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TITLE PAGE

ETHICAL FRAMEWORKS FOR QUALITY IMPROVEMENT ACTIVITIES: AN ANALYSIS OF INTERNATIONAL PRACTICE

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TITLE PAGE

ETHICAL FRAMEWORKS FOR QUALITY IMPROVEMENT ACTIVITIES: AN ANALYSIS OF INTERNATIONAL PRACTICE

ABSTRACT

Purpose: To examine international approaches to the ethical oversight and regulation of quality improvement and clinical audit in healthcare systems.

Data sources: We searched grey literature including websites of national research and ethics regulatory bodies and health departments of selected countries.

Study selection: National guidance documents were included from six countries: Ireland, England, Australia, New Zealand, the United States of America and Canada.

Data extraction: Data were extracted from 19 documents using an a priori framework developed from the published literature.

Results:

We organised data under five themes: ethical frameworks; guidance on ethical review; consent, vulnerable groups and personal health data. Quality improvement activity tended to be outside the scope of the ethics frameworks in most countries. Only New Zealand had integrated national ethics standards for both research and quality improvement. Across countries, there is consensus that this activity should not be automatically exempted from ethical review, but requires proportionate review or organisational oversight for minimal risk projects. In the majority of countries, there is a lack of guidance on participant consent, use of personal health information and inclusion of vulnerable groups in routine quality improvement.

Conclusion: Where countries fail to provide specific ethics frameworks for quality improvement, guidance is dispersed across several organisations which may lack legal certainty. Our review demonstrates a need for appropriate oversight and responsive infrastructure for quality improvement underpinned by ethical frameworks that build equivalence with research oversight. It outlines aspects of good practice, especially The New Zealand framework that integrates research and quality improvement ethics.

Key words: quality improvement, clinical audit, ethics, consent, personal health data,

Background

Quality improvement (QI) is described as 'systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of healthcare in particular settings' [1]. It encompasses a broad range of activities including clinical audit, routine QI and experimental QI research. Routine QI activities are considered to be a fundamental part of high quality learning healthcare systems [2, 3] *'in which knowledge generation is so embedded into the core of the practice of medicine that it is a natural outgrowth and product of the healthcare delivery process and leads to continual improvements in care'* [4].

The valuable role of QI in driving improvements in service delivery and patient outcomes is well accepted [5, 6]. However, QI has been described as existing in a grey area between clinical practice and health research and distinctions between QI activities, health research and clinical practice have become blurred due to rapid changes in health systems, data analytics and technological advances. Health care organisations and clinical staff are uncertain as to what constitutes QI activities and what is required in terms of ethical oversight and by whom [4]. The lack of clear guidance has led to inconsistent ethical review decisions, confusion on requirements for participant written consent and use of personal health data for secondary analysis [7, 8].

Moreover, unlike approaches to health research, there is limited international collaboration aimed at achieving consensus on what ethical oversight or frameworks might apply to QI activities [8]. The consequences of this is both under and over-regulation that can lead to the use of less rigorous study designs in order to avoid the ethical review process or overly burdensome criteria that make the evaluation of changes to clinical practice unfeasible [9]. The lack of formal ethical frameworks and mechanisms for national oversight also impacts on the ability of QI activities to respond to changes in legislation and regulation [10]. To date, there has been no attempt to review how different countries address the ethical dimensions of QI activities and where these are situated relative to national research ethical frameworks.

The aim of this review is to examine international approaches to the ethical oversight and regulation of QI and clinical audit, including guidance on participant consent and secondary use of health data. The review focused on the main health research regulatory bodies and government health departments of six purposefully sampled countries: Ireland, England, Australia, Canada, New Zealand (NZ) and the Unites States of America (USA). These countries

were selected as official documents are published in English and they have established QI activity.

