saw only playing football. But I just thought it was interesting that they went down that route.	Providers have a low threshold for reporting potential abuse	Over-reporting of incidents	General views about service providers	Overall views on the regulatory system
the legislation is the only thing that's driven change in a lot of the service providers to get funding. To put pressure on the politicians to fund the disability sector particularly. They've been so underfunded for years and years and left to the fore. And it's only	Reputational damage caused by poor reports often produces additional funding	Escalation as currency	Inspectors as agents of change	Positive effects of regulation

through that legislation, the reports, you know, and the news…they've been reported then in the news, you know, so many reports. It's hard because some providers are being, you know, politically like, you know, reputationally damaged because they've got bad reports. But actually it helps them because what you find is, 'oh, God, we've got to give them some money, we don't want this again'. So that's how it works. It's terrible, but…				
Like I was somewhere before and it was a cultural issue. And they're doing huge staff moves, they hadn't missed so much around, like that, I think it was, like, activities of daily living were changing the bins, you know? Things that…you're going, 'that's not how you…you know? You're so focused on something that you've missed...So I think for us as well that	Excessive inspection focus on one issue can detract from identifying other problems	Risk of inspector not identifying a problem due to tunnel vision	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

you walk out and you are so focused on a big, like, tick box issue that they have, that you've missed something else that's rumbling in the background.				
I think we do a good job of using them to support improvement in services and I think, you know, some of them lend themselves more to that than others.	Differential impact of individual regulations	Some regulations are more consequential for quality than others	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
the language is broad enough that it's still meaningful, but that's what that was. Every centre is different, every provider is different. It does allow that as it's based on the evidence that you have, it does allow the inspector to use that regulation, rather than being too prescriptive. So there's the challenge. I know the challenges with the regulations is you don't want to be too prescriptive, you want to be broad enough, and it's trying to find that balance.	Regulations with broad language are more appropriate	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

So as people are becoming a bit more, I don't mean knowledgeable, but informed and aware around rights and things like that, it's impacting, I think, a lot on 13 as well. Whether that is that they choose to do things, or they choose ‘no, I don't want to do that’. And there's a kind of a respect for that choice as well if they decide ‘I don't want to go, but everyone else is gone. But I really don't want to go’	Residents are more knowledgeable around their rights and choices	Regulations have empowered residents	The role of regulations in culture change	Positive effects of regulation
as everybody said here, what we should be doing is talking to residents, observing and having the time to do that properly.	Preference to spend more time engaging with residents	Getting information directly from residents is important	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
The need for more time around communication with residents. I would feel definitely that should be our priority. That we do get that chance to communicate with them if they want it. But also to observe the practise and all the rest because, you know, we do observe, practise. But	Preference to spend more time engaging with residents	Getting information directly from residents is important	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

how long do we observe it for, you know? You don't sit there for…ok, you're seeing the general conversations and you're seeing what's happening when they come in from work and all the rest.				
where there's, like, increased complexities or changing needs, how quickly the system can change to support it in terms of premises replacement. So where there's placement breakdown, in order to find alternative placement…Like, I've one case where they are almost two years trying to identify. And it's not, I suppose, the provider is most definitely trying to support that resident to the right place, but they're not available. Like, 15 to 20 providers have assessed this resident so…within disability, in itself, being able to support changing need in an	Lack of housing options can inhibit new placements	Provider reliance on third parties can be barrier to compliance	General views about service providers	Overall views on the regulatory system

appropriate time frame is really lacking.				
they're black and white. They're not a comprehensive slew to illustrate every situation you're going to come across.	Rigidity of the regulations	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
The regulations don't fit….it's not one-size-fits-all, but we have a set of regulations and that's it.	Rigidity of the regulations	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
You're looking at governance and management, risk, fire, premises, rights, you know? Protection, they are the hard hitting ones where actually if, you know, if providers are found compliant with those, you're sure that actually, residents have really positive outcomes. They have a good quality of life. If you find providers are non-compliant and that would then, you know, there's a red flag.	Differential impact of individual regulations	Some regulations are more consequential for quality than others	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

the different section 38/39, different pension entitlements and maternity leave, all of them, they're all absolute external variables that impact.	Service funding model affects ability to comply	Contrast between private and public providers	General views about service providers	Overall views on the regulatory system
I don't so much see it in terms of equipment, specialised equipment, than I thought. I wouldn't see that in terms of resources.	Services appear to have sufficient access to specialist equipment	Services have all the specialist equipment they need	General views about service providers	Overall views on the regulatory system
I think they were of their time, but that they certainly need to be looked at in the context of the findings that services are working to them. Because the services has been able to look at the regulations and meet those requirements, like complaints, for example, follow their complaints policy. But actually the issue at heart is something completely different. So it's how they're adapted to meet the new answers of real life in centres, I think that's a huge challenge.	Services have worked out how to just comply, nothing more	Compliance techniques	General views about service providers	Overall views on the regulatory system

And I think, and this is not trying to be sneaky, this is not, I don't mean this to sound…I think providers are so good at reading the regulations now. As in, they know, especially the private ones. They know how to align everything within the regulations.	Services have worked out how to just comply, nothing more	Compliance techniques	General views about service providers	Overall views on the regulatory system
I mean ultimately, like, we should all have the same aim, which is, like, improving the quality of the service that people are receiving. And I think people who have that mindset, you know, they tend to be, you know, to provide better services. Therefore, they're more in compliance with the regulations, you know?	Shared goal of improving service quality	Positive culture among disability providers towards regulation	General views about service providers	Overall views on the regulatory system
I think 5 is a good one, you know? I think it's a good one for quality of life, personal outcomes, that sort of thing. And then the measurement of them and the progression of them and that sort of thing. And I think you can get a good quality, you know, to enhance	Differential impact of individual regulations	Some regulations are more consequential for quality than others	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

the quality of life for residents. And I agree, I suppose, fire, you know? If this is not a safe service, then if there's not good fire procedures in place, that's very serious.				
The governance management is probably, in terms of strength, the impact that it can have both, negative and positive. And then, I suppose, like you had mentioned, safeguarding to a point. Risk, that would be the safety aspect, I think, you know, that within services, residents are generally safe. So from my experience it's rare I walk away from the centre going 'they're really unsafe', you know? There's an immediate response required at that point. But it's those other, I suppose, more qualitative pieces that aren't…like rights or finances, you know? Look, there's the other…the insurance like you mentioned, isn't	Differential impact of individual regulations	Some regulations are more consequential for quality than others	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

going to…like, has anybody found insurance not compliant, you know? They're the kind of pieces that don't have that greater impact on residents.				
I think it's [Regulation 13] impactful. So, like, for example, I just was in a centre where, when you looked at it, two residents had not left that centre on a weekend for months. Like they'd been out once, I think we did it in July and they had been out once. So I mean, on paper, to a layperson, that's completely unacceptable. So it was very clear what the response should be. Whereas we could have gone down the rights angle, but you would, like, in terms of impact, where you want very clear action.	Differential impact of individual regulations	Some regulations are more consequential for quality than others	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

regulation five I would say is critical. And it's becoming more critical because there's different types of residents being admitted to services now. So a comprehensive assessment, I guess, externally, we're seeing providers being challenged with a different type of resident. And that's growing and changing with every year. There is far more and it's an overused word in HIQA, the new robust: complex residents, you know what I mean? There's a high level of residents who are displaying behaviours that are requiring very specific services. And at a younger age coming into services. So we're seeing a rise in different types of providers to meet that market. But that fundamentally highlights the importance of Regulation 5, individualised assessment, MDT assessment, comprehensive	Increasing importance of the regulation governing resident assessment and care planning	Some regulations are more consequential for quality than others	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

assessment and really focusing on that in relation to us as regulator making a determination and a judgement whether a provider is actually suitable to provide that service to those residents. Because it'll all come back to the assessment. And it'll come back to the quality of that assessment. So I would just like that, kind of, on the record in terms of your question to the most important regulations.				
a lot of them I don't rate at all as, you know, things like certain ones that are very paperwork specific like directory of residents or even like the one on records.	Regulations focused on checking paperwork	Some regulations are more consequential for quality than others	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

I think you use the word there, Paul, inconsequential. And, you know, I think if you're not safe, if you don't feel safe on a day-to-day basis, well then pretty much all of your regulations are inconsequential to you. Because I'm not safe today and that's what matters most to me. Like, of course things like fire and risk management and other areas like that are very, very important. But like I said all sometimes, you know, fire for example. We might see it as being very significant, but actually the residents don't, you know? If we're getting hot and bothered over a fire door, or over, you know, fire containment, it's not…obviously the results could be catastrophic…but in terms of a day-to-day basis, the residents, you know, aren't too bothered about it. But I, just for me, it's really about the right to feel safe,	Some regulations have more importance for residents than others	Some regulations are more consequential for quality than others	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

the right to not be subject to abuse of any of any sort, be it from peers or from anybody else. And I think that word inconsequential was, you know, really important there because as I said already, if I don't feel that, well, then it's, kind of, everything else is by the by almost.				
what happens…sometimes when you're in a designated centre and if there's three or four houses, what happens is, the staff chopping between different centres to cover leave and do all this kind of stuff. So there's no consistency of care for the residents because staff keep moving all the time, you know? Whereas if you have a one unit, it would have got, you know, with dedicated staff that, kind of, cover for themselves and leave and all that. Then it's more homely.	Smaller centres have greater staff consistency	Consistent staffing as a facilitator of compliance	General views about service providers	Overall views on the regulatory system

when we started doing the regulations, there was an awful lot of congregated settings and multi occupancy centres and, like, it was really difficult. It was difficult for the residents living there because they were, you know, dual rooms, double rooms and triple rooms and all sorts, you know? You had a lot of that at the start and, you know, if you think over the last few years like, now we're going to centres, those residents have moved into the community. And the difference in the quality of their life is amazing, you know? So I think no matter what, like, I'm not saying all individualised services are right either, because it's not. That could be very isolating. But a smaller, a more specific, kind of, a smaller centre. Two to three before people, whatever, like with their own staffing, I think is the ideal.	Smaller centres tend to be higher quality	Smaller centres tend to have higher compliance	General views about service providers	Overall views on the regulatory system

That's what I used to find was a more homely atmosphere then because, you know, it was just very individualised. Even though there might be three or four people in the house, it's more individualised than the big congregated settings where it is common that you're waiting for buses to get access to buses to go here. They're never, they have their own transport, you know? They have their own staff setting. They have a lot more access to local community and their families and all that. So that's the ideal.	Smaller centres tend to be higher quality	Smaller centres tend to have higher compliance	General views about service providers	Overall views on the regulatory system
You are getting a snapshot in time….you have to be, you know, you have to be realistic about that.	Snapshot nature of inspections	Inspection findings are point in time	General views about regulation	Overall views on the regulatory system
the biggest thing that needs to change, and I think it is changing, is collecting more of the voice of people with disabilities. And implementing, I suppose, systems into our inspection	Preference to spend more time engaging with residents	Getting information directly from residents is important	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

process or outside that inspection process that enables us to collect that.				
then family members themselves, especially when, in terms of residents' finances and handing over some of that, or you know, allowing access to bank statements.	Some families are reluctant to facilitate access to resident finances	Third-party barriers	General views about service providers	Overall views on the regulatory system
GP services, that you know, GPs that aren't signing kardexes. Or just difficulty in getting kardexes from GPS.	Some GPs do not engage with providers	Third-party barriers	General views about service providers	Overall views on the regulatory system
I think Regulation 13 in comparison to the others: it means the most for residents. Like, if you look at healthcare or you look at medication management which are a little bit clinical, do they care if they have a healthcare plan? Well they probably don't. And do they care whether they get the medication at 8 or 9.30 when they wanted to wake up, not 8:00. So the regulations can be, I'm not saying medicalised, but they're very, you	Some regulations have more importance for residents than others	Some regulations are more consequential for quality than others	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

