Improving the quality of diabetes care in a real world community context: influences, trends, and the implementation of a model of integrated care

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Declaration

I declare that this thesis has not been submitted as an exercise for a degree at this or any other University. The work, upon which this thesis is based, was carried out in collaboration with a team of researchers and supervisors who are duly acknowledged in the text of the thesis. The Library may lend or copy this thesis upon request.

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Abbreviations

ACE	Angiotensin Converting Inhibitor
ACR	Albumin Creatinine Ratio
AHP	Allied Health Professionals
AMP	Advanced Midwife Practitioner
ANP	Advanced Nurse Practitioner
AOR	Adjusted Odds Ratio
ARB	Angiotensin II Receptor Blockers
BMI	Body Mass Index
BP	Blood pressure
CHD	Coronary Heart Disease
CHO	Community Health Organisations
CI	Confidence Interval
CPD	Continuing Professional Development
CQI	Continuous Quality Improvement
CVD	Cardiovascular disease
DMP	Disease Management Programmes
DNS	Diabetes Nurse Specialist
eGFR	Estimated Glomerular Filtration Rate
EPOC	Cochrane Effective Practice and Organisation of Care group
FTE	Full Time Equivalent
GMS	General Medical Services
HDL-C	High-Density Lipoprotein Cholesterol
HR	Hazard Ratio
ICD-10	International Classification of Diseases 10^{th} revision
ICT	Information Communication Technology
IQR	Interquartile Range
LDL-C	Low-Density Lipoprotein Cholesterol
MDT	Multidisciplinary team
MeSH	Medical Subject Headings
NP	Nurse practitioners
OR	Odds Ratio
OHA	Oral Hypoglycaemic Agent
PHN	Public Health Nurse
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
QI	Quality Improvement
RCT	Randomised Controlled Trial
SD	Standard Deviation
SE	Standard Error
SES	Socio-economic status
SMD	Standardised Mean Difference
SMR	Standardised Mortality Ratios
WTE	Whole Time Equivalent

Acknowledgements

Firstly, a sincere thank you to my two supervisors, Professor Patricia Kearney and Dr Sheena McHugh, for your continued guidance and support over the past three years. Thank you for being generous with your time and always giving me valuable feedback and advice. I have learned a huge amount from both of you over the course of the PhD and I am really very grateful. Also, a sincere thanks to my other co-authors who have guided and advised me on different pieces of work during the PhD; Dr Anthony Fitzgerald, Professor Sean Dinneen, and Katie Murphy. Many thanks to Katie, and Marie Courtney, Professional Development Coordinator for Practice Nursing, for all your help when I was organising focus groups. A big thank you to all the nurse specialists who took part in the two studies in this PhD, and who were willing to make time in very busy schedules to engage with the research. You are an inspiring and motivated group and I have learned a huge amount from you.

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Abstract

Background and aim

Despite consensus on what optimal diabetes care should look like, this is not always achieved in 'real world' practice. Attention has shifted from solely testing the *effectiveness* of interventions to improve diabetes care, to also trying to uncover the influences, the *how and why* they work. Integrated care, organising care delivery within and between services, is a strategy to improve the quality of diabetes care; however, few studies have examined its implementation and whether quality improvements can be sustained. This thesis aims to understand whether and how integrated diabetes care can improve and sustain the quality of care in a real world community context using two approaches to integrated care in the Irish health system, a bottom-up locally-driven (structured primary care) initiative and recent top-down nationally-led reforms (a new model of integrated care supported by diabetes nurse specialists (DNS)).

Methods

A systematic review comprising a narrative synthesis and meta-analysis was conducted to identify the evidence on physician and practice factors associated with the quality of diabetes primary care management. Trends in process of care recording and intermediate patient clinical outcomes (i.e. risk factors; blood pressure, cholesterol, HbA1c, creatinine) were examined over time using a series of cross-sections (1998, 2003, 2008, and 2016) from an existing structured primary care initiative. Data from the original cohort enrolled in this programme in 1999, were used to examine all-cause mortality and survival among people with diabetes, comparing mortality to the general population using Standardised Mortality Ratios (SMR). Excess mortality was compared with international estimates. The intended role of both hospital and community DNS is to support integrated care by managing patients with complicated type 2 diabetes, liaise with other professionals, deliver professional and patient education, and clinics. A national survey of DNS was conducted to examine their role. Interviews and focus groups were conducted with DNS, purposively sampled by region and type (hospital or community-based), to understand how they support the implementation of integrated care, including what factors influence their behaviours.

Results

Physician factors (female gender, younger age, and a higher volume of patients with diabetes), and practice factors (Electronic Health Record (EHR) and low deprivation) were associated with higher quality of care. Process of care recording delivered by the structured care programme improved significantly over time ($p < 0.001$), although there was levelling-off in later years. Mortality among the original cohort was greater than the background population (overall SMR = 1.20 (95% Confidence Interval: 1.01-1.42)) though lower than some international estimates. Most DNS preformed their intended role. However, nurse-led clinics had variable support from

other specialities, and access to the community DNS service was not available to all GPs. From qualitative analysis there was evidence that community DNS had to adapt and use initiative to make integrated care ‘workable’: responding to the lack of an integrated EHR between primary and secondary care by using workarounds, adapting to the lack of multidisciplinary team “*safety net”* in the community by working more autonomously, linking in with professional networks as an alternative ‘safety net’, managing role misconceptions by colleagues and managers, and adapting their service to “*blend in”* with differences in diabetes care organisation and experience at practices.

Conclusions

Integrated diabetes care *within* primary care is feasible in a real world community setting, achieving improvements over time, and integrated care *across* services is ‘workable’ through innovation and adaptation in a complex healthcare context. To scale up integrated care nationally, making this model available to *all* patients, practices may need targeted support, based on physician practice profile or other factors (e.g. information systems, deprivation, experience) to improve and organise diabetes care delivery. To embed and sustain integrated care requires system-level investment in building a supportive culture (e.g. acceptance of new roles, supporting professional networks) and infrastructure (e.g. integrated EHRs, access to specialists in the community or across boundaries). Integrated care should continue to be evaluated as services are delivered, recognising the local and system-level context (e.g. physician factors, EHRs, role understanding, available community resources) can challenge efforts to improve care. There is a need to learn from service delivery as it is implemented and consider how to guide adaptations to ensure integrated care in the real world is both ‘workable’ and effective.

So there has been an epidemic of type 2 diabetes as everybody knows and hospitals are not equipped to provide the care that all patients with diabetes need all the time when it could be provided much more efficiently and effectively by the patient’s GP. So GP's like it, patients like it, consultants like it too, other allied health professional like it and the government likes it, it’s good policy, so how do you actually implement that?

- National stakeholder participating in an evaluation study on the National Clinical Programme for Diabetes) [1].

1 Introduction

1.1 Introduction

The number of people affected by type 2 diabetes is growing rapidly worldwide [2, 3], the result of an aging population and increasing levels of obesity [3, 4]. The co-morbidities and rate of complications [5, 6] associated with diabetes place a significant financial burden on health systems [7]. People with diabetes also have higher mortality compared to people without the condition [8-12].

Integrated care is seen as an effective way to deliver high-quality care for people with chronic diseases like type 2 diabetes [7, 13, 14]. Integrated care involves organising and co-ordinating management between and within care settings [15]. Diabetes affects multiple organ systems, requiring the involvement of healthcare professionals from different disciplines and settings to achieve effective management [16]. This makes diabetes the exemplar chronic condition to study integrated care as a strategy to improve the quality of care.

Internationally, integrated care for chronic conditions, including diabetes, has involved structuring care to deliver routine care for uncomplicated diabetes, enhancing specialist support in primary care, and co-ordinating management across primary and secondary care [17-19]. This change in care delivery has required investment in primary care to better support chronic disease management in the community [20, 21]. The specialist nurse has become central to supporting chronic disease management in primary care and facilitating integration between settings [22], with the role increasingly moving into community settings [22].

While integrated diabetes care has been shown to improve quality in the short term as part of trials or evaluative studies [17, 23-25], we do not know whether quality improvements are sustained over time in everyday practice. Moreover, effectiveness is not always achieved in different healthcare or policy contexts [26]. There is consensus on the core aspects of optimal diabetes management, however, a gap remains between ideal and actual practice [21]. In short, while we may know what integrated diabetes care should look like, the question is whether it can be successfully implemented and sustained in a real world community setting.

Approaches to improve and integrate diabetes care in Ireland include both long-standing, locally driven, and more recent, nationally led changes, which build on local efforts. Local primary care initiatives provide more structured care within general practice for people with diabetes [27]. A number of national reforms have been introduced to support routine management in primary care and better integration of care between primary and secondary care, including a model of integrated care supported by new 'integrated' diabetes nurse specialists (DNS) [28].

As the Irish health system embodies many real world challenges for integrated care, studying these approaches presents a way to learn whether and how integrated care improves quality in a complex service context. There is an opportunity to learn from existing initiatives; how they perform over time, and how enrolled patients fare with respect to intermediate and long-term outcomes. DNS are central to the national strategy to improve and integrate diabetes care, yet unlike other countries [29-31] there is a dearth of information on how the DNS service currently operates in Ireland. Understanding the role DNS perform is important to inform how it can be best utilised within the specific health system to support integrated diabetes care, and to determine whether there are aspects of service delivery which need to be addressed. Previous work highlighted potential challenges to implementing integrated care in Ireland from the GP perspective [32]. Now that integrated care has been introduced, there is a need to understand its delivery, whether it is working as intended, and whether and how this model should be better supported.

1.2 Aim

This thesis aims to examine whether and how integrated diabetes care (structuring primary care management and improving coordination across primary and secondary care settings) can improve and sustain quality of care in a real world community context.

1.3 Objectives

1. What physician and practice factors (contextual influences) have been associated with the quality of care in 'real-life' primary care?
    - Systematically review the evidence on the relationship between physician- and practice- level factors and the quality of diabetes care (type 1 or type 2) in primary care (Paper 1/Chapter 3)

2. Does a structured care programme to integrate and improve diabetes management in primary care, implemented in 'real-life' practices over a long period, deliver improvements in the quality of care and outcomes for patients?
    - Examine trends in the quality of care (processes of care) performed for people with type 2 diabetes and benchmark the programme against international standards over time. (Paper 2/Chapter 4)
    - Examine all-cause mortality (type 1 or type 2 diabetes) compared with the general population and conduct a survival analysis to examine predictors of mortality (Paper 3/Chapter 5)

3. How do DNS support and implement integrated care between primary and secondary care?
    - Examine current DNS service provision, specifically aspects of the DNS role which are important in the integration of care and compare these

by type of DNS (hospital or community-based) and region (Paper 4/Chapter 6)

- Explore how they support the implementation of integrated care in a complex health system and respond to challenges and opportunities working within and between settings. (Paper 5/Chapter 7)

The research questions and corresponding studies are summarised in **Figure 1**.

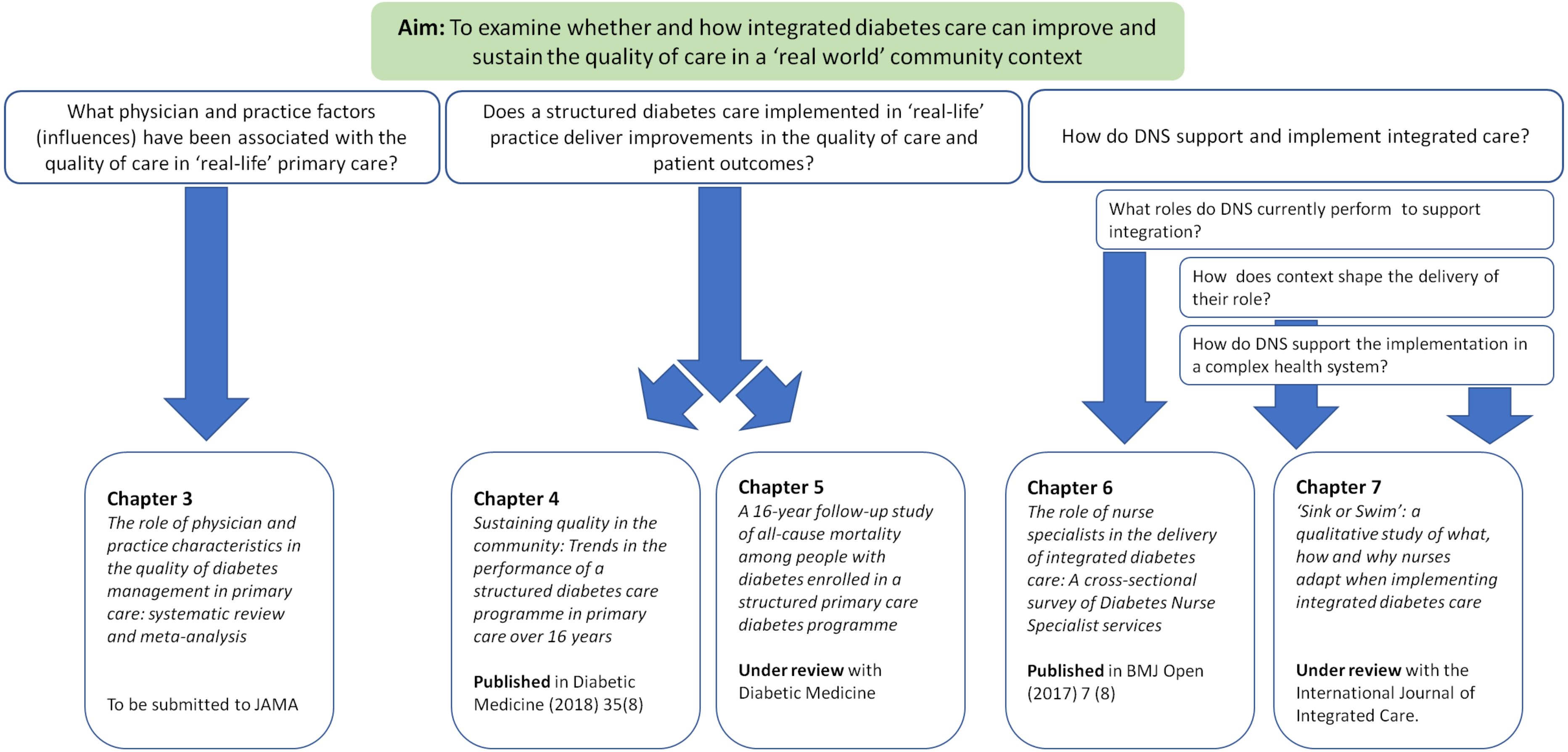

Figure 1 Overview of thesis including research questions and corresponding studies

Abbreviations: DNS, diabetes nurse specialist

1.4 Thesis outline

This thesis contains eight chapters. Five are studies which address the aims and objectives outlined above, with chapters 3-7 corresponding to individual research (Figure 1). Chapter 2 introduces diabetes as an exemplar for studying quality improvement (QI). The chapter provides an overview of QI, introduces integrated care as an 'organising principle' to improve the quality of chronic disease management, and reviews its effectiveness as an intervention to improve the quality of diabetes care. The challenges of implementing integrated care are mentioned. Lastly, the chapter provides an overview of integrated diabetes care in Ireland. Chapter 8 provides a discussion of the main findings, the strengths and limitations of the thesis and makes recommendations for future research.

1.5 Authors contribution

I was the lead author of each research paper presented in Chapters 3, 4, 5, 6 and 7. This involved formulation of the research question for each chapter, literature screening, data collection and analysis, and drafting each manuscript. My supervisors, Prof. Patricia Kearney and Dr Sheena McHugh guided me on the study design, data analysis and interpretation for all research papers. Chapters 4 and 5 involve data from the Midland Structured Diabetes Care Programme. The audit data for this work were collected in 1999, 2003, 2008 and 2016 by nurse specialists working with the programme. Together with my supervisors I collaborated with Dr Velma Harkins and Paul Marsden to plan data collection for the 2016 audit. Data entry was carried out by Paul Marsden, Public Health Researcher at the time. Before analysis I performed data checks and corresponded with Paul Marsden to resolve any errors and discrepancies. For the analysis conducted in Chapter 5, I collected additional data on cause and date of death from national death certificates stored at the General Registrar Office. Together with my supervisors, Dr Anthony Fitzgerald advised on the statistical analysis for this work. Chapter 6 involves a national survey of diabetes nurse specialists. The survey was drafted by Dr Sheena McHugh before I began my PhD. I finalised the survey, constructed the sampling frame, administered and coordinated the survey, cleaned and analysed the data. Katie Murphy, Diabetes Nurse Facilitator was co-author on this paper. She advised on interpretation and reviewed the final draft. Prof. Sean Dinneen, Clinical Lead for the National Clinical Programme for Diabetes, was co-author on the work in Chapter 7. Prof. Dinneen reviewed and advised on the paper. Julie Barrett and Niamh McGrath were second coders for the qualitative data in Chapters 6 and 7 respectively, and reviewed drafts of these papers. Clodagh O'Donovan and Mavis Nomsa Mtshede were second reviewers during the screening stages of the systematic review (Chapter 3). Co-author contributions in Chapter 3, 6 and 7 are reported as part of the methods sections.

2 Background

2.1 Diabetes as the exemplar chronic condition

Diabetes is often used as an exemplar to study improvements in the management and coordination of care for complex chronic conditions. It is characterised by high prevalence which places a substantial burden on global health systems. The condition is associated with a number of co-morbidities and requires on-going management by primary care with input from a variety of specialist care providers. While there is consensus on what good quality diabetes care should look like, this is not always achieved in real world practice [21, 33].

Diabetes is a chronic disease characterised by hyperglycaemia resulting from defects in insulin secretion, use, or both [34]. While type 1 diabetes arises from a problem with insulin production, type 2 diabetes results from ineffective use of the insulin produced [34]. The rise in global prevalence [2, 35-37], which has almost doubled in the past 30 years [36], together with the demand management places on health systems, has led diabetes to be called one of the greatest challenges of the 21st century[38]. In Europe, the overall prevalence in 2013 was 8.5% [21]. In Ireland, the prevalence of diagnosed diabetes among adults has increased from 2.2% in 1998 to 5.2% in 2015 representing a mean increase of 0.17% per annum [37].

Diabetes is associated with a number of serious microvascular (diabetic retinopathy [39-41], neuropathy, and nephropathy, including kidney failure [42, 43]) and macrovascular (Coronary Heart Disease (CHD), stroke, and peripheral vascular disease) complications [5, 6, 44]. People with diabetes have up to a threefold increase in all-cause mortality compared to those without diabetes [8-12, 45]. This excess mortality is substantially higher with worsening glycaemic control [46, 47], renal function [47], and among those with lower socio-economic status (SES) [48], younger age [11, 46-50], and women [9, 48]. Complications are largely preventable if the condition is well-managed and risk factors (glucose levels, lipids, blood pressure (BP)) are well-controlled [51-55]. Declining rates of complications [56, 57] may reflect improvements in care, including, but not limited to, a greater focus on delivering more structured chronic disease management, increased opportunistic screening, improvements in medication and treatments over time, and better management of risk factors. The declining complication rates are against the backdrop of other population-level changes, including declines in smoking and CHD [58-60]. There is also evidence to suggest that excess mortality has declined in recent years, for example, in Denmark [61], Sweden [62], UK [49, 63], and US [64]. However, there is variability in the extent of excess mortality and its decline across countries [57, 65].

The core elements of good diabetes management are well-established: 1) focus on managing blood glucose levels, BP, and lipids, and; 2) carrying out regular screening for complications. These processes are facilitated through patient registration, recall and regular review, the provision of protected time and commitment to following a standard protocol [66-68]. Individuals with diabetes often have other chronic diseases and medical problems [69], making management more challenging. Diabetes requires on-going monitoring and treatment of risk factors which can be largely delivered in primary care. However, the range of complications of diabetes means that good management requires input from several specialities, including podiatry, dietetics, cardiology, vascular surgery, ophthalmology and endocrinology. This necessitates effective coordination of care across multiple health care professionals, making it a good condition to explore efforts to improve the quality of chronic disease management.

2.2 Quality improvement

Improving the quality of care is a goal of health systems worldwide, gaining substantial attention since the release of the seminal report, “Crossing the Quality Chasm”, in 2001[70]. QI can be described as “systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of health care” [71]. A key part of QI is measurement [72, 73]. However, quality can be defined in different ways and may consist of many different dimensions. According to the Donabedian model, quality can be assessed in terms of structure (organisational aspects of the health system in which care is delivered), process (the delivery and receipt of care), or outcomes of care (consequences of care) [74, 75]. For individual patients, Campbell et al. reduce these to two all-encompassing dimensions of quality of care: access (availability, affordability) and effectiveness (clinical, interpersonal). For populations, they suggest three additional factors play a part; equity, efficiency and cost [74].

Suitable quality indicators need to be measurable and supported by existing evidence or expert consensus; ideally they should be acceptable, feasible, reliable, sensitive to change, and have predictive validity [73]. Developing and choosing quality measures will depend on the level at which improvements are envisioned (population vs. individual patient), the perspective one wants to reflect (e.g. patients or professionals), and the aspect of care deemed most important for the QI intervention; is the end goal to improve processes or outcomes [72], keeping in mind that an improvement in processes does not guarantee that outcomes will improve also [76, 77]. Balance also needs to be struck between using acceptable indicators and those which are feasible; measures of quality can be driven by data availability rather than other considerations (epidemiological, clinical) [78]. The quality of diabetes care delivery is often measured in line with the Donabedian dimensions.

2.2.1 Achieving quality improvements in practice

Achieving QI in a complex health care system is far from easy, and delivering change in the care of chronic diseases is cited as particularly challenging [79]. 'System inertia', whereby systems tend to continue to do what they already do despite change, is a central problem of improvements in healthcare [80]. This inertia includes *clinical inertia* or 'satsificing' at the physician level, making a 'good enough' decision under the strain of competing demands or multiple goals, and *organisational inertia* where static or inflexible organisational structures struggle to achieve change on a larger scale. Healthcare systems are complex, and, as such, unpredictable, adaptive and self-organising [81], a challenge when introducing change. Coiera suggests system inertia is "natural emergent behaviour" of a complex system and the competing priorities therein, and/or may simply reflect a lack of resources [81]. That is, a reform may be a good idea in principle but the behavioural changes necessary to deliver it will not be achieved in an over-constrained system.

Given this challenge of introducing change, attention has shifted from solely testing the *effectiveness* of QI interventions, to also trying to uncover the influences, the *how and why* of interventions work [82]. There has been a shift from a passive translation of evidence into practice (e.g. diffusion of innovations theory) to more engaged approaches [83], with research in recent years focusing on the development of strategies to guide and support implementation to bridge the 'second translational gap' or 'evidence to practice' gap [84, 85] between knowing what works in interventional studies and trials, and making that work in real life [83].

As such, QI operates on a continuum from finding out what works, to understanding how and why it worked or not [86]. The ultimate aim is to be able to translate research evidence into everyday practice, improving the quality of care through embedded and sustained change. QI interventions which are effective in one setting need to be delivered in a way that they bring about similar improvements in a different setting[86-88]. For this reason, understanding the role of context, described as a 'poorly understood mediator of change' [89], is essential in QI.

There are many dimensions to context [89-91] which can be categorised as the outer context (e.g. the extent to which organisations are networked, external polices and incentives) and the inner context (e.g. social architecture, intra-organisational networks and communications, culture) [92]. Examining how models of care work within the specific context provides insight into how to implement, embed and sustain them [93]. The context into which a QI intervention was originally introduced can change over time; therefore it has been suggested that efforts to study QI interventions should consider testing effectiveness in a variety of contexts and under different conditions, and use repeated measurements over time [94]. Contexts are 'dynamic', and a context which supports implementation of an intervention in one area may, in another, act as a barrier [93]. As such, there is value in going beyond identifying contextual barriers and facilitators, to understanding how, and the mechanism by which, they act to influence implementation, understanding the interplay between context and intervention, and how the intervention achieves outcomes [95]. Summarised by Ovretveit [87, 96], the key questions in QI are:

- Does it work?
- Will it work here?
- What conditions do we need to implement and sustain it?
- Can we adapt it?

The Consolidated Framework For Implementation Research (CFIR) was developed by Damshroder et al., in an effort to combine the existing implementation theories, elements of which often overlap.. Although it is not used as an overarching guide for the studies in this thesis, the framework provides a structure for describing the contextual factors identified in the qualitative work (Chapter 7). It was considered a good choice to conceptualise the context for implementation given that it takes account of older theories. The questions proposed by Ovretveit, rather than a specific theoretical framework, act as a guide for the pieces of work conducted as part of this thesis. The findings from each study are brought together in Chapter 8 to help address these questions as they relate to integrated care as an intervention to improve the quality of diabetes care in a real world context.

2.2.2 Integrated care as an intervention to improve quality

In response to the converging issues of aging populations and the growing prevalence of chronic disease, health systems have focused on integrated care as an 'organising principle' [97-99] to deliver better quality and more cost-effective chronic disease management. Referred to as the "international health care buzzword" [100], in essence, the aim of integrated care is to organise and coordinate care delivery within and between healthcare settings, guided by an overarching principle that patients receive the "right services" in the "right place" appropriate to their needs [15]. There are several different ways of classifying integrated care, according to level, orientation, type, and focus [98, 101]. Definitions of the terms used in this thesis are provided in

Table 1. Ideally, both horizontal integration (integration or coordination *within* one organisation or setting) and vertical integration (integration or coordination of care *across* settings) are required to achieve a true coordination and organisation of care for patients [102]. The definition of integrated care adopted by the recent Slaintecare report focuses on quality, patient access, and services being well-organised [103].

<u>Integrated care is:</u> "Healthcare delivered at the lowest appropriate level of complexity through a health service that is well organised and managed to enable

comprehensive care pathways that patients can easily access and service providers can easily deliver.”

Table 1 Definitions relating to integrated care

Term	Definition
Integrated care	An organising principle' for how care is delivered [97-99].
Integration	Methods and strategies used to integrate care [97-99].
Integrated care – level [101].	
Micro	Integrating care at the clinical level e.g. coordinating care for individual patients or conditions, considered to be more disease-focused integration.
Meso	Integrating care at the organisational level e.g. promoting collective action of organisations, and the different professionals within those organisations, across the care continuum for a patient group.
Macro	Integrating care at the systems level e.g. to meet the needs of populations.
Integrated care – orientation [101].	
Horizontal	Strategies to link or integrate professionals or organisations at the same level of care, for example integration or coordination *within* one organisation or setting (e.g. primary care).
Vertical	Strategies to integrate professionals or organisations at different levels, for example integration or coordination of care *across* settings (e.g. between primary and secondary care).
Integrated care – types [100, 101].	
System	Rules and policies within a system.
Organisational	Coordination across different organisations.

Professional	Coordination of care across different professional disciplines.
Service or clinical	Coordination of services.
Functional	Integration of support or infrastructure e.g. financing, information technology.
Normative	Alignment of values, shared vision, culture and attitudes.

2.2.3 Integrated diabetes care

To integrate chronic disease management health systems have focused on strengthening primary care in terms of accessibility, resources, and capacity, and improving the co-ordination and integration of care between different settings: the community, out-patient/ambulatory and in-patient settings [20, 21]. Efforts to integrate *diabetes* care typically focus on improving primary care management [18, 104-107] (e.g. establishing disease management programmes), and/or care coordination between primary care and specialist services [17-19, 108] (e.g. developing intermediary care settings or roles), strategies which represent the horizontal and vertical *orientation* of integration respectively. Specific approaches used also represent different *types* of integration (Table 2).

Table 2 Types of integration used in strategies to improve diabetes care

Type of integration	Examples
Functional	• Shared budgets, financial incentives [104, 106, 109, 110]. • Integrated information systems [18, 104, 111].
Professional	• Intermediary care teams and/or individual clinicians working at the interface of community and secondary care [17-21, 107, 112, 113]. • Establishment of multi-disciplinary teams [109, 114]. • Joint care planning or shared communication [105, 108, 109]. • Task delegation [115, 116] or role expansion [117-119].
Service or clinical	• Coordination of care processes through agreed clinical care standards and guidelines [18, 104-107].

Some of these align with QI strategies classified using the taxonomy developed by the Cochrane Effective Practice and Organisation of Care (EPOC) group [120] (Appendix 1 Table 14). This taxonomy groups interventions by whether they relate to healthcare delivery, financial, or governance arrangements.

Different interventions are sometimes considered synonymous with integrated care, including 'disease management', 'case management' 'managed care', 'coordinated care', 'shared care', 'structured care', 'comprehensive care', 'multidisciplinary care', 'organised and coordinated care', 'team care', 'managed care cooperation' and 'chronic care models' [98, 100, 121-123]. Some definitions are included in Appendix 1 Table 15. What these definitions all have in common is that they align with the broad goal of integrated care, to better organise and coordinate care to improve outcomes. The focus of this thesis is integrated care in the community, comprising: 1) horizontal integration within one service through a multifaceted structured diabetes management programme and; 2) vertical integration, co-ordinating management across primary and secondary care through role expansion and task shifting of the DNS role.

This approach to integrated care has elements of disease management (i.e. taking a systematic approach to care), structured care (i.e. multifaceted interventions focused on structuring and organising care in general practice), and shared care (i.e. which can involve clinics run by specialists in primary care; liaison between specialists and primary care professionals) (Appendix 1 Table 15). As such, the next sections focus on improvements in the quality of diabetes care, and the existing evidence of the effectiveness of interventions to specifically organise care delivery in primary care, and coordinate management across settings.

2.2.4 Quality of diabetes care

The quality of diabetes care delivery is often measured in line with the Donabedian dimensions (Section 2.2), focusing on 1) structure, resources, infrastructure, staffing); 2) processes; recording of clinical tests performed, intermediate clinical outcomes or risk factors (e.g. BP, HbA1c, cholesterol), or screening for complications, and; 3) outcomes e.g. mortality, complications, quality of life, patient satisfaction. As mentioned in Section 2.2.1, delivering change in chronic disease management is particularly challenging, and indeed interventions to improve the quality of diabetes management are not always successful, sometimes with limited impact on risk factors [23, 124]. Changes achieved by these interventions also may not be *clinically* significant. For example, in their review of diabetes management programmes, Egginton et al. reported a statistically significant, albeit minimal, change in HbA1c (weighted difference in means -0.21%, 95% CI -0.40 to -0.03, $p < 0.03$) and LDL-cholesterol (weighted difference in means -3.38 mg/dL, 95% CI -6.27 to -0.49, $p < 0.02$) [125]. Internationally, risk factor control among people with diabetes continues to be suboptimal and variable [126-130].

For this reason, there is interest in understanding what factors might influence the quality of diabetes care. Existing research has synthesised the qualitative evidence on barriers and facilitators to effective management of diabetes [131-133], highlighting the role of factors at different levels: the clinician, i.e. lack of time and workload [132], communication style [131], competencies and knowledge [131, 132], and attitudes [131], and challenges managing co-morbidities [132]; organisation, i.e. information technology [132], protocols to structure care [132], division of labour ambiguities within the team [132, 133], and; patient knowledge, i.e. language, finances, social support and co-morbidities [131]. While a number of quantitative studies have investigated whether specific physician and/or practice factors are associated with measured quality of care [134-151], these studies have not been formally synthesised.

2.2.5 Interventions to organise care delivery in primary care

Given that primary care provides first-contact, continuous, comprehensive and coordinated care [152] it serves as “a starting point from where to improve and integrate care” [101, 153]. Over the past few years, health systems have moved away from reactive, episodic management in the acute setting and shifted management of chronic disease to the community where patients can be managed at the lowest level of complexity [29].

Strategies to structure and improve the quality of diabetes care within general practice can include a mix of different elements, registration systems [110, 154], audit and feedback [155], clinician reminders [154, 156], and patient [110, 155, 156] and professional education[110, 155]. There appears to be consensus that multi-component interventions do better than single component interventions for improving diabetes management [157, 158]. However, their multifaceted nature means it is difficult to determine which *specific* elements have led to improvements in the quality of care and patient outcomes. Some studies have categorised interventions and tried to elucidate the key components [23, 158-161]. A review conducted in 2008 determined that studies specifically involving delivery system design and/or self-management support had the greatest impact on clinical outcomes i.e. HbA1c, BP and total cholesterol [160]. Both reviews and primary studies, indicate that components at the level of health system organisation have delivered improvements in clinical outcomes [17, 23-25, 158, 161-163], processes [163], reduced referrals to secondary care [112] and preventable hospitalisations for diabetes-related complications [164]. These components included team changes [158, 161], for example, access to a multidisciplinary team [17, 25, 164]; case management [23, 158] (particularly case managers who can make some medication changes without waiting for approval from physicians), including provision of care in general practice by specialists [24, 112, 165] or the partial replacement of physicians by nurses in organising care [162, 163]; patient education and self-management [161]; interventions to prompt recall and review of patients, including electronic registries and tracking systems [161, 163] and; relay to improve patient-provider communication [161].

Reviews of the evidence on multifaceted interventions to improve and organise diabetes management [23, 124, 125, 157-161, 163, 166-172] suggest these approaches can improve quality, both clinical outcomes [23, 125, 158, 160, 161, 168-171], and receipt of care processes [23, 167, 168, 171]. Specifically, these approaches have improved HbA1c levels [125, 158, 160, 161, 168-171], with pooled mean reductions of 0.46% [173] to 0.22% [125], blood pressure [23, 160, 161, 168], with a mean differences of 2.2mmHg [173]to 3.1mmHg [23], and blood lipid concentrations [23, 125, 160, 161], with pooled mean differences in LDL of 0.1 mmol/L [23, 161]. These approaches have also improved the receipt of care processes: increased the proportion receiving HbA1c test by 15.6% [167]; the likelihood of eye tests[23, 167, 168, 171], with relative risk (RR) of 1.22 [23] to 1.88 [168]; foot exams [23, 167, 168, 171], with RR of 1.27 [23] to 2.11 [168], and renal function checks (RR = 1.28) [23].

However, not all studies included in these systematic reviews reported improvements in clinical outcomes. Baptista et al. found only 6 of 12 included studies identified an improvement [172]. In a review of professional, organisational and patient-centred interventions in primary care categorised according to the EPOC taxonomy, Seitz et al. found only 17 of 45 included studies reported a significant improvement in glycated haemoglobin (HbA1c), and 11 of 32 reported a significant improvement in systolic BP and/or diastolic BP [166]. Norris et al. reported insufficient evidence of the effect of case management interventions on lipid concentrations and BP[167]. Lastly, a review of interventions found little impact for people with prevalent type 2 diabetes, only identifying improvements in those with screen-detected newly diagnosed diabetes [124]

Review authors highlighted some issues with the quality of the existing evidence. A review of interventions involving components of chronic care model, reported just 59% of included randomised controlled trials (RCT) were of high quality [173], while a more recent review of care models in the US, reported the quality of most RCT as fair [125]. Other reviews highlighted specific issues; the inability to blind participants [125, 161], contamination [125, 161], poor reporting of allocation concealment [23, 125, 161], and inadequate (poor reporting or incomplete) follow-up [125, 158, 161]. Pimouguet et al. also considered the likelihood that findings may be underestimated given that usual care in control groups in RCTs can be better than that provided in everyday clinical practice [170]. A further issue with the existing evidence is the range of different methodologies and outcomes across studies which makes it challenging to come to conclusions about effectiveness [168]. The effectiveness of strategies may also depend on baseline control; a review by Tricco et al. found team changes, case management and self-management promotion were most effective strategies where patients had baseline HbA1c of over 8%, while facilitated relay, team changes, patient reminders and electronic registers of patients were more effective where baseline HbA1c was 8% or less [174].

Mortality has been infrequently used as an outcome measure in studies of interventions to improve management of diabetes [98, 159, 166, 175] and few studies have examined mortality using data from patients enrolled in structured primary care programmes [119, 175, 176]. While these have examined predictors of all-cause mortality [119, 176], they have not compared mortality with the general population. One Danish study which conducted six years follow-up of a randomised trial of a structured programme involving a number of changes to improve primary care organisation, did demonstrate an improvement in intermediate clinical outcomes. However, it was underpowered to detect a difference in complications and all-cause mortality between intervention and control groups [175].

2.2.6 Effectiveness of interventions to improve coordination

Some reviews have focused on specific interventions to improve coordination across settings[108, 116]. A Cochrane review of shared care interventions involving one or more of the following, liaison meetings, shared care record cards and computer-assisted shared care [177], and excluding those without ongoing joint management between settings, was inconclusive regarding effectiveness, with the authors suggesting this could be due to the short follow-up time of the included studies [108]. A review of 15 trials, reported that 'transmural care' (a Dutch approach to care coordination characterised by agreements between GPs and hospital specialists on the nature of collaboration, clarity on clinical roles and responsibilities and retention of sub-responsibilities) can be effective, albeit more so for process rather than clinical outcomes [116]. This review included studies of DNS working transmurally at the interface of primary and secondary care. The evidence was less conclusive for interventions involving task delegation or allocation to a professional with a lower level of training [116], for example, a review of task allocation from specialists to diabetes nurses, demonstrated only short-term effects on HbA1c [178].

Internationally, the nurse specialist has become an increasingly important part of interventions to integrate care across the continuum for chronic disease [22, 106, 179-185], evolving from its original focus on patient education to a more specialised and autonomous role [31, 186-188]. By engaging in liaison with other services and coordinating care between different specialties and providers [24, 107, 189, 190], the nurse specialist has a central part to play in the delivery of integrated care. The role of the nurse specialist in the community has expanded [19, 22, 107, 112, 115]. Models of 'vertical substitution' involving task shifting between professionals at different levels of expertise (e.g. GPs to nurses (practice nurse, nurse specialists, nurse practitioner specialised in diabetes) [24, 112, 115, 162, 191-193]), or intermediary care provided by multidisciplinary teams including DNS [112, 115], have delivered favourable results in terms of clinical outcomes [24, 115, 162], inappropriate referrals to secondary care [112], and outpatient attendance [193].

2.3 Challenges of implementing integrated care in complex real world settings

While there may be growing interest in integrated care as way to achieve quality and efficiency in care delivery, it can be difficult to achieve in practice [106, 194]. Gaps in the quality and provision of diabetes care remain despite a consensus on optimal management [21, 33]. The effectiveness of chronic care models is not always demonstrated [108, 124] and may be variable [168].

One reason why it can be challenging is that models of integrated care for chronic diseases are introduced into systems which are configured for the delivery of acute and episodic care. In short, the real world health care context is complex, often characterised by fragmented services, with divisions between primary and secondary care services [109, 195], not only in terms of funding and delivery models [106, 195], but with respect to how information is shared and managed [106, 195-198]. Moreover, QI interventions which integrate and structure care for chronic conditions like diabetes, can often be multifaceted, creating added complexity when trying to implement change [124]. For this reason, the transferability of effective integrated care models across settings or contexts, 'scaling out', is a challenge. Models of integrated care for long term conditions which are successful in one setting may not achieve the same outcomes when transferred to a different healthcare and policy contexts [26].

2.3.1 Sustaining quality of care delivery over time

A second issue is that while improvements may be achieved over a short time period¸ they may not be maintained over longer periods [168]; sustaining effectiveness over time can be difficult. The end goal of integrated care is to achieve a system-wide reconfiguration which can be sustained as part of 'everyday' practice. However, most studies examining integrated diabetes management in primary care have a relatively short follow-up [108, 117, 118]. Few can demonstrate sustainability of structured care models in everyday practice [199] particularly over a longer period, of 10 years or more [119, 200, 201]. In their review of study heterogeneity in chronic care management programmes, Elissen et al. identified variation in the length of follow up. They suggest this is a particularly important given that delivery of these models require changes to behaviour, organisation and culture (e.g. self-management promotion) which must be embedded over time [168]. These types of changes may be effective [169, 174], but are potentially difficult to sustain over longer time periods. In general, few studies examine sustainability [93]; this is generally beyond the remit of most interventional studies and services research [202], and it is a topic that has only recently gained more traction [202, 203].

2.3.2 Barriers and facilitators to integrated care

Given these challenges, there is interest in understanding which factors can hinder or support integrated care delivery. Broad principles for successful integrated care have been outlined by Suter et al. (Table 3). These were consistent with a recent review of integrated models of care, which also cited workforce stability, professional identity, role boundaries and hierarchies, staff training, and patient engagement, as key factors influencing the implementation of integrated care [204]. Internationally, integration has been supported by: 1) shared values between organisations and individuals [198], a culture of interdisciplinary work [198, 205], willing and motivated providers [32, 206] or senior leaders 'champions' [206]; 2) a focus on local, rather than top down planning [207], affording flexibility to identify [206], meet local population needs [208], and to be able to capitalise on local professional (GP) networks to implement service developments [207], and; 3) funding models which remove competition between individual providers [207] incentivise guideline adherence [18] or reduce the burden of out of pocket expenditures for patient attending general practice [209].

In contrast, factors hindering integration include: 1) a culture of 'silo-working' [198, 205] tension between primary and secondary care settings and building new relationships [32, 210], and no tradition of interdisciplinary work [206]; 2) limited financial support available to GPs [206]; 3) unlinked information systems across settings [18, 196, 198, 210-212], and; 4) the complexity of the intervention and burden of administrative work to deliver it [206, 210].

Few of these studies specifically looked at barriers and facilitators to implementation, and the part context plays in the delivery of integrated *diabetes* care [18, 32, 206, 210, 213]. Existing studies suggest there are system [187, 214-218] and organisational level [185, 214, 216, 218] barriers to the nurse specialist role. However, none have focused on understanding how the nurse specialist role operates within the health system to support delivery of integrated care [192], and what challenges might be inherent in a new way of working to integrate care through provision of intermediary care and role expansion.

In short, we have a sense of what high-quality integrated diabetes care should look like, that it can be an effective improvement strategy, at least in short-term evaluative studies. However, the critical question is can we successfully implement and sustain this intervention to improve quality in a real world setting.

Table 3 Principles for successful integrated care
1. A shared patient-centred focus and philosophy 2. Providing comprehensive services across the care continuum 3. Ensuring geographic coverage i.e. system responsibility for an identified population 4. Facilitating standardised delivery of care irrespective of where or by which professional a patient is cared for (e.g. through clinical guidelines and pathways) 5. Monitoring performance (e.g. examining processes and outcomes at different levels)

6. Information systems that can improve communication and collect and track data and activity
7. Shared organisational culture, vision and leadership committed to integrated care
8. Integrate physicians such that they have a role in the implementation and reforms
9. Governance and organisational structures that promote integration
10. Funding that provides enough resources to sustain integration and service reform, and funding mechanisms that promote integration and inter-professional teamwork

2.4 Integrated diabetes care in Ireland

Delivering integrated care, shifting care from the hospital to community and providing care at a lower level of complexity in an appropriate setting as close to home as possible, has long been on the reform agenda in Ireland [103, 219-223]. Recent national reforms to support integrated diabetes care have been preceded by locally driven and long-standing initiatives to structure management in primary care. The structure of the health system in Ireland embodies many of the challenges facing integrated care: primary and secondary care services are funded and resourced separately, chronic disease management is often not well integrated between hospitals and general practice, and there is variation in the provision of diabetes management in primary care [224, 225]. Studying the delivery of integrated care in Ireland presents an opportunity for transferrable learning about whether and how integrated care can successfully improve quality of diabetes care in a complex real world service context.

2.4.1 Primary care

In Ireland, most GPs are independent, self-employed practitioners, funded by a mix of state capitation payments for individuals who hold a means-tested General Medical Services (GMS) card, and fees paid by private patients. Some GPs choose to work on a fully private practitioner basis [226]. GMS cardholders who are eligible for free GP care currently make up just over 40% of the population [227]. Free access to GP care has expanded and been made available to anyone over 70 (independent of income) and all children under six [228]. Like other countries, GPs often act as a gateway to services in the hospital. However, as is the case internationally, Irish general practice is facing a workforce shortage [229-231], which challenges efforts to build capacity. GPs experienced financial cuts in the wake of the economic recession and the Financial Emergency Measures in the Public Interest Act, 2009 [232] and there are on-going issues with GP recruitment and retention [231].

2.4.1.1 Diabetes management in primary care

Type 2 diabetes care in Ireland was traditionally delivered in secondary care, that is, once people were diagnosed they were referred to specialist endocrinology services after which their management was largely carried out in this setting [233]. However, management in primary care has changed in the past few years. Primary care initiatives developed out of a local response to the lack of secondary care diabetes services and the need to improve care [107, 234-237]. As such, management between primary and secondary care settings is not consistent across the country. In some regions GPs deliver care opportunistically while others are engaged in structured care delivery as part of initiatives [224]. There are currently 10 initiatives across Ireland. While these have demonstrated quality (process and outcomes of care) [234-237] they continue to be the exception rather than the rule, often driven by what McHugh and colleagues refer to as 'vocational' rather than financial incentives [32].

Financial remuneration does form part of the Health Service Executive Midland Structured Diabetes Care programme. This programme is the longest established primary care-based diabetes care programme in Ireland, established in 1997/1998 as a 'ground up' effort to improve the quality of care for people with diabetes in the counties of Longford, Westmeath, Laois and Offaly (Appendix 10.1.1). The programme incorporates several strategies to integrate and coordinate diabetes management which align with elements shown to be effective in the international literature and map to QI approaches (EPOC categories) (Appendix 1 Table 16).

2.4.2 National reforms

At a national level there have been several reforms to support integrated care. Similar to other countries, building capacity in primary care has been the focus of a number of strategies and policy documents in the past few years [103, 220, 223, 238], including resourcing and structuring management for chronic disease [122, 220]. Part of the vision of strengthening primary care was to bring together different services (e.g. public health nurses, occupational therapy) through establishing primary care teams [220, 238, 239]. More recently, Slaintecare envisions primary care centres as resource centre hubs for health and social care services [103]. Until recently GPs were not incentivised to deliver chronic disease management. As part of the phased introduction of free GP care [231] the Diabetes Cycle of Care initiative was introduced in 2015. The Cycle of Care for the first time remunerates GPs on a national scale for structured management of patients with type 2 diabetes [28]. It entitles all patients with diabetes holding a GMS card to two free GP visits per annum. It aims to better structure and organise primary care management of diabetes through establishing formal requirements for registering, recording and reporting processes of care (clinical parameters, routine foot screening and referral, lifestyle review) [28].

Established in 2010, the National Clinical Care Programmes brought together representatives from different clinical disciplines to improve access to services, quality, safety and cost effectiveness of care. Prior to their establishment there had been limited work to integrate primary and secondary care. These programmes were tasked with developing standardised patient pathways and evidence-based models of care [240] and formed part of the “supporting architecture” in the phased introduction of integrated care [241]. The National Clinical Care Programme for Diabetes was one of the earlier Clinical Care Programmes and “early implementers” [241] of integrated care models envisioned for Ireland. The national model of integrated care developed by the National Clinical Care Programme for Diabetes aimed to establish stratified patient pathways and outline the role of professionals involved in care for people with diabetes: DNS, practice nurses and GPs. The model specified how patients should be managed according to the complexity of their diabetes (Table 4).

Table 4 National model of integrated care

Patient type	Care delivery
Uncomplicated type 2 diabetes	To be managed by primary care (seen 3 times a year for structured review visits) and discharged accordingly from secondary care services.
Complicated type 2 diabetes	To be managed between primary and secondary care.
Other patient groups i.e. type 1 diabetes	To be cared for solely in secondary care.

In Ireland, before these new changes were introduced, the DNS service was predominantly hospital-based. However, prior to the National Clinical Programme for Diabetes there were some community DNS in post, as some existing primary care initiatives had already introduced the role and found it to be successful [107]. To support the roll-out of the model of integrated care the National Clinical Programme for Diabetes oversaw the recruitment of additional 'integrated' community DNS to provide specialist support to primary and secondary care services and act as a link between settings.

2.5 Summary

A substantial body of work has determined which interventions to improve diabetes care work. However, a gap remains between the effect reported in these trials and that achieved in actual practice. Existing studies are typically not conducted in 'real-life' conditions, are short and do not provide insight into the long-term (>10 years) sustainability of interventions within a changing context. Evidence on factors (physician and practice level) associated with the quality of primary care diabetes management, which has not been consolidated to date (Section 2.2.4), was synthesised in a systematic review and meta-analysis (Chapter 3). Trends in the performance of a multifaceted structured primary care model delivered between 1998 and 2016 were examined to determine whether this model works in everyday practice over a longer period (Chapter 4). Although, monitoring excess mortality from diabetes can indicate improvements in the quality of diabetes care, it is not often used as an outcome measure in studies of interventions to improve management of diabetes. Chapter 5 examines excess mortality and predictors of survival among a cohort enrolled in a structured care programme.

Few studies have examined the implementation of integrated diabetes care, including how models which involve a new way of working across care-boundaries, e.g. 'integrated' DNS, operate 'on the ground'. Conducting research as a service evolves and develops may be beneficial. A national survey (Chapter 6), and a qualitative work following the roll-out of the new 'integrated' service (Chapter 7) were used to understand how DNS support and implement integrated care.

In summary, this thesis contributes to an understanding of whether and how integrated diabetes care can improve and sustain quality of care in a real world community context by: 1) determining what factors may influence quality of care in primary care; examining trends in the performance of existing structured care model and long term outcomes among people receiving structured care, and; 2) exploring how integrated diabetes care involving the expansion of DNS role is implemented in practice.

3 The role of physician and practice characteristics in the quality of diabetes management in primary care: systematic review and meta-analysis

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3.1 Abstract

Importance: Despite the existence of evidence-based guidelines on diabetes management, quality of care is not always achieved. Identifying factors associated with the quality of management in primary care may explain inter-practice variation and enable tailoring of QI interventions delivered in everyday practice.

Objective: Conduct a systematic review of physician and practice-level factors and their association with the quality of diabetes care delivered in primary care.

Data Sources: Four databases (MEDLINE, EMBASE, CINAHL and Web of Science) from January 1990 to July 2017.

Study Selection: Cohort studies, cross-sectional studies, and randomised controlled trials (baseline data) conducted among adults with diabetes, which examined the relationship between physician and/or practice factors and any objective measure(s) of quality. Studies examining patient factors only were excluded. Studies were screened independently by two reviewers. Any disagreements were resolved through consultation with a third reviewer.

Data Extraction and Synthesis: Using a standard form, data were abstracted, and quality assessed, by one reviewer. Random-effects meta-analyses evaluated associations between factors and quality measures. Narrative synthesis of studies ineligible for the meta-analyses was performed.

Main Outcome(s) and Measure(s): Primary outcomes were individual and composite measures of quality. Individual measures were processes of care, and intermediate clinical outcomes (risk factors e.g. BP, cholesterol, HbA1c). Secondary outcomes were patient-reported functional status, quality of life, satisfaction, and treatment adherence.

Results: In total, 76 studies were included, examining physician factors only (n = 20), practice factors only (n = 44), or both (n = 12). The range of individual quality measures and the construction of composite measures varied considerably. Female physicians compared to males (OR = 1.06, 95% Confidence Interval (CI): 1.03-1.10, 7 studies), physicians with higher diabetes volume compared to lower volume (OR = 1.24, 95% CI: 1.05–1.47, 4 studies), and practices with Electronic Health Records (EHR) versus practices without (OR = 1.43, 95% CI: 1.11-1.84, 4 studies) were associated with a higher quality of care. There was no association between physician experience, practice location and type of practice and quality. Based on the narrative synthesis, increasing physician age and higher practice deprivation were associated with a lower quality of care. There was mixed evidence of an association between practice diabetes prevalence and quality.

Conclusions and Relevance: Identification of physician and practice level factors associated with the quality of care (female gender, younger age, diabetes volume, practice deprivation and EHR use) may explain differences at the physician or practice level when measuring and comparing quality, provide potential targets for quality improvement interventions, and indicate where practice may need specific supports to deliver improvements in diabetes care.

3.2 Introduction

Routine management of diabetes is increasingly delivered in primary care where patients can be treated at the lowest level of complexity [7, 242]. However, despite the abundance of guidelines recommending regular monitoring and management with treatment goals for BP, glucose control and lipids, screening for complications, and input from multidisciplinary professionals [68, 243, 244], high quality of care is not always achieved. Risk factor control continues to be suboptimal [126-130], with international variation in the achievement of clinical targets [127]. Interventions to improve diabetes management are not always successful, with limited impact on clinical outcomes [23, 124].

Understanding how to close the ‘evidence to practice gap’ [79, 84], and address the difficulty of introducing and embedding evidence-based care into real life practice, is central to the delivery of effective, appropriate and safer clinical care [84]. The diversity of primary care in terms of team composition, organisational structure, size, and workflow, may make it a particularly challenging setting in which to deliver evidence-based care. Identifying what factors influence quality of diabetes management in primary care is an important step towards addressing these challenges, which may inform strategies to improve adherence to evidence-based care and tailor QI interventions to the real life context [245].

As outlined in Section 2.2.4, existing reviews have synthesised the qualitative literature on patient and physician perspectives, attitudes or knowledge, and identified several factors that *may* influence quality of diabetes care [131-133].

Several quantitative studies have investigated whether a number of specific physician and/or practice factors are associated with objectively measured quality of care as part of management [134-151] but these studies have not been synthesised. Previous reviews of the quality of chronic disease management in primary care have focused the relationship of *one* specific practice factor [246]. This review assembles existing evidence on multiple primary care factors and their relationship with objective measures of quality of diabetes care to: 1) explore variation in quality across practices or physicians (and indicate factors which could potentially be accounted for to ensure fair comparisons); 2) identify modifiable factors which act as obstacles to good quality care and which can be addressed in QI interventions and; 3) determine what factors may contribute to the 'evidence to practice' gap, and which could be taken into consideration when translating interventions to improve the quality of diabetes care into everyday practice. The aim of our study, therefore, was to conduct a systematic review of physician and practice-level factors and their association with the quality of diabetes care delivered in primary care.

3.3 Research design and methods

We conducted and reported the review in accordance with the PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) statement [247] and the published protocol [248]. A copy of the completed PRISMA statement is included in Appendix 2 .

3.4 Eligibility criteria

Eligible studies were cohort studies, cross-sectional studies, and baseline data from randomised controlled trials (RCTs) conducted among adults aged ≥18 years with diabetes (type 1 or type 2). Studies were excluded if people with diabetes formed a subgroup of the study population (e.g. diabetes as a covariate) or where management of people with diabetes was not specifically examined. Studies which examined patient factors only were excluded. A preliminary search of the literature identified physician and practice factors and the results were used to inform the search strategy. Physician factors identified *a priori* (n = 8) were age, gender, interest, experience, working hours, location, diabetes knowledge, and training. If studies examined other physician factors they were also included. Studies were included if they examined practice factors which were classified as one of the four Cochrane EPOC components related to 'Delivery Arrangements': 1) where care is provided; 2) who provides care; 3) how and when care is delivered, and; 4) Information and Communication Technology (ICT). *A priori* practice factors (n = 10) were practice location, type, deprivation, staffing (e.g. number of partners/GPs/practice nurses/administrators), list size, diabetes prevalence, GP or nurse training in diabetes, whether a reminder/recall system, register, diabetes protocol or guideline is in place. Studies of other practice factors that fit within an EPOC category were included.

3.4.1 Outcomes

The primary outcome of interest, *quality of diabetes care,* was a broad construct comprising of either individual objective measure(s) of quality, that is performance of care processes or control of intermediate clinical outcomes (risk factors including BP, cholesterol, HbA1c), screening for complications or attendance at screening services, prescribing of appropriate medications, treatment inertia or intensification, or a composite of individual measures [248]. Patient-reported outcomes, including functional status, health-related quality of life, satisfaction with treatment, and treatment adherence were recorded as secondary outcomes. Studies which examined several individual or composite measures of quality, or both, were included. Studies which examined only one individual quality measure were excluded.

3.4.2 Data sources and searches

We conducted literature searches of MEDLINE, EMBASE, CINAHL and Web of Science for studies conducted between January 1990 and July 2017, and published in English, which examined the association between physician and/or practice-level factors and quality of diabetes care in primary care. We searched databases using Medical subject headings (MeSH) and keywords for (1) diabetes (2) primary care (2) practice or physician factors, broad (e.g. 'physician attributes', 'practice characteristics') or specific (e.g. 'gender', 'experience', 'list size', 'practice location') terms and (4) quality of care. A full copy of the EMBASE search strategy is included in Appendix 2 **Table 17**.

3.4.3 Study selection

After de-duplication, two reviewers (FR and COD) independently screened titles and abstracts against inclusion criteria. Any article marked as 'include' or 'unsure' was retrieved for full text review. Full texts were reviewed independently (by FR and

MNM). Any disagreement at this stage was resolved through consultation with a third author (PK or SMH). Reference lists of all included papers, along with relevant meta-analyses and literature reviews, were reviewed for further publications not identified by the original search.

3.4.4 Data extraction and quality assessment

Using a standard form, FR abstracted data on study design, region, sample size, patient and physician characteristics and quality measure(s). Authors were contacted for additional data if required. Study quality was assessed (by FR) using the modified Joanna Briggs Institute critical appraisal checklists for descriptive studies[249]. Articles were not excluded from the review based on the quality assessment.

3.4.5 Data synthesis and analysis

A meta-analysis was conducted where at least two studies examined a comparable individual or composite quality measure. In general, studies were not included in a meta-analysis if the data were unavailable, exposure or outcome variables were not comparable, there was no adjustment for confounders, or, if a continuous outcome variable was measured but data were unavailable to calculate the standardised mean difference (SMD) (Appendix 2 Table 18). Studies which could not be included in a meta-analysis were included in a narrative synthesis.

We conducted random-effects meta-analyses of the adjusted effect estimates using the inverse variance method in RevMan 5.3 (Nordic Cochrane Centre). Where unavailable from the article or study authors, 95% CIs and/or standard errors (SE) were calculated from the effect estimate and p-value[250, 251]. Forest plots were used to visually assess the estimates and corresponding CIs across studies. Statistical heterogeneity was assessed with the I^2 statistic. Forest plots are presented with and without pooled effects. Where analyses indicated significant heterogeneity ($I^2 >$ 60%), this was highlighted.

3.5 Results

3.5.1 Study characteristics

From 6269 citations identified through electronic database searching, 72 were retained (Figure 2), and four studies were identified from reference lists. Most studies were from the US (n = 34), or UK (n = 17) (Table 5). Sample size varied considerably from smaller local studies of 226 patients (54 practices) [252] to large-scale national studies of 1, 852, 762 patients (8970 practices) [144]. Some studies focused on specific sub-groups e.g. Medicare beneficiaries (≥65 years) [252-255], patients with type 2 diabetes [141, 252, 256-264], private patients [265], patients with screen-detected type 2 diabetes [252], non-insulin treated patients [134], or patients with hypertension [266].

Included studies examined individual (n = 36), composite (n = 23) or both (n = 11) measures of quality of care, and six examined treatment intensification or inertia. Individual indicators used to construct composite measures ranged from four process measures [267, 268] to 18 process and outcome indicators from the Quality and Outcomes Framework (QOF) [140, 151, 257, 267] (Appendix 2 Table 19). Most frequent individual measures (>20 studies) were HbA1c testing (n = 31), eye examination or referral to ophthalmology (n = 29), lipid testing (n = 26), and HbA1c level/target (n = 24). Detailed information on outcomes is available on studies of physician only factors (n=20) [134, 135, 255, 260, 261, 266, 269-282] (Appendix 2 Table 20), practice only factors (n = 44) (Appendix 2 Table 21) [138, 140-144, 150, 151, 252, 254, 257-259, 262, 265, 267, 283-310] or both factors (n = 12) (Appendix 2 Table 22) [253, 256, 263, 268, 311-318]. Overall, three physician factors (gender, experience, and diabetes volume), and three practice factors (location, type, and presence of an EHR) were included in the meta-analyses.

Some studies did not adjust for confounders (n = 10)[142, 144, 252, 271, 287, 291, 295, 300, 308, 319], did not examine patient-level factors or include them as covariates (n = 33) [140-142, 144, 150, 151, 252-254, 257, 259, 267, 271, 274, 275, 283, 287-289, 291, 294, 295, 298-301, 307-309, 311, 315, 317, 318] (Appendix 2 Table 23). Where General Practice data were used to determine outcomes, few explained the data abstraction process [150, 266, 269, 271, 276, 285, 290, 294, 297, 310, 314], or cited the reliability [151, 257, 262, 276, 284, 290, 294, 297, 310, 314]. In some studies, exposure ascertainment [136, 142, 151, 255, 262, 263, 269, 277, 281, 288, 300, 320] and inclusion criteria for practices and/or physicians [142, 150, 264, 273, 286, 288, 289, 294, 295, 297, 300, 315, 318, 319, 321] were unclear or not reported. Two studies used volunteer practices [135, 256]. Studies did not consistently report the total number of patients, physicians or practices.

3.5.2 Physician factors

3.5.2.1 Gender

Nineteen studies examined gender [134, 256, 259-261, 263, 268-270, 272, 276, 280, 281, 311-313, 315-317].

Individual measures

Eleven studies used individual outcome measures [134, 256, 259-261, 263, 269, 270, 272, 276, 280, 281, 313, 316]. Eight reporting individual quality outcome measures [134, 260, 269, 270, 272, 280, 313, 316] were included in a meta-analysis (Figure 3). Overall, female gender was associated with higher quality of care (any individual measure) (Odds Ratio (OR)=1.06, 95% CI: 1.03-1.10) (Appendix 2 Figure 14). There was substantial statistical heterogeneity (I^2 = 81%). Of the six studies examining individual measures which could not be included in the meta-analysis [256, 259, 261, 263, 276, 281], four did not report a significant association [256, 259, 263, 281] while two found that among female physicians quality was higher [261, 276].

Composite measure

The seven studies using a composite measure [268, 272, 311-313, 315, 317] could not be pooled (Appendix 2 Table 18). Four [272, 312, 315, 317] reported no significant association, while three [268, 311, 313] found an association between female gender and higher quality.

3.5.2.2 Professional Experience

Seven studies defined experience as years since graduation [315, 318] or in practice [256, 259, 261, 280, 317].

Individual measures

Five studies used individual outcome measures [256, 259, 261, 280, 318]. Two of the studies using individual measures of quality were suitable to include in a meta-analysis [256, 318] (Figure 4). The pooled estimate was not significant (OR = 1.01, 1.00-1.02) (Appendix 2 Figure 15). Of the three other studies which examined individual measures [259, 261, 280], two found no association [259, 261], while one reported physicians with >15 years in practice had higher odds of proteinuria testing [280].

Composite measure

Two studies used a composite measure of quality [315, 317]. Only one had data available[315]. Neither study found experience was associated with quality [315, 317].

3.5.2.3 Diabetes volume

Seven studies examined the volume of patients with diabetes per physician [134, 261, 278-281, 284].

Individual measures

Seven studies used individual outcome measures [134, 261, 278-281, 284]. Four studies examining individual measures of quality (care processes) were included in a meta-analysis [134, 278-280] (Figure 5). The pooled estimate indicated higher volume was associated with higher quality (OR = 1.24, 1.05–1.47) (Appendix 2 Figure 16). There was substantial statistical heterogeneity (I^2 = 90%). Three other studies examined individual measures [261, 281, 284], one of which found higher volume was associated with higher quality [284].

Composite measure

Only one study used a composite measure [278]. This study found higher volume was associated with higher quality [278].

3.5.2.4 Other physician factors

Other common primary care physician factors (≥5 studies) not included in a meta-analysis were age [134, 259, 263, 266, 268, 281, 311, 313, 317, 318], training [255, 266, 275, 306, 308, 312, 316, 317], and panel size/ workload [140, 252, 256, 261, 267, 268, 277, 281, 282, 284, 311-313, 317]. The relationship with quality was inconsistent. Age and training were the exception. Of ten studies which examined physician age, six reported a significant association: older physician age was associated with lower quality [134, 268, 281, 311, 313, 318]. Four of seven studies examining training reported a significant association: board certification was associated with better performance [255, 266, 275, 317].

Practice factors

3.5.2.5 Location

Ten studies examined practice location (rural vs. urban practices) [135, 253, 259, 286-288, 311-313, 317].

Individual measures

Three studies examined individual measures [253, 259, 287]. These were not included in a meta-analysis. One found no association with quality [259]. Results were inconsistent among the two studies which found an association [253, 287].

Composite measure

Eight studies used a composite measure [135, 262, 286, 288, 311-313, 317]. Three were included in a meta-analysis [135, 288, 313]. There was no association between location and quality (OR = 1.02, 0.87-1.19) (Figure 6a). Of the five other composite studies, three found no association with quality [311, 312, 317], two reported mixed results by intervention arm [286] and one study favoured urban practices [262].

3.5.2.6 Type of practice

Twelve studies compared group to solo/single-handed practices [140, 252, 257-259, 267, 285, 289, 306, 313, 316, 318].

Individual measures

Nine studies used individual outcome measures [252, 257-259, 289, 306, 313, 316, 318]. Three studies examining individual care processes were included in a meta-analysis [313, 316, 318]. There was an association between practice type and delivery of lipid test (favouring group practices) (Figure 6b). Of six other studies examining individual measures [252, 257-259, 289, 306], four found no association [252, 257, 259, 289], one study found group practices performed better on some measures [306], and one study found patients attending group practices were more likely to be treated with lipid-lowering drugs [258].

Composite measure

Four studies used a composite outcome measure [140, 267, 285, 313], and two were included in a meta-analysis. There was no association between type and a composite quality measure (OR = 1.58, 0.74-3.38) (Figure 6b). Of two other composite studies, one reported an association favouring group practices [140].

There was no association between type and quality overall (any measure, individual or composite) (OR = 1.27, 0.99–1.64) and high statistical heterogeneity (I^2 = 68%). (Appendix 2 Figure 17).

3.5.2.7 Electronic Health Records

Sixteen studies examined the use of EHRs [135, 254, 256, 285, 286, 294, 296-298, 302, 306, 307, 310, 311, 314, 316].

Individual measures

Five studies examined individual quality of care measures [256, 296, 306, 307, 316]. Two studies examining individual outcome measures were included in a meta-analysis.[256, 306] Having an EHR was only significantly associated with one measure, HbA1c control (OR = 1.54, 1.11-2.14) (Figure 7). Of three other studies examining individual measures [296, 307, 316] all found the presence/use of an EHR was associated with better performance on some measures [296, 307, 316].

Composite measure

Eleven studies used a composite quality measure [135, 254, 285, 286, 294, 297, 298, 302, 310, 311, 314]. Two studies using the same exposure (EHR vs. no EHR) were included in a meta-analysis [254, 285, 294, 311] (Figure 7). Having a practice EHR was associated with higher quality (OR = 2.23, 1.60-3.09) . Of nine other studies using composite measures [135, 286, 294, 297, 298, 302, 310, 311, 314], four did not report a significant association [135, 286, 298, 314] while five found the presence/use of a practice EHR was associated with better performance[294, 297, 302, 310, 311].

Overall, practices with EHRs were more likely to achieve higher quality (any measure, individual or composite) (OR = 1.43, 1.11-1.84) (Appendix 2 Figure 18).

3.5.2.8 Other practice factors

Other practice factors identified (in ≥5 studies) were practice deprivation [140, 144, 150, 151, 265, 267, 289, 293, 301, 312], practice prevalence of diabetes [140, 144, 150, 259, 267, 289, 293, 299, 301, 312] or practice diabetes volume [258, 263, 268, 287, 294, 302, 322], number of patients in a practice [138, 140, 142, 144, 150, 259, 262, 267, 290, 301, 304, 312] or number of GPs [135, 150, 151, 252, 268, 286, 290, 309, 312, 315]), nurse or physician assistant involvement [143, 256, 258, 259, 287, 292, 300, 304, 305], number of nurses [135, 140, 150, 267, 290, 306, 312], and use of a register or recall system [141, 150, 256, 291, 306, 308, 312]. The relationship of these factors with quality was inconsistent.

Nurse practitioner or physician assistant involvement in care delivery at the practice was associated with lower HbA1c values [256], and receipt of HbA1c test; if they were used in a supplemental role and not responsible for treating highly complex patients [304]. However, the roles of the nurse practitioner and physician assistant were not distinguished or examined separately. While two studies found nurse involvement was associated with higher rates of some care processes [143, 292, 300], there was no association with intermediate outcome targets [143], with the exception of HbA1c [292]. Conversely, a US study of Medicare patients (≥65 years) found care delivery by nurse practitioner at the practice was associated with lower performance of care processes; eye exam, HbA1c test, statin-prescribing [305].

One exception was practice deprivation; all studies which reported a significant association (8/10) found higher deprivation was associated with lower quality [140, 144, 150, 265, 289, 293, 301, 312].

3.6 Discussion

This study identified physician and practice level factors associated with the quality of diabetes management in primary care. The range of individual quality measures and the construction of composite measures varied considerably among identified studies. Composite scores are considered more reliable than individual measures for measuring physician performance [323, 324], and almost half of all identified studies used a composite measure. Among studies which were combined in a meta-analysis, female gender, higher physician volume of patients with diabetes, and a practice EHR favoured higher quality of care. Findings were not significant for physician experience, practice location or type of practice. Among studies which could not be included in a meta-analysis, increasing physician age, and higher practice deprivation were associated with lower quality.

Our finding in relation to physician age fits with other studies indicating a relationship between older age and poorer quality among hospital-based physicians [325] and primary care physicians providing preventative cardiovascular disease care [326]. Furthermore, a review which treated physician age and years of experience as interchangeable found physicians with more experience may provide poorer quality care [327]. However, studies have found higher mortality among patients cared for by hospitalists with less experience [328], and that patients of obstetricians with more years of experience had fewer maternal complications [329]. One possible reason for our finding is that older GPs may be less inclined to adopt and implement new practices and standards of care [330]. Also, they may only appear to have a lower quality of care; as senior physicians they may have an older and more complex patient cohort. However, most studies which reported a relationship between older age and quality controlled for patient co-morbidities or patient complexity [134, 281, 311, 313, 331]. Understanding reasons why older GPs perform differently could enable delivery of structured diabetes care to be better supported, for example, through promoting Continuing Professional Development (CPD), or examining and addressing the caseload of older physicians.

The association between female physicians and higher quality of care fits with existing studies on the delivery of preventative care for women [332, 333], management of chronic health failure [334], and inpatient care [335]. Provider attitudes and beliefs about diabetes [131], the quality of patient-provider communication and interpersonal skills [131, 132], can support or hinder management. Previous work has posited that different communication styles between male and female physicians [336], and/or greater focus by female physicians on preventive care [337, 338] may be some reasons for differences in the quality of care. An interaction between age and gender should also be considered. With changes in the patterns of recruitment to medical schools and specialisation preferences, female primary care physicians may tend to be younger [339, 340]. Of the studies included in the meta-analysis [134, 260, 269, 270, 272, 280, 313, 316], many did not adjust for physician age [260, 269, 270, 280, 316], while some used years of experience [280, 315, 316] or years since graduation [270].

Our results are consistent with a previous review which found limited evidence to support a relationship between practice size and the quality of chronic disease management [341]. However, the diabetes volume-quality relationship is less clear. The relationship between *practice-level* diabetes prevalence/volume and quality was inconsistent. However, in a meta-analysis we found diabetes volume at the *physician level* was associated with better quality, fitting with work in the acute setting [342, 343]. We might expect practices with high diabetes prevalence to be more proactive in improving management. However, higher GP utilisation by people with diabetes [344] may place greater demand on practices staff and resources, with a negative effect on quality. The association between prevalence and poorer quality reported by some of the studies could also reflect the higher prevalence in more deprived areas [21, 345]; we found practice deprivation was associated with lower quality of care [144, 150, 265, 289, 293, 301]. This being said, studies which demonstrated a relationship between prevalence and quality and the reverse [289, 293, 301] all adjusted for deprivation. Notably, most studies which examined deprivation [140, 144, 150, 151, 265, 267, 289, 293, 301, 312], did so at the practice level; with two exceptions which examined both patient and practice-level deprivation [265, 312]. Practices with higher prevalence may require specific supports to achieve high-quality structured management. The positive relationship between physician-level diabetes volume and quality of care could reflect greater expertise gained with more exposure [343], and may suggest the benefits of having GP or nurse dedicated to delivery of diabetes care at the practice. Only two identified studies examined GP interest and quality and found an association [150, 312]. Models of care where GPs with specialist interest work with specialist teams to provide intermediary type 2 management in the community may reduce outpatient attendances [193, 346] and achieve better HbA1c control compared to outpatient care [347]. Given the key role of nurses, both practice nurses and nurse specialists, in diabetes management, as established in Section 2.2.6, it was interesting that studies which examined nurse staffing and their role found no clear association with the quality of care. This could in part, be due to the different ways in which involvement and nurse staffing examined, for example, one study grouped nurse practitioners and physician assistants together [304]. Moreover, staffing was represented in different ways; presence of practice nurse [135], list size per WTE [140, 267], number of trained nurses at each clinic session [290], number of nurses [312], nurse per 100 patients [306].

We found practices with EHRs performed better. Our findings support existing qualitative work suggesting the quality of information technology [132] and lack of EHRs [133] is a barrier to diabetes management. The magnitude of the overall effect estimate across quality measures (OR = 1.43, 1.11-1.84) was greater than that observed for physician gender (OR = 1.06, 1.03-1.10) or diabetes volume (OR = 1.24, 1.05–1.47). It was also greater than the effect achieved in trials of diabetes quality improvement interventions where the relative risk of receipt of care processes has been found to range from 1.22 (1.13–1.32) for eye screening, to 1.28 (1.13–1.44) for performance of a renal function check [23]. Apart from supporting the core components central to structured care delivery (i.e. establishment and maintenance of a patient registry, recalling patients for review, tracking and monitoring risk factors) EHRs facilitate additional capabilities like clinician decision support [348]. Our finding lends support to on-going calls improve the health information infrastructure for greater use of electronic healthcare (e-health) in primary care [349]. As a modifiable practice factor which *can* be addressed, the adoption and use of EHRs should be facilitated and addressed as part of QI interventions.

An awareness of practice profile, physician diabetes volume, and practice deprivation may be relevant when introducing national service changes to support diabetes management in primary care. Practices asked to implement initiatives may have very different real life situations (e.g. operating without an EHR, a longer established practice with older GPs, higher volume of patients with diabetes, or based in a deprived area) and may implement these initiatives differently, adapting to their local context, and to what May et al. refer to as the 'normal conditions' of their practice [93]. These are features of the context which may contribute to the aforementioned 'evidence to practice' gap and yet may not be identified or accounted for during evaluative studies [93]. They could be taken into consideration when translating interventions to improve the quality of diabetes care into everyday practice. Tailored interventions have been shown to be effective [350]. Understanding the practice profile may facilitate local tailoring to provide targeted support to practices [351, 352].

Strengths and limitations

Unlike reviews which have focused on one specific practice factor [246] we used broad search terms together with a range of *a priori* factors identifying all possible studies which examined a given factor. It is possible our search strategy may have missed other specific factors not identified *a priori*. However, we are confident we have identified all literature for the *a priori* factors (n = 18), and for the main additional factors (in ≥5 studies). Furthermore, reviewing the reference lists of included studies indicated that most relevant studies had been identified. As our review includes factors which may not necessarily be the focus of a given study (e.g. model covariate but with available effect estimates) data were less well-reported and sometimes not available from study authors. For example, data were often not reported for factors found to have no significant association with quality.

The included studies were for the most part, cross-sectional, and, as such, the causal relationship between physician and practice factors is tentative. Owing to variation in exposures and outcomes used, together with the lack of reported data, the meta-analyses included only a small number of studies and results should be interpreted with caution. To aid the reader we have also summarised the findings from the studies which could not be included in a meta-analysis. Some analyses indicated considerable statistical heterogeneity ($I^2 > 60\%$); namely studies which examined physician gender, diabetes volume, and practice type. As few studies could be included in the meta-analyses this precludes an investigation of sources of heterogeneity; however, we suggest this was largely due to variation in composite outcome measures and have provided details of these composite measures for the reader to make their own judgment.

The term ‘quality’ can be defined broadly as “the degree to which health care services for individuals and populations increase the likelihood of desired outcomes and are consistent with current professional knowledge” [353]. The wide range of approaches used to construct composite quality measures in the current review seems to reflect this broad definition. We also found different approaches were used to categorise composite measures e.g. ‘one or more’ [254, 285, 297] or ‘all or none’ approach [135, 255, 277, 278, 285, 288, 294, 297, 302, 310]. While the latter may promote optimal performance [354], it has also been criticised for poor sensitivity

[355]. These differences greatly limit comparability across studies. Some studies also provided little information on how outcome data were obtained and how the scores were constructed, with few reporting on the internal consistency of the score [290, 312].

The findings suggest the need for agreement on a composite quality of diabetes care measure. There are several factors to be considered in the development of a standardised composite measure. First, while many studies used nationally agreed diabetes management performance measures (e.g. QOF [140, 151, 257, 267, 293]) not all studies collected information on these indicators, raising the question of which and how many indicators are feasible to collect. While information on risk factors from blood results (i.e. HbA1c, BP, cholesterol), may be automatically updated and readily available to extract from primary care records, other important outcome indicators, like receipt of screening, if conducted outside of general practice, or complications, if manually coded, may not be available, or may be less reliably recorded. Using only data to hand may lead to 'availability bias', generating a composite which is feasible but reductive, taking only a narrow view of quality [356, 357]. Studies using composite measures included in this review were largely limited to receipt of clinical tests and blood results.

Certain indicators may be more clinically useful than others. Authors have criticised a reliance on process measures, given that improved processes do not necessarily lead to improvements in intermediate outcomes [76, 77]. However, care processes are under the control of physicians or practices, while control of intermediate clinical patient outcomes (risk factors) depends on physician actions *and* patient behaviours. This raises the question of whether it is useful to construct a composite from intermediate outcomes alone. Some studies used different composites consisting of process indicators, intermediate outcomes, and a combination [285, 297, 299, 310, 312, 317], which may be a compromise.

How ‘optimal’ quality is defined for dichotomised scores may substantially affect conclusions [355]. In this study, composites were often based on dichotomised intermediate targets [140, 151, 257, 267, 277, 283, 285, 288, 293, 294, 297, 299, 310, 312, 314, 317]. While largely based on guidelines, the recommended thresholds vary between countries [67, 68, 244, 358], and thresholds (e.g. HbA1c) may not be appropriate for all patient groups [359-361]. O’Connor et al. propose the use of three alternatives [362]: ‘clinical action measures’ that link an intermediate outcome target to a process of care (e.g. patient on a lipid lowering agent if LDL-cholesterol >100 mg/dL) [143]; weighted quality measures that apply a ‘full’ or ‘partial’ credit weighting to individual indicators, or; personalised patient-specific performance measures [362].

Composite measures are also sometimes criticised for a lack of transparency. Indeed, the validity of the composite depends on the reliability of several underlying indicators. If one is less well recorded then this compromises the overall composite, and variation in one indicator will affect the overall measure. Barclay et al suggest being clear about what is included in a composite measure and why, together with the uncertainty surrounding certain indicators [356].

Conclusion

As stated by the Institute of Medicine in their seminal report, quality is a property of institutions not individuals [353, 363]. Factors identified in this review can be used to explain differences at the physician or practice level both when measuring and comparing quality and could potentially be accounted for to ensure fair comparisons. The findings may suggest factors which could be addressed in QI interventions; one of the significant factors identified by this study is directly modifiable, namely the practice informational infrastructure (i.e. EHR). The findings may also inform targeted support of practice-level improvements, and guide strategies to better implement structured diabetes management. Work is already underway to guide and tailor chronic care delivery based on *patient* characteristics [364], beginning with a systematic review of patient characteristics important in delivery of type 2 integrated care [365]. Our findings also suggest a need to be aware of the physician profile at practices, diabetes volume of individual physicians, which may suggest the need for support at certain practices e.g. physician/nurse dedicated to diabetes management. Further research is needed to understand the way in which specific physician (gender, age and experience) and practice diabetes volume determines quality. Standard composite quality measures should be agreed to increase comparability across studies.

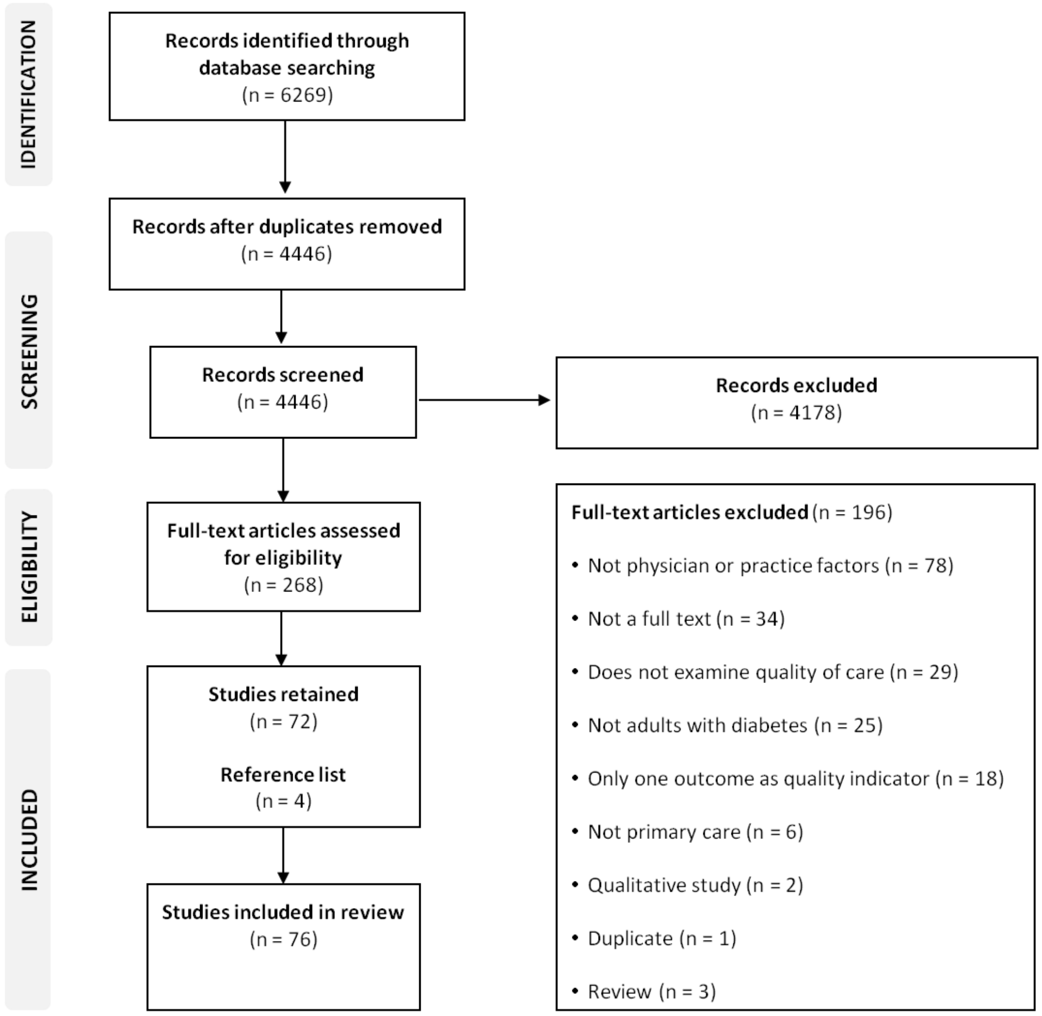


Figure 2 Flow diagram showing study selection process for the current review

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
Alberti et al.[312]	Cross-sectional	Identify patient, physician, and organizational factors associated with the quality of care	Tunisia	Random sample of public primary health centres throughout 24 regions of country (2 per region)	102 physicians Age unavailable; 40% female 2,160 patients 59.9 (14.1) years; 61.8% female 48 primary health centres	Physician Practice	Composite
Balkau et al.[263]	Longitudinal survival analysis	Identify the factors associated with the delay before treatment intensification	France	Representative national sample (selected by methods of quotas) of GPs	1200 physicians Further details unavailable 3188 **type 2** patients ≥18 years Further details unavailable	Physician Practice	Intensification
Fantini et al.[313]	Cross-sectional	Explore the influence of different organizational arrangements on the adherence of GPs to	Italy	All practices in the Local Health Authority of Bologna	637 physicians 53.5 (5.5) years; 32.5% female 35,912 patients 68.5 (12.0) years; 47.8% female,	Physician Practice	Multiple Composite

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		evidence-based guidelines					
Keating et al.[314]	Cross-sectional	Examine the influence of physicians' practice management strategies and financial arrangements on quality of care	US	Administrative data provided by 3 health plans in Minnesota	399 physicians 47 (9) years;21% female 652 patients ≥ 18 years 60 (16) years; 54% female	Physician Practice	Composite
Kern et al.[311]	Cross-sectional	Determine the effect of EHRs on ambulatory quality in a multi-payer community	US	Data from five health plans collected in context of an initiative led by THINC (the Taconic Health Information Network and Community). Members of Taconic Independent Practice	466 physicians 52 (10) years; 32% female 74,618 patients (also includes patients for breast cancer screening; chlamydia screening; colorectal cancer screening; appropriate medications for people with asthma; testing for children with pharyngitis; and treatment for children with upper respiratory infection)	Physician Practice	Multiple Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.							
Reference	**Design**	**Aim**	**Region**	**Sampling**	**Population**	**Factors**	**Outcome**
				Association (private practices and federally qualified health centres) and volunteers to THINC	Further details unavailable		
McGinn et al.[318]	Cross-sectional	Determine if physician office location and other physician practice characteristics' impact on diabetes measures	US	Kansas City Quality Improvement Consortium (KCQIC) contracted with Primaris, a healthcare consulting company, to create physician-specific dashboards	N physicians unavailable 45.03 (95% CI 44.32-45.73) years; % gender unavailable 31831 patients; pooled years 2002 (8851) and 2003 (22979)	Physician Practice	Multiple
Parkerton et al. 2004[315]	Cross-sectional	Examine whether physician physician	US	Administrative data from primary care practices in	25 clinics 182 physicians.	Physician Practice	Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.							
Reference	**Design**	**Aim**	**Region**	**Sampling**	**Population**	**Factors**	**Outcome**
		continuity is associated with better patient outcomes Examine whether practice structures are associated with better patient outcomes, independent of continuity		all western Washington state medical clinics of a single group model health maintenance organization	Age unavailable;37% female N patients unavailable Age unavailable;56% female		
Pham et al.[316]	Cross-sectional	Examine the relationship between attributes of physicians and their practices and the extent to which their Medicare patients received preventive services	US	Community Tracking Study (CTS) Physician Survey: biannual, nationally representative telephone survey of non-federal US physicians, linked to claims data	3,660 physicians Age unavailable;14.3% female 24 581 Medicare beneficiaries **≥65 years** 75.4 years; 63.5% female	Physician Practice	Multiple

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
Spann et al.[256]	Cross-sectional	Examine practice design strategies for diabetes care, the composition of the health care team, the complexity of the health problems experienced by patients with type 2 diabetes, control of diabetes, and the spectrum of treatment provided by their clinicians	US	Physicians who volunteered to take part in the Diabetes Outcome Study conducted in 4 primary care practice-based research networks (physician collaborative)	95 physicians 45.7 (7.8) years; 28.4% female 822 **type 2 patients** ≥18 years 59.5 (13.1) years; 55.5% female	Physician Practice	Multiple
Vinker et al.[317]	Cross-sectional, 2 years	Identify primary care physicians' characteristics associated with their QI scores over 2 years	Israel	Administrative data from Central District primary care clinics of the largest HMO. Jan. 2003 – Dec. 2005	161 physicians 51.2 (7.8) years; 52.2% female N patients unavailable	Physician Practice	Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
Visca et al.[268]	Cross-sectional	Evaluate the impact of team practice in family medicine using chronic disease management process indicators as a measure of outcome	Italy	Six Italian regions volunteering administrative data for one or more of their health districts for the years 2003–2008	1678 physicians 54.1 (5.0) years; 21% female 73,920 patients ≥16 years 71.9 years; 47.1% female	Physician Practice	Composite
Weiner et al.[253]	Cross-sectional	Identify physician and geographic related factors associated with higher or lower conformance to recommended criteria of care	US	Medicare claims data for services provided to aged beneficiaries residing in Alabama, Iowa and Maryland during 12-mth July 1990 - 1991	2980 practices 10,000 physicians Further details unavailable 97,388 patients ≥ 65 years Age, sex breakdown by state only	Physician Practice	Multiple
Bower et al.[257]	Cross-sectional	Determine whether practice structure and team process in	UK	Stratified random sample of English general practices from six health	42 practices N patients with **type 2 diabetes** unavailable	Practice	Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.							
Reference	**Design**	**Aim**	**Region**	**Sampling**	**Population**	**Factors**	**Outcome**
		turn predict team outcomes		authorities 1998-1999	(approx. 18 per practice ≈ 756) Further details unavailable		
Bredfelt et al.[283]	Cross-sectional	Evaluate the association between use of phone and secure messaging separately and a measure of the delivery of high-quality healthcare for patients with diabetes	US	Primary care physicians practicing with Kaiser Permanente, Mid-Atlantic States, Jan 2007-Dec 2008	174 physicians 47.8 (8.1) years in panels predominantly white 46.6 (8.7) years in panels predominantly black or Hispanic N patients >18 years unavailable Further details unavailable	Practice	Composite
Campbell et al.[151]	Cross-sectional	Assess variation in the quality of care in general practice and identify factors associated with high quality care	UK	Stratified random sample of nationally representative English general practices from six health authorities 1998-1999	42 practices N patients unavailable (approx. 20 patients with 20 from each practice - 840)	Practice	Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
Cebul et al.[310]	Cross-sectional	Examine the independent association of EHR use with achievement of quality standards for the care of patients with diabetes	US	Primary care practice partners of Better Health Greater Cleveland - Cuyahoga country, Ohio, July 2007 and June 2010	46 practices of 7 care organizations 569 providers 27,207 patients 57.8 years; 52.4% female	Practice	Multiple Composite
Cheung et al.[284]	Cohort study	Explore the associations of both overall ambulatory volume and diabetes-specific volume with quality of diabetes care among primary care physicians	Canada	All adult residents recorded in the Ontario Diabetes Database as having been diagnosed with diabetes as of the index date (31 March 2011)	9014 physicians 1,018,647 patients 20-104 years	Practice	Multiple
Cho et al.[258]	Cross-sectional	Describe the differences in treatment quality of patients with	The Netherlands	Data collected in 2012 from a large care group in the GIANTT (Groningen	183 practices 24,628 **type 2** patients 67.0 (17.0) years; 51% female	Practice	Multiple

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		diabetes between general practices, and identify patient and practice level characteristics that may explain these differences		Initiative to Analyze Type 2 Diabetes) - data extracted from electronic medical records of almost all patients (<1% opted out) managed in general practice			
Crosson et al.[285]	Baseline RCT data	Assess the relationship between EHR usage and diabetes care quality	US	Convenience sample of family medicine practices in New Jersey and Pennsylvania for the Using Learning Teams for Reflective Adaptation (ULTRA) study. April 2003 to December 2004	50 practices 927 patients 57.3 (15.1) years; 53.9% female (EHR) 60.7 (14.4) years; 48.7% female (non-EHR)	Practice	Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
Dickinson et al.[286]	Cluster RCT	Determine whether inner and outer practice context would moderate intervention effectiveness	US	Stratified random sample of practices and community health centres in Colorado; recruited for participation in a QI trial. Feb. 2005 – end 2012; change examined at 9 and 18 months	40 practices 822 patients Intervention arms: RAP: 60.5 (12.6) years; 55.8% female CQI: 61.9 (12.1) years; 47.1% female SD: 60.0 (13.2) years; 49.5% female	Practice	Multiple Composite
Dunn et al.[308]	Cross-sectional	Determine whether gathering data on structure enabled the process and outcome of diabetic care to be predicted	UK	Survey of 51 practices in East Dorset 1992-1993	37 practices N patients not available	Practice	Multiple
Ellerbeck et al.[287]	Cross-sectional	Identify the types of office system tools	US	All primary care providers in Kansas state	210 physicians/practices	Practice	Multiple

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		being used to promote diabetes care in practices and assess their impact on delivery of diabetes care		linked to Medicare claims data. April 1, 1999 - March 31, 2001.	11,623 patients (excluding >75 years) 67 (range: 22-75) years; 58% female		
Erickson et al.[288]	Cross-sectional	Examine the clinical associates' level of training, along with dyad tenure, clinician tenure, and clinician type, and how they relate to dyad performance in achieving diabetic metrics, patient satisfaction, and productivity	US	Family medicine practices of a Midwestern health system - comprised of practices at 10 clinic sites, 1 secondary level hospital in a small city, and 2 rural critical access hospitals, 2010	55 dyads 2,584 patients (18-74 years) Further details unavailable	Practice	Composite
Esterman et al.[135]	Baseline RCT data	Determine whether certain	Australia	Practices across 7 primary care	147 practices	Practice	Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		characteristics of practices are associated with good glycaemic control in patients with diabetes and with completing an annual cycle of care		organisations in 3 states volunteering to take part in the Australian Diabetes Care Project conducted between 2011 and 2014.	5455 patients (≥18 years) 65.3 (11.6) years; 44.1% female		
Everett et al.[304]	Cross-sectional	Evaluate the impact of primary care roles for physician assistants and nurse practitioners on the quality of diabetes care and the use of health services	US	Medicare claims data linked to providers in large mid-western multispecialty physician group in 2007- 2008	261 primary care panels 2,576 patients aged 23-102 72 (11) years; 54.9% female	Practice	Multiple
Franks et al.[265]	Cross-sectional	Analyse the association of SES with health care indicators	US	Claims data from the largest local managed care organization in	568 physicians 437,743 patients (**private only**, 21-64 years)	Practice	Multiple

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		among privately insured patients, separating the effects of patient and physician practice SES		10-county area around Rochester, New York. 1996-1999.	42.7 (10.9) years; 53% female		
Friedberg et al.[307]	Coss-sectional	Determine whether primary care practices with selected structural capabilities have higher performance on widely used clinical quality measures than practices lacking these capabilities	US	Performance data on Healthcare Effectiveness Data and Information Set measures of primary care quality from Massachusetts Health Quality Partners	305 practices N patients unavailable	Practice	Multiple
Griffiths et al. 2010[140]	Cross-sectional	Examine whether practices that	UK	2005/2006 QOF data	7441 practices 1,709,752 patients Further details unavailable	Practice	Multiple Composite

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		employ more registered nurses deliver better clinical care as measured by the clinical indicators of the QOF					
Griffiths et al. 2011[267]	Cross-sectional	Determine whether relationships between the quality of clinical care and nurse staffing in general practice are attenuated or enhanced when organisational factors associated with quality of care are considered	UK	2005/2006 QOF data.	7441 practices 1,709,752 patients Further details unavailable	Practice	Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
Gulliford et al. 2001[290]	Cross-sectional	Determine whether characteristics of health centres accounted for identified variations in medical care	Trinidad, Tobago	Government health centres each of the eight administrative counties in Trinidad and Tobago. Survey of health centres conducted in 1998; 3-week census of all attenders	23 health centres 1579 patients 61 years; 69% female	Practice	Composite
Gulliford et al. 2007[289]	Cross-sectional	Quantify socio-demographic and organizational variables associated with achievement of metabolic targets in 2005	UK	2005 QOF data	8164 N patients unavailable, >50 million	Practice	Multiple
Harris et al.[291]	Cross-sectional	Determine whether GPs using diabetes shared-care	Australia	Claims data. GPs practicing within South Western Sydney Area	614 physicians N patients unavailable	Practice	Multiple

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		registers had different patterns of practice from GPs not using registers		Health Service 1996-1998			
He et al.[254]	Cross-sectional	To examine whether patient or physician practice characteristics predict the likelihood of diabetes care	US	A nationally-representative sample of ambulatory care visits from the 2006 and 2007 National Ambulatory Medical Care Survey	N practices unavailable 2912 patients ≥65 years 74.6 (0.18) years; 51.8% female	Practice	Composite
Juul et al. 2012[292]	Cross-sectional	Assess whether involvement of practice nurses in type 2 diabetes care in Danish general practice is associated with improved	Denmark	Patients identified in the Aarhus Diabetes Database as of June 2009	193 practices 12,960 patients with **type 2** diabetes, 40–80 years Further details unavailable	Practice	Multiple

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.							
Reference	**Design**	**Aim**	**Region**	**Sampling**	**Population**	**Factors**	**Outcome**
		adherence to national guidelines on regular type 2 diabetes monitoring, and with lower HbA1c and cholesterol levels in the type 2 diabetes population					
Juul et al. 2009[252]	Prospective cohort	Assess adherence to guidelines for consultations with GP and treatment initiation with an ACE inhibitor or an angiotensin-II receptor antagonist in people with screen-detected	Denmark	General practices part of the intervention arm of the Anglo–Danish–Dutch study of intensive treatment in people with screen-detected diabetes in primary care (ADDITION) study, Denmark.	54 practices 226 patients (screen detected type 2 diabetes) 82.3% were aged 55-69 years; 48.2% female	Practice	Treatment initiation

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		type 2 diabetes; to identify predictors for adherence		Recruitment 2001–2004			
Khunti et al.[150]	Cross-sectional	Determine which features of practices are associated with delivering good quality care	UK	Multi-practice audit in three districts (Leicestershire, Durham, and Suffolk) 1995-1996	169 practices 18 642 people with diabetes Further details unavailable	Practice	Multiple
Kontopantelis et al.[293]	Longitudinal, interrupted time series	Assess whether there was variation in the impact of the introduction of the QOF depending on patient and practice characteristics	UK	Nationally representative sample of practices in the General Practice Research Database. Three pre- (2000/1, 2001/2 and 2002/3) and three post-implementation time points	148 practices 23 920 (23 780 patients included in regression) 62.9 (14.8) years; 45.6% female	Practice	Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
				(2004/5, 2005/6 and 2006/7)			
Kuo et al.[305]	Retrospective cohort	Compare processes and cost of care of older adults with diabetes mellitus cared for by nurse practitioners with processes and cost of those cared for by primary care physicians	US	Medicare claims data linked to primary care providers 2008-2009	N practices unavailable 64354 patients ≥66 years Nurse practitioner group: 76.2 (6.2) years; 67.8% female Primary care physician group: 77.6 (6.5) years; 66.1% female	Practice	Multiple
Matthews et al.[262]	Retrospective longitudinal	Examine trends in the quality of Type 2 diabetes processes of care over time for participating health centres and identify the influence of regional, health	Australia	Audit data collected between 2005 and 2012 by health centres voluntarily enrolled in a continuous QI program in both Aboriginal and Torres Strait	132 health centres 10,674 patients with **type 2** diabetes ≥ 16 years 52 (15–97) years; 57% female	Practice	Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		centre, and individual patient level factors on delivery of services scheduled in current guidelines		Islander communities			
McCullough et al.[294]	Longitudinal	Examine whether changes in physician practice quality measures are linked to EHR adoption using data from public reports of diabetes care	US	Data provided voluntarily by physician clinics in Minnesota and neighbouring states from 2008 to 2010.	557 clinics N patients unavailable but on average, clinics submitted a sample of 273 patient records (≈ 152,000 patients)	Practice	Composite
McLean et al.[295]	Cross-sectional	Examine how the quality of primary care varies by remoteness	UK	Routinely collected data for all general practices in	912 **GMS** practices N patients unavailable Further details NR	Practice	Multiple

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
				Scotland 2004/2005.			
Millett et al.[144] **	Cross-sectional	Examine the association between general practice size and caseload, and outcomes for people with diabetes, in English and Scottish general practices, and whether the association between volume/size and outcome was influenced by deprivation	UK	QOF data from practices in Scotland and England.	8970 practices 1 852 762 people with diabetes Further details unavailable	Practice	Multiple
Mitchell et al.[296]	Before-after retrospective case	Determine the effects of computers in consulting	UK	Practices in Scotland recruited through newsletters of the	6 practices 939 patients Further details unavailable	Practice	Multiple

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
	note review	rooms on the management of chronic disease		main computing companies matched to control practices identified from health board lists and who did not use a consultation computer. January 1994 to December 1995			
Ohman et al.[143]	Cross-sectional	Evaluate whether the quality of care provided to patients with diabetes differs between practices with and without physician assistants or nurse practitioners	US	Convenience sample of family medicine practices in New Jersey and Pennsylvania for the Using Learning Teams for Reflective Adaptation study April 2003 to December 2004	46 practices 846 patients 60.4 (5.1) years; 50.9% female	Practice	Multiple

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
Orzano et al.[297]	Cross-sectional	Examine whether clinical information systems favourably impacts patient-level measures of diabetes assessment, treatment and achievement of targets among all diabetic patients	US	Convenience sample of family medicine practices in New Jersey and Pennsylvania for the Using Learning Teams for Reflective Adaptation study April 2003 to December 2004	50 practices 883 patients 60.1 (14.3) years; 51% female	Practice	Composite
Poon et al.[298]	Cross-sectional	Evaluate the association between the use of EHR features and quality	US	Stratified random sample of physician surveyed on use and adoption of ambulatory electronic health records conducted in 2005	507 physicians 150 unique medical groups N patients unavailable Further details unavailable	Practice	Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
Ricci-Cabello et al.[299]	Cross-sectional	Explore whether the practice-level prevalence of diabetes-concordant and -discordant conditions could explain variations in the quality of health care provided to patients with diabetes	UK	All family practices participating in QOF 2012–2013	7,884 practices 54,220,050 patients Further details unavailable	Practice	Composite
Spigt et al.[141]	Cross-sectional	Investigate whether differences in quality of care among general practices could be explained by differences in how they organize their diabetes care	The Nether lands	Academic health care centres supervised by Registration Network General Practitioners. 2006-2007 (1 year of follow-up)	10 health centres 45 physicians 1849 patients with **type 2 diabetes** Further details unavailable	Practice	Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
Stearn et al.[300]	Cross-sectional	Determine the role of the practice nurse in diabetes care	UK	Audit performed among practice in Lanarkshire Health Board Sept. 1990	50 practices 3550 patients 67(12) years; 51% female	Practice	Multiple
Suleman et al.[301]	Cross-sectional	Examine whether practices characterized in patients' surveys as providing better access to nurses and greater patient education and involvement in consultations would be more likely to achieve targets for intermediate outcomes in people with diabetes	UK	QOF data relating to nine primary care trusts in the East Midlands of England, 2008-2009	629 practices N patients unavailable 199,485 patients Further details unavailable	Practice	Multiple

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
Tahrani et al.[142]	Longitudinal (three cross-sections 2004, 2005 and 2006)	Assess the impact of practice size on diabetes care in Shropshire before and after the QOF	UK	Shropshire practices participating in QOF implementation in April 2004 and after April 2005, 2006	66 practices 16 858 patients Further details unavailable	Practice	Multiple
Vamos et al.[138]	Longitudinal, interrupted time series	Examine whether patients attending larger family practices receive better care for diabetes Test whether larger practices derived more benefit from the Quality and Outcomes Framework	UK	General Practice Research Database extract containing the medical records of participating practices between 1997 and 2005	422 practices 154,945 patients (≥ 18 year) Further details unavailable	Practice	Multiple

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
Van Bruggen et al.[259]	Baseline RCT data	Investigate the occurrence of clinical inertia in the intervention and control group and the relationship between inertia and the outcome of diabetes care	The Nether lands	All practices in the greater Apeldoorn region participating in a trial to treat their patients either in accordance with local guidelines or in line with the 1999 Dutch College of General Practitioners guidelines	30 practices 1283 **type 2** patients Intervention: 66.6 (11.2) years; 54.1% female Control: 66.9 (11.6) years; 48.2% female	Practice	Treatment intensification
Van Doorn-Klomberg et al.[306]	Cross-sectional	Identify organizational determinants of the following outcomes: HbA1c, BP, and cholesterol levels	The Nether lands	Primary care practices that participated for the first time in a Dutch Accreditation program between 2006 and 2009	354 practices 11 751 patients 65.9 (12.1) years; 49% female	Practice	Multiple
Wang et al.[309]	Cross-sectional	Examine the performance of urban general	UK	Data for the year 2002 from	638 practices	Practice	Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		practices in Scotland comparing the QOF points attained by practices according to the size of the practice		Information Services, NHS National Services Scotland for all **urban** general practices in Scotland	Almost 1 million patients (N not available)		
Wencui et al.[302]	Cross-sectional	Examine the impact of using a registry for patient reminders and for improvement of the quality of care, hospital utilization, and cost saving	US	Claims data linked to practices enrolled in the Beacon Community Cooperative Agreement Program 2010-2011	50 practices 12 514 patients; 18-75 years. 58.5 (11.2) years; 49.9% female	Practice	Composite
Wong et al.[303]	Retrospective cohort	Assess the association of patient volume with quality of diabetes care in	Hong Kong	Clinical data management system administrative database of the Hospital Authority	74 clinics 87,031 patients 66.8 (12.0) years; 54.3% female	Practice	Multiple

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		primary care setting		of Hong Kong, on patients attending outpatient department or family medicine clinic at least once 1 April 2011 to 31 March 2012			
Angstman et al.[277]	Cross-sectional	Define an optimal and individual physician panel size for our team-based practice, to model methods that could be generalized to other clinical practices to help evaluate their family medicine panel sizes with clinical outcomes	US	Department of Family Medicine of the Mayo Clinic in Rochester, Minnesota - multisite practice, 2014	36 physicians Age NR; 38.8% female N patients unavailable - panel size ranged 768-1921	Physician	Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
Berthold et al.[260]	Cross-sectional	Determine whether physician gender plays a role in the quality of diabetes care	Germany	Practice-based physicians participating in the DUTY (Diabetes mellitus needs unrestricted evaluation of patient data to yield treatment progress) study. Feb. 2002 – Nov. 2003	3096 physicians Age unavailable; 33.7% female 51 053 patients with **type 2** diabetes 65.2 (10.9) years; 51.4% female	Physician	Multiple
Bralic Lang et al.[261]	Cross-sectional	Assess the extent of clinical inertia in treating diabetes in primary care in Croatia and to investigate its association with patient, physician, and	Croatia	National, multi-centre, study conducted in random sample of primary care physician offices across all Croatian regions between 2008 and 2010	449 physicians 49.2(7.64) years; 84.4% female 10 275 patients with **type 2** diabetes (≥40 years) 65.7 (10.1) years; 51.9% female	Physician	Intensification

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		health care setting characteristics					
Brody et al.[269]	Retrospective medical record review	Evaluate whether physician characteristics and patient clinical characteristics affect the delivery of preventive services in an insured but non–health maintenance organisation population	US	Primary care clinics in Atlanta part of a larger primary care centre, 1997	26 physicians Further details unavailable 924 patients >21 years 61 years; 48.1% female	Physician	Multiple
Dahrouge et al. 2016[270]	Cross-sectional	Investigate the relationship between physician gender and quality of primary care	Canada	Population-based study of primary care services in Ontario, Canada using multiple datasets conducted April 1,	4195 physicians 53 (46-59) median (IQR) years; 31% female 837778 patients 41 (21-56) median (IQR) years; 51.7% female	Physician	Multiple

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
				2008 and March 31, 2010.			
Dahrouge et al. 2016[282]	cross-sectional	Investigate the relationship between panel size and a comprehensive set of primary care quality indicators using linked, population-based health administrative databases	Canada	Population-based study of primary care services in Ontario, Canada using multiple datasets conducted April 2008 and March 2010	4,195 physicians 53 (46-59) years; 31.1% female 8.3 million patients (overall no N for patients with diabetes)	Physician	Multiple
Ferroni et al.[134]	Cross-sectional	Evaluate whether physician and patient characteristics affect diabetes management	Italy	Local Health Units of the Veneto Regional Health Service, 2013	21 health units 4660 physicians 85% older than 50 years; 30% female 139,935 **non-insulin-treated** patients; 18-84 years 79% aged 55–84 years; 43% female	Physician	Multiple

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
Holmboe et al. 2008[255]	Cross-sectional	Examine the association between cognitive skills, as measured by maintenance of certification exam performance, and performance on a set of Centre for Medicare and Medicaid Services quality measures for patients with diabetes	US	Random sample of internists who initially certified in internal medicine between 1990 and 1995, linked to claims data	3602 physicians Age unavailable; 36.8% female 52307 patients (Medicare) 78.9% ≥65 years; 53.4% female	Physician	Composite
Holmboe et al. 2006[278]	Cross-sectional	Determine the association between the number of Medicare diabetic patients cared for by a primary	US	Claims data from all Connecticut Medicare beneficiaries (2001)	1261 physicians Further details unavailable 26260 patients ≥ 65 years 76.1 (6.8) years; 57% female	Physician	Multiple Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		care physician and the receipt of important diabetic processes of care					
Kamien et al.[271]	Cross-sectional	Record general practitioners' opinions, attitudes, practices and outcomes for the care of people with type 2 diabetes	Australia	Two lists of GPs (300 doctors on the vocational register at 1 November 1991; 300 doctors who were not on the register at that date) randomly selected by the Health Insurance Commission from the population of all GPs in the Perth metropolitan area	110 practices 204 physicians 18.6% female; 42.4 (10.0) years among females, 46.6 (10.3) years among males 467 patients 61.5 (9.7) years; 44.8% female	Physician	Multiple Composite
Kim et al.[272]	Baseline RCT data	Compare the preventive services and intermediate	US	Stratified, random sample of adults with diabetes from 10 health	1686 physicians Further details unavailable 3459 patients (≥18 years)	Physician	Multiple Composite

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		outcomes provided by male and female physicians for their patients with diabetes before and after adjustment for patient and physician characteristics and after adjustment for clustering within provider groups and health plans		plans and 68 provider groups for the Translating Research Into Action for Diabetes (TRIAD) multi-centre study. Sept. 2001 - 2003	62 years; 54% female		
LeBlanc et al.[281]	Cross-sectional	Understand reasons for inaction in the context of elevated A1Cs, by examining the extent to which clinician	US	Primary care physicians continuously employed with Kaiser Permanente Northwest, a non-profit, group-	107 physicians 48.8 (42.2-54.6) median (IQR) years; 44.9% female 921 patients Median (IQR) 62 (54.0-69.0) years; 45.8% female	Physician	Intensification

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		and patient characteristics were associated with glycaemic control and treatment intensification after loss of glycaemic control		model Health Maintenance Organisation providing care to individuals in a 75-mile radius around Portland, Oregon, during 2011			
Linder et al.[273]	Baseline RCT data	Examine if primary care physicians who more intensively interact with the EHR through their documentation style have better quality of care	US	Practices participating in a physician-randomized, controlled trial of a novel documentation-based clinical decision support system for coronary artery disease and diabetes called Smart Forms (March 3, 2007 to August 10, 2007)	10 practices 234 physicians 8 (11) years; 53% female 7000 patients (coronary artery disease or diabetes) 65 (14) years; 52% female	Physician	Multiple

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
Parkerton et al. 2003[274]	Cross-sectional	Examine association between the number of physician primary care clinical hours and diabetic management	US	Primary care practices in all western Washington state medical clinics, of a single group model health maintenance organization, 1998	25 clinics 194 physicians Further details unavailable N patients unavailable (nearly 20,000 - N ranged from 8 to 267)	Physician	Composite
Shuval et al.[275]	Baseline RCT data	Examine the association between evidence-based medicine knowledge and quality of care for patients with diabetes, coronary heart disease and hypertension	Israel	Physicians were from one region of the largest Health Maintenance Organization participating in a controlled trial of evidence-based medicine intervention between March	74 physicians 49.9 (6.8) years; 53.3% female 8334 patients Further details unavailable	Physician	Multiple

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
				and September 2004			
Streja et al.[280]	Retrospective chart audit	Determine characteristics of physicians and their practice that might determine their behaviour in the area of prevention of complication of diabetes	US	Primary care providers of Community Medical Group of the West Valley, a managed care medical group in southern California 1993-1994	22 physicians Age unavailable; 41% female 524 patients >16 years 51.0 (1.0) years; 41% female	Physician	Multiple
Tabenkin et al.[276]	Baseline RCT data	Conduct a multilevel analysis of the effects of the sex of the patient and physician, as well as physician-patient interactions by	US	Representative primary care physician practices in south-eastern New England participating in a cluster randomized trial aimed at testing the effectiveness	30 practices 55 physicians 46 (7.4) years; 29.1% female 4,195 patients 52.53 (13.3) years; 60% female	Physician	Multiple

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		sex, on the management of CVD risk factors in primary care		of translating the Adult Treatment Panel III 2 cholesterol treatment guidelines into primary care Data collection: 2004			
Turchin et al. 2007[279]	Retrospective cohort	Assess whether the number of diabetic patients cared for by an individual physician (diabetes volume) is an independent predictor of quality of diabetes care	US	Patients followed by primary care physicians at Massachusetts General Hospital and Brigham and Women's Hospital between 1 January 2000 and 31 August 2005	368 physicians Further details unavailable 7,120 patients (≥18 years) 63.7 years; 55.8% female	Physician	Multiple
Turchin et al. 2008[266]	Retrospective cohort	Examine the association between the	US	Diabetic patients followed up by internists at the	301 internists at primary care practices Median age 41 years	Physician	Intensification

Table 5 Characteristics of the included studies (n = 76). Studies included in the meta-analysis are highlighted.

Reference	Design	Aim	Region	Sampling	Population	Factors	Outcome
		time since the last board certification of the patient's physician and the frequency of antihypertensive treatment intensification		Massachusetts General Hospital and Brigham and Women's Hospital between January 1, 2000, and August 31, 2005	8127 **hypertensive** patients with diabetes (≥18 years) 63.7 years; 55.8% women		

*patients are both type 1 and type 2 unless otherwise stated; adult patients unless age range stated; physicians are primary care physicians unless otherwise stated

**detailed statistical analysis was not undertaken as large sample size

Abbreviations: RAP, intervention arm receiving practice facilitation using reflective adaptive process change model based on complexity theory; CQI, continuous quality improvement arm received practice facilitation based on the model for improvement; SD, self-directed arm received limited feedback; QOF, Quality and Outcomes Framework; RCT, randomised controlled trial; IQR, interquartile range; QI, quality improvement; EHR, Electronic Health Record; CVD, Cardiovascular disease; BP, blood pressure

Multiple; several individual quality measures were examined

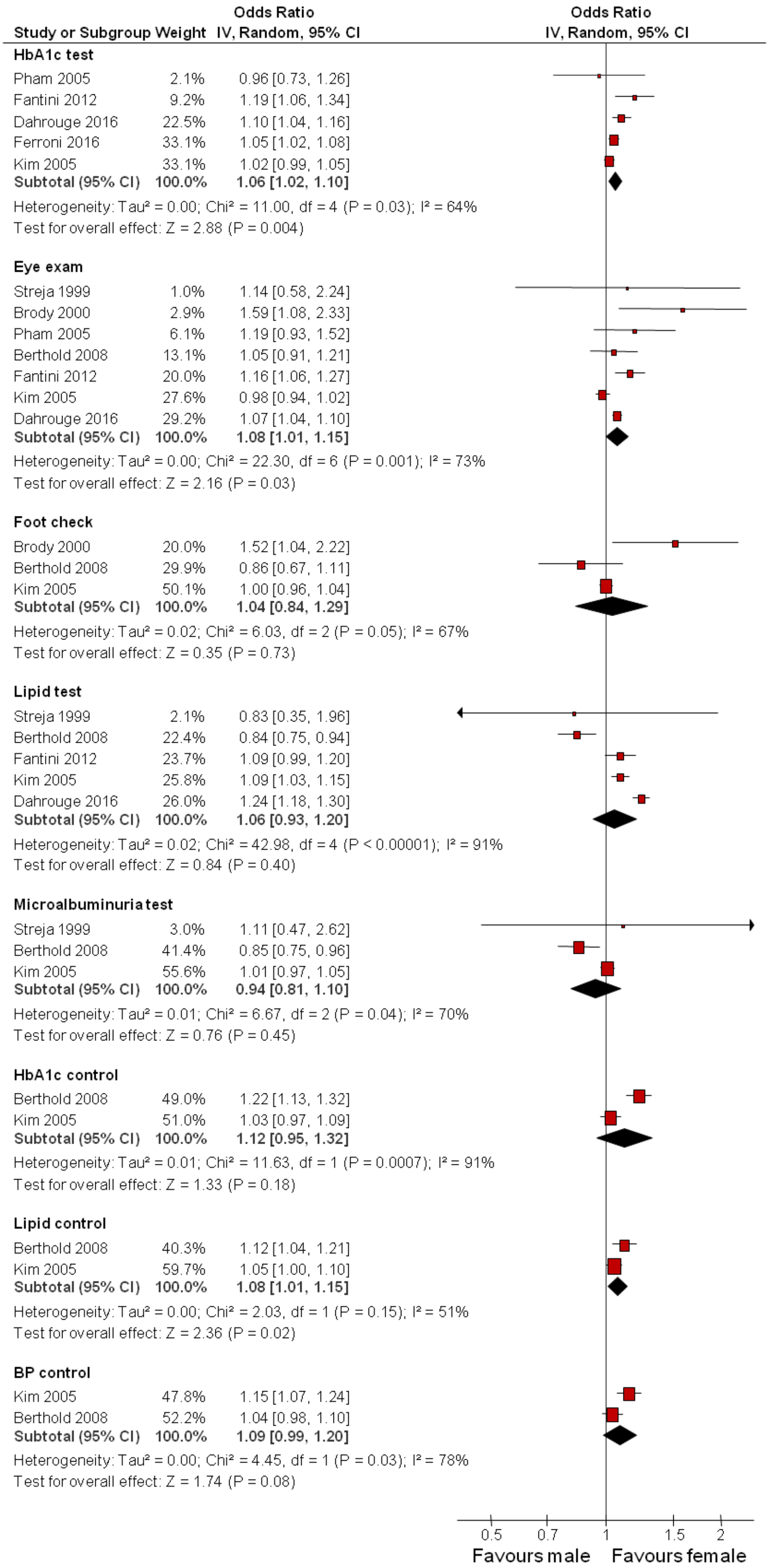


Figure 3 Physician gender and individual measures of quality*

*Berthold et al. included patients with type 2 only; Ferroni et al. included non-insulin treated patients only; Pham et al. analysed data from Medicare beneficiaries ≥65 years. Berthold et al. used targets HbA1c <7.0%; LDL-C <130mg/dl; Kim et al. used targets HbA1c <8.5%; LDL-C <130mg/dl

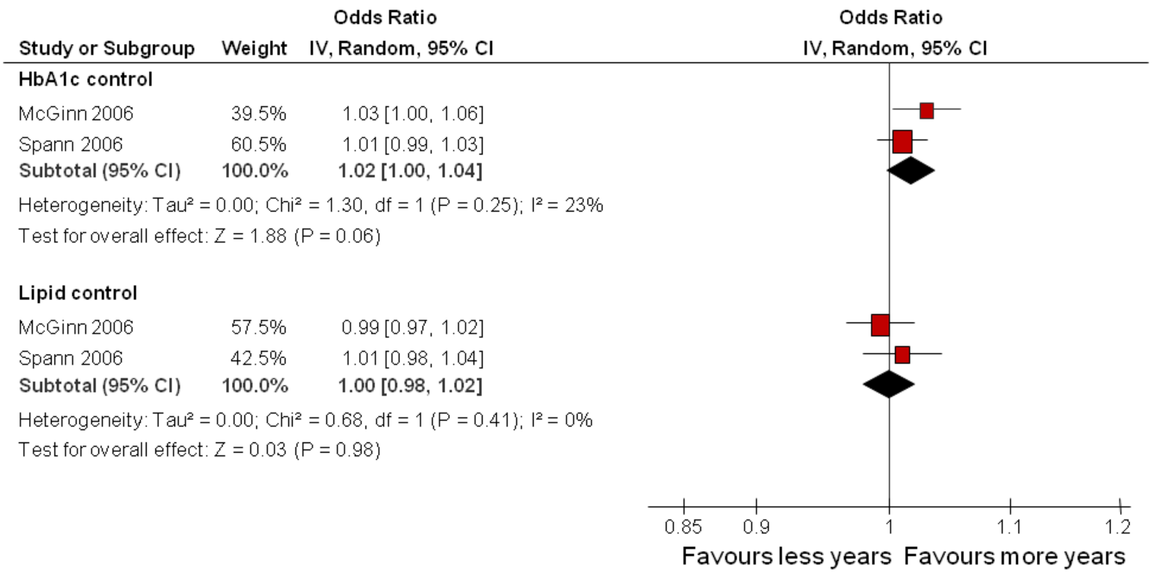


Figure 4 Physician years of experience and individual measures of quality*

*Spann et al. used targets HbA1c < 7.0%, LDL-C <100mg/dl; McGinn et al. useds target HbA1c <9%, LDL-C <130mg/dl

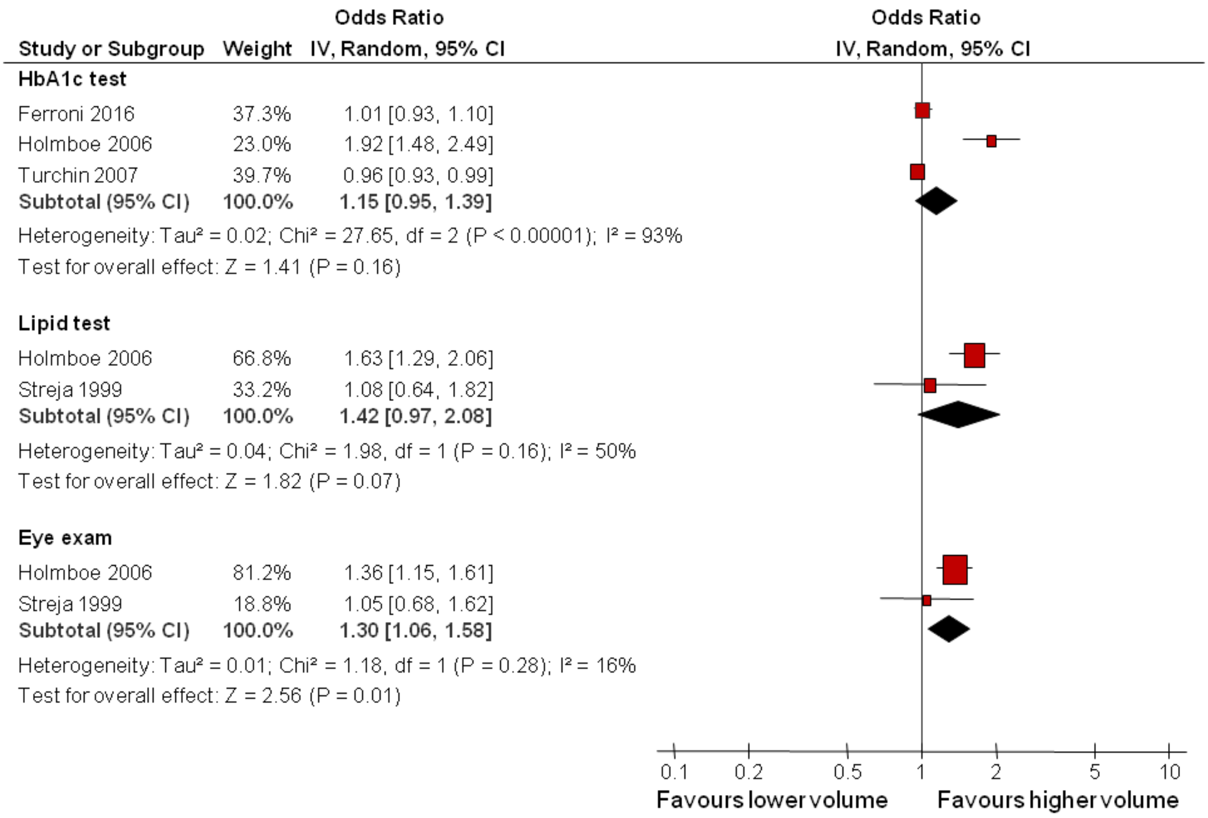
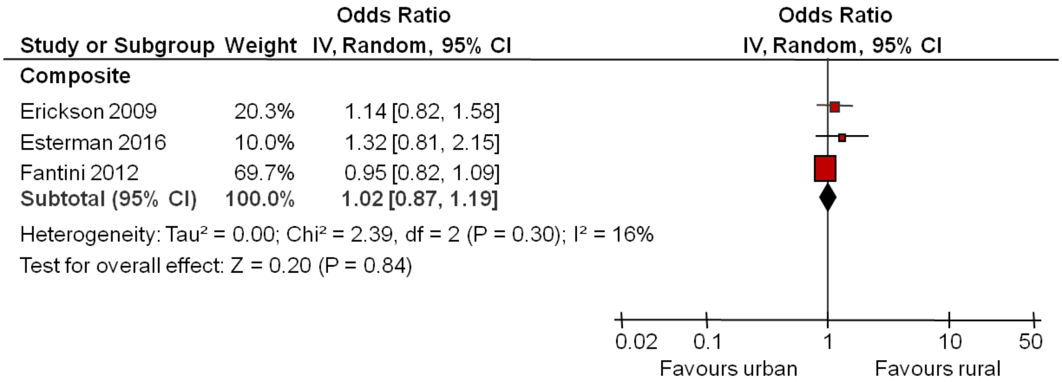


Figure 5 Physician volume of patients with diabetes and individual measures of quality*

*Holmboe et al. volume group V (32-66 patients) vs. volume group I (1-4 patients); Ferroni et al. 56–70 patients vs. ≤55 patients; Turchin et al. per 10 patients annually; Streja et al. >20 patients vs. ≤20 patients

(a) **Location and composite measure of quality**



(b) **Type and individual measures of quality**

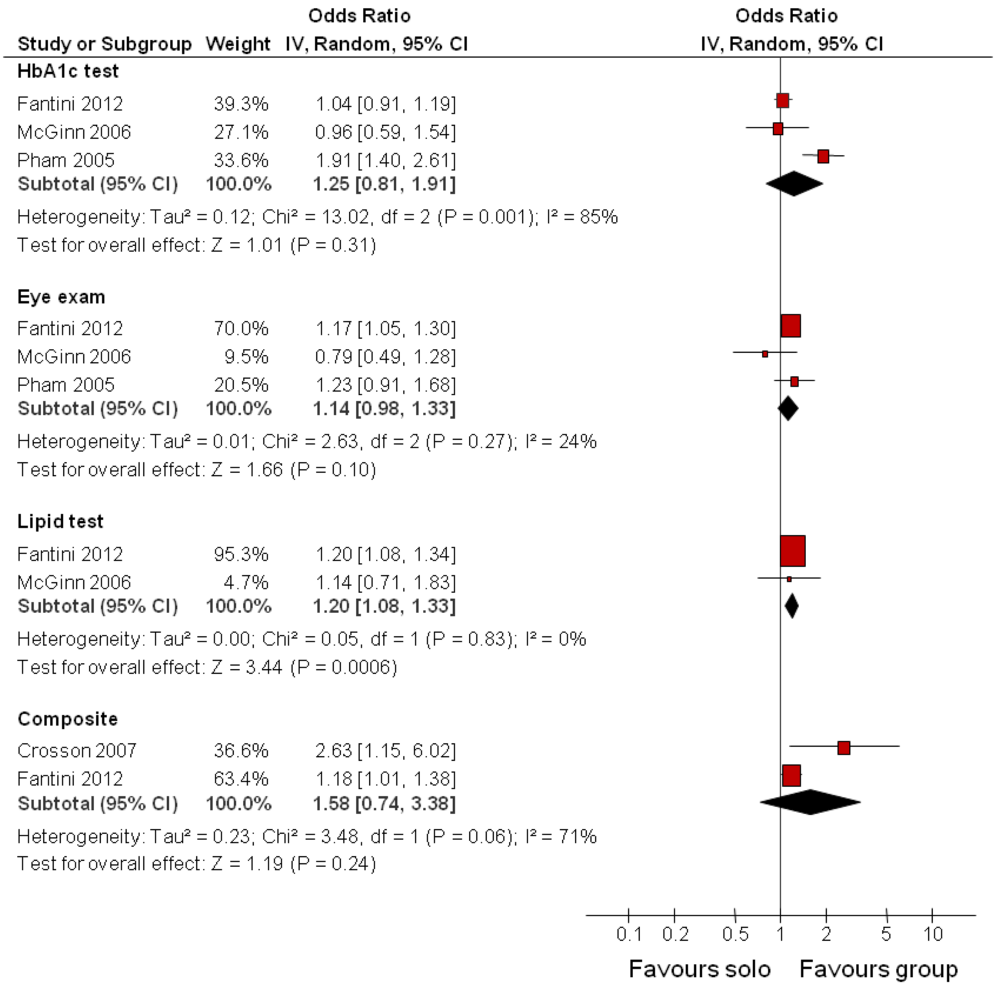


Figure 6 Practice location and type and quality of care

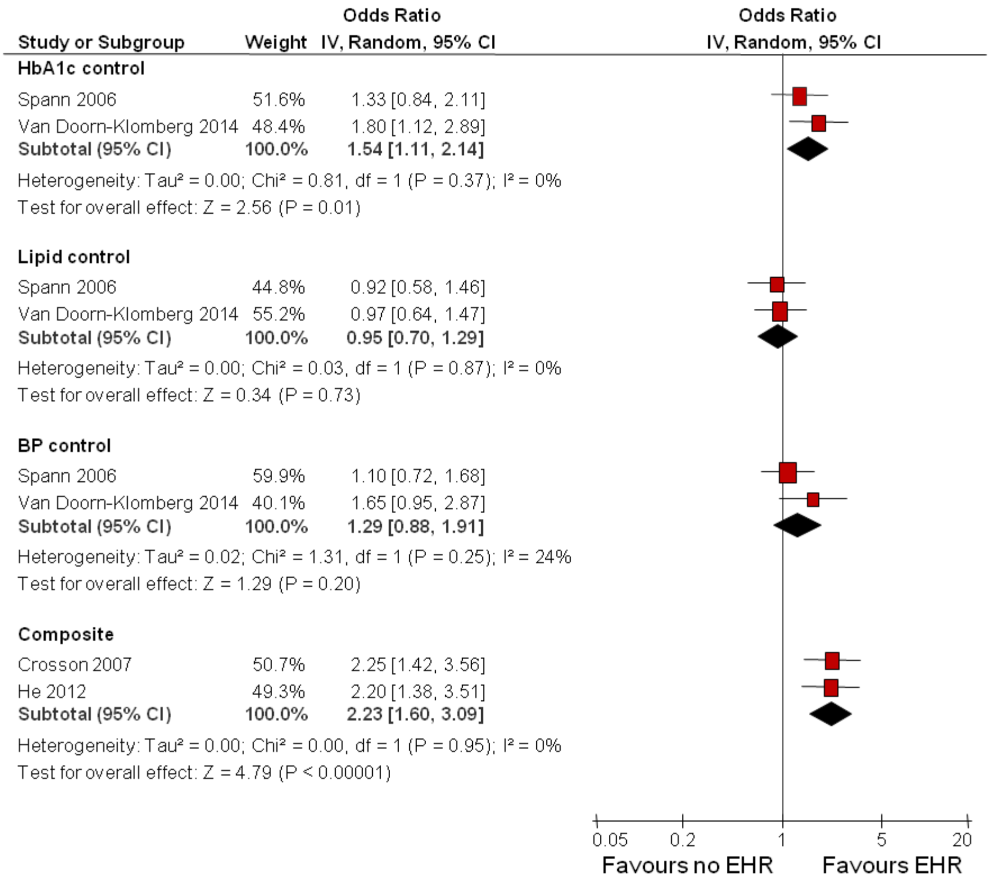


Figure 7 Electronic Health Record (EHR) at practice and the association with quality*

*He *et al* estimates relate to older men only, estimates for older women were not significant (OR = 1.1, 0.63-1.91), with inclusion of this data the pooled estimate is still significant. Van Doorn Klomberg et al. compared practice performance in highest vs. lowest quartile for HbA1c, BP and cholesterol control; Spann et al. used targets for good control of HbA1c (≤7%), BP (≤130/85mmHg), LDL-C (<100mmol/mol)

4 Sustaining quality in the community: Trends in the performance of a structured diabetes care programme in primary care over 16 years

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4.1 Abstract

Aim: Examine the quality of care delivered by a structured primary care-led programme for people with type 2 diabetes mellitus 1999-2016.

Methods: The Midland Diabetes Structured Care Programme provides structured primary care-led management. Trends over time in care processes were examined (chi-squared trend test; age, gender adjusted logistic regression). Screening and annual review attendance were reviewed. A composite of eight National Institute for Clinical Excellence recommended processes was used as a quality indicator. Participants referred to DNS were compared to those not referred (Student's t test; Pearson's chi-squared test; Wilcoxon-Mann-Whitney test). Proportions achieving outcome targets (HbA1c ≤58mmol/mol (7.5%), blood pressure (BP) ≤140/80mmHg, cholesterol <5.0mmol/l) were calculated.

Results: Data were available for people with diabetes ≥18 years: 1998/1999 (n = 336), 2003 (n = 843), 2008 (n = 988), 2016 (n = 1,029). Recording of some processes improved significantly over time (HbA1c, cholesterol, BP, creatinine), in 2016 exceeding 97%. Foot assessment and annual review attendance declined. In 2016, only 29% had all eight National Institute for Clinical Excellence processes recorded. A higher proportion of people with diabetes referred to a diabetes nurse specialist had poor glycaemic control compared to those not referred. The proportion meeting BP and lipid targets increased over time.

Conclusions: Structured primary care sustained improvements in the quality of care over time. Poorer recording of some processes, a decline in annual review attendance, and participants at high risk, suggest limits to what structured care alone can achieve. Engagement in continuous quality improvement to target other factors, including attendance and self-management, may deliver further improvements.

Key words: Primary Health Care, Quality of Health Care, Outcome and Process Assessment (Health Care), Standard of Care

4.2 Introduction

Diabetes Mellitus is a complex chronic condition requiring structured management, including a focus on treatment goals for BP, glucose control and lipids, regular review and recall, screening for complications, and input from multidisciplinary professionals [366]. Primary care, as a first point of contact, and source of continuous, comprehensive, and coordinated care is often seen as a starting point for the delivery and organisation of diabetes care [152]. Evidence suggests that primary care management can be as effective as hospital-led care if well supported and organised [152]. Efforts to optimise care across different health systems have led disease management programmes to better organise management in primary care and improve co-ordination between the community, out-patient/ambulatory and in-patient settings [104, 117, 367].

Disease management programmes in primary care incorporate different components: multidisciplinary cooperation, registration systems, audit and feedback, clinician reminders, patient and professional education, and/or the establishment of a specific communication system and ongoing collaboration between specialities and primary care (shared care). Structured approaches to diabetes care, combining some or all of these elements, demonstrate improvements in glycaemic control and cardiovascular risk factors [117, 118], albeit evidence for the effectiveness of shared care is less certain [23, 108]. Specific components delivering significant improvements in clinical outcomes [23, 118, 162] and care processes [118], include access to a multidisciplinary team [23], case management [23], partial replacement of physicians by nurses [162], self-management promotion[23], and interventions to prompt recall and review of patients, including electronic registries, reminders and tracking systems [118]. However, interventions operating at all levels of the health system (system, provider and patient) have demonstrated a greater effect on glycaemic control than interventions targeting a single level [23].

Despite growing evidence on ways to improve the quality of diabetes care, some uncertainties remain, including whether the effects achieved by evaluative quality improvement studies can be replicated in 'real life' practice. Despite international consensus on optimal diabetes management, a gap persists between recommendations and actual practice [21]. With increasing pressure on primary care, growing patient numbers and workforce shortages [152, 199], demonstrating the long-term sustainability of structured primary care management is a challenge. Internationally, high quality service evaluations to address this evidence gap are lacking [199]. Most studies examining diabetes management in primary care have a relatively short follow-up [108, 117, 118], cannot provide an insight into the sustainability of these programmes over time, and may not be able to demonstrate effectiveness [108]. Few studies evaluate enhanced models of primary care management over a longer period, of 10 years or more [119, 200, 201].

In Ireland [188], as elsewhere in Europe [367], national policy in recent years has focused on moving from hospital-led management to deliver care in the community. Diabetes care is historically unstructured, however, formal primary care initiatives developed across the country to improve the quality of care and service delivery at a local level. The longest running is the HSE Midland Diabetes Structured Care Programme, established in 1997/1998. We aimed to examine the quality of care delivered by the Midlands programme over a long follow-up period (1999–2016) through a series of cross-sections. We reviewed the delivery of the programme by examining trends in the processes of care performed for people with type 2 diabetes and benchmarked the programme against international standards [67, 244].

4.3 Methods

4.3.1 Setting

In Ireland, the national prevalence of doctor diagnosed diabetes among adults aged 18 years and over is 5.2 %, an increase from 2.2 % in 1998 [37]. Over one third of adults (37%) are overweight and 23% are obese. The prevalence of smoking is 23% [368].

4.3.2 Midland Diabetes Structured Care Programme

The Midlands programme, based in 4 counties in Ireland (Longford, Westmeath, Laois and Offaly), employs several evidence-based intervention components: adoption of clinical guidelines, patient register and recall and protected time for review (three 30-minute visits per year), organisation and coordination of care by practice nurses, structured multidisciplinary support, and professional and patient education [23, 162]. Practices are remunerated for patients' visits through an existing chronic disease programme, Heartwatch, or reimbursed for practice nurse time. Practices receive clinical (DNS, podiatry/chiropody, dietetic), educational, and administrative support, which has changed since the programme was first established e.g. loss of dietetic support (Figure 8). Additional detail on the programme is available in Appendix 10.1.1.

4.3.3 Data collection

DNS extracted data from practice records on people with type 1 diabetes and type 2 diabetes (≥18 years) enrolled at four time points: 1998/1999, 2003, 2008, and 2016. Owing to resources constraints, reliability checks at each timepoint were not performed by DNS on the extracted data. However, quality checks at data entry were carried out by PM. A census sample was selected in 1998/1999 and 2003 and a systematic sample in 2008 and 2016. In 2008, participants were sampled by sorting alphabetically first by name and selecting every third person. In 2016, all participants who were still alive and were part of the census sample in 1998/1999 were selected. After ordering randomly, every third person was sampled from these participants. The remainder of the participants in 2016 was sampled by sorting alphabetically first by name then sampling every third person. This approach was taken to approximate a random sample overall in 2016. A flow chart is included in Appendix 3 Figure 19.

Sample size was calculated based on precision of HbA1c estimates. In 2003, mean HbA1c for the total sample was 60mmol/mol (7.6%) and the 95% CI was ± 1mmol/mol (0.11%) which equates to ~1.5%. Therefore, a confidence level of 95% and CI of 2% was chosen to calculate the sample size for 2008 and 2016. Based on the total population of 2,275 participants in 2008, the sample size was 1,168. Based on the total population of participants in 2016 of 3,797, the sample size was 1,471. Only participants with type 2 diabetes are reported here.

Data sources included clinical notes (electronic and paper), outpatient appointments letters and referrals to chiropody/podiatry, retinopathy and dietetics. Data were collected on demographics: age, gender, and GMS status (a means tested method of public health insurance; GMS cardholders have free access to general practitioner services and medications) [369].Data were also collected on diabetes type, duration, annual review attendance, use of diabetes-related services (retinopathy screening, specialist eye services (any service in community or hospital, private or public), diabetes nurse specialist or podiatrist/chiropodist), prescription of diabetes medications (oral hypoglycaemic agents (OHAs), insulin, injectables) and other medications (statins, angiotensin converting enzyme inhibiters, aspirin). Data were collected on care processes carried out in the previous 12 months: foot assessment carried out by any healthcare professional (i.e. GP, practice nurse, DNS, consultant, podiatrist), measurement of HbA1c, cholesterol, BP, creatinine, albumin creatinine ratio, body mass index (BMI), smoking status) and intermediate clinical outcomes (i.e. risk factors; HbA1c, cholesterol, triglycerides, BP, creatinine). Smoking status (yes/no) in the past 12 months was determined on the basis of participants' response to a question about whether they smoke now. Data on complications were also collected: retinopathy, macrovascular (heart attack (myocardial infarction), heart failure (congestive cardiac failure), stroke (cerebrovascular accident), and mini stroke (transient ischemic attack)), peripheral neuropathy, autonomic neuropathy, foot risk category, and ulcer. Both eyes are checked and people were classified as having retinopathy if it was recorded in at least one eye. Both feet are checked and classification of foot risk (low / moderate/ high) was recorded on the basis of the highest risk in either foot. Ulcer was recorded as "yes" if the person had an ulcer in at least one foot.

4.3.4 Analysis

Practice addresses were mapped to Electoral Divisions and assigned a deprivation score and decile using the 2011 National Deprivation Index for Health and Health Services Research developed by the Small Area Health Research Unit [370]. Data were represented as means ± SD or median (interquartile range (IQR)) (continuous) or numbers and proportions (categorical data). Quality of care was defined using a composite of eight care processes recommended by the National Institute for Clinical Excellence (HbA1c, BP, cholesterol, smoking status, BMI, creatinine, albumin creatinine ratio, and foot examination) [371]. While recording of triglycerides was reported, this process was excluded from the composite. Trends over time in the proportion with processes recorded were examined using chi-square test for trend, and logistic regression models adjusted for age and gender. Trends in recording was examined for selected processes collected across all four years (HbA1c, BP, cholesterol, smoking status, BMI, and creatinine) across practices. Differences in the proportion with processes recorded between participants aged <75 years and ≥75 years were examined using Pearson's chi-squared test. The proportion attending annual review and diabetes-related services were reported at different time-points. Differences in the demographic and clinical profile of participants referred and those not referred to a diabetes nurse specialist were tested using Student's t test or Wilcoxon-Mann-Whitney test (continuous data), and Pearson's chi squared test (categorical data).

Guidelines recommend people with *complicated* type 2 diabetes attend a DNS[68]. Complicated type 2 diabetes is defined as those requiring insulin, people with HbA1c >58mmol/mol (7.5%) on two or more glucose lowering agents (not insulin), and people with complications or graded as having a high risk foot[68]. Continuous outcome data were categorised according to international standards: BP ≤140/80mmHg, triglycerides <2.0 mmol/l, cholesterol <5.0mmol/l, HbA1c ≤58mmol/mol (7.5%) [67, 244, 372], and proportions of participants meeting clinical outcome targets were calculated. All analysis was carried out in Stata v.12 for windows (StataCorp, College Station, TX, USA).

4.4 Results

4.4.1 Profile of the sample population

Data on 336 people with type 2 diabetes in 1998/1999 (10 practices), 843 in 2003 (20 practices), 988 in 2008 (30 practices), and 1,029 (30 practices) in 2016, were available for analysis. Overall less than 10% of data were missing, with some exceptions depending on time-points: creatinine (1-31%), BMI (27-44%), smoking status (21-32%), podiatrist/chiropodist attendance (0-17%) and dietician attendance (0-40%). Where missing data occurs, the figures represent the recorded data. Over 85% of GPs were based in practices within the lowest deprivation deciles, 9 (n = 14, 41%) or 10 (n = 15, 44%). In 2016, the cohort was aged 68 (60-76) years. Most were men (n = 603, 59%) and had a GMS card (n = 823, 80%). Median duration of diabetes was nine years. The profile of people with type 2 diabetes was similar across time-points (Table 6).

4.4.2 Process measures

In 2016, recording for most care processes was >97%. Recording improved significantly since 1998/1999, with change more evident between earlier time-points (Figure 9). BMI and smoking status recording remained consistently lower than other processes. Although there was a significant improvement between 1998/1999 and 2008 (BMI: 60% vs. 73%; smoking status: 68% vs. 77%) recording remained below 80% from 2008 to 2016. The proportion of participants with a foot assessment in the past 12 months declined from 2008 to 2016 (77% vs. 53%). In 2016, only 29% (n = 296) of participants had all eight National Institute for Clinical Excellence recommended processes recorded.

Trends in recording were similar when stratified by age (<75 years and ≥75 years) with the exception of smoking status and BP recording among participants <75 years (Appendix 3 Table 24). At individual time points certain processes were consistently less well recorded ($p < 0.05$) among participants ≥75 years: 1999 (BMI: 64% vs. 48%; triglycerides: 72% vs. 51%), 2003 (BMI: 58% vs. 48%; triglycerides: 93% vs. 87%), 2008 (BMI: 75% vs. 67%; triglycerides: 99% vs. 96%; albumin creatinine ratio: 74% vs. 67%), and 2016 (albumin creatinine ratio: 85% vs. 75%)

Consistent improvements in recording were seen across all practices for HbA1c, systolic BP, cholesterol, triglycerides and creatinine. There was some variation in proportions recorded in 1999 among the 10 originally enrolled practices (HbA1c 0-100%; BP 69-100%; cholesterol 0-100%; triglycerides 0-100%; creatinine 0-97%). BMI and smoking status recording did not improve consistently, with some practices showing a decline in recording over time. Data for the 10 original practices are shown in Appendix 3 Table 25.

4.4.3 Attendance at annual review and diabetes-related services

Annual diabetes review attendance increased between 1998/1999 (18%, n = 46 /261) and 2008 (91%, n = 895 / 980), but dropped in 2016 (77%, n = 788 / 1,025). In 2016, clinical parameters were recorded for most participants who attended and did not attend annual review (HbA1c: 100% vs. 97%; BP: 99% vs. 93%; cholesterol: 100% vs. 96%; creatinine: 100% vs. 95%). However, there were differences in foot assessment (57% vs. 38%), BMI (79% vs. 47%) and smoking status (86% vs. 56%) recording. A similar pattern was observed in 2008. In 2008, 58% (n = 548 / 949) of participants had seen a chiropodist or podiatrist in the past 12 months, which declined further by 2016 (51%, n = 439 / 863). In 2008, only 51% (n = 507 /988) had attended specialist eye services but in 2016, 80% (n = 800 /1006) of participants had attended either the national screening programme (RetinaScreen) or specialist eye services. The proportion who had seen a hospital or community dietician dropped from 50% (n = 167 / 336) in 1998/1999 to 7.1% (n = 42 / 610) in 2016. However, recording quality also declined; 41% (n = 419 / 1029) were missing data in 2016 compared to 0.3% (n = 1 /336) in 1998/1999.

Attendance at a DNS increased between 2008 and 2016 (11% vs. 15%). Participants who were referred had diabetes for longer and were younger than those who were not referred (Table 7). A greater proportion of people referred had poor glycaemic control (HbA1c >58mmol/mol [7.5%]) (50% vs. 20%, $p<0.001$), were on OHAs or injectables (98% vs. 81%, $p<0.001$), and had retinopathy (41% vs. 30%, $p<0.01$). However, a lower proportion were classified as having a high risk of foot disease (1.9% vs. 4.4%, $p<0.05$).

4.4.4 Outcome targets

Over time, the proportion meeting BP and lipid targets increased, whereas the proportion with HbA1c ≤58mmol/mol (7.5%) was similar (Table 6). Across time points, the proportion meeting all three outcome targets (HbA1c, BP and cholesterol) ranged from 12% (1999) to 39% (2016). Those at high risk, HbA1c >58mmol/mol (7.5%), had diabetes for longer. The proportion on OHA only was similar across high and low risk groups. A greater proportion at low risk were on OHAs or injectables (Appendix 3 Table 26).

4.5 Discussion

We examined the quality of care delivered by a structured primary care management programme for people with type 2 diabetes. We found significant improvements in process of care recording. These are consistent with changes in recording [104, 118, 200, 201] reported by multifaceted international programmes with similar components: registration [118, 200, 201], practice guidelines [104, 201], incentives [104], on-going professional education [118, 201], nurse case management [200], and structured multidisciplinary support [104]. Our findings suggest these changes can be sustained over time in a 'real life' setting. However, despite evidence of ongoing improvement there may be limits to what structured programmes can achieve in the long term. BMI and smoking status were consistently less well recorded, performance of foot assessment, and attendance at dietetic and annual review declined in the later years of the programme, and some participants remained at high risk.

Unlike QOF in the UK, payment as part of the Midlands programme is not based on process recording. Smoking status and BMI recording remained lower than other processes, comparing poorly with the recent National Diabetes Audit [371], based on QOF data, and other European countries [126]. However, BMI and smoking status recording in the National Diabetes Audit was also lower than recording of other processes. While incentivising individual indicators can improve recording to a degree, poor documentation of certain processes may persist. Some may be prioritised less than other clinical measurements during review visits. BMI recording, for example, may only occur if a general practitioner or practice nurse recognises the patient as overweight/obese, intends to offer management, or feels willing or able to engage in discussions about weight [373]. We found variation across practices in recording of BMI and smoking status, with some practices showing a decline in recording over time. With the exception of 2016, BMI was consistently less well recorded among older participants (≥75 years). Foot assessments, also poorly recorded, have been more frequently performed among people with low income, poorer metabolic control, or complications, and less frequently by general practitioners compared to specialists [374]. Assessments may be time-consuming and unfeasible as part of regular review, or only prioritised when the general practitioner is aware of an increased risk of amputation.

We found a significant, improving trend over time in recording of care processes. However, this was driven by more substantial improvements between earlier time-points. There was minimal change between 2008 and 2016 once recording >97% had been achieved. However, a similar pattern was observed for BMI and smoking status, although these were less well-recorded. This suggests that recording may plateau irrespective whether near maximal recording has been achieved or not. A plateau was also observed in the UK a year after the introduction of QOF [375] suggesting limits to what can be achieved through incentives, regardless of the reimbursement method. This raises the question of replacing QOF with a model to deliver more sustained improvements [376]. This has implications for the new Diabetes Cycle of

Care initiative introduced in Ireland in 2015, which remunerates general practitioners for care of people with stable type 2 diabetes holding a GMS card. Practices are paid on the basis of registering eligible people with diabetes, delivering two review visits per year, recording and reporting on care processes (clinical parameters, routine foot screening/referral, lifestyle review), not on the basis of meeting clinical targets. The initiative may improve the delivery of care processes, but only up until a point. Scotland have recently replaced QOF, establishing GP quality clusters, small groups of practices which engage in local, peer-led quality improvement activities[376]. While they may see an initial decline in care processes, there is scope for improvement beyond what is achievable through payments.

Although we did not track clinical outcomes in a fixed population, by reviewing outcomes in separate cross-sections we gain some insight into the profile of people with diabetes receiving structured care. In Ireland, 40% of older adults (≥55 years) are reported to have high BP (systolic BP ≥140 mmHg), and 41% have cholesterol >5 mmol/l [377]. Although recording of most processes in the Midlands programme was >97%, many participants were in high risk categories in terms of glycaemic control and their cardiovascular profile. Between 2003 and 2016 26-40% had HbA1c >58mmol/mol (7.5%), 41-52% had BP >140/80mmHg, and 15-42% had cholesterol >5mmol/l, consistent with research showing recording does not necessarily translate to better outcomes [76].

Recording clinical values is a quality measure in itself which may indicate the need to intensify treatment. However, achieving outcome targets requires appropriate action by professionals and patients. Emphasising processes alone, as with the Cycle of Care, may not deliver improved outcomes. Patient motivation, adherence, and the efficacy of self-management, influence risk factor management [21], but are not captured in the current study. We found the proportion with HbA1c ≤58mmol/mol (7.5%) was similar across time points, which could reflect the long disease duration among participants or the declining effect of OHAs [378]. While treatment goals provide a benchmark for quality, Lipska *et al* have recently questioned the use of 'surrogate' outcome targets like HbA1c as a quality indicator. They may not be appropriate for certain subgroups (e.g. the elderly, or those with co-morbidities) and should be individualised according to complication risk, preferences, and control strategy [361]. Greater emphasis has been placed on involving people with diabetes in the decision about their individual HbA1c target [67, 244]. Future monitoring of the Midlands programme should consider incorporating this information; i.e., recording whether a target has been agreed, documenting the agreed target, and using this as a basis for evaluating the quality of care.

Although retinopathy screening attendance improved, in 2016, 20% had not attended specialist eye services or RetinaScreen, the new national screening and treatment programme introduced in 2013. National guidelines recommend that people with complicated type 2 diabetes should attend a DNS including people requiring insulin, people with HbA1c >58mmol/mol (7.5%) on two or more glucose lowering agents (not insulin), or people with complications or graded as having a high risk foot [68]. In line with this recommendation, we found participants with more complicated diabetes were referred to a DNS. While the rate of non-attendance was low overall, those who did not attend had a higher median HbA1c than attenders. Further work is necessary to understand barriers to attendance among these participants, ways to improve attendance, and facilitate risk management. Although most participants attended for annual review, this declined between 2009 and 2016 (91% vs.77%). Transport, work and family commitments, and lack of motivation have been cited as reasons for non-attendance at annual review [379]. However, practice-level resource constraints could also account for this decline. An official annual review may not be performed at a single visit but instead components spread over several visits to lessen practice nurse workload. The increasing complexity of management may require longer reviews that cannot be incorporated into one visit [151]. Unlike clinical measurements, BMI, smoking status and foot assessment were less well recorded among those who did not attend annual review. These processes may not be a priority during regular visits, particularly for people with poor attendance.

Ireland is moving towards the delivery of structured, integrated diabetes management in primary care, with the establishment of the National Clinical Programme for Diabetes, resourcing of community-based 'integrated' DNS to facilitate delivery of the new model of integrated care which manages people with diabetes according to their complexity, and the Cycle of Care [68]. However, as a multi-component programme with good specialist support, the Midlands programme provides an insight into the impact of providing structured care in the community that predates these national changes. As enhanced access to community-based specialist resources does not form part of the Cycle of Care initiative, care may be moved to the community in areas with less access to a well-resourced multidisciplinary team. Programmes like the Midlands programme may also be influenced by health service changes. We found a drop in dietetic screening alongside a loss of resources further indicating the importance of sustained resources to deliver care in the community.

A strength of the current study is that it examines, over a long follow-up period, the impact of structured primary-care led service model delivered in routine practice rather than as part of a QI trial. However, participants were not the same at each time point (although some were represented at each). We also took different approaches to sampling at each time point. In 2008 and 2016, as the number enrolled in the programme exceeded 2,000, it was not feasible to manually collect data on every participant. Therefore, an appropriate random sample was taken. In 2016, as part of the larger sample taken at this time point, data were collected on all participants who had been enrolled in 1998/1999 and were still alive in 2016. This was done in order to facilitate a separate analysis which examines survival in the original cohort enrolled in the programme since its initiation. We can judge the overall delivery of the programme, but not infer the impact on individual participants since enrolment. Although different individuals were represented across different time points, it is encouraging that participants enrolled in this structured care programme were meeting outcome targets. However, we lack control practices to determine whether changes in clinical outcomes reflect overall improvements in medication (e.g. new OHAs) and management in the time-period, or the organisation and delivery of the programme. Most participants enrolled were on lipid-lowering or

BP medication. The programme is multifaceted therefore we cannot prove that one component was more effective than others. Data were extracted from GP records, and we depend on the reliability of data from this source. As highlighted in Section 3.6 a composite measure depends on the reliability of the underlying indicators. A composite was used in the current study comprised of eight National Institute for Clinical Excellence recommended processes. However, while certain processes, i.e. HbA1c test, BP check, may be automatically added to the patient file, others, for example, retinopathy screening obtained through an external provider, may be recorded manually in the patient notes. As such, the reliability of individual processes may have varied.

4.6 Conclusion

Our findings illustrate sustained improvements in the care delivered by practices in a multifaceted, primary-care led programme over time, suggesting this approach is feasible in ‘real-life’ primary care. However, our findings also identify limits to what can be achieved by structured care programmes, particularly when operating within the resource constraints of primary care and the wider health service context. We need to better understand general practitioner management decisions, patient attendance, adherence and self-management, and whether these factors moderate the impact of these programmes. Programmes like the Midlands programme should move beyond monitoring and engage in a continuous cycle of QI to respond to the challenges of delivering optimal primary care-led diabetes care in everyday practice.

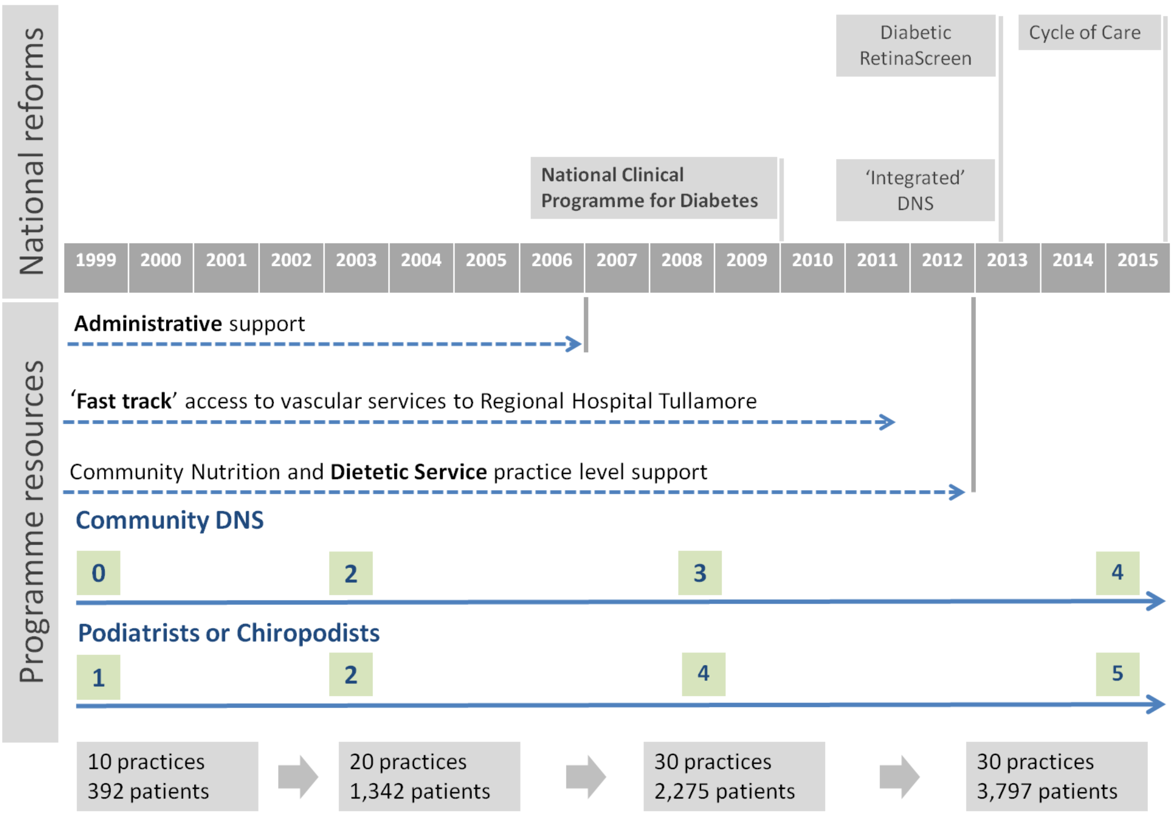

Figure 8 National reforms, resources available to the programme, and participating GPs and people with diabetes enrolled 1999 – 2016

Abbreviations: DNS, diabetes nurse specialist

Information on numbers of resources (DNS and podiatrists/chiropodists) were unavailable at time points between data collection.

Table 6 Characteristics and clinical profile of participants with type 2 diabetes 1998/1999 – 2016*

	1998/1999 N = 336	2003 N = 843	2008 N = 988	2016 N = 1,029
Age (years)				
Median (IQR)	65 (56-74)	65 (56-73)	66 (59-74)	68 (60-76)
Male	168 (50)	438 (52)	562 (57)	603 (59)
Diabetes duration (years)				
Median (IQR)	NA	NA	6 (3-9)	9 (5-12)
GMS	NA	NA	NA	823 (80)
BMI (kg/m^2)				
Mean (SD)	29.3 (4.7)	30.6 (4.8)	30.6 (4.8)	31.2 (5.9)

Table 6 Characteristics and clinical profile of participants with type 2 diabetes 1998/1999 – 2016*

	1998/1999 N = 336	2003 N = 843	2008 N = 988	2016 N = 1,029
N (%) <25	33 (16)	42 (9)	94 (13)	81 (11)
Smokers, N (%)	58 (25)	123 (20)	146 (19)	121 (15)
Diabetes Treatment N (%)				
Diet only	60 (18)	187 (22)	131 (13)	173 (17)
OHA only	262 (80)	532 (70)	685 (70)	643 (63)
Insulin + OHA	0 (0)	39 (4.6)	131 (13)	140 (14)
Insulin only	10 (3.0)	25 (3.0)	38 (3.9)	21 (2.0)
Statins, N (%)	NA	NA	799 (81)	854 (83)
ACE inhibitor, N (%)	NA	NA	734 (74)	680 (67)
Aspirin, N (%)	NA	NA	740 (75)	611 (59)
HbA1c (mmol/mol [%])				
Mean (SD)	55 (18) [7.2 (1.7)]	58 (18) [7.5 (1.6)]	53 (13) [7.0 (1.2)]	54 (14) [7.1 (1.3)]
N (%) <48 (6.5)	104 (37)	229 (29)	351 (36)	364 (36)
N (%) ≤53 (7.0)	156 (55)	382 (48)	589 (61)	607 (59)
N (%) ≤58 (7.5)	191 (67)	481 (60)	720 (74)	770 (75)
BP (mmHg)				
(systolic) Mean (SD)	144.4 (19.9)	140.5 (18.7)	135.9 (16.3)	135.1 (16.0)
N (%) <130/80	25 (8.0)	96 (12)	212 (22)	212 (21)
N (%) ≤140/80	112 (36)	405 (48)	560 (57)	597 (59)
Cholesterol (mmol/l)				
Mean (SD)	5.3 (1.2)	4.9 (1.0)	4.1 (1.1)	4.1 (1.0)
N (%) <4.5	60 (23)	268 (33)	647 (67)	711 (70)
N (%) <5.0	102 (38)	450 (55)	785 (81)	846 (83)
Triglycerides (mmol/l)				
Mean (SD)	2.4 (1.5)	2.1 (1.9)	1.8 (1.2)	1.7 (1.5)
% <2.0	103 (46)	460 (60)	684 (71)	760 (75)
Creatinine (µmol/l)				
Mean (SD)	86.5 (30.1)	84.8 (20.7)	87.8 (46.0)	86.5 (34.0)

Abbreviations: NA, not available -data on this variable were not collected at this time point; ACE, angiotensin-converting-enzyme inhibitor; OHA, oral hypoglycaemic agent; SD, standard deviation; IQR, interquartile range; BMI, Body Mass Index; BP, blood pressure

*Based on available data**: Age:** 1999 (336), 2003 (842), 2008 (987), 2016 (1,028). **Diabetes duration:** 2008 (848), 2016 (1,005). **GMS:** 2016 (1,027). **BMI:** 1999 (203), 2003 (470), 2008 (725), 2016 (736). **Smoking status:** 1999 (230), 2003 (629), 2008 (759), 2016 (813). **Diabetes treatment**: 1999 (332), 2003 (843), 2008 (985), 2016 (1,026). **Statins:** 2008 (987), 2016 (1,028). **Aspirin:** 2008 (986), 2016 (1,027). **ACE inhibitor**: 2008 (984), 2016 (1,017). **HbA1c:** 1999 (284), 2003 (799), 2008 (967), 2016 (1,021). **BP:** 1999 (311), 2003 (836), 2008 (979), 2016 (1,008). **Cholesterol:** 1999 (267), 2003 (815), 2008 (973), 2016 (1,018). **Triglycerides:** 1999 (226), 2003 (771), 2008 (968), 2016 (1,012). **Creatinine:** 1999 (234), 2003 (695), 2008 (971), 2016 (1,016).

Continuous variables were represented as means and SD for the normally distributed values; median (IQR) for non-normal values, as indicated.

Categorical variables were represented as numbers and proportions.

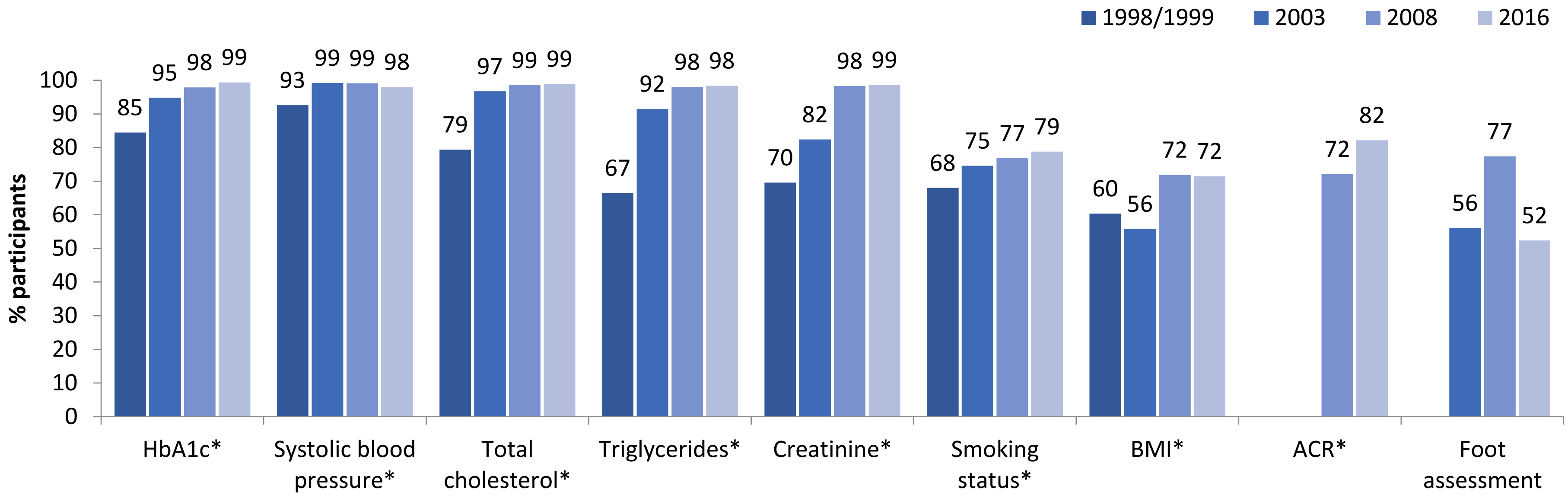

Figure 9 Participants with nine care processes recorded 1999 – 2016

Abbreviations: ACR, Albumin Creatinine Ratio; BMI, Body Mass Index

*$p < 0.05$

ACR was not recorded in 1999 and 2003; foot assessment was not recorded in 1999

Proportions were analysed using chi squared test for trend and logistic regression adjusted for age and gender

Table 7 Profile of participants who were referred to a DNS[β] in 2016

	Referred to DNS		
	Yes **N = 153** **N (%)**	**No** **N = 866** **N (%)**	**Yes, but did not attend** **N = 9** **N (%)**
Age* Median (IQR)	65 (56-71)	69 (61-76)	58 (53-63)
Male	88 (58)	511 (59)	4 (44)
Diabetes duration (years)* Median (IQR)	10 (6-14)	9 (5-12)	9.5 (9-12)
BMI (kg/m^2) Mean (SD)	32.1 (6.1)	31.0 (5.9)	32.6 (4.4)
Smoker	21 (18)	99 (14)	1 (13)
Diabetes control*			
Diet only	3 (2.0)	168 (19)	1 (11)
OHA only	71 (47)	569 (66)	3 (33)
Insulin only	5 (3.3)	15 (1.7)	1 (11)
Insulin and OHA	57 (38)	81 (9.3)	2 (22)
Injectables and OHA	16 (11)	31 (3.6)	2 (22)
OHA or injectable*‖	149 (98)	696 (81)	8 (89)
HbA1c (mmol/mol [%])			
> 58 (7.5)	80 (50)	172 (20)	4 (50)
Median (IQR)*	60 (50-69) [7.6 (6.7-8.5)]	50 (44-57) [6.7 (6.2-7.4)]	64 (52-69) [8.0 (6.9-8.5)]
Systolic BP (mmHg)			
Mean (SD)	133.7 (14.2)	135.4 (16.3)	127.2 (12.2)
Complications			
Retinopathy*	54 (41)	197 (30)	3 (50)
Macrovascular	8 (5.2)	89 (10)	2 (22)
Peripheral neuropathy	7 (4.6)	29 (3.4)	0 (0)
Autonomic neuropathy	5 (3.3)	28 (3.2)	0 (0)
High risk foot*	2 (1.9)	14 (4.4)	1 (17)
Ulcer	4 (2.7)	20 (2.3)	0 (0)

Abbreviations: OHA, oral hypoglycaemic agent; IQR, interquartile range; SD, standard deviation; BMI, Body Mass Index; DNS, diabetes nurse specialist; BP, blood pressure [β]People with complicated type 2 diabetes should attend a diabetes nurse specialist. This includes people requiring insulin, people with HbA1c >58mmol/mol (7.5%) on two or more glucose lowering agents (not insulin), and people with complications or graded as having a high risk foot[68].

*p < 0.05; difference in people attending and not attending DNS were analysed using Students t test or Wilcoxon-Mann-Whitney test for continuous data and Pearson's chi squared for categorical data

‖OHA, insulin or other injectable

Continuous variables were represented as means and SD for the normally distributed values; median (IQR) for non-normal values, as indicated

Categorical variables were represented as numbers and proportions

5 A 16-year follow-up study of all-cause mortality among people with diabetes enrolled in a structured primary care diabetes programme

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5.1 Abstract

Objective

Multifaceted structured approaches to diabetes management in primary care have demonstrated improvements in the quality of care. However, no studies have examined mortality among people receiving structured management over a long period (≥10 years). We examined all-cause mortality, and predictors of mortality among people attending a structured diabetes care programme 1999-2016.

Research design and methods

Routine data were collected from GP records on adults (≥18 years) enrolled in the programme since 1999. Cause and date of death were extracted from national death certificates. Trends in clinical parameters were examined using linear regression models adjusted for age and sex. Survival analysis was conducted using multivariable proportional hazards Cox models. Data was split by calendar year periods, during which each participant contributed to the corresponding 5-year age groups based on current age. As a result, each participant contributed multiple records. Standardised Mortality Ratios (SMR) were calculated.

Results

There were 376 people with diabetes enrolled in 1999. By 2016, 184 (48.9%) had died. Over time, mean systolic BP, cholesterol, and triglycerides declined ($p < 0.0001$). Older age and lower estimated glomerular filtration rate were associated with higher mortality risk in the multivariate model. Age-adjusted mortality was higher than in

the general population: overall SMR = 1.20 (95% CI: 1.01-1.42); significant among women (1.34 (1.05-1.70)), not men (1.07 (0.85-1.35)).

Conclusions

People with diabetes receiving structured care have an excess mortality compared to the general population. However, this excess risk was lower than international estimates. Factors associated with mortality (macrovascular complication, impaired renal function) were evident at enrolment. Ensuring access to regular review and specialist referral pathways as part of structured care is necessary to detect and manage the early signs of preventable complications and reduce the mortality burden.

5.2 Introduction

Diabetes is associated with an increased risk of all-cause mortality [8, 9, 47, 48]; in 2012, 1.5 million deaths worldwide were estimated to have been directly caused by diabetes [36]. Reducing this risk is a goal of health systems worldwide [33]. Monitoring excess mortality from diabetes is a way to assess achievement of this goal and can be an indicator of improvements in the management of risk factors, or the quality and organisation of diabetes care. However, the extent of excess mortality from diabetes is highly variable [57]. People with diabetes have a two [9, 11, 45] to threefold increase in all-cause mortality compared to those without diabetes [10, 12], albeit some studies have reported a lower excess risk [8]. In recent years some studies have reported a reduction in excess mortality but the magnitude of this decline differs between countries [57]. Given this variability, it is important to establish country-specific mortality estimates among people with diabetes.

Diabetes is often underreported on death certificates [380] and studies using national statistics may underestimate mortality as a result of diabetes. Studies using “fixed” cohorts with diagnosed diabetes can more reliably assess mortality risk [9, 57]. In Ireland there is no national diabetes register. However, data on people with diabetes are routinely collected from GP practices participating in primary care initiatives to improve diabetes care [381]. Using data from the longest-running structured diabetes programme in primary care we determined all-cause mortality compared with the general population and examined predictors of mortality in the cohort. We also examined whether general practice records were a reliable source of mortality data as compared to national death certificates.

5.3 Research Design and Methods

5.3.1 Sampling

Data were extracted from GP records by DNS on all people with diabetes (type 1 and type 2) aged 18 years and older enrolled in practices participating in the Midlands programme when first initiated in 1997/1998. Owing to resource constraints, reliability checks at each timepoint were not performed by DNS on the extracted data. However, quality checks at data entry were carried out by PM.

Practices participating in the programme are based in the four Midland counties of Ireland (Laois, Westmeath, Longford, and Offaly). A census sample of the baseline population was collected in 1999 and 2003. In 2003, informed consent had not been obtained for some patients at the time of data collection, so these individuals were not sampled. In 2008, participants enrolled in the programme were sampled by sorting alphabetically first by name and selecting every third person. Some of the original cohort were not part of this random sample. In 2016, all participants who were still alive and were part of the census sample in 1999 were sampled. In addition to the census sample, a further random sample was selected of programme participants. The larger 2016 sample (census and random sample) was used to examine the reliability of mortality data from GP records for the current study.

5.3.2 Data collection

Data were collected on demographics (age, sex, diabetes type), lifestyle factors (BMI, smoking status), clinical parameters (HbA1c, cholesterol, triglycerides, BP, creatinine, estimated glomerular filtration rate [eGFR]), and complications (retinopathy, ulcer, attendance at renal clinic, macrovascular complications [myocardial infarction/stroke/heart failure]) in the 12 month period before first data collection in 1999 (Appendix 4 Table 27). Clinical data were collected from participants alive at each time point. For the purposes of the current study, eGFR was calculated using the CKD-EPI creatinine equation [382].

Vital status for the cohort was collected in 2016, and participants were classified as survivors or decedents. Name, date of birth, date and cause of death (if available) and GP practice location (town and county) of decedents were obtained from GP records. National death certificates were accessed from the General Registrar Office database. The database was searched initially using decedent name and date of death if available. Following this, date of birth and GP location were used to verify the correct match. Once the record was identified, cause of death, underlying cause of death and date of death were extracted from the death certificate. Primary cause was the condition directly leading to death, underlying cause of death was coded as the last listed antecedent cause on the death certificate. Cause of death was coded according to the International Classification of Diseases 10th revision (ICD-10). Mortality data from the general population and four Midland counties for corresponding age groups and calendar years 1999-2013 were obtained from the Central Statistics Office [383]. Cause of death extracted from GP records were compared with that extracted from national death certificates.

5.3.3 Analysis

The characteristics of survivors and decedents were compared using Student's t test or Wilcoxon Mann-Whitney test for continuous data, and Pearson's chi squared test for categorical data.

Current age rather than baseline age was used for the assignment to 5-year age groups. Lexis expansion [384] was performed to split the data by calendar year periods, during which each participant contributed to the corresponding age groups. As a result, each participant contributed multiple records. Standardised mortality ratios (SMRs) were used to compare mortality with the general population and Midland counties. Age (≤65 years and >65 years) and sex-stratified SMRs were calculated. The 95% CI were calculated using the jackknife method to account for clustering of records due to Lexis expansion. To examine whether mortality in the Midland counties was higher than the rest of Ireland, mortality rates in these counties were directly standardised by age and sex using the European Standard Population 2013. These rates were then compared with directly standardised rates in the general population excluding Midland counties.

To avoid generating biased results and decreasing power in the multivariable analysis, missing data were imputed for clinical parameters and lifestyle factors using chained equations (30 imputations), with values at preceding and subsequent time points included as predictors in the imputation model. Trends over time in mean clinical values were examined using linear regression models adjusted for age and sex.

Uni- and multivariable proportional hazards Cox models were used for survival analysis. Independent variables included demographics, clinical parameters and macrovascular complications. Models were adjusted for clustering by participants' GP. Kaplan-Meier curves and log-rank tests were used to compare survival by categorical variables. The proportional hazards assumption was tested using Schoenfeld residuals and examining time-dependent interactions. No violation or significant interaction was observed. The fit of the final model was evaluated using Cox Snell residuals. Models were run using data with multiple records per participant; each record containing data for that time period: 1999-2003, 2003-2008 and 2008-2016, allowing time-varying covariates (clinical parameters and BMI) at discrete intervals to be incorporated. Smoking status was used as a baseline variable. Each participant was censored at date of death or date of last data collection (15th January 2016). All analysis was carried out in Stata v12 for windows (StataCorp, College Station, TX, USA).

5.4 Results

5.4.1 Baseline characteristics and follow up deaths

There were 376 people enrolled at baseline. The mean age was 63.0 (13.2) and 190 (50.5%) were male (Table 8). Of the 184 (48.9%) who died over the 16-year period, date of death could be established for 166 (90%) and cause of death for 161 (87.5%). Cardiovascular disease (CVD) was the main cause of death (54% men; 42.5% women). Among those alive at each time point, missing (not recorded or the individual was not sampled) data ranged from 7% (systolic BP) to 39% (BMI) in 1999; 31% (systolic BP) to 69% (BMI) in 2003; 64% (eGFR) to 75% (BMI) in 2008; 31% (cholesterol) to 54% (BMI) in 2016. In 2003 and 2008 some individuals were not sampled (2003: n = 147, 39%; 2008: n = 280, 74%). At these time points, missing data (not recorded) among those still alive and who were sampled ranged from 1% (HbA1c) to 55% (BMI) and 1% (cholesterol) to 33% (BMI), respectively.

Compared to survivors, decedents were older (69.7 (11.2) vs. 56.6 (11.8) years, $p<0{\cdot}001$), with lower eFGR (mL/min/1.73 m²) (68.5 (21.1) vs. 83.4 (15.2) $p<0.001$), and a greater proportion had a macrovascular complication (10.9% vs. 3.7%, $p<0.05$) (logrank p <0.0001) (Table 9). The absolute mortality rate was 36.97 (95% CI: 31.52-43.08) deaths per 1000 person-years; 34.29 (27.15-42.74) among men and 39.86 (31.83-49.28) among women (Table 9). Rates in the Midland counties (12.00 (11.85

- 12.14) deaths per 1000 person-years) were similar to the general population (11.80 (11.76 - 11.83). Diabetes was recorded as the underlying cause of death in 15% (n = 25) of decedents; 17% (n = 15) among women, 13% (n = 10) among men. Over time, systolic BP, cholesterol, and triglycerides declined among the survivors (Appendix 4 Table 28)

5.4.2 Survival analysis

Older age and lower eGFR were significantly associated with mortality in the fully adjusted model (Table 10): age and eGFR among women; age and having experienced a macrovascular complication among men (Appendix 4 Table 29).

5.4.3 Standardised mortality ratios

Age-adjusted mortality among people with diabetes was greater than in the general population (overall SMR = 1.20 (95% CI: 1.01-1.42)), significant among women (1.34 (1.05-1.70)) but not men (1.07 (0.85-1.35)). When stratified by age, excess mortality was greater among younger age groups (≤65 years: 4.53 (3.10-6.83); >65 years: 1.20 (1.02-1.40)). When compared to mortality in the Midland counties, the SMR was similar (overall SMR = 1.16 (0.98-1.38), significant among women (1.30 (1.01-1.65)) but not men (1.04 (0.83-1.32)).

5.4.4 Comparison of death certificates and GP records

In addition to the 184 decedents identified from the original cohort established in 1999 and reported in the survival analysis, 38 deaths occurred among the 1099 additional participants in the 2016 random sample. Thus, overall there were 226 decedents during the 16 years of programme delivery. Of the 226 decedents, cause of death was recorded in less than one-third of GP records (n = 60, 27%). These 60 records listed only one cause of death and none recorded diabetes as a cause of death. Main causes were cardiovascular disease (n=25, 45%), neoplasms (n = 15, 27%) and respiratory disease (n = 8, 15%). Death certificates were located for 198. Of these, 105 (53%) had diabetes (unspecified, type 1, type 2, or maturity onset diabetes of the young) recorded somewhere on the death certificate. None of the certificates had diabetes recorded as the first cause, and 29 (15%) had diabetes recorded as the underlying cause of death.

Of 55 GP records which could be compared to national certificates, 75% (n = 41) had recorded a cause of death which was also present somewhere on the national certificate, either the direct cause of death present on the certificate (n = 24, 59%), the only cause listed on the certificate (n = 7, 17%) or an underlying cause on the certificate (n = 10, 24%).

5.5 Conclusions

This study conducted among people with diabetes enrolled in a structured primary care diabetes programme for 16 years, found mortality was greater than the background population. However, it was considerably lower than some international studies reporting excess mortality among people with diabetes two to threefold that observed in the general population [8-11, 47, 48]. The programme was multifaceted, incorporating several components: evidence-based clinical guidelines, patient register and recall, protected time for review, case management by practice nurses, multidisciplinary specialist support, and professional and patient education.

One reason for the low excess mortality may be the fact that cardiovascular risk factors were well-managed as part of this programme [27]. This is consistent with declines in cardiovascular risk both internationally and nationally, partly in response to better medication and treatment [59, 60]. Despite such treatment therapeutic advances, men who experienced a new macrovascular complication between 1998 and 1999, independent of age and other risk factors, were at higher risk of death in the subsequent 16-year period. This highlights the importance of early prevention and detection of complications among people with diabetes. Structured care and regular review can enable the early signs of complications to be detected and managed proactively, for example, through referral to appropriate specialist providers. Independent of age, lower renal function (eGFR) was associated with mortality, consistent with existing studies [385]. We used time-varying eGFR in our models to take account of changing exposure (risk) over time and use all available data. At baseline differences in eGFR between survivors and decedents were evident and particularly marked among women. Unlike other studies [176, 386, 387] we did not find HbA1c was associated with mortality. HbA1c was similar among survivors and decedents at baseline, despite a higher proportion of decedents with complications. However, HbA1c in 1998/1999 may not reflect the history of HbA1c control. The effects of HbA1c can persist until years afterwards, a phenomenon known as ‘metabolic memory’ [388]. Furthermore, we used measurements of HbA1c at longer time intervals than previous studies which have used yearly measurements

[386, 387], and we cannot account for variability in the interim periods. Similar to previous work [10], we did not find a difference in mortality risk between males and females, consistent with the observation that diabetes removes the survival advantage for women for cardiovascular mortality [12].

To date, few studies have examined mortality among people receiving structured management in primary care over a long period [119, 175, 176], and none over 10 years. Strengths include the long follow-up time, and the use of a fixed cohort with clinical data derived from GP records. A further strength is the access to data from national death records; date and cause of death were available for most participants. Using GP records provides an insight into routinely delivered, longitudinal management of diabetes; however, our study limitations arise from the fact data collected during actual clinical practice may be less complete and lack detail in comparison with data collected specifically for a study. There were three key issues: 1) we lacked data on important predictors of mortality, including disease duration and socio-economic status (SES). GMS status was only recorded in 2016 by which time the majority were eligible (Table 6); 2) there were large numbers missing data in follow-up years, and; 3) smoking status history prior to 1999 was unknown, therefore we could not distinguish ex-smokers or ever smokers, and the length of time smoked. We used smoking status at baseline, given the persistent effect of former smoking on mortality [389], and since few participants changed smoking status (n = 34) over the time period. The quality of this indicator may be one reason why we did not find smoking to be a significant predictor of mortality; a finding which is inconsistent with other studies [9, 390]. However, it is also important to consider that the proportion of smokers was 25% among both decedents and survivors. Lastly, our data is limited to a single population within Ireland and may not be generalisable to other regions. Caution should be taken when comparing excess mortality between countries; differences may reflect the age structures of the study populations and differences in background mortality rates. The age structure of people with diabetes can be different between countries.

GP records do not appear to be a reliable source of cause of death data. Firstly, cause of death was poorly recorded. This may be because practices are not routinely informed following a patient's death. Secondly, there were differences between GP records and certificates with respect to the cause recorded. Lastly, diabetes was not recorded as a cause on any GP records. Further work is needed to ascertain the reasons for the discrepancies between the cause of death recorded in GP and national certificates. While establishing a death register in general practice has been shown to be feasible[391], in Ireland the development of a national diabetes register should be prioritised. Currently the national infrastructure to facilitate linkage between data sources is lacking; as such, there is limited capacity to fully examine the relationship between quality of diabetes management and outcomes, namely mortality and complications.

Although well-managed as part of a structured care programme [27], mortality among people with diabetes was still greater in the general population, albeit, among men, the SMR was not significant. Since 1999, the programme has seen steady improvements in the quality of care over time [27] and the profile of future cohorts enrolled in the later years of the programme may be different. International work has reported declines in excess mortality for people with diabetes over the time period of the current study [61, 62, 64]; Gregg et al. suggest this may reflect improvements in the organisation of care, management of risk factors, and rates of complications [64]. While an encouraging trend, the current study found factors associated with mortality, macrovascular complications and impaired renal function, were evident at enrolment, suggesting the importance of structured care for people with diabetes.

Recent policy reforms in Ireland have aimed to support structured management in primary care on a national level. These have included: 1) resourcing of community-based ‘integrated’ diabetes nurse specialists to facilitate the delivery of a new model of integrated care which manages people with diabetes according to their complexity, and; 2) introducing the Cycle of Care initiative to remunerate GPs for patient registration and regular diabetes reviews for people with type 2 diabetes. However, the latter initiative is restricted to people who hold a GMS card entitling them to access GP services free of charge. Our findings highlight the importance of ensuring *all* people with diabetes have access to structured management, including regular review and referral to specialist services. This is crucial to detect and effectively manage the early signs of preventable complications and ultimately reduce the mortality burden.

Table 8 Baseline characteristics and clinical profile of survivors and decedents (2016) overall and by sex (n = 376)*

	Overall		Men		Women	
	Survivors N = 192 N (%)/ mean (SD)	**Decedents N = 184 N (%)/ mean (SD)**	**Survivors N = 100 N (%)/ mean (SD))**	**Decedents N = 90 N (%)/ mean (SD)**	**Survivors N = 92 N (%)/ mean (SD)**	**Decedents N = 94 N (%)/ mean (SD)**
Age†	56.6 (11.8)	69.7 (11.2)	55.8 (10.8)	68.6 (9.9)	57.6 (12.7)	70.7 (12.3)
Smoker	35 (25.4)	30 (24.8)	18 (35.7)	14 (23.0)	17 (25.0)	16 (26.6)
BMI (kg/m^2)	30.0 (5·0)	28.2 (4.0)	29.4 (5.0)	28.2 (3.4)	30.7 (4.9)	28.2 (4.6)
Treatment						
Diet	29 (15.3)	29 (15.9)	12 (12.2)	18 (20.0)	17 (18.7)	11 (11.8)
Diet and tablets	126 (66.7)	134 (73.2)	67 (68.4)	61 (67.8)	59 (64.8)	73 (78.5)
Diet and insulin	34 (18.0)	20 (10.9)	19 (19.4)	11 (12.2)	15 (16.5)	9 (9.7)
Complications						
Macrovascular complication (last 12 months)†	7 (3.7)	20 (10.9)	5 (5.0)	13 (14.4)	2 (2.2)	7 (7.5)
Attending renal clinic	0 (0)	4 (2.2)	0 (0.0)	2 (2.2)	0 (0.0)	2 (2.1)
Retinopathy	14 (14.9)	19 (20.4)	9 (18.8)	7 (18.4)	5 (10.9)	12 (21.8)
Foot ulcer	2 (1.6)	5 (4.4)	2 (3.1)	2 (3.5)	0 (0.0)	3 (5.2)
Amputations (minor)	0 (0)	1 (0.5)	0 (0.0)	0 (0)	0 (0)	(1.1)
Clinical						
HbA1c (% [mmol/mol])	7.3 (1.8) [56 (19.7)]	7.2 (1.5) [55 (16.4)]	7·5 (2.0) [58 (21.9)	7.2 (1.6) [55 (17.5)]	7.1 (1.6) [54 (17.5)]	7.2 (1.4) [55 (15.3)]

Systolic BP (mmHg)	143.1 (21.0)	145.5 (19.9)	142.0 (19.8)	143.3 (16.7)	144.3 (22.4)	147.4 (22.3)
Cholesterol (mmol/l)	5.4 (1.1)	5.3 (1.2)	5.1 (1.1)	5.0 (1.1)	5.6 (1.1)	5.7 (1.2)
Triglycerides (mmol/l), median (IQR)	2.1 (1.8)	2.0 (1.4)	2.6 (1.8)	2.3 (1.4)	2.2 (1.3)	2.5 (1.5)
eGFR (mL/min/1·73 m²), median (IQR)†	83.4 (15.2)	68.5 (21.1)	85.0 (14.9)	72.8 (20.3)	81.8 (15.4)	62.8 (21.9)

Abbreviations: IQR, interquartile range; BP, blood pressure; eGFR, estimated glomerular filtration rate

*Based on available data: Smoking status, 259; BMI, 228; Treatment, 372; Macrovascular complications, 376; Renal clinic, 376; Retinopathy, 187; Foot ulcer, 238; Minor amputation, 375; Systolic BP, 351; Cholesterol, 288; Triglycerides, 241; eGFR, 255

†significant difference between survivors and decedents (overall) $p < 0.01$

Table 9 Follow up and cause of death (n = 184)*

	Men	Women
Person-years of follow-up	2304	2133
Deaths (n)	90	94
Mortality rate per 1000 person years (95% CI)	34.3 (27.2-42.7)	39.9 (31.8 – 49.3)
Primary cause of death		
CVD†	41 (54.0)	37 (42.5)
Respiratory disease (including pneumonia)	17 (22.4)	19 (21.8)
Neoplasms	11 (14.5)	17 (19.5)
Kidney disease (including renal failure)	3 (4.0)	3 (3.5)
Underlying cause of death		
None recorded	24 (31.6)	30 (34.5)
Diabetes mellitus	10 (13.2)	15 (17.2)
IHD	13 (17.1)	5 (5.8)
Neoplasms	5 (6.6)	2 (2.3)
Diseases of respiratory system	4 (5.3)	11 (12.6)

Abbreviations: CVD, cardiovascular disease; IHD, Ischemic heart disease; CI, confidence interval

*Date of death was available for 166 decedents (81 men and 85 women); cause of death was available for 163 participants (76 men and 87 women)

†CVD: ICD-10 codes I00-I79

Table 10 Multivariate Cox survival analysis (n = 356)

	Model 1			Model 2		
	HR	**95% CI**	**P**	**HR**	**95% CI**	**P**
Age (per 10 years)	2.36	[2.01,2.78]	<0.001	2.15	[1.78,2.60]	<0.001
Sex						
Male (ref)						
Female	0.88	[0.59,1.31]	0.53	0.80	[0.49,1.31]	0.37
BMI (kg/m²)	0.99	[0.95,1.04]	0.77	0.99	[0.94,1.05]	0.85
Smoking						
No (ref)						
Yes	1.06	[0.73,1.55]	0.75	1.13	[0.75,1.71]	0.57
Clinical						
Systolic BP (per 10mmHg)	0.98	[0.86,1.11]	0.74	0.98	[0.86,1.11]	0.73
Cholesterol (mmol/l)	1.09	[0.89,1.32]	0.41	1.10	[0.90,1.34]	0.34
HbA1c (%)	1.12	[0.99,1.26]	0.08	1.13	[1.00,1.28]	0.06
eGFR (per 15mL/min/1.73 m²)	0.80	[0.66,0.95]	0.01	0.79	[0.65,0.96]	0.02
Triglycerides (mmol/l)	0.97	[0.81,1.18]	0.78	0.89	[0.71,1.12]	0.33
Macrovascular complication						
No (ref)						
Yes	1.90	[1.00,3.61]	0.05	1.83	[0.82,4.08]	0.14

Abbreviations: BP, blood pressure; eGFR, estimated glomerular filtration rate; HR, hazard ratio
Model 1 adjusted for age and sex; Model 2 adjusted for all covariates

6 The role of nurse specialists in the delivery of integrated diabetes care: A cross-sectional survey of diabetes nurse specialist services

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This paper was published in BMJ Open in 2017 (Appendix 10)

6.1 Abstract

Objectives

International evidence suggests the diabetes nurse specialist (DNS) has a key role in supporting integrated management of diabetes. We examine whether hospital and community DNS currently support the integration of care, examine regional variation in aspects of the service relevant to the delivery of integrated care, and identify barriers to service delivery and areas for improvement.

Design

A cross-sectional survey of hospital and community-based DNS in the Republic of Ireland.

Methods

Between September 2015 and April 2016, a 67-item online survey, comprising of closed and open questions on their clinical role, diabetes clinics, multidisciplinary working, and barriers and facilitators to service delivery, was administered to all eligible DNS (n = 152) in the Republic of Ireland. DNS were excluded if they were retired or on maternity leave or extended leave.

Results

The response rate was 66.4% (n = 101); 60.6% (n = 74) and 89.3% (n = 25) among hospital and community DNS respectively. Most DNS had patients with stable (81.8%) and complicated type 2 diabetes (89.9%) attending their service. Most were delivering nurse-led clinics (81.1%). Almost all DNS had a role liaising with (91%) and

providing support and education to (95%), other professionals. However, only a third reported that there was local agreement on how their service should operate between the hospital and primary care. Barriers to service delivery which were experienced by DNS, included deficits in the availability of specialist staff (allied health professionals, endocrinologists and DNS), insufficient space for clinics, structured education, and issues with integration.

Conclusions

Delivering integrated diabetes care through a nurse specialist-led approach requires that wider service issues, including regional disparities in access to specialist resources and formalising agreements and protocols on multidisciplinary working between settings, be explicitly addressed.

Keywords: Clinical Nurse Specialist, Integrated Care, Diabetes and Endocrinology, Health Services Research

6.2 Background

In recent years, internationally and in Ireland, there has been increased interest in how to deliver integrated care for people with chronic diseases such as type 2 diabetes [7, 13], co-ordinating management so that patients receive the ‘right services’ in the ‘right place’ [15]. The complex nature of diabetes necessitates the involvement of healthcare professionals from different disciplines and settings to achieve effective management [7]. Integrated diabetes management across community-based and specialist services has been shown to improve quality of care

[24, 25], and reduce preventable hospitalisations for diabetes-related complications, with patients in an integrated care group almost half as likely to be hospitalised (incidence rate ratio of 0.53, 95% CI 0.29, 0.96, 24 months after study initiation) [164].

International evidence suggests the nurse specialist has a key role in supporting the integrated management of chronic disease [179] through delivering nurse-led clinics in primary care [107, 115], liaising between care providers [24, 107, 189, 190], and providing specialist education and support to other professionals [24, 189], including those in primary care [19, 107, 112]. The shift towards primary-care management of type 2 diabetes, has meant the role has been increasingly moved into community settings [22]. The UK [112], and the Netherlands [24, 115], have seen the introduction of models of care where the diabetes nurse specialist (DNS) supports GPs or practice nurses in diabetes management [112, 115], (e.g. intermediate care clinics for diabetes which accept referrals of more complex patients to reduce the burden the hospital system [346]), or performs tasks previously conducted by the GP, including co-ordination and organisation of care ('vertical task substitution') [115]. These models have been found to improve clinical outcomes [24, 115]. In the Netherlands, among patients enrolled in shared care with task delegation to DNS, the proportion with BP ≤150/85 mmHg and cholesterol ≤5 mmol/mol increased by 12% over three years with no change in the usual care group. The proportion with HbA1c ≤7.0% remained stable while declining 8% the usual care group. These models have also been associated with significant decreases in total (31%) and inappropriate (57%) referrals to secondary care [112]. They also may reduce outpatient attendances;

Nocon et al. documented a decline in mean monthly hospital attendance from 478.5 to 361.8 (25% reduction) after the introduction of intermediate care clinics [193, 346]. However, the role and work setting of DNS differs between countries [31, 392, 393]. For example, in Sweden and the Netherlands, half or more of DNS may work in integrated or community, settings, and have prescribing rights [190, 392]. In contrast, most DNS in Ireland are hospital-based, and, although nurse prescribing has been introduced since 2008, not all nurses perform this role. Given these differences, it is important to establish how the DNS role works to inform how it can be best utilised within the specific health system to support an integrated and sustainable model of diabetes care.

In Ireland, the importance of nurse specialists in chronic disease management and facilitating integrated care between settings has been recognised [32, 185, 394]. The National Clinical Programme for Diabetes, established in 2010 to improve care for people with diabetes in Ireland, is developing the DNS service by introducing more community-based DNS to facilitate the delivery of a new model of integrated diabetes care[395]. These changes are taking place within a traditionally hospital-centric healthcare system where there is a disconnect between secondary and primary care services in how they are funded, managed and resourced. Diabetes services have historically been unstructured and characterised by pockets of good provision and a mix of care arrangements [32]. In some areas diabetes care is primarily hospital-led. In others, care is delivered in general practice on an opportunistic and ad-hoc basis. Chronic disease management in secondary care is also not well-integrated with general practice [394], not all areas have a local diabetes service, and within general practice the delivery of diabetes care may be variable. There may be deficiencies in terms of access to specialist resources, including DNS [224, 225, 396]. This has driven the development of formal diabetes initiatives (10 nationally) which seek to improve the quality and organisation of care at a local level. These include models of structured or shared care with local clinical guidelines and support from a community DNS to facilitate communication between these practices and the hospital [107], or enhanced access to specialist community resources, including dietetics, podiatry and DNS [397].

The purpose of the new integrated care model is to standardise management of patients with diabetes, ensure patients are cared for the most appropriate setting and by the most appropriate health care professionals according to the complexity of their condition. As outlined in the latest guidance on diabetes management[68] patients with uncomplicated type 2 diabetes are managed in primary care, patients with complicated type 2 diabetes are managed between primary and secondary care, and management of type 1 diabetes and gestational diabetes takes place in secondary care. Implementation of the new model could vary depending on local circumstances and context including the existing models of care. Newly introduced DNS have, in some areas, been linked to existing initiatives, whereas in other areas the service was entirely new. The current study may identify some of this regional variation, and forms part of a programme of work evaluating the implementation of the National Clinical Programme for Diabetes [1].

The new reforms can be understood as evidence-based strategies to integrate care at the level of service organisation and delivery (e.g. promoting multi-disciplinary teamwork through establishing the DNS as a 'link' between services; providing dedicated support by nurse specialists to primary care professionals) and the clinical level (e.g. introduction of guidelines on practice management) [68]. Similar to intermediate care clinics for diabetes established in the UK, these new DNS will provide necessary intermediary specialist support in the community in the management of more complex patients. They provide education and support for GPs and practice nurses, and work between community (80%) and hospital settings (20%) facilitating integration between the two settings [68]. DNS may deliver clinics in general practice, independently, or in some cases initially jointly with the practice nurse or GP, to build capacity, confidence and skills in the management of more uncomplicated patients.

Although DNS support for patients and health professionals is a pillar of our national strategy for delivering integrated diabetes care, unlike other countries [18, 24, 31, 189, 190], there is a dearth of information on how DNS services are delivered in Ireland. Our aim is to examine the way, and extent to which, DNS services currently support the integration of care, and identify areas for improvement. We expect hospital and community DNS to differ in terms of the patients they provide care to, and the professionals they support and are supported by. Therefore, we describe the role of these DNS separately. Given the current variation in how diabetes services are delivered in Ireland, some aspects of the DNS role which are important in the integration of care (nurse-led clinics, agreements on working across primary and secondary care, access to other professionals) may differ across the country. Therefore, we examine these aspects by region. Finally, we identify barriers and facilitators to delivering diabetes care from the DNS perspective. The study will provide an insight into how the DNS role works in the context of a traditionally fragmented health system characterised by regional variation and ongoing efforts to standardise and improve how diabetes care is delivered [395].

6.3 Methods

6.3.1 Participants

The eligible study population comprised of all currently employed DNS (n=152), excluding retired DNS, those on maternity or extended leave. Registration with the Irish Diabetes Nurse Specialist Association is not mandatory, and there is no national register of DNS posts in Ireland. Therefore, we compiled a list through regional primary care initiatives, the Irish Diabetes Nurse Specialist Association, Diabetes Ireland, the national diabetes charity which funds the provision of some DNS posts, and the National Clinical Programme for Diabetes, who highlighted the survey at national and local conferences and meetings. The Irish Diabetes Nurse Specialist Association asked their members to register their details with the study researchers.

6.3.2 Questionnaire

Participants were invited by email to complete the self-administered, 67-item questionnaire electronically (Surveymonkey™) between September 2015 and April 2016. The survey was based on a questionnaire developed by Diabetes UK and ABCD Specialist Services Study Group[31], modified for the Irish health system in collaboration with a local nurse network, and piloted with two DNS, both of whom worked across hospital and community settings. Adaptations related to the questionnaire are included in Appendix 10.5.1. The survey comprised of closed and open-ended questions addressing the DNS' role in diabetes, clinic activity, links with other services, the nature of service agreements and their liaison role, and barriers and facilitators to service delivery (Appendix 10.10). Three reminders were sent, the final in conjunction with an email notification from the Irish Diabetes Nurse Specialist Association (Appendix 10.5.2).

6.3.3 Data management and analysis

Data were cleaned in Excel before importing into Stata v12 for windows (StataCorp, College Station, TX, USA) for analysis. Fisher's exact tests were used to test differences in the role performed between hospital and community, and to examine service provision (clinics, referrals, local agreements) across the four regions defined according to Diabetes Services Implementation Groups, which are clinically-led regional networks responsible for local implementation of the national programme. A p value of <0.05 was considered statistically significant. The Bonferroni correction was used to adjust for multiple comparisons. Complete case analysis was used, and missing data is highlighted as applicable. NVivo (Version 11) was used to manage and categorise open-ended responses. FR conducted a thematic analysis of responses to the question on barriers and facilitators. The grouping of codes to generate overarching themes were reviewed by JB.

6.4 Results

The response rate was 66.4% (n = 101), 60.6% (n = 74) of hospital and 89.3% (n = 25) of community DNS. This included six Advanced Nurse Practitioner (ANP) or Advanced Midwife Practitioner (AMP) grade nurses; two Clinical Nurse Managers and three diabetes nurses not graded as DNS but who were qualified and performing role of DNS. Two DNS in non-clinical roles were classified as ‘Other’. DNS from all four DSIGs, and all counties in the Republic of Ireland participated. Most were hospital-based (Table 11). Respondents were working as a DNS for an average of 11 years. Although most had completed a postgraduate diploma in diabetes, few (10.9%) had a Masters level qualification, and just over a third (36.6%) were nurse prescribers.

6.4.1 DNS role

Most DNS had a written job description (n = 89, 88.1%). All DNS were involved in some aspect of patient management (Table 12) but this differed by setting. More hospital than community DNS were involved in inpatient care, and specific elements of care for patients with type 1 diabetes (referrals, glucose monitoring, insulin initiation or education, checking injection sites) ($p < 0.001$) and provision of specialist clinics (non-significant) (Table 12). While most hospital and community DNS reported that patients with complicated type 2 diabetes attended their service, the majority also saw patients with stable type 2 diabetes (Figure 10). In two regions a greater proportion of nurses reported seeing patients with stable type 2 diabetes (R1:95.7%; R2: 70.8%; R3: 88.9%; R4: 72%). Other patients seen were reported in open-ended comments (Appendix 10.5.3).

Of the 58 (59.2%) DNS who spent time on administrative work, mean hours per week were 4.8 ± 2.5, and 5.7 ± 2.8 among hospital and community DNS respectively. Few spent time on research or audit (n = 36, 35.6%); on average, hospital DNS spent 1.5 ± 0.8 hours per week while community DNS spent 2.3 ± 1.6 hours. Few DNS had a dedicated budget (n = 16, 16.3%) or protected time (n = 27, 27.5%) for CPD.

6.4.2 Clinics

Nurse-led clinics can be understood as clinics where DNS may work without immediate supervision and are responsible for case management. Overall, 81.1% (n = 82) of DNS delivered nurse-led clinics including generalised clinics (n = 31, 37.8%), specialised (n = 27, 32.9%) or both (n = 24, 29.3%).

The greatest proportion of DNS provided ≥4 clinics per week (48.8%). While similar across most regions (R1: 55.6%; R2:61.9%; R3:54.6%; R4: 23.8%) frequency in R4 was consistently lower. This was true among both DNS types: overall 52% community DNS provided ≥4 clinics (R1: 57.1%; R2:50%; R3:80% R4: 28.6%); and 47.5% of hospital DNS provided ≥4 clinics (R1: 54.5%, R2: 64.7%, R3:47.1%, R4:21.4%) (Table 30).

Some DNS were supported in clinics by other members of the multidisciplinary team (MDT) e.g. a podiatrist (n = 30, 36.6%) or dietician (n = 44, 53.7%). Most community DNS were supported in clinic by a practice nurse (73.9%). According to hospital and community DNS, patients generally saw a consultant (74.6%) or GP (56.5%) at a later date rather than on the day of the clinic.

Half reported a waiting list for their clinic service. Where reported (n = 41), the waiting time was commonly 1-3 months (n = 20), ranging from >1 month (n = 5), to a year or more (n = 4). The main reasons reported in open-ended comments (n = 51) were the referral volume (n = 24) and shortage of clinical staff (n=12). Of 24 respondents who provided clinics in the community, 12 reported that GPs were eligible to access those clinics, and, in open-ended comments (n = 11), indicated the service was available to GPs who were enrolled in a shared or structured care scheme (n = 6), interested in diabetes care or willing to engage with the integrated care programme (n = 3), or practices employing a practice nurse (n = 2). Respondents reported that clinics were currently inaccessible where the service was at capacity or the catchment area was too large for the DNS to cover (n = 4).

6.4.3 Links with other professionals

Most DNS (n = 94, 95%) were educating other professionals, primarily hospital-based nursing staff by hospital DNS (81.2%), and practice nurses (92%) and GPs (88%) by community DNS. Community DNS were involved in education of allied health professionals (52%) and staff in nursing homes (21.6%) (Table 12).

Most DNS liaised with other healthcare professionals (n = 92, 91.1%) (Table 12). As outlined in open-ended responses (n = 83), this role involved patient case discussion (n = 40) and follow-up (n = 8), referrals (advising but also being able to facilitate fast-track into hospital) (n = 18), providing advice (n = 13) and education (n = 7) to other staff, seeking advice from consultants (n = 6), and being a coordinator or 'link' between services (n = 10).

Over one third of DNS, (n = 37, 36.6%) reported there was no discharge pathway to primary care for ward discharges (R1: 30.4%; R2: 40%; R3: 44.4%; R4: 30.8%), and a third (n=36, 36.7%), reported there was an agreement between the hospital and primary care outlining how their service operates (R1: 50%; R2: 16.7%; R3: 33.3%; R4: 48%). As outlined in open-ended comments (n = 29) local agreements included following a shared care model (n = 6) or integrated model (regular GP review with annual secondary care review) (n = 5), working 80/20 between community/hospital (n = 5), rapid referral pathways from primary care into hospital (n = 3), or being able to discharge patients to primary care (n = 2).

While almost all DNS reported referral access to other professionals (n = 92, 91.1%), there were regional differences in access to social workers (p = 0.01) and psychologists (p = 0.01) (Figure 11) (non-significant after adjustment).

6.4.4 Barriers and facilitators to delivering diabetes care

Most participants outlined barriers and facilitators to delivering their service in open-ended comments (n = 89, 88%). DNS suggested it was not feasible to conduct audit, research and quality improvement (n = 14), citing time constraints (n = 7), and poor IT systems (n = 4) as the main reasons. They identified limited opportunities for professional development (n = 9), which was not supported by managers (n = 3) or allocated protected time (n = 3).

Being supported by the multidisciplinary team facilitated service delivery (n = 15), and DNS identified a shortage of specialist staff (allied health professionals, endocrinologists, DNS) as a main barrier to providing care (n = 48). Other barriers were a lack of clerical support (n = 19), poor ICT (n = 8), and space limitations (n = 19), which affected clinic (n = 10) and structured education (n = 8) provision. Barriers to integration included inappropriate referrals of people with uncomplicated type 2 diabetes to secondary care (n = 7), GP reluctance to engage with the new community DNS service (n = 7), and the lack of information communication technology (ICT) to facilitate information-sharing between primary and secondary care (n = 6).

6.5 Discussion

6.5.1 Main findings

Our study indicates that most hospital and community DNS supported integrated care through management of complicated type 2 diabetes; liaising with, and educating, other professionals, and; working independently to deliver nurse-led clinics. The latter is consistent with the move towards greater autonomy in the role. In the UK, nurse-led clinics were identified as a new development in 2008, with 90% of DNS services providing this service [31]. However, we also identified specific areas for attention, in terms of the types of patients being managed by DNS, access to other professionals, the provision of clinics, and support for CPD, research and audit.

Although the role of the DNS is to support management of complex patients, most reported that patients with stable type 2 diabetes attend their service. DNS also highlighted ongoing issues with inappropriate referrals to secondary care. Many lacked a formal agreement on how their service operates between primary and secondary care, and a protocol to guide discharge from secondary to community care. Although most DNS had a liaison role with other care providers, referral access to specialist staff varied regionally. Space limitations, a shortfall in specialist staff, and the lack of shared ICT between primary and secondary care were highlighted by DNS as barriers to service delivery. Half of DNS reported a waiting list for clinics, and the frequency varied, as did the support available in clinics from multidisciplinary professionals. These differences in clinic delivery may reflect the availability of space and staff at a given hospital or GP practice. Although most community DNS delivered community clinics, access to this service was not universal. In some areas it depended on GP willingness to engage with the integrated service, practice participation in an existing diabetes care scheme, practice nurse availability, or DNS service capacity.

Research and audit is considered a key component of the nurse specialist role nationally [185, 398], and internationally [399]. However, as in the UK and Sweden [31, 392, 400], we found that few DNS spend time on research or audit, lacking opportunity or support to do so. Although DNS were highly trained and experienced, as in the UK, few (11%) had completed a masters qualification [187]. Lack of support for CPD, was identified as an issue in the UK [31, 187], and was also highlighted by the current survey.

6.5.2 Strengths and limitations

This study is the first to examine the provision of DNS services nationally in Ireland. One strength is the use of a comprehensive questionnaire employed in a previous UK study [31], which was adapted for the Irish context. Although there is no definitive list of all DNS in Ireland, we enlisted the support of the Irish Diabetes Nurse Specialist Association, and this increases the likelihood that all potential participants were aware of the study. All four Diabetes Service Implementation Group regions and counties were well-represented, and we are confident the results capture the national situation in terms of DNS services. The balance of hospital to community DNS in the study reflects the national profile of DNS. Due to the small number of nurses working in both roles, our results did not distinguish between DNS solely based in the community and those in new posts working between hospital and community. The latter group spend 80% of their time in the community and their role is likely to be very similar to community DNS. Our question on patients who attend DNS services provides some insight into whether the role aligns with the national model. However, it does assume that DNS have the same understanding, of what is meant by complicated and uncomplicated (stable) type 2 diabetes. A further limitation is that this question does not capture why certain patients are being seen by the DNS. For example, we do not know whether there is a process by which DNS can discharge patients who become stable, given that patients may transition from complicated to stable and vice versa. While we are lacking routinely-collected, administrative data on the number and nature of referrals, community DNS have begun to collect data on their activity (number of complex/stable patients seen, practices visited, GPs interested in engaging, patients were discussed with the MDT, formal professional education sessions). This data may also be harnessed to further assess the implementation of the model.

6.5.3 Implications

Our study has implications for the implementation of integrated care models which rely substantially on the role of the DNS. First, the findings suggest the need for organisational and professional changes i.e. better resourcing of specialist staff, provision of dedicated space, and changes in the receptiveness to the DNS role, to better enable DNS to support the integration of care as intended. Specific barriers which affect DNS service delivery (space and staff resources, inappropriate referrals to secondary care) may also not be unique to Ireland, and their implications for integrated care may be relevant for the delivery of DNS services internationally.

Secondly, DNS continued to manage stable type 2 diabetes, and mentioned the volume of inappropriate referrals in open-ended comments. This appears to suggest the model of care, where DNS primarily see complex patients, has not been fully realised. Variation in diabetes services and the capacity of primary care may mean that moving to a scenario where DNS only see complicated patients will be a gradual process. There were also regional differences in terms of patients with stable type 2 diabetes attending DNS services, which may reflect the structure of primary care locally, access to secondary care services and other specialists.

Thirdly, while nurse-led community clinics have been implemented effectively in parts of the Netherlands as a strategy to integrate care[24, 115], our findings suggest that local arrangements and resourcing may affect delivery. There were issues at a local level in terms of accessing DNS support through community-based clinics which have reached capacity or operate outside their catchment. Where GPs did have access, other factors (e.g. being part of an existing initiative) affected eligibility. Although more work is required to fully understand how nurse-led clinics can operate effectively in this context, formal agreements and protocols to guide patient management across settings and healthcare providers are likely important[401]. Without a formal structure and adequate resourcing in place, as the DNS services become oversubscribed, they may contribute to, rather than address, any existing regional variation in diabetes care.

Finally, discharge pathways to community care, and formal agreements on how DNS services operate between the hospital and primary care did not always appear to be in place; this may be one reason why existing arrangements continue to dictate patient management across the two settings. We show that the liaison role described by DNS in this study did align with elements of international models; i.e., patient case discussion [17, 19, 24] and care planning [115], provision of advice, support [24, 112] and education [112, 189] to other care providers. However, without formal guidance in place, DNS availability for advice and support could vary nationally. This is something which needs to be further explored.

Our study was carried out at a time of on-going policy reform. In 2015 a new funding initiative, known as the Diabetes Cycle of Care was introduced. This scheme will for the first time nationally, remunerate GPs for care of patients with stable type 2 diabetes (two structured visits of per year) who hold a GMS card. The initiative will establish formal requirements for registering, recording and reporting processes of care (clinical parameters, routine foot screening and referral, lifestyle review)[28].

Payment will be made on the basis of registering eligible patients and delivering two review visits, and data will be reported/collected as per a standard proforma. While this may translate to more appropriate referrals and structured patient management, enhanced access to community resources does not form part of the initiative, and it is likely to further stretch already limited specialist resources, and the demand for community DNS. Almost one fifth of DNS surveyed will be eligible to retire in the next 10 years or fewer, which may place an additional strain on services. Our survey respondents identified the lack of DNS as a barrier to providing care. The shortfall in nurses has also been highlighted as a concern in the UK where DNS posts are stagnating[402]. It is concerning that the shift of patient care to the community may continue in areas unsupported by a well-resourced multidisciplinary team. Such deficiencies will influence how successfully a DNS can coordinate care and support the delivery of an integrated service.

6.6 Conclusion

Our results suggest that hospital and community DNS, working in a traditionally fragmented health system and against a backdrop of service variation, perform key roles to support the integration of care. Yet our findings suggest there is some regional variation in terms of how the new model of care is being implemented; in terms of management of uncomplicated type 2 diabetes, clinic delivery, and available support from multidisciplinary professionals. There are areas for improvement if the DNS role is to be used to its full potential and if a standardised model of care is to be achieved. Changes to the wider service infrastructure (resourcing, space allocation, ICT, attitudes of professionals involved) are required to align the health system towards the delivery of integrated care. Expanding the DNS service into the community to support primary care as an isolated strategy may be limited in its potential to fully integrate care on a national level. While this study provides a useful 'snapshot' into DNS service delivery, future qualitative work is required to explore and understand how the role supports integration, and changing requirements of the service as reforms continue.

Table 11 Characteristics of the sample population (n = 101)

	N (%)
Based	
Hospital	74 (73.3)*
Community	25 (24.8)†
Other	2 (2.0)
Service area	
Adult	66 (65.4)
Paediatric only	14 (13.9)
Maternity only	5 (5.0)
All 3 service areas	9 (8.9)
Adult and Paediatrics	3 (3.0)
Adult and Maternity	2 (2.0)
Other	2 (2.0)
Region	
1	23 (22.8)
2	25 (24.8)
3	27 (26.7)
4	26 (25.7)
Age	
25-34	9 (8.9)
35-44	36 (35.6)
45-54	38 (37.6)
55-64	18 (17.8)
Education	
Masters in Diabetes	11 (10.9)
Diabetes counselling course	7 (6.9)
PGDip in Diabetes Nursing	81 (80.2)
Cert. in Diabetes Nursing (including e-learning)	22 (21.8)

Masters in Primary Care	1 (1.0)
Registered Nurse Prescriber	37 (36.6)
Employer‖	
HSE	84 (83.1)
Private	9 (8.9)
Other	6 (5.9)
Employment	**Mean (SD)**
Years working as a DNS¶	11.2 (7.4)
Years in current position[β]	8.1 (6.8)

*includes 6 Advanced Nurse Practitioner or Advanced Midwife Practitioner grade nurses; 2 Clinical Nurse Managers; 3 diabetes nurses not graded as a DNS but qualified and performing the role of a DNS

†includes 16 integrated care nurses recruited as part of the national programme

‖missing data for 2 respondents

¶missing data for 3 respondents

βmissing data for 1 respondent

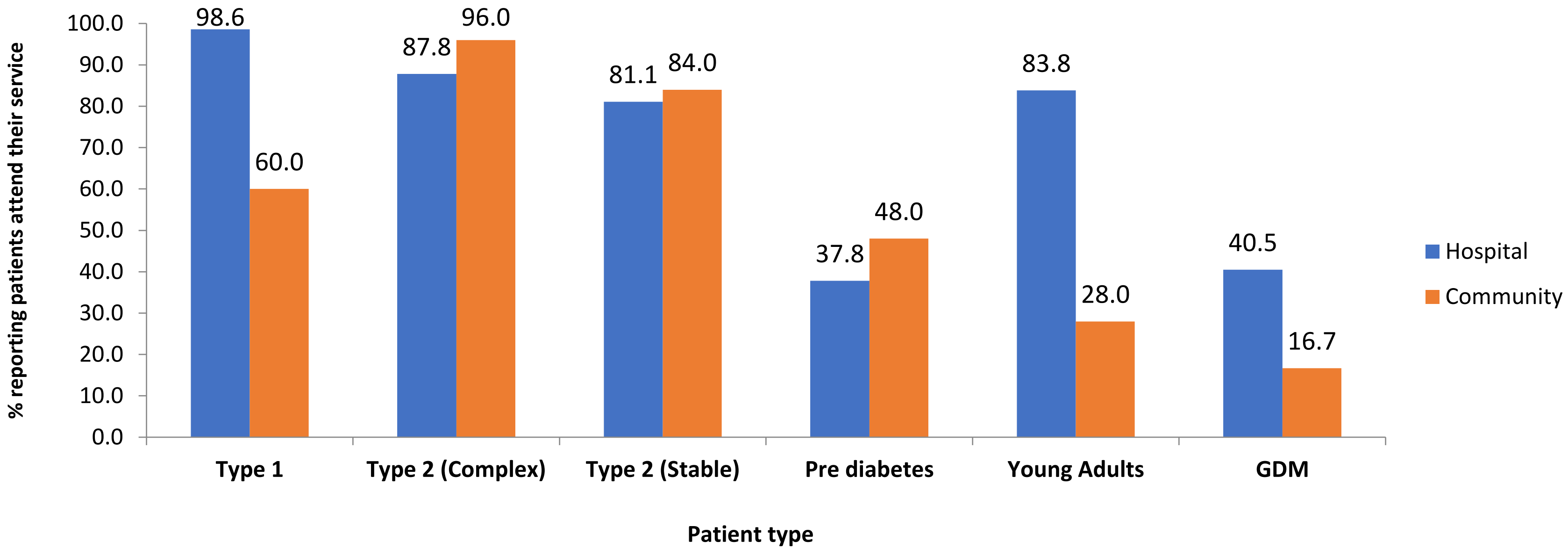

Figure 10 Patient types seen by nurse type; hospital (n = 74) or community (n = 25)

Abbreviations: GDM, gestational diabetes

Table 12 Specific roles performed by diabetes nurse specialists (DNS)

	Overall (n = 99)[‡]		Hospital (n = 74)		Community (n = 25)	
	Type 1	Type 2	Type 1	Type 2	Type 1	Type 2
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Core role						
Patient management *	88 (88.9)	90 (90.9)	73 (98.6)	67 (90.5)	15 (60.0)	23 (92.0)
Medical review	54 (54.5)	57 (57.6)	46 (62.2)	44 (59.5)	8 (32.0)	13 (52)
Telephone advice*	89 (89.9)	89 (89.9)	72 (97.3)	66 (89.2)	17 (68.0)	23 (92.0)
Referrals*	73 (73.7)	74 (74.7)	62 (83.8)	57(77.0)	11 (44.0)	17 (68.0)
Dose adjustment	73 (73.7)	72 (72.7)	58 (78.4)	51 (68.9)	15(60.0)	21 (84.0)
Insulin/GLP initiation/education*	81 (81.8)	89 (89.9)	68 (91.9)	66 (89.2)	13 (52)	23 (92.0)
Checking injection sites*	90 (90.9)	89 (89.9)	73 (98.6)	66 (89.2)	17 (68)	23 (92.0)
Glucose monitoring*	89 (89.9)	91 (91.9)	73 (98.6)	67 (90.5)	16 (64.0)	24 (96.0)
Inpatient care*†	77 (77.8)	71 (71.7)	69 (93.2)	61 (82.4)	8 (32)	10 (40.0)
Hypo management*	89 (89.9)	90 (90.9)	73 (98.6)	67 (90.5)	16 (64)	23 (92.0)
Specialist roles						
Hypertension clinics	5 (5.1)	6 (6.1)	5 (6.8)	5 (6.8)	0 (0)	1 (4.0)
Renal clinics	10 (10.1)	13 (13.1)	10 (13.5)	12 (16.2)	0 (0)	1 (4.0)
Assessment clinics prior to surgery	25 (25.3)	23 (23.2)	23 (31.1)	21 (28.4)	2 (8.0)	2 (8.0)
Pre-conception discussion	52 (52.5)	48 (48.5)	41 (55.4)	36 (48.6)	11 (44.0)	12 (48.0)
Prescribing	31 (31.3)	34 (34.3)	27 (36.5)	29 (39.4)	4 (16.0)	5 (20.0)
Other						
Providing foot care	76 (76.7)		52 (70.3)		24 (96.0)	
RetinaScreen registration	62 (62.3)		43 (58.1)		19 (76.0)	

Liaison			
Consultant	81 (81.8)	60 (81.1)	21 (84)
Hospital DNS[‖]	43 (43.4)	22 (29.7)	21 (84)
Community DNS	48 (48.5)	40 (54.1)	8 (32)
GP[‖]	70 (70.7)	46 (62.2)	24 (96)
Practice nurse[‖]	58 (58.6)	35 (47.3)	23 (92)
	Overall (n = 101)	**Hospital (n = 74)**	**Community (n = 25)**
Professional education			
GP[‖]	48 (47.5)	25 (33.8)	22 (88.0)
Practice nurse[‖]	60 (59.4)	35 (47.3)	23 (92.0)
Nursing staff in hospitals[‖]	82 (81.2)	71 (95.9)	11(44.0)
Medical staff in hospitals[‖]	49 (48.5)	47 (63.5)	2 (8.0)
Allied health professionals	41(40.6)	27 (36.5)	13 (52)
Medical staff in nursing homes[‖]	35 (34.7)	16 (21.6)	17 (68.0)
Patient education	101 (100)	74 (100)	25 (100)

‡2 respondents were excluded as they did not perform a clinical role

*significant difference in role performed for patients with T1DM after adjustment for multiple comparisons (Bonferroni corrected p < 0.002)

†significant difference in role performed for patients with T2DM after adjustment for multiple comparisons (Bonferroni corrected p < 0.002)

‖significant difference in role performed after adjustment for multiple comparisons (Bonferroni corrected p < 0.002)

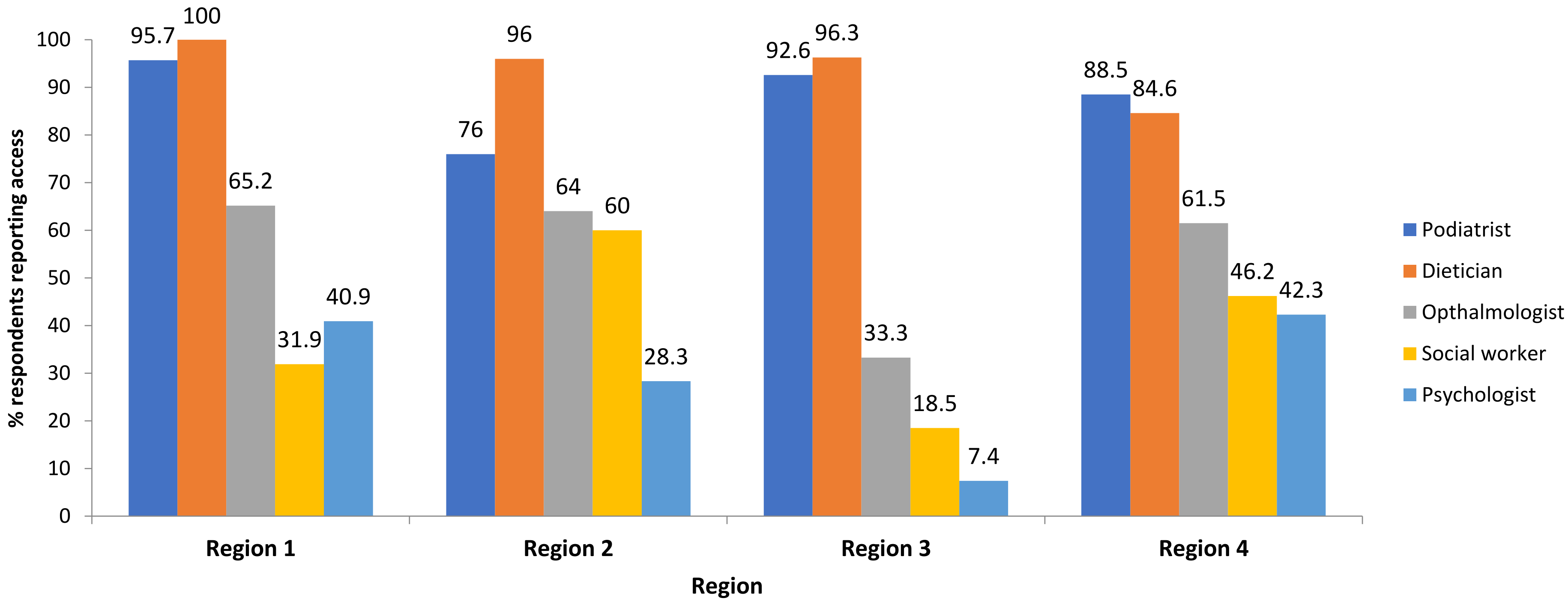

Figure 11 Referral access by region

7 'Sink or swim': a qualitative study of what, how and why nurses adapt when implementing integrated diabetes care.

Fiona Riordan

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Niamh McGrath

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7.1 Abstract

Background

Expanding nurse specialist support in the community is a strategy to integrate and improve the quality and efficiency of chronic disease management; however, little is known about how to successfully implement this model in a health system designed for acute and episodic care. We examine how new diabetes nurse specialists (DNS) working across care boundaries, together with hospital-based DNS, support the implementation of integrated care, including determinants of their behaviours.

Methods

We purposively sampled DNS (n = 30) from national survey respondents by work setting (community, hospital) and four administrative health service regions. We conducted focus groups and interviews using a semi-structured topic guide. Interviews were digitally recorded and transcribed verbatim. Analysis was data-driven, using action coding.

Results

Facing a choice of 'sink or swim' when introduced with limited guidance, community DNS used initiative and adapted to the local context. When first introduced, both community and hospital DNS actively managed role misconceptions. To establish clinics in general practices, community DNS capitalised on professional contacts and targeted GPs. They built GP trust by adopting practice norms and responding to individual needs. They adapted to the lack of multidisciplinary team '*safety net'* in the community, by '*practicing at a higher level',* working more autonomously.

Developing professional links and pursuing on-going education was a way to create an alternative ‘safety net’. Workarounds facilitated information flow between settings in the absence of a shared electronic record.

Conclusions

A capacity for flexibility and innovation facilitates a new way of working across boundaries. Successful implementation of integrated care supported by nurse specialists requires strategies to address elements in the inner context (e.g. differences in practice organisation, role acceptance) and outer context (e.g. information systems). context.

Keywords

Clinical Nurse Specialists, Integrated Care, Quality Improvement, Diabetes Mellitus

7.2 Introduction

Integrated care is seen as a way to improve both the quality and efficiency of healthcare delivery for people with chronic conditions [123]. Intermediary support by community-based multidisciplinary teams [17, 25, 164], or expanding nurse specialist roles in the community to support primary care [17-19, 24, 112] are strategies to integrate diabetes care both in Ireland and internationally. These models have delivered better clinical outcomes for patients [17, 23-25], reduced referrals to secondary care [112] and preventable hospitalisations [164]. However, models of integrated care do not always deliver improvements [163, 168, 172], in part because successful implementation in different healthcare or policy contexts is challenging; health care systems are inherently complex, characterised by unpredictability and self-organising practices [81], making it difficult to introduce and embed change. Moreover, health systems are traditionally designed for delivery of acute or episodic care and not necessarily configured for integrated care. Interventions are often adapted during implementation to increase compatibility and 'fit' with the given context [92].

Integration can be supported by existing relationships and shared values between organisations and individuals[198] and a culture of interdisciplinary work [198, 205]. Professional networks can serve as a platform for engagement in service development [207]. Lastly, integration can be supported by financing models which remove competition, placing emphasis on collective rather than individual performance [207]. In contrast, integration has been hindered by an organisational culture of 'silo-working' [198, 205], difficulties with data-sharing and communication caused by different or unlinked IT systems across settings [196, 198], and the failure to secure information-sharing agreements between services [198]. Existing frameworks [92] categorise these factors as implementation determinants. The CFIR, developed by Damschroder et al. consolidates existing theories, and provides a useful and comprehensive structure to describe contexts, whether they belong to the outer context (e.g. the extent to which organisations are networked; external polices and incentives) and inner context (e.g. social architecture, intra-organisational networks and communications, culture) [92].

The Irish health system is not necessarily suitable for integrated care; primary and secondary care services are funded and resourced separately, chronic disease management is often not well integrated between hospitals and general practice [394], and there is variation in the provision of diabetes management in primary care [32, 224]. Efforts to integrate care include a model of integrated care developed by the National Clinical Programme for Diabetes (2010) to improve the quality of care and ensure patients receive care in the most appropriate setting according to the complexity of their condition [68]. To support the delivery of this new model, community-based 'integrated' DNS, who work across primary-secondary care boundaries, were recruited from 2013 onwards to complement the predominantly hospital-based DNS service. Nurse specialists are central to the integration of chronic disease management [17-19, 112]; running nurse-led clinics [115, 188], providing specialist education and support to other professionals [19, 24, 112, 188], and liaising with other care providers from multiple specialities and co-ordination of patient care [24, 106, 107, 188]. 'Integrated' DNS in particular reflect an international shift towards expanding nurse specialist support in the community [24, 107, 112, 115, 188]. As a new way of working to support care in a system designed for episodic care, it is important to understand how context shapes the delivery of the role. Studies which have specifically explored the role of the DNS [186, 215, 216, 392, 403-406], have focused on role perceptions [186, 215, 392, 400, 403, 404], and specific aspects, such as nurse prescribing [405, 406]. Previously reported barriers of service delivery, have included resource constraints [214, 215], inefficiencies in data-sharing and documentation [407], understanding of the role by colleagues [185, 214, 216], and lack of funding for, or restrictions on, Continuing Professional Development (CPD)

[216, 217, 408]. However, few studies have explored the nurse specialist role as it pertains to the delivery of integrated care in practice [205], including how these models may be adapted during implementation [409]. Our aim therefore was to understand how DNS support the implementation of integrated care in a complex health system, including determinants of their behaviours.

7.3 Methods

7.3.1 Setting

In Ireland, both hospital and community DNS support integrated care by managing complex patients with type 2 diabetes, liaising with other professionals, delivering professional and patient education, and nurse-led clinics [188]. While hospital DNS spent 100% of their Whole Time Equivalent (WTE) in hospital, new community DNS are distinct in that they split their WTE between the community (80%) and hospital (20%) to facilitate integration between the two settings[68]. At the end of 2016 when this study was carried out, there were 26 nurses in post. Community DNS include: 1) existing community DNS in place before 2013, in some areas attached to primary care initiatives; 2) additional new posts placed into areas with an existing community DNS; and 3) community DNS posts entirely new to an area (no previous community DNS) (Appendix 6 Figure 20). At the time of the study, community DNS reported to the Director of Nursing in the hospital they were attached to.

7.3.2 Participants and sampling

We carried out semi-structured focus groups and individual interviews with hospital and community DNS across Ireland. Participants were sampled from respondents to a national DNS survey who indicated their willingness to be contacted about the follow-up qualitative study [188]. Participants were purposively sampled according to their main work setting (hospital or community) across the four administrative regions of the Health Service Executive, the national health system in Ireland (Table 13). A greater proportion of community-based DNS were sampled to explore the new integrated care role. Participants were invited by email and were provided with an information sheet explaining the study aims and methodology.

7.3.3 Data collection

Interviews and focus groups were conducted between December 2016 and February 2017. They took place in participants' workplace (i.e. offices within hospitals or primary care centres) or in hotels when interviews were arranged to coincide with conferences or meetings. All interviews were conducted by a single researcher (FR) with a background in Public Health and Health Services Research and no experience of working within the health service. Participants knew the interviewer as an independent researcher conducting the study as part of her PhD training.

Topic guides (Appendix 10.6.1) were developed based on the findings from the national survey and two pilot interviews (one community DNS; one hospital-based DNS). Topic guides included questions about the DNS experience delivering care, governance, working with other professionals in the community and hospital, strengths and weaknesses of the current service, and, in the case of new DNS, their approach to establishing the service. Hospital DNS were also asked about the introduction of the new community DNS role. Some interviews were conducted as part of a broader study on the implementation of the National Programme for Diabetes so some questions focused on particular aspects of that programme [1]. The topic guide was modified after an initial set of interviews to pursue emergent themes. For example, additional questions were included about the challenges of working between primary and secondary care, and how nurses worked with other professionals.

Prompts and probes were used throughout the interviews to encourage discussion. Signed informed consent was obtained before each interview. All interviews were audio-taped and transcribed in full. The average duration of individual interviews was 40 minutes, and 1.5 hours for focus groups.

7.3.4 Data analysis

Open-coding of transcripts was carried out with a broad aim of understanding the experiences of DNS in delivering care. Analysis was data-driven, drawing on some of the principles of grounded theory: coding actions or processes to stay closer to the data, and using *In Vivo* codes to preserve meaning [410]. Unlike classical grounded theory, the aim of the study was not to generate a hypothesis or theory. However, the purpose of grounded theory according to Noble and Michell [411], to uncover an understanding of behaviours, did align with the focus. The analysis approach has some but not all the features of grounded theory, for example, categories and analytic codes were developed from the data i.e. not pre-conceptualised. Two transcripts (one community DNS; one hospital DNS) were read and open-coded by two other members of the research team (SMH, NMG), and the analysis approach and emerging themes were discussed. Subsequently, codes were organised and refined with a focus on DNS reported actions or behaviours (how they acted to support integrated diabetes care), the factors leading them to respond this way, and any consequences of those actions. Actions were grouped according to conceptual similarity, and concepts were discussed with the research team. Memo writing was used throughout, particularly to establish conceptual links between the DNS actions, the conditions or causes, and the outcomes of these. Throughout the analysis the language and expressions of DNS were maintained to preserve meaning and context. NVivo (Version 11) was used for data management. The CFIR was not used as a framework to explicitly guide the analysis or reporting of the results. Instead this framework was used in the discussion as a means of classifying and reflecting on the identified determinants. To assess the validity of the synthesized themes, we presented the findings to a sub-group of community-based diabetes nurse specialists to check whether they accurately represented their views.

Ethical approval to carry out the study was obtained from the Clinical Research Ethics Committee of the Cork Teaching Hospitals. The consolidated criteria for reporting qualitative research statement (COREQ) was used to inform reporting of the findings. Participant quotations from community DNS (CDNS) and hospital DNS (HDNS) have been selected to illustrate findings. To assess the validity of the synthesized themes, findings were presented to a sub-group of community DNS.

7.4 Findings

Response rate to the initial survey was 67% (n = 101). Most (n = 96, 95%) indicated their willingness to be contacted about the follow-up qualitative study [188]. Of 40 DNS invited, 30 took part in total, in two focus groups (n = 8) and individual interviews (n = 23). One DNS took part both in a focus group and a subsequent interview. Ten DNS did not take part, due to sick or maternity leave (n = 4), lack of time (n = 3), or non-response (n = 3). Characteristics of participating DNS (region and type) are shown in Table 13.

7.4.1 Overview of themes

Most themes were specific to the community DNS experience. Therefore, we present themes as they relate to community DNS, and, where appropriate, highlight similarities or differences with the hospital DNS experience within each theme. When establishing and delivering their new service, community DNS faced a choice of '*sink or swim'*. The decision to 'swim' comprised of two main behaviours; using initiative and adapting role delivery to the health service context (Figure 12).

7.4.2 Establishing the service

When first employed, DNS who were not linked to an existing initiative felt there was no one to oversee their role or organise logistical issues. At the time of their introduction the official Model of Integrated Care document was also not published. Community DNS' options were to '*sink or swim'* when setting up the service locally (CDNS5, CDNS4-FG1). They established the service by '*doing a sales job'* (CDNS14) among local GPs and Practice Nurses to enrol practices. To reach GPs, they used existing contacts or knowledge they had from previous positions or took advantage of practice visits made by pharmaceutical reps, study days or information events. In areas where the service was entirely new, nurses had to '*start from scratch'* (CDNS1, CDNS5) in some cases generating contacts with GPs through cold calls:

> One [practice] rang and asked me to come for a meeting which I did, and started a clinic there. And no contact from anybody else. Had to start going around and making calls, and then, knocking on doors. (CDNS3-FG2).

> So it's a case of using my contacts that I previously had. It was hard at the start [laughs] but only because I had experience in [hospital] I would have…it was either sink or swim…there was nobody else to say right this the way you should do it, because nobody else had a clue? (CDNS5)

7.4.3 'Well, no, that's not part of my role' – managing role misconceptions

When community DNS were first introduced, other staff lacked clarity about their role, and they had to manage misconceptions by 1) using initiative to clarify and explain the role and, 2) asserting role boundaries. Some hospital DNS saw the community role as a different role to their own, while others saw it as part of the hospital team, '*complementary to*' (HDNS13) or a version of their own role.

> It's a valuable service I think really and can help to keep people out [of hospital], but in terms of what it helps to secondary care I'm not sure really. It's more of us, it's an extension of what we were doing (HDNS4)

Where community DNS were perceived as separate to the hospital team, it was difficult to integrate care:

> I think it would have been much more helpful if the consultants and the hospital-based team were engaged, were aware of what the role was, and that you were part of that team… The idea is that we're meant to integrate care, but you can't integrate anything if your team aren't on board. (CDNS7)

Community DNS managed misconceptions by explaining their role, educating other staff, and establishing role boundaries, justifying the need for flexibility in their role to managers (i.e. their working hours, how they spent their time, and tasks performed). Where community DNS had faced a lack of understanding from managers, managing misconceptions sometimes involved organising their own hours, forgoing explanation to save time.

> People are going to wonder what is your role, or what you can and cannot do, or maybe a public health nurse thinks that you can go in and give insulin every day, or...So, I think you just would need quite good interpersonal skills, and explain, 'Well, no, that's not part of my role, or...' (CDNS#19)

Although a much more established role, when first introduced, hospital DNS had faced a similar scenario; they also felt their role had not been appreciated or well understood. Other staff had not used the role appropriately, sometimes unnecessarily referring patients:

> Maybe about 5 or 6 years ago, we were getting a phone call just because they had diabetes. It didn't matter really, they just saw 'diabetes' and they'd asked us, from the nurses on the wards, or from the doctors. But I think they're appropriate referrals now and they tend to know when to call us. they probably realise that... We're trying better. We've done a lot of guidelines, and a lot of input on how to manage somebody with diabetes when they come in for procedures. (HDNS23)

Managing these misconceptions through ongoing education by hospital DNS, together with an increasing number in post, meant that understanding of the hospital-based role developed over time. There was an expectation that understanding of the newer community DNS service would develop in the same way.

7.4.4 'Practicing at a higher level' without a 'safety net'

Community DNS had to adapt to '*a whole different MDT'* in the community and work without the '*safety net'* (CDNS14) usually present in the hospital, that is, equipment and supplies '*on tap'* (CDNS10), and other experts to check with who act as '*backup*' (CDNS22) for one another.

> I'll get in my car and I'll drive off. You perhaps haven't got the people around to bounce ideas off. You've got to be the one making some decisions. But also as well for your own planning and stuff, nobody comes to me and says, 'Oh,

> there's your clinics.' You are responsible for your own workload…..So it is a different role, you don't have as much as a safety net of the team that you would do in a hospital, you are very much more… in some ways you can be more isolated but I prefer autonomous to isolated (CDNS14)

They adapted to the lack of this traditional 'safety net' by '*practicing at a higher level'* (CDNS22), which meant asserting themselves as autonomous practitioners, and assuming greater responsibility and ownership over their workload and service organisation, for example, using initiative to '*look for services'* (CDNS21) in the community to refer to and link in with. It also involved exercising greater autonomy in clinical decision-making as the '*diabetes expert'* (CDNS22) in GP practices, '*daunting*' (CDNS22, CDNS11) for some. To support themselves in this latter role they required confidence in their abilities and needed to maintain their skills and have a '*much broader knowledge'* (CDNS7) to deal with the patient mix and range of recommended medications.

> You are expected to make decisions and to be advising the GP I suppose technically on paper but I mean the GP is looking to you as a diabetes person to give the best advice on what we should do with particular patients. So, you are practising really at a higher level in primary care than you are within the hospital. (CDNS22).

> The dynamics [in community] are different. I wouldn't have been aware of the way things are done in primary care. It's very different to the hospital.

> You have everything at hand in the hospital really. It's very different out in the community. You have to look for services. You have to see what's available. It probably took me a good 12 months settling in period. That's just to get to know the system. (CDNS21)

Both community and hospital DNS recognised the need to further their specialist skills; however, a lack of protected time and resources meant they had to use their initiative to participate in their CPD on their *'own time'* (HDNS8). As a result, undertaking some professional education was considered unfeasible, for example, becoming a nurse prescriber. This course required an extended period of study leave, with a lack of remuneration for a '*very big responsibility'* (HDNS3).

> You have to be more up to date with all the medications and doses and side effects…Because you're advising the GP what to do, at the end of the day, whereas you would have always had somebody to run that off. But then, I'm in it now [ ] years, and I probably feel more au fait and on top of my drugs, than I did before. …. I think you have to be quite confident in your own practice, but if you are, then it's fine (CDNS19)

7.4.5 Developing professional links

Both community and hospital DNS used their initiative to reach out to other professionals, for support and guidance, to share information and standardise care, or to support patients.

Creating an alternative safety net

To support themselves to practice *'at a higher level'*, community DNS, along with pursuing CPD, developed links with other professionals to create an alternative 'safety net' (Figure 13). They did this by: 1) linking in with other community DNS for advice, to be '*shown the ropes'* (CDNS21), to discuss concerns about patients, to compare service delivery with colleagues and learn from those in post longer, the '*biggest saving grace'* (CDNS10) and; 2) linking in with hospital colleagues for advice and to up-skill through case discussion. For some community DNS, the 80/20 WTE split between time spent in the community and hospital settings had been delayed, leaving DNS feeling '*isolated*' (CDNS16).

> It was great to compare what you were doing with the other diabetes nurses, so at least then you knew you were somewhere on track. If you're going down a similar road, that at least you knew you were somewhere on track and that you were doing the right things (CNS#10)

Developing links to support patients

Both community and hospital DNS linked with Public Health Nurses (PHNs) to identify and support patients who needed their service, that is, those not attending a GP or hospital services who '*can fall through the gaps'* (CDNS3-FG1). Community DNS considered the '*bigger picture'* (CDNS5), liaising with PHNs and not restricting their contact to primary care professionals and the secondary care diabetes team (CDNS5). Both community and hospital DNS benefited from PHNs' knowledge and the links

PHNs had, but also supported PHNs in their role, providing education and advice (Appendix 6 Table 31).

> I know we link in with the GP, ultimately but you have to think of the bigger picture. Fair enough you have to say grand you don't refer to me, I don't accept referrals through the PHN but I can listen to what she has to say and I can get her to link in with the GP and get the patient sorted instead of saying I don't have anything to do with them (CDNS5)

Developing links to standardise care

A lack of national guidance meant hospital DNS were responsible for developing guidance on diabetes management at their individual hospitals. Some hospital DNS could reach out to other hospital DNS to develop standard guidelines, harnessing existing nurse networks, to avoid '*all reinventing different ones* [guidelines]' (HDNS4) or '*starting from scratch'* (HDNS17).

7.4.6 Blending in with practice norms and needs

In contrast with the autonomy they had in establishing their service, community DNS relied on GPs to facilitate their service in general practice, they '*couldn't go in solo and do our own thing'* (CDNS4-FG1). Although confident in their own abilities, community DNS were a '*complete stranger'* (CDNS10) when they first started in a practice. To build GPs' trust in their service, community DNS needed to adapt and with how things were done in the practices and to be flexible and responsive to practice needs.

> You can't be too dogmatic. You barely get in the door of a practice so you can't be dictating everything to them, you know. You're not going to muddy the waters. It takes a long time to build up trust with a GP practice so they've to trust you, you're a complete stranger walking in the door to them, they don't know you from Adam. (CDNS#10)

> I just can't emphasise enough how flexible you have to be when you're working in the community, and you have to acknowledge that you're going in to somebody's private business and that, it's very much defined by the personalities in it. And it's not all, the GP, it could be the nurse, you know. But you have to blend in with how things are done (CDNS2-FG2)

Community DNS built trust by respecting the GP's autonomy, remembering to '*run everything by them'* (CDNS10), and including GPs in medication decisions where feasible. Community DNS involvement in nurse prescribing depended on their situation with the practice, that is, whether they were starting a new service or joining an existing primary care initiative. If community DNS felt they were '*hardly inside the door*' (CDNS10) rather than somewhere they had '*already built that trust and relationship'* (CDNS21), they saw nurse prescribing as a challenge to GP autonomy which would remove opportunities for relationship-building, and they did not pursue it.

Community DNS were flexible about the referrals they accepted, recognising that patients referred to their service varies:

> So, I ask them to send the newly diagnosed patients to me so that varies from practice to practice because some practices are maybe doing diabetes 20 years and some are new to it. So, then the ones that are new to it mightn't have a practice nurse so they send everything to me, and then ones who are doing it a while would send the complex type news to me. (CDNS5)

They developed GPs' skills and expertise, for example ensuring GPs were informed of, and understood, any treatment changes. They did this by being responsive to practice workflow, creating time to discuss their decisions with GPs, waiting until the '*doctor has the headspace'* (CDNS16) or developing workarounds, '*leaving notes with the practice manager to pass on'* (CDNS20) to explain what they had done. The type of service community DNS provide to practices, including the patients they see, was something felt to change over time, as practice experience builds.

> If you think a new drug is recommended or something like that, [to make sure] that they know why, and where, and when, and that they're not just following your word, that they understand why, and that they understand the drug, and that they have their own opinion on it as well. (CDNS16).

> I had to call out to them [the practice] a few times and show them how to set up a practice, show them how to educate patients, how to use the meter,

show them what literature to use, start from scratch and now he's [the GP] fine. They see the newly diagnosed, uncomplex, and now they send the complex to me. (CDNS5)

7.4.7 Using workarounds to manage information gaps

Working between primary and secondary care, community DNS adapted to a complex information environment, becoming '*the only link [or] bit of integration between the hospital and GP'* (CDNS4-FG1), and using initiative to develop workarounds to address information gaps. Community DNS provided information to secondary care to inform management decisions. However, patient follow-up after community DNS left GP practices, case discussion with consultants, and fast-track of patients to specialist services, were hindered by two elements: 1) the absence of a shared record between settings, and; 2) GP ownership over patient data with no standard for how DNS could safely share or transfer information out of the practice. As a result, DNS were not always aware of what had taken place during a patient's hospital or GP appointment.

They adapted by bringing back '*basic*' data (CDNS14) to the hospital and entering that, or filling out information twice, once in practice, and again on the hospital system, a '*time-consuming'* (CDNS21) and '*frustrating*' (CDNS15) process, checking patient information, ringing the hospital or e-mailing colleagues. Others used initiative to manage the information deficit: establishing a patient passport or their own system to remember patients, using the clinic dates and patient visit order. They recognised the risks inherent in relying on memory and notes. Sometimes, filling in information gaps meant unnecessary appointments in secondary care could be avoided. These approaches contrasted with situations where community DNS were based in a primary care centre, arranged for referrals to be sent directly to them, and established their own system for recording patient data electronically, giving them ownership over that data.

> You have the issue of patient information belongs to the GP. But I might have to ring a particular person about their insulin, but I'm not supposed to have that information beside me. So if I have 20 people to ring, how am I supposed to remember exactly all of those people, and be safe in doing that? (CDNS7)

7.5 Discussion

We found that the capacity of DNS to adapt and innovate is important for implementation of their role. For community DNS in particular it enabled them to work with, and around, features of the outer and inner context as conceptualised by CFIR [92]. These features included inter-organisational networks and connectedness (i.e. general practice delivery by independent self-employed practitioners, absence of a shared record between primary and secondary care), and intra-organisational culture and norms (i.e. practice workflow, practice organisation and experience in diabetes management, the expectation to engage in CPD on their ‘own time’, and a lack of role understanding by peers and managers). These findings highlight the challenge of introducing boundary-spanning roles to facilitate integration and improve the quality of care when the wider system is not yet configured to support this model. The fact that both community and hospital DNS shared experiences of role misconceptions indicates the persisting challenges of introducing new clinical roles, and the need for greater clarity on nurse specialist roles integral to integrated care, to ensure they are used appropriately and effectively.

We identified inefficiencies in data-sharing and documentation and clinical information systems, also reported as barriers to other nurse-led services, regardless of the condition being managed [202, 407]. Poor coordination and information systems between secondary and primary care, in particular continue to pose a problem for integrated care [106, 195, 196]. The current study identified the specific consequences of this issue for implementation: curtailing aspects of the role such as case discussion and follow-up; placing additional demands on time, including liaison to address information gaps and duplication of data entry; missing opportunities to streamline services and appointment slots.

Inter-professional relationships [198, 207] and understanding of new roles [205] are important in the delivery of integrated care. Role ambiguity is an international challenge in the establishment of advanced nursing roles [412, 413]. As evident in the current study, ambiguity can lead to inappropriate or ineffective use of the service [205], and hinder interdisciplinary collaboration [205]. While both community and hospital DNS in this study managed role ambiguity, it may be circumvented through advance planning. Preparation for this new service could include ensuring readiness in terms of infrastructure and resources [414], making policies and protocols which outline the role available [412, 415], formally designating an individual (e.g. local nurse administrator) to oversee implementation and facilitate systems entry [414, 415], and engaging stakeholders [414], in particular influential or senior professionals to 'champion' the role within the organisation [415, 416]. Since this study was completed, the National Clinical Programme for Diabetes has developed a guidance document to help community DNS to explain their role and introduce their service in new practices.

As nurse specialists have become more autonomous [31, 188] and move to the community to facilitate the integration of care [24, 115, 417], they may face professional isolation[418]. We found nurse specialists work without the usual 'safety net' of other experts and a link to the hospital. Peer support [216, 217] and engagement in communities of practices [205], have been identified as facilitators of the nurse specialist role [216, 217]. In the current study, pursuing CPD, fostering links to secondary care professionals and other DNS were ways for nurses to create an alternative 'safety net'. A blend of 'formal and tacit knowledge' is required in boundary-spanning roles [419]. Professional networks provide an avenue for sharing knowledge and developing specific skills (e.g. care coordination, promoting service engagement) which cannot be supported through formal training. Limited study leave, as reported in the current study, is not unique to Ireland [31, 205]. Adequate training for boundary-spanning roles created to support the integration of care [419] is increasingly important to ensure these roles are sustainable, do not rely wholly on 'exceptional' and committed individuals with local links [419], and can be replicated in the event of staff turnover.

Implementation will be affected by the degree to which the intervention is workable in, and can be integrated into, existing practice [420]. Our findings illustrate the creative, self-organising behaviours [421] inherent in complex systems, and how providers make trade-offs between achieving intervention fidelity and sustaining the quality of care delivery. The adaptations made by community DNS to their role and the model of integrated care to make it 'workable' can be classified as intervention content modifications [422]: 1) adding elements consistent with the principles of integrated model (e.g. reaching out to, and educating PHNs); 2) refining the intervention to make it more appropriate (e.g. being flexible with referrals); 3) removing elements (e.g. nurse prescribing). However, this raises the question about which elements of community DNS role to support integration are 'core' and which belong to the 'adaptable periphery' [92]. Some variation is to be expected in complex systems; in Ireland, diabetes management in general practice ranges from ad hoc and opportunistic to structured approaches [32, 224]. We might expect variation in the service delivered by community DNS to GP practices according to GP experience and quality of the GP-DNS relationship. The community service is still in its infancy and some elements may be accorded some flexibility in the earlier stages of implementation. As the service develops however it will be important to support community DNS to navigate the "dance between flexibility and consistency" [423], providing some specification, and clarity around which elements can continue to be adapted, and, if deemed essential, how these can be consistently implemented [81].

Interventions may be made 'workable' at a local level. However implementation will also be affected by the system capacity (social-structural resources available to those enacting implementation) and whether it enables professionals like community DNS to contribute to the implementation process [420]. Our findings illustrate their ongoing contribution to embedding change by cultivating trust and building relationships with GPs and managing role misconceptions among peers and managers. The current study distinguishes between aspects of system capacity which will change over time e.g. social norms (role acceptance), cognitive resources (knowledge and experience of GPs), and those outside of the control of local actors e.g. material resources (information systems). The latter will continue to affect service delivery, and to constrain the role of the community DNS and its potential to support integration of care, and demand ongoing workarounds.

We believe findings from our study are transferable to other countries facing similar health service constraints e.g. poor integration across service providers[106], incompatible information systems [196, 197], GPs working as independent practitioners. Moreover, the clinical responsibilities and core competencies of DNS are similar internationally [31, 188, 392]. That the researcher who conducted the interviews was not a clinician may be a limitation; when interviewing clinicians, peer researchers can enlist greater trust and may be able to elicit richer data on more sensitive topics [424]. However, the position of the researcher as a non-clinician 'outsider' also meant they had no preconceptions or opinions about how the nurse specialist role works and may have been less susceptible to 'shared conceptual blindness' [424]. The researcher also made her position as a non-clinician clear to participants at the outset of interviews. Almost all community-based DNS were sampled for this study. However, since a lower proportion of hospital DNS were invited to take part their perspectives may not be as well-represented. While using action coding allowed themes to be guided by DNS responses in line with the data-driven principle of grounded theory, core behaviours only became apparent during the later stages of analysis. The study was not designed to specifically explore how interventions (including the DNS role) are adapted; a more nuanced understanding of the process of adaptation may have been achieved had this been the sole aim. The CFIR was used as a way to classify contextual determinants once they were identified but not as an explicit guide during the analysis. Had the aim been to elucidate DNS views on specific determinants, using the CFIR to structure the topic guide may have been beneficial. This may have prompted a discussion around other elements of the outer context, for example, financing and incentives, leading the researcher to probe whether and how this influenced the DNS role. As it stands, that these factors were not discussed suggests their impact may be less apparent or important to DNS when reflecting on their service delivery, as compared to other factors such as peer relationships. Adopting a phenomenological approach to inquiry may have been appropriate, had the explicit sole purpose been to explore the DNS shared experience of establishing a new service. The study is limited to the DNS perspective on their role. Future research should consider eliciting the views of other stakeholders on the service, specifically patients and primary care professionals. Evaluations of new integrated care service models in the UK and Australia have taken this approach [198, 210] A final strength is the fact that when we presented the findings to a sub-group of community-based DNS they expressed recognition of the behaviours identified.

Our findings have implications for the implementation of integrated care internationally. Strategies to avoid ambiguity when introducing new roles to support integrated care are important to ensure their appropriate and effective use. To support greater autonomy specialist nurses should be facilitated to engage in education and training, and to link in with peer networks and other professionals. An ability to adapt, and a capacity for flexibility and innovation, can facilitate the implementation of integrated care delivery into existing practice and specific contexts. However, there is a need for clarity on core elements, to support standardisation of new care models. Successful implementation and spread of integrated care models supported by nurse specialists requires a combination of strategies to address determinants in the inner context (e.g. differences in practice organisation in diabetes management, role acceptance) and outer context (e.g. information systems).

Table 13 Participant matrix (n = 30)*

Region	Population**	Diabetes prevalence***	Community DNS N = 19	Hospital DNS N = 11
			N (% sampled) (% region)	**N (% sampled) (% region)**
South (n = 7)	1,162,112	5.0	5 (26) (83)	2 (18) (10)
West (n = 9)	1,083,011	5.2	5 (26) (71)	4 (36) (22)
DNE (n = 6)	1,022,184	4.5	4 (21) (80)	2 (18) (11)
DML (n = 8)	1,320,945	4.4	5 (26) (71)	3 (27) (19)

Abbreviations: DNE, Dublin North East; DML, Dublin Mid-Leinster *1 DNS from focus group also participated in an interview

**2011 population *(Public Health Information System Data Table)*

***Estimated prevalence; type 1 and type 2 combined [425]

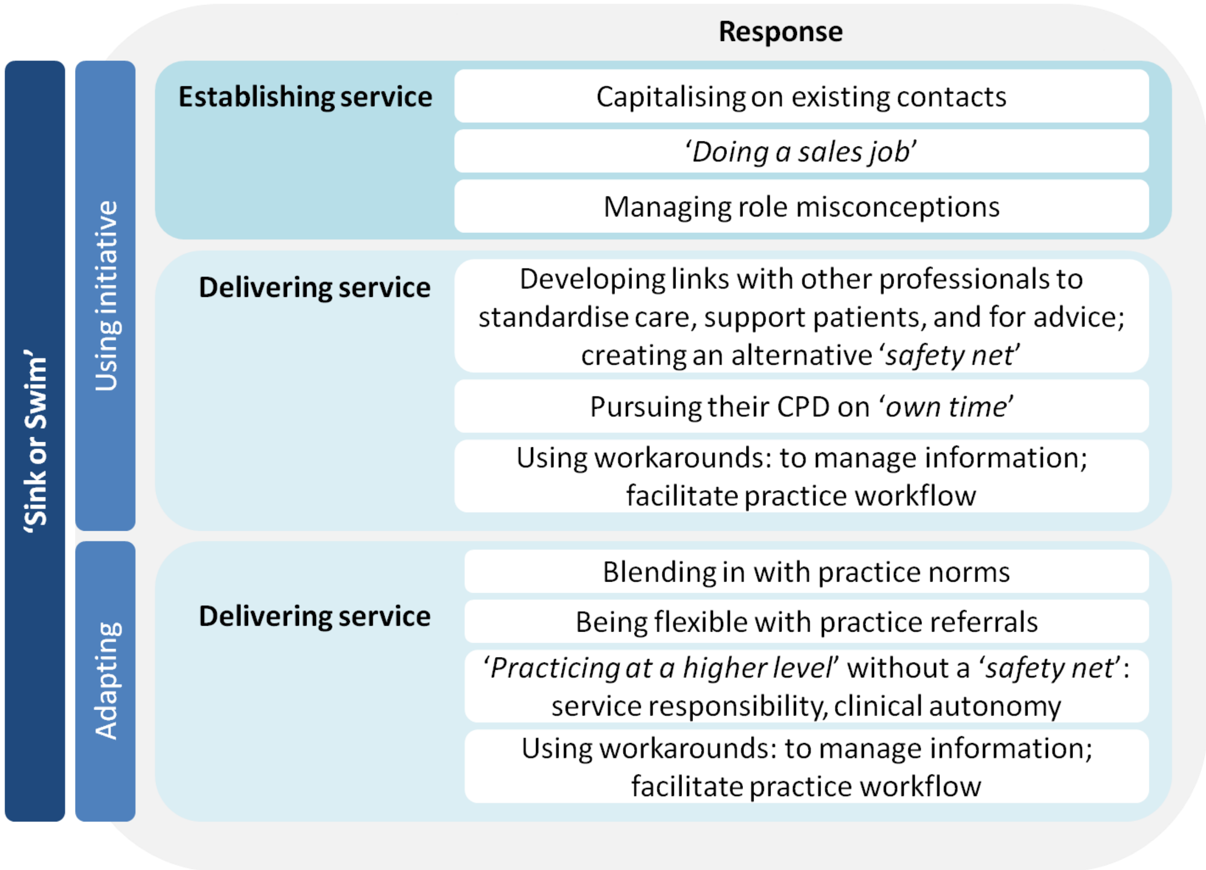

Figure 12 Examples of 'sink or swim'; DNS using initiative or adapting their role to the health service context to establish and deliver their service

Abbreviations: CPD, Continuing Professional Education

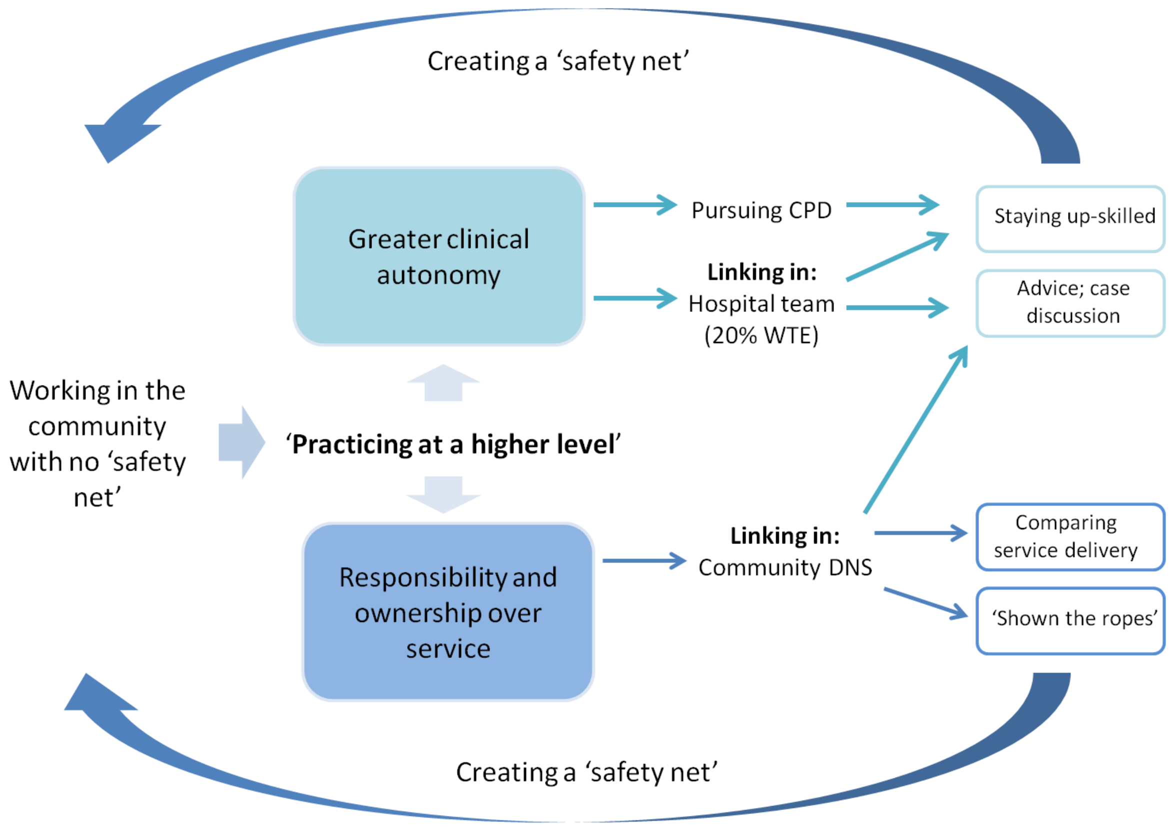

Figure 13 'Practicing at a higher level' and linking in with other professionals

Abbreviations: CPD, Continuing Professional Development; WTE, Whole Time Equivalent

8 Discussion

The overarching aim of this thesis was to understand whether and how integrated care can improve and sustain quality of care in a 'real world' community context. This chapter summarises the main findings of the thesis and discusses the health services research and policy implications. Main strengths and limitations of the thesis are outlined. Areas for future research are proposed and an overall conclusion is provided.

8.1 Summary of main findings

This thesis highlights that while structured care in a real world context may deliver benefits to patients in terms of their clinical profile and mortality, there continues to be variation in service delivery across general practice. Evidence from the international literature together with the qualitative work suggests that some practices, those in more deprived areas or with higher volume of patients with diabetes per physician, may need additional support to deliver high-quality diabetes care. As evidenced from the work based on the Midland programme, even with structured management some patients have a higher risk profile and may need more intensive support. The intended role of the DNS within integrated care is to focus on complicated, poorly controlled patients. However, the current work highlights how DNS continue to see patients with stable diabetes, along with the challenges inherent in establishing and accessing the role in the community, and the lack of guidance on how the service should be delivered in practice. These issues necessitate innovation and adaptation at an individual level to make integrated care 'workable'.

Overall, the thesis suggests that integrated diabetes care, comprised of structured management in general practice and specialists working across primary and secondary care settings, may be feasible and 'workable' in a real world community setting. However, there is a need to move beyond 'workable' to better understand if and how this model can be optimised to deliver effective care for *all* people with diabetes. This may be achieved through focusing on how best to measure the quality of integrated diabetes care, and engaging in further evaluation, in particular exploring the perspectives of multiple stakeholders.

The systematic review (Chapter 3) found that there was substantial variation in the number and type of measures used individually to represent quality, or to construct composite measures, limiting comparability across studies. Based on the meta-analysis and narrative synthesis, some physician (female gender, younger age, and higher volume of patients with diabetes), and practice (EHR, low deprivation) factors were associated with higher quality of care.

The structured care programme in general practice achieved significant improvements in process of care recording over time (Chapter 4). However, improvements levelled off in later years. BMI and smoking status were less well recorded than other care processes and recording varied by GP practice. While sustainable improvements in the quality of care (processes) can be achieved these may be limited by resource constraints locally and in the wider service context.

Chapter 5 found mortality among people with diabetes enrolled in the programme when first initiated in 1999 was greater than the background population (overall SMR = 1.20 (95% CI: 1.01-1.42)), and lower than some other international studies [8-11, 47, 48]. However, there has been a decline in excess mortality internationally in the past decade [61, 62, 64]. Improved clinical profile over time suggests cardiovascular risk factors are well-managed as part of the programme. This may explain the lower excess mortality. However, this is against the backdrop of declines in cardiovascular risk both internationally and nationally [59, 60]. Renal function (eGFR) and having experienced a macrovascular complication differed between decedents and survivors at baseline and these factors predicted mortality.

The national survey (Chapter 6) found most DNS supported integration through management of complicated type 2 diabetes; liaising with, and educating, other professionals, and delivering nurse-led clinics [188]. However, a substantial proportion of DNS had people with uncomplicated type 2 diabetes attending their service. There was also variation in referral access to different specialities regionally, and space and availability of specialist staff were limited. Support from other specialities for nurse-led clinics was variable. Access to their service (community clinics) was not universal. In some areas it depended on GP willingness to engage with the service, or their participation in an existing diabetes care initiative.

Chapter 7 found community DNS adapted to the lack of a shared record between primary and secondary care, lack of role understanding by peers and managers, and limited provision for CPD. They also adapted to differences in practice organisation and experience, and the position of GPs as independent practitioners. The study concluded DNS should be facilitated to link in with a ‘safety net’ of peer networks and other professionals. It highlighted the need for: 1) strategies to avoid ambiguity when introducing new roles (e.g. better initial communication and clearer role definitions [214], nurse administrators to oversee their introduction [414, 415], and senior professionals to promote the role [415, 416]), and; 2) EHR interoperability, at the very least ensuring specialists working across boundaries have access to patient data stored on multiple systems [212].

8.2 Implications for policy and practice

Integrated care is often used as a buzzword, a catch-all term, and an overarching solution to all problems in the health system. Its importance is reiterated in numerous Irish policy documents and national strategies [103, 219-223]. However, in Chapter 2 we saw that integrated care can mean many different things. Often high-level policy discussions and strategies fall short of outlining how, in practical terms, a model of integrated care should work in real world settings and everyday practice.

Since the advent of the National Clinical Care Programmes, the priority has been standardising care and “implementing proven solutions to save lives, prevent complications, remove waiting lists and save money” [426]. On a national level there is recognition that the approach to integrated care studied in this thesis, structured management in primary care and nurse specialist support in the community, represents a ‘proven solution’. Primary care services, identified “as a cornerstone” [427] of the response to population ageing and the rise in chronic disease, have been better supported to deliver diabetes care through the Cycle of Care[28]. The most recent National Service Plan (2018) has prioritised the negotiation of the GP contract [428]. There is a plan for on-going investment in the specialist and advanced nursing infrastructure in the community [429].

As such, in Ireland we are interested in knowing, will this 'proven solution' work here, what conditions do we need to implement and sustain it, and can we adapt it. This brings us back to the questions posed at the start of this thesis (Section 2.2.1). The thesis provides insights into how integrated service delivery works within, is shaped by, and adapts to, the service context. These insights are encapsulated in the next sections as three key messages relevant to integrating and improving the quality of diabetes care in Ireland and internationally.

8.2.1 Delivering integrated care 'at scale' while addressing access and equity

Firstly, when considering 'does it work?' and 'will it work here?' in relation to structured primary care, the answer appears to be 'yes', suggesting this model should be rolled out to the whole population. Chapter 5 concluded it is essential that integrated structured management be made available to *all* patients, to identify and manage the early signs of preventable complications and reduce excess mortality as a result of diabetes. The most recent National Service Plan is focused on progression of the Integrated Care Programme for the Prevention and Management of Chronic Disease to deliver integrated care "at scale" [428]. As outlined in the framework developed by Campbell et al. [74], effectiveness is only one dimension of quality; dimensions of equity and access are relevant for populations and individual patients respectively. Improvements to diabetes care to date in Ireland have often been locally driven, accentuating variation in care provision and access to services. Chapters 6 and 7 found access to the DNS service (community clinics) was not universal, with evident challenges accessing and making contact with practices who were not previously engaged. These findings suggest there is a need to be mindful that efforts to scale up, address rather than contribute to, existing inequity in care delivery. New DNS in areas without initiatives had to “start from scratch”, resorting to “knocking on doors” to get their service up and running. Routinely collected activity data (care processes, including patients seen, type (uncomplicated vs. complicated), practices attended, and patients discussed with the multidisciplinary team) collected by new DNS (Appendix 7 10.7.1) suggests that, despite this, the majority are now at capacity. As suggested by the survey, part of the issue around capacity may be that DNS receive referrals of patients with relatively stable diabetes who may be more appropriately managed by practice nurses. Improving nurse skills and education may address this issue. While DNS play an important role in building practice team capacity and skills, time needed to engage with practice for structured development and education is not always available. This was evidenced by the workarounds used by DNS to communicate with busy GPs. With DNS resources limited, Ireland runs the risk of facing the same problem reported in the UK, referred to as the ‘black hole’ in diabetes care [430]. The NHS has been criticised for the stagnation in DNS posts, citing recruitment embargo and the failure to staff appropriately for the rising numbers with diabetes [430]. If numbers of community DNS remain limited in Ireland, patterns in how they are accessed and used may add to existing variation in diabetes care. The Cycle of Care may also contribute to inequity by making free structured review visits available only to people with GMS or GP visit cards. Future reforms to deliver care in the community also need to be cognisant of the fact not all patients attend their GP. As highlighted in this thesis, there is a "little cohort of patients in community who sees nobody", patients who DNS felt can "fall through the gaps". Beyond the Cycle of Care, there needs to be some consideration of how to structure and standardise care delivery to this cohort, be it through formally expanding the remit of community nurse specialists or engaging in active efforts to build and support the education of PHNs in diabetes.

Scaling up may not be as simple as rolling out a standard care delivery package across Ireland. Findings from this thesis, that some physician and practice factors were associated with higher quality of care, and that DNS adapted their role in response to practice experience, suggest some practices may need targeted support. For example, those lacking informational infrastructure, those with less experience in diabetes care, and/or based in more deprived areas. The audit indicated some patients had a higher risk profile, despite structured management, suggesting some patients with poorer control may need more or different types of support [431]. While practice audits like that conducted in the Midlands regions could *identify* patients who are at higher risk, further patient-level data is needed to fully understand who may require more support. At present, some activity data is manually collected by community DNS, namely the number of complicated and uncomplicated patient episodes. There may be some scope for this data, if collected and collated electronically, to highlight regional variation and indicate areas of greater need.

Internationally, there have been some promising interventions to improve diabetes care among socially disadvantaged populations [432]. Features include one-on-one interventions, feedback provision to patients, involving community or lay people in intervention delivery, cultural tailoring, and implementing high-intensity interventions over a long duration [432]. The issue of socio-economic deprivation and general practice has captured national media attention through GPs at the Deep End, a group of GPs working in disadvantaged areas of Ireland [433]. This group have highlighted the difficulties of treating patients with multiple health and social needs served by these practices, and the need for additional resourcing, better access to secondary care and diagnostics [433, 434]. Over 85% of GPs enrolled in the Midlands programme were based in practices within the lowest deprivation deciles suggesting good quality care can be provided to patients in these areas. However, this incentivised programme is more comprehensive and better resourced than the Cycle of Care and does not necessarily reflect service provision nationally.

This thesis identified variation in the quality of primary care management (e.g. as part of the Midlands programme and international studies), which could reflect GP demographics, management decisions, their diabetes volume, along with patterns of patient attendance, adherence and self-management. Previous work conducted in the UK as part of the 'Improving Quality in Diabetes' (IQuad) study, tried to understand national variability in diabetes care through examining factors (organisational, team, individual) which influence professional behaviours [435, 436]. Most variability was found to exist between clinicians within practices rather than between practices [435]. Though variability in care quality may be due to patient characteristics and behaviour, these findings, together with the work in this thesis, suggest there is a need to better understand physician behaviour and consider theory-based interventions to target this in the Irish context, along with taking steps to address broader system-level challenges.

8.2.2 Embedding and sustaining integrated care

This brings us to the second key message arising from the work in this thesis. When considering ‘what conditions do we need to implement and sustain it [integrated care]?’, the findings suggest that “islands of excellence” [381] and central pillars of care delivery need to be supported by system-level changes in culture, training, infrastructure and resourcing for integrated care. This is essential to embed and sustain integrated care in the Irish health service. The aforementioned ‘islands of excellence’, the primary care initiatives, have led the way in terms of delivering high-quality structured care in Ireland. With the introduction of new DNS service we see again a somewhat isolated strategy to organise care, a good service which does perform functions to integrate care but which is challenging to implement within a resource-constrained and misaligned infrastructure. Chapters 6 and 7 found local arrangements for diabetes care delivery played part in how DNS services operate, be it where they deliver clinics in the community or the type of referral access they have. The findings indicate that at the time of the study the wider healthcare system was not completely ready to support this new way of integrating care involving professionals working across care boundaries. In short, integrated care is more than just putting the right professionals in the right place.

For the different parties involved in integrated care to work together there needs to be a shared vision, what Evans et al. refer to as a shared mental model [437]. We know that integrating care can require a cultural shift to facilitate interdisciplinary work and to counter silos of expertise, and the siloed thinking which is often ingrained in current healthcare delivery [198, 205, 210]. The stakeholder' statement on integrated care introduced at the start of this thesis asserted that "patients like it". Integrated chronic disease management, although challenging to implement, aligns with the national vision for patient-centred care. The Patient Narrative Project looks to patients and service users to guide the delivery of healthcare through the integrated care programmes [428]. Cost-effectiveness and the need to address the burden of chronic disease on health systems are cited as drivers of integrated care. However, organising services to ultimately make things easier and better for patients is a vision which can unite service providers in shaping a better health system.

It was evident from the work in this thesis that a shared vision of integrated care may not yet have filtered through at a local level. Social norms (role acceptance) are aspects of system capacity which can change over time [420]. However, they may hinder integration in the interim. Aptly put by one DNS: "you can't integrate anything if your team aren't on board". With professionals, including new 'integrated' DNS, increasingly working across boundaries, issues around role understanding and acceptance, blurring of professional roles and clinical responsibility will likely continue to arise [438, 439]. A systematic review of barriers to primary care type 2 diabetes management, found there was "uncertainty and unease" about clinical responsibility when coordination across numerous professionals occurred [132]. A qualitative study of GP-led integrated care in Australia, found there was a need to build trust and change the "mindset" of specialists to recognise the benefits and quality of moving more complex diabetes care to the community, and to counter resistance from GPs who did not want to "deal with" more complex management [210]. A study of the integration of health and social care in mental health services in the UK, identified concerns about the "erosion" of professional roles and identities among individuals who worked across boundaries [440]. Future efforts to integrate care in Ireland will need to consider how to generate receptiveness to new roles and new ways of interdisciplinary working. A practical issue arising from this thesis was the lack of clarity on the role of the DNS. Although guidance on integrated care was published in 2016 after new DNS were in post, there was no formal agreed document in place from the outset to outline their role, particularly how it should operate in relation to the other key professionals involved.

As mentioned, building the advanced nursing infrastructure in Ireland is central to delivering chronic disease management in the community [441]. Developing a workforce with the right competencies to facilitate integrated and coordinated care is important but needs to be part of a long-term plan involving wider service changes [442-444]. There is a need, not only for adequate training for boundary-spanning roles created to support the integration of care [419], but system-level changes in training of *all* professionals involved in the integrated care. This should include better support for additional training in diabetes in general practice, but also address the specialisation and "siloed nature of training" [419] of healthcare professionals, which can challenge collaborative working across professions and settings. Developing skills to support new ways of working may need to begin at the undergraduate and postgraduate level, and be further developed through on-going learning and CPD. However, as highlighted by Erens et al. there may be limited scope to change nationally set curriculums [444].

Restrictive information sharing across settings and poor information technology continues to challenge efforts to engage in QI and integrate care internationally [19, 133, 212]. This thesis showed that practices without EHRs delivered lower quality care, and that un-linked information systems affected the delivery of the DNS service and required workarounds; a tangible example of how this presents a day-to-day problem and limits elements of what is otherwise a good model of care delivery. The between-service disconnect in information systems and the difficulty accessing and synthesising information across organisations is a key challenge in Ireland. Encouragingly, this is being addressed as part of the eHealth strategy, which recently began piloting of interoperable EHRs and making provisions for the operational use of the national Individual Health Identifier [445]. To support integrated care, Darker et al. [122] and the more recent Slaintecare report, have recommended building the ICT infrastructure, along with changing governance structures, funding mechanisms, workforce planning and building networks and coordination between services [103].

8.2.3 Learning from service delivery 'on the ground'

This thesis not only indicates what 'conditions' may be important to embed and sustain integrated care but highlights how integrated care can be shaped by context.

Interestingly, changes in context of the Midlands programme appeared to have a knock-on effect on attendance at dietician services. GP demographics, diabetes caseload, and practice factors were associated with quality of primary care management as evidenced by the systematic review findings, while the qualitative study showed that practice experience and existing relationships shaped delivery of the DNS service in the community. While the answer to 'can we adapt it [integrated care]?' appears to be 'yes', a third key message from this thesis is that integrated care should continue to be evaluated as it is rolled out to determine what adaptations occur, why and whether they influence effectiveness. However, in doing so we should take context, 'conditions', into consideration.

Without learning from delivery on the ground to understand why things worked and why they did not, and why they were adapted, integrated care runs the risk of remaining an idealistic concept rather than a practical solution. Encouragingly, there is now on-going commitment to learning from the progress of pioneer and demonstrator sites of integrated care delivery across Ireland [428, 441]. While the DNS activity data goes some way towards demonstrating the contribution of the new posts, the Department of Health are moving towards developing key performance indicators for integrated nursing roles as part of demonstrator projects, to answer 'does it work' [446]. Future evaluations can take a standardised approach to measurement, using acceptable indicators of quality, but need to be mindful of that: 1) the delivery of new services can be shaped by context to account for local needs, and; 2) context can change over the course of an evaluation (e.g. resources available to structured programmes). In an effort to better capture the dynamic nature of context some studies have used a longitudinal qualitative design [447, 448]. For example, a study of the implementation of new infection control practices in hospitals representing ‘extremes’ (selected by whether or not they were most likely to succeed or face challenges in implementation) [447]. As a highly detailed approach, consisting of multiple non-participatory observations, it may be impractical for real world service evaluation and beyond the scope of many research grants. However, some effort should be made to record baseline differences and changes in context alongside evaluations. This, at the very least will mean that knowledge of what might affect implementation can be brought to new sites, to guide scale-up and anticipate issues.

When implementing and evaluating new models of integrated care, as asserted by Foster et al. in their study of GP-led integrated care [210], there is a need to “balance the ‘ideal’ model with the realities of resourcing”. It is important to allow for interventions to be adapted to the local context, rather than insisting on rigid standardisation [449]. Some guidance is needed on how to suitably modify DNS service delivery, if necessary. In Ireland and internationally, the focus is often on developing interventions that work, but less so on how to guide delivery of services and interventions once already in place, or how to adapt them so they are still effective[450]. Continuing to monitor and adapt interventions *during* delivery can identify important influences on service delivery which may not have been prioritised, were missed, or simply not apparent before the implementation began [351].

8.2.4 Summary of policy recommendations

There are several key recommendations arising from this thesis:

1. Extending coverage

There is evidence from this thesis to indicate structured care is beneficial to people with diabetes, particularly in terms of ensuring they receive regular checks and screening. The Midland programme is not limited to people holding a GMS card. The Cycle of Care should be extended to the whole population with diabetes.

2. Embedding flexibility

The Cycle of Care covers two visits in general practice annually to patients holding a GMS card. However, it was evident from this thesis that some patients and practices may need additional support. Some flexibility may need to be built in to the initiative, for example, considering how to introduce additional visits for patients with poorly controlled diabetes or those who are newly diagnosed who may need more intensive follow-up in general practice for a period of time.

3. Needs-based allocation

Greater attention is needed to ensure limited access to resources like DNS does not accentuate disparities in care delivery. Policymakers should consider how these resources are allocated on a national level, and whether a systematic approach to documenting and allocating resources on the basis of need, be it practice or patient-level, can be implemented.

5. Protocol and guidance for introducing new roles

Future efforts to integrate care in Ireland will need to consider how to generate receptiveness to new roles and new ways of interdisciplinary working. A practical issue arising from this thesis was the lack of clarity on the role of the DNS. Although guidance on integrated care was published in 2016 after new DNS were in post, there was no formal agreed document in place from the outset to outline their role, particularly how it should operate in relation to the other key professionals involved.

6. Investment in education

Wider system changes are necessary to support integrated care, the first being greater investment in education. Arguably skills and competencies for collaborative and cross-boundary working should be embedded in early training and could be built into existing curricula through engagement with the higher education authority. However, education could also be further supported in general practice by better structuring the role of the outreach specialist (e.g. DNS). One recommendation would be to resource not only the specialist role, but the time required for the practice to engage with DNS and jointly identify education and support needs for the practice, developing practice plans for how these needs can be met by the DNS or external courses.

7. Supporting integrated information sharing

The second key change to support integrated care had already been recognised at a national level, namely the need to improve the informational infrastructure, and implement interoperable EHRs.

8. Incorporating adaptation in models of care

A final recommendation would be to develop guidance for professionals who are working to deliver integrated care. This guidance should recognise the need for adaptation and indicate which aspects of the model of care in question are flexible and can be tailored to local settings and circumstances.

8.3 Strengths and limitations

This section provides an overview of the overall strengths and limitations of this thesis. The strengths and limitations of the five individual papers have been acknowledged in the previous chapters (3-7).

'Integrated care' is a nebulous term. As such, deriving clear messages from research in this area is challenging. The thesis has tried to mitigate this issue by limiting its focus to well-articulated approaches to integrated diabetes care; 1) horizontal integration within one service through a multifaceted structured diabetes management programme and; 2) vertical integration, co-ordinating management across primary and secondary care through role expansion and task shifting of the diabetes nurse specialist role. This thesis addresses existing research gaps; i.e. whether quality improvements achieved by interventions to integrate care in primary care can be sustained within a changing real life context, what factors influence quality, and how models which involve a new way of working across care-boundaries operate 'on the ground'). It does this by focusing on learning from the delivery of primary care diabetes management internationally (Chapter 3) and real world efforts to integrate diabetes care in the Irish setting (Chapters 4, 5, 6 and 7).

The results of this research are timely. The thesis was conducted while service provision was changing; a new service and integrated model of care were being rolled out nationally, and the Cycle of Care had been launched (2015). Researchers and policy makers are interested in understanding whether integrated diabetes care can be sustained in everyday practice, and how to achieve this [428, 429]. The author has had the opportunity present the work at national and international conferences in the areas of primary care, integrated care and quality in healthcare (Appendix 10.7.4) and to prepare the audit report on the Midland Structured Diabetes Care Programme [451]. Two of the included papers have been published. A policy brief was prepared for the National Clinical Programme for Diabetes on the work relating to DNS (Appendix 10.7.3). This brief outlined important factors which could lead to differences in the role of DNS nationally; i.e. practice experience in diabetes, GP-DNS relationship, links with other professionals and services. These issues may explain differences in activity data collected by new 'integrated' nurses; the author analysed and co-authored an annual report on this data published in draft format by the HSE (Appendix 10.7.1). These issues highlight the challenges of improving the quality of diabetes care and standardising management within health systems that may have a legacy of long-standing 'ground up' primary care programmes. The pressure to maintain the structure of local services, together with the different baseline service delivery created by existing professional relationships and GP or nurse training may influence the implementation of new initiatives and reforms.

Although this thesis has shown that the intervention to structure diabetes management in primary care demonstrated improvement, the multifaceted nature of interventions like this means it is difficult to determine which specific elements led to improvements. To answer this question some studies have categorised interventions according to their components, and tried to elucidate the key components [23, 158-161, 169] or determine whether the number of components is important [157, 160, 168, 169]. While the existing literature does not demonstrate a clear association between the number of intervention components and clinical outcomes [160, 168, 169]; as outlined in Appendix 10.1.1, the components incorporated by the Midlands programme reflect those found to be effective, such as clinical guidelines, establishing a patient register and recall system, and protected time for review. The causal link between the context (highlighted physician and practice factors) and quality outcome measures established in Chapter 3 is tentative, given this link was based largely on evidence from cross-sectional studies.

The thesis is strengthened by using routinely collected data to examine long-term service performance. In Ireland, data to study primary care management of diabetes are limited. Harnessing existing data collected for service audits is an efficient way to obtain 'added value' from these data sources [452] and study real world care delivery. However, this thesis was also limited by challenges relating to the use of routine data: substantial missing data, using sub-section of population, no appropriate comparison data to assess the performance of those participating in the structured care programme [452]. Within the structured programme it may have been beneficial to examine patient-level factors and their relationship with outcomes, for example, relationship between patient demographic factors, medications, their risk profile and development of complications. However, data were not available on important factors, including duration of diabetes, and medications. Data on complications were also not recorded consistently across different audit years. This, together with the missing data in 2003 and 2008, meant it was not feasible to examine the development of complications over time. To separate background trends in cardiovascular profile from the potential effect of the programme, and control for other practice features (e.g. location, team infrastructure, practice size) requires a more rigorous study design and additional resources to engage in primary care data collection. Comparison across practices delivering more or less structured care would also need to take account of patient case mix. Electronic data capture by DNS on a routine basis could help highlight and explain some of the regional variation in how the service is used. For example, there may be scope to record more detailed patient information, treatment approaches, changes in risk factor profile over time, which would not only help understand the impact of the DNS, but potentially identify patients and practices required more support or highlight regions which may require more DNS resources. Currently activity data collected by DNS is done so manually; and comparing the volume of complicated versus uncomplicated patient episodes per DNS provides some limited insight into referral patterns.

The availability of national data on patients would afford further scope to address some of these issues; i.e. gaps in data and the lack of comparison groups. Although progress has been made, currently there is no national diabetes register and no unique health identifier to enable linkage of patient data from different sources e.g. general practice and hospital inpatients. The fact that mortality among people with diabetes had not been examined in Ireland before this thesis clearly indicates the need for change. Future data from the Cycle of Care or the database established by the new national retinopathy screening service, RetinaScreen [453] may serve as a basis for a national diabetes register [13, 454]. National data on diabetes prevalence, complications and mortality are important to plan and organise health services. This data can also allow the health impacts of the disease to be monitored and serve as an indicator of improvements in the management of risk factors, or the quality and organisation of care. The data would enable population-level risk factors and long-term outcomes to be monitored following changes to care delivery (e.g. Cycle of Care). Although the UK has struggled to establish acceptable consent processes for extraction and centralised storage of data from EHRs in primary care [455, 456], they have been able to reap the benefits of the General Practice Extraction Service, examining the quality of diabetes care nationally [457, 458]. They can do, on a large scale, what Ireland, as evidenced in this thesis, can only do on a very small scale with laborious efforts in data collection and collation [107, 234-237].

Quality indicators used in the international literature on diabetes care varied substantially in terms of the individual indicators selected, and whether and how these are combined as a composite measure (Chapter 3). Measures of the quality of integrated care used by this thesis may have been too limited or should have been more closely aligned with international studies (e.g. measures based on QOF, constructing a composite measure from individual measures) [140, 151, 257, 267]. Although an important dimension for integrated care, culture was not specifically measured by this thesis. This is an aspect infrequently examined by existing studies[459]. Previous work in Ireland has indicated there may be openness to integrated care [32] but with new reforms occurring since then (model of integrated care, Cycle of Care, 'integrated' DNS) the current climate may be different. Although, user evaluation is one dimension of quality (consequences of care) [74], the patient perspective is also missing from this thesis. Measuring continuity of care [460] among people enrolled in primary care initiatives, or patient experience [461] may extend previous work in Ireland which has examined the quality of care from the patient point of view [462, 463].

8.3.1 Risk of bias

Reporting guidelines were used for Chapter 3 (PRISMA) and Chapter 7 (COREQ). Joanna Briggs checklists (observational and cohort studies) were used to reflect on the other studies (Chapter 4, 5 and 6). Most consideration is given to the main source of bias, namely the processes by which data were measured and collected. A number of issues may have undermined the reliability of measurement of the clinical outcome variables used in Chapter 4 and 5. Firstly, there was no quality check performed on the data collected from EHRs. Given this process comprised manual data extraction from files onto paper-based audit proforma, there was potential for error. A second concern is the repeatability of the clinical measurements. Recorded clinical values were based on the most recent measurement on the patient in the last 12 months. Given the variability in HbA1c

[464], for example, taking a value at one point in time could be viewed as a limited approach. With the introduction of the Cycle of Care, within a 12-month period people with diabetes should have at least two sets of blood results. In future audits, recording both rather than the most recent value may provide a more reliable measure. A final consideration is that certain items may have been less well recorded, for example, confirmation of attendance at screening services or diagnosis with complications. These were verified by the presence of a letter from outpatient services or external providers, or in notes on the patient file, and rely on the consistency of certain processes; i.e., updating files and coding complications, within each practice. Poor recording of attendance at dietetic services in 2016 could reflect a change in service provision or changes in how this was recorded. These considerations are also relevant for the follow-up study (Chapter 5). Additionally, in Chapter 5 certain important confounders, duration of diabetes, SES, were not available and could not be adjusted for and examined as predictors in the survival model. In terms of Chapter 6, limitations of the survey instrument should be taken into consideration. While the survey was based on one developed in the UK, validation appears to have been limited to a pilot of the questionnaire conducted among a group of DNS [31]. A similar approach was used for the Irish version. While this was valuable to check the clarity of wording and understanding, it is insufficient to fully test the validity of the instrument [465, 466]. For example, no tests were performed for repeatability. More comprehensive approaches could have been used, for example, cognitive interviewing. As part of the cognitive interview, respondents who represent the study group of interest, can be probed face-to-face as they answer questions to gain a better understanding their thinking

and whether they truly comprehend the items in the manner intended by the researchers [467].

8.4 Future research recommendations

Although this thesis found that the quality of structured primary care delivery can be sustained, this study was not designed to specifically examine and understand sustainability. Future qualitative work may be needed to understand what factors influence sustainability and why certain interventions, like the Midlands programme, are sustained while others are not [409].

The thesis is unable to fully explain variation in quality of care (e.g. process of care recording across practices, or the fact there was levelling-off of improvements in some processes). Further qualitative work with purposively sampled patients according to whether they received higher or lower quality care (e.g. high-risk category or not, care processes recorded or not) and their GPs could help better understand management decisions, patient attendance, adherence and self-management.

Variation in what measures constitute quality of diabetes care in primary suggests future work, at least in Ireland, may be needed to obtain consensus on core outcomes, including how to construct composites in order to standardise how the quality of diabetes care is evaluated. Since composite measures continue to be favoured and used widely to study quality, agreement on a standardised measure may be beneficial. As the data from the Cycle of Care is collected and reviewed, this raises the question of whether fulfilling these care processes will truly constitute quality, or will this instead represent, as one DNS suggested, a "tick box"[1], unable to indicate whether care delivery has really improved. Going forward there is a need for consideration of how quality of integrated care in primary care *should* be measured. Is the aim to monitor performance with respect to individual processes/indicators or overall? Should practices be considered to have achieved optimal quality of care on the basis of an 'all or nothing' approach with respect to individual processes, or should a quality score be derived from these? If the Cycle of Care is taken as the Irish equivalent of QOF then an approach could be modelled on existing studies which have constructed a score based on QOF indicators [140, 151, 257, 267], using this to examine changes in quality over time [468].

This study of integrated care is limited to the DNS perspective on their role integrating management between primary and secondary care. Future research should consider eliciting the views of other stakeholders on the service, specifically patients and primary care professionals, in line with international approaches to evaluating integrated care [198, 210]. Given the apparent variation in how DNS the service works within different practices, it would be particularly valuable to explore GP or practice nurse perspectives. This would help elucidate whether the service meets their needs, and how the role might better support them and operate most effectively within general practice.

[1] DNS participating in the qualitative study and national evaluation study

A final recommendation would be to consider exploring the role of practice nurses or PHNs in diabetes care, for example examining their education and training needs. The author has been involved in the development and administration of a national survey on practice nurse role in diabetes. This work is currently been prepared for submission. The value of PHNs as a link to reach patients was highlighted by DNS in this thesis. Existing work in Ireland has recognised the role of PHNs as “pivotal”, calling for greater focus on their role, CPD, and structures for how they communicate and work with secondary care [469]. Extending outpatient care to include a period of home-monitoring by PHNs has shown some success in terms of improving diabetes self-management and control [470, 471]. Inclusion of PHNs as part of the interprofessional primary care practice team to deliver stepped-care intervention for people with type 2 diabetes has been demonstrated to be feasible [472].