METHODS

SEARCH STRATEGY

The focus of this review was national policy and guidance related to ethical frameworks for QI activities. A grey literature search plan was developed to incorporate different searching strategies, including targeted website searches and customised Google searches. We focused on the identification of documents and websites of the main research ethical guidance frameworks published by organisations with primary responsibility for research or QI ethical guidance in each country. Where a central organisation could not be identified or the research ethical framework did not address QI or audit, broader web searches were undertaken. Targeted websites included the national research and ethics regulatory bodies and the health departments in each country. The following search terms were used, as a minimum for each website search: “ethics or ethical”; “audit"; “quality improvement”; and “consent”.

Given the vastness of the grey literature, results were organised based upon relevance and the first 10 pages, or 100 hits, were reviewed for each search. Two team members independently conducted the search for relevant material and results were discussed with a third member. Inclusion criteria were: primary research ethics documents in each country, English language, organisations with a national remit to provide guidance on research or QI ethics. (Supplemental file).

DATA EXTRACTION

A thematic analysis, based on a hybrid inductive and deductive approach, was used to organise and analyse the data from the selected documents [11]. Data were extracted using an a priori framework developed from a preliminary review of the literature. The categories for data extraction included: country, organisation, national ethics framework, recognition of QI/audit, governance on QI, consent, minimal/low risk, vulnerable groups, health data (supplementary data). A narrative synthesis of the data is provided with exemplars to illustrate guidance from specific countries.

RESULTS

We drew on 19 documents or websites across the six countries (Table 1) and one document from the European Union that prompted changes in two of the countries [10]. Data sources included two legislative Acts [12, 13], five reports pertinent to countries' research ethics legislative frameworks [14-18, 29], eight guidance documents [10,19-24], and four webpages [25-28] (Table 1). The characteristics and variation in ethical guidance between the six countries are presented under the following themes: ethical frameworks; guidance on ethical review; consent, vulnerable groups and personal health data.

ETHICAL FRAMEWORKS

Five of six countries reviewed have a central, independent agency or office with responsibility for determining national ethical standards in health research (Table 2). Across the six countries there is considerable variability in the way QI activity is recognised within national research ethics documents. In England, Canada and the USA, the research ethics frameworks explicitly state that QI activities are outside of their scope [13, 14, 18], though there is acknowledgement that such activities may raise ethical issues. Where central agencies do not provide ethical guidance, the advice on ethical conduct of QI activities tends to be dispersed across several organisations (Table 2).

The central research ethics bodies in Australia and New Zealand provide specific QI ethical guidance. Australia has a separate ethical guidance document for QI activities alongside its national framework on ethical conduct in human research [17, 23]. Up to 2019, New Zealand took a similar approach [15], but following an extensive review and public consultation, the NZ National Ethics Advisory Committee published an integrated 'National Ethical Standards for Health and Disability Research and Quality Improvement' [16]. This framework articulates an expectation that all projects (research or QI) adhere to or exceed the 'Ethical Standards' [16] and provides a chapter on QI [16, pg 216].

The NZ model is the exception - in the majority of countries, there remains a reluctance to address the ethical ambiguities around QI and audit. This is evident in the recent updates to the USA Federal Policy for the Protection of Human Subjects, known as the "Common Rule" [13]. The advice on QI activities is contained in the 'Frequently Asked Questions' section of the Office for Human Research Protections (OHRP) website rather than the 'Common Rule' framework [27].

GUIDANCE ON ETHICAL REVIEW

There is a consensus across the six countries that when a QI activity is considered minimal risk, it 'normally or 'typically' does not require ethical review by Research Ethics Committee (REC) or Institutional Review Board (IRB) [14, 16, 19, 21, 23, 27]. However, there is no standardised definition of minimal risk (supplemental file). Addressing this point, NZ and Australia provide a list of criteria that indicate when a project may pose more than minimal risk and thus requires ethical review (Table 2). The criteria include whether a QI activity constitutes a departure from usual care, involves human tissue, secondary use of identifiable information without consent, or involves vulnerable groups [16, 23].

The other four countries use criteria to establish boundaries between QI and research and apply broad principles to distinguish between the two [27, 28, 29]. For example, an activity may constitute research if one of the following criteria apply: 1) participants are randomised; 2) the study protocol demands changes to usual care; and 3) the findings are going to be generalizable [28]. In the USA, if an activity represents 'a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge', it fits the definition of research and requires formal ethics review [27].

Where ethical review is required, the level of oversight necessary, full or expedited review or organisational oversight alone, differs across countries. In many cases, QI activities qualify for an expedited review by alternative low-risk/quality assurance committees either within the healthcare organisation or sub-committees of the ethics committee [14, 23, 27].

CONSENT

There is a similar lack of clarity on participant consent where there is little guidance on requirements for written consent, verbal consent or notification and provision of information alone. NZ is the only country which explicitly sets a standard for consent in relation to QI for projects that are considered more than minimal risk:

> '18.12 Informed consent should be obtained where practicable prior to commencing QI activities, preferably in writing. Verbal consent and discussions related to written consent should be documented' [16, p219].

In the other five countries, the general guidance is that if there is any doubt that an activity may constitute research or involves using data beyond the original purpose for which it is collected, the default approach is to obtain explicit informed consent from participants.

All of the reviewed documents suggest that countries are cognisant of not impeding clinically important QI activities for patient benefit [19, 21, 23, 24, 27]. Most allow for caveats in cases where consent may not be feasible or practical to obtain. In Australia, NZ, the USA and Canada, an ethics committee may waive the requirement for consent if a number of stringent criteria are met. These include the following: that involvement carries no more than low risk to participants; the public interest in the proposed activity substantially outweighs the public interest in the protection of privacy; the research activity is likely to be compromised if the participation rate is not near complete; and the requirement for explicit consent would compromise the necessary level of participation [13, 14, 16, 23].

VULNERABLE GROUPS

Any QI activity with vulnerable groups, such as individuals with impaired cognition, tends to be treated as research regardless of the level of risk associated with the activity. Both Australian and New Zealand QI guidelines recommend that any QI activity involving a vulnerable group undergo ethical review [16, 23]. While not explicitly stated in the other four countries reviewed, the same principles are likely to apply. None of the countries reviewed have guidance on low risk QI activity where vulnerable groups are part of larger study populations.

PERSONAL HEALTH DATA

There is a general principle among the countries reviewed that if clinical staff have a legitimate relationship with the data subjects and the project poses minimal risk then there is not a requirement for patients to give explicit consent for their data to be used [12, 22]. This is based on the assumption that QI activity is part of good medical practice and the patient's consent to treatment or participation in the health system implies consent to have their data used for improvement purposes [13-16, 20, 24]. As countries update general data protection legislation to keep pace with digital technology, there are implications for research and QI [10,12]. An example of this is the introduction of the General Data Protection Regulation (GDPR) legislation, which is designed to harmonise data privacy laws across Europe [10].

Under GDPR, data protection is a fundamental right for all EU citizens, and any use of personal data, including health information, constitutes 'data processing' which is subject to strict accountability [10]. EU countries individually interpret GDPR requirements through country specific legislation [12, 22].

In anticipation of this legislation, England has introduced a new ethical infrastructure, including a national data opt-out service which provides the public with a way of excluding their identifiable healthcare information being used for reasons other than their individual care [22]. In Ireland, under the Health Research Regulations 2018 [12], all researchers who access personal data, including retrospective chart reviews for the purpose of research, are required to obtain the explicit consent of all data subjects [25]. The National Office for Clinical Audit (Ireland) has provided guidance on the circumstances where clinical audit may be exempt from the requirements of explicit consent, but it is informational guidance and lacks legal certainty [24]. In the USA, the updates to the 'Common Rules' allow for secondary use of data without explicit consent when certain criteria apply (supplemental file). Similarly, New Zealand has clarified use of secondary data in the context of QI as distinct from research [16].

DISCUSSION

This is the first publication that summarises and considers national approaches and frameworks for QI across countries. Individual country research ethical frameworks are based on the 'Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects' [30] which provides a common language and approach. In contrast, this review confirms that there is a lack of ethical frameworks and guidance for QI within individual countries and this is also well documented elsewhere [2, 3, 7, 8, 9, 31, 32]. Across the six countries reviewed, QI activities are conceptually distinguished from health research. Only one country, New Zealand, has developed an integrated standards framework for the ethical conduct of research and QI. No country gives a blanket exemption for ethical review to any project based on the claim that it is QI activity. However, it is generally accepted that certain 'low/minimal risk' activities can be exempted from full ethical review, though these require organisational oversight to ensure compliance with ethical principles [16, 19]. Issues on participant consent and the use of personal health data is a concern for the countries reviewed, especially in the EU.

There is a tension in the published literature between some authors who advocate that all QI should be treated as research and subject to standard ethical review [3, 7] and others who propose more proportionate and streamlined systems based on alternative ethics frameworks that are focussed on learning in healthcare [2, 33, 34, 35, 36]. In the latter, the level of ethical review is based on the risk posed to participants and a waiver of consent is possible for low-risk QI activities [2, 3]. In much of this commentary and research there is limited engagement with patients and the general public to elicit their views on consent and the use of personal health data for QI activities, and in particular the voice of vulnerable groups is absent [36,37,38].

Debates about the ethical standing of QI activities have continued for over 20 years. Moreover, as clinical research and clinical practice has become more integrated, a growing number of activities that take place in the healthcare system cannot be easily classified as research or 'non-research' [31, 34, 35, 36]. While the majority of countries have well established infrastructure to pre-empt the implications of national and international regulatory and legislative changes for research activity, this is not replicated for QI.

The lack of national QI ethics frameworks has created a vacuum and a deficit in standardised and best practice guidance in the governance and regulation of QI. This in turn has given rise to a 'spectrum of ethical issues' that mainly revolve around conflict between current regulatory systems designed for research and the flexibility required by learning health care systems that depend on QI [9].

This review suggests that the New Zealand provision of an integrated National Ethical Standards for Research and QI, is a pragmatic solution that could be considered by other countries. When countries place QI ethical guidance outside of their core research ethical frameworks and infrastructure they create ambiguity, differences in organisational responses and legal uncertainty [8, 19, 24, 35]. One of the unintended consequences is that activities aimed at improving services and, ultimately, patient safety may become vulnerable to disruption with the introduction of new regulations or legislation such as GDPR.

Limitations

This was not an exhaustive search of QI guidance documents in the selected countries but it does capture the guidance from the main regulatory bodies. There is a need to review QI guidance in non-English speaking countries to inform best practice. Our review has not captured how countries operationalise the QI guidance or how recent changes has impacted on ethical decision making or clinical practice.

Accepting these limitations, we have made a number of observations to inform this debate going forward (Box 1).

Insert Box 1 Observations to promote best-practice on ethics oversight for QI activity

1. QI and clinical audit should be recognised as core and legitimate activities for clinical staff with appropriate national ethics guidance and infrastructure.
2. To protect patients and clinical staff there is need for national QI ethics frameworks and proportionate ethics review structures that balance patient safety and rights with service improvement activities.
3. Overarching governance by a central agency with responsibility for ethical conduct of research and QI activities is required to ensure that there is appropriate

interpretation and compliance with national and international regulation and legislation.

4. Public engagement should form part of the development of national ethics frameworks and local guidance. Building public awareness and trust requires targeted efforts to improve population health literacy on principles of QI, consent and use of personal data to support learning healthcare systems.
5. Health care organisations need support and infrastructure to provide ethical oversight for low-risk, locally driven QI. Research ethics review boards require frameworks to support consistent decision making for QI activity.
6. In the case of vulnerable groups, guidance is required to ensure that they are not excluded from QI activities (especially low-risk activity) while ensuring their rights are protected.

CONCLUSION

Allowing QI activities to exist in a 'borderline space' between clinical practice and research leaves it vulnerable to disruption due to changes in regulation and legislation. This in turn negatively impacts on health care organisations and clinical staff confidence to lead QI within their services. Our review demonstrates that there is a need for appropriate oversight and responsive infrastructure for QI underpinned by ethical frameworks that builds equivalence with research. We highlighted good practice in the six countries reviewed which provide opportunities for shared learning and the flourishing of QI as a vital part of learning healthcare systems.

Data availability: No new data were generated or analysed in support of this review. The detailed data extraction tables are available from the authors.

Table 1: Sources of information from each country

Country	Resources that were used to inform this review
Ireland	Government of Ireland (2018) *Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations.* [Legislative Act] [12] Health Research Board (2018) *Health Research Regulations 2018 FAQ.* [Webpage] *[25]* Health Service Executive (HSE) Quality and Patient Safety Directorate (2017) *A Practical Guide to Clinical Audit.* [Report] [21] HSE, National Office of Clinical Audit (2019) *GDPR Guidance for Clinical Audit.* [Report] [24]
England	National Health Service Health Research Authority (2017) *UK Policy for Health and Social Care Research.* [*Report, made in accordance with the country's legislative framework*] [18, 29] Dixon, N., Healthcare Quality Improvement Partnership (2017) *Guide to managing ethical issues in quality improvement (QI) or clinical audit projects.* [Report] [19] Healthcare Quality Improvement Partnership (2017) *Using Clinical Audit in Commissioning Healthcare Services.* [Report] [20] National Data Guardian for Health and Care (2016) *Review of Data Security,Consent and Opt-Outs.* [Report] [22] National Health Service (2019) *National Data Opt-Out. [Webpage]* [26] NHS Health Research Authority, The Medical Research Council. Is my study research? [28]]
Australia	National Health and Medical Research Council. (2007, Updated 2018) *National Statement on Ethical Conduct in Human Research. [Report, made in accordance with a Legislative Act]* [17] National Health and Medical Research Council. (2014) *Ethical Considerations in Quality Assurance and Evaluation Activities.* [Report] [23]
New Zealand	National Ethics Advisory Committee (2012) *National Ethical Standards for Health & Disability Research Ethical Guidelines for Observational Studies: Observational research, audits and related activities. Revised edition [Report, made in accordance with the country's legislative framework]* [15] National Ethics Advisory Committee (2019) National Ethical Standards for Health and Disability Research and Quality Improvement [16]
Canada	Canadian Institutes of Health Research (2010), Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada. *Tri-Council Policy Statement. Ethical Conduct for Research Involving Humans.* [*Report, made in accordance with the country's legislative framework*] [14]
USA	US Department of Health and Human Services Office for Human Research Protections (2018) *Federal Policy for the Protection*

	of Human Subjects (The Common Rule). [Legislative Act] [13] US Department of Health and Human Services Office for Human Research Protections. (2018). *Quality Improvement Activities FAQs.* [Webpage] [27]
European Union	European Union. Regulation (EU) 2016/679 (General Data Protection Regulation). 2016 [10]

Table 2: Summary of approaches to ethical oversight of quality improvement and clinical audit activities for each country

	Ireland	England	Australia	New Zealand	USA	Canada
National regulatory body for research	None	National Health Service Health Research Authority (HRA)	National Health & Medical Research Council (MRC)	National Ethics Advisory Committee (NEAC)	Office for Human Research Protections (OHRP)	The Interagency Advisory Panel on Research Ethics *
Is QI activity within the scope of the national document / framework for research ethics?	No; main guidance is contained in the Health Service Executive (HSE) Quality and Patient Safety Directorate (2017)	No;'Audit of practice' and 'service evaluation' are exempt from this framework (QI not mentioned) Section 3.1 (pg 6) Main guidance on ethical issues related to QI and audit is provided by Healthcare Quality Improvement Partnership (HQIP)[19]	Yes; 'Ethical considerations in quality assurance and evaluation' [23].	Yes; National Ethical Standards for Health and Disability Research and Quality Improvement [16]. Integrated research and QI ethics framework. Outlines standards that are applicable for research, QI and evaluation.	No; but limited guidance on OHRP website 'Typically, QI activities are not considered research subject to the HHS protection of human subjects regulations.	No; Limited mention in in Tri-Council Policy Statement: 'In relation to QA and QI studies…. such activities do not normally follow the ethical and consent procedures outlined in this Policy'
Is ethical review required ?	Quality Assurance studies, clinical audits, and service evaluations do not normally require Research Ethics Committee (REC) review	HQIP: Clinical audit or local QI may not require review by an ethics committee but	In many situations, oversight of the activity is required, but ethical review is not necessary [23].	'While some level of ethical oversight is necessary, Health and Disability Research Ethics	If the purposes of a QI activity are limited to (a) delivering healthcare, and (b) measuring and	'..These activities[QA, QI] may still raise ethical issues. In such instances, activities should be

		at the very least requires organisational ethical oversight [19]		Committee review processes are often not the optimal pathway for review of these activities' [16, p20]	reporting provider performance data for clinical, practical, or administrative uses… there is no requirement under these regulations for such activities to undergo review by an Institutional Review Board (IRB),	overseen by independent guidance, other than a Research Ethics Board (REB).
Are criteria for proportionate ethical review / exemption from ethical review provided	No; Staff are advised that ethical advice should be sought if audit practices may be considered intrusive, sensitive, or if there is uncertainty on the ethical implications	Yes: HRA provides and online decision tool to determine if a study is research (3 questions). 1.Randomisation 2.Departure from Standard practice, 3.Generate generalizable/transferable data + HQIP lists 7 criteria for QI/audit to trigger an ethical review but this is not a national standard. (supplemental file)	Yes; 7 criteria to trigger ethical review: (Supplemental file) 1.Infringes the privacy or professional reputation of participants, providers or organisations. 2.Secondary use of data 3.Data collection beyond clinical need 4. Comparison of cohorts 5.Testing non- standard protocol /equipment 6.use of randomisation, control group 7. Targeted analysis of data involving minority/ vulnerable groups	Yes; 8 criteria QI activities are generally low risk. Some factors that may increase ethical risk are when: (16 p 217) 1.it poses additional risks to or burdens on a patient and/or their family or whānau beyond their routine care. 2. the data to be collected is of a sensitive nature 3. secondary use of data/ 4.use of identifiable data 5.use of algorithms – (related to artificial intelligence and machine learning) 6. it allocates interventions	No specific criteria except in above definition	No; These non- REB entities may be professional or disciplinary associations, or within best practices guidelines for such particular disciplines.

				differently among groups 7. it is unlikely to provide direct benefits to patients1 8. it involves body parts or bodily substances		
Is their guidance on consent specific to QI?	Following GDPR: Health Research Regulations (2018)'All researchers that access personal data for health research purposes, including retrospective chart reviews …, are required to obtain the explicit consent of all data subjects'. The National Office for Clinical Audit have provided guidance on when local or national clinical audit may not require explicit consent. (NOCA 2019)	No explicit guidance for QI/Audit) NHS-HRA: Proportionality should be applied to the provision of information to potential research participants; the closer the research is to standard practice, the less need there is to provide patients and service users with detailed and lengthy information	Not explicit: 'Those conducting the activity need to consider a range of issues including consent, privacy, relevant legislation' pg 2	Yes, Participants should be asked for their informed consent if a quality improvement activity imposes more than minimal risk, as defined by categories of risk in these Standards [16, p219].	Yes; Waiver of consent: The HHS regulations protecting human subjects allow an IRB to waive the requirements for obtaining consent when: 1.The risk to the subjects is minimal; 2.Subjects' rights and welfare will not be adversely affected by the waiver; 3.Conducting the research without the waiver is not practicable; 4) If appropriate, subjects are provided with additional pertinent information after their participation.	No explicit guidance in relation to QI/audit
Can ethics committees	Unclear	Not clear;	Yes, (supplemental file)	Yes, strict criteria	Yes (Supplementary file)	Yes for research

grant a waiver of consent for secondary use of patient information in certain circumstances?		A "national data opt-out" was introduced in England in May 2018, as a service that allows patients to opt-out of their confidential patient information being used for research or planning		outlined (supplemental file)		(Supplementary file)

* Comprises Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada,

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