know, processes and things like that. But these are the ones the residents can tell you about themselves. They can tell you how their impacted by either compliance or non compliance with it. Or, you know, ‘I wanted to go out, but I'm not being brought out. I'd love to get out to the cinema once a month’. So you can hear the real story. They're not going to tell you, ‘look, I never got to meet the pharmacist and that's really upsetting me’. They probably won't tell you that, you know what I mean?				
We should be able to point them in the right direction, I think. And there has always been this thing of ‘you can't make recommendations’ and all the rest. So in some sense have to go the roundabout way and even say, well, you won't tell them where, what centre. But you'd say ‘there's a provider in the North East, very large	Some inspectors sign-post providers to good practice in other centres	Soft engagement with service providers	General views about service providers	Overall views on the regulatory system

who have a really good system. So would you not give them a ring and just see what they're doing'.				
There is still some, you know, there are obviously third parties that have, I suppose, a big say in how services are run.	Some providers are dependent on third parties for compliance	Third-party barriers	General views about service providers	Overall views on the regulatory system
I was out in the centre where they had, sort of, holes in the tarmac at the front of it and said it's impossible to get somebody from construction here quickly because, you know, they're so busy and getting more money in Dublin or places like that. If you're in the West of Ireland….and so there's things like that, I suppose, really.	Some providers are dependent on third parties for compliance	Third-party barriers	General views about service providers	Overall views on the regulatory system
I think what we've got better at is spending more time with residents and staff and then using what they're telling us and what we're observing to then focus in on documentation.	Using resident engagement to identify problems	Getting information directly from residents is important	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

In national terms, look, it varies across providers, some of the providers are very siloed. And, you know, they could they have different policies from one region to the next that could be completely different. Like we've, kind of, seen it from group inspections where we're going into different sub groups within the organisation in our region, and they're very different. So nationally, I only can imagine. Like, to give an example, in our region, they don't have a policy on restrictive practises. Or, you know, kind of things that you'd expect at this stage, whereas other areas are very advanced, so as a provider, they're not sharing it nationally, never mind us.	Some providers have inconsistent policies across regions	Quality of provider processes	General views about service providers	Overall views on the regulatory system
residents can have four or five files where other services have one succinct file and appear to manage this quite correctly.	Different documentation approaches among providers	Non-standardised document management systems among providers	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

I find sometimes with some providers you've too much information, but you have to get through to make a decision. Others can be more succinct with it.	Different documentation approaches among providers	Non-standardised document management systems among providers	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
Is one day in two years or one day in a year…and, you know, six hours, seven hours in a place giving us the truest picture? No, but it's given us a hell of a lot of better picture than we had before 2013. And when we have a litany of at least 30 plus national enquiries in the last 25 years of abuse, safeguarding.	Any amount of inspection is a good thing	Some regulation is better than none	Regulation has improved the quality of services	Positive effects of regulation
it's the fear that when you're out on that day…and I know everything is a snippet in time, and it's all in real time, it's that something comes in a couple of weeks later and you're thinking 'I was in that centre. How did I miss this?' And I know residents can have, like, any of us, you know, things can break down. Things can not go right	Anxiety that you miss an issue on inspection	Stress imposed by inspector role	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

and they can just come out of the blue. But that's the fear. That, you're like, 'I was there. I was there last week. I was there a month ago. I was there six months ago. How did I, how did I miss this?				
It's the challenge to be able to walk out of a centre and 'have I looked at enough? Have I…am I assured that those residents are safe and having a good quality of life?' And that's the question at the end of the inspection.	Anxiety that you miss an issue on inspection	Stress imposed by inspector role	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
A provider has come back and said that there was huge financial irregularities that have been going on for a period of time. Umm, there is an investigation going on. And I had been in there with a support inspector and I immediately went to look at that field work and say 'had I looked at finances?' Or how was I assured walking out that residents were being consulted?	Anxiety that you miss an issue on inspection	Stress imposed by inspector role	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

I can't think of any situations where I was conflicted in the sense that I think, you know, that the inspector just uses their judgement to, kind of, say, you know, like…say, if there was an example of, like, positive risk-taking, you know? Where, you know, all the, kind of, risk assessment was done but something maybe still happened. Or, you know, but that you, like, you know, even, like, people trip when they're out like, you know, I do most days, that kind of thing, you know? I think people do use their professional judgement to, kind of, balance that properly. Like I can't think of anything where I've been like 'oh, you know, that's really a non-compliance but it's really good person-centred care'. Like, I get what you're saying [Insp1] about that notification, but for me, like, you're just closing that off early and you're not concerned, do you know	Inspector's exercising professional judgment	Using professional judgment	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

what I mean? Like, I, you know, no one's coming down on them saying, you know, ‘why are there instance of unwitnessed bruising', do you know?				
I always found, you know, when I was on the other side of the table when I was a service manager, when I was PIC for the four weeks before we had, I think it was six weeks back then we had announced inspections. It was like everything came to a standstill. Like, people were, like, trying to do every bit of documentation. I remember I used to come into houses, like, where have the guys gone today? What have they done, you know? And everyone's like, ‘oh, panic stations’.	Stress placed on staff by announced inspections	Inspection-induced stress on management and staff	General views about service providers	Overall views on the regulatory system
At the end of the day, like, as regards their compliance levels, you know, the regulations are black and white. And	Acknowledging barriers while assessing as not compliant	The provider is accountable regardless of their resource needs	Walking the tightrope between assistance and sanctions	The importance of skill and strategy for the role of inspector

in a certain regard, like you know, you can't just say, ‘well, look, they've made a good effort’. You can reflect it in the report and you can reflect it to a certain level, maybe in compliance. But not like if they're not compliant, they're not compliant.				
And then, you know, you have people with, like, kind of, hand marks on their arm, you know, bruising? And they never send it in at all, do you know? So, like…And that's a very different concern. So, I mean, I think that's where professional judgement, kind of, comes into it so much. And, I suppose, that's why I don't think we'll ever be replaced by AI I hope, you know? Like, you do need that, kind of…And I think people's experiences of working in services informs that a lot as well, you know?	Inspector's exercising professional judgment	Using professional judgment	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

if you look a provider that's going through a significant blip, for example, and they're experiencing high levels of non-compliance and it's impacting quality of life for residents; you'll see that their governance arrangements have been impacted or that something has happened their governance arrangement. Their key person is gone, or key people have gone or they've changed something significant that has impacted on them.	The loss of key people often precipitates a slip in compliance	Key people drive compliance	General views about service providers	Overall views on the regulatory system
if you don't have good people you can't do it. If we go in, we find there's a couple of vacancies…or a good manager — is a classic one — has left and all of a sudden things starts falling down.	The loss of key people often precipitates a slip in compliance	Key people drive compliance	General views about service providers	Overall views on the regulatory system

probably a part of it is if you have an experienced inspector like [Insp14], going out to that centre and having that conversation with provider, through having ten years plus experience and then also another background before HIQA in social care…has obviously very good insights and have built up to, you know, intelligence over the last 10 years and how to expect and how to get the best data from that provider in terms of lines of enquiry. Whereas if you have a more junior inspector, you know, they may not have got the same assurance as [Insp14] may have gotten that in that time. So that's part of it. It's then, and it might not be the answer you're looking for…but I think, in terms of, you know, it does still depend on the person regulating them and not only the regulations or the line of enquiry. It's about the individual	More experienced inspectors will identify issues sooner	Value of inspector experience	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector

and their experience and expertise as well.				
I can walk into a centre tomorrow and I can meet, you know, 4 residents who are extremely independent. And I could sit down and talk to them and I could probably walk out within four hours, you know, because they have told me what it's like to live. I don't need to read their personal plan because they know everything that's in it. They know everything that's going on in the centre, you know? And, so, records are not really important in that centre because the residents' voice is there. Whereas I can walk into another centre where there may be 10 people who have significant communication difficulties, which for me	The profile of residents impacts on the time needed for inspection	Different inspections for different settings	General views about regulation	Overall views on the regulatory system

documentation then is really, really important because I need to be able to see the voice of the person, I suppose, in their plans and what their life is like. And that takes a considerable amount of time, which is probably more than two days. So it's not, it can't be a one size fits all.				
One of the other really good things that regulation has brought in is the requirements under Regulation 23. So the, you know, the insistence on a six monthly unannounced visit by the provider, you know?	The regulation on governance requires providers to act as quasi regulator	Regulation requires providers to self-regulate	Regulation has improved the quality of services	Positive effects of regulation
if they're doing really good audits, if they're doing good six monthly reports, annual reports, etc, that again…back to that point, that they're identifying the issues and that they are a responsive provider, responding to the needs of the residents.	The regulation on governance requires providers to act as quasi regulator	Regulation requires providers to self-regulate	General views about service providers	Overall views on the regulatory system

I feel like some of the section 38 and 39s, again, going back to that accountability piece, no one's really going to lose their job if a centre is not compliant, not that they should. I don't mean to be that drastic or anything. But the consequences aren't as reaching for maybe	There is a lack of accountability in some quasi-public services	Contrast between private and public providers	General views about service providers	Overall views on the regulatory system
in other centres you'll need to dig deeper, where maybe residents require more support, so that's where you'll need to rely on your documentation.	Centres for residents with high support needs can mean greater effort is needed to find information	Resident profile can impact on accessibility of information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
The more experienced you are doing this, I think the quicker you see past the window dressing, you know? And a curtain just hung will only hang for so long, you know, to use that as an analogy. But, I think we can tell fairly quickly	More experienced inspectors will identify issues sooner	Value of inspector experience	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
we take a lot of assurances from providers and persons in charge. And, you know, sometimes you go out an inspection, I don't want to waste too	Inspector's trusting the assurances of providers	Trusting providers	Walking the tightrope between assistance and sanctions	The importance of skill and strategy for the role of inspector

much of your time now, Paul…But sometimes you're out an inspection. You might have a lot of faith in the provider representative and maybe a bit less in the person in charge. And yes, really, if they give us an assurance, it's very hard to say, ‘don't really believe her. I don't think she's got the competence’, you know?				
I think it's that verification piece. Maybe it's back to [Insp15]’s point in terms of saying experience and…you know…I guess we've also worked in services as well. So we've that experience too, you know? I certainly think, you know, an experienced person knows within 5 minutes of walking in the front door, you know?	More experienced inspectors will identify issues sooner	Value of inspector experience	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
we did see evidence of when we…during COVID, when we weren't able to get into centres and then we went back.	Necessity of verifying what providers tell the regulator	Trusting providers	Walking the tightrope between assistance and sanctions	The importance of skill and strategy for the role of inspector

And what they were telling us and what we were seeing were two very different things. So definitely I think it is, kind of, a deterrent for a provider that we will…they know HIQA was coming				
another one, like a very obvious one, directory of residents, you know? It's clear that that was a hangover from the older person's regulations. A directory of residents is absolutely inconsequential to the vast majority of designated centres for people with disabilities because they're people's homes. OK, you could argue it might be relevant for a respite or something like that. But in the main run of things, you know, you don't need a directory of residents for, you know, the standards five or six people living in a community house somewhere.	Unnecessary regulations	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

If you're going to a centre and residents are quite independent and can tell you about their lives, or you might see them heading off to work or on activities and they'll have told you about goals. So, you nearly have a good assessment of that regulation [13] just from speaking to residents and making a few observations very early into your inspection.	Residents that are highly independent can provide a lot of information to inspectors	Resident profile can impact on accessibility of information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
I feel being in there is really important, speaking with the people that live there is really important. The people that work there, the people that manage, all that kind of stuff.	Value of 'boots on the ground'	Inspections are optimal means of judging compliance	General views about regulation	Overall views on the regulatory system
I think you have to go out into a centre. Like, you….there has been times where you do what they call desktop reviews and, you know, paper never refused ink. So like you're only taking the reliability of what's coming into you in terms of what's been, you know, what you receive…you have to	Value of 'boots on the ground'	Inspections are optimal means of judging compliance	General views about regulation	Overall views on the regulatory system

go out and verify it on inspection. That's the key.				
inspection is key, you know? You can read forever and not get a true picture of the lived experience of residents	Value of 'boots on the ground'	Inspections are optimal means of judging compliance	General views about regulation	Overall views on the regulatory system
I've done desktop review and I would have felt six months ago that centre was just riding high. Not, you know…and now you're, like,' oh, I could, if I hadn't done the desktop review'. Or gone out the week before I would have been, like, 'I've missed that entirely'.	Value of 'boots on the ground'	Inspections are optimal means of judging compliance	General views about regulation	Overall views on the regulatory system
in my opinion, you cannot beat feet on the ground to get, you know, we can do the governance pieces [Insp14] was talking about and that's a very good way of doing the governance piece. But the quality of life for residents, you cannot beat feet on the ground because you're seeing, you're observing, you're looking, you're seeing what's going on, you're seeing	Value of 'boots on the ground'	Inspections are optimal means of judging compliance	General views about regulation	Overall views on the regulatory system

the engagement between residents and, you know, staff and what they're doing and that, you know? As good as providers will be, I feel you just…you have to see, you have to be in a centre and get the feel for the centre and get a feel for what it's like.				
your engagement with residents is part of that inspection process. And we've obviously other engagement with the residents which we can touch on later on. But I think we had a really good sense from talking to residents and, you know, that comes as well obviously from the boots on the ground piece.	Value of 'boots on the ground'	Inspections are optimal means of judging compliance	General views about regulation	Overall views on the regulatory system
look at the amount of change in the last 10 years. By the nature of the fact that you have a [Insp16] or [Insp14] walking through the door saying ‘show me evidence that all of your staff are Garda vetted, show me evidence that all of your staff are	Value of 'boots on the ground'	Inspections are optimal means of judging compliance	General views about regulation	Overall views on the regulatory system

trained to do the job that they're doing, show me evidence that you have a roster in place that shows that there's two to one here for this person, requiring two to one support'. So all very basic, but basic needs that weren't being met always before 2013 I can tell you.				
things like certain ones that are very paperwork specific like directory of residents or even like the one on records. I mean you could spend a month trying to do that regulation on its own. Do you know what I mean? Like it's just, it's too broad.	Impossibility of assessing some regulations	Very difficult to gather enough information to judge compliance with broad regulations	The inspector skills required for effective implementation	The importance of skill and strategy for the role of inspector
as an inspection methodology I'd say it is up there with the strongest in most regulatory bodies in this country, operating in this country, and across Europe in that services are being inspected…as [Insp16] says: there's somebody going in asking questions.	Value of 'boots on the ground'	Inspections are optimal means of judging compliance	General views about regulation	Overall views on the regulatory system

I can walk into a centre tomorrow and I can meet, you know, 4 residents who are extremely independent. And I could sit down and talk to them and I could probably walk out within four hours, you know, because they have told me what it's like to live. I don't need to read their personal plan because they know everything that's in it. They know everything that's going on in the centre, you know? And, so, records are not really important in that centre because the residents' voice is there.	Residents that are highly independent can provide a lot of information to inspectors	Resident profile can impact on accessibility of information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
we get notified about certain incidents and, like, some of those, I don't know, do we need to know about?	Questionable value of some notifications	Some information is unnecessary for inspectors	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
the finance one, very important. You could miss it because, generally, like a lot of the medication, it's hard to, kind of, have time to go through bank accounts and bank statements unless they're very focused inspections. And	Having sufficient time to gather and assess detailed information	Time constraints imposed by breadth of regulatory responsibilities	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

I have, I have gone into centres where, you know, I just, you know, started looking at the medication. That was one of the things I used to work on in my previous role, and I was a quick at picking it up. And I identified that they were being charged for diesel and petrol, you know? For the buses and for maintenance and, you know, things like that. So and next thing you know, there was no consent or no agreement, right? So it's like…but you'd have to have time, you know? You have to have time to go in and delve into all that kind of stuff.				
I think it's time in terms of gathering the information.	Having sufficient time to gather and assess detailed information	Time constraints imposed by breadth of regulatory responsibilities	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
And your man is right about, say, the week in the service to be able to observe it. But it's having the time and gathering enough information that will	Having sufficient time to gather and assess detailed information	Time constraints imposed by breadth of regulatory responsibilities	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

allow you to triangulate and make the judgement.				
there is always time constraints, you know? If you get an inspection where you can spend quite a bit of time talking to residents and all the rest, that is your priority. We go out with the intention that it is your priority. But sometimes the residents, well, sometimes they don't want to talk to you. That's fair enough. Sometimes there is then time constraints where you don't get that real, kind of, conversation as much as you want to get and all the rest, and you're rushing and racing. So, you know, I think there could be room for improvement in terms of a bit more flexibility around time.	Time pressure on inspection limits engagement with residents	Time constraints imposed by breadth of regulatory responsibilities	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector
you can have all the information and you walk into a house and a staff says something to you or a resident and you're like, you know, and you're	Inability to prepare for all potential issues on inspection	Uncertainty around what might be found on inspections	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

literally…Yeah. You're then opening up things you didn't think you were because you have to, obviously. I was an inspection there a while ago with another colleague and we ended up going in a second day because…I went as a support because it was a really, really big centre on campus. We never imagined…we spent a whole day looking at bed rails, like in a whole day.				
Depends on the provider. I know that's really difficult. But some providers: easy peasy. Good systems. You go in, you know, get what you want, what you're asking for. There's other providers who would, sort of, be known…let's, shall we say that they can make inspections difficult, you know? It's not that they withhold information, but it's drip, drip, drip, drip and they're the difficult inspections. They're the ones that	Some providers engage with inspectors more than others	Variable engagement in inspection process inhibits access to information	Compiling evidence to make judgments	The importance of skill and strategy for the role of inspector

you're…you have what you need, but you could have gotten more				
the regulations themselves, I think there's huge room for improvement in them, you know? Like, say, the rights one, you know? Obviously rights is really important but that regulation isn't great, do you know what I mean? Like parts of it are good but it could be…it could be better if you know what I mean? Like I think the risk regulation…it's mainly about a policy, it's not actually about the management of risk in a service.	Weakness in text of regulations	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
I came across an issue a while back where admissions, the admissions really did not work out. But it was very hard to actually action it under admissions because they followed the regulation. And they were saying…and then I found, as you said,	Weakness in text of regulations	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

how do I manage this and where will this non-compliance go? Because they were, kind of, going, ‘we followed our policy, your regulation’. And I was going, ‘yeah, but some serious issues occurred for three of these young people’. And then we found because of what they were challenging us on was, kind of, correct. It was kind of a governance issue then and said, ‘look, you didn't have the oversight of this’, but that was hard to actually hard to put…the issue was admissions. So we didn't action it there, we actioned it somewhere else. As I said, well, when I looked at that admissions regulation ‘oh God, if that had been tweaked to actually, you know, or made look different, or had different wording’, you could have used it more effectively.				

Yeah, like omissions, documentation errors, all of those things, that's not captured in the regulation. So what you're trying to do is you shove it all under 29, 4(b), uh or, yeah, 29, 4(b). You put everything in there because it's the only regulation, or the only sub regulation that you can capture the stuff that's happening under 29 because the rest is not specific enough.	Weakness in text of regulations	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
Positive behaviour support. I think there could be more clarity around peer-to-peer abuse there because when some people have it, they don't have a clear understanding in terms of peer-to-peer, you know? Like, it's like, unless a resident gets actually assaulted, like a slap from another resident or whatever, you know? That it's not…behavioural, you think, there's no clear indication around verbal abuse, intimidation, fear, all of those kinds of things under…that reg	Weakness in text of regulations	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation

is missing, to be specific, because it's around interpretation, that particular one I always found.				
it's just how many each different sub categories and yes, there it could be better-worded, more specific you know? In terms of protecting residents and safety of residents and you know, all that kind of thing. Because, it's really like you have one, like, you have literally one, you know, protect residents from abuse. It's so broad. It's not specific enough. I think they need to think about the wordings of the subcategories of a lot of these ones, you know?	Weakness in text of regulations	Quality of the regulations	Flaws and gaps in the regulatory framework	Impediments to effective inspection and regulation
So there are some situations in our centres still, where there is a congregated settings and there is still huge room for improvement. But it is a journey, that the provider is willing to engage with us	Willingness of providers to engage and improve	Positive culture among disability providers towards regulation	General views about service providers	Overall views on the regulatory system