8.5 Conclusions

The prevalence of chronic conditions like diabetes is growing worldwide. The burden this confers on health systems has led to a greater focus on integrated care as a way to deliver better quality, and more effective care. This thesis suggests that integrated diabetes care may be feasible and sustainable in a real world community setting. Structured care can deliver quality improvements over time alongside policy and resource changes and integrated management between settings led by nurse specialists is made ‘workable’ through innovation and adaptation in a challenging context. This thesis supports the national roll-out of structured care, making this accessible to all. However, with respect to integration between settings led by nurse specialists, there is a need to move beyond ‘workable’ and feasible, to better understand if and how this model can be optimised to deliver effective care for *all* people with diabetes. There are a number of key considerations based on the findings of this thesis in conjunction with existing research, Irish general practice is not starting from an even baseline, and some practices may need to be offered targeted support to improve and organise diabetes care delivery. Attention is needed to ensure limited access to resources like DNS does not accentuate disparities in care delivery. Wider system changes are necessary to support integrated care; investing in skills and competencies for collaborative and cross-boundary working, communicating a shared culture and vision, and improving the informational infrastructure. Finally, further evidence on the effectiveness of integrated care is required. This model should continue to be evaluated as services are delivered, giving due attention to what measures constitute quality, recognising context can challenge efforts to standardise, learning from service delivery as it is implemented, and considering how to guide adaptations to ensure integrated diabetes care in the real world is both workable *and* effective.

9 References

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10 Appendices

10.1 Appendix 1 Supplementary files for Chapter 2

Table 14 EPOC Delivery arrangements

Category: Changes in how, when and where healthcare is organized and delivered, and who delivers healthcare	
Sub category	Definition
Group versus individual care	Comparisons of providing care to groups versus individual patients
Queuing strategies	A reduction or increase in time to access a healthcare intervention
Coordination of care amongst different providers	Organizing different providers and services to ensure timely and efficient delivery of healthcare.
Quality and safety systems	Essential standards for quality of healthcare, and reduction of poor outcomes related to unsafe healthcare.
Triage	Management of patients attending a healthcare facility, or contacting a healthcare professional by phone, and receiving advice or being referral to an appropriate service
Category: Where care is provided and changes to the healthcare environment	
Sub category	Definition
Environment	Changes to the physical or sensory healthcare environment, by adding or altering equipment or layout, providing music, art.
Outreach services	Visits by health workers to different locations, for example involving specialists, generalists, mobile units
Site of service delivery	Changes in where care is provided, for example home vs. healthcare facility
Size of organizations	Increasing or decreasing the size of health service provider units
Transportation services	Arrangements for transporting patients from one site to another
Category: Who provides care and how the healthcare workforce is managed	

Role expansion or task shifting	Expanding tasks undertaken by a cadre of health workers or shifting tasks from one cadre to another, to include tasks not previously part of their scope of practice.
Self-management	Shifting or promoting the responsibility for healthcare or disease management to the patient and/or their family.
Length of consultation	Changes in the length of consultations
Staffing models	Interventions to achieve an appropriate level and mix of staff, recruitment and retention of staff, and transitioning of healthcare workers from one environment to another, for example interventions to increase the proportion of healthcare workers in underserved areas.
Exit interviews	A verbal exchange or written questionnaire between employees' resignation and last working day
Movement of health workers between public and private care	Strategies for managing the movement of health workers between public and private organizations
Pre-licensure education	Changes in pre-licensure education of health professionals
Recruitment and retention strategies for underserved areas	Strategies for recruiting and retaining health workers in underserved areas
Recruitment and retention strategies for district health managers - LMIC	Interventions for hiring, retaining and training district health systems managers in LMIC
Category: coordination of care and management of care processes	
Sub category	Definition
Care pathways	Aim to link evidence to practice for specific health conditions and local arrangements for delivering care.
Case management	Introduction, modification or removal of strategies to improve the coordination and continuity of delivery of services i.e. improving the management of one "case" (patient)
Communication between providers	Systems or strategies for improving the communication between health care providers, for example systems to improve immunization coverage in LMIC
Comprehensive geriatric assessment	A multidimensional interdisciplinary diagnostic process focused on determining a frail older person's medical, psychological and functional capability to ensure that problems are identified, quantified and managed appropriately
Continuity of care	Interventions to reduce fragmented care and undesirable consequences of fragmented care, for example by ensuring the responsibility of care is passed from one facility to another so the patient perceives their needs and circumstances are known to the provider

Discharge planning	An individualized plan of discharge to facilitate the transfer of a patient from hospital to a post-discharge setting.
Disease management	Programs designed to manage or prevent a chronic condition using a systematic approach to care and potentially employing multiple ways of influencing patients, providers or the process of care
Integration	Consolidating the provision of different healthcare services to one (or simply fewer) facilities.
Packages of care	Introduction, modification, or removal of packages of services designed to be implemented together for a particular diagnosis/disease
Patient-initiated appointment systems	Systems that enable patients to make urgent appointments when they feel they cannot manage their condition or where something has changed unexpectedly
Procurement and distribution of supplies	Systems for procuring and distributing drugs or other supplies
Referral systems	Systems for managing referrals of patients between health care providers
Shared care	Continuing collaborative clinical care between primary and specialist care physicians
Shared decision-making	Sharing healthcare decision making responsibilities among different individuals, potentially including the patient.
Teams	Creating and delivering care through a multidisciplinary team of healthcare worker
Transition of Care	Interventions to improve transition from one care provider to another, for example adolescents moving from child to adult health services.
Category: Information and communication technology (ICT)	
Subcategory	Definition
Health information systems	Health record and health management systems to store and manage patient health information, for example electronic patient records, or systems for recalling patients for follow-up or prevention e.g., immunization.
The use of information and communication technology	Technology based methods to transfer healthcare information and support the delivery of care.
Smart home technologies	Electronic assistive technologies
Telemedicine	Exchange of healthcare information from one site to another via electronic communication

Table 15 Other terms used for integrated care

Term	Definition
Disease management	Broadly understood as "any intervention involving coordination of diagnosis, treatment, or other aspects of ongoing management by a person or multidisciplinary team in collaboration with or supplementary to the primary care provider"[83]. The EPOC definition states that disease management programmes are those "designed to manage or prevent a chronic condition using a systematic approach to care and potentially employing multiple ways of influencing patients, providers or the process of care"[120]. According to Norris et al. disease management should be '*proactive*' and '*multi-component*' comprised of the following: (1) the identification of the population with diabetes or a subset with specific characteristics (2) guidelines or performance standards for care, (3) management of identified people, and (4) information systems for tracking and monitoring[167].
Shared care	Sometimes considered a specific form of integrated care, is characterised by "joint participation" between primary care and secondary care to plan the delivery of care, including establishing a specific communication system between specialist services and primary care[108]. Shared care is distinct from structured care in that management can be structured and organised in primary care without enhancing communication with other services beyond usual referral systems, a feature which would distinguish the model as shared care according to the above definition. Approaches falling under the definition of shared care include clinics run by specialists in primary care, formal communication systems between primary and secondary care, liaison meetings both specialists and primary care professionals attend to discuss patient planning, a patient record card (e.g. patient passport), and shared IT systems with electronic communication system[177].
Structured care	Used to describe primary care delivery as part of national chronic disease management programmes, but can also be used as a general term to describe multifaceted interventions outside of these programmes, which focus on structuring and

Table 15 Other terms used for integrated care	
Term	**Definition**
	organising care in general practice with[105, 109, 117, 118, 473] or without[175] the provision of additional specialist support to GPs.
Chronic care model	Interventions are often guided by Wagner's Chronic Care Model[474] which suggests organisation with respect to four components is important to achieve high-quality care for chronic disease patients: patient self-management support, delivery system design, decision support and clinical information systems. Health care organisation and community resources and policies are two further overarching components related to management of chronic disease[66, 366]. The Chronic Care Model has been used both to operationalise integrated care[213] and classify interventions[157, 160, 168, 169, 172].
Case management	Person other than physician has an active role in coordinating diagnosis, treatment and ongoing management[23].
Care coordination	"Care coordination is the deliberate organization of patient care activities between two or more participants (including the patient) involved in a patient's care to facilitate the appropriate delivery of health care services. Organising care involves the marshalling of personnel and other resources needed to carry out all required patient care activities and is often managed by the exchange of information among participants responsible for different aspects of care."[475]

10.1.1 Overview of the Midland Structured Diabetes Care programme

Overall there is very little data available to evaluate the performance of primary care in Ireland[226]. Efforts to examine diabetes care models within the Irish health system often rely on data collected as part of primary care initiatives[234, 381]. This thesis uses data from the Midlands programme. To date there are 82 GPs and 63 practice nurses across 30 GP practices, actively participating in the programme, with 3,797 patients have enrolled since initiation. Monitoring and audit are a core part of the programme; data have been collected by nurse specialists in 1998/1999, 2003, 2008 and 2016, and four audit reports have been published to date. Practices participating in the Midlands programme receive clinical, educational and administrative support. The programme incorporates a number of strategies to integrate and coordinate diabetes management namely the use of evidence-based clinical guidelines, patient register and recall and protected time for review visits, ongoing organisation and coordination of care by practice nurses, structured multidisciplinary support and professional and patient education. The programme incorporates a number of strategies to integrate and coordinate diabetes management which align with elements shown to be effective in the international literature: team changes[158, 161], for example, access to a multidisciplinary team[17, 25, 164]; case management[23, 158], including provision of care in general practice by specialists[24, 112, 165] or the partial replacement of physicians by nurses in organising care[162, 163]; patient education and self-management[161]; interventions to prompt recall and review of patients, including electronic registries and tracking systems[161, 163] and; relay to improve patient-provider communication[161].

Table 16 Approaches to quality improvement in diabetes management (EPOC categories) incorporated by the Midland Diabetes Structured Care Programme*

Strategy	Description	Midlands
Targeting health systems		
Case management	Person other than physician has an active role in coordinating diagnosis, treatment and ongoing management.	√ Practice nurse leads on organisation and coordination of care
Team changes	Adding a team member or 'shared care' i.e. routine visits with personnel other than primary care team; active participation of MDT; expansion or revision of professional roles.	√ Enhanced access to multidisciplinary personnel: Practice level dietetic support (until 2013) Chiropody/podiatry practice support
Electronic patient registry		√
Facilitated relay of clinical information to clinicians		
Continuous quality improvement		
Structured care		√
Shared care		
Targeting health-care provider		
Audit and feedback		√ Research and audit is carried out under the Diabetes Structured Care Research and Audit Group
Clinician education		√ Annual study days 5-day Dublin City University accredited programme
Clinician reminders		
Financial incentives		√

	Remuneration for practice nurse time or payment by review visit through Heartwatch programme
Evidence-based guidelines	√ "A Practical Guide to Integrated Type 2 Diabetes Care" (2008, 2016)
Specialist expertise	√ Community DNS support at practice level
Targeting patients	
Patient education	√ Patient education programmes provided by DNS and dieticians
Promotion of self-management	√ Practice nurse and group education
Patient reminder systems	

Abbreviations: MDT, multidisciplinary team; DNS, diabetes nurse specialist

*Sub-components which are not specific to the EPOC categories are highlighted

10.2 Appendix 2 Supplementary files for Chapter 3

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	37
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	38
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	40,41
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	41,42
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	41
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	41,42
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	43
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	228

Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	41,42
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	44
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	44
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	44
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	44
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	44,45

Table 17 EMBASE search strategy		
#	**Search type**	**Results**
1	diabet*:ti,ab	
2	'diabetes mellitus'/exp	
3	**1 or 2**	**924,551**
4	'primary medical care'/exp	
5	'general practitioner'/exp	
6	'general practice'/exp	
7	'primary health care'/exp	
8	'private practice'/exp	
9	(‘primary care’ or ‘primary health care’ or ‘primary medical care’ or ‘family practice’ or ‘family doctor’ or ‘family physician’ or ‘family practitioner’ or ‘family medicine’ or ‘general practice’ or ‘general practitioner’ or GP or ‘private practice’ or ‘private practitioner’):ti,ab	
10	**4 or 5 or 6 or 7 or 8 or 9**	**369,548**
11	(practitioner* or doctor* or physician* or GP or GPs) NEAR/3 (characteristic* or factor* or attribute* or feature* or pattern* or practice*)):ti,ab	
12	((practitioner* or doctor* or physician* or GP or GPs) NEAR/2 (age or gender or experience or interest or training or knowledge or qualification* or education)):ti,ab	
13	'clinical education'/exp	
14	'work experience'/exp	
15	'working time'/exp	
16	(‘working hours’ or ‘work hours’ or ‘work experience’):ti,ab	
17	(physician* or practitioner* or doctor* or GP or GPs) NEXT/2 location):ti,ab	
18	**11 or 12 or 13 or 14 or 15 or 16 or 17**	**87,160**
19	((practice* or ‘primary care’ or ‘primary-care’) NEAR/2 (characteristic* or attribute* or feature* or organi?ation or structure*)):ti,ab	
20	((practice* or ‘primary care’ or ‘primary-care’) NEXT/2 (factor* or pattern*)):ti,ab	
21	(organi?ational NEXT/2 (characteristic* or attribute* or feature* or structure* or practice* or factor* or determinant*)):ti,ab	

22	((healthcare or health-care or 'health care') NEXT/2 organi?ation):ti,ab	
23	'practice management':ti,ab	
24	(patient* NEAR/3 (volume or number)):ti,ab	
25	caseload:ti,ab	
26	('solo practice' or single-handed or 'group practice' or 'practice size' or 'size of practice' or 'list size' or 'panel size' or 'diabetes prevalence'):ti,ab	
27	('practice type*' or 'type of practice*'):ti,ab	
28	((physician or doctor or nurs* or practitioner) NEXT/1 patient NEXT/1 ratio):ti,ab	
29	'nurse patient ratio'/exp	
30	(practice* NEAR/2 (location or deprivation)):ti,ab	
31	((rural or urban) NEXT/2 practice*):ti,ab	
32	((physician* or doctor* or nurs* or administrat* or practitioner*) NEAR/3 (volume or number*)):ti,ab	
33	((staff or staffing) NEAR/2 (volume or number)):ti,ab	
34	((physician* or doctor* OR nurs* or practitioner*) NEAR/3 (training or education)):ti,ab	
35	'staff training'/exp	
36	("patient registry" or register or 'reminder system*' or 'recall system*'):ti,ab	
37	'reminder system'/exp	
38	('diabetes protocol' or 'diabetes guideline' or 'practice protocol' or 'clinical protocol' or 'practice guideline'):ti,ab	
39	'practice guideline'/mj	
40	'clinical protocol'/mj	
41	**19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40**	**385, 025**
42	'health care quality'/exp OR 'quality control'/exp	
43	((guideline* OR protocol) NEAR/2 (adhere* OR uptake OR compliance)):ti,ab	

44	('standards of care' OR 'standard of care'):ti,ab	
45	(quality NEAR/2 (healthcare OR health?care OR care OR indicator* OR measure* OR assess* OR treatment OR score* OR metric*)):ti,ab	
46	'quality-of-care score':ti,ab	
47	(quality NEAR/3 indicator* NEAR/5 health?care):ti,ab	
48	'optimal care':ti,ab	
49	(quality NEAR/2 (assurance OR improvement* OR measurement*)):ti,ab	
50	((quality OR practice) NEAR/2 (gap OR gaps)):ti,ab	
51	(variation NEAR/2 care):ti,ab	
52	(process* NEAR/3 care):ti,ab	
53	(outcome* NEAR/3 care):ti,ab	
54	42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53	2,853,079
55	3 and 10 and 18 and 54	863
56	3 and 10 and 41 and 54	1679
57	55 or 56	2228
58	Limit 57 to English	2082
59	**Search dates 01-01-1990 – 01-07-2017**	**2071**

Search was conducted in EBSCO

Table 18 Reasons for exclusion from meta-analysis		
Measure	**Study references**	**Meta-analysis performed**
Gender[134, 256, 259-261, 263, 268-270, 272, 276, 280, 281, 311-313, 315-317]		
Composite	[268, 272, 311-313, 315, 317]	No, five studies used continuous measures Group level (male/female) mean (SD) were unavailable for 4/5 studies to estimate SMD[268, 272, 311, 313, 317] One study used binary outcome measure[313]
HbA1c test	[134, 260, 269, 270, 272, 311, 313, 316]	Yes, data available from at least two studies Data NA[260, 269, 311]
Eye exam	[134, 260, 269, 270, 272, 280, 311, 313, 316]	Yes, data available from at least two studies Data NA[311]
Foot check	[260, 269, 272]	Yes, data available from all studies
Lipid test	[134, 260, 269, 270, 272, 280, 311, 313, 316]	Yes, data available from at least two studies Data NA.[134, 269, 311]
Microalbuminuria test	[134, 260, 269, 272, 280]	Yes, data available from at least two studies. Data NA[134, 269]
HbA1c value	[256, 260, 272, 276]	Yes, data available from two studies with similar targets (HbA1c <7.0%[260]; HbA1c <8.5%[272]) Data NA[276]
Lipid value	[256, 260, 272, 276]	Yes, data available from two studies with similar targets (LDL-C <130[260]; LDL-C <130[272]) Data NA[276]
BP value	[256, 260, 272, 276]	Yes, data available from two studies with similar targets (BP >130/85mmHg[260]; systolic BP < 140[272]) Data NA[276]
Age[134, 259, 263, 266, 268, 281, 311, 313, 317, 318]		

Table 18 Reasons for exclusion from meta-analysis		
Measure	**Study references**	**Meta-analysis performed**
Composite	[268, 311, 313, 317]	No, two had available data using same exposure (10 years)[311, 331] Measured composite as continuous outcome, but group level (male/female) mean (SD) unavailable to estimate SMD
HbA1c test	[134, 311, 313, 318]	No, data NA[311], age measured in different categories[134, 313]
Lipid test	[134, 311, 313, 318]	No, data NA[311], age measured in different categories[134, 313]
Eye test	[311, 313, 318]	No, data NA[311], age measured in categories[313] or continuous variable[318]
Urine albumin	[134, 313]	No, different age categories used
Years since graduation[315, 318] or years in practice[256, 259, 261, 280, 316, 317]		
Composite	[315, 317]	No, only one had data available.
Eye test	[280, 318]	No, different exposure variables (>15 years in practice[280]; years since graduation[318])
Lipid test	[280, 318]	No, different exposure variables (>15 years in practice[280]; years since graduation[318])
HbA1c value	[256, 318]	Yes
LDL-C value	[256, 318]	Yes
Training[255, 266, 275, 306, 308, 312, 316, 317]		

Table 18 Reasons for exclusion from meta-analysis		
Measure	**Study references**	**Meta-analysis performed**
Composite	[255, 312, 317]	No, data NA[312], different exposures (board certified physician or not board certified[317], patients of physicians in top quartile of MOC score vs. lowest quartile[255])
HbA1c test	[275, 308, 316]	No, different exposures (board certification[316] vs. total EBM score[275] vs. postgraduate training in diabetes[308])
HbA1c value	[306, 308]	No, different exposures (GP education: dichotomous measure, amount of accredited education less than 50 hours per year or exactly/more than 50 hours[306],postgraduate training in diabetes[308])
BP value	[306, 308]	No, different exposures (GP education: dichotomous measure, amount of accredited education less than 50 hours per year or exactly/more than 50 hours[306], postgraduate training in diabetes[308])
Panel size and workload[140, 252, 256, 261, 267, 268, 277, 281, 282, 284, 311-313, 317]		
Composite	**[140, 267, 277, 311, 313, 317, 331]**	No, different exposure variables (panel in groups of 200 patients[311], categorised as ≥1500 vs. < 1500 patients[313], number of patients[317], list size (effect by 100)[331], panel size above the mean (>2959) vs. those below mean[277], list size per FTE GP[140, 267]
HbA1c test	[282, 284, 311, 313]	No, data NA[311], different exposure variables (≥1500 vs. < 1500[313]; volume per day <20, 20-35, 25-30, 30-40,>40[284]; performance levels across panel size 1200, 1500, 1800, 2100, 2400[282])
Lipid test	[282, 284, 311, 313]	No, data NA[311], different exposure variables (≥1500 vs. < 1500[313]; volume per day <20, 20-35, 25-30, 30-40,>40[284]; performance levels across panel size 1200, 1500, 1800, 2100, 2400[282])
Eye test	[282, 284, 311, 313]	No, data NA[311], different exposure variables (≥1500 vs. < 1500[313]; volume per day <20, 20-35, 25-30, 30-40,>40[284]; performance levels across panel size 1200, 1500, 1800, 2100, 2400[282])
HbA1c value	[140, 256]	No, different exposure variables (number of patients seen in a typical month; list size per FTE GP[140])
BP value	[140, 256]	No, different exposure variables (number of patients seen in a typical month; list size per FTE GP[140])
Lipid value	[140, 256]	No, different exposure variables (number of patients seen in a typical month; list size per FTE GP[140])

Table 18 Reasons for exclusion from meta-analysis		
Measure	**Study references**	**Meta-analysis performed**
ACE/ARB prescribed	[252, 282, 284]	No, different exposure variables (volume per day <20, 20-35, 25-30, 30-40,>40[284]; performance levels across panel size 1200, 1500, 1800, 2100, 2400[282], number of patients per GP in percentiles[252])
Diabetes volume[134, 261, 278-281, 284, 322]		
Lipid test	[134, 278-280, 284, 303]	Yes[278, 280] Data NA[134], different exposures (diabetes-specific volume in increments of 100[284], number of patients with diabetes (<55, 56-70, 71-85,>85; <55 = reference)[134], volume in quintiles[278], per 10 patients with diabetes treated annually[279], number of patients with diabetes >20[280]; annual volume in quartiles[303] Reported predictive margins[284]
HbA1c test	[134, 278, 279, 284, 303]	Yes[134, 278, 279] Reported predictive margins[284]
Eye test	[134, 278-280, 284, 303]	Yes[278, 280] Reported predictive margins[284] Data NA[134, 279]
Microalbuminuria test	[134, 280, 303]	No, data NA[134], different exposure variables (number of patients with diabetes >20[280]; annual volume in quartiles[303])
Credential (MD or DO)[288, 311, 318]		
Composite	[288, 311]	No, data NA[311]
HbA1c test	[311, 318]	No, data NA[311]
Nephropathy check	[311, 318]	No, data NA[311]

Table 18 Reasons for exclusion from meta-analysis		
Measure	**Study references**	**Meta-analysis performed**
Eye test	[311, 318]	No, data NA[311]
HbA1c value	[288, 318]	No, data NA[288]
Cholesterol value	[288, 318]	No, data NA[288]
Practice size[138, 140, 142, 144, 150, 259, 262, 267, 290, 301, 304, 312]		
Composite	[140, 262, 267, 290, 312]	No, data NA[312] Studies with available data used different exposure variables (number of patients during a census period[290], size of service population <=500, 501-999 or >= 1000[262], number of patients[140, 267])
HbA1c test	[138, 142, 150, 304]	No, data NA[142], different exposure (number of patients[304], list size per 1000s[150]), or outcome (improvement in quality[138])
Lipid test	[138, 142, 144]	No, data NA[142], different outcome (improvement in quality[138]), did not carry out detailed statistical analysis.[144]
BP test	[138, 142, 144, 150]	No, data NA[142], different outcome (improvement in quality[138]), did not carry out detailed statistical analysis[144]
Eye test	[142, 144, 150, 302]	No, data NA[142, 150], did not carry out detailed statistical analysis[144]
Foot check	[142, 144, 150]	No, data NA[142],did not carry out detailed statistical analysis[144]
Microalbuminuria check	[142, 144, 150]	No, data NA[142],did not carry out detailed statistical analysis[144]
HbA1c value	[138, 140, 142, 144, 150, 301, 304]	No, data NA[142, 150, 301], different outcome (improvement in quality[138]), did not carry out detailed statistical analysis[144]

Table 18 Reasons for exclusion from meta-analysis		
Measure	**Study references**	**Meta-analysis performed**
BP value	[138, 140, 144, 301]	No, data NA[301], different outcome (improvement in quality[138]), did not carry out detailed statistical analysis[144]
Cholesterol value	[138, 140, 144, 301]	No, data NA[301], different outcome (improvement in quality[138]), did not carry out detailed statistical analysis[144]
Practice location (urban compared to rural practices).[135, 253, 259, 286-288, 311-313, 317]		
Composite	[135, 262, 286, 288, 311-313, 317]	Yes[135, 288, 311, 313, 317], three with binary outcome[135, 288, 313], two with continuous but group level (urban/rural) mean (SD) unavailable to estimate SMD
HbA1c test	[253, 287, 311, 313, 318]	No, data NA[311, 313], different exposure variable (uses region not urban v. rural[318]), reports adjusted proportions[253], analysis not adjusted for confounders[287]
Lipid test	[253, 287, 295, 311, 313, 318]	No, data NA[311, 313], different exposure variable (uses region not urban v. rural[318]), reports adjusted proportions[253], adjusted mean %[295], analysis not adjusted for confounders[287]
Eye test	[253, 287, 295, 311, 313, 318]	No, data NA[311, 313], different exposure variable (uses region not urban v. rural[318]), reports adjusted proportions[253], adjusted mean %[295], analysis not adjusted for confounders[287]
Solo or single-handed to group practices[140, 252, 256-259, 267, 285, 289, 306, 313, 316, 318]		
Composite	[140, 267, 285, 313]	Yes, two with binary outcome measure[285, 313]
HbA1c test	[313, 316, 318]	Yes
Lipid test	[313, 318]	Yes

Table 18 Reasons for exclusion from meta-analysis		
Measure	**Study references**	**Meta-analysis performed**
Eye test	[313, 316, 318]	Yes
HbA1c value	[140, 289, 306, 318]	No, different outcome variables (mean difference in % achievement between solo and group[289], HbA1c <7.4%[140], % HbA1c[306], HbA1c poorly controlled rate[318])
Lipid value	[140, 289, 306, 318]	No, different outcome variables (mean difference in % achievement[289], total cholesterol ≤5mmol/l[140], total cholesterol[306],LDL-C poorly controlled rate[318])
BP value	[140, 289, 306]	No, different outcomes (mean difference in % achievement[289], BP ≤150/90 mmHg[140], total SBP (mm Hg)[306])
Practice deprivation[140, 144, 150, 151, 265, 267, 289, 293, 301, 312]		
Composite	[140, 151, 267, 293, 312]	No, continuous outcome measure
HbA1c test	[150, 265]	Reported as standardised beta coefficient.[265]
Eye test	[150, 265]	Reported as standardised beta coefficient.[265]
HbA1c value	[140, 144, 150, 289, 301]	No, data NA[150], reported mean difference in % achievement[289], did not carry out detailed statistical analysis[144], different outcomes[140, 301]
BP value	[140, 144, 289, 301]	No, reported mean difference in % achievement[289], did not carry out detailed statistical analysis[144], different outcomes[140, 301]
Lipid value	[140, 144, 289, 301]	No, reported mean difference in % achievement[289], did not carry out detailed statistical analysis[144], different outcomes[140, 301]
Practice prevalence of diabetes[140, 144, 150, 259, 263, 267, 268, 289, 293, 299, 301, 312]		

Table 18 Reasons for exclusion from meta-analysis		
Measure	**Study references**	**Meta-analysis performed**
Composite	[140, 267, 268, 293, 299, 312]	No, continuous outcome measure
HbA1c value	[140, 144, 150, 289, 301]	No, reported mean difference in % achievement[289], did not carry out detailed statistical analysis[144], different outcomes[140, 301]
Lipid value	[140, 144, 150, 289, 301]	No, reported mean difference in % achievement[289], did not carry out detailed statistical analysis[144], different outcomes[140, 301]
BP value	[140, 144, 150, 289, 301]	No, reported mean difference in % achievement[289], did not carry out detailed statistical analysis[144], different outcomes[140, 301]
EHRs at the practice[135, 254, 256, 285, 286, 294, 296-298, 302, 306, 307, 310, 311, 314, 316]		
Composite	[254, 285, 286, 294, 297, 298, 302, 310, 311, 314]	Yes, four studies using the same exposure (EHR vs. no EHR)[254, 285, 294, 311]
HbA1c test	[296, 307, 310, 311]	No, data NA[296, 311], matched pairs[307], difference in means[310]
Eye exam	[296, 307, 310, 311]	No, data NA[311], matched pairs[307], difference in means[310]
HbA1c value	[256, 306, 310]	Yes[256, 306], adjusted difference in means[310]
BP value	[256, 306, 310]	Yes[256, 306], adjusted difference in means.[310]
Lipid value	[256, 306, 310]	Yes[256, 306], adjusted difference in means.[310]
Number of GPs[135, 150, 151, 252, 268, 286, 290, 309, 312, 315]		

Table 18 Reasons for exclusion from meta-analysis		
Measure	**Study references**	**Meta-analysis performed**
Composite	[151, 268, 286, 290, 309, 312, 315]	No, exposure unclear[151, 312], different exposures (i.e. categorised per session rather than per practice[290], categorised as two or more GPs[135], as % of GP on the team[331]), did not adjust for confounders[319], examined the improvement in quality score[286]
HbA1c test	[150, 151, 286]	No, did not conduct detailed statistical analysis[151], examined the improvement in quality score[286]
Eye exam	[150, 151, 286]	No, did not conduct detailed statistical analysis[151], examined the improvement in quality score[286]
Foot check	[150, 151, 286]	No, did not conduct detailed statistical analysis[151], examined the improvement in quality score[286]
Microalbuminuria test	[150, 151]	No, did not conduct detailed statistical analysis[151]
Nurse practitioner (NP) or physician assistant (PA) involvement[143, 256, 258, 259, 287, 292, 300, 304, 305]		
HbA1c test	[143, 264, 287, 304, 305]	No, no adjustment for confounders[287], reports difference in proportions[264], different exposure variables (PA vs. physician only[143], PA/NP role type[304], care delivery by NP[305])
Lipid test	[143, 264, 287, 305]	No, no adjustment for confounders[287], reports difference in proportions[264], different exposure variables (PA vs. physician only[143], care delivery by NP[305])
ACE/ARB:	[143, 305]	No, different outcomes (microalbumin in urine >30 mg in 24 hr and on an ACE inhibitor or ARB[143], prescription of ACE/ARB[305])
Lipid-lowering drugs	[136, 143, 305]	No, different exposures (presence of diabetes assistant at practice[136], different outcomes (LDL-cholesterol ≤100 mg/dL, or >100 mg/dL and on a lipid lowering agent[143],: use of statin[305])
BP-lowering drugs	[136, 143]	No, different exposures (presence of diabetes assistant at practice[136], practices with NP vs. PA, NP vs. Physician only, PA vs. Physician only[143])
Glucose-lowering drugs	[136, 143]	No, different exposures (presence of diabetes assistant at practice[136], practices with NP vs. PA, NP vs. Physician only, PA vs. Physician only[143])

Table 18 Reasons for exclusion from meta-analysis		
Measure	**Study references**	**Meta-analysis performed**
HbA1c value	[143, 256, 264, 300, 304]	No, reports difference in proportions[264], no adjustment for confounders[300], different exposure variables (PA involvement[256], PA vs. physician only[143], PA/NP role type[304])
Cholesterol value	[143, 256, 264]	No, reports difference in proportions[264], different exposure variables (PA involvement[256], PA vs. physician only[143]
BP value	[143, 256, 264]	No, reports difference in proportions[264], different exposure variables (PA involvement[256], PA vs. physician only[143]
Composite	[135, 140, 267, 290, 312]	No, data NA[312], different exposure variables (number of nurses at the practice[290], whether the practice had a nurse[135], list size per nurse[140, 267])
HbA1c value	[140, 150, 306]	No, different exposure variables (number of nurses at the practice[290],list size per nurse[140, 267, 306]), different outcomes (HbA1c <7.4%[140], HbA1c value[306])
BP value	[140, 306]	No, different outcomes (BP <145/85[140], total SBP[306])
Cholesterol value	[140, 306]	No, different outcomes (cholesterol <5mmol/l[140], total cholesterol[306])
Staff/clinician ratios[257, 285, 288]		
Composite	[257, 285, 288]	No, different exposure variable
Team tenure[257, 288, 315]		
Composite	[257, 288, 315]	No, data NA[257], different exposure variables ("Team tenure" is defined as the number of years that each physician has worked with the majority of physicians currently constituting the team—a range of zero to 19 years in the practices studied[315], clinician Associate years working in the current dyad (tenure)[288]
Booking interval length[151, 257]		

Table 18 Reasons for exclusion from meta-analysis		
Measure	**Study references**	**Meta-analysis performed**
		No statistical test[151]
Use of a register or recall system[141, 150, 256, 291, 306, 308, 312]		
Composite	[141, 312]	No, different outcomes (continuous score[312], optimal QoC score (binary)[141])
HbA1c test	[150, 291, 308]	No, different outcomes (difference in proportions[291], difference in means[308]), different exposures (register[291], recall[150], reminder or register[308])
BP test	[150, 308]	No, different outcomes (difference in means[308]), different exposures recall[150], reminder or register[308])
Eye exam	[150, 308]	No, different outcomes (difference in means[308]), different exposures recall[150], reminder or register[308])
HbA1c value	[150, 256, 306, 308]	No, different outcomes (difference in means[308], OR highest vs. lowest quartile[306]), different exposures (register[256], recall[150], reminder or register[308], recall or register[306])
BP value	[256, 306, 308]	No, different outcomes (difference in means[308], OR highest vs. lowest quartile[306]), different exposures (register[256], reminder or register[308], recall or register[306])
Cholesterol value	[256, 306, 308]	No, different outcomes (difference in means[308], OR highest vs. lowest quartile[306]), different exposures (register[256], reminder or register[308], recall or register[306])
Guidelines[141, 306, 314]		
Composite	[141, 314]	No, different outcomes (mean quality score[314], optimal quality score[141])
Education programmes[135, 141, 312]		

Table 18 Reasons for exclusion from meta-analysis		
Measure	**Study references**	**Meta-analysis performed**
Composite	[135, 141, 312]	No, different outcomes (binary[135, 141], continuous[312])
Nurse training[288, 300, 306, 308]		
Composite	[288, 300, 306, 308]	No, different exposures (CAs, RNs, LPNs), or MAs[288], nurse education (hours per year)[306], nurse with diabetic training[308]), no adjustment for confounders[300]
Diabetes clinic[150, 306, 312]		
HbA1c value	[150, 306]	No, different outcomes (HbA1c 'normal' - Since normal ranges for glycated haemoglobin vary between different centres,1 the cut-off for the respective local laboratories was taken as normal[150]; OR in highest vs. lowest quartile for HbA1c[306])

Abbreviations: ACE, Angiotensin Converting Inhibitor; ARB, Angiotensin II Receptor Blockers; EHR, Electronic Health Record; NA, Not available; SMD, Standardised mean difference; EBM, Evidence-based medicine; MOC, Maintenance of Certification; BP, blood pressure; CAs, clinical associates; RNs registered nurses; LPNs, licensed practical nurses; MA, medical assistants; MD, doctor of medicine; DO, doctor of osteopathic medicine; OR, Odds Ratio; If they were not listed then all other individual outcomes were only examined by one study or by studies which did not conduct statistical analysis or adjust for confounders.

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
Kern et al.[311]	Physician Practice	**Continuous** Number of eligible patients receiving **four indicators** of recommended care (HbA1c test, eye exam, LDL-C, nephropathy) divided by the total number of eligible patients for that measure. Compared each physician's performance on each measure to NCQA's 2008 national benchmark for that measure, and then expressed the physician's performance as the number of standard deviations from that benchmark. **Composite quality score for each physician** = average of the standard deviations across measures.	Lower performance among older physicians (10-year increase) (β = −0.238, p = 0.001), family medicine vs. internal medicine physicians (β = -0.640, p <0.001). Higher performance among female physicians (β = 0.422 (p =0.005), practice with EHR vs. paper (β = 0.373, p = 0.008). n.s. (non-significant) results for practice location, panel size and physician credentials.
Alberti et al.[312]‖	Physician Practice	**Continuous** **Non-weighted process-of-care score:** assigning to each patient a score of 1 for each measurement undertaken (fasting glucose assessment, BP, weight, total cholesterol, creatinine, foot examination, cardiovascular examination, electrocardiogram, eye exam, HbA1c in last year) (maximum score: 10).	Higher weighted process of care scores among physicians with higher motivation (β = 0.37, 95% CI: 0.22-1.68, p = 0.013), and higher affluence practices (β = 0.51, 95% CI: 0.12-0.53, p = 0.003). n.s. results for physician gender, training, workload, time commitment, practice interest, number of clinicians, location, practice size, frequency of medical clinics, distance from capital city, use of disease register, disease specific medical records, total patients, diabetes prevalence, equipment, patient education sessions, availability of medication, patient affluence.

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
		Weighted process-of-care score: Glucose and BP measurement given a weighted score of 4 rather than 1; other measurements remained with a score of 1 (maximum score: 16). **Four-variable outcome-of-care score:** calculated based on how many of the targets (BP <140/80 mmHg; fasting glucose ≤7.8mmol/l; total cholesterol ≤5mmol/l; BMI ≤25 kg/m^2) achieved. A score was assigned to each patient based on the proportion of targets achieved. **Two-variable outcome-of-care score: c**alculated using fasting glucose and blood pressure levels only. Assigned score of 2 for good control, 1 for borderline control, and 0 for poor control for both fasting glucose and blood pressure using a denominator of 2 (if only one variable recorded) or 4 (if both variables recorded). **Reliability:** The scores were assessed for normality, and the value of Cronbach's alpha was calculated to measure the internal consistency of each score.	
Fantini et al.[313]‖	Physician Practice	**<u>Dichotomised</u>** **Six indicators**: receipt of HbA1c (at least 2), microalbuminuria (any test), creatinine (any test), lipid profile (at least 1), electrocardiogram, retinal eye examination by ophthalmologist or optometrist.	Better management in group practices (vs. those with no organisational arrangement) (OR = 1.179, 95% CI: 1.010-1.376). Worse management among males (vs. females) (AOR = 0.81, 95% CI 0.71-0.93).

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
		Composite: % with good management.	n.s. results for patients on roster (≥1500 vs. < 1500), location (rural vs. urban; mountain vs. urban), physician age.
Keating et al.[314]*‖¶β	Physician Practice	**<u>Continuous</u>** **Quality of care score** = **six indicators** for which care performed according to defined standards (HbA1c <8% (if none documented, defined as poor control); LDL <100mg/dl (none documented = poor control); BP <130/80mmHg; nephropathy, retinopathy, and foot disease assessment.	n.s. results for physician satisfaction with career, % incomes from incentives, use of email for communication, use of EHR, use of guidelines for diabetes, flow sheets, type of practice payment.
Parkerton et al.[315] β	Physician Practice	**<u>Continuous</u>** The rates for each physician's patients across **four indicators** were averaged for the full year and their means computed to form the aggregate measures: microalbuminuria test (rates), HbA1c test (rates), (annual) retinal exam, and (annual) foot exam.	Better management in shared practices (β = 0.248 p < 0.05), and larger medical clinics (β = 0.252 p < 0.05), with longer team tenure (β = 1.241 p <0.001). n.s. results for physician gender, administrative role, years since graduation, continuity.
Vinker et al.[317]	Physician Practice	**<u>Continuous</u>** The performance of each physician on each indicator was ranked and then divided into quartiles. According to the quartile, the physicians' performance was ranked as 1 for those with indicator performance score in the first quartile, 2 for the second, 3 for the third, and 4 for the fourth quartile. Total score was the total of new quartile ranks for all quality indicators.	Greater diabetic care score in 2003 (β = 0.185, p < 0.05) and diabetic control score in 2003 (β = 0.196, p < 0.05) and 2005 (β = 0.348, p < 0.05) among board certified physicians (vs. non-board certified physicians) n.s. results for physician age, gender, managerial position, years in practice, workload, practice location.

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
		Diabetic care score (six indicators): sum of quartile ranks for eye exam, HbA1c test, urine microalbumin, LDL, HbA1c <7%; LDL < 100mmol/mol. **Diabetic control score (two indicators):** sum of quartile ranks for HbA1c <7%; LDL < 100mmol/mol.	
Visca et al.[268]‖	Physician Practice	**<u>Continuous</u>** **Composite of four indicators:** adherence to guidelines: (at least one during year) GFR or serum creatinine, HbA1c test, lipid profile, eye exam (score ranged from 0 to 4).	Lower adherence among older physicians (effect x 10 years) (β = -0.092 (95% CI: -0.123, -0.061)), greater number of patients 85+ (β = -0.004 (95% CI: -0.007, -0.001)). Greater adherence among female physicians (β = 0.058, 95% CI: 0.022-0.094), practices with greater list size (effect x 100) (β = 0.009, 95% CI: 0.004-0.014), greater number of patients with dx >4 years (β = 0.003, 95% CI: 0.001-0.005), greater number of GPs on team (β = 0.016, 95% CI: 0.006-0.026), and financial incentives (β = 0.085, 95% CI: 0.022-0.147). n.s. results for physician panel diabetes prevalence, practice types.
Bower et al.[257]	Practice	**<u>Continuous</u>** **18 indicators** based on QOF • In past 14 months: HbA1c, foot check, creatinine, proteinuria, eye exam, weight, BP, hypo symptoms if patient taking sulphonylurea • In past 5 years: cholesterol, diabetes education, smoking status, smoking advice, weight advice	Better management associated with higher number of staff (β = 0.54, 95% CI: 0.12-0.96, p = 0.014), longer booking interval (β = 9.70, 95% CI: 2.79-16.63, p = 0.007). n.s. results for practice type, deprivation practice payments, training status, length employment practice staff, skill-mix.

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
		• Offer BP treatment: <80 years if DBP>100 mmHg, or BP >150/90 mmHg; > 80 years if DBP >110 mmHg, or BP >160/100mmHg • Treatment: prescribed ACEi inhibitor, creatinine and potassium (measured within one month of ACEi), taking ACEi (if hypertension and proteinuria), therapeutic intervention for glycaemic control (<70, if HbA1c was >9; >70, if HbA1c was >10), referral to a specialist if serum creatinine is >200 mmol/l **Composite:** scored on a 0/1 basis; patient scores obtained for each condition from the rescaled residuals of the item response model and rescaled to range from 0 to 100.	
Bredfelt et al.[283][¶β]	Practice	**Continuous** In year of study performance of **10 indicators**: foot exam, eye exam, nephropathy assessment, smoking assessment/counselling, value and proportion of values above or below the cut-off values for each physician: HbA1C, LDL, BP. Indicators combined to produce one overall score that ranges from 0 to 100.	Improvement in scores among practice using out of office communication with patients: secure messaging (4.7, p < 0.01) or phone (1.3, p< 0.1), both (1.6-unit increase).
Campbell et al.[151]	Practice	**Continuous**	Higher scores among larger (vs. smaller) practices (adjusted difference: 2.16, 95% CI: 0.22-4.10), p = 0.029), and practices with

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
		18 indicators based on QOF • In past 14 months: HbA1c, foot check, creatinine, proteinuria, eye exam, weight, BP, hypo symptoms if patient taking sulphonylurea • In past 5 years: cholesterol, diabetes education, smoking status, smoking advice, weight advice • Offer BP treatment: <80 years if DBP>100 mmHg, or BP >150/90 mmHg; > 80 years if DBP >110 mmHg, or BP >160/100mmHg • Treatment: prescribed ACEi inhibitor, creatinine and potassium (measured within one month of ACEi), taking ACEi (if hypertension and proteinuria), therapeutic intervention for glycaemic control (<70, if HbA1c was >9; >70, if HbA1c was >10), referral to a specialist if serum creatinine is >200 mmol/l **Composite:** calculated a score for each practice by using a random intercept constant only multilevel model (patients within practices). This is equivalent to calculating a mean score for each practice but adjusting for different pools of patients in different practices and the fact that many items were conditional variables that did not apply to all patients (for example, action to be taken if cholesterol exceeded a certain value). Only items that were applicable for individual patients were included in the score for the practice.	Higher (10 minute) vs. lower (5 minute) booking intervals (adjusted difference 10.0, 95% CI: 1.06-18.95, p = 0.028). n.s. results for practice deprivation.

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
Cebul et al.[310]‖	Practice	**<u>Dichotomised</u>** **Care standards (all or none composite)** based on **four indicators:** test for HbA1c value, urinary microalbumin or prescription of an angiotensin-converting–enzyme inhibitor or an angiotensin-receptor blocker, an eye examination to screen for diabetic retinopathy, pneumococcal vaccination. **Intermediate outcome standards (all or none composite)** based on **five indicators:** HbA1c < 8%, BP < 140/80 mm Hg, LDL < 100 mg/dl or documented prescription for a statin medication, BMI < 30, and non-smoking status.	Higher performance among EHR (vs. paper-based) sites: adjusted difference 35.1 percentage points (95% CI: 28.3-41.9, p <0.001) across all practices. Higher performance among EHR (vs. paper-based) sites: adjusted difference 15.2 percentage points (95% CI: 4.5-25.9, p = 0.005).
Crosson et al.[285]‖	Practice	**<u>Dichotomised</u>** **Five indicators**: HbA1c (in last 6 mths), urine microalbumin (last 12 mths), smoking status (last 5 mths), LDL (last 12 mths), BP record (at each of 3 previous visits). **Composite:** scored 1 if 3 or more of the 5 criteria were met and 0 if fewer than 3 criteria were met. **Three indicators**: HbA1c ≤8% or >8% on hypoglycemic agent; LDL≤100mg/dl or >100mg/dl if on lipid-lowering	Higher performance among EHR (vs. without) and physician-owned practices, and lower performance among solo practices (vs. group practices). AOR = 2.25, 95% CI:1.42-3.57, p <0.001 [EHR]. AOR = 0.38, 95% CI: 0.17-0.87, p = 0.02 [Solo].

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
		agent; BP ≤130/85mmHg or >130/85 mmHg and on antihypertensive medication **Composite 1:** patients meeting all three outcome targets were given a score of 1, with all others scoring 0. **Composite 2:** patients were given a score of 1 for partial achievement (if 2 of 3 laboratory values were at or below the target value). **Composite 3:** patients were given a score of 1 for complete achievement (if all 3 laboratory values were at or below the target value).	 AOR = 1.67, 95% CI:1.07-2.60, p = 0.02 [EHR]. AOR = 0.63, 95% CI: 0.41-0.98, p = 0.04 [Solo]. AOR = 1.44, 95% CI: 1.05-1.18, p = 0.02 [physician-owned]. AOR = 1.67, 95% CI:1.25-2.24, p <0.001 [EHR]. AOR = 2.68, 95% CI:1.49-4.82, p = 0.001 [EHR] n.s. results for staff/clinician ratios
Dickinson et al.[286]‖	Practice	**<u>Continuous</u>** **Nine indicators** within the 12 months before the end of each audit period: HgA1c, foot exam, BP, eye exam, cholesterol, nephropathy screen, flu shot, nutrition counselling, self-management support. **Composite score:** ranging from 0 to 9.	Greater improvement in rural practices among intervention arms (RAP: +0.70 p = 0.006, CQI: +2.44 p <0.001). Greater improvement in urban among control arm (SD: −0.75, p = 0.004). Greater improvement in smaller practices among intervention arms (RAP: +0.56 p = 0.02; CQI: +1.96 p <0.001; SD n.s.). n.s. results for EHR, % Medicare patients.
Erickson et al.[288]	Practice	**<u>Dichotomised</u>**	Higher likelihood of quality goal with longer clinician tenure (p = .0319) [data not available], among practices with registered nurse (vs. licensed practical nurse) (AOR = 1.37, 95% CI: 1.01-1.84,

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
		Performance of **five indicators**: nontobacco use, daily aspirin use, BP < 130/80 mm Hg, LDL-C <100 mg/dL, HbA1c <7.0%. **Composite:** % patients with diabetes between the ages of 18 and 74 who met the goal in all 5 metrics defined by the health system at the time of the study.	p<0.001), practices with MD/Doctor of Osteopathic medicine (vs. associate provider) (AOR = 2.33, 95% CI: 1.23-4.41, p = 0.022), rural practices (vs. urban) (AOR = 1.14, 95% CI: 0.82-1.57, p = 0.78). Lower quality among practices with medical assistant (vs. licensed practical nurse) (AOR = 0.60, 95% CI: 0.44-0.81, p <0.001)). n.s. results for team tenure, allied health staff-to-clinician ratio.
Esterman et al.[135]	Practice	**<u>Dichotomised</u>** Completion of **Annual Cycle of Care** based on **nine indicators**:** HbA1c test (annual); eye examination (every two years); BMI measurement (twice yearly), blood pressure (twice yearly), feet check (twice yearly); total cholesterol (annual), triglyceride (annual), HDL cholesterol test (annual), microalbuminuria (annual).	Greater likelihood of completion among practices with chronic disease-focused nurse (AOR = 2.01, 95% CI: 1.07-3.77, p = 0.036), practices with patient education events (AOR = 1.92, 95% CI: 1.21-3.06, p= 0.004). n.s. number of GPs, chronic disease planning software, audit and feedback, metropolitan practice, presence of practice nurse, corporate practice, co-located allied health professionals, regular MDT meetings, staff education, shared EHR.
Griffiths et al. 2010[140]	Practice	**<u>Continuous</u>** **Composite:** overall population achievement for **18 QOF indicators** for diabetes (see Campbell et al.. above).	Greater performance associated with higher % female physicians (β = 0.394, SE = 0.112, p < 0.001), higher % trained in UK (β = 0.613, SE = 0.130, p < 0.001), lower list size per FTE nurse (Q1: β = 1.935 SE = 0.604, p <0.01; Q2: β = 1.777, SE = 0.618, p <0.05; Q3: β = 1.505, SE = 0.630, p <0.05; Q4: β = 1.430, SE = 0.627, p <0.05). n.s. results for diabetes prevalence, % patients ethnic minority, % ≥65 years, practice population density, deprivation, practice size, % physicians ≥45 years.

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
Griffiths et al. 2011[267]	Practice	**<u>Continuous</u>** **Composite:** overall population achievement for **18 QOF indicators** for diabetes (see Campbell et al.. above).	Greater performance associated with higher % qualified in UK (β = 0.694, SE = 0.080, p < 0.001), lower list size per FTE nurse associated with greater quality of care score (Q1: β = 1.227, SE = 0.166, p <0.001; Q2: β = 1.603, SE = 0.287, p < 0.001; Q3: β = 1.352, SE = 0.298, p < 0.001; Q4: β = 1.093, SE = 0.300, p < 0.001; Q5: β = 0.990, SE = 0.302, p < 0.01), clinical recording (β = 2.632, SE =0.235, p < 0.001) and education & training (β = 0.900, SE =0.144, p < 0.001). Lower performance associated with greater area density (β = -0.317, SE = 0.082, p < 0.001), higher diabetes prevalence (β = -0.571, SE = 0.081, p <0.001), higher % patients ≥65 years (β = -0.372, SE = 0.123, p <0.01). n.s. results for % physicians ≥45 years, % female physician, % patients ethnic minority, practice type, deprivation, practice size, list size per full time equivalent (FTE) GP.
Gulliford et al. 2001[290] ‖	Practice	**<u>Continuous</u>** Performance of **12 indicators**. In last year: BP, blood glucose, foot exam, urine glucose, urine protein, fundoscopy, urea or creatinine, weight Ever: dietary advice, exercise advice, smoking, alcohol **Composite:** summing the responses using values of ‘1’ for item of care recorded and ‘0’ for item of care not recorded or not known if recorded (score range 0-12).	Higher scores among practices with ≥2 GPs (β = 1.90, 95% CI: 0.73-3.06), 2 nurses per session (β = 1.16, 95% CI: 0.032-2.00), and ≥ 3 nurses (β = 1.18, 95% CI: 0.27-2.09), more equipment items (8-9 items vs. 6-7 items: β = 0.72, 95% CI: -0.51-1.96); 10-11 items vs. 6-7: β = 2.02, 95% CI: 0.56-3.47). Lower scores among practices with higher number of patients: practices in second quartile had lower mean score (β = -0.31, 95% CI: -2.01- -1.39), as did practices in highest quartile (β = -1.12, 95% CI: -3.22-0.99).

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
		Reliability: the score was approximately Normally distributed. The value of Cronbach's alpha, as a measure of the internal consistency of the scale, indicated a moderate level of consistency for the overall scale (0.60).	
He et al.[254]‖	Practice	**Dichotomised** Diagnostic testing (**four indicators**): glucose, HbA1c, BP, cholesterol. Patient counselling (education on diet ⁄ nutrition and exercise). **Composite:** two outcome variables were created; dichotomised as 'yes' – indicating the provision of 1 or more diagnostic testing and patient counselling vs. 'no'.	Higher likelihood of diagnostic testing among EHR practices (older men: AOR = 2.2, 95% CI: 1.38-3.58), practices with on-site laboratory tests (older men: AOR = 2.9, 95% CI: 1.99-4.42, older women: AOR = 5.1, 95% CI: 3.20–8.32). n.s. results for practice setting, whether physicians were employees or contractors vs. owners.
Kontopantelis et al.[293]‖	Practice	**Continuous** **17 QOF indicators:** • In past 15 months: HbA1c, foot check, neuropathy testing, creatinine testing, proteinuria, eye exam, weight, BP, cholesterol, smoking status, smoking advice • In past 6 months: flu vaccination • Last BP ≤145/85 mm Hg • Last measured total cholesterol ≤5 mmol/l	Patients attending practices from the most deprived quartile gained less from the QOF intervention; practices in higher quartile of diabetes prevalence gained more.

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
		• Treated with ACEi or A2 antagonists if hypertension and proteinuria, • Last HbA1C (or equivalent) is ≤7.4% • Last HbA1C (or equivalent) is ≤10% **Composite score**: calculated for each patient and time point as the number of indicators achieved for that patient as % of number that applied to that patient; an indicator was deemed to be achieved if a relevant process event or outcome was identified in the required time period (usually 15 months prior to the end of the financial year) and a diagnosis of diabetes pre-dated the event.	
Matthews et al.[262]‖	Practice	**Continuous and dichotomised** **15 indicators**: ACR, eGFR, lipid profile, HbA1c, physical checks (weight, waist circumference, BMI, BP, visual acuity, dilated eye check, foot check), counselling for certain risk factors (nutrition, physical activity, tobacco and alcohol use). **Process of care performance:** proportion of services received out of the 15 scheduled services. A mean adherence in a given health centre represented an overall performance score for the health centre in a given audit cycle. Each aggregate score was converted	Increased odds of improvement with practice remoteness, and in practices with higher patient attendance (AOR = 1.40, 95% CI 1.22-1.61, p <0.001). n.s. results for size of service population, and governance.

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
		into a binary outcome variable that categorised 'higher' performance as being within the top quartile of delivery across all health centres measured at baseline (greater than 76% service delivery).	
McCullough et al.[294]	Practice	<u>**Continuous**</u> Percentage of patients with diabetes (type I and type II) aged 18 to 75 years who reach **5 treatment goals**: HbA1c < 8%, BP < 130/80 mmHg, LDL-C < 100 mg/dL, Daily aspirin use unless contraindicated (ages 41-75 years only), Documented tobacco-free status. **Composite:** optimal diabetes care (ODC) scores = reach 5 treatment goals.	Increased quality score in EHR (vs. paper) practices (β = 0.028, SE = 0.012, p < 0.05), and greater number of clinics in medical group (β = 0.004, SE = 0.000, p < 0.001). n.s. results for diabetes prevalence.
Orzano et al.[297]‖β	Practice	<u>**Dichotomised**</u> **Assessment:** at least 3 of the **four items** completed In past 6 months: HbA1c test In past 12 months: LDL-C, microalbumin, BP at every visit Ever: smoking status **Treatment: acceptable =** all **four items** adhered to HbA1c ≤8% or >8% and on a hypoglycemic agent; LDL-C ≤100mmol/l or >100 mmol/l and on a lipid-lowering agent; BP ≤130/85mmHg or >130/85mmHg and on an	Achievement of at least 2 of 3 outcome targets improved with the use of identification systems (AOR = 1.23, 95% CI: 1.06-1.44, p = 0.007), as it did with the use of tracking systems (AOR = 1.32, 95% CI: 1.11-1.59, p = 0.002).

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
		antihypertensive; urine microalbumin >30 and on ACEi/ARB. **Target:** acceptable = all **three items** achieved; partial = any two items achieved HbA1c ≤7%, LDL-C ≤100, BP ≤130/85mmHg.	
Poon et al.[298] ¶	Practice	**<u>Continuous</u>** **Four indicators**: HbA1c, LDL-C, eye exam, nephropathy monitoring. **Composite:** sums of the numerators and denominators for each component measure.	n.s. results for EHR use.
Ricci-Cabello et al.[299] β	Practice	**<u>Continuous</u>** Arithmetic mean of the logit-transformed achievement rates of the corresponding indicators in each set. **Process measure (eight indicators):** BMI, neuropathy testing, microalbuminuria, ACEi, influenza immunization, retinal screening, renal function record (eGFR or serum creatinine), foot risk testing. **Outcome measure (three indicators):** cholesterol ≤5 mmol/L, Diabetes control (HbA1c = 7.5%), BP ≤140/80 mm Hg.	Lower achievement of process measures associated with higher diabetes prevalence (β = - 31, 95% CI -0.41, -0.21).

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
Spigt et al.[141]	Practice	**Continuous** **Eight process indicators** (1 per year): HbA1c test, LDL-C test, creatinine level, proteinuria, SBP, weight, foot exam, eye exam. **Quality of care (QoC) index** ranging from zero to eight.	More likely to receive optimal quality of care if yearly medical check-ups done by both the GP and nurse (AOR = 5.51, 95% CI: 4.16–7.30, p <0.05), at practices with diabetes education programme (AOR = 4.29, 95% CI: 3.40–5.41, p <0.05), if after the patient visited the nurse practitioner the patient is discussed with the GP (AOR = 1.80, 95% CI: 1.62–2.00, p <0.05). n.s. results for practice protocol, registration, multidisciplinary collaboration, use of report cards.
Wang et al.[309]	Practice	**Continuous** No details provided. Using data on the points attained under the QOF.	n.s. results for practice size.
Wencui et al.[302]‖	Practice	**Dichotomised** **Lab testing:** HbA1c, LDL-C, nephropathy test. Binary variable capturing whether the patients received all **three types of tests** or not.	Likelihood of lab testing greater in practices using records for patient reminders (AOR = 1.26, 95% CI: 1.15-1.38, p <0.01), with increasing number of patients (AOR = 1.03, 95% CI: 1.02-1.04, p < 0.01, per 100 patients). n.s. results for using registries for quality improvement.
Angstman et al.[277]‖	Physician	**Dichotomised** **Composite:** % patients achieving the combined outcome of **three indicators** HbA1c <8.0%, BP <140/90 mmHg, and LDL-C <100 mg/dL. Physicians placed in ≤25th or ≥75th percentile of performance.	More likely to have poor-quality ranking (≤225th percentile) in quality of care if physician panel size is above the mean (>2959) (AOR = 7.61, 95% CI: 1.13–51.46, p = 0.04).
Holmboe et al. 2006[278]‖¶	Physician	**Dichotomised**	More likely to achieve all 3 processes with higher physician volume (group III AOR = 1.31, 95% CI: 1.07-1.61; group IV AOR = 1.35, 95% CI: 1.10-1.64; group V AOR = 1.48, 95% CI: 1.22-1.81).

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
		HbA1c measurement (previous year), Lipid profile (in past 2 years), Eye exam (in past 2 years). **Composite:** proportion who received all **three processes of care:** "1" = achieved all; "0" = any other combination).	
Holmboe et al. 2008[255]‖¶	Physician	**<u>Dichotomised</u>** HbA1c measurements (at least two in past year). Lipid test, eye examination (in past year). **Composite measure:** value of "1" if all **three measures** had been performed and "0" if two or fewer measures had been performed.	More likely to receive all 3 diabetes processes of care if physicians scored in top quartile vs. lowest quartile of American Board of Internal Medicine maintenance of certification examination (AOR = 1.17, 95% CI: 1.08-1.27).
Kamien et al.[271]	Physician	**<u>Continuous</u>** • Blood tests (5 items): HbA1c (1 per annum), blood glucose (2 per annum), cholesterol, triglycerides, creatinine (3 yearly) • Annual physical exam (3 items): BP, eye exam (or referral to ophthalmologist), weight • Feet examined (4 items): pulses, sensation, nails, reflexes • Urinalysis (3 items): glucose, protein, nitrite • History (6 items): duration of known diabetes, alcohol intake enquiry and advice, dietary enquiry and advice, exercise enquiry and	Mean total quality score of vocationally registered (VR) doctors was significantly higher than those of the non-vocationally registered (NVR) doctors. (VR mean (sd) = 6.07 (2.3), NVR = 5.5 (2.2), p <0.05).

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results
		advice, smoking enquiry and advice, impotence/vaginitis enquiry and advice **Overall score**: checklist of 12 main items with a value of one point each. Several items were sub-divided into several parts each receiving fractional scores resulting in a total of **21 separate processes** each of which was given a weighting ranging from 0.25 of a point to 1 point.	
Kim et al.[272]	Physician	**<u>Continuous</u>** In 12-month period: HbA1c, lipid, eye exam, urine microalbumin/protein testing, foot exam, recommendation to take aspirin or aspirin use, influenza vaccination (self-reported). **Composite measure:** un-weighted sum of these **seven process measures** as a continuous variable ranging from 0 (no services delivered) to 7 (all services delivered).	n.s. results for physician gender.
Parkerton et al. 2003[274]¶	Physician	**<u>Continuous</u>** Rates of **four process of care indicators**: microalbuminuria, HbA1c testing, annual eye exam, annual foot exams. **Composite**: mean of process measures formed the diabetic management outcome measure.	Lower physician appointment hours associated with higher quality score (favours part-time practice) (β = -0.107, 95% CI -1.86, -0.029, p = 0.008).

Table 19 Studies which used a composite measure of quality (n = 34).

Reference	Factors	Composite	Results

Abbreviations: n.s. non-significant; OR, Odds Ratio; AOR, Adjusted Odds Ratio; EHR, Electronic Health Record; CI, Confidence Interval; AHP, Allied Health Professionals; MOC, Maintenance of Certification examination; MDT, Multidisciplinary team; WTE, Whole Time Equivalent; GPs, General Practitioners; RAP, intervention arm receiving practice facilitation using reflective adaptive process change model based on complexity theory; CQI, Continuous quality improvement arm received practice facilitation based on the model for improvement; SD, Self-directed arm received limited feedback on their baseline practice culture and level of implementation of the Chronic Care Model based on practice; FTE, Full Time Equivalent;

‖Patient-level covariates adjusted for in multivariate analysis

¶Physician-level covariates (additional to explanatory variables) adjusted for in multivariate analysis

βPractice-level covariates (additional to explanatory variables) adjusted for in multivariate analysis

*also examined LDL-C and BP but among patients with coronary artery disease and hypertension

**excluded all newly diagnosed patients as they would not have had time to have a completed Annual Cycle of Care

Table 20 Main results for studies which examined physician factors only (n = 20)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
Angstman et al.[277]*‖	36 physicians Patients not reported (NR)	Panel size	Physician-adjusted panel size above the mean (>2959) were more likely to have poor-quality ranking (≤225th percentile) in quality of care (AOR = 7.61, 95% CI: 1.13–51.46, p = 0.04).
Berthold et al.[260]‖	3096 physicians 51 053 patients	Gender	Patients of female physicians more likely to have some processes of care performed: urine albuminin (AOR = 0.85, 95% CI: 0.75–0.96, p = 0.008), creatinine (AOR = 1.42, 95% CI: 1.04–1.94, p =0.027) and less likely to have lipid profile (AOR = 0.84, 95% CI: 0.76–0.94, p = 0.002). n.s. for HbA1c, neurological exam, eye exam. Patients of female physicians less likely to have some OHAs (AOR = 0.88, 95% CI: 0.82–0.95), p = 0.001) OHAs alone (AOR = 0.88, 95% CI: 0.77–0.999, p = 0.048), Biguanides (AOR = 0.88, 95% CI: 0.81–0.96, p = 0.003) prescribed. n.s. results for sulfonylureas, statins. Among patients of female physicians, mean HbA1c levels (AOR = 0.92, 95% CI: 0.87–0.96, p <0.0001), and LDL levels (AOR = 0.16, 95% CI: 0.03–0.78, p = 0.024) were lower and patients were more likely to have HbA1c <6.5% (AOR = 1.14, 95% CI: 1.05–1.24, p = 0.002) HbA1c <7.0% (AOR = 1.22, 95% CI: 1.13–1.32, p <0.001), LDL-C < 100 mg dL−1 (AOR = 1.16, 95% CI: 1.06–1.27, p = 0.002), LDL-C <130 mg dL−1 (AOR = 1.12, 95% CI: 1.04–1.21, p = 0.005). n.s. for HDL-C, triglycerides and meeting all 3 lipid targets.
Bralic Lang et al.[261]‖	449 physicians	Gender	Male physicians more likely to be clinically inert (AOR = 1.2, 95% CI 1.00-1.35)
		Years of work experience	n.s.

Table 20 Main results for studies which examined physician factors only (n = 20)			
Reference	**N**	**Factors**	**Main results (multivariate analysis unless otherwise stated)**
	10 275 patients	Total number of patients on panel	n.s.
		Total number of type 2 patients on panel	n.s.
		Average daily visits	n.s.
		Working status (health care centre employee; private practice outside health care centres; private practice inside health care centres)	Private practice outside health centre vs. health care centre employee: n.s. Physicians working in private practice inside health care centre vs. health centre employees less likely to be inert (AOR = 0.8, 95% CI 0.66-0.90).
Brody et al.[269]‖	26 physicians 924 patients	Gender	Patients of female physicians more likely to receive eye exam (AOR = 1.59, 95% CI: 1.09 to 2.33) and foot exam (AOR = 1.52, 95% CI: 1.03 to 2.22); n.s. for HbA1c, LDL-C, microalbuminuria screening
		Specialty (family medicine; internal medicine)	Patients of internal medicine physicians more likely to receive eye exam (AOR = 1.85, 95% CI: 1.29-2.66), foot exam (AOR = 1.83, 95% CI: 1.26-2.68), HbA1c test (AOR = 2.48, 95% CI: 1.85-3.31) and microalbuminuria screening (AOR = 22.0, 95% CI: 2.96-163.52) than family medicine physicians.
Dahrouge et al. 2016[270]‖¶	4195 physicians 837,778 patients	Gender	Patients of female physicians more likely ($p < 0.05$) to have eye exam (AOR = 1.07, 95% CI: 1.04-1.10), lipid test (AOR = 1.14, 95% CI: 1.18-1.31), HbA1c test (AOR = 1.10, 95% CI: 1.04-1.17), prescription of metformin (AOR = 1.18, 95% CI: 1.05-1.57), ARB/ACEi (AOR = 1.04, 95% CI: 1.01-1.08) and lipid-lowering agent (AOR = 1.10,95% CI: 1.06-1.15).
Dahrouge et al. 2016[282]‖¶β	4,195 physicians 8.3 mil. patients	Physician panel size	n.s.

Table 20 Main results for studies which examined physician factors only (n = 20)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
Ferroni et al.[134]‖β	21 health units 4660 physicians 139,935 patients	Age	Among patients not attending a diabetes clinic (at least 1 specialist visit in the year) patients of younger physicians more likely to receive two HbA1c test: ≤50 years (RR = 1.15, 95% CI: 1.06–1.25); 51-55 years (RR = 1.07, 95% CI: 0.99-1.15, p =0.008); 56-60 years (RR = 1.07, 95% CI: 1.00-1.14) compared to physician >60 years. Among patient attending a diabetes clinic n.s.
		Gender	Among patients not attending a diabetes clinic those with female physicians more likely to receive two HbA1c tests (RR = 1.08, 95% CI: 1.02–1.14). Among patients attending a diabetes clinic n.s.
		Total number with diabetes on panel	Among patients not attending a diabetes clinic, those whose physicians had >85 diabetes patients (compared to ≤55) were more likely to receive tests (RR = 1.06, 95% CI: 0.99-1.15) Among patients not attending a diabetes clinic n.s.
Holmboe et al. 2006[278]*‖	1261 physicians 26,260 patients	Patient volume (in quintiles: 1-4; 5-10; 11-18;19-31 and 32-166)	Compared to physicians with lowest volume (1-4), those in higher volume groups were more likely to have a HbA1c test (group III AOR = 1.67, 95% CI: 1.27-2.19; group IV AOR =1.66, 95% CI: 1.28-2.15; group V AOR = 1.92, 95% CI: 1.48-2.49), a lipid test (group III AOR = 1.44, 95% CI: 1.13-1.84; group IV AOR =1.57, 95% CI: 1.24-1.99; group V AOR = 1.63, 95% CI: 1.29-2.06), and eye exam (group III AOR = 1.25, 95% CI: 1.05-1.49; group IV AOR =1.24, 95% CI: 1.05-1.47; group V AOR = 1.36, 95% CI: 1.15-1.60).

Table 20 Main results for studies which examined physician factors only (n = 20)			
Reference	**N**	**Factors**	**Main results (multivariate analysis unless otherwise stated)**
			Those in higher volume groups were also more likely to achieve all 3 processes (group III AOR = 1.31, 95% CI: 1.07-1.61; group IV AOR = 1.35, 95% CI: 1.10-1.64; group V AOR = 1.48, 95% CI: 1.22-1.81).
Holmboe et al. 2008[255]*‖¶	3602 physicians 52307 patients	MOC score - divided into 3 percentile groups (<25th, 25-75th, and >75th)	Patients of physicians in top quartile vs. lowest quartile were more likely to receive all 3 diabetes processes of care (AOR = 1.17, 95% CI: 1.08-1.27).
Kamien et al.[271]*	110 practices 204 physicians 467 patients	Vocational registration	With the exception of blood pressure and urinalysis, vocationally registered (VR) doctors recorded all items more frequently than did non-vocationally registered (NVR) doctors. Mean total quality score of VR doctors was significantly higher than those of the NVR doctors. (VR mean (SD) 6.07 (2.3), NVR 5.5 (2.2), P <0.05).
Kim et al.[272]*‖¶	1686 physicians 3459 patients	Gender	Patients of female physician more likely to have lipid (AOR = 1.09, 95% CI 1.02–1.15), HbA1c (AOR = 1.02, 95% CI: 1.00–1.05) measurements and LDL <130 mg/dl (AOR = 1.05, 95% CI: 1.00–1.10). Female physicians and male physicians did not differ significantly on other processes of care, control of risk factors, or satisfaction.
LeBlanc et al.[281]‖	107 physicians 921 patients	Age	n.s.
		Gender	n.s.
		Duration of employment	n.s.
		Primary care training (internal medicine vs. family medicine)	n.s.
		Education (MD vs. nurse practitioner/physician assistant)	n.s.

Table 20 Main results for studies which examined physician factors only (n = 20)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		Total number of patients on panel	n.s.
		Percentage of patients with diabetes on panel	n.s.
		Mean Charlson co-morbidity index of patients on panel	n.s.
Linder et al.[273]‖¶	10 practices 234 physicians 7000 patients (coronary artery disease or diabetes)	Physician documentation styles—dictation, structured documentation, and free text - mutually exclusive groups by predominating documentation style.	Greater adjusted % patients of structured documenters (53%) and free text (54%) had eye exam than dictators (39%) (p <0.001). Similarly for BP: dictators (81%); structured documenters (98%); free text (89%) (p<0.001); BMI: dictators (28%); structured documenters (40%); free text (35%) (p<0.001); tobacco use documentation: dictators (22%); structured documenters (38%); free text (36%) (p <0.001) and flu vaccination: dictators (60%); structured documenters (64%); free text (68%) (p <0.001). Foot exam: dictators (11%); structured documenters (14%); free text (9%) (p<0.001)
Parkerton et al. 2003[274]*¶	25 clinics 194 physicians Patients NR	Part-time status	Physician appointment hours (favours part-time practice) (β = -0.107; 95% CI -1.86, -0.029; p = 0.008).
Shuval et al.[275]¶	74 physicians 8334 patients	Total evidence-based medicine (EBM) knowledge score; continuous variable 0–100	Higher EBM score associated with performance of microalbumin tests (β = 0.33; p = 0.001), eye exam referrals (β = 0.16; p = 0.021), HbA1c tests (β = 0.17; p = 0.036), and LDL tests (β = 0.13; p = 0.037). Quality of care was independently associated with the total EBM knowledge while controlling for covariates (F = 4.65; p = 0.004).

Table 20 Main results for studies which examined physician factors only (n = 20)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		Component of EBM score: critical appraisal skills (a continuous variable of 0–53)	Higher critical appraisal skills score associated with performance of microalbumin tests (β = 0.46; p = 0.002), and eye exam referrals (β = 0.20, p = 0.048) but not HbA1c and LDL-C tests.
		Component of EBM score: information retrieval skills (a continuous variable of 0–47)	Higher score associated with HbA1c testing (β = 0.43; P = 0.004), not microalbumin, eye exam referrals or LDL tests.
Streja et al.[280]‖	22 physicians 524 patients	Physician gender	n.s.
		Practice experience (less vs. more than 15 years in practice	Having > 15 years in practice associated with greater odds of proteinuria testing (AOR = 2.62, 95% CI: 1.61-4.37, p = 0.001); n.s. for receipt of HDL-C test and ophthalmology referral. In sub-group analysis (removing 110 patients with eye disease; patients treated with diet and oral agents, or insulin) practice experience was associated with an ophthalmology referral (OR = 1.80, 95% CI: 1.16-3.43, p = 0.014).
		Specialty (internal medicine vs. family medicine or surgery)	n.s.
		Practice style ("fast" and "slow." = count the number of claims for each physician for a minimum of 3 months and to divide it by the number of half days of work. "Fast" = above average; "slow" = below average)	Practice style, "Fast" associated with lower odds of HDL-C test (AOR = 0.56, 95% CI: 0.35-0.89, p = 0.001), proteinuria test (AOR = 0.42, 95% CI: 0.26-0.67, p = 0.001) but n.s. for ophthalmology referral. In sub-group analysis (removing 110 patients with eye disease; patients treated with diet and oral agents, or insulin) fast style was associated with a lower referral rate (AOR = 0.25; 95% CI: 0.07-0.85, p = 0.03).
		Size of diabetic practice (more vs. less than 20 patients)	n.s.

Table 20 Main results for studies which examined physician factors only (n = 20)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
Tabenkin et al.[276]‖¶	30 practices 55 physicians 4,195 patients	Gender	Female physicians more likely to provide dietary and weight loss and physical activity advice than male physicians (AOR = 6.55, 95% CI: 2.01 - 21.33, p<0.05) but n.s. for other processes.
Turchin et al. 2007[279]‖¶	368 physicians 7,120 patients	Diabetes volume	Number of diabetes patients (per 10 patients) treated by physician associated with decreased likelihood of HbA1c test (AOR = 0.96, 95% CI: 0.93-1.0, p = 0.05) but n.s. for receipt of LDL test, and BP, HbA1c, and LDL control.
		Frequency of encounters with patients with diabetes	Increase in daily encounters with diabetes patients associated with lower odds of HbA1c test (AOR = 0.75, 95% CI: 0.58-0.97, p =0.03) and LDL test: (AOR = 0.80, 95% CI: 0.70-0.91, p<0.001), but n.s. for BP, HbA1c, and LDL control.
		Fraction of patients with diabetes among all of the physician's patients	Fraction of diabetic patients associated with lower likelihood of LDL test (AOR = 0.59, 95% CI: 0.39-0.88, p =0.01), but n.s for receipt of HbA1c test, and BP, HbA1c, and LDL control.
		Fraction of encounters with patients with diabetes among all of the physician's encounters	Greater fraction of encounters associated with increased odds of patients having HbA1c <7.0% (AOR = 1.19, 95% CI: 1.05-1.36, p = 0.009) but n.s. for receipt of HbA1c test, LDL test, and BP, HbA1c, and LDL control.
Turchin et al. 2008[266]‖	301 physicians 8127 patients	Physician age	n.s.
		Number of years since last board certification	Every decade since the physician’s last board certification was associated with a 21.3% drop in the probability of treatment intensification (p = 0.0097).

Table 20 Main results for studies which examined physician factors only (n = 20)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)

Abbreviations: NR, Not Reported; OR, Odds Ratio; Adjusted Odds Ratio (AOR); OHAs, Oral Hypoglycaemic Agents; ARBi, Angiotensin II Receptor Blockers; ACE, Angiotensin Converting Inhibitor HER; Electronic Health Record; MDT, Multidisciplinary team; VR, Vocationally Registered; NVR, Non-Vocational Registered

*Composite outcome

‖Patient-level covariates adjusted for in multivariate analysis

¶Physician-level covariates (additional to explanatory variables) adjusted for in multivariate analysis

βPractice-level covariates (additional to explanatory variables) adjusted for in multivariate analysis

** Indicators grouped as 'Records and information about patients (19), Patient communication' (8), Education and training (9), Practice management (10), Medicines management (10).

§also includes patients for breast cancer screening; chlamydia screening; colorectal cancer screening; appropriate medications for people with asthma; testing for children with pharyngitis; and treatment for children with upper respiratory infection.

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
Bower et al.[257]*	42 practices Patients not reported (NR)	Practice type (solo or other)	n.s.
		Team size (number of employed staff)	Greater number of staff associated with better management: β = 0.54, 95% CI: 0.12-0.96, p = 0.014.
		Existence of deprivation payments to the practice	n.s.
		Training status of the practice	n.s.
		Mean length of employment of staff at the practice	n.s.
		Routine booking intervals for patient consultations (5, 7.5, or 10 minutes)	Booking interval of 10 minutes compared to 5 minutes associated with better management: β = 9.70; 95% CI: 2.79-16.63, p = 0.007.
		Skill-mix: ratio of doctors to nurses, ratio of doctors to non-medical clinical staff, ratio of clinical to administrative staff	n.s.
Bredfelt et al.[283]*[¶β]	174 physicians Patients NR	Use of out-of-office communication (phone, secure messaging)	Physicians whose patient panels predominantly white or mixed race: n.s. Physicians whose patients predominantly black or Hispanic: on average, a 0.1 increase in the proportion of the patient panel that shared out-of-office communication (including both phone and secure messaging) with their primary care provider was associated with a 1.6 unit increase in quality scores. A 0.1 increase in the proportion of the patient panel that used secure messaging was associated with an increase in score of 4.7 (p < 0.01)

Table 21 Main results for studies which examined practice factors only (n = 44)			
Reference	**N**	**Factors**	**Main results (multivariate analysis unless otherwise stated)**
			A 0.1 increase in the proportion of the patient panel that used phone to communicate was associated with an increase in scores of 1.3 (p < 0.1)
Campbell et al.[151]*	42 practices Patients NR	Practice size (number of GPs)	Larger practices had higher scores for diabetes than smaller practices (adjusted difference: 2.16, 95% CI: 0.22-4.10, p = 0.029)
		Routine booking interval for consultations (5, 7.5, or 10 minutes)	Compared to practice with 5 minutes interval, adjusted mean scores in practices with routine 10-minute booking intervals were higher (adjusted difference = 10.0, 95% CI: 1.06-18.95, p = 0.028)
		Practice deprivation score	n.s.
Cebul et al.[310]‖*	46 practices 569 providers 27,207 patients	EHR	Process of care composite: adjusted difference between EHR and paper-based sites was 35.1 percentage points (95% CI: 28.3-41.9; p <0.001) across all practices and 29.8 percentage points (95% CI: 24.0-35.7, p <0.001) at safety-net sites. Intermediate outcome composite: adjusted difference between EHR and paper-based sites was 15.2 percentage points (95% CI: 4.5-25.9, p = 0.005); for safety-net sites, the difference was 9.7 percentage points (95% CI: 3.4-16.1, p = 0.002.
Cheung et al.[284]‖¶β	9014 physicians 1,018,647 patients	Overall ambulatory volume = number of outpatient visits of any type the physician had during the 3 years preceding the index date divided by the number of days the physician worked during this period	Compared to practices with lowest volume, patients of practices with highest volume had lower marginal rates (ptrend <0.001) of eye exam (≤20 patients/day = 72, 95% CI:71.7-72.4 vs. >40 patients/day = 67.1, 95% CI: 66.6-67.5), HbA1c testing (55.0, 95% CI: 54.1-55.8 vs. 50.1, 95% CI: 49.1-51.1), LDL cholesterol testing (85.5, 95% CI: 85.0-85.9) vs. 84.4, 95% CI: 83.9-84.9), prescriptions for ACEIs /ARBs) 74.7, 95% CI: 74.2-75.2) vs. 70.8, 95% CI: 70.2-71.4), prescriptions for statins (74.9, 95% CI: 74.3-75.5) vs. 70.3, 95% CI: 69.6-71.1).
		Diabetes-specific volume = number of patients with diabetes for whom the physician was the usual primary	Compared to practices with lowest volume (≤100 patients), patients of practices with highest volume (≥301 patients) had higher rates (ptrend <0.001) of eye exams (67.0, 95% CI: 66.7-67.4) vs 69.8, 95% CI: 69.2-70.4), HbA1c testing (50.0, 95% CI: 49.3-50.8 vs. 53.0, 95% CI: 51.6-54.4), LDL cholesterol testing (82.2, 95% CI: 81.7-82.6 vs. 87.5,

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		care provider (100, 150, 200, and 300 patients)	95% CI: 86.9-88.1), prescriptions for ACEIs /ARBs (70.6, 95% CI: 70.0-71.1 vs. 74.4, 95% CI: 73.9-75.6), prescriptions for statins (68.4, 95% CI: 67.6-69.0 vs. 76.1, 95% CI: 75.2-77.1).
Cho et al.[258]‖	183 practices 24,628 patients	Practice type (solo or group)	Patients in solo practice (vs. group) were less likely to receive treatment with lipid-lowering drugs (OR = 0.86, 95% CI: 0.75-0.99); n.s. RAAS-blockers, glucose-lowering drug, BP-lowering drugs, lipid-lowering drugs.
		Number of diabetes patients	Increased number of patients associated with decreased odds of treatment with glucose-lowering drugs (OR = 0.99, 95% CI: 0.99-0.99), lipid-lowering drug (OR = 0.99, 95% CI: 0.99-0.99), BP-lowering drugs (OR = 0.99, 95% CI: 0.99-0.99), RAAS-blockers (OR = 0.99, 95% CI: 0.99-0.99).
		Presence of educated diabetes assistant	Patients of practices with an assistant present were less likely to receive treatment with glucose-lowering drug (OR = 0.72, 95% CI: 0.54-0.95), and more likely to receive treatment with statins (OR = 1.54, 95% CI: 0.87-2.71); n.s. RAAS-blockers, BP-lowering drugs, lipid-lowering drugs.
Crosson et al.[285]*‖	50 practices 927 patients	EHR usage	Patients in practices with an EHR compared to practice without EHR were more likely to have processes of care (3 of 5 guidelines met) performed (AOR = 2.25, 95% CI:1.42-3.57, p <0.001), meet treatment targets (all treatment target guidelines met) (AOR = 1.67, 95% CI:1.07-2.60, p = 0.02), or have 2 of 3 outcomes met (AOR = 1.67, 95% CI:1.25-2.24, p <0.001) or all outcomes met (AOR = 2.68, 95% CI: 1.49-4.82, p = 0.001).
		Practice type (solo or other)	Solo practices were less likely to have processes of care performed (AOR = 0.38, 95% CI: 0.17-0.87, p = 0.02), meet treatment targets (AOR = 0.63, 95% CI: 0.41-0.98, p = 0.04), n.s. for other measures.
		Ownership (physician-owned or other)	Physician owned practices were more likely to have 2 of 3 outcomes met (AOR = 1.44, 95% CI: 1.05-1.18, p = 0.02); n.s. for other measures.
		Staff/clinician ratios	n.s.

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
Dickinson et al.[286]*‖	40 practices 822 patients	Location (rural or urban)	Greater improvement in rural practices (RAP: +0.70 p = 0.006, CQI: +2.44 p <0.001); Greater improvement in urban (SD −0.75, p = 0.004)
		Practice size (number of GPs)	Greater improvement in process of care scores in smaller practices (RAP: +0.56, p = 0.02; CQI: +1.96, p <0.001; SD n.s.).
		EHR	n.s.
		% Medicaid patients (<20%; ≥20%)	Greater improvement in process of care scores in practices with <20% Medicaid patients (SD: + 0.60, p =0.02; RAP n.s.; CQI n.s.).
Dunn et al.[308]	37 practices Patients NR	Register	**each structure criterion only tested for specific processes and outcomes, not all** More practices with a register vs. those without register had blood glucose test done (89 vs. 73; diff in mean 16 (6, 26) p = 0.004), a HbA1c test done (89 vs. 64, diff in means 24 (13,36) p<0.001), cholesterol test (37 vs. 16, 22 (9, 35) p = 0.009), BP test done (88 vs. 74, 14 (5,24) p = 0.004), urinanalysis (74 vs. 55, 19 (4.34) p = 0.012), weight taken (77 vs. 57, 19 (5, 33) p = 0.011).
		Recall system	Recall system n.s. for blood glucose tested, mean HbA1c and BP tested.
		One partner sees all patients with diabetes	Practice where one partner sees all diabetics had more patients with urinalysis done (72 vs. 56, 16 (0, 32) p = 0.027), n.s. for blood glucose and mean HbA1c.
		Availability of chiropodist	Availability of chiropodist n.s. for foot exam.
		Availability of optician	Availability of optician n.s. for eye exam or retinopathy present.
		Physician with postgraduate training	n.s. for mean Hba1c, blood glucose test, cholesterol.
		Nurse with postgraduate training	n.s. for blood glucose test or mean hba1c
Ellerbeck et al.[287]	210 physicians	Diabetes specific flow sheets	**note results of bivariate regression model with proportions weighted by number of patients per practice** n.s.

Table 21 Main results for studies which examined practice factors only (n = 44)			
Reference	**N**	**Factors**	**Main results (multivariate analysis unless otherwise stated)**
	11,623 patients	Use of non-physician personnel to identify patients due for preventative care	n.s.
		Practice location (urban or rural)	Lower proportion with lipid measurement among rural (67.0%) vs urban (71.5%) practices; n.s. for HbA1c and eye exam.
		Number of patients with diabetes	Lower proportion with lipid measurement among practices with 18-35 patients (64.4%), compared to those with 5-17 patients (71.6%), 36-58 (70.1%), and 59-1559 (72.4%); n.s. for HbA1c and eye exam.
Erickson et al.[288]*	55 dyads 2,584 patients	Physician tenure	Longer clinician tenure (p = 0.0319) associated with better diabetes scores (data not shown).
		Practice training of "Office nurses" or CA training was divided 3 categories: RN (registered nurse), LPN (licensed practical nurses), and MA (medical assistants)	Practices with medical assistant (vs. LPN) less likely to meet (5 metric) quality goal (AOR = 0.60, 95% CI: 0.44-0.81, p <0.001) and less likely to receive positive responses on patient satisfaction (AOR = 0.65, 95% CI: 0.53-0.80, p <0.001). Practices with RN (vs. LPN) were more likely to meet quality goal (AOR = 1.37, 95% CI: 1.01-1.84, p <0.001) and less likely to receive positive responses (AOR = 1.14, 95% CI: 0.88-1.48, p <0.001).
		Clinician type (Associate provider (AP) or MD/Doctor of Osteopathic medicine (DO))	Practices with MD/DO (vs. AP) more likely to meet goal (AOR = 2.33, 95% CI: 1.23-4.41, p = 0.022) and more likely to receive positive responses on patient satisfaction (AOR = 1.75, 95% CI 1.41-2.17, p <0.001).
		Location (rural or urban)	Rural practices (vs. urban) were less likely to receive positive responses (AOR = 0.65, 95% CI: 0.53-0.81, p = 0.0068).
		Team tenure	n.s.
		Allied staff to clinician ratio	Allied health staff-to-clinician ratio was not associated with better scores (p = 0.348) (data not shown).

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
Esterman et al.[135]‖	147 practices 5455 patients	Metropolitan practice	n.s.
		Practice size (number of GPs)	n.s.
		Practice nurse	n.s.
		Chronic disease focused nurse	Patient of practice with a nurse was more likely to have Annual Cycle of Care completed (AOR = 2.01, 95% CI: 1.07-3.77, p = 0.036).
		Chronic disease planning software used	n.s.
		Corporate practice	n.s.
		Co-located AHPs	n.s.
		Practice has audit and feedback	n.s.
		Practice involved in QI collaboration	n.s.
		Practice has dedicated case management	n.s.
		Practice has regular MDT meetings	n.s.
		Practice has regular staff education	n.s.
		Practice uses shared EHR	n.s.
		Practice has patient diabetes education events	Patient of practice with events more likely to have Annual Cycle of Care completed (AOR = 1.92, 95% CI: 1.21-3.06, p= 0.004).
		Practice has self-management activities	n.s.
Everett et al.[304]‖	261 practices 2,576 patients	Involvement of the physician assistant or nurse practitioner (6 categories)	[Compared to practices which had no physician assistant (PA)/nurse practitioner(NP)]. Patients of practices with supplemental PA/NP who do not Treat High Complexity Patients and do not Deliver Chronic Care were less likely to have HbA1c >9% (AOR = 0.46, 95% CI: 0.22,0.97, p = 0.04), n.s. for remaining outcomes.

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
			Patients of practices with supplemental PA/NP who do not Treat High Complexity Patients but Deliver Chronic Care were more like to receive at least 2 HbA1c tests annually (AOR = 1.4, 95% CI: 1.05,1.82, p = 0.02). Patients of practices with Supplemental PA/NP Treat High Complexity Patients but do not Deliver Chronic Care were more likely to have Mean A1c >9% (AOR= 1.80, 95% CI: 1.21,2.67, p <0.01). Patients of practices with Supplemental PA/NP who Treat High Complexity Patients and Deliver Chronic Care were less likely to have Mean A1c 7-9% (AOR = 0.70, 95% CI: 0.59,0.84, p <0.01). Patients with PA/NP as usual provider n.s. for all outcomes: receipt of HbA1c tests, mean HbA1c >9%, mean HbA1c 7-9%.
		Number of diabetes patients	n.s.
		% patients female	n.s.
		Usual provider (FM or IM/geriatrics)	n.s.
Franks et al.[265][‖]		Deprivation	Independent of their own socio-economic status (SES) patients in lower SES practices were less likely to receive a HbA1c test (β = 0.09, SE = 0.03, t = 3.09), and eye exam β = 0.04, SE = 0.03, t = 1.69).
Friedberg et al.[307][β]	305 practices Patients NR	Assistance of patient self-management	n.s.
		System for contacting patients for preventive services	Higher performance on nephropathy screening: 2.3, 95% CI: 0.3-4.4, p < 0.007; n.s. for HbA1c, eye exams, cholesterol screening.

Table 21 Main results for studies which examined practice factors only (n = 44)			
Reference	**N**	**Factors**	**Main results (multivariate analysis unless otherwise stated)**
		Paper-based physician reminder systems	Lower performance on eye exams: -3.3, 95% CI: -5.9- -0.6, p <0.007; n.s. for HbA1c, eye exams, nephropathy screening.
		EHR	Higher performance on eye exams: 3.4, 95% CI: 0.6-6.2, p <0.007 and nephropathy screening: 3.1, 95% CI: 0.9-5.3; n.s. for HbA1c, cholesterol screening.
		Language interpreters	n.s. for all
		Providers' spoken languages	n.s. for all
		Regular appointment hours on weekends	n.s. for all
Griffiths et al. 2010[140]*	Practices to between 7431 and 7456*** Patients NR	% physician aged ≥45 years	Greater % ≥45 years associated with lower proportion of patients with HbA1c ≤7.4% (β = -0.523, SE = 0.116, p < 0.001), HbA1c ≤10% (β = - 0.250, SE = 0.056, p < 0.001) and Total cholesterol ≤5mmol/l (β = -0.315, SE = 0.113, p < 0.01).
		% female physicians	Greater % female associated with better overall performance (β = 0.394, SE = 0.112 p < 0.001), higher proportion with HbA1c ≤7.4% (β = 0.851, SE = 0.114, p < 0.001), HbA1c ≤10% (β = 0.537, SE = 0.063, p < 0.001) and total cholesterol ≤5mmol/l (β = 0.546, SE = 0.111, p <0.001).
		% qualified in the UK	Greater % associated with better overall performance (β = 0.613, SE = 0.130, p < 0.001), and meeting targets HbA1c ≤7.4% (β = 0.615 , SE = 0.159, p < 0.001) HbA1c ≤10% (β = 0.703 , SE = 0.095, p < 0.001), BP ≤145/85mmHg (β = 0.667 , SE = 0.157, p < 0.001), total cholesterol ≤5mmol/l (β = 0.939 , SE =0.130 , p<0.001).
		List size per FTE practice nurse (quintiles)	Lower list size per FTE nurse associated with greater quality of care score (Q1: β = 1.935, SE = 0.604, p <0.01; Q2: β = 1.777, SE = 0.618, p <0.05; Q3: β = 1.505, SE = 0.630, p <0.05; Q4: β = 1.430, SE = 0.627, p <0.05), more patients with HbA1C ≤7.4% (Q1: β =2.249, SE = 0.713, p <0.01; Q2: β = 2.046, SE = 0.695, p <0.01; Q3: β = 1.505, SE = 0.718, p <0.001) and HbA1C ≤10% (Q1: β = 1.763, SE = 0.449, p <0.001; Q2: β = 1.639 SE = 0.440, p <0.001; Q3: β = 1.420, SE = 0.438, p <0.01; Q4: β = 1.499, SE = 0.460, p

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
			<0.01; Q5: β = 0.915, SE = 0.425, p <0.001), and total cholesterol ≤5mmol/l (Q1: β = 1.862, SE = 0.632, p <0.01; Q2: β = 1.537, SE = 0.619, p <0.05; Q3: β = 1.335, SE = 0.655, p <0.05; Q4: β = 1.754, SE = 0.670, p <0.05; Q5: β = 1.122, SE = 0.648, p <0.01).
		List size per GP	Practices with greater list size per GP had more patients HbA1C ≤7.4% (β = 0.15, 95% CI: 0.05-0.25, p = 0.007).
		Type (solo or other)	Single-handed practices performed worse: HbA1C ≤10% (β = –0.544, SE = 0.251, p < 0.05).
		Size (number of patients)	Larger practice population associated with poorer performance: HbA1c ≤10% (β = 0.115, SE = 0.051, p < 0.05) and BP ≤145/85mmHg (β = - 0.282, SE = 0.122, p < 0.05).
		Primary medical services contract	n.s.
		Diabetes prevalence	(unadjusted) higher prevalence associated with higher performance HbA1c ≤7.4% (β = 0.689, SE = 0.245, p <0.001); n.s. for other outcomes and better management overall.
		Deprivation	Greater deprivation associated with poorer performance HbA1c ≤7.4% (β = -0.460, SE = 0.155, p < 0.01) and HbA1c ≤10% (β = -0.517, SE =0.069, p < 0.001).
		Geographic area density	Greater population density associated with poorer performance: HbA1c ≤10% (β = -0.275, SE =0.076, p < 0.001).
		% patients ≥65 years	Greater % patients ≥65 years associated with greater performance: HbA1c ≤7.4% (β = 1.599, SE = 0.172, p < 0.001); HbA1c ≤10% (β = 0.884, SE = 0.081, p < 0.001); total cholesterol ≤5mmol/l (β 0.377, SE = 0.158, p <0.05) but lower performance BP ≤145/85mmHg (β = -0.552, SE = 0.166, p < 0.001).
		% patients from a racial or ethnic minority	Greater % patients racial or ethnic minority associated with poorer performance: HbA1c ≤7.4% (β = -1.529, SE = 0.187, p < 0.001); BP ≤145/85mmHg (β = -0.417, SE = 0.198, p < 0.05); total cholesterol ≤5mmol/l (β =- 0.508, SE = 0.158, p<0.01).

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
Griffiths et al. 2011[267]*	N practices between 7431 and 7456*** Patients NR	List size per FTE practice nurse (quintiles)	Lower list size per FTE nurse associated with greater quality of care score (Q1: β = 1.227, SE = 0.166, p <0.001; Q2: β = 1.603, SE = 0.287, p < 0.001; Q3: β = 1.352, SE = 0.298, p < 0.001; Q4: β = 1.093, SE = 0.300, p < 0.001; Q5: β = 0.990, SE = 0.302, p < 0.01).
		% physician aged ≥45 years	n.s.
		% female physicians	n.s.
		% qualified in the UK	Increasing % qualified in UK associated with better quality of care score (β = 0.694, SE = 0.080, p < 0.001).
		Geographic area	Area density (people per hectare 2001) associated with lower score: β = -0.317, SE = 0.082, p < 0.001.
		Deprivation	n.s.
		Practice size (number of patients)	n.s.
		List size per GP	n.s.
		Type (solo or other)	n.s.
		Primary medical services contract,	n.s.
		Diabetes prevalence	(unadjusted) higher prevalence associated with lower quality of care (β = -0.571, SE = 0.081, p <0.001).
		Organisational factors**	Organisational factor - clinical recording (β = 2.632, SE =0.235, p < 0.001) and Organisational factor - education & training (β = 0.900, SE =0.144, p < 0.001) associated with greater quality of care scores. Other organisational factors: patient communication, practice management and medicines management n.s.
		% patients from a racial or ethnic minority	n.s.

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		% patients ≥65 years	Greater % older associated with lower quality of care (β = -0.372, SE = 0.123, p <0.01)
Gulliford et al. 2001[290]*‖	23 health centres 1579 patients	Number of doctors at each clinic	Compared with practices with 1 doctor per session, those with ≥2 had higher scores: β = 1.90, 95% CI: 0.73-3.06.
		Number of trained nurses at each clinic	Compared to practices with 1 nurse per session, practices with 2 nurses per session had higher mean score (β = 1.16, 95% CI: 0.032-2.00), as did those with ≥ 3 nurses (β = 1.18, 95% CI: 0.27-2.09).
		Number of equipment items	Practices with more equipment items had greater mean score: 8-9 items vs. 6-7 (β = 0.72, 95% CI: -0.51-1.96); 10-11 items vs. 6-7 (β = 2.02, 95% CI: 0.56-3.47).
		Distance from capital	Results were not consistent across categories.
		Number of patients seen during the census period	Compared to those in first quartile, practices in second quartile had lower mean score (β = -0.31, 95% CI: -2.01, -1.39), as did practices in highest quartile (β = -1.12, 95% CI: -3.22-0.99).
Gulliford et al. 2007[289]	8164 practices Patients >50 mil.	List size per GP	Mean difference in % between practices in the highest tertile and lowest tertile achieving HbA1c ≤7.4%: -0.64, 95% CI: -1.25--0.03, p = 0.04.
		Size (number of GPs)	n.s.
		Training practice status	[Mean difference in % achieving HbA1c ≤7.4% from non-training practices] Training practices: -0.60, 95% CI: -1.16--0.04, p = 0.036.
		Type (solo or other)	n.s.
		Practice engaged in postgraduate medical training	n.s.
		QOF organisational score	[Mean difference in % achieving HbA1c ≤7.4% from practices in lowest tertile] Middle: 3.24, 95% CI: 2.68-3.80, p <0.001;

Table 21 Main results for studies which examined practice factors only (n = 44)			
Reference	**N**	**Factors**	**Main results (multivariate analysis unless otherwise stated)**
			Highest: 5.03, 95% CI: 4.43-5.64, p<0.001
		Diabetes prevalence	[Mean difference in % achieving HbA1c ≤7.4% from practices in lowest tertile] Middle: 0.97, 95% CI: 0.41-1.54, p = 0.001 Highest: 1.97, 95% CI: 1.34-2.59, p <0.001
		% patient ethnic minority	[Mean difference in % achieving HbA1c ≤7.4% from practices in lowest tertile] Middle n.s. Highest: -2.73, 95% CI: -3.61- -1.85, p<0.001
		Deprivation	[Mean difference in % achieving HbA1c ≤7.4% from practices in lowest tertile] Middle: n.s. Highest: -2.96, 95% CI: -3.69--2.23, p <0.001 Middle tertile compared to highest tertile: -1.03, 95% CI: -1.63- -0.43, p = 0.001
			Similar patterns of association for blood pressure ≤ 145/85 mmHg and cholesterol ≤ 5.0 mmol/l (data not shown)
Harris et al.[291]	614 physicians Patients NR	Use of register	Practices with a register had a higher proportion of patients with HbA1c test, microalbuminuria test, and across the different study periods (Jan - Jun 1996; Jul - Dec 1996: Jan-Jun 1997; Jul-Dec 1997 with exception of 1998 which was n.s.; proportion with lipid testing only significant in Jul-Dec 1998.
He et al.[254]*	Practices NR 2912 patients	Practice setting (free standing clinic, community health centre, other vs. private practice)	Older men: free standing vs. private practice (OR = 2.7, 95 CI: 1.06, 7.07); Other vs. private practice (OR = 0.2, 95% CI: 0.05, 0.79); community health centre vs. private practice n.s. Older women: n.s.
		Physicians (employees or contractors vs. owners)	n.s.
		EHR usage	Older men:

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
			Use of EHRs associated with greater likelihood of diagnostic testing (AOR = 2.2, 95% CI: 1.38-3.58). Older women: n.s.
		Laboratory tests (at office or off-site)	Older men: On-site laboratory tests associated with greater likelihood of diagnostic testing (AOR = 2.9, 95% CI: 1.99-4.42). Older women: On-site laboratory tests were associated with a higher likelihood of diagnostic testing (AOR = 5.1, 95% CI: 3.20–8.32).
Juul et al. 2009[252]	54 practices 226 patients	Size (number of GPs)	n.s. (association with treatment initiation)
		Number of inhabitants registered in the postcode of the practice (<10000; ≥10000)	n.s. (association with treatment initiation)
		Type (solo or group)	n.s. (association with treatment initiation)
		List size per GP	n.s. (association with treatment initiation)
		Average GP age (<50 years; ≥50 years),	n.s. (association with treatment initiation)
		Gender (both represented; only female; only male)	n.s. (association with treatment initiation)
Juul et al. 2012[292]‖	193 practices 12,960 patients	Nurse involvement (1) "No nurses employed", (2) "Nurses employed, no nurse-led type 2 diabetes consultations", (3) "Nurses employed, nurse-led type 2 diabetes consultations less	Compared to practices with no nurse employed, practices with nurse-led consultation well-implemented had a greater mean proportion with HbA1c measurement (mean diff. = 6.4% points, 95% CI: 1.5-11.4), and had lower proportions HbA1c ≥8% (mean diff. = −3.7% points, 95% CI: −6.7- −0.6). Differences for cholesterol n.s.

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		implemented", and, (4) "Nurses employed, nurse-led type 2 diabetes consultations well-implemented"	
Khunti et al.[150]	169 practices 18 642 patients	Size (number of patients)	Larger practices have lower compliance with annual assessment of glycated haemoglobin and blood pressure (HbA1c check: -1.1, 95% CI: -1.8- -0.38; BP check: -1.7, 95% CI: -2.6--0.8).
		Fund-holding status	Fundholding practices associated with greater annual compliance of some process measures (urine check: 9.5, 95% CI: 1.4-17.6); feet check: 9.4, 95% CI: 1.7-17.1); n.s. for other measures.
		Deprivation	Practices with higher socioeconomic deprivation performed poorly for most process measures (HbA1c check: -1.6, 95% CI: -2.6- -0.6); fundi check: -1.3, 95% CI: -2--0.03; feet check: -2.0, 95% CI: -3.3- -0.8); BP check: -1.2, 95% CI: -2.3-0.0); n.s. for urine check, HbA1c level
		Training practice status	n.s.
		Number of practice nurses	n.s.
		Size (number of GPs)	Higher number of GPs associated with poorer performance of feet check (-1.9, 95% CI: -3.7- -0.2); n.s. for other measures.
		Diabetes mini clinic	n.s.
		Recall system	Practices with a recall system associated with annual compliance of some process measures (fundi check: 25.6, 95% CI: 2.9, 48.9); feet check: 33.9, 95% CI: 10.5-57.2).
		Diabetes prevalence	Increasing prevalence associated with poorer performance of HbA1c check (-6.3, 95% CI: -10.7- -1.9) but n.s. for fundi check, feet check, BP check, urine check and HbA1c level.
		Practice: % patients under GP care	n.s

Table 21 Main results for studies which examined practice factors only (n = 44)

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Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		Practice: % patients under hospital care	Practices with greater proportion of patients under hospital care associated with lower compliance with process and outcome of care: (HbA1c check -0.3, 95% CI: -0.5 - -0.2); fundi check: -0.5, 95% CI: -0.7 - -0.3; urine check: -0.5, 95% CI: -0.7 - -0.3); feet check: -0.3, 95% CI: -0.5 - -0.1); BP check: -0.4, 95% CI: -0.6 - -0.2); HbA1c normal range: -0.2, 95% CI: -0.4 - -0.002).
		Personal care (single-handed or having a personal list system)	n.s
		GP interest in diabetes	n.s
		Nurse interest in diabetes	n.s
Kontopantelis et al.[293]*‖	148 practices 23 780 patients	Deprivation	Patients attending practices from the most deprived quartile gained less from the intervention compared with patients in the most affluent quartile of practices: short term (2004/5) score minus predication from pre-QOF trend) = -4.9%, 95% CI: -7.2 - -2.7) p <0.001; long term (2004/05) score minus prediction from pre-QOF trend) = -3.8%, 95% CI: -6.8 - -1.1, p = 0.002.
		Diabetes prevalence	Compared with practices in the first quartile (lowest diabetes prevalence), effect was larger for practices in the second and third quartiles: short term (2004/5) score minus predication from pre-QOF trend): 2nd Q = 1.4%, 95% CI: -0.7 - 3.5), 3rd Q = 2.1%, 95% CI: -0.02 - 4.1, p = 0.004; long term (2004/05) score minus prediction from pre-QOF trend 2nd Q - 3.2%, 95% CI: 0.7 - 5.4, 3rd Q = 4.8%, 95% CI: 2.5 - 6.8, p <0.001.
Kuo et al.[305]‖β		Care delivery by nurse practitioner (NP) vs. primary care physician (PCP)	Patients with care delivered by NP less likely to receive eye exam (AOR = 0.89, 95% CI = 0.84–0.93), HbA1c test (AOR = 0.88, 95% CI = 0.79–0.98), and be prescribed statins (AOR = 0.94, 95% CI = 0.89–0.99). LDL-C test, nephropathy monitoring, and prescription of ACEIs or ARBs n.s.
		Size of service population	n.s.

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
Matthews et al.[262]*‖	132 health centres 10,674 patients	Governance (community-controlled or government operated),	n.s.
		Location (very remote, remote or non- remote),	Increased odds of improvement in delivery of services to patients with type 2 diabetes from non-remote (1-2 cycles of participation: AOR = 1.47 (95% CI: 1.06-2.04) p <0.05), to remote (1-2 cycles: AOR = 2.91 (95% CI: 1.36,6.22) p <0.01; ≥3 cycles AOR = 3.29 (1.44-7.54) p < 0.01)) and very remote centres (1-2 cycles: AOR = 4.31 (95% CI: 2.43-7.67) p <0.001; ≥3 cycles AOR = 5.06 (95% CI: 2.63-9.67) p<0.001)).
		Rates of patient attendance (higher or 'lower regular attendance' - if more than 3% of patients did not attend within the previous six months)	Practices with higher attendance more likely to adhere to delivery of type 2 services (AOR = 1.40; 95% CI 1.22-1.61) p <0.001).
McCullough et al.[294]*	557 clinics Patients NR (≈ 152,000)	EHR usage	Compared to paper-based system EHR utilization associated with increase in diabetes quality score: β = 0.028, SE = 0.012, p < 0.05.
		Number of diabetes patients	n.s.
		Number of clinics within the medical group	Greater number of clinics associated with increase in score: β = 0.004, SE = 0.000, p < 0.001
McLean et al.[295]	912 practices Patients NR	Location (not remote; remote; very remote)	Care processes: eye exam, peripheral pulses, neuropathy testing, BP recorded, cholesterol recorded n.s. Outcomes: HbA1c ≤7.4%, HbA1c ≤10%, BP ≤145/85mmHg n.s. Compared to not remote practices, remote practices had lower mean (IQR) proportion with cholesterol ≤5 mmol/l (67.9 (14.4) vs. (68.0 (12.2)).
Millett et al.[144]	8970 practices	Size (number of patients)	Larger practices achieved the highest quality of care scores, particularly for process of care measures.

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
	1 852 762 patients		Process of care: With the exception of retinal screening (0-3000 list size (78.2%) vs ≥10,000 list size (86.1%)), peripheral pulses (0-3000 list size (73.1%) vs ≥10,000 list size (81.1%)) and neuropathy testing (0-3000 list size (71.2%) vs ≥10,000 list size (80.0%)), absolute differences in achievement between small and large practices was modest (<5%). Clinical outcomes: performance of small practices was broadly similar to larger practices in achievement of intermediate outcome targets for HbA1c, blood pressure and cholesterol. Clinical outcomes: the trend of higher achievement with increasing practice size was less marked in affluent areas e.g. smaller practices were more likely to achieve the lower treatment target for HbA1c (47.4%) than larger practices in affluent areas.
		Number of diabetes patients (quintiles)	Similar trends between achievement of indicators and caseload (i.e. achievement broadly similar between practices with high and low caseload) (data not shown).
		Deprivation	Process of care: practices located in deprived areas performed less well on quality measures than those based in affluent areas e.g. neuropathy testing (deprived = 72.9% vs. affluent = 81.4%). Differences in achievement between small practices in deprived areas and large practices in affluent areas were considerable on some indicators >10% (peripheral pulses; neuropathy testing; retinal screening; microalbuminuria testing).
Mitchell et al.[296]‖	6 practices 939 patients	EHR	Use of electronic system associated with greater odds of recording: BP: Practice Pair 2: AOR = 3.3 (95% CI: 1.2-10.9); Pair 6: AOR = 6.0 (95% CI: 2.1-17.1)) Smoking: Pair 1 AOR = 0.2 (95% CI: 0.04-0.7) Height: Pair 2 AOR = 7.3 (95% CI: 2.9-18.5); Pair 4 AOR = 0.1 (95% CI: 0.01-0.8); Pair 6 95% CI: AOR = 4.7 (95% CI: 1.5-14.5) Weight: Pair 2 AOR = 3.6 (95% CI: 1.5-8.7); Pair 5 AOR = 6.4 (95% CI: 2.3-56.4), foot pulses: Pair 3 AOR = 5.6 (95% CI: 1.8-17.2); Pair 6 AOR = 6.5 (95% CI: 1.8-23.5)

Table 21 Main results for studies which examined practice factors only (n = 44)			
Reference	**N**	**Factors**	**Main results (multivariate analysis unless otherwise stated)**
			Foot sensation: Pair 2 AOR = 2.4 (95% CI: 1.1-5.0) n.s. HbA1c or fundoscopy
Ohman et al.[143]‖β	46 practices 846 patients	Practices with NPs, practices with physician assistants (PA), and practices with physician-only	Practices with NP had higher rate of HbA1c tests than PA (RR = 1.96 ,p = 0.005) and physician only (RR = 1.34, p <0.001), higher rates of lipid test than PA (RR = 1.37, p = 0.004) and physician only practices (RR = 1.17, p = 0.007), higher rates of microalbumin test than PA (RR = 5.26, p < 0.001) and physician only practices (RR = 1.72, p = 0.10). Patients were more likely to meet lipid targets if attending practices with PA (RR = 1.37, p = 0.004) or physician only (RR = 1.17, p = 0.03), but less likely to be assessed and at target than practices with PA (RR = 1.45, p = 0.001) or Physician only (RR = 0.98, p = 0.85). Compared to practices with physician only, those with PA had lower rates of HbA1c tests (RR = 0.68 p = 0.21), lower rates of lipid tests (RR = 0.85 p = 0.29), microalbumin test (RR = 0. 33 p = 0.02), patients were less likely to meet lipid targets (RR = 0. 85 p = 0.20) and less likely to be assessed and at target (RR = 0. 68 p < 0.01). Receipt of BP check, and meeting targets for HbA1c, microalbuminuria, BP were n.s.
Orzano et al.[297]* ‖β	50 practices 883 patients	Use of clinical information systems in 2 categories: 1) Identification of patients 2) tracking systems	Use of identification systems improved achievement of at least 2 of 3 outcome targets (AOR = 1.23 (95% CI: 1.06-1.44), p = .007), as did use of tracking systems (AOR = 1.32 (95% CI: 1.11-1.59) p = 0.002).

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
			Adherence to assessment or treatment guidelines was n.s.
Poon et al.[298]*¶	507 physicians 150 unique medical groups Patients NR	EHR usage	n.s.
Ricci-Cabello et al.[299]*β	7,884 practices 54,220,050 patients	Diabetes prevalence	Increased prevalence was negatively associated with processes of care measure (back-transformed effect, −0.31%). For a practice with an average achievement rate, a relative increase of 1% in the prevalence of diabetes was associated with a 0.31% higher achievement rate across the overall processes of care. Outcome of care measure n.s.
		Prevalence of diabetes-concordant conditions	4 /7 conditions were positively associated with achievement rate (%) of process of care and outcomes of care measures: obesity (process: 0.33%; outcome: 0.24%), chronic kidney disease (process: 0.18%; outcome: 0.30%), atrial fibrillation (process: 0.57%; outcome: 0.97%), and heart failure (process: 0.60%; outcome: 0.98%). No association was observed for stroke or transient ischemic attack. 2/7 conditions were negatively associated: hypertension (process: −0.08%; outcome: -0.22%) and coronary heart disease (process: −0.38%; outcome: -0.31%).
		Prevalence of diabetes-discordant conditions	2/8 conditions were negatively associated: epilepsy (process: −0.80%; outcome: -0.58%) and severe mental health disorders (process: −0.76%; outcome: -0.95%). No associations were observed for 3 other discordant conditions (dementia, depression, and hypothyroidism)

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
			3/8 conditions were positively associated: asthma (process: 0.19%), cancer (process: 0.59%; outcome: 0.89%), and COPD (process: 0.23%; outcome: 0.95%)
Spigt et al.[141]*	10 health centres 45 physicians 1849 patients	Practice protocol	n.s.
		Active measures taken in case a patient does not show up (1, 2 or 3 measures)	If more active measures in place then more likely to receive optimal care: 1 vs. 3: AOR: 0.65, 95% CI: 0.47–0.89, p <0.05; 2 vs. 3: AOR: 0.59, 95% CI: 0.50–0.69, p <0.05.
		Registration system	n.s.
		Yearly check-ups (done by GP and NP; GP or NP)	If yearly medical check-ups done by both the GP and NP then patients were more likely to receive optimal quality of care (AOR: 5.51; 95% CI: 4.16–7.30, p <0.05).
		Diabetes education programme	Greater odds of receiving optimal quality of care at practices with diabetes education programme: AOR: 4.29; 95% CI: 3.40–5.41, p <0.05.
		Practice multidisciplinary collaboration	n.s.
		After visit NP patient discussed with GP	Greater odds of receiving optimal quality of care if after the patient visited the NP the patient is discussed with the GP (AOR = 1.80, 95 CI%: 1.62–2.00, p <0.0).
		Use of report cards	n.s.

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Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
Stearn et al.[300]	50 practices 3550 patients	Practice nurse training level (not involved vs. involved, not trained vs. involved, trained and involved)	(Comparison of % recording; ANOVA) In practices where the nurse was not involved compared to involved there was lower recording of BP (75% vs 82% (8.9-34.0) p > 0.05), weight (23% vs. 45% (1.2-13.9) p > 0.05), performance of foot exams (6% vs 28% (9.7-33.2) p > 0.05), visual acuity tests (2% vs. 13% (3.0-19.6) p > 0.05). Smoking status recording n.s. In practices where nurse was trained but involved compared to practice where nurse was trained and involved there was lower proportions with foot exams performed (8.9% vs. 38% (5.3-52.9) p > 0.05), visual acuity tests (0.3% vs. 20% (2.9-38.2) p > 0.05). All other variables, weight, BP, smoking status recording n.s.
Suleman et al.[301]	629 practices 199,485 patients	Size (number of patients)	n.s.
		Diabetes prevalence	Higher prevalence associated with higher achievement of HbA1c ≤7.5 (β = 1.188, SE = 0.280, p <0.001) but lower achievement of HbA1c ≤10 (β = -0.342, SE = 0.141, p = 0.016), and BP ≤145/85 (β = -0.835, SE = 0.272, p = 0.002) and cholesterol ≤5 mmol (β = -0.835, SE = 0.272, p = 0.002).
		Obesity prevalence	Higher prevalence associated with higher achievement of BP ≤145/85 (β = 0.432, SE = 0.116, p<0.001), cholesterol ≤5 mmol (β = 0.247, SE = 0.081, p <0.002); HbA1c n.s.
		Deprivation	Higher deprivation score associated with lower achievement of HbA1c ≤7.5 (β = -0.002, SE <0.001, p <0.001) and HbA1c ≤10 (β = -<0.001, SE <0.001, p = 0.002); BP and cholesterol n.s.

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
Tahrani et al.[142]	66 practices 16 858 patients	Size (number of patients)	Compared to large practices, smaller practices had a lower mean % (sd) with HbA1c ≤7.4% (36 (18) vs. 46 (12) p = 0.02, CI for difference -17 to -2), HbA1c ≤10% (64 (16) vs. 73 (6) p = 0.003, CI for difference -15 to -3), eye exam (40 (22) vs. 52 (18) p = 0.02; 95% CI of difference -22 to -2), prescription of ACE/ARB: small vs. large (96 (7) vs. 90 (9) p = 0.001, 95 % CI 3 to 11) HbA1c ≤7.4%, HbA1c ≤10% n.s. in 2005, 2006, BP ≤145/85, total cholesterol ≤5 n.s., eye exam n.s. 2005, 2006, ACE/ARB prescribing n.s. 2004, 2005
Vamos et al.[138]‖	422 practices 154,945 patients	Size (number of patients)	No statistically significant variations in achieving BP or HbA1c targets between the smallest and largest practices in any year during 1997-2005. Cholesterol target achievement was lower in the larger practices than in the smallest practices in 1998, but there were no statistically significant variations in performance between small and large practices for other years during the study period.
Van Doorn et al.[306]‖	354 practices 11 751 patients	NP per 1000 patients	n.s.
		EHR use (sum score of seven items)$^{\mu}$	Greater use (increase of one on a scale of seven) associated with performance within the highest quartile of HbA1c level (AOR = 1.80, 95% CI: 1.12-2.88, p = 0.014); n.s. for BP or cholesterol.
		GP education (<50 hours per year ≥50 hours)	n.s.
		Nurse education (< 15 hours per year, ≥ 15 hours)	Higher nurse education (compared to < 15 hours per year) associated with performance within the highest quartile of total cholesterol values (AOR = 2.51, 95% CI: 1.02-6.15, p = 0.045); n.s. for others.
		Guidelines	n.s.
		Reminder system	n.s.

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		Type (solo or other)	Health centre (compared to > 1 GP but not health centre) associated with higher total cholesterol values (β = 0.149, 95% CI: 0.037, - 0.262, p = 0.010); HbA1c n.s.
		Diabetes clinic	Higher HbA1c levels in practices with diabetic clinic (β = 0.327, p < 0.000)
		Annual report	n.s.
		Patient leaflets	Practices with availability of patient leaflets were in SBP (highest quartile) AOR = 2.59, 95% CI: 1.06-6.15, p = 0.037; HbA1c or cholesterol n.s.
		Composite score of 12 determinants related to target areas for improvement strategies	Higher determinant score associated with decrease in SBP: β = -50, 95% CI:-0.91, -0.09, p = 0.017; HbA1c or cholesterol levels n.s.
Wang et al.[309]*	638 practices Patients NR (≈ 1 mil.)	Practice size (number of GPs)	n.s.
Wencui et al.[302]*‖	50 practices 12 514 patients	EHR usage	Using records for patient reminders increased likelihood of lab testing (composite of HbA1c, nephropathy, LDL) (AOR = 1.26, 95% CI: 1.15-1.38, p <0.01) and eye exam (OR = 1.14, 95% CI: 1.04-1.23, p < 0.01). Using registries for quality improvement: n.s.
		Number of diabetes patients	Increasing number of patients increased likelihood of lab testing (AOR = 1.03, 95% CI: 1.02-1.04, p < 0.01, per 100 patients), n.s. for eye exam.
Wong et al.[303]‖β	74 clinics 87,031 patients	Annual patient volume at clinic level (quartiles)	Patients of practices in Q4 vs. Q1 were less likely to have HbA1c test (OR = 0.646, 95% CI: 0.425,0.981, p = 0.040).

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
			Q3 vs. Q1 were less likely to have HbA1c test (AOR = 0.655, 95% CI: 0.435,0.986, p = 0.043), renal function test (AOR = 0.367, 95% CI: 0.172,0.786, p =0.010), full lipid profile (AOR = 0.612, 95% CI: 0.384,0.974, p =0.038). Q2 vs. Q1 were less likely to have renal function test (AOR = 0.357, 95% CI: 0.178, 0.716, p = 0.004), full lipid profile (AOR = 0.508, 95% CI: 0.333,0.774, p = 0.002). Prescription of ACEI/ARB for patients with microalbuminuria, urine protein analysis, and eye exam, meeting HbA1c, LDL-C and BP targets were n.s.

Abbreviations: NR, Not Reported; OR, Odds Ratio; EHR, Electronic Health Record; MDT, Multidisciplinary team; WTE, Whole Time Equivalent; GPs, General Practitioners; RAP, intervention arm receiving practice facilitation using reflective adaptive process change model based on complexity theory; CQI, Continuous quality improvement arm received practice facilitation based on the model for improvement; SD, Self-directed arm received limited feedback on their baseline practice culture and level of implementation of the Chronic Care Model based on practice; RN, registered nurse; LPN, licensed practical nurses; MA, medical assistants; AP, Associate provider; NP, Nurse Practitioners; FTE, Full Time Equivalent; SES, socio-economic status

*Composite outcome

‖Patient-level covariates adjusted for in multivariate analysis

¶Physician-level covariates (additional to explanatory variables) adjusted for in multivariate analysis

βPractice-level covariates (additional to explanatory variables) adjusted for in multivariate analysis

**Indicators grouped as ‘Records and information about patients (19), Patient communication’ (8), Education and training (9), Practice management (10), Medicines management (10)

***depending on the condition being studied

Table 21 Main results for studies which examined practice factors only (n = 44)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)

µ(a) General practitioners (GPs) always use the EHR to create prescriptions, (b) Incoming lab results are processed automatically, (c) Hospital referrals are completely created in EHR, (d)Referrals to other disciplines (e.g. physiotherapy) are completely created in EHR, (e) Application forms for diagnostic procedures are generated in the EHR, (f) Contraindications and intolerances are systematically recorded in the EHR, (g) GPs have the support of an electronic referral system during visiting hours)

Table 22 Main results for studies which examined both physician and practice factors (n = 12)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
Alberti et al.[312]*‖	102 physicians 2,160 patients	**Physician**	
		Gender	n.s.
		Training (postgraduate, diabetes)	n.s.
		Workload (average number of patients per clinic)	n.s.
		Time commitment	n.s.
		Motivation	Increased motivation associated with increase in weighted process of care score: β = 0.37 (95% CI: 0.22- 1.68) p = 0.013; other scores n.s.
		Practice Interest in diabetes (presence of regional coordinator of the national program)	n.s.

Table 22 Main results for studies which examined both physician and practice factors (n = 12)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		Size (number of GPs)	n.s.
		Nutritionist available	n.s.
		Number of nurses	n.s.
		Location (urban or rural)	n.s.
		Size (number of patients)	n.s.
		Frequency of medical clinics	n.s.
		Distance from capital city	n.s.
		Affluence of region	Higher affluence associated with increase in weighted process of care score: β = 0.51 (95% CI: 0.12-0.53) p = 0.003; other scores n.s.
		Motivation of the regional director	n.s.
		Distance from secondary care	n.s.
		Diabetes prevalence	n.s.
		Disease-specific medical records	n.s.
		Register and patient-held records	n.s.
		Availability of medication	Four variable outcome of care score: β = 0.27 (95% CI: 0.00-0.60) p = 0.04; other scores n.s.
		Affluence of the patients	n.s.
		Chronic disease clinics	Use of clinics associated with increased in weighted process of care score: β = 0.36 (95% CI: 0.01-0.70) p = 0.029; other scores n.s.
		Equipment items	n.s.

Table 22 Main results for studies which examined both physician and practice factors (n = 12)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		Patient education sessions	n.s.
Balkau et al.[263]‖	1200 physicians 3188 patients	**Physician**	
		Age	n.s.
		Gender	n.s.
		Practice Location	n.s.
		Number of type 2 patients at practice	n.s.
Fantini et al.[313]*‖	637 physicians 35,912 patients	**Physician**	
		Age	Younger age (<50 years) favoured good management across several indicators; HbA1c (56-60 vs ≤ 50 AOR = 0.83, 0.72-0.97; >60 vs ≤ 50 AOR = 0.77, 0.60-0.96), microalbuminuria (56-60 vs ≤ 50 AOR = 0.98, 0.81-1.18), creatinine (51-55 vs ≤ 50 AOR = 0.89, 0.80-0.99, 56-60 vs ≤ 50 AOR = 0.85, 0.75-0.95, >60 vs ≤ 50 AOR = 0.74, 0.61-0.89), lipid profile (>60 vs ≤ 50 AOR = 0.74, 0.61-0.88).
		Gender	Female gender favoured good management across several indicators; HbA1c (AOR = 0.84, 0.75-0.95), microalbuminuria (AOR = 0.85, 0.73-0.99), creatinine (AOR = 0.88, 0.80-0.97), eye exam (AOR =0.81, 0.79-0.95).
		Panel size	
		Practice Type (no organisational arrangement, association, network, group practice)	[Compared to practice with no organisational arrangement] **Network practices** had greater odds of microalbuminuria test (AOR = 1.404 (95% CI: 1.158-1.702), creatinine (AOR = 1.195 (95% CI: 1.057-1.351)), lipid profile (AOR = 1.214 (95% CI: 1.076-1.369)), n.s. for electrocardiogram, eye exam, HbA1c, good management overall.

Table 22 Main results for studies which examined both physician and practice factors (n = 12)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
			Group practices had greater odds of microalbuminuria test (OR = 1.413 (95% CI: 1.194-1.672)), creatinine (AOR = 1.253 (95% CI: 1.126-1.395)), lipid profile (OR = 1.202 (95% CI: 1.080-1.335)), electrocardiogram (AOR = 1.170 (95% CI: 1.055-1.298)), eye exam (AOR = 1.170 (95% CI: 1.055-1.298)), and good management overall (composite AOR = 1.179 (95% CI: 1.010-1.376)); n.s. HbA1c. **Association practices** had greater odds of creatinine test (AOR = 1.379 (95% CI: 1.084-1.755)), lipid profile (AOR = 1.331 (95% CI: 1.050-1.687)), n.s. for electrocardiogram, eye exam, HbA1c, good management overall.
		Location (urban, rural, or mountain)	[Compared to practices in urban areas] Location in a rural area was associated with increased prescription of HbA1c test (data not shown). Location of the ambulatory facility in a mountain area associated with a higher frequency of examination of lipid profile (data not shown).
Keating et al.[314]*‖¶β	399 physicians 652 patients	**Physician**	
		Satisfaction with career in medicine	Physicians dissatisfied with overall career in medicine less likely to have microalbumin testing (p = 0.047) and retinopathy screening (p = 0.03) [data not shown]; n.s. for composite quality outcome.
		% income earned from incentives	n.s.
		Use email for communication,	n.s.
		EHR usage	n.s.

Table 22 Main results for studies which examined both physician and practice factors (n = 12)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		Practice Guidelines	n.s.
		Flow sheets	n.s.
		Type of payment	n.s.
Kern et al.[311]*	466 physicians 74,618 patients[§]	**Physician** Age	Patients of older physicians (10-year increase) have lower quality score (β = −0.238 (p = 0.001).
		Gender	Patients of female physician have higher scores (β = 0.422 (p =0.005).
		Credential (MD or Doctor of Osteopathic medicine)	n.s.
		Specialty	Family medicine vs. internal medicine: β = -0.640 (p <0.001).
		Panel size	n.s.
		Practice	
		EHR	EHR vs. paper: β = 0.373 (p = 0.008).
		Location (urban or rural)	n.s
McGinn et al.[318]	Physicians NR 31831 patients	**Physician** Age	Patients of older physicians were more likely to have poor HbA1c control: OR = 1.037 (95% CI: 1.010-1.065); n.s. HbA1c test, LDL-C test, LDL-control, eye exam referral, nephropathy screening.

Table 22 Main results for studies which examined both physician and practice factors (n = 12)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		Speciality	Physicians with non-primary care subspecialty had lower odds of poor LDL-C control: OR = 0.340 (95% CI: 0.156-0.738); n.s. HbA1c test, HbA1c control, LDL-C test, eye exam referral, nephropathy screening.
		Years since graduation	Patients of physician with more years since graduation had lower odds of poor HbA1c control: OR = 0.971 (95% CI: 0.945-0.997); n.s. HbA1c test, LDL-C test, LDL-C control, eye exam referral, nephropathy screening.
		Credential (MD or DO)	n.s.
		Practice	
		Type (solo or group)	Group practices had better nephropathy screening rates: OR = 1.441 (95% CI: 1.270-1.721); n.s. HbA1c test, HbA1c control, LDL-C test, LDL-C control, eye exam referral.
Parkerton et al. 2004[315]*[β]	25 clinics 182 physicians Patients NR	**Physician**	
		Gender	n.s.
		Administrative role	n.s.
		Years since graduation	n.s.
		Continuity (percentage of a panel's visits that were to the primary care physician rather than any other clinician)	n.s.
		Practice	

Table 22 Main results for studies which examined both physician and practice factors (n = 12)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		Usual Provider Continuity (specified physician, rather than any other clinician in a specified time period),	n.s.
		Shared practice (clarified communication structure, team roles, and practice styles),	Being in shared practice associated with better management (β = 0.248 p < 0.05).
		Size (number of GPs)	Larger medical clinic size associated with better management (β = 0.252 p < 0.05).
		Team tenure	Long tenure associated with better management (β = 1.241 p <.001).
Pham et al.[316]‖β	3,660 physicians 24 581 patients	**Physician** Gender	n.s.
		Specialty (internal medicine or family medicine)	Family/GP compared with general internal medicine had lower odds of eye exam: OR = 0.81, 95% CI 0.67-0.97, p <0.05; n.s. HbA1c test.
		Training - board certification	n.s.
		Training - whether their medical school education was completed in the United States (including Puerto Rico) or Canada, rather than another country.	Physicians qualified in other country than US or Canada had lower odds of eye exam: OR = 0.82, 95% CI: 0.68-0.99, p <0.05; n.s. for HbA1c test.

Table 22 Main results for studies which examined both physician and practice factors (n = 12)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		Years in practice	n.s.
		Practice	
		Type (solo/2 person or other)	Compared to solo/2-person practices, small group practices had greater odds of performing HbA1c test (OR = 1.90, 95% CI: 1.45-2.48), as did medium/large group practices (OR = 1.91, 95% CI: 1.40-2.60); n.s. for eye exam. All other practice types: n.s.
		Practice payer mix	Compared to practices with 0-5% revenue from Medicaid those with 6-15% had lower odds of HbA1c test: OR = 0.74 (95% CI: 0.60-0.92), as did those with 16-100%: OR = 0.73 (95% CI: 0.57-0.95); n.s. for eye exam.
		Information technology available to generate physician reminders about preventive services, or to obtain information about treatment alternatives or recommended guidelines	Practices using information technology for guidelines or reminders were more likely to perform eye exams (OR = 1.21, 95% CI: 1.08-1.35); n.s. HbA1c test.
Spann et al.[256]‖	95 physicians 822 patients	**Physician**	
		Gender	n.s.
		Number of patients with diabetes seen in month	n.s.
		Years in practice	n.s.

Table 22 Main results for studies which examined both physician and practice factors (n = 12)

Reference	**N**	**Factors**	**Main results (multivariate analysis unless otherwise stated)**
		Practice Type (single speciality, academic setting, solo practices, multispecialty group, combo of settings)	[Compared to single-specialty practices] Patients of practices in an academic setting had greater HbA1c values (β = 0.61 (95% CI: 0.25-0.97)) and greater odds of HbA1c >7% (poor control) (OR = 2.90 (95% CI 1.56-5.38)); n.s. BP > 130/85mmHg, poor LDL-C control >100mg/dl. Patients of solo practices had greater HbA1c (β = 0.40 (95% CI: 0.03-0.77)), higher odds of poor HbA1c control (OR = 1.88 (95% CI: 1.01-3.50)), and higher odds of BP > 130/85mmHg (OR = 2.12 (95% CI: 1.14-3.94)); n.s. for poor LDL-C control >100mg/dl. Multispecialty practices had greater HbA1c β = 0.39 (95% CI: 0.03-0.75); n.s. for other outcomes.
		Flow sheets	n.s.
		EHR	n.s.
		Involvement of nurse practitioner (NP) or physician assistant (PA)	Involvement associated with lower HbA1c values: β = -0.37 (95% CI: -0.67 - -0.08); n.s. for other outcomes.
		Patient registries	n.s.
		Dietician	n.s.
		Diabetes educators	n.s.
		Endocrinologists	n.s.
Van Bruggen et al.[259]¶	30 practices	**Physician** Age	n.s.

Table 22 Main results for studies which examined both physician and practice factors (n = 12)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
	1283 patients		
		Gender	n.s.
		Time in practice	n.s.
		Involvement in diabetes care	n.s.
		Practice	
		% GPs working part time	n.s.
		Size (number of patients)	n.s.
		% patients > 55 years	n.s.
		Diabetes prevalence	n.s.
		Location	n.s.
		Type (solo, duo or group practice)	n.s.
		Presence of a practice nurse	Nurses were more often involved in diabetes care in practices which intensified anti-hypertensive treatment in >60% of their poorly controlled patients vs. practices that did not made these changes adequately (77.8% versus 67.9%, p = 0.016). All other differences between inert and non-inert practices n.s. [in all practices (intervention & control)] Clinical inertia in response to poor BP control was less common if a practice nurse was actively involved in diabetes care (AOR = 0.12, 95% CI: 0.02–0.91).
		Role of the practice assistant (participating vs. non-	n.s.

Table 22 Main results for studies which examined both physician and practice factors (n = 12)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		participating in diabetes care)	
Vinker et al.[317]*	161 physicians Patients NR	**Physician** Age	n.s.
		Gender	n.s.
		Training - board certification	Patients of board certified physician had greater diabetic care score (β = 0.185, p < 0.05) in 2003, greater diabetic control score in 2003 (β = 0.196, p < 0.05) and 2005 (β = 0.348, p < 0.05).
		Managerial position held in clinic	n.s.
		Years in practice	n.s.
		Panel size	n.s.
		Practice Location (urban or rural)	n.s.
Visca et al.[268]*‖	1678 physicians 73,920 patients	**Physician** Age	Older physicians had lower adherence to guidelines (effect x 10 years): β = - 0.092 (95% CI: -0.123 - -0.061).
		Gender	Female GPs had greater adherence to guidelines: β = 0.058 (95% CI: 0.022-0.094).

Table 22 Main results for studies which examined both physician and practice factors (n = 12)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		Team membership ("solo", base group, network group or group practice)	n.s.
		Panel size	Physician with greater list size (effect x 100) had greater adherence: β = 0.009 (95% CI: 0.004,-0.014).
		Number of diabetes patients on panel	n.s.
		% patients aged 85+ on panel	Physicians with greater number of patients 85+ had lower adherence β = -0.004 (95% CI: -0.007, -0.001).
		% patients dx > 4 years on panel	Physicians with greater number of patients with dx >4 years had higher adherence: β = 0.003 (95% CI: 0.001,0.005).
		Average Charlson index of panel	n.s.
		Practice District mean of diabetes prevalence,	n.s.
		District mean of % patients aged 85+	Practices with greater proportion of patients 85+ had higher adherence: β = 0.073 (95% CI: 0.010-0.137).
		District mean of charlson index	n.s.
		District mean of % dx >4 years	Practices with greater proportion of patients dx >5 had higher adherence: β = 0.043 (95% CI: 0.009-0.077).

Table 22 Main results for studies which examined both physician and practice factors (n = 12)

Reference	N	Factors	Main results (multivariate analysis unless otherwise stated)
		Size (number of GPs)	Greater adherence in practices with greater number of GPs on team: β = 0.016 (95% CI: 0.006-0.026)
		Financial incentives	Practices with financial incentives had greater adherence: β = 0.085 (95% CI: 0.022-0.147)
Weiner et al.[253] [β]	2980 practices 10,000 physicians 97,388 patients	**Physician** Specialty (GP, internal medicine), multispecialty or single specialty (solo, partnership, single specialty group)	A greater (adjusted) proportion of patients of family medicine vs. internal medicine physicians had blood glucose measured during the study period: 84.0% vs. 79.9%, p = 0.001 A lower (adjusted) proportion of patients of general practice vs. internal medicine had an eye exam: 45.1% vs. 47.8%, p =.01, HbA1c test 10.8% vs. 16.7%, p =0.001, and cholesterol 49.8% vs. 57.5%, p =0.001 A lower (adjusted) proportion of patients of multidisciplinary physicians vs. internal medicine had an eye exam: 44.1% vs 47.8, p =.001, and cholesterol tested: 51.9% vs. 57.5%, p =0.001
		Practice Location (urban or rural)	Practices in an urban location had a higher (adjusted) proportion of patients with HbA1c test 17.2% vs. 14.5%, p = 0.001, cholesterol test 58.1% vs. 48.4%, p=0.001, and blood glucose 81.6% vs. 78.1%, p=0.001

Abbreviations: NR, Not Reported; OR, Odds Ratio; EHR, Electronic Health Record; GPs, General Practitioners

*Composite outcome

‖Patient-level covariates adjusted for in multivariate analysis

¶Physician-level covariates (additional to explanatory variables) adjusted for in multivariate analysis

[β]Practice-level covariates (additional to explanatory variables) adjusted for in multivariate analysis

§also includes patients for breast cancer screening; chlamydia screening; colorectal cancer screening; appropriate medications for people with asthma; testing for children with pharyngitis; and treatment for children with upper respiratory infection

Table 23 Quality assessment								
Study	**Were the criteria for inclusion in the sample clearly defined?**	**Were the study subjects and the setting described in detail?***	**Was the exposure measured in a valid and reliable way?‖**	**Were objective, standard criteria used for measurement of the condition?§**	**Were confounding factors identified?**	**Were strategies to deal with confounding factors stated?**	**Were the outcomes measured in a valid and reliable way?[α]**	**Was appropriate statistical analysis used?**
Alberti et al.	No	Partial	Yes	Unclear	Yes	Yes	Yes	Yes
Angstman et al.	Yes	Partial	Unclear	Unclear	Yes	Yes	Unclear	Yes
Balkau et al.	Yes	Yes	Unclear	Unclear	Yes	Yes	Unclear	Yes
Berthold et al.	Yes	Partial	Unclear	No	Yes	Yes	Unclear	Yes
Bower et al.	Yes	Partial	Yes	Unclear	Yes[β]	Yes	Yes	Yes
Bralic-Lang et al.	Yes	Partial	Yes	Unclear	Yes	Yes	Yes	Yes
Bredfelt et al.	Yes	Yes	Yes	Yes	Yes[β]	Yes	Yes	Yes
Brody et al.	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes

Campbell et al.	Yes	Partial	Unclear	Yes	Yes$^{\beta}$	Yes*	Yes	Yes*
Cebul et al.	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes
Cheung et al.	Yes	Partial	Yes	Yes	Yes	Yes	Yes	Yes
Cho et al.	Yes	Partial	Unclear	Yes	Yes	Yes	Yes	Yes
Crosson et al.	Yes	Partial	Yes	Yes	Yes	Yes	Yes	Yes
Dahrouge et al.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Dahrouge et al. (2016)	Yes	Partial	Yes	Yes	Yes	Yes	Yes	Yes
Dunn et al.	Yes	Partial	Yes	Yes	No	No	Yes	No
Ellerbeck et al.	Yes	Partial	Yes	Unclear	No	No	Yes	Yes
Erickson et al.	Unclear	Yes	Unclear	Unclear	Yes$^{\beta}$	Yes	Unclear	Yes
Esterman et al.	Yes	Yes	Yes	Unclear	Yes	Yes	Yes	Yes
Everett et al.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Fantini et al.	Yes	Partial	Yes	Yes	Yes	Yes	Unclear	Yes
Ferroni et al.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Franks et al.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Friedberg et al.	Yes	Partial	Yes	Unclear	Yes$^{\beta}$	Yes	Yes	Yes
Griffiths et al. (2010)	Yes	Partial	Yes	Unclear	Yes$^{\beta}$	Yes	Yes	Yes
Griffiths et al. (2011)	Yes	Partial	Yes	Unclear	Yes$^{\beta}$	Yes	Yes	Yes
Gulliford et al. (2001)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Gulliford et al. (2007)	Unclear	Partial	Yes	Unclear	Yes$^{\beta}$	Yes	Yes	Yes
Harris et al.	Unclear	Partial	Yes	Yes	No	No	Yes	No
He et al.	Yes	Yes	Yes	No	Yes$^{\beta}$	Yes	Yes	Yes
Holmboe et al. (2008)	Yes	Yes	Unclear	Yes	Yes	Yes	Yes	Yes
Holmboe et al. (2006)	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Juul et al. (2009)	Yes	Yes	Yes	Yes	Yes$^{\beta}$	No	Yes	Yes
Juul et al. (2012)	Unclear	Yes	Yes	Unclear	Yes	Yes	Yes	Yes
Kamien et al.	Yes	Partial	Yes	Unclear	No	No	Yes	No

Keating et al.	Yes	Partial	Yes	Yes	Yes	Yes	Yes	Yes
Kern et al.	Yes	Partial	Yes	Unclear	Yes$^{\beta}$	Yes	Yes	Yes
Khunti et al.	Unclear	Partial	Yes	Unclear	Yes$^{\beta}$	Yes	Yes	Yes
Kim et al.	Yes	Partial	Yes	Unclear	Yes	Yes	Yes	Yes
Kontopantelis et al.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Kuo et al.	Yes	Yes	Yes	Yes	Yes$^{\beta}$	Yes	Yes	Yes
Leblanc et al.	Yes	Partial	Unclear	Yes	Yes	Yes	Yes	Yes
Linder et al.	Unclear	Partial	Yes	Yes	Yes	Yes	Yes	Yes
Matthews et al.	Yes	Partial	Partial	Unclear	Yes	Yes	Yes	Yes
McCullough et al.	Unclear	Yes	Yes	Unclear	Yes$^{\beta}$	Yes	Yes	Yes
McGinn et al.	Unclear	Partial	Yes	Unclear	Yes$^{\beta}$	Yes	Yes	Yes
McLean et al.	Unclear	Partial	Yes	Unclear	No	No	Yes	Yes
Millett et al.	Yes	Partial	Yes	Unclear	No	No	Yes	Yes**
Mitchell et al.	Yes	Partial	Yes	Yes	Yes	Yes	Yes	Yes
Ohman et al.	Yes	Partial	Yes	Yes	Yes	Yes	Yes	Yes
Orzano et al.	Unclear	Partial	Yes	Yes	Yes	Yes	Yes	Yes
Parkerton et al. (2003)	Yes	Partial	Yes	Unclear	Yes$^{\beta}$	Yes	Yes	Yes
Parkerton et al. (2004)	Unclear	Partial	Yes	Unclear	Yes$^{\beta}$	Yes	Yes	Yes
Pham et al.	Yes	Partial	Yes	Yes	Yes	Yes	Yes	Yes
Poon et al.	Yes	Partial	Yes	Unclear	Yes$^{\beta}$	Yes	Yes	Yes
Ricci-Cabello et al.	Yes	Partial	Yes	Unclear	Yes$^{\beta}$	Yes	Yes	Yes
Shuval et al.	Yes	Partial	Yes	Unclear	Yes$^{\beta}$	Yes	Yes	Yes
Spann et al.	Yes	Partial	Yes	No	Yes	Yes	Yes	Yes
Spigt et al.	Yes	Partial	Yes	Yes	Yes$^{\beta}$	Yes	Unclear	Yes
Stearn et al.	Unclear	Partial	Partial	Unclear	No	No	Yes	No
Streja et al.	Yes	Partial	Yes	Yes	Yes	Yes	Yes	Yes
Suleman et al.	Yes	Yes	Yes	Unclear	Yes$^{\beta}$	Yes	Yes	Yes

Tabenkin et al.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Tahrani et al.	Unclear	Partial	Unclear	Unclear	No	No	Yes	Yes
Turchin et al. (2007)	Yes	Partial	Yes	Yes	Yes	Yes	Yes	Yes
Turchin et al. (2008)	Yes	Partial	Yes	Yes	Yes	Yes	Yes	Yes
Vamos et al.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Van Bruggen et al.	Yes	Partial	Yes	Unclear	Yes[β]	Yes	Yes	Yes
Van Doorn et al.	Yes	Partial	Yes	Unclear	Yes	Yes	Yes	Yes
Vinker et al.	Yes	Partial	Yes	Unclear	Yes[β]	Yes	Yes	Yes
Visca et al.	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Wang et al.	Unclear	Partial	Yes	Unclear	No	No	Yes	No
Weiner et al.	Yes	Yes	Yes	Yes	Yes[β]	Yes	Yes	Yes
Wencui et al.	Yes	Yes	Yes	Unclear	Yes[β]	Yes	Yes	Yes
Wong et al.	Yes	Partial	Yes	Yes	Yes	Yes	Yes	Yes
	Was true randomization used for assignment of participants to treatment groups?	**Were treatment groups treated identically other than the intervention of interest?**	**Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed?**	**Were participants analyzed in the groups to which they were randomized?**	**Were outcomes measured in the same way for treatment groups?**	**Were outcomes measured in a reliable way?**	**Was appropriate statistical analysis used?**	**Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and**

								analysis of the trial?
Dickinson et al.***	Unclear	No	Yes	Yes	Yes	Yes	Yes	Yes

*Partial if location and time period reported but no information (e.g. demographics) on population sampled from

‖Most studies used self-report survey to derive information on practice or physician factors so marked as 'yes' if this approach was used

§Most studies only stated that people with diabetes were included; some referred to ICD codes or diagnostic criteria. Marked as 'Unclear' where limited information was provided (e.g. QOF data), 'No' if diagnosis on basis of clinical judgement or patient self-report

βPatient-level confounders not identified

αGenerally this was determined from medical records, claims data, or data submitted to QOF (all taken as valid for this QA). Few studies mention the abstraction process or whether abstracters were trained, and whether quality assessment done.

**no detailed analysis because of large sample size

***The following questions were not applicable: Was allocation to treatment groups concealed? Were participants blind to treatment assignment? Were those delivering treatment blind to treatment assignment?

