

Meeting the physical health needs of people with
serious mental illness in primary care

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Abstract

Background

People with serious mental illness (SMI) die 15-20 years earlier than the general population, principally from cardiovascular and respiratory disease. Under-recognition and under-treatment of the physical health needs of people with SMI is one of the biggest health inequalities in England. Despite growing policy attention, evidence suggests the mortality gap between people with and without SMI is widening. This thesis aimed to enhance understanding about factors affecting the quality of primary care for people with SMI.

Methods

Mixed methods. Qualitative: thematic analysis of semi-structured interviews provided new insights from patients and practitioners on the quality of primary care. Quantitative: a difference-in-differences approach used to estimate the effect of removal of financial incentives on the proportion of patients who had physical health checks (blood pressure/BMI/cholesterol/glucose) recorded in primary care. Using a process of triangulation, findings from contrasting paradigms were synthesised.

Results

Qualitative study: quality of care for people with SMI is inadequate. Patient and practitioner aspirations for continuity and patient-centred care, increasingly undermined by new models of care delivery; Quality and Outcomes Framework (QOF) regarded as having been detrimental by prioritising a biomedical box ticking agenda in favour of holistic care; and a breakdown in communication between primary care and mental health services further eroded quality of care. Quantitative study: each difference-in-differences estimate for indicators where financial incentives were removed, compared with blood pressure which remained incentivised, indicated a significant decrease ($p < 0.01$) in the proportion of patients with health checks recorded: BMI (-14.6%), cholesterol (-9.8%) and glucose (-8.8%).

Conclusion

Despite growing interest in addressing the mortality gap, policy has focused on a biomedical approach in attempts to extend life expectancy, at the expense of addressing what matters to patients: being able to enhance their daily functioning and quality of life, to enable them to live better with their condition.

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Declaration

I declare that this thesis is a presentation of original work and I am the sole author. This work has not previously been presented for an award at this, or any other, University. All sources are acknowledged as References.

I have presented aspects of this work at a number of conferences and forums – see overleaf.

Presentations

- Society of Academic Primary Care annual scientific meeting, the Barbican Centre, London, 11-12th July 2018
- Primary Care Mental Health conference, University of Manchester, Manchester, 23rd May 2019 (award winning abstract)
- Society of Academic Primary Care annual scientific meeting, University of Exeter, 3-5th July 2019
- World Psychiatric Association, World Congress of Psychiatry, Lisbon, 21-24th August 2019
- Society of Academic Primary Care annual scientific meeting, University of Leeds, 15-17th July 2020 (abstract accepted but event postponed until 2021 due to Coronavirus)

Forums

- Mental Health Research Roundtable with Minister of Health, Greg Hunt, Parliament House, Canberra, 5th March 2018
- Primary Care Forum, University of New South Wales, Sydney, 7th March 2018 (keynote speaker)

Thesis structure

Chapter One introduces the thesis and provides evidence of the poor physical health and reduced life expectancy faced by people with serious mental illness (SMI).

Chapter Two sets out the context for the qualitative and quantitative research studies, the two core components of this thesis, by discussing existing literature on the effects of financial incentive schemes in primary care. The chapter concludes by defining the aims and objectives of the thesis.

Chapter Three discusses the research methodology and the contrasting philosophical underpinnings of the different paradigms selected for the mixed methods approach adopted for this thesis.

Chapter Four describes the methods used to carry out the qualitative study and considers the strengths and limitations.

Chapter Five presents the results from the qualitative study, which explored patient and practitioner perspectives on factors believed to enhance or erode the quality of primary care.

Chapter Six describes the methods used to carry out the quantitative study and considers the strengths and limitations.

Chapter Seven presents the results from the quantitative study, which examined electronic health records data to estimate the effect that removal of financial incentives had on the proportion of patients who received a physical health check.

Chapter Eight summarises what the research found and discusses what the findings mean in the context of existing literature. It presents the strengths and limitations specific to this thesis and synthesises findings from the contrasting paradigms. The chapter then considers the implications of this thesis for policy; clinical practice; and future research.

Chapter One: Introduction

1.1 Chapter content

This chapter provides the context for the thesis. It begins by summarising the characteristics and epidemiology of schizophrenia and bipolar disorder, the two psychiatric conditions central to the research. It then provides background information on the poor physical health and reduced life expectancy associated with serious mental illness. The chapter goes on to summarise policy attempts to reduce the mortality gap, highlighting the need for further research to provide new insights into how to better meet the physical health needs of people with serious mental illness.

1.2 Serious mental illness

The term ‘serious mental illness’ (SMI) – also known as ‘severe mental illness’ or ‘severe mental disorder’ – is used in the scientific literature to refer to a group of serious, and typically enduring, mental health conditions. SMI refers principally to schizophrenia and bipolar disorder but includes other non-organic psychoses such as schizoaffective disorder and psychotic depression (Keeley et al., 2015, NHS England, 2018a). Whilst it is recognised that SMI encompasses several other conditions, this thesis focuses on schizophrenia and bipolar disorder. Hence, from now on the term SMI refers to people with schizophrenia or bipolar disorder, unless otherwise specified.

1.2.1 Diagnostic criteria

The two diagnostic classification systems most commonly used in psychiatry are the World Health Organisation’s International Classification of Disease, 10th revision (ICD-10) and the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) (American Psychiatric Association, World Health Organization). Both diagnostic classification systems share similar definitions for schizophrenia and for bipolar disorder.

Schizophrenia is a condition characterised by: positive symptoms (also known as psychotic symptoms) which include disturbed thoughts, hallucinations, delusions; and negative symptoms such as social withdrawal and neglect of daily routine (Saha et al., 2005). Bipolar disorder, formerly known as manic depression, is a severe mood disorder characterised by extreme highs (known as mania) as well as periods of extreme lows, marked by depressive symptoms (Rowland and Marwaha, 2018). Typically, people with bipolar disorder experience periods of stable mood between episodes.

Both these conditions profoundly impair a person's level of functioning and negatively impact on quality of life. Although people can 'recover' to some extent, and regain aspects of functioning they had lost, they cannot be 'cured' and many endure substantial disruption across the life course (Ruggeri, 2000).

1.2.2 Epidemiology

The aetiology of serious mental illnesses is uncertain and multifactorial (Addington et al., 2018). For both schizophrenia and bipolar disorder onset is attributable to a complex array of risk factors rather than being determined by a single cause (Rowland and Marwaha, 2018). Furthermore, evidence suggests that interaction between multiple risk factors substantially increases the likelihood of a person developing a serious mental illness, although knowledge of which combinations of factors present the highest risk is limited (Zammit et al., 2010). At present, there are a number of known biological, socioeconomic and environmental risk factors, including: genetics, age, gender, ethnicity, deprivation level, traumatic life experiences, living in an urban area, and social isolation (Kirkbride et al., 2012). Moreover, evidence suggests that living in areas characterised by social fragmentation increases the risk of serious mental illness independent of deprivation or urban/rural status (Allardyce et al., 2005).

Schizophrenia

Lifetime prevalence of schizophrenia is approximately 1 per cent of the population (McGrath et al., 2008) coupled with a relatively stable incidence over time (Kirkbride et al., 2012). Men tend to have earlier onset of schizophrenia, typically between the ages of 15-25 years (Häfner et al., 1993) and men also have a higher incidence (Ochoa et al., 2012). Furthermore, schizophrenia appears to be more common in urbanised areas and among migrant populations (McGrath et al., 2004).

Bipolar disorder

Lifetime prevalence of bipolar disorder is around 1 to 1.5 percent of the population (Bebbington and Ramana, 1995). Incidence has increased slightly following the inclusion of bipolar II to the DSM-IV (Ferrari et al., 2016). Bipolar II is a less severe form of the condition on the bipolar disorder spectrum, for individuals who have never experienced a full blown manic episode (American Psychiatric Association, 1994). Typically women have an increased risk of bipolar II though gender ratios for bipolar disorder are relatively equal (Diflorio and Jones, 2010). As with schizophrenia, men appear to have an earlier onset of bipolar disorder (Kennedy et al., 2005) although evidence suggests that there are two peaks when men and women are more likely to present with bipolar disorder: during early adulthood (15-24 years) or later in life (45-54 years) (Kroon et al., 2013).

1.3 Health inequalities

Evidence of a 15-20 years mortality gap across the developed world suggests that men with SMI tend to die 20 years earlier, and women 15 years earlier, than those without SMI (Thorncroft, 2011). This is one of the biggest health inequalities of the modern era with the mortality gap for SMI far exceeding those attributed to smoking or type 2 diabetes (Chang et al., 2011). Moreover, the early deaths are predominantly attributable to common physical health conditions such as cardiovascular and respiratory disease (Correll et al., 2017), which tend to be managed better in people without SMI (Osborn et al., 2011). Furthermore, evidence suggests the health inequalities are more pronounced at younger ages, so that the relative risk of an individual with SMI developing diabetes or COPD is far greater when they are younger than when they are older where the difference in risk level between those with and those without SMI narrows (Public Health England, 2018).

The reasons why people with SMI have a shorter life expectancy than the average person are complex and multifactorial, which may explain why the mortality gap has proved difficult to address. Health inequalities are deeply rooted in the fabric of society and underpinned by numerous socioeconomic and environmental factors. Consequently, people with SMI tend to face multiple challenges to stay healthy and carry an increased risk of developing common physical conditions such as heart disease and diabetes (Pearsall et al., 2014, Osborn et al., 2011). They often have higher levels of health need than the average person but poorer access to health services (Robson and Gray, 2007). They are less likely to seek help; to have their health needs met; or to be targeted for health promotion activities such as smoking cessation (Connell et al., 2012).

The risk of premature death among people with SMI is increased by unhealthy diets, physical inactivity and addictive behaviours such as smoking, alcohol and substance misuse (Reilly et al., 2015, Lester et al., 2010). The physical health of people with SMI is further burdened by adverse metabolic effects and weight gain caused by psychotropic medication, principally from anti-psychotics (De Hert et al., 2011). In addition, people with SMI are likely to be subjected to the largely unknown effects of polypharmacy and interactions from medications prescribed to treat physical health comorbidities and/or multiple types of psychotropic drugs (RCPSYCH, 2015a, RCPSYCH, 2015b).

People with SMI face additional challenges looking after their physical health due to aspects relating to their mental health which may include self-neglect, lack of motivation and difficulty communicating their health needs (Kirkbride et al., 2012, Lawrence and Kisely, 2010). Added to this are structural socio-economic inequalities, often marked by poor housing and living conditions, social isolation and exclusion, poverty and unemployment (Luciano and Meara, 2014).

1.4 Mortality gap: ‘lethal discrimination’

The mortality gap persists despite having been targeted by a number of policy initiatives over recent years such as the Quality and Outcomes Framework (NHS Employers), Parity of Esteem (Davies, 2014), the Five Year Forward View (NHS England et al., 2014), the Five Year Forward View for Mental Health (The Mental Health Taskforce, 2016) and the NHS Long Term Plan (NHS, 2019). Indeed, evidence suggests the mortality gap is widening rather than narrowing (Lomholt et al., 2019, Hayes et al., 2017, Saha et al., 2007). This implies that existing policy attempts to address the inequality have thus far been ineffective at closing the mortality gap.

Evidence that people with SMI die at younger ages than people without SMI from the same types of physical health conditions, such as lung and heart disease, is a huge social injustice and one of the biggest health inequalities in England (NHS England, 2014a, Yeomans et al., 2014, NHS England, 2014b, RCPSYCH, 2013). It is unacceptable that in high income countries such as the UK, the life expectancy of people with SMI is equivalent to the average adult in the 1950s (Public Health England, 2019). This inequality has been categorised as an issue of human rights (Lawrence and Kisely, 2010) and labelled as ‘lethal discrimination’ (Thornicroft, 2013: online).

1.5 Gaps in knowledge

Even though the problem of premature mortality is well recognised and has become topical, there seems to be uncertainty about how to tackle it effectively. Evidence the mortality gap is widening underscores the need for critical appraisal of existing evidence and further research about how to better address the problem. Efforts to improve the physical health of people with SMI include the Lester Tool (Shiers et al., 2014) designed to optimise the conduct of physical health checks for people with SMI and reports by royal colleges and faculties (RCPSYCH, 2016). In addition, an expanding scientific literature includes systematic reviews and meta-analyses of physical activity interventions (Rosenbaum et al., 2014) and the effect of exercise on sleep (Lederman et al., 2019), as well as a number of randomised controlled trials on modifiable risk factors such as smoking and cardiovascular disease (Gilbody et al., 2019, Osborn et al., 2018). The Lancet Psychiatry Commission’s recent ‘blueprint’ for protecting physical health in people with mental illness (Firth et al., 2019a) further demonstrates a building of momentum in attempts to address the health inequalities. Much of this activity, however, has focused on interventions to support health promotion for SMI through behaviour change such as giving up smoking, which focuses on the individual and may have limited reach. Moreover, evidence on the effectiveness of interventions targeted at improving physical health outcomes of people with SMI remains limited (Vancampfort et al., 2019).

So far, little is known about system level solutions that may enhance quality of care and improve the physical health of people with SMI at the population level, thereby reducing the risk of premature mortality. To expand understanding about other factors underpinning the mortality gap, in addition to risky behaviours such as smoking and a sedentary lifestyle, it is timely to explore the perspectives of people with lived experience of managing SMI, by speaking to patients and practitioners about what factor enhance or erode the quality of primary care: to provide insight into what is happening in practice. This should provide pointers and new evidence from a different angle on how to address the mortality gap and improve both the quality and longevity of life for people with SMI.

1.6 Rationale for this thesis

The management of serious mental illness is conducted principally within primary care and specialist secondary care mental health settings. Typically, it is primary care where people with SMI have most of their physical health needs met (Planner et al., 2014) – regarded as the cornerstone of healthcare for people with SMI (Lester et al., 2005) – and secondary care where their mental health needs are addressed. However, both care settings have responsibilities for monitoring the physical health of people with SMI as those that are more difficult to manage are monitored in secondary care until their condition has stabilised when their care is transferred to primary care (NICE, 2018).. Primary care thus has the substantive responsibility for meeting the physical health needs of people with SMI: indeed, up to 30 per cent of SMI patients in the UK are seen only in the primary care setting (Reilly et al., 2012). Consequently, primary care has a pivotal role in addressing the mortality gap, which accounts for why both of the research studies conducted for this thesis are based in the primary care setting. Following on from this introduction, Chapter Two sets out the context for the qualitative and quantitative research studies, the two core components of this thesis, by discussing existing literature on the effects of financial incentive schemes in primary care. It also defines the aims and objectives of the thesis.

Chapter Two: Financial Incentives in Primary Care

2.1 Chapter content

This chapter provides background to the qualitative and quantitative research studies conducted for this thesis by exploring evidence on the effects of pay-for-performance in primary care. It begins by outlining the historical context and development of financial incentives in general practice before focusing on the Quality and Outcomes Framework (QOF), which was introduced nationwide across the UK in 2004. It goes on to critically examine evidence on the effectiveness of QOF with reference to a selection of primary research studies and systematic reviews. A scarcity of evidence on the impact of QOF financial incentives on the quality of care for people with serious mental illness underpins the rationale for the thesis. The chapter concludes by defining the aims and objectives of the thesis.

2.2 Overview of financial incentives

The origins of financial incentive schemes stem from a social sciences behavioural economics paradigm, drawing on aspects of psychology and economics to influence human behaviour (Vlaev et al., 2019). Widely used across a range of industries in the private and public sector, financial incentives have, in recent decades, become increasingly popular amongst health policymakers as a tool to promote quality improvement (Roland and Olesen, 2016). Also termed pay-for-performance the intent of financial incentives is to motivate behaviour change (Michie and West, 2013). In the context of healthcare, the intended outcome is either to improve the quality of care by motivating practitioners to change their actions and/or meet targets (Conrad and Perry, 2009), or by rewarding patients to adopt healthier behaviours (Marteau et al., 2009). Given the continuous rising costs of healthcare across the world, interest in the potential for pay-for-performance to improve quality of care has grown markedly, particularly in high-income countries in Europe, North America and Australasia (Christianson et al., 2009).

To date, however, despite extensive discussion and evaluation of the effectiveness of pay-for-performance schemes on quality of care, evidence remains uncertain and inconclusive (Mandavia et al., 2017). A Cochrane meta-review found that whilst there is limited evidence that financial incentives may be effective at changing process and practice, there is no evidence that they affect patient outcomes (Flodgren et al., 2011). Indeed, a more recent review underpinned those findings,

stating that studies typically focus on process measures rather than health outcomes (Ogundeji et al., 2016), which produces evidence on measures of clinical activity rather than outcomes.

2.3 Pay-for-performance in primary care in the United Kingdom

Before the Quality and Outcomes Framework (QOF) was introduced in 2004, primary care in the UK had relatively limited experience of pay-for-performance (Roland, 2004) with practice funding comprising largely of capitation payments (Rhys. G et al., 2010). Indeed, capitation was the principal payment system in England and provided core practice funding based on the number of patients in a population rather than on the amount or type of care delivered (BMA, 2017). However, there were a few examples of early pay-for-performance schemes prior to the QOF (Horder et al., 1986). During the 1990s evidence emerged from two different quality improvement initiatives, which indicated that financial incentives can be effective at improving clinical activity. The first involved practices being offered payment if they vaccinated a high proportion of children with the MMR vaccine (Middleton and Baker, 2003). The second offered payments to practices who achieved high rates of cervical screening (Baker and Middleton, 2003). Both studies provided evidence that financial incentives had a positive effect, increasing coverage as intended. Moreover, for cervical screening financial incentives had a positive effect on reducing inequality as they resulted in an increased proportion of women from more deprived areas attending practices for a smear test.

2.4 Quality of care

Quality of care is a complex term which is challenging to define, particularly in the context of primary care, as it relates to an array of different – sometimes competing – elements. As such, the World Health Organisation asserts that a culture of quality needs to be embedded in primary care to foster sustainable quality improvement of healthcare (WHO, 2018). There are a number of core aspects, however, which appear central to defining quality of care including: access, holistic care, patient-centred care, continuity of care, coordination of care, treatment effectiveness and clinical safety (Goodwin et al., 2011). Evidence suggests that quality of care in primary care was improving prior to the introduction of the QOF (Campbell et al., 2005) as a result of the development of clinical IT systems in the late 1990s (de Lusignan and Chan, 2008), and a number of reforms introduced by the New Labour government to raise standards, and to increase efficiency and equity in the care delivered (Bloor et al., 1999).

2.5 Quality and Outcomes Framework

2.5.1 Overview

The UK Quality and Outcomes Framework (QOF) is an annual incentive scheme that financially rewards general practices for achieving targets for evidence-based indicators developed by the National Institute for Health and Care Excellence (NICE) (Sutcliffe et al., 2012). Introduced in 2004, it was at the time the largest and most comprehensive pay-for-performance scheme in the world (Roland, 2004). Driven by decades of underinvestment compared with other health services, the principal aim of the QOF was to improve the quality of care across the nation and reduce variation within primary care, which had become an increasing concern (Doran et al., 2006). Given that QOF was a national scheme, however, it did not provide the opportunity to address healthcare needs at the local level (Roland and Olesen, 2016). From the outset QOF encompassed all nations in the United Kingdom: until 2016, when Scotland abolished the QOF (Roland and Guthrie, 2016).

QOF payments supplement core practice funding (capitation payments), which is based on the number of patients registered at a practice after adjustment for certain patient and geographical area characteristics (NHS Digital, 2017). The QOF financially rewards practices based on their achievement in relation to individual indicators by a payment-per-point system. Since the QOF was introduced, payment-per-point has risen from £76 in the first year 2004/05, to £188 in 2019/20 (NHS England, 2019a) though this has not resulted in practices being paid more as the number of QOF indicators has been reduced. Furthermore, the QOF now accounts for a smaller share of overall practice income. (Moberly and Stahl-Timmins, 2019). However, there still remains wide geographic variation in how much income practices derive from the QOF. For example, in 2017/18 QOF payments accounted for more than 11% of income for some practices in England whilst for others it was less than 1% (NHS England, 2018b).

The QOF consists of a complex set of indicators divided into four domains: clinical care; practice organisational; patient experience and additional services (HSCIC, 2005). Although serious mental illness has been part of the clinical domain since the inception of the QOF (along with common chronic conditions such as cardiovascular disease, diabetes, asthma and COPD) (NHS Confederation, 2004) research studies investigating the effectiveness of QOF indicators have tended not to include SMI. Generally, the QOF does appear to have narrowed the gap in performance between the least and most deprived practices, though the evidence on whether it has reduced health inequalities and improved outcomes for patients from more deprived practices remains limited (Dixon A et al., 2011). It has been argued, however, that offering financial rewards to meet certain targets based on clinical activity or the recording of measurements forces practitioners to make compromises on the quality of

care they deliver given the time constraints imposed under the current system of primary care (Peckham and Wallace, 2010).

2.5.2 Evidence on the effectiveness of the QOF

Evidence on the effectiveness of the QOF derives largely from quantitative studies, which have examined its impact on clinical activity for a range of long-term conditions incentivised by the QOF. Fewer studies have used qualitative methods to explore the effectiveness of the QOF.

Quantitative evidence

Quantitative studies examining the effectiveness of the QOF have tended to use observational data to conduct research using retrospective longitudinal designs: from primary care databases (Calvert et al., 2009, Serumaga et al., 2011) or from IT systems supporting the QOF (Kontopantelis et al., 2012). Effectiveness is typically defined by performance level as measured by achievement of QOF indicators, but this indicates clinical activity rather than patient outcomes. Although numerous studies have examined the impact of the QOF on aspects of clinical activity, evidence of its effectiveness at improving the quality of primary care remains weak (Doran et al., 2017). Indeed, systematic reviews appraising evaluations of the QOF have consistently concluded that the evidence is uncertain and inconclusive (Gillam et al., 2012, Langdown and Peckham, 2014, Houle et al., 2012, Emmert et al., 2012, Forbes et al., 2017, Mandavia et al., 2017). Furthermore, in 2018 NHS England reviewed outcomes of the QOF (NHS England, 2018b) concluding that the scheme needs to be refreshed to deliver better patient-centred care and support the growth and sustainability of practices.

Effectiveness of the QOF on quality of care for SMI

Evidence is particularly sparse in relation to the impact of QOF financial incentives on people with serious mental illness. Only one study (Kontopantelis et al., 2015b) has focused specifically on the impact of clinical indicators targeted at SMI patients. Examining the effect of QOF incentives on consultation rates, it found the frequency of contact between SMI patients and practitioners increased. However, it was unable to determine whether the increase in monitoring had any effect on patient outcomes.

Removal of incentives

A few studies have examined the effect of withdrawal of incentives on the quality of care documented to determine if there is any continued effect in clinical activity after financial incentives have been removed. However, the evidence is both limited and inconsistent. In 2014, a study by Kontopantelis et

al (2014) found that removal of incentives across a range of clinical indicators did not have a significant effect on performance with levels of recorded activity remaining relatively stable in subsequent years. In contrast, findings from later studies produced different results. In 2018, NHS England commissioned a group of experts to examine changes in recorded achievement of indicators across a range of clinical diseases where QOF incentives had been removed. Results showed there was an immediate decrease in the proportion of patients who had an indicator recorded in the first year after incentives were removed (Wilding et al., 2018). Another study (Minchin et al., 2018) demonstrated similar findings showing significant decreases in documented quality of care measures in the year directly after incentives were removed.

Qualitative evidence

Fewer studies have used qualitative methods to explore perceptions of the impact of QOF on quality of care (Gillam et al., 2012), and those that have tended to focus solely on provider experiences. One study (Campbell et al., 2008) which explored practitioner views found that whilst there were noticeable improvements in disease-specific aspects of care and the recording of data, there were also unintended consequences, including less scope to deliver patient-centred care. This was similar to another study (Maisey et al., 2008) which found that disease-specific aspects of care had improved and the role of practice nurses had increased, but that GPs felt the QOF had compromised their capacity to listen to patients concerns, which undermined a core aspect of quality of care. Closely aligned to this was a study by Lester et al (2013) which found that although the QOF was generally welcomed, GPs questioned its impact on their clinical autonomy and decision making skills.

However, very little is known about patient views of the QOF and its impact on quality of care (Gillam, 2015). One study by Lester et al (2011), which conducted focus groups with patients as well as practitioners, found that the QOF negatively impacted on person-centred care and prioritised incentivised procedures over non-incentivised procedures. Furthermore, findings from a study by Hannon et al (2012) indicated that most patients were not aware of the QOF and few could identify any changes to quality of care or the way in which their care was delivered.

2.6 Rationale for this thesis

At present, evidence that the QOF has produced improvements in quality of care in any of its clinical areas is unclear (Mandavia et al., 2017, Forbes et al., 2017). Although there is some evidence that financial incentives influence practitioner behaviour (Vlaev et al., 2019) and increase clinical activity in incentivised domains (Peckham and Wallace, 2010), there is concern that unintended consequences

of the QOF adversely affect patient-centred care (Lester et al., 2011). Evidence on the effectiveness of the QOF at enhancing the quality of care stems principally from studies which have used observational data to quantitatively examine changes in activity relating to quality indicators, though these are measures of process not outcome. Fewer studies have examined the effect of the QOF on outcomes such as mortality (Kontopantelis et al., 2015c, Ryan et al., 2016) and/or hospital admissions (Ride et al., 2019, Ride et al., 2018), which can be used as proxies for quality of care. Virtually no studies have investigated the effect of the QOF on patient reported outcomes (McShane and Mitchell, 2015).

Several qualitative studies have explored practitioner views of how QOF affects quality of care (Campbell et al., 2008, Maisey et al., 2008, Gillam et al., 2012, Lester et al., 2013) as well as a few that have explored patient views (Hannon et al., 2012). Given that the evidence on the effectiveness of the QOF for all its clinical areas is uncertain and largely unconvincing (Gillam, 2015, Forbes et al., 2017), there remain gaps in knowledge about the impact of the QOF on the quality of primary care. Furthermore, as discussed earlier, evidence is particularly sparse relating to how the QOF affects quality of care for people with serious mental illness.

This thesis therefore aims to expand the quantitative and qualitative evidence base about the role of financial incentives for the management of SMI, to deepen understanding about the impact of such incentives on the quality of care for this population.

2.7 Aims and objectives of the thesis

2.7.1 Aims

This thesis aims to assess the association between the QOF financial incentive scheme and the quality of care for people with SMI, and to provide new insights into what quality of care means for people with SMI. The overarching aim is to produce evidence that will provide pointers about how the quality of primary care can be enhanced to improve SMI patients' physical health, so they can live longer, healthier lives. The five main objectives underpinning this central aim will be examined using a mixed methods approach.

2.7.2 Objectives

Qualitative research study

- 1) To explore how people with SMI perceive and experience quality of care in general practice.
- 2) To explore practitioner perspectives on the quality of care provided to people with SMI in general practice.

Quantitative research study

- 3) To assess if removal of financial incentives for three QOF indicators impacted on the proportion of SMI patients who received physical health checks.
- 4) To compare rates of health check where incentives were removed with an indicator where incentives remained.
- 5) To investigate if certain types of patients were more likely to receive a physical health check.

This is the first study to address these specific objectives using a mixed methods approach, with the aim of providing new insight into factors affecting the quality of primary care for people with SMI.

Chapter Three: Methodology

3.1 Chapter content

The previous chapter examined the literature relating to quality improvement in healthcare and underlined the aims of the thesis, its objectives and research questions. This chapter provides rationale for the research methodology adopted to guide the mixed methods approach, selected as the best way of meeting the aims of this thesis. It outlines the longstanding philosophical debates relating to different ontological and epistemological beliefs about how the world is viewed and what counts as knowledge. It then discusses how these philosophical standpoints informed decisions about what type of methods were used in this thesis. It goes on to compare differences in how quality is assessed for quantitative and qualitative approaches. The chapter then explains why a mixed methods approach was chosen to address a complex research question, concluding that using different methodological approaches and methods adds value to study findings by providing a broader and deeper understanding of the topic.

3.2 Philosophical underpinnings

Different research paradigms such as the natural world paradigm or social world paradigm reflect different ways of thinking about the world and are shaped by two core concepts, ontology (the nature of reality) and epistemology (the theory of knowledge). For centuries many complex and opposing understandings about how we view the world have been contested and debated. Indeed, disagreement over the theoretical and philosophical underpinnings of research methodologies continues today. However, research paradigms and their ontological and epistemological stances offer researchers guidance about the best methodological framework to adopt to structurally support their methods. Researchers, therefore, choose to adopt a particular ontological and epistemological position depending on their own personal beliefs and the aims of their research study.

3.2.1 *Ontology*

The natural world paradigm emerged during the period of Enlightenment and was characterised by the concept of realism, which believes there is a single truth and that external reality is not dependent on human factors (Guba, 1990). However, given the aims of this thesis a different understanding of what reality is and how the world is viewed was required. Consequently, a post-realist ontological approach was adopted, which views reality from a social world paradigm (Lincoln and Guba, 1985) with the belief there is no single reality given the complexity of the world, and that multiple realities can only

be understood through human experiences (Ritchie and Lewis, 2003). A post-realist paradigm seemed a preferable guide to address the research questions of this thesis, to enable different accounts of reality to be explored through human experiences of healthcare.

3.2.2 Epistemology

Epistemology relates to the theory of knowledge, how it is created and what is accepted as credible knowledge. Different epistemological stances reflect different world views. A positivist approach, stemming from a natural sciences paradigm, believes knowledge is created objectively and acquired deductively. Positivism believes the research process and production of knowledge is neutral, unaffected by the researcher (Neuman, 2000). In contrast, a social sciences paradigm believes research cannot be objective or neutral as researchers unavoidably, even if unintentionally, impact on the research process due to human nature (Mason, 2002).

Given that one of the primary aims of this thesis was to explore the experiences of SMI patients and primary care practitioners, a social constructionist post-positivist approach was adopted in the belief that knowledge is subjective and acquired inductively, constructed by people who attach meaning to their experiences (Guba and Lincoln, 1994). This was a pragmatic decision as it was deemed the most appropriate way to guide the aims of the thesis which include research questions relating to quality of care from contrasting research paradigms: a qualitative approach exploring human experiences to address *what* and *why* questions; and a quantitative approach using numerical data to address questions about *how many* and *how much* (Green and Thorogood, 2004).

3.3 Assessing quality in research

Given the opposing ontological and epistemological positions held by the natural science and social science paradigms, it is not surprising that there has been continuous debate in the scientific literature about whether or not concepts such as reliability and validity, originally coined for quantitative research, can be applied to qualitative research. These concepts stem from a natural sciences paradigm and focus on standardising measurements and controlling external variables to determine causality, hence they do not fit readily with the different philosophical underpinnings of social sciences. Consequently, questions have been raised about alternative ways to assess quality in qualitative research (Silverman, 2000).

3.3.1 Reliability or trustworthiness

The concept of reliability emerged from a positivist philosophy. It relates to replicability and whether findings would reoccur if the same methods were adopted for another study. In qualitative research the notion of replicability is contested, however, given the belief that there is no single reality (Lincoln and Guba, 1985). Furthermore, given that qualitative research is a dynamic process where researchers are required to respond to participants, precise replication of the same methods is rarely possible. Consequently, the concept of ‘trustworthiness’ (Glaser and Strauss, 1967) has been deemed a better way to assess the quality and soundness of qualitative research. This has led to an emphasis on truth and transparency as core aspects of assessing quality (Lincoln and Guba, 1985). In an attempt to demonstrate trustworthiness for the qualitative research undertaken for this thesis, a detailed and transparent description of the methods is provided in the proceeding chapter, to enable readers to assess the quality of the research for themselves. Furthermore, a statement of reflexivity in Chapter Eight provides evidence of critical reflection on the research process.

3.3.2 Validity or credibility

The concept of validity also stems from a positivist approach about how knowledge is created. It relates to assessing the precision of data and accuracy of findings to determine if a study is sound and robust. The quantitative part of this study focused on internal validity (quality of data) and external validity (how well the findings translate to the real world). However, due to its numerical focus validity is an inappropriate concept for the qualitative part of the study where alternative concepts such as ‘plausibility’ and ‘credibility’ (Glaser and Strauss, 1967) seemed more relevant. This thesis aimed to demonstrate credibility for the qualitative study by illustrating how interpretation of findings meaningfully reflects the data (Mays and Pope, 2000). Given that qualitative results are so dependent on context and the individuality of participants, however, it was not expected that results would be readily generalisable to other settings (Patton, 1999).

3.3.3 Reflexivity

Reflexive practice is an essential part of qualitative methodology, used to establish trustworthiness and rigour by providing the reader with insight into how decisions were made during the research process (Seale, 1999). More than just recalling an event and remembering what happened, reflexive practice enables researchers to learn by experience, known as experiential learning (Kolb, 1984). Throughout the research process for this thesis, reflexivity was practiced and conscious effort was made to examine why things happened in a certain way, and how, on the basis of that experience, it may be better to do things differently in the future (Boyd and Fales, 1983).

Reflexivity encourages researchers to constantly critique the research process. It enabled me to question my own beliefs and assumptions and how they might impact on research participants, potentially skewing the process of data collection (Silverman, 2000). It also made me consider aspects of qualitative research that can challenge its credibility such as becoming over-involved and not retaining a level of objectivity (Jasper, 2005). This was vital due to the contradictory demands placed on qualitative researchers, who are expected to be deeply involved in data collection and analysis, whilst maintaining distance and objectivity (Malterud, 2001). I therefore endeavoured to strike a balance and remain neutral while continuing to show empathy towards participants (Noble and Smith, 2015).

In addition, I considered what effect my physical presence may have on the participants with serious mental illness, who were interviewed face-to-face. I chose to dress informally rather than wearing professional attire to minimise the distance between researcher and participants (Mays and Pope, 2000). I also remained consciously aware of my body language, tone of voice and eye contact. Furthermore, I was aware that as a female who attended interviews unaccompanied, it may have prompted participants to reveal sensitive and personal information, which had not been requested (Padfield and Proctor, 1996). As discussed later, in Chapter Five, sensitive information was disclosed voluntarily by a number of participants who talked about distressing side-effects of medication, such as sexual dysfunction or wetting the bed.

Using a notebook to record learning points allowed me to document critical and constructive thinking about what happened during interviews (Silverman, 2000). This helped me to further develop self-awareness and think creatively about alternative ways to address a problem (Pope and Mays, 2006). For example, despite intending to actively listen to participants (Abrahams, 2017), I learnt early on from the initial interviews that I needed to resist the temptation to interrupt long silences. Developing self-awareness made me realise that when people stop talking and pause for some length they may not have finished, but rather, they may be in deep thought and contemplating their response. Learning to not fill the silence and providing participants with time and space to consider their thoughts is a valuable skill to develop, which was demonstrated in subsequent interviews by the richness of data that typically followed a prolonged silence.

3.3.4 Other validation methods

This thesis will adopt a number of other techniques used to validate qualitative research findings. Constant comparison (Silverman, 2000) will be used to continuously check and compare data during the coding and analysis process, which will take place concurrently. This will enable analysis of deviant cases or outliers, which differ from the rest of the sample, thus acting as a point of

comparison. Triangulation (Denzin, 1978) is another technique used to check the validity of data which can take a number of different forms (Patton, 2002). This thesis adopted triangulation of methodologies and methods to provide broader and deeper understanding of the topic. Therefore, the process of triangulation was used to gain a more complete picture of the problem being investigated rather than to improve accuracy and precision (O'Cathain et al., 2010). Respondent validation, which involves returning findings to research participants to check for accuracy and meaning, is another technique used to enhance validity of qualitative research, though it is not always feasible (Lincoln and Guba, 1985). Although the value of giving participants the opportunity to validate findings is acknowledged, it was not deemed necessary for this study given that interviews were digitally recorded to ensure a high level of accuracy of participant data.

3.4 Mixed methods approach

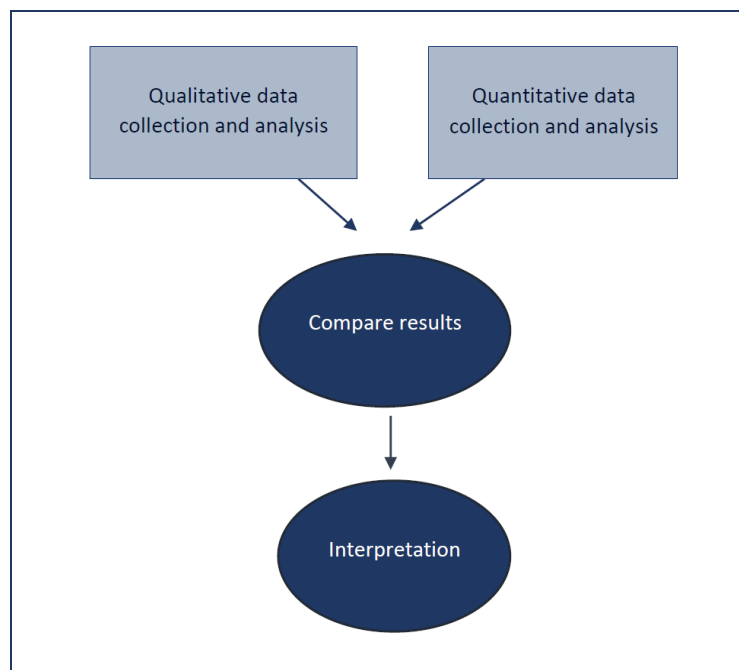
Despite continuous debate over whether or not quantitative and qualitative research paradigms and their methods should be mixed (Teddlie and Tashakkori, 2009), there is a pragmatic philosophical approach which advocates choosing the most appropriate methodology and method to examine the research question (Creswell and Plano Clarke, 2011). This thesis thus adopted a mixed methods approach to examine research questions relating to quality of care from contrasting research paradigms: to address both qualitative *what* and *why* questions, as well as quantitative *how many* and *how much* questions.

Selecting methods from different philosophical paradigms, known as 'methods triangulation' (Patton, 1999), allows data to be looked at from different standpoints: numerically, to examine to what extent something is happening, alongside words to reveal meaning and explanation about why something is happening (O'Cathain et al., 2010). This thesis examined data from different philosophical paradigms using different methods to enable broader and deeper understanding of the problem than would be possible with a single method (Bryman, 2001). Furthermore, the process of triangulation has the potential to uncover new, unexpected findings which may not have been visible through the lens of a single method of research (Barbour, 1999).

A convergent, parallel mixed methods design was selected for this thesis, using two methods from contrasting theoretical paradigms, to enable questions relating to the mortality gap to be explored from different angles. Typically researchers using this type of design would collect and analyse data in parallel. However, delays obtaining access to the quantitative data (as discussed in Chapter Six and Chapter Eight) resulted in a more sequential approach to data collection and analysis, though the integration and synthesis of findings remained convergent.

Overall, the research focus for this thesis was exploratory rather than explanatory in response to gaps in our current knowledge about the unmet physical health needs of people with serious mental illness. Consequently, the qualitative component of this thesis was prioritised, a type of mixed methods approach described by Morse as ‘QUAL + quant’ (Morse, 2003) to demonstrate that the qualitative research is dominant. This type of research approach is also defined as a ‘parallel mixed methods design’ (Teddlie and Tashakkori, 2009) where the two phases are conducted independently of each other – either at the same time or shortly after the other, chronologically. The research for this thesis was conducted using a ‘parallel’ design rather than a ‘sequential’ design as data collection and analysis for the quantitative component (part two) were not dependent on findings from the qualitative component (part one). –Creswell’s ‘convergent parallel mixed methods design’ (Creswell, 2015), as shown below, illustrates the research approach adopted for this thesis, demonstrating how the two parts were conducted independently before interpretation of the data was guided by themes emerging from the qualitative study, with the quantitative findings adding context and breadth of understanding.

Figure 3. 1 Convergent parallel mixed methods design



The qualitative study for this thesis involved talking to patients and primary care practitioners to explore their perspectives on the quality of care for people with SMI. The process of speaking to people and listening to their experiences aimed to generate new insights about factors that enhance and erode the quality of primary care, providing valuable information about how we can better meet the physical health needs of SMI patients and address the ‘scandal’ (Thornicroft, 2011, p.441) of premature mortality.

To complement this approach, the quantitative study examined quality of care from a different standpoint by interrogating a large dataset of routinely collected electronic health records, to look at the impact of a quality improvement initiative on care quality. Following analysis of both datasets, the findings were compared and integrated. The process of synthesising data provided interlinked strands of research evidence, particularly valuable to policy makers and practitioner audiences.

Chapter Four: Qualitative Study Methods

4.1 Chapter content

The previous chapter provided rationale for the pragmatic philosophical approach adopted to select the most appropriate methodologies to address the research questions for this thesis. This chapter describes the methods used to carry out the qualitative study, which was the first of the two core components of this thesis. It begins by highlighting gaps in the evidence relating to human perspectives about the quality of care for people with SMI, before defining the aims and objectives of the qualitative study. It then explains why the method of individual semi-structured interviews was chosen to explore patient and practitioner perspectives. The chapter goes on to describe ethical considerations given to the study and the involvement of Experts by Experience. It then describes the methods used for data collection and analysis. Finally, it considers the strengths and limitations of conducting individual interviews. Findings are discussed in the proceeding chapter.

4.2 Rationale

Chapter two demonstrated that existing evidence on the quality of primary care and unmet physical health needs of people with SMI is relatively sparse, particularly with regard to qualitative studies (Doran et al., 2014, Liu N et al., 2017). Whilst a small number of qualitative studies have explored practitioner views of the Quality and Outcomes Framework (QOF) (Campbell et al., 2008, Mercer et al., 2007, Maisey et al., 2008, Lester et al., 2011, Lester et al., 2013), fewer have explored SMI patient views of general practice (Lester et al., 2005, Hannon et al., 2012), and, to my knowledge, none since Lester et al (2005) have provided a voice for both providers and patients. This demonstrates the need for new evidence and provides rational for the exploratory study conducted for this component of the thesis.

4.3 Aims and objectives

The aim of the qualitative study for this thesis was to explore views on the quality of primary care for people with serious mental illness from a dual perspective by speaking with patients and providers.

Objectives:

- 1) To explore the views and experiences of people with SMI on their use of physical healthcare in general practice.

- 2) To explore practitioner views on the current provision of physical and preventative healthcare in general practice.
- 3) To identify factors which enhance and erode the quality of care for people with SMI.
- 4) To investigate the perceived effect of the Quality and Outcome Framework (QOF) on the quality of care for people with SMI.
- 5) To consider potential pathways to improve the quality of, physical healthcare for people with SMI.

4.4 Study design

A qualitative study design using individual semi-structured interviews was selected to explore patient and practitioner perspectives on the quality of care for people with SMI. Individual interviews were chosen as the qualitative method for this thesis because they provide researchers with a useful way of exploring complex and sensitive issues from participant perspectives (Mason, 2002). Furthermore, semi-structured interviews were deemed most appropriate to meet the aims of the thesis to ensure core topics were discussed with each respondent whilst providing the scope to explore issues that emerged during discussion, which had not been anticipated before the interview (Patton, 2014). Given the potentially sensitive nature of the topic relating to the physical health needs of participants, individual interviews were chosen in favour of focus groups (Creswell, 2007) to enable respondents to talk openly about their experiences without fear of being judged by other participants (Barbour and Kitzinger, 1999).

4.5 Ethical and Research Governance approvals

Ethical approval from an NHS Research Ethics Committee (REC) is required for all research studies where NHS patients are participants. In addition, any NHS site involved with data collection requires Research Governance approval. Furthermore, because this study was being conducted by a PhD student at the University of York, it required approval from the Health Sciences Research Governance Committee before documents could be submitted to the NHS REC.

Approval from the University of York Health Sciences Research Governance Committee was granted in March 2017. Following this, documents were submitted to the NHS REC which entailed the researcher attending a REC meeting face-to-face in May 2017. Approval was granted in June 2017 by the Social Care Research Ethics Committee, London (17/IEC08/0025) (Appendix 4.1).

Research Governance approval from the Health Research Authority followed in July 2017 for all the CCGs and six mental health trusts in the Yorkshire and Humber Region. Letters of Access were obtained in August 2017 for one mental health trust and all general practices located in four of the Yorkshire and Humber CCGs. The approval process took approximately 6 months from start to finish.

4.5.1 Main ethical considerations

The main ethical issues raised during the approval process for this study are outlined below.

Safeguarding participants

Before starting the study, the issue of risk had been carefully considered given that SMI patients are a vulnerable population. The Participant Information Sheet (Appendix 4.2) informed participants that if they demonstrated a risk of harm to themselves or others the researcher would ask them questions to explore the nature of the risk, and it may be reported to their General Practitioner (GP). The Research Ethics Committee further reinforced the importance of safeguarding SMI patients as research participants and a protocol was written by the researcher, which systematically detailed how to respond should a participant disclose a risk to themselves or others (see Appendix 4.3).

Researcher safety

The REC raised concern about the safety of the researcher in relation to two items. First, it questioned the researcher's plan to conduct interviews unaccompanied, which it perceived as a risk given the study population concerned; and the researcher's plan to allow participants the choice of being interviewed at their homes. The researcher was advised to adhere strictly to the documented University of York lone worker policy (see appendix 4.4). Secondly, the REC rejected the final method of recruitment (which had proposed to use social media to recruit people with SMI) on the grounds that there would be no mechanism for screening out participants who posed a risk. Instead the REC advised that participants be recruited via primary care or mental health trusts where the identity of those invited was known to health professionals.

Reward for participation in research study

The Research Ethics Committee approved that patients should be thanked for taking part in the study and rewarded with a gift voucher to the value of £10. In contrast, the REC discouraged the reimbursement of GPs and practice nurses for their time, claiming it was an unwarranted cost.

Confidentiality

Confidentiality is critical throughout the entire research process and the REC sought assurance from the researcher about how this issue had been considered. For this study, each participant was assigned a unique four digit, anonymised participant identifier once they had consented to take part (HPXX for practitioners, PTXX for patients). This ID code was written on their consent form (Appendix 4.5) and used as the participant identifier throughout the rest of the research process. Consent forms were the sole documents that included personally identifiable data. They were kept separately from all other study data in a locked filing cabinet, which only the researcher had access to, in a room with restricted access at the University of York. The ID code was then added to the anonymised transcript and any other data relating to the participant, which ensured it was the only means of distinguishing participants within the dataset. Electronic data were stored on the University of York secure IT system. In line with REC approvals, participant digital data will be removed after 5 years. Study data protection is GDPR compliant (<https://www.york.ac.uk/records-management/dp/>).

4.6 Sample

4.6.1 Inclusion criteria

Primary care practitioners were eligible to be included in this study if they were GPs or practice nurses working in general practice in the Yorkshire and Humber region. Patients were eligible to be included in this qualitative study if they were: aged 18 years or over; had a documented diagnosis of schizophrenia or bipolar disorder from a GP practice or mental health trust; lived in the community (including residential facilities); and had capacity to provide informed consent to participate in the study.

4.6.2 Sampling strategy

This thesis used a form of purposive sampling, to sample participants with a range of experiences and different characteristics, in an attempt to maximise data variation (Patton, 2014, Strauss and Corbin, 2008). Several variables were identified as important, and potentially feasible to sample by, to show variations in participant experiences. Practitioners were sampled by clinical role and gender. Patients were sampled by diagnosis, gender and age – see Tables 4.1 and 4.2 for summary of each group samples.

Table 4. 1 Primary care practitioner characteristics

Participants in individual interviews (<i>n=11</i>)			
Clinical role	No.	Male	Female
GP	7	5	2
Practice nurse	4	0	4

Table 4. 2 SMI patient characteristics

Participants in individual interviews (<i>n=19</i>)					
Diagnosis	No.	Gender		Age	
		Male	Female	mean (yrs)	range (yrs)
Bipolar disorder	11	5	6	54	21-71
Schizophrenia	8	6	2	55	37-69

4.7 Recruitment of participants

Interviews were conducted between September 2017 and May 2018 in the Yorkshire and Humber region. Practitioners and the majority of patients were invited to interview from a range of general practices who had expressed interest in the study after receiving information from the local Clinical Research Network (CRN). Typically it was a GP who first expressed interest in the study and who acted as the practice point of contact with the researcher for recruitment of patients to the study. On two occasions, however, it was the lead research nurse who contacted the researcher and coordinated the practice involvement in the research study.

Patients with schizophrenia or bipolar disorder, who had been selected from the Quality and Outcomes Framework (QOF) SMI register, were sent an invitation pack from their practice. This included a letter of invitation (Appendix 4.6) and Participant Information Sheet (Appendix 4.2) along with a reply slip and stamped envelope, which was addressed to the researcher at the University of York who had provided the practices with the invitation packs. Those interested in taking part were able to contact the researcher directly by telephone (mobile or landline), email or post.

4.7.1 Practitioner recruitment

The sampling strategy used to recruit practitioners to interview was a hybrid (Barbour, 2001) of purposive and snowballing. Although the plan had been to select a purposive sampling strategy based on practitioners' clinical role and gender, in reality the recruitment of practitioners was more opportunistic, based on a pragmatic rather than a theoretical approach. Initially, the researcher invited – and subsequently interviewed – each of the 'key contact' practitioners who had expressed interest to the CRN about their practice taking part in the study. Several of these GPs or practice nurses went on to recommend one of their colleagues who they believed would be interested in the study. Following up these leads resulted in the recruitment of all the remainder of participants required for the sample and introduced a snowballing effect (Patton, 2014) as potential respondents were identified by existing participants. Where feasible, however, to ensure the sample included a range of participants, practitioners were still selected on the basis of clinical role or gender although this was not always possible. For example, there was no opportunity to invite any male practice nurses to take part in the study within the sample of participating practices.

4.7.2 Patient recruitment

The sampling strategy used to recruit patients to interview was purposive with the emphasis on generating maximum variation in the data. The aim was to ensure the sample varied by diagnosis (schizophrenia or bipolar disorder) and core demographics (age and gender) to enable the data to include a range of experiences, which may be more generalisable to the wider SMI population. Eligible patients were identified by searching the practice QOF SMI register and removing any patients without a current diagnosis of schizophrenia or bipolar disorder; aged under eighteen; without capacity to provide informed consent.

Constructing a sampling frame for patients

Rather than inviting all eligible participants, or selecting a sample at random, practices purposively selected a sample of ten patients at a time (classed as one mail out) who varied according to diagnosis, age and gender. This model was adopted to avoid generating a large number of positive respondents from a single practice, which would have skewed the sample. It was expected, based on the researcher's previous experience of recruiting patients via postal invitation to a large mental health study in primary care (Gilbody et al., 2017) that response rates would be around 10 to 20 per cent, given the mean for that study was 16 per cent. Consequently, it was predicted that there would likely be one or two positive responses per 10 invitations, which was believed to safeguard against one practice recruiting a disproportionate share of the sample. In reality though, only two practices

generated more than one response from their first mail out. The other five practices mailed out a second time to 10 different patients in order to generate additional respondents; and one practice mailed out on three separate occasions without a single response.

Flexibility to adapt sampling frame

Obtaining a varied sample of SMI patients was complicated by the practicalities of recruiting patients through primary care, which meant that potential participants could not be contacted by the researcher unless they responded to invitation from the practice mail out. There was no guarantee, however, which patients would respond or whether or not they would vary by characteristics. In an attempt to achieve a varied sample by diagnosis, age and gender, the sampling process was shaped by a process of next selection, guided by emerging categories (Glaser and Strauss, 1967). As such, selection of who to invite at future practices was guided by who responded from previous mail outs. For instance, the first few practices invited eligible patients with a broad range of characteristics. Early respondents were predominantly older, however, which resulted in the next few practices being asked to adjust the sampling criteria to invite a younger age range in order to recruit younger participants.

Alternative method of recruitment

As the study progressed it became evident that fewer people with schizophrenia had responded to invitations sent from their practice compared with those with bipolar disorder. Even though early on in the recruitment process there had been three positive responses from people with schizophrenia, from three different practices, subsequent mail outs generated no more interest from people with schizophrenia. To rebalance the sample size an alternative, more opportunistic, method of recruitment was adopted based on advice from CO, an Expert by Experience advisor. This involved approaching people directly at two different clozapine clinics run by a local mental health trust. The researcher was able to sit in on one-to-one sessions between patients and the Healthy Living (HLA), which lasted approximately 10-15 minutes, and was given the opportunity to briefly describe the study to individuals and hand out information packs to those who were interested to take home to read. Whilst not all patients attending the clozapine clinic opted to see the HLA, 19 of the 28 who met the HLA during the two morning sessions, expressed interest in the study and took home an information pack. This resulted in six positive responses from people with schizophrenia, five of whom were interviewed.

4.8 Consent

All potential participants were sent a written information sheet about the study and what taking part would involve – for patients this was done by post and for practitioners by email. All participants who returned an expression of interest in the study were then contacted by the researcher who called them to explain the study and discuss any queries they may have before arranging a time to conduct an interview. Before data collection began, informed written consent was obtained from participants after they had been given time to ask any further questions about the study. This was done via email for practitioners and face-to-face for patients with schizophrenia or bipolar disorder. Once patients had signed two copies of the consent form they completed a background information sheet to provide details of their demographics before the interview began (Appendix 4.7).

4.9 Participant characteristics

All practices in the sample were located within four Yorkshire and Humber CCGs. There were marked differences in list size (7,200 to 32,700 patients), rural/urban classification, area of deprivation using the index of multiple deprivation (IMD) by decile (1 = most deprived) and QOF achievement score for clinical mental health (93.0% to 100%) (see sample demographics Appendix 4.8). Participant characteristics are shown in Table 4.3 for practitioners and Table 4.4 for patients.

Table 4.3 Practitioner characteristics

ID code	CCG	Clinical role	Gender	IMD decile* (practice level)
HP01	Harrogate and Rural District	GP	Male	4
HP02	Vale of York	GP	Female	2
HP03	Vale of York	Practice Nurse	Female	2
HP04	Leeds West	GP	Male	6
HP05	Vale of York	GP	Male	2
HP06	Vale of York	GP	Male	5
HP07	Vale of York	Practice Nurse	Female	5
HP08	Vale of York	Practice Nurse	Female	5
HP09	Vale of York	GP	Female	3
HP10	Hull	Practice Nurse	Female	1
HP11	Vale of York	GP	Male	2

* English indices of deprivation 2015 (LSOA) <http://imd-by-postcode.opendatacommunities.org/>

Table 4.4 Patient characteristics

ID code	Diagnosis	Gender	Age	IMD* decile (patient level)	Comorbidities	Method of recruitment	Participant response
PT01	Bipolar disorder	Female	62	9		via GP practice	Telephone
PT02	Schizophrenia	Male	67	9	High cholesterol, hypertension, hypothyroidism	via GP practice	Telephone
PT03	Bipolar disorder	Male	63	10	High cholesterol	via GP practice	Email
PT04	Bipolar disorder	Male	71	5		via GP practice	Email
PT05	Bipolar disorder	Female	50	3		via GP practice	Email
PT06	Schizophrenia	Male	69	9	Hypertension	via GP practice	Telephone
PT07	Bipolar disorder	Female	48	9	ADHD, fibromyalgia	via GP practice	Telephone
PT08	Bipolar disorder	Female	49	5	Arthritis, asthma, hypothyroidism, incontinence	via GP practice	Post
PT09	Bipolar disorder	Male	59	9		via GP practice	Post
PT10	Schizophrenia	Female	62	5	Asthma, autism, hypothyroidism	via GP practice	Post
PT11	Bipolar disorder	Male	58	6		via GP practice	Post
PT12	Bipolar disorder	Male	50	10	Cancer	via GP practice	Email
PT13	Bipolar disorder	Female	21	**unmatched**		via GP practice	Email
PT14	Bipolar disorder	Female	64	1	Asthma, cancer, high cholesterol,	via GP practice	Post
PT15	Schizophrenia	Male	37	5	Anxiety, depression	Clozapine clinic A	Telephone
PT16	Schizophrenia	Male	50	3	Arthritis, depression, type 2 diabetes	Clozapine clinic A	Post
PT17	Schizophrenia	Female	57	3	Pre-type 2 diabetes	Clozapine clinic B	Post
PT18	Schizophrenia	Male	49	7	Asthma	Clozapine clinic B	Post
PT19	Schizophrenia	Male	49	8	Type 2 diabetes	Clozapine clinic A	Post

* English indices of deprivation 2015 Lower Layer Super Output Area (LSOA) <http://imd-by-postcode.opendatacommunities.org/>
unmatched new LSOA; created post-2015

4.9.1 Patient characteristics

All patients were White British, eight female (three with schizophrenia, five with bipolar disorder), eleven male (five with schizophrenia, six with bipolar disorder), age ranged from 21 to 71 years (mean age 54 years). There was wider variation in deprivation level for patients than for practices, spanning across the full range of IMD deciles from 1 (most deprived) to 10 (least deprived). Four of the nineteen patients, all with bipolar disorder, attained higher education. Four worked full time, three with bipolar disorder (two female, one male), and one with schizophrenia (female). Twelve of the nineteen patients had worked previously but had stopped working due to their condition and/or the side-effects of medication (five with schizophrenia and seven with bipolar disorder). Living arrangements varied from owner occupied and privately rented, to council houses and social housing/supported accommodation. Eleven patients lived alone (four with schizophrenia, seven with bipolar disorder). Five were married (three with bipolar, two with schizophrenia), seven were divorced/separated (all with bipolar disorder) and seven were single.

Eight of the nineteen patients (42 per cent) were current smokers, four with bipolar disorder and four with schizophrenia. Around half of the sample (nine patients) had a community psychiatric nurse (CPN) at the time of being interviewed. All patients with schizophrenia had been diagnosed in their late teens or early twenties. A number of those with bipolar disorder had been diagnosed later in their life course: in their forties and early fifties. Thirteen patients, more than two thirds of the sample, had at least one comorbidity (eight with schizophrenia and five with bipolar disorder) – see Table 4.4.

4.10 Data collection

Semi-structured interviews were conducted with patients and practitioners supported by a topic guide, tailored to each group (Appendix 4.9). As this research study was designed to be deductive and data driven it did not use a theoretical framework. Whilst there are limitations to not using a theory, there are also advantages as emergent findings from the data tend to be more visible (Collins and Stockton, 2018). Topic guides were informed by relevant literature, particularly previous research on barriers to healthcare and the effect of the QOF. The researcher then developed the interview schedules by constructing a groups of topics central to the research question and consulted with with thesis advisors and Experts by Experience who offered guidance on both content and language. Topic guides were further refined following the pilot interviews, resulting in a framework of the core topics to be covered during interviews, whilst still providing the scope to explore issues that emerged during data collection.

Interviews followed more of a conversation style than a question and answer formulae. Participants were asked to consider their own experiences and given time to reflect on what aspects of care they valued and what they perceived as challenging. The researcher endeavoured to actively listen to participants and to respond to them by seeking additional information in the context of what they had spoken about rather than following a list of pre-set questions (DeJonckheere and Vaughn, 2019). As the interview progressed questions moved away from personal experiences and focused more on how participants envisaged the future of primary care, not just relating to the challenges faced in providing and accessing good quality of care for SMI patients, but also relating to enablers and what could be done to improve care.

4.10.1 Pilot interviews

Pilot interviews were conducted with one GP and two people with SMI before data collection began. As mentioned earlier, this enabled the topic guides to be further honed in relation to each group (Kim, 2010). The pilot interviews were particularly informative on use of language, highlighting some subtle differences about terms used by people with SMI. They also demonstrated the value of including a narrative opening question which helped build rapport by encouraging people to tell their story and feel comfortable speaking to the researcher. In addition, they forewarned the researcher the potential for participants to wander off topic. A balance had to be struck, therefore, between allowing participants to respond to questions freely without restriction, and refocusing their attention if required. The pilot interviews were not included in the analysis.

4.10.2 Main interviews

Practitioner interviews were conducted over the telephone at a convenient time for the participant. Interviews lasted for a mean duration of 30 minutes, ranging from 23 to 39 minutes. Discussion focused on practitioner experiences of providing care to people with SMI, their views of the challenges associated with meeting the physical health needs of this group, and their perception of the physical health checks for SMI patients reimbursed by the QOF. Patient interviews were conducted face-to-face at a convenient time for the participant. All interviews took place at participant homes as this was every participant's preferred choice of venue. Interviews lasted for a mean duration of 53 minutes, ranging from 29 to 107 minutes. Discussion focused on exploring patient views and experiences of quality of care with questions about what worked well and what they found challenging. Whilst the term 'QOF' was not used directly during interviews with patients they were asked questions about being invited for a health check and their experiences of what happened when they attended. From the responses it seemed likely that patients and practitioners were talking about the same issues in relation to QOF health checks. However, given that patients were not asked

precisely the same questions as the practitioners, differences in the discussion of QOF between the two groups cannot be ruled out.

Before interviews began, the researcher reminded participants about the research aim and asked them if they had any questions relating to the study information sheet. The researcher reiterated to participants the expected length of the interview and reminded them that they could stop the interview at any point and that any direct quotations used from the interviews would not be identifiable to them. Following consent from participants, all interviews were digitally recorded which enabled the researcher to actively listen to participants without being distracted by having to take notes during the interview. This ensured the interviews were able to adopt a conversational style rather than needing to pause for note taking after each response. Furthermore, being able to audio-record all the interviews enhanced the truth value of the data by minimising risk of bias through inaccurate or incomplete note taking (May, 2001).

Data collection ended when there appeared to be sufficient depth of material relating to the research question and little new information was emerging (Nelson, 2016). The decision was not based on the size of the sample (Bowen, 2008) but on the apparent richness of data and relevance of information, which suggested a level of saturation had been reached (Morse et al., 2002). As described earlier, recruitment of the final five patients with schizophrenia via secondary care had entailed a delay of approximately two months to the planned timetable. It succeeded, however, in bringing a more balanced representation of diagnoses to the sample as the number of participants with schizophrenia increased from three to eight, more in line with the eleven with bipolar disorder. At this point, the sample appeared rich enough in breadth and depth to explore the research topic effectively (Saunders et al., 2018).

4.11 Data analysis

Thematic analysis was chosen to identify patterns in the data and to highlight similarities and differences between participants and groups of participants. Despite being widely used, thematic analysis has until recently been poorly demarcated from other qualitative methods (Braun and Clarke, 2006). It is, however, increasingly regarded as a method in its own right rather than just as a tool used by other more established analytic methods, which also seek to describe patterns such as grounded theory (Glaser and Strauss, 1965, Strauss, 1997) or interpretive phenomenological analysis (IPA) (Smith and Osborn, 2015). A key strength of thematic analysis as a method is that it can be used to identify, analyse and report patterns both within and across data (Pope and Mays, 2006). Furthermore,

it can generate unanticipated insights through the theoretical freedom it offers compared to grounded theory or IPA which are theoretically bounded (Braun and Clarke, 2006).

A scarcity of literature on the research topic determined that coding should be data driven (inductive) rather than theoretically driven (Patton, 2014). It was not deemed appropriate to construct a list of codes pre-data analysis, which were unsupported by research evidence (Barbour, 2001). Consequently the data analysis was largely inductive. Drawing on grounded theory, a constant comparative method (Strauss and Corbin, 2008) was used to enable continuous comparison of the views and experiences of participants who had been purposively selected to highlight subtle, but potentially important, differences. Using a constant comparison method in combination with thematic analysis strengthened the validity of data interpretation, and identification of both anticipated and emergent themes (Pope and Mays, 2006). Validity was further increased by actively seeking unusual cases who differed from the rest of the sample (Patton, 2014) and endorsing anomalies to highlight the exception (Barbour, 1999).

4.11.1 Data transcription

All interviews were transcribed verbatim by an external professional transcription service (<http://www.uk-transcription.co.uk/about.htm>). To ensure participant anonymity, any identifiable information from the recordings was not included in the transcripts. To comply with University of York data security, all digital recordings and transcripts were deleted by the transcription service seven days after the researcher had received them. As stated previously, no identifiable data were included on transcripts, which were recognisable by a four digit ID code. Only the researcher had access to participant consent forms and personally identifiable data.

On receipt of a transcript the researcher re-listened to each digital audio recording to check the accuracy of the corresponding transcription. Listening back to the interview audio recordings served two functions. First, it began the process of data familiarisation (Ziebland and McPherson, 2006), which was further enhanced by the researcher's subsequent reading and rereading of the interview transcripts to become more deeply immersed in the data. Second, it allowed the researcher to identify and correct transcription errors and check there were no identifiable data included in the text. Transcription errors consisted largely of singular words having been misheard and incorrectly typed by the transcriber, which altered the meaning of what participants had reported (Marshall and Rossman, 2006), coupled with instances where transcribers had replaced colloquial dialect with Standard English.

4.11.2 Data management

NVivo version 11 (NVivo) was the computer software programme which was used to support the organisation and management of data. Once transcripts had been checked for accuracy they were uploaded onto NVivo, which enabled interview transcripts to be stored in an easily retrievable way (Nowell et al., 2017). NVivo offered a useful platform to begin the analysis process by providing the tools required to organise and code data. Nvivo could not, however, assist in the analytical thinking required for data analysis and interpretation.

4.11.3 Thematic analysis

Braun and Clarke (2006) identify six phases as core components of thematic analysis, which are broadly defined in Table 4.5. They emphasise, however, that thematic analysis is not a linear process where one phase needs to be completed before the next one begins, but rather a recursive process where elements are revisited. Consequently, analysis was an iterative process, which began with the researcher becoming familiar with the audio recordings and transcripts and making hand written notes on the early interview transcripts to construct a coding framework. To enhance validity a second researcher and PhD supervisor (PC) coded the first few transcripts independently, also by hand. Any differences identified were compared and discussed and the emergent coding framework was refined in response. The researcher then uploaded transcripts to NVivo 11 to begin working with the data electronically. Interview data were coded according to the coding framework, but with the flexibility to include new unanticipated codes that emerged from the data. When new codes emerged, they were checked against existing codes to ensure data were coded appropriately.

Table 4. 5 Six stages of thematic analysis

1) *Becoming familiar with the data*

Required the researcher to immerse themselves in the data; listening to audio-recordings at least once; reading and re-reading transcripts, making notes of any observations.

2) *Generating codes*

Required the researcher to generate codes by labelling interesting aspects of the data across the whole dataset and then collating all data extracts relevant to each code.

3) *Searching for themes*

Required the researcher to look for meaningful patterns in the data relevant to the research question. Identifying themes was an active process which required analytical thinking. Following this, all the coded data relevant to each theme were collated.

4) *Reviewing themes*

Required the researcher to think about whether the themes ‘worked’ in relation to both the coded extracts and the full data-set and to make any necessary revisions.

5) *Defining and naming themes*

Required ongoing analysis by the researcher to contemplate the key essence of each theme and construct a fitting name and description to demonstrate the story it tells.

6) *Writing up*

Required the researcher to weave together the analytic narrative with illustrative data extracts to tell the reader a coherent and persuasive story about the data, relating it back to the research question and existing literature.

Drawn from (Braun and Clarke, 2006)

Once coding was completed, common codes were merged to create categories, enabling the analysis of data to reflect recurring and representative themes. Themes represented meaningful patterns in the data, which became visible during the analytic process. An OSOP (‘one sheet of paper’) method (Ziebland and McPherson, 2006) was used to summarise different and sometimes contradictory issues within sections of data by writing them on a single sheet of paper in a free thinking, non-systematic manner. This enabled ideas to be mapped in order to visualise what story the data were telling and prompted a move away from codes and categories to a more conceptual understanding of the data.

Following on from the thematic analysis of data, a case study research method was used to provide a more in-depth investigation (Creswell, 2007) . This type of method was adopted to enable deeper examination of patient and practitioner perceptions of the effect of the QOF on quality of care, which enabled the nuances and complexities arising from the data to be discussed in more detail.

4.12 Strengths and limitations

One of the key strengths of semi-structured interviews is that they provide flexibility by including a topic guide of core questions, as well as providing respondents with the freedom to speak freely about their experiences (Mason, 2002). Moreover, the researcher is able to probe respondents for additional information to explore certain questions in greater depth or to obtain clarification (Creswell, 2007). Researchers also given the freedom to refine the data collection approach by seeking information on topics that have emerged during earlier interviews (Patton, 2014). One-to-one interviews provide rich sources of information about a topic, which can be compelling. Providing respondents trust the researcher and feel comfortable talking to them, they often offer powerful insights into sensitive or personal matters (Hinton et al., 2012), which display the complexities and subtleties associated with human experiences.

However, there are a number of limitations associated with of semi-structured interviews. Primarily, given sample sizes are relatively small, data are not easily generalisable to the study population or the wider community(Creswell, 2007). Furthermore, semi-structured interviews require a considerable amount of time – to conduct data collection as well as analysis and interpretation – which can limit feasibility (Patton, 1999).The quality of the interview data is also largely dependent on the skills of the researcher and their ability to conduct reflexive and transparent research to enhance validity (Pope and Mays, 2006), which accounts for their personal biases and potential influence during the research process. Reflexivity refers to the influence of the researcher on each stage of the research process in relation to their background, values and preconceptions (Malterud, 2001). To be reflexive, researchers need to carefully consider what effect they may have had on the data collected and the findings drawn from the analysis (Britain et al., 1995) – see Chapter Eight for a statement of reflexivity on this research process.

4.13 Chapter summary

This chapter has provided rationale for why individual semi-structured interviews were the method chosen to collect primary source data for this thesis. It has described the ethical considerations and data protection requirements needed to involve vulnerable adults in research. It then discussed the sampling strategy and process of recruiting patients and practitioners to interview. It went on to describe the process of data collection providing summaries of the study sample and participant characteristics. The chapter then discussed the methods of thematic analysis with constant comparison used to conduct data analysis. Finally, it presented strengths and limitations associated with using

individual semi-structured interviews. Findings from this research study are presented next in Chapter Five.

Chapter Five: Qualitative Study Findings

5.1 Chapter content

This chapter presents findings from the qualitative study, the first of two core components for this thesis. The methods used to conduct the research were described in the previous chapter, along with participant characteristics. This chapter begins by providing justification for why the dual perspectives of patients and practitioners were presented together rather than as two separate pieces of analysis. It then summarises each of the four core themes that emerged through thematic data analysis in relation to factors perceived to enhance or erode quality of care for SMI patients. Themes are supported with quotations, which enrich the findings by providing illustrative insight from patients and providers. The chapter then explores patient and practitioner views of the implementation of physical health checks, mandated by the quality and outcomes framework (QOF). Consolidating many of the key findings, the QOF illustrates how a policy intervention affected participant experiences of delivering or receiving care in practice. This chapter concludes by outlining the concept of visibility, which acted as a thread throughout the findings, interweaving many of the core themes and subthemes.

Figure 5.1 Clarifying a term of reference: referring to people as ‘patients’

Consistent with the rest of the thesis, interview participants diagnosed with schizophrenia or bipolar disorder are referred to as ‘patients’ in preference to other terms such as ‘service user’, ‘customer’ or ‘client’. Aligning with recent research evidence that revealed people receiving healthcare prefer ‘patient’ to other terms (Costa et al., 2019), it was considered acceptable to adopt an unambiguous and uniform term of reference for SMI participants throughout the thesis, which reflected the healthcare context of the study. Furthermore, the term was used neutrally without any connotation that it undermines the whole person perspective or labels individuals as passive recipients of care rather than active participants.

5.2 Context behind presenting dual perspectives in parallel

It is important to contextualise the process of data collection and analysis to explain why, despite there being some distinct differences between patient and practitioner perspectives on the quality of care provided to people with SMI, findings were presented in parallel. As described in Chapter Four, a

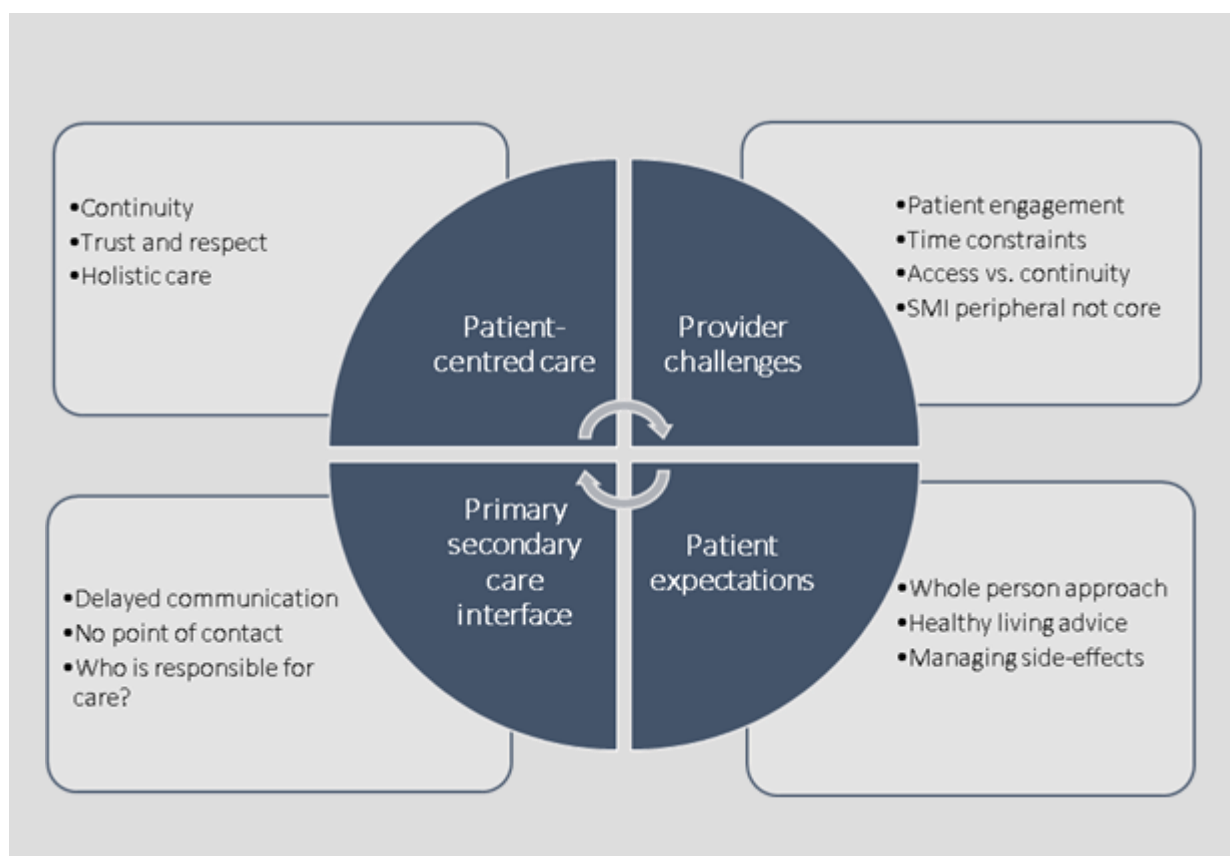
total of 30 interviews were conducted: 11 with practitioners (seven GPs, four practice nurses) and 19 with patients (eleven diagnosed with bipolar disorder, eight diagnosed with schizophrenia).

With the exception of the final five patients who were recruited from clozapine clinics (see Chapter Four), the first fourteen patients interviewed were registered at participating general practices, the same practices from which practitioners were interviewed. Data were also analysed concurrently to enable comparisons to be drawn and to deepen understanding by triangulating patient and practitioner perspectives. However, it is important to emphasise that practitioners did not know which patients from their practice had participated in interviews. Hence, practitioner views did not directly refer to patients in the sample, but rather to their wider experiences of caring for SMI patients in general.

Consequently, during the analysis process, some themes were driven more by patient data, whereas others were primarily a reflection of practitioner data. Presenting the dual perspective of patients and practitioners simultaneously, therefore, resulted in some themes being more representative of the patient narrative whilst others were more indicative of practitioner views. However, despite imbalances in how data in each theme were weighted, it was deemed more appropriate to present findings from both patient and practitioner perspectives together to demonstrate how some themes were particularly salient to one group. Although it was more challenging to present the two discourses in conjunction, it provided a richer narrative by offering insights from both the provider and the recipient. By doing so, it was possible to pull out elements of discord as well as congruence between patient and practitioner perspectives within each theme which strengthened the evidence.

Four core themes encompassing a number of subthemes were identified from the thematic analysis of patient and practitioner interview transcripts, as shown in Figure 5.2. . Each core theme: Theme 1) Patient-centred care; Theme 2) Provider challenges; Theme 3) Patient expectations; Theme 4) Primary/secondary care interface, and respective subthemes, are then presented and discussed with illustrative quotations selected from the interview transcripts.

Figure 5.2 Themes and subthemes identified from patient and practitioner interviews



5.3 Theme 1: Patient-centred care

Patient-centred care was regarded by both patients and practitioners as being critically important to people with SMI. Both groups spoke about how seeing the same practitioner and developing a trusting relationship were key elements for enhancing the quality of care for this group.

5.3.1 Continuity

Nearly all patients spoke of how much they valued being able to see a doctor they knew when they attended the practice. Practitioners also stressed the importance of patients developing a relationship with a doctor, particularly for those managing a complex condition such as serious mental illness. Seeing the same practitioner – known as relational continuity of care (Freeman and Hughes, 2010) – was regarded as vital to enhancing quality of care by both patients and practitioners.

Many patients reported that finding a doctor they liked and trusted was challenging, but once they had found one, they would endeavour to see them again, even if it entailed a substantial wait. Such

patients were often willing to compromise one aspect of care for another, sacrificing speed of access for relational continuity of care.

'It's very difficult to get an appointment. I prefer to see [my doctor] if I can, but he's very popular, and so they're booked up a couple of months in advance ... it's just that we have a relationship and I don't have to explain my situation to him.' (PT03, bipolar disorder)

There were two notable exceptions, however, relating to patients who claimed to prioritise urgency over continuity. Patients PT04 and PT05 revealed they preferred to take the next available appointment and risk seeing a doctor they were unfamiliar with rather than waiting to see their GP of choice.

'To ask for a specific doctor, it's like four weeks ... if I want to see somebody I want to see somebody, not in four-weeks-time, so I just really take whoever is going to be on.' (PT04, bipolar disorder)

The only apparent difference between these two patients and the rest of the sample was that both worked (one full-time, one voluntary) and neither had a long term condition. Whilst this could explain their different perspective regarding access and continuity, it may simply reflect individual preferences.

Supporting the patient narrative, practitioners also viewed continuity as critical to enhancing quality of care. Moreover, they viewed it as dually beneficial to both patient and provider. GPs reported that this group of patients tended to opt for continuity over being seen quickly.

'[SMI patients] are always keen to have their own GP, so they would rather wait.' (HP01, GP)

Many also spoke of how continuity prevents duplication by removing the need for patients to continuously repeat information to different doctors, described as 'going over old ground' (HP04). Furthermore, continuity was regarded as a protective factor against patient disengagement, which links closely to the subtheme of patient engagement, discussed later in Theme 2.

Regarding the beneficial effects of continuity to them as providers, several GPs explained that seeing a particular patient regularly allowed them to develop understanding of their idiosyncrasies, enabling them to detect subtle changes that may have been missed by other practitioners.

'Continuity helps because they know me, and they seem to trust me and I get to know the nuances of how they are. And, if they're suddenly looking very blank and can't talk it's just the way they are and they just need a bit of a chat and closer monitoring.' (HP04, GP)

Moreover, several GPs reported that building a relationship with SMI patients not only fosters better understanding of their health needs, but reduces the likelihood of an uncomfortable interaction between a patient and one of their colleagues who may be unfamiliar with their characteristics.

'Continuity of care with these folk is a definite benefit to them, and to us, in that they can be quite startling. They can be – if you're not used to it – frightening, when you first come across them.' (HP05, GP)

With the exception of the two patients who preferred to opt for rapid access, continuity of care was regarded by all the other participants, both patients and practitioners, as critical to enhancing quality of care.

5.3.2 Trust and respect

Patients claimed that having a GP who actively listened was crucial for fostering a trusting relationship, based on mutual respect. Many patients revealed they could only be open about their concerns with GPs who actively listened to them and believed them because it gave them confidence to share their inner thoughts without fear of being judged.

'He's [my GP] been brilliant, he's always been prepared to listen.' (PT05, bipolar disorder)

Patients regarded seeing a practitioner who listened to them and who treated them as a 'normal human being' (PT14), as crucial to enhancing their quality of care.

Furthermore, nearly all patients seemed to favour the relationship aspect – how well they communicated with a GP and trusted them – over a GP's clinical expertise. Many revealed they did not expect a GP to have expert knowledge about their mental health condition, but what mattered to them was that they trusted the GP to take their concerns seriously and respect them; and to refer them to specialist services if necessary.

'I've got a good doctor now ... I picked him, because he was the only one who helped me ... he believes me.' (PT07, bipolar disorder)

In contrast, several patients recalled the difficulties they had encountered trying to find a GP they trusted. One patient described his frustrations.

'[I] used to see a different doctor every time and they would just say, "oh, try this, oh that hasn't worked, I'll tell you what ... try this." It was pot luck.' (PT12, bipolar disorder)

For patients, finding a GP they trusted and respected seemed a critical component for enhancing quality of care.

5.3.3 Holistic care

Holistic care and being treated as a whole person was also highlighted throughout the patient narrative as imperative to enhancing quality of care. Virtually all patients spoke about how much they valued practitioners who used a holistic approach rather than those who treated their mental and physical complaints separately. Many patients revealed, however, that holistic care was more of an aspiration than a reality and that, typically, there was too little time to focus on the interconnectedness of the mind and body.

'For me, a care package would be designed around eating, sleep patterns and physical activity, and that would help ...a whole person, for the wellbeing of all the body ...rather than just cater for them highs and lows. You can mend your head but if you can't mend everything else there's no point in mending that, is there? But I don't think that's going to happen sometime soon because they haven't got the time, have they?' (PT14, bipolar disorder)

Furthermore, several patients described how their mental health condition impacted on their physical health with distinct physical symptoms, but that GPs tended to overlook their concerns about the effects of their mental health on their physical health, preferring to concentrate on their state of mind.

'Everything's faster [during manic episodes], so you look like you've actually taken amphetamines ... the sweating, irregular heartbeats, totally soaked ...the anxiety is just horrendous, it goes through the roof. Then, depressed ... I can't be bothered, I put loads of weight on, I overeat to extreme. I just eat and eat and eat. I cannot be bothered ... I'll sleep and wear the same clothes for a week and won't bath or anything.' (PT07, bipolar disorder)

Most patients claimed holistic care was lacking and that practitioners did not appreciate how interdependent and closely intertwined their physical and mental health were. They reported that the shortness of consultation length – discussed further in Theme 2 – meant that there was virtually no time to discuss their complex needs relating to how their mental health was impacting on their physical health.

'Because that's the problem, you go in and you've got a ten-minute appointment, so you can only nail one thing at a time ... being able to get a double appointment would be useful so you can deal with at least two things, the bipolar disorder and whatever else it is ... causing a problem at the moment.' (PT11, bipolar disorder)

Patients repeatedly claimed that time deprivation severely limited what could be discussed during consultations, preventing GPs from adopting a holistic approach and engaging in discussion about the interdependency between their physical and mental health.

5.4 Theme 2: Provider challenges

Practitioner discourse about the challenges of providing care to SMI patients focused on patient engagement along with a number of system level factors, which they believed undermined their ability to provide adequate quality of care. Most practitioners spoke of the conflict which arose between the type of care they aspired to provide and the reality of what was achievable under the current model of primary care.

5.4.1 Patient engagement

Patient engagement emerged as a recurrent theme within practitioner responses. Many GPs referred to the challenges associated with providing care for SMI patients who, they claimed, were more likely to miss appointments and who proved more difficult to engage than the average patient.

'Quite a lot of them [SMI patients] just don't turn up, despite repeated letters and things, and telephone calls. They just sort of decline to, more so than normal patients ... they're just a challenging cohort of patients really, they often aren't engaging particularly well and it is more difficult to manage them.' (HP04, GP)

Added to this, several GPs spoke of the difficulties they had encountered engaging patients, even when they did attend an appointment, because their physical presence did not necessarily translate into patients engaging with them and communicating their health needs.

'[SMI patients]They fall into two categories really. The ones who are very dependent will appear lots and lots, and sometimes it's difficult to see the wood for the trees because they bombard you with so many bits of information ... then there are the ones who are chaotic, who often live in a worse state, but never roll up. You can't pin them down, they never respond other than in a crisis.' (HP05, GP)

Patient engagement (or dis-engagement) was a concern voiced repeatedly by practitioners regarding their experiences of providing care for SMI patients.

5.4.2 Time constraints

Nearly all GPs spoke about how time constraints imposed at the system level, such as ten minute appointments, eroded quality of care by reducing their capacity to provide patient-centred care. A number admitted, however, that they felt a sense of relief when a patient did not attend (DNA) an appointment as it presented them with an opportunity to catch up on unfinished paperwork, despite their concern about the unmet need and invisibility of patients who missed appointments.

'Because of the treadmill problem from our point of view, which is we still work on ten-minute appointments. But you can't do it in that, if someone doesn't turn up, actually, there's a feeling of "phew" it gives me a breather, and I can actually catch up to where I was before.' (HP05, GP)

Furthermore, many GPs revealed that given the unrelenting time pressures they operated under, they tended not to chase patients who missed appointments.

'If a patient makes an appointment and then they don't come, unless we've got concerns about safeguarding, we tend not to follow up people who have DNAed.' (HP11, GP)

'Patients who had got lost to follow-up were ... it's just the lack of time ... unfortunately [we're] paying lip service to managing them.' (HP04, GP)

From the practitioner perspective, time constraints accounted for their passive response to patients who did not engage. Nevertheless, GPs were troubled by the absence of patients who disengaged, concerned that by not being seen they became less visible and missed out on having their needs met. Practitioners consistently expressed regret that not enough primary care resources were invested in engaging this group of SMI patients. Furthermore, many GPs claimed that at the personal level they were under too much pressure 'firefighting' and dealing with their day-to-day commitments to have the time to reach out to the most vulnerable patients who they were struggling to engage.

However, not all GPs adhered to practice time boundaries on appointment length. Two GPs stood out as exceptions to the other respondents, revealing they offered some SMI patients longer appointments to extend the scope of what could be discussed.

'Patients with severe mental health problems need more time, may need double appointments ... one or two who I've got ... they have a double appointment so that I've got time to talk to them and discuss problems.' (HP04, GP)

'A consultation takes how long it's going to take ... sometimes we might book a double appointment for somebody but generally, in our practice anyway, we just accept the fact that sometimes the consultation is going to take half an hour or longer. And that's just life really, you give the patient the time they need.' (HP02, GP)

Although all GPs unanimously agreed that ten minute consultations were too brief to address the complexity of SMI patients' needs, in practice only two practitioners revealed they offered SMI patients additional time, which reinforces the issue raised in Theme 1 where patients claimed that time deprivation undermines holistic care.

5.4.3 Access vs. continuity

A recurring theme throughout practitioner interviews was the tension between access and continuity. GPs claimed that current policy initiatives to create larger practices and improve access – increasing the volume and availability of care – compromised their capacity to provide continuity. As reported within Theme 1 the patient/practitioner relationship and continuity were regarded as integral to delivering appropriate care for SMI patients. Many GPs expressed deep regret that structural changes within the primary care model had made continuity increasingly difficult to provide.

'It is one of my sadnesses of general practice, it's been made bigger and bigger and more, oh they love this word "corporate", and "practice at scale", and that simply means we're distant and inaccessible to the patient ... as you get bigger, you get more remote and you get less personal, and the continuity goes.' (HP05, GP)

'The larger the practice the less the continuity, because, if they want to see someone urgently on the day, they will just get pushed in with someone random.' (HP01, GP)

Nearly all GPs claimed that the policy drive to expand practice size and to improve access had systematically eroded important aspects of care quality by undermining their ability to provide patient-centred care, forcing patients to be more 'distant' and 'remote'.

5.4.4 SMI: peripheral not core

Many practitioners claimed serious mental illness occupied a second tier position in primary care, being placed on the margins rather than being part of its core practice. Practice level factors, such as lack of specialist SMI training and the minimalist role given to practice nurses, were identified as key reasons why serious mental illness has remained marginalised despite the increased policy attention over recent years (as described in Chapter One).

Practitioners attributed lack of specialist training on mental health – and SMI in particular – as one of the key barriers to enhancing quality of care.

'There was a mental health update I went to as part of my PDP, but there are no updates on that [SMI]. We have lots of things for dementia wise, but not with serious mental illness.' (HP06, GP)

Added to this, nearly all practice nurses revealed they lacked confidence treating patients with SMI conditions because they had not received any specialist training and had limited experience of caring for patients from that group.

'It [training] would be worthwhile ... I don't know about my colleagues, but you do have a certain apprehension when you're seeing a patient if you aren't very clued up on what their problem is.' (HP03, PN)

A minority of practitioners revealed, however, that they compensated for the lack of professional training by offering less confident colleagues peer support, drawing on their years of experience caring for patients with serious mental illness.

'If someone has got a serious breakdown of their mental health, if the GP or trainee doctor themselves feel that they're out of depth, they might refer it to me or ask my opinion. So, some GPs tend to be like mini-consultants within the practice. I suppose that happens with me and severe mental health. But we haven't done any training in the practice.' (HP11, GP)

In addition, a number of GPs asserted that training around serious mental illness should be delivered to more than just practitioners, given the influential role played by non-clinical staff such as receptionists who were often the first point of contact with patients.

'I think it would be really good for us all as a practice to get specific training to help understand these conditions better ... [Receptionists] deal with all the phone calls that are presented, they're making the decision when these patients come in as to how urgent appointments are, or whether they need seeing straight away, or whether it can wait until tomorrow, or another week. So, if they don't pick up on these triggers then these patients are vulnerable really ... so they've got quite a lot of responsibility.' (HP08, PN)

Furthermore, practitioners spoke about the marginal role given to practice nurses in providing care for SMI patients. This was seen as a missed opportunity to enhance the quality of care as many practitioners suggested that practice nurses may have more time and be better placed to engage with SMI patients' complex needs.

'[Nurses] more time to approach a patient in a more appropriate manner' (HP07, PN).

'If we had nurses who were trained in speaking to and giving advice and treating people with mental health issues, it would be really good. Because, as I said, if they're coming in and having injections, they're perfect for the nurses to kind of have a chat with when they come in, over and above that they've come for an injection and giving them that.' (HP09, GP)

Moreover, several GPs questioned why practice nurses were not empowered to have delivered physical health advice to SMI patients in the same way they did with patients they see for other chronic QOF conditions, which had specialist clinics run by specially trained nurses.

'I don't think we deal with it particularly well as a chronic disease, we haven't got a specific chronic disease clinic that we do for asthma, COPD, ischaemic heart disease, diabetes, but it is a chronic disease. Maybe things will change in the future ... it's just hard to manage at the moment because we're snowed under with diabetics and COPD.' (HP04, GP)

This GP highlighted an underlying tension relating to the gap between aspirations and delivery of care. Although GPs repeatedly stated that SMI deserved the same quality of care as other chronic conditions, in practice it missed out because other chronic conditions were prioritised in front of SMI when resources were overstretched. GPs stated it was difficult to address the needs of SMI patients because they were so busy, ‘snowed under’ even, with other patient groups. The inverse care law (Tudor Hart, 1971) was therefore reinforced as those SMI patients with the highest level of need would have been least likely to engage. As discussed earlier in this theme, despite acknowledgement from practitioners that the most vulnerable patients were the most difficult to engage, they also admitted that they did not have capacity to chase those patients who disengaged. Consequently, it was those SMI patients most at need who were most likely to have missed out.

5.5 Theme 3: Patient expectations

Patient expectations about quality of care emerged as a core theme because much of the patient discourse centred on aspects of care where expectations had not been met or where patients had not been able to convey their needs effectively. In contrast to Theme 1, where the subthemes displayed congruence between patient and practitioner perspectives, Theme 3 demonstrates elements of apparent discord. The respective subthemes illustrate a number of tensions that emerged from the data showing differences in how patients and practitioners prioritised health needs, which often resulted in patient expectations being unaddressed. Furthermore, the topic of side-effects from psychotropic medication is an illustrative example of where an issue was raised by virtually all in the patient group but was largely ignored by practitioners.

5.5.1 *Whole person approach*

All patients expected to be treated as a whole person and stressed the importance they placed on this. Practitioner interviews revealed, however, that this expectation was increasingly difficult to meet given the time constraints they operated under, as described in Theme 2. There appeared to be real tension between the type of care GPs wanted to provide and the reality of what they were able to deliver with so many competing priorities. Despite having been trained to offer holistic care and it being one of the core principles of primary care (Baird et al., 2018), GPs stated repeatedly that it had become more difficult to provide in practice. Consequently, even though the aspiration for treating someone as a whole person was uncontested, evidence from the patient interviews suggested that in practice it was largely absent.

[GPs]They're just interested in controlling the disease, they're not interested in the whole person.' (PT03, bipolar)

This claim was supported by many patients who reported that GPs tended to focus on one issue rather than treating them as a whole person. One patient described his daily routine, which had contracted substantially compared with life before his mental health diagnosis and subsequent treatment. He reflected on how his condition had negatively impacted on his quality of life as he had been forced to stop working. He also revealed that he never been given the opportunity to discuss the issue with his GP because of time pressures, which left him feeling despondent and hopeless.

'Typically, at the moment, I'm woken at eight o'clock to take tablets, then I go back to sleep again because it's olanzapine so it tends to knock me out. And I then, I don't really move until about half eleven, twelve o'clock. I then get up, have breakfast, and sometimes fall asleep again. I'll maybe go out and get a paper, read the newspaper. That's about it really. Things are not tremendous at the moment.' (PT11, bipolar disorder)

The challenges patients reported engaging with their GP as a whole person suggests that GPs do not have adequate visibility of SMI patients' needs, partly due to competing priorities with other aspects of care and also due to time constraints (both discussed earlier in Theme 2).

5.5.2 Healthy living advice

All patients and practitioners spoke about how health promotion and prevention are key factors to enhancing quality of care, although patients referred to it as healthy living advice rather than preventative medicine. Tensions emerged, however, in relation to how patients and practitioners perceived its delivery and uptake. Nearly all patients revealed that, despite high expectations, they had not received adequate or relevant information about how to look after their physical health. Most practitioners, on the other hand, stated that health promotion had limited value for this group as it was generally poorly received by SMI patients.

'Motivation has to come from them and loss of motivation is a well-recognised issue with schizophrenia.' (HT05, GP)

However, according to patients, even when written materials were provided, they tended to be inaccessible and meaningless. Several claimed that leaflets were not user-friendly and did not tell them what they wanted to know.

'You get the leaflet ... and when you read, really read it, you think, "why have they give me that? How's that going to help me?'" (PT14, bipolar disorder)

Regarding verbal physical health promotion and advice, patients reported similar frustrations. Most

could only recall being asked brief questions about smoking, alcohol, diet and exercise without any discussion about the risks and benefits of behaviours or why it is important to adopt a healthy lifestyle.

'They say, "do you go for walks?" and stuff like that. But the ones they focus on are the five a day, and the drink, and the smoking.' (PT04, bipolar disorder)

In addition, several patients called for more personalised care, claiming that healthy living advice was generic and not tailored to them as an individual.

'I suppose I could always join a keep fit class or something like that, but it's not really my scene.' (PT02, schizophrenia)

Furthermore, a number of patients revealed GPs had failed to take into account their personal situation, which meant that advice was often rendered purposeless. For example, one patient contested the concept of healthy eating when he could barely afford to buy any food.

'But that [healthy diet] goes out the window because you just have to eat anything you can food banking. Second hand food, third hand food.' (PT16, schizophrenia)

The absence of meaningful physical health advice about how to adopt healthier lifestyles and how to access support was viewed by most patients as a missed opportunity as they deemed practitioners well placed to educate them or signpost them to relevant information. One patient described it as being made to feel 'neglected' (PT07) by not being treated as a whole person where mind and body are interdependent. This links back to subthemes earlier in this theme and Theme 1.

'Nobody has said, "we'll sort out a diet for you," or "what activities can you do?" It's more about, "are you taking your medication?" ... I'd just like them to look at me as a normal human being.' (PT14, bipolar disorder)

In contrast, practitioners viewed health promotion from a different perspective. They believed it had limited impact on SMI patients due to two factors. First, practitioners questioned patients' capacity to 'receive' information and 'act' on healthy living advice. Many claimed that SMI patients tend to be less receptive and motivated than people without SMI to receive and implement advice about healthy living.

'In terms of health promotion and trying to get them to quit smoking or cut down alcohol or get regular exercise, you know, it doesn't really sort of work particularly well. I don't think they are particularly receptive to doing those sorts of things on the whole ... it's just the motivation and inclination that they often don't have, most of them, I don't think. I'm not tarring them all with the same brush but I think the majority just won't.' (HP04, GP)

Second, a number of GPs pointed to structural changes in primary care and cuts in practice funding

which have further impeded the delivery of health promotion to this group.

'We don't have a smoking cessation service in general practice anymore. That's been defunded. There is a council driven one, and I don't know how effective – or active – it is. But we're specifically not funded to provide any smoking cessation advice other than to tell people generally about it.' (HP05, GP)

There was an exception, however, which contrasted with the majority of respondents. One patient (PT17) described a positive experience, which illustrated what could be achieved. Recruited via a clozapine clinic, PT17 had been invited by her family practice (not part of this study) to attend a pre-diabetic clinic as part of a preventative measure, an example of good practice. In addition, she was offered a place on a weight maintenance programme. No other patients or practitioners reported anything similar, highlighting that few practices were engaged in delivering proactive health promotion or preventative care.

5.5.3 Managing side-effects

The patient narrative on psychotropic medication centred on managing side-effects. Although patients did not question having to take medication to control their psychiatric symptoms, nearly all claimed that side-effects had severely reduced their quality of life by impacting on their emotional and physical health. Patients revealed deep frustration at the limited opportunity they had to consult with their practitioner about how they could manage the side-effects of their psychotropic medication. Contrastingly, practitioner data demonstrated different priorities, which may explain why patient expectations were often marginalised. The issue of side-effects from psychotropic medication was hardly touched upon by practitioners who made virtually no reference to patients' concerns, demonstrating that the theme of managing side-effects was particularly salient to patients. . Practitioners' primary concern when discussing psychotropic medication was whether SMI patients were adhering to what had been prescribed alongside how well the medication was managing the patient's mental health condition, rather than reported side-effects.

'[SMI patients] more at risk of not taking the medication regularly, because if they're not feeling well, they're motivation is down.' (HP03, PN)

Consequently, a clear tension emerged indicating patients and practitioners had conflicting values. However, the data showed that given the time constraints of consultations, practitioners prioritised any discussion about medication, which tended to leave patients' concerns about side-effects largely unheard and unaddressed.

Nearly all patients reported finding it difficult to raise the issue of side-effects or to ask for meaningful information about how to manage them because GPs were often unreceptive or they ran out of time. One patient claimed his GP would ‘skirt round’ (PT16) the subject in an effort to avoid talking about side-effects of psychotropic medication. Even when patients were able to raise the issue they reported that practitioners commonly downplayed their concerns by telling them it is just one of the side-effects of that drug, to be expected and tolerated in order to control their psychiatric symptoms.

‘I was on depakote and olanzapine ... I went up to 14 stone [from 9 stones]. I went to the doctors ... she weighed me and she said, “oh well, you know, it is one of the side-effects of the medication.” She doesn’t see me as overweight, but I am, and I don’t feel right.’ (PT14, bipolar disorder)

This disconnect between how a patient rates the severity of a side-effect compared with practitioners was echoed by virtually all patients.

Weight gain

Many patients reported weight gain as their principal cause of distress, due to its impact on their self-esteem, motivation and physical health (Curtis et al., 2016). Whilst weight gain seemed to be a side-effect of all psychotropic medication, those prescribed atypical antipsychotics, particularly olanzapine, reported gaining an unprecedented amount of weight. Many also claimed that unrelenting hunger, which they attributed to psychotropic medication, made their life miserable as they were constantly ravenous and never felt satiated.

‘Nobody is really interested in the fact that I’m struggling with my appetite because I’m permanently hungry. I’m permanently hungry ... because of the Olanzapine, because my metabolism has slowed ... I’m just surviving day to day at the moment’ (PT11, bipolar disorder)

Patients repeatedly claimed that insatiable hunger severely impacted on their quality of life, though this suffering was not visible to practitioners.

‘...it’s olanzapine, and I’m just getting up in the middle of the night and eating packets of biscuits, anything I can eat. So, I went a couple of weeks ago to see the GP ... but she hasn’t said anything about my diet... I can sit and eat a full packet of chocolate biscuits at 2 o’clock in the morning, and the craving, it’s an awful feeling because it wakes you up ... it wakes you up and unless you eat something you can’t go back to sleep and I have trouble sleeping anyway.’ (PT14, bipolar disorder)

However, other patients claimed they had not altered their diet since their diagnosis, hence, they could not understand why they had gained so much weight or why they had not been offered any advice from their GP about how to address the problem.

'They talk about the obesity thing in hospitals, it's costing the NHS millions, and I'm sat there thinking, "some of the side-effects of my meds are weight gain." You know, I'd like to lose another four stones if I could, but that's not going to happen at the minute ... when I was growing up in school and that, I was big into sport. I played football every day, I had a six-pack ... I'm thinking, "how did I put all that weight on?" You know, I'm eating the same sorts of things that I was back then.' (PT15, schizophrenia)

Weight gain was seen as all pervasive by patients. Practitioners did not share patients' concern, however, despite its physical nature and it being a potent manifestation of a patient's health problem.

Although all patients attributed weight gain to the side-effects of psychotropic medication, two patients (PT05, PT12) conceded they had struggled with their weight before being diagnosed with SMI, but that psychotropic medication had resulted in additional weight gain. These two patients also reported feeling let down by their GPs who made no effort to offer them advice about how to address it. In response to the lack of support offered by her GP, PT05 revealed she had tackled the problem herself by paying privately to have a gastric band fitted, fearing that she would have had to give up her job as she was becoming increasingly out of breath and tired at the workplace.

'My BMI in July 2016 was 44 ½, so I actually used some PIP money to get a gastric band. So, for the last year, or just over a year, I've been working with the gastric band, because the medication that I take changes your metabolism, how you metabolise food. Although I could lose a bit of weight, it was very, very difficult, even something like Slimming World, to actually continually lose, because the medication fights against it.' (PT05, bipolar disorder)

This highlights the difficulty widely reported by patients that antipsychotics biologically affect their metabolism and make achieving a healthy body weight particularly challenging (Firth et al., 2019b).

Other side-effects

Other side-effects patients felt uncomfortable discussing with their GP magnified the tension between what patients were willing to present openly to practitioners and what they kept hidden and covered up, which further demonstrated the difficulty patients faced in having their expectations met. Many patients referred to the disempowerment and physically disabling effect of medication which reinforced the evidence that side-effects severely impacted on quality of life and limited daily functioning. Patients claimed they found it difficult, however, to raise feelings of lethargy with their GP for fear of being judged and accused of being unmotivated and lazy.

'Some drugs make you that you can't even get out of a chair for three hours of a morning ... like you've been hit by a truck.' (PT07, bipolar disorder)

'It's like carrying rocks and walking on sand. Your body feels heavy. You drag your feet. You feel a bit off balance.' (PT19, schizophrenia)

One patient (PT01) who revealed (voluntarily) that psychotropic medication had adversely affected her sex life, admitted she had not been able to bring herself to discuss sexual dysfunction with her GP. Consequently, by not raising the issue with her GP, this participant had not made her physical health problem visible, so it had not been addressed.

'I just don't have any physical feelings anymore. I think the sodium valproate and the olanzapine dampen any emotions, physical feelings that you do have. I'm just not interested ... it must be frustrating for [my partner].' (PT01, bipolar disorder)

In contrast, another patient admitted to having had a particularly humiliating side-effect which involved wetting the bed. He claimed to have only told a few people about it – his mum, GP and CPN (and myself) – given how shameful it had made him feel, but because he had spoken to his GP the problem had been successfully addressed.

'Sometimes of an evening I wet myself. So, they put me on meds ... I'm off that now and I haven't had a problem with that for months now, so that's a good thing, 'cause it was quite embarrassing, I'm thirty-seven and I've wet the bed.' (PT15, schizophrenia)

These personal stories illustrated how humiliating problems were able to be dealt with if patients were willing to share them with their GP, but if they were reluctant to speak about their needs, such as the sexual dysfunction, then practitioners could not be expected to see a problem that had not been disclosed. One participant illuminated this tension further when she revealed how frustrated she was at not being able to open up to her GP about her concerns.

'It's real strange because when I set off to go to the doctors I get a taxi, and in the taxi I'm saying to myself, "I'm going to tell her [my GP] this and I'm going to tell her that", and when I get there I don't, I just say, "oh I'm fine"... you learn to cover up how you really feel.' (PT14, bipolar)

This demonstrated further how some patients found it difficult to raise issues that were important to them, opting to keep them hidden during consultations despite their good intentions. Consequently, patients' impression that practitioners did not share their concerns about side-effects may reflect a practitioner's blind spot of a patient's beliefs (Alderson et al., 2014) rather than a lack of concern for the patient's overall wellbeing.

When side-effects were visible, however, there was evidence of additional tension in that practitioners did not regard them as being as functionally impairing as the person experiencing them. One patient claimed his GP was not concerned about his tremors even though they prevented him from driving and doing routine tasks that required a steady hand.

'They don't see the tremors being an issue, whereas I do. So, there is a conflict there.' (PT03, bipolar)

Not all patients felt so burdened by side-effects, however, as illustrated by one patient who claimed that her side-effects on clozapine (obesity and excess nocturnal salivation) are a small price to pay for managing her mental health condition and enabling her to continue to work.

'Excess salivation, that can be a pain ... so at night-time, you know, I dribble ... if I wake up during the night, sometimes my pillow case is quite wet ...it's a small drawback really for keeping me so well. And I mean thankfully, over all this time, I've managed to keep a full-time job.' (PT17, schizophrenia)

This example, though not typical of the sample, illuminated how individuals experienced and responded to side-effects differently. What may be debilitating for one person may be manageable for another.

5.5.4 Summary

In summary, patients regarded side-effects of psychotropic medication as the primary concern relating to their physical health, principally weight gain and its negative impact on their self-esteem, motivation to do physical activity and overall quality of life. Nearly all patients' initial response to being asked about physical health problems was to cite the side-effects of psychotropic medication. This seemed to take precedence over long term physical health conditions such as asthma and diabetes, as any patients with chronic disease(s) had to be probed further to talk about them, even when asked direct questions about their physical health. The enduring message from patients was that despite their expectations and strong desire to have been able to discuss how to manage side-effects with their GP, in reality the issue tended to be marginalised and their concerns were either not raised or not heard.

5.6 Theme 4: Primary/secondary care interface

5.6.1 Delayed communication

Timely and effective communication between primary care and mental health services was seen by respondents as essential to providing good quality of care for SMI patients. However, most patients and practitioners reported that, in recent years, there had been a marked deterioration in communication between general practices and community mental health teams. Practitioners revealed

the sharing of information had slowed down and been reduced, which resulted in it becoming increasingly distanced: stretched across time and space.

Nearly all GPs spoke about the apparent disconnect between services, which had impacted on the quality of care they could provide. The primary issue reported by GPs was a progressive breakdown in communication, which meant they were no longer confident that they received up-to-date information about patients still under secondary care. According to some practitioners, they either received information late, or in some cases, not at all. Consequently, as communication broke down, patient information was either missing or out-of-date at the time when it was most needed.

'The communication, in terms of letters from clinics and things is terrible, often waiting months to get a letter about medication changes. By the time you get the letter, the medication has changed again, so that's really difficult.' (HP02, GP)

'We have difficulty with the medication side of things because of poor communication with psychiatry services.' (HP05, GP)

Furthermore, GPs reported that even when information was received, it was generally difficult to decipher or to identify the important details.

'It's usually by – if they let us know at all, and they don't always – it would usually be by letter. Some letters highlight it quite clearly that there has been a change in medication. And then they're easy to pick up. Sometimes the change in medication is hidden in the text. And you have to read each letter carefully, sometimes, in order to be sure you're not missing something.' (HP11, GP)

Delays in communication and the sharing of information from mental health services was repeatedly flagged as poor practice. Many GPs claimed that not having up-to-date information limited how effectively they could respond to a patient's health needs, in some cases endangering their safety.

However, the problem encountered by most GPs was brought into sharp relief by the positive experience of a GP whose proactive approach showcased how care delivery and sharing of information might be improved.

'[communication] has improved ... we had a meeting with the mental health service providers and highlighted two issues. Then they changed the [patient letter] format and now they say, "GP to action" as a separate line at the end. So, that helps because otherwise it's buried in the whole information. So, we have an entry for "GP to action": "change this", or "do this", or "take bloods"... if anything urgent comes in, they either call or fax things now. So, those things have got better.' (HP06, GP)

This GP deviated from the others in this study sample, standing out as a positive example. It highlights, however, that for most practices communication with mental health services had become

increasingly stretched, which distanced patients and eroded quality of care. Furthermore, the language used by GPs reinforced the overarching theme around visibility, discussed at the end of this chapter, as even when they received correspondence, key information was not visible but rather ‘hidden’(HP11, GP) or ‘buried’(HP06, GP) in the text.

5.6.2 No point of contact

Practitioners also spoke about how it had become increasingly difficult to identify a professional point of contact in secondary care as system level structural changes over recent years have further distanced primary care from mental health services. Many GPs recalled a time when communication with mental health providers was more embedded, and CPNs had a physical presence at practices, which enabled GPs to share information with them face-to-face. According to some, current mental health teams are far more transient than in the past with fewer CPNs present at practices, causing further fragmentation and delays in communication.

‘I remember when I was training, you would know the local CPN and they would be able to come to practice meetings and discuss patients they were concerned about ... now, that all seems to have broken down completely, there seems to be a new team every five minutes ... we don’t really know who’s under what team so it’s difficult to know who to speak to.’ (HP02, GP)

Most practitioners claimed the current lack of integration of community mental health workers within practices was a key barrier to providing adequate quality of care to SMI patients. Moreover, GPs revealed that any direct communication via telephone or email with members of the community mental health team was becoming increasingly rare.

‘We don’t have a great relationship with secondary care. I mean if a patient has got a CPN ... we don’t have any records particularly of who their CPN is unless they’ve got that information in a letter. And we don’t have any regular contact with anybody’s CPN.’ (HP09, GP)

One GP spoke despairingly at how communication between primary and secondary care services had deteriorated.

‘I have no contact with secondary care. None whatsoever. I do not know who the psychiatrists are who are supposedly overseeing our patients ... I don’t have a contact psychiatrist anymore. I’m unable to get a psychiatric opinion, even if I specifically ask for it.’ (HP05).

He questioned how practitioners could be expected to provide SMI patients with the quality of care they deserved when the gap between primary care and mental health services was widening, and they now had virtually no point of contact with professionals from psychiatric care.

5.6.3 *Who is responsible for care?*

The patient narrative on the interface between primary and secondary care centred on their frustration about having to endure increasing delays in decisions on their care. Closely linked to subthemes in Theme 3, their principal concern related to medication and who was responsible for making changes to it or discussing its side-effects. All patients still under secondary care revealed that GPs avoided discussing possible changes to their psychotropic medication as they did not regard it as their responsibility. However, due to the increasing difficulty of communicating with psychiatric care, patients claimed they were left unsupported and felt in limbo, unsure about when a decision would be made or who would be making it.

'It's kind of difficult because it's the psychiatrist who's prescribed the drugs ... and the GP doesn't want to really interfere with that. So, if I'm having side-effects from the drugs, the GP says, "speak to the psychiatrist".' (PT11, bipolar disorder)

'I can talk to [my GP] about it, but he won't do anything about adjusting the medication, he'll just refer me to the mental health team again.' (PT03, bipolar disorder)

Patients revealed the apparent breakdown in communication between their general practice and mental health provider had caused substantial delays to decisions made about their care. Not only did they report finding it difficult to initiate discussion about their medication, but, even when they did speak up, little action was taken. One patient described feeling 'lost' and 'abandoned' (PT14) because neither her GP nor psychiatrist seemed willing to take responsibility for certain aspects of her care.

5.7 **Narrative case study**

Core themes encapsulated by implementation of the QOF

The next section examines how patient and practitioner data, relating specifically to the Quality and Outcomes Framework (QOF) physical health checks, impacted on the quality of care delivered to and received by SMI patients. It draws on aspects of care and experiences described in Themes 1 to 4, reinforcing many of the key findings.

5.7.1 Background

The QOF, a nationwide quality improvement scheme, was rolled out across the UK in 2004 to improve quality of care (Roland, 2004). One of the aims within the mental health category was to reduce the mortality gap (Kendrick, 1996), underpinned by evidence that people with SMI have a 15-20 year reduced life expectancy (Thornicroft, 2011) compared with the general population (discussed in Chapter One). From the outset QOF offered practices financial incentives (discussed in Chapter Two) to conduct physical health checks on SMI patients in an attempt to reduce the likelihood of premature mortality from common chronic conditions such as cardiovascular and respiratory disease.

Physical health checks for SMI patients, which are discussed in more detail in Chapter Six and Chapter Seven, have been part of the QOF mental health category since its inception in 2004 (NHS Employers). In summary:

- From 2004/05 until 2010/11 GPs were offered financial incentives to conduct an annual review for SMI patients, which included taking a number of physical health measurements.
- In 2011/12 the annual review was removed and four separate physical health indicators were introduced. These rewarded practices for recording measurements of a patient's blood pressure, cholesterol, body mass index (BMI) and blood glucose.
- In 2014/15, the indicators for cholesterol, BMI and glucose were removed. Blood pressure was the only physical health indicator to remain incentivised.

Consequently, given the interviews were conducted between September 2017 to May 2018, and asked participants about their previous experiences of providing or receiving health checks, patient and practitioner responses could have been referring to time periods when different incentives were in place compared with the recent period, since April 2014, when only blood pressure was incentivised.

5.7.2 Effect of QOF implementation on SMI patient care

In practical terms QOF increased the physical visibility of SMI patients as they were invited to attend the practice to undergo physical health checks. As practices were financially rewarded to record measurements for each patient, there was a direct incentive to encourage patients to attend, at least once a year. During the interviews, all patients and practitioners were asked what they thought about the QOF physical health checks, although the term 'QOF' was not used with patients as it could have been an unfamiliar term to them. With the exception of the youngest (PT13), each patient claimed

they had undergone at least one annual health check. All practitioners were familiar with the QOF.

The principal finding from both the patient and practitioner discourse was that, despite its good intentions to improve quality of care, the QOF had negatively impacted on patient-centred care, which encapsulated many of the key findings and core themes discussed previously. Respondents claimed the QOF focused attention on disease risk and recording of measurements at the expense of a whole person approach. From both the patient and provider perspectives, the discourse suggested that health checks had prioritised the ticking of boxes at the expense of other aspects of care, which created unwanted outcomes, described as ‘unintended consequences’ (Lester et al., 2011).

5.7.3 Participant perceptions of the implementation of the QOF

Participant experiences of the QOF physical health checks, detailed throughout the patient and practitioner interviews, were closely intertwined with the core themes and subthemes around patient-centred and holistic care, the whole person approach, healthy living advice, time constraints and patient engagement. Focusing directly on views of the QOF as part of a narrative case study therefore exemplified a number of the key findings, further reinforcing many of the core themes and subthemes.

Patient perspective

Nearly all patients claimed QOF physical health checks had eroded the quality of primary care. Most recalled their disappointment at attending a health check, describing it as a rapid ‘in-out’ (PT07) once a year event, which involved a few questions and the ticking of boxes on the computer.

‘They take the samples, ask all the questions, tick the boxes on the computer ...I know they’ve got a lot on, I’m not trying to be facetious or anything, it’s just that’s the way it happens. (PT04, bipolar disorder)

‘Just weight, height, questions about lifestyle, how many units of alcohol, do I smoke ... there’s no discussion about it, they just take the measurements.’ (PT03, bipolar disorder)

Moreover, many patients revealed the absence of any dialogue during health checks made them feel they were not being treated as a whole person, corresponding closely to subthemes in Theme 1 and Theme 3. Patients questioned why there was no explanation for why they had been invited to attend a health check. Furthermore, most could not understand why practitioners did not discuss what the checks meant for their physical health or offer any healthy living advice. These frustrations were exemplified by one patient who revealed that her GP would weigh her and record the measurement, but, even when it was obvious she had gained a substantial amount of weight, would not offer any

advice about how to lose weight.

'We get one a year [health check]. You jump on the scales ... I'd put three stones on ... they have no interest in helping you lose weight, none of that gets done. You just jump on the scales, blah, blah, blah. And then you're gone. It's just in and out as quick as you can ... blood test, your weight, and that's it, anything you need to do you've got to do it yourself, basically, because there's no time.' (PT07, bipolar disorder)

In theory, patients regarded health checks as an ideal opportunity for meaningful discussion about why the checks were being done and what it meant for their health risk. In practice, they felt let down as many believed the opportunity for practitioners to give them healthy living advice was repeatedly missed, further reinforcing subthemes in Theme 1 and Theme 3.

Practitioner perspective

Similar to the patient discourse, most practitioners revealed the QOF physical health checks had undermined the quality of care they could feasibly provide. A number of GPs who had been in practice for several decades claimed that patient-centred care had been eroded because the QOF had prioritised the recording of measurements and bureaucratic administrative tasks, which left virtually no time to provide holistic care and speak to a patient as a whole person. Once again, this exemplified subthemes from Theme 1 and Theme 3.

Furthermore, most practitioners questioned the value of QOF health checks for SMI patients given that it is the recording of measurements that is incentivised rather than taking any action or follow-up. Many GPs mirrored patients' concerns that the QOF simplified their complex health needs and reduced health promotion to a box ticking exercise.

'To be quite frank ... our requirement to report for the Quality Outcomes Framework is just a little nudge to remind us to do some health promotion. But then again, it's only recording the information, there's no particular incentive for acting on the information. The reward is simply having recorded that someone drinks too much, you don't get any benefit for actually treating them. So, that relies on our professional integrity to go further than that.' (HP11, GP)

'Just to check they've got a higher risk of health problems ... but the follow-up is difficult after that. It won't generally be on my radar to check ... if I've taken the blood and it comes back normal that's reassuring, but it's not actually helping them get their weight down, it's just acting on a normal blood result.' (HP04, GP)

Moreover, practitioners complained about the difficulty of persuading patients to attend a health check, which may account for the relatively high rates of exception reporting among SMI patients (Campbell et al., 2011). This corresponds with subthemes in Theme 2 around patient engagement and

time constraints.

Nuanced perceptions of the QOF

Perceptions of the QOF were not all negative, however, with a minority of participants delivering more nuanced responses. First, a few patients revealed that they welcomed receiving invitations for a health check as it demonstrated the practice was taking an interest in their health; and second, a number of GPs spoke positively about the QOF, though it was only those who had not experienced general practice in the pre-QOF era, as more experienced GPs were unequivocal that patient-centred care had been eroded by the implementation of the QOF, exemplifying key findings in Theme 1 and Theme 3.

A few more recently qualified GPs did claim, however, that the QOF had raised awareness of the physical health risks facing SMI patients and brought into view the unmet needs of this vulnerable group. Moreover, they revealed financial incentives had encouraged them to persevere with more vigour in engaging patients to attend for a health check in a way they would not do routinely for non-incentivised aspects of care.

'QOF makes you do it [a health check], and it's probably good in a way that it does make you do it because otherwise, it's easy to think, "Well, we've written to people and said, you need a health check and they haven't come, so let's just ignore that for another year." So, I think QOF probably helped in terms of these people getting a health check.' (HP09, GP)

Furthermore, several practitioners claimed they had continued to conduct checks for cholesterol, BMI and blood glucose, even after the incentives had been removed in 2014 (NHS Employers, 2014). These GPs explained that if they had succeeded in engaging a patient to attend surgery and be seen, it was as a missed opportunity not to take the full range of checks.

'QOF has helped because it's made us realise that this group should have an annual health check. And ... cutting down what's required is not a great thing really, because if we're going to call them in, we might as well be doing everything we can for them.' (HP09, GP)

'We're still doing it, it's still on our template to do it, so I think as a rule we generally follow the template rather than notice what the [QOF] points are.' (HP02, GP)

These two GPs, who incidentally were both female and relatively newly qualified, provided a rare example of where the QOF had arguably embedded good practice (Roland and Lester, 2007). However, it was only a minority of GPs who reported that they had continued to record retired QOF indicators without incentives. The majority of GPs admitted to breathing a sigh of relief that they were no longer expected to record a series measurements for the QOF, for which there was no evidence of benefit to quality of care or patient outcomes (Doran et al., 2014).

5.7.4 *Exception reporting*

Patients who do not respond to invitation for a QOF health check, or who do not present at another time where the check can be done opportunistically, can be removed from the indicator denominator to avoid penalties for the practice (Roland and Guthrie, 2016). This used to be known as exception reporting whereby GPs could remove a patient from an indicator for a specific reason such as clinical inappropriateness or patient choice (NHS England, 2019a), though its practice in relation to performance targets has been widely questioned (Doran et al., 2006).

'We generally have to exception report quite a few people because we do go through the process of inviting them for a review appointment, or doing it if they present for another reason ... but quite a lot of them just don't turn up, more than normal patients [with LTCs].' (HP04, GP)

'We do quite often struggle to get patients to come in ... they can just be difficult to communicate with.' (HP09, GP)

Exception reporting is thus another instance of where the visibility of SMI patients within practices was compromised, discussed further in Chapter Eight.

5.8 Chapter summary

This chapter has presented findings from the qualitative component of this thesis, which explored perceptions about factors believed to enhance or erode quality of care for SMI patients. Categorized into four core themes the main findings are summarised below.

- Theme 1: Patients and practitioners viewed continuity as a critical factor for developing a trusting and respectful relationship to enhance quality of care.
- Theme 2: Practitioners attributed time constraints and system level factors for the decline in their capacity to deliver patient-centred care.
- Theme 3: Evidence of discord and conflicting priorities between patients and practitioners resulting in patient needs not being heard or addressed.
- Theme 4: Shared perspective between patients and practitioners that quality of care has been undermined by disconnect and a slowing down of communication with secondary care.

Consolidating many of the key findings, the narrative case study of the QOF health checks provided an example of the ways in which a quality improvement scheme affected how care was provided and received, underlining many of the core themes and subthemes. Although opinions were nuanced, the

principle finding from both patient and practitioner perspectives was that the QOF had eroded quality of care by prioritising box ticking and the recording of measurements at the expense of patient-centred holistic care. Moreover, with the option to exception report patients who did not engage, the QOF further demonstrated that the visibility of SMI patients is transitory and inadequate.

Chapter Six: Quantitative Study Methods

6.1 Chapter content

The previous chapter presented and interpreted findings of the qualitative component of this thesis, which explored quality of care from the perspectives of patients with serious mental illness (SMI) and primary care providers. This chapter describes the methods used for the quantitative component, which examined quality of care for SMI patients from a different methodological standpoint. It begins by providing background and context to the study before defining the research questions and study objectives. It then describes the study design, data source and processes of data extraction. The chapter goes on to explain the methods used for statistical analysis which included a difference-in-differences design and a multivariate logistic regression model, before considering strengths and limitations associated with observational data. The chapter concludes with a summary of the key points.

6.2 Contextual background to research questions

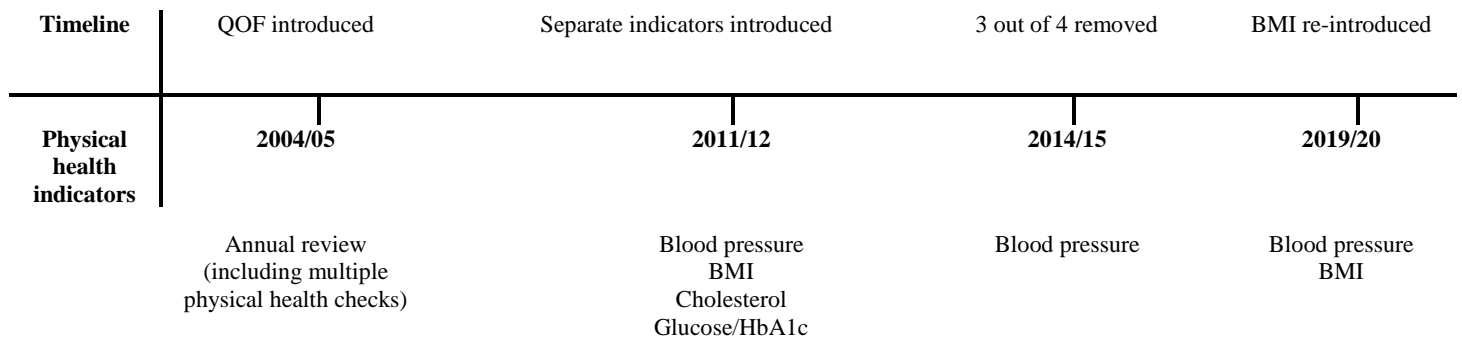
Since its inception in 2004, the Quality and Outcomes Framework(QOF) incorporated SMI as an area of clinical focus under the heading Mental Health, which referred specifically to diagnoses of serious mental illness: schizophrenia, bipolar disorder or other psychoses (NHS Employers, 2011).

One of the original QOF indicators was an annual review, along with a practice register of SMI patients, and lithium monitoring. The annual review required GPs to: record a selection of physical health measurements; review a patient's medication; and if relevant, check coordination with secondary care. The introduction of a programme of physical health monitoring reflected increased awareness in the scientific literature that SMI patients had higher levels of unmet physical health need compared with the general population (Kendrick, 1996). Elements of the QOF annual review were, therefore, viewed as a way of improving the quality of physical healthcare for SMI patients, particularly in relation to monitoring an increased cardiometabolic risk faced by SMI patients (De Hert et al., 2009).

Figure 6.1 displays a timeline demonstrating at what point QOF physical health indicators were introduced and removed. The timeline shows that from the outset in 2004/05, QOF incentivised GP practices to conduct and record an annual review of SMI patients' physical health. Initially, the time

period was every 15 months (NHS Employers, 2011) though this was reduced to 12 months in 2013/14 (NHS Employers, 2013).

Figure 6.1 QOF timeline: SMI patient physical health indicators



In 2011/12 policy changed and the annual review was divided into separate physical health indicators – blood pressure, body mass index (BMI), cholesterol and glucose/HbA1c – which were rewarded individually, rather than being combined to form a single incentive as had previously been the case. This system change lasted for only three years, however, until the end of 2013/14, after which three of the four cardiometabolic indicators – BMI, cholesterol and glucose/HbA1c – were retired (NHS Employers, 2014). Consequently, for the final two years of this study (2014/15 and 2015/16) blood pressure was the only physical health indicator to remain incentivised.

However, the decision to remove the 3 indicators was not supported by the NICE advisory committee, and in 2015 it recommended that the 3 indicators should be reintroduced along with a new indicator using QRISK2 to assess cardiovascular risk (NICE, 2015). In addition, the NICE QOF menu proposed that the age range be reduced from ≥ 40 years to ≥ 18 years for the cholesterol and glucose/HbA1c indicators, to match the age range for the blood pressure indicator (the BMI indicator had also been for anyone aged ≥ 18 years).

Finally, before moving onto the study design and methods, it is worth noting that Figure 6.1 displays additional changes to QOF physical health indicators, which occurred after this study time period ended. It provides two key pieces of information relevant to this thesis, which are discussed in Chapter Eight: first, blood pressure has remained incentivised up to the present time (March 2020); and second, BMI was reintroduced in 2019/20.

6.2.1 A natural experiment

The removal of QOF indicators in 2013/14 thus presented a unique opportunity to carry out a natural experiment (Craig et al., 2017), to investigate the effect that withdrawal of incentives had on the proportion of patients who received a health check. Given that blood pressure remained financially rewarded throughout the study period, it acted as a control for the other three indicators – BMI, cholesterol and glucose/HbA1c – where incentives had been removed.

6.3 Aims and objectives

6.3.1 Research questions

The quantitative arm of the study, which is the second core component of research for this thesis, aimed to address two main research questions:

- 1a.) Did the removal of incentives for three QOF indicators – BMI, cholesterol, and glucose/HbA1c – affect the proportion of SMI patients who received a health check for those indicators?
- 1b.) Were there any differences between the proportion of SMI patients who received a recording for BMI, cholesterol, and glucose/HbA1c compared with blood pressure, which continued to be incentivised, in the time period before and after incentives were removed?
- 2.) Is there any evidence that certain types of SMI patients were more likely to have received physical health checks, in relation to the demographic variables of: age; gender; ethnicity; SMI diagnosis type; or deprivation level?

6.3.2 Objectives

- 1) To conduct descriptive analysis of patient level data to:
 - a. Examine patient demographics and the representativeness of the dataset
 - b. Measure the crude proportions of patients who received a health check by financial year for each indicator.
- 2) To estimate the effect of policy change (removal of incentives) on the proportion of SMI patients who received a physical health check by measuring differences before and after

incentives were removed for BMI, cholesterol, and glucose/HbA1c compared with blood pressure, which remained incentivised.

- 3) To investigate the effect of other, potentially confounding, independent variables on the proportion of patients who received a health check, to determine which patients were more likely to have received a check.
- 4) To conduct descriptive analyses at the practice level to examine variation in practice performance (proportion of a practice's SMI population who received a health check) before and after incentives were removed, in relation to the number of SMI patients registered at a practice and practice deprivation level.

6.4 Study design

The design for this study was a retrospective, longitudinal observational cohort.

6.5 Study setting

The study setting was a UK primary care database, the Clinical Practice Research Datalink, which provided access to electronic health records from over 700 general practices. The study period was five years: from 1 April 2011 until 31 March 2016.

6.6 Data source

6.6.1 CPRD

The principal data source for this study was the Clinical Practice Research Datalink (CPRD), previously known as the General Practice Research Database, established over 30 years ago. CPRD provided this study with anonymised real world patient data, routinely collected from general practices in the UK (Clinical Practice Research Datalink, 2019). Until recently CPRD collected data solely from participating practices using Vision (Vision) software, though it now also collects data from practices using EMIS Web (Emis Health), known as CPRD AURUM. These two software systems have not yet been synthesised, however, so at present the datasets cannot be combined. Consequently, the dataset for this study was extracted from the CPRD GOLD database, consisting of data from Vision practices.

CPRD is a rich source of observational data, which has provided increasingly high quality data over the years (Springate et al., 2014), particularly since the introduction of the QOF in 2004, which enhanced the quality of data recoding in primary care (Herrett et al., 2015). Indeed, in the UK CPRD is one of the most widely used sources of primary care health data, valued for providing access to real-world data (McDonald et al., 2018). It supplies data across a range of variables including demographics, symptoms, diagnoses (from Read codes), prescriptions and referrals, from electronic health records of all patients registered at participating practices, except for those patients who have actively requested to opt-out from having their data shared. To ensure data quality, CPRD checks that data are of an ‘acceptable’ level from a practice before issuing an ‘up to standard’ date, which reflects the time point from when data are deemed to be of high enough quality to be included in research studies (Padmanabhan, 2017).

The expansion of CPRD over recent decades has vastly increased its coverage. By 2017, it included around 8% of the UK population, comprising of approximately 17 million patients – historical and current – registered at over 700 practices (Kontopantelis et al., 2018). The CPRD database is also considered to be broadly representative of the UK population in relation to key demographic variables such as age, sex and ethnicity (Mathur et al., 2014). Practices are not considered to be nationally representative, however, in relation to either practice list size or geographic location (Campbell et al., 2013). In general, CPRD practices have larger list sizes than the national average and are disproportionately located in urban areas within the South and North West regions of the country (Herrett et al., 2015).

6.6.2 Data accessed for this study

This thesis obtained access to CPRD data from the dataset used by EMERALD, a related study (Bellass et al., 2019) conducted at the University of York, which explored variation in diabetes outcomes for people with serious mental illness. This had not been part of the original plan, rather it reflected a pragmatic response to overcoming challenges presented at the time GDPR was being introduced. From the outset, the intended plan had been to obtain access to a CPRD dataset remotely via CALIBER (UCL Institute of Health Informatics). After prolonged delay, however, with no indication from the CALIBER team about when remote access provision would resume, an alternative plan was adopted. The EMERALD study dataset was a timely and suitable substitute, consisting of SMI patient data extracted from the CPRD GOLD database. Moreover, linkages to additional sources of health and demographic data were already in place, which had been the plan for the original dataset to provide a richer dataset than would have been possible from the CPRD database alone.

6.6.3 Data linkages with CPRD

CPRD provides the opportunity for electronic data linkages at the individual patient level with other health related datasets such as Hospital Episode Statistics (HES), the Office for National Statistics (ONS) mortality data and the Index of multiple deprivation (IMD). Linkages are carried out by a trusted third party (Padmanabhan et al., 2019) using an identifiable data variable – typically a patient’s NHS number for HES and ONS, or a patient’s postcode for IMD – for patients registered at practices who have consented to have their data linked with other sources (Herrett et al., 2015).

Hospital Episode Statistics (HES)

HES is a secondary care database containing detailed information on all admissions, emergency presentations and outpatient appointments at NHS hospitals in England (NHS Digital). CPRD had provided linkage to HES data for hospital admissions for the EMERALD study. This study combined the CPRD and HES recordings of a patient’s ethnicity to strengthen the data and minimise recordings of missing data.

Office for National Statistics mortality data (ONS)

The ONS mortality data provides information recorded on the death certificate for all deaths registered in England and Wales (NHS Digital). CPRD provided linkage with the ONS mortality data for all patients included in the EMERALD study. Consequently, this study had access to a dataset with information on both cause and date of death for any patients who died during the study period.

Index of multiple deprivation (IMD)

The IMD is an English indices of deprivation used to measure relative deprivation in small areas in England – known as lower-layer super output areas (LSOAs) – which include populations of approximately 1500 people (Allik et al., 2020). Combining seven multiple socioeconomic indicators – income, employment, health and disability, education, barriers to housing and services, living environment, and crime – the IMD provides a broad measure of deprivation (Department for Communities and Local Government). Deprivation level is categorised into either quintiles or deciles, though this study used quintiles where the first category (1) represents the least deprived and the last category (5) the most deprived. Patient level IMD is assigned by the patient’s postcode of residence; practice level IMD is based on the postcode of the general practice. CPRD provided dual linkage to the EMERALD study, allowing this study to access data for area deprivation at both the patient and the practice level.

6.7 Ethical approval

Access to data from CPRD required approval of the study protocol by the Independent Scientific Advisory Committee (ISAC). Scientific approval for the original CPRD protocol for this thesis was granted by ISAC in April 2018 to access the CPRD dataset remotely via CALIBER (UCL Institute of Health Informatics) (see Appendix 6.1). However, as previously described, plans had to be revised and access to a suitable dataset was granted by Professor NS the EMERALD study's chief investigator at the University of York. In addition, an EMERALD study protocol amendment was submitted to ISAC to obtain approval for this thesis to use the EMERALD dataset (see Appendix 6.2).

6.8 Data preparation

The EMERALD dataset accessed by this study consisted of electronic health records for patients with and without SMI (see Appendix 6.3), however, this thesis was only concerned with SMI patients. Hence a subset of the dataset was created, which only included patients with an SMI diagnosis who were eligible for all linkages. In total, there were 32, 759 individual patients from 328 different practices.

6.8.1 Data cleaning and extraction

Early stages of the data cleaning process had already been conducted by LH, –one of the investigators on the EMERALD study (NIHR HS&DR study (Lister et al., 2021)) and a co-supervisor for this PhD. Principally, this involved importing linkages to the patient file (including deprivation level, ONS death dates, ethnicity categorisation from HES data) along with cross referencing SMI diagnosis dates to check whether the earliest date documented in CPRD was accurate, as patients seen in secondary care may not have had their earliest diagnosis date recorded in primary care. Consequently, the subset of the EMERALD dataset used to conduct secondary data analysis for this thesis was already relatively 'clean', requiring fewer data quality checks than a dataset extracted directly from CPRD. The reliability of the dataset was, however, further validated by cross checking core demographics included in the data (such as age, gender, SMI diagnosis) to check their representativeness and performing checks to assess the extent of missing data particularly for the core variables (Virdee et al., 2020).

6.9 Participant eligibility

Participant eligibility for the study was determined by whether or not they were aged 18 and above at the time of SMI diagnosis; they had been diagnosed for at least 3 months before the start of each financial year; and they had been registered for the duration of each financial year, including 3 months before it began – see Table 6.1.

6.10 Configuration of CPRD data files

The way in which CPRD data are configured enabled analysis to be conducted at different levels – patient, staff or practice – all of which have unique identifiers. As shown in Table 6.2 information on different aspects of patient care is held in ten files, and this study merged and appended different units of data from other CPRD files to attain a more comprehensive set of data into an overarching patient file. The aggregation of different types of data into a singular file created a rich source of information at the individual patient level allowing multiple variables to be included in analyses.

Table 6.1 Data specifications for patient eligibility

Inclusion criteria	Justification
Diagnosed with SMI at least 3 months (90 days) before start of each financial year.	<i>In line with QOF Business Rules (HSCIC, 2013) which allow practices to exception report patients who have been registered for less than 90 days or been newly diagnosed with an SMI in the last 90 days.</i>
Registered at practice for 15 months (includes 3 months before start and full term of each financial year).	<i>To ensure each year only included prevalent cases excluding incident cases.</i>
Aged 18 years or over at first SMI diagnosis.	<i>SMI diagnosis more difficult to ascertain in children. Also QOF mental health indicators only relate to SMI patients aged 18 and above (NICE, 2015).</i>

Table 6.2 CPRD data files and how they are linked

Dataset	Description
Patient file	Information on patient (demographic/registration details) <i>unique patient identifier</i>
Practice file	Details on practice (region and last collection date) <i>unique patient and staff identifier</i>
Staff file	Information on practice staff (gender/role) <i>unique patient and staff identifier</i>
Consultation file	Information on consultations (type/duration/event date) <i>unique patient and staff identifier</i>
Clinical file	Information on all medical events (symptoms/signs/diagnoses) <i>unique patient and staff identifier</i>
Additional clinical details file	Data linked to events in clinical file <i>unique patient identifier and additional identifier</i>
Immunisation file	All immunisations recorded on GP system <i>unique patient and staff identifier</i>
Referral file	Any patient referrals to secondary or tertiary care <i>unique patient and staff identifier</i>
Test file	All tests requested for patients <i>unique patient and staff identifier</i>
Therapy file	All information on prescriptions issued to patients <i>unique patient and staff identifier</i>

Based on CPRD GOLD Data Specification (Padmanabhan, 2017)

6.11 Statistical analyses

Stata v.15 (stata) was used to conduct analyses for both the descriptive and the statistical modelling parts of this study.

- Descriptive analysis, carried out at both the patient and practice level, was used to describe the main features of the data:
 - 1) Patient level – included patient demographics and the crude proportion of patients who received a health check by financial year for each indicator.
 - 2) Practice level – included practice demographics and comparisons between practice performance (proportion of patients to have received a health check) before and after incentives were removed, in relation to the number of SMI patients registered and deprivation level.
- Statistical analysis used two types of mathematical modelling to investigate the primary and secondary aims of the study.
 - 1) Primary outcome: a difference-in-differences approach was used to estimate the effect of removal of incentives on the proportion of patients who received a health check, compared with an indicator that remained incentivised.
 - 2) Secondary outcomes: a multivariate logistic regression model was constructed to measure the effect of independent variables on the likelihood of a patient receiving a health check.

6.11.1 Rationale for methods

Quasi-experimental methods

For evaluating public health policies, quasi-experimental methods such as interrupted time series and difference-in-differences designs provide a strong alternative to the gold standard method of randomisation (Kontopantelis et al., 2015a). Quasi-experimental methods have become an increasingly popular way of measuring the impact of large-scale population health interventions that cannot be tested experimentally for ethical or practical reasons (Wagner et al., 2002). Given the primary aim of this study was to measure the effect of a health policy change that occurred at the national level – removal of QOF incentives across the UK – it was not feasible to conduct a randomised control trial (RCT). Quasi-experimental methods were the next best alternative.

Moreover, such designs offered stronger external validity through the use of real-world data, compared with RCTs where data are collected under control conditions (Shadish et al., 2002). Furthermore, because the policy change under investigation for this study took place at a single point in time and at the population level, it provided the opportunity to conduct a natural experiment (Kontopantelis et al., 2015a) to assess outcomes before and after, amongst the same population.

Selecting a quasi-experimental design

Choosing which quasi-experimental design to use to evaluate a natural experiment should depend on specific features of the study such as allocation of the intervention, data time points and size of the sample exposed, rather than which methods are viewed as strongest (Craig et al., 2017). Based on these criteria, at the planning stage of this study, either interrupted time series or a difference-in-differences design would have been an appropriate guide to measuring the effect of policy removal as the intended dataset would have satisfied the criteria for both designs (Shadish et al., 2002).

From interrupted time series to a difference-in-differences design

Initially, interrupted time series had been the favoured option to inform data analysis. Plans had to be revised, however, as the dataset which replaced the original one that had been approved by ISAC (to be accessed remotely via CALIBER, as discussed earlier), did not have sufficient post-intervention time points for interrupted time series analysis, which requires a minimum of three data points post-intervention (Cochrane Effective Practice and Organisation of Care Review Group, 2013). Given that QOF reports annually, there were only two data points (2014/15 and 2015/16) post intervention available from the EMERALD study dataset. Furthermore, it was not feasible to increase the number of data points by introducing monthly or quarterly measures as they would not have been an accurate reflection of QOF achievement (Minchin et al., 2018). Consequently, a difference-in-differences design was selected as the preferred method to conduct analysis and the study design and statistical analysis plan were revised accordingly.

6.11.2 Difference-in-differences design

A difference-in-differences design compares change in outcome between people exposed to an intervention with the outcome change of those who were not exposed. Developed as a method within econometrics, the origins of the difference-in-differences approach stem back to the 1850s when John Snow's evidence was published (1855) showing cholera was transmitted through the water supply rather than the air. In recent years, difference-in-differences designs are being used increasingly to evaluate health policy impact, principally, because they control for one of the key confounders

associated with observational data: background changes in outcomes that occur over time (Ryan et al., 2015). A difference-in-differences design thus offered a robust means of estimating the impact of a QOF health policy intervention, by comparing changes in outcomes over time between a group exposed to the intervention (Group 1), which was removal of incentives, and a group unexposed to the intervention (Group 2).

Modelling the outcome

The study aimed to measure the difference in the proportion of patients who received a health check for BMI, cholesterol and glucose/HbA1c, before and after incentives were removed, comparing the difference in outcomes with blood pressure, which remained incentivised, so acted as a control. Given this study involved a single difference-in-differences analysis (Villa, 2016) the statistical model used, shown in Figure 6.2, was a standard regression model for difference-in-differences estimation, as described by Craig et al (2017).

Figure 6.2 Regression model for difference-in-differences estimation

$$\text{Model 1: } Y_{it} = \beta_0 + \beta_1 E_i + \beta_2 P_t + \beta_3 E_i \times P_t + \varepsilon_{it}$$

In Model 1 Y is the outcome, observations are made on different units i , at times t , and the regression model includes an additional term for the period (P) in which the observation took place (coded 0 for pre-intervention or 1 for post-intervention), and an interaction term between the period and exposure, which provides the difference-in-differences effect estimate β_3 :

Source: (Craig et al., 2017)

Figure 6.3 Difference-in-differences predictive model

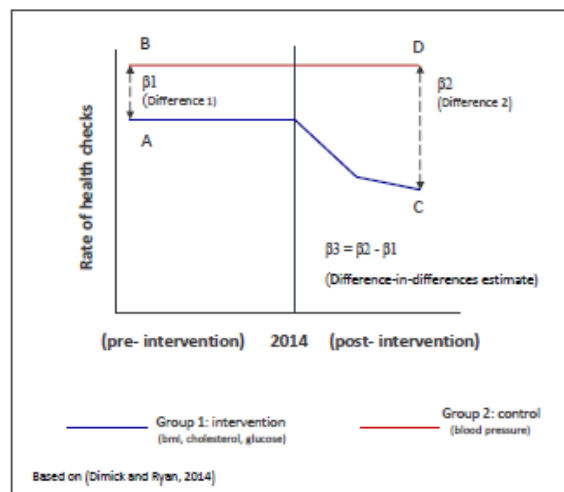


Figure 6.3 visually displays the predictive model for the difference-in-differences estimate for this study. It shows the removal of incentives was expected to have resulted in a negative outcome, displayed by a smaller proportion of patients receiving health checks in Group 1 after financial incentives had been removed.

The difference-in-differences estimate β_3 is demonstrated by the difference between two differences: difference 2 minus difference 1, displayed in the model by β_2 (C-D) minus β_1 (A-B). The difference-in-differences coefficient β_3 thus equates to the ‘treatment effect’ or, in the case of this study, the ‘removal of incentives effect’. It is the difference in outcomes between group 1 (retired incentives) and group 2 (still incentivised) post-intervention, minus the difference in outcomes between group 1 and group 2 pre-intervention. If, however, there was no change in outcomes between Group 1 and Group 2, and the difference-in-differences estimate was equal to zero, it would be assumed that the removal of incentives had had no effect (Ryan et al., 2015).

6.11.3 Secondary outcomes analysis

A multivariate logistic regression technique was selected to examine the effect of other (potentially confounding) factors on the dependent variable of whether or not a patient received a health check each financial year. Due to the *yes/no* binary outcome of the dependent variable, logistic regression was the most appropriate statistical model to use (Peng et al., 2010). Thus, a multivariate logistic regression model was constructed, shown in Figure 6.4, to measure the likelihood of a patient receiving a health check whilst holding other independent variables to account.

Figure 6.4 Multivariate regression model

$$\text{Model 2: } Y_i = \beta_0 + \beta_1 E_i + \beta_2 X_i + \varepsilon_i$$

A standard multivariate regression model was used to estimate the effect of exposure to the intervention (E), removal of incentives, on the outcome (Y), proportion of patients who received a health check, with adjustment for independent variables, which may have influenced the outcome (X).

Source: (Craig et al., 2017)

Selecting independent variables

Construction of a multivariate regression model for this study involved selecting a range of independent variables, which may have influenced the outcome of whether or not a patient received a health check. The purpose was to understand the influence of each independent variable on the

likelihood of a participant receiving a health check for each financial year from 2011/12 to 2015/16 whilst holding the other independent variables constant.

Potential independent variables were selected based on background knowledge of the literature (Shipe et al., 2019) and discussion with thesis supervisors about what would be meaningful and what was feasible given the delay in acquiring access to CPRD data. It was agreed that due to time constraints data analysis should concentrate on core demographics of each patient rather than include comorbidities. The logistic regression model, built on an empirical basis, involved individually testing independent variables such as age, gender, SMI diagnosis (Bursac et al., 2008), before adding them to the model in a step-by-step iterative construction, known as stepwise forward selection procedure (Heinze et al., 2018). The multivariate model thus provided a more accurate estimate of effect between each independent variable and the dependent variable by adjusting for the other independent variables in the model (Bland, 2015). The final selection included in the regression model consisted of six core demographic variables: age; gender; SMI type; ethnic origin; and deprivation level.

Categorising variables

Reference categories were chosen on the basis of size and association with the outcome of interest (Ranganathan et al., 2017). Generally, a larger group within a variable, such as schizophrenia for SMI type, would form the reference point for the other categories (Tabachnick and Fidell, 2013). For continuous variables such as age, decisions had to be made about how best to group the variable into categories in a way that would minimise information loss and the associated reduction in statistical power (Altman and Royston, 2006). For variables that were already categorical, but which had numerous categories, pragmatic decisions were made in an attempt to keep the model simple. Consequently, some of the very small categories within variables were merged, for example, ‘mixed’ and ‘other’ were combined in the ethnicity category. The sole dichotomous independent variable included in the model was gender, which remained unaltered from its binary state within the CPRD dataset.

Independent variables included in the model

For the variables with multiple categories or continuous numbers, decisions about how to categorise them were based on testing out different ways of doing it and then discussing the results with thesis supervisors. The final list of covariates included in the model comprised of six: financial year, age, gender, SMI type, ethnicity and patient level area deprivation.

- Age was converted from a continuous variable to a categorical variable, grouped into 4 categories, with the reference category selected as 40-59 years. The other three categories were: under 40 years; 60-74 years; and 75 years and over. The age of 40 years was chosen as the first cut-off point because two of the health checks (cholesterol and glucose/HbA1c) were only incentivised for patients aged 40 years and above, meaning that sensitivity analyses could be conducted comparing outcomes relative to that age.
- Gender was a dichotomous category in the CPRD dataset consisting only of male/female. For this study, male was selected as the reference category, to be compared with female.
- SMI type was categorised into 4 types of diagnosis. Schizophrenia was chosen as the reference category to be compared with: bipolar disorder; depression with psychosis; and other affective disorders, which included other smaller categories of diagnosis including schizoaffective disorder.
- Ethnicity used categories from the core 2011 Census Ethnic Categories (GOV.UK.). It consisted of White (disproportionately the largest group); Asian; Black; and Other, which included Mixed, another very small category.
- Patient level area deprivation as measured by the Index of Multiple Deprivation in 2010 (Department for Communities and Local Government). Deprivation was categorised by quintile: 1 the least deprived, selected as the reference category, and 5 the most deprived.

6.11.4 Fixed effects

Given that the core demographic variables were time invariant, a fixed effects model was selected to control for omitted variable bias, based on the assumption that whatever the effect omitted variables have on the outcome, they will have the same effect at a later time, therefore, the effects would be constant or ‘fixed’ (Allison, 2009). Financial year was thus included as a dummy variable for four out of the five years to control for the specific effect of time.

6.11.5 Adjusting for standard error

Both models adjusted the standard errors for clustering (Ryan et al., 2015) at the practice level.

6.11.6 Missing data in CPRD

Missing data within the CPRD dataset was minimal. Ethnicity and deprivation level were the only two covariates included in the model that contained missing data, consisting of less than 4.5% for ethnicity and 0.1% for deprivation across all five years. Despite there being no standardised cut-off point in the literature for what percentage level of missing data is acceptable for statistical analyses, it is

considered that less than 5% is unlikely to introduce bias (Bennett. D. A, 2001). Consequently, given the categories with missing data had less this, missing data was removed from the analyses.

6.12 Strengths and limitations of observational data

6.12.1 Data source

One of the key strengths of using observational data from a primary care database such as CPRD is that it provides a much larger sample with wider geographical reach than would be possible with experimental data (Herrett et al., 2015). In addition, its sample of patients is largely representative of the general population. Moreover, because it is routinely recorded in clinical practice, it enables researchers to use real-world data, which has stronger external validity compared with RCTs (Kontopantelis et al., 2015a). Another core strength of CPRD is the quality of data recording which is consistently high, particularly after the introduction of QOF in 2004 (Khan et al., 2010). Finally, as data in the CPRD database are recorded at the patient level, it provides a rich dataset of granular data, which is particularly valuable to researchers (Gallagher et al., 2019).

There are, however, potential limitations associated with using observational data. Primarily, there is an inherent risk of biases being introduced through inconsistent or inaccurate recording of data (McDonald et al., 2018). In addition, variation in coding may occur between practices and/or over time affecting the quality of data recorded, which may introduce bias in how care is recorded compared with how care is delivered (Springate et al., 2014). Sample size, though rarely a problem for primary care databases, can present an issue when using multiple data linkages, which typically reduce the number of eligible patients by up to half (Herrett et al., 2015). In addition, there is a possibility that separate data sources provide strands of unmatched data, although previous studies which used multiple data sources reported all data linkages to be of high quality (Ride et al., 2018, Jacobs et al., 2015a). Finally, relating specifically to CPRD, the database is overrepresented by larger GP practices in urban areas in the South and the North West of the country. Consequently, questions remain over the representativeness of UK practices regarding deprivation and practice list size (Kontopantelis et al., 2015b).

6.12.2 Methods

A core strength of quasi-experimental study designs is that researchers can estimate causal effects, which is not feasible using most observational approaches (Kontopantelis et al., 2015a). Indeed, evidence suggests a difference-in-differences design is the quasi-experimental design that gets closest

to being able to measure causal inference (Wing et al., 2018). In addition, simple pre-post study designs cannot detect underlying trends: however, methods such as a difference-in-differences design addresses the problem by using a comparison group (in this case blood pressure) experiencing the same time trends, but not exposed to the policy change (Dimick and Ryan, 2014). As such, using a difference-in-differences approach is reliant on having access to and using pre-intervention data and it is this feature that allows for control of unobserved variables that typically bias estimates of causal effect. Furthermore, another strength of the statistical methods used for this study was the multivariate logistic regression model, which enabled the effect sizes of individual variables to be adjusted for while keeping other covariates constant. This controlled for confounding and provided estimates for the relative influence of independent variables (Peng et al., 2010).

There are potential limitations, however, associated with using quasi-experimental methods. For difference-in-differences designs these relate largely to the assumptions that need to be met to ensure internal validity. As discussed earlier, a difference-in-differences design is not able to use randomisation to avoid bias from unmeasured confounders. Therefore, to compensate for not being able to randomly assign participants, assumptions are imposed to minimise the effect of possible confounders (Ryan et al., 2015). Principally, the key assumption that needs meeting is the ‘parallel trends’ assumption based on the premise that, in the absence of policy intervention, the difference between the treatment group (indicators where incentives were removed) and control group (indicator where incentives remained) would have remained constant over time (Zhou et al., 2016). Additional risk to internal validity is caused when the ‘common shocks’ assumption cannot be met, when it is likely an unexpected event (unrelated to the policy change) would have affected the intervention and the control group differently (Dimick and Ryan, 2014). Finally, the main limitation associated with using regression models relates to the quality of data. Missing data or inconsistently recorded data can limit the strength of data analysis (Bland, 2015), however, this is unlikely to have affected this study as the basic demographics are very well recorded in CPRD (Ride et al., 2018).

6.13 Chapter summary

This chapter has provided rationale for why CPRD was selected as a suitable data source for this thesis. It has outlined the decisions made about the study design and statistical analysis plan, principally in relation to controlling for confounding, to maximise internal validity and ensure robustness of findings. The chapter explained why an interrupted time series design was not deemed appropriate given the small number of post-intervention time points in the dataset and why a difference-in-differences design was a preferable alternative. It then discussed construction of a multivariate logistic regression model used to measure the influence of other confounding factors on

the outcome of interest. Finally, it described the strengths and limitations associated with using observational data, both in terms of data sources and methods.

Chapter Seven: Quantitative Study Results

7.1 Chapter content

This chapter presents findings from the quantitative study carried out for this thesis, using the methods described in the previous chapter. Analyses were conducted primarily at the patient level, accompanied by some descriptive analysis at the practice level. The chapter begins by summarising data preparation and outlining participant characteristics. It then presents results from analysis using a difference-in-differences approach, which estimated the effect of removal of financial incentives on the proportion of participants receiving a health check, using blood pressure as a control. It goes on to present findings from analysis of secondary outcomes using a multivariate logistic regression model, which examined the likelihood of a participant receiving a health check whilst controlling for independent variables. Practice level data were then analysed to examine variation in indicator performance by number of SMI patients registered at a practice and area level deprivation.

7.2 Data preparation

Identifying eligible patients

The study sample for this thesis comprised of 32,159 patients with a diagnosis of SMI recorded in primary care who met eligibility criteria (see Table 6.1, Chapter Six) for the five financial years included in the study period (2011/12 to 2015/16). As described in Chapter Six, the dataset for this thesis was drawn from the EMERALD study (Bellass et al., 2019), a larger longitudinal CPRD dataset spanning from April 1st 2000 to March 31st 2016 that included patients with and without SMI. Data preparation consisted of a number of procedures outlined in Appendix 7.1.

7.3 Patient level descriptive analyses

7.3.1 Summary statistics

As shown in Table 7.1, once eligibility criteria had been applied, the total number of eligible patients decreased year on year across the study period. The study sample consisted of: 11,768 patients in 2011/12; 11,682 patients in 2012/13; 10,630 patients in 2013/14; 9,057 patients in 2014/15; and 6,185 patients in 2015/16, indicating the largest decrease in number of eligible patients was from 2014/15 to 2015/16, the final year of the study.

7.3.2 *Participant characteristics by financial year*

Table 7.1 shows participant characteristics for each of the five financial years included in the study:

- In **2011/12**, the sample consisted of 11,768 patients of whom 50.2% were female with a mean age of 51.7 years old. Ethnic origin was recorded as White in 85.3% of patients, Asian in 4.0% of patients and Black in 3.8% of patients. SMI diagnosis was recorded in 51.4% of patients as schizophrenia, 35.6% of patients as bipolar disorder, 6.5% of patients as depression with psychosis and 6.5% of patients as other affective disorder, which included schizoaffective disorder. By deprivation quintile, 14.6% of patients were in the least deprived category and 25.3% of patients were in the most deprived category.
- In **2012/13**, the sample consisted of 11,682 patients of whom 50.0% were female with a mean age of 51.7 years old. Ethnic origin was recorded as White in 84.7% of patients, Asian in 4.2% of patients and Black in 4.2% of patients. SMI diagnosis was recorded in 51.1% of patients as schizophrenia, 36.0% of patients as bipolar disorder, 6.4% of patients as depression with psychosis and 6.5% of patients as other affective disorder, which included schizoaffective disorder. By deprivation quintile, 14.4% of patients were in the least deprived category and 25.8% of patients were in the most deprived category.
- In **2013/14**, the sample consisted of 10,630 patients of whom 50.2% were female with a mean age of 51.9 years old. Ethnic origin was recorded as White in 84.7% of patients, Asian in 4.2% of patients and Black in 4.1% of patients. SMI diagnosis was recorded in 50.3% of patients as schizophrenia, 37.0% of patients as bipolar disorder, 6.4% of patients as depression with psychosis and 6.2% of patients as other affective disorder, which included schizoaffective disorder. By deprivation quintile, 15.2% of patients were in the least deprived category and 24.9% of patients were in the most deprived category.
- In **2014/15**, the sample consisted of 9,057 patients of whom 50.6% were female with a mean age of 52.1 years old. Ethnic origin was recorded as White in 85.0% of patients, Asian in 4.2% of patients and Black in 4.1% of patients. SMI diagnosis was recorded in 49.9% of patients as schizophrenia, 37.2% of patients as bipolar disorder, 6.4% of patients as depression with psychosis and 6.4% of patients as other affective disorder, which included schizoaffective disorder. By deprivation quintile, 15.8% of patients were in the least deprived category and 25.4% of patients were in the most deprived category.
- In **2015/16**, the sample consisted of 6,185 patients of whom 50.7% were female with a mean age of 51.9 years old. Ethnic origin was recorded as White in 85.0% of patients, Asian in

4.1% of patients and Black in 4.0% of patients. SMI diagnosis was recorded in 48.8% of patients as schizophrenia, 37.5% of patients as bipolar disorder, 6.5% of patients as depression with psychosis and 7.3% of patients as other affective disorder, which included schizoaffective disorder. By deprivation quintile, 16.9% of patients were in the least deprived category and 25.5% of patients were in the most deprived category.

7.3.3 *SMI patient sample*

Looking at the participant characteristics by financial year revealed similarities between this CPRD SMI patient sample and other studies that have used primary care databases in relation to SMI diagnosis type (Hayes et al., 2017) and deprivation level (Osborn et al., 2018). Gender and ethnicity were nationally representative of the UK population in general.

- **Gender:** the proportion of males and females was relatively evenly distributed for each year of the study period with slightly more females compared with males (Clark, 2020).
- **Age:** the overall mean and median ages were also consistent by financial year, although the median age demonstrated a small difference by gender with males slightly younger than females, at 48 years and 53 years, respectively.
- **SMI diagnosis type:** the sample had a higher proportion with schizophrenia compared with bipolar disorder, similar to other studies that have used primary care databases (Hayes et al., 2017).
- **Ethnicity:** the sample was broadly representative of the population of England and Wales based on the 2011 census (GOV.UK.).
- **Deprivation:** patient level area deprivation indicated little variation between years across the study period in the proportion of patients in each quintile. However, the proportions were not evenly distributed across the five quintiles of deprivation. Similar to other corresponding studies (Osborn et al., 2018, Kontopantelis et al., 2015b), there was a smaller proportion of SMI patients in less deprived quintiles with the largest proportion in the most deprived quintile.

In summary, the participant characteristics of the sample for this thesis were largely comparable with other studies using similar populations from primary care databases.

Comorbidities

People with SMI have high rates of comorbidities (Smith et al., 2013). While comorbidities were not included in the dataset analysis for this thesis, reference to studies using similar data can provide a useful context for why the physical health checks were being conducted. Notably, a study using comparable CPRD data, found the most common comorbidities for people with SMI were: hypertension (>10%); diabetes (~10%); cardiovascular disease (>5%) (Lister et al., 2021). Evidence of elevated levels of comorbidity in the SMI patient sample underlines why the type of health checks (blood pressure, blood glucose/HbA1c, cholesterol) were originally selected – to identify patients with heightened risk of developing conditions most likely to cause premature mortality and morbidity (Martin et al., 2014).

Inequalities

People with SMI are more likely to have comorbidities than the general population though the level of inequality varies between conditions (Reilly et al., 2015). Analysis using data from THIN (The Health Improvement Network), a primary care database similar to CPRD, demonstrated higher rates of comorbidities among the SMI population compared with the general population. Rate ratios were particularly high for conditions targeted by the SMI QOF indicators such as diabetes (1.9), obesity (1.8) and cardiovascular disease (~1.5) though there was no apparent difference for hypertension between patients with SMI and the general population (Public Health England, 2018). In addition, patients with SMI are nearly twice as likely as the general population to experience multimorbidity (the diagnosis of more than one physical health condition along with their psychiatric condition). Furthermore, a recent study (under peer review) demonstrated SMI patients had a higher prevalence of multimorbidity at a younger age compared to comparators without SMI (Launders et al., 2021) which may account for why the relative risk of mortality is higher for SMI patients at a younger age (Osborn et al., 2007).

Table 7.1 Participant characteristics by financial year

Financial year	No. eligible* patients (total = 49,322)	Gender		Age (years)		No. of patients by SMI diagnosis type		Ethnicity		Deprivation level** (1 least, 5 most deprived)	
		Male	Female	Mean	Median						
2011/12	11,768	5,857 (49.8%)	5,911 (50.2%)	51.7 (SD 15.8)	50 (male 48) (female 53)	Bipolar disorder Schizophrenia Depression psychosis Other affective disorder	4,184 (35.6%) 6,051 (51.4%) 763 (6.5%) 770 (6.5%)	White Asian Black Mixed Other Not stated	85.3% 4.0% 3.8% 1.3% 1.5% 4.1%	1. 2. 3. 4. 5. Missing	14.6% 17.4% 18.8% 23.8% 25.3% 0.1%
2012/13	11,682	5,842 (50.0%)	5,840 (50.0%)	51.7 (SD 15.8)	50 (male 48) (female 53)	Bipolar disorder Schizophrenia Depression psychosis Other affective disorder	4,202 (36.0%) 5,974 (51.1%) 742 (6.4%) 764 (6.5%)	White Asian Black Mixed Other Not stated	84.7% 4.2% 4.2% 1.3% 1.6% 4.0%	1. 2. 3. 4. 5. Missing	14.4% 17.1% 18.7% 23.8% 25.8% 0.1%
2013/14	10,630	5,292 (49.8%)	5,338 (50.2%)	51.9 (SD 15.8)	51 (male 48) (female 54)	Bipolar disorder Schizophrenia Depression psychosis Other affective disorder	3,936 (37.0%) 5,351 (50.3%) 682 (6.4%) 661 (6.2%)	White Asian Black Mixed Other Not stated	84.7% 4.2% 4.1% 1.3% 1.6% 4.0%	1. 2. 3. 4. 5. Missing	15.2% 17.7% 18.4% 23.6% 24.9% 0.1%
2014/15	9,057	4,475 (49.4%)	4,582 (50.6%)	52.1 (SD 15.7)	51 (male 49) (female 53)	Bipolar disorder Schizophrenia Depression psychosis Other affective disorder	3,371 (37.2%) 4,521 (49.9%) 584 (6.4%) 581 (6.4%)	White Asian Black Mixed Other Not stated	85.0% 4.2% 4.1% 1.3% 1.3% 4.1%	1. 2. 3. 4. 5. Missing	15.8% 17.6% 17.7% 23.5% 25.4% 0.1%
2015/16	6,185	3,049 (49.3%)	3,136 (50.7%)	51.9 (SD 15.6)	51 (male 49) (female 54)	Bipolar disorder Schizophrenia Depression psychosis Other affective disorder	2,317 (37.5%) 3,016 (48.8%) 401 (6.5%) 451 (7.3%)	White Asian Black Mixed Other Not stated	85.0% 4.1% 4.0% 1.2% 1.3% 4.3%	1. 2. 3. 4. 5. Missing	16.9% 16.7% 18.1% 22.8% 25.5% 0.0%

* Eligible patients: aged 18 years or over at first SMI diagnosis; diagnosed with SMI at least 3 months (90 days) before start of each financial year; registered at practice 3 months before until end of each financial year

** The English Indices of Deprivation 2010 (<https://www.gov.uk/government/collections/english-indices-of-deprivation>)

SD = standard deviation

7.3.4 Descriptive statistics: health checks by financial year

Preliminary analysis consisted of generating the outcome variable for each different indicator: blood pressure, BMI, cholesterol and glucose/HbA1c, which involved calculating the proportion of eligible patients who had received a health check by financial year (from 2011/12 to 2015/16). The dependent variable was dichotomous, either 'yes' a patient had a recording of one or more checks for an individual indicator during a financial year, or 'no' there was no recording of a check. Table 7.2 shows the crude numbers and proportion of eligible patients who received a check for each of the four different indicators by financial year, alongside the proportion who received a check for all four indicators during the same financial year. The same data are shown in Figure 7.1 using a two-way line graph to visually display the variation between indicators and across time, with a vertical line indicating the point at which incentives were removed.

Pre-intervention

As shown in Table 7.2, in the three years before financial incentives were removed (pre-intervention period), blood pressure was the indicator with the highest proportion of patients to receive a check with 84.2% in 2011/12; 81.2% in 2012/13; and 85.1% in 2013/14. Next was cholesterol, 78.6% in 2011/12; 73.0% in 2012/13; and 79.4% in 2013/14. This was followed by BMI, 70.5% in 2011/12; 64.2% in 2012/13; and 73.4% in 2013/14. The indicator with the lowest proportion of patients to receive a check was glucose/HbA1c with 64.9% in 2011/12; 58.1% in 2012/13; and 66.1% in 2013/14. During the pre-intervention period, the proportion of patients to receive a check for all four indicators in the same financial year was: 52.7% in 2011/12; 42.7% in 2012/13; and 54.6% in 2013/14.

Post-intervention

Post-intervention, the two years after financial incentives were removed, blood pressure was the indicator with the highest proportion of patients to receive a check with 83.1% in 2014/15; and 82.1% in 2015/16. This was followed by cholesterol, 67.3% in 2014/15; and 65.1% in 2015/16. There was little difference between BMI and glucose/HbA1c, 55.4% and 53.4% in 2014/15; and 51.6% and 53.4% in 2015/16, respectively. During the post-intervention period, the proportion of patients to receive a check for all four indicators in the same financial year was 35.2% in 2014/15; and 32.5% in 2015/16.

Overall, as illustrated in Figure 7.1, in the period before incentives were removed the proportion of patients to receive a check varied by indicator: the highest was for blood pressure (>80%); the lowest

for glucose/HbA1c (~63%). Around half of the eligible patients received a check for all four indicators in the same financial year. In the period after incentives were removed, the proportion of checks recorded declined for all indicators, though it declined more for some than others. Blood pressure, which remained incentivised, continued to be the indicator with the highest proportion of checks recorded (> 80%). It also had the smallest percentage decline (< 5%) compared with the other three indicators (> 10%), where incentives had been removed. Similarly, the proportion who received a check for all four indicators in the same financial year also declined markedly post-intervention: from around a half to a third of eligible patients.

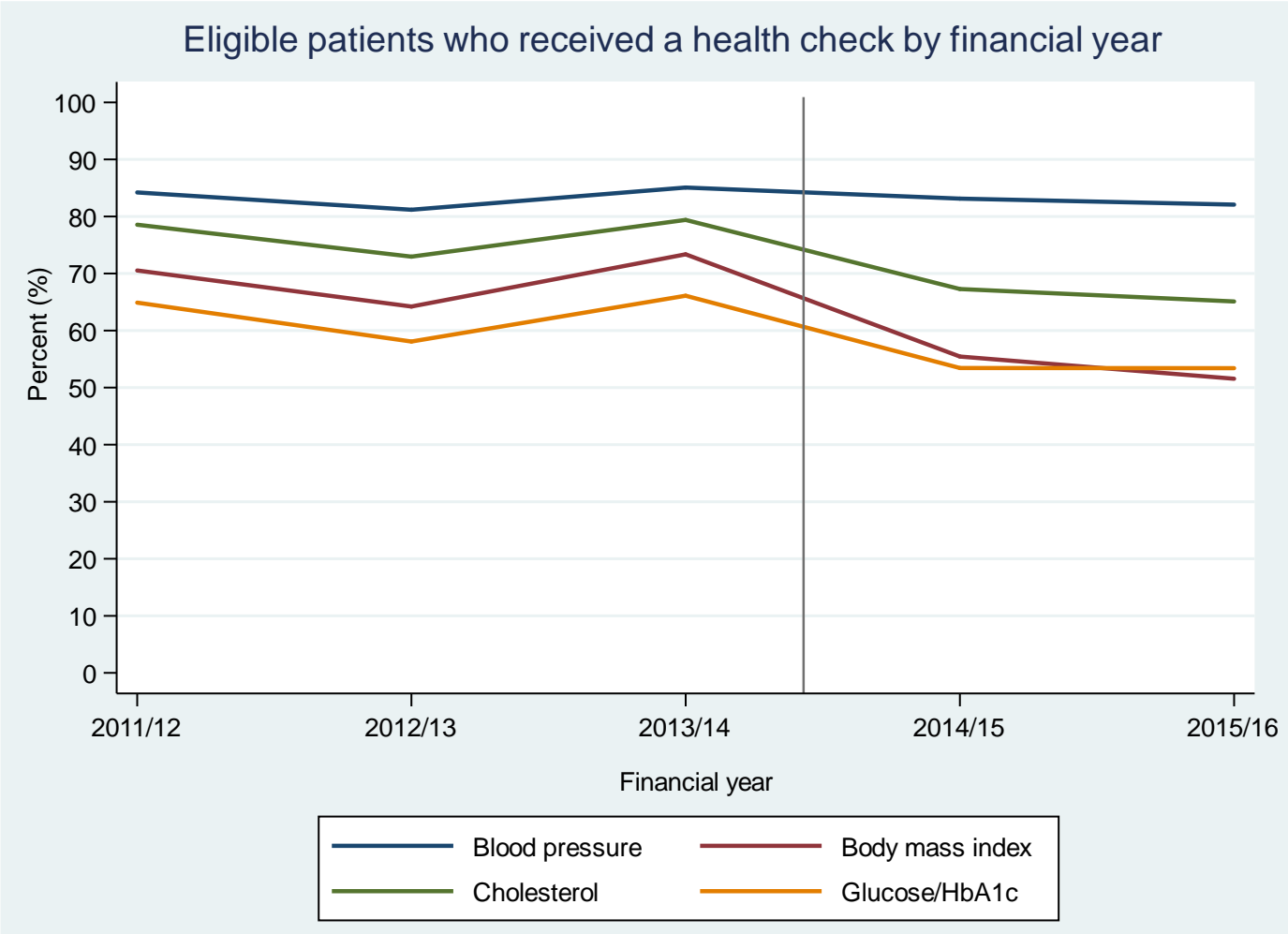
Table 7.2 Proportion of eligible patients who received a health check by financial year

Financial year	No. eligible* patients	No. of patients who received a health check (% of eligible patients)				
		Blood pressure	Body mass index	Cholesterol	Glucose/HbA1c	All 4 health checks
2011/12	11,768	9,911 (84.2%)	8,301 (70.5%)	9,244 (78.6%)	7,637 (64.9%)	6,205 (52.7%)
2012/13	11,682	9,484 (81.2%)	7,502 (64.2%)	8,523 (73.0%)	6,785 (58.1%)	4,993 (42.7%)
2013/14	10,630	9,043 (85.1%)	7,799 (73.4%)	8,441 (79.4%)	7,028 (66.1%)	5,802 (54.6%)
2014/15**	9,057	7,529 (83.1%)	5,022 (55.4%)	6,094 (67.3%)	4,840 (53.4%)	3,184 (35.2%)
2015/16	6,185	5,077 (82.1%)	3,189 (51.6%)	4,027 (65.1%)	3,303 (53.4%)	2,010 (32.5%)

* Eligible patients: aged 18 years or over at first SMI diagnosis; diagnosed with SMI at least 3 months (90 days) before start of each financial year; registered at practice 3 months before until end of each financial year

** Financial incentives removed for body mass index, cholesterol and glucose/HbA1c

Figure 7.1 Proportion of eligible patients who received a health check: before and after the removal of incentives



7.4 Patient level statistical analyses

As described in Chapter Six, a difference-in-differences design was used to statistically analyse the effect of policy change (removal of incentives) on the proportion of patients who had health checks recorded. The difference-in-differences design consisted of two groups and two time periods: Group 1 (BMI, cholesterol and glucose/HbA1c) exposed to policy change; and Group 2, the control group (blood pressure), unexposed to the intervention; before and after incentives were removed. Thus the removal of incentives for only three of the four physical health indicators created a natural experiment (Craig et al., 2017) as blood pressure, which remained incentivised, acted as a control.

7.4.1 Meeting difference-in-differences assumptions

As discussed in more detail in Chapter Six, the two main assumptions affecting the robustness of difference-in-differences designs are the ‘parallel trends’ assumption and ‘common shocks’ assumption (Zhou et al., 2016). Principally, the parallel trends assumption stipulates that if there had been no policy intervention, any differences between the control and the intervention group would have remained constant over time (Dimick and Ryan, 2014).

Parallel trends assumption

For this thesis, visual evidence was used to assess validity of the parallel trends assumption. A two-way line graph in Figure 7.2 shows that the difference between the mean average outcome score of the treatment group combined (BMI, cholesterol and Glucose/HbA1c) compared with the control group (blood pressure) was more or less constant across the three time points during the period before the policy intervention.

The parallel trend assumption was further demonstrated at the individual indicator level, as shown by Figure 7.3 for BMI, Figure 7.4 for cholesterol and Figure 7.5 for glucose/HbA1c, which compared the outcomes of each intervention indicator with the control in separate line graphs. Visually, the lines displayed for BMI, cholesterol and glucose/HbA1c were constant and in parallel with blood pressure for the period between 2011/12 and 2013/14, before incentives were removed. Given that the intervention and control group had parallel trends in the pre-intervention period, the trend for the control group (blood pressure) during the post-intervention period would have likely represented the counterfactual trend for the intervention group, had incentives not been removed (Angrist and Pischke, 2008). However, uncertainty remains and it has been argued that parallel trends pre-intervention can only be a suggestion of what may have happened without policy intervention: it

should not be assumed that the control post-intervention represents the counterfactual (Kahn-Lang and Lang, 2019).

Common shocks assumption

The second assumption is the common shocks assumption whereby any unexpected events (unrelated to the policy change) that take place during the study period are likely to have affected both treatment and control groups equally (Angrist and Pischke, 2008). In the case of this thesis, as discussed in Chapter Six, this assumption was strengthened as both Group 1 and Group 2 were part of the same population in the same primary care system over the same time period. The only difference between the treatment and control group was exposure to the policy change for the indicators where incentives were removed (Dimick and Ryan, 2014). Consequently, confounding between treatment and control groups was minimised.

7.4.2 Difference-in-differences estimate

Having visually displayed evidence that the parallel trends assumption was valid for this study by there being little difference between data points for the treatment and control groups in the two-way line graphs shown in Figure 7.3, Figure 7.4 and Figure 7.5 for the pre-intervention period, the next step was to formally test the size of the difference-in-differences effect using the Stata diff-in-diff command (Villa, 2016). This technique measured the difference between the post-intervention difference and pre-intervention difference, meaning that any significant differences between intervention and control groups post and pre-intervention would indicate ‘treatment effect’, or in the case of this study, removal of incentives effect.

Before statistically measuring the difference-in-differences effect for each treatment indicator, an estimation of the differences could be seen by looking at the two-way line graphs displayed in Figure 7.3, Figure 7.4 and Figure 7.5, which visually displayed the trends, showing that there was an immediate decrease in 2014/15 for all three indicators in the treatment group following removal of incentives, both in the level and gradient of the slope. In 2015/16, the final year of the study, there was a levelling off of the slopes for all the indicators where incentives had been removed.

As shown in Figure 6.3 in Chapter Six, the difference-in-differences estimate was calculated as the difference between the differences (intervention – control group) after the intervention, minus the difference between the differences (intervention – control group) pre-intervention (Dimick and Ryan, 2014). Although the changes were absolute increases or decreases, they represented changes relative to the underlying trends.

7.4.3 Difference-in-differences estimate by indicator

Table 7.3 and Figure 7.2 show the difference-in-differences estimate for all treatment indicators combined (BMI, cholesterol and glucose/HbA1c) compared with blood pressure, which was -11.1% ($p < 0.01$), which suggests that overall activity for health checks where incentives had been removed had decreased by more than 10%. Analysis at the individual indicator level displayed more detailed findings. Table 7.4 and Figure 7.3 show the difference-in-differences estimate for BMI compared with blood pressure was -14.6% ($p < 0.01$). Table 7.5 and Figure 7.4 show the difference-in-differences estimate for cholesterol compared with blood pressure was -9.8% ($p < 0.01$). Table 7.6 and Figure 7.5 show the difference-in-differences estimate for glucose/HbA1c compared with blood pressure was -8.8% ($p < 0.01$).

Overall, variation in the estimates between the three treatment indicators and the control indicate that the largest difference-in-differences pre and post-intervention was 14.6% for BMI. As discussed earlier, this corresponded with BMI having the largest decline in the proportion of health checks after incentives were removed. In contrast, the smallest difference-in-differences was 8.8% for glucose/HbA1c. This could be because glucose/HbA1c had the smallest proportion of checks pre-intervention, which meant the overall difference with blood pressure was wide during both time periods, resulting in a smaller difference-in-differences

Table 7.3 Proportion of eligible patients who received a health check by financial year

Removal of financial incentives for recording of all treatment indicators (body mass index (BMI), cholesterol and glucose/HbA1c) compared with blood pressure

Time	Health check	(%)*	Standard error	p-value
Before	Control	83.4		
	Intervention	69.7		
	Intervention – control	-13.7	0.003	P<0.01
After	Control	82.7		
	Intervention	53.9		
	Intervention – control	-28.8	0.004	P<0.01
	Difference-in-difference	-11.1	0.005	P<0.01

*Percent of eligible patients who received a health check

**Means and Standard Errors are estimated by linear regression

***Clustered Std. Errors

R-square: 0.04

Figure 7.2 Removal of financial incentives for recording of all three treatment indicators combined

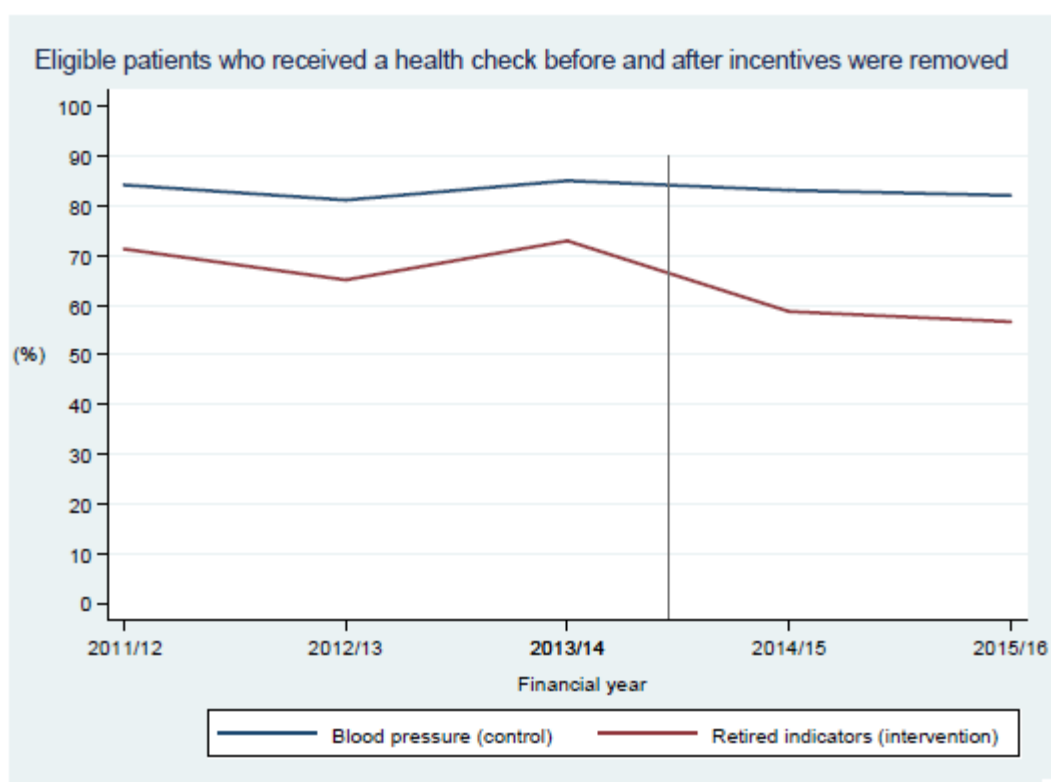


Table 7.4 Difference-in-differences estimate (BMI-blood pressure)

Removal of financial incentives for recording of body mass index (BMI)

Time	Health check	(%)*	Standard error	p-value
Before	Control (blood pressure)	83.4		
	Intervention (BMI)	69.3		
	Intervention – control	-14.2	0.005	P<0.01
After	Control (blood pressure)	82.7		
	Intervention (BMI)	53.9		
	Intervention – control	-28.8	0.009	P<0.01
	Difference-in-difference	-14.6	0.009	P<0.01

*Percent of eligible patients who received a health check

**Means and Standard Errors are estimated by linear regression

***Clustered Std. Errors

R-square: 0.06

Figure 7.3 Difference-in-differences estimate – removal of financial incentives for recording of body mass index (BMI)

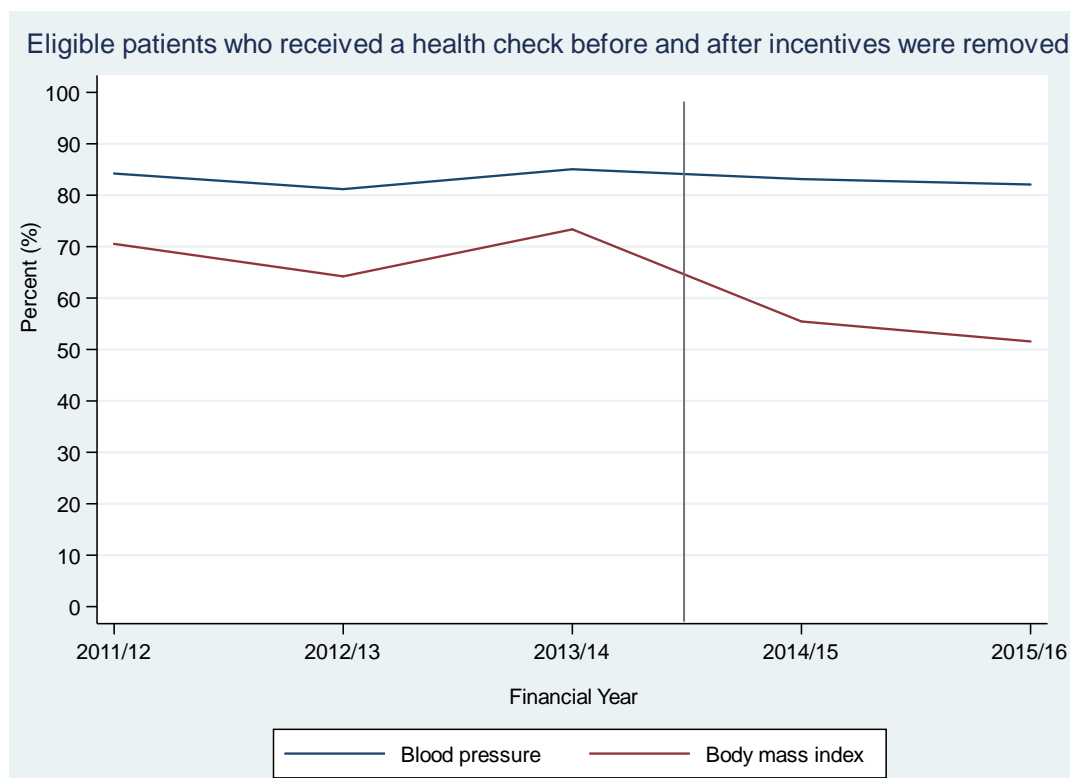


Table 7.5 Difference-in-differences estimate (cholesterol-blood pressure)

Removal of financial incentives for recording of cholesterol

Time	Health check	(%)*	Standard error	p-value
Before	Control (blood pressure)	83.4		
	Intervention (cholesterol)	76.9		
	Intervention – control	- 6.5	0.004	P<0.01
After	Control (blood pressure)	82.7		
	Intervention (cholesterol)	66.4		
	Intervention – control	- 16.3	0.007	P<0.01
	Difference-in-difference	- 9.8	0.007	P<0.01

*Percent of eligible patients who received a health check
 **Means and Standard Errors are estimated by linear regression
 ***Clustered Std. Errors
 R-square: 0.02

Figure 7.4 Difference-in-differences estimate – removal of financial incentives for recording of cholesterol

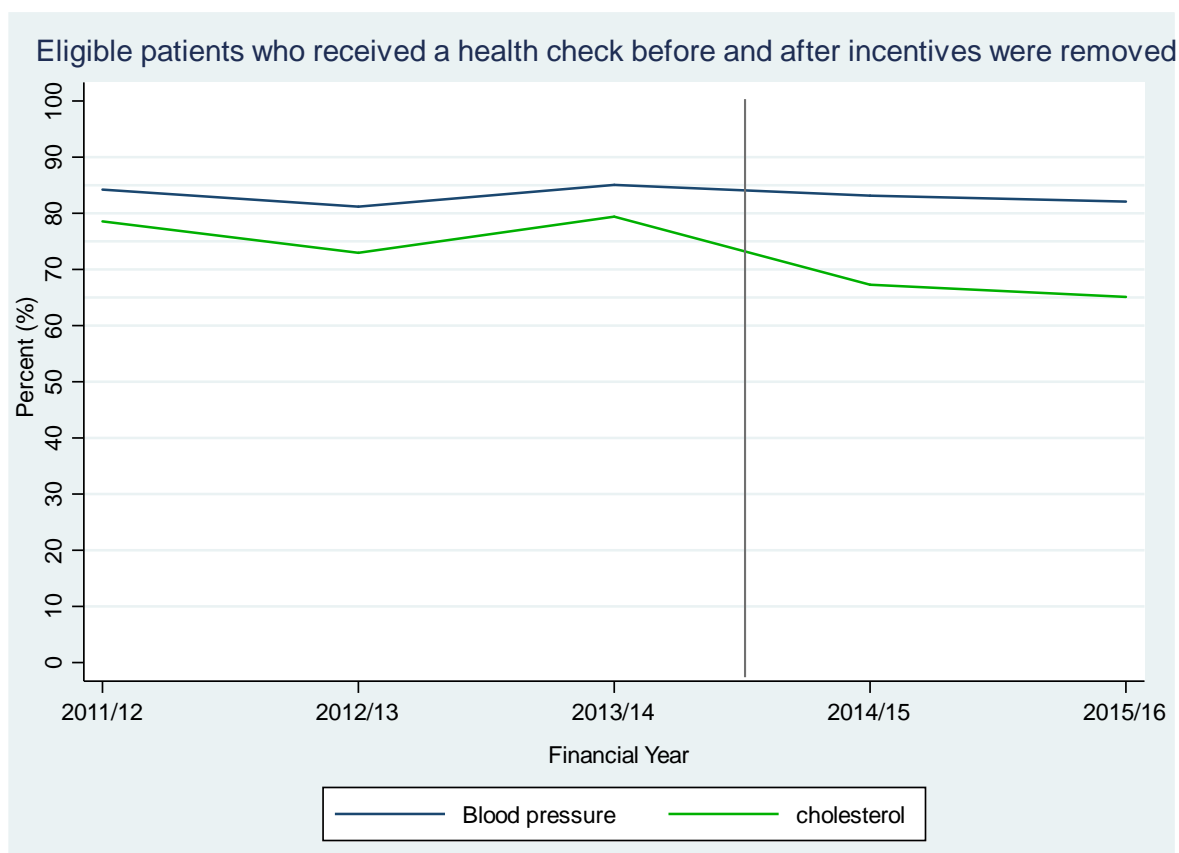


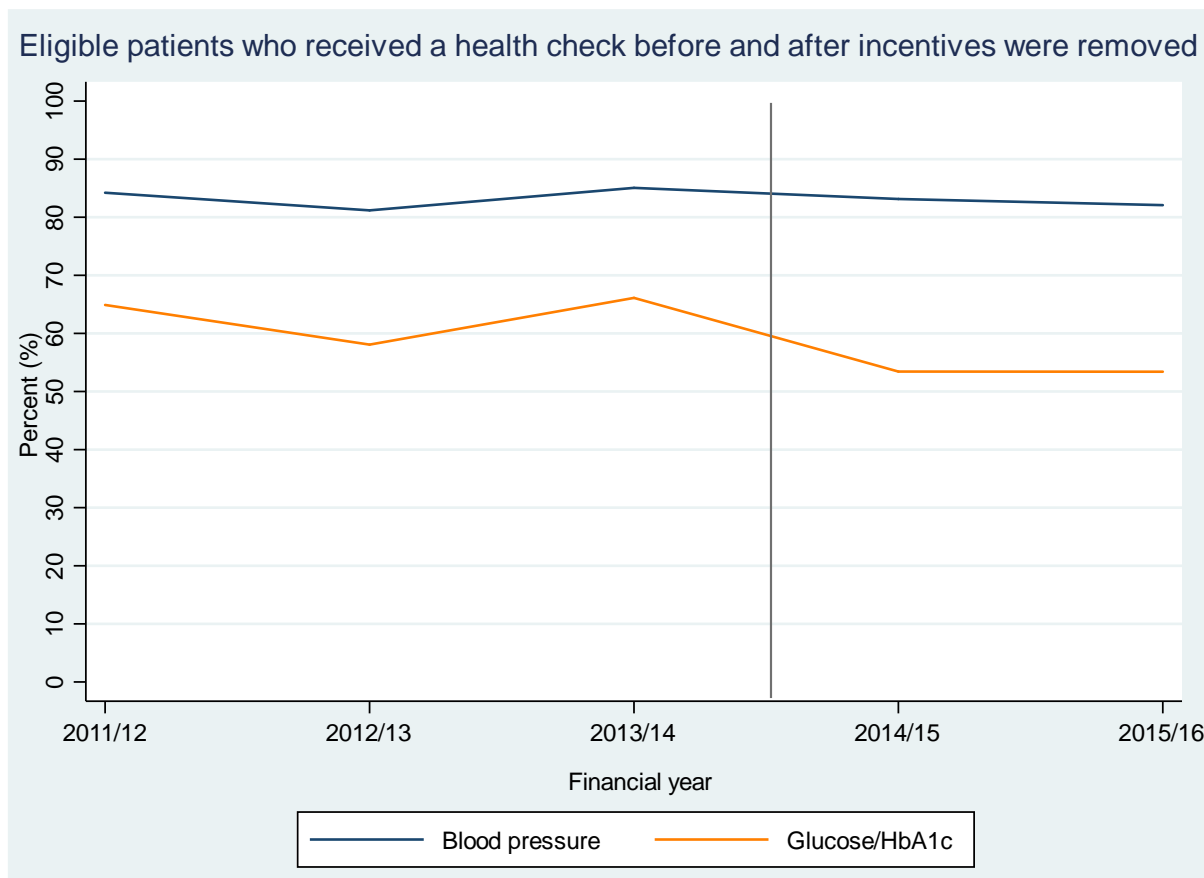
Table 7.6 Difference-in-differences estimate (glucose/HbA1c-blood pressure)

Removal of financial incentives for recording of glucose/HbA1c

Time	Health check	(%)*	Standard error	p-value
Before	Control (blood pressure)	83.4		
	Intervention (glucose/HbA1c)	62.9		
	Intervention – control	- 20.5	0.005	P<0.01
After	Control (blood pressure)	82.7		
	Intervention (glucose/HbA1c)	53.4		
	Intervention – control	- 29.3	0.009	P<0.01
	Difference-in-difference	- 8.8	0.008	P<0.01

*Percent of eligible patients who received a health check
 **Means and Standard Errors are estimated by linear regression
 ***Clustered Std. Errors
 R-square: 0.07

Figure 7.5 Difference-in-differences estimate – removal of financial incentives for recording of glucose/HbA1c



7.4.4 Multivariate logistic regression

Multivariate logistic regression was selected as the most appropriate technique to conduct analysis to estimate the likelihood of a receiving a health check whilst adjusting for other factors that may have influenced the outcome, such as time or demographic characteristics (Peng et al., 2010). As discussed in Chapter Six, this method required construction of a statistical model, to include individual variables which may have affected the outcome.

Selecting variables

As described in Chapter Six, variables were selected to be part of the regression model based on an understanding about what factors were likely to influence the outcome of interest, informed by background knowledge from the literature (Shipe et al., 2019) and discussion with thesis supervisors. Financial year was selected to measure the effect of time, accompanied by five core demographic variables: age; gender; SMI type; ethnic origin; and deprivation level.

Categorising variables

Reference categories were chosen on the basis of size and association with the outcome of interest (Ranganathan et al., 2017), described in more detail in Chapter Six.

7.4.5 Missing data

Ethnicity and deprivation level were the only two covariates included in the model that contained missing data. For each financial year, the maximum level of missing data was $\leq 4.5\%$ for ethnicity; and $\leq 0.1\%$ for deprivation. However, as discussed in Chapter Six, missing data of less than 5% is unlikely to introduce bias into statistical analyses (Bennett. D. A, 2001).

7.4.6 Secondary outcomes

Table 7.7 shows the odds ratios for the likelihood of receiving a health check by financial year for each of the four indicators: blood pressure, body mass index, cholesterol and glucose/HbA1c. There was virtually no difference between the unadjusted and adjusted odds estimates for all four indicators, suggesting that the effect of financial year was not dependent on other covariates – age, gender, ethnicity, SMI type, deprivation – in the regression model (Bursac et al., 2008). The adjusted odds ratios in Table 7.7 therefore account for the overall likelihood of a patient receiving a health check for each financial year based on the mean effect of the other independent variables.

Multivariate analysis

It is important to note that the financial year variable displayed in Table 7.7 has been presented separately from the demographic co-variables of age, gender, SMI type, ethnicity and deprivation, even though they were part of the same logistic regression model. This was to allow the effect of time on each different health check indicator outcome to be visually displayed within the same table. However, it does not present a univariate analysis, rather it is part of the multivariate analysis presented in a separate table to enhance the visual display of data. All other independent variable odds ratios are displayed together under each individual health check (see Table 7.8, Table 7.9, Table 7.10 and Table 7.11).

Year by year

- In **2011/12** the likelihood of receiving a check for blood pressure, cholesterol and glucose/HbA1c was not significantly different from the likelihood in 2013/14 (reference category), the final year before incentives were removed. For BMI, however, the likelihood of receiving a check was 14% less in 2011/12 (OR: 0.86; 95% CI: 0.80 to 0.94) compared with 2013/14.
- In **2012/13**, the odds of receiving a check were reduced for all indicators compared with 2013/14: blood pressure was 25% less likely (OR: 0.75; 95% CI: 0.69 to 0.82); cholesterol 31% less likely (OR: 0.69; 95% CI: 0.64 to 0.74); glucose/HbA1c 32% less likely (OR: 0.68; 95% CI: 0.64 to 0.73); and BMI 36% less likely (OR: 0.64; 95% CI: 0.59 to 0.69).
- In **2014/15**, the first year following the removal of incentives, the odds of receiving a check were reduced for all indicators, compared with 2013/14: blood pressure was 14% less likely (OR: 0.86; 95% CI: 0.79 to 0.95); glucose/HbA1c was 45% less likely (OR: 0.55; 95% CI: 0.52 to 0.59), cholesterol 49% less likely (OR: 0.51; 95% CI: 0.47 to 0.56) and BMI 56% less likely (OR: 0.44; 95% CI: 0.40 to 0.48).
- In **2015/16**, the final year of the study, the odds of receiving a check were reduced for all indicators, compared with 2013/14: blood pressure was 19% less likely (OR: 0.81; 95% CI: 0.71 to 0.93); glucose/HbA1c was 44% less likely (OR: 0.56; 95% CI: 0.51 to 0.62); cholesterol 53% less likely (OR: 0.47; 95% CI: 0.42 to 0.52); and BMI 63% less likely (OR: 0.37; 95% CI: 0.33 to 0.42).

Table 7.7 Odds ratios for the likelihood of receiving a health check by financial year

Health check	Financial year	Unadjusted odds ratio	Adjusted odds ratio ¹	95% confidence interval	P value
Blood pressure	2011/12	0.94	0.96	0.87 to 1.05	0.326
	2012/13	0.76	0.75	0.69 to 0.82	<0.001
	2013/14 ²	1.0	1.0		
	2014/15	0.86	0.86	0.79 to 0.95	0.003
	2015/16	0.80	0.81	0.71 to 0.93	0.003
Body mass index	2011/12	0.87	0.86	0.80 to 0.94	<0.001
	2012/13	0.65	0.64	0.59 to 0.69	<0.001
	2013/14 ²	1.0	1.0		
	2014/15	0.45	0.44	0.40 to 0.48	<0.001
	2015/16	0.39	0.37	0.33 to 0.42	<0.001
Cholesterol	2011/12	0.95	0.96	0.88 to 1.04	0.281
	2012/13	0.70	0.69	0.64 to 0.74	<0.001
	2013/14 ²	1.0	1.0		
	2014/15	0.53	0.51	0.47 to 0.56	<0.001
	2015/16	0.48	0.47	0.42 to 0.52	<0.001
Glucose/HbA1c	2011/12	0.95	0.95	0.90 to 1.01	0.107
	2012/13	0.71	0.68	0.64 to 0.73	<0.001
	2013/14 ²	1.0	1.0		
	2014/15	0.59	0.55	0.52 to 0.59	<0.001
	2015/16	0.59	0.56	0.51 to 0.62	<0.001
¹ Adjusted for: financial year; age; gender; ethnicity; SMI type; patient level area deprivation (see Table 7.8, Table 7.9, Table 7.10 and Table 7.11) ² Reference category No. of observations = 47,271					

7.4.7 Findings by individual indicators

Results of the multivariate logistic regression analysis for blood pressure, BMI, cholesterol and glucose/HbA1c are displayed in Table 7.8, Table 7.9, Table 7.10 and Table 7.11, respectively, showing the effect of each independent variable in relation to other predictor variables, held at a constant. Unadjusted odds estimates are presented alongside adjusted odds ratios to indicate how much the effect size changed when other independent variables were accounted for (Tabachnick and Fidell, 2013).

Individual checks rather than a combined model

It is important to remember, as discussed in Chapter Two and Chapter Six, that the health checks for blood pressure, BMI, cholesterol and glucose/HbA1c were incentivised separately during the time period of this study: they were not part of a collective group of health checks, incentivised as a combined model, as had been the case prior to 2011/12. Consequently, for this thesis each indicator was analysed on its own, rather than as part of a collective group, which was indicative of the QOF annual physical health review prior to 2011/12 (see Figure 6.1). To enhance comparability, each indicator was analysed using the exact same regression model.

Although there may have been a preconceived expectation that patients who presented to a GP would have received all four of the physical health checks, the results in Table 7.2 indicate otherwise, showing that patients did not typically receive all four checks. For instance, in 2011/12, the first year the indicators had been separately rewarded, only 53% of patients received a check for all four indicators, compared with 84% for blood pressure, 71% for BMI, 79% for cholesterol and 65% for glucose/HbA1c. The multivariate analysis conducted for this study, therefore, focused on the effect of independent variables on each indicator outcome rather than the interrelationship between indicators.

Figure 7.6 Model 1: Blood pressure

- **Age** was a predictor variable. Patients aged 60-74 years were nearly twice as likely to receive a blood pressure check (OR: 1.83; 95% CI: 1.64 to 2.04), and those aged 75 years and over were more than twice as likely (OR: 2.06; 95% CI 1.75 to 2.42), compared with those aged 40-59 years. By contrast, those aged under 40 years were 49% less likely (OR: 0.51; 95% CI: 0.47 to 0.56). No difference between the unadjusted and adjusted odds ratios suggested that aside from the other confounders, age was having an independent effect (Szumilas, 2010).
- **Gender** was a predictor variable. Females were 73% more likely to have had a blood pressure check recorded compared with males (OR: 1.73; 95% CI: 1.60 to 1.88). The difference between the unadjusted and adjusted odds ratio was a 40% decrease, suggesting that the effect of gender was associated with other independent variables in the model (Bland and Altman, 2000).
- **Ethnic origin** was not a strong predictor variable. One category, Asian, was 19% more likely than White to have had a check for blood pressure (OR: 1.19; 95% CI: 1.01 to 1.42). Black and Other categories were not significantly different from White. The difference between unadjusted and adjusted odds ratios for Asian was more than a 20% increase, suggesting it was associated with other factors in the regression model.
- **SMI type** was a predictor variable for two of the three categories. Patients with bipolar disorder were 43% more likely (OR: 1.43; 95% CI: 1.31 to 1.56) and patients with depression with psychosis 29% more likely (OR: 1.29; 95% CI: 1.09 to 1.51) to have had a blood pressure check compared to those with schizophrenia. The category of other affective disorders, which included schizoaffective disorder, was not significantly different from schizophrenia. The difference between unadjusted and adjusted odds ratios for bipolar disorder and depression with psychosis decreased by 30% and 40%, respectively, suggesting that other factors in the regression model were influencing the effect (Peng et al., 2010).
- **Patient level area deprivation** was not a strong predictor variable. There were no significant differences in the likelihood of receiving a blood pressure check for any of the other categories compared with category 1, least deprived.

Table 7.8 Likelihood of receiving a health check for blood pressure*

Variable		Unadjusted OR	Adjusted OR ¹	95% CI	P value
Age (years) <i>40-59</i> ²	Under 40	0.49	0.51	0.47 to 0.56	<0.001
	60-74	1.83	1.83	1.64 to 2.04	<0.001
	75 and over	2.22	2.06	1.75 to 2.42	<0.001
Gender <i>Male</i> ²	Female	2.13	1.73	1.60 to 1.88	<0.001
Ethnicity <i>White</i> ²	Asian	0.97	1.19	1.01 to 1.42	0.043
	Black	0.68	0.92	0.79 to 1.07	0.291
	Mixed	0.73	0.94	0.76 to 1.17	0.590
SMI diagnosis <i>Schizophrenia</i> ²	Bipolar disorder	1.7	1.43	1.31 to 1.56	<0.001
	Depression psychosis	1.7	1.29	1.09 to 1.51	0.002
	Other affective disorder	1.3	1.16	1.00 to 1.35	0.066
Patient level area deprivation (1=least, 5= most deprived) <i>1 least deprived</i> ²	2	0.92	0.92	0.79 to 1.07	0.299
	3	0.84	0.90	0.77 to 1.04	0.158
	4	0.86	0.96	0.82 to 1.13	0.639
	5	0.73	0.90	0.77 to 1.08	0.277
Constant			4.53	3.86 to 5.30	<0.001

¹Adjusted for: financial year; age; gender; ethnicity; SMI type; patient level area deprivation
²Reference category
*Mean odds ratios for study period (from 2011/12 to 2015/16)
No. of observations = 47,271

Figure 7.7 Model 2: Body Mass Index (BMI)

- **Age** was a predictor variable. Patients aged 60-74 years were 23% more likely (OR: 1.23; 95% CI: 1.14 to 1.32) to have had a BMI measurement recorded, compared with those aged 40-59 years. By contrast, patients aged under 40 years were 37% less likely (OR: 0.63; 95% CI: 0.59 to 0.68) and those aged 75 years and over 20% less likely (OR: 0.80; 95% CI: 0.72 to 0.89) to have had a BMI measurement recorded, compared with those aged 40-59 years. There were no differences between the unadjusted and adjusted odds ratios for each category, suggesting that aside from the other confounders, age was having an independent effect.
- **Gender** was a predictor variable. Females were 24% more likely to have had a BMI measurement recorded compared with males (OR: 1.24; 95% CI: 1.18 to 1.31). The difference between the unadjusted and adjusted odds ratio was a decrease of less than 10%, suggesting that aside from the other confounders, gender was having an independent effect.
- **Ethnic origin** was not a strong predictor variable. One category, Asian, was 28% more likely than White to have had a BMI measurement recorded (OR: 1.28; 95% CI: 1.14 to 1.44). Neither Black nor Other categories were significantly different from White. The difference between the unadjusted and adjusted odds ratios increased by less than 10% for all categories, suggesting that aside from the other independent variables, ethnic origin was having an independent effect.
- **SMI type** was a predictor variable for only one category. Patients with bipolar disorder were 19% more likely (OR: 1.19; 95% CI: 1.11 to 1.40) to have had a BMI measurement recorded, compared to those with schizophrenia. Patients with depression with psychosis were 12% more likely (OR: 1.12; 95% CI: 1.00 to 1.27). There was no difference between other affective disorders and schizophrenia. Differences between unadjusted and adjusted odds ratios for all categories less than 10%, suggesting that SMI type was having an independent effect.
- **Patient level area deprivation** was a predictor variable for categories 4 and 5, the two most deprived categories. Category 4 was 21% more likely (OR: 1.21; 95% CI: 1.08 to 1.36) and category 5 was 25% more likely (OR: 1.25; 95% CI: 1.11 to 1.40) to have had a BMI measurement recorded compared with 1, the least deprived category. All unadjusted and adjusted odds ratios were the same, suggesting that patient level deprivation was having an independent effect.

Table 7.9 Likelihood of receiving a health check for body mass index* (BMI)

Variable		Unadjusted OR	Adjusted OR ¹	95% CI	P value
Age (years) <i>40-59</i> ²	Under 40	0.64	0.63	0.59 to 0.68	<0.001
	60-74	1.22	1.23	1.14 to 1.32	<0.001
	75 and over	0.83	0.80	0.72 to 0.89	<0.001
Gender <i>Male</i> ²	Female	1.31	1.24	1.18 to 1.31	<0.001
Ethnicity <i>White</i> ²	Asian	1.18	1.28	1.14 to 1.44	<0.001
	Black	1.03	1.11	0.96 to 1.29	0.162
	Mixed	0.97	1.07	0.91 to 1.25	0.414
SMI diagnosis <i>Schizophrenia</i> ²	Bipolar disorder	1.23	1.19	1.11 to 1.27	<0.001
	Depression psychosis	1.22	1.12	1.00 to 1.27	0.052
	Other affective disorder	1.04	1.00	0.83 to 1.21	0.995
Patient level area deprivation (1=least, 5= most deprived) <i>1 least deprived</i> ²	2	1.06	1.03	0.93 to 1.15	0.529
	3	1.07	1.06	0.94 to 1.20	0.335
	4	1.20	1.21	1.08 to 1.36	0.001
	5	1.17	1.25	1.11 to 1.40	<0.001
Constant			2.31	2.05 to 2.60	<0.001

¹Adjusted for: financial year; age; gender; ethnicity; SMI type; patient level area deprivation
²Reference category
*Mean odds ratios for study period (from 2011/12 to 2015/16)
No. of observations = 47,271

Figure 7.8 Model 3: Cholesterol

- **Age** was a predictor variable. Patients aged 60-74 years were 42% more likely to have had a recording of cholesterol (OR: 1.42; 95% CI: 1.30 to 1.55) compared with those aged 40-59 years. In contrast, those aged under 40 years were 50% less likely (OR: 0.50; 95% CI: 0.47 to 0.54). For the 75 years and over category there was no difference compared with those aged 40-59 years. Unadjusted and adjusted odds ratios were virtually the same for each category, suggesting that aside from the other independent variables, age was having an independent effect.
- **Gender** was a predictor variable. Females were 30% more likely to have had a recording of cholesterol compared with males (OR: 1.30; 95% CI: 1.22 to 1.38). The difference between the unadjusted and adjusted odds ratio was a 15% decrease, suggesting that gender was associated with other independent variables in the model.
- **Ethnic origin** was not a strong predictor variable. One category, Asian, was 32% more likely than White to have a recording of cholesterol (OR: 1.32; 95% CI: 1.15 to 1.53). Black or Other categories were not significantly different from White. The difference between unadjusted and adjusted odds ratios for Asian was an increase of more than 15%. There was also a 20% increase between the unadjusted and adjusted odds ratios for Black and Other categories, suggesting that ethnicity was associated with other factors in the model.
- **SMI type** was a predictor variable for two of the three categories. Patients with bipolar disorder were 27% more likely (OR: 1.27; 95% CI: 1.18 to 1.36) and patients with depression with psychosis 17% more likely (OR: 1.17; 95% CI: 1.03 to 1.33) to have had a recording of cholesterol, compared with those with schizophrenia. The other affective disorders category was no different from schizophrenia. The difference between the unadjusted and adjusted odds ratios for all categories was less than 10%, suggesting that aside from the other independent variables, SMI type was having an independent effect.
- **Patient level area deprivation** was a predictor variable for the two most deprived categories. Categories 4 and 5 were both 16% more likely to have had a cholesterol check, (OR: 1.16; 95% CI: 1.03 to 1.31) and (OR: 1.16; 95% CI: 1.02 to 1.31) respectively, compared with 1, the least deprived category. All unadjusted and adjusted odds ratios were the same, suggesting that aside from the other independent variables, patient level deprivation was having an independent effect.

Table 7. 10 Likelihood of receiving a health check for cholesterol*

Variable		Unadjusted OR	Adjusted OR ¹	95% CI	P value
Age (years) <i>40-59</i> ²	Under 40	0.50	0.50	0.47 to 0.54	<0.001
	60-74	1.40	1.42	1.30 to 1.55	<0.001
	75 and over	1.06	1.02	0.91 to 1.14	0.736
Gender <i>Male</i> ²	Female	1.46	1.30	1.22 to 1.38	<0.001
Ethnicity <i>White</i> ²	Asian	1.15	1.32	1.15 to 1.53	<0.001
	Black	0.92	1.10	0.97 to 1.25	0.148
	Mixed	0.89	1.06	0.89 to 1.27	0.493
SMI diagnosis <i>Schizophrenia</i> ²	Bipolar disorder	1.36	1.27	1.18 to 1.36	<0.001
	Depression psychosis	1.36	1.17	1.03 to 1.33	0.020
	Other affective disorder	1.06	1.02	0.84 to 1.23	0.845
Patient level area deprivation (1=least, 5= most deprived) <i>1 least deprived</i> ²	2	1.04	1.01	0.91 to 1.13	0.816
	3	1.01	1.01	0.91 to 1.15	0.859
	4	1.12	1.16	1.03 to 1.31	0.017
	5	1.03	1.16	1.02 to 1.31	0.020
Constant			3.33	2.93 to 3.79	<0.001
¹ Adjusted for: financial year; age; gender; ethnicity; SMI type; patient level area deprivation ² Reference category *Mean odds ratios for study period (from 2011/12 to 2015/16) No. of observations = 47,271					

Figure 7.9 Model 4: Glucose/HbA1c

- **Age** was a predictor variable. Patients aged 60-74 years were 49% more likely to have had a recording of glucose/HbA1c (OR: 1.49; 95% CI: 1.39 to 1.59), and those aged 75 years and over 25% more likely (OR: 1.25; 95% CI: 1.14 to 1.38), compared with those aged 40-59 years. In contrast, those aged under 40 years were 70% less likely (OR: 0.30; 95% CI: 0.28 to 0.32). Unadjusted and adjusted odds ratios were the same for each category, suggesting that aside from the other independent variables, age was having an independent effect.
- **Gender** was a predictor variable. Females were 21% more likely to have had a recording of glucose/HbA1c compared with males (OR: 1.21; 95% CI: 1.14 to 1.28). The difference between the unadjusted and adjusted odds ratio was a 20% decrease, suggesting that gender was associated with other independent variables in the model.
- **Ethnic origin** was not a strong predictor variable. One category, Asian, was 47% more likely than White to have had a recording of glucose/HbA1c (OR: 1.47; 95% CI: 1.28 to 1.68). Black or Other categories were not significantly different from White. The difference between unadjusted and adjusted odds ratios for Asian was an increase of 35%. There was also a 20% increase between the unadjusted and adjusted odds ratios for Black and Other categories, suggesting that ethnicity was associated with other independent variables in the model.
- **SMI type** was a predictor variable for two of the three categories. Patients with bipolar disorder were 22% more likely to have had a recording of glucose/HbA1c (OR: 1.22; 95% CI: 1.15 to 1.30) and patients with depression with psychosis 18% more likely (OR: 1.18; 95% CI: 1.05 to 1.33), compared with schizophrenia. The other affective disorders category was no different from schizophrenia. The differences between the unadjusted and adjusted odds ratios for bipolar disorder and depression with psychosis were 10% and 40%, respectively, suggesting that SMI type was associated with other independent variables in the model.
- **Patient level area deprivation** was not a strong predictor variable. There were no significant differences in the likelihood of receiving a glucose/HbA1c check for any of the other categories compared with least deprived, the reference category.

Table 7. 11 Likelihood of receiving a health check for glucose/HbA1c*

Variable		Unadjusted OR	Adjusted OR ¹	95% CI	P value
Age (years) <i>40-59</i> ²	Under 40	0.31	0.30	0.28 to 0.32	<0.001
	60-74	1.47	1.49	1.39 to 1.59	<0.001
	75 and over	1.29	1.25	1.14 to 1.38	<0.001
Gender <i>Male</i> ²	Female	1.42	1.21	1.14 to 1.28	<0.001
	Male				
Ethnicity <i>White</i> ²	Asian	1.15	1.47	1.28 to 1.68	<0.001
	Black	0.80	1.03	0.91 to 1.17	0.587
	Mixed	0.76	1.00	0.85 to 1.17	0.958
SMI diagnosis <i>Schizophrenia</i> ²	Bipolar disorder	1.32	1.22	1.15 to 1.30	<0.001
	Depression psychosis	1.44	1.18	1.05 to 1.33	0.004
	Other affective disorder	1.10	1.08	0.93 to 1.26	0.287
Patient level area deprivation (1=least, 5= most deprived) <i>1 least deprived</i> ²	2	1.02	1.01	0.91 to 1.13	0.784
	3	1.00	1.03	0.92 to 1.17	0.575
	4	1.03	1.09	0.97 to 1.24	0.157
	5	0.93	1.10	0.97 to 1.24	0.133
Constant			1.92	1.72 to 2.19	<0.001

¹Adjusted for: financial year; age; gender; ethnicity; SMI type; patient level area deprivation
²Reference category
*Mean odds ratios for study period (from 2011/12 to 2015/16)
No. of observations = 47,271

7.4.8 Summary: multivariate logistic regression

By financial year

The adjusted odds ratios displayed in Table 7.7 represent the likelihood during each financial year of a participant receiving a health check for all four different indicators, compared with 2013/14 (year before incentives were removed). Results summary by financial year:

- In **2011/12**, no significant differences in the odds of receiving a check for blood pressure, cholesterol and glucose/HbA1c, compared with 2013/14, year before incentives were removed and the reference category, though odds of having a BMI recording were 14% less.
- In **2012/13**, all indicators had a significant reduction in odds, compared with 2013/14: the smallest decline was 25% for blood pressure; the largest, 36% for BMI.
- In **2014/15**, year immediately after incentives were removed, there were substantial decreases in the odds for each health check, compared with 2013/14: the smallest was a 14% decline for blood pressure; the largest, a 56% decline for BMI.
- In **2015/16**, the final year of the study, odds ratios for each indicator were at their lowest compared with 2013/14, ranging from 19% less for blood pressure to 63% less for BMI.

Overall, findings showed that the odds of receiving a health check both before and after incentives were removed varied, though in the period post-intervention the decreases in odds were larger. Before incentives were removed, year on year changes in odds ratios for blood pressure, cholesterol and glucose/HbA1c followed a similar pattern. The exception was BMI where odds were significantly reduced in 2012/13, compared with 2013/14. After incentives were removed, in 2014/15 and 2015/16, odds declined significantly for cholesterol, BMI and glucose/HbA1c compared with 2013/14. The largest decrease for both years was for BMI. Despite remaining incentivised, odds also declined for blood pressure, though to a lesser extent.

By predictor variable

Identifying similarities and differences between indicators, in relation to the effect of independent variables, was made possible by having used the exact same regression model to adjust for independent variables, enhancing comparability. Having compared the data for each indicator, it was evident that there were both differences and similarities in the effect that independent variables had on the outcome, whilst controlling for other potentially confounding factors. These similarities and differences between indicators are summarised overleaf, grouped by independent variable.

- **Age:** For all four indicators the under 40 years category was up to 70% less likely to have a check recorded compared with those aged 40-59 years. Conversely, the 60-74 years category was up to 83% more likely to have a check recorded. The 75 years and above category differed widely: a blood pressure recording was more than twice as likely compared with those aged 40-59 years, whereas a BMI measurement was 20% less likely. There were no differences between the unadjusted and adjusted odds ratios, suggesting that age had an independent effect, aside from other independent variables.
- **Gender:** For all four indicators females were more likely than males to have a check recorded. Blood pressure had the largest increase in odds of 73%, whereas the other health checks had a smaller increase of ~25%. With the exception of BMI, there was a decrease in odds between the unadjusted and adjusted odds for all indicators. The largest was a 40% decline for blood pressure, suggesting that the effect of gender was not independent, but rather, it was associated with other independent variables in the model.
- **Ethnic origin:** For all four indicators, Asian was up to 47% more likely than White to have had a measurement recorded. With the exception of BMI, there was an increase in odds between the unadjusted and adjusted odds for all indicators. The largest was a 32% increase for glucose/HbA1c, suggesting that other factors were accounting for the variation.
- **SMI type:** For all four indicators, patients with bipolar disorder were up to 43% more likely, and those who had depression with psychosis up to 29% more likely, to have had a measurement recorded, compared with schizophrenia. For BMI and cholesterol were no differences between the unadjusted and adjusted odds ratios. In contrast, for blood pressure and glucose/HbA1c there was a decrease of up to 30% for bipolar disorder and up to 40% for depression with psychosis between the unadjusted and adjusted odds ratios, suggesting the effect of SMI type was not independent from other independent variables.
- **Patient level area deprivation:** For blood pressure and glucose/HbA1c there were no significant differences between any of the four other categories compared with the least deprived, category 1. In contrast, for BMI and cholesterol, the two most deprived categories (4 and 5) were up to 25% more likely to have had a measurement recorded, compared with the least deprived, category 1. Differences between the unadjusted and adjusted odds ratios were minimal, suggesting deprivation had an independent effect on the likelihood of receiving a check for BMI or cholesterol.

Overall, mean effect size of independent variables varied in relation to whether or not a patient received a health check. Moreover, some effects were independent, whereas for others there was marked difference between the unadjusted estimates and adjusted odds ratios, indicating that the variable was associated with other factors.

For the four health check indicators, the key similarities and differences in odds ratios between independent variables are shown in Figure 7.10.

Figure 7. 10 Similarities and differences between independent variables

- **Age:** all indicators more likely to receive a check if patient older than 40-59 years; blood pressure most likely; glucose/HbA1c least likely.
- **Gender:** all indicators more likely to receive a check if patient female; blood pressure most likely; glucose/HbA1c least likely.
- **Ethnicity:** all indicators more likely to receive a check if patient Asian; glucose/HbA1c most likely; blood pressure least likely.
- **SMI type:** all indicators more likely to receive a check for patients with bipolar disorder; blood pressure most likely; BMI least likely.
- **Deprivation:** only BMI and cholesterol more likely to receive a check if patient more deprived; BMI most likely.

7.5 Practice level analyses

Following on from patient level analyses, data were analysed at the practice level to examine variation in practice performance with regards to the number of SMI patients registered at a practice and area level deprivation.

7.5.1 Research questions and objectives

- 1) How does the number of SMI patients registered at a practice (proxy for practice size) affect the proportion of patients who received a health check?
- 2) How does practice level deprivation affect performance?

The main objective was to increase understanding about the association between practice characteristics (size and deprivation level) and the proportion of patients who received a health check. In contrast with patient level analyses where the outcome was a dichotomous binary (whether or not a patient received a health check), at the practice level the outcome was continuous (the proportion of a practice's SMI patients who had received a health check).

7.5.2 Practice characteristics

Before examining the spread of data and variation in practice performance in relation to number of registered SMI patients and deprivation, practice characteristics were summarised and presented in Table 7.12.

Table 7.12 displays characteristics of all the practices included in the study by financial year. It shows the number and percentage of small/medium/large practices, categorised in relation to the number of registered SMI patients; the number and percentage of the patient sample within each practice category; and the proportion of patients within each deprivation quintile at the practice level.

Small, medium, large practices – in relation to number of SMI patients registered

This thesis used the number of SMI patients registered at a practice as a proxy for practice size as in the CPRD dataset the list size variable did not measure practice size as defined by the number of registered 'active' patients for a given year, but rather it represented the sum total of all patients ever registered at the practice, which included former patients who had died or left the practice. As a result,

the CPRD practice size variable was not an accurate reflection of the number of patients registered for each individual year. Indeed, some practices had list sizes of over 120,000 which was in excess of the largest practice list size recorded in England (NHS Digital, 2020). Consequently, to avoid practices being categorised as larger than they were, based on the CPRD definition, a new categorical variable was created using number of registered SMI patients. While also not an accurate measure of practice size, the proxy measure did reflect a practice's level of responsibility for SMI patients and hence provided a useful alternative for this study. Practices were thus categorised into three groups relating to the number of patients with an SMI diagnosis registered at a practice (small: less than 28 SMI patients; medium: 28-48 SMI patients; and large: more than 48 SMI patients).

In 2011/12, the first year of the study, the number of practices per category was relatively evenly distributed. However, as the years progressed the number of practices declined substantially, and unevenly, more so for small practices than large, which led to an increasing imbalance in the number of practices between categories. It is likely, however, that there would be correlation between practice list size and the number of SMI patients registered at a practice. Therefore, the rise in the proportion of practices with a high number of SMI patients would, on the whole, reflect a rise in the proportion of large practices as measured by practice list size, which was one of the structural changes occurring in primary care at the time (Kelly and Stoye, 2014).

7.5.3 Proportion of practices by number of SMI patients registered

Column A in Table 7.12 shows the number of practices in each category (small, medium, large) relating to the number of SMI patients registered at each practice, which is a reflection of their representation by that group. In 2011/12, there was a total of 315 practices in the study: 39% small; 31% medium; 30% large. In 2012/13, the number of practices was 301: with 36% small; 33% medium; 31% large. In 2013/14, the number of practices was 264: with 30% small; 36% medium; 34% large. In 2014/15, the number of practices was 214: with 24% small; 36% medium; 40% large. In 2015/16, the number of practices was 150: with 25% small; 34% medium; 41% large.

Overall, the number of practices declined year on year throughout the study, in line with the decline in the number of patients, as described earlier in this chapter. Between the first and the final year, 2011/12 and 2015/16, the total number of practices more than halved from 315 to 150. There was also a trend for large practices, as measured by the number of registered SMI patients, to become overrepresented, from 30% in 2011/12 to 41% in 2015/16. By contrast, small practices followed a reverse trend and went from being overrepresented to becoming underrepresented, from 39% in 2011/12 to 25% in 2015/16.

7.5.4 Number of patients by practice representation of SMI patients

Column B in Table 7.12 shows the number of patients in the study by financial year in relation to the number of SMI patients registered at practices. This demonstrates the proportion of the patient sample within each category. Comparing column A (number of practices) with column B (number of patients) in relation to the number of registered SMI patients within each category (small/medium/large) demonstrates that, year by year across the study period, the proportion of large practices (those with highest numbers of SMI patients) increased, whilst the proportion of small practices decreased.

Specifically, in 2011/12, the first year of the study, the total number of patients from large practices was 5,593 (48%) and from small practices was 2,824 (24%). Comparing the amount of *patients* with the amount of *practices* by the category for the number of SMI patients, it is evident that large practices had a disproportionate share of the patient sample. In 2011/12, large practices consisted of 30% of the practice sample but contained 48% of the patient sample, whereas small practices were 39% of the practice sample but only 24% of the patient sample. In 2015/16, the final year of the study, the disparity had increased further: large practices had 66% of the patient sample whereas small practices only had 8%. Contrastingly, practices with a medium number of SMI patients registered did not exhibit such profound changes in their share of the patient sample, remaining relatively consistent throughout the study period, from 26% to 31%.

7.5.5 Practice level deprivation by practice representation of SMI patients

Column C in Table 7.12 shows practice level area deprivation for all five financial years of the study in relation to the number of SMI patients registered at a practice. It displays the mean proportion of patients per quintile of deprivation for small, medium and large practices. For each financial year, large practices with the highest number of SMI patients had the highest proportion of patients in the most deprived quintile, category 5, which was ~3 times higher than the proportion in the least deprived quintile, category 1. By contrast, medium sized practices had the highest proportion of patients in the middle category throughout the study. For small practices, with the lowest number of SMI patients, there were no evident patterns as data displayed variability both between deprivation category and by financial year.

Table 7. 12 Practice characteristics

Financial year	(A) Number of practices by practice representation of SMI patients* (%)				(B) Number of patients by practice representation of SMI patients (%)				(C) Proportion of eligible patients by practice deprivation** (1 least, 5 most deprived)			
	Large	Medium	Small	Total	Large	Medium	Small	Total	Quintile	Large	Medium	Small
2011/12	93 (30)	99 (31)	123 (39)	315	5,593 (48)	3,351 (28)	2,824 (24)	11,768	1	12.1%	11.3%	17.8%
									2	16.6%	17.9%	19.0%
									3	10.3%	29.1%	22.1%
									4	24.7%	17.4%	23.0%
									5	36.2%	24.3%	18.1%
									Total	100%	100%	100%
2012/13	93 (31)	99 (33)	109 (36)	301	5,883 (50)	3,502 (30)	2,297 (20)	11,682	1	12.5%	11.2%	19.9%
									2	16.4%	17.7%	16.3%
									3	10.2%	29.3%	26.0%
									4	24.5%	17.7%	20.7%
									5	36.5%	24.1%	17.1%
									Total	100%	100%	100%
2013/14	91 (34)	94 (36)	79 (30)	264	5,907 (56)	3,304 (31)	1,419 (13)	10,630	1	11.1%	12.3%	27.4%
									2	17.1%	17.9%	27.1%
									3	11.0%	32.4%	19.1%
									4	24.8%	19.4%	16.6%
									5	36.0%	18.0%	9.9%
									Total	100%	100%	100%
2014/15	86 (40)	77 (36)	51 (24)	214	5,715 (63)	2,596 (29)	746 (8)	9,057	1	12.2%	15.5%	20.0%
									2	17.9%	18.7%	24.3%
									3	10.5%	30.8%	13.9%
									4	23.8%	14.3%	26.5%
									5	35.6%	20.8%	15.3%
									Total	100%	100%	100%
2015/16	61 (41)	51 (34)	38 (25)	150	4,051 (66)	1,622 (26)	512 (8)	6,185	1	14.1%	10.9%	13.1%
									2	16.9%	18.3%	25.0%
									3	6.3%	34.0%	16.4%
									4	24.1%	13.5%	32.0%
									5	38.5%	23.3%	13.5%
									Total	100%	100%	100%

* Category defined by number of SMI patients registered at a practice: Large >48 patients; Medium 48-28 patients; Small <28 patients

** The English Indices of Deprivation 2015 (<https://www.gov.uk/government/collections/english-indices-of-deprivation>)

7.5.6 Variation in practice performance

To increase understanding about the association between practice characteristics and performance, box plots were used to graphically display dispersion in the distribution of data indicating the proportion of a practice's SMI patients who received a health check.

By number of registered SMI patients (proxy for practice size)

Figure 7.11, Figure 7.12, Figure 7.13 and Figure 7.14 display variation in performance between practices with similar numbers of SMI patients, categorised into small, medium, large. For each health indicator (blood pressure, BMI, cholesterol, glucose/HbA1c) there are two box plots for the before and after time periods, labelled pre-intervention and post-intervention. Results are summarised below:

- **Blood pressure:** Figure 7.11 shows minimal changes to the spread of data post-intervention. Median values were similar for each category before and after, suggesting performance was not notably affected by the removal of incentives for other indicators. Large practices had the narrowest data range before and after, signalling less variation in performance compared with small and medium practices. Negative outliers, indicative of poorly performing practices, were present for each category at both time points.
- **Body Mass Index:** Figure 7.12 shows a number of changes to the dispersion of data post-intervention. Median values decreased for all, suggesting practice performance declined for each category in relation to the number of SMI patients registered at a practice. In contrast, the spread of data (length of the box plot) widened, more for medium practices, which indicated increased variation in performance. Large practices, which reflected the category of practices with the highest number of SMI patients, had the narrowest data range before and after.
- **Cholesterol:** Figure 7.13 shows limited changes to the spread of data post-intervention. A decrease in median values suggested a decline in performance. Increase in the spread of data signalled wider variability in practice performance, particularly for medium practices. Large practices, reflecting the category of practices with the highest number of SMI patients had the narrowest range of data before and after.
- **Glucose/HbA1c:** Figure 7.14 shows moderate changes to the spread of data post-intervention. A decrease in the median values for all categories indicated a decline in performance. There was minimal change, however, to the spread of data post-intervention. Large practices had the narrowest range of data before and after.

Figure 7. 11 Blood pressure by practice size

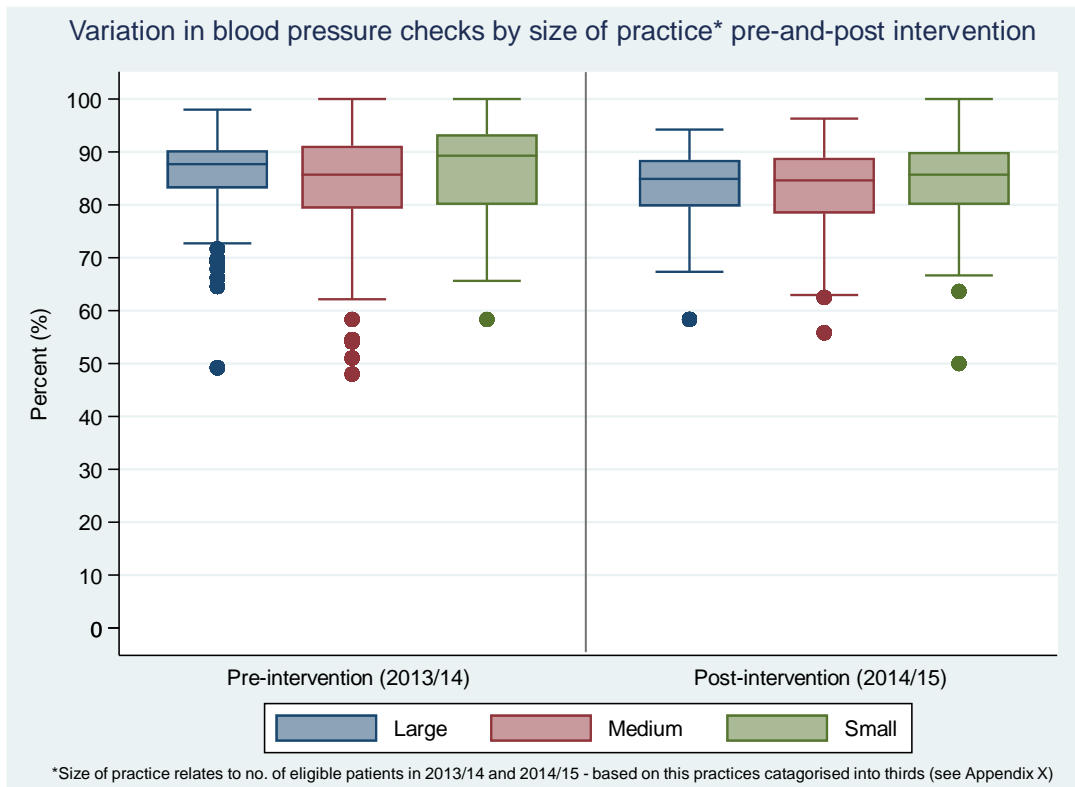


Figure 7. 12 BMI by practice size

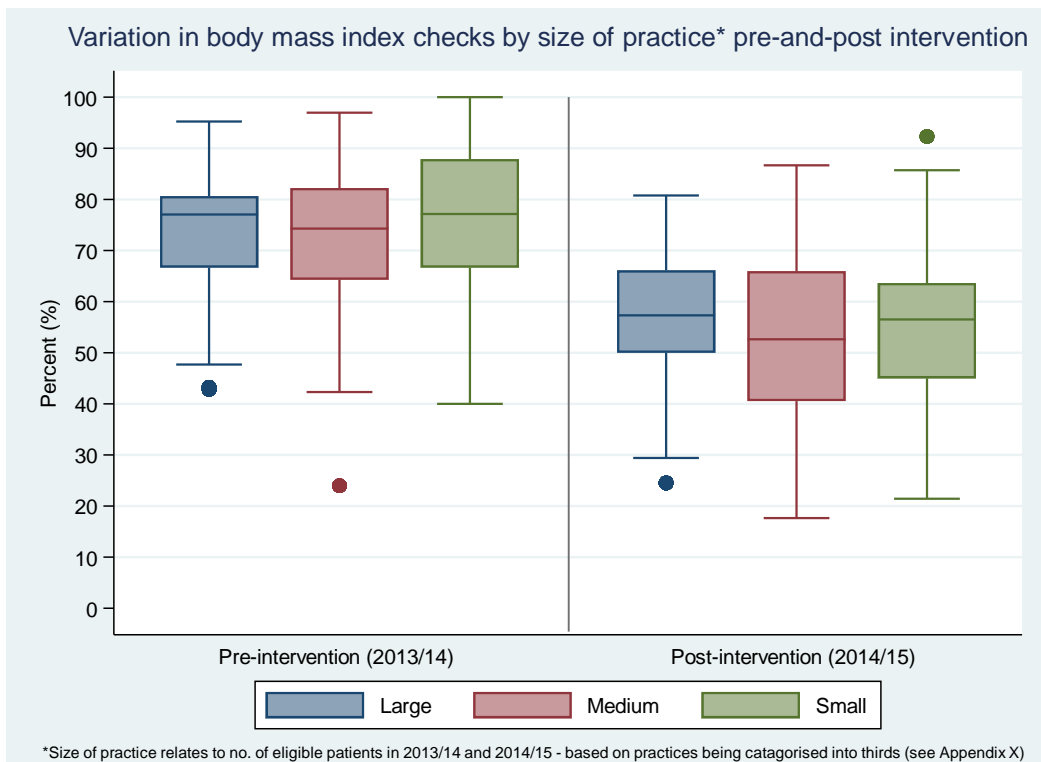


Figure 7. 13 Cholesterol by practice size

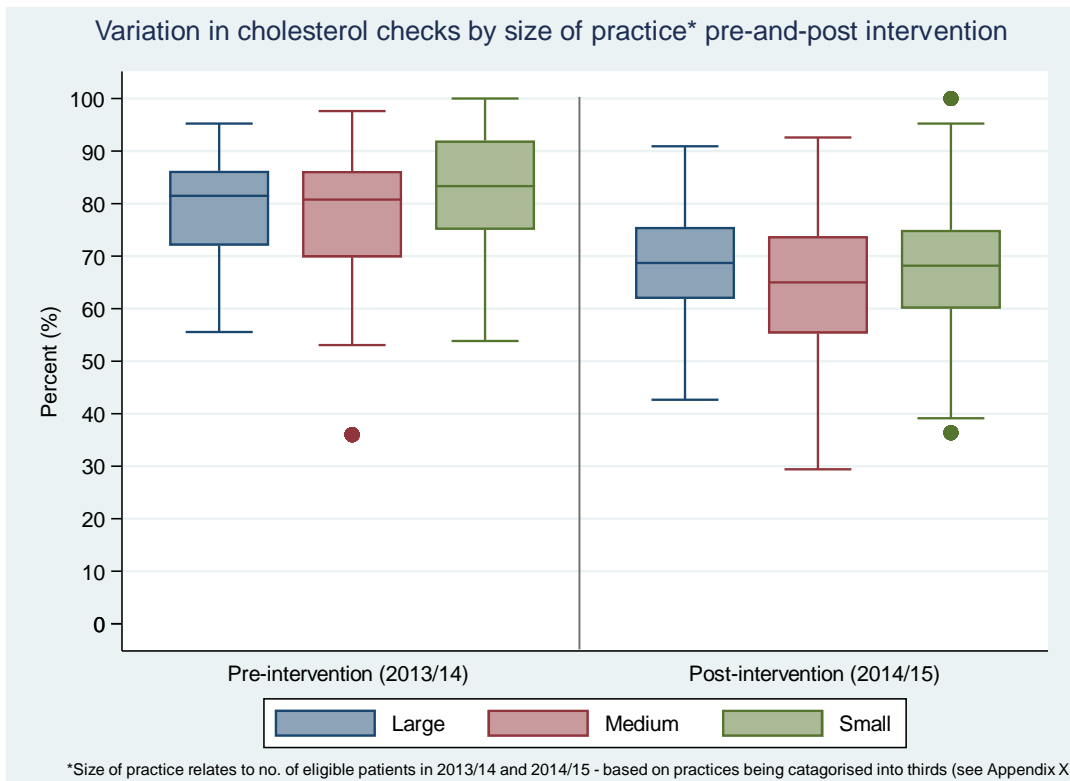
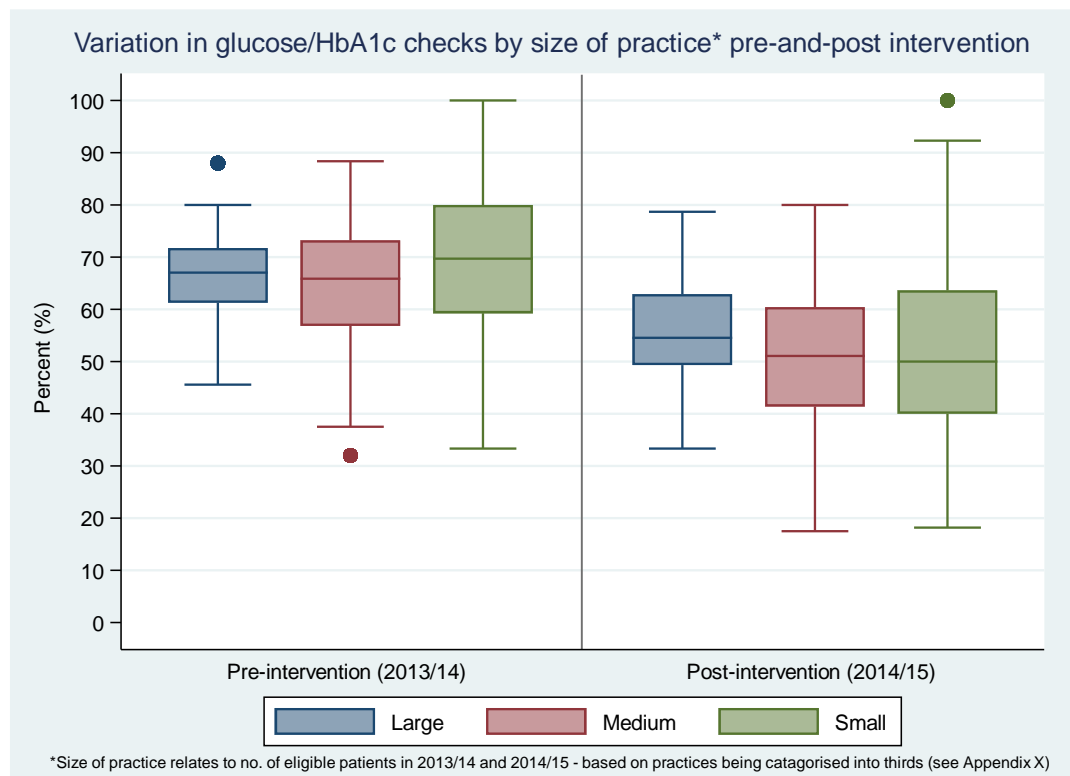


Figure 7. 14 Glucose/HbA1c by practice size



By practice level area deprivation

Area deprivation at the practice level was measured by the Index of Multiple Deprivation in 2015 (Department for Communities and Local Government), which categorised practices into quintiles: 1 the least; 5 the most deprived. Figure 7.15, Figure 7.16, Figure 7.17 and Figure 7.18 display variation in performance for each health indicator relating to deprivation level. There are five box plots for the year before and five for the year after incentives were removed, which shows the variation in the spread of data for each quintile of deprivation. Results are summarised below:

- **Blood pressure:** Figure 7.15 shows minimal changes to the spread of data post-intervention. Negative outliers were present for all quintiles in both the before and after time periods.
- **Body Mass Index:** Figure 7.16 shows notable changes to the spread of data post-intervention. Median values decreased for each category, suggesting practice performance declined for all categories after incentives were removed.
- **Cholesterol:** Figure 7.17 shows moderate changes to the spread of data post-intervention. Median values decreased for each category, suggesting practice performance declined. However, there were differences between quintiles: in the least deprived category 1, practice variation contracted indicating reduced variability; whereas for more deprived categories 3 and 4, practice variation expanded, indicating wider variability in performance.
- **Glucose/HbA1c:** Figure 7.18 shows modest changes to the spread of data post-intervention. Median values decreased marginally for all categories, suggesting practice performance declined slightly across all quintiles. Similar to cholesterol, there was notable contraction of variability for practices in category 1, coupled with expansion of variability in performance for the most deprived categories, 4 and 5.

Figure 7. 15 Blood pressure by practice deprivation

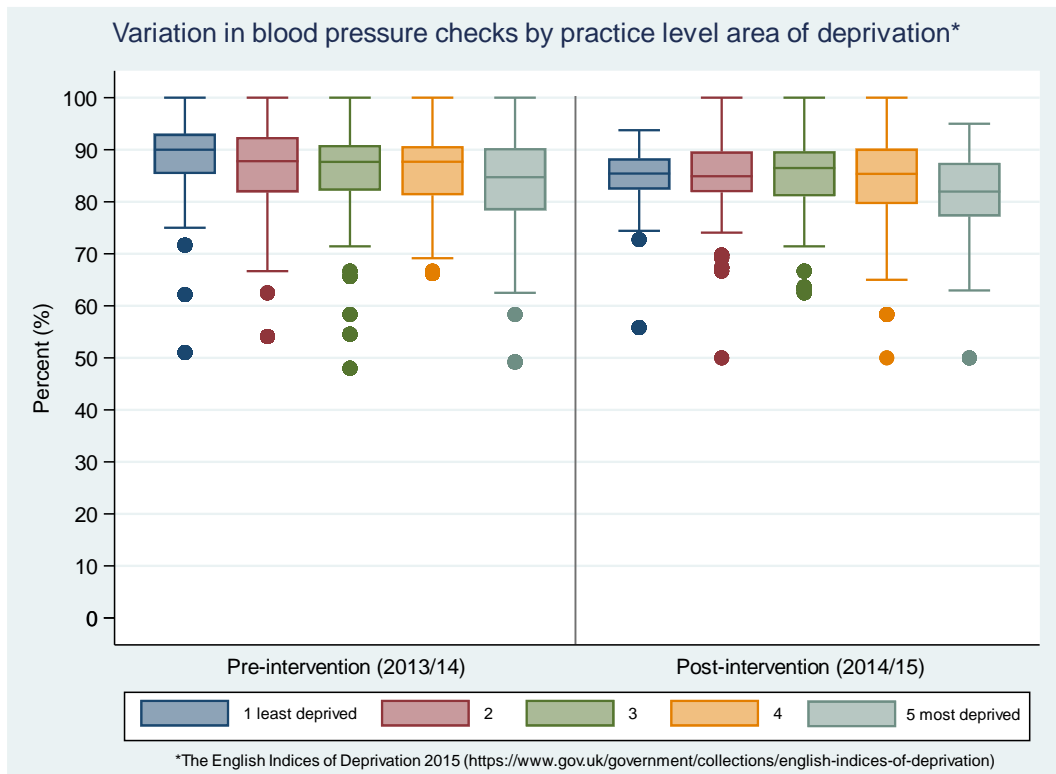


Figure 7. 16 BMI by practice deprivation

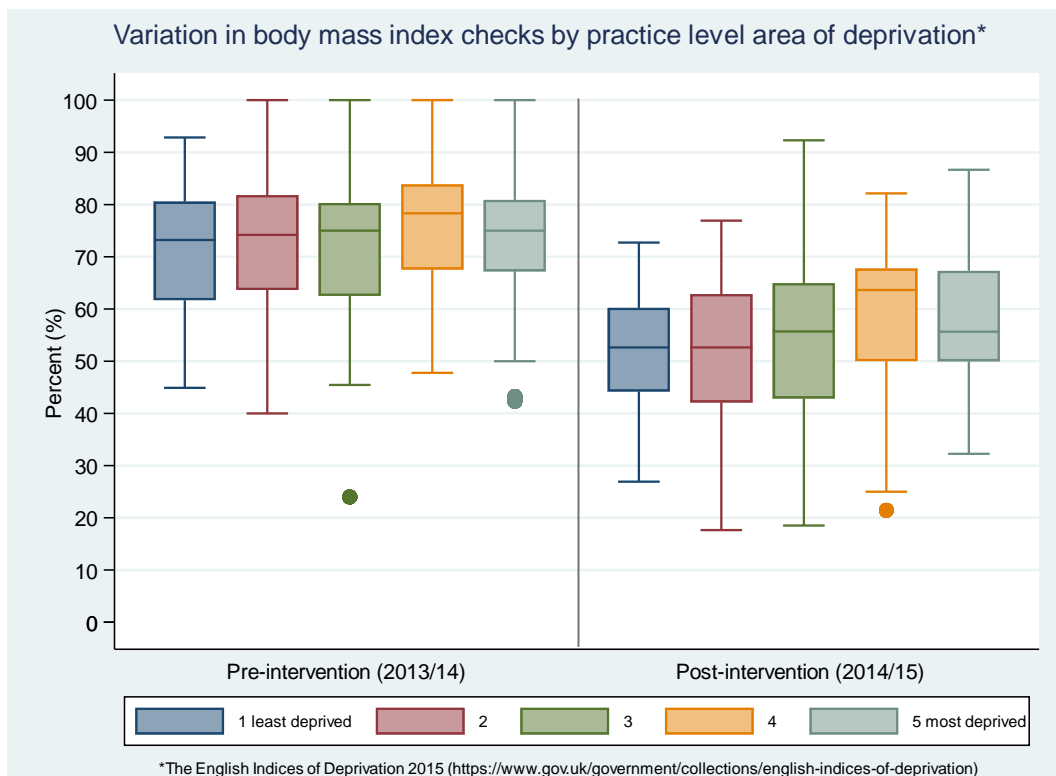


Figure 7. 17 Cholesterol by practice deprivation

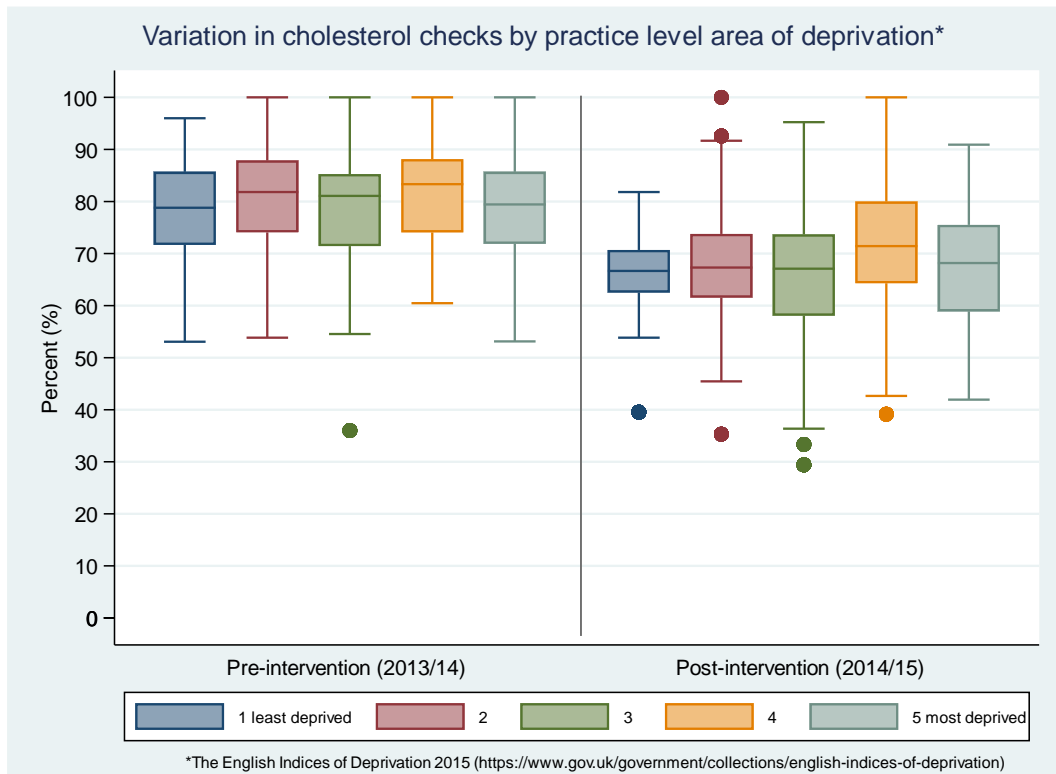
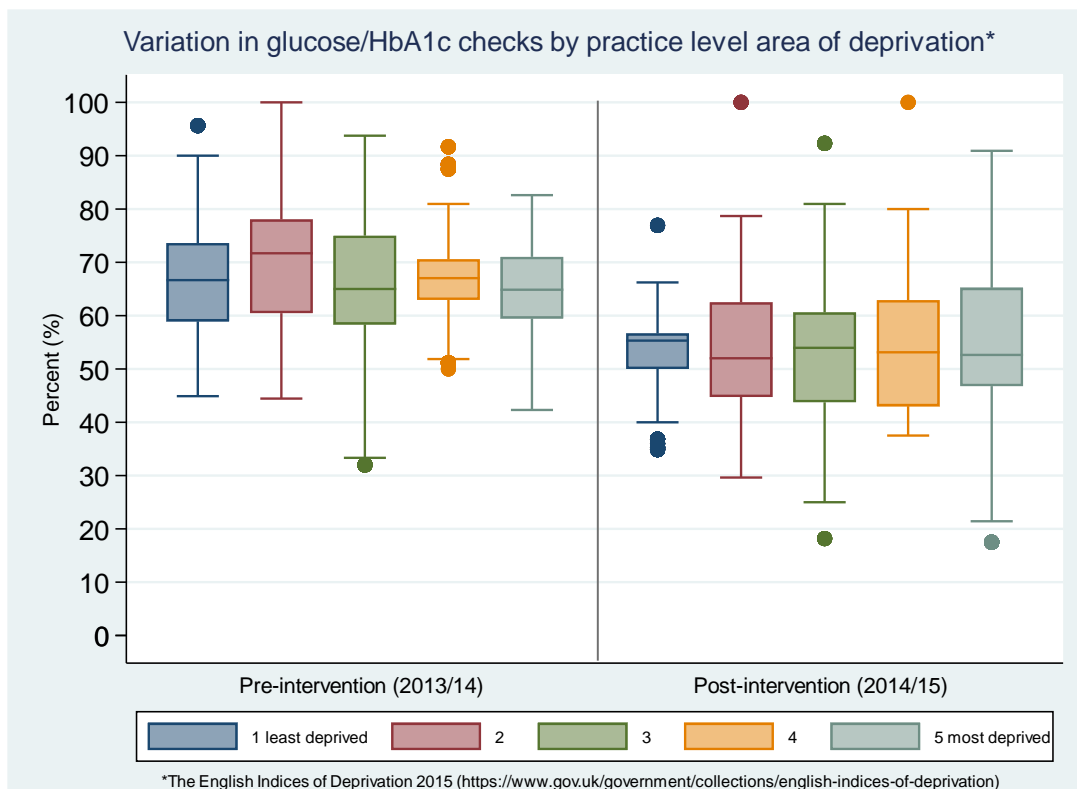


Figure 7. 18 Glucose/HbA1c by practice deprivation



7.5.7 Summary of practice level analyses

Box plots provided graphical evidence of the dispersion of data and variation in practice performance, regarding the proportion of a practice's patients who had a health check recorded: pre-and-post-intervention.

Association between number of SMI patients registered (proxy for practice size) and practice performance:

- Blood pressure had the narrowest box plots for all categories (small, medium, large), indicating the least variation in performance between practices; and the smallest changes post-intervention.
- BMI, cholesterol and glucose/HbA1c all had a decrease in median values post-intervention, indicating a decline in the proportion of patients who received a health check; and a widening of the data range, particularly for small and medium practices. This demonstrated increased variability, which equated to patients being less likely to have had a test recorded at practices with fewer SMI patients.
- The only similar finding for all indicators was that large practices had the narrowest data range, both before and after incentives were removed, suggesting practices with the highest number of registered SMI patients had a more consistent level of performance irrespective of incentives.

Association between practice level deprivation and practice performance:

- Blood pressure did not show any notable changes in the spread of data across both time periods.
- BMI, cholesterol and glucose/HbA1c all displayed a decline in median values after incentives were removed, most substantially for BMI.
- There was also a distinct widening of variability for the more deprived categories, suggesting that the performance of practices from more deprived areas became more inconsistent after incentives had been removed.

7.6 Chapter summary

This chapter has presented findings from the quantitative analyses conducted for this thesis at both the patient and the practice level. The key findings showed:

- The removal of incentives resulted in a significant decrease in the proportion of patients who received a health check for all three indicators, compared with blood pressure the control.
- Age was the most influential factor determining the likelihood of whether or not a patient received a health check (younger patients less likely; older patients were more likely to), accompanied by several other demographic factors.
- Patient level deprivation had virtually no effect on the likelihood that a patient received a health check.
- Practices with a higher number of SMI patients registered and from less deprived areas were less likely to see marked changes in performance levels following the removal of incentives.

Chapter Eight – Discussion, Implications and Conclusions

8.1 Chapter content

This final chapter brings together the principal findings from the qualitative and quantitative studies undertaken for the thesis. The chapter summarises what the research found and considers what the findings mean. It begins by restating the purpose of the thesis. It then presents key findings from each core component of research, followed by a discussion about how these relate to the wider literature. It goes on to discuss strengths and limitations specific to this thesis. It then synthesises findings from the contrasting paradigms, before considering the implications of the findings for policy and clinical practice. The chapter concludes with recommendations for future research.

8.2 Purpose of the thesis

The purpose of this thesis was to enhance understanding about the complex array of factors affecting the quality of primary care for people with SMI. To achieve this, a mixed methods approach was selected to conduct two research studies from contrasting methodological paradigms. The main objectives for the thesis are restated below:

- To provide contextual background for the research studies with an overview of the use of financial incentives to promote quality improvement in healthcare activity (Chapter Two).
- To explore how patients and practitioners perceived and experienced the delivery of primary care for people with SMI (Chapter Five).
- To estimate the effect that removal of financial incentives had on the likelihood that patients had physical health checks recorded, to ascertain how policy intervention impacted on the quality of primary care in relation to physical health monitoring of SMI patients (Chapter Seven).

8.3 Summary of the key findings

This thesis has attempted to strengthen understanding about factors that enhance and erode quality of primary care for patients with serious mental illness.

8.3.1 Part One - Qualitative research

Key findings from the thematic analysis of the qualitative research data, presented in Chapter Five, are summarised below:

- Patients and practitioners shared an aspiration for patient-centred, holistic care but in reality expectations of being treated as a whole person were rarely met. Whilst practitioners claimed that system level factors such as implementing the QOF compromised their capacity to provide patient-centred care, patients believed their expectations were not met because practitioners prioritised other aspects of care over what was important to them, such as their daily functioning and quality of life.
- There was a strong consensus among patients and practitioners that a breakdown in communication with secondary care had undermined quality of care, distancing services and delaying the sharing of information. Patients were left feeling ‘abandoned’ and ‘in limbo’ given the uncertainty about who would take responsibility for addressing their physical health needs relating to psychotropic medication.
- Practitioners felt the current structure and organisation of primary care limited their agency, compromising their ability to enhance patient care. Despite displaying empathy for SMI patients, recognising their complex needs and vulnerabilities, most practitioners displayed frustration that serious mental illness was marginalised as a condition in primary care. They claimed SMI was not accorded the same level of priority or resources as other chronic conditions, which undermined their capacity to provide adequate quality of care to this patient group.
- QOF physical health checks were viewed by both patients and practitioners as having had a detrimental effect on quality of care by prioritising a biomedical box ticking agenda in favour of holistic care. Moreover, patients claimed an ideal opportunity to discuss their physical health needs and to receive healthy living advice had been missed due to time constraints and a reluctance by practitioners to engage in dialogue during health checks.

Meta-theme: concept of visibility

The concept of visibility emerged inductively throughout the process of thematic analysis, acting as a thread that interwove many of the core themes and subthemes. Both patient and practitioner interview transcripts were densely populated with language and references to what was seen and what was missed, what was displayed and what was covered up, what was disclosed and what was hidden. Visibility thus evolved as a conceptual thread to link the core themes identified from the

findings. For instance, high levels of patient visibility – as reported in continuity of care – appeared to reflect good quality of care whereas partial or inadequate visibility – as shown by the lack of a whole person approach – represented poor quality of care.

As discussed in Chapter Five, Theme 2 practitioner data displayed unanimity that serious mental illness existed on the margins and was not a core priority in primary care. Consequently, SMI was less visible and less well-resourced than other QOF chronic conditions such as COPD or diabetes, which had specialist clinics run by trained nurses. Patient discourse demonstrated a more complex understanding of the concept of visibility, however, as detailed within each core theme. Ultimately, even when patients attended practice and were physically visible, many felt their needs were not seen or heard by practitioners who tended to prioritise other aspects of care.

The narrative case study of the QOF physical health checks discussed in Chapter Five further demonstrated the concept of visibility being transitory and inadequate, failing to see the patient as a whole person. Although patients who were engaged and who presented for a health check were more visible and had measurements recorded, patients who did not respond to invitation for a health check would likely have been exception reported and removed from the QOF outcomes data before payment calculation, a process which is reported to have boosted practice income (Jacobs et al., 2015b). As such, there was no incentive for GPs to chase those patients hardest to engage, typically the most vulnerable, who found it difficult to attend. This may have reflected a duty of care issue (CQC, 2021) where insufficient adjustments had been made to provide adequate access to all SMI patients. Given the high levels of exception reporting of SMI patients (Gutacker et al., 2015) it seems that implementation of the QOF reinforced the inverse care law (Tudor Hart, 1971) by rendering patients who did not engage as largely invisible. However, future research studies could now look in more detail about why patients are not included on a QOF denominator as exception reporting has been replaced by Personalised Care Adjustment (PCA) which requires practices to differentiate from a selection of reasons as to why a patient is removed from an indicator denominator (NHS England and BMA, 2021).

8.3.2 Part Two – Quantitative research

Key findings from the quantitative research study, presented in Chapter Seven, are summarised below:

- The analysis of the primary outcome showed that the removal of QOF financial incentives for BMI, cholesterol and glucose/HbA1c resulted in a significant decrease in the proportion of patients who had health checks recorded for all three indicators compared with blood

pressure, which remained incentivised so acted as a control. The decrease was most marked for BMI.

- Analyses of the secondary outcomes examined the effect of demographic factors on the likelihood of a patient receiving a health check, and showed that age was the most influential factor, followed by gender. Patient level deprivation had no significant effect on the likelihood of a patient receiving a health check, except for BMI and cholesterol where patients from more deprived areas were significantly more likely than patients from less deprived areas to have received a health check.

8.4 Discussion – what the findings mean in the context of wider literature

8.4.1 Part One - Qualitative research

The findings from the qualitative research component of this thesis build a complex picture about factors believed to enhance and erode quality of primary care. Despite previous literature on serious mental illness and primary care being relatively sparse, one piece of research resonated with a number of core findings from this thesis. The Lester et al (2005) focus group study, which explored patient and health professional views on primary care for people with serious mental illness, was the only other study – to my knowledge – to examine the topic from a dual perspective. Its patient narrative demonstrated a precedence for relational continuity, a finding that was mirrored by this thesis where patients accentuated the importance of seeing a GP who listened to them and who took them seriously.

Regarding the practitioner narrative, Lester et al (2005) provided evidence that although health professionals believed continuity was a critical element for enhancing quality of care for SMI patients, they felt it was being increasingly threatened by the policy drive to increase access and practice size, a finding that was consistently echoed by this thesis. Furthermore, both the Lester study and this thesis identified a discord between patient and professional perspectives. On the one hand, both studies showed that practitioners had relatively low expectations for SMI patients, considering them to be a challenging group to engage, typically unreceptive to health living advice. Contrastingly, each piece of research demonstrated patients' quest for knowledge about how to optimise their physical health, coupled with disappointment that they were consistently denied the opportunity to engage in dialogue with their GP about what mattered to them.

However, other comparable studies looking at serious mental illness and primary care examined the topic from either the patient or the practitioner perspective. One study exploring patient needs and preferences, conducted in the Netherlands (van Hasselt et al., 2013), chimed with evidence from this thesis, particularly in relation to a decline in communication between primary care and mental health services, which was shown to have eroded quality of care. Regarding perceptions of how the QOF impacted on care for people with SMI, several pieces of research provided corroborative evidence. One study exploring practitioners' views of the QOF (Lester et al., 2011) found that GPs believed it undermined other aspects of care, a finding strongly supported by this thesis, which has highlighted that practitioners believed that person centred care has diminished under the QOF. Lester et al (2011) defined this unplanned outcome as being one of the 'unintended consequences' of the QOF whereby incentivised aspects of care took priority over non-incentivised care. Additional corresponding evidence, which found that practitioners felt the QOF undermined GPs' clinical judgement and compromised medical professionalism (Lester et al., 2013), was also mirrored by findings from this thesis. From the patient perspective, evidence on the effect of the QOF also chimed with findings from this thesis, which revealed patients' principal concern was that the QOF focused on recording measurements on a computer at the expense of other – in their eyes – more important aspects of care (Chevance et al., 2020).

Aligning findings from this thesis with evidence from the wider literature that has explored views from other vulnerable patient groups, there are some notable comparisons. From the patient perspective, one of the key findings from this thesis was that SMI patients valued personalised and what they described as holistic care, over and above other aspects of care that are typically used to define care quality (Goodwin et al., 2011) such as rapid access (Gerard et al., 2008). This resonated with evidence from several studies of vulnerable patient groups that have emphasised the importance that patients place on a whole person approach (Mercer et al., 2007). From the practitioner perspective one of the key findings from this thesis was that, despite their aspiration to meet the complex needs of SMI patients, practitioners felt their capacity to provide personalised care had been compromised by structural changes which had affected the primary care delivery model (Freeman and Hughes, 2010), principally – as discussed earlier in relation to Lester et al (2005), – by expanding practice size which made achieving continuity of care increasingly challenging.

In addition, findings from this thesis showed that the QOF can be reductionist and undermine clinical judgment in the context of care of patients with SMI. Similar findings about the QOF have been reported in the context of care of people with common mental health problems (Alderson et al., 2012) and long term conditions (Coventry et al., 2011), suggesting that, irrespective of the type of mental health condition, patients often feel the imposition of the QOF impaired other aspects of their care.

Moreover, by showcasing that patients' critique of the QOF centred on lack of time and opportunity to engage in dialogue with their GP about how to optimise their physical health, this thesis builds on the evidence from other studies exploring the impact of QOF on self-management of chronic conditions (Blakeman et al., 2011).

The findings from this aspect of the thesis are indicative of a wider and long-standing debate about the tension in primary care between a biomedical model and a more humanist biopsychosocial model of healthcare (Engle, 1979). Although patients displayed a strong preference for a humanist approach to enhance their quality of life, rather than focusing on efforts to extend its longevity, recent policy initiatives (NHS England, 2019b, NHS England, 2018a, NHS England, 2017) have demonstrated a more biomedical approach to addressing the SMI mortality gap, which has prioritised risk monitoring and the recording of measurements over patient-centred care. This resonated with other studies exploring self-management for people with chronic physical conditions, which have demonstrated that GPs tended to prioritise biomedical aspects of care over a more person-centred approach (Blakeman et al., 2006, Owens et al., 2017). Furthermore, there have been calls for a paradigm shift away from the biomedical model of clinically managing a condition, towards a more biopsychosocial model of enabling patients to live well with their condition (Entwistle et al., 2018a, Entwistle et al., 2018b).

In summary, findings from the qualitative study in this thesis support evidence from comparable studies which have shown that the quality of care for SMI patients was suboptimal. Both patients and practitioners have reported that policy interventions, such as the QOF, have reinforced the pre-eminence of a biomedical model of monitoring risk of physical ill health at the expense of patient-centred care, resulting in patients' preferences being neglected. While efforts to address the mortality gap in people with SMI are much needed to correct the profound health inequalities experienced by this group, the unintended consequence might be that efforts to improve quality of life become less of a priority.

8.4.2 Part Two – Quantitative research

Findings from the quantitative research component of this thesis strengthen the relatively sparse literature on the effect of removing financial incentives from quality improvement schemes. As discussed in Chapter Two, research on the impact of financial incentive schemes has tended to focus on the effect of their introduction rather than their removal (Lester et al., 2010) hence, comparison with comparable studies was limited. To date, only a few studies have examined withdrawal of QOF indicators (Kontopantelis et al., 2014) and fewer still have included any of the four indicators examined in this thesis (Minchin et al., 2018, Wilding et al., 2018). To my knowledge, no study has

focused specifically on the impact of removing QOF physical health indicators for people with SMI. Consequently, the findings from this study provide new evidence about the effect of policy change on the rate of physical health monitoring for people with SMI.

Findings from this study supported those from a corresponding study (Minchin et al., 2018) that examined the effect of removing QOF incentives on the proportion of patients who had a health check recorded. Its selection of eighteen indicators included three of the same ones investigated for this thesis (blood pressure, BMI and glucose/HbA1c) although Minchin et al (2018) examined data at the practice level, whereas this thesis examined data at the individual patient level. The findings from Minchin et al for SMI indicators correspond with those from this thesis, showing an immediate decrease in the recording of health checks for BMI and glucose/HbA1c in the first year after incentives were removed. Moreover, both studies estimated a larger decline for BMI compared with glucose/HbA1c. This could mean that fewer BMI checks were carried out, or it could mean, as proposed by Minchin et al (2018), that BMI checks were less rigorously recorded compared with glucose/HbA1c.

Findings from this thesis resonated with Wilding et al (2018) which investigated the effect of removal of QOF indicators across a range of disease domains, commissioned by NHS England. Corresponding with this thesis and Minchin et al (2018), Wilding et al (2018) demonstrated a significant decline in the proportion of patients who had a health check recorded, with the most pronounced decrease being in the year directly after incentives were removed, indicating the response to the removal of financial incentives was immediate. This was evident across all indicators including the one indicator shared with this thesis, which was cholesterol for patients with SMI.

Furthermore, Wilding et al (2018) used the same data source as this thesis (CPRD data at the individual patient level), which meant secondary outcomes were comparable. Findings from the secondary outcome analysis of this thesis supported those from the Wilding et al study, which demonstrated that independent variables such as age and gender affected the likelihood that a patient received a check. For instance, both studies showed that age was a strong independent variable, with the youngest and oldest groups least likely to have had a check recorded, both before and after incentives were removed. In addition, neither piece of research found evidence that the proportion of patients who had a check recorded was differentially affected by deprivation level.

In contrast to findings from this thesis and the ones reported by Minchin et al (2018) and Wilding et al (2018), an earlier study (Kontopantelis et al., 2014) that examined the withdrawal of QOF financial incentives (for eight indicators relating to long-term conditions such as asthma, diabetes and

cardiovascular disease) found that indicator performance levels remained relatively stable after incentives were removed. However, the authors stressed that there were caveats as all the indicators they had investigated remained indirectly or partially incentivised by other indicators, which may explain why the withdrawal of incentives appeared to have had no effect. Consequently, findings from the more recent Minchin et al and Wilding et al studies are more comparable to those in this thesis.

In summary, findings from this thesis have reinforced the evidence that removal of incentives resulted in an immediate and significant decline in indicator performance.

8.5 Strengths and limitations of this thesis

This section considers strengths and limitations specific to this thesis in relation to the mixed methods research design and the conduct of the two research studies, which consisted of a statement of reflexivity for the qualitative component. A more generic and detailed consideration of the strengths and limitations associated with the contrasting methodological approaches used is presented in Chapter Four (qualitative) and Chapter Six (quantitative).

8.5.1 *Mixed methods design*

Using a mixed methods design to conduct the research, guided by a pragmatic philosophical approach, was one of the main strengths of this thesis as it enabled the most appropriate methodology and methods to be selected to address the research questions (Creswell and Plano Clarke, 2011). As discussed in Chapter Three, using two methods from contrasting research paradigms enabled the thesis to explore *what* and *why* questions, as well as to examine *how many* and *how much* questions (Green and Thorogood, 2004) allowing the research topic to be investigated from different angles. Moreover, integration and synthesis of findings from the qualitative and quantitative studies generated deeper understanding (Bryman, 2007) about the factors which enhanced and eroded quality of care, uncovering findings which may not have been visible through the lens of a single method of research (O'Cathain et al., 2010). Furthermore, given that this thesis appears to have been the first study to have used a mixed methods approach to examine the effect of the QOF on quality of care, one of its key strengths is originality.

However, there are a number of limitations associated with using a mixed methods approach. Principally, as discussed in Chapter Three, it is challenging to combine methodologies from different paradigms using an approach that is still relatively new (Creswell, 2015). Another challenge of using a mixed methods design was ensuring that there was adequate integration of quantitative and

qualitative data during analysis and interpretation, so that the findings of the combined analysis were greater than the sum of their parts (Tariq and Woodman, 2013). An additional challenge is that there may be resistance from scientific purists with conflicting worldviews who typically display disregard for mixed methods studies (Bryman, 2007), which can hinder dissemination. Nevertheless, when mixed methods studies are well conducted they can offer new insights and enrich understanding. This strength has been particularly useful for this thesis during the examination of such a complex health research problem (Yardley and Bishop, 2015).

8.5.2 Qualitative study – A Statement of Reflexivity

Reflexivity is a critical part of enhancing the validity of qualitative research, as discussed in Chapter Four. Consequently, as detailed below, I endeavoured to be critically reflexive of my actions and their outcomes throughout the entire qualitative research process:

Design

One of the key strengths of this thesis was determined at the design stage where the decision was made to research the topic from the dual perspective of patients and practitioners. Although it entailed more complexity, it enriched the data and provided a more balanced account of primary care from different viewpoints. Given the literature on experiences of SMI in primary care has been dominated by studies that explored the perspectives of either patients or practitioners alone, this study makes an important contribution to the evidence base, building on the knowledge created by the few studies that have explored both SMI patient and provider views of primary care (Lester et al., 2005).

REC approval

Contrary to expectation from the literature (Patel et al., 2017) and my previous experience of primary care based studies (Gilbody et al., 2017), the Social Care Research Ethics Committee (REC) advised against reimbursing GPs or practice nurses for their time. This could have negatively impacted on GP recruitment by making it difficult for practices to commit to taking part in the study. In reality, however, it had virtually no effect on recruitment. There was only one instance where a GP decided her practice would not take part on account that the practitioners would not be reimbursed, even though it had been clearly stated on the study outline that GPs and practice nurses would not be remunerated. On the other hand, the REC positively endorsed offering patients a voucher to thank them for their time (Head, 2009). Interestingly the initial proposal to use a *Love-to-shop* voucher, which could have been used at multiple outlets, was rejected by the REC who specified that they did not consider it advisable to give patients with serious mental illness a voucher that could have been spent on alcohol. Consequently, a £10 Boots voucher was used instead but this could be viewed as

another example of stigma, demonstrated by the research ethics committee being overprotective of a vulnerable patient group (Millum et al., 2019) who they did not deem trustworthy to spend a *Love-to-shop* voucher appropriately.

Recruitment and engagement

Whilst it proved more challenging to recruit patients with schizophrenia than patients with bipolar disorder, this was not entirely unexpected as a number of the GPs who I had liaised with prior to recruitment had suggested that it may be more difficult to engage patients with a diagnosis of schizophrenia. Fortunately, having envisaged it being challenging to recruit people with SMI (Bower et al., 2009), ethical approval and permissions were already in place to adopt alternative methods of recruitment that did depend on primary care, which minimised delay to the research process.

Following recommendation by one of the study's Expert by Experience advisers (CD), the final five patients were recruited via local mental health trust clozapine clinics. Being able to successfully recruit five additional patients with schizophrenia helped to rebalance the sample so it was more evenly represented by patients with diagnoses of bipolar disorder and schizophrenia. Overall, engagement with the study was excellent as nearly all the patients who agreed to take part completed their interview, with the exception of one patient who had been recruited via a clozapine clinic but who did not present for interview.

Being reflexive about the process of recruitment also highlighted patient preferences for responding to an invitation to take part in the study. Initially, offering participants the opportunity to respond by completing a hand written expression of interest (EOI) form and posting it to the researcher in a pre-stamped addressed envelope seemed a little outmoded, but in reality this proved the most popular way of responding as nearly two thirds of the sample opted to post back the EOI. The remainder of the sample used email or telephoned the landline number to confirm their interest in the study. Not one single patient contacted the researcher using the mobile phone number provided, which was somewhat surprising considering evidence from the literature (Young et al., 2019). This finding may be useful though in informing future studies about the benefit of including a written postal response option for this patient group.

Expert by Experience advisers

Another important contribution made the Expert by Experience advisers for this thesis related to designing patient materials and topic guides. Advisers played a central role in refining documents for the invitation packs, which included the participant information sheet, consent form and letter of

invitation (see Chapter Four). They were particularly helpful in recommending changes to language and vocabulary to make it less academic and easier to read and comprehend (Gilbert and Stickley, 2012). Furthermore, they advised on key aspects of the topic guide, stressing the importance of an opening narrative question to encourage participants to tell their story and feel comfortable speaking to the researcher, which echoed findings in the literature (Newman et al., 2017). Again, they recommended changing certain terms to make the language more meaningful for the target audience, for example, replacing the term ‘medication’ with ‘meds’ which was deemed more akin to how SMI patients would speak.

Qualitative data collection

During the process of data collection I made a conscious effort to be reflexive by following a number of procedures. First, I made notes at the end of each interview to record initial thoughts and observations about the participants and their living environment (Pope and Mays, 2006). Second, I tried my best to remain impartial and not to ask leading questions or to interrupt prolonged silences where participants took lengthy time to consider their responses. Finally, I focused on actively listening and responding to what participants had said rather than being governed by an agenda and moving swiftly on to the next topic (Abrahams, 2017).

Generalisability

As described in Chapter Four, due to the small sample size of the qualitative study it is difficult to make generalisations about the wider population of general practice practitioners or SMI patients. While the study sample contained a diverse range of views and experiences there are a number of factors that limit its representativeness.

First, the practitioner sample was under-represented by female GPs and it had no representation from male practice nurses. Second, although the patient sample had a relatively even distribution of patients with different diagnoses (eleven with bipolar disorder and eight with schizophrenia), similar to gender (eleven men and eight women), schizophrenia was disproportionately represented by men (six males and two females). Furthermore, even though the age range for both diagnostic groups in the sample was relatively broad (spanning across four to five decades, with similar mean ages in the mid-fifties), the patient sample was under-represented by young people.

In addition, the study sample was recruited from research active practices which may not have been representative of practices in general. Moreover, the practitioner sample was represented by GPs and practice nurses who were interested in mental health and health research. Similarly, the patient sample was populated by patients engaged with care. Typically, patients who respond to an invitation to be

interviewed tend to be healthier and have fewer unmet needs than those patients who are harder to reach (Ellard-Gray et al., 2015).

Finally, the study sample contained no ethnic diversity as all participants identified as White British. This may reflect the demographics of where participants were recruited from as apart from two practices in Leeds the rest of the sample were recruited from practices in Harrogate, York, Hull, and the rural areas in between, which have fewer ethnic minorities compared with the larger urban areas within the Yorkshire and Humber region. Alternatively, it may reflect a lower uptake by ethnic minorities to participate in research as reported in the literature (Woodall et al., 2010). However, despite these limitations it should be remembered that qualitative research does not seek to be representative (Creswell, 2007).

Safeguarding participants

On reflection, the safeguarding of participants should have extended to practitioners as well as to patients. It would have been beneficial to have considered how to safeguard against distress and potentially difficult issues which may have arisen during practitioners' discussion about the care provided for vulnerable SMI patients with complex needs (Guillemin and Gillam, 2016). Furthermore, consideration should have been given to the potential for practitioners to disclose sensitive information in relation to whistle blowing or revealing possible malpractice (Baez, 2002).

In summary, consistently engaging in a process of reflexivity allowed me to consider aspects of the qualitative research that worked well, as well as to critically examine elements that were more challenging. Practicing reflexivity has enabled me to further develop my skills as an independent researcher.

8.5.3 Quantitative study

Data source – electronic health records

One of the principal strengths of this thesis was that it used observational data (electronic health records) from the CPRD database, which enabled access to a large sample of SMI patients containing high quality data (Kontopantelis et al., 2018). Given that since the introduction of QOF in 2004 (Khan et al., 2010) data have been consistently well recorded, the data analysed during the timeframe of this thesis (2011-2016) were all up-to-standard and comprehensively recorded. Furthermore, as the data were recorded at the patient level they provided a rich granular dataset. The benefit of this, compared with using other primary care data such as NHS Digital – recorded at the practice level – is that it enabled analysis to investigate the effect of individual patient demographics on outcomes.

However, there were a number of limitations to using CPRD as a data source. First, given that the dataset contained multiple data linkages, including HES and ONS, the number of eligible patients was substantially reduced (Herrett et al., 2015). Even so, the sample size remained large enough to ensure there was sufficient power to conduct statistical analysis, despite a fall in the number of patients during the study. While it is not clear exactly why patient numbers declined throughout the study period, a number of factors may have contributed to this decline. For instance, if a patient was removed from a practice, either by moving to another practice or were deceased, they were not replaced by new patients so the overall number of patients declined. Furthermore, there was a decline in the number of practices year on year which can be explained by a combination of practice mergers, in addition to a decline in the proportion of practices contributing data to CPRD as Vision (the clinical computer system providing data to CPRD) occupied an increasingly smaller share of the market compared with competitors such as EMIS and SystmOne (Kontopantelis et al., 2018).

The second limitation related to data access, which involved a change to the data specification and a lengthy delay. As discussed in Chapter Six, the original plan had been to access a CPRD dataset remotely via the CALIBER platform at UCL, but this proposition had to be shelved due to licensing complications arising from the introduction of GDPR. While the EMERALD dataset (Bellass et al., 2019) proved a valid replacement, changing to a different database did have limitations. Principally, despite having a large sample of SMI patients, it also included patients without SMI. Consequently, this thesis used a sample with fewer SMI patients than originally planned for, though as mentioned above there was still sufficient power to conduct analysis., Furthermore, the delay caused by discovering the CALIBER platform could not deliver data access to external institutions, and then having to obtain a replacement dataset, substantially limited the time available for analysis.

Quasi-experimental methods

Following a different-in-differences approach was one of the principal strengths of this thesis given that it is regarded as the quasi-experimental design that gets closest to being able to measure causal inference (Wing et al., 2018). Moreover, following a quasi-experimental design to analyse real world data resulted in findings that have stronger external validity than the gold standard method of randomisation (Kontopantelis et al., 2015a). Consequently, the findings are more representative of what happens in practice and arguably more useful than experimental studies for informing health policy (Shadish et al., 2002).

However, there were limitations associated with using a difference-in-differences design. First, several assumptions had to be met to ensure internal validity including the ‘parallel trends’ and ‘common shocks’ assumptions (Dimick and Ryan, 2014), as discussed in Chapter Six. In addition the

lower attainment of all indicators in 2012/13 was inconsistent with data for the other financial years. It is unclear why this happened and what caused the drop in performance for all indicators in that year. While it is possible that the introduction of the Health and Social Care bill in 2012 could have negatively impacted on practices' QOF performance, there is no direct evidence from this thesis to support this. There were also limitations associated with using regression models for secondary outcome analysis. Primarily this related to data quality as missing data or inconsistently recorded data would have limited the strength of data analysis (Bland, 2015). However, as discussed in Chapter Six, CRPD data were consistently recorded throughout the dataset used for this thesis and missing data was minimal. This compares similarly to other studies, which have reported CPRD data to be of high quality (Ride et al., 2018).

Health checks – data issues

One limitation of this study was that it only documented patients who had received a health check in primary care, and patients who had health checks elsewhere could have been missed. Some patients with SMI may have had a health check conducted in a different setting (secondary care mental health trust) which would not have been recorded in primary care. Because these data were not included in the CPRD dataset, this thesis may have underestimated how many patients had a health check each year. Moreover, at the same time QOF incentives were removed in primary care for (BMI, glucose and cholesterol), a CQUIN incentive was introduced for mental health trusts to carry out physical health checks on patients under their care (England, 2014). However, the absence of a shared IT system between primary and secondary care data sharing is an ongoing issue, which makes it challenging for researchers to obtain a complete picture (NHS England, 2016).

An additional limitation regarding health checks is that, due to time pressures discussed earlier, it was not possible to compare the rate of health checks for SMI patients with the rate for the general population. NHS health checks for the general 'healthy' population, sometimes referred to as an 'MOT', were introduced in 2009 with the aim of preventing people developing long term conditions (Robson et al., 2016). People aged 40-74 years were invited to have a check once every 5 years to assess their risk of heart disease, stroke, kidney disease and diabetes (Public Health England, 2021). So far there is limited evidence whether these NHS health checks were effective (Bunten et al., 2020) and observed uptake and attendance is lower than anticipated (Martin et al., 2018). Moreover, there is uncertainty about whether participants in this study aged 40 and above were invited for a general health check because of their age or invited for a health check because they had a diagnosis of SMI. However, NHS health check invitations are once every 5 years compared with the QOF SMI physical health checks, which are annual, meaning that most participants in this study recalled experience of an SMI health check.

8.6 Synthesis of findings

8.6.1 *Integration of findings*

Findings from the qualitative and quantitative studies were synthesised using a process of triangulation (Denzin, 1978). As defined in Chapter Three, the process of triangulation used for this thesis referred to using different methods to gain a more complete picture of the problem being investigated (O'Cathain et al., 2010). By integrating findings from two contrasting paradigms, it was possible to relate findings about complex human experiences of the QOF and its effect on quality of care for people with SMI with quantitative data driven findings about removal of QOF indicators. This resulted in deeper understanding of the research topic than would have been possible using a single methodological approach (Creswell and Plano Clarke, 2011). Evidence from the qualitative and quantitative studies on the removal of financial incentives was corroborative with both studies showing that removal of incentives resulted in a decline in the proportion of SMI patients who received a health check. Furthermore, the qualitative evidence uncovered a possible explanation for the quantitative findings, enriching understanding about the factors that influenced indicator performance.

Prior to the integration of findings from the contrasting paradigms, analysis from the quantitative study suggested that the decline in performance following the removal of incentives was economically driven, due to the withdrawal of financial reward. However, the qualitative evidence suggested there were other factors underpinning the change in practice. These included the finding that GPs viewed the QOF as a barrier to providing patient-centred care and thus welcomed the removal of incentives, which could explain the immediate and significant decline in the first year. These practitioners revealed that without QOF incentives they would no longer record measurements for indicators unless there was a clinical need, reinforcing the argument that QOF undermined clinical judgment by incentivising GPs to conduct health checks on all patients rather than those most at risk. This could explain why there was an immediate decrease in the first year followed by a levelling off, which may indicate that after incentives were removed GPs stopped conducting health checks on patients where it was deemed unwarranted.

Summary of the two studies

Integrating findings from the qualitative and quantitative components of this thesis resulted in a deeper understanding of the research problem. Patient and practitioner narratives consisted of rich data which identified elements of practice that enhanced or eroded quality of care. The qualitative study provided valuable insight from patients and practitioners on the limitations of the QOF and the

biomedical model. The quantitative study, on the other hand, demonstrated that the removal of QOF incentives resulted in a decrease in health checks. Considering both sets of findings together adds value as the qualitative study explains the outcome of the quantitative study (why health checks declined) which can provide useful information for future policy.

What this means for future research

A key message from this thesis is that qualitative studies should be an integral part of research design rather than just an ‘add-on’ as they are critical for identifying patient and practitioner concerns and aspirations. While quantitative data can measure outcomes, qualitative data can offer explanation and insight into how care can be improved and become more patient-centred – for example, by focusing on their needs for daily functioning. Evidence from this thesis suggests that incentivisation pushes practitioners to focus on the biomedical model which reduced practitioners’ capacity to provide holistic, patient-centred care and reinforced the prescriptive biomedical model.

Looking ahead, the reintroduction of QOF indicators in April 2021, which had been removed in March 2014, represents a significant U-turn and re-affirms the importance and topical nature of this thesis. While some critics will welcome the reinstatement of cholesterol and glucose indicators (NHS, 2021), evidence from this thesis sends a warning that reverting to the same biomedical model may not necessarily address physical health care priorities among people with SMI. Research is therefore needed to identify how to adapt QOF health checks or offer an alternative, which better addresses the unmet psychosocial and physical healthcare needs of people with SMI. Furthermore, the COVID pandemic has highlighted a widening of inequalities between people with SMI and those without (Spanakis et al., 2021). As such, it is a critical time to be conducting research in this area in attempt to prevent the gap from widening.

8.6.2 *Integrated findings: in context of current policy and research*

Before considering the implications of this thesis for policy and practice, it is useful to place the findings within the context of current policy and existing programmes of research. First, a recent policy change flagged in Chapter Six, which consisted of the reintroduction of the BMI indicator in 2019 (NHS England, 2019a), appears at odds with evidence from this thesis. Given there was a significant decline in the rate of health checks for cholesterol and glucose/HbA1c, as well as for BMI, it is questionable as to why only the BMI indicator was reintroduced, particularly as an abnormal BMI measurement is arguably more visible to practitioners than abnormal cholesterol and glucose levels, which require a clinical test to determine if a patient has levels outside the normal range.

However, there is closer alignment between findings from this thesis and comparable studies such as the DIAMONDS programme of research (DIAMONDS), which is focused on improving patient self-management of diabetes in people with SMI. Such research is also looking beyond the confines of the QOF and could signal a new horizon of hope for people living with SMI. Additionally, the SCIMITAR study (Gilbody et al., 2019) produced pioneering evidence, which showed that contrary to expectation SMI patients had strong aspiration to give up smoking and improve their physical health, and, when given a bespoke smoking cessation intervention, they could be successful.

Evidence that SMI patients benefit from tailored support was further reinforced by a recent meta-review of interventions (Meader et al., 2020) conducted by the Centre for Review and Dissemination (CRD), which explored the merits of addressing multiple SMI risk behaviours. The CRD study found that people with SMI need a personalised approach to healthy living and require existing interventions to be carefully tailored to their needs (HEALTH Study team, 2020). Furthermore, studies examining the physical health of young people at risk of developing psychosis have shown that providing customised support to improve an individual's physical health can enhance their self-esteem and positively impact on their psychological wellbeing, which increases their motivation and confidence to improve their daily functioning (Carney et al., 2017).

In summary, a rising number of research studies investigating SMI health inequalities has been accompanied by a growth in policy interest on the topic. Indeed, an NHS England lead interested in improving the physical healthcare for people with serious mental illness has enquired about the findings from this thesis in a quest to find alternatives to the biomedical model of the QOF.

8.7 Implications for policy and clinical practice

Implications for policy

Findings from this thesis have uncovered considerable uncertainty on the policy front about how best to manage the physical health needs of SMI patients and reduce the mortality gap. The key findings point towards a need to:

- Look beyond the QOF as a means of enhancing the quality of primary care for SMI patients as findings from this thesis indicate the QOF is too focused on the biomedical model of recording measurements at the expense of person-centred care.
- Invest more resources in social prescribing to support SMI patients to make healthy lifestyle choices and promote self-management given the time constraints of primary care. Despite a

lack of robust research evidence on patient outcomes for social prescribing (Husk et al., 2019), there are signs emerging that it can improve quality of life (Skivington et al., 2018) by empowering patients to take greater control over their health (Kimberlee, 2013).

- Improve communication and contact between primary and secondary care, which underpins evidence from a recent King's Fund report that highlighted the need for closer alignment between primary care and mental health trusts (Naylor et al., 2020). Findings from this thesis reinforce the report's principal message that current arrangements for mental health in primary care are inadequate and do not serve the interests of patients or professionals. Furthermore, it recommended that primary care networks increase investment in mental health resources in general practice, ensuring they are carefully tailored to meet local need (Dixon Woods et al., 2005, Dixon-Woods, 2014) for effective implementation of NHS England's Community Mental Health Framework.

Implications for clinical practice

Findings from this thesis have identified a need to:

- Rebalance primary care priorities to ensure patients with SMI are no longer marginalised. Rather, they are accorded the same level of resources and quality of care as patients with other chronic conditions.
- Provide training on mental health, including specifics on serious mental illness, for all employees within practices, including receptionists who are typically the first point of contact for assessing the urgency of care.
- Enhance the role of practice nurses so they can deliver more aspects of care to SMI patients, capitalising on the extra time they may be able to give patients compared with GPs who are governed by increasing time constraints.

8.8 Recommendations for future research

Findings from this thesis have raised other important research questions, which could be investigated by future research studies:

- Explore the role of incentives targeted at patients to find out what motivates people with SMI to look after and monitor their physical health, including the role of digital technology.

- Critically evaluate how digital technology could be used to enable patients to establish more regular and sustained contact with practitioners, and to promote the sharing of information and healthy living advice.
- Conduct research specifically targeted at groups who were not part of this qualitative study, namely people from a non-White ethnic origin and those identifying as a gender alternative to male/female, to explore outcomes of marginalised groups.
- Research geographical differences in perceptions of quality of primary care to identify if there are particular regions or localities where patients and practitioners report better or worse outcomes, to investigate the importance of place.
- Explore perceptions of quality of care for the most vulnerable group of SMI patients with respect to the late Helen Lester's James McKenzie Lecture 2012 *Bothering about Billy* (Lester, 2013). To investigate what matters to those people with the highest level of unmet need who often disengage and become invisible in primary care, defined as the inverse care law (Tudor Hart, 1971).
- Conduct ethnographic research to explore the interactions between patients and practitioners during consultations. To gain an alternative, more nuanced interpretation of the exchange of information and communication between patient and GP.
- Conduct experimental research using randomisation to test the effectiveness of social prescribing.

8.9 Conclusion

Findings from this thesis have unearthed high levels of unmet patient need. Despite growing interest in addressing the mortality gap, policy has thus far focused on a biomedical approach in attempts to extend life expectancy at the expense of addressing what matters to patients, namely how to enhance their daily functioning and improve their quality of life. This thesis has provided valuable evidence on factors affecting the quality of care for people with serious mental illness from both the patient and provider perspective. It has shown that currently the delivery of primary care to this patient group is inadequate: practitioners felt disempowered and too pressed for time to provide person-centred care; patients felt there was no time or scope for them to share their concerns, which prevented them being treated as a whole person. Future policy needs to draw on evidence from this thesis and comparable studies to raise expectations for people with SMI and begin listening to their call to be treated as a 'normal human being'. Furthermore, the issue of time deprivation needs to be addressed as investing

more time in primary care for this group would likely have added value longer-term and avoid a need to access more costly health services.

Finally, it is a grave social injustice that people with SMI die 15-20 years earlier than the general population. Moreover, evidence showing the mortality gap is widening deepens this inequity. People with SMI deserve parity of esteem and they deserve to be granted the same quality of physical healthcare as those without SMI. The key message from this thesis is that we need to actively listen to people with SMI and to treat them as experts of their condition, so they can effectively inform research and policy development: to ensure future practice better meets their needs. In conclusion, this thesis has provided unique insight into the pressing need to enable people living with SMI to *live well* with their condition, so they can live longer, healthier (and more meaningful) lives.

Appendices

Chapter Four

- 4.1 REC approval
- 4.2 Participant Information Sheet
- 4.3 Safeguarding vulnerable research participants
- 4.4 Lone worker policy
- 4.5 Consent forms
- 4.6 Letters of invitation
- 4.7 Background information sheet
- 4.8 Sample demographics
- 4.9 Topic guides

Chapter Six

- 6.1 Original ISAC approval
- 6.2 ISAC approval of EMERALD amendment
- 6.3 EMERALD data specification

Chapter Seven

- 7.1 Data specification

Appendix 4.1 REC approval



Health Research Authority

Social Care REC

Ground Floor
Skipton House
80 London Road
London
SE1 6LH

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

19 June 2017

Ms Katharine Bosanquet
ARRC Building Area 4, Dept. of Health Sciences,
University of York, Heslington, York
YO105DD

Dear Ms Bosanquet

Study title: Meeting the physical healthcare needs of people with serious mental illness in primary care
REC reference: 17/IEC08/0025
IRAS project ID: 225235

Thank you for your letter responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require

further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at <http://www.rdforum.nhs.uk>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

Non-NHS sites

The Committee decided that the research did not require Site-Specific Assessment at non-NHS sites as it involves no clinical interventions and the Committee was satisfied that the risk to participants is likely to be negligible, and the study procedures will not significantly interfere with participant's freedom of action or privacy or be unduly invasive or restrictive.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		18 July 2016
GP/consultant information sheets or letters	2.2	18 May 2017
GP/consultant information sheets or letters	2.2	18 May 2017
Letter from funder		25 August 2016
Letters of invitation to participant	2.1	17 February 2017
Letters of invitation to participant	2.1	23 February 2017
Letters of invitation to participant	2.1	23 February 2017
Other [CRN engagement]		10 April 2017
Other [CV of Supervisor]		
Other [Background information]	2.1	23 February 2017
Other [Safeguarding policy]	2.2	19 June 2017
Participant consent form	2.2	22 May 2017
Participant consent form		17 February 2017
Participant information sheet (PIS)	2.2	18 May 2017

Research protocol or project proposal	2.3	19 June 2017
Summary CV for Chief Investigator (CI)		01 February 2017

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document “*After ethical review – guidance for researchers*” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

17/IEC08/0025	Please quote this number on all correspondence
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With the Committee’s best wishes for the success of this project.

Yours sincerely



PP Dr Martin Stevens Chair

Email: nrescommittee.social-care@nhs.net

Enclosures: "After ethical review – guidance for researchers" [\[SL-AR2\]](#)

Copy to: *Ms Katharine Bosanquet*
Sarah Daniel, Tees Esk & Wear Valleys NHS Foundation Trust

Appendix 4. 2a Participant Information sheet



Participant Information Sheet – Interviews

Research study: A face-to-face interview to talk about the physical health of people who have experienced mental ill-health

Invitation to take part in research

- I would like to invite you to take part in a research study.
- Before you decide, it is important for you to understand what it will involve. Please take time to read this information sheet carefully.
- If you have any questions or would like more information, my contact details are overleaf.

What type of study is this?

This is known as a 'qualitative study' which uses the method of interviews to explore people's views and experiences. This approach will be used to understand your experiences and views of the healthcare you receive at your GP practice.

What is the purpose of this study?

The purpose of this study is to find out from you how you look after your physical health. We would like to hear your views about what could be done to make it easier to manage your physical health. The study aims to improve our understanding of the difficulties faced by people who have experienced mental ill-health, to enable you to live longer, healthier lives.

Why have I been invited to take part?

We would like to speak to you to talk about your views of receiving care from your GP practice. We would welcome your suggestions for any changes that could be made to improve how things are done.

What do I need to do if I want to take part?

If you would like to take part you need to contact the study researcher, Kate Bosanquet. Her contact details are listed at the end of this information sheet. You can contact her either by email or text or telephone call (please leave a message if there is no reply) or you can fill in your

details on the expression of interest slip and post it back using the prepaid envelope provided.

What will the interview involve?

The interview will take place face-to-face at a time and place convenient for you. Any out of pocket and travel expenses will be reimbursed upon your arrival. Before the interview begins you will be able to ask Kate further questions. The interview will then begin and Kate will talk to you about your views and personal experiences of looking after your physical health.

What about my medical records?

The research team will **not** have access to your medical records. The only information they will have about you is what you tell the researcher.

What questions will be asked?

There will not be a fixed set of questions but, instead, a discussion guide will be used to explore various issues. The interview will last approximately 40 to 60 minutes and will, with your permission, be recorded using a digital voice recorder. If you do not wish to have the interview recorded, you can indicate this on the consent form. Instead the researcher will take some handwritten notes during the interview.

Do I have to take part?

No, you do not have to take part. Your participation is entirely voluntary. Even if you initially decide to take part, you can still change your mind at a later point and choose to withdraw from the study at any time, without giving a reason.

What are the possible benefits of taking part?

If you take part, you will contribute to our understanding about how healthcare is provided at GP practices to people who have mental ill-health. This will help inform any improvements that can be made. You may also find the experience of talking to the researcher

interesting. It will give you a chance to tell us what you think about these issues. Many people find this a satisfying experience. You will also be given a £10 voucher as a thank you for taking part.

What are the possible disadvantages and risks of taking part?

There is a risk you may become distressed answering questions about your medical care. If you do, the researcher will stop the interview and let you calm down. It will be your decision whether or not you want to continue.

Will everything I say be kept confidential?

Everything you say/report is confidential unless you tell us something that indicates you or someone else is at risk of harm. We would discuss this with you before telling anyone else such as your GP. With your agreement, we may quote some of the things you have said when we write up the research but your name will not appear in any of the reports.

What are the security and storage arrangements of audio recordings and what will happen to them after transcription has been completed?

The audio recordings will be deleted from the voice recorder once the transcription is completed. The recordings and the transcriptions will be stored on a secure computer at the University of York for 10 years after the study has completed, when they will be deleted.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This research has been reviewed and approved by: The Social Care Research Ethics Committee on 19/06/2017; and the University of York, Department of Health Sciences Research Governance Committee on 17/03/2017.

Who is organising and funding the research?

This study is being organised by Kate Bosanquet, a researcher at the University of York who is conducting these interviews as part of her PhD. The research has been funded by the National Institute for Health Research (NIHR).

Taking part in a second interview?

There will be an opportunity to take part in a second interview, some months after the first one. If you would like to be considered, you can indicate this on the consent form.

What will happen when the interviews are finished?

When all the interviews are finished a report will be prepared for the funder and the results will be published in relevant journals. We may also present the findings at conferences. Everyone who has been interviewed as part of the research study will be sent a summary of the results. If you wish to be sent a summary you can indicate this on the consent form and provide a contact email or postal address.

What do I need to do now?

If you would like to be considered for interview, please let the researcher, Kate, know by contacting her via telephone or email (see below).

Researcher contact details

Name: Kate Bosanquet
Tel: 01904 321112 / 07768 021970
Email: kate.bosanquet@york.ac.uk

Alternatively, you can fill in your details on the expression of interest slip and post it to Kate using the prepaid envelope provided.

Where can I get more information about this study?

If you do not understand anything on this information sheet or would like more details please contact Kate Bosanquet (see above for contact details).

What if I need to make a complaint about this study?

If you wish to make a complaint about the study, please contact Professor Simon Gilbody (clinical lead and study supervisor) at the University of York 01904 321370 or simon.gilbody@york.ac.uk

Appendix 4.2b Practitioner Information



Research Study Information Sheet: Health Professionals

'Meeting the physical healthcare needs of people with serious mental illness in primary care'

An invitation to support research

- As part of my NIHR Doctoral Research Fellowship, I would like to invite you to take part in a research study.
- Please read this information sheet. If you have any questions or would like more information, contact me on: 01904 321112/ 07768 021970/kate.bosanquet@york.ac.uk
- Taking part will involve a 20-30 minute interview either over the telephone or face-to-face, whichever you prefer.

Study background

People who have a serious mental illness die 15-20 years earlier than the rest of us, largely from the same preventable physical diseases. This is known as the mortality gap, and, it represents one of the biggest health inequalities in England.

What is the purpose of this study?

The purpose of the study is to better understand the healthcare needs of people with serious mental illness. It aims not just to explore the challenges associated with providing care to this patient group, but also to find examples of good practice – to learn what enables the physical health needs of this group to be managed more effectively.

What do I need to do if I want to take part?

The study researcher, Kate Bosanquet, will contact you in the next week or so to discuss your potential participation, and if you wish to take part, to schedule an interview.

What will happen to my data?

The interview will be digitally recorded and the transcript will be anonymised. The audio recordings will be deleted from the voice recorder once the transcription is completed. Your name will not appear in any written reports or

dissemination of the research. Findings of the research may be presented at conferences but, if they are, only anonymised excerpts from the interview would be used. All your data will be stored securely at the University of York for a period of 10 years after the study is finished, before being destroyed.

Possible benefits of taking part?

Taking part will contribute to the evidence base about how care at general practice is provided to people with serious mental illness. It will give you the opportunity to provide intelligence from the front-line about what is happening in practice. Your views and experiences will give us valuable insight and may act as pointers for quality improvement, so that people with serious mental illness can live longer, healthier lives.

Possible disadvantages of taking part?

The interview will take up to around 20-30 minutes of your time.

Who has reviewed the study?

This research has been reviewed and approved by: The Social Care Research Ethics Committee on 19/06/2017; and the University of York, Department of Health Sciences Research Governance Committee on 17/03/2017.

Who is organising and funding this research?

This study is being organised by Kate Bosanquet at the University of York. It is funded by the National Institute of Health Research as part of her Doctoral Research Fellowship Award.

What if I need to make a complaint about this study?

If you wish to make a complaint about the study please contact Professor Simon Gilbody (study supervisor) at the University of York on 01904 321370 or simon.gilbody@york.ac.uk.



Appendix 4.3 Safeguarding Vulnerable Research Participants

The following principles and procedures will govern the safeguarding of research participants during the interview study.

People with serious mental illness are vulnerable research participants and require safeguarding. Although participants will not be asked any questions on suicide ideation, they may become distressed when talking about their physical health or the challenges they face navigating the health system. The researcher (chief investigator) will follow a humanist approach to this protocol when conducting participant interviews and will be alert to any potential vulnerability.

Three main types of concern:

- A) Participant distress (quite likely)
- B) Non-suicide risk (less likely)
- C) Suicide risk (unlikely – exceptional circumstances)

A) Participant distress and discomfort

- If a participant becomes distressed while answering questions about their medical care, the researcher will stop the interview, listen carefully to their concerns and give them time and space to calm down and decide whether or not they want to continue with the interview.
- Before recommencing the interview (if desired), the researcher would ask the participant about what other means of support they have from family and friends.
- The researcher would also advise the participant to contact their GP or mental health team for support and signposting.
- The researcher could suggest other sources for support, such as social services or Third Sector organisations, but as not qualified to offer professional advice, the participant's GP or mental health team is the preferred option.

If a participant discloses risk, either to themselves or someone else, the researcher will stop the interview and listen calmly to what they say. The risk may be non-suicidal or suicidal.

B) Non-suicide risk

Instances of non-suicide risk may include, but are not restricted to:

- Risk to others
- Self-neglect
- Risk from others (this includes events such as domestic violence)
- Alcohol or substance abuse

- If a participant discloses any information which raises concern, the researcher will stop the interview and discuss the concern with the participant and ask them what they would like the researcher to do. However, the researcher will also acknowledge that in some circumstances, he or she will have to break confidentiality without the consent of the participant.
- If the participant would like the researcher to call the supervisor for advice, but the supervisor is unavailable to speak on the phone, the researcher will arrange to get back to the participant, once they have sought guidance from their supervisor.
- The researcher would also advise the participant to contact their GP or mental health team for support and signposting.
- To document the course of action, the researcher will complete the Non-Suicide Risk Form (Appendix 1) which, once countersigned and dated by the clinical lead, will be filed in the participant's personal (non-data) file.

C) Suicide risk

- If a participant indicates that they are at risk of self-harm or have suicidal thoughts, the researcher will contact the clinical lead (supervisor) immediately by telephone in order to involve a supervisory clinician to discuss the level of risk and the necessary actions to take.
- If the researcher is unable to contact the clinical lead they will contact the participant's GP or mental health team. Even if a participant objects to this, the researcher will override their wishes and enact the breaching confidentiality statement from the patient information sheet and consent form: *'Everything you say/report is confidential unless you tell us something that indicates you or someone else is at risk of harm'*, and contact the GP/mental health team directly.
- If necessary, if the participant displays active suicide ideation, the researcher will call a taxi to take the participant to A&E. The researcher would accompany the participant to A&E and not leave the participant until a clinician has taken responsibility for their care.
- To document the course of action, the researcher will complete the Suicide Risk Form (Appendix 2) which, once countersigned and dated by the clinical lead, will be filed in the participant's personal (non-data) file.

Appendix 1: Non-Suicide Risk Form

The participant below has been identified as being a risk (other than self- harm/ suicide) during a qualitative interview.

Participant ID Code:

P	T		
---	---	--	--

Date of interview:

	/		/	
--	---	--	---	--

Has the participant been advised to contact their GP/MHT? Yes No

Has the GP/MHT been contacted by the researcher? Yes No

Have any other services been contacted? If yes, who? Yes No

Summary of actions taken:

(What advice was given by clinical lead, if spoken to? Was risk judged as passive or active? If GP contacted – name of practice, name of GP spoken to, date of contact)

Researcher Name:

Research Signature: **Date:**

Name of Clinical Contact:

Clinical Contact Signature: **Date:**

Appendix 2: Self- Harm / Suicide Risk Form

The patient below has expressed thoughts of suicidal intent / self-harm during a qualitative interview.

Participant ID Code:

P	T		
---	---	--	--

Date of interview:

/	/
---	---

Has the participant been advised to contact their GP/MHT? Yes No

Has the GP/MHT been contacted by the researcher? Yes No

Have any other services been contacted? If yes, who? Yes No

Summary of actions taken:

(What advice was given by clinical lead, if spoken to? Was risk judged as passive or active? If GP contacted – name of practice, name of GP spoken to, date of contact)

Researcher Name:

Research Signature: **Date:**

Name of Clinical Contact:

Clinical Contact Signature: **Date:**

Appendix 4.4 Lone Worker Policy



The Department of Health Sciences

Guidelines for students and staff undertaking interviews or other research in participant's homes.

1. INTRODUCTION

This is a summary of the Departmental policy on lone working when undertaking research. This is primarily aimed at the early career researchers however even experienced researcher should be familiar with the policy of what to do if a problem does occur. Beyond this guide additional information is available from the staff intranet (see link below) and from your research group lead, research project lead or the group research administrator.

<https://hswebstaff.york.ac.uk/docs/committee/staff-meetings/#tab-4>

2. UNDERTAKING LONE WORKING: ESSENTIAL SUMMARY

- Research groups with lone workers will set up a formal contact arrangement ('buddy' system) where a friend, colleague or line manager is informed about the fieldwork timetable, including who the researcher meets, where the meeting takes place and for how long (detailed in the next bullet point). An updated itinerary will be communicated before each interview/fieldwork trip so that the buddy is aware of any changes in plans.
- Information about each interview will be recorded in advance on a Lone Working Contact Sheet (see Appendix A). The day before the interview this will be forwarded to the contact person and the supervisor; a copy will also be left in the researcher's home. The Lone Working Contact Sheet will include the mobile number of the researcher for use in case of emergency.
- The researcher will carry a personal alarm (see section 8) throughout the fieldwork trip and interview situations in case of emergency.
- On arrival to the interview location, the researcher will text or call the contact person. When the interview is finished, the researcher will again call them to confirm safety. If more than two hours have passed after the first call and the interview is still ongoing, the contact person will call the researcher to confirm that the researcher is safe. When the interview is finished, the researcher text/calls the contact person to confirm the completion of the interview and her/his exit from the home. A further text will be sent when the researcher returns home.
- If no interview completion (or home arrival) text is received within the expected timeframe for the interview (journey home), then the contact person must immediately contact the supervisor / line manager. At the same time, they must make every attempt to locate and contact the researcher, including alerting the police.
- All Lone Workers Contact Sheets will be destroyed after each fieldwork trip is concluded to safeguard the anonymity of the participants.



3. PREPARATION FOR THE VISIT

- Gather all available information about the participant/family.
- If colleagues have met with the participant, check with them about the safety of a home visit.
- Make an appointment with the participant, and inform them of the visit
- Where possible have a mobile phone that is used solely for the research project, and only give participants this number or a University number. Never give your personal phone number.

4. VENUE

- Check the address.
- Consider the geographic area and know as much about it as you can. If the location is considered high-risk for violence or substance abuse, consider taking a colleague with you, or have a driver (colleague / taxi) wait outside during the visit.
- Check ahead whether there are any dogs in the house and whether these will be tethered or not during the visit; if concerned about an animal you should not enter/withdraw.
- Know exactly where you're going. Check weather conditions and be prepared appropriately.
- If driving be familiar with route (see below).
- Look as confident as you can and try to blend in as much as you can. Try not to look as if you are not sure of where you are going.
- Remember localities can be very different places at night than they are during the day.

5. BEFORE SETTING OFF

- Check equipment.
- Dress appropriately in a way that does not make you stand out. Try avoiding being too obvious about carrying equipment, such as lap top computers.
- Remember to leave your itinerary and notify colleagues of any changes. Set up a Buddy system to ensure that someone (line manager, co-worker, group secretary) has responsibility for ensuring that you have completed the home visit safely. For students, the supervisor must monitor the visits. The Buddy or supervisor should know where you are going, the time your visit starts and the expected time that it will finish.
- They should have your contact details (including next of kin) and always know where you are. Arrange to let them know when the interview has finished and that you are safe.
- The Buddy must know and agree to take on this role, and contingency plans must be in place to cover absence of the Buddy (see above)
- Agree action with the Buddy to be taken if you have not phoned in by an agreed time and do not answer a call to your mobile phone. This will include a set of escalation procedures to alert more senior management (if applicable) and the police. This is essential and must be done.
- Consider whether a code word system would be useful. This means that you can alert your Buddy / colleagues via a text or brief call that you need to be phoned so that you have an excuse to leave, or that you are in an emergency situation.
- Have some change and/or a phone card available in case you need to use a public phone. It is not always possible to get a mobile telephone signal.
- If possible, access training in recognising aggression and using de-escalation techniques.

6. THE VISIT

- When on public transport or walking from your car, carry your keys and mobile phone in your pocket, so that if your bag is snatched you can still drive home / get into your house. (Keys can also be used in defence if necessary).
- Remember you have a choice. If in doubt don't go in. Exercise extreme caution if you think that substance misuse may be occurring at the time of the visit, or if anyone in the household is obviously under the influence of alcohol/drugs.
- Do not show interest in people's property or whatever else is inside the house / surrounding area.
- Be aware of any delicate issues involved with discussions or interviews.
- Follow the participant in, noting locks and access and try to dissuade participants from locking you in.
- Note the layout of the house, in particular the way out and always try to sit between the participant and the exit. When offered a seat try to sit in a position that gives you access to the door.
- Before asking questions, explain why you need to know certain things and ensure people know who you are and what you are doing.
- Remember your own behaviour can trigger or prevent aggression, treat participants courteously and allow them to retain optimum control and dignity; you are a guest in their home.
- Be prepared to show some form of identity if asked.
- Consider issues of Child Protection and vulnerable adults.
- Do not underestimate the importance of body language. Avoid an aggressive stance. Crossed arms, hands on hips or raised hands will challenge and confront. Keep your distance.
- Bring the interview to a halt if the situation changes at anytime. Do any of the family members give cause for concern?
- Remember the dynamics of the visit can change; such as if someone else comes into the house or room.
- If violence is threatened, leave immediately.

7. TRAVELING BY CAR

- Make sure the vehicle is in good working order before setting off (and that it is insured for business use).
- Plan your journey in advance and tell someone which route you mean to take.
- If possible, and if travelling to areas that you do not know, consider using a satellite navigation aid (although this must be packed out of sight when parking).
- Do not leave valuables visible in the car, even when you are in it, and keep bags out of reach of open windows.
- When parking in daylight, consider what the area will be like after dark. If there is a chance that it will be dark when you return to your car, park near a street light if possible.
- When returning to the vehicle, quickly look around it to make sure there is no-one waiting for you.

- If you are forced to stop by another car, stay in the car, lock the doors and speak through a slightly open window.
 - Make sure you know what to do if the car breaks down (i.e. who to phone, where to phone and so on).
8. **TRAVELLING BY PUBLIC TRANSPORT**
- Before setting off, have a timetable of the route using online resources such as the <https://www.gov.uk/search?q=planning+your+route> which allows you to plan routes using public transport. A copy of this should be given to your Buddy and if you need to vary your route, inform them.
 - If possible, wait for your transport at a busy, well-lit stop or station. If this isn't possible, be vigilant at all times.
 - On buses, sit downstairs near the bus driver, in an aisle seat if possible. On trains sit near the emergency alarm and familiarise yourself with the emergency procedures.
 - Avoid upper decks on buses, or empty compartments on trains and also avoid these if there is only one other passenger.
 - If threatened by another passenger, alert the guard/driver as soon as possible.
 - Always carry the numbers of local taxi companies, as a backup.
9. **HIGH RISE FLATS**
- Always use the door entry system so that the participant knows you are on your way up.
 - Be confident and know what floor you want before you get in the lift.
 - Do not get into a lift if you feel unsure about its condition, e.g. doors not closing properly or the lift or lights aren't working correctly.
 - Trust your instincts; do not get into a lift with a person you feel unsure about.
 - If someone gets into a lift and you do not feel safe get out even if it's the wrong floor.
10. **EQUIPMENT**
- Be prepared to give up equipment/bags without a fight, things can be replaced, you can't.
 - Keep a list of emergency contact numbers, including those for out of hours.
 - Make sure your mobile phone is charged and that you know how to use it. Mobile phones should also be programmed for the local police number and your base number.
 - Remember the limitations of mobile phones; they are unlikely to work properly in basements, lifts and high rise buildings.
 - Always carry a personal alarm (available for the Department, free of charge.), check the battery and remember it is useless in the bottom of your bag.

11. MANAGING AGGRESSION

- Talk yourself out of problems; placate rather than provoke. Do not turn your back on someone who is behaving aggressively. Stay calm, speak gently and slowly. Do not be enticed into an argument. Never try to touch someone who is angry – this will not calm the situation.
- Recognise the limits of your own ability to deal with a situation and the time when it becomes prudent to leave; trust your instincts.
- Keep your eye on potential escape routes.
- Try to get away as quickly as possible. Move towards a place where there will be other people. Be prepared to use your personal alarm. Set it off as close to the aggressor's ear as possible and then throw it out of reach. Shout and scream – shout something practical like 'call the Police!' or 'Fire!'

12. ACTION FOLLOWING AN INCIDENT

- Allow yourself time to recover; seek practical support from your colleagues and manager.
- Contact the police, if appropriate.
- Seek proper medical attention for any physical injuries.
- Contact your manager.
- Report all incidents through the formal reporting procedures, including informing the Head of Department and Director of Research. This must be done.
- Share information with others who work in the area or who are likely to visit that particular address.
- Even after very minor incidents, feelings may be difficult to control and may affect your ability to deal with any further problems that arise. This is a perfectly natural reaction; if in doubt, take time out.
- Ask for a de-briefing and further counselling if necessary.
- Try to identify where control was lost and how, so that practice and training can be improved accordingly.

For more comprehensive guidance on these points see the HSE <http://www.hse.gov.uk/pubns/indg73.pdf> and the NHS Lone Working Guide which is available from <http://www.nhsbsa.nhs.uk/4248.aspx>

Updated March 2016

**Appendix A. Lone Working Contact Sheet
(Use a separate sheet for each interview)**

<p>Researcher's details</p> <p>Researcher's name:</p> <p>Researcher's mobile numbers:</p> <p>Researcher's home number and address:</p> <p>Personal/home details of contact person</p> <p>Name:</p> <p>Mobile number: Home number:</p> <p>Academic supervisor contact</p> <p>Name:</p> <p>Mobile number:</p> <p>Interview details</p> <p>Date of lone working:</p> <p>Names of research participants (interviewees):</p> <p>Full address of participant (or interview location if not interviewee's home):</p>
--

Travel plans and transport arrangements:

Mobile contact number during interview:

Estimated time of departure from home:

Estimated time of arrival (at interview location):

Estimated time of departure (from interview location):

Estimated time of arrival at home (from interview location):

Appendix 4. 5a Patient Consent Form



Patient ID	P	T			For office use only
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PATIENT CONSENT FORM

Research study: A face-to-face interview to talk about the physical health of people who have experienced mental ill-health

If you wish to take part in this study, please initial each box below, and sign/date this form.

<u>All information on this form will be kept confidential and will not be released to anyone outside the research team.</u>		<i>Please initial each box</i>	
1.	I confirm that I have read the information sheet version 2.2 dated 18/05/2017 for the above study and have had the opportunity to ask questions.	<input type="checkbox"/>	
2.	I understand that my participation is entirely voluntary, that I am free to withdraw at any time without giving a reason, and that my healthcare will not be affected.	<input type="checkbox"/>	
3.	I understand that everything I say/report is confidential unless I tell the researcher something that indicates I am, or someone else is, at risk of harm, in which case I give permission for my GP to be contacted.	<input type="checkbox"/>	
4.	I understand that the interview will be recorded on a digital voice recorder and the sound file will be stored on a secure computer at the University of York.	<input type="checkbox"/>	
5.	I understand that written quotations from the interview(s) may be used in presentations and publications, but they will be anonymised so my name will not be included in the text.	<input type="checkbox"/>	
6.	I understand that the information collected about me may be used to support other research in the future, and may be shared anonymously with other researchers.	<input type="checkbox"/>	
7.	I agree to complete the short questionnaire attached to this document.	<input type="checkbox"/>	
8.	I agree to take part in this study by taking part in the interview.	<input type="checkbox"/>	
9.	I agree to write either my email or postal address (overleaf) so I can be sent a summary of the study findings	<input type="checkbox"/> Y	<input type="checkbox"/> N
10.	I agree that the interview can be recorded	<input type="checkbox"/> Y	<input type="checkbox"/> N
11.	I give permission for the researcher to contact me during the course of the study to discuss taking part in a second interview	<input type="checkbox"/> Y	<input type="checkbox"/> N

..... /.....
 Name of participant (BLOCK CAPITALS) Date Signature of participant

..... /.....
 Name of researcher (BLOCK CAPITALS) Date Signature of researcher



Two signed forms: one for researcher; one to be kept by patient – REC Reference: 17/1/EC08/0025, IRAS Project ID: 225235
 Bozanquet K, NIHR DRF Qualitative Research Study - patient consent form v2.2 (22May2017)

Appendix 4.5b Health professional consent form



ID code

H	P		
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For office use only

HEALTH PROFESSIONAL CONSENT FORM

Research study: Interview to talk about the physical health of people who have experienced mental ill-health

If you wish to take part in this study, please place your initials in each of the boxes below, sign and date this form.

<u>All the information on this form will be kept confidential and will not be released to anyone outside the research team.</u>		<i>Please initial each box</i>	
1.	I confirm that I have read the information sheet version 2.2 dated 18/05/17 for the above study and have had the opportunity to ask questions.	<input type="checkbox"/>	
2.	I understand that my participation is entirely voluntary and that I am free to withdraw at any time without giving a reason.	<input type="checkbox"/>	
3.	I understand that my participation in this study is confidential and that no materials which could identify me will be used in any reports of this study.	<input type="checkbox"/>	
4.	I understand that the interview will be recorded on a digital voice recorder and the sound file will be stored on a secure computer at the University of York.	<input type="checkbox"/>	
5.	I understand that anonymous written quotations from the interview(s) and observations may be used in presentations and in publications.	<input type="checkbox"/>	
6.	I understand that the information collected about me may be used to support other research in the future, and may be shared anonymously with other researchers.	<input type="checkbox"/>	
7.	I agree to take part in this study by taking part in the interview.	<input type="checkbox"/>	
8.	I agree to write either my email or postal address (overleaf) so I can be sent a summary of the study findings.	<input type="checkbox"/> Y	<input type="checkbox"/> N
9.	I agree that the interview can be recorded.	<input type="checkbox"/> Y	<input type="checkbox"/> N
10.	I give permission for Kate Bosanquet to contact me during the course of the study to discuss taking part in a second interview.	<input type="checkbox"/> Y	<input type="checkbox"/> N

.....
Name of participant (BLOCK CAPITALS)

.../.../.....
Date

.....
Signature of participant

.....
Name of researcher (BLOCK CAPITALS)

.../.../.....
Date

.....
Signature of researcher

Doctoral Research Fellowship funded by



Original for researcher; one copy to health professional – REC Reference: 17/IEC08/0023, IRAS Project ID: 225233
Bosanquet K, NIHR DRF Qualitative Research Study health professional consent form v2.2 (18May2017)

Appendix 4. 6a Patient letter of invitation

<GP PRACTICE HEADED PAPER>

<Date>

Dear Patient,

We would like to invite you to take part in a study to explore how people with mental ill-health look after their physical health. The aim of the study is to better understand the physical health needs of this group of people. You have been invited because we understand you have received care for mental ill-health. An information sheet is enclosed in this pack which describes the research study and what to expect if you decide to take part. Please read it carefully and discuss it with others if you wish.

To arrange to take part you need to contact the study researcher, Kate Bosanquet, at the University of York on 01904 321112 / 07768 021970/ kate.bosanquet@york.ac.uk, alternatively you can fill in your details on the expression of interest slip (enclosed with a prepaid envelope) and post it to the study team. Kate will then contact you to discuss the study in more detail and answer any questions you may have. Providing that you still want to take part, you can arrange a convenient time and place to do the interview.

If you do not wish to take part, you do not need to do anything. Please remember that your participation in this study is entirely voluntary and we have not given your name or any of your personal details to the research team. If you decide not to take part the standard of care you receive from the NHS will not be affected in any way.

Yours sincerely

<GP e-signature>

<GP name>

<Practice team>

Funded by:


National Institute for
Health Research

Bosanquet K, NIHR DRF Qualitative Research Study - GP practice patient invitation v2.1 (17/02/2017)
REC Reference: 17/IECOS/0025, IRAS Project ID: 225235

Appendix 4.6b Patient invitation (generic)



Would you like to take part in a research study?

I am looking for volunteers to take part in a study to explore how people with mental ill-health look after their physical health.

- As a participant in the study you would take part in a face-to-face interview with me, Kate Bosanquet (the study researcher). It will last between 40-60 minutes.
- An information sheet is enclosed which describes the research study and what to expect if you decide to take part. Please read it carefully and discuss it with others if you wish.
- To arrange to take part you need to contact me at the University of York on 01904 321112 / 07768 021970/ kate.bosanquet@york.ac.uk, or you can fill in your details on the expression of interest slip, which is enclosed with a prepaid envelope.
- I will then contact you to discuss the study in more detail and answer any questions you may have. Providing that you still want to take part, we can arrange a convenient time and place to do the interview.

If you do not wish to take part, you do not need to do anything. Please remember that your participation in this study is entirely voluntary. If you decide not to take part the standard of care you receive from the NHS will not be affected in any way.

Thank you for reading this.

<KB signature>

Kate Bosanquet

Funded by:

National Institute for
Health Research

Bosanquet K, NIHR DRF Qualitative Research Study – generic patient invitation v2.1 (23/02/2017)
REC Reference: 17/IEC08/0023, IRAS Project ID: 225235

Appendix 4.6c Health professional invitation



The Department of Health Sciences

Mental Health & Addictions Research Group
Department of Health Sciences
ARRC Area 4
University of York
Heslington
York
YO10 5DD

<Title> <Initial> <Health professional surname>
<GP practice name>
<Address>
<Address>
<Postcode>

<Date>

Dear <Title> < Health professional surname>,

I would like to invite you to take part in research I am undertaking as part of my PhD which is exploring how we look after the physical health of people with serious mental illness in primary care. The aim of the study is to better understand the health needs of this group of people.

If you agree to help I would like to carry out an interview with you. I estimate this will take around 20-30 minutes. It can be conducted either over the telephone or face-to-face at your premises, whichever you prefer. The interview will be recorded but it will be anonymised and all information will remain confidential. Your name will not appear in any written reports or dissemination of the research.

Please read the enclosed information sheet. I will then contact you within the next week or so to discuss any questions you may have. If you are willing to take part, we can arrange a convenient time to conduct the interview.

Of course, your participation is entirely voluntary and if you do not wish to take part you can email me, text or leave a voicemail (kate.bosanquet@york.ac.uk /07768 021970/01904 321112) to let me know that you do not wish to be contacted about participation in this study.

Yours sincerely

<KB signature>

Kate Bosanquet

Funded by:



Bosanquet K, NIHR DRF Invitation letter to health professional v2.1 (19/02/2017)
REC Reference: 17/IEC08/0025, IRAS Project ID: 225235

Appendix 4.7 Patient background information sheet

Patient ID	P	T			For office use only
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Participant background information

What is your date of birth? <i>(Month/year only)</i>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	What is your postcode district? <i>(first 4 digits only)</i>	
	M	M	Y	Y	Y	Y		
What is your sex?	Male	<input type="checkbox"/>	Transgender	<input type="checkbox"/>	Female	<input type="checkbox"/>	Prefer not to say	<input type="checkbox"/>
What is your GP practice called? <i>(And GP if there is one you usually see)</i>	<input type="text"/>							
Have you been told you have one of these conditions – if yes, which one?	Schizophrenia	<input type="checkbox"/>	Schizoaffective Disorder	<input type="checkbox"/>	Bipolar Disorder	<input type="checkbox"/>	Other	<input type="checkbox"/>
<i>(if other, please write in)</i>	<input type="text"/>							
What is your ethnic group?	White	<input type="checkbox"/>	Mixed/multiple ethnic groups	<input type="checkbox"/>	Asian/Asian British	<input type="checkbox"/>	Black/African/Caribbean/Black British	<input type="checkbox"/>
<i>(if other, please write in)</i>	Other	<input type="checkbox"/>	<input type="text"/>					

Appendix 4. 8a Practitioner and practice sample demographics

Sample characteristics of practitioners and GP practices (Participants in individual interviews (n = 11))							
No.	CCG	Clinical role	Gender	Practice size*	Rural urban classification**	IMD*** (decile)	QOF achievement**** (%)
1	Harrogate and Rural District	GP	Male	20,000	Urban	4	95.8 3.2 percentage points below CCG Average, 2.2 above England Average
2	Vale of York	GP	Female	17,000	Rural	2	98.7 9.3 percentage points above CCG Average, 5.1 above England Average
3	Vale of York	PN	Female	17,000	Rural	2	98.7 9.3 percentage points above CCG Average, 5.1 above England Average
4	Leeds West	GP	Male	25,400	Urban	6	97.3 3.9 percentage points above CCG Average, 3.7 above England Average
5	Vale of York	GP	Male	19,900	Urban	2	93.0 3.7 percentage points above CCG Average, 0.6 below England Average
6	Vale of York	GP	Male	10,500	Rural	5	100 10.6 percentage points above CCG Average, 6.4 above England Average
7	Vale of York	PN	Female	10,500	Rural	5	100 10.6 percentage points above CCG Average, 6.4 above England Average
8	Vale of York	PN	Female	10,500	Rural	5	100 10.6 percentage points above CCG Average, 6.4 above England Average
9	Vale of York	GP	Female	32,700	Urban	3	100 10.6 percentage points above CCG Average, 6.4 above England Average
10	Hull	PN	Female	7,200	Urban	1	95.0 15.2 percentage points above CCG Average, 1.3 above England Average
11	Vale of York	GP	Male	19,900	Urban	2	93.0 3.7 percentage points above CCG Average, 0.6 below England Average

* Rounded up to the nearest 100 patients (data accessed on 03/08/18 <https://www.nhs.uk/Service-Search/GP/LocationSearch/4>)

** Rural urban classification 2011 <https://www.gov.uk/government/statistics/2011-rural-urban-classification-of-local-authority-and-other-higher-level-geographies-for-statistical-purposes>

*** English indices of deprivation 2015 (LSOA) <http://imd-by-postcode.opendatacommunities.org/>

**** QOF achievement clinical mental health 2016/17 <https://qof.digital.nhs.uk/>

* English indices of deprivation 2015 (LSOA) <http://imd-by-postcode.opendatacommunities.org/>

Appendix 4.8b Patient sample demographics

Sample characteristics patients with SMI							
Participants in individual interviews (n=19)							
ID code	Diagnosis	Sex	Age	IMD* (patient level)	IMD* (practice level)	Method of recruitment	Method of response to invitation
PT01	Bipolar disorder	Female	62	9	4	Invitation posted via GP practice	Telephone call to landline
PT02	Schizophrenia	Male	67	9	4	Invitation posted via GP practice	Telephone call to landline
PT03	Bipolar disorder	Male	63	10	4	Invitation posted via GP practice	Email
PT04	Bipolar disorder	Male	71	5	6	Invitation posted via GP practice	Email
PT05	Bipolar disorder	Female	50	3	6	Invitation posted via GP practice	Email
PT06	Schizophrenia	Male	69	9	5	Invitation posted via GP practice	Telephone call to landline
PT07	Bipolar disorder	Female	48	9	5	Invitation posted via GP practice	Telephone call to landline
PT08	Bipolar disorder	Female	49	5	5	Invitation posted via GP practice	Post of EOI reply slip
PT09	Bipolar disorder	Male	59	9	5	Invitation posted via GP practice	Post of EOI reply slip
PT10	Schizophrenia	Female	62	5	6	Invitation posted via GP practice	Post of EOI reply slip
PT11	Bipolar disorder	Male	58	6	2	Invitation posted via GP practice	Post of EOI reply slip
PT12	Bipolar disorder	Male	50	10	3	Invitation posted via GP practice	Email
PT13	Bipolar disorder	Female	21	**unmatched**	2	Invitation posted via GP practice	Email
PT14	Bipolar disorder	Female	64	1	1	Invitation posted via GP practice	Post of EOI reply slip
PT15	Schizophrenia	Male	37	5	8	Invitation f-to-f at Clozapine clinic A	Telephone call to landline
PT16	Schizophrenia	Male	50	3	3	Invitation f-to-f at Clozapine clinic A	Post of EOI reply slip
PT17	Schizophrenia	Female	57	3	7	Invitation f-to-f at Clozapine clinic B	Post of EOI reply slip
PT18	Schizophrenia	Male	49	7	2	Invitation f-to-f at Clozapine clinic B	Post of EOI reply slip
PT19	Schizophrenia	Male	49	8	6	Invitation f-to-f at Clozapine clinic A	Post of EOI reply slip

* English indices of deprivation 2015 (LSOA) <http://imd-by-postcode.opendatacommunities.org/>

unmatched new postcode created post 2015

Most patients had an IMD (decile) score for their personal postcode lower than their practice which suggests a health volunteer effect.

Appendix 4. 9a Topic guide practitioners

Interview topic guide – health professionals

1. To start

Thanks again for agreeing to speak to me today. As you'll have seen from the information sheet, I'd like to ask you some questions about your experience of providing care to people with serious mental illness, commonly known as SMI, and which refers predominantly to people with schizophrenia and bipolar disorder.

I'm keen to explore your views and experiences about the challenges associated with meeting the physical health needs of this group but also to identify examples where things have worked well. The interview should take about 20 to 30 minutes. Is it still convenient for you to speak to me today? And do you have any questions before we begin?

2. Main

Okay, so could you start off by telling me a bit about your experiences of providing care for people with serious mental illness?

Prompts

Challenges – what hinders

Enablers – what works well, what helps

Relationship with patients

Health promotion activity (e.g. cervical smear tests, smoking cessation, lifestyle changes)

Preventative measures (e.g. information and support)

QOF physical health checks/NICE guidance

Mental health training for GPs and practice nurses

Is SMI a core part of the business

Relationship with secondary care – community mental health teams

Any changes physical health needs of SMI patients in recent years?

3. To finish

One final question, I wondered if you could tell why you decided to take part in the study? Before we finish, do you have any questions or is there anything else you'd like to say?

Thank you...

Appendix 4.9b Topic guide patients

Interview topic guide – SMI patients

1. To start

Thanks again for agreeing to speak to me today. Before we begin, let me remind you that we can stop the interview at any time and if you do not wish to answer a question we can just move onto the next one. As you'll have seen from the information sheet, I'd like to ask you some questions about your experience of looking after your physical health needs and explore your views about the care provided to you.

I'm keen to find out what is challenging and difficult but also to hear about things that have gone well. The interview should take between 40 and 60 minutes. Is it still convenient for you to speak to me today? And do you have any questions?

2. Main

Okay, so I wonder if you could you start off by telling me a bit about your daily routine, typically what do you do on a day to day basis?

And it would be helpful if you could tell me briefly about the history of your mental health condition...okay, so when you think about what's important to you regarding your health, do you have any concerns relating to your physical health?

Prompts

Mind/body dual

GP practice care – what works and what doesn't work so well

Relationship with doctor and/or practice nurse

Information/advice/sources of support

Reviews/health checks/measurements

Experience of contact with secondary care

Future goals/hopes/concerns

What would make it easier to keep well

3. To finish

One final question, I wondered if you could tell why you decided to take part in the study? Okay before we finish, do you have any questions or is there anything else you'd like to add?

Thank you... [give participant £10 Boots voucher]

Appendix 6.1 Original ISAC approval

ISAC EVALUATION OF PROTOCOLS FOR RESEARCