

UNIVERSITY OF BIRMINGHAM

**Understanding variation in the clinical quality of primary care: A typology of
general practice organisations**

by

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**A thesis submitted to the University of Birmingham for the degree of Doctor of
Philosophy**

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Institute of Applied Health Research
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October 2016**

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ABSTRACT

Introduction

The presented research sought to understand variation in the clinical quality of general practice.

Methods

Clinical quality indicators relating to Cardiovascular Disease and Diabetes were analysed in general practices in Sandwell and the Black Country. General practices showing unusually high or low performance across indicators were identified. Semi-structured interviews were then conducted with practice staff to explore reasons for variation.

Results

Differences emerged between practices' leadership, culture, care systems and approaches to quality measurement and improvement. General practices were categorised into four types within a newly developed typology of general practice organisations: "biomedical", "holistic", "corporate" and "externally reactive", where there was some evidence that practice type influenced variation.

Discussion

Variation in general practice clinical quality appeared linked to differences staff held in their views of what constitutes quality in general practice, as explained through the practice typology, with an implied trade-off between achievement of different quality priorities. The research is limited by the study population, specified disease focus and quality measures adopted to examine variation. However, the results highlight the importance of moving to a shared definition of quality in general practice which may influence the measurement and understanding of variation in this setting and the developed practice typology.

ACKNOWLEDGEMENTS

I would like to especially thank and express my sincere gratitude to my supervisors, Prof. Tom Marshall, Prof. Tim Stokes and Dr. Antje Lindenmeyer for their support, guidance and mentorship throughout the PhD, together with their valued contribution made to the thesis research and research outputs. I am particularly grateful for their encouragement, teaching and advice throughout the PhD and in supporting me to develop both personally and academically during this period.

I also humbly extend my thanks to those who supported in the thesis research through contributions to the various research stages, such as colleagues at the University of Birmingham and through various organisations that supported research access, development and delivery, including local health and care professionals who offered their time to take part in the research.

I especially thank the National Institute of Health Research (NIHR) School of Primary Care Research for funding this PhD studentship and through financing and providing supporting PhD activities that have allowed me to develop my personal knowledge, skills and abilities as a researcher.

I would finally like to thank and acknowledge my wife and family for their important ongoing support which is always valued.

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LIST OF ABBREVIATIONS

CVD: Cardiovascular Disease	OT: Other Practice (Not HP or LP)
QI: Quality Improvement	GP: General Practitioner
HP: High Performing (GP Practice)	HCP: Healthcare Professional (Non-GP and not based in/ employed by Practice)
LP: Low performing (GP Practice)	PM: Practice Manager
RI: Ryan Irwin (Interviewer)	PN: Practice Nurse
PP: Participant	NP: Nurse Partner
Pp: Page	HCA: Health Care Assistant
	GPr: GP Registrar

CHAPTER 1: INTRODUCTION

1.1 Introduction

The introductory chapter sets the context for the thesis research, providing early indication of important topics, whilst recognising the need to frame the research area (Dunleavy, 2003). The research set out in this thesis represents an area of strong personal interest, notably measuring and understanding variation in the quality of healthcare with the aim of supporting quality improvement (QI). Primary care is the fulcrum of the UK health system and understanding variation in this setting is integral to improving whole system quality and ultimately population health outcomes.

To allow sufficiently rich analysis and specificity, it is important to determine a clear scope and focus of study (Bentley, 2006). The disease areas of Cardiovascular Disease (CVD) and Diabetes Mellitus (Diabetes) have been chosen as a research focus due to their significant contribution to the global burden of disease, the associated economic burden this creates, and their prominence and importance within primary care disease management both nationally and globally (Sowers *et al*, 2001; Chobanian *et al*, 2003; Fox *et al*, 2007; NICE, 2011; Department of Health, 2013; Ornstein *et al*, 2013; St.Sauver *et al*, 2013).

1.2 Introduction to primary care research

Internationally, primary care is recognised as an important contributor to improved health system outcomes, where Starfield and others in particular have made a significant contribution to demonstrating the importance of primary care in population health management (Starfield *et al* 1994; 2001; 2005). In the UK, around 90% of all patient contacts within the healthcare system occur in a primary care setting,

equating to more than 300 million consultations annually (Thomas, 2000; Royal College of General Practitioners, 2011). Equally, the development of Clinical Commissioning Groups in England (statutory organisations replacing Primary Care Trusts in 2013), responsible for the planning and commissioning of the majority of the NHS budget at a local level, have resulted from the recognised need of primary care involvement to shape national health system commissioning and provision (Mason and Moran, 2012; Checkland *et al*, 2013).

Primary care research is fundamental in supporting health improvement from the individual to system level, where Mant *et al* (2004) concisely articulate:

"Research in primary care is essential because: (1) clinical and preventive care must be underpinned by research evidence; (2) the bulk of such care in most countries, especially poorer countries, is delivered in primary care; and (3) evidence to underpin this care cannot be informed by laboratory and hospital-based research alone." (Mant *et al*, 2004. Pp. 1004).

From the perspective of thesis research, it is important to demonstrate research originality and contribution to the primary care research base. The thesis has a focus on understanding variation in the clinical quality of primary care, which is defined subsequently. Whilst there is significant interest and research in clinical and medical practice variation in clinical quality in an acute care setting, there is less research around understanding the causes of clinical quality variation in primary care at the practice level (the level of each individual general practice unit, differentiated from primary care at a population level and the level of individual primary care practitioners and staff). Research into variation in primary care at the practice level does however exist. In searching the literature, there are examples of practice-level analysis of variation in the quality of primary care across areas such as

understanding chronic care process delivery, practice mortality and treatment of minor ailments, in addition to utilising variation analysis methodology for practice-based QI interventions (Mohammed *et al*, 2001; Marshall and Mohammed, 2003; Thor *et al*, 2007; Siriwardena and Gillam, 2013).

The proposed research aims to explore and understand the reasons for variation in the clinical quality of primary care through a mixed-methods research approach to identify implications for QI. Quantitative techniques are used to identify *where* variation exists, with qualitative methods used to understand *why* such variation exists.

1.3 Introduction to variation and quality improvement

1.3.1 Introduction to quality, QI and variation

As demand for healthcare rises due to factors such as population ageing, increased disease chronicity and multimorbidity, and capacity reduces due to budgetary, inflationary and resource pressures, there is an inherent need to ensure continual improvement in primary care quality to deliver optimal outcomes and value from health services (Marengoni *et al*, 2011; Wennberg, 2011).

Whilst numerous definitions exist, QI in a healthcare context can be defined as:

"a continuous process that identifies problems in healthcare delivery, examines solutions to those problems, and regularly monitors solutions for improvement"
(Urowitz *et al*, 2006. Pp. 117)

Using the World Health Organisation dimensions of quality, high quality healthcare is synonymous with care that is effective, efficient, accessible, acceptable/patient-centred, equitable and safe (World Health Organisation, 2006). Therefore, QI in

healthcare can be viewed as a process which seeks to improve performance against these domains. Clinical quality, the focus of the thesis research, describes the ability of care providers to achieve high care standards in accordance with best practice and clinical guidelines through diagnosis, procedures and treatment that create desired physiological effects on patients. Clinical quality is therefore most aligned to the component of quality termed "effectiveness" by the Institute of Medicine (2001), where services are delivered based on scientific knowledge. Equally, using Donabedian's conceptual model of quality in health care, clinical quality is most likely to align to categories of clinical process and (intermediate) clinical outcomes (Donabedian, 1988; Groonroos, 1990; Mant, 2001; Marley *et al*, 2004; Institute of Medicine, 2001, Shekelle, 2013). The importance of measuring and improving clinical quality through clinical quality indicators is described subsequently in this introduction.

W. Edwards Deming and Walter Shewhart are widely cited for highlighting the importance of understanding and appropriately managing unwarranted variation as fundamental to QI (Deming, 1982). In a healthcare context, it is widely recognised that reducing adverse clinical variation produces a simultaneous reduction in healthcare costs and improvement in healthcare quality, where Shewhart's theory of variation states that quality is inversely proportional to variability (Duclos and Voirin, 2010; James and Savitz, 2011). Statistical theory was developed to identify two distinct origins of variation in a process; "Common Cause" (non-assignable) variation and "Special Cause" (assignable) variation. Common cause variation is variation in control, attributable primarily to a given process. Special cause variation however is extrinsic to process, requiring further investigation to identify the *cause* of variation

which may aid in understanding factors that both improve and worsen quality (Shewhart, 1981; Deming, 1982; James and Savitz, 2011).

Recognising the difference between common cause and special cause variation is critical for a number of reasons. Failing to correctly understand special cause from common cause variation can lead to unintended and often negative consequences (Shewhart, 1986). Noyez (2009) notes some of the common pitfalls for consideration when examining variation and statistical process control, with three being summarised. Firstly, that variation within defined limits as seen through statistical process control charts does not provide solutions to managing variation, where measurement of variation is not an end point in itself in the context of QI. Secondly, that variation in control within a defined range does not necessarily negate the need for further examination or QI. Thirdly, when applying any statistical method for understanding variation, one must be mindful that indications of special cause variation are *indicators* only, with further exploration required to identify the underlying cause of variation (Noyez, 2009).

As noted, there is a research gap within primary care at the practice level understanding the causes of variation in clinical quality through theories of common cause and special cause variation. Understanding the measurement of variation and application of QI methodology in primary care is essential to inform research and practice (Davis *et al*, 2002).

1.3.2 Measurement of Variation

Shewhart (1986) used control charts as a statistical tool with heuristic purpose for measuring variation in a system or process. *Three sigma* was assigned as the

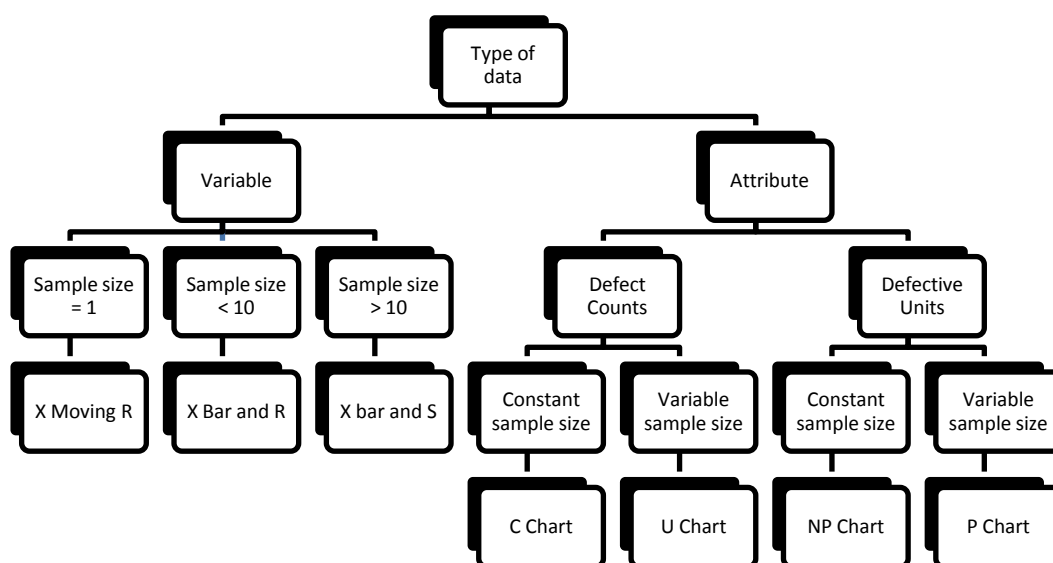
differentiating point distinguishing between a measurement that displays common compared to special cause variation (with sigma as a statistical measure of variability and three sigma expressing a level where "nearly all" data lies within three standard deviations of the mean). Whilst it may be criticised that the use of a statistical measure such as *three sigma* is arbitrary as a signal for indicating special cause variation as described, Shewhart (1986) used the *three sigma* level based on the application of statistical theory and numerous empirical data observations. As an element of critical justification for the use of *three sigma*, Shewhart used Tchebysheff's inequality, which provides an upper limit to the probability that the deviation of a random variable will exceed a given threshold. Formulaically, this defines that at least $1-1/K^2$ of data from a sample must fall within K standard deviations from the mean. Tchebysheff's inequality can be applied to any data set and not just the normal distribution, where Shewhart's use of *three sigma* is generally accepted for use in QI in the healthcare environment (Faltin *et al*, 2012).

The variation observer should also recognise the relationship between the level applied to identify special cause variation and the relationship this has in making both a Type 1 or Type 2 error, defined as making either a false positive or false negative conclusion on assignability of cause from process control observation as a result of narrowing or widening the special cause trigger level (Noyez, 2009). For example, it follows that in using a two sigma limit for assigning special cause variation instead of a *three sigma* limit, there is increased likelihood of assigning special cause to a process under control or normal fluctuation. Deming (1986) describes type I and type II error to common cause and special cause variation. A type I error occurring

where common cause variation is treated as special cause and type II error where special cause is treated as common cause.

The use of control charts in healthcare for measuring statistical process control and supporting QI is increasing in parallel with compliance to recommended control chart criteria, such as the use of *three sigma* in control limit placement (Noyez, 2009; Koetsier *et al*, 2012). Cumulative sum methods and funnel plots may be used in preference to, or indeed simultaneously with, other control charts. The former being useful particularly when examining processes with smaller measurement trend shifts and the latter for comparisons between sites or organisations with differing variation sensitivity (Wood and Lambert, 2010; Mohammed *et al*, 2008). Whilst not within the scope of this introduction to analyse the number of control charts and charts in existence, it is important to recognise the decision making process for control chart selection (Figure 1) and the scope of charts and techniques available for measuring variation.

Figure 1: Control Chart Selection



(Adapted from the Oakridge Institute for Science and Education, 2013)

For the purposes of the thesis, funnel plots were used as the preferred method for understanding variation. Historically, funnel plots have been commonly used in healthcare and other research predominantly for the identification of publication bias (Guyatt *et al*, 2011; Baskerville *et al*, 2012). However, funnel plots have since become widely recognised and used as a flexible, simple and effective tool in examining variation and performance in healthcare from areas as diverse as examining healthcare organisation performance in care processes and individual practitioner performance to patient satisfaction and care outcomes (Spiegelhalter, 2005; Woodhall, 2006; Noyez, 2009; Griffen *et al*, 2012; Manktelow and Seaton, 2009).

1.4 Introduction to clinical quality focus areas

CVD and Diabetes were identified as key areas of focus in which to investigate variation in the clinical quality of care, with CVD covering a range of circulatory and vascular diseases: Heart disease, stroke, transient ischaemic attack, and peripheral vascular disease (Frostegard, 2013). The justification for focussing on these two areas was three-fold. Firstly, CVD and Diabetes are common diseases representing a significant burden of disease in the UK and globally, making up a high proportion of primary care visits for which unwarranted variation in clinical care quality has a significant impact on healthcare utilisation, morbidity and mortality (Sowers *et al*, 2001; Hobbs, 2004; Faculty of Public Health, 2005; Fox *et al*, 2007; Department of Health, 2013; Joffres *et al*, 2013; Ornstein *et al*, 2013; St. Sauver *et al*, 2013). Secondly, these conditions have a clear and recognised evidence base defining

clinically effective interventions that should be delivered in primary care (NICE, 2008; NICE, 2010; NICE, 2011; NICE, 2013). Finally, these diseases have a significant economic burden in the UK where the majority of the costs of care are due to treating avoidable risk factors and complications of the diseases that can be affected through effective primary care management (NICE, 2011; Hex *et al*, 2012; NICE, 2013). It is estimated around 2.7 million people live with CVD, one of the UK's largest causes of death and disability, at a financial cost of over £15 billion to the NHS and over £30 billion to the wider economy (NHS Evidence, 2003; NHS Choices, 2012; Department of Health, 2013). Similarly, the global economic burden represented through Diabetes-associated costs is estimated at around 12% of overall healthcare expenditure (Zhang *et al*, 2010; Nolan *et al*, 2011; Diabetes UK, 2013). CVD and Diabetes are intrinsically linked as disease areas, particularly due to similar contributory metabolic risk factors.

Hypertension was also deemed an important area for inclusion within the research as is a significant risk factor for Diabetes and CVD, associated with healthcare costs of over £1 billion in the UK alone, but more than £12 billion when widening the resulting impact of Hypertension in CVD and Stroke development (Liu *et al*, 2002; NICE, 2011). NICE (2011) report the prevalence of *established* Hypertension in the UK to be over 13% based on primary care QOF data, however other estimates of *actual* prevalence indicate a figure closer to 30% and rising, with the largest contributory factors being genetic predisposition and preventable lifestyle factors (Faculty of Public Health, 2005; NICE, 2011, Joffres *et al*, 2013). Whilst the clinical management of hypertension accounts for a significant proportion of primary care clinical activity, variation in hypertension management within primary care is

significant. NICE (2010) provides an estimate that £446, 627 can be saved per 100,000 patients if primary care clinical management of hypertension was fully compliant to NICE guidelines. This was estimated particularly in examining the impact of following prescribing and referral guidance reducing over-prescribing, mis-prescribing and ineffective or inaccurate clinical assessment and treatment.

Exploring the causes of variation in the clinical quality of Hypertension care appears a worthwhile pursuit given the relative lack of variation research, exploring thematic trends, at the general practice level in primary care (Saxena *et al*, 2007).

The importance placed on both CVD and Diabetes management in primary care in England is evident as seen through the General Medical Services (GMS) contract-linked quality outcome framework (QOF) scheme (British Medical Association, 2016). QOF is an incentive scheme for general practices based on the management of a number of disease areas. Practices must keep a register of patients with CVD and Diabetes amongst other clinical conditions, where performance is measured as the percentage of patients on the register who have had appropriate diagnostic tests, who receive appropriate annual monitoring and receive appropriate evidence based treatments. There are agreed rules for recording data in clinical records on diagnoses, diagnostic tests, monitoring and treatment of these chronic diseases and the data are thought to be of high quality (Herrett *et al*, 2015). CVD and Diabetes-related indicators make up more than 25% of all points in the clinical domain field, where QOF itself has supported quality measurement and improvement of such conditions compared to existing pre-QOF trends (Roland and Guthrie, 2016). The opportunity to therefore examine variation in clinical quality across these areas through existing available data is recognised, where the focus on the defined disease

areas also allowed for a clear research scope and deeper exploration of variation causes that may be disease-specific.

1.5 Introduction to clinical quality indicators

A key feature of the presented thesis research is the use of clinical quality indicators for identifying variation in clinical quality. Clinical quality indicators measure the clinical quality of care provided as described within the thesis introduction and are differentiated from performance measures that may measure an aspect of care (such as utilisation, cost or activity) that is not necessarily related to quality (Campbell *et al*, 2003). It is recognised that indicators can measure structures (organisational, human and material resources), processes (the sum of the actions delivered in healthcare) or outcomes of care (the effects on patients or populations), where outcome indicators are generally of most interest and importance in reflecting the overall performance of a healthcare system (Donabedian, 1988, Mant, 2001; Shekelle, 2013). However as a number of authors note, outcomes and outcome indicators are influenced by a much wider range of determining factors than healthcare alone, such as the environment, deprivation and lifestyle to name a few (Mant, 2001; Campbell *et al*, 2002; Mainz, 2003; Shekelle, 2013). Evidence-based clinical quality indicators however are cited as more direct and sensitive measures of health and care quality and suggested as a more useful type of indicator when the primary concern is related to QI (Mant, 2001; Campbell *et al*, 2003; Nothacker *et al*, 2016). Mainz (2003) further suggests monitoring QI is impossible without clinical quality indicators, provided these are developed and used with scientific rigour.

As Campbell *et al* (2003) highlight, quality indicator application should recognise the stakeholder perspectives reflected through indicator use, the purpose and scope of measurement (such as the setting and aspects of care for indicator focus), and the evidence that exists to support their use. The King's Fund (2010) further add that the impact of indicator use should also be understood (for example where measurement impact may differ depending on measurement use for research compared to performance management purposes). Equally, the practical issues of measurement selection and use should also be considered, such as data sources and availability, data coverage and access (The King's Fund, 2010).

Many of the included indicators used in the research are approved by NICE, or derived from clinical practice guidelines, intending to incentivise disease management and prevention, enhance primary care quality and productivity and optimise compliance with evidence-based guidelines through processes that can be managed and affected by General Practice (Stokes *et al*, 2010; HSCIC, 2014). Kotter *et al* (2012) identify clinical practice guidelines as an acceptable and useful source for quality indicator selection. The thesis methods pay attention to this relevant theory on quality indicators when selecting and applying indicators.

CHAPTER 2: METHODOLOGY

2.1 Introduction

The focus of this chapter is on describing the research approach and process used to identify the causes of variation in the clinical quality of primary care across general practices in Sandwell and the Black Country (West Midlands). The importance of framing the research within a QI context is again restated, given the inherent relationship between variation and quality. Mixed methods research constituting quantitative and qualitative approaches was adopted in order to generate answers to the question of where variation exists and why. The distinction between research methodology and methods is recognised, with the former relating to how the research is conducted through explanation and justification of the methods available for use and the latter relating to the specific tools and techniques used in the research (Kothari, 2011). Throughout the chapter, researcher reflections on the research process are used to illustrate the experiences and challenges of conducting the research.

2.1.1 Quality Improvement

The methodology adopted in the presented research follows recognised QI theory. Previous chapters have noted and described the components and emergence of QI methodology, with the measurement and understanding of variation being a critical first component of implementing QI. Consistent across QI methodologies is the need to initially identify a process or area for improvement, using data and measurement to understand variation and baseline performance (Health Foundation, 2013). Whilst the methodology in measuring for improvement and measuring for research are

slightly different, the need for appropriate selection and application of a suitable analysis tool is common to both (Health Foundation, 2013).

Having established an area for analysis through selected disease areas and indicators (defined subsequently), variation was analysed through the use of funnel plots with control limits set at three standard deviations. Three standard deviation limits are used to differentiate special cause from common cause variation, based on justification from both statistical theory (Tchebysheff's theorem) and practical experience of QI methodology. In identifying special cause outliers, variation analysis and improvement activity can be more focussed and economic, compared to assessing each individual data point within a dataset (Benneyan *et al*, 2003).

The relationship between the quantitative and qualitative methods applied is important in serving to both *identify* (quantitatively) and *understand* (qualitatively), reasons for variation. It is from this understanding that QI efforts and strategies can be informed.

2.2 Mixed methods approach

Mixed methods research is being increasingly adopted as a methodology in health care research (Creswell *et al*, 2011). "Mixed methods" do not define a single approach to research, however, Johnson *et al* (2007) provide a definition which most fits the research in this thesis:

"the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches for the broad purposes of breadth and depth of understanding and corroboration."
(Johnson *et al*, 2007. Pp. 123).

Mixed methods research builds on the strengths of both quantitative research (providing measurable evidence, assessing probable cause and effect and facilitating insight from statistical analysis which allows potential replication and generalisation of data) and qualitative research (with a focus on context, meaning and experience), to support improved understanding of a given problem or research question in the round (Creswell *et al*, 2011). Mixed methods approaches vary from concurrent to sequential mixed methods data collection, and for research areas spanning across policy, clinical and organisational aspects of primary care (Creswell *et al*, 2004; Curry *et al*, 2013; Zhang and Creswell, 2013). In the presented research, a sequential approach was used by *connecting data* where quantitative methods were used to identify variation in the clinical quality of primary care and inform participant selection for qualitative methods, which were used to investigate the causes of variation (Creswell *et al*, 2010). Using qualitative data after quantitative data acquisition can allow for a wider understanding of a given research question, provide insight to the processes and experiences relevant to quantitative outcomes, to act to explore and highlight the reasons for quantitative data findings, and to supplement quantitative findings with meaning or validation (Plano Clark and Creswell, 2010). As Plano Clark and Creswell (2010) note, it is also common to use quantitative analysis prior to qualitative analysis in mixed methods research to support the selection of participants, cases or similar in which to explore specific quantitative data points or outcomes - an important feature in the presented research.

Consideration was given to the justification for using mixed methods through the research proposal and the quantitative and qualitative frameworks used. In discussing the early research proposal with my supervisors, it was felt important to

use a mixed methods approach, particularly where analysis of variation in primary care is often lacking or misunderstood. For example, where assignable causes are applied to non-assignable variation, or where special cause variation is incorrectly used for performance management without understanding the reasons for variation. It was agreed that a mixed methods approach would add greater understanding of the causes of variation and also identify potential important implications for QI in primary care at the practice level. The mixed methods adopted in the data analysis and interpretation were pre-defined (fixed), however an emergent approach was then used to follow up initially planned qualitative semi-structured interviews with more in-depth deviant case analysis.

2.3 Qualitative research

Qualitative research allows subjective meaning and interpretation to be applied to real world and multifaceted phenomena in understanding the reality of a defined research area (Olsen, 2004, Griffin 2012). Specifically, qualitative research is about the non-numeric analysis of data, where it is central that the qualitative researcher utilises an appropriate method and theoretical framework that has been deliberately decided upon based on their research aim (Braun and Clarke, 2008). Qualitative research approaches, which are many and diverse, can provide clarity, idea generation, insight and interpretation of research topics, particularly in enquiry seeking, to understand people, their thoughts and experiences, interpersonal or artefactual interactions, and structural, cultural and organisational perspectives (Griffin, 2012).

Griffin (2012) highlights key areas of consideration for the use of a qualitative approach to primary care research which were considered in line with other relevant quality criteria checklists and best practice standards in primary and health care research (Mays and Pope, 2000; Barbour, 2001). Methods for data collection and analysis were clearly identified and are described subsequently to demonstrate rigour and integrity to the qualitative approach adopted.

In the mixed methods research, semi-structured interviews were used as the qualitative interview method. Use of semi-structured interviews as the primary qualitative approach, interview delivery, data analysis and presentation were also considered in ensuring methodological rigour of qualitative methods (Griffin, 2012). Semi-structured interviews, in contrast to structured interviews, are often used in research to allow flexibility and freedom from the perspective of the participant in answering identified interview questions (Steckler, 1992; Morse and Field, 1998). Free exploration of research questions throughout the interview, conversational inquisition and an element of participant flexibility in answering topic questions can allow more rich and diverse data acquisition than structured interview techniques, whilst retaining focus on a given research area (Steckler, 1992; Morse and Field, 1998).

A number of authors describe the use of semi-structured interviews in mixed methods research as a common approach to generate integrated, practical and useful data that adds rigour to research through triangulation of data across methods that explore perspectives arising from both "numbers and people" - both of which being important in developing insight in healthcare research (Steckler, 1992; Morse and Field, 1998; Bryman, 2006). The topic of variation explored lends itself to a semi-

structured approach that maintains interview focus whilst recognising the diversity and complexity of variation influences and perspectives.

In addition to the provided rationale, semi-structured interviews were deemed the most appropriate qualitative method to use as the causes of variation at the point of conducting the qualitative research were not fully known. It was felt through discussion between the researcher and research supervisors that semi-structured interviews would allow early identification and exploration of variation causes across a high number of general practices and with a number of different individual perspectives. It was agreed that such an approach would allow identification of potential themes in relation to variation causes and corroboration of themes across practices. It was however also recognised that other qualitative methods could be used, such as ethnographic methods, particularly observational methods, to study what was happening in practices in terms of the people, behaviours and cultures, that may contribute to variation (Angrosino, 2007). However, it was discussed that this may ignore causes of variation that were not related to people, behaviours and culture. It was agreed other methods could be used in follow-on research once early themes were identified through use of semi-structured interviews. There was also a recognition that practically adding these methods within the scope of the presented research may not be possible from a time or resource perspective.

2.4 Aims and objectives of mixed-methods research

The aims and objectives for the mixed-methods research are presented.

2.4.1 Aim and Research Questions

The specific aim that the mixed methods research intended to address was as follows:

"To understand the reasons for variation in the clinical quality of primary care at the practice level and identify the implications for quality improvement in this setting"

As is common in research development, the research aim was amended slightly following supervision sessions. It was agreed to not only focus on identifying the reasons for variation but also to seek to understand such influencing factors in the context of QI. The parallel research questions were as follows:

1. Which practices display frequent special cause variation using the clinical quality indicators identified within defined disease areas?
2. What are the reasons for variation in the clinical quality of care at the practice level?
3. What can be learned about those practices with higher and lower than expected performance across indicators examined?
4. What approaches exist to reduce variation and improve clinical quality in the practices studied?
5. What are the implications of the findings for QI (relevant at the general practice level)?

2.4.2 Objectives

Objectives were defined as follows:

1. To identify general practice level data from both national and local sources that will support understanding practice level variation in the clinical quality of primary care as measured through defined and appropriate clinical quality indicators.
2. To apply quantitative analysis techniques in identifying special cause variation in the clinical quality of primary care at the practice level.
3. To explore the emerging reasons for variation, particularly for identified outliers.
4. To utilise findings from the mixed methods research in defining implications for QI in primary care at the practice level.

2.5 Research governance and approval

2.5.1 Primary care study site selection

The primary care study site of Sandwell and the Black Country (West Birmingham) was identified through association with local research network links with the University of Birmingham, Sandwell Metropolitan Borough Council (for which practices within the Sandwell and West Birmingham area were aligned), and National Institute of Health Research (NIHR) local research coordinating unit. NHS Assurance for the research study was granted by the Clinical Research Network: West Midlands Consortium Office to include all primary care providers based within West Birmingham, Solihull, Dudley, Sandwell and Walsall.

2.5.2 Ethical approval

The study was reviewed, approved and given full ethical approval by the University of Birmingham Ethical Review Committee on 01/04/2014 (Ref number: ERN_1036). Advice was sought by the University of Birmingham Research Support Group and

Birmingham and Black Country Comprehensive Local Research Network in relation to requirements for Health Research Authority and NHS Research Ethics Committee approval. As the study only involved only involved NHS staff and health professionals and previously collected non-identifiable patient information it was advised Health Research Authority and NHS Research Ethics Committee approval was not required, however, the study was registered and approved through the NHS Integrated Research Application System (IRAS) and gained additional assurance and approvals as detailed in section 2.5.3. The advice provided is consistent with NHS Health Research Authority guidance to researchers (NHS Health Research Authority, 2016).

2.5.3 NHS Assurance, research sponsorship and research approval

The Clinical Research Network: West Midlands provided research and development assurance in addition to review and confirmation that the research met the NIHR criteria for research undertaken within the NHS. The Clinical Research Network also provided the letter of access to undertake research in general practice organisations in the defined area. The University of Birmingham acted as the sponsor and insurer of the project.

CHAPTER 3: METHODS

3.1 Introduction

To understand the causes of variation in the clinical quality of primary care, mixed methods were adopted. Quantitative, funnel plot analysis was used to identify special cause variation across clinical quality indicators. After which qualitative semi-structured interviews, thematic analysis and deviant case analysis was used to understand the reasons for variation. A typology of general practice organisations was then developed as an explanatory model to explain differences in the clinical quality of primary care at practice level.

3.2 Quantitative methods

3.2.1 Introduction

This section describes the study population, selection of quality indicators, data acquisition and quality checking, data analysis and data use, including for identification of participants for qualitative methods.

3.2.2 Study Population

The study population included 51 general practices in the Sandwell and Black Country area of the West Midlands. Practices within this area were members of two CCG "local commissioning groups" within the wider Sandwell and West Birmingham CCG. The practices were selected given their membership of these groups and their geography within the Sandwell Metropolitan Borough Council geographical boundary. This boundary was chosen given the access Sandwell Metropolitan Borough Council had to local practice data through a locally commissioned Merck Sharp and Dohme Limited practice comparison software database called "MSDi Practice Comparator"

(MSDi), which is described subsequently in this thesis. The health of people in Sandwell and the Black Country (the Sandwell Metropolitan Borough Council geography) is generally worse than the England average with deprivation higher than average: Table 1 compares the Sandwell Metropolitan Borough Council area to England across key public health indicators in order to provide context for the generalisability of research findings.

Table 1: Characteristics of Sandwell Metropolitan Borough council population

Indicator	Sandwell Metropolitan Borough Council Area Value	England Value (England Best-Worst)
Average registered persons per GP practice (Practice registered list size, NHS Information Centre, 2013)	5,440	7,324
Deprivation Score (Index of Multiple Deprivation Score, Department of Communities and Local Government, 2015)	34.6	21.8 (5.7-42)
Male Life Expectancy at Birth in Years (ONS mortality data and mid-year population estimates, Office for National Statistics, 2012-2014)	77	79.5 (83.3-74.7)
Female Life Expectancy at Birth in Years (ONS mortality data and mid-year population estimates, Office for National Statistics, 2012-2014)	81.3	83.2 (86.7-79.8)
Long-term unemployment (People in long-term unemployment per 1000 working-age population, Nomisweb, 2015)	12.6	4.6 (0.5-15.7)
Statutory Homelessness (Eligible homeless people not in priority need per 1000 households, Department for Communities and Local Government, 2015-2016)	0.6	0.9 (0.1-8.9)
Education (Percentage GCSE attainment 5A*-C for the population including English and Maths, Department for Education, 2014-15)	48.9	57.3 (71.4-42)
Smoking Prevalence in adults (Current smokers as a percentage of the total population, Public Health England; Annual population survey, 2015)	17.7	16.9 (9.5-26.8)
Excess weight in adults (Percentage of adults classified as overweight or obese based on body mass index as a percentage of the total population, Active People Survey, Sport England, 2013-14)	70	64.8 (46.5-76.2)

(Public Health England, Health Profiles Key Population Indicators, 2015).

Whilst Sandwell and West Birmingham demonstrates worse than expected values across population health indicators as displayed in Table 1, the study area is grouped within the "cities and services" supergroup by the Office for National Statistics and displays many similar health summary indicator values compared to other areas in this supergroup (NHS England, 2012).

3.2.3 Indicator Selection

The clinical quality indicators for CVD and Diabetes were selected and agreed via a three-person review group. In addition to the lead researcher, the group included an academic public health physician (Professor of Public Health and Primary Care at the University of Birmingham) and a Professor of General Practice (University of Otago, New Zealand), who were both research supervisors. It was felt important that indicators were accessible and readily available for analysis, as a key criteria for indicator selection, as the identified resource and scope of the research did not include the development or extraction of new indicators. As such indicators chosen were already constructed and available through the QOF and MSDi sources used and did not require new development which may have created a time constraint. Secondly, indicators were selected based on the definition of clinical quality provided within this thesis. It was discussed that intermediate clinical outcomes for diabetes should be included as important indicators of clinical quality and the review group agreed that cholesterol, HbA1c and blood pressure were the most important of these based on knowledge of best practice guidance, such as NICE quality guidelines, together with blood pressure and CVD risk. Finally, following discussion amongst the three person review group, it was determined that it would be helpful to utilise indicators predominantly from MSDi together with comparable QOF indicators (where

these existed) and therefore available MSDi indicators in the areas of Diabetes and CVD that were captured across all the 51 practices in the research group were included. MSDi allowed more recent (past month) data analysis which would allow analysis of more recent practice performance than QOF (collected at year end to 31st March each year with publication in October each year). The reason for including some similar indicators from MSDi and QOF sources was to identify if there were some differences in practices achieving targets at both mid-year and end-year intervals and if there were differences in achievement of indicators across these two data sources (in the sense of one data source being a public database and one being a non-public database). Equally, the use of a public and non-public database was identified recognising that average scores achieved through QOF alone may stabilise at defined payment thresholds creating little observable variation in overall scores. This may be due to a range of factors such as improved recording, measure fixation and even gaming (Lester, 2011; Caley *et al*, 2014). Comments have been provided in the thesis results and discussion on this point, however, as indicators did not match exactly in terms of indicator definitions this analysis was difficult and not particularly useful. MSDi and QOF sources were not exactly comparable however and this was a limitation for analysis.

A list of potential indicators for acquisition was created by the first reviewer and then narrowed to 25 CVD and Diabetes-related indicators that were readily available through MSDi and the national QOF database. Following discussion, a final list of 12 indicators was adopted that met the criteria described (Table 2). It was recognised that deriving a composite measure from more than seven indicators would not necessarily add greater precision or relevance of analysis and so after ascertaining

indicators available through MSDi for the areas of CVD and Diabetes defined, together with their comparable QOF indicators where available, no new indicators were added (Van-Doorn Klomberg, 2013). The review group also reflected that as interviews would include providing practices with their results for each indicator, it would not be helpful from a time perspective to have a higher number of graphs than required for presentation. Additionally, control charts were completed for the 12 indicators chosen and informed the decision that additional indicators were not needed for analysis where there was clearly identified special cause variation within indicator areas selected and for composite score development

Emphasis was placed on selecting indicators related to clinical quality, where indicators selected were primarily process-related in line with the study scope. It is recognised that the indicator selection for the PhD research was not systematic in utilising approaches such as formal consensus methods e.g. modified Delphi techniques and others such as those described by Murphy *et al* (1998). However, the indicators selected were evidence-based: They were either already included in the NHS Quality and Outcomes Framework or were derived from evidence-based clinical guidelines e.g. NICE guidelines. An assumption was made that indicators were broadly acceptable, feasible, reliable, sensitive to change and with high predictive value. Such components are essential for effective indicator use in assessing quality (Mant, 2001; Campbell *et al*, 2002; Mainz, 2003 Shekelle, 2013). Indicators were also assessed retrospectively during semi-structured interviews with research participants to assess acceptability, feasibility and reliability from a subjective participant perspective.

Table 2: Final clinical quality indicators selected for variation analysis by indicator source, type and inclusion/exclusion reason

Source	Indicator	Measurement period	Reason for (I)Inclusion/(E)Exclusion
QOF	1. The percentage of patients with diabetes whose last measured total cholesterol within the preceding 15 months is 5mmol/l or less	1 April 2012 - 31st March 2013	(I) Met all inclusion criteria.
QOF	2. The percentage of patients with diabetes in whom the last IFCC-HbA1c is 75 mmol/mol or less in the preceding 15 months	1 April 2012 - 31st March 2013	(I) Met all inclusion criteria.
MSDi	3. Patients with Diabetes with Serum Cholesterol > 4mmol/l	31st July 2014 for preceding month	(I) Met all inclusion criteria.
MSDi	4. Patients with Diabetes whose last 3 HbA1c results are > 7.5%	31st July 2014 for preceding month	(I) Met all inclusion criteria.
MSDi	5. Patients with Diabetes whose last SBP is > 140	31st July 2014 for preceding month	(I) Met all inclusion criteria.
MSDi	6. Patients with Diabetes with no urine or electrolyte testing in previous 12 months	31st July 2014 for preceding month	(I) Met all inclusion criteria.
MSDi	7. Patients with Diabetes with no dietary advice in the last 12 months	31st July 2014 for preceding month	(I) Met all inclusion criteria.
QOF	8. The percentage of patients with hypertension in whom the last blood pressure (measured in the preceding 9 months) is 150/90 or less	1 April 2012 - 31st March 2013	(I) Met all inclusion criteria.
MSDi	9. Patients with Hypertension and CVD risk probably over 20% but no statin prescribed	31st July 2014 for preceding month	(I) Met all inclusion criteria.
MSDi	10. Stroke and TIA patients with no lipid lowering therapy in last 12 months	31st July 2014 for preceding month	(I) Met all inclusion criteria.
MSDi	11. Patients with congestive heart failure or heart failure with ECG referral or ECG result recorded	31st July 2014 for preceding month	(I) Met all inclusion criteria.
MSDi	12. Patients with Hypertension and BP over 140/90 (uncontrolled hypertension)	31st July 2014 for preceding month	(I) Met all inclusion criteria.
QOF	13. The percentage of patients with diabetes in whom the last blood pressure is 150/90 or less.	1 April 2012 - 31st March 2013	(E) Decision to use 140/90 mmHg or less blood pressure MSDi target as greater differentiation of clinical quality, with less significant variation at 150 mmHg or less target following view of the data within QOF for useful comparison.
QOF	14. The percentage of patients with diabetes in whom the last blood pressure is 140/80 or less	1 April 2012 - 31st March 2013	E) Excluded to focus on smaller number of clinical quality indicators. It was deemed adding more measures for the purpose of developing a composite score, in addition to those that met all the inclusion criteria, was not deemed valuable based on discussion and referenced research.
QOF	15. The percentage of patients with diabetes whose notes record BMI in the preceding 15 months	1 April 2012 - 31st March 2013	E) Excluded to focus on smaller number of clinical quality indicators. It was deemed adding more measures for the purpose of developing a composite score, in addition to those that met all the inclusion criteria, was not deemed

Source	Indicator	Measurement period	Reason for (I)Inclusion/(E)Exclusion
			valuable based on discussion and referenced research.
QOF	16. The percentage of patients with diabetes in whom the last IFCC-HbA1c is 59 mmol/mol in the preceding 15 months	1 April 2012 - 31st March 2013	E) Excluded to focus on smaller number of clinical quality indicators. It was deemed adding more measures for the purpose of developing a composite score, in addition to those that met all the inclusion criteria, was not deemed valuable based on discussion and referenced research.
QOF	17. The percentage of patients with diabetes in whom the last IFCC-HbA1c is 64 mmol/mol or less in the preceding 15 months	1 April 2012 - 31st March 2013	E) Excluded to focus on smaller number of clinical quality indicators. It was deemed adding more measures for the purpose of developing a composite score, in addition to those that met all the inclusion criteria, was not deemed valuable based on discussion and referenced research.
QOF	18. The percentage of patients with diabetes with a record of neuropathy testing in the preceding 15 months	1 April 2012 - 31st March 2013	E) Excluded to focus on smaller number of clinical quality indicators. It was deemed adding more measures for the purpose of developing a composite score, in addition to those that met all the inclusion criteria, was not deemed valuable based on discussion and referenced research.
QOF	19. The percentage of patients with stroke or TIA who have a record of total cholesterol in the preceding 12 months	1 April 2012 - 31st March 2013	E) Excluded to focus on smaller number of clinical quality indicators. It was deemed adding more measures for the purpose of developing a composite score, in addition to those that met all the inclusion criteria, was not deemed valuable based on discussion and referenced research.
QOF	20. The percentage of patients with a diagnosis of heart failure (diagnosed on or after 1 April 2006) which has been confirmed by an echocardiogram or by specialist assessment between 3 months before or 12 months after entering on to the register	1 April 2012 - 31st March 2013	E) Excluded to focus on smaller number of clinical quality indicators. It was deemed adding more measures for the purpose of developing a composite score, in addition to those that met all the inclusion criteria, was not deemed valuable based on discussion and referenced research.
QOF	21. The percentage of patients with diabetes with a record of neuropathy testing in the preceding 15 months	1 April 2012 - 31st March 2013	E) Excluded to focus on smaller number of clinical quality indicators. It was deemed adding more measures for the purpose of developing a composite score, in addition to those that met all the inclusion criteria, was not deemed valuable based on discussion and referenced research.
QOF	22. The percentage of patients with diabetes who have a record of micro-albuminuria testing in the preceding 15 months	1 April 2012 - 31st March 2013	E) Excluded to focus on smaller number of clinical quality indicators. It was deemed adding more measures for the purpose of developing a composite score, in addition to those that met all the inclusion criteria, was not deemed valuable based on discussion and referenced research.
QOF	23. The percentage of patients with diabetes with a diagnosis of proteinuria or micro-albuminuria who are treated with ACE inhibitors (or A2 antagonists)	1 April 2012 - 31st March 2013	E) Excluded to focus on smaller number of clinical quality indicators. It was deemed adding more measures for the purpose of developing a composite

Source	Indicator	Measurement period	Reason for (I)Inclusion/(E)Exclusion
			score, in addition to those that met all the inclusion criteria, was not deemed valuable based on discussion and referenced research.
QOF	24. The percentage of patients with diabetes who have a record of estimated glomerular filtration rate (eGFR) or serum creatinine testing in the preceding 15 months	1 April 2012 - 31st March 2013	E) Excluded to focus on smaller number of clinical quality indicators. It was deemed adding more measures for the purpose of developing a composite score, in addition to those that met all the inclusion criteria, was not deemed valuable based on discussion and referenced research.
QOF	25. The percentage of patients with diabetes with a record of a foot examination and risk classification: 1) low risk (normal sensation, palpable pulses), 2) increased risk (neuropathy or absent pulses), 3) high risk (neuropathy or absent pulses plus deformity or skin changes in previous ulcer) or 4) ulcerated foot within the preceding 15 months	1 April 2012 - 31st March 2013	E) Excluded to focus on smaller number of clinical quality indicators. It was deemed adding more measures for the purpose of developing a composite score, in addition to those that met all the inclusion criteria, was not deemed valuable based on discussion and referenced research.

Key: (I) denotes indicator included (E) denotes indicator excluded

The indicators selected were incorporated within a definition of clinical quality, however some indicators could also be categorised as (intermediate) clinical outcomes (indicators 1-5, 8 and 10) or process indicators (indicators 6, 7, 9, 11 and 12) (Donabedian, 1988).

3.2.4 Data acquisition

The indicators identified were acquired from two different sources:

1. The UK national QOF database publicly available through the Health and Social Care Information Centre (HSCIC, 2013).

2. A local indicator portal and informatics solution owned by Merck Sharp and Dohme Limited called "MSDi Practice Comparator" (MSDi). MSDi was purchased through Sandwell Metropolitan Borough Council with access gained through the local software manager - NHS Central Midlands Commissioning Support Unit. Approval for the use of the tool was through Sandwell Metropolitan Borough Council. The

MSDi solution used, "practice comparison", is a web-based application and database allowing analysis and comparison of practice data for bespoke search and reporting of clinical quality areas (MSDi, 2016).

Data used for the identified indicators covered a period from 1st April 2012 to 31st March 2013 for QOF indicators and the latest month at time of extraction, July 2014, for MSDi indicators. Data was extracted from both sources in August 2014.

3.2.5 Data quality

Data quality was analysed through available data quality checks in the software utilised for MSDi indicators. Specifically, the MSDi software provided a yes/no answer for each practice, in the form of a table within MSDi software, in respect of whether practice data for each indicator had been successfully imported to the MSDi database. No problems in relation to data importing were reported. QOF indicators (indicators 1, 2 and 8) were analysed with exception-reported patients included.

The population (denominator) analysed for each indicator was the registered patient cohort *reported* by the practice to have the disease of focus within each indicator as per the practice's disease register. As noted within QOF guidance;

"An important feature of the QOF is the establishment of disease registers. These are lists of patients registered, created by collating data from patient records to provide an overview of those coded appropriately with the relevant condition, with the contractor who have been diagnosed with the disease or risk factor described in the register indicator. While it is noted that these may not be completely accurate, it is the responsibility of the contractor to demonstrate that it has systems in place to maintain a high quality register and this may be verified by commissioners by comparing the reported prevalence with the expected prevalence and ask contractors to explain any reasons for variations." (NHS Employers, 2016)

The read codes used within MSDi for disease registers mirrored exactly those of QOF. Anonymisation of practice data was limited to removal of practice names and practice codes for funnel plot construction.

3.2.6 Control chart: Funnel plot analysis

Funnel plot charts were selected as an appropriate method for quantitative data analysis based on a typology of control charts for use in healthcare and due to the type of data held in examining variation across the selected indicators (discrete/count data) where proportions were analysed (Flowers, 2009). Funnel plot charts, as a type of P-Chart (named due to the expression of proportion data), express the denominator on the horizontal axis with wider control limits towards the lower denominator end and narrower control limits at the higher denominator end, accounting for larger expected variation where the denominator value is lower (Mohammed *et al*, 2008). Funnel plot use in healthcare QI and research has been recommended by UK organisations including the Association of Public Health Observatories and the National Clinical Audit Advisory Group (Manktelow and Seaton, 2012).

Funnel plot analysis was completed for each indicator using Microsoft Office Excel 2007 software. Using practice indicator performance data (generally with the relevant disease register as the denominator and total patients at the identified indicator value as the numerator), data was sorted from the smallest to largest population. Data was then expressed as a percentage, standard error values calculated, and upper and lower control limits calculated. Data checks were conducted at each stage of the charting process. Final funnel plots were then

charted expressing the percentage (%) of patients that met/ did not meet the indicator criteria.

3.2.7 Composite score analysis

A composite score was developed to identify practices which were *frequent* special cause outliers. Those practices which were frequent special cause outliers in the positive direction were identified as high performing (HP) and those who were frequent special cause outliers in the negative direction being identified as low performing (LP). The descriptions applied to high or low performing practices were a reference to their performance relative to other practices (OT) and do not indicate that practices were "better" or "worse" given that the causes for variation at the point of identification were unknown. HP and LP practices were identified using a summed score derived from their performance across all indicators (a score of +1 being applied for special cause performance in the positive direction and -1 being applied for special cause performance in the negative direction for each indicator). HP and LP practices were defined as the top 10% of practices in either direction of the mean practice composite score.

3.3 The process of linking quantitative and qualitative methods

Zhang and Creswell (2013) note that mixed methods research often involves a mixing procedure to utilise and demonstrate the relationship between the methods used. The authors suggest three main mixing methods; merging data, connecting data and embedding data (Zhang and Creswell, 2013). The current research used the procedure of connecting data as the development and use of sampling procedures for qualitative data was based on the results of the first, quantitative data

analysis phase. Qualitative semi-structured interviews were used to assess the causes for variation from identified special cause outliers in the initial quantitative funnel plot data analysis. It was designed that quantitative data analysis would inform the subsequent qualitative phase and the research project plan reflected this approach, with effort and priority divided equally between phases. The point of interface of the two phases was following the initial quantitative data collection which informed the qualitative sampling. Quantitative data used represented a period from April 2012 to July 2014 and was extracted during August 2014. The first participant for the qualitative semi-structured interviews was recruited and interviewed on 1st September 2014, with recruitment closed to all participants on 28th February 2015. Therefore, the timing between phases was minimal with little lag between quantitative data analysis and qualitative data collection. This was an important design feature, as participants were being interviewed on past clinical quality performance and therefore participant memory and organisational and environmental change at the practice level were more likely to change the longer the lag between phases occurred.

3.4 Qualitative methods

3.4.1 Participant recruitment and sample size

Practices were invited and recruited for the qualitative aspect of the study through various methods and in all cases targeting all practices in the study population. These methods included a practice email communication sent personally by a Sandwell and West Birmingham CCG Clinical Research Lead and a formal research request emailed through the National Institute of Health Research support team office. In both cases, emails were sent to lead GPs and practice managers held on a

database by the CCG and National Institute of Health Research support team office respectively. After invitations were emailed out, expressions of interest were followed up directly by the lead researcher through the contact method provided by the practice representative responding (either email or phone). Practices were also invited and recruited purposively via researcher-initiated emails and phone calls to practice managers and lead GPs for practices identified as special cause outliers.

It helped to gain the support of a local Clinical Commissioning Group (CCG) research lead who provided CCG-led communications to practices explaining they may be contacted. Email and phone contact was initiated following this to maximise recruitment. Some practices recruited via the CCG research lead and National Institute of Health Research support team office were not identified as outliers, however, results of interviews were used to triangulate data with that of outliers, to assess whether causes of variation were also evidenced, suggested or experienced in non-outlier practices and therefore allowing some discrimination of themes identified as reasons for special cause variation.

GPs and staff within practices were opportunistically sampled based on response to invitations to participate in the research. A total of 29 participants were interviewed between September 2014 and March 2015. The study used participants working within and across 26 practices to gain perspectives on practices recognised as HP or LP outliers and other non-outlier practices (OT), however representative lead GPs and practice managers from all 51 practices were invited. A total of 10 practices were recruited via research-initiated communication, nine practices via the Sandwell and West Birmingham CCG Clinical Research Lead and a further seven via the National Institute of Health Research support team office. A total of four practices

declined to take part in the research following requests for expressions of interest from the NIHR Clinical Research Network, West Midlands, described subsequently in section 5.2. All other practices did not respond to communication requests.

Variation was sought to some extent across different practice team member roles and profiles however sampling was opportunistic predominantly based on staff availability.

Drever (1995) notes the importance in explaining the purpose, process and context of research to participants from the perspective of both providing research information and from an ethical standpoint, where it was made clear to participants that research may be published in future and every effort would be made to anonymise data. In all invitations for research participation, participants were sent a covering letter including contact details for the researcher and a participant information sheet (Appendices 1, 2 and 3). Participant information sheets included the process and option of withdrawal from the research. Prior to interview, all participants had the study explained to them and signed a consent form before the interview (verbal consent was taken on 4 occasions for phone interviews, however participants were provided copies of the consent form prior to providing verbal consent). All interviews were audio-recorded with informed consent and transcribed.

It was identified early and prior to practice recruitment that it may have been difficult to gain access to interview practices given the nature of the topic examining variation and performance in the clinical quality of care. I was particularly cognisant of the fact that practices could be suspicious, defensive or cautious of allowing an external person to interview them about their clinical quality of care. It was important to me that the research was framed in a non-confrontational and open manner, being

explicit, honest and transparent in how data was being used and particularly framing the research from a QI perspective. The research was communicated in the manner intended, that is, identifying variation causes and learning from variation, without intending to create a feeling (perceived or otherwise) that data would be used to assume that variation was purely as a result of good or bad care. The process of recruitment was perhaps not as challenging as I had expected. Partly, I feel this was due to practices not necessarily knowing how they performed against various indicators compared to peers and were therefore interested in understanding this (although all practices had access to data used and the ability to benchmark their performance). Practices were deliberately not provided with their own practice data prior to interview to avoid immediate focus on this aspect of the interview.

I was pleasantly surprised at the number of practices that willingly opted in to the research without personal contact. There were some challenges in contacting some practices however (with as many as 12 calls made to one practice in order to arrange an interview having been passed between various staff after the practice had agreed to take part). However, of practices targeted through email and phone contact as HP or LP practices, there was good uptake and eventual numbers recruited which was supported by personal perseverance and relationships with and between local GPs.

3.4.2 Semi-structured interviews

3.4.2.1 Interview Process

Prior to interviewing practices, an interviewer's pack was developed detailing the practice size, deprivation, patient mix and staffing, together with the practices performance against indicators examined. This helped gain early context on the practice and ensure time was spent exploring the key interview questions.

A topic guide (Appendix 4) for the semi-structured interviews was developed. Gaskell (2003) notes that an effective topic guide should be used flexibly and provides a framework for semi-structured interviews ensuring interviews are conducted with the research questions in mind, making best use of the interview time through providing interview direction, and serving to support transcript analysis. A number of drafts of the topic guide were developed prior to finalisation through a four person research group (consisting of the lead researcher, the aforementioned Professor of Public Health and Primary Care from the University of Birmingham and Professor of General Practice from the University of Otago, together with a lecturer in Qualitative Methods at the Department of Primary Care Clinical Sciences, University of Birmingham), who were the three research supervisors. The topic guide was linked to the research questions and intended to explore the following key areas to support the research questions:

- The practice context as an introduction to the practice itself and to allow the interviewees to "warm up" to the interviewer.
- Practice views on QI, both from a national primary care perspective and in relation to local practice QI initiatives, processes and behaviours.
- Practice views and processes in relation to the use of quality indicators and measures.
- Exploring causes of variation (both specific and non-specific to the practice).
- Examining views and lessons for QI in the areas examined.

Respondent validation (also known as member checking or informant feedback) was completed during the interview process through restating, clarifying and summarising

responses and information back to participants to ensure accuracy, including through use of paraphrasing and summarising responses gained (Creswell, 1994). This was completed primarily where there was risk of different interpretation of responses between the interviewer and interviewee, for example, where aspects such as culture were explored and to ensure that interviewees and the interviewer had a shared understanding of what was meant by culture. In some cases interpretation of responses from the interviewer was different to what was meant by the interviewee and respondent validation helped to identify such differences to ensure viability of the interpretation. Equally, during interviews rapport was aimed to be established, including through the "warm up" within interviews described to support open and honest participant responses. As Creswell (1994) notes, such respondent validation is not perfect and cannot be used as a true verification strategy, however supports improving the authenticity and credibility of findings.

The majority of interviews were conducted on the site of primary care surgeries, with interviews lasting up to 1 hour 30 minutes in duration.

3.4.2.2 Data analysis

Data analysis took place from completion of the first interview in September 2014 to March 2015. Thematic analysis using the constant comparative method was used to analyse interview data, using the approach defined by Braun and Clarke (2008), highlighted in table 3 (Glaser and Strauss, 1967; Braun and Clarke, 2008).

Table 3: Phases of thematic analysis

Phase	Description of the process
Phase 1: Familiarizing yourself with your data	Transcribing data (if necessary), reading and re reading the data, noting down initial ideas
Phase 2. Generating initial codes	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code
Phase 3. Searching for themes	Collating codes into potential themes, gathering all data relevant to each potential theme.
Phase 4. Reviewing themes	Checking if the themes work in relation to the coded extracts (Level 1) and the entire data set (Level 2), generating a thematic 'map' of the analysis
Phase 5. Defining and naming themes	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme
Phase 6. Producing the report:	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis

(From Braun and Clarke, 2008. Pp.87)

Interviews were transcribed externally and verbatim through a third party supplier and checked by the researcher for accuracy. Standard and common transcribing conventions were used in the transcription process and throughout transcripts. For example, the use of "..." to indicate an untimed pause, the use of a square bracket ("[") to indicate the start point of overlapping conversation and use of brackets to denote the best guess of conversation difficult to hear. Square brackets have also been used following quotes to denote whether practices were HP, LP or OT practices (e.g. High performing practices identified as *[HP]*), with participant numbers (denoted as "PP" followed by the participant number). Practice and staff names were replaced with "X" to ensure anonymity. Such transcribing conventions are commonly used in line with transcription theory, such as the transcribing conventions developed by Gail Jefferson or the so called "Jeffersonian conventions" (Jefferson, 1984; Ochs, 1979). It was noted by myself and an external researcher that the quality of transcribing was

sometimes poor and/or inconsistent in some places and required amendment, however, this was not a significant issue as interviews were conducted and analysed by myself as the lead researcher and it was clear where mistakes had been made in transcription which could be easily amended. Whilst common conventions were generally used, transcriptions only represented talk as opposed to theory and conventions that can be applied to non-verbal or behavioural interactions, such as posture, gestures and body language (Jefferson, 1984; Ochs, 1979). It is recognised that such approaches to transcribing can be extremely useful in qualitative analysis, however, were not seen as a significant requirement for the current research due to the research focus. It is important to stress that whilst interviews were transcribed externally, I spent time transcribing the first two interviews myself in order to engage early on with the interview content.

After transcripts were read and re-read, initial codes were generated and data systematically assigned to codes (phases one and two of the Braun and Clarke (2008) approach). Data analysis of interviews was completed and supported through the use of NVivo v.10 Software, where Richards and Richards (1994) highlight the usefulness of computer assisted qualitative data analysis software in supporting data acquisition, management, organisation and analysis. Prior to the initiation of thematic analysis, pre-defined categories from existing theory relating to examining variation in primary care were partially adopted to organise initial codes. For example, categories relating to variation causes of "data", "patient case mix", "structure or resource" and "process of care". Codes were then combined into potential themes using constant comparison as new codes were generated to assess appropriateness of themes. Themes were developed based on the description

summarised by Braun and Clarke (2008) relating to prevalence and importance of codes generated as determined by the researcher, whilst recognising that prevalence does not necessarily denote a fixed numerical or proportionate quantity. At this point an initial coding framework was discussed with three research supervisors and some themes combined based on discussion. Themes were again reviewed following triangulation with external researcher corroboration, where two additional researchers, blinded to the clinical quality data results of practices, were used to code around 15% of the interview transcripts to assess common themes and plausibility of the existing lead researcher's thematic framework. Whilst this could be said to complete phases three and four of Braun and Clarke's (2008) six-phase process referenced, the process of thematic analysis was non-linear and themes were reviewed through a constant development process, a common feature of thematic analysis (Braun and Clarke, 2008). To complete the analysis my supervisors suggested refining themes and using the data, codes and themes identified to find the story in the data (moving from *description* of themes across the entire dataset to *interpretation*). It was discussed and agreed that themes could be used to develop a typology of general practice organisations based on reference to the variation causes and influencing factors on practice variation, the result of which is discussed further in the results section. The overall approach to analysis is described as a qualitative, inductive, interpretive approach. The final coding framework utilised is summarised and provided below in table 4:

Table 4: Coding Framework

Themes	Code descriptors
Leadership and Culture	<ul style="list-style-type: none"> - Leadership: Practice leadership; Staff experiences and training influencing leadership style; Clarity of vision within practice; Motivations/ aspirations/ enthusiasm - Culture: Team values; Team beliefs; Team behaviours including team working and communication - Patient interaction: Role of practice; Role of patient; Compliance; Interaction and activation approach e.g. Proactive vs. responsive; Practice-patient relationships
System of care	<ul style="list-style-type: none"> - Structures: Care team capacity; Team capability; Training and education; Resource use - Processes: Protocol use; Guideline use; Management systems; Patient review and recall; Risk profiling and screening; Access; Continuity of care; Co-ordination of care; Practice management; Technology use e.g. Point of care templates/ reminders
Quality measurement and improvement	<ul style="list-style-type: none"> - Quality measurement: Definitions of quality; Measurement use (purpose, type, frequency etc.); Measurement sources and systems; Issues with measures; Attitudes to Measures - Quality improvement approach: QI system (e.g. Continual); Evidence of improvement cycles; Improvement initiatives and activities
External and non-modifiable factors	<ul style="list-style-type: none"> - National policy and strategy; Local healthcare economy factors (e.g. Secondary care effectiveness); Patient case-mix; Funding and financing

3.5 Case analysis

3.5.1 Introduction

Case analysis is a qualitative research method that utilises a range of data to explore and understand a given phenomena in the context it occurs (Baxter and Jack, 2008). Case studies are often employed in research to understand the "how" and "why" of a given phenomenon, exploring the context and conditions under which it occurs, and where a boundary or delineation between phenomena and context is not always immediately apparent or clear (Yin, 2003). As Baxter and Jack (2008) note, there are numerous types and methods of case study, for example case studies which are explanatory, exploratory, descriptive, intrinsic, instrumental or collective. One type of case analysis, deviant case analysis, has been utilised by social scientists for some time and refers to the qualitative process in which a small number of cases are focussed on for additional analysis that can revise, refine, broaden, confirm, or sometimes deny emerging patterns in data analysis (Molnar, 1967).

3.5.2 Deviant case selection and use

In case study research, 'deviant case analysis' is defined differently than in qualitative thematic analysis where it denotes cases contradicting emerging themes. Gerring's theory (2002) defines deviant case selection and use for case study research, that is, one or more cases that deviate from a cross-case relationship, where the deviant case is a high residual case (significant outlier or anomaly), where case corroboration may be applied through cross-case testing. In the presented research, HP and LP practices were defined, where the most extreme cases across measures analysed were selected as deviant cases. Two outliers representing high performance in data analysis (Practice numbers 3 and 31 in Table 5) and one outlier representing low performance (Practice number 40 in Table 5) were used for further deviant case analysis, with analysis of these cases incorporated into the results.

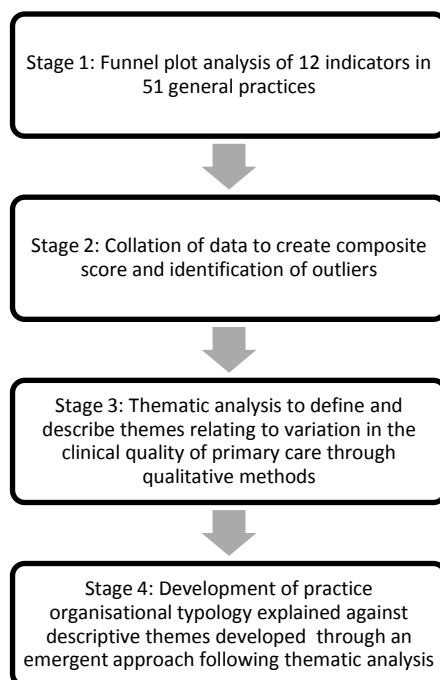
Whilst deviant cases can represent outlier cases or those which are exceptional or untypical, deviant case analysis is most often exploratory or confirmatory; it can be used to identify new explanations in outlier data *or* in ratifying existing themes in data analysis for a wider group of cases (Molnar, 1967; Kazancigil, 1994; Djuric *et al*, 2010). In the thesis research, deviant case analysis was used in a confirmatory manner to distinguish causes of variation between identified HP and LP practices (in addition to corroboration of the practice typology), consistent with referenced literature around the use of deviant case analysis, to confirm what participants had said in interview was in fact true through further analysis (Molnar, 1967; Kazancigil, 1994; Djuric *et al*, 2010). Additional data (in the form of additional deviant case data analysis and interviews with practice staff) was collected. This included gaining practice protocols for disease management, understanding further practice structures and processes and analysing practice performance across indicators in greater depth

to confirm and corroborate developed themes. Analysis was limited to some extent by the time and availability staff had to support research and therefore was perhaps not as robust or detailed as a pure case study approach. This is not necessarily a significant issue, where deviant cases can often become over-studied (Djuric *et al*, 2010).

3.6 Typology development

A typology of primary care organisations was developed based on identified practice themes and through recognition via discussion amongst the four person research group following the thematic analysis that themes identified were often not separate and independent of each other, but were inter-related in contributing to the complex and multifaceted environment of primary care delivery. The four person research group agreed that by using the key themes already identified it would be possible to differentiate different practice types based on their differences displayed across these thematic areas. The typology was developed between the research group from the development of an initial typology by the lead researcher with a "label" assigned to each practice type and a subsequent confirm and challenge discussion between the group. Figure 2 provides an overview of the approach used to develop the practice typology.

Figure 2: Process for practice typology development



Respondent validation was also completed once the practice typology was developed by providing three deviant case practices identified with the General practice typology overview: Summary of practice types (Table 9). These practices were told which practice "type" they were identified against and a discussion had around whether they agreed both with the typology overview and their practice placement within this, particularly to assess the authenticity of the typology. The results of this process are provided in the thesis chapter relating to the practice typology.

3.7 Researcher interactions, ethics and research quality

This section addresses key areas related to researcher interaction with the research, ethics and qualitative research quality, whilst considering relevant impact on delivering the research objectives. The methodological issues, considerations and weaknesses of the research are presented in Chapter 8 for the research as a whole.

3.7.1 Researcher interactions and reflexivity

It is important to consider and acknowledge prior assumptions and experiences when conducting research and the impact that these prior experiences could have on the way research was designed, developed and conducted where I had personal experience of primary care delivery in a clinical, research and management context prior to starting the research. Reflexivity is often used to describe the process of reflection on research, both in terms of researcher experiences and a priori knowledge, and the research relationship (Fisher, 2009). The importance of neutrality is central to developing high quality research and whilst true neutrality may not be achieved, I used a process of bracketing to help mitigate subjectivity and bias in research. Tufford (2012) describe bracketing as a method in which the researcher aims to reduce the negative impact of preconceptions on the research process. The process of bracketing was introduced to me during a course on qualitative research methods at the University of Oxford and following this, I practically thought about things that may impinge on my objectivity and strategies to safeguard against their impact. I identified areas such as pre-determined views of general practices and practice management, relationships primary care teams may have with a PhD student and my personal thoughts around the reasons why variation may exist. Examples of strategies I employed to counter these impacts included the methods and frameworks adopted in the research that helped to provide an evidence-based approach to research delivery, the use of triangulation of codes in data analysis with external researchers, and the use of continual reflection on research development and analysis periodically throughout the research. I also tried to maintain critical distance through, for example, re-examining qualitative data and gaining assistance

and involvement of others in my research. Additionally, during practice interviews I also attempted to ensure that I created an environment conducive to developing rich research data with all participants. This was supported by the topic guide, but also through ensuring I was personally allowing space within interviews for participants to be actively engaged with the research topic through stimulating and inciting thought, in addition to allowing participants to tell their own stories related to the subject matter.

3.7.2 Ethical issues

As Israel and Hay (2006) note, ethical behaviour is essential in increasing "the sum of good" through research and is integral in protecting individuals, communities and environments in research whilst seeking to avoid long-term, systematic harm wherever possible. In addition to the ethical approval requirements detailed earlier in the chapter, ethics were considered throughout the research and considered when conducting research at all times. During my research I was careful to ensure I paid attention to my own ethical code, for example, by being respectful to participants and data, by being responsible in the methods for recruiting participants, and aiming to conduct interviews in a competent and professional manner. I aimed to be particularly clear and transparent in communicating my role to participants during the research and in communicating the research aims. The research topic potentially had the ability to be quite sensitive, given that I was exploring reasons for variation and many practices could have found this intrusive or responded negatively where data suggested they were an outlier. During interviews I aimed to establish rapport with participants early on whilst maintaining objectivity, and deliberately didn't start interviews discussing sensitive topics (for example, where I had identified practices

that were outliers in data that could be perceived as the practice having poor performance). I was flexible in allowing participants to discuss reasons for variation, and stressed the important feature of the research as being focussed on QI as opposed to performance assessment or otherwise where such framing could elicit negative behaviours and responses from participants.

Given the research topic and potential presentation of practice performance across quality indicators demonstrating variation through future research publication, it was particularly important to pay attention to practice anonymity. The practice data used was predominantly publicly available, with the exception of the MSDi dataset data, however I made clear through the consent form and consent process that research may be published in future and that confidentiality would be maintained as far as possible (using practice pseudonyms where needed). That being said, it could be possible to identify practices from publicly available databases (for example, in identifying disease register numbers in funnel plot denominator data) and for that reason I felt extra clarity had to be given to participants around how data would be used. Equally, as both data sources were available through public organisations, practice data could also likely be gained through freedom of information requests. Other ethical issues, such as clear contact details and opt-out arrangements, were used as would be expected of a study such as that performed.

Section 2.5.2 details why NHS Health Research Authority and Research Ethics Committee approval was not required for the research. Patient identifiable information was not used in the course of the research as data sources used only provided numbers of patients within indicator values. However it is important to be respectful in the use of data during the course of research, limiting any adverse

effects patients and the public may experience where research is communicated, through publication or otherwise (Israel and Hay, 2006).

3.7.3 Quality of qualitative research

In conducting qualitative research, it is important to consider the quality of the approach adopted. There has been for some time a lack of consensus about criteria for appraising qualitative research, although tools exist such as the CASP Qualitative checklist (CASP, 2013). A range of authors note the importance of quality in qualitative research and highlight methods in which quality can be enhanced. For example, Lincoln and Guba's (1985) evaluative criteria that centres around creating trustworthiness in qualitative research through establishing credibility (confidence in the truth of findings), transferability (robust descriptions of research to allow applicability of findings across settings), dependability (consistency and repeatability of findings), and confirmability (neutrality and lack of bias in findings). Yardley (2000) also provide an alternative view in developing and assuring quality in qualitative research, suggesting a need for qualitative researchers to demonstrate and assure research against principles of sensitivity to context, commitment to rigour, transparency and coherence, and impact and importance.

In the methods of the presented research, a range of approaches were used to improve quality of the qualitative research against these identified criteria and principles. The data engagement process, constant comparison method in thematic analysis, member checking and triangulation of data through use of external researchers and the existing thematic framework are good examples of enhancing credibility, data validation and confirmability. For the purposes of the thesis research triangulation is explained as the combined use of two or more sources or methods to

study the same phenomenon (Bogdan and Biklen, 2006). The use of non-outlier practices within the recruited participants could also be seen to enhance credibility in findings by allowing confirmation of themes relating to special cause variation. The descriptions of methods used, such as the Braun and Clarke (2008) thematic analysis criteria and maintenance of a clear audit trail through electronically (CAQDAS) organised and analysed transcripts also serve to demonstrate transferability and dependability. The aid of my supervisors in developing the research design and corroborating themes helped to enhance research quality and facilitated a more robust approach to both method design and delivery and data analysis.

CHAPTER 4: QUANTITATIVE RESULTS

4.1 Introduction

The following two chapters present the results of the research to understand the causes of variation in the clinical quality of primary care at practice level.

Quantitative funnel plot analysis of variation was used to identify special cause variation across clinical quality indicators and used to create a composite score identifying HP and LP practices, i.e. identifying *where* variation exists.

4.2 Quantitative analysis

Data for funnel plot analysis of clinical quality of care covered 12 indicators across 51 general practices in Sandwell and the Black Country, West Midlands covering a period from April 2012 to July 2014. Funnel plots are provided in Appendix 5. A composite score was developed to identify practices which were *frequent* special cause outliers. Across the 12 indicators used, the median composite score across practices was 0 (range -4 to +5, with a maximum score possible of +12 and minimum score possible of -12). The top and bottom 10% of special cause outliers in either direction of the mean practice composite score analysed across all indicators were considered HP (high performing) or LP (low performing) practices respectively. Six practices were identified as HP practices and seven practices were identified as LP practices (Table 5). All but one of these practices were represented in the practice interviews for further investigation (an LP practice).

Table 5: Practice composite performance results across all clinical quality indicators

Practice No.	Indicator No. and Practice Score												Total Score
	1	2	3	4	5	6	7	8	9	10	11	12	
1	0	-1	0	0	0	0	0	1	1	0	-1	-1	-1
2	0	0	0	-1	0	0	0	0	1	0	1	-1	0
3	1	1	1	1	-1	0	1	1	1	0	-1	-1	4
4	0	1	0	0	0	0	0	-1	1	0	1	0	2
5	0	0	-1	-1	0	0	1	-1	-1	0	1	0	-2
6	-1	-1	0	0	0	0	0	0	1	0	0	1	0
7	0	0	0	-1	0	0	0	0	0	0	1	0	0
8	0	0	0	1	0	0	0	0	-1	0	1	1	2
9	0	0	0	0	-1	0	1	-1	-1	0	-1	0	-3
10	0	0	0	1	0	-1	0	0	1	0	0	0	1
11	0	1	0	0	0	0	0	0	0	0	-1	0	0
12	0	0	0	0	0	0	0	1	0	0	0	0	1
13	1	1	0	0	0	0	0	1	1	0	0	1	5
14	0	0	0	1	0	0	1	1	0	0	1	0	4
15	0	0	0	-1	0	0	0	0	0	0	0	0	-1
16	0	0	-1	0	0	0	-1	0	0	0	-1	-1	-4
17	0	-1	-1	0	0	0	-1	0	0	0	0	0	-3
18	0	0	-1	1	0	0	0	-1	0	0	0	0	-1
19	0	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	-1	1	0	-1	0	0	0	1	0	0	0
21	0	0	-1	0	0	0	0	0	0	0	1	-1	-1
22	0	-1	-1	0	0	0	0	0	-1	0	1	0	-2
23	0	0	0	0	0	0	0	0	-1	0	0	0	-1
24	0	0	0	0	0	0	0	1	-1	0	0	0	0
25	0	0	1	0	0	0	1	0	-1	0	0	0	1
26	0	0	0	0	0	0	-1	1	0	0	0	0	0
27	0	1	0	0	0	0	0	0	0	0	0	0	1
28	0	0	-1	0	0	0	0	0	0	0	0	0	-1
29	0	0	0	0	0	0	-1	0	0	0	0	0	-1
30	0	0	1	0	0	0	0	1	1	0	0	0	3
31	1	0	1	0	0	0	0	0	1	0	1	0	4
32	-1	0	-1	0	0	0	0	1	-1	0	0	1	-1
33	1	0	0	0	0	0	0	1	0	0	0	0	2
34	0	0	0	0	0	0	1	0	0	0	0	0	1
35	0	0	0	0	0	0	0	0	-1	0	0	0	-1
36	0	0	0	0	0	0	0	1	0	0	0	0	1
37	0	-1	0	0	0	0	-1	0	0	0	0	0	-2
38	0	0	0	1	0	-1	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	1	0	0	0	1
40	-1	0	0	0	0	0	0	0	-1	0	0	0	-2
41	0	-1	0	0	0	0	-1	1	0	0	0	0	-1
42	0	0	0	0	0	0	0	0	0	0	0	0	0
43	0	0	1	0	0	0	0	0	0	0	0	0	1
44	0	0	0	0	0	0	0	0	0	0	0	1	1
45	0	0	0	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	1	0	0	0	0	1
47	0	0	0	0	0	0	0	0	1	0	0	0	1
48	0	0	1	0	0	0	0	1	1	0	0	0	3
49	-1	0	0	1	0	-1	0	0	0	0	0	0	-1
50	0	0	0	0	0	0	0	-1	0	0	0	0	-1
51	0	0	0	-1	0	0	0	0	0	0	0	0	-1

Key 1: High performing and low performing practices

High performing practices
Low performing practices

Key 2: Indicator number and description

Indicator Number	Description
1	The percentage of patients with diabetes, on the register, whose last measured total cholesterol (measured within the preceding 12 months) is 5 mmol/l or less
2	The percentage of patients with diabetes, on the register, in whom the last IFCC-HbA1c is 75 mmol/mol or less in the preceding 12 months
3	Patients with Diabetes with Serum Cholesterol > 4mmol/l
4	Patients with Diabetes whose last 3 HbA1c results are > 7.5%
5	Patients with Diabetes whose last SBP is > 140
6	Patients with Diabetes with no urine or electrolyte testing in previous 12 months
7	Patients with Diabetes with no dietary advice in the last 12 months
8	The percentage of patients with hypertension in whom the last blood pressure reading (measured in the preceding 9 months) is 150/90 mmHg or less
9	Patients with Hypertension and CVD risk probably over 20% but no statin prescribed
10	Patients with Hypertension and BP over 140/90 (uncontrolled hypertension)
11	Stroke and TIA patients with no lipid lowering therapy in last 12 months
12	Patients with congestive heart failure or heart failure with ECG referral or ECG result recorded

As noted previously and as can be seen from Table 2, the thesis research included indicators from both QOF and MSDi. The reasons for inclusion of similar indicators was to assess differences from the two databases which had differences in terms of accessibility and financial incentive for achievement, and collected indicators at different intervals; QOF being a public database with data collected at year-end and being linked to practice funding (QOF achievement attracting income for practices) and MSDi being a non-public database with data collected in-month (with no identified practice *financial* incentive for achievement). As can be seen from Table 5, cross-referencing Table 2 for indicator definitions, there were differences in achievement (and identification of practices as special cause outliers) across similar indicators for these two sources across practices. For example indicator 8 and indicator 12 both measuring hypertension values, albeit at different levels of systolic blood pressure, where there were more positive special cause outliers for the QOF indicator in this example. However, it is a recognised limitation, noted in the thesis discussion subsequently, that the analysis of these indicators was not particularly useful due to the difference in indicator definitions.

In order to assess whether HP or LP practices were significantly different in terms of socio-demographic factors, characteristics of HP and LP practices were identified from public data (Table 6). Such data was not used to identify causes of special cause variation which were assessed through qualitative methods.

Table 6: Characteristics of HP and LP practices based on key general practice profile indicators of practice size, deprivation, QOF achievement, patient satisfaction and selected disease prevalence

Characteristic	CCG	HP practices	LP practices
Mean List Size (Practice registered list as head count, NHS Information Centre, 2013/14)	5193	7141 (Range: 2241-18342)	6958 (Range: 1999-13417)
Percentage of list size aged 75 and above (As percentage of practice registered list as head count, NHS Information Centre, 2013/14)	11.4%	7.9% (Range: 5.3-10.1%)	7.9% (Range: 5.2-11.9%)
Deprivation score (Indices of Deprivation, Department of Communities and Local Government, 2010, where a score of 1/10 = most deprived)	-	2.5/10 (Range:1/10-4/10)	3/10 (Range:2/10-7/10)
QOF Achievement (Quality and outcomes framework, total points, NHS Information Centre, 2013/14)	842	878 (Range:856.08-896.67)	794 (Range: 684.93-842.19)
Percentage of patients that would recommend the practice (GP patient survey, percentage of total sampled GP population, 2013/14)	64.2%	77.6% (Range: 52.1%-93.9%)	65.6% (Range:31.4%-68.3%)
Hypertension prevalence (Reported prevalence as percentage of total practice list, NHS Information Centre; Quality and outcomes framework, 2013/14)	13.9%	14.9% (Range: 12%-18.7%)	16.0% (Range: 13.6%-20%)
Diabetes prevalence (Reported prevalence as percentage of total practice list, NHS Information Centre; Quality and outcomes framework, 2013/14)	6.8%	6.1% (Range: 4.8%-10.3%)	6.0% (Range: 4.8%-7.6%)

Key:

HP: Denotes high performing practices

LP: denotes low performing practices

(Data from Public Health England, General Practice Profiles, 2014)

Whilst practice characteristics were not statistically analysed in terms of statistical significance and other factors, they provide some useful insight and allow some important observations to potentially dispel some practice characteristics as having a

significant influence on the reasons for special cause variation in the research conducted.

For both HP and LP practices, the average list size was greater than the CCG average. Deprivation was similar across both groups, with the HP practice group having a slightly more deprived population as measured using the recognised "index for multiple deprivation" (2010). QOF achievement was higher for the HP practice group which may be expected where some of the CVD and Diabetes indicators used in the research were similar to those in QOF and occupy a significant proportion of the total QOF points available. Patient satisfaction, as measured by those who would recommend the practice, was lower in the LP practice group. Prevalence indicators most aligned to the indicator areas used in the research relating to CVD and Diabetes were selected as Hypertension and Diabetes prevalence. Hypertension prevalence was slightly higher in the HP practice group, but prevalence for Diabetes was similar across both groups.

CHAPTER 5: QUALITATIVE RESULTS

5.1 Introduction

Qualitative semi-structured interviews were used following the quantitative methods (identifying where variation exists) to identify the causes and factors associated with variation. These were then presented as themes i.e. identifying *why* variation exists and used to develop a typology of general practice organisations.

5.2 Participants

A total of 29 participants were recruited working within or across 26 practices. Of these participants, 14 were general practitioners (GP), 1 was a general practice registrar (GPr), one was a nurse partner (practice lead partner, trained as a general practice nurse consultant) (NP), four were practice managers (PM), five were practice nurses (PN), one was a practice health care assistant (HCA) and three were health professionals external to any practice team but working across practices - two from in-reach community teams and one health trainer (HCP). Participant role characteristics are summarised in table 7. Across practice staff interviewed, all six HP practices were included with six LP practices. A recruitment goal of 30 participants was set at the beginning of the study, however 29 participant interviews were achieved up to the point where data saturation was deemed to have occurred by the researcher. This judgement was made where categories and relationships between categories following thematic analysis were deemed well established and comprehensive and no new themes were emerging in the view of the researcher and following discussion amongst the four-person review group (Strauss and Corbin, 1998). The participant role characteristics are defined below:

Table 7: Recruited participants by job role

Participant Number	Practice Number (See Table 5)	Participant Job Role
1	31 (Practice A)	General Practitioner
2	31 (Practice A)	General Practice Registrar
3	31 (Practice A)	Practice Nurse
4	21 (Practice B)	Nurse Partner
5	21 (Practice B)	Practice Nurse
6	21 (Practice B)	Health Care Assistant
7	9	General Practitioner
8	4 (Practice C)	General Practitioner
9	37	General Practitioner
10	39	Practice Nurse
11	3	General Practitioner
12	3	Practice Nurse
13	3	Practice Manager
14	5	Practice Manager
15	50	Practice Nurse
16	48	General Practitioner
17	47	General Practitioner
18	30	Practice Manager
19	26	General Practitioner
20	40 (Practice D)	General Practitioner
21	13	General Practitioner
22	14	General Practitioner
23	19	General Practitioner
24	40 (Practice D)	Practice Manager
25	16	General Practitioner
26	22	General Practitioner
27	Various	Health professional external to practice team
28	Various	Health professional external to practice team
29	Various	Health professional external to practice team

A total of four practices declined to take part in the research following requests for expressions of interest from the NIHR Clinical Research Network, West Midlands. It was not known why practices chose not to take part as the four declines were provided on a reply slip to the NIHR administration team. However, another LP practice declined to take part from request over the phone with the reason cited as a lack of time to take part. The practice was a single-handed GP practice and the

decline was made by the practice manager. An attempt was made to speak to the lead GP however this was declined too.

5.3 Themes

5.3.1 Overview of Themes

Thematic analysis was conducted to understand the reasons for variation in the clinical quality of care within the practice group researched. An initial coding framework was developed, corroborated with two additional external researchers. From this, four major themes were developed incorporating descriptive codes. These themes were *leadership and culture*, the *system of care*, *quality measurement and improvement* and *external and non-modifiable factors*. Reasons for variation in the clinical quality of care were provided from those practices identified as special cause outliers (either across single indicators or within the HP/LP practice groups) in addition to practices which were not outliers to ensure some triangulation and accuracy in interpreting those factors most likely contributing to variation.

Leadership and culture was one theme which particularly recognises the role of practice leaders (often but not always a lead GP) in shaping the practice culture to maintain high standards of care, where leadership and culture translated into the relationships practices held with their patients. The theme relating to the practices' *system of care* included most predominantly the practice structures and processes used to guide what they did on a day to day basis. This theme was differentiated from that of *quality measurement and improvement*, which was a further distinction around how practices approached their own quality agenda and QI or indeed where this was absent. Finally, a range of factors that were indicated as causes for

variation were *external* in nature or *non-modifiable* at the practice level. This included reasons for variation that were promoted by practices but were either not modifiable by the practices themselves or were in fact reasons that from the perspective of the interviewer were not actually related to variation in practice.

5.3.1.1 Leadership and Culture

Leadership

Differences in practice leadership appeared to have an impact on clinical quality of care, where practices leaders and leadership was deemed to be more effective in HP compared to LP practices, as evident from interviews of practice staff and health care professionals working in practices. A good example of this is shown by interviewees descriptions of how leaders and leadership influenced the practice. Leaders in HP practices were often singled out by staff and were recognised for the vision, high aspirations and expectations they had for their practice in terms of striving to provide the best care relative to their peers, whilst creating an informal, team-focussed and results-driven working environment (characteristics which were often found collectively in HP practices):

i) PN: Well you want to do well with Dr.X. She sets very high standards which you work to... Which I don't think every (practice) has. I know that sounds horrible but she's a perfectionist. So, 110% is enough but 99% is way off. [PP12, HP]

ii) HCP: Dr.X at the practice is great, he gets the whole team behind improving care. [PP27, In reference to HP]

The impact of individual practice leaders was also highlighted by staff external to those practices:

HCP: I can probably hazard a guess that Practice X isn't great.

RI: In terms of?

HCP: Poor... If they're above or below (average). If they were below that wouldn't surprise me.

RI: Really. And why not?

HCP: That one would be the GP himself, being very offhand about patients... Like Oh that's okay. High blood pressure, they'll live... it affects the way the practice works... [PP 28, In reference to LP]

Within this LP practice, led by a single handed lead GP, it was also observed that relationships between staff were more formal, for example, where staff would not address each other on a first name basis and nursing staff (both from within the practice and external in-reach teams) talked about the boundaries and silo-working between roles that limited effective joint working.

Primary care staff themselves would also highlight leadership as a key reason for variable practice performance, as the below examples show:

i) RI: Do you have any sort of ideas for kind of looking at these (disease areas), what things have the biggest impact (on variation)?

GP: Yeah. It's a complex issue, isn't it? And how do we bring about change for the positive? And, I don't think there's ever one thing that you'll say, Okay, we'll do this, and this will have this impact. I think good leadership, good organisation from the practice itself, and good support from the CCG, and good support from the teaching side [PP23, OT]

ii) RI: And what do you think are the reasons for that (variation)?

HCP: It's about management from the top... you know, the practice GP or manager sort of guiding everybody in the right direction and pulling everybody together and saying actually, this is really important. This is a priority... You know a good GP at the helm of it all... [PP29, HP]

Interviewees often assigned the practice leadership role to that of a lead GP, particularly in single-handed practices. Where practice leaders were described in a positive light, their leadership ability and influence was commonly described in

relation to the characteristics they displayed, such as having a clear idea around their "care approach" in the practice:

PM: We probably look after, I don't know, possibly 90% to 95% of the patients in the practice rather than going to the hospital... We understand our patients and it's not a surprise to me we are high (on indicator performance)... It's a very primary care led approach to patient management compared to others... Dr.X ensures this... And they'll see a doctor immediately if there's any problem or if the results are not up to target. [PP13, HP]

Effective leaders were described by themselves and others using characteristics related to credibility, authenticity, ambition, relentlessness and enthusiasm:

HCP: Those two practices have really committed GP leads, they're always giving ideas at the CCG forum and seem to really know their stuff about Diabetes. [PP 27, In reference to two HP practices]

There appeared to be a natural hierarchy across many practices in which the GP was seen as the practice leader in a functional sense (regardless of practice performance or perceived performance). However, practice managers and nurses were sometimes credited with this role and particularly where they were recognised for leading the practice in terms of the individual role they played in improving practice care:

HCP: I would say in that practice for Diabetes especially the lead specialist Diabetes nurse is the clinical champion. She knows her patients inside out and leads all the Diabetes quality improvement audits [PP28, In relation to an OT practice]

Other staff appeared to hold leaders of HP practices with high regard and their role appeared to have a direct influence on the practice culture and team working:

PN: Since he (new GP Partner) has come in its changed... He's added a structure to things and involves staff in making changes... That's helped a lot and the other one wasn't like that

RI: Do you have an example?

PN: Yeah so for the Diabetes clinics I play a much more active role now and am trained on the template so can take more of a lead with some patients [PP3, HP]

Culture

There were differences in practice culture (values, beliefs and behaviours) that appeared linked to clinical quality of care. LP practices attributed clinical quality of care to external factors whereas HP practices shared a number of cultural features particularly in relation to within-practice communication.

There was a general acceptance across practices that staff values were relatively consistent regardless of the practice in aiming to provide the best care:

GP: One thing I think on the whole, there is no doubt that, you know, everybody who provides patient care: the doctors, the nurses, the rest of the staff. There's no doubt that their motivation is to try to improve patient care... we all want to do the best we can for our patients [PP17, OT]

Whilst there are clearly differences in staff values on a personal level, this commonality from a professional value perspective in aiming to achieve the best possible care was often described.

However, there were clear differences in the beliefs that primary care staff within practices had in their ability to achieve and deliver the best standard of care possible. LP practices would often describe a lack of time to improve quality, or assign causes of variation in clinical quality of care to external factors, such as patient demographics, funding or other factors. This in turn appeared to affect their ambition and aspiration, which was also linked to points around leadership:

i) GP: *We're normally in the middle 30, aren't we? We're not in the top 30, not in the bottom 30. We stick in the middle 30. That's because (of) the mix of the population.... we try hard to keep ourselves in the middle.* [PP19, OT]

ii) RI: *And in terms of time and workload being the significant pressures, what is creating that pressure?*

GP: *...there are issues around bureaucratic requirements... and it boils down to financial restraints to a greater extent* [PP25, LP]

iii) GP: *I guess there will always be a little bit of difference between different people in terms of leadership. Some people will have higher aspirations. Others may think, "Okay. Well, I'll be happy if I could achieve this, but not right at the top."* [PP8, OT]

These beliefs that practices held in terms of their ability to improve did appear to influence variation, where HP practices faced the same challenges however maintained a more positive outlook:

GP: *We've done that (quality improvement initiative) ourselves. It's not something we've been paid for. I mean, we're very enthusiastic about diabetes and a lot of that has not been money-led. That kind of thing can be improved easily.* [PP11, HP]

Equally most practices interviewed recognised that their ability to influence the clinical quality indicators examined was in their control. In this sense it could be suggested that a practice's *beliefs* in relation to its ability to improve could be self-fulfilling. Alternatively, such an attitude may be *caused* by achieving relatively higher performance or a combination of these factors.

Practice behaviours varied significantly and seemed related in part to the practice care system and QI approaches in facilitating and promoting certain behaviours. HP practices displayed and highlighted a range of common behaviours. These included open and informal team communication (particularly observed through in-practice observations and combined interviews with large practice teams), recognition and value of the role each team member plays in the practice, information sharing

amongst team members to improve care processes, effective, joint team working, and behaviours aligned to a systematic and structured care management approach (discussed in subsequent themes). Practice staff themselves and external staff that in-reached to practices identified these characteristics as reasons that provided improved care and care processes:

i) GP: We work very well as a team and each team member is valued. We know each other well and have worked with each other for so long... We are all friends as well outside work.

PN: Our kids have grown up together too so we're almost like family! [PP12, HP]

ii) HCP: You can tell at that practice that they all get on... Everyone knows each other and it's just like a really friendly environment. [PP27, In reference to HP]

This was compared to LP practices who appeared to have less open communication between team members, where the practice team appeared to work more in isolation and there was less evidence of shared team working and behaviours such as through regular practice meetings, integration of community service staff in practice delivery and informal working arrangements which are explored further in the structure of care theme.

Patient engagement

Contrasting views were held by practices in terms of the role they felt they played in their relationship with patients across areas such as health promotion and advocacy, health literacy, health education and healthcare treatment compliance (e.g. medication compliance). Examples of these contrasting views are illustrated from passages from interview scripts:

i) RI: In terms of CVD and Diabetes (management), where would you say that you are as a practice generally compared to others?

GP (Passage 1): I think we would be around average, although we do have a number of complex difficult (patients), which it is difficult to achieve targets with, particularly the Asian patients... Their compliance to medication is very poor... I think the problem is that their management is that it becomes, you know, it's totally down to them...

GP (Passage 2): I think it all boils down to the lack of awareness for lifestyle changes really. If we could get everybody to lose weight and exercise, I'm sure all the parameters would come into line. That's an unrealistic expectation. [PP7, LP]

ii) GP: If they don't come for check up here then it is not controlled... I've seen one diabetic patient; he came after two years to see me. [PP9, LP]

iii) GP: It's only when you say, 'Well, I'm not going to give you any medication.' You can't not give them insulin but you can say, you know, 'You need to come. Otherwise, you need to change doctor.' They will actually come for a check. [PP11, HP]

iv) GP: We're very proactive with patients... We send appointment reminders, follow-up DNA's, make sure they are seeing the health trainer etcetera... Some patients also don't speak English or are also not very health literate so we use translators and different visual methods of communication to make sure they understand advice around how to take their medication or what foods to eat etcetera...[PP23, OT]

These quotes are illustrative of significant differences in the way practices viewed their role in relation to their patients. The first two practices (LP practices) had a very passive approach to Diabetes management; suggesting only responding on request to patient request for reviews and lifestyle advice, with a lack of regular follow up for patients who did not attend appointments. Practices iii) and iv) had a more proactive approach, actively ensuring patients were complying with medication and lifestyle advice, having a more systematic approach to use of health trainers in supporting lifestyle changes, and having a scheduled, managed approach for patient reviews and those who "did not attend" appointments for example, such as calling patients who DNA'd (Did Not Attend) to identify the reason why they failed to attend and re-book the patient where appropriate.

There were distinct differences related to the approach practices and staff took to the patient relationship in terms of building and managing the relationship with patients

on a personal level. One practice described their approach to patient care through the lens of patient experience:

i) NP: The practice here has been a different model because it's been run -- as I said, nurse-led. It's not that we just do nursing things, it's just the difference is I use medicine, but I deliver it through a nursing framework. So the things that people find important like the friendly attitude to customer service, the way that you talk to people, you explain things to people it's been a success. And we came second two or three times in the country nationally for patient satisfaction. [PP4, OT]

ii) HCP: They (the staff) all know the patients as well really well. They all know their first names and they ring them up saying 'can you just do this for me' and, you know, we offer a personal service as well. [PP28, OT]

The practice here achieved a fairly average score across indicators examined (-1 summed score overall across indicators compared to an average of 0) and described a "holistic" care approach, placing emphasis on the patient engagement and experience as the most critical feature of care delivery. This practice was as competitive and aspirational to improve care as many HP practices, however placed a greater emphasis on patient satisfaction indicators (not measured in the thesis research) compared to clinical quality indicators. This was substantiated through interventions such as case management, social care interventions, increasing direct patient phone access and time-slot lengths for elderly co-morbid patients to optimise care experience and increased time spent with patients across the multidisciplinary team. There was an implied trade-off between providing optimal patient experience and achieving improved clinical process and outcome indicators:

NP (Passage 1): you have to actually look at the person at a certain age of what you're trying to achieve, rather than protocol says it's got to be this so I'm just going to whack at all the different agents I can to get something out. [PP4, OT]

NP (Passage 2): I think we are talking about people here. I understand the general rule that if we get everybody to a certain level (of blood pressure) we will have less events, et cetera, et cetera, I don't argue with that... but we can't just tick boxes and

say getting everyone to this blood pressure -- that makes us great because it doesn't. If you've got people whose quality of life is impaired by trying to do that. [PP4, OT]

In this case, the practice had a specific approach to care centred around patient experience, however other practices also cited the importance of patient experience and the possible conflict between their experience and the care process:

GP: It's not because I don't think we check them because our hypertensive figures are fine, aren't they, for a year. But once someone gets on quite a lot of medications, it's difficult for them to take more and more medication. Sometimes, they don't always take it if they've got more than three or four medications and the experience of care could be really poor if we keep bringing them back in for reviews and checks... [PP17, OT]

There was also a recognised link between care experience and clinical indicator achievement, where patient experience was suggested to link to intermediate clinical outcome readings by some staff:

GP: If you're seeing the same doctor, even for hypertension, you're going to be calm and have confidence in that situation. The blood pressure readings are probably going to be better. If you go and see a different doctor, your blood pressure was very high, and Doctor A changed the medication, then you have to see Doctor B for the follow-up. That, immediately, that's going to introduce a variable which is unfavourable. So, I'm not being simplistic here. But, to me, all these things actually make a difference... and to make sure the patients are kept as the priority. [PP8, OT]

In the research presented, indicators related to *clinical* quality indicators measures, where patient experience was not a key measure. However, patient experience, whilst important and recognised in HP practices, was generally seen as less important than the achievement of clinical indicators and clinical outcome compared to patient outcome achievement.

5.3.1.2 System of Care

The theme related to the system of care was assigned predominantly to describe the practice structures, processes and way in which practices managed care on a day to day basis where there were striking differences between practices.

Care structures

Care structures include organisational structures (from the organisational provider model to the care team and staffing ratios, for example), material resources (such as the care setting, environment, equipment use and technology use) and human resources of care (for example the staff involved in care, staff competencies, training, education and capabilities) (Donabedian, 1988).

A number of practices had recently embarked on various organisational strategies to increase the size (as defined by patient list size) of their organisations, with an interesting narrative gained around how delivering primary care at scale was perceived to improve quality. This was particularly the case across corporate practice type within the subsequently presented and discussed practice typology. The main reason presented for this strategy was that increased practice size improved practice performance and outcomes through a variety of methods illustrated through interview quotes below.

i) GP (Passage 1): And the way that NHS was going, it seemed like you have to have a big enough number (of patients) to run your own kind of things because we have always been in a situation where we run our own outpatient clinics in the practice... So the idea was that we have enough number (of clinics) whereby we can provide our own services to patients and improve the quality of care to local patients... So I think more of general practice is going that way because previous, single-hander is going... So we're thinking ahead...

RI (Passage 2): What was the kind of reasons for expanding?

*GP: I think the initial aim was providing a good quality of care in a managed way.
[PP8, OT]*

ii) NP: I think anybody who's looking forward are seeing where that model is going. I think -- I personally think they're looking at managed care organisations. I think the likelihood of independent contractor status will fritter (out) with either the emergence of commercial organisations that are formed for large practices with secondary care organisations or organisations that will be brought in to mop up the rest. [PP4, OT]

iii) PN: There's no doubt that bigger practices are better... Because there is a relationship between size and quality... If you're an independent contractor you don't have the same skills and ability to manage multiple conditions as say... A large practice with lots of GPs with various special interests. [PP15, OT]

These practices did not have particularly improved performance across the examined clinical quality indicators, however, believed that practice size allowed greater innovation, more comprehensive care management, more efficiency through shared services and improved care quality with a greater ability to manage more conditions in primary care. These practices placed a greater emphasis on GP sub-specialisation (including *GP with special interest* roles), increasing specialist care delivery and diagnostics in a primary care setting and improving back office and practice administration.

Another area related to organisational structure was the composition of the primary care team in terms of the staff involved, their capability and capacity. A number of practices suggested that the availability and range of staff involved in care, such as secondary care specialists and health trainers, had an impact on clinical quality of care. Whilst this was often promoted as a reason for variation by practices, it did not appear to be a primary cause of variation as there were no apparent differences in access to these staff groups between practices as demonstrated through the selected quotes below. For example access to specialist Diabetes clinics was largely universal through CCG-wide initiatives that provided equitable access for all practices.

i) GP: I've always had an interest in diabetes and it's.... So we've got very good figures for our QOF from that. And that's recently been I think enhanced because we've got a consultant coming into practice now as part of the local enhanced service. [PP11, HP]

ii) GP: The other thing that's happened to the practice... is we get a consultant clinic here once a month I think, today, who's a diabetologist comes in. [PP19, OT]

The availability of additional staff such as hospital specialist consultants, community nurses and health trainers, whilst clearly positive in terms of providing practices with access to additional and different skill sets for optimal patient management, appeared to be less relevant than the way in which these staff worked within the practice team that promoted effective team working and multidisciplinary patient management, in explaining variation between practices:

PM: I think, just in the nature that we use our health trainer, having spoken to the previous health trainer that we had that...because they work in numerous practices themselves and the type of referrals they get from us are different to the referrals they get from other surgeries and the amount of volume of referrals that we give them is more as well. So, I think we utilise them a lot better. [PP18, HP]

A second area promoted as a cause for variation from an organisational sense was the use of specialist clinics and the volume of CVD-related and Diabetes patients seen within the practice. There were no apparent differences between outliers in relation to the type of clinics employed to manage CVD and Diabetes (most practices had specialist clinics for this group of patients). Also, as is demonstrated through the practice characteristics, prevalence of CVD-related conditions and Diabetes was similar across both HP and LP practices.

Practices also often explained variation by reference to a number of human factors, such as the training, competencies and capabilities of staff, continuity of care provided by staff, staff turnover and absence. It is important here to distinguish

between the type of training staff had received and also the capability of staff in applying training to practice. HP practices demonstrated wide team disease-specific training, as per the example below:

GP: And we've all done the Warwick course, we've all done the diabetic course.

RI: All right.

GP: So, I think that's one, two... four of us done the Warwick course... Which is unusual in practices I would think. [PP22, HP]

The Warwick Diabetes course was cited by a number of practices and includes course content relating to blood glucose monitoring, behaviour change nutritional interventions, relationship of Diabetes to CVD and other areas (Warwick Medical School, 2015). Of the LP practices interviewed, whilst there were specialist nurses (e.g. Diabetes nurses) who were described as being up-skilled by the practice, there was less evidence of external training. The personal capabilities of staff in *applying* training to practice also appeared to influence variation. HP practices commonly described the valuable role of experienced individual practice nurses, where their ability to manage CVD and Diabetes patients independently without significant GP input appeared to affect care processes and outcomes. In this sense they applied best practice evidence and initiated improved activities independent of input from practice GPs or management:

i) PN: I'm a nurse prescriber, so, they get a one-stop shop, really, so they can get medication changed without authorisation by the GP in many cases... My training really helps with providing a better care process for patients. [PP12, HP]

ii) GP: I used to do the clinic and then X-nurse name used to help. And then X-nurse name got so much knowledge, I don't know, expertise over the years probably from me... That she can run that more or less herself now and then she just refers to us if there's a problem. [PP1, HP]

This individual contribution was not limited to practice nurses. One practice cited the role of a health care assistant (HCA) case managing elderly frail and hypertensive patients as a primary reason for improved performance against an indicator related to patients with high blood pressure. In this instance indicator improvement is correlated with the appointment of the HCA and a new case management initiative applied to the group of hypertensive patients:

RI: So you have a slightly higher number of hypertensives with a blood pressure over 150/90. However, this has changed significantly in the last year, so you're actually sort of one of the positive outliers in terms of (this indicator). So that was quite interesting in terms of the change, is there anything that over the last year you think you've done from a hypertension perspective that might have improved that or --

NP: X-HCA name

PN: Yeah.

NP: Our HCA practicing on that area

PN: She's more likely to relax people as well and look after their hypertension properly... for the whole person [PP4 and 5, OT]

Another pertinent area discussed in relation to care structures was continuity of care including staff turnover and absence. Particularly across LP practices, staff absence, commitment or turnover among salaried GPs and practice nurses was provided as a reason for variation in performance:

i) RI: So why do you think you (outlie) in this area?

GP: For that specific indicator, it was X-nurse name's job. So when she left probably no-one was picking it up. [PP7, LP]

ii) PM: We've had a high turnover of staff which always makes it difficult then to re-train them and get them working in the right way... It's the same with locums. [PP14, LP]

iii) GP: Having salaried doctors has been beneficial but they don't have the same commitment. So, it's about the skill mix we have. It's kind of their commitment to the task is not much the same as having three partners or four partners, the luxury of which we had years gone by. [PP26, LP]

Externally employed staff working in the practices also indicated staff capacity was an issue in terms of variation:

HCP: And we've finally tracked them down and spoken to them and they're just really short staffed. And we've arranged that one of our staff will go in once a week and support with that process. So, it's worked out in the end... again, you get some of the smaller surgeries, that because they're small, don't have enough staff, therefore don't have good handle on it. [PP29, In reference to LP]

However, HP practices also cited staff changes in recent years and so it may be possible that variation causes related to practice capacity, staff turnover and care continuity are based more on the practices ability to plan for and manage such changes effectively. Having a system for initiating locum and salaried doctors, for example through communicating standardised protocol use (described later) was also a distinguishing feature for positive outliers. As one GP noted:

GP: The key is having the system in place. If you don't have the system, no matter how many number of staff you have, it becomes difficult. [PP16, HP]

Other than organisational and human resources of care within practice care structures, access to in-house diagnostics and software that could support practice care delivery also came up in discussion with practices around causes of variation, specifically, the use of practice I.T systems and software packages to support care delivery. HP practices noted a greater inclination to use online software systems for processes such as risk profiling and supporting point of care protocol use. In these instances however the differentiating factor between HP and LP practices was not the presence of such a system, but the use of it in practice - explored further within the section on care processes. An interesting finding however did relate to two HP

practices who both had in-house staff members with an I.T management role. This specific role, appeared to support the practice with using technology and software to improve practice management and care delivery, as illustrated in the practice below:

GP: There are QOF templates on the computer, ours is a clinical template, which incorporates the QOF but is our clinical template.

RI: All right. And how have you designed that?

GP: Well, I designed it but X-IT staff name... we've got a very good IT member of staff called X-IT staff name. She puts it into... We say what we want and she'll do it for us. [PP1, HP]

Care Processes

Care processes appeared to have an associated impact on both individual clinical indicators (distinct processes that were correlated with individual indicator performance achievement e.g. point of care assessment protocols incorporating urine and electrolyte testing) and overall performance across all indicators (for general and standardised processes that were adopted by the practice e.g. risk profiling).

Patient profiling and screening

Patient profiling and screening was regularly promoted as a reason for special cause variation across clinical indicator performance. A good example of a practice adopting such an approach is in relation to the individual indicator measuring patients who had a CVD risk score of over 20% but no statin prescribed. Two practice performing particularly well against this indicator suggested that their relatively lower percentage of high risk CVD patients without a statin prescribed could be due to their approach to profiling and screening patients:

i) RI: Patients with a CVD risk of 20% and managed with a statin... you performed higher than average for (this) indicator... You were a positive outlier, if you like. Is there any reason you think that might be?

GP: ...We have a very good healthcare assistant and she is very, very keen on blood pressure. You know, she's well trained in there. She will screen hypertensive's regularly with Framingham and make sure they're medicated if needed liaising with us doctors. [HP]

ii) GP (Passage 1): All patients who come and see the nurses regularly, they will all do the CVD risk so that, you know, the QRISK and the CVD risk.

(Passage 2) GP: It's reinforced by our approach to managing. We're very hot in making sure people with diabetes and hypertension get the full required screening and management.... So they will have their CVD risk assessed. [PP21, HP]

These practices appeared more likely to identify patients at risk of chronic diseases such as CVD and Diabetes. Conversely, when discussing screening with other practices not associated with special cause variation, approaches to screening appeared to be less formalised, structured and frequent or seen as less of a priority:

GP (Passage 1): We do try and do the CVD risk scores for most of our patients... and opportunistically we try and get anybody who's 40 or above...

GP (Passage 2): We try and repeat their score even though there's probably no exact science behind having to do it, might've been like a five year follow-up would've been appropriate. [PP17, OT]

In this instance the approach to screening was more casual and not seen as a critical task within the practice.

A number of practices also discussed a wider approach to patient risk profiling. This was not necessarily specific screening, such as using CVD risk screening approaches as described previously, but in identifying across their patient list those patients that were at high risk of hospital admission or increased health and care utilisation. Risk profiling in this respect was described as having a positive impact on the practice's patient management approach, however, practices described this affect

as impacting mostly on clinical indicators and areas not examined, such as hospital admissions and care utilisation.

Patient review and recall (including access, co-ordination and continuity of care)

The practice approach and system for patient review and recall, in terms of new patient registration through to the process and frequency of reviews was another finding related to causes of variation. This appeared closely linked to patient access for reviews, co-ordination of patient management and continuity of care. One important differentiator between HP and other practices appeared to be the way in which practices managed patient reviews and actively ensured reviews were regular and effective, with strategies employed to reduce DNAs:

GP: We'll telephone or send a letter if they don't come. And then the failsafe is the prescriptions. If they've, you know, we authorise prescription for so many months and then if they've not had a check, we're calling them in.

RI: So, that's really interesting. So you sort of – with your prescriptions – they'll only be re-authorised up to a certain (point), will they, yeah?

GP: So, when they're seen maybe in the diabetic clinic, they'll be reauthorized say for six months or seven months perhaps because they're coming in six months. And then if they've not been, they'll be called in again... Because that means if they don't come to the clinic, they won't be able to get the medication. Well, we will give it then but we'll give them the months medication rather than, you know, to keep getting it on repeat.

RI: And will that sort of flag up on the system when that period ends?

*GP: Well, they can't get another prescription. What happens is it comes up for review and the doc...well, that might be the difference in our repeat prescription service as well... The doctor always reviews the notes and sees whether they need any bloods done or should they go into the clinic or need a blood pressure check.
[PP11, HP]*

Across non-HP practices, patient reviews appeared less frequent, for example, being reliant on patient initiation or being limited to a once a year process prior to year-end QOF reporting.

HP practices would also describe other processes for ensuring effective reviews occurred, from auditing patient review attendance, utilising text and phone reminders, and providing more regular monitoring of high risk and complex patients. Particularly important to these practices was having a system of review that ensured reviews were conducted with current blood and any relevant diagnostic results, whilst also providing clinics that addressed the multimorbidity of patients:

PN: So, I tend to do a one-stop shop. I would do all of their ailments all at the same time. And then the time scale I have with each patient is adjusted because obviously, I've got to do more things than one thing and I'll have a little more time. And again, they're put onto this rolling programme. So, depending on their blood results or whether I've got to add another inhaler, then I'll bring them back in a month or if everything is good, I'll bring them back in three months, so, it's a 12-month plan and it's a really tightly structured plan. [PP3, HP]

However, a number of practices (not just HP practices) noted conducting one-stop shop or chronic disease clinics and so the effective management, care approach, regularity and access to clinics are perhaps more likely to be differentiating factors.

There was also significant importance placed on single practice team roles whereby a single staff member (e.g. a practice nurse) was responsible for reviewing a defined list of patients; effectively ensuring continuity of care for certain patient groups in terms of the staff they saw. One interview included a locum doctor who had worked across a range of practices locally. They differentiated the approach taken by a HP practice compared to other practices who were less coordinated and structured in their approach to reviews. They described the role of the practice nurse coordinating and "owning" the hypertension list of patients as important, together with a very robust new patient check process and better managed process for ensuring patients

gained a rolling review programme, with same-day hypertension and diabetes clinics for patients who were newly diagnosed.

Protocol and guideline use

Protocol and guideline adoption and use in practice was a significant area of differentiation described between HP and LP practices and appeared to be an important factor in explaining variation.

There was wide recognition amongst all practices that applying guidelines and evidence-based practice was the "right thing to do". However, a number of practices noted the difficulty in keeping up to date with multiple guidelines in a generalist primary care environment providing care covering multiple disease areas, together with other related difficulties,

NP (Passage 1): ...And the differing guidelines, Scottish Colleague, you're talking about NICE, you're talking about American Associations or British Foundations. The conflicting advice that comes through, articles that people read, personal beliefs, personal experience... I think all these things have a part to play where people actually can't deal with the sheer workload. [PP4, OT]

NP (Passage 2): Easy flow charts help where I can sit down and say okay, this is what I want to do. I need the messages of how my practice needs to change today as opposed to go and sit there (at an educational meeting) for three hours and listen to a number of -- things that just aren't appropriate because sometimes -- you can't do that for everything. [PP4, OT]

However, whilst also recognising these challenges, HP practices identified effective protocol use as an effective strategy to reduce variation in practice whilst ensure practice was in line with guidelines and best practice. These practices identified a number of ways to enhance protocol use and effectiveness in practice that included:

- Protocols for all major disease areas, with regular, structured and diarised processes for practice protocol review (e.g. named leads with responsibility for specific disease areas, protocol review meetings and update schedules):

i) GP: I've got a template for everything... [PP21, HP]

ii) HCP: They regularly hold meetings to update their clinical protocols and make sure it's in line with any new guidance. I think the practice manager says she gets a weekly email or something from a company that alerts her when a new guideline is out. [PP27, In reference to HP]

- Practice-developed in-house protocols modified in line with best practice (as opposed to generic protocols available to all staff publicly or electronically):

i) GP: We took the system one template and we tweaked it. I told him (X-I.T staff name) what I wanted and he tweaked it. [PP1, HP]

ii) GP: And that's not a QOF template... There are QOF templates on the computer, ours is a clinical template, which incorporates the QOF but is our clinical template. [PP11, HP]

- Easy to read and follow protocol formats accessible at the point of care (e.g. templates in practice electronic systems) and complete for each patient:

i) GP (Passage 1): All the clinic is done on templates. So, we know everything is covered. That's probably it as well isn't it? That we have templates. [PP1, HP]

ii) GP: So no matter who sees the patients, they (the staff) ask for the same thing. [PP1, HP]

- Electronic point of care reminders re-iterating protocol and template actions and tasks required (e.g. diagnostic test ordering):

GP: So the new software... actually reminds you and it says -- if it says target below 140/85, it makes you think about it. So when you're talking to someone about something else, thinking that you actually have an actual (target) as opposed to I haven't thought about it because I'm listening to how they've just lost their husband and their granddaughter's got leukaemia and everything else and the whole thing goes out the window because you're just engrossed in the moment with that person's tragedy. [PP22, HP]

- Processes in staff induction around how and why to use protocols:

i) GP: I have a new nurse coming in and it will take me some time but I'll teach her all the protocols like I did with the last one. [PP1, HP]

ii) GP: But I think the good thing about the protocols is that when you're explaining how to use the protocol or the template you're actually disseminating the information. I think that's where the advantage comes from rather than the actual template itself. [PP21, HP]

In combination, these strategies appeared to influence practice variation where HP practices recognised the importance and convenience that protocols and templates offered in terms of reducing variation, improving quality and saving time through a comprehensive and consistent approach to disease management. Such strategies should not necessarily be employed to the detriment of patient experience, as noted above where point of care reminders can be used whilst dealing with personal and emotional patient issues.

Other practices were less enthusiastic about protocol use, less aware of how to modify and use them in practice, or less convinced around the benefits that could be achieved. Whilst they suggested they regularly used protocols and templates, they were less able to demonstrate how to access them during interviews or described generic, non-modified protocols in vague terms:

GP: There's special kind of protocols and stuff comes from the CCG and stuff. So yes, we do kind of always work on them. [PP20, LP]

An example of where protocols were demonstrated to improve practice comparing HP to LP practices, was in the indicator "Patients with Diabetes with no urine or electrolyte (U&E) testing in previous 12 months". There was a clear differentiation between two practices that were special cause outliers in the positive direction, compared to two practices that were special cause outliers in the negative direction

for the indicator. The two positive outliers incorporated U&E testing as a process within their Diabetic patient review protocol. This compared to the two negative outlier practices; One of these practices did not frequently use protocols in practice and the second used a generic, non-modified QOF template for Diabetic reviews.

Interestingly, the indicator noted was measured through the local MSDi software and was not a QOF indicator. One of the negative outlier practices noted suggested this may have been why their performance was relatively lower; the lead GP suggested they mostly measure and work to improve QOF indicators, of which urine and electrolyte testing was not one for the QOF period examined. Whilst the example provided is a single indicator, HP practices regularly cited their practice clinical protocols and templates as an important feature in providing standardised care processes to all patients.

Practice management processes

Practice management is defined as a slightly separate area and was often described as a contributor to improved practice performance in HP practices. Practice management included both structural factors (such as the competence of the practice manager) and process factors (such as the processes practice managers initiated to ensure the practice was effectively administered). These processes included areas such as effective practice capacity and demand planning (e.g. clinic scheduling) and back office management (including managing factors such as ensuring appropriate locum and agency use, improving prescription dispensing and reducing practice consumable spend through better ordering processes). Some of these processes have been described previously, for example in relation to care structures, access,

co-ordination and continuity and so practice management processes could also be seen as an enabler to delivering these other processes.

Information and communications technology (ICT)

The role of ICT systems in improving care has been described, for example in areas such as online protocol use and point of care reminders. The effective use of such systems did appear to be a differentiator between HP and LP practices. The former group of practices more commonly citing the use of ICT support staff and systems in their practice and promoting the role of ICT in care delivery. Similar to practice management, the use of ICT may also be seen as an enabler and whilst not singled out as a specific theme in this research, is recognised as an important feature both from a structural sense (access to ICT infrastructure and software to support QI) and process perspective (utilisation of ICT-based processes such as point of care reminders).

5.3.1.3 Quality measurement and improvement

Quality Measurement

The use of measurement was another important feature in the analysis of variation conducted and whilst some interesting narrative was captured on this area, the focus of this section is to describe *how measurement affected variation*, as opposed to general themes relating to measurement in primary care. Recognising this, the areas where measurement appeared to influence variation most have been grouped under three areas; *attitudes and beliefs in relation to measures and measurement*, *measurement systems* and *issues with measures*.

Attitudes and beliefs in relation to measures and measurement

HP practices had a more positive view of the use of measurement in improving practice than LP practices, demonstrating this view through the importance they placed on measuring what they do in practice, whilst articulating being interested in measurement use:

GP: without the standards, without guidelines, without protocols, without that tick box, there's no...we're all working randomly. [PP21, HP]

Amongst HP practices, there was also a recognition of how measures could be used as a tool to drive positive behaviour change and QI in the practice:

i) GP: We're relentless to working to targets [PP1, HP]

ii) GP: I do think it's been really good having the QOF indicators from the point of view of.... I do think it has improved patient care [PP22, HP]

iii) GP: If you measure it, it will happen [PP11, HP]

These practices saw measures (including, but not limited to QOF) as positive to supporting improvements in primary care. This was a stark difference to LP practices, who were less clear on the benefits of measures, felt overwhelmed by measurement or had a generally negative view of measurement use. These practices were less likely to use measures to guide practice and their view of measures appeared to be primarily linked to their view of QOF:

i) GP: I think they (GPs) are becoming disillusioned because they're changing so quickly every year. You are taking some indicators from one area and you're putting into different areas. And if you're putting in a new area in and you don't know the business rules until six months' gone, then people don't bother because it's not going to work. So that causes a lot of stress, a lot of distrust, and illusion as you said because it makes life difficult. [PP7, LP]

ii) GP: Unfortunately, because of the QOF has changed so much...the goal posts have shifted so much [PP9, LP]

iii) GP: We looked at these MSDI indicators in the past and it just seemed overwhelming what we had to do. [PP25, LP]

These quotes also highlight subtle differences in how practices use measures, discussed in "measurement systems and use", where HP compared to LP and other practices were more likely to use measures for improvement and not just reporting, for example in relation to QOF. Some LP practices had an attitude that QOF targets were there to be "hit" as opposed to exceeded, with some believing that exceeding expectations was unrealistic for their patient demographic:

i) GP: We're normally in the middle 30, aren't we? We're not in the top 30, not in the bottom 30. We stick in the middle 30. That's because (of) the mix of the population.... we try hard to keep ourselves in the middle. [PP19, OT]

ii) GP: They (the staff) don't do these because U&E isn't a QOF point. [PP23, OT]

This element of measurement appears also linked to the practice leadership and culture in that their aspirations for achievement appeared lower than HP practices.

Finally, there was also a difference between positive outliers and other practices in the beliefs they held about measures. Negative outliers would often use a different measurement narrative to describe variation, suggesting that their performance in relation to the indicators examined may be due to their approach to care which is more patient centred or less measurement focussed:

i) GP: If we have a diabetic whose cholesterol is 4.2, I'm not going to kill myself getting them back to get it to below four. So, in that way is how we sort of juggle it a bit. [PP19, OT]

ii) NP: So, we have to have key performance indicators. I'm also aware of the limitations of those because, what we mustn't do is become obsessed with those indicators; and then, you forget about the patients. [PP4, OT]

With these practices there was almost a trade-off described between achieving performance against the clinical quality indicators examined and delivering high patient experience and holistic care. When pressed further however, all three practices quoted above, and more widely across all practices interviewed, agreed that the indicators selected were useful and effective for examining variation:

i) GP: They're the right indicators so that's probably why MSDI look at them, why they're recorded. They're the right ones [PP23, OT]

ii) GP: they are very useful. Absolutely. [PP19, OT]

Many HP practices cited the importance and value of clinical measures over or compared to patient experience-related measures (not examined in the presented research) as summarised by one GP within a HP practice:

GP: I think clinical indicators are probably better... They are more scientific... And a better guide to the quality of care we're providing [PP21, HP]

The practice's definition of quality is important here in determining to some extent their attitude to measurement generally and specific measures used to assess variation.

Measurement systems and use

There were some differences between HP and LP practices in relation to how and why they used measures in practice that appeared to influence variation. There was a recognition that practices would perhaps perform better in areas they were most interested in, as one GP noted:

GP: I think, if clinicians are interested in a particular field, that would tend to improve [PP23, OT]

HP practices appeared to use measures in a different way to LP practices; they described the use of measures for improvement purposes compared to assurance or income generation (as through QOF). Measures can be used in a healthcare setting for a number of purposes from assurance, accountability and performance management to learning and QI (Freeman, 2002). Equally, measures may be combined with extrinsic sources of financial incentive (Flodgren *et al*, 2011). HP practices appeared more likely to use measures for QI and appeared more intrinsically motivated to measure and improve quality, compared to relying on external financial incentives. A series of interview passages illustrate these points from positive outlier practices:

i) GPr: We use them (measures) to plan improvements for the next year [PP2, HP]

ii) GP: it (quality improvement initiative) sort of gives us a reason why we're doing it as opposed to, it's money. It's actually trying to keep people out of hospital because you're on the front line and you're actually seeing people and dealing with them [PP11, HP]

LP and other non-HP practices were less likely to use measures for behaviour change and QI seeing them mainly from a functional perspective for gaining income through QOF:

i) PN: I think if you're providing a good enough care, those indicators happen anyway [PP10, OT]

ii) GP: I mean, the QOF we know, we've got to do those for our incomes [PP20, LP]

HP practices also had a better system for using measurement and incorporating them into their practice to improve quality and assess their performance. This included regular collection and frequent communication of measures (i.e. at least monthly) amongst practice teams (and sometimes patient groups), use of

measurement tools (e.g. control charts) and data visualisation, setting internal QI targets and benchmarks to improve their performance against, and linking QI measures to behaviours:

i) GP: We work to 10% here (instead of 20% risk score) because of the population, it is a massive heart disease area with a massive family history of heart disease. [PP1, HP]

ii) GP: We've actually had a patient participation meeting talking about that as well, all our high figures in various areas... [PP11, HP]

*PM: Every month as a practice we look at our QOF figures, but we also have an audit at least quarterly planning and measuring improvements using our practice data, such as frequent hospital attendees... We talk about this too and look... here is our improvement from the last time *show's graph... [PP13, HP]*

This point of differentiation was substantiated by asking negative outliers how and if they communicated measures in the practice, with little evidence of such activity.

Issues with measures

In examining variation using the defined indicators, there were some issues with measures, their collection and application, that also provided some explanation for variation. The main issue presented that appeared to impact variation was that of coding or the quality of the data output based on the inputs at practice level. A specific example related particularly to coding dietary and lifestyle advice:

i) PN: We certainly won't be coding that for patients with congestive heart failure with dietary and lifestyle advice because we don't put a code in for that because it's not a QOF code [PP10, OT]

ii) GP: That's why we didn't tick the box. All our patients had the dietary advice that a general nurse would give. The QOF change is it had to be specific. And so if we can't do it we don't claim for the points. We try and be as conscientious as we can. [PP23, OT]

The extent to which coding, or lack thereof, influenced variation was not entirely known as even those practices who stated that coding was an issue, returned data with diet and lifestyle interventions recorded. This suggests that this activity was coded for at least some patients on their list. Equally, this specific issue primarily related to one indicator examined.

In the narrative on measurement presented by practices there were also other issues with measures noted. These were more general points related to measurement in a healthcare context, as opposed to those measures selected for the research which were widely accepted as useful and helpful to assess variation in the disease areas examined by practices during interviews. Issues discussed included indicator selection (particularly in relation to the focus, number and type of indicators e.g. structure, process and outcome indicator use), specificity, sensitivity, relevance, consistency, access (e.g. available online for practice access) and timeliness of reporting. Practices also noted the importance of measures being able to be influenced by primary care teams. Additionally, practices suggested that gaming of measures may have been a reason for some practices to have "better" performance than others, although this was not directly analysed or observed during the research process:

i) GP: So a lot of people they cheat. But we don't cheat [PP25, LP]

ii) NP: It's (QOF) just easy to manipulate [PP4, OT]

Notwithstanding the wider issues with measures, the greater use of measures by HP practices to clarify practice priorities, influence behaviour and improve quality was apparent.

Quality Improvement Approach

In examining variation through semi-structured interviews, specific probes within the semi-structured interview script included questions related to practices' knowledge and experience of QI locally, together with asking staff about examples of practice-based QI. The QI *approach*, whilst a leading thematic area within the research design, also appeared an important differentiator in relation to variation observed amongst practices across indicators.

There are a range of recognised key features relating to effective QI in a healthcare setting, with a number of QI approaches developed across industry such as utilisation of the "plan, do, study, act" cycle, "lean" and "six sigma" systems (The Health Foundation, 2013). The concept of quality and QI is covered elsewhere in this thesis. However, key features within recognised QI approaches include the use of data and measurement for improvement, understanding and mapping the care context and process and involving staff and patients in planning and implementing improvement solutions based on evidence-based practice (Batalden and Davidoff, 2007; The Health Foundation, 2013). It was evident from practice staff interviews and responses that there were differences in the knowledge staff had in relation to QI and how they applied QI in practice. Non-HP practices appeared to have less knowledge and awareness of QI practice and principles when asked around their knowledge of QI generally and in relation to local QI initiatives. They were less able to describe their approach to QI, or provide evidence of QI initiatives or interventions. One GP from one of these practices suggested that structured QI was perhaps not that relevant as they needed to focus on everything:

GP: Problem is we do general things so objective is to improve everything. [PP20, LP]

In the case of many but not all HP practices, their approach to QI differed in a number of ways. These practices had a system of *continual* QI; a QI system that was structured and regular, supported by frequent use of data and measurement to support improvement initiatives.

GPr: I have to say that is something they are very good at here, I've learnt about quality improvement from the regular quality meetings held. [PP2, HP]

This was supported by practices describing frequent QI meetings (as standalone meetings or incorporated into regular practice management meetings), identifying clearly their QI priorities and at least some evidence of staff QI learning and training from an academic or self-taught perspective. QI efforts in these practices was more internally practice-led as opposed to externally-led. There was also evidence of improvement cycles, where practices would identify an area of care, such as cholesterol management in Diabetics, measure baseline data for their disease register and complete two or more cycles of different interventions to assess improvement effect consistent with recognised QI approaches.

5.3.1.4 Non-modifiable factors

Throughout the interviews, a number of "non-modifiable" factors were presented as causes of variation by practices. Non-modifiable factors related to causes of variation that were suggested by practices but were not able to be influenced by practices themselves in the view of the research group.

This theme included some suggested socio-demographic factors that were identified as causing variation, such as local deprivation and co-morbidity;

i) *GP: We have a higher deprivation in this area compared to other practices that means we have more patients and they are more complex, too, because they are less well educated in lifestyle and things like that [PP26, LP]*

ii) *GP: We've got a lot of patients now with co-morbidity. And, more people, polypharmacy. And, you know, on the one hand, we try to sort out the clinical presentation—the problem that they presented with. But then, at the same time, we're trying to keep the other eye on what's needed to try to get these kind of chronic disease issues in control. So, lots of factors affecting variation. [PP8, OT]*

These factors did not always appear present as per socio-demographic comparisons of HP and LP practices (Table 6). These factors were often external environmental factors or related to national primary care policy, the health system as a whole e.g. poor secondary care management or a lack of access to community teams, practice regulation, financing or resourcing in a more general sense;

i) *RI: And... do you think that this bureaucracy you mention has an impact on practice variation?*

GP: Yes... And now, we have NHS England. It's so remote and so ignorant. It just doesn't know the lay of the situation and the reality of running a practice. NHS England is a big disaster zone. They are run by people who know nothing, demand a lot, and imposing them in [inaudible 00:27:19] restrictions and [inaudible 00:27:21] what happens is we have to be the people in the middle trying to tell the patients who can't have the associated service because NHS England doesn't commission it, or that the commissioning group doesn't commission it because NHS England doesn't allow it to commission. [PP25, LP]

ii) *PM: If we had more money we could probably spend more time on quality improvement initiatives, but I just don't have the staff to solely focus on that, I suppose it's the same for all practices though. [PP24, OT]*

iii) *PN: Well I think things like access to community teams has an impact on quality between practices*

RI: In what sense?

PN: Well just having access to Diabetes specialists, community nurses etcetera

RI: So does that differ you think between practices in this area?

PN: Come to think of it, no, most practices have the same team actually, it's something that is brought up as a common thing at CCG meetings [PP10, OT]

iv) GP: And that's the other thing (creating a difference in quality). There's so much paperwork to be done, really. It's reports for this and reports for that. And everybody now wants to see the GP. [PP26, LP]

v) PM: The hospitals, secondary care, don't help us... they don't look after the complex patients like they should and they send them back to us before they're ready. [PP14, LP]

These factors were also often applicable to all practices. For example, many practices suggested an increasing regulatory burden, increasing population needs resulting from ageing and increased disease prevalence impacting their ability to provide high quality care. Such factors could be deemed applicable to all practices and therefore perhaps not a significant differentiating feature at practice level.

Examining practice characteristics (Table 6), there also did not appear to be significant differences in practice demographics, size (as per registered list) and deprivation between HP and LP practices that explained variation between these practice groups. However, these factors were not quantitatively analysed as part of the research where qualitative research was used to understand causes of variation in the clinical quality of care.

It is well recognised that the determinants of health go beyond the healthcare system and are influenced by, for example, socio-economic factors (e.g. social networks, local cultural factors, support, education, income and employment), differences in the physical environment (e.g. housing and water quality) and personal behaviours (e.g. diet, lifestyle and activity, including influences from the media and other family and friends) to name a few. Practices would sometimes use these factors to explain differences in practice list characteristics that could contribute to variation in clinical outcomes;

i) GP: *I would say something like the patient income and employment might be different between practices, that could affect quality, what do you think?* [PP9, LP]

ii) PN: *We do need more input from the education side, for patient education. That's where we lack support we think. It affects variation.* [PP12, HP]

iii) GP: *In this area we have a lot of Pakistani, Bangladeshi, Indian patients and they have very high sugar and carbohydrate diets... but its true of many areas of [REDACTED].* [PP8, OT]

iv) RI: *And what are the sort of common reasons that variation exists (across practices for Hypertension)*

PN: *A few years ago, it was a Trevor McDonald programme. (Laughter) that did us no favours at all. So I printed off the diet sheet that they recommended and showed them, "Now, this is what Trevor McDonald programme recommends. Can you eat tofu? Can you eat this?" And they're like, "No." (Laughter) So that didn't do us any favours. And then it's that, "My friend is on a statin and he aches all over." It's the usual things. And also, by the nature of statins, how the work on the liver, they're not keen to be on the treatment forever.* [PP3, HP]

Similar to points made previously around practice demographics however this was not necessarily substantiated through actual evidence of such differences provided by practices or were broadly applicable to all practices. However, this was not fully analysed in the thesis research beyond examining basic practice characteristics.

5.3.2 Characteristics of HP practices

The analysis of variation, including the practice typology subsequently presented in this thesis, also provides some insight into the most important areas that appear to influence variation and performance across the clinical quality indicators examined. Table 8 provides a summary of the characteristics of HP practices informed from the research results, particularly with reference to the themes developed and presented in the qualitative results (column 1), with cross-reference to relevant sections of the results where key factors are summarised and have been developed from sections outside the key thematic area. These characteristics provide a possible indication around some of the key areas practices may need to focus on to deliver improvement

in the clinical quality of care and care indicators that fell within the scope of the thesis research.

Table 8: Practice characteristics associated with high performance across clinical quality indicators

Theme	Factors contributing to frequent positive special cause outlier performance
Leadership and Culture	<ul style="list-style-type: none"> - Clear practice vision, purpose and strategy aligned to clinical quality improvement (see also "biomedical general practices in practice types") - Clinical leader(s) with interest and expertise in disease area (see also "care structures") - Authentic (intrinsically clinically quality-focussed), reflective, enthusiastic leader respected by staff with high and consistent aspirations for practice as defined by measurable clinical goals and "results-driven" but adaptable style; Ambitious and "relentless" approach to achieve improvement (see also "Attitudes and beliefs in relation to measures and measurement") - Practice belief in ability to improve and that the practice has access to the people and resources to improve clinical quality - Practice places high importance on clinical outcome improvement (for clinical indicators) with shared values relating to delivering high quality and safe clinical care (see also "biomedical general practices in practice types") - Staff with clear role responsibility and autonomy, opportunity and capability to deliver high quality clinical care, respect and recognition, and development opportunities (see also "care structures, "patient engagement" and "biomedical general practices" in practice types") - Recognition of the value each team member plays across the team, particularly from practice leader(s); Commitment across team to improve clinical quality with feeling that their role is important; Ability for staff to influence improvement initiatives (see also "care structures" and "biomedical general practices" in practice types") - Open, informal and effective communication and team-working with high staff satisfaction, mutual trust and respect, combined with regular formal, structured team meetings (see also "care structures", "measurement systems and use" and "biomedical general practices" in "practice types") - Intrinsic versus extrinsic motivation (e.g. dependence on funding or external support) to improve clinical quality (see also "measurement systems and use") - Demonstration of an allowance or tolerance of mistakes that inform continual improvement; Improvement success appeared to positively reinforce "improvement cultures"
System of Care	<ul style="list-style-type: none"> - System for continual patient profiling and risk screening that supports care delivery - Standardised new patient checks with patient risk assessment of disease areas examined (CVD and Diabetes) - Rapid access clinics for newly diagnosed patients (i.e. same-day or within one week); More frequent monitoring (at least quarterly) of patients at high risk of CVD - Practice-led patient review and frequent recall with patient reminder system; Recall system facilitates patient attendance (e.g. linked to repeat

Theme	Factors contributing to frequent positive special cause outlier performance
	<p>medication prescription)</p> <ul style="list-style-type: none"> - Evidence-based and regularly updated (at least annually) clinical protocol integrated at the point of care and based on disease-specific clinical guidance (e.g. NICE) - Evidence of use of patient groups to support practice improvement (see also "measurement systems and use" - Process for staff induction and training on clinical care protocols and process for checking staff compliance to protocols (at least annually) (see also "biomedical general practices") - Multi-disciplinary team trained to relevant, disease-specific, best practice standard of care and applying knowledge in practice with regular professional development (e.g. through annual personal development plan) (see also "biomedical general practices") - Effective use of non-medical and junior staff to support care delivery (e.g. health care assistants) - Effective use, communication with, and referral to community and wider teams e.g. health trainers and specialist nurses and social care, which may support impact on the wider determinants of health such as lifestyle, behavioural and social/environmental factors; Particular emphasis is placed on the need for effective integration of pathways and interventions based on patient profiling (see also "patient engagement") - "Enhanced" primary care environment which includes in-practice point of care diagnostics, investigations, treatment and staff with special clinical interest knowledge reducing need for secondary care referral and increasing continuity of care (e.g. for ECG assessment and CVD-related diagnoses)
Quality Measurement and Improvement	<ul style="list-style-type: none"> - Quality improvement framework or plan defined at least annually, supported by staff knowledge of clinical quality improvement principles and evidence-based interventions (which varied amongst practice significantly) - Positive view of measurement for clinical quality improvement compared to measurement just for reporting and income requirements (e.g. QOF); - Clinical information systems supported measurement use where positive outliers had adapted or applied novel approaches to ICT. - Clinical quality improvement "targets" which are specific, measurable, achievable, realistic and time-phased; Targets agreed within practice and process for continual improvement e.g. through quarterly audit cycle; Measures benchmarked against peers to inform clinical quality goals compared to measurement for achieving a minimum threshold standard - Regular reporting and feedback of clinical quality measures (i.e. at least monthly) amongst team which is regular, open and improvement focussed making use of simple visual data presentation - Measurement focussed on internally-driven quality-improvement and not reliant on externally-focussed incentives - Clear link between measures and expectations/ accountability of staff to influence or improve clinical quality

CHAPTER 6: PRACTICE TYPOLOGY

6.1 Introduction

The previous chapter provided a descriptive analysis of the themes relating to variation in the clinical quality of care. In discussing relationships between themes following thematic analysis across the four person research group, it became apparent that there were a number of practice organisational types emerging that could be used to develop a typology of general practices as described through themes of practice leadership, culture, systems of care and practice approaches to quality measurement and QI. Practice type has been used to explain the differences practices display across themes identified that ultimately impact variation. This section describes the emergent practice types with a summary of the key characteristics within each using the themes defined. The four practice types identified were described as "biomedical", "holistic", "corporate" and "externally reactive".

The description of each practice type indicates the dominant approach to care that practices displayed in their overall approach to practice organisation, care delivery and QI. However, the type assigned to each practice does not suggest that the practice only displayed characteristics related to that type. For example, practices identified as "biomedical" also displayed characteristics of the "holistic" type. For each practice type, a prototypical practice (Practice A, B, C and D for each type respectively) is used to illustrate findings. In cross-referencing Table 5, Practice A is practice number 31, Practice B is practice number 21, Practice C is practice number 4 and Practice D is practice number 40. Externally reactive practices could be differentiated from other practice types which, whilst displaying different

characteristics, appeared more internally proactive in the nature of their approach to QI. An overview of each practice type is provided below in table 9.

Table 9: General Practice typology overview: Summary of practice types

Practice Type	Key Features	Nature of QI
Biomedical	<p>"Quality" in the practice is dominated through a focus on biomedical clinical outcomes; Intrinsically focussed on clinical quality improvement; High importance placed on use of standardised clinical protocols and templates developed in practice; Clear, structured system for new patient checks, patient screening, patient review and recall; Regular monitoring and communication amongst the practice team of practice clinical outcomes across disease areas; High importance placed on effective prescribing for clinical outcome improvement; Quality improvement approach driven by clinical data measurement; More direct approach to patient management to ensure clinical outcomes are optimised; Evidence of knowledge and application of evidence-based quality improvement interventions (e.g. measuring/auditing clinical care and putting in place quality improvement actions); Regular team meetings centred around improving clinical outcomes.</p>	<p>Internally Proactive (Intrinsically Motivated)</p>
Holistic	<p>Take a "holistic" and less biomedical view of care i.e. More focussed on patient experience and quality of life over clinical care process and clinical outcomes; Less task orientated (e.g. less use of standardised clinical protocols) and more likely to tailor care to individual needs; Will spend more time on patient lifestyle and non-healthcare related interventions e.g. Patient housing, social care, patient self-care, compared to medical interventions e.g. prescribing (whilst recognising these are also important); Importance placed on personalisation of care and care co-ordination; Prefer to focus on preventative interventions e.g. pre-Diabetes and admission avoidance than purely clinical outcomes; Quality improvement approach driven by patient experience and patient-reported outcomes.</p>	<p>Internally Proactive (Intrinsically Motivated)</p>

Practice Type	Key Features	Nature of QI
Corporate	More "corporate" and business focus to care delivery; Focus on organisational growth, innovation and primary care delivery at scale perhaps through practice mergers, federations and "super-partnerships; Focus on "enhanced" primary care through extended GP roles and specialist teams managing more patients in primary care through greater access to non-core diagnostics and interventions; Importance placed on additional non-core (GMS) income sources e.g. research and development, private patients, wider community services and specialist clinics; Regular and structured practice business meetings and more corporate style management e.g. through a board and corporate management processes; Significant practice attention given to practice management and back office systems, practice productivity and efficiency; Practice more likely to perceive practice growth and organisation development as central to quality improvement.	Internally Proactive (Intrinsically Motivated)
Externally Reactive	Practice focussed on sustainability and managing risk; Perhaps less engaged in quality improvement due to a focus on practice demand, practice pressures and challenges; Less evidence of practice quality improvement application, staff training and development systems; Less "active" role in patient management through lifestyle approaches to care and personalisation; Importance placed on external funding and support in order to secure practice sustainability; Practice may be going through significant change in partners or turnover in staff, or is responding to improvement requirements from regulators.	Externally Reactive (Extrinsically Motivated)

As is noted earlier in the thesis, respondent validation was completed once the practice typology was developed by providing three deviant case practices identified with the General practice typology overview: Summary of practice types (Table 9). These practices (through interviewed staff) were told which practice "type" they were identified against and a discussion had around whether they agreed both with the typology overview and their practice placement within this, particularly to assess the

authenticity of the typology. All three practices thought the typology developed was both interesting and novel, agreeing that could see how the key features of each type could be displayed in and across practices. It was discussed that the practice types may not be independent of each other, such that some practices may display features of all types, and some practices may have stronger affiliations with a type than others (where practice type may not be so easily identified). This is recognised within the thesis typology and results, which describes more the types as a dominant practice type, recognising that practices could display features of all types. One deviant case practice was identified as an "externally reactive" practice type and whilst agreeing with the rationale indicated this could be construed as a more negative type compared to the other practice types. It was discussed between the four person research group that this does not necessarily invalidate the type itself. Notwithstanding this, following discussion, this practice type label was changed to "externally reactive" from "Survival-biased". The two other practices were identified as biomedical practice types and agreed that this was the type that best described their practice. It was suggested by these two practices that this biomedical type could perhaps be the most common type amongst general practices, due to the nature of primary care incentivisation which was geared towards perhaps incentivising biomedical care process delivery over other areas.

In providing results of the practice typology and description of practice types, reference to the themes identified in chapter 5 has been made given the typology was developed using the thematic areas as key categories within practice types. As such, there is some recognised over-lap between these thesis chapters.

6.2 Practice Types

6.2.1 Biomedical General Practices

“Biomedical” general practices were defined through a leadership and culture aligned predominantly to achieving improved *clinical* targets from the use of standardised, protocol-driven care based on recognised clinical guidelines and aspirations to improve more biomedical and intermediate clinical outcomes:

i) GP: The protocol we use is based on NICE guidelines, it follows the pathway, but I've added some of my own things, so say there is more detail on second line treatments if the first line treatment doesn't work and so on... I train all my team on it and it's part of every consultation. [PP1, Practice A, a HP practice]

ii) GP: I'm more interested in targets like blood pressure and HbA1c, these clinical indicators give a better indication of future events... These are the things we can actually influence in general practice [PP1, Practice A, a HP practice]

These practices appeared to align practice working around clearly defined biomedical/clinical quality practice standards and processes. This appeared to help promote a sense of responsibility amongst team members, supporting clinical process-based behaviour change in the practice, which in turn provided employee engagement and clarity in relation to what is expected of them within the practice team;

i) PN: I know what I need to do in the team because of the way the clinics are structured... It's clear... Which helps let patient's know the journey and review process as well as helping the team function best [PP12, HP]

ii) PN: I feel like, compared to other nurses I know, I have more responsibility for the Diabetic patient list - mainly the Type 2 Diabetics, and Dr.X, people like the community nurses, outside people like the CCG know they can come to me... The protocol developed definitely helps this as every patient gets the clinical checks... [PP3, Practice A, a HP practice]

In addition, this biomedical approach also meant staff had clinically-focussed training and development that was aligned to clinical processes that could lead to

measurable impacts in relation to their role and input. For example, by following a new patient check and prescribing protocol for hypertension patients, staff could see the impact this had on clinical hypertension indicators.

PN: It (the protocol) allows me to work more like by myself, because I know I'm covering everything off. Of course if I need anything Dr.X is in the next room. But probably for most patients I can manage them and that helps the practice as well as me knowing I'm having a real impact on care by myself working independently. [PP3, Practice A, a HP practice]

The biomedical practice type was heavily reliant on practice systems and structures based on standardised, protocol-based care aligned to evidence-based *clinical* guidelines and best practice. Again whilst this was described by other practices in the "system of care" theme, biomedical practices described regularly updated, locally modified protocols acting as clinical templates that ensured patients received a standardised assessment, diagnostic and treatment plan required for their condition. Similarly, these practices often adopted approaches, such as point of care reminders, that facilitated these clinically process-driven approaches to care more so than other practice types. For example, reminding clinicians through online disease assessment templates to order certain clinical diagnostics for specified conditions unless contraindicated. The extent to which this resulted in over-use of diagnostics, drugs or devices was not examined, however could be an important consideration for future research development. In Practice A, the lead GP took an active role in promoting clinical protocols to other practices in an attempt to support wider QI in relation to blood pressure management. It was evident that the enthusiasm that the lead GP had in this area translated to better practice care processes, which were widely communicated and used across the whole practice team. This enthusiasm appeared inherent (an intrinsic motivation) in the lead GP as opposed to being driven

through a need to achieve external recognition or reward; financial (e.g. increasing QOF income) or otherwise.

As has been described in previous chapters, HP practices were commonly of the biomedical practice type, where table 8 incorporates many features of biomedical practices. For example, care management in these practices was mainly focussed around managing and standardising clinical processes, with greater evidence of implementation of risk profiling and screening, new patient checks, patient review and recall and optimisation of clinic utilisation through effective patient appointment scheduling and reminders. Practice A would describe a "meticulous" approach to ensuring all new patients were screened for CVD risk where appropriate, which was incorporated into their new patient check template. The practice also worked to a 10% 10-year CVD risk score for targeting patients with CVD risk, compared to a 20% CVD risk which was defined through a local improvement target as they felt they wanted to be more proactive in identifying CVD risk due to the high prevalence of CVD-related conditions across their practice list:

GP: We work to 10% here (instead of 20% risk score) because of the population, it is a massive heart disease area with a massive family history of heart disease. [PP1, Practice A, a HP practice]

Where patient risk was high, a same-day appointment was booked with a health trainer or practice nurse to address the risk factors more comprehensively. This differed from some other practice types who would conduct risk assessment but not demonstrate the same organisation in terms of follow-up and use of other community services, as noted by a visiting GP Registrar who was interviewed at the practice and had experience of working with a number of other practices locally:

GP: I'm not sure, but some other bigger practices I've worked in aren't as strict about follow up, making because no one person is taken the lead on it and they don't have a schedule like here [PP2, Practice A, a HP practice]

Essential to this clinically-driven approach was the practices internal training and development programme that ensured staff were competent in delivering defined clinical care processes through staff induction, personal development and continuing professional development activities. In this way staff were supported to deliver the defined clinical processes effectively. It was felt by the lead practice GP that this clinical protocol-driven approach to care reduced clinical errors and improved the quality and consistency of clinical care to patients.

Finally, in relation to quality measurement and improvement, these practices appeared biased to measuring clinical indicators of care quality and could clearly articulate their performance relative to peers across clinical indicators examined, often citing their achievement against certain clinical indicators (for example in QOF) relative to a local or national benchmark. The lead GP in practice A would often describe being "the best" for blood pressure management in the area; illustrating performance against clinical blood pressure indicators through graphs and charts displayed in the practice:

GP: If you take a look here we record and display our quality against all other practices in the current... Of course we're the top! [PP1, Practice A, a HP practice]

The whole practice team would often describe their sustained achievement across clinical indicators as an indication of the high performance of the practice compared to others. Many biomedical practices described continual, regular collection, analysis

and communication of clinical quality indicators, for example through practice team meetings and even through patient involvement groups.

GP: We met every week looking at these (blood pressure indicators) [PP1, Practice A, a HP practice]

Practices of the "biomedical " type displayed a greater focus towards improving *clinical* (intermediate) outcomes (e.g. reduction in cholesterol recordings) relative to other practices, compared to patient outcomes (e.g. improving patient experience), and as described by a GP in Practice A:

GP: It's harder to cheat them and you can clearly see the impact you're having against the clinical standard compared to other non-clinical measures. [PP1, Practice A, a HP practice]

This was evidenced through the narrative given by practices, for example in describing the importance of medicating to reduce blood pressure even if this meant a slighter higher degree of tolerance on behalf of the patient in relation to "non-serious" side effects such as nausea. During interviews with Practice A, the approach to "*hammer*" patients with their protocol-driven approach to blood pressure prescribing was a humorous but accurate description of the approach to clinically-driven improvement. There was to some extent a recognised and deliberate trade-off of patient experience in these practices in order to achieve improved clinical outcomes, that in turn may reduce patient risk of chronic diseases or adverse clinical outcomes in future. However, it was equally noted during interviews with Practice A staff of the importance and extra time they spent educating patients on the importance of medication compliance for CVD management and Diabetes, for example. In contrast to some other practice types, it appeared the practice would not

simply accept a patient declining to take a drug, but would spend more time understanding why the patient wanted to decline and attempt to educate them of the importance of medication compliance and influence their decision more proactively in order to optimise medicine use. If for example a patient declined to take a statin for lowering cholesterol (for example due to concerns around non-serious side-effects or liver toxicity), they would continue to offer alternatives and spend time supporting the patient on medication compliance until the patient was comfortable with their prescription and understood the importance of medication use in relation to their overall clinical health outcome.

The HP practices in our quantitative analysis of variation were comprised *almost* exclusively of this practice type.

6.2.2 Holistic General Practices

The general practice type referred to as “holistic” general practices describes those practices with a dominant focus towards optimising and achieving positive patient experience through a more holistic care approach. These practices focussed more on patient-identified needs and goals and the wider social determinants of health, as described by practices themselves. One prototypical practice, to be referred to as Practice B, articulated this approach in relation to providing primary care through a non-medical care model, for example using nursing as opposed to medical frameworks for care delivery:

NP: The practice here has been a different model because it's been run -- as I said, nurse-led. It's not that we just do nursing things, it's just the difference is I use medicine, but I deliver it through a nursing framework. So the things that people find important like the friendly attitude to customer service, the way that you talk to people, you explain things to people it's been a success. And we came second two or three times in the country nationally for patient satisfaction. [PP4, Practice B, OT]

In this specific practice, this appeared to be strongly linked to the fact that the practice had a partnership legal form with a registered nurse, as opposed to a general practitioner, holding the General Medical Services primary care contract.

The practice culture in these practices appeared non-hierarchical and centred around developing the practice as a central support to the local community, where staff valued the importance of taking a whole-person approach to care as opposed to focusing on care delivery based around clinical diagnosis or disease groups:

HCA: We're part of the community definitely, so we advertise other voluntary community services and have community events here sometimes also. [PP6, Practice B, OT]

In practice, this meant providing initiatives such as frail elderly case management with clinics co-delivered by health and social care staff that looked comprehensively at biopsychosocial factors of each individual patient's health. There was a strong belief that patients would respond better to care and gain better outcomes where care was more personal and they felt more comfortable with practice teams, for example through seeing the same member of staff with extended appointment times where required:

i) HCP: They (the staff) all know the patients as well really well. They all know their first names and they ring them up saying 'can you just do this for me' and, you know, we offer a personal service as well. [PP28, Practice B, OT]

ii) NP: I think what we major here on is actually looking at individuals [PP4, Practice B, OT]

Staff would often describe an approach aiming to address a patient's health and social needs comprehensively during appointments as opposed to the single issue or ailment they presented with. For example, a frail elderly patient presenting with

hypertension would also be assessed in relation to their social support network, housing conditions and other factors contributing to general quality of life. Practice B talked about the importance of individual social support systems for patients, where the practice would proactively make links with local voluntary and community groups to help patients find local support networks.

The practice system of care in this type was less structured and standardised compared to biomedical practices. One practice for example explicitly indicating that clinical guidelines were important but not as important as how patient's felt about themselves and the care they were receiving. Care was prioritised based on individual needs and preferences as opposed to being driven by clinical templates. This meant a greater tolerance for missing clinical targets (such as those used for the thesis research) if achieving such indicators compromised patient experience of care. In this sense practices were accepting of their own variation in the delivery of care interventions based on individual patient needs. In Practice B, this approach appeared in some respect to stem from the experience the lead nurse had of working within more medically-centred care models that created a personal frustration in the lack of a patient-centred approach to care:

NP: You can't just work to protocols as 1. There's too many [for all conditions experienced in primary care] and 2. You can lose the patient's story by just following rigid criteria and that impact's their experience. [PP4, Practice B, OT]

The lead nurse partner also indicated a desire to challenge existing "medical models" in primary care that presented a "glass ceiling" for non-medical professionals. It was felt that by adopting a more holistic approach, the practice could offer a different model of primary care that allowed greater non-medical staff development and demonstration of competencies in optimising patient care related to patient

experience (such as through a friendly, compassionate and caring approach to patient engagement that could improve overall patient experience of care):

PN: The HCAs here are more trained on identifying social risks and about the importance of knowing the patients, their needs, goals and pressures, so simple things like what their daily habits are and how these are affected. [PP5, Practice B, OT]

This approach being in contrast to staff requiring extensive knowledge of clinical care and clinical, task-orientated processes. An example of this presented was the role of health care assistants in checking elderly patients had appropriate in-home heating and meal arrangements, as an equally important feature of care as clinical treatments related to medication compliance and other clinical interventions. The practice felt that by allowing staff to develop in roles through a holistic versus medical-model also provided a greater ability of the practice to recruit and retain a wider variety of staff, citing present workforce supply issues in general practice.

Practice B suggested that their primary care team had been working together with the same staff for a long period of time (over ten years) and that some staff that were initially employed part-time had increased their hours to support the practice over this period. There was an indication that this was due to the patient-focussed, team-based and cohesive working environment:

HCA: Yeah that's true, I've increased my hours and of course I probably wouldn't have done that if I didn't enjoy it but its a nice place to work and I get to know the patients really well so I think they like that. [PP6, Practice B, OT]

It was felt that more medical models of care contributed in part to increasing workforce stress and disengagement due to a belief that they were not able to meet the requirements expected from national clinical guidelines and best practice.

In this practice type staff favoured training, development and in-practice improvement initiatives related to general care co-ordination and admission avoidance as opposed to being driven by single-indicator or clinical disease area improvement interventions (for example, as demonstrated in Practice B, choosing to focus practice measurement on admission avoidance generally). It could be that the general approach to holistic care described and adopted by the practice was in part a reflection on the difficulty the practice had in organising care based on single clinical disease areas. The narrative provided around looking at individual, as opposed to clinically-determined, patient needs and treatment goals could have partly developed in response to a recognition that adopting a clinical protocol-driven approach to care would be too time-consuming and difficult where patients present with multiple co-morbidities. There was also a recognition that through strict adherence to clinical guidelines and protocols with multi-morbid patients, there was a risk of overwhelming patients and reducing individual overall quality of life and experience of care where patients would be constantly receiving assessment, diagnostics and treatment for multiple ailments. Practice B responded to this through use of case management and chronic disease clinic approaches that aimed to reduce total primary care visits, whilst improving care co-ordination, for patients with multimorbidity:

PN: The software we have measures risk of admission so we look mostly at that than clinical indicators because it's a better measure I think of how we're providing a comprehensive primary care service that affects the total needs of patients. [PP5, Practice B, OT]

Staff suggested that this approach to managing patients allowed for greater care continuity and experience, for example where staff would speak with their case

managed patients on a first-name basis and be able to provide a more "personal, relaxed service".

Practice attitudes to measures and improvement initiatives in this practice type were more focussed on patient experience and lifestyle indicators including in-practice audits of improved outcomes related to areas such as pre-Diabetes and admission avoidance. This provided some self-suggested justification for their care approach as being more focussed on disease prevention, patient experience and health promotion. In focussing on a few, targeted and specific holistic indicators, practice staff in this practice type were often more able to succinctly articulate the practices care model and approach around a holistic-care narrative based on simple, general and easily-understood measures, such as reducing hospital admissions and improving patient experience.

Measures and initiatives such as those described may not necessarily support achievement of QOF-related indicators in the short-term, however, were often supported by funding locally by the CCG or similar. In Practice B, support for their care approach by the CCG was perhaps also influenced by the inclusion of both the nurse partner and practice nurse (with management responsibility) on CCG boards and sub-groups, which helped them deliver new and novel care approaches through influencing local commissioning decision-making:

PN: The groups we're in include the practice manager's forum and the CCG quality group. [PP5, Practice B, OT]

This included for example the practice gaining investment in admission avoidance measurement software that allowed the practice to adopt and focus on a more

generalist approach to care, compared to the disease specific measurement systems in primary care, such as QOF.

6.2.3 Corporate General Practices

“Corporate” General Practices had a particular focus on organisational structure, development and administration. This was often (but not always) aligned to a plan for increasingly growing the practice list size, for example through merging and federating with other practices. Practices in this type perceived this organisational focus as a key determinant of improvement which was often combined with a view that organisational growth would inherently support QI through standardisation of practice structures and processes, whilst equally supporting achievement of economies of scale, improvement in back-office function (such as I.T and telephony support, and centralised administration teams) and efficiency. In this sense there was a perception that what was good for the practice would also benefit the patient. A practice group (Practice C) prototypical of this type had recently grown in size following a merger across three practices in the CCG area, with a total combined list size across multiple primary care sites of over 50,000. They described their focus on organisational development and scale through a narrative based around innovation:

i) *GP: We've had a strategy of increasing the number of registered patients through merging with other practices, including the recent merger I mentioned. Because we're bigger, we're able to do things other practices can't I think, offer more services, be more innovative and increase quality through a greater range of roles in the group. [PP8, Practice C, OT]*

ii) *GP: We have three practices together now. So we are sharing our (processes). We are sharing our telephoning system together. So if practices can do that, then I think it will improve the chronic disease (management) [PP8, Practice C, OT]*

Leadership of these practices, often held by a group of senior general practitioners and in one example operating under a private limited company ownership model, was focussed on organisational development through innovation with a culture aligned to achieving a more corporate approach to care with traditional corporate governance structures and management processes:

GP: Our board is GP-led, but we have other roles, like business development, HR, finance etcetera. We're more business like I think than say if you look at some single-handers locally. We have GP specialists across most of the main disease areas, like Cardiovascular, Musculoskeletal, Dermatology... [PP8, Practice C, OT]

Practices of this type described the importance of specialty and diagnosis-driven clinics with staff training and development aligned to more specialist rather than generalist care. This is perhaps congruent with a wider view practices held of the benefit of moving some services from secondary care to primary care environments. When interviewing a GP from Practice C who specialised in Musculoskeletal and Rheumatology medicine, it was apparent that each sub-specialty area had a lead GP and there was perhaps less knowledge of aspects of clinical performance for the GP interviewed on areas outside his or her specialist area:

GP: I don't really know about that indicator because it's not my area, so you need to speak to the Diabetes lead GP. I don't really look after these patients. [PP8, Practice C, OT]

It could be possible that this creates some lack of continuity of patients with multimorbidity who would perhaps require multiple appointments across sub-specialty areas. However, equally this approach may support improved disease management in a primary care environment without the need for secondary care referral, thus optimising patient care co-ordination and continuity in the practice. The GP interviewed from Practice C did suggest this approach to organising care at scale

with multiple GPs with specialist interests allowed all GPs to contact and communicate with each other within the practice on any disease-specific patient needs, without a requirement for secondary care intervention:

GP: If I've got a problem for example in Dermatology, I can just pick up the phone to that doctor and ask for advice, instead of call secondary care where I might not get through or even get a response. It's better for the patients. [PP8, Practice C, OT]

Practices of this type often focussed on primary care delivery through scale, with greater emphasis on organisational structures and systems over clinical or patient-centred processes. Practice C detailed a more corporate organisational approach with structured and frequent board, sub-board and management meetings that focussed particularly on practice organisational performance and compliance requirements. For example, scheduled weekly business meetings looking at financial and operational performance and monthly staff meetings to communicate practice changes and developments. There was explicit and frequent reference to prioritisation of practice sustainability and development through income generation (for example, citing the importance of QOF and locally commissioned service-level data over other data collection due to their impact on practice income):

GP: Money isn't the only thing but in some respects it can be most important as if you don't have the income you can't sustain and grow the business, to add and develop services. So for that reason we look mainly to maximise QOF income and we make sure we're meeting all the LCS standards from a quality perspective. If you don't have first a sustainable business, you don't get the quality [PP8, Practice C, OT]

This included practices taking on wider research, development and training commitments (e.g. accepting GP trainees), expressing how this supported practice capacity (additional clinical time at low cost) and improvement (e.g. use of juniors to support audit activities). There was also a productivity and cost focus on workforce

structures. Practice C for example discussing the introduction of physician assistant roles to free up GP time and reduce need for additional GP recruitment.

From the perspective of quality measurement and improvement, this practice type demonstrated an approach to improvement that focussed on organisational indicators relating to care volume and income, indicating that development of organisational structures and administration processes would inherently improve quality:

GP: If you have a well-run ship, full clinics, less DNA's, better phone triage before patients are provided an appointments, it helps lower costs and in turn that reflects in quality. [PP8, Practice C, OT]

QI interventions in this practice type were based on less-structured, sub-specialty audits and end-of-year reviews in parallel with QOF reporting periods; In practice C, there was frequent discussion of the need to meet QOF thresholds rather than exceed them, with a view that organisational structures and systems meant that QOF "took care of itself". QI did appear to be internally-driven however change appeared reliant on communication of organisational policy changes to staff. For example, in Practice C, through communication of new policies in relation to booking of bank and agency staff that reduced practice overheads - An "improvement" suggestion by the practice that was more organisationally than clinically aligned. Another more clinically focussed initiative was that of optimising hypertension clinic utilisation through patients taking their own blood pressure at home or through a self-service in-practice blood pressure machine. Practice type A in the "holistic" approach described home blood pressure readings in a context of being better for patient comfort and relaxation whilst reducing "white coat" syndrome. However, Practice C

described this initiative through the lens of improving clinic productivity and utilisation by reducing time taken in clinics to record blood pressure. These two different perspectives on the same initiative highlight to some extent the difference between practice philosophies of care.

A sub-type of this practice type noted particularly through interviews with multiple staff from a single-site practice, were practices with a temporary as opposed to permanent corporate focus. This occurred primarily due to the practice being in transition with changing practice partner ownership; the new partners were temporarily "*distracted*" on ensuring the practice administrative and organisational compliance functions were maintained during the transition period. The new partners articulated a corporate focus for the interim period of practice handover to the new ownership model.

6.2.4 Externally Reactive General Practices

The final group of general practices are described as "externally reactive" general practices with Practice D, a deviant case, being used as a prototypical example. Such practices appeared more extrinsically motivated, being dependent on, or reactive to external factors or forces in relation to their care approach and QI. The reasons for this more externally focussed, reactive approach to care were many and varied. For example, some practices advised that change and QI in general practice could only occur through external incentives and motivations such as funding for QI activities, additional services being provided in the community to support chronic disease management, or changes to healthcare policy. Practices held a belief that without this they could not achieve high performance against clinical indicators, or

demonstrated a motivation only to achieve compliance to external regulatory standards:

GP: Like I said, the system is bureaucratic, so if we have all these demands on primary care and want better quality, it has to be funded, we can't be expected to do it ourselves. [PP25, LP]

Additionally, some practices of this type simply described a care approach which was reactive to patient demands. Such practices were unable to describe a planned, proactive approach to care and solutions to their patient demographic and needs:

GP: We just provide care as best we can. That's it. We're general practice so we don't have particular strategy. [PP20, Practice D, LP]

This was contrary to other practice types which demonstrated more internally-driven and proactive QI and care approaches.

Staff in these practices were unable to articulate a clear vision for the practice or held a belief that practice improvement, in the near term particularly, was unrealistic.

They predominantly cited external causes relating to primary care policy, contextual factors in relation to the wider healthcare system (for example the lack of ownership of the acute sector in health promotion and chronic disease management), practice funding, demographics or external practice support:

GP: It's the hospital that's the problem. They suck in patients and take all the resources so there's nothing left for primary care. [PP25, LP]

Practice D suggesting for example that their practice list had a higher ethnicity estimate and CVD and Diabetes prevalence than others, which on examination comparing demographic data across practices, did not appear to be the case.

Within these practices there was less evidence of effective team working and communication, with elements of a passive and defeatist attitude to their role in improving care structures and processes:

GP: There's not much more we can do, the patients themselves has to make the change, so changing how we work isn't going to have the biggest impact [PP25, LP]

Whilst not directly analysed, there was some reference by staff from external teams, such as community nurses and health trainers, of high practice staff turnover, less interaction with community teams and less well organised practice systems related to referral into community teams and clinic scheduling processes:

HCP: The team there don't really communicate with us and I think that's just how it is in the practice. They all sit in their separate rooms and don't seem to talk much. When we come in there isn't a clinic schedule like in other practices its just very loose and so we have to identify patients for review and follow-up ourselves as the practice don't have a system. [PP28, In reference to Practice D, an LP practice]

HCP: They've had quite a few staff leave recently [PP29, In reference to Practice D, an LP practice]

Practice D demonstrated this in part where the lead GP was unable to answer on when a community nurse held clinics (scheduled weekly at the same time each week as confirmed by the community nursing team member), without a clear understanding of how patients were prioritised and invited to the community nurse-run clinic, or the interventions that a visit included. Whilst this could equally suggest a need for the community nurse to better communicate their role, given the nurse was using practice space and systems, it could perhaps be expected the lead and sole GP partner would have a better understanding of what the nurse contributed within the team.

Practices of this type would be mainly focussed on maintaining an acceptable standard of care that satisfies external regulatory or compliance requirements, rather than internally-driven QI approaches:

RI: And how would you say you approach quality improvement in the practice?

GP: Our aim is to meet standards. [PP20, Practice D, LP]

Care was usually focussed on areas where the practice was an outlier for QOF performance. The lead GP partner for Practice D indicated they mainly look at QOF, for example, and focus on the areas that show they are an outlier compared nationally whilst aiming to keep everything else "where it is".

Two GP partners in this practice type particularly expressed feelings of low morale and motivation which were attributed partly to increasing bureaucratic burdens on GP partners, with the below quote illustrative of this:

GP: Morale is low, that's for sure. I'm close to retirement and I'm not as enthusiastic in general practice as I was 10 years ago... [PP25, LP]

Care within these practices appeared based on reactive needs of patient groups with less evidence of proactive patient profiling, risk assessment and recall systems and health prevention and promotion activities, together with less evidence of structured practice management and systems. Indeed, the lead GP in Practice D did not provide any indication when asked around a structured approach to practice team meetings or communication, or the approach of patient reviews (such as patient appointment booking, review frequency and content) for Hypertension and Diabetes patients. When asked if he used a clinical protocol or template to guide practice, the

lead GP in Practice D suggested that these were mainly used as a "tick box" exercise to meet QOF:

GP: Patient come, you tick, that's all [PP20, Practice D, LP]

The GP could also not locate any clinical protocols or templates on the practice clinical system during interview when asked, equally stating that none of these were developed by the practice. This was in stark contrast particular to biomedical practices who used protocols and templates designed in-practice for both clinical care delivery and improvement.

Staff training and development in this practice type was variable, however, particularly lacking in relation to continuing professional development:

PM: We don't really have formal CPD as such, it's more sort of identified as we go along. [PP24, Practice D, LP]

The lead GP in Practice D when asked about personal career history and training did not indicate any special clinical interests and preferred to refer to being a "*generalist*" with no interest in any specific area. Whilst GPs from other practices were also "*generalists*", they tended to be involved, engaged or enthused about particular areas of care, even if these were "*generalist*" in nature, such as admission avoidance or improving care access.

In relation to QI, practices of this type demonstrated little knowledge and engagement in QI when directly asked. Where improvement activity was discussed, this mainly related to externally-driven improvement not necessarily specific to the practice, as described. For example, a recent medicines management audit, which was a CCG rather than practice-led improvement supported through financial

incentivisation of practices. In Practice D, when asked about whether he had any opinions on QI in primary care, examples of QI or could explain QI from his perspective (either generally or related to the practice), the lead GP partner was unable to answer, discussing that they generally tried to improve, but without any further detail on how, even when prompted. It was not entirely clear during or after the interview whether this was because the GP lacked knowledge about QI (and therefore felt unable to articulate a view point or answer to related questions), generally had no opinion on the topic or felt unable to answer due to a lack of an approach in practice. However, as QI was explained during the interview with opportunity to discuss the topic as it related to primary care rather than the practice itself, it was felt that it was likely due to a combination of these factors. This general observation around QI attitude, engagement and delivery in Practice D was distinctly different from other practice types who would articulate a view on, and approach towards, QI even though definitions of quality and priorities and approaches for QI differed.

Quality measurement was another topic explored during interview. Practice D had no clear quality measurement system demonstrated for example by an inability to define any quality measures used in the practice and only citing an annual "print-out" of QOF results when asked about practice quality measurement, data and indicator use. When provided with funnel plot data used in the research, for which the practice was an LP practice, the lead GP indicated that a possible reasons for their presence as an outlier was likely due to the fact they didn't "cheat":

GP: So a lot of people they cheat. But we don't cheat. If I got 141 I put 141. If it's 81, I put 81. I won't put 140 or 139. So that's the reason. [PP25, LP]

A secondary opinion offered up was the aforementioned view the Practice had on their demographic profile which in the view of the lead GP could not be controlled. Common to both these options is that they reflect external, rather than internal, causes of variation.

Overall, this latter group of practices were more commonly LP practices which has potential implications in terms of identifying such practices and prioritising improvement activity for these practices.

CHAPTER 7: DISCUSSION

7.1 Introduction

To examine variation in the clinical quality of primary care across practices in Sandwell and the Black Country, quantitative funnel plot analysis identified *where* special cause variation existed at practice level across a range of clinical quality indicators for CVD and Diabetes. Quantitative analysis further identified practices displaying frequent special cause variation in the positive and negative direction (HP and LP practices respectively) based on a composite score. Qualitative semi-structured interviews were then conducted to identify factors associated with variation (*why* variation exists), where a number of themes emerged. These themes were defined under the following descriptive headings; *leadership and culture, system of care, quality measurement and improvement and other or non-modifiable* factors at practice level. Finally, following thematic analysis, a typology of primary care organisations was used to explain variation in the clinical quality of care, identifying four practice types: "biomedical", "holistic", "corporate" and "externally reactive" practices. HP practices typically displayed characteristics of the "biomedical" practice type and LP practices typically displayed characteristics of the "externally reactive" practice type.

This chapter begins by discussing identified themes as causes of variation in the clinical quality of primary care and relates these themes to existing research and literature. Whilst these findings are influenced by the clinical indicators selected to examine variation, they provide an understanding of the conditions that exist in influencing variation in clinical quality at both ends of the spectrum (high and low performance) which are discussed to inform the conditions of improved clinical quality

of primary care. Nevertheless, given the focus on clinical quality within the thesis, it would not be possible to extrapolate findings to other aspects of quality, such as patient-centredness for example, as defined within the Institute of Medicine's (2001) components of quality. Discussion then moves to focus on the practice typology which helps to explain differences in general practice care approaches via different identified practice "types". This includes examination of the different narratives within practice types around how practice staff define quality and how this may influence primary care delivery and variation. For example, the narrative around delivering primary care at scale particularly present within the corporate practice type and the patient-centred narrative in the holistic practice type. The discussion compares and contrasts the practice typology developed with theory on typology development and existing typologies in primary care, healthcare and wider non-healthcare contexts to support understanding of the influence of practice type on variation, with implications for QI.

7.2 The factors associated with variation in the clinical quality of care discussed and compared with existing literature

The research identified a number of themes as being associated with variation in the clinical quality of primary care. This section explores the extent to which these themes are consistent with existing literature.

7.2.1 Leadership

The influence of leadership, and specifically clinical leadership, in determining the clinical quality of care in practices was a key theme. However, it was not the presence alone of a leader that appeared to have the impact, but rather the

characteristics and attributes of the leader that attest to *effective* leadership that influenced variation.

As Gillam and Siriwardena (2013) note, there are a number of leadership theories that attempt to identify whether leadership traits are subject to nature or nurture. However, common leadership qualities recognised are similar to those attributed to effective clinical leaders in the presented research and these include; Leader self-assurance, high-energy levels (and "enthusiasm" in the research results), ability to adapt and change, an ambitious and goal-directed approach (or "results-driven" approach in the presented research), and good team-working and communication skills. Ham (2003) also notes the importance of clinical leaders with knowledge and skills related to QI, a characteristic that defined both an inability to change in negative outlier practices, such as a lack of understanding of QI by GP leaders (for example, in externally reactive practices), and a facilitator of improvement in positive outliers. Also identified through the analysis of interviews with practices and perhaps less well cited in other literature were characteristics in clinical leaders of "relentlessness" or a "strong ambition" in achieving a defined vision for the practice to provide the best clinical quality care as compared to peers. Whilst leadership behaviours may be easily identified, instilling and developing such behaviours and qualities can be more challenging. A clear motivation for the clinical leaders in HP practices was a desire to improve quality that was *intrinsic*. As Van Hoof *et al* (2012) note, this recognition of intrinsic motivation for QI, particularly strong amongst healthcare staff compared to other industries, can also be utilised by clinical leaders to inspire change amongst primary care teams through communicating practice goals that focus on quality.

Van Hoof *et al* (2012) also present an analysis of the most important leadership behaviours for adoption in relation to primary care QI, through reviewing available research related to this topic. Above some of those previously noted, they suggest that leaders who self-reflect on their leadership approach, have an explicit leadership approach and utilise a guiding leadership paradigm are more likely to be able to lead their practice to improve quality. These suggestions contrast somewhat to the research findings presented. Specific "leadership approaches" did not seem to be explicitly referenced or recognised by interviewees themselves and what could be perceived as leadership approaches were defined more as "approaches to care", such as is defined through the typology of practices. Equally, whilst not explicitly analysed, practices did not appear to adopt or even be aware of a specific leadership theory or framework that would guide QI. In this sense, the use of a leadership theory or framework to guide improvement may be less important than the presence of effective leadership traits as found in the thesis research. The need for leaders to self-reflect on quality and performance, whilst actively assessing current areas of care that need to change with care delivery teams, is also recognised by Dixon-Woods *et al* (2014). The authors note that instilling and developing leadership behaviours where poor leadership is recognised can be extremely challenging but set out some practical strategies that promote positive care cultures through leadership, informed through a large multimethod study of culture and behaviour in the NHS (including large data sets collected from primary care teams) (Dixon-Woods *et al*, 2014). The authors suggest that leaders should:

" Continually reinforce an inspiring vision of the work of their organisations... Listen to staff and encourage them to be involved in decision making, problem solving and innovation at all levels... Provide staff with helpful feedback on how they are doing

and celebrate good performance... Develop and model excellent teamwork... Make sure that staff feel safe, supported, respected and valued at work"
(Dixon-Woods *et al*, 2014. Pp. 114).

The thesis research suggests that such a vision should be centred around improving quality and that staff may feel more valued where there is a clear link between their role and the quality metrics or outcomes fed-back within the practice; a process which is significantly influenced by clinical leaders. Similar principles are also echoed by Deming (1982) in his observations and work on organisational effectiveness and improvement. Deming (1982) states that creating a "constancy of purpose" linked to the central aim of continual QI is more likely to lead to competitive and effective organisations and particularly where this is consistent in workforce management and development based on organisational trust and self-improvement.

In examining the importance of leadership for QI, particularly in a primary care setting, Gillam and Siriwardena (2013) note the important difference between leaders and *leadership* where a distinction is made between the presence of a leader and the ability of the leader to demonstrate leadership characteristics that impact quality. As recognised in the research results, in many practices the lead GP partner occupied the role of "leader" in the eyes of staff. However in this role the variable ability of the leader to apply leadership qualities and skills that create change in clinical quality, can lead to differences between practices actually delivering QI, a finding supported by Gillam and Siriwardena (2013). It appears this distinction is not widely recognised. For example, Van Hoof *et al* (2012) suggesting that *leadership* may relate to a formal position of authority, creating a potentially unhelpful perception that leaders can assert influence on quality through role definition rather than

demonstration of aligned leadership behaviours. However the authors do continue to provide examples of actions that are more important in determining QI, such as building team-based competencies that encourage multi-disciplinary working amongst staff. Howe *et al* (2012) go further by providing a summary of how variation can be addressed and how QI can be delivered within an agenda for improving GP leadership. This includes leaders guiding effective data collection and monitoring, recognising variation, and focussing on embedding QI activities in routine practice.

However, whilst many articles on leadership in primary care settings highlight the importance of leadership qualities and actions, there are a few examples of how to improve leadership through approaches that support leader self-reflection and learning that may support improvements in clinical quality of primary care. Equally, there is less available literature that helps leaders practically identify barriers to change and challenges of QI implementation. As was found in the presented research, a lack of time and financial support are often cited barriers to improvement; a finding replicated in wider research (Holmboe *et al*, 2005). However, HP practices found ways to affect improvement that improved staff time management, such as using protocols at the point of care that allowed rapid, consistent intervention selection, and making best use of wider community teams, through improved multidisciplinary communication and working, in supporting care delivery. Whilst providing support for the notion that time is a significant barrier to improvement in primary care (using data estimates for the time needed to implement guidelines for chronic disease management and preventative services in US family practice versus time available per physician), Yarnall *et al* (2009) suggest that one of the most effective ways to address this barrier is through improved multi-disciplinary team

working, use of non-general practitioner staff in primary care and use of professionals with expertise in affecting wider determinants of health, such as diet and lifestyle. Whilst the examples in the paper by Yarnall *et al* (2009) could be perceived as having been delivered in UK primary care for some time, these approaches were seen amongst positive outlier practices, but also other practices. This was demonstrated by the use of health care assistants in care co-ordination of patients with multimorbidity, nurse-led clinics with nurses with prescribing powers for hypertension list management and use of health trainer staff. Health trainers assess lifestyle and wellbeing factors with patients, support them to set goals for health improvement and behaviour changes, and agree action plans centred around practical support and information. The use of wider health professionals in this way supports the notion of the importance of leader knowledge of QI strategies and skills to apply improvements in practice. Bohmer (2013) also observes here the inclusion of leadership development as part of clinical training only as a recent development in medical curricula and the fact that many clinicians feel unprepared or disempowered to lead - this is congruent with the research findings that indicate LP practices particularly being resistant to change and improvement, unable (or with a perceived inability) to change and improve, or lacking the knowledge and belief to adapt their practice. As Ham (2003) notes, there is a requirement to understand how variation and quality aligns to motivations for QI and an organisational culture of improvement, with support that enables clinical leaders to have time and space to review and improve practice, with effective "followers" to implement change. The thesis research presented offers some potential support in this area by demonstrating the importance of clinical leaders having access to practice comparison data and tools that allow

them to self-reflect on their leadership style in relation to their practice type and delivery.

Finally, in examining clinical leadership within the presented research it is also pertinent to observe that many interviewees cited the role of individual leaders, as opposed to collective leadership approaches (such as through network leadership across practices or wider organisations) in determining practice performance. For example, interviewees would most often name individual General Practitioners or staff members as individual leaders who inspired change and improvement in the practice. However, Fitzgerald *et al* (2013) also state the importance of new collective and distributed leadership approaches in increasingly complex system-level care environments that have been linked to improvements in service outcomes through an inductive, comparative multiple case study analysis. Their work demonstrates the importance of professional (or clinical)/managerial hybrid leadership roles and the value of pre-existing relationships in supporting service improvement that form collective leadership approaches, as opposed to defining leadership impact on outcomes through single leadership styles. Whilst this body of research on system-level and networked leadership requires further research contribution, it seems important that leaders in general practice, who are not exclusively General Practitioners, also recognise the importance of achievement of system-level outcomes, in addition to those relevant to general practice (McNellis *et al*, 2013). Another important finding noted by the authors is that QI success is rarely attributable to a single factor, such as effective leadership, and this finding is certainly mirrored in the presented thesis research suggesting that those HP practices were more likely to have achieved continual improvement through the cumulative impact of multiple

factors, of which effective and authentic clinical leadership is one (Fitzgerald *et al*, 2013).

Throughout the analysis of leadership on variation in the clinical quality of primary care, reference is made to the relationship between leadership and culture. Indeed, McNellis *et al* (2013) cite these two themes as being the most important in defining QI success from evaluations of 14 primary care transformation programmes (albeit across the United States which does not have universal, free at the point of delivery, first-contact primary care coverage). Some authors state that leadership in primary care plays a significant role in defining the practice culture and team working amongst both clinicians and non-clinicians (Lanham *et al*, 2009; Dixon-Woods *et al*, 2014), particularly when care is delivered in single-practice locations, with culture being explored in the following section.

7.2.2 Culture

The organisational culture (to be referred to as "culture") within general practices was highlighted as an important theme in influencing variation in the presented research results. However, perhaps equally important is the definition and understanding of culture itself as related to the research conducted. This includes exploring the aspects of culture that primary care teams most associate with and those components of culture (for example, team values, beliefs and behaviours) that appear to influence variation in general practice. In this sense, briefly revisiting definitions of culture as related to organisations is important for discussion, together with examining the relationship between culture and primary care clinical quality through existing literature.

Culture is generally accepted to describe the values, beliefs and behaviours of an organisation (Sinclair and Collins, 1994; Davies *et al*, 2000); where behaviours are sometimes described to include "traditions" or "norms" depending on the definition adopted. Whilst definitions of culture exist, Davies *et al* (2000) note that the very nature of "culture" is a contested concept. Different schools of thought exist in relation to the definition of culture as a concrete concept, its relationship to organisations (i.e. whether an organisation *is* its culture or *has* a culture), and whether it exists as a variable within organisations that can be manipulated - which the authors describe as a "seductive" if not necessarily proven idea for those studying and seeking to improve organisational performance through influencing culture (Davies *et al*, 2000). A Cochrane review examining strategies to change organisational culture to improve healthcare performance found a lack of well designed and rigorous studies to answer this question (Parmelli *et al*, 2011). Additionally, other authors also recognise that different "sub-cultures" may exist within the same organisation; therefore making the study of culture difficult at organisational level (Scott *et al*, 2003). However, components of culture within the presented research, such as the recognised values and team working behaviours of the practice staff, were often described consistently amongst different staff within the same practice and indeed other non-practice staff as external observers.

Culture is also sometimes further recognised by its discrimination from organisational climate. Organisational climate describes more superficial and measurable components of an organisation comprised of organisational strategies, structures, historical forces, processes, communication, trust, commitment, standards of accountability and accountability behaviours (including reward structures) (The

Kennedy Group Executive, 2015). However, examining these components of climate in relation to those of culture can create further confusion and as Hann *et al* (2007) observe from related research, the extent to which culture and climate are separate concepts is unclear. It is therefore important to further focus on and clarify the components often associated with culture that are important from the perspective of examining variation and QI in primary care.

At general practice level, specific components of culture and climate, as described in previous definitions, were often discussed without specific reference to culture and climate themselves. "Standards of accountability" for example appeared to exist inherently in some practices and were described by "the way care was managed" in practices, without reference to a particular accountability or performance framework or approach. This presents a question of how practices develop such approaches, whether from past experiences or "trial and error", in the absence of defined frameworks or taught approaches, such as those promoted in management literature. This demonstrates a consistently recurring theme between the way in which concepts such as culture, leadership and management are understood by policy-makers, academics and managers, compared to staff delivering primary care at practice level who may understand the same ideas and concepts through different language and experiences.

The core aspects of culture that interviewees describe as determinants of variation appeared to relate predominantly to practice values and different approaches to care between practices, practice team working, communication and team relationships, practice aspirations and motivations, and practice behaviours - specifically, behaviours related to quality measurement and improvement that either did or did not

exist in practices. These core aspects are partly mirrored in research by Grant *et al* (2014) who completed a meta-ethnography of organisational culture in primary care medical practice to determine an understanding of key dimensions of primary care organisational culture. These four dimensions were responsiveness (internal to external), team hierarchy (egalitarian to hierarchical), care philosophy (biomedical to holistic) and communication (coherent to fragmented), which are discussed later in this section. In the research results and regardless of performance across the clinical quality indicators, there did appear to be shared and recognised values across general practice teams. These shared values placed importance on the need to provide the best care for patients and seem to be present within those working in healthcare more generally. However, staff working across and within different practices also described unique and variable team working beliefs and behaviours that were very different across the practices studied. The use of the descriptive term of "microsocieties" used by authors in early study of organisational culture seems appropriate here (Morgan *et al*, 1983), to describe the unique environment in each practice.

HP practices had differentiated values centred around improving clinical outcomes, effective team working relationships characterised through trust and frequent, open, formal and informal practice communication, and high practice aspirations to achieve the best clinical outcomes relative to peers. Such practices had a *belief* that the team had the ability to influence and improve quality with demonstrated *behaviours* and examples relating to practice QI (e.g. recognisable QI interventions and methods in practice, such as clinical audit, patient review and recall systems). Grant *et al*

(2014), describe similar aspects of culture such as those recorded by interviewees in the presented research, for example open communication that is;

"characteristic of informal everyday face-to-face communication and collaboration that took place within shared workspaces"
(Grant *et al*, 2014. Pp.35)

In contrast to the presented research results, existing literature does not appear to favour a strong link between culture and performance or quality in a healthcare or primary care context. Examples of culture in previous research are explored from single culture domains (such as team behaviours) to multiple aspects of culture utilising evidence-based culture assessment tools and performance outcomes (such as multiple care outcomes for coronary artery bypass grafts in secondary care and QOF in UK primary care) (Davies *et al*, 2000; Shortell *et al*, 2000; Scott *et al*, 2003; Hann *et al*, 2007; Goh *et al*, 2009). However, there are examples of relationships between culture and quality that appear particularly in observational in-depth studies in primary care settings. For example, studies which highlight a link between cultural domains, such as positive beliefs of primary care teams in relation to teamwork, perceptions on ability to change practice, positive attitudes to patient monitoring, and engaged and involved lead general practitioners in successful implementation of improvement processes (Stevenson *et al*, 2001; Bower *et al*, 2003). These results were found across similar settings as the presented research results (for example, studies of Diabetes clinical quality indicators across 18 GP practices in Leicestershire). However it is important to note that the findings of the study by Bower *et al* (2003) were not repeated during a follow-up study of similar design (Hann *et al*, 2007).

When considering existing literature in parallel with the research results in the presented thesis research, it may be possible that a consistent link between culture and quality or performance may be lacking due to the finding that different components of culture may impact the same or different aspects of the clinical quality of care. Research adopting culture assessment tools that aim to link specific domains and components of culture to quality or performance may not find a consistent link. This in itself however does not disprove a relationship between culture and quality or performance. The thesis research results suggest that different aspects of culture, such as practice aspirations and QI behaviours may be linked to different measures of the clinical quality of care. For example, a practice which values a more preventative care approach to care delivery may perform better on indicators relating to pre-hypertension than hypertension. Also, more often than not, cultural determinants of variation will be combined with other determinants (such as the other themes of variation identified). Consequently, proving causality in a relationship between culture and quality in the complex environment of care delivery and recognising the sometimes ambiguous nature of culture, may be very difficult; a point made by DiCuccio (2015) in a systematic review of the relationship between patient safety culture and patient outcomes. Further, many authors cite the difficulties in examining the relationship between culture and quality that relate to the difficulties presenting from the various definitions and understanding of culture, quality and performance. This includes issues with methodological approaches exploring such relationships, such as the lack of sensitivity in culture assessment tools, the bias based on outcomes selected, the over-reliance on team behaviours as indicative of culture and the inherent issues and subjectivity of often-used survey

tools in this area (Scott *et al*, 2003; Hann *et al*, 2007; Goh *et al*, 2009; DiCuccio, 2015).

When looking further into the literature relating to culture and quality, there are additional findings relating to culture and quality *improvement* that are also interesting, where a number of studies cite a link between culture and QI implementation. Stevenson *et al* (2001) suggest that shared positive beliefs and attitudes of primary care teams towards QI are more likely to be correlated with QI success. Dugan *et al* (2011) also find a further link between culture and the use of QI initiatives, such as use of clinical information systems and clinician reminders in QI approaches. In the wider healthcare setting, Speroff *et al* (2010) examine various types of culture and safety climate linked to QI initiatives using multiple instruments across 40 US hospitals and over 1400 staff. The authors conclude that culture is a critical factor in improvement success (whilst similarly recognising that culture and climate are closely aligned). However, across these studies there are variable definitions of culture that prevent replication and comparison of results between studies.

As Hann *et al* (2007) describe in their research on the association between culture, climate and quality of care in primary health care teams, an important feature for QI research is understanding how culture and climate interact with QI to influence success. In the presented research results, the ability of practices to improve quality appeared to both influence, and be influenced by, culture. Where practice teams had values aligned to clinical QI, held beliefs that improvement could occur and demonstrated improvement behaviours that result in success, this appeared to further reinforce an "improvement culture". For this reason it is important that

practices recognise their own culture and aspects of culture that are unique to either promoting or hindering improvement. The practice types identified in this thesis through the practice typology, in addition to previous research on the dimensions of culture, may be a way in which this reflection could be supported. Certain values, beliefs and behaviours in practices did appear to be more likely to stifle improvements in the clinical quality of care - such as a lack in the belief that QI could occur without external resource and support, belief that quality measurement in primary care was a "tick box" exercise, or beliefs that practice demographics made improvement too difficult. Other authors also note the importance of identifying practice cultures resistant to QI in order to reduce clinical care variation (Stevenson and Baker, 2005).

Another area of the impact of culture on primary care delivery relates to motivation and satisfaction of primary care teams. Within the research results it was found that the lead GPs of two LP practices particularly had outwardly expressed reduced motivation and satisfaction with their present GP Partner role. Additionally, other GPs across practices cited increasing demand, challenge and difficulty of the role in the current healthcare climate. Various reasons for this were given, for example, views relating to "increased bureaucracy" of reporting requirements from commissioners and regulators, or increased expectation of primary care to manage care demand, for example in seeing increasing outpatient follow-ups (usually seen in secondary care) due to acute care activity and cost reduction requirements. Beliefs and behaviours manifested from these views that influenced practice culture and appeared to subsequently affect the practice's attitude and ability to change and improve. In primary care and wider healthcare qualitative studies researching GP

and generalist physician satisfaction with turnover and care quality, some authors suggest that focussing on clinicians who are most dissatisfied as opposed to working towards improving general satisfaction rates, may be more helpful in impacting on the resultant effects of dissatisfaction on workforce turnover. However there is less evidence that dissatisfaction impacts on care quality (Pathman *et al*, 2002; Linzer *et al*, 2009).

Some authors have also presented a link between the role of general practice culture, physician burnout and job satisfaction. There is suggestion that aspects of culture, such as perceived practice effectiveness and communication, have an impact on physician burnout and turnover, where affecting perceptions of effectiveness, team working and communication could in turn "improve" internal practice culture that leads to greater job satisfaction and lower exhaustion in primary care team members (Hall *et al*, 2010; Willard-Grace *et al*, 2014). There is also some evidence to suggest high primary care and healthcare staff turnover is associated with a reduced ability to implement and achieve successful change and improvement in care quality, if not necessarily proven impacts on care outcomes (Waldman *et al*, 2004; Linzer *et al*, 2009; Sandberg *et al*, 2009). The thesis research results suggest staff engagement are likely also linked to culture and the aspects of practice working that are valued by staff, such as role accountability, responsibility and autonomy, opportunity to deliver high quality care, role recognition and development opportunities. Okello and Gilson (2015) present results of a systematic review exploring the influence of trust relationships on motivation in the health sector which also links to this area providing insight to potential causes of demotivation and ineffective team working. The authors indicate that trust relationships in the

workplace improve motivation and subsequently performance of health care workers and can furthermore be strengthened through:

"positive social interactions, effective communication and good supervisory mechanisms."
(Okello and Gilson, 2015)

The findings of the review are consistent with the recognition of positive and informal practice relationships, respect and appreciation of the roles of all members of the general practice team, and open communication and feedback that contributed to improved quality in the clinical quality of primary care researched at practice level (Okello and Gilson, 2015).

Scott *et al* (2003) suggest that the identification of variable organisational cultures is easier than understanding the reasons behind why cultures are different. Whilst the research presented does not adopt a specific cultural assessment tool, it appeared that culture in general practices was particularly sensitive to the beliefs of practice leaders; possibly more so in small general practice organisations which function as small, multi-disciplinary teams, however this was not fully tested. Additionally, it was apparent that primary care leaders in practices had very different and sometimes divergent values in terms of the purpose of primary care, which in turn, appeared to influence practice staff beliefs and behaviours, and therefore performance across clinical quality metrics. For example, practice partners with a focus on operational efficiency could directly or indirectly influence staff beliefs and behaviours to achieve this purpose. Examples of past internally-driven QI initiatives and delivery in practices appeared to reinforce positive beliefs and behaviours or improvement

cultures in practices. Conversely, where practices had become reliant on external funding or support, this appeared to have an effect of external dependency.

Whilst recognising the literature on the impact of culture on primary care quality, performance and delivery, the research results presented indicate that differences in culture have complex interactions on primary care quality and performance.

Therefore, it is important to identify the individual and unique components of practice culture that are most likely to impact on the delivery of high quality clinical care and care improvement, recognising that some evidence exists that signal which aspects of culture, such as QI beliefs and behaviours, trust relationships and effective team working, will most likely lead to improved performance.

7.2.3 System of Care

The system of care a practice adopted at practice-level included a number of elements which appeared to contribute as determinants of variation in the clinical quality of primary care. In the research results, the system of care was mainly reflective of the structures and processes that existed and varied between practices. Care structures impacting on variation included organisational structures (particularly multidisciplinary care team (MDT) utilisation in patient management), material resources (such as availability of software in managing care processes e.g. utilisation of point of care protocols), and human resources of care (especially staff competencies evidenced through disease-specific training and staff ability to autonomously apply knowledge in practice). Care processes impacting on variation included patient profiling and screening, patient review and recall systems, protocol and guideline use in practice and practice management processes such as effective capacity and demand planning. There was less clear impact in terms of access to

specialists and community health teams - which was largely consistent across practices and therefore not a differentiating feature. However, the effective use and co-ordination of these teams by practices did appear to have an impact and is discussed subsequently.

A range of systematic reviews exist exploring the systems, structures and processes general practices employ and their relationship with performance across various quality and outcome measures, with many providing findings aligned to the results of the presented research. A key feature in supporting improved clinical quality of primary care across the areas researched included the way in which the primary care team approached care in relation to multi-disciplinary working. There appeared to be two components to this. Firstly, that improved quality of care was achieved by better communication and more effective use of wider health professionals both employed by the practice and in other community or secondary care teams. Secondly, that it was important for team members to feel valued, respected and allowed to work autonomously. Alongside development of trust between team members and positive informal practice relationships, structured and frequent (at least monthly) open team meetings with measurable quality indicators appeared to support communication and co-ordination of quality-centred care. Such factors were often present in HP practices and relatively absent in LP practices, congruent with existing literature linking shared and regular meeting structures and trust relationships to successful change implementation and motivation in healthcare teams (Sandberg *et al*, 2009; Okello *et al*, 2015).

HP practices commonly cited the use of multiple professionals in care delivery. For example, the use of both GP and specialist-nurse clinics in chronic disease management, HCA use, health trainer use and regular communication with wider secondary and community care professionals. It is important to note that this latter point distinguishes effective communication and utilisation of other team members in the practice environment from access alone, for example using teams for better care co-ordination and delivery of patient diagnostic, assessment and treatment interventions. In a Cochrane review of inter-professional collaboration, albeit with a small number of included studies (n=5) and difficulties in generalisability of findings due to study heterogeneity, Zwarenstein *et al* (2009) found positive impacts of practice-based inter-professional collaboration on both care processes and outcomes. The most relevant study within this review to the presented results being the impact of multidisciplinary team meetings and collaborative working between primary and secondary care clinicians across a five-continent review of 73 specialist outreach interventions in primary care (Zwarenstein *et al*, 2009), similar to the "shifted outpatient" Diabetes clinic model present in Sandwell and the Black Country. Whilst demonstrating improved access and outcomes from such interventions, the review indicated that the effects of outreach are more likely to be achieved where practical constraints to use are removed (such as knowledge of clinic access and availability), and where interaction between primary and secondary care clinicians is more effective (Zwarenstein *et al*, 2009), which was similar to the thesis findings. In a second Cochrane review of the "effectiveness of shared care across the interface between primary and specialist care in chronic disease management", Smith *et al* (2009) find little evidence of benefit on care processes and outcomes. However, the

review did suggest improved prescribing processes and outcomes as one benefit of shared care. In a more recent systematic review into health professional networks, Cunningham *et al* (2011) conclude that time spent developing networks did not necessarily improve patient care. As these health professional networks are not the same as practice-level collaborative MDT care, it may be useful to further explore how far inter-professional working, networks and relationships are required to be maintained and developed at the practice-level in order to achieve the improvements in care processes and quality described in the results.

The thesis research results support and build on existing literature in placing more importance on the *effectiveness* of general practice-level MDT relationships and working rather than the *presence* of an MDT alone. It appeared better utilisation, coordination and integration of care processes through more structured patient management targeting those most likely to benefit from MDT input would have a greater impact on measures of the quality of clinical care. For example, primary care teams assessing patient lists and discussing patient cases for health trainer and secondary care clinician referral based on their knowledge of the patient list, instead of these MDT members case-finding or selecting patients from lists in isolation.

In examining the introduction and use of an MDT-approach, other literature would also suggest that it is important that any MDT-approach ensures maintenance of continuity of care (i.e. the same person co-coordinating the patient pathway or caring for the patient), which is linked closely to both patient perceptions of quality of care and care outcomes (Rodriguez *et al*, 2007; Huntley *et al*, 2015). This supports the recognised need for effective MDT working with collaborative co-ordination of

patients in order to improve quality. Some practices in the thesis research had recognised continuity as an important feature particularly in the management of patients with chronic diseases (such as Diabetes) and had responded through greater use of specialist nurses and HCAs to deliver a wider-MDT approach in managing CVD and Diabetes, not solely dependent on General Practitioners. This approach was less present in LP practices which were characterised by managing demand for the entire list reactively, as opposed to proactive and structured screening, allocation and review of patients with defined team accountabilities. The substitution and allocation of certain care processes between doctors and other primary care professionals such as nurses and HCAs has been demonstrated to improve care processes, if not necessarily care outcomes and cost (predominantly due to supply-led demand of increasing primary care provision related to screening and access), without negative impacts on patient safety (Laurant *et al*, 2004; Zwar *et al*, 2007; The Health Foundation, 2011). Recognising the national and international concerns around General Practitioner workforce shortages (Kringos *et al*, 2013), which was also articulated by a number of interviewees, the increasing use of wider non-GP primary care workforce roles may become more common in order to meet primary care demand requirements in future (Green *et al*, 2013; Kringos *et al*, 2013).

The education and training of staff in disease-specific processes, coupled with an ability of staff to apply new competencies in practice, was also cited within the structure of care theme to contribute to variation. Across practices there was fairly consistent evidence of staff attendance on Diabetes continuing education or post-graduate courses - particularly the "Warwick Diabetes Course" highlighted in the results and attended commonly by practice staff. A critical feature of this education

and training component within the care system theme was not simply the attendance and completion of additional training and education, but the ability of staff to apply new knowledge in practice. In a systematic review of multiple studies evaluating interventions to improve Diabetes in primary care and other settings, Renders *et al* (2000) specifically highlight the positive impact of post-graduate education on Diabetes care process outcomes. The authors however make two important clarifications on this point. Firstly, that postgraduate education was often part of complex interventions combining multiple components (such as audit and feedback, local consensus procedures and others), reflecting observations in the present research that causality of specific determinants of variation may be difficult to isolate. Secondly, that the effect of education was dependent on the motivation and application skills of individual practitioners and organisational factors which served as facilitators or barriers to use (Renders *et al*, 2000). In the presented research, such barriers could be observed to relate to the way in which patients were reviewed and recalled in practice (promoting or inhibiting the ability the ability of nurses to work autonomously in applying skills) and in-practice initiatives that support knowledge application (such as care protocol use).

Two other areas which were suggested by interviewees as potential determinants of variation included practice list size and the organisation of specified disease clinics (whether diagnosis-specific such as defined Diabetes clinics or less specific multimorbidity or chronic disease clinics). Practice list size is discussed in the context of the corporate practice type in the subsequent discussion around the practice typology, where participants of this practice type particularly used the argument that practice list size improved quality. In relation to multimorbidity,

interviewees across practices indicated different arrangements and clinic organisation for the management of patients with CVD and Diabetes. Examples included the management of patients through symptom specific clinics (for example managing acute exacerbations and issues), clinics targeted at specific patient groups (e.g. the frail elderly where chronic disease would also be managed), combined chronic disease clinics (generic clinics able to see, treat and review patients with multiple chronic diseases), multimorbidity clinics (for patients with one or more chronic diseases), and disease or diagnosis specific clinics (e.g. targeted Diabetes clinics). Of these, the latter three were most discussed in relation to the researched areas of CVD and Diabetes. This area was not explored in sufficient detail within the thesis to identify any conclusions. However, in a Cochrane review examining multimorbidity interventions in primary and community care settings, Smith *et al* (2012) suggest there is limited research on the evidence and outcomes of care for strategies targeting patients with multimorbidity (Smith *et al*, 2012). However, there is recognition and evidence that multiple medication/polypharmacy issues and multimorbidity risks and functional problems (such as falls risk and reduced physical function) associated with multimorbidity are likely to be better managed through targeted interventions assessing whole person care compared to specific diseases or diagnoses in isolation (Smith *et al*, 2012). It appears that more research and evidence exists around the importance of specific interventions that ensure chronic disease management evidence and best practice is translated in practice, such as in the "primary care chronic care model" which has been shown to achieve improved chronic care management processes due to a greater focus on implementation of evidence in practice (Bodenheimer *et al*, 2002; Kadu and Stolee, 2015). Disease

specific clinics in this respect may allow more time and effort to be focussed on evidence-based disease specific interventions and guidance with aligned staff resources with more specialist disease expertise, however as noted this was not explored in detail in the interviews conducted.

7.2.4 Quality Measurement and Improvement

Quality measurement and improvement approaches were highlighted as critical differences between practices and appeared to contribute to variation as demonstrated through differences found between HP and LP practices. As noted within the results section, the areas where quality measurement appeared to influence variation most are grouped under three areas; attitudes and beliefs in relation to measures, measurement systems and use and issues with measures.

The thesis results suggest improved performance across clinical quality indicators examined where indicators were used for internally-driven QI (as opposed to just regulatory or financial reporting), and where measures were regularly reported, benchmarked with peers and fed-back to the practice team with action plans in place for continual improvement against internal practice goals and improvement targets. HP practices had a more positive attitude towards the use and importance of measures for improvement, a point which was often reflected in the additional resource, effort and investment practices appeared to contribute for measuring care in the practice (such as through internally resourced I.T roles and measurement software systems). Research into the attitudes and use of measures in primary care indicate that primary care staff have common perceptions of quality and performance metrics as being time consuming or assurance-focussed, rather than improvement-focussed, even when this is not their purpose (Kansagara *et al*, 2014; Sutcliffe *et al*,

2012). The research results indicated that one reason why HP practices were differentiated was that they used indicators for internal improvements compared to aiming to meet a minimum or threshold standard (for example through QOF). This appeared closely linked to their aspirations to provide "the best care" compared to local peers, often communicated and led through the ambitions of a recognised clinical leader. Authors have suggested that evidence around extrinsic financial incentives and external public performance reporting to improve quality and change primary care clinician behaviours is insufficient (Gosden *et al*, 2011; Ketelaar *et al*, 2011; Scott *et al*, 2011). Equally in some reviews of extrinsic motivation through financial incentives, results have indicated such approaches can actually reduce intrinsic motivation (Lester, 2010; Eijkenaar *et al* 2013). However, whilst understanding the relationship between intrinsic and extrinsic motivation is complex, reviews of such relationships in primary care and healthcare more generally suggest that clinicians are more likely to be engaged in improving quality where the definition of quality and performance is shared and that peer comparison and benchmarking, when aligned to an agreed definition and measure of quality, may support QI in care processes (Lu *et al*, 2008; Lester, 2010; Phillips *et al*, 2010; Eijkenaar *et al* 2013). That HP practices more commonly adopted approaches such as internal practice-agreed and peer-compared quality measures and targets, is indicative of the need for locally-developed and agreed views of quality to inform measurement and improvement at practice level. However, instilling intrinsic motivation may be more difficult, where previous discussion supports the role of practice facilitation and quality audit and feedback to begin a change process to improve quality.

The knowledge and understanding of QI as a process varied significantly between practices. In turn, this appeared to influence the confidence and ability of practice staff to identify and apply QI interventions in practice. The term "quality improvement" is broad and associated with a number of approaches and interventions. However, there is some consistency in the aspects that constitute effective QI approaches that are shared across the literature. These include the use of data and measurement for improvement, understanding and mapping the care context, process and pathway, and involving and engaging staff and patients in planning and implementing improvement solutions based on evidence-based practice (Batalden and Davidoff, 2007; The Health Foundation, 2013). An area of difference in HP compared to LP practices, was the use and application of these aspects of QI and recognised evidence-based QI initiatives. Such initiatives have been highlighted in previous chapters and shown to demonstrate positive improvements across both care processes and outcomes. Many of these may be practice-initiated and include point of care reminders, computerised advice and care protocols, and processes for patient review and recall (See Appendix 6). Practices with relatively better performance on clinical quality indicators demonstrated through interview questions, discussions and responses, cited the adoption and practice-based development of such initiatives.

Dixon-Woods *et al* (2012) discuss the challenges of QI in a healthcare setting from formal evaluations of QI programmes. The authors note the importance of key aspects of QI noted, such as effective use of data collection and monitoring, but also some of the more difficult to measure aspects of effective QI implementation that include engaged leadership and improvement focussed-organisational cultures

amongst other areas (Dixon-Woods *et al*, 2012). HP practices demonstrated many of these QI approaches and behaviours in their practice context, where ensuring greater knowledge of QI approaches and techniques may be useful for other practices and primary care staff. The research results indicate QI may be supported through regularly measuring, feeding back and improving quality through practice improvement plans that are part of the daily running and delivery of the practice, as opposed to one-off initiatives or projects.

The definition of quality employed in measuring quality and applying QI processes appears important, together with the ability of measurement systems to reflect quality of care. The research examined indicators that particularly related to *clinical* processes and whilst there was agreement amongst practices these measures were "good" measures of CVD and Diabetes care, they may have biased the allocation of practices to HP or LP practice groups based on those which favoured a clinically-centred (or biomedical) care model. As quality encompasses a number of other areas (such as patient-centredness, equity, efficiency and safety), it would not be fair to suggest that practices in the HP group have "better quality care", rather the indicators used for research are *indicative* of higher clinical care quality. As has been noted in the discussion previously, practices may perform better in areas of care they are most interested in and based on the practice's definition of quality, which is identified as a critical area for discussion subsequently.

Also presented in the research results were anomalies and issues with measurement itself that practices suggested gave rise to variation, such as differences in practice systems and coding. The issues in the development and use of indicators are well known and recorded with wide recognition that no indicator is perfect. However, a

number of authors have defined important characteristics of indicators that include ensuring, as far as possible, that indicators are acceptable, feasible, reliable, sensitive and valid, as well as being understandable and achievable where improvement goals are defined (Campbell *et al*, 2002; Kotter *et al*, 2012). Additionally, the process by which indicators are developed and used is equally important to ensure indicators are effective for their intended use, which includes being clear on measurement purpose and gaining clinical engagement in measurement use (Raleigh and Foot, 2010). On these points, the indicators used for the presented research were broadly accepted by practices as reflective of good quality care and appropriate for examining variation from a research perspective, which is particularly important given that indicators may be used and perceived differently depending on their purpose (Mainz, 2003).

7.3 The conditions of improved clinical quality of primary care

The research results presented in this thesis have allowed for the discrimination and presentation of practice-level conditions leading to improved performance across the clinical quality indicators examined, as displayed in HP practices. Having discussed the evidence and examined the literature in relation to the impact of themes on variation, the current discussion section aims to identify the themes and factors which are consistent, or different, to existing literature in relation to the conditions and characteristics of improved clinical quality in primary care at the practice level (whilst recognising the thesis has a focus on clinical quality specifically and is therefore not assessing all components of recognised definitions of quality, such as that provided by the Institute of Medicine, 2001).

A number of factors appear to support higher clinical quality of primary care at practice level as summarised in table 8. Some of these factors predominantly influenced single clinical indicators (such as the inclusion of U&E testing in practice clinical protocols for Diabetic review on U&E recording). However, the majority of these were identified as common factors present in practices with higher performance across clinical quality indicators, which creates a difficulty in discriminating between cause and effect across individual factors. Notwithstanding this point, the presence of consistent themes and factors in HP practices identified allows comparison with existing literature on the conditions of improved clinical quality in primary care at practice level. In addition, there is recognition from other authors of the cumulative effect of multiple organisational factors, as opposed to single factors alone, that influence QI outcomes (Fitzgerald *et al*, 2013).

Bodenheimer *et al* (2014) provide a summary of the elements of care which existed across visits to exemplar general practices, identified through an iterative process examining case-study reports from practice site visits. Whilst the research is conducted in the US setting, with limited systematic quantitative identification of good performance or comparison with non-exemplar practices (exemplar practices were identified predominantly through their reputation and some external framework recognition), the results provide useful for comparison given the emphasis on elements which were focussed on, and were influenced by, practice-level characteristics. The ten "building blocks" of exemplar practices identified were; 1. Engaged leadership, 2. Data-driven improvement, 3. Empanelment, 4. Team-based care, 5. Patient-team partnerships, 6. Population management, 7. Continuity of Care, 8. Prompt access to care, 9. Comprehensiveness and care co-ordination, and 10.

Practice with a template of the future (Bodenheimer *et al*, 2014). Comparison of these elements with the factors in the presented thesis results provides some similarities and differences. The authors allude to similar characteristics of practice leaders such as leader engagement and a results-driven style, the importance of clinical measurement and software systems in practice delivery, the utilisation of wider, multi-disciplinary team members in care, a patient-team partnership approach (or active role in patient management in the thesis results), patient profiling and elements associated with the structure of care such as care access and co-ordination. Indeed, some of these factors, such as leadership and data measurement are recognised key features of QI more broadly (The Health Foundation, 2013). Others such as access, continuity of care, comprehensiveness of care and care co-ordination are recognised simply as important characteristics associated with good primary care systems and therefore may not represent particularly unique findings (Kringos *et al*, 2010). Aspects not found in the thesis results are also presented, such as the use of alternative care approaches for demand management with e-visits, telephone encounters and group appointments given as examples of good practice in the "template of the future" theme (Bodenheimer *et al*, 2014). However, similar to the discussion around clinic types based on single or multiple conditions in the thesis results, these aspects of care were not extensively explored with practices in the thesis research which may explain their absence in the factors presented.

Beaulieu *et al* (2013) also explore characteristics of high quality primary care identified through a composite quality score measure using a stratified random sample of 37 Canadian general practices. Multi-level statistical regression found

strong associations between quality and sharing of administrative resources, the presence of allied health professionals, mechanisms for maintaining competence and organisational access (in relation to funding additional capacity). It is difficult to identify the detail behind the definitions of these characteristics. However, the importance of continuing professional development (CPD) and audit as a characteristic of high quality care provides similarity to the factors of improved clinical care quality presented within the system of care theme (albeit with the thesis results recognising more the importance of *application* of CPD learning to practice). The moderate association of team climate through the team climate inventory (incorporating components assessing organisational vision, participative safety, task orientation, and support for innovation), is also important in potentially highlighting the role of aspects of team climate that influence quality. Other authors however have found weak associations between factors of climate and quality of care and suggest it may be more important and useful to identify the different *types* of practices (and variations in the components of climate unique to each practice) that impact quality, where inter-practice variation may make team climate inventory scores (as associated with average quality scores across practices) difficult to analyse (Hann *et al*, 2007).

A number of QI organisations have also completed evidence reviews, summaries of improvement programmes and syntheses of the themes and factors relating to high quality primary care which are also useful for comparison. Many themes are consistent with those already explored and recognised, such as leadership, visual data feedback and benchmarking, effective patient profiling and risk stratification, improved care co-ordination, access and continuity (The King's Fund, 2010; Goodwin

et al, 2011; Knight *et al*, 2012; The Health Foundation, 2014). Other themes and factors reflective of high quality primary care mirror those in the thesis, such as evidence of a "quality improvement culture" in the practice, involving patients and patient groups in both self-care and practice QI initiatives, ensuring primary care teams have knowledge around "the science of quality improvement", and the importance of team motivation and clear expectations of team members for care quality centred around clear practice quality goals (The King's Fund, 2010; Goodwin *et al*, 2011; Knight *et al*, 2012; The Health Foundation, 2014). Additionally, other factors shown to be effective in practices displaying high quality of care include the systematic use of evidence-based QI interventions (which is the focus of a systematic review contained in Appendix 6 completed during the PhD). Such evidence includes use of decision support, regular use of standardised clinical protocols and point of care reminders and enhancing general primary care through additional multi-disciplinary team use, diagnostic and assessment services not routinely available in primary care (The King's Fund, 2010; Goodwin *et al*, 2011; Knight *et al*, 2012; The Health Foundation, 2014).

There are also some factors not found in the thesis results but noted in wider literature which are interesting. These include patient-level factors, such as patient attitudes to risk and lifestyle management (not explored in the thesis research), the duration of practice appointments which supported improved comprehensiveness of care and patient access to care records with feedback to primary care teams around care delivery (The King's Fund, 2010; The Health Foundation, 2014). Whilst it must be noted that some evidence summaries rely on improvement initiatives that are based on less rigorous service evaluation as opposed to rigorous research

methodologies, the degree of consistency to thesis themes is present, with an additional recognition that measures of clinical quality (such as those used in the thesis research) offer a very good assessment of general quality in primary care (Goodwin *et al*, 2011).

The presented thesis research also however identifies some features of improved clinical quality of primary care that appear less commonly noted in existing literature. The variation in clinical quality related to practice definitions of quality is one. This particularly recognises the significantly divergent views of practices in relation to what constitutes quality and more importantly, how this subsequently influences the way care is delivered in the practice (such as through the clinical measures selected and approaches to QI) and the role of general practice and quality measurement from a health system context, which is discussed later in this thesis. It is important to recognise that "quality" therefore may be understood and subjectively interpreted in different ways by different individuals and that whilst recognised frameworks and definitions of quality exist, these may not align to the view of quality held by patients or practitioners. Furthermore, there is an argument that quality should be strongly determined through the impact of care on outcomes (both clinical and patient-reported) as the end-point of care. It is again recognised that the thesis has a focus on clinical quality, as described previously, that may not fully reflect a view of quality based on patient-centredness or patient-reported outcomes, for example. This means generalisability of findings and assertions around quality in the whole cannot be made (Donabedian, 1988; Grootenboer, 1990; Mant, 2001; Marley *et al*, 2004; Institute of Medicine, 2001, Shekelle, 2013).

The thesis results also place more emphasis on the context of improvement, such as the engagement, trust and motivation among staff, or the *effective* use of protocols in practice compared to structural factors related to staff numbers and capacity or simply the *presence* of a protocol described elsewhere (Sinsky *et al*, 2013; Bodenheimer *et al*, 2014).

Authors note the importance of primary care staff having knowledge of the "science of improvement" (Ham, 2003; Taylor *et al*, 2013), however the thesis results suggest this must be supported in language that primary care staff understand, or by using common clinical and practice-based scenario examples. There was little recognition of terms and phrases used in QI literature such as "improvement cultures" and "leadership approaches", particularly amongst more junior staff. There is a potential danger of cynicism of QI amongst such staff if language is not meaningfully deployed and made relevant to staff. Through interviews conducted in the thesis research, it also seems useful to demonstrate as well as define QI interventions (i.e. practices with access to knowledge of how to integrate protocols and point-of-care reminders in clinical systems, in addition to knowing these may support clinical quality improvements), which may be facilitated through better practice knowledge sharing. Equally, it is important that the features of measurement systems which enable clinical quality measurement and improvement, outside measurement alone, are recognised to support implementation in practice (such as measure agreement, simplicity, relevance and the influence of peer comparison).

Whilst common factors and themes present in practices with high clinical quality are noted, the thesis results further highlight the importance of identifying reasons for variation and barriers to improvement at *individual* practice level. This includes

recognising the complexities and context of quality, and considerations of QI implementation. Such ideas are explored subsequently in the discussion.

7.4 A typology of general practice organisations

7.4.1 Introduction and relevance of a typology of general practice organisations

The thesis research culminated in the development of a typology of general practices, using the themes associated with practice variation as categories to highlight differences within each practice type. The typology acts as an explanatory model to help understand how themes are inter-connected and possibly relate within each practice type. As noted previously, the typology attempts to highlight *dominant* practice types, however a practice's dominant type did not necessarily indicate the practice did not value or demonstrate characteristics of other types, for example those identified within the summary of practice types (Table 9).

The themes identified that appear to influence variation in the clinical quality of primary care do not exist through simple, linear, cause and effect relationships but through a wide and complex range of interactions where themes effect, connect, influence and relate to each other within a single practice environment. As Plsek and Wilson (2001) note, thinking around how healthcare organisations are led, managed and run, has moved from a view that organisations are "*akin to a well oiled machine*" to one that views organisations as complex adaptive systems where understanding the *relationships* between organisational parts is more important than the individual parts themselves (Plsek and Wilson, 2001. Pp.1). This argument can be applied to the thesis research where variation in the clinical quality of primary care between practice organisations appears more often than not as a product of multiple factors

combined, such as the relationship between a practice's leadership and culture on care structures and processes. However, the idea that types may exist, driven by a practice's primary purpose bears some relationship to previous findings around primary care organisations as complex adaptive systems. As Miller *et al* (1998) note;

"Primary care practices are understood as complex adaptive systems consisting of agents, such as patients, office staff, and physicians, who enact internal models of income generation, patient care, and organizational operations. These internal models interact dynamically to create each unique practice. The particular shape of each practice is determined by its primary goals."
(Miller *et al*, 1998. Pp. 396.)

The typology identified recognises the different beliefs and preferences primary care staff have within their own practice environment around the delivery of primary care, where such types could also be thought of as different strategies to deliver primary care.

Existing research suggests that QI in primary care cannot be achieved through simply isolating and fixing single parts or processes within a practice but must respect the overall practice context (Miller *et al*, 1998; Litaker *et al*, 2006). A number of authors recognise that primary care practices are significantly influenced and governed by their primary goals, where change in practice is highly dependent on the practices primary goals and values (Miller *et al*, 2008; Stroebel *et al*, 2009). Such primary goals in turn impact other components with the primary care practice, such as the care structures, processes and measurement approaches, but more critically, the relationships and behaviours between practice agents that characterise the uniqueness of the practice and determine change (Miller *et al*, 2008; Stroebel *et al*, 2009). If primary care practices are governed by their primary goals, with ability to change sensitive to such goals, it follows that understanding the primary goals of

practices is important in identifying how change may best be brought about. This has important implications in terms of the thesis results, whereby understanding the varying types of general practices and the differing views held in terms of an individual practice's purpose could be useful in supporting understanding reasons for variation and identifying improvement strategies. This is supported to some extent through existing literature suggesting that utilising knowledge about individual organisations should shape improvement interventions (Litaker *et al*, 2006).

The practice typology supports the notion that general practices are shaped by the primary goals of each practice. These primary goals have some influence on the complex nature of primary care delivery and the behaviours and relationships between staff within each individual practice, that in turn influences practice delivery. This was seen in the research results where high performing practices, identified through performance on *clinical quality* measures, were typically biomedically-orientated. Understanding the different philosophies of care and practice type characteristics within each general practice identified in the thesis research, together with the recognition of common conditions aligned to improved clinical quality, potentially offers a way to support practice self-reflection and identification of individual practice improvement strategies. Given that many practices may lack knowledge and skills around QI, helping practices to think about their practice type and primary goals could support early engagement with QI in practice.

7.4.2 Practice types and narratives

The thesis results, particularly the definition of practice types, identify significant variation in practice definitions of quality and guiding attitudes that influence care

delivery approaches and QI. As has been identified elsewhere in this thesis, quality in healthcare is generally recognised through components relating to care access, equity, efficiency, effectiveness, person-centredness and safety (Institute of Medicine, 2001). As other authors have noted, few would argue around the importance of each of these components in delivering high quality clinical care (Kitson *et al*, 2012). An interesting and significant finding in the thesis results however is the variability in how practice staff define quality within their own practice context, together with those aspects of quality which are *most* valued by practice staff and within practices as a whole. This finding was expressed in the developed practice typology. In very simple terms, to summarise previous results and discussion, biomedical practice types generally viewed QI as occurring through standardisation and protocolisation of clinical and biomedical care processes, holistic practice types in relation to a holistic approach to patient-determined biopsychosocial needs, and corporate practice types in relation to practice growth, corporate development and innovation. Externally reactive practices demonstrated less knowledge, understanding and application of QI due to various reasons previously discussed, but appeared to have a higher dependence on extrinsic factors to support practice improvement, or attributed practice performance to external influences.

Other authors have described the presence of different approaches or philosophies of care within a primary care context for some time (Toon, 1994), albeit without a clear link described between different philosophies of care and practice clinical quality of care. Wiles and Robinson (2008), following analysis of semi-structured interviews with primary care staff, describe how primary care nursing staff recognise variable general practice philosophies of care that impact on practice team working,

together with other factors such as team leadership, team management and team roles and responsibilities. The aspects of care philosophy that particularly vary are suggested by authors as the importance placed on direct, physical and interventional medical care processes compared to indirect, psychosocial care and support of the patient (Wiles and Robinson, 2008). This finding supports in some way the difference noted in the thesis results between the "biomedical " and more "holistic " practice types; A differentiation noted also by Grant *et al* (2014), where an emphasis on patient engagement as a determinant of a particular philosophy of care is highlighted through other studies (Perrault and Smreker, 2013). However previous research, such as that by Grant *et al* (2014), defines practice categorisation across binary characteristics, with no recognised relationship between such categorisation and practice performance, and less recognition of the differences in practice understanding of QI at a theoretical and practical level.

Another key area that went some way to explaining differences in practice care types (particularly between biomedical-type and holistic-type practices), was the differing views of primary care staff in relation to the role of primary care in affecting the wider determinants of a patient's health, outside delivery of primary healthcare. As is noted in a summary by the King's Fund (2016) with reference to academic literature, healthcare is a relatively small contributor (c.9-25% based on a summary of relevant studies conducted by the King's Fund) to health outcome compared to wider determinants of health such as other socioeconomic factors (for example income, education and employment), health behaviour patterns, environmental factors and genetics. Practice staff varied particularly in their opinions on the extent to which primary care could and should influence these wider determinants of health, and

particularly determinants of health outcome relating to health behaviour patterns, for example the role and ability of primary care to affect lifestyle change (for example activity and diet) that impact on Diabetes and CVD risk factors and outcomes.

Practices of the holistic type appeared more likely to spend greater time in appointments (as was self-reported by staff) on aiming to identify and solve reasons for poor lifestyle habits, and indeed, wider psycho-social factors that may influence this area such as social support and interactions on health-related behaviours. This was particularly supported through lifestyle modification interventions by HCA's and practice nurses supported by regular patient review and recall, where other research has identified practice nurses being more likely to initiate lifestyle behaviour discussions with patients compared to GPs (Noordman *et al*, 2012). This is possibly attributable in part to longer average appointment times with patients for these staff groups (Noordman *et al*, (2012), however, there are recognised limitations within this research that make comparisons between these staff groups difficult, such as the variation in training, such as motivational interviewing training and general differences in care priorities, complexity and tasks that exist between groups. Holistic practices however described the importance of this greater focus on social and lifestyle interventions in also supporting "at risk" patients without a confirmed CVD-related or Diabetes diagnosis, for example those with pre-Diabetes. Related to this, staff emphasised less the measurement of clinical indicators relating to blood pressure and cholesterol for example compared to improving patient understanding, engagement and activation in relation to their own health and experience of primary care delivery in supporting patient health improvement. In a systematic review

utilising 40 articles searched across three health and care databases, Rathert *et al* (2012) found that there was no clear relationship between patient-centred care (incorporating features such as patient engagement) and clinical outcomes, however, stronger evidence for the influence of patient-centred care on patient satisfaction and self-management, notwithstanding the heterogeneity in defining and measuring patient-centred care that must be recognised. This finding is extremely relevant to the thesis research. Holistic-type practices indicated their preference for measuring and improving patient risk and experience over clinical indicators, and also suggested that clinical indicators may not be as useful as indicators relating to admission avoidance, patient satisfaction and patient-reported outcomes which were not measured through the approach to the thesis research. This potentially further highlights the recognised link as has been described such that "what gets measured gets delivered" but also that a focus on one area of care (such as patient experience), may result in lack of focus, improvement or prioritisation in another (e.g. clinical processes).

It is well recognised through NICE guidance that primary care has a clear role in the prevention and management of CVD and Diabetes risk factors and diseases through supporting behaviour change and lifestyle management with patients that improve health outcomes and reduce adverse events (Fagart, 2006; NICE, 2011), as was advocated by holistic practice types. As is noted in existing research, greater time spent supporting patient engagement and activation in their own health and healthcare in primary care environments significantly contributes to improving patient outcomes and reducing care utilisation, therefore understanding this variation in relation to patient relationships and lifestyle intervention is important and particularly

for those with chronic conditions (Donald *et al*, 2011; Wong *et al*, 2011; Hibbard and Greene, 2013). In an analysis of GP consultations between 1975 and 2008, Noordman *et al* (2010) highlight that lifestyle choices (particularly alcohol use and nutrition) are still discussed in a relatively minor number of GP consultations, even though lifestyle discussion in consultations has increased over time. Noordman *et al* (2010) interestingly also found that lifestyle choices were more likely to be discussed with patients with a higher level of education (e.g. with a college or university degree). However, differences also appeared to be linked to knowledge and confidence staff had in affecting behaviour change with self-recognition amongst some staff of the limited skills they had in lifestyle modification and behaviour change. Equally, some practices just placed a higher reliance on pharmacological intervention (particularly in biomedical-type practices). In a separate paper, Noordman *et al* (2012) also note a lack of recognised techniques, such as motivational interviewing, being applied in primary care practices by GPs and practice nurses in Dutch general practice. The authors note this appeared partly to be due to lack of time to apply such interventions, given the complexity of affecting lifestyle choices and behaviours during short primary care appointment slots. It could be possible to postulate, but was not extensively explored during the thesis research, that a reliance/preference on pharmacological intervention for CVD and Diabetes management in some practices, particularly of the biomedical type, is also due to prescribing interventions taking less time than complex, lifestyle modification interventions, and indeed this is recognised through prior research (LeBlanc *et al*, 2015).

There appears to be less recognition in the literature around those practices which are of the "corporate" type, which were often focussed on organisational growth in practice size, practice development in terms of services offered in primary care and a more corporate style to care management. During practice interviews and analysis of themes from interviews, there was a recognition that primary care is being increasingly delivered through new, "non-traditional" models of care. Traditional models of primary care are generally thought of as General Practitioner Partnerships operating under GMS contracts delivering core primary care for lists of around 7,000 patients (Rosen and Parker, 2013). There is certainly evidence from the national policy context, health policy commentary and to a lesser extent, research and academic literature, of the increasing development away from traditional models of primary care and towards new primary care models that deliver primary care and other services at a larger scale. Such models include primary care providers as part of accountable care organisations and networks (including integrated acute, primary and community care), multispecialty community providers (integrated primary and community care teams), provider federations, primary care networks and super-partnerships with varying ownership arrangements, including corporately owned and non-General Practitioner-led practices (Rosen and Parker, 2013; Smith *et al*, 2013; Ham and Addicott, 2014). Many of these models reflect a growing emphasis on primary care delivery at scale, with illuminating narrative gained particularly from corporate type practices which indicated that delivering primary care through larger provider models, for example achieved through practice mergers or federations, would support both improved quality and efficiency of primary care, with the ability to

provide access to more specialist and enhanced services in the primary care setting through larger scale delivery.

Multiple studies have sought to examine statistically the relationship between primary care practice list size and quality indicator performance, with many using the UK primary care setting and QOF indicators for analysis. There is little evidence to suggest that list size is associated with variation in performance across care quality measures (including from research examining CVD and Diabetes care quality in isolation). However, some evidence that larger practices may perform better on organisational measurement domains relating to areas such as patient record keeping, patient information, practice management and practice productivity (Saxena *et al*, 2006; Wang *et al*, 2006; Doran *et al*, 2010; Vamos *et al*, 2011; Ng and Ng, 2013). A general limitation across these studies exists however whereby reliance on QOF indicators to examine quality and size relationships is open to criticism of QOF indicators in general as appropriate measures to comprehensively assess quality or organisational performance, compared to other indicators such as mortality-based outcome indicators (Drennan, 2016).

Evaluations of new models of primary care, delivering primary care "at scale", in the UK appear limited or still in progress (Rosen and Parker, 2013; Ham and Addicott, 2014). However, some authors have studied new types of primary care provider delivering primary care at scale, with important discussion points relevant to the thesis research conducted. Baker *et al* (2014) studied a privately owned primary care provider consisting of a chain of 50 general practices in the UK. Whilst recognising the limitation of the research being based on a single case study and not

linked to examination of provider quality, the authors found that the new, non-traditional model of primary care at scale through a single, corporate ownership structure provided many advantages and some areas of potential weakness. The study suggested that the provider demonstrated a clear vision and goals for the organisation, together with evidence of good standardisation of clinical systems, policies, guidelines and processes across practices that may occur less within traditional primary care models (Baker *et al*, 2014). However, the authors also found the provider had faced key challenges around GP recruitment and retention which threatened care continuity, possibly attributed to a corporate, controlling, performance management approach (Baker *et al*, 2014). Manns *et al* (2012) have also published research of large Canadian GP networks providing enhanced primary and community care for populations of around 90,000 outside core, fee for service primary care. The scope of the research was to assess the impact of primary care networks in relation to Diabetes care processes and outcomes, compared to providers not within a network. Within this work, the authors found that primary care network providers demonstrated better adoption of evidence-based guideline recommendations through care processes with greater glycaemic control within Diabetic patients and fewer Diabetic and Diabetes-related hospital admissions, however recognising relative changes were small in absolute terms (Manns *et al*, 2012).

Whilst the thesis research does not explore new models of primary care in large detail, within the practices interviewed there was an example of both an independent, private, "corporate-chain" style provider (providing primary care across a national network of practices including 2 practices in the CCG area researched) and a larger

super-partnership practice of around 50,000 patients where recent practice mergers had contributed to practice growth. The latter was also presented as a prototypical type of practice within the "corporate" practice type. This practice demonstrated similar features to that described by Baker *et al* (2014), such as a focus on corporate governance and efficiency, standardised management structures and care processes, with a high reliance on change through policy dissemination and communication. The thesis research has limitations in relation to the number of people working within or across this practice that were interviewed, however nonetheless presents an interesting question as to whether practice features of a corporate, organisationally-focussed primary care provider are present as a cause or effect of practice growth. The thesis research, which also linked practice types to performance across clinical quality indicators, suggests that reliance on features such as standardised care systems and processes and a single ownership structure is not sufficient alone to create a high quality clinical environment. This is based on the practices within this type not necessarily achieving the highest clinical quality performance based on indicators measured.

As noted, whilst the thesis research presented does not explore specifically the impact of practice size on quality, some possible areas of future research or consideration to practices moving to larger, "at scale" models can be described, particularly given that there does appear to be a definite shift to these newer care models in the UK context (Rosen and Parker, 2013; Smith *et al*, 2013; Ham and Addicott, 2014). The thesis results could imply that larger, growing practices should aim to realise the benefits of a single corporate leadership approach by creating a quality-focussed in addition to corporately-focussed approach to care measurement

and improvement. This could include ensuring larger practices do not create an overly-controlling and restrictive approach to practice development and allow the opportunity for primary care teams to contribute to QI activity. This may also impact on the challenge of staff recruitment and retention noted by Baker *et al* (2014) of new corporate-style providers. It also seems important that larger providers do not lose the important feature of care continuity that contributes to clinical quality (that may be lost due to constant referral between GPs with special interests instead of regular contact with a single GP). Equally recognising the clear advantages of larger provider models that potentially allow for improved access to enhanced, more specialist services in primary care settings, not possible due to smaller demand and patient numbers in smaller practices. In terms of implications for future research not widely explored within the thesis, it may also be interesting to explore how leadership characteristics and requirements change between different types and size of primary care provider and also the extent to which increasing scale of primary care providers reduces the threat of competition to, or weakening of, primary care such that may occur from primary care providers being contracted through a larger healthcare system provider (such as acute NHS Foundation Trusts) due to emerging population-based or accountable care organisation approaches. Given the move to new primary care provider models, it seems necessary to re-examine the impact of these models on quality of care, where existing research in primary care quality as noted is primarily based on traditional primary care models as defined previously.

As noted in the results, externally reactive practices could be differentiated from other practice types which, whilst displaying different characteristics, appeared more internally proactive in the nature of their approach to QI. Externally reactive practices

predominantly described an approach to QI which was more commonly reactive or responsive to external demands and change factors (such as extrinsic financial motivations and rewards, or in response to externally required regulatory or commissioning changes, for example, new requirements for quality data collection mandated through QOF or CCG local incentive schemes). Their approach to care could be compared to the concept of "satisficing", which is a cognitive strategy or approach to decision-making where the decision-maker seeks only to meet a given need, identified criteria or acceptability threshold, often, but not always, the least path of resistance. Such an approach may not necessarily result in the optimal solution being selected but in the view of the decision-maker may be preferable to spending time identifying and considering all options (Simon, 1956; Manktelow, 2000; Colman, 2006). This approach to achieving a minimum standard or threshold may be compounded by unintended effects of QOF, where general practitioners view QOF targets as a "threshold to meet" rather than an opportunity to measure and improve quality (Doran, 2014). Conversely, biomedical, holistic and corporate practices were more internally proactive in identifying strategies and approaches to QI. A number of authors, predominantly in the area of organisational strategy and change, have recognised differences in organisational change defined as proactive (anticipatory change in response to a perceived future internal/ external environment) or reactive (responsive change due to past or real-time internal/external stimuli) (Holsapple and Young, 2014; Hodges and Gill, 2014). Authors suggest both strategies and approaches to organisational change can be successful in supporting organisational improvement, which perhaps differs from the thesis findings where LP practices,

identified as lower performers across clinical quality indicators, were more commonly "externally reactive" (Holsapple and Young, 2014; Hodges and Gill, 2014).

7.4.3 Practice type in relation to quality measurement and improvement

The thesis results and previous discussion (within the section on patient engagement in the culture theme and the practice typology particularly) highlight a perceived trade-off between different components of quality between practices, notwithstanding that all practices could display some featured characteristics all practice types. For example, trade-off between achievement of externally determined clinical effectiveness indicators (particularly prioritised in biomedical type practices) and evidence-based health care that takes account of an individual patient's situation and experience (particularly prioritised in holistic type practices). Examples exist also in corporate-type practices prioritising practice growth and corporate functions or externally reactive practices responding more to externally driven risks and compliance requirements.

This trade-off appeared to impact practice quality measurement priorities and performance, for example, where biomedical practices were more likely to perform better on clinical quality and effectiveness indicators compared to other practices. A key reason for this "trade-off" may be the recognition from the thesis results and existing literature that "what gets measured gets improved", where other practices may have performed better on indicators not examined through the research; For example, indicators relating to care productivity, patient experience, clinic utilisation or admission avoidance (Lu *et al*, 2008; Lester, 2010; Phillips *et al*, 2010; Eijkenaar *et al* 2013). As Curoe *et al* (2003) also note in research examining practice size on

culture and quality in a US setting, there appears to be a risk that practices which focus on corporate development and growth (possibly aligned most to the corporate practice type in the thesis) are less cohesive and collegial, and also have a reduced focus on quality possibly due to prioritising organisational and corporate growth and development - a finding they note as interesting given the potentially greater capacity larger providers have to improve quality. The use of the mixed methods approach in the present research to determine this link between quality priorities or trade-offs and performance provides weight to previous arguments such as that by Scott *et al* (2003) who state that those areas of performance which are most valued are more likely to be enhanced within a given culture.

A number of authors have published research and commentary around the measurement and interpretation of "quality" in primary care and the impact this may have in practice. QOF in the UK has provided rich discussion on this topic. The view from some authors suggests QOF has not had a demonstrable impact on population level outcomes, such as mortality, as was originally intended and has led to plateaus in quality of care for non-incentivised conditions. Others would point to the improvements in clinical processes, particularly for chronic diseases, that have recognised links in improving outcomes (Stokes *et al*, 2010; Sutcliffe *et al*, 2012; Gillam *et al*, 2012; Drennan, 2016; Ryan *et al*, 2016). However, it is also recognised that absolute benefits to individual outcomes are too small to determine the impact of performance schemes in the primary care practice setting (Spence, 2016). This in part highlights the importance of developing not only a shared view of quality in primary care, but also a shared view in how quality should be measured and improved, including through utilisation of wider care outcomes, over structure and

process measures. Gillam *et al* (2012), in a systematic review of QOF, conclude that quality, its measurement and improvement, should incorporate a wider, balanced number of domains to ensure a complete picture of quality is gained, for example, incorporating impacts of data recording, professional and team behaviours, patient-reported outcomes, patient experience and system-wide outcomes and costs of care. The authors also suggest a level of caution in pay for performance schemes, particularly in terms of adverse effects across some of these wider domains. The thesis research and understanding of practice type would support this notion and indicate the importance of translating quality measurement and improvement evidence in primary care, where practices have divergent views of quality and QI. However, such an approach should recognise previous research, such as by Steele *et al* (2014), which indicates QI measurement and interventions may be more effective at the health system level, compared to individual or practice level. This research was focussed on quality of care for older adults however found that variation in quality indicators at individual level were small and inconsistent, pointing to a need for system level intervention to improve quality over time (incorporating system-level care outcomes), including through assessing and reducing other adverse effects such as polypharmacy and reductions in care continuity (Steel *et al*, 2014). Evidence from other patient cohorts would need to be assessed to apply these findings, however, similar conclusions have been made across other areas, such as for system-level interventions for improving quality of primary care for depression, given small variation at the patient and practice level (Vedavanam *et al*, 2009). Through measuring and improving broader measures of quality (including outcomes) at system-level, it may be possible to reduce variation that emerges from

different practice priorities at practice level as demonstrated through the typology presented. As other authors have noted, this approach would need to link back to the role (and funding) of primary care in affecting such outcomes and in relation to existing schemes, such as QOF, and new models of primary care discussed in this thesis (Vedavanam *et al*, 2009).

7.4.4. The typology of general practice organisations in the context of existing typology theory and research

This section explores relevant typology theory and compares and contrasts the developed typology to existing typologies, both within the healthcare sector but also more widely in other research and industries to gain the benefit of cross fertilisation. There is discussion around the important implications around practice type on primary care practice performance throughout.

It is important to consider the key aspects of typology theory, development and use before exploring and discussing the typology developed within the presented thesis research. Existing literature indicates that any typology should go beyond simple classification to improve the legitimacy of the typology as a theory or tool, to better understand identified types within the classification system. Further, the assumptions used for typology development should be clear and recognised (Sheps *et al*, 1983, Doty and Glick, 1994; Wiklund and Shepherd, 2005). As an example from the presented typology within the research thesis, the typology could be seen to be legitimised through the recognition and description of general practice type on clinical quality examined, identifying the practice types which appear most linked to higher and lower performance across indicators of clinical quality in primary care.

Furthermore, the typology supports understanding that bias to any specific practice type may create a lack of focus in other areas of primary care delivery (e.g. a focus on clinical process improvement may mean less focus and achievement in relation to organisational development and improvement). This finding however is highly dependent on interviewee self-reported practice performance in other domains of quality outside the clinical quality indicators examined.

Doty and Glick (1994) go on to argue that typologies meet the criteria of a theory particularly when they are linked to theoretical assertions, define the set of ideal types, provide complete descriptions using the same set of dimensions, and are tested with conceptual and analytical models. In the presented research, the typology constructed appears to meet these criteria, specifically through linking typology classification to recognised QI theory and in the use of consistent dimensions (leadership and culture, practice system of care, and quality measurement and improvement) to describe practice type, derived from the mixed methods analysis of variation in the clinical quality of primary care. The presented thesis research particularly demonstrates originality in moving beyond classification of practices into types, by describing the link between practice type and performance across clinical quality indicators (particularly for the practice types relating to "biomedical" practices, the dominant type in HP practices and "externally reactive practices", the dominant type in LP practices). It is important to again note that HP practices were defined based on clinical quality indicators which do not encompass all quality domains.

Other authors also note the importance of defining the purpose of classification through the use of a typology (Welch *et al*, 1990; Rijnders and Boer, 2004). In the

presented thesis research clear purpose for classification and identification relates to areas such as using practice type to identify areas for potential QI focus at practice level and identifying the strengths and limitations of each practice type in affecting clinical QI, for example. The use of prototypical cases to illustrate practice type and characteristics used in the thesis research has also been identified as a helpful method by others to emphasise the importance and implications of types with typology use (Ma and Timberlake, 2012). Orzano *et al* (2008) identify a further potential use of organisational assessment (such as understanding practice type) as a method for knowledge mobilisation, where the use of practice assessment or self-assessment of practice type could act as a initial gateway to further support practices to engage in learning about, and initiating, QI in practice. When recognising that practice type could impact on clinical quality in primary care, the understanding of different practice types within the defined practice typology also supports a need for general practices to measure and seek to improve quality through a balanced approach across domains related to clinical/biomedical care, patient-centredness, organisational development and safety. Such a balanced approach to the measurement and improvement of quality in primary care should also recognise the core components of quality identified previously, these being effectiveness, efficiency, equity, patient-centredness, safety and access of care (Rhydderch *et al*, 2005). When examining typology theory as has been described in this section, it is argued that the presented typology through the thesis research appears to meet the criteria defining a typology not only through the classification approach, but in demonstrating the implications of practice type on practice clinical quality performance from both a theoretical and practical perspective.

As has been noted elsewhere in this discussion and through examination of primary care and wider healthcare literature, there are a number of existing typologies and classification theories present that can be compared to the typology developed within the thesis research. Most notably, Grant *et al* (2014) completed a meta-ethnography of organisational culture in primary care medical practice to determine an understanding of key dimensions of primary care medical practice organisational culture. These four dimensions were responsiveness (internal to external), team hierarchy (egalitarian to hierarchical), care philosophy (biomedical to holistic) and communication (coherent to fragmented), which have been discussed previously and bear some resemblance to the research typology, particularly in relation to the care philosophies characterising each practice type. The thesis research typology added other philosophies described within corporate and externally reactive practice types, going beyond classification of practice type to examine the impact of practice type on achievement against clinical quality indicators - this is an important point. Research in primary care identifying different practice types dates back at least to research in the 1980's, such as that by Sheps *et al* (1983) who identify different primary care practice types through an evaluation and development of a typology of subsidised rural primary care programmes (the four practice types being comprehensive health centres, organised group practices, primary care centres, institutional extension practices and others, including solo practices). However, whilst such typologies exist, Baker *et al* (2014) discuss the importance of research in primary care that goes beyond classification of practice types into understanding the implications of type and practice characteristics on primary care delivery and quality. The thesis research addresses some of the authors questions around how different philosophies shared

amongst primary care staff within a given practice influence care delivery and QI in the areas of clinical quality, including creating a potential trade-off in relation to aspects of quality which are prioritised.

Exploring the literature base more widely, beyond looking at practice types and typologies in primary care, wider healthcare literature also allows for comparison of healthcare organisation typologies. Many of these, such as a typology of healthcare organisations developed by Westrum *et al* (2004), focus on classifying different organisational types by their organisational culture, which is also a key domain in the thesis typology developed. The focus on culture in differentiating types of organisation appears particularly influenced through the development and widespread use of the competing values framework for cultural assessment developed by Quinn and Rohrbaugh (1983). The competing values framework identifies four different organisational types (clan, adhocracy, hierarchy and market) based on the organisation's focus (internal versus external) and decision-making (stability and standardisation compared to flexibility). Hann *et al* (2007) suggest that primary care practices typically fit the "clan" organisational type based on the traditional general practice model. This organisational type is characterised as flat-structured and inward-focussed, with teams that act autonomously based on socially recognised, rather than documented rules, with leaders that act in a parental-type role to support the team to achieve shared goals, outputs and outcomes. Clan type organisations are also described as being less aware of external or market influences on their organisation, less focussed on competitive market forces, with fewer well-defined organisational structures and processes compared to other organisation types (Quinn and Rohrbaugh, 1983). Whilst this use of culture to characterise

healthcare organisations appears common, there is less agreement on the extent to which different organisational culture types influence healthcare quality and safety (Westrum, 2004; Hann *et al*, 2007). Speroff *et al* (2010) do however suggest that hospitals with greater group culture and less bureaucracy are more likely to engage in and deliver successful QI, with Tapp *et al* (2008) finding that primary care practice types demonstrating greater organisational development (through assessments of organisational maturity) had greater characteristics of an improvement culture. Equally however, the typology developed within the thesis research identified other domains beyond culture that characterise different practice types and there is therefore not an over-reliance on this domain in isolation, where variation in clinical quality of primary care appears linked to multiple, complex factors that appear strongly influenced by a practices purpose.

In examining the literature around organisation type beyond the healthcare context it is interesting to compare the thesis typology developed with typologies developed within other industry settings and contexts. Reviewing the literature it appears that many typologies use similar domains to categorise organisational types to that within the thesis research. For example using areas such as culture, leadership, structures, processes and behaviours to differentiate organisation and system types within typologies covering areas such as business, the not-for-profit sector, sports bodies and federations and even to categorisation of terrorist organisations and cities. Across these areas there is less cited recognition and reference to the themes of measurement and improvement (Hornaday, 1990; Theodoraki and Henry, 1994; Brach *et al*, 2000; Wiklund and Shepherd, 2005; Golmour, 2007; Ganor, 2008; Tapp *et al*, 2008; Ma and Timberlake, 2012; Winand *et al*, 2013). It is interesting however

that these areas, such as leadership and culture and organisational systems and processes have been found to differentiate organisational types across this diverse range of settings. Furthermore, there is some similarity in the impact of differences in these areas to organisational performance and results that mirror those in the research findings. For example, sports federations valuing staff involvement in decision-making and embracing change being more likely to innovate and improve, entrepreneurial businesses being more likely to perform better across indicators of business performance and terrorist organisations with more standardised organisational structures and processes being more likely to be resilient to external threats and sustain their existence (Wiklund and Shepherd, 2005; Ganor, 2008; Winand *et al*, 2013) . This perhaps suggests that there are some commonalities in the thematic reasons behind variation in organisational performance and differences in organisational types across settings and contexts, beyond those from the research completed in primary care. The consequences of this could support the need for understanding and using organisational types in primary care to assess and impact clinical quality, whilst equally recognising findings from other research that different organisations, characterised by their organisational type, could require different strategies to be engaged in and implement improvement activities (Boer, 2004).

CHAPTER 8: RESEARCH LIMITATIONS, CONSIDERATIONS AND IMPLICATIONS

8.1 Introduction

It is important to discuss key limitations and considerations of the thesis research, including research generalisability which are presented in this section, together with a summary of the key contributions made to the existing research base following the research findings.

8.2 Research limitations and considerations

8.2.1 Quantitative Phase

The research had a focus on understanding variation in the clinical quality of primary care across CVD and Diabetes, with justification for the focus on these disease areas provided in the thesis introduction. Justification particularly emphasises the disease areas "contribution to the global burden of disease, the associated economic burden this creates, and their prominence and importance within primary care disease management both nationally and globally". Other disease areas were not measured, meaning inferences about research findings to other disease areas are not made.

The indicators selected to investigate variation were based on the definition of clinical quality adopted within the thesis, with justification for this focus provided in the thesis introduction section 1.5, where the number of indicators selected was informed by referenced evidence around indicator and composite indicator use for analysing performance. Research could have more explicitly focussed on one, many or all of the components of quality referenced through recognised health and care quality institutions (such as the Institute of Medicine, Institute for Healthcare Improvement

and others), or focussed specifically on areas of care relating to care structures, processes or outcomes, for example. There exist a number of standardised outcome sets developed through evidenced based processes that equally could have been used where exploring outcomes of care, such as the core outcome measures in effectiveness trials initiative. Equally, for areas such as Diabetes, the UK National Diabetes Audit (supported through the Healthcare Quality Improvement Partnership) has developed a set of widely agreed indicators for analysing quality in Diabetes care, informed through consensus methods. Future research from the lead researcher would therefore likely include utilisation of recognised, standardised quality and outcome indicator sets (utilising balanced measures incorporating all aspects of quality), or include the development of such standardised sets for example through consensus-based methods. However, the research design recognised these limitations with research findings being presented specifically in relation to making conclusions based on understanding variation in clinical quality.

The selection process of indicators is recognised as a potential weakness of the research where formal consensus methods for indicator selection were not used. On reflection it would have been preferable to define clearer criteria for QI selection, where clinical quality includes a broad range of areas of care relating to care assessment, procedures, treatment and resulting physiological outcomes from care. Indicator selection was also strongly based on the accessibility and availability of indicators, particularly through MSDi software, as this allowed in-month practice performance readings. It would have perhaps been preferable to define criteria well in advance of indicator analysis that may also have allowed time to create new indicators where possible. However, the PhD scope did not allow time or resource

for new indicator development or extraction. Whilst indicators were not tested with primary care clinicians before adoption, they were deemed suitable through retrospective validation with interviewees.

In the quantitative methods it was planned to compare practice achievement across similar indicators for QOF and MSDi for reasons provided. This analysis was ultimately deemed not that useful due to differences in indicator definitions.

However, this analysis could be useful in future research where indicator definitions were aligned to compare in-month to year-end performance, to compare indicator achievement across public versus non-public databases, and to assess impacts of financial incentives on indicator performance, though there is extensive literature on this presently and this thinking was not developed further within the remit of the thesis analysis.

Another weakness in the quantitative phase relates to the sole use of funnel plot analysis at a moment in time as opposed to other statistical techniques or assessment of processes over time. The justification for funnel plot use has been provided and is recommended in health research for analysis of variation by various referenced healthcare quality and improvement agencies and organisations. Equally, the data used often measured results over a 12 month period, so while data was captured at a moment in time, this often related to practice performance over a 12 month period.

Finally, the QOF results utilised for the thesis research included exception reported patients. As can be seen from Appendix 5, different results may be produced excluding exception reported patients. This analysis producing funnel plots excluding

exception reported patients was completed retrospectively, however, it would be useful in future research to pre-define and agree justification for including or excluding exception-reported patients. In terms of funnel plot analysis, funnel plot charts did not include application of any weighting to patient lists. This may be appropriate for future research, together with utilising any new methodological approaches and controls in funnel plot development for quality measurement.

8.2.2 Qualitative phase

Practices for the qualitative stage were purposively sampled. Whilst selection bias is not seen as a weakness, where the research design specifically aimed to identify and conduct interviews with special cause outliers, there were some practices who declined to participate and therefore this could have impacted on results. However, the majority of practices which declined were not significant outliers and declined following a global request for research participation amongst all practices.

As is recognised though the use of qualitative methods, a methodological approach which can be inherently subjective, researcher interpretation can influence analysis of qualitative results. This is not a problem in itself, where qualitative research analysis is by nature dependent on researcher interpretation. However, there remains risk of over-interpretation of data that needs to be counter-acted through methodological controls. In the methods used for the presented research, a range of approaches were adopted to counteract the risk of researcher over-interpretation and to improve research credibility and confirmability. These included, but were not limited to, use of the constant comparison method in thematic analysis using sense-checking through the four-person research group, triangulation of codes in data

analysis with two additional external researchers (who were blinded to the results of practices), and the use of other approaches described, such as researcher reflexivity, maintenance of critical distance, neutrality and bracketing to help reduce subjectivity and bias in research.

In the discussion of the presented thesis, it is stated that there is a "difficulty in discriminating between cause and effect across individual factors" and that performance across clinical quality indicators is "rarely attributable to a single factor". The themes identified that appear to influence variation in the clinical quality of primary care do not exist through simple, linear, cause and effect relationships but through a wide and complex range of interactions and relationships and care has therefore been taken not to assert *direct* causation between practice performance across clinical quality indicators and the themes identified contributing to variation and the practice typologies. The qualitative results have intended to be worded and phrased such that direct causation is not asserted, for example, by describing results that "appeared" or "indicated" a link between themes and practice typologies and performance across clinical quality indicators, without going so far as suggesting a direct causative relationship. A strength of the presented research in the analysis of outlier practices is that non-outlier practices were also used to recruit participants to enhance credibility in findings by allowing confirmation and corroboration of themes relating to special cause variation. It is also important to note that the themes generated within the qualitative results are illustrated through a *selected* number of the wider interview transcripts and do not present all of the source material. There are some important implications for future research in potentially testing the themes and practice typology in the thesis results across a larger number of practices.

As noted within the thesis, a clear weakness could be suggested where the qualitative results of some practices were informed by the views of only one staff member for a practice (e.g. the lead GP) and therefore it may have been preferable to get a number of views from different staff across the every practice. However, this was not the case for all practices and the effect of this was mitigated to some extent where interviews included some participants that worked within and across a number of practices but were part of external teams (such as community teams). This allowed some triangulation of data between staff working external to a practice and the individual working with the practice.

Other qualitative methods beyond semi-structured interviews could also have been utilised, with reference particularly to ethnographic, observational methods. It was agreed between the researcher and research supervisors that as causes of variation were unknown, methods such as ethnographic, observational methods, with a focus especially on studying people, behaviours and culture could distract focus on other causes of variation that may not be identified through such approaches (Angrosino, 2007). However, given the themes that were generated around the causes of variation, particularly in respect of practice leadership, culture and team behaviours, it would perhaps be appropriate to utilise other methods, such as observations of practice teams and qualitative surveys and instruments exploring culture, to examine such themes in more detail. Deviant case analysis was used in the research methods, however, as is noted this was primarily to confirm what practices had suggested in interviews was true through further analysis of practice care protocols and team structure documentation, for example. Deviant case analysis could have been used to understand where emerging themes from semi-structured interviews

were perhaps not true or even contradicted findings, which present an opportunity for research development. There was however opportunity for practices to confirm or deny answers used in interviews through respondent validation described.

Furthermore, it was recognised on completion of the thesis research that future research could include detailed case study analysis of deviant cases and practices defined with different practice types to further confirm or contradict findings, including for example, development and use of a practice type questionnaire to inform potential assessment of practice strengths and weaknesses in respect of practice type.

8.2.3 Generalisability

Generalisability of the research is explicitly considered where Polit and Hungler (1991) define generalisability as;

"the degree to which the findings can be generalised from the study sample to the entire population" (Polit and Hungler, 1991. Pp.645).

The thesis research had a study area of Sandwell and West Birmingham, a relatively high deprivation area of England with lower than expected life expectancy compared to the England average (see Table 1). However, in terms of generalisability to other areas, it is plausible that findings could be generalisable to other "cities and services" supergroup areas in the UK, which are mapped based on deprivation and other population attributes by the Office for National Statistics (NHS England, 2012). To assess the extent of this generalisability further, it would be sensible to assess the wider primary care environment of these comparable areas to understand other shared attributes in respect of the primary care setting (e.g. practice list attributes and practice performance).

The research had a specific focus on clinical quality as defined for CVD (including Hypertension) and Diabetes indicators. As such, inferences cannot be made to other recognised areas of quality as described in the thesis, such as patient centredness and access, or indeed other condition areas. However, as CVD and Diabetes are often grouped as chronic conditions with a range of evidence-based indicators that can be affected in primary care, it may be possible to generalise to other chronic conditions with these and similar characteristics. The need to assess quality more broadly (outside the predominantly process-based clinical quality indicators used in the research) is highlighted as a research limitation and future consideration. This may be achieved through use of recognised evidence-based standard outcome and quality indicator sets, including through considering both practice-level and system-level quality indicators and outcomes that are influenced by general practice.

8.3 Research implications and contribution

The presented thesis provides original contribution to the research base, with implications both for primary care practice and future research. Key contributions include the development of a new typology of general practice organisations, recognition of an implied trade-off between different components of quality between general practices and the consolidation of characteristics of high performing practices within the studied practice population. Table 10 summarises the original research contribution and associated research implications for practice and future research which should be considered in parallel with the research limitations and considerations previously defined.

Table 10: Original contribution of research and implications for practice

Original contribution of the research	Implications of the research (denoted as (I)) and pathways to implementation/ future research (denoted as (P)), linked to the original contribution of the thesis.
<p>1. The thesis research brings together characteristics of general practice organisations into a single, new and original typology, defining four practice types, labelled biomedical, corporate, holistic and externally reactive practices.</p>	<p>(I) The practice typology indicates that practices display different characteristics across areas such as practice leadership, culture, care systems and quality measurement and improvement. The typology may help to explain variation in the clinical quality of primary care, however, requires further research to test this assertion.</p> <p>(I,P) Given the emergence of a corporate practice type, it seems necessary to re-examine the definition and impact of this practice type in relation to quality of care, where existing research in primary care is primarily based on traditional primary care models as defined previously.</p> <p>(P) It would be important to further test, develop and amend the typology of general practice organisations to support improved validity and generalisability of the typology, including through use of additional research methodologies, such as ethnographic methods, for example.</p> <p>(P) It may be possible to develop a general practice type tool to identify different practice types and associated strengths and weaknesses of such types to inform quality improvement.</p>
<p>2. a) The thesis research results and practice typology highlight that variation in the clinical quality of primary care appears linked to the definition and interpretation general</p>	<p>(I) General practice staff appear to prioritise some aspects of quality over others based on their view of quality itself as is recognised in the practice typology; An implied quality trade-off that may impact quality of care.</p>

Original contribution of the research	Implications of the research (denoted as (I)) and pathways to implementation/future research (denoted as (P)), linked to the original contribution of the thesis.
<p>practice staff have of quality and quality improvement.</p> <p>2. b) The research indicates a possible link between practice type and performance, where HP practices (measured using a definition of clinical quality and predominantly clinical processes indicators provided in the thesis) predominantly displayed characteristics of biomedical type practices. LP practices predominantly displayed characteristics of the externally reactive practice type.</p>	<p>(I, P) In recognising the potential trade-off between components of quality that general practices make, it is important to measure general practice quality across a range of agreed, balanced indicators that are not biased to a single component of quality (such as clinical quality). This may include recognising wider patient-reported and system care quality and outcome indicators that are influenced by general practice but may be difficult to measure at this level.</p> <p>(I) There is highly variable understanding and knowledge of quality and QI delivery in primary care practice, which has implications for promoting QI education and awareness amongst primary care professionals (e.g. through medical curricula, local health care system schemes and national policy). The thesis results suggest this must be supported in language that primary care staff understand, for example, where there was little recognition by practice staff of terms and phrases used in QI literature such as "improvement cultures" and "leadership approaches".</p> <p>(I) It may be particularly important to identify "externally reactive" practices to focus quality improvement efforts given LP practices most commonly displayed characteristics of this practice type.</p> <p>(P) Future research could examine practice variation across wider areas of care, incorporating standardised outcomes sets and quality indicator sets or across wider system outcomes influenced by primary care,</p>

Original contribution of the research	Implications of the research (denoted as (I)) and pathways to implementation/ future research (denoted as (P)), linked to the original contribution of the thesis.
	including in relation to practice type. This would provide a greater understanding of practice variation in relation to other aspects of quality (such as patient-reported and others outcomes) and help to understand and influence improvement across other quality and outcome areas at general practice and wider health system level.
3. Utilisation of a composite score, derived from funnel plot analysis of variation, may be an effective way to identify practice differences in clinical quality performance and outliers demonstrating both high or low performance across selected indicators	(I) In conducting the research using and feeding back clinical quality indicators, it seemed apparent that a number of practices were unaware of their performance across indicators as compared to peers. There is an implication for primary care delivery in ensuring primary care teams have access to, and regularly review, benchmarked clinical quality data (together with clinical outcome data). Use of composite scores such as in the thesis research may be helpful in preventing "measurement fatigue" and supporting QI where too many measures can create a lack of focus.
4. A number of characteristics representative of high performing practices as measured through the selected clinical quality indicators have been identified. A central finding within these practices was an intrinsic focus on QI as opposed to a reliance on extrinsic motivational sources (e.g. funding for QI initiatives) where staff had clear accountability, responsibility and autonomy through their role definition to improve quality in the practice.	(I) Characteristics leading to improved performance across clinical indicators examined as displayed through HP practices have been identified with learning that may support primary care clinical quality improvement at practice level (See Table 8).

In recognising the research contribution to date and implications, future research would likely involve further examining variation in primary care through measurement of wider aspects of quality beyond clinical quality (such as through recognised, evidence-based agreed quality and outcome indicator sets) and the impact this has on the developed typology of general practice organisations and characteristics of high performing practices. It would also be important to further assess generalisability of the research findings across a larger range of primary care practices and whether the practice typology could be used to assess and identify strengths and weakness across practice types, recognising that practices may display affinity towards characteristics of some practice types compared to others. Additionally, given the variable views of quality of general practice staff and the link between measurement and performance, implementation research could support development and use (e.g. through practice audit and feedback) of improved indicators examining wider aspects of quality to influence primary care QI and in developing a shared view of what constitutes quality in primary care, recognising the wider health system context and outcomes. In this context, it would be interesting to also examine how quality measurement and improvement knowledge is mobilised within general practice.

CHAPTER 9: CONCLUSION

The presented research sought to understand variation in the clinical quality of primary care at practice level and subsequently identify important implications for current practice and future research. Mixed methods were adopted using quantitative funnel plot analysis to identify special cause variation across clinical quality indicators and qualitative semi-structured interviews with thematic analysis to understand the causes of variation. Differences emerged between practices' leadership, culture and care systems, and approaches to QI that were used to develop an explanatory typology of general practice organisations. General practices could be categorised into four types of practice, described as "biomedical", "holistic", "corporate" and "externally reactive" practices.

In conclusion, three clear areas of importance are summarised which present new and original findings in relation to understanding clinical quality variation in general practice. Firstly, the thesis research brings together characteristics of general practice organisations into a single, new and original typology. The practice typology highlights the differences found between general practices across areas of practice leadership, culture, care systems and quality measurement and improvement. Future research is required to further assess the validity of this typology and understand its application in supporting practice quality improvement by recognising the inherent strengths and weaknesses of each practice type. Given the emergence of a corporate practice type, it seems necessary to re-examine the definition and impact of this practice type in relation to quality of care, where existing research in primary care is primarily based on traditional primary care models as defined previously.

Secondly, the thesis research results and practice typology highlight that variation in the clinical quality of primary care appears linked to the definition and interpretation general practice staff have of quality and quality improvement. Given the indicators used in the thesis researched were biased to clinical quality, the performance of practices against other measures, such as patient satisfaction/ experience, was not known. However, there was some indication during practice interviews of effort substitution or an implied trade-off between different components of quality, where a focus on one area of quality creates a lack of focus on another, where clinical GP practice staff often described their superior performance across indicators related to their area of interest (e.g. clinical disease area or practice focus e.g. avoiding admissions). In recognising this, it appears important that quality in general practice is based on a shared and agreed definition of quality that is measured through use of a range of balanced indicators that assess all components of quality (access, efficiency, effectiveness, equity, patient-centredness and safety, for example). Equally, quality measurement in general practice should consider the impact of general practice on wider patient and system outcomes, in reference to the use of measurement in general practice from existing literature. Use of composite scores such as in the thesis research may be helpful in preventing measurement fatigue described by general practices and in supporting quality measurement, benchmarking and QI through simplifying the measurement of quality and communication and presentation of indicators.

Thirdly, a number of characteristics representative of high performing practices as measured through the selected clinical quality indicators have been identified. Developing such characteristics in practice may support primary care clinical QI at

the practice level. Key areas are summarised in Table 8. HP practices appeared to create a culture of continual QI within the practice, led through authentic, respected, quality-focussed clinical leaders. Integral to these HP practices was the positive and informal practice relationships between staff, the mutual respect and appreciation of the roles of all members of the general practice team, and open communication and feedback amongst team members (including through regular team meetings and communication). Other authors have noted the importance of trust relationships within primary care delivery and the thesis findings appear to support the importance of open, respectful and trust-based team relationships within both general practice teams and with wider, multidisciplinary teams in acute and community care, for example (Okello and Gilson, 2015). A central finding within these practices was an intrinsic focus on QI as opposed to a reliance on extrinsic motivational sources (e.g. funding for QI initiatives) where staff had clear accountability, responsibility and autonomy through their role definition to improve quality in the practice.

It is important to restate the limitations of research described in the thesis, where the research had a particular focus on examining clinical quality across CVD and Diabetes in Sandwell and the Black Country, West Midlands. As such, whilst the research areas may be broadly comparable to other cities and services sub-group areas in England and other chronic conditions for example, generalisability is possibly most limited in respect of the focus on clinical quality (as one aspect of quality) and clinical quality measures adopted for the research. Notwithstanding this, the thesis research indicates the importance of a shared view of quality in general practice given the different perspectives of quality and quality priorities general practice staff hold. The research presents a pathway to measuring and

understanding variation in wider components of quality in general practice and supporting implementation of effective quality measurement and improvement approaches within general practice. Such research may provide further development of the presented typology of general practice organisations and characteristics of both high and low performing practices, identified through performance against a shared definition of quality, to support quality measurement and improvement.

APPENDIX

Appendix 1: Research invitation letter

6 August 2014

Practice Code

Lead GP for Research

Insert Address 1

Insert Address 2

Insert Address 3

Postcode

Dear Lead GP for Research

Re: PhD Student Research: Understanding Clinical Variation in Primary Care (CVD, Hypertension and Diabetes)

Ryan Irwin, PhD student, University of Birmingham is interested in clinical variation and quality improvement in primary care. In order to find opportunities for quality improvement, he would like to understand the variation between general practices for the management of cardiovascular disease, hypertension and diabetes using MSDi software.

He would like to conduct interviews with practice staff to ascertain why indicators may differ across practices, work with them and to learn lessons from the findings.

This study is funded by the National Institute for Health Research and has been adopted onto the NIHR portfolio. Sandwell and West Birmingham CCG is supporting this important study which aims to support local quality improvement.

For your further information, please find attached a Participant Information Sheet. It would be appreciated if this could be circulated to the relevant staff within your practice. If you are interested in taking part, please complete and return the enclosed yellow Expression of Interest Form to myself either by fax or post.

For any further information relating to this project, Ryan can be contacted direct on [redacted] or email: [redacted]

We look forward to hearing from you.

Yours faithfully

Research Facilitator, CRN:PC

Encs: Participant Information Sheet; Expression of Interest Form; FREEPOST Envelope

c.c. Practice Manager

Appendix 2: Participant information sheet - cover

To: CCG GP Member Practices and Practice Managers

RE: PhD Student Research - Understanding variation in primary care (CVD, Hypertension, Diabetes)

Date: 5th July 2014

Ryan Irwin is a PhD student at the University of Birmingham who has an interest in clinical variation and quality improvement in primary care. Ryan is particularly interested in understanding variation between general practices in the management of CVD, Hypertension and Diabetes and from this, learning about opportunities for quality improvement. With the support of Sandwell & West Birmingham CCG, Ryan plans to work with member general practices to conduct some research around variation and support quality improvement locally.

It is intended that Ryan may use the MSDi Clinical Manager software to investigate local variation using related MSDi indicators in the clinical management of CVD, Hypertension and Diabetes, where MSDi software is currently commissioned by the local authority for all general practices in the CCG.

Ryan intends to analyse the indicators to identify general practices whose indicators show unusual deviation/variation from the average. He will then interview staff in these practices to find out more about why indicators might be different across practices and to work with practices to learn lessons about the reasons for differences. Ryan wishes to speak with practices to support this work and to conduct short (30-60minute) interviews with staff in practices to understand reasons for variation as described. Ryan is more than happy to discuss his work with you and attend any relevant practice meetings or fora where possible. It is intended that there will be a brief summary of this work at a relevant CCG/locality meeting or similar in future. A contact email for Ryan, his PhD supervisor Dr. Tom Marshall and Mytime Active Senior Manager, Paul Westerby are below. All necessary approvals such as ethical approval, sponsorship confirmation, research and development approval and others have been gained and it is hoped that this work will be well supported.

Please could you provide contact details below if there is anyone specific at your practice that it would be best for Ryan to liaise with or otherwise Ryan may be in touch to arrange a convenient time to discuss this. Please note, this just provides details for initial contact and does not commit you to participate in the research or interviews, where consent will be gained for this purpose.

Appendix 3: Participant information sheet

Participant Information Sheet

Study title: Understanding common cause and special cause clinical variation in primary care; A study of multiple GP practices in the West Midlands.

You are being invited to take part in a study being run in general practices in the West Midlands exploring clinical variation for a range of clinical indicators across areas such as CVD, Diabetes and Hypertension management in primary care. This Information Sheet is provided to explain why this research is being done and what it will involve, in order to help you decide if you want to participate. Please take time to read the following information carefully and to discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

Thank you for reading this and for your consideration of this request.

About the researcher

I am a PhD student in the Department of Primary Care Clinical Sciences, University of Birmingham, funded through the National Institute of Health Research. I am currently investigating variation in primary care by examining practice-level clinical indicators, whilst understanding the role of quality improvement in this context. I am supervised by Dr. Tom Marshall (), Department of Primary Care Clinical Sciences, University of Birmingham and Professor Tim Stokes (), Division of Health Sciences, University of Otago, New Zealand.

What is the purpose of the study?

The research is exploring variation in primary care using a range of clinical indicators from locally and nationally reported datasets, particularly looking at;

- Reasons for common cause and special cause clinical variation (deviation from the "average") for practice level management of CVD, Diabetes and Hypertension assessment, treatment and condition control, amongst other areas. "Variation" will be examined by using local clinical indicators.
- The possible solutions and approaches to reducing unwarranted clinical variation (deviation from the average) in primary care for conditions and disease areas identified, whilst understanding also what works well for the management of the disease areas identified.

Why have I been invited?

I would like you to participate in this study because I wish to seek the views of health professionals in understanding variation in primary care. You have been invited as it is felt you could be well placed to provide information and discussion on variation in primary care, particularly where this relates to use of local clinical indicators which your practice or primary care organisation contribute to or are included within.

What does it involve?

Your involvement in the study would be to take part in an interview where we discuss variation across clinical indicators, including any clinical indicators relevant to your practice and reasons for variation, where this exists. Through the interview, we also wish to talk about your thoughts, opinions and experiences around variation in primary care, opportunities for quality improvement and any further relevant discussion which may be relevant to the research title. The interview will probably last between 20 and 90 minutes depending on the time you have available and the amount of information you wish to share. The recordings will be written up and you will be offered a copy of the transcript, encrypted and sent via email, to keep if you would like.

What if there are any problems?

Given the nature of the study, it is highly unlikely that you will experience distress from the interview, however you may contact Dr. Tom Marshall [REDACTED], if you have concerns

Do I have to take part?

It is up to you to decide. Participation in the interview is entirely voluntary. At the start of the interview the researcher will discuss this information sheet and ask you to sign the consent form to show you have agreed to take part. Even after you have given consent to take part, you may stop participating in the interview at any time and can also refuse to answer any question at any time without providing a reason.

What will happen if I don't want to carry on with the study?

If you withdraw from the interview, we will destroy all your identifiable information, but we will use the data collected up to your withdrawal.

Expenses and payments

Interviews will be held at a location convenient for yourself where no expenses will be incurred.

What are the possible disadvantages of taking part?

If you have particularly strong feelings or misunderstanding about the research posed, you may find some questions difficult, however please feel free to contact me using the contact details overleaf if this is the case.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. The only contact information required will be either a mobile telephone number or email address. The interview data will be kept completely confidential and reported anonymously. Any details that could identify you (such as names or places) will be removed before the study is reported or published. The interviews will be recorded and transcribed (a written copy will be made). In line with the University of Birmingham's Code of Conduct for Research, the interview transcripts will be preserved and accessible for ten years after publication of the study's findings. The transcripts will not identify the interviewees by name. Your signed consent form will be held in a secure place.

What will happen to the results of the research study?

The results will be used to inform future developments in the research itself and possibly inform the development of a quality improvement initiative locally. Key findings from the study will be published in relevant scientific or professional journals.

Who is organising and funding the service evaluation?

The service evaluation is being organised by the University of Birmingham and funded by the National Institute of Health Research as part of a PhD project.

Can I tell other people about the research?

Yes

How can I get further information?

Please ask Ryan Irwin [REDACTED] if you would like to get any more information about the study or to let him know that you would like to take part.

Department of Primary Care Clinical Sciences
School of Health and Population Sciences
University of Birmingham
Birmingham
B15 2TT

Declaration of consent

Study title: Understanding common cause and special cause clinical variation in primary care; A study of multiple GP practices in the West Midlands.

- I confirm that I have read and understood the participant information sheet for this study and have had the opportunity to ask questions.
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.
- I agree to take part in the study.
- I confirm that I am happy to have my interview recorded and transcribed.
- I confirm that I give permission to use direct quotations.

Name of Interviewee [please print] _____

Signature _____ Date ____ (day)/ ____ (month)/ ____ (year)

Name of Researcher [please print] _____

Signature _____ Date ____ (day)/ ____ (month)/ ____ (year)

Appendix 4: Qualitative interview topic guide

Qualitative Interview Topic Guide

Practice (code); _____

Address: _____

List Size: _____

Deprivation: _____

Ethnicity: _____

Semi-structured interviews

*Initiate recording of interview and introductions

Introduction

1. Can you tell me a bit about your practice (career history)

General background and QI context

2. What are your thoughts about local and national quality improvement initiatives in relation to managing chronic diseases (e.g. diabetes, heart disease) generally.

3. Do you use any clinical indicators? Do you use or aware you aware of the MSDi clinical indicators? Are they useful?

4. Can you tell me about quality improvement initiatives in your practice?

Do you have quality improvement objectives?

Who gets access to information about quality indicators?

Do you review quality indicator data? Who? In what context?

Who generates ideas for improvement?

Do you take time out to generate improvement ideas?

Is it easy to change things in the practice if you wanted to change something?

Variation exploration- explain variation

5. What do you think are the reasons for why practices vary in their performance in the observed indicators... (explore data, patient case mix, structure or resource, process of care, carer)

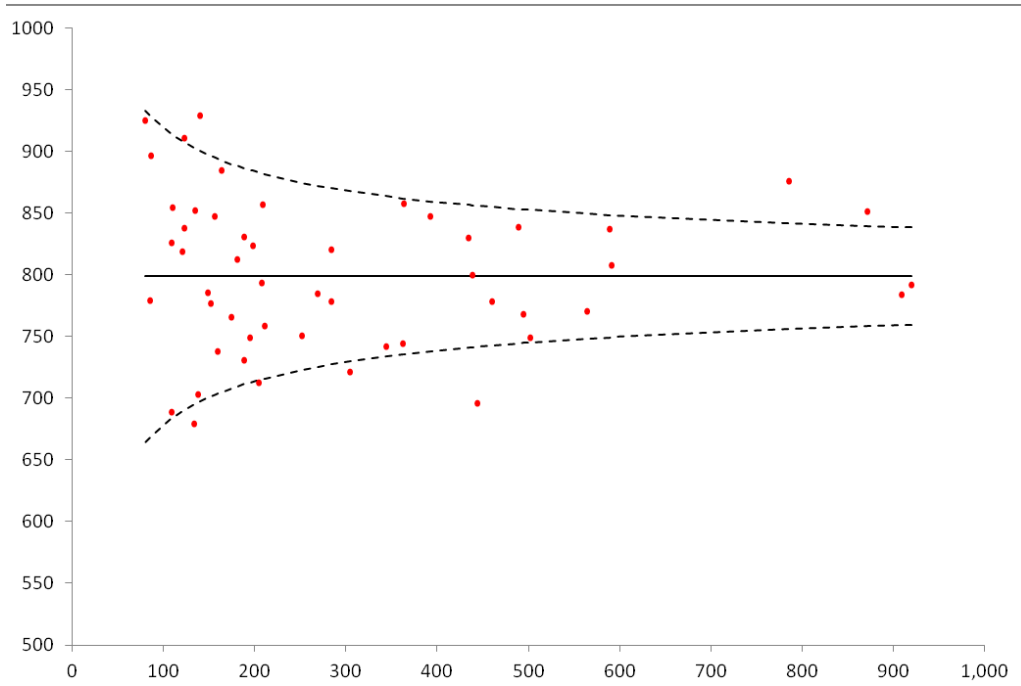
6. Where do you think you are in relation to other practices in your CCG locally against these indicators? Do you do anything differently at this practice compared to others that you are aware of?

7. Do you have any ideas on how to improve the indicators across the areas we have examined? Are they the right indicators to measure quality? Are there the right number - too many/ too few?

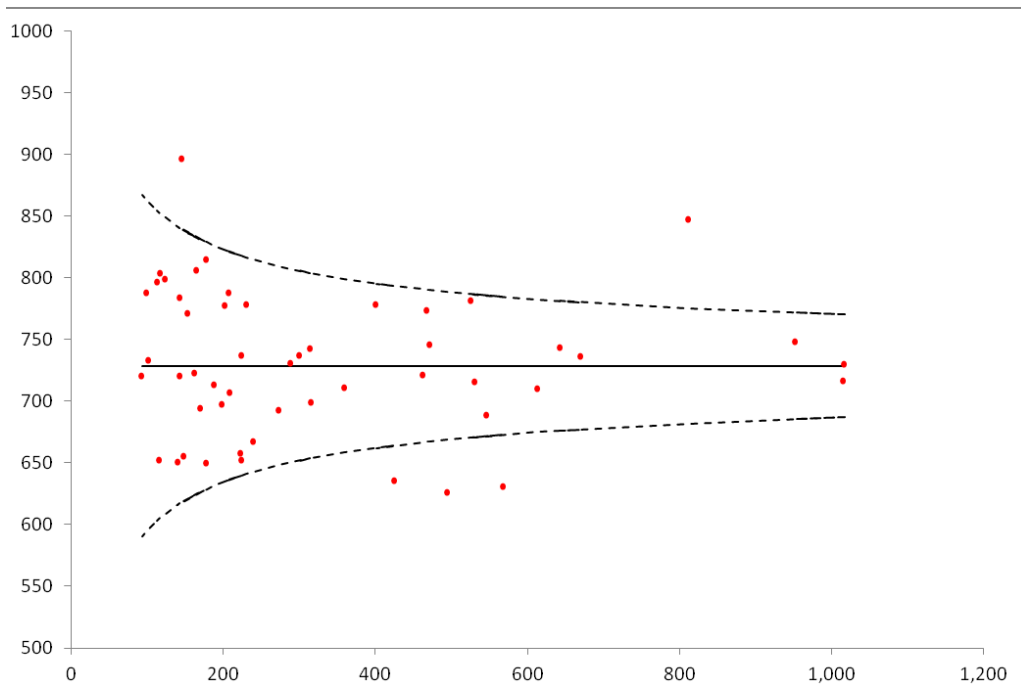
8. What support do you think is needed for practices in improving quality across the areas we have examined? What motivates/drives you to improve quality?

Appendix 5: Funnel plot analysis of clinical quality indicators¹

Indicator 1 (without exception reported patients within denominator population)

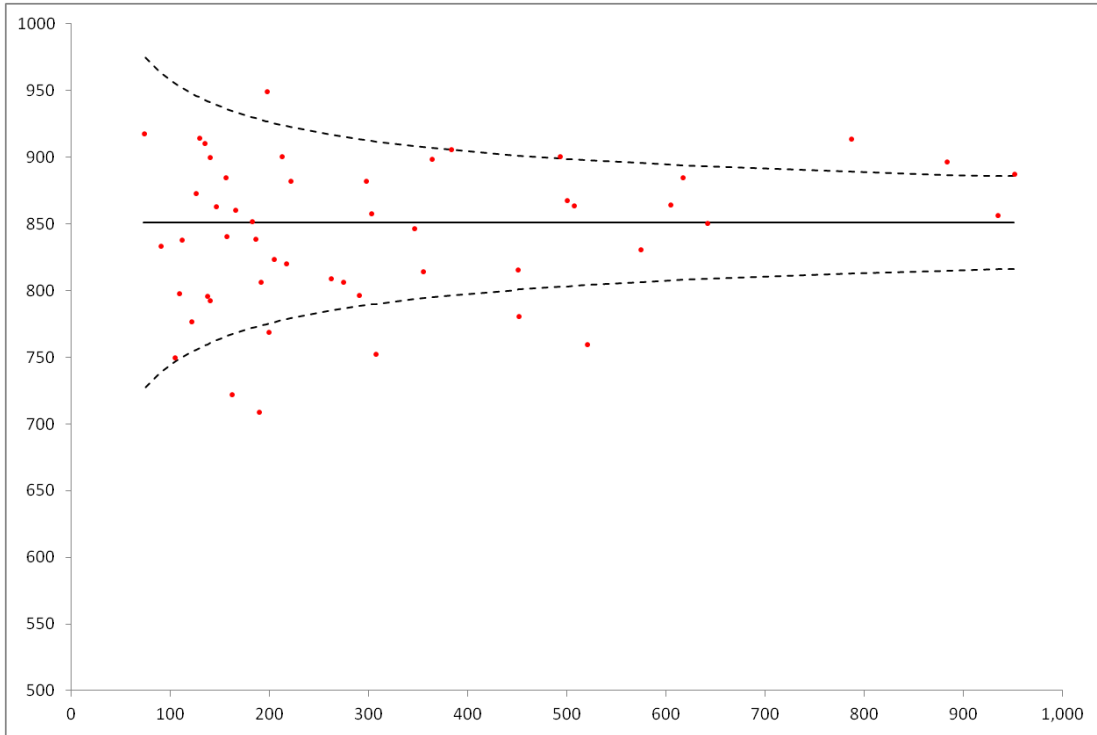


Indicator 1 (with exception reported patients within denominator population)

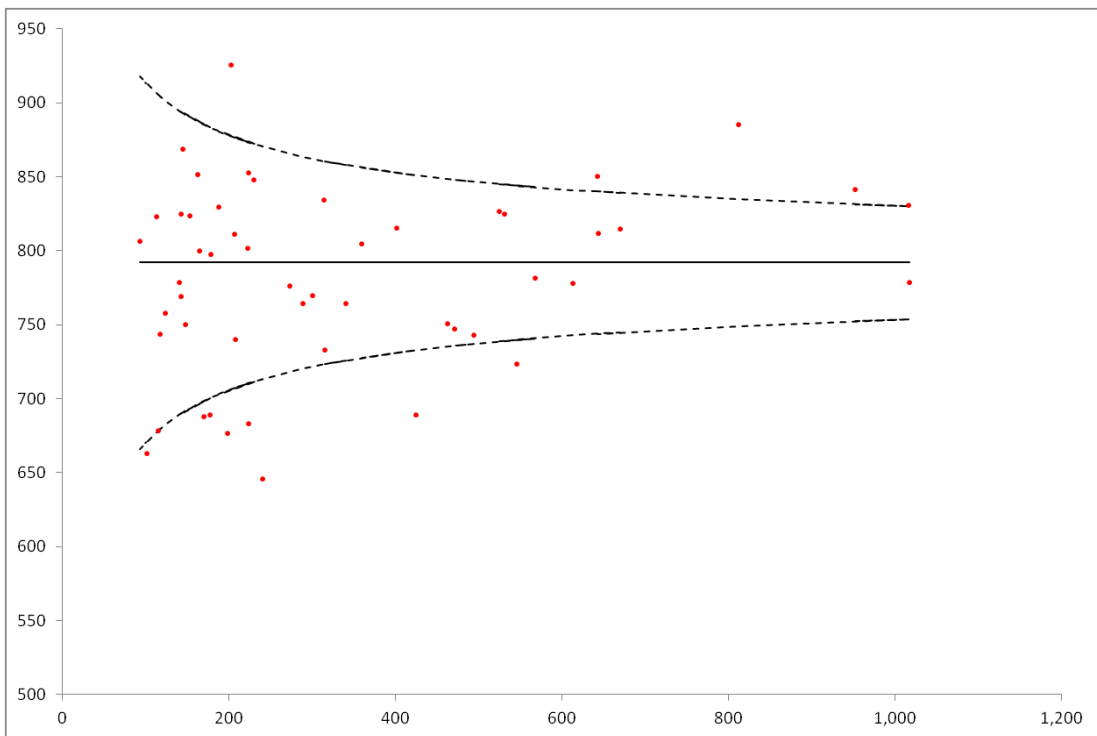


Indicator 2 (without exception reported patients within denominator population)

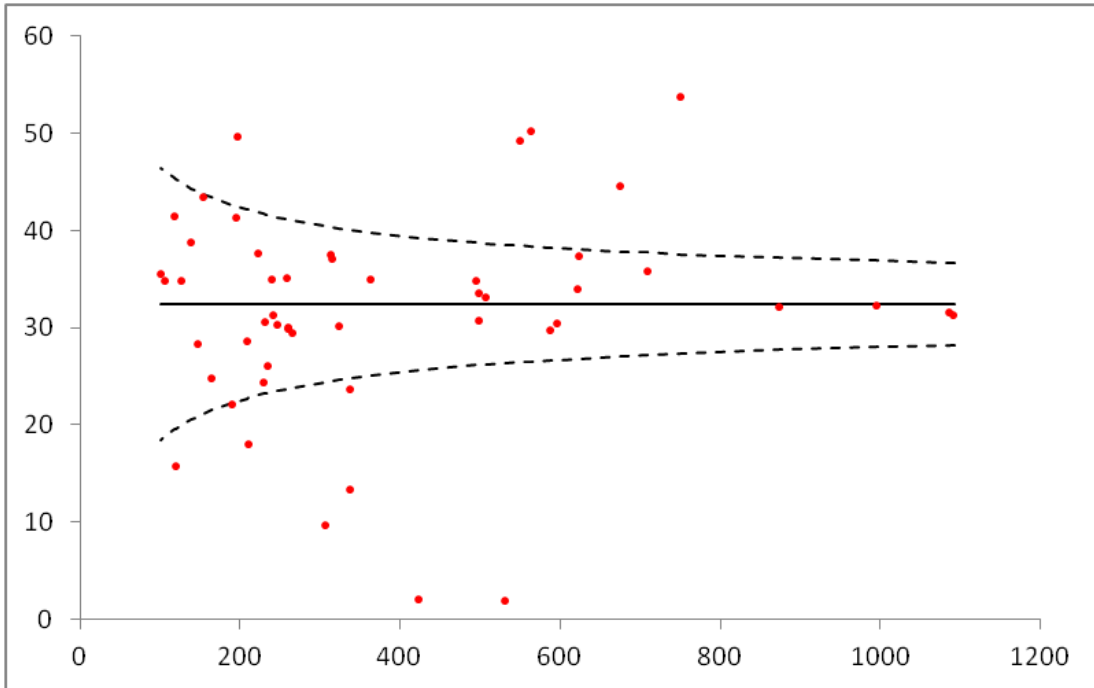
¹ Please see Table 2 for Indicator numbers and definition; Graphs are displayed with the denominator - total population on the x-axis and numerator - rate per 1,000 on the y-axis



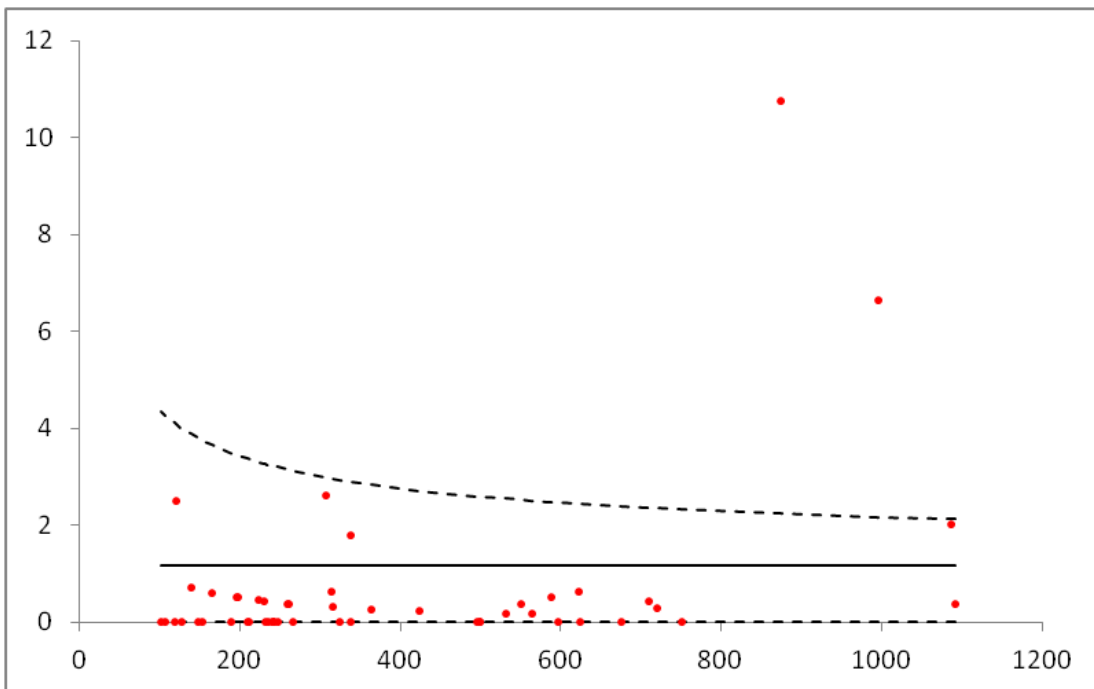
Indicator 2 (with exception reported patients within denominator population)



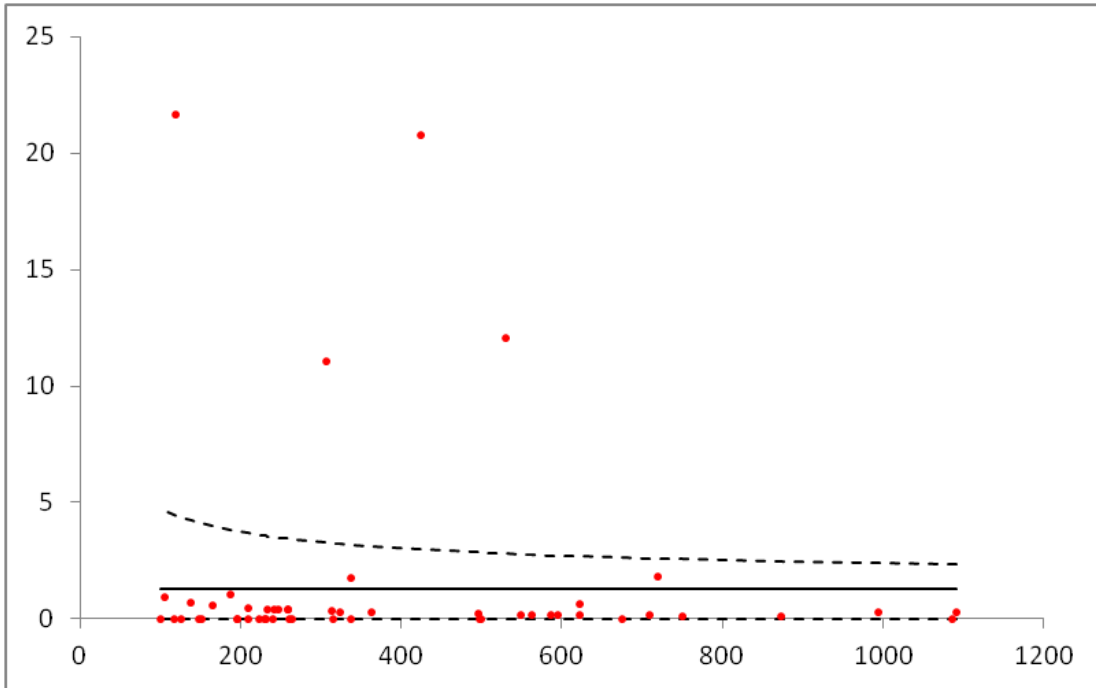
Indicator 3



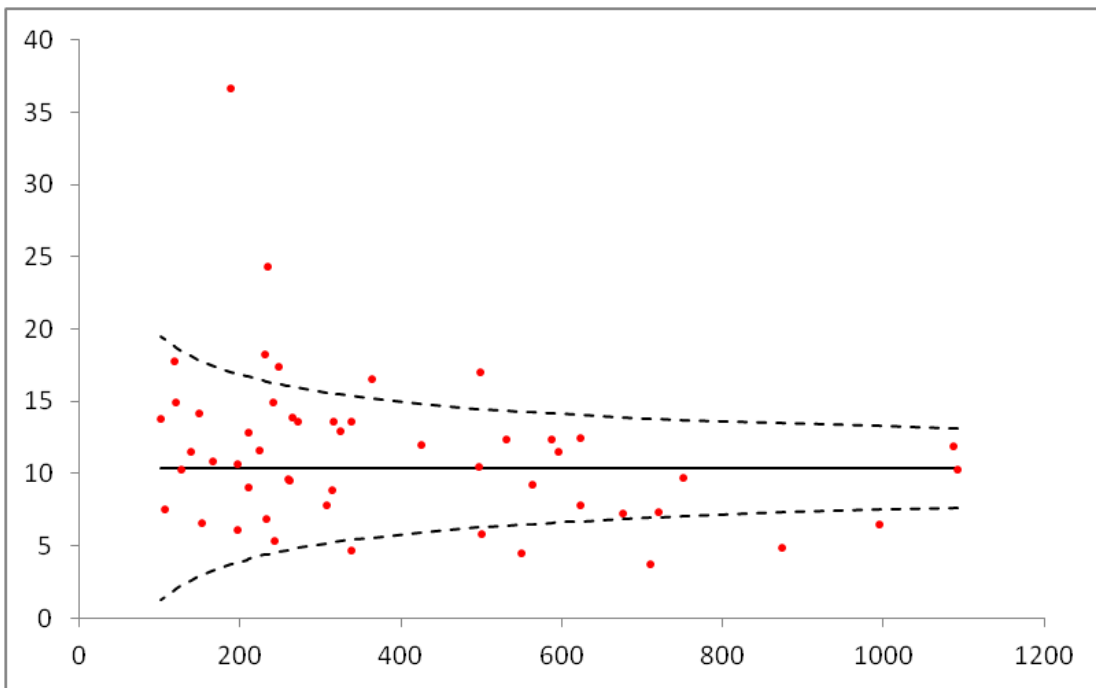
Indicator 4



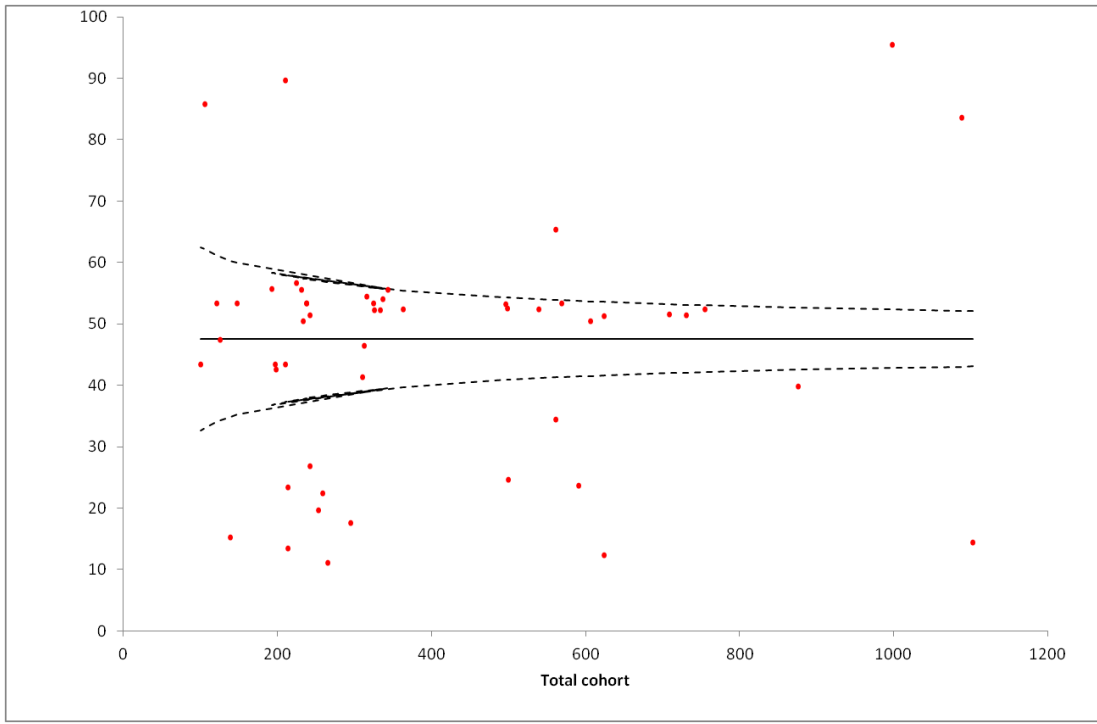
Indicator 5



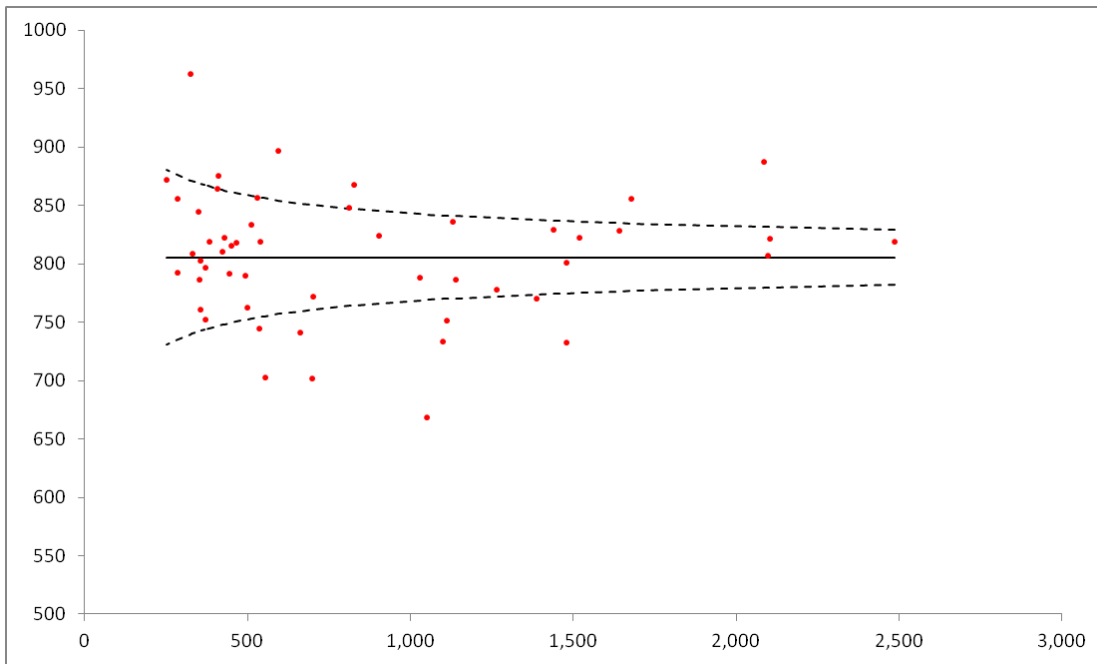
Indicator 6



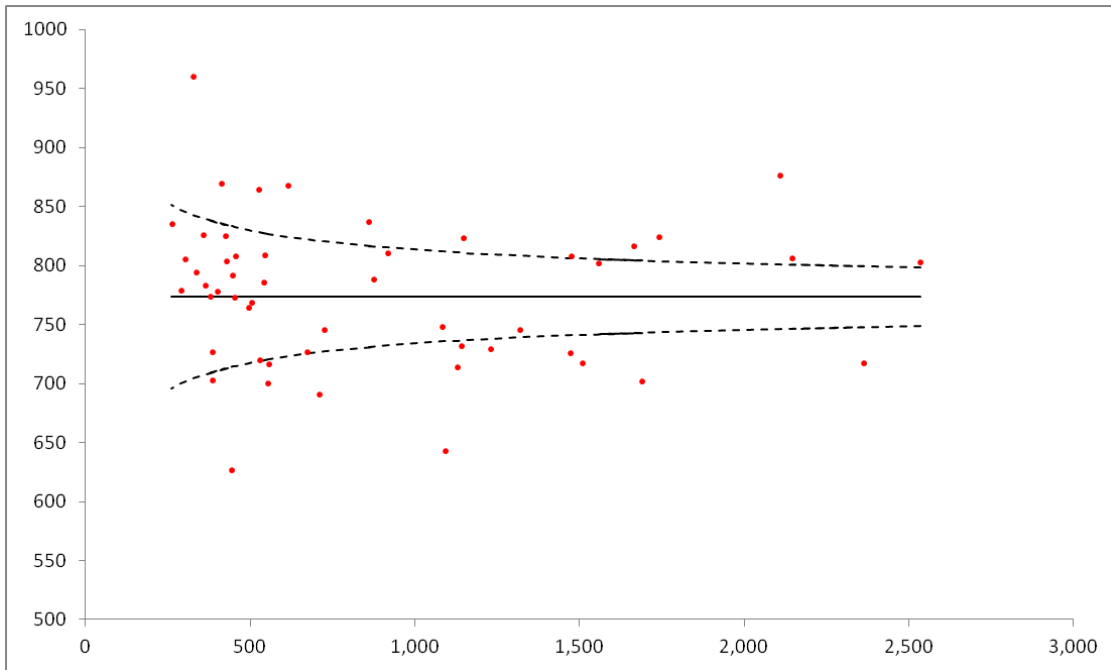
Indicator 7



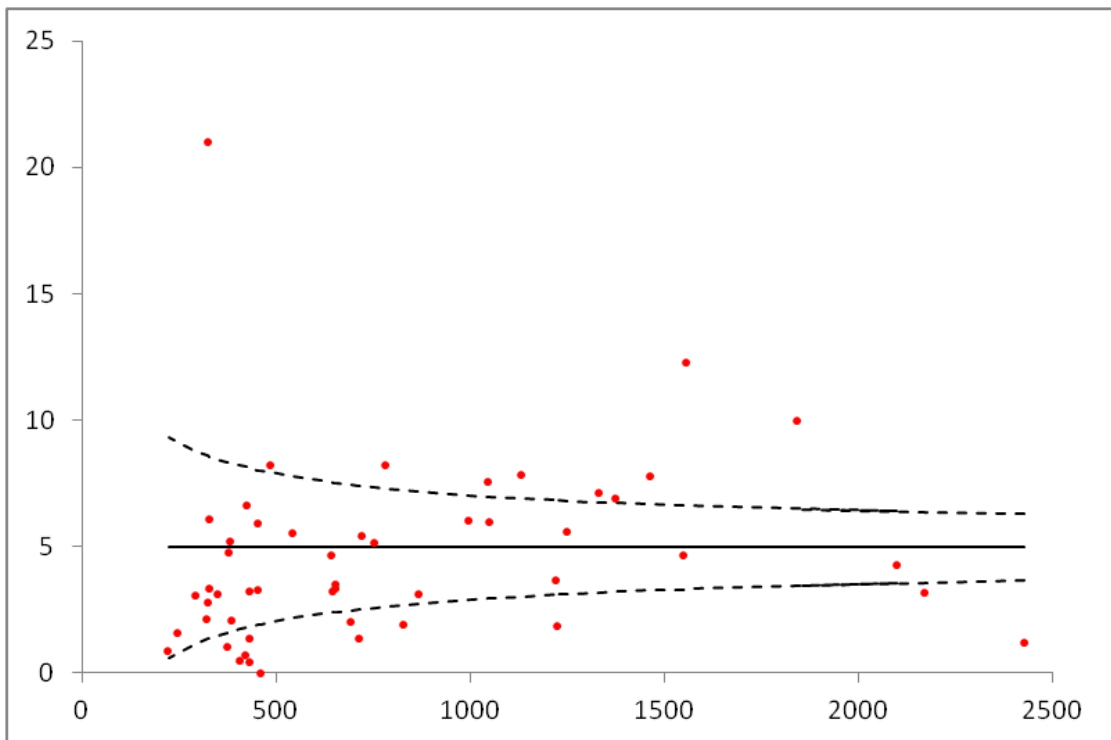
Indicator 8 (without exception reported patients within denominator population)



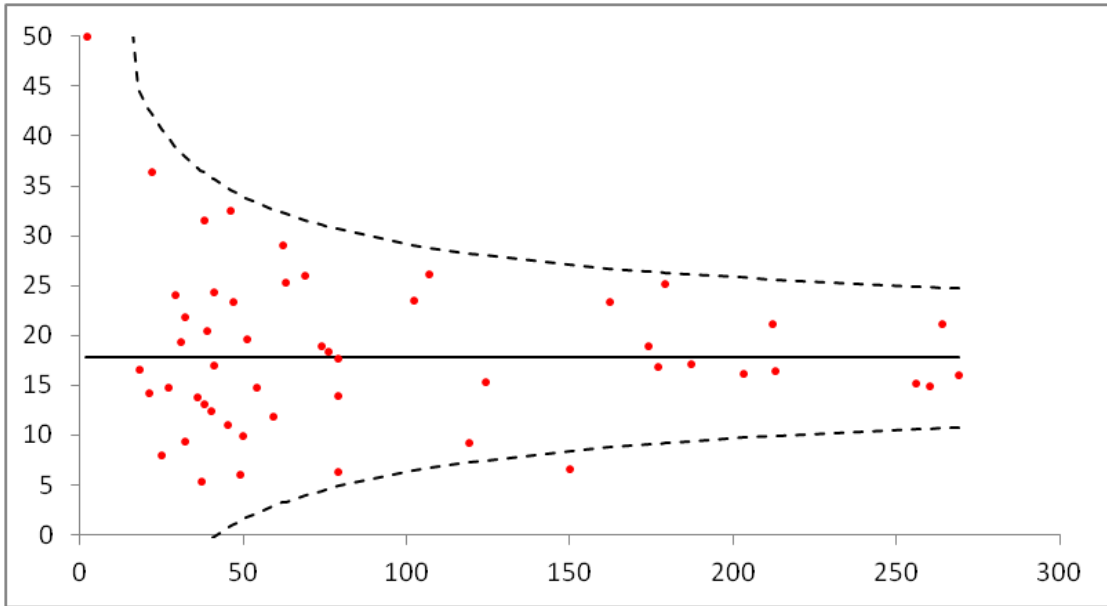
Indicator 8 (with exception reported patients within denominator population)



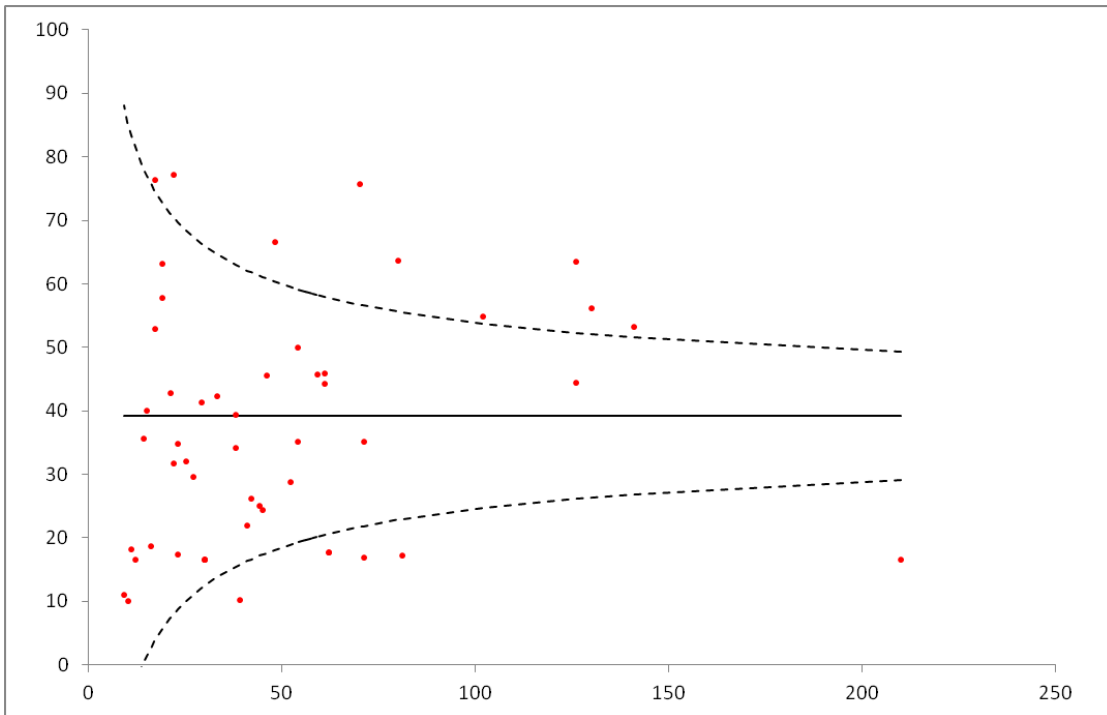
Indicator 9



Indicator 10



Indicator 11



Appendix 6: Published article - Practice-level quality improvement interventions in primary care: a review of systematic reviews

Published Article; Practice-level quality improvement interventions in primary care: a review of systematic reviews

Primary Health Care Research & Development

doi:10.1017/S1463423615000274

Volume 16, Issue 06, November 2015, pp 556-577

Ryan Irwin, Tim Stokes and Tom Marshall

Abstract

Aim: To present an overview of effective interventions for quality improvement in primary care at the practice level utilising existing systematic reviews.

Background: Quality improvement in primary care involves a range of approaches from system-level to patient-level improvement. One key setting in which quality improvement needs to occur is at the level of the basic unit of primary care: the individual general practice. There therefore is a need for practitioners to have access to an overview of the effectiveness of quality improvement interventions available in this setting.

Methods: *Design;* A tertiary evidence synthesis was conducted (a review of systematic reviews). A systematic approach was used to identify and summarise published literature relevant to understanding primary care quality improvement at the practice level. Quality assessment was via the Critical Appraisal Skills Programme (CASP) tool for systematic reviews, with data extraction identifying evidence of effect for examined interventions. *Scope;* Included reviews had to be relevant to quality improvement at the practice level and relevant to the UK primary care context. Reviews were excluded if describing system level interventions. *Outcome measures;* A range of measures across care structure, process and outcomes were defined and interpreted across the quality improvement interventions.

Findings: Audit and feedback, computerised advice, point of care reminders, practice facilitation, educational outreach, and processes for patient review and follow-up all demonstrated evidence of a quality improvement effect. Evidence of an improvement effect was higher where baseline performance was low and was particularly demonstrated across process measures and measures related to prescribing. Evidence was not sufficient to suggest multifaceted approaches were more effective than single interventions.

Conclusion: Evidence exists for a range of quality improvement interventions at the primary care practice level. More research is required to determine the use and impact of quality improvement interventions using theoretical frameworks and cost-effectiveness analysis.

Keywords: Primary care, quality improvement, systematic review.

How this fits in with Primary Health Care Research and Development:

What do we know? Evidence for the effect of quality improvement interventions exist across a range of healthcare settings and implementation levels; Quality improvement interventions can be successful in improving care structure, processes and outcomes.

What does this paper add? This paper reviews systematic reviews of quality improvement interventions specifically in primary care and specifically at the practice level, highlighting those interventions most likely to produce a positive quality improvement effect and the context in which this effect may be enhanced. For example, through recognising baseline performance and assessing improvement potential, planning quality improvement design and intervention selection and being aware of the improvement opportunity in targeting prescribing behaviours. The paper identifies areas for future research, such as the use of theoretical quality improvement frameworks and cost-effectiveness analysis in analysing primary care quality improvement interventions.

Background

Primary care occupies a significant and increasing role in healthcare in the UK and internationally. There is available research literature on quality improvement (QI) across a range of primary care settings and contexts and these include quality improvement at various levels of care: The individual patient level (e.g. patient self-care promotion), practitioner level (e.g. practitioner audit and feedback), practice level (e.g. practice-based patient review and recall), and the wider national and policy level (e.g. standard setting, accreditation development and financial incentives schemes such as the UK quality and outcomes framework)(Ferlie and Shortell, 2001). "Quality improvement" is a broad term with a number of different definitions and interpretations. With roots in the early work of W. Edwards Deming and Walter Shewhart in understanding variation, QI is usually described as a continuous effort to improve processes that includes identifying a problem, examining and applying solutions, and monitoring for improvement (Shewhart, 1931; Deming, 1982; Urowitz *et al*, 2006; Varkey *et al*, 2007).

This tertiary evidence synthesis (a review of systematic reviews) identifies and appraises primary care QI interventions relevant to UK primary care and other health systems at the *practice level*. For the purpose of the review, a "practice" is described as an organisation including a multidisciplinary primary care team of a single or multiple general practitioner(s), health professionals and administrative staff, often based within an ambulatory setting or environment and acting as a gatekeeper, central entry and co-ordination point for healthcare delivery (Moore *et al*, 2007). Given that systematic reviews usually focus on one type of intervention, there is an increasing need to carry out an overview, also termed a "review of reviews", of given topics to ensure all relevant systematic reviews are synthesised and presented in a form that is useful to health care practitioners and those delivering QI in routine clinical practice (Grimshaw *et al*, 2003). The specific objective of this review

of reviews was to examine and critically appraise the evidence relating to practice level primary care QI initiatives relevant to UK primary care.

Methods

This review was informed by available guidance on conducting systematic reviews of systematic reviews and particularly in the context of source identification, study selection, quality assessment, presentation of results and defining implications of research conducted (Smith *et al*, 2011).

Searches

A literature search of the following databases was performed: ATHENS, MEDLINE, EBSCO HOST, EMBASE, CINAHL, the University of Birmingham E-Library and the Cochrane Database (with date search discrimination of papers from June 1994 to June 2014). Use of specified databases was chosen based on reputation and the requirement to use two or more databases to provide a comprehensive search (Ayevard, 2008). In searching for appropriate literature, key terms related to the research objective were utilised. Key terms included examples such as: “quality improvement”, “variation”, “outcome improvement”, “performance improvement” and “practice improvement”. Using these key terms, related terms, Boolean and phrase searches to focus the search strategy and in using operators in between key words to combine them, enabled acquisition of literature through the use of databases and journal searching programmes. Where available for bespoke adaptation, electronic searches were targeted by specified inclusion criteria, search modes, expanders and limiters, for example, by ensuring returns of systematic reviews after application of limited publication dates and Boolean/phrase searches. The reference lists and bibliographies of included reviews were also searched for relevant reviews.

Table 1 details the number of results obtained from each database source after applying search criteria.

Selection of systematic reviews

At least two reviewers independently assessed the retrieved studies for inclusion against the inclusion and exclusion criteria and reached agreement through discussion.

Inclusion criteria

Selected studies had to satisfy the following criteria for inclusion based on examination of the full review text: Literature had to be a systematic review (using the key principles and characteristics of systematic reviews as defined by Hemingway and Brereton, 2009, Pp.1), including all relevant Cochrane Effective Practice and Organisation of Care Group (EPOC) reviews working to defined Cochrane review protocols (Cochrane Effective Practice and Organisation of Care Group, 2014); Literature had to be published after 1994 (representing a 20-year search span); Literature had to be relevant to the research questions and include QI and/or understanding variation as included and prioritised aspects of study; Literature had to be from the UK primary care setting and/or comparable first contact primary care settings elsewhere. These were defined through the three person author group as: The United Kingdom, Republic of Ireland, Netherlands, Finland, Denmark, Sweden, New Zealand, Norway, Spain, Italy and Portugal. This was based on criteria where a) Patients register with a practice which is their usual provider b) Strong gatekeeping exists i.e. Primary care is first point of contact and non-emergency access to secondary care is via primary care c) Primary care is delivered through a team rather than a physician alone d) Primary care is funded via a largely capitation based payment system (i.e. not fee for service); Finally, literature had to be focussed at primary care practice level or with QI interventions practically implementable at practice level.

Further verification of comparable primary care settings was cross-referenced through the following sources; The Health Systems and Policy Monitor, The Commonwealth Fund International Profiles of Health Care Systems and conference proceedings from the European Forum for Primary Care (European Forum for Primary Care, 2011; The Commonwealth Fund, 2012; European Observatory on

Health Systems and Policy, 2014). The qualification of countries representing primary care with relevance to the UK setting is provided, given that within different primary care settings present in international comparisons, variable factors such as payment method, financial incentives and features of the primary care system can have an impact on areas as diverse as resource utilisation, compliance, performance target improvement, quality and outcomes (Chaix-Courtier *et al*, 2000; Atun, 2004; Gosden *et al*, 2011).

Exclusion criteria

Reviews were excluded where the primary intervention or focus of research was on primary care funding, financing and regulatory change, due to these being influenced at the system as opposed to practice level. Reviews covering topics already examined through the Cochrane Effective Practice and Organisation of Care group were excluded and were often part of, or referenced within, EPOC review updates.

Assessment of quality

The lead author (RI) assessed the quality of each of the included systematic reviews using the Critical Appraisal Skills Programme (CASP) tool. The other two authors (TS, TM) independently assessed the quality of assessment of a sample of included studies. The CASP appraisal checklist for systematic reviews was selected for use in the defined literature review in order to provide an economical and structured approach to systematic review appraisal, where the widely recommended and reputable CASP tool in particular promotes understanding in review validity, meaning and applicability (CASP, 2013; McLean *et al*, 2013; Singh, 2013). Two systematic reviews were excluded after application of the CASP tool due to lack of clarity around defining a clear research question which resulted in interventions not easily categorised as QI interventions, and where the systematic review was not specifically focussed enough to be relevant to UK primary care at the practice level. Table 2 provides a summary of the application of the CASP checklist for systematic reviews included for full review.

Table 3 details the flow chart and results of papers included for the review after application of inclusion and exclusion criteria, quality check and CASP appraisal.

Data extraction

Data from included reviews was extracted by one author to record the author(s), date of publication, review purpose, QI intervention, review outcomes and review conclusions.

Data synthesis

The presented review of reviews is a tertiary level synthesis of secondary level data i.e. systematic reviews, which were analysed by the overall effect of the intervention examined within each review. The overall effect was determined in different ways across different systematic reviews, as can be seen in Table 4, by review author(s) adopting various quantitative (for example meta-analysis) or qualitative (for example meta-synthesis) methods for synthesising primary level data. The overall examined and reported intervention effect within each systematic review and author conclusions were used as the basis for assessing the intervention effect. Clearly evidence of overall QI intervention effect in systematic reviews is influenced by the number and quality of included primary level studies. However, whilst individual analysis of included studies within systematic reviews was not conducted in this review of reviews, quality assessment and application of the CASP tool for systematic review inclusion assessed the appropriateness and rigour of included studies within reviews. Randomised control trials (RCTs) were the most common study design present in systematic reviews, however, non-randomised controlled clinical trials (CCT), interrupted time series (ITS) and before and after (B/A) studies were also present.

Heterogeneity was present in included reviews across areas such as interventions applied, disease area and primary outcome measures and were not comparable in nature, therefore, purely quantitative statistical approaches to present findings was deemed not appropriate. Furthermore,

numerical and statistical values across both reviews and their included studies were not comparable, sample size discrimination was not always conducted and therefore the computation of standard error was deemed unfeasible. The included reviews were examined for whether the QI intervention applied demonstrated evidence of an effect for the intervention with reported confidence intervals where stated (Table 4). Further data synthesis occurred through examining QI intervention effect by outcome category (Table 5) and level of change using the framework produced by Ferlie and Shortell as summarised in Table 6 (Ferlie and Shortell, 2001). The Ferlie and Shortell framework was applied to further distinguish whether QI intervention effects were primarily conducted within, and influenced by, a specific level of change; For example, interventions applied at individual compared to team level within a practice setting.

A number of included systematic reviews made reference to QI strategies or multiple interventions as part of a wider QI programme. These reviews were analysed with single-intervention reviews as above and assessed for general themes, assessing any impact that individual interventions had within these combined QI strategies and approaches.

Results

A total of 31 systematic reviews were included for further assessment after application of the search strategy, application of inclusion criteria and full paper review. Eight systematic reviews were excluded through the three-person review group; Common reasons for exclusion included systematic reviews with a published date prior to 1994, reviews with a focus on primary care settings either not comparable to the UK setting (for example, research based exclusively in the United States) or not relevant to the practice setting, and reviews not clearly demonstrating a QI intervention.

Single interventions

The specific QI interventions reviewed that demonstrated strongest effect (whether on care structure, process or outcomes) included audit and feedback, point of care reminders, computerised advice, practice facilitation and interventions for evidence-based guideline adoption, adherence to clear practice structures and processes for patient review, continuing education and educational outreach, as presented in Tables 4 and 5 (Renders *et al*, 2000; Grimshaw *et al*, 2003; Holden *et al*, 2003; Fahey *et al*, 2005; O'Brien *et al*, 2007; Smith *et al*, 2007; De Belvis *et al*, 2009; Forsetlund *et al*, 2009; Shojania *et al*, 2009; Gallagher *et al*, 2010; Baskerville *et al*, 2012; Gillaizeau *et al*, 2012; Ivers *et al*, 2012; Lau *et al*, 2012; Smith *et al* 2012; Tricco *et al*, 2012). The evidence of effect for these interventions was also replicated in reviews of broader QI approaches comprising several interventions. For example, in their review of interventions for improving vaccination rates, Lau *et al* (2012) observe many of the described interventions (audit and feedback, point of care reminders and practice outreach) as having a particularly large individual and combined effect for improvements in disease-specific vaccination rates as measured through statistical analysis of odds ratios. Audit (whether individual, single practice or multi-practice), feedback and continuing education are cited as having the greatest direct effect on patient outcomes, with other interventions primarily affecting process improvement. Where baseline performance or achievement was low for the measured outcome, the resultant effect size was larger (Ivers *et al*, 2012). For those reviews which did not measure outcomes directly, it must be recognised that care structure and process improvement can also be correlated with improved outcomes (The King's Fund, 2012).

In categorising evidence of QI effect against three outcome areas of process improvement/ adherence with desired practice, improvement in physiological/ biological outcomes and other patient outcomes, QI intervention effect was more consistently successful in improving process and/or adherence with desired practice compared to other outcomes. However, it must be stated that categorisation of outcomes in this way is not necessarily sensitive or scientific enough to draw conclusions on QI success across these areas.

Prescribing

A number of reviews sought to improve prescribing or prescribing behaviour as the key outcome. Ivers *et al* (2012: 10) describe prescribing behaviours as; "*important but not complex*". Of those reviews aiming to affect prescribing behaviour, point of care reminders, computerised advice and educational outreach visits had the greatest impact (O'Brien *et al*, 2007; Shojania *et al*, 2009; Gillaizeau *et al*, 2012). There was also evidence that QI interventions produced improvements in prescribing that were greater than the effects from other measured outcomes, such as patient-level physical and mental health outcomes (Smith *et al*, 2007; Smith *et al*, 2012). In these cases, QI interventions that affected prescribing behaviour and practice were more effective than other interventions and particularly when the intention was to improve care for patients with multi-morbidity, where disease management above improving prescribing behaviour may be more complex (Smith *et al*, 2007; Ivers *et al*, 2012; Smith *et al*, 2012). The effects on noted QI interventions for prescribing also produced improvement across a range of prescribing-related outcomes, from increased appropriate prescribing volume, improved prescribing compliance, improved prescribing accuracy and dosage, and reduced adverse prescribing incidents (O'Brien *et al*, 2007; Smith *et al*, 2007; Shojania *et al*, 2009; Gillaizeau *et al*, 2012; Ivers *et al*, 2012; Smith *et al*, 2012).

Multi-faceted interventions

A number of reviews looked at combined or multi-faceted interventions (defined as more than one intervention) as part of a QI approach, where multi-faceted interventions were sometimes used as comparative arms to single-intervention systematic reviews. The effects on outcomes of multi-faceted interventions was seen across a range of review areas, from condition-specific reviews, such as multi-faceted interventions for primary care management of diabetes, to single measurement areas, such as reductions in hypertension (Renders *et al*, 2000; Fahey *et al*, 2005; O'Brien *et al*, 2007; De Belvis *et al*, 2009; Baskerville *et al*, 2012; Ivers *et al*, 2012). Multi-faceted interventions achieved

positive outcomes compared to no intervention or single-intervention in both single practice and multiple-practice QI initiatives (Renders *et al*, 2000; Fahey *et al*, 2005; O'Brien *et al*, 2007; De Belvis *et al*, 2009; Baskerville *et al*, 2012; Ivers *et al*, 2012). Hulscher *et al* (1999) provide one sensible hypothesis for explaining the multifaceted effect applied to primary and preventive care, stating that the high number of influencing factors involved in this care area are more likely to be affected by a greater number of interventions. Table 7 summarises the impact of multifaceted interventions by included systematic review. In one review, however, completed by Shojania *et al* (2009), examining point-of-care reminders and other interventions, single interventions realised a higher median improvement compared to multifaceted interventions and previous authors have also indicated no significant effect of multi-faceted approaches to QI through guideline dissemination (Grimshaw *et al*, 2004; Squires *et al*, 2014). For these reasons, the evidence is not conclusive to suggest multifaceted approaches are more effective than single interventions.

Organisational level interventions

Reviews by Fahey *et al* (2005) and Rhydderch *et al* (2005) focussed their aims on organisational elements of QI in primary care with some important findings. On QI intervention at the organisational level, Fahey *et al* (2005) observe that QI programmes addressing primary care structure, management, organisation and systematic process implementation had a statistically significant effect on blood pressure control and hypertension outcomes. Particularly referenced is the "Hypertension detection and follow-up programme", which, whilst based on some data from trials over 20 years old, demonstrated that organisation-focussed QI intervention that included hypertension detection and regular review, including addressing medication adherence and blood pressure goal achievement, had a significant impact on hypertension outcomes (Davis and Ford, 2001). Hulscher *et al* (1999) also cite organisational patient identification and follow-up referral as an effective strategy for included reviews which focus on screening and referral for breast and cervical

cancer and alcohol-related problems. The authors additionally note from an included study that when targeting health promotion behaviour change, extended length of GP appointment by just over one minute (7.16 minutes in control versus 8.25 minutes in intervention arm), meant GPs were more likely to offer screening and provide or elaborate on health promotion advice that could have a positive impact on disease outcomes.

Ferlie and Shortell (2001) cite four levels of change for improving quality of healthcare, namely, QI at the individual, group/team, organisation and system/environment level and reference to this framework in the current review was made when analysing results, whilst recognising the exclusion of system level QI interventions for the present review. Comparing the different levels of QI intervention from individual to organisational level, all levels contained a mixture of evidence for an effect and evidence of no effect, whether relating to care structure, process or outcomes. In this respect, it did not appear immediately apparent that any single level of intervention realised greater QI outcomes than another.

Discussion

Summary of findings

Audit and feedback, point of care reminders, computerised advice, practice facilitation and interventions for evidence-based guideline adoption, adherence to clear practice structures and processes for patient review, continuing education and educational outreach all demonstrated evidence of quality improvement effect. Wider QI strategies, which included these interventions, such as clinical practice guideline implementation strategies, also demonstrated evidence of effect (Grimshaw *et al*, 2004). The evidence of an effect for quality improvement was higher where baseline performance was low. Prescribing was a healthcare process commonly targeted and improved by QI interventions. Multi-faceted interventions achieved positive outcomes compared to no intervention across a range of disease areas in both single practice and multiple-practice QI initiatives. However,

this finding was not present in the review conducted by Shojania *et al* (2009) and has not been replicated in the wider literature reviewed here (Grimshaw *et al*, 2004). We also note that a recent review of reviews addressing this question also concluded that there is no compelling evidence that multifaceted interventions are more effective than single-component interventions in affecting healthcare professional behaviours (Squires *et al*, 2014). The reason for this may be because multifaceted interventions are usually adopted when there is a need to affect change for an outcome or outcomes which are inherently more difficult to improve (Shojania *et al*, 2009). Equally, in examining literature around the impact of multifaceted interventions, the primary outcome measure is important. In this review, multifaceted interventions predominantly aimed to affect change through structured QI programmes or QI interventions aimed at whole care areas and appeared to show a positive effect of multifaceted approaches compared to no intervention or single intervention. This is compared to other available literature using multifaceted approaches to affect individual healthcare professional behaviour change or compliance to practice which appears to demonstrate multifaceted interventions are no more effective than single interventions (Grimshaw *et al*, 2004; Squires *et al*, 2014). Recognising this, from the reviews examined, multi-faceted approaches delivered measured quality improvements across a range of research areas and outcomes and could lead to greater compounded gains when implemented successfully. It must be noted that challenges also exist in discriminating multifaceted interventions from single interventions (for example, where interventions such as educational outreach are inherently multifaceted).

Other areas of the literature review demonstrated considerations around QI programmes or interventions that showed negative findings, little or no effect of QI interventions. Both of the examples relating to role substitution (for example, between doctors and nurses) demonstrated relatively weak evidence for any impact on improved outcomes (Thompson *et al*, 2003; Royal *et al*, 2006). In examining all reviews, there were also less clear impacts of QI initiatives on areas like mortality and morbidity, but this was mostly due to lack of appropriate follow-up or indeed primary

measure of these areas (Thompson *et al*, 2003; Royal *et al*, 2006). In respect of this, it is important not to discount QI interventions as having an effect on morbidity and mortality outcomes, where the wider literature highlights a relationship here, particularly in showing that QI for effective prescribing and drug treatment has a clear impact on mortality and morbidity (Turnbull, 2003; Fahey *et al*, 2005). Smith *et al* (2012) also found mixed effects of interventions (most commonly care co-ordination and enhanced multidisciplinary team care approaches) for improving outcomes related to multimorbidity; Other than an indication of improved prescribing, medication adherence and patient satisfaction following intervention, there was mixed evidence that interventions had effects on a wider range of patient health, care utilisation and patient behaviours.

Strengths and limitations of this study

A key strength of this review and the methodology adopted is that it allows the findings of individual systematic reviews on quality improvement interventions in general practice to be compared, contrasted and summarised (Smith *et al*, 2011). We also sought to ensure relevance by explicitly identifying quality improvement research in primary health care settings where first contact primary care is the norm, such as UK primary care. As a consequence, some potentially relevant systematic reviews which did not meet this criteria were excluded (e.g. reviews exclusively including studies set in the United States). The justification provided for this inclusion criteria is that it may be difficult to draw firm conclusions regarding QI intervention impact from other primary care settings that could be influenced by significant external factors, such as the political, regulatory or other contexts that primary care operates within (Chaix-Courtier *et al*, 2000; Atun, 2004; Gosden *et al*, 2011).

Additionally there are other considerations to note, where the variation in primary care delivery in the United States, for example, makes differentiation of a first contact primary care research setting difficult to identify. For example, where primary care operates within an accountable care system, purely corporate arena, demographically biased insurance market, or other contexts (Starfield *et al*,

2005; Kringos *et al*, 2010). It is suggested however that review findings are still likely to be relevant to those operating in other primary care settings for two reasons. Firstly, due to research summaries and systematic reviews from other settings, for example the United States and Australia, identifying and promoting similar improvement effects for the key QI interventions examined, such as audit and feedback, practice facilitation and point of care reminders (Garg *et al*, 2005; Taylor *et al*, 2014). Secondly, that whilst reviews *exclusively* from settings outside the defined inclusion criteria were excluded, many reviews included contained a mix of research settings, including those such as North America and Australasia. One of the key limitations to this study is the possibility of omission of QI research that was not captured through the targeted search strategy, however, a broad search strategy was deployed which generated a high number of systematic reviews in primary care which were subsequently reviewed for relevance to primary care quality improvement. A potential limitation also arises where the same individual study or studies could be included in more than one review. Whilst this is possible given the high total number of overall studies, it was not felt the impact of this would be significant based on assessing the occurrence of this in reviews of similar topics. The systematic reviews included were analysed as the unit of analysis and therefore lack of primary study applicability within reviews to UK primary care could be seen as a limitation of the review. In terms of the methodological quality of the review of reviews it is noted that we did not rigorously apply dual author study appraisal and data extraction. The fact that a single author led on these steps may have introduced bias, although we attempted to minimise these by ensuring the other two authors quality assured the appraisal process.

Other considerations

Financial and economic considerations

From an economic and financial analysis perspective, cost-effectiveness was not explored in the current review and this is primarily because, as is common in QI literature, data around cost and

cost-effectiveness was lacking and limited to evaluation of specific areas identified under health technology assessment as opposed to QI initiatives (NHS Quality Improvement Scotland, 2009). For the included reviews, whilst cost effectiveness analysis was limited, for reviews which do make reference to cost-effectiveness, the impact was either cost neutral or cost saving compared to usual care; However, it must be stated that comprehensive cost-effectiveness analysis was not completed and usually based on a small number of studies (Thompson *et al*, 2003; O'Brien *et al*, 2007; Gillaizeau *et al*, 2012). Furthermore, some authors comment that cost-effectiveness is highly dependent on the manner in which a QI intervention is delivered and the variation present in this respect could be difficult to examine (Thompson *et al*, 2003; O'Brien *et al*, 2007; Gillaizeau *et al*, 2012).

The importance of cost-effectiveness, whilst not examined in this review, is recognised as central to supporting effective decision-making for the health economy in application of health research.

Implementation and change science and theory

Other combined areas of importance not specifically explored or indeed present in included reviews is that of theoretical and scientific perspectives of and on change, implementation science, knowledge translation and addressing barriers to change in quality improvement. Groh *et al* (2007) describe the importance of using theoretical and scientific perspectives in planning and studying improvement in patient care. Within their paper the authors describe the complexity of healthcare and indeed, QI in healthcare, that is influenced by contextual factors not always considered in healthcare improvement interventions which typically target individual professionals as opposed to the wider, complex environment of change. The authors argue for an increasing need for improvement research to use theoretical perspectives to plan and study for improvement that helps create understanding of the obstacles, success criteria and incentives of change in the healthcare setting (Groh *et al*, 2007). The authors continue to comprehensively review the range of impact and process theories present in change implementation (summarised in table 8), stating that whilst no

single theoretical framework appears superior, evidence exists for their use and application depending on the change intervention, and therefore these frameworks should be applied to improve QI understanding and implementation (Grol *et al*, 2007). Furthermore, there is a large and growing body of research that suggests implementation of improvement initiatives is as important as the evidence-based QI initiative itself (Cheater *et al*, 2009; May *et al*, 2009; Dixon-Woods *et al*, 2011).

Sustainability

As a final note on implementation, the topic of sustainability deserves attention. Keller and Aiken (2009) note that one of the key problems in QI and change management is that of sustainability and draw attention to the findings by John Kotter in 1995 that change programmes typically only have around a 30% success rate; A rate which was mirrored in examining the change programmes of a large, global management consultancy firm in 2008 (Keller and Aiken, 2009). Among the reasons for lack of sustainability, areas such as leadership commitment, organisational capacity and capability, reinforcement and motivational alignment are cited (Keller and Aiken, 2009). Models for improving sustainability exist, however the application of theoretical frameworks in this context is further underlined to understand the issues surrounding sustainability (Feldstein and Glasgow, 2008).

Related to this, two areas perhaps most closely related to organisational QI that are interestingly absent from the literature review are features of leadership and the role of leaders in creating a QI culture. In their paper around improving quality of healthcare in the UK and in previously referencing and utilising their levels of change for quality improvement, Ferlie and Shortell (2001) discuss leadership and culture extensively in relationship to quality improvement. Leadership may not necessarily present as an individual, but may take the form of network or group leadership, including clinical leadership and is cited as being of central importance in creating and working within a culture that facilitates QI through learning, collaboration and a patient-focus (Ferlie and Shortell, 2001). It

may be perhaps the conceptual levels of terms such as leadership and culture that create their absence in literature which is biased to discussing clinical QI interventions.

Implications for policy and practice

The review of reviews presented has many potential implications for policy and practice. Most notably, highlighting key interventions that may be most suitable for designing QI interventions in primary care at the practice level including audit and feedback, point of care reminders, computerised advice, practice facilitation and interventions for evidence-based guideline adoption, adherence to clear practice structures and processes for patient review, continuing education and educational outreach. Development of QI interventions should recognise a larger improvement opportunity may exist where baseline performance is low. Clinicians and non-clinicians alike involved in QI at the primary care practice level should also recognise the importance of effective QI implementation in parallel with evidence-based interventions , evaluating any QI approaches through a clear framework to support future learning and development.

Areas for future research

Areas for future research identified within the review process were identified as the following;

- Understanding the role of group/team development in primary care quality improvement
- Understanding the evidence base around leadership and culture in primary care development; Exploring the types and impact of leadership and culture
- Understanding the cost-effectiveness of quality improvement interventions in primary care
- Identifying the characteristics of successful quality improvement in primary care and successful practices in terms of quality outcomes
- Identifying the common barriers to change in primary care quality improvement
- Evaluating the impact of primary care quality improvement interventions using theoretical frameworks

Conclusion

There is evidence of effectiveness for a range of primary care quality improvement initiatives relevant to UK primary care at the practice level. Particularly effective interventions include audit and feedback, point of care reminders (computerised and other), practice facilitation and interventions for evidence-based guideline adoption, adherence to clear practice structures and processes for patient review, continuing education and educational outreach.

Multifaceted interventions and interventions aiming to affect prescribing practice appear particularly successful and QI implementers can enhance success through focussing on effective QI implementation, addressing barriers to change, whilst recognising that QI will be more effective when baseline performance is low.

More research is required to determine the use and impact of quality improvement interventions using theoretical frameworks and cost-effectiveness analysis.

Ethical Approval

Ethics committee approval was not required for this review.

Declaration of competing interests and conflict of interest

No competing interests or conflicts of interest declared

Disclaimer

The first and corresponding author is funded by the National Institute for Health Research School for Primary Care Research (NIHR SPCR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health. The NIHR SPCR is a partnership between the Universities of Birmingham, Bristol, Keele, Manchester, Nottingham, Oxford, Southampton and University College London.

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