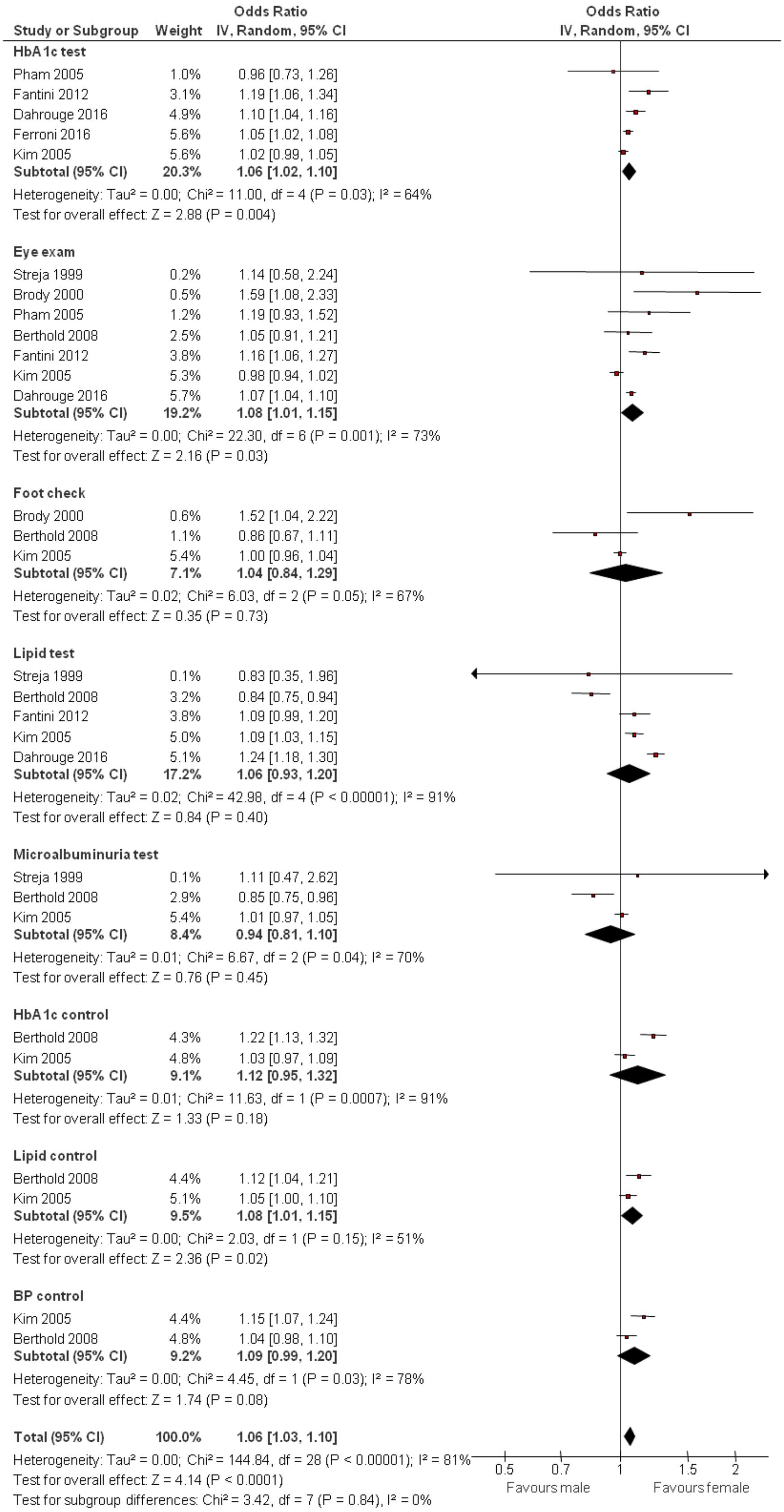


Figure 14 Gender and quality

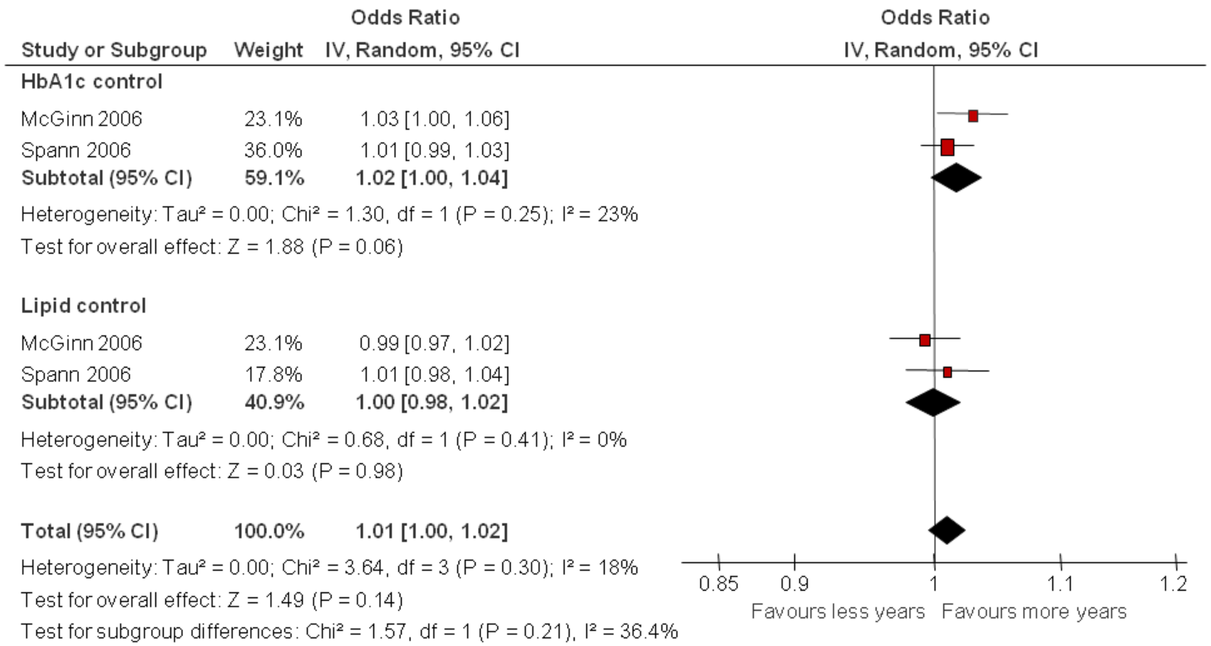


Figure 15 Physician experience and quality

Study or Subgroup	Weight	Odds Ratio IV, Random, 95% CI
HbA1c test		
Ferroni 2016	19.3%	1.01 [0.93, 1.10]
Holmboe 2006	13.6%	1.92 [1.48, 2.49]
Turchin 2007	20.1%	0.96 [0.93, 0.99]
Subtotal (95% CI)	**53.1%**	**1.15 [0.95, 1.39]**
Heterogeneity: Tau² = 0.02; Chi² = 27.65, df = 2 (P < 0.00001); I² = 93%		
Test for overall effect: Z = 1.41 (P = 0.16)		
Lipid test		
Holmboe 2006	14.6%	1.63 [1.29, 2.06]
Streja 1999	6.8%	1.08 [0.64, 1.82]
Subtotal (95% CI)	**21.4%**	**1.42 [0.97, 2.08]**
Heterogeneity: Tau² = 0.04; Chi² = 1.98, df = 1 (P = 0.16); I² = 50%		
Test for overall effect: Z = 1.82 (P = 0.07)		
Eye exam		
Holmboe 2006	16.9%	1.36 [1.15, 1.61]
Streja 1999	8.6%	1.05 [0.68, 1.62]
Subtotal (95% CI)	**25.5%**	**1.30 [1.06, 1.58]**
Heterogeneity: Tau² = 0.01; Chi² = 1.18, df = 1 (P = 0.28); I² = 16%		
Test for overall effect: Z = 2.56 (P = 0.01)		
Total (95% CI)	**100.0%**	**1.24 [1.05, 1.47]**
Heterogeneity: Tau² = 0.04; Chi² = 60.05, df = 6 (P < 0.00001); I² = 90%		
Test for overall effect: Z = 2.51 (P = 0.01)		
Test for subgroup differences: Chi² = 1.32, df = 2 (P = 0.52), I² = 0%		

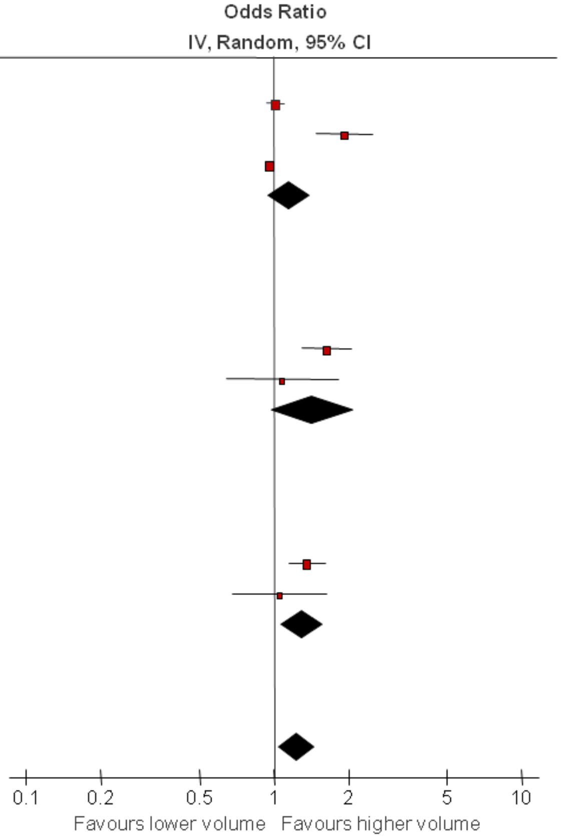


Figure 16 Diabetes volume and quality

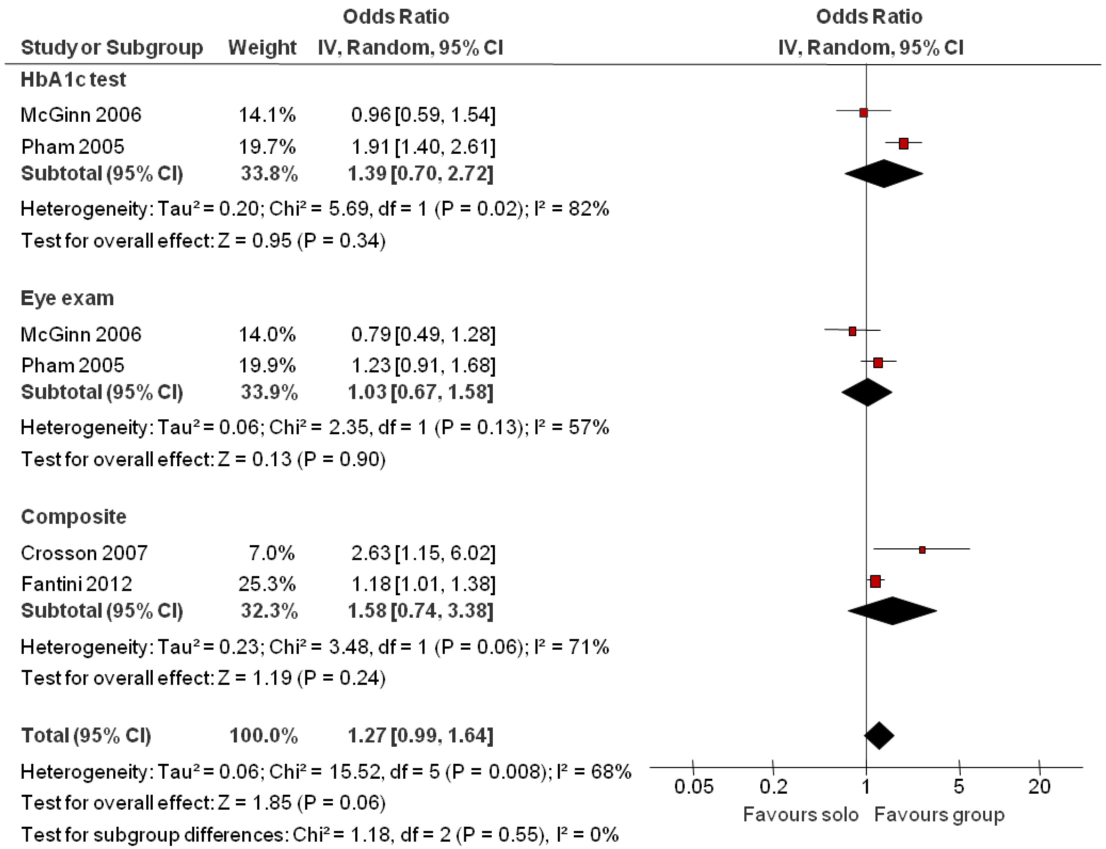


Figure 17 Type and quality

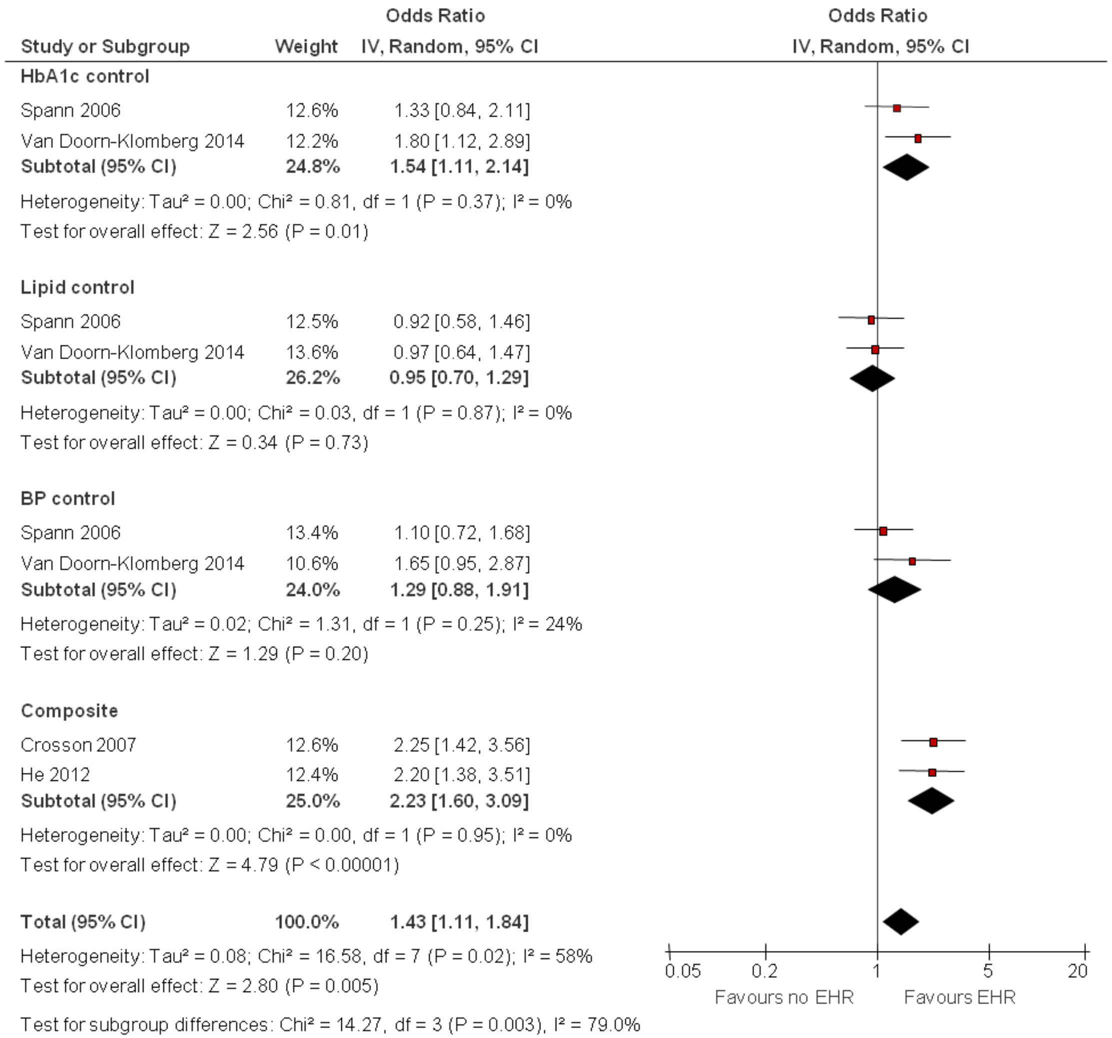


Figure 18 Electronic Health Record (HER) use and quality

10.3 Appendix 3 Supplementary files for Chapter 4

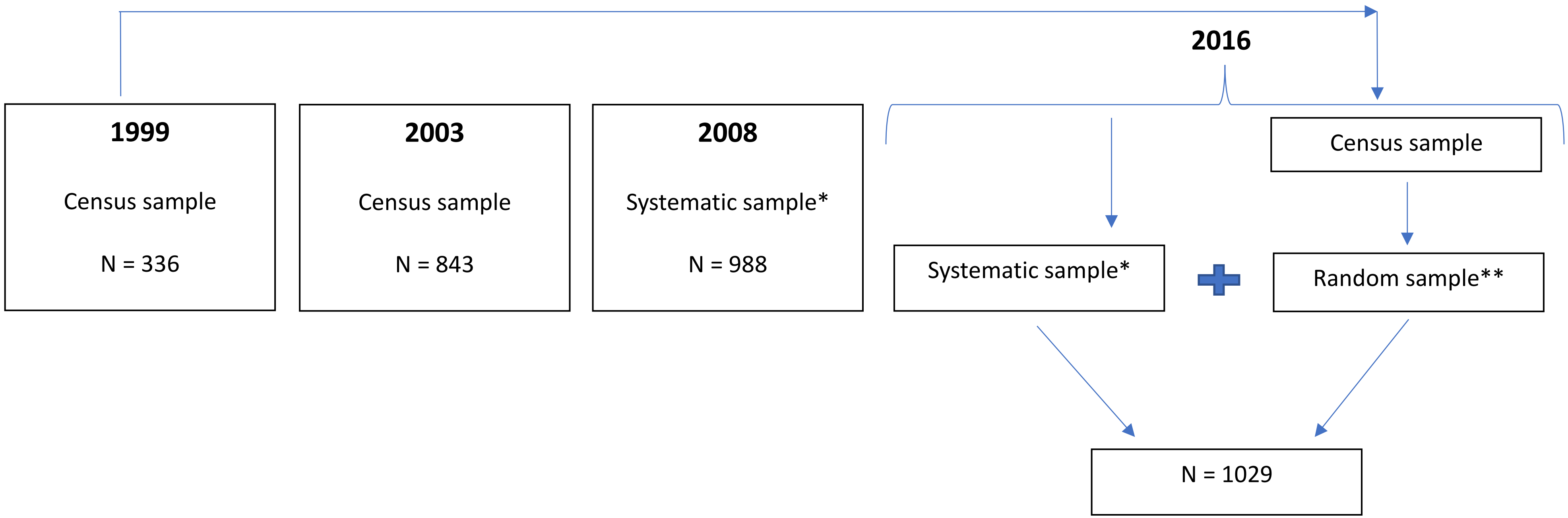


Figure 19 Sampling flow chart

*Participants were sampled by sorting alphabetically first by name and selecting every third person.

**After ordering randomly, every third person was sampled .

Table 24 Processes recorded among participants aged <75 years and ≥75 years with type 2 diabetes 1999 – 2016

	<75 years				**≥75 years**			
	1998/1999 N = 257	**2003 N = 655**	**2008 N = 745**	**2016 N = 741**	**1999 N = 79**	**2003 N = 187**	**2008 N = 243**	**2016 N = 287**
	N (%)	**N (%)**	**N (%)**	**N (%)**	**N (%)**	**N (%)**	**N (%)**	**N (%)**
BMI[*¶µβα]	165 (64)	380 (58)	560 (75)	517 (70)	38 (48)	90 (48)	164 (67)	219 (76)
Smoking status[¶]	181 (70)	493 (75)	572 (77)	578 (78)	49 (62)	136 (73)	186 (77)	234 (82)
HbA1c[*¶α]	216 (84)	625 (95)	735 (99)	734 (99)	68 (86)	173 (93)	231 (95)	286 (100)
Blood pressure[¶α]	242 (94)	649 (99)	740 (99)	725 (98)	69 (87)	186 (99)	238 (98)	282 (98)
Cholesterol[β*¶]	219 (85)	638 (97)	735 (99)	733 (99)	48 (61)	176 (94)	237 (98)	284 (99)
Triglycerides[µβα]	186 (72)	607 (93)	733 (99)	731 (99)	40 (51)	163 (87)	234 (96)	280 (98)
Creatinine[*¶]	175 (68)	541 (83)	732 (98)	730 (99)	59 (75)	154 (82)	238 (98)	285 (99)
ACR[*¶α‖]	NA	NA	549 (74)	628 (85)	NA	NA	162 (67)	214 (75)
Foot assessment	NA	363 (55)	523 (77)	398 (54)	NA	110 (59)	170 (78)	141 (49)

Abbreviations: ACR, Albumin Creatinine Ratio; BMI, Body Mass Index; NA, not available, data on this variable were not collected at this time point

*significant trend in <75 age group p < 0.05

¶significant trend in ≥75 age group p <0.05

[μ]significant difference in recording between <75 and ≥75 in 1999 $p < 0.05$

[β]significant difference in recording between <75 and ≥75 in 2003 $p < 0.05$

[α]significant difference in recording between <75 and ≥75 in 2008 $p < 0.05$

[‖]significant difference in recording between <75 and ≥75 in 2016 $p < 0.05$

Table 25 BMI and smoking status recording among participants with type 2 diabetes 1999 – 2016 attending 10 general practices enrolled in programme since 1999

Practice	Process	1998/1999 N (%)	2003 N (%)	2008 N (%)	2016 N (%)
1		N = 34	N = 61	N = 46	N = 47
	BMI*	9 (26)	32 (52)	46 (100)	47 (100)
	Smoking status	33 (97)	59 (97)	44 (96)	46 (98)
2		N = 29	N =29	N = 27	N = 14
	BMI	27 (93)	17 (59)	23 (85)	14 (100)
	Smoking status	22 (76)	12 (41)	24 (89)	12 (86)
3		N = 58	N = 116	N = 63	N = 49
	BMI*	42 (71)	90 (78)	48 (76)	48 (98)
	Smoking status	52 (88)	109 (94)	53 (84)	47 (96)
4		N = 53	N = 39	N = 31	N = 40
	BMI*	15 (27)	4 (10)	4 (13)	17 (43)
	Smoking status	14 (26)	20 (51)	7 (23)	18 (45)
5		N = 26	N =24	N =24	N = 29
	BMI	20 (74)	5 (21)	17 (71)	20 (70)
	Smoking status**	21 (78)	22 (92)	14 (58)	16 (55)
6		N = 16	N = 30	N =16	N = 17
	BMI**	16 (100)	18 (60)	12 (75)	1 (5.9)
	Smoking status**	15 (94)	29 (97)	15 (94)	7 (41)
7		N = 29	N = 28	N = 20	N = 27
	BMI*	19 (66)	19 (68)	19 (95)	27 (100)
	Smoking status	16 (55)	15 (54)	16 (80)	18 (67)
8		N = 30	N = 62	N = 56	N = 50
	BMI**	28 (88)	31 (50)	33 (60)	2 (4)
	Smoking status**	28 (87)	50 (81)	50 (91)	30 (60)
9		N = 39	N = 62	N = 54	N = 47
	BMI*	15 (38)	23 (37)	49 (91)	45 (96)
	Smoking status*	16 (41)	26 (42)	48 (89)	46 (98)
10		N = 17	N = 37	N = 20	N = 52
	BMI*	12 (71)	14 (38)	20 (100)	51 (98)
	Smoking status	13 (76)	27 (73)	20 (100)	39 (75)

Abbreviations: BMI, Body Mass Index

*significant $p < 0.05$

**significant decline in recording $p < 0.05$

Proportions were analysed using chi-squared test for trend and logistic regression adjusted for age and gender

Table 26 Demographics, duration and diabetes control among participants with type 2 diabetes in 2016 (n = 1,029)		
	HbA1c ≤58mmol/mol (7.5%) N = 770	**HbA1c >58mmol/mol (7.5%) N = 251**
Age Median (IQR)	69 (61-76)	65 (56-73)
Male	453 (59)	145 (58)
Diabetes duration (years)* Median (IQR)	8 (5-11)	11 (7-14)
Diabetes control*		
Diet only	167 (22)	6 (2.4)
OHA only	512 (67)	138 (49)
Insulin only	10 (1.3)	10 (3.9)
Insulin and OHA	54 (7.0)	84 (33)
Injectables and OHA	24 (3.1)	25 (10)
OHA or injectable‖	600 (78)	245 (98)

Abbreviation: OHA, oral hypoglycaemic agent; IQR, interquartile range

*significant p<0.001; difference in people with HbA1c ≤58mmol/mol and HbA1c > 58mmol/mol were analysed using Students t test or Wilcoxon-Mann-Whitney test for continuous data and Pearson’s chi squared for categorical data

‖OHA, insulin or other injectable

10.4 Appendix 4 Supplementary files for Chapter 5

Table 27 Data collected 1999 - 2016

Variable	1999	2003	2008	2016
Demographics				
Age	√	√	√	√
Sex	√	√	√	√
Diabetes type	√	√	√	√
Lifestyle				
BMI	√	√	√	√
Smoking status	√	√	√	√
Clinical				
HbA1c	√	√	√	√
Cholesterol	√	√	√	√
BP	√	√	√	√
Serum creatinine	√	√	√	√
eGFR (calculated using	√	√	√	√

CKD-EPI equation*)				
Complications				
Retinopathy	√	√	√	√
Foot ulcer	√	√	√	√
Macrovascular complication (new in past 12 months)	√	-	-	-
Attendance at renal clinic	√	√	√	√
Minor amputation	√	√	√	√
Death	-	-	-	√

Abbreviations: eGFR, estimated glomerular filtration rate; BP, blood pressure

*Females: eGFR = 141 X min(creatinine/0.7, 1)$^{-0.329}$ X max(creatinine/0.7, 1)$^{-1.209}$ X 0.993^{age} X 1.018; Males: eGFR = 141 X min(creatinine/0.9, 1)$^{-0.411}$ X max(creatinine/0.9, 1)$^{-1.209}$ X 0.993^{age}

Table 28 Clinical profile of participants 1999 – 2016

	1999 N = 376 Mean (95% CI)	2003 N = 337 Mean (95% CI)	2008 N = 271 Mean (95% CI)	2016 N = 192 Mean (95% CI)	Ptrend*
BMI (kg/m²)	29.3 (28.6-30.0)	29.2 (28.3-30.2)	30.2 (27.9-32.4)	29.9 (28.0-31.8)	0.100
HbA1c (mmol/mol [%])	55 (54-57) [7.2 (7.1-7.4)]	63 (60-66) [7.9 (7.6-8.2)]	56 (53-61) [7.3 (7.0-7.7)]	58 (55-62) [7.5 (7.2-7.8)]	0.03
Systolic BP (mmHg)†	144.3 (142.1-146.5)	141.1 (138.1-144.2)	135.3 (131.4-139.1)	133.7 (130.2-137.3)	<0.0001
Cholesterol (mmol/l)†	5.4 (5.2-5.5)	4.8 (4.7-4.9)	3.9 (3.7-4.1)	3.9 (3.8-4.2)	<0.0001
Triglycerides (mmol/l)†	2.4 (2.2-2.6)	2.0 (1.8-2.2)	1.5 (1.3-1.7)	1.4 (1.3-1.7)	<0.0001
eGFR (mL/min/1.73 m²)†	77.1 (74.3-80.0)	73.3 (70.7-75.9)	74.0 (68.4-79.6)	64.3 (58.5-70.1)	0.59

Abbreviations: eGFR, estimated glomerular filtration rate; BP, blood pressure

Adjusted for clustering by participant

*significant based on linear regression models adjusted for age and sex;

†significant p<0.05 unadjusted for age and sex

Table 29 Multivariable Cox survival analysis (n = 356)*

	Males (n = 179)						Females (n = 176)					
	Model 1			Model 2			Model 1			Model 2		
	HR	**95% CI**	**P**	**HR**	**95% CI**	**P**	**HR**	**95% CI**	**P**	**HR**	**95% CI**	**P**
Age (per 10-year increase)	2.66	[2.19,3.24]	<0.001	2.66	[2.11,3.34]	<0.001	2.14	[1.69,2.72]	<0.001	1.83	[1.40,2.40]	<0.001
BMI	1.01	[0.94,1.08]	0.82	1.02	[0.95,1.09]	0.65	0.98	[0.93,1.02]	0.51	0.98	[0.92,1.04]	0.47
Smoking												
No (ref)												
Yes	1.04	[0.61,1.79]	0.88	1.19	[0.63,2.24]	0.59	1.07	[0.64,1.79]	0.80	1.10	[0.63,1.91]	0.76
Clinical												
Systolic BP (per 10mmHg increase)	0.96	[0.81,1.13]	0.61	0.96	[0.82,1.14]	0.67	1.00	[0.86,1.16]	0.97	1.00	[0.85,1.17]	0.97
Cholesterol (mmol/l)	1.11	[0.83,1.47]	0.48	1.17	[0.89,1.60]	0.26	1.07	[0.83,1.38]	0.60	1.06	[0.80,1.40]	0.71
HbA1c (%)	1.16	[0.98,1.37]	0.08	1.18	[1.00,1.40]	0.06	1.09	[0.93,1.28]	0.29	1.09	[0.92,1.30]	0.32
eGFR (per 15 mL/min/1·73 m² increase)	0.83	[0.63,1.10]	0.19	0.83	[0.62,1.12]	0.22	0.76	[0.60,0.95]	0.02	0.75	[0.58,0.96]	0.03
Triglycerides (mmol/l)	0.92	[0.72,1.16]	0.46	0.82	[0.62,1.09]	0.17	1.02	[0.80,1.32]	0.85	0.97	[0.71,1.28]	0.74
Macrovascular complication												
No (ref)												
Yes	1·94	[1·35,2·79]	<0·001	2·06	[1·08,3·92]	0·03	1·92	[0·54,6·89,]	0·32	1·78	[0.49,6.48]	0.38

Abbreviations: eGFR, estimated glomerular filtration rate; BP, blood pressure; HR, hazard ratio

Model 1 adjusted for age and sex; Model 2 adjusted for all covariates

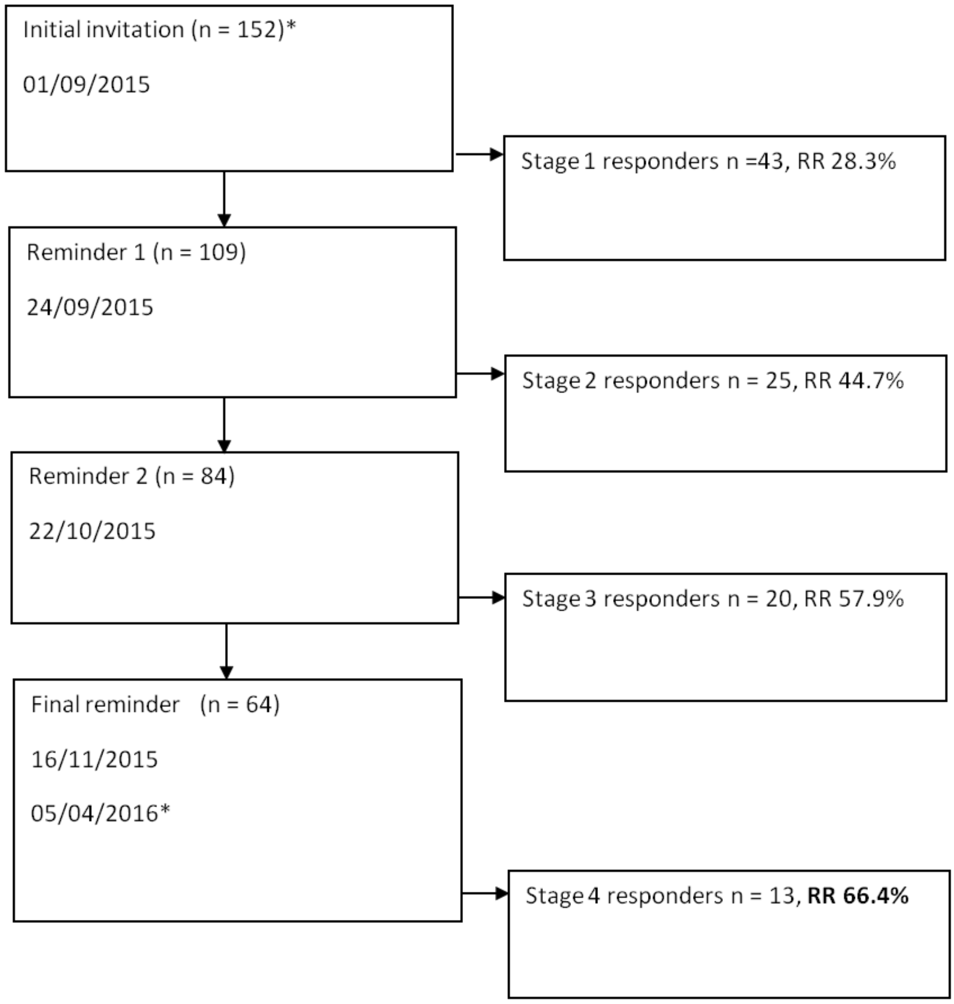
*imputed dataset; 164 with date of death; 79 men, 85 women; 18 excluded as no date of death derived from national records; 2 excluded as date of death preceded first data collection point

10.5 Appendix 5 Supplementary files for Chapter 6

10.5.1 Main modifications made to the questionnaire

- Questions on who employs and manages DNS were modified.
- The response to the question on the grade of their current position was changed.
- The direct question on research involvement (yes/no) was changed to instead ask the amount of time spent on research.
- There was no question on the content or topics covered in patient education sessions, or on the frequency or location of these sessions.
- DNS were asked about liaison not only with practice nurses but also with other professionals, GPs, hospital or community DNS, consultants, and the nature of this role.
- DNS were not asked specifically about involved in paediatric nursing.
- There was no open-ended question on reasons for not using nurse prescribing.

10.5.2 Recruitment response



Recruitment and survey response September 2015 – April 2016

*An alternative email address for one participant who had not responded was obtained in April and subsequently an invitation sent to this address also.

10.5.3 Other patients seen reported in open-ended comments

Other patients attending DNS services

Other patients attending DNS services mentioned by participants were patients with cystic fibrosis-related diabetes (n = 10) or steroid induced diabetes (n = 6), neonatal (n = 4), Maturity Onset Diabetes of the Young (MODY) (n = 4), posttransplant (n = 2), post pancreatic surgery (n = 3) patients, or with patients pancreatitis (n = 3), and those using insulin pumps (n = 3).

Other roles in patient care

Other roles in patient care were mentioned by hospital and community nurses (n = 35) and included, Diabetic Ketoacidosis (DKA) management (n = 2), endocrine patients with conditions involving the pituitary, thyroid, adrenal and other endocrine glands (n = 1), preparation for transition to adult services (n = 1), health screening for traveller groups (n = 1), primary and secondary school education (n = 1) and involvement in social care work (n = 1).

Types of clinics

Forty-four respondents reported the type of clinic they run. Most reported they ran clinics run for patients with T2DM (n = 15) or T1DM (n=11) needing review. Specialist clinics reported were pump training clinics (n = 5), clinics for GDM (n=8), pre-pregnancy/pre-conception (n = 5), transition clinics for young adults (n = 5), and paediatric clinics (n = 5).

Non-diabetic roles[2]

Fourteen respondents reported the roles they perform unrelated to diabetes, which included endocrine work (n = 4), management duties (n = 3), administration (n = 2)[3], patient advice (n =2), and teaching (n = 1).

[2]A closed question asked respondents "Do you cover roles not solely related to diabetes?" Fifteen responded "Yes" to this question, 14 of whom expanded on this in the open-ended comments.
[3]Administrative work relating to diabetes may have been seen by respondents as being different to general administrative work. When asked about time spent in administration, 58 respondents reported they spent time on this type of work, however, just 2 respondents indicated administration was work unrelated to diabetes

Table 30 Clinic activity, location and support by hospital (n = 59) and community (n = 23) nurses within each region

	Overall (n = 82)		Region 1 (n = 18)		Region 2 (n = 21)		Region 3 (n = 22)		Region 4 (n = 21)	
	Hospital (n = 59)	Community (n = 23)	Hospital (n = 11)	Community (n = 7)	Hospital (n = 17)	Community (n =4)	Hospital (n =17)	Community (n = 5)	Hospital (n =14)	Community (n= 7)
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Run nurse-led clinic										
Both	23 (39.0)	1 (4.3)	3 (27.3)	0 (0)	9 (52.9)	0 (0)	5 (29.4)	0 (0)	6 (42.9)	1 (14.3)
Generalised clinics only	19 (32.2)	12 (52.2)	5 (45.5)	4 (57.1)	3 (17.6)	2 (50.0)	9 (52.9)	3 (60)	2 (14.3)	3 (42.9)
Specialised clinics only	17 (28.8)	10 (43.3)	3 (27.3)	3 (42.9)	5 (29.4)	2 (50.0)	3 (17.6)	2 (40)	6 (42.9)	3 (42.9)
Number of nurse-led clinics per week										
1	9 (15.3)	3 (13.0)	2 (18.2)	1 (14.3)	3 (17.6)	0 (0)	1 (5.9)	0 (0)	3 (21.4)	2 (28.6)
2	17 (28.8)	5 (21.7)	3 (27.3)	1 (14.3)	3 (17.6)	2 (50.0)	5 (29.4)	0 (0)	6 (42.9)	2 (28.6)
3	5 (8.5)	3 (13.0)	0 (0)	1 (14.3)	0 (0)	0 (0)	3 (17.6)	1 (20)	2 (14.3)	1 (14.3)
≥4	27 (47.5)	12 (52.2)	6 (54.5)	4 (57.1)	11 (64.7)	2 (50.0)	8 (47.1)	4 (80)	3 (21.4)	2 (28.6)
Number of patients per clinic										
< 5	14 (23.7)	1 (4.3)	7 (63.6)	1 (14.3)	2 (11.8)	0 (0)	4 (23.5)	0 (0)	1 (7.1)	0 (0)
5	17 (28.8)	15 (65.2)	3(27.3)	4 (57.1)	4 (23.5)	3 (75.0)	4 (23.5)	4 (80)	6 (42.9)	4 (57.1)
10	17 (28.8)	7 (30.4)	0 (0)	2 (28.6)	6(35.3)	1 (25.0)	6 (35.3)	1 (20)	5 (35.7)	3 (42.9)
≥15	10 (16.9)	0 (0)	0 (0)	0 (0)	5 (29.4)	0 (0)	3 (17.6)	0 (0)	2 (14.3)	0 (0)
NA	1 (1.7)	0 (0)	1 (9.1)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Patients also see a consultant/GP										
No	8 (13.6)	7 (30.4)	0 (0)	1 (14.3)	3 (17.6)	1 (25.0)	4 (23.5)	2 (40)	1 (7.1)	3 (42.9)
At a later date	44 (74.6)	13 (56.5)	9 (90.9)	4 (57.1)	10 (58.8)	3 (75.0)	13 (76.5)	2 (40)	11 (78.6)	4 (57.1)
During the same visit	7 (11.9)	2 (8.7)	1 (9.1)	2 (28.6)	4 (23.5)	0 (0)	0 (0)	0 (0)	2 (14.3)	0 (0)

Table 30 Clinic activity, location and support by hospital (n = 59) and community (n = 23) nurses within each region

	Overall (n = 82)		Region 1 (n = 18)		Region 2 (n = 21)		Region 3 (n = 22)		Region 4 (n = 21)	
	Hospital (n = 59)	Community (n = 23)	Hospital (n = 11)	Community (n = 7)	Hospital (n = 17)	Community (n =4)	Hospital (n =17)	Community (n = 5)	Hospital (n =14)	Community (n= 7)
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
NA	0 (0)	1 (4.3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	0 (0)
Clinic location										
GP surgery	1 (1.7)	18 (78.3)	1 (9.1)	5 (71.4)	0 (0)	3 (75.0)	0 (0)	5 (100)	0 (0)	4 (57.1)
Primary care centre	0 (0)	7 (30.4)	0 (0)	1 (14.3)	0 (0)	1 (25.0)	0 (0)	4 (80)	0 (0)	1 (14.3)
Community outreach clinic	0 (0)	3 (13.0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (20)	0 (0)	2 (28.6)
Hospital	47 (79.7)	10 (43.5)	6(54.5)	2 (28.6)	14 (82.4)	2 (50.0)	14 (82.4)	2 (40)	13 (92.9)	4 (57.1)
Outpatients Dept.	27 (45.8)	7 (30.4)	8 (72.7)	1 (14.3)	8 (47.1)	1 (25.0)	5 (29.4)	3 (60)	6 (42.9)	2 (28.6)
Clinic support										
Consultant	50 (84.7)	10 (43.5)	11 (100)	2 (28.6)	12 (70.6)	1 (25.0)	14 (82.4)	2 (40)	13 (92.9)	5 (71.4)
Specialist Registrars	34 (57.6)	4 (17.4)	3 (27.3)	1 (14.3)	14 (82.4)	1 (25.0)	9 (52.9)	0 (0)	8 (57.1)	2 (28.6)
Senior House Officer	21 (35.6)	2 (8.7)	6 (54.5)	0 (0)	5 (29.4)	0 (0)	4 (23.5)	0 (0)	6 (42.9)	2 (28.6)
Intern	14 (23.7)	0 (0)	5 (45.5)	0 (0)	3 (17.6)	0 (0)	1 (5.9)	0 (0)	5 (35.7)	0 (0)
Practice nurse	2 (3.4)	17 (73.9)	1 (9.1)	4 (57.1)	1 (5.9)	2 (50.0)	0 (0)	4 (80)	0 (0)	7 (100)
GP	4 (6.8)	19 (82.8)	2 (18.2)	5 (71.4)	2 (11.8)	3(75.0)	0 (0)	4 (80)	0 (0)	7 (100)
Hospital DNS	31 (52.5)	11 (47.8)	8 (72.7)	2 (28.6)	9 (52.9	2 (50.0)	6 (35.3)	2 (40)	8 (57.1)	5 (71.4)
Community DNS	11 (18.6)	3 (13.0)	4 (36.4)	1 (14.3)	3 (17.6)	0 (0)	0 (0)	0 (0)	4 (28.6)	2 (28.6)
Podiatrist	21 (35.6)	9 (39.19)	6 (54.5)	3 (42.9)	7 (41.2)	1 (25.0)	3 (17.6)	1 (20)	5 (35.7)	4 (57.1)
Dietician	35 (59.3)	9 (39.19)	8 (72.7)	4 (57.1)	12 (70.6)	0 (0)	8 (47.1)	2 (40)	7 (50)	3 (42.9)
Psychologist	6 (10.2)	0 (0)	2 (18.2)	0 (0)	3 (17.6)	0 (0)	0 (0)	0 (0)	1 (7.1)	0 (0)
Healthcare Assistant	10 (16.9)	1 (4.3)	3 (27.3)	0 (0)	3 (17.0)	0 (0)	0 (0)	0 (0)	4 (28.6)	1 (14.3)

10.6 Appendix 6 Supplementary files for Chapter 7

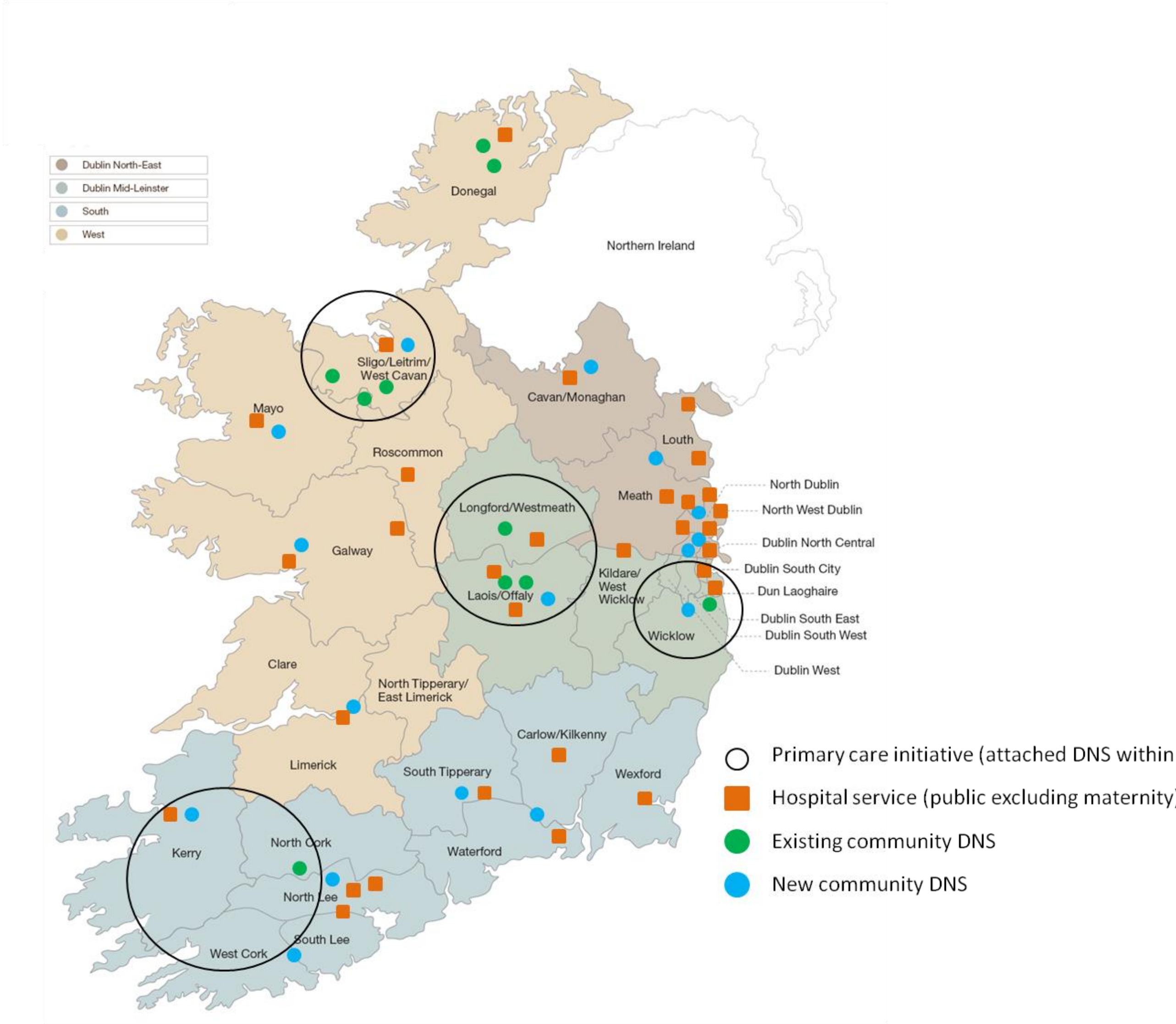


Figure 20 Hospital services, new and existing 'integrated' community posts (n = 26) across the four administrative regions of the health service

<u>Initiatives:</u> Diabetes in General Practice (69 practices in Cork and Kerry); HSE Midland Diabetes Structured Care Programme (30 practices in Laois, Offaly, Longford and Westmeath); HSE West (19 practices in Sligo and Leitrim); East Coast Area Diabetes Shared Care (25 practices in Dublin South and Wicklow)

10.6.1 Topic Guides

Topic guides exclude sections which focused specifically to other aspects of the National Programme for Diabetes (i.e. RetinaScreen, Model of Care for the Diabetic Foot) being explored as part of the broader study.

National Clinical Programme for Diabetes
Rationale: The role of the Diabetes Nurse Specialist is central to diabetes care and continues to evolve in response to the policies and practices within the health system. The number of Diabetes Nurse Specialists working in Ireland has increased in recent times, due in part to the changes introduced by the National Clinical Programme in Diabetes (NCPD). We want to know what you think about these changes, and how the national programme has impacted on your local service. As you know, we recently conducted a national survey of Diabetes Nurse Specialists in Ireland to assess the availability of specialist services in Ireland. We now want to hear about your experience providing diabetes care to understand in more detail, the challenges and opportunities for integrated care. We did some preliminary interviews about how services implemented as part of the NCPD are working so I would like to ask you about some of the theories that have come up and what your experience has been

The interview should last about 30 minutes

Just some general house-keeping before we start (Briefly go through consent form)

- If it is ok with you I will audio record the interview so I can give you my full attention and don't have to take any notes. This way I can be sure I don't miss anything.
- Anything we discuss will be confidential and your identity will remain anonymous on any reports or publications. We may use direct quotes from this interview but again I stress that your name will **not** appear anywhere. Your identity and position will be kept completely anonymous.
- Finally you can stop the interview at any point, if you wish. And you are free to withdraw from the study at any time.
- Do you have any questions for me before we get started?
- Sign consent and give copy.

NCPD outline

The National Clinical Care Programme for Diabetes was set up a couple of years ago. It brought together representatives from all the different disciplines involved in diabetes care to try and improve the way services are delivered. They do this in a number of different ways, for example designing models of care for patients or trying to secure additional resources and posts for diabetes. The National Programme was instrumental in developing the new model of integrated care (including the recruitment of integrated care nurses), the national retinopathy screening programme, RetinaScreen, and developing a standard Model of Care for the Diabetic Foot (including the recruitment of additional podiatrists etc).

TOPIC GUIDE (Community DNS)	
<u>Service provision/ DNS role</u> Can you tell me a bit about the diabetes service you provide here in XX? (i.e. Type of patients, referrals, where are you based, how does governance work)	Has this changed over time? How?
What is your role in the community?	What is your role for the 1 day in the hospital?
How did you set up the service in this area?	What was your approach to contacting GPs (day 1)? List of GPs? What was your approach to GPs who may not link in? What happens with those who do not engage with the service? Are all GPs able to access the service? Why (not)?
<u>Working with other professionals /across settings</u> How has your service received in your area? By GPs, PNs, In the hospital by consultants, by other DNS, patients?	Why do you think this is? How have you responded?
How has your role been received in secondary care?	
Do you have a liaison role with other professionals in the hospital/community?	With who? What does this involve/look like?

Anything which could be done differently in terms of the DNS role to facilitate working with other services/professionals? How do you find being based in both primary and secondary care?	Is there an agreement for how your service should work (primary & secondary care? What does this cover? How does it work? Between primary & secondary; within secondary care or the community? What are the challenges?
<u>Service changes</u> Have you seen any recent changes in how patients are managed between primary & secondary care here? Would you describe care as integrated[4]? (Why/Why not?) Do you follow the national model of care[5] in this area? Are you familiar with the National Clinical Programme for Diabetes?	What was this change? What do you think the impact of this is on patient care? On your own work?
<u>GP engagement with DNS</u> GP engagement with the new integrated DNS service has been varied (by which we mean in some areas DNS couldn't 'get in the door' in other areas they were 'welcomed'). Would this fit with your experience?	Why do you think that is?

[4]What we mean by integrated care is that patients are managed by primary and secondary care services depending on the complexity of their diabetes. There are good links between primary and secondary care (e.g. better access to hospital services for integrated care patients) and professionals in both sectors have an understanding of where different patients should be cared for. So, this would mean joint management of more complex patients, with less complex Type 2s mainly managed in primary care.

[5]The national model of care aims to standardise management of patients with diabetes, including management across primary and secondary care. It outlines the different roles of those involved in care i.e. GP, PNs, DNS, dieticians, their roles and responsibilities, along with the types of patients to be cared for across the two sectors, and those to be cared in secondary care

<u>Role of DNS</u> It has been suggested in previous interviews that there is variation in the nurse role in different areas. So the nurses have different roles[6] in practices (e.g. see different patient types of patients) What does your role involve in the practices you work with? Would you say your role varies - are there any parts you feel don't happen in certain places?	Why do you think that is?
<u>Integrated care in secondary care</u> We are trying to find out how the integrated role and the model of care is being implemented in secondary care. What has your experience been?	Clear how the model of care is meant to work in secondary care? (e.g. discharge back to community) Anything you think needs to be done in secondary care services for the MOC to work? (e.g. standardisation of GP referrals forms to facilitate discharge; discharge + advice to GPs) -MOC been seen as a positive or negative change? If so, why? - Is it clear how your role is meant to work in the hospital? How does governance work?
<u>Final questions</u> What parts of the DNS role work well and what don't? What facilitates or impedes you in delivering your role? Is there anything that I haven't touched on that you think is important?	Any way the role could be changed or improved?

TOPIC GUIDE (Hospital DNS)	
<u>Service provision/ DNS role</u> Can you tell me a bit about the diabetes service you provide here in XX? (i.e. Type of patients,	Has this changed over time? How?

[6]The intended role of the ICN was that they would act as a link between primary & secondary care, run clinics in primary care, provide training and support to practice nurses, serve as specialist support for GPs/practice nurses for complex patients & support GP/practice nurses in management of uncomplicated type 2 diabetes, be involved in structured education

referrals, where are you based, how does governance work) **<u>Working with other professionals / across settings</u>** How is your service received in your area? By GPs, PNs, In the hospital by consultants, by other DNS, patients?	Why do you think this is? How have you responded?
How are patients managed between primary & secondary care here? Would you describe care as integrated[7]? (Why/Why not?) Do you follow the national model of care[8] in this area? Are you familiar with the National Clinical Programme for Diabetes?	-Always been the case? -Any change in how they are managed? (Why (not)? -If change in secondary care…What was this change? Why? Impact of this is on patient care? On your own work?
<u>GP engagement with DNS</u> GP engagement with the new integrated DNS service has been varied (by which we mean in some areas DNS couldn't 'get in the door' in other areas they were 'welcomed').	Why do you think that is?

[7]What we mean by integrated care is that patients are managed by primary and secondary care services depending on the complexity of their diabetes. There are good links between primary and secondary care (e.g. better access to hospital services for integrated care patients) and professionals in both sectors have an understanding of where different patients should be cared for. So this would mean joint management of more complex patients, with less complex Type 2s mainly managed in primary care.

[8]The national model of care aims to standardise management of patients with diabetes, including management across primary and secondary care. It outlines the different roles of those involved in care i.e. GP, PNs, DNS, dieticians, their roles and responsibilities, along with the types of patients to be cared for across the two sectors, and those to be cared in secondary care.

Would this fit with your experience? Why do you think that is?	
<u>Integrated care in secondary care</u> We are trying to find out how the integrated role and the model of care is implemented in secondary care. What has your experience been?	Clear how the model is meant to work in secondary care? - Anything you think needs to be done in secondary care services for the MOC to work? (e.g. standardisation of GP referrals forms to facilitate discharge; discharge + advice to GPs) -Has the model of care been seen as a positive or negative change? If so, why? -How has the ICN service/role been received in the hospital by consultants and other DNS? Seen positively or negatively? Why? -Clear how this role is meant to work in the hospital? How does governance work?
<u>Final questions</u> What parts of the DNS role work well and what don't? What facilitates or impedes you in delivering your role? Is there anything that I haven't touched on that you think is important?	Any way the role could be changed or improved? -At level of nurse (e.g. support networks; own experience) -Wider infrastructure (e.g. space, staffing, ICT)

Table 31 DNS behaviours in relation to public health nurses which facilitate delivery of the DNS service and support public health nurses in their role
Contact public health nurses to arrange for patients to receive insulin in the community **Liaise with public health nurses to follow-up discharged patients in community** **Facilitate a faster turnaround for public health nurses on prescribing or adjusting insulin** *"They [*public health nurses*] know that we adjust the insulin…then the other thing is that it's done that day, it's a time turnaround. It's fast. It's not waiting for a week or maybe calling the GP out to adjust insulin when it can be done from here"* (HDNS17) **Facilitate or advise public health nurses to link with the GP to get the "*patient sorted"* (CDNS5)** **Facilitate public health nurse access to bloods or appropriate equipment** **Provide public health nurses with informal advice and education:**

"*They [*public health nurses*] were astounded to think that they would have to check a patient's glucose level before they would leave a dressing clinic, if they were a diabetic or on sulphonylureas. Because they didn't see it as being part of, a. the overall care and b. part of their role*" (CDNS7)

"*Because I'm in the open plan office they'll come by to run something by me. So they'll have learned a lot about diabetes*" (CDNS5)

Benefit from public health nurse knowledge:
"*They have direct links, they know the family dynamics and everything, they're on the ground*" (CDNS1)

10.7 Appendix 7 Research output and dissemination

10.7.1 Reports

- **Riordan F**., McHugh S., Marsden P., Kearney P., Harkins V. Audit Report of the HSE Midland Diabetes Structured Care Programme. Department of Public Health, Health Service Executive Dublin Mid-Leinster. 2017. Available from: http://www.lenus.ie/hse/handle/10147/621484

- Overview of Activity Data in Primary Care from Clinical Nurse Specialist (CNSp) Diabetes Integrated Care Group. Available from: https://www.hse.ie/eng/about/who/cspd/ncps/diabetes/resources/an-overview-of-activity-data-from-clinical-nurse-specialist-report.pdf

10.7.2 Additional non-thesis related research published during the PhD

- **Riordan F**, McGann R, Kingston C, Perry I. Schulze M, Andersen L, *et al* (2018) A systematic review of methods to assess intake of saturated fat among healthy European adults and children: A DEDIPAC (Determinants of Diet and Physical Activity) study. *BMC Nutrition,* 4(21)

- Spillane A., Larkin C., Corcoran P., Matvienko-Sikar K., **Riordan F**., Arensman E. (2017) Physical and psychosomatic health outcomes in people bereaved by suicide compared to people bereaved by other modes of death: a systematic review. *BMC Public Health*, 17:939.

- **Riordan F**, Ryan K, Perry I, Schulze M, Andersen L, Geelen A *et al* (2017) A systematic review of methods to assess intake of sugar-sweetened beverages among healthy European adults and children: A DEDIPAC study. *Public Health Nutrition,* 20(4), 578-597

- **Riordan F**, Ryan K, Perry I, Schulze M, Andersen L, Geelen A *et al* (2017). A systematic review of methods to assess intake of fruits and vegetables among healthy European adults and children: A DEDIPAC study. *Public Health Nutrition,* 20(3), 417-448

- McHugh S, Tracey ML, **Riordan F**, O'Neill K, Mays N, Kearney PM. (2016) Evaluating the implementation of a national clinical programme for diabetes to standardise and improve services: a realist evaluation protocol. *Implementation Science,* 11:107

- Fealy G, Munroe D, **Riordan F**, Croke F, Conroy C, McNamara M, Shannon M. Clinical handover practices in maternity services in Ireland: A qualitative descriptive study. *Midwifery*, 2016 39: 20-26

- **Riordan F**, Papoutsi C, Reed JE, Marston C, Bell D, Majeed A. (2015) Patient and public attitudes towards informed consent models and levels of awareness of Electronic Health Records in the UK. *International Journal of Medical Informatics*, 84(4):237-247

10.7.3 Policy briefs

Health Policy Brief. Supporting Community Diabetes Nurse Specialists to integrate care in the Irish health service: Qualitative findings from the National Study of Diabetes Nurse Specialists. Prepared by F Riordan, SM McHugh, PM Kearney. December 2017

10.7.4 Research dissemination

Table 32 Conferences attended by the author

Paper	**Conference proceedings**

Diabetes Nurse Specialist services in Ireland: A cross-sectional survey. Riordan F, McHugh SM, Murphy K, Barrett J, Kearney PM.	*Oral presentation* Society for Social Medicine Annual Scientific Meeting, York, Sept. 2016. National Health Services Research Institute Research day, Cork, Nov. 2016 *Poster presentation* UCC School of Nursing and Midwifery Annual Research Conference, Nov. 2016 UCC New Horizons conference, Dec. 2016
Trends in the Quality of Structured Diabetes Care in Primary Care. Riordan F, McHugh SM, Marsden P, Harkins V, Kearney PM.	*Oral presentation* Jacqueline Horgan Bronze Medal Meeting, Dublin, Nov. 2016 International Conference on Integrated Care, Dublin, May 2017 International Society of Quality in Healthcare (ISQua) Conference, London, Oct. 2017 *Poster presentation* Society for Social Medicine Annual Scientific Meeting, York, Sept. 2016. National Health Services Research Institute Research day, Cork, Nov. 2016 Association of University Department of General Practice in Ireland Scientific meeting, Limerick, March 2017
Long term outcomes and mortality among patients enrolled in a structured primary care-led diabetes programme. Riordan F, McHugh SM, Marsden P, Harkins V, Kearney PM.	*Oral presentation* Association of University Department of General Practice in Ireland Scientific meeting, Limerick, March 2017 *Elevator pitch* Society for Academic Primary Care Annual Scientific Meeting, Coventry, July 2017 *Poster presentation*

	International Conference on Integrated Care, Dublin, May 2017
Challenges experienced by community-based clinical nurse specialists in supporting the delivery of integrated diabetes care: a qualitative study. Riordan F, McHugh SM, McGrath NM, Kearney PM.	*Oral presentation* Society for Social Medicine Annual Scientific Meeting, Manchester, Sept. 2017 Jacqueline Horgan Bronze Medal Meeting, Dublin, Nov. 2017 School of Nursing and Midwifery Annual Research Conference, Cork, Nov. 2017 Structured Population and Health Services Research Education (SPHeRE) conference, Dublin, Jan. 2018 *Poster (not presented)* International Conference on Integrated Care, Utrecht, May 2018

10.8 Appendix 8 PhD education and training

10.8.1 Awards

- Short-listed for the Jacqueline Horgan Bronze Medal Prize for Epidemiology, 2016 and 2017
- Awarded student travel bursary by the College of Medicine and Health to attend a course on focus groups at the University of Oxford (March 2016)
- Awarded student bursary by Society of Social Medicine to cover registration fees, travel and accommodation for Society for Social Medicine Annual Conference, University of York (September 2016)

Table 33 Training and workshops attended during PhD

Year	Course	Facilitator
	Modules for credit	
	PG 7021 The Ethics of Healthcare Research Module	Dr Kieran Doran
	PG 6003 Teaching and Learning for Graduate Studies	Dr Marian McCarthy
	Other courses	
2016	PG7016 Systematic reviews for the health sciences	Prof. John Browne
2016	Introduction to Focus Groups Oxford Health Experiences Research Group (HERG)	Dr Jenny Hislop
2016	PG6008 Qualitative Data Analysis and Computer Assisted Qualitative Data Analysis (CAQDA) Software for the Social Sciences and Humanities, Day 1 and 2	Mr Ben Meehan
2017	Analysing Qualitative Interviews, Oxford HERG	Dr Jenny Hislop
2017	Mixed Methods Research Training, RCSI	Prof. Alicia O’Cathain

2017	Cochrane Ireland, Cochrane Systematic Review course	
	Workshop	
2016	Symposium on Evidence Synthesis in Health Professions Education Workshop 3: Introduction to Realist Reviews.	Dr Geoff Wong
2016	Health Economics Masterclass NUIG	Multiple speakers

10.9 Appendix 9 Department contribution

Table 34 Teaching and supervision contributions

Teaching			
Year	**Course**	**Module**	**Role**
2016-2017	BSc Public Health	EH3012	Tutor
2017-2018	BSc Public Health	EH3012	Tutor
2017-2018	BSc Public Health	EH2007	Tutor (substitute)
2017	Masters Occ. Health	EH6080	Guest lecturer (Introduction to Survey Design)
2018	BSc Public Health	EH2007	Tutor
Supervision			
Year	**Course**	**Lead supervisor(s)**	
2015	MPH student	Dr Eoin Coughlan	
2015	MPH student	Dr Janas Harrington	
2016	MPH student	Dr Martin Davoran	
2016	MPH student	Dr Sheena McHugh	
2017	MPH student	Dr Eilis O'Reilly	
2018	MPH student	Prof. Patricia Kearney	

Department seminars

Organised for 2016/2017 academic year (30 seminars in total)

10.10 Appendix 10 Published papers, ethical approval for the studies included in the thesis, and the national DNS survey (Chapter 6)

BMJ Open

The role of nurse specialists in the delivery of integrated diabetes care: a cross-sectional survey of diabetes nurse specialist services

Fiona Riordan,[1] Sheena M McHugh,[1] Katie Murphy,[2] Julie Barrett,[1] Patricia M Kearney[1]

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► Prepublication history and additional material for this paper are available online. To view these files please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2016-015049).

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ABSTRACT

Objectives International evidence suggests the diabetes nurse specialist (DNS) has a key role in supporting integrated management of diabetes. We examine whether hospital and community DNS currently support the integration of care, examine regional variation in aspects of the service relevant to the delivery of integrated care and identify barriers to service delivery and areas for improvement.

Design A cross-sectional survey of hospital and community-based DNS in Ireland.

Methods Between September 2015 and April 2016, a 67-item online survey, comprising closed and open questions on their clinical role, diabetes clinics, multidisciplinary working, and barriers and facilitators to service delivery, was administered to all eligible DNS (n=152) in Ireland. DNS were excluded if they were retired or on maternity leave or extended leave.

Results The response rate was 66.4% (n=101): 60.6% (n=74) and 89.3% (n=25) among hospital and community DNS, respectively. Most DNS had patients with stable (81.8%) and complicated type 2 diabetes mellitus (89.9%) attending their service. The majority were delivering nurse-led clinics (81.1%). Almost all DNS had a role liaising with (91%), and providing support and education to (95%), other professionals. However, only a third reported that there was local agreement on how their service should operate between the hospital and primary care. Barriers to service delivery that were experienced by DNS included deficits in the availability of specialist staff (allied health professionals, endocrinologists and DNS), insufficient space for clinics, structured education and issues with integration.

Conclusions Delivering integrated diabetes care through a nurse specialist-led approach requires that wider service issues, including regional disparities in access to specialist resources and formalising agreements and protocols on multidisciplinary working between settings, be explicitly addressed.

Strengths and limitations of this study

- This study is the first to examine the provision of diabetes nurse specialist (DNS) services nationally in Ireland.
- A comprehensive questionnaire that was employed in a previous UK study and adapted for the Irish context was used for the study.
- Although the support of the Irish Diabetes Nurse Specialist Association and other sources was enlisted to generate the sampling frame, there is no definitive list of all DNS in Ireland.
- Only a small number of nurses work in both hospital and community roles; therefore, we did not distinguish between DNS who are solely based in the community and those in new posts working between hospital and community.

BACKGROUND

In recent years, internationally and in Ireland, there has been increased interest in how to deliver integrated care for people with chronic diseases such as type 2 diabetes mellitus (T2DM),[1 2] coordinating management so that patients receive the 'right services' in the 'right place'.[3] The complex nature of diabetes necessitates the involvement of healthcare professionals from different disciplines and settings to achieve effective management.[2] Integrated diabetes management across community-based and specialist services has been shown to improve quality of care[4 5] and reduce preventable hospitalisations for diabetes-related complications.[6]

International evidence suggests the nurse specialist has a key role in supporting the integrated management of chronic disease[7] through delivering nurse-led clinics in primary care,[8 9] liaising between care providers[5 9–11] and providing specialist education and support to other professionals,[5 10] including those in primary care.[9 12 13] The shift towards primary care management of T2DM has meant the role has been increasingly moved into community settings.[14] The UK[13] and the

Netherlands[5 8] have seen the introduction of models of care where the diabetes nurse specialist (DNS) supports general practitioners (GPs) or practice nurses (PNs) in diabetes management[8 13] (eg, intermediate care clinics for diabetes (ICCD), which accept referrals of more complex patients to reduce the burden to the hospital system[15]), or performs tasks previously conducted by the GP, including coordination and organisation of care (vertical task substitution).[8] These models have been found to improve clinical outcomes,[5 8] reduce inappropriate referrals to secondary care,[13] and may reduce outpatient attendances.[15 16] However, the role and work setting of DNS differ between countries.[17–19] For example, in Sweden and the Netherlands, half or more of DNS may work in integrated or community settings and have prescribing rights.[11 17] In contrast, most DNS in Ireland are hospital-based, and although nurse prescribing has been introduced since 2008, not all nurses perform this role. Given these differences, it is important to establish how the DNS role within the specific health system supports an integrated and sustainable model of diabetes care.

In Ireland, the importance of nurse specialists in chronic disease management and facilitating integrated care between settings has been recognised.[20–22] The National Clinical Programme for Diabetes (NCPD), established in 2010 to improve care for people with diabetes in Ireland, is developing the DNS service by introducing more community-based DNS to facilitate the delivery of a new model of integrated diabetes care.[23] These changes are taking place within a traditionally hospital-centric healthcare system where there is a disconnect between secondary and primary care services in how they are funded, managed and resourced. Diabetes services have historically been unstructured and characterised by pockets of good provision and a mix of care arrangements.[20] In some areas diabetes care is primarily hospital-led; in others, care is delivered in general practice, sometimes on an opportunistic and ad-hoc basis. Chronic disease management in secondary care is also not well integrated with general practice,[22] not all areas have a local diabetes service, and within general practice the delivery of diabetes care may be variable. In many areas, there are deficiencies in terms of access to specialist resources, including DNS.[24–26] This has driven the development of formal diabetes initiatives (10 nationally) that seek to improve the quality and organisation of care at a local level. These include models of structured or shared care with local clinical guidelines and support from a community DNS to facilitate communication between these practices and the hospital,[9] or enhanced access to specialist community resources, including dietetics, podiatry and DNS.[27]

The purpose of the new integrated care model is to standardise management of diabetes. It aims to ensure patients are cared for in the most appropriate setting and by the most appropriate healthcare professionals. As outlined in the latest guidance on diabetes management,[28] patients with uncomplicated T2DM are managed in primary care, patients with complicated T2DM are managed between primary and secondary care, and management of type 1 diabetes mellitus (T1DM) and gestational diabetes mellitus (GDM) takes place in secondary care. Implementation of the new model may vary depending on local circumstances and context, including existing models of care. Newly introduced DNS have, in some areas, been linked to existing initiatives, whereas in other areas the service was entirely new. The current study may identify some of these regional variations and forms part of a programme of work evaluating the implementation of the NCPD.[29]

The new reforms can be understood as evidence-based strategies to integrate care at the level of service organisation and delivery (eg, promoting multidisciplinary teamwork through establishing the DNS as a ‘link’ between services; providing dedicated support by nurse specialists to primary care professionals) and at the clinical level (eg, introduction of guidelines on practice management).[28] Similar to the ICCDs established in the UK, these new DNS will provide necessary intermediary specialist support in the community in the management of more complex patients. They provide education and support for GPs and PNs, and work between community (80%) and hospital settings (20%), facilitating integration between the two settings.[28] DNS may deliver clinics in general practice, independently, or in some cases initially jointly with the PN or GP, to build capacity, confidence and skills in the management of more uncomplicated patients.

Although DNS support for patients and health professionals is a pillar of the national strategy for delivering integrated diabetes care, unlike other countries,[5 10 11 19 30] there is a dearth of information on how DNS services are delivered in Ireland. Our aim is to examine the way and extent to which DNS services currently support the integration of care and identify areas for improvement. We expect hospital and community DNS to differ in terms of the patients they provide care to and the professionals they support and are supported by. Therefore we describe the role of these DNS separately. Given the current variation in how diabetes services are delivered in Ireland, some aspects of the DNS role that are important in the integration of care (nurse-led clinics, agreements on working across primary and secondary care, access to other professionals) may differ across the country. Therefore, we examine these by region. Finally, we identify barriers and facilitators to delivering diabetes care from the DNS perspective. The study will provide an insight into how the DNS role works in the context of a traditionally fragmented health system characterised by regional variation and ongoing efforts to standardise and improve how diabetes care is delivered.[23]

METHODS

Participants

The eligible study population comprised all currently employed DNS (n=152), excluding retired DNS, those on maternity or extended leave. Registration with the Irish Diabetes Nurse Specialist Association (IDNSA) is not mandatory, and there is no national register of DNS posts in Ireland. Therefore, we compiled a list through regional primary care initiatives, IDNSA, Diabetes Ireland, the national diabetes charity which funds the provision of some DNS posts, and the NCPD, which highlighted the survey at national and local conferences and meetings. The IDNSA asked their members to register their details with the study researchers.

Questionnaire

Participants were invited by e-mail to complete the self-administered, 67-item questionnaire electronically (SurveyMonkey) between September 2015 and April 2016. The survey was based on a questionnaire developed by Diabetes UK and Association of British Clinical Diabetologists (ABCD) Specialist Services Study Group,[19] modified for the Irish health system in collaboration with a local nurse network, and piloted with two DNS, both of whom worked across hospital and community settings. Adaptations related to the questionnaire are included as online supplementary material. The survey comprised closed and open-ended questions addressing the DNS' role in diabetes, clinic activity, links with other services, the nature of service agreements and their liaison role, and barriers and facilitators to service delivery (online supplementary material). Three reminders were sent, the final in conjunction with an e-mail notification from the IDNSA (online supplementary material).

Data management and analysis

Data were cleaned in Excel before importing into Stata (SE V.12) for analysis. Fisher's exact tests were used to test differences in the role performed between hospital and community, and to examine service provision (clinics, referrals, local agreements) across the four regions defined according to the Diabetes Services Implementation Groups (DSIG), which are clinically led regional networks responsible for local implementation of the national programme. A p value of <0.05 was considered statistically significant. The Bonferroni correction was used to adjust for multiple comparisons. Complete case analysis was used and missing data are highlighted as applicable. NVivo (V.11) was used to manage and categorise open-ended responses. FR conducted a thematic analysis of responses to the questions on barriers and facilitators. The grouping of codes to generate overarching themes was reviewed by JB.

RESULTS

The response rate was 66.4% (n=101): 60.6% (n=74) of hospital and 89.3% (n=25) of community DNS. This included six advanced nurse practitioner or advanced midwife practitioner grade nurses, two clinical nurse managers, and three diabetes nurses not graded as DNS but who were qualified and performing the role of DNS. Two DNS in non-clinical roles were classified as 'Other'. DNS from all four DSIGs and all counties in the Ireland participated. Most were hospital-based (table 1).

Table 1 Characteristics of the sample population (n=101)

	N (%)
Based	
Hospital	74 (73.3)*
Community	25 (24.8)†
Other	2 (2.0)
Service area	
Adult	66 (65.4)
Paediatric only	14 (13.9)
Maternity only	5 (5.0)
All three service areas	9 (8.9)
Adult and paediatrics	3 (3.0)
Adult and maternity	2 (2.0)
Other	2 (2.0)
Region	
1	23 (22.8)
2	25 (24.8)
3	27 (26.7)
4	26 (25.7)
Age	
25–34	9 (8.9)
35–44	36 (35.6)
45–54	38 (37.6)
55–64	18 (17.8)
Education	
Masters in diabetes	11 (10.9)
Diabetes counselling course	7 (6.9)
PGDip in diabetes nursing	81 (80.2)
Certificate in diabetes nursing (including e-learning)	22 (21.8)
Masters in primary care	1 (1.0)
Registered nurse prescriber	37 (36.6)
Employer‡	
Health Service Executive	84 (83.1)
Private	9 (8.9)
Other	6 (5.9)
Employment	**Mean (SD)**
Years working as a DNS§	11.2 (7.4)
Years in current position¶	8.1 (6.8)

*Includes six advanced nurse practitioner or advanced midwife practitioner grade nurses, two clinical nurse managers, and three diabetes nurses not graded as DNS but qualified and performing role of DNS.
†Includes 16 integrated care nurses recruited as part of the national programme.
‡Missing data for two respondents.
§Missing data for three respondents.
¶Missing data for one respondent.
DNS, diabetes nurse specialist.

Respondents were working as a DNS for an average of 11 years. Although most had completed a postgraduate diploma in diabetes, few (10.9%) had a master's-level qualification, and just over a third (36.6%) were nurse prescribers.

DNS role

Most DNS had a written job description (n=89, 88.1%). All DNS were involved in some aspect of patient management (table 2), but this differed by setting. More hospital than community DNS were involved in inpatient care, and specific elements of care for patients with T1DM (referrals, glucose monitoring, insulin initiation or education, checking injection sites) (p<0.001) and provision of specialist clinics (non-significant) (table 2). While most hospital and community DNS reported that patients with complicated T2DM attended their service, the majority also saw patients with stable T2DM (figure 1). In two regions a greater proportion of nurses reported seeing stable T2DM (R1: 95.7%; R2: 70.8%; R3: 88.9%; R4: 72%). Other patients seen were reported in open-ended comments (online supplementary material).

Of the 58 (59.2%) DNS who spent time on administrative work, the mean hours per week were 4.8±2.5 and 5.7±2.8 among hospital and community DNS, respectively. Few spent time on research or audit (n=36, 35.6%); on average, hospital DNS spent 1.5±0.8 hours per week while community DNS spent 2.3±1.6 hours. Few DNS had a dedicated budget (n=16, 16.3%) or protected time (n=27, 27.5%) for continuing professional development (CPD).

Clinics

Nurse-led clinics can be understood as clinics where DNS may work without immediate supervision and are responsible for case management. Overall, 81.1% (n=82) of DNS delivered nurse-led clinics, including generalised clinics (n=31, 37.8%), specialised (n=27, 32.9%) or both (n=24, 29.3%).

The greatest proportion of DNS provided ≥4 clinics per week (48.8%). While similar across most regions (R1: 55.6%; R2: 61.9%; R3: 54.6%; R4: 23.8%), frequency in R4 was consistently lower. This was true among both DNS types: overall 52% community DNS provided ≥4 clinics (R1: 57.1%; R2: 50%; R3:8 0% R4: 28.6%) and 47.5% of hospital DNS provided ≥4 clinics (R1: 54.5%, R2: 64.7%, R3: 47.1%, R4: 21.4%) (online supplementary material).

Some DNS were supported in clinics by other members of the multidisciplinary team, for example a podiatrist (n=30, 36.6%) or dietician (n=44, 53.7%). Most community DNS were supported in clinic by a PN (73.9%). According to hospital and community DNS, patients generally saw a consultant (74.6%) or GP (56.5%) at a later date rather than on the day of the clinic.

Half reported a waiting list for their clinic service. Where reported (n=41), the waiting time was commonly 1–3 months (n=20), ranging from >1 month (n=5) to a year or more (n=4). The main reasons reported in open-ended comments (n=51) were the referral volume (n=24) and shortage of clinical staff (n=12). Of 24 respondents who provided clinics in the community, 12 reported that GPs were eligible to access those clinics, and in open-ended comments (n=11) indicated the service was available to GPs who were enrolled in a shared or structured care scheme (n=6), interested in diabetes care or willing to engage with the integrated care programme (n=3), or those practices employing a PN (n=2). Respondents reported that clinics were currently inaccessible where the service was at capacity or the catchment area was too large for the DNS to cover (n=4).

Links with other professionals

Most DNS (n=94, 95%) were educating other professionals, primarily hospital-based nursing staff by hospital DNS (81.2%), and PNs (92%) and GPs (88%) by community DNS. Community DNS were involved in education of allied health professionals (52%) and staff in nursing homes (21.6%) (table 2).

Most DNS liaised with other healthcare professionals (n=92, 91.1%) (table 2). As outlined in open-ended responses (n=83), this role involved patient case discussion (n=40) and follow-up (n=8), referrals (advising but also being able to facilitate fast-track into hospital) (n=18), providing advice (n=13) and education (n=7) to other staff, seeking advice from consultants (n=6), and being a coordinator or 'link' between services (n=10).

Over one third of DNS (n=37, 36.6%) reported there was no discharge pathway to primary care for ward discharges (R1: 30.4%; R2: 40%; R3: 44.4%; R4: 30.8%), and a third (n=36, 36.7%) reported there was an agreement between the hospital and primary care outlining how their service operates (R1: 50%; R2: 16.7%; R3: 33.3%; R4: 48%). As outlined in open-ended comments (n=29) local agreements included following a shared care model (n=6) or integrated model (regular GP review with annual secondary care review) (n=5), working 80/20 between community/hospital (n=5), rapid referral pathways from primary care into hospital (n=3) or being able to discharge patients to primary care (n=2).

While almost all DNS reported referral access to other professionals (n=92, 91.1%), there were regional differences in access to social workers (p=0.01) and psychologists (p=0.01) (figure 2) (non-significant after adjustment).

Barriers and facilitators to delivering diabetes care

Most participants outlined barriers and facilitators to delivering their service in open-ended comments (n=89, 88%). DNS suggested it was not feasible to conduct audit, research and quality improvement (n=14), citing time constraints (n=7), and poor IT systems (n=4) as the main reasons. They identified limited opportunities for professional development (n=9), which was not supported by managers (n=3) or allocated protected time (n=3).

Being supported by the multidisciplinary team facilitated service delivery (n=15), and DNS identified a

Table 2 Specific roles performed by DNS

	Overall (n=99)*		Hospital (n=74)		Community (n=25)		
	Type 1, N (%)	Type 2, N (%)	Type 1, N (%)	Type 2, N (%)	Type 1, N (%)	Type 2, N (%)	
Core role							
Patient management†	88 (88.9)	90 (90.9)	73 (98.6)	67 (90.5)	15 (60.0)	23 (92.0)	
Medical review	54 (54.5)	57 (57.6)	46 (62.2)	44 (59.5)	8 (32.0)	13 (52)	
Telephone advice†	89 (89.9)	89 (89.9)	72 (97.3)	66 (89.2)	17 (68.0)	23 (92.0)	
Referrals	73 (73.7)	74 (74.7)	62 (83.8)	57 (77.0)	11 (44.0)	17 (68.0)	
Dose adjustment	73 (73.7)	72 (72.7)	58 (78.4)	51 (68.9)	15 (60.0)	21 (84.0)	
Insulin/GLP (glucagon-like peptide) initiation/education†	81 (81.8)	89 (89.9)	68 (91.9)	66 (89.2)	13 (52)	23 (92.0)	
Checking injection sites†	90 (90.9)	89 (89.9)	73 (98.6)	66 (89.2)	17 (68)	23 (92.0)	
Glucose monitoring†	89 (89.9)	91 (91.9)	73 (98.6)	67 (90.5)	16 (64.0)	24 (96.0)	
Inpatient care‡	77 (77.8)	71 (71.7)	69 (93.2)	61 (82.4)	8 (32)	10 (40.0)	
Hypo management†	89 (89.9)	90 (90.9)	73 (98.6)	67 (90.5)	16 (64)	23 (92.0)	
Specialist roles							
Hypertension clinics	5 (5.1)	6 (6.1)	5 (6.8)	5 (6.8)	0 (0)	1 (4.0)	
Renal clinics	10 (10.1)	13 (13.1)	10 (13.5)	12 (16.2)	0 (0)	1 (4.0)	
Assessment clinics prior to surgery	25 (25.3)	23 (23.2)	23 (31.1)	21 (28.4)	2 (8.0)	2 (8.0)	
Preconception discussion	52 (52.5)	48 (48.5)	41 (55.4)	36 (48.6)	11 (44.0)	12 (48.0)	
Prescribing	31 (31.3)	34 (34.3)	27 (36.5)	29 (39.4)	4 (16.0)	5 (20.0)	
Other							
Providing foot care	76 (76.7)		52 (70.3)		24 (96.0)		
RetinaScreen registration	62 (62.3)		43 (58.1)		19 (76.0)		
Liaison							
Consultant	81 (81.8)		60 (81.1)		21 (84)		
Hospital DNS§	43 (43.4)		22 (29.7)		21 (84)		
Community DNS	48 (48.5)		40 (54.1)		8 (32)		
GP§	70 (70.7)		46 (62.2)		24 (96)		
PN§	58 (58.6)		35 (47.3)		23 (92)		
	Overall (n=101)		Hospital (n=74)		Community (n=25)		Other (n=2)
Professional education							
GP§	48 (47.5)		25 (33.8)		22 (88.0)		1 (50)
PN§	60 (59.4)		35 (47.3)		23 (92.0)		2 (100)
Nursing staff in hospitals§	82 (81.2)		71 (95.9)		11 (44.0)		0 (0)
Medical staff in hospitals§	49 (48.5)		47 (63.5)		2 (8.0)		0 (0)
Allied health professionals	41 (40.6)		27 (36.5)		13 (52)		1 (50)
Medical staff in nursing homes§	35 (34.7)		16 (21.6)		17 (68.0)		2 (100)
Patient education	101 (100)		74 (100)		25 (100)		2 (100)

*Two respondents were excluded as they did not perform a clinical role.
†Significant difference in role performed for patients with type 1 diabetes mellitus after adjustment for multiple comparisons (Bonferroni corrected, p<0.002).
‡Significant difference in role performed for patients with type 2 diabetes mellitus after adjustment for multiple comparisons (Bonferroni corrected, p<0.002).
§Significant difference in role performed after adjustment for multiple comparisons (Bonferroni corrected, p<0.002).
DNS, diabetes nurse specialist; GP, general practitioner; PN, practice nurse.

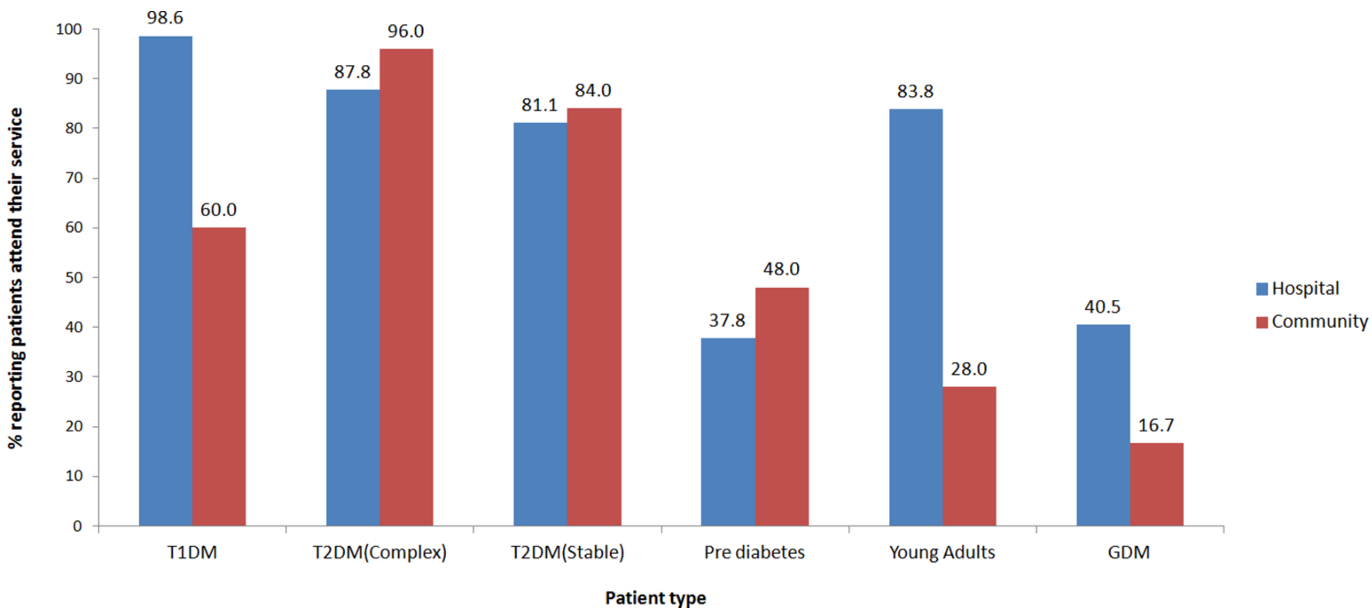

Figure 1 Patient types seen by nurse type: hospital (n=74) or community (n=25).

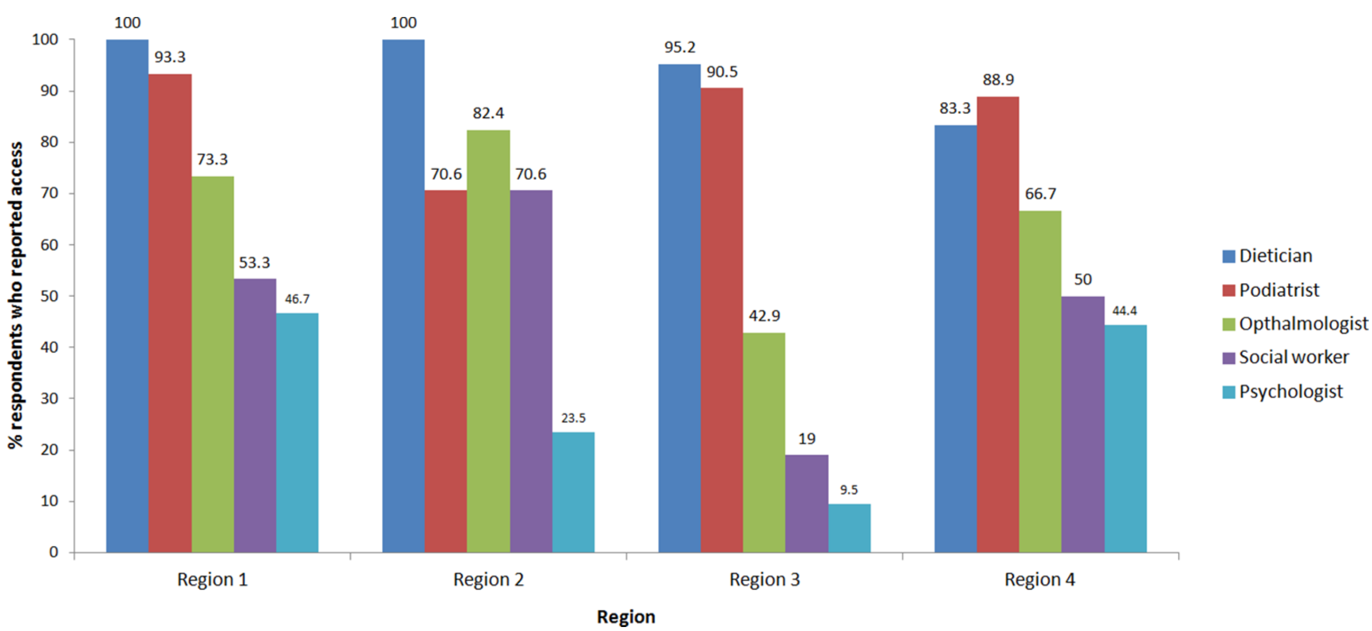

Figure 2 Referral access by region.

shortage of specialist staff (allied health professionals, endocrinologists, DNS) as a main barrier to providing care (n=48). Other barriers were a lack of clerical support (n=19), poor ICT (information and communication technology) (n=8) and space limitations (n=19), which affected clinic (n=10) and structured education (n=8) provision. Barriers to integration included inappropriate referrals of stable T2DM to secondary care (n=7), GP reluctance to engage with the new community DNS service (n=7) and the lack of ICT to facilitate information-sharing between primary and secondary care (n=6).

DISCUSSION

Main findings

Our study indicates that most hospital and community DNS supported integrated care through management of complicated T2DM, liaising with and educating other professionals, and working independently to deliver nurse-led clinics. The latter is consistent with the move towards greater autonomy in the role. In the UK, nurse-led clinics were identified as a new development in 2008, with 90% of DNS services providing this service.[19] However, we also identified specific areas for attention, in terms of the types of patients being managed by DNS, access to other professionals,

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the provision of clinics, and support for CPD, research and audit.

Although the role of the DNS is to support management of complex patients, most reported that patients with stable T2DM attend their service. DNS also highlighted ongoing issues with inappropriate referrals to secondary care. Many lacked a formal agreement on how their service operates between primary and secondary care, and a protocol to guide discharge from secondary to community care. Although most DNS had a liaison role with other care providers, referral access to specialist staff varied regionally. Space limitations, a shortfall in specialist staff and the lack of shared ICT between primary and secondary care were highlighted by DNS as barriers to service delivery. Half of DNS reported a waiting list for clinics, and the frequency varied, as did the support available in clinics from multidisciplinary professionals. These differences in clinic delivery may reflect the availability of space and staff at a given hospital or GP practice. Although most community DNS delivered community clinics, access to this service was not universal. In some areas it depended on GP willingness to engage with the integrated service, practice participation in an existing diabetes care scheme, PN availability or DNS service capacity.

Research and audit is considered a key component of the nurse specialist role nationally[21 31] and internationally.[32] However, as in the UK and Sweden,[17 19 33] we found that few DNS spend time on research or audit, lacking opportunity or support to do so. Although DNS were highly trained and experienced, as in the UK, few (11%) had completed a master's qualification.[34] Lack of support for CPD was identified as an issue in the UK[19 34] and was also highlighted by the current survey.

Strengths and limitations

This study is the first to examine the provision of DNS services nationally in Ireland. One strength is the use of a comprehensive questionnaire employed in a previous UK study,[19] which was adapted for the Irish context. Although there is no definitive list of all DNS in Ireland, we enlisted the support of the IDNSA, and this increases the likelihood that all potential participants were aware of the study. All four DSIG regions and counties were well represented, and we are confident the results capture the national situation in terms of DNS services. The balance of hospital to community DNS in the study reflects the national profile of DNS. Due to the small number of nurses working in both roles, our results did not distinguish between DNS solely based in the community and those in new posts working between hospital and community. The latter group spend 80% of their time in the community and their role is likely to be very similar to community DNS. Our question on patients who attend DNS services provides some insight into whether the role aligns with the national model. However it does assume that DNS have the same understanding of what is meant by complicated and uncomplicated (stable) T2DM. A further limitation is that this question does not capture why certain patients are being seen by the DNS. For example, we do not know whether there is a process by which DNS can discharge patients who become stable, given that patients may transition from complicated to stable and vice versa. While we are lacking routinely collected administrative data on the number and nature of referrals, community DNS have begun to collect data on their activity (number of complex/stable patients seen, practices visited, GPs interested in engaging, patients were discussed with the multidisciplinary team (MDT), formal professional education sessions). These data may also be harnessed to further assess the implementation of the model.

Implications

Our study has implications for the implementation of integrated care models that rely substantially on the role of the DNS. First, the findings suggest the need for organisational and professional changes — that is, better resourcing of specialist staff, provision of dedicated space and changes in the receptiveness to the DNS role — to better enable DNS to support the integration of care as intended. Specific barriers that affect DNS service delivery (space and staff resources, inappropriate referrals to secondary care) may also not be unique to Ireland, and their implications for integrated care may be relevant for the delivery of DNS services internationally.

Second, DNS continued to manage stable T2DM and mentioned the volume of inappropriate referrals in open-ended comments. This appears to suggest that the model of care, where DNS primarily see complex patients, has not been fully realised. Variation in diabetes services and the capacity of primary care may mean that moving to a scenario where DNS only see complicated patients will be a gradual process. There were also regional differences in terms of patients with stable T2DM attending DNS services, which may reflect the structure of primary care locally, access to secondary care services and other specialists.

Third, while nurse-led community clinics have been implemented effectively in parts of the Netherlands as a strategy to integrate care,[5 8] our findings suggest that local arrangements and resourcing may affect delivery. There were issues at a local level in terms of accessing DNS support through community-based clinics that have reached capacity or operate outside their catchment. Where GPs did have access, other factors (eg, being part of an existing initiative) affected eligibility. Although more work is required to fully understand how nurse-led clinics can operate effectively in this context, formal agreements and protocols to guide patient management across settings and healthcare providers are likely important.[35] Without a formal structure and adequate resourcing in place, as the DNS services become oversubscribed, they may contribute to, rather than address, any existing regional variation in diabetes care.

Finally, discharge pathways to community care and formal agreements on how DNS services operate between the hospital and primary care did not always appear to be in place; this may be one reason why existing arrangements continue to dictate patient management across the two settings. We show that the liaison role described by DNS in this study did align with elements of international models, that is, patient case discussion[5 12 36] and care planning,[8] and provision of advice, support[5 13] and education[10 13] to other care providers. However, without formal guidance in place, DNS availability for advice and support could vary nationally. This is something that needs to be further explored.

Our study was carried out at a time of ongoing policy reform; in 2015 a new diabetes 'cycle of care' funding initiative, known as the 'cycle of care', was introduced. This scheme will for the first time nationally remunerate GPs for care of patients with stable T2DM (two structured visits of per year) who hold a general medical services card. The initiative will establish formal requirements for registering, recording and reporting processes of care (clinical parameters, routine foot screening and referral, lifestyle review).[37] Payment will be made on the basis of registering eligible patients and delivering two review visits, and data will be reported/collected as per a standard proforma. While this may translate to more appropriate referrals and structured patient management, enhanced access to community resources does not form part of the initiative, and it is likely to further stretch already limited specialist resources and the demand for community DNS. Almost one-fifth of DNS surveyed will be eligible to retire in the next 10 years or fewer, which may place an additional strain on services. Our survey respondents identified the lack of DNS as a barrier to providing care. The shortfall in nurses has also been highlighted as a concern in the UK where DNS posts are stagnating.[38] It is concerning that the shift of patient care to the community may continue in areas unsupported by a well-resourced multidisciplinary team. Such deficiencies will influence how successfully DNS can coordinate care and support the delivery of an integrated service.

CONCLUSION

Our results suggest that hospital and community DNS, working in a traditionally fragmented health system and against a backdrop of service variation, perform key roles to support the integration of care. Yet our findings suggest there is some regional variation in how the new model of care is being implemented, in terms of management of uncomplicated T2DM, clinic delivery and available support from multidisciplinary professionals. There are areas for improvement if the DNS role is to be used to its full potential and if a standardised model of care is to be achieved. Changes to the wider service infrastructure (resourcing, space allocation, ICT, attitudes of professionals involved) are required in order to align the health system towards the delivery of integrated care. Expanding the DNS service into the community to support primary care as an isolated strategy may be limited in its potential to fully integrate care on a national level. While this study provides a useful 'snapshot' into DNS service delivery, future qualitative work is required to explore and understand how the role supports integration and changing requirements of the service as reforms continue.

Contributors FR and JB contributed to the design of the study, conducted data collection, analysis and interpretation, drafted and revised the paper and approved the final version to be published. SMM, PMK and KM contributed to the conception and design of the study, interpretation of the data, revised the paper and approved the final version to be published.

Ethics approval Clinical Research Ethics Committee of the Cork Teaching Hospitals.

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BMJ Open

The role of nurse specialists in the delivery of integrated diabetes care: a cross-sectional survey of diabetes nurse specialist services

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Research: Care Delivery

Sustaining quality in the community: trends in the performance of a structured diabetes care programme in primary care over 16 years

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Abstract

Aim To examine the quality of care delivered by a structured primary care-led programme for people with Type 2 diabetes mellitus in 1999–2016.

Methods The Midland Diabetes Structured Care Programme provides structured primary care-led management. Trends over time in care processes were examined (using a chi-squared trend test and age- and gender-adjusted logistic regression). Screening and annual review attendance were reviewed. A composite of eight National Institute for Health and Care Excellence-recommended processes was used as a quality indicator. Participants who were referred to diabetes nurse specialists were compared with those not referred (Student's *t*-test, Pearson's chi-squared test, Wilcoxon–Mann–Whitney test). Proportions achieving outcome targets [HbA_{1c} ≤58 mmol/mol (7.5%), blood pressure ≤140/80 mmHg, cholesterol <5.0 mmol/l] were calculated.

Results Data were available for people with diabetes aged ≥18 years: 1998/1999 (n=336); 2003 (n=843); 2008 (n=988); and 2016 (n=1029). Recording of some processes improved significantly over time (HbA_{1c}, cholesterol, blood pressure, creatinine), and in 2016 exceeded 97%. Foot assessment and annual review attendance declined. In 2016, only 29% of participants had all eight National Institute for Health and Care Excellence processes recorded. A higher proportion of people with diabetes who were referred to a diabetes nurse specialist had poor glycaemic control compared with those not referred. The proportions meeting blood pressure and lipid targets increased over time.

Conclusions Structured primary care led to improvements in the quality of care over time. Poorer recording of some processes, a decline in annual review attendance, and participants remaining at high risk suggest limits to what structured care alone can achieve. Engagement in continuous quality improvement to target other factors, including attendance and self-management, may deliver further improvements.

Diabet. Med. 00: 000–000 (2018)

Introduction

Diabetes mellitus is a complex chronic condition requiring structured management, including a focus on treatment goals for blood pressure, glucose control and lipids, regular review and recall, screening for complications, and input from a multidisciplinary professional team [1]. Primary care, as a first point of contact and source of continuous, comprehensive and coordinated care, is often seen as a starting point for the delivery and organization of diabetes care [2]. Evidence suggests that primary care management can be as effective as hospital-led care if well supported and organized [2]. Efforts to optimize care across different health systems have led disease management programmes to better organize management in primary care and improve coordination between the community, outpatient/ambulatory and inpatient settings [3–5].

Disease management programmes in primary care incorporate different components: multidisciplinary cooperation; registration systems; audit and feedback; clinician reminders; patient and professional education; and/or the establishment of a specific communication system and ongoing collaboration between specialities and primary care (shared care). Structured approaches to diabetes care, combining some or all of these elements, demonstrate improvements in glycaemic control and cardiovascular risk factors [4,6],

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What's new?

- Most studies on the impact of multifaceted, structured, primary care programmes on the quality of diabetes care have a short follow-up time; studies demonstrating long-term sustainability are lacking.
- We found significant improvements in quality of care (care processes delivered) among practices enrolled in a primary care programme over a 16-year period.
- Lifestyle processes were less well recorded, and there were declines in foot assessment and attendance at annual review, and participants continued to have poor risk factor control.
- Programmes may be limited when operating within the constraints of primary care and the wider service context.

although the evidence for the effectiveness of shared care is less certain [7,8]. Specific components delivering significant improvements in clinical outcomes [6,8,9] and care processes [6], include access to a multidisciplinary team [8], case management [8], partial replacement of physicians by nurses [9], self-management promotion [8], and interventions to prompt recall and review of patients, including electronic registries, reminders and tracking systems [6]. Interventions operating at all levels of the health system (system, provider and patient), however, have demonstrated a greater effect on glycaemic control than interventions targeting a single level [8].

Despite growing evidence regarding ways to improve the quality of diabetes care, some uncertainties remain, including whether the effects achieved by evaluative quality improvement studies can be replicated in 'real-life' practice. Despite international consensus on optimal diabetes management, a gap persists between recommendations and actual practice [10]. With increasing pressure on primary care, growing patient numbers and workforce shortages [2,11], demonstrating the long-term sustainability of structured primary care management is a challenge. Internationally, high-quality service evaluations to address this evidence gap are lacking [11]. Most studies examining diabetes management in primary care have a relatively short follow-up [4,6,7], cannot provide an insight into the sustainability of these programmes over time, and may not be able to demonstrate effectiveness [7]. Few studies evaluate enhanced models of primary care management over a longer period, of 10 years or more [12–14].

In Ireland [15], as elsewhere in Europe [5], national policy in recent years has focused on moving from hospital-led management to delivering care in the community. Diabetes care is historically unstructured, but formal primary care initiatives have been developed across the country to improve the quality of care and service delivery at a local level. The longest running is the HSE Midland Diabetes Structured Care Programme (Midland Programme), established in 1997/1998. We aimed to examine the quality of care delivered by the Midland Programme over a long follow-up period (1999–2016) through a series of cross-sections. We reviewed the delivery of the programme by examining trends in the processes of care performed for people with Type 2 diabetes mellitus and benchmarked the programme against international standards [16,17].

Methods

Setting

In Ireland, the national prevalence of doctor-diagnosed diabetes among adults aged ≥18 years is 5.2%, an increase from 2.2% in 1998 [18]. Over one-third of adults (37%) are overweight and 23% are obese. The prevalence of smoking is 23% [19].

Midland Diabetes Structured Care Programme

The Midland Programme, based in four counties in Ireland (Longford, Westmeath, Laois and Offaly), includes several evidence-based intervention components: adoption of clinical guidelines; patient register and recall and protected time for review (three 30-min visits per year); organization and coordination of care by practice nurses; structured multidisciplinary support; and professional and patient education [8,9]. Practices are remunerated for patients' visits through an existing chronic disease programme, Heartwatch, or reimbursed for practice nurse time. Practices receive clinical (diabetes nurse specialists, podiatry/chiropody, dietetic), educational, and administrative support, which has changed since the programme was first established; for example, there has been a loss of dietetic support (Fig. 1).

Data collection

Diabetes nurse specialists extracted data from practice records on people with Type 1 and Type 2 diabetes (aged ≥18 years) enrolled at four time points: 1998/1999; 2003; 2008; and 2016. A census sample was selected in 1998/1999 and 2003, and a random sample in 2008 and 2016. In 2008, participants were sampled by sorting alphabetically first by name, and selecting every third person. In 2016, all participants who were still alive and were part of the census sample in 1998/1999 were selected. After ordering randomly, every third person was sampled from these participants. The remainder of the participants in 2016 were sampled by sorting alphabetically first by name, then sampling every third person. This approach was taken to approximate a random sample overall in 2016. Sample size was calculated

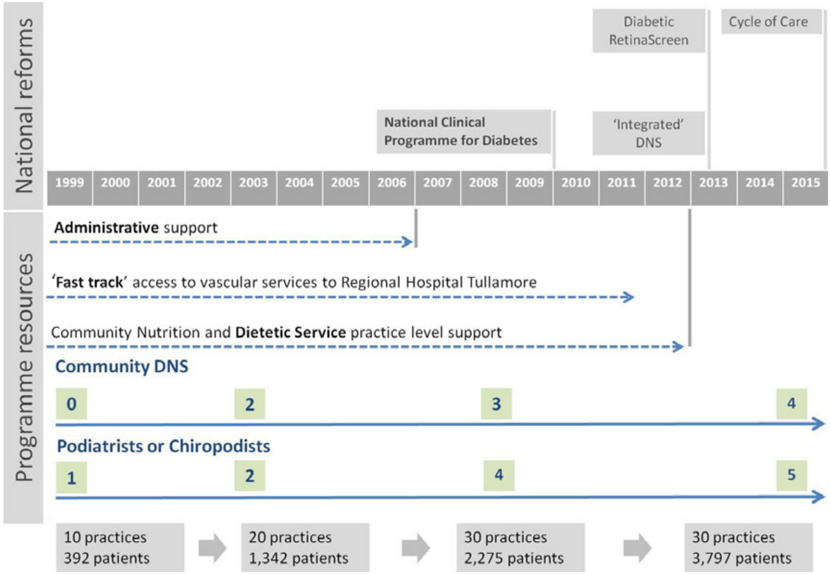

FIGURE 1 National reforms, resources available to the programme, and participating general practitioners and people with diabetes enrolled 1999–2016. Information on numbers of resources (diabetes nurse specialists and podiatrists/chiropodists) were unavailable at time points between data collection. DNS, diabetes nurse specialist.

based on precision of HbA_{1c} estimates. In 2003, the mean HbA_{1c} for the total sample was 60 mmol/mol (7.6%) and the 95% CI was ± 1 mmol/mol (0.11%), which equates to ~1.5%; therefore, a confidence level of 95% and CI of 2% was chosen to calculate the sample size for 2008 and 2016. Based on the total population of 2275 participants in 2008, the sample size was 1168. Based on the total population of participants in 2016 of 3797, the sample size was 1471. Only data on participants with Type 2 diabetes are reported here.

Data sources included clinical notes (electronic and paper), outpatient appointments letters and referrals to chiropody/podiatry, retinopathy and dietetics. Data were collected on demographics: age, gender and general medical services status (a means-tested method of public health insurance; general medical services cardholders have free access to general practitioner services and medications) [20]. Data were also collected on diabetes type, duration, annual review attendance, use of diabetes-related services (retinopathy screening, specialist eye services (any service in community or hospital, private or public), diabetes nurse specialist or podiatrist/chiropodist), prescription of diabetes medications (oral hypoglycaemic agents, insulin, injectables) and other medications (statins, angiotensin-converting enzyme inhibiters, aspirin). Data were collected on care processes carried out in the previous 12 months: foot assessment carried out by any healthcare professional (i.e. general practitioner, practice nurse, diabetes nurse specialist, consultant, podiatrist), measurement of glycated haemoglobin (HbA_{1c}), cholesterol, blood pressure, creatinine, albumin creatinine ratio, BMI, smoking status) and intermediate clinical outcomes (HbA_{1c}, cholesterol, triglycerides, blood pressure, creatinine). Smoking status (yes/no) in the past 12 months was determined on the basis of participants' response to a question about whether they smoke now. Data on complications were also collected: retinopathy, macrovascular [heart attack (myocardial infarction), heart failure (congestive cardiac failure), stroke (cerebrovascular accident), and mini stroke (transient ischemic attack)], peripheral neuropathy, autonomic neuropathy, foot risk category, and ulcer. Both eyes are checked during assessments and people were classified as having retinopathy if it was recorded in at least one eye. Both feet are also checked and classification of foot risk (low/moderate/high) was recorded on the basis of the highest risk in either foot. Ulcer was recorded as 'yes' if the person had an ulcer in at least one foot.

Analysis

Practice addresses were mapped to Electoral Divisions and assigned a deprivation score and decile using the 2011 National Deprivation Index for Health and Health Services Research developed by the Small Area Health Research Unit [21]. Data were represented as means ± SD or median (interquartile range; continuous data) or numbers and proportions (categorical data). Quality of care was defined using a composite of eight care processes recommended by the National Institute for Health and Care Excellence (NICE): HbA_{1c}, blood pressure, cholesterol, smoking status, BMI, creatinine, albumin creatinine ratio and foot examination [22]. Although recording of triglycerides was reported, this process was excluded from the composite. Trends over time in the proportion with processes recorded were examined using the chi-squared test for trend, and logistic regression models adjusted for age and gender. Trends in recording were examined for selected processes collected across all 4 years (HbA_{1c}, blood pressure, cholesterol, smoking status, BMI, creatinine) across practices. Differences in the proportion with processes recorded between participants aged <75 years and ≥75 years were examined using Pearson's chi-squared test. The proportions attending annual review and diabetes-related services were reported at different time points. Differences in the demographic and clinical profile of participants referred and those not referred to a diabetes nurse specialist were tested using Student's *t*-test or Wilcoxon–Mann–Whitney test (continuous data), and Pearson's chi-squared test (categorical data). Guidelines recommend people with complicated Type 2 diabetes mellitus attend a diabetes nurse specialist [23]. People with complicated Type 2 diabetes are defined as those requiring insulin, those with HbA_{1c} >58 mmol/mol (7.5%) on two or more glucose-lowering agents (not insulin), and those with complications or graded as having a high-risk foot [23]. Continuous outcome data were categorized according to international standards: blood pressure ≤140/80 mmHg, triglycerides <2.0 mmol/l, cholesterol 5.0 mmol/l and HbA_{1c} ≤58 mmol/mol (7.5%) [16,17,24], and proportions of participants meeting clinical outcome targets were calculated. All analysis was carried out in STATA v.12 for windows (StataCorp, College Station, TX, USA).

Results

Profile of the sample population

Data on 336 people with Type 2 diabetes in 1998/1999 (10 practices), 843 in 2003 (20 practices), 988 in 2008 (30 practices), and 1029 (30 practices) in 2016 were available for analysis. Overall <10% of data were missing, with some exceptions depending on time points: creatinine (1–31%), BMI (27–44%), smoking status (21–32%), podiatrist/chiropodist attendance (0–17%) and dietitian attendance (0–40%). Where missing data occur, the figures represent the recorded data. Over 85% of general practitioners were based in practices within the lowest deprivation deciles: 9 (*n*=14, 41%) or 10 (*n*=15, 44%). In 2016, the median (interquartile range) age of the cohort was 68 (60–76) years, most were men (*n* = 603, 59%) and most had a general medical services card (*n* = 823, 80%). The median duration of diabetes was 9 years. The profile of people with Type 2 diabetes was similar across time points (Table 1).

Process measures

In 2016, recording for most care processes was >97%. Recording improved significantly since 1998/1999, with change more evident between earlier time points (Fig. 2). Recording of BMI and smoking status remained consistently lower than other processes. Although there was a significant improvement between 1998/1999 and 2008 (BMI: 60% vs 73%; smoking status: 68% vs 77%) recording remained below 80% from 2008 to 2016. The proportion of participants with a foot assessment in the past 12 months declined from 2008 to 2016 (77% vs 53%). In 2016, only 29% (*n* = 296) of participants had all eight NICE-recommended processes recorded.

Trends in recording were similar when stratified by age (<75 years and ≥75 years) with the exception of smoking status and blood pressure recording among participants <75 years (Table S1). At individual time points certain processes were consistently less well recorded ($P < 0.05$) among participants aged ≥75 years: 1999 (BMI: 64% vs 48%; triglycerides: 72% vs 51%), 2003 (BMI: 58% vs 48%; triglycerides: 93% vs 87%), 2008 (BMI: 75% vs 67%; triglycerides: 99% vs 96%; albumin creatinine ratio: 74% vs 67%), and 2016 (albumin creatinine ratio: 85% vs 75%).

Consistent improvements in recording were seen across all practices for HbA_{1c}, systolic blood pressure, cholesterol, triglycerides and creatinine. There was some variation in proportions recorded in 1999 among the 10 originally enrolled practices (HbA_{1c} 0–100%; blood pressure 69–100%; cholesterol 0–100%; triglycerides 0–100%; creatinine 0–97%). BMI and smoking status recording did not improve consistently, with some practices showing a decline in recording over time. Data for the 10 original practices are shown in Table S2.

Attendance at annual review and diabetes-related services

Annual diabetes review attendance increased between 1998/1999 (18%, *n* = 46/261) and 2008 (91%, *n* = 895/980), but dropped in 2016 (77%, *n* = 788/1025). In 2016, clinical characteristics were recorded for most participants who attended and did not attend annual review (HbA_{1c}: 100% vs 97%; blood pressure: 99% vs 93%; cholesterol: 100% vs 96%; creatinine: 100% vs 95%); however, there were differences in recording of foot assessment (57% vs 38%), BMI (79% vs 47%) and smoking status (86% vs 56%). A similar pattern was observed in 2008. In 2008, 58% of participants (*n* = 548/949) had seen a chiropodist or podiatrist in the past 12 months, which declined further by 2016 (51%, *n* = 439/863). In 2008, only 51% (*n* = 507/988) had attended specialist eye services, but in 2016, 80% (*n* = 800/1006) of participants had attended either the national screening programme (RetinaScreen) or specialist eye services. The proportion who had seen a hospital or community dietitian dropped from 50% (*n* = 167/336) in 1998/1999 to 7.1% (*n* = 42/610) in 2016, but recording quality also declined; 41% (*n* = 419/1029) were missing data in 2016 compared with 0.3% (*n* = 1/336) in 1998/1999.

Attendance at a diabetes nurse specialist increased between 2008 and 2016 (11% vs 15%). Participants who were referred had diabetes for longer and were younger than those who were not referred (Table 2). A greater proportion of

Table 1 Characteristics and clinical profile of participants with Type 2 diabetes 1998/1999–2016*

	1998/1999 *n* = 336	2003 *n* = 843	2008 *n* = 988	2016 *n* = 1029
Median (IQR) age, years	65 (56–74)	65 (56–73)	66 (59–74)	68 (60–76)
Male, *n* (%)	168 (50)	438 (52)	562 (57)	603 (59)
Median (IQR) diabetes duration, years	NA	NA	6 (3–9)	9 (5–12)
General medical services	NA	NA	NA	823 (80)
Mean (SD) BMI, kg/m^2	29.3 (4.7)	30.6 (4.8)	30.6 (4.8)	31.2 (5.9)
BMI <25 kg/m^2, *n* (%)	33 (16)	42 (9)	94 (13)	81 (11)
Smokers, *n* (%)	58 (25)	123 (20)	146 (19)	121 (15)
Diabetes treatment, *n* (%)				
Diet only	60 (18)	187 (22)	131 (13)	173 (17)
OHA only	262 (80)	532 (70)	685 (70)	643 (63)
Insulin + OHA	0 (0)	39 (4.6)	131 (13)	140 (14)
Insulin only	10 (3.0)	25 (3.0)	38 (3.9)	21 (2.0)
Statins, *n* (%)	NA	NA	799 (81)	854 (83)
ACE inhibitors, *n* (%)	NA	NA	734 (74)	680 (67)
Aspirin, *n* (%)	NA	NA	740 (75)	611 (59)
Mean (SD) HbA$_{1c}$				
mmol/mol	55 (18)	58 (18)	53 (13)	54 (14)
%	7.2 (1.7)	7.5 (1.6)	7.0 (1.2)	7.1 (1.3)
HbA$_{1c}$ concentration, *n* (%)				
<48 mmol/mol (6.5%)	104 (37)	229 (29)	351 (36)	364 (36)
≤53 mmol/mol (7.0%)	156 (55)	382 (48)	589 (61)	607 (59)
≤58 mmol/mol (7.5%)	191 (67)	481 (60)	720 (74)	770 (75)
Mean (SD) systolic blood pressure, mmHg	144.4 (19.9)	140.5 (18.7)	135.9 (16.3)	135.1 (16.0)
Systolic blood pressure, *n* (%)				
<130/80 mmHg	25 (8.0)	96 (12)	212 (22)	212 (21)
≤140/80 mmHg	112 (36)	405 (48)	560 (57)	597 (59)
Mean (SD) cholesterol, mmol/l	5.3 (1.2)	4.9 (1.0)	4.1 (1.1)	4.1 (1.0)
Cholesterol concentration, *n* (%)				
<4.5 mmol/l	60 (23)	268 (33)	647 (67)	711 (70)
<5.0 mmol/l	102 (38)	450 (55)	785 (81)	846 (83)
Mean (SD) triglycerides, mmol/l	2.4 (1.5)	2.1 (1.9)	1.8 (1.2)	1.7 (1.5)
Triglycerides <2.0 mmol/l, *n* (%)	103 (46)	460 (60)	684 (71)	760 (75)
Mean (SD) creatinine, μmol/l	86.5 (30.1)	84.8 (20.7)	87.8 (46.0)	86.5 (34.0)

NA, not available (data on this variable were not collected at this time point); ACE, angiotensin-converting-enzyme; IQR, interquartile range; OHA, oral hypoglycaemic agent.
*Based on available data: age: 1999 (336), 2003 (842), 2008 (987), 2016 (1,028). Diabetes duration: 2008 (848), 2016 (1005). GMS: 2016 (1027). BMI: 1999 (203), 2003 (470), 2008 (725), 2016 (736). Smoking status: 1999 (230), 2003 (629), 2008 (759), 2016 (813). Diabetes treatment: 1999 (332), 2003 (843), 2008 (985), 2016 (1026). Statins: 2008 (987), 2016 (1028). Aspirin: 2008 (986), 2016 (1027). ACE inhibitor: 2008 (984), 2016 (1017). HbA$_{1c}$: 1999 (284), 2003 (799), 2008 (967), 2016 (1021). Blood pressure: 1999 (311), 2003 (836), 2008 (979), 2016 (1008). Cholesterol: 1999 (267), 2003 (815), 2008 (973), 2016 (1018). Triglycerides: 1999 (226), 2003 (771), 2008 (968), 2016 (1012). Creatinine: 1999 (234), 2003 (695), 2008 (971), 2016 (1016).

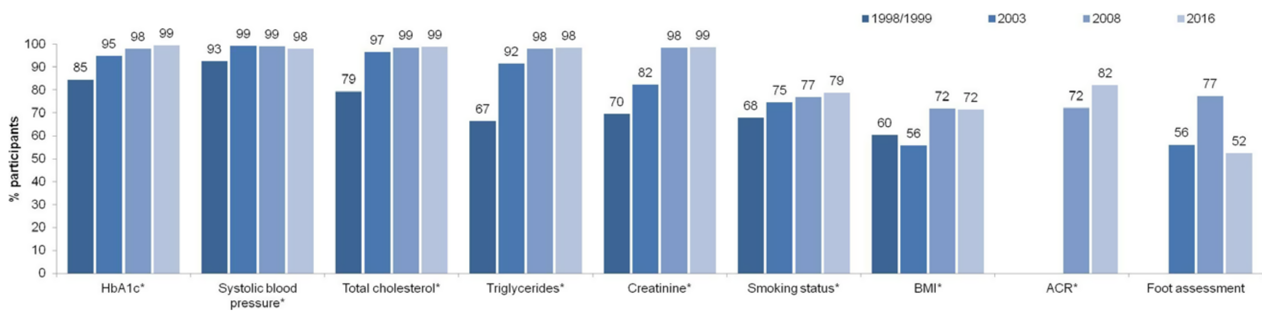

FIGURE 2 Participants with nine care processes recorded 1999–2016. *$P < 0.05$. Albumin: creatinine ratio was not recorded in 1999 and 2003; foot assessment was not recorded in 1999. Proportions were analysed using a chi-squared test for trend and logistic regression adjusted for age and gender. ACR, albumin:creatinine ratio.

people referred had poor glycaemic control [HbA$_{1c}$ >58 mmol/mol (7.5%); 50% vs 20%; P<0.001], were on oral hypoglycaemic agents or injectables (98% vs 81%; P<0.001), and had retinopathy (41% vs 30%; P<0.01); however, a lower proportion were classified as having a high risk of foot disease (1.9% vs 4.4%; P<0.05).

Table 2 Profile of participants who were referred to a diabetes nurse specialist* in 2016

	Referred to diabetes nurse specialist		
	Yes n = 153	No n = 866	Yes, but did not attend n = 9
Median (IQR) age†, years	65 (56–71)	69 (61–76)	58 (53–63)
Men, n (%)	88 (58)	511 (59)	4 (44)
Median (IQR) diabetes duration†, years	10 (6–14)	9 (5–12)	9.5 (9–12)
Mean (SD) BMI, kg/m^2	32.1 (6.1)	31.0 (5.9)	32.6 (4.4)
Smoker, n (%)	21 (18)	99 (14)	1 (13)
Diabetes control†, n (%)			
Diet only	3 (2.0)	168 (19)	1 (11)
OHA only	71 (47)	569 (66)	3 (33)
Insulin only	5 (3.3)	15 (1.7)	1 (11)
Insulin and OHA	57 (38)	81 (9.3)	2 (22)
Injectables and OHA	16 (11)	31 (3.6)	2 (22)
OHA or injectable†‡	149 (98)	696 (81)	8 (89)
HbA_{1c} > 58 mmol/mol (7.5%), n (%)	80 (50)	172 (20)	4 (50)
Median (IQR) HbA_{1c}†			
mmol/mol	60 (50–69)	50 (44–57)	64 (52–69)
%	7.6 (6.7–8.5)	6.7 (6.2–7.4)	8.0 (6.9–8.5)
Mean (SD) systolic blood pressure, mmHg	133.7 (14.2)	135.4 (16.3)	127.2 (12.2)
Complications, n (%)			
Retinopathy†	54 (41)	197 (30)	3 (50)
Macrovascular	8 (5.2)	89 (10)	2 (22)
Peripheral neuropathy	7 (4.6)	29 (3.4)	0 (0)
Autonomic neuropathy	5 (3.3)	28 (3.2)	0 (0)
High-risk foot†	2 (1.9)	14 (4.4)	1 (17)
Ulcer	4 (2.7)	20 (2.3)	0 (0)

IQR, interquartile range; OHA, oral hypoglycaemic agent.
*People with complicated Type 2 diabetes should attend a diabetes nurse specialist. This includes people requiring insulin, people with HbA_{1c} >58 mmol/mol (7.5%) on two or more glucose-lowering agents (not insulin), and people with complications or graded as having a high-risk foot [23].
†$P < 0.05$; difference in people attending and not attending diabetes nurse specialist visit were analysed using Student's t-test or Wilcoxon–Mann–Whitney test for continuous data and Pearson's chi-squared for categorical data.
‡OHA, insulin or other injectable.

Outcome targets

Over time, the proportion meeting blood pressure and lipid targets increased, whereas the proportion with HbA_{1c} ≤58 mmol/mol (7.5%) was similar (Table 1). Across time points, the proportion meeting all three outcome targets (HbA_{1c}, blood pressure and cholesterol) ranged from 12% (1999) to 39% (2016). Those at high risk [HbA_{1c} >58 mmol/mol (7.5%)] had diabetes for longer. The proportion on oral hypoglycaemic agents only was similar among high- and low-risk groups. A greater proportion at low risk were on oral hypoglycaemic agents or injectables (Table S3).

Discussion

We examined the quality of care delivered by a structured primary care management programme for people with Type 2 diabetes. We found significant improvements in process of care recording. These are consistent with changes in recording [3,6,13,14] reported by multifaceted international programmes with similar components: registration [6,13,14], practice guidelines [3,14], incentives [3], ongoing professional education [6,14], nurse case management [13], and structured multidisciplinary support [3]. Our findings suggest these changes can be sustained over time in a real-life setting; however, despite evidence of ongoing improvement, there may be limits to what structured programmes can achieve in the long term. BMI and smoking status were consistently less well recorded, and performance of foot assessment and attendance at dietetic and annual review declined in the later years of the programme, and some participants remained at high risk.

Unlike the Quality and Outcomes Framework in the UK, payment as part of the Midland Programme is not based on process recording. Smoking status and BMI recording remained lower than other processes, comparing poorly with the recent National Diabetes Audit [22], based on Quality and Outcomes Framework data, and with other European countries [25]. BMI and smoking status recording in the National Diabetes Audit, however, was also lower than recording of other processes. While incentivizing individual indicators can improve recording to a degree, poor documentation of certain processes may persist. Some may be given lower priority than other clinical measurements during review visits. BMI recording, for example, may only occur if a general practitioner or practice nurse recognizes the person with diabetes as overweight/obese, intends to offer management, or feels willing or able to engage in discussions about weight [26]. We found variation across practices in recording of BMI and smoking status, with some practices showing a decline in recording over time. With the exception of 2016, BMI was consistently less well recorded among older participants (aged ≥75 years). Foot assessments, also poorly recorded, have been more frequently performed among people with low income, poorer metabolic control, or complications, and less frequently by general practitioners compared with specialists [27]. Assessments may be time-consuming and unfeasible as part of regular review, or only prioritized when the general practitioner is aware of an increased risk of amputation.

We found a significant, improving trend over time in recording of care processes; however, this was driven by more substantial improvements between earlier time points. There was minimal change between 2008 and 2016 once recording >97% had been achieved; however, a similar pattern was observed for BMI and smoking status, although these were less well recorded. This suggests that recording may plateau irrespective of whether near maximal recording has been achieved or not. A plateau was also observed in the UK 1 year after the introduction of the Quality and Outcomes Framework [28], suggesting limits to what can be achieved through incentives, regardless of the reimbursement method. This raises the question of whether the Quality and Outcomes Framework should be replaced with a model to deliver more sustained improvements [29]. This has implications for the new Diabetes Cycle of Care initiative introduced in Ireland in 2015, which remunerates general practitioners for care of people with stable Type 2 diabetes who hold a general medical services card. Practices are paid on the basis of registering eligible people with diabetes, delivering two review visits per year, recording and reporting on care processes (clinical characteristics, routine foot screening/referral, lifestyle review), not on the basis of meeting clinical targets. The initiative may improve the delivery of care processes, but only up to a point. Scotland has recently replaced the Quality and Outcomes Framework, establishing general practitioner quality clusters, small groups of practices which engage in local, peer-led quality improvement activities [29]. While they may see an initial decline in care processes, there is scope for improvement beyond what is achievable through payments.

Although we did not track clinical outcomes in a fixed population, by reviewing outcomes in separate cross-sections, we gained some insight into the profile of people with diabetes receiving structured care. In Ireland, 40% of older adults (≥55 years) are reported to have high blood pressure (systolic blood pressure ≥140 mmHg), and 41% have cholesterol >5 mmol/l [30]. Although recording of most processes in the Midland Programme was >97%, many participants were in high risk categories in terms of glycaemic control and their cardiovascular profile. Between 2003 and 2016, 26–40% had HbA_{1c} >58 mmol/mol (7.5%), 41–52% had blood pressure >140/80 mmHg, and 15–42% had cholesterol >5 mmol/l, consistent with research showing recording does not necessarily translate to better outcomes [31].

Recording clinical values is a quality measure in itself which may indicate the need to intensify treatment; however, achieving outcome targets requires appropriate action by professionals and people with diabetes. Emphasizing processes alone, as with the Cycle of Care, may not deliver improved outcomes. Motivation of the person with diabetes, adherence to treatment and the efficacy of self-management, influence risk factor management [10], but were not captured in the present study. We found the proportion of people with HbA_{1c} ≤58 mmol/mol (7.5%) was similar across time points, which could reflect the long disease duration among participants or the declining effect of oral hypoglycaemic agents [32]. While treatment goals provide a benchmark for quality, Lipska *et al.* [33] have recently questioned the use of 'surrogate' outcome targets, such as HbA_{1c}, as quality indicators. They may not be appropriate for certain subgroups (e.g. the elderly or those with comorbidities) and should be individualized according to complication risk, preferences and control strategy. Greater emphasis has been placed on involving people with diabetes in the decision about their individual HbA_{1c} target [16,17]. Future monitoring of the Midland Programme should consider incorporating this information; that is, recording whether a target has been agreed, documenting the agreed target, and using this as a basis for evaluating the quality of care.

Although retinopathy screening attendance improved, in 2016, 20% had not attended specialist eye services or RetinaScreen, the new national screening and treatment programme introduced in 2013. National guidelines recommend that people with complicated Type 2 diabetes should attend a diabetes nurse specialist, including people requiring insulin, people with HbA_{1c} >58 mmol/mol (7.5%) on two or more glucose-lowering agents (not insulin), or people with complications or graded as having a high-risk foot [23]. In line with this recommendation, we found participants with more complicated diabetes were referred to a diabetes nurse specialist. While the rate of non-attendance was low overall, those who did not attend had a higher median HbA_{1c} than attenders. Further work is necessary to understand barriers to attendance among these participants, ways to improve attendance, and facilitate risk management. Although most participants attended for annual review, this declined between 2009 and 2016 (91% vs 77%). Transport, work and family commitments, and lack of motivation have been cited as reasons for non-attendance at annual review [34]; however, practice-level resource constraints could also account for this decline. An official annual review may not be performed at a single visit but instead components spread over several visits to lessen practice nurse workload. The increasing complexity of management may require longer reviews that cannot be incorporated into one visit [35]. Unlike clinical measurements, BMI, smoking status and foot assessment were less well recorded among those who did not attend annual review. These processes may not be a priority during regular visits, particularly for people with poor attendance.

Ireland is moving towards the delivery of structured, integrated diabetes management in primary care, with the establishment of the National Clinical Programme for Diabetes, the resourcing of community-based 'integrated' diabetes nurse specialists to facilitate delivery of the new model of integrated care that manages people with diabetes according to their complexity, and the Cycle of Care (Fig. 1) [23]; however, as a multi-component programme with good specialist support, the Midland Programme provides an insight into the impact of providing structured care in the community that predates these national changes (Fig. 1). As enhanced access to community-based specialist resources does not form part of the Cycle of Care initiative, care may be moved to the community in areas with less access to a well-resourced multidisciplinary team. Programmes such as the Midland Programme may also be influenced by health service changes. We observed a drop in dietetic screening alongside a loss of resources, further indicating the importance of sustained resources to deliver care in the community.

A strength of the present study is that it examines, over a long follow-up period, the impact of structured primary care-led service model, delivered in routine practice rather than as part of a quality improvement trial; however, participants were not the same at each time point (although some were represented at each). We also took different approaches to sampling at each time point. In 2008 and 2016, as the number enrolled in the programme exceeded 2000, it was not feasible to collect data manually on every participant, therefore, an appropriate random sample was taken. In 2016, as part of the larger sample taken at this time point, data were collected on all participants who had been enrolled in 1998/1999 and were still alive in 2016. This was done in order to facilitate a separate analysis which examines survival in the original cohort enrolled in the programme since its initiation. We can judge the overall delivery of the programme, but cannot infer the impact on individual participants since enrolment. Although different individuals were represented across different time points, it is encouraging that participants enrolled in this structured care programme were meeting outcome targets; however, we lacked control practices to determine whether changes in clinical outcomes reflected overall improvements in medication (e.g. new oral hypoglycaemic agents) and management in the time period, or in the organization and delivery of the programme. Most participants enrolled were on lipid-lowering or blood pressure medication. The programme is multifaceted so we cannot prove that one component was more effective than others. Data were extracted from general practice records, and we depended on the reliability of data from this source.

Our findings illustrate sustained improvements in the care delivered by practices in a multifaceted, primary-care led programme over time, suggesting this approach is feasible in real-life primary care; however, our findings also identify limits to what can be achieved by structured care programmes, particularly when operating within the resource constraints of primary care and the wider health service context. We need to better understand general practitioner management decisions, patient attendance, adherence and self-management, and whether these factors moderate the impact of these programmes. Programmes such as the Midland Programme should move beyond monitoring and engage in a continuous cycle of quality improvement to respond to the challenges of delivering optimal primary care-led diabetes care in everyday practice.

Funding sources

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Competing interests

None declared.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Table S1. Processes recorded among participants aged <75 years and ≥75 years with Type 2 diabetes 1999–2016.

Table S2. BMI and smoking status recording among participants with Type 2 diabetes 1999–2016 attending 10 general practices enrolled in programme since 1999.

Table S3. Demographics, duration and diabetes control among participants with Type 2 diabetes in 2016 ($n = 1029$).

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Coláiste na hOllscoile Corcaigh, Éire
University College Cork, Ireland

Our ref: ECM 4 (n) 03/03/15 & ECM 3 (yyyyyy) 07/07/15

19th June 2015

Professor Patricia Kearney
Research Professor
Department of Epidemiology & Public Health
University College Cork
4th Floor,
Western Gateway Building
Western Road
Cork

Re: A survey of diabetes nurse specialists in Ireland.

Dear Professor Kearney

The Chairman approved the following:

- Amendment Application Form
- Addition of Fiona Riordan, PhD Student as a co-investigator in the above study
- Information Leaflet and Consent Forms Version 3 dated 8th June 2015
- Invitation Letter Version 2 dated 8th June 2015.

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospitals

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Our ref: ECM 4 (i) 15/12/15 & ECM 3 (pppp) 01/03/16

25th February 2016

Professor Patricia Kearney
Department of Epidemiology & Public Health
University College Cork
4th Floor
Western Gateway Building
Western Road
Cork

Re: Long-term follow up of patients with diabetes enrolled in a structured care initiative in Ireland: examining quality of care and patient outcomes.

Dear Professor Kearney

The Chairm an approved the following:

- Data Collection Sheet Version 3.

Full approval is now granted to carry out the above study.

Yours sincerely

Michael G Molloy

Professor Michael G Molloy
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Our ref: ECM 4 (g) 11/08/15

21st July 2015

Professor Patricia Kearney
Department of Epidemiology & Public Health
4th Floor
Western Gateway Building
Western Road
Cork

Re: Examining the quality of models of diabetes care in Ireland.

Dear Professor Kearney

Expedited approval is granted to carry out the above study at:

- GP Practices
- University College Cork.

The following documents have been approved:

- Protocol Submission Form
- Study Protocol Version 1 dated 8th July 2015
- CV for Chief Investigator.

We note that the co-investigators involved in the study will be:

- Dr Sheena McHugh, Post-Doctoral Research Fellow
- Ms Fiona Riodan, PhD Student.

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospital

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Our ref: ECM 4 (f) 11/08/15

21st July 2015

Professor Patricia Kearney
Department of Epidemiology & Public Health
4th Floor
Western Gateway Building
Western Road
Cork

Re: An audit of a GP practice participating in the Diabetes Interest Group Cork (DIG) initiative – pilot study.

Dear Professor Kearney

Expedited approval is granted to carry out the above study at:

- The K-Practice, Macroom
- University College Cork.

The following documents have been approved:

- Protocol Submission Form
- Study Protocol Version 1 dated 8th July 2015.

We note that the co-investigators involved in the study will be:

- Dr Sheena McHugh, Post-Doctoral Research Fellow
- Ms Fiona Riodan, PhD Student.

Yours sincerely

Professor Michael G Molloy
Chairman
Clinical Research Ethics Committee
of the Cork Teaching Hospital

Survey of Diabetes Nurse Specialists in Ireland (Wave 2)

Consent Form

1. We want to gain a greater understanding of your role in diabetes care.This study is going to improve our understanding of how services are currently organised in Ireland. This information is important to inform plans for changes in diabetes management in the future.

Before proceeding with the survey, we ask that you please read the following and indicate your consent below.

The purpose and nature of the study has been explained to me in writing.

I am participating voluntarily.

I understand that I can withdraw from the study, without repercussions, at any time.

I understand that I can withdraw permission to use the data, in which case the material will be deleted.

I understand that anonymity will be ensured in the write-up of results.

I understand that anonymised data will be used in the report and any subsequent publications.

- ◯ I consent to participate in the National Survey of Diabetes Nurse Specialists in Ireland.

Survey of Diabetes Nurse Specialists in Ireland (Wave 2)

Contact Information

2. Please provide the following information:

Name: ________

Address 1: ________

Address 2: ________

City/Town: ________

Email Address: ________

Mobile Number: ________

3. The survey will be followed by a qualitative study exploring Diabetes Nurse Specialists' experiences providing care in the Irish health system. If you do not wish to be contacted about this follow-up study please tick this box:

○ Do not contact me

Survey of Diabetes Nurse Specialists in Ireland (Wave 2)

Education & Employment

4. What is your job title?

[ ]

5. Are you a:

- ○ Community DNS
- ○ Hospital DNS
- ○ Both community and hospital DNS
- ○ ANP (Primary Care)
- ○ CNS (General Practice)
- ○ Other (please specify below)

[ ]

6. Where are you based? (Tick all that apply)

- ☐ Community
- ☐ General Practice
- ☐ Hospital
- ☐ Other (please specify below)

[ ]

7. Do you work in:

- ○ Adult services
- ○ Paediatric services
- ○ Maternity services
- ○ Other (please specify below)

[ ]

8. What is your catchment area?

[ ]

9. What age group are you in?

◯ 25-34 ◯ 35-44 ◯ 45-54 ◯ 55-64 ◯ 65 or older

10. Post basic qualification (please tick all that apply)

- ☐ Masters in Diabetes
- ☐ Post Graduate Diploma in Diabetes
- ☐ Masters in Nursing Studies
- ☐ Certificate in Diabetes Nursing
- ☐ PhD (completed or undertaking)
- ☐ Certificate in Diabetes through E-learning (ICGP module)
- ☐ Diabetes counselling course
- ☐ Diabetes in Primary Care (NUIG/UCC module)
- ☐ Higher Diploma (HDip) in Diabetes Nursing
- ☐ Masters in Primary Care
- ☐ Other (please specify below)

11. Are you a Registered Nurse Prescriber (RNP)?

◯ Yes

◯ No

12. How many years experience do you have working as a DNS?

13. How many years experience do you have working in your current position?

14. What is the grade of your current position?

◯ Staff nurse

◯ Senior staff nurse

◯ Clinical Nurse Specialist

◯ Advanced Nurse Practitioner

◯ Clinical Nurse Manager

◯ Other (please specify below)

15. Do you know the whole time equivalent (WTE) of your position?

◯ Yes

◯ No

16. If yes, please estimate the WTE.

17. Who are you employed and funded by?

	Employed by	Funded by
HSE	☐	☐
Diabetes Ireland	☐	☐
Pharmaceutical company	☐	☐
Diabetes initiative	☐	☐

Other (please specify)

18. How many hours per week do you spend working in each setting(s)?

Community

General Practice

Hospital

Total hours per week

19. How many hours per week do you spend working in each of these services?

Adult services

Paediatric services

Young person's clinic

Diabetes in pregnancy

In-patient services

Out-patient services

Community clinics

GP practices

Research/audit

Administration

20. Are you linked to a specific hospital?

- Yes
- No

If yes, which hospital(s)?

21. Is there a clinical governance lead for your service?

- Yes
- No

22. If yes, who is responsible for clinical governance?

- Consultant
- GP
- Other (please specify below)

23. Who is your manager?

- Hospital
- GP
- General manager for community
- Transformation Development Officer
- Director of Nursing
- Director of Public Health Nursing
- Other (please specify below)

Providing Diabetes Care

24. Is there a written job description for your role?

- ◯ Yes
- ◯ No

25. What type of patients attend your service? (Tick all that apply)

- ☐ Type 1 diabetes
- ☐ Stable Type 2 diabetes
- ☐ Complicated Type 2 diabetes
- ☐ Gestational Diabetes
- ☐ Young adults with diabetes
- ☐ Pre-diabetes
- ☐ Other patient groups (please specify below)

26. Regarding diabetes, what are your specific roles in patient care? (tick all that apply)

	Type 1 diabetes	Type 2 diabetes	Other patient groups
Patient management	☐	☐	☐
Prescribing	☐	☐	☐
Dose adjustment only	☐	☐	☐
Insulin/GLP1 initiation/education	☐	☐	☐
Checking injection sites	☐	☐	☐
Glucose Monitoring	☐	☐	☐
Hypo Management	☐	☐	☐
Medical review	☐	☐	☐

Other (please specify)

27. Are you involved in any of the following? (Tick all that apply)

	Type 1 diabetes	Type 2 diabetes	Other patient groups
Hypertension clinics	☐	☐	☐
Renal clinics	☐	☐	☐
Pre-conception discussion	☐	☐	☐
In-patient diabetes care	☐	☐	☐
Referrals	☐	☐	☐
Telephone advice	☐	☐	☐
Assessment clinics prior to surgery	☐	☐	☐

Other (please specify)

28. What are your specific roles in education? (Tick all that apply)

	Type 1 diabetes	Type 2 diabetes	Other patient groups
Patient education	☐	☐	☐
Family education	☐	☐	☐
Pump Training	☐	☐	☐

Other (please specify)

29. Are you involved in any of the following aspects of lifestyle management? (Tick all that apply)

	Type 1 diabetes	Type 2 diabetes	Other patient group
Smoking cessation advice	☐	☐	☐
Dietary advice	☐	☐	☐
Physical activity advice	☐	☐	☐
Weight management	☐	☐	☐

Other (please specify)

30. Are care plans developed with patients?

- ◯ Yes
- ◯ No

31. Are you involved in providing foot care?

- ◯ Yes
- ◯ No

If yes, which screening tool do you use?

32. Do you register patients for RetinaScreen?

- ◯ Yes
- ◯ No

If no, who is responsible for this?

33. Do you have referral access to other services? (Tick all that apply)

- ☐ No
- ☐ Podiatrist
- ☐ Dietician
- ☐ Ophthalmologist
- ☐ Psychologist
- ☐ Social Worker
- ☐ Other (please specify below)

34. Do you advise patients with diabetes to self-monitor blood glucose levels?

- ◯ Yes
- ◯ No

If yes, which patients are advised to self-monitor?

35. Is there a local agreement between the hospital and primary care regarding how your DNS service operates?

- ◯ Yes
- ◯ No

If yes, please outline what has been agreed locally.

36. Do you have a liaison role with any of the following colleagues? (Tick all that apply)

- ☐ No
- ☐ GP
- ☐ Practice Nurse
- ☐ Hospital DNS (if applicable)
- ☐ Community DNS (if applicable)
- ☐ Consultant
- ☐ Other (please specify)

37. What does this liaison role involve?

38. Do you cover other roles not solely related to diabetes?

- ◯ Yes
- ◯ No

If yes, please specify

39. Are there other nurses engaged in the diabetes service in your area? (Tick all that apply)

- [ ] No
- [ ] Diabetes Nurse Facilitator
- [ ] Staff Nurses
- [ ] Practice Nurses
- [ ] Public Health Nurses
- [ ] Other (please specify below)

Clinics

40. Do you run a nurse-led diabetes clinic?

- ◯ No
- ◯ Yes, generalised clinics only
- ◯ Yes, specialised clinics only
- ◯ Both

What type of specialist clinic you do you lead?

41. How many nurse-led clinics do you run each week?

- ◯ None
- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4 or more

42. On average, how many patients do you see per clinic?

- ◯ Less than 5
- ◯ 5
- ◯ 10
- ◯ 15
- ◯ 15 or more
- ◯ Not applicable

43. Do patients also see a consultant/GP?

- ◯ Yes, during the same visit
- ◯ Yes, at a later date
- ◯ No
- ◯ Not applicable

44. Where are these clinics held? (Tick all that apply)

- [ ] General Practice
- [ ] Primary care centre
- [ ] Community outreach clinic
- [ ] Hospital
- [ ] Out-patients clinic
- [ ] Not applicable
- [ ] Other (please specify below)

45. If you provide clinics in the community, are all GP practices eligible to access your service?

- ( ) Yes
- ( ) No
- ( ) Not applicable

If no, who is the service available to?

46. Who is generally available to support you in the diabetes clinic? (Tick all that apply)

- [ ] Consultant
- [ ] SpRs or equivalent
- [ ] Senior House Officer
- [ ] Intern
- [ ] Practice Nurse
- [ ] GP
- [ ] Hospital DNS
- [ ] Other (please specify below)
- [ ] Community DNS
- [ ] Podiatrist
- [ ] Dietician
- [ ] Psychologist
- [ ] Health care assistant
- [ ] Not applicable

47. Is there a waiting list for your service?

- ○ Yes
- ○ No

If yes, please estimate how long people wait to attend the service

[ ]

48. In your opinion, what are the main reasons for the waiting list in your area?

[ ]

49. Do you provide out-of-hours diabetes consultations?

- ○ Yes
- ○ No

50. If 'yes', when are the out-of-hours sessions held in your area? (please tick all that apply)

- ☐ At weekends
- ☐ In the evenings
- ☐ Other (please specify below)

[ ]

51. Do you provide a drop-in service for patients?

- ○ Yes
- ○ No

52. Are any of the following telephone services available to patients? (Tick all that apply)

	Telephone support service	Messaging service
Yes, universal access for all patients	☐	☐
Urgent only	☐	☐
Specialist patient groups	☐	☐
Pregnancy	☐	☐
Paediatric	☐	☐
None available	☐	☐

53. When is the telephone support service available? (Tick all that apply)

- [ ] Weekday office hours
- [ ] Weekend office hours
- [ ] Weekday evenings
- [ ] 24hours- 7 days a week
- [ ] Not applicable

54. Which members of staff operate the telephone support service? (Tick all that apply)

- [ ] DNS
- [ ] Secretaries
- [ ] Medical staff
- [ ] Consultant
- [ ] Podiatrist
- [ ] Other (please specify below)
- [ ] Dietician
- [ ] Practice Nurse
- [ ] GP
- [ ] Not applicable

55. How quickly do patients get a response to messages?

56. Is there a discharge follow-up pathway from wards to diabetes out-patient care?

- ( ) Yes
- ( ) No
- ( ) Not known

57. Is there a discharge follow-up pathway to primary care for ward discharges?

- ( ) Yes
- ( ) No
- ( ) Not known

58. Do all people with diabetes admitted to hospital in your area have ready access to specialist diabetes team support?

- ( ) Yes
- ( ) No

Education

59. Is a structured patient education programme available in your area for the following patient groups ? (Tick all that apply)

- ☐ Type 1
- ☐ Type 2
- ☐ Paediatric
- ☐ Gestational Diabetes
- ☐ Prevention
- ☐ None available
- ☐ Other (please specify below)

60. If yes, which programmes are available in your area?(Tick all that apply)

- ☐ DESMOND
- ☐ XPERT
- ☐ CODE
- ☐ DAPHNE
- ☐ Walk Away from Diabetes
- ☐ Not applicable
- ☐ Other (please specify below)

61. Are you involved in providing education to any of the following professional groups?

- ☐ GP
- ☐ Practice Nurse
- ☐ Nursing staff in hospitals
- ☐ Medical staff in hospitals
- ☐ Allied health professionals
- ☐ Medical staff in nursing homes
- ☐ None of these groups

If yes, how is this education provided? (e.g. information only, one-to-one sessions, groups sessions)

Recording Activity

62. Are any of the following records used? (Tick all that apply)

- [ ] Paper record
- [ ] Shared care book
- [ ] Electronic patient health record
- [ ] None of the above
- [ ] Patient passport

63. If yes, who completes the record? (Tick all that apply)

- [ ] Me
- [ ] GP
- [ ] Another DNS
- [ ] Practice Nurse
- [ ] Patient
- [ ] Not applicable
- [ ] Consultant
- [ ] Other (please specify below)

64. Please estimate the percentage of time (%) per month spent on each of these additional activities.

Telephone advice

Informal patient drop-in activity

In-patient contact

Running clinics

Multidisciplinary team activity/meetings

GP/Practice liaison

65. Are these activities recorded? (Please tick all that apply)

- [ ] Telephone advice
- [ ] Informal patient drop-in activity
- [ ] In-patient contact
- [ ] Number of clinics
- [ ] Multidisciplinary team meetings
- [ ] GP/Practice liaison
- [ ] None recorded

66. Do you have protected time for continuing professional development?

◯ Yes ◯ No

67. Is there a protected budget for diabetes continuing professional development?

◯ Yes ◯ No

Opportunities & obstacles for diabetes care in Ireland

68. We value your insight into diabetes care. Please use the space provided to describe the main barriers and facilitators to delivering the diabetes service in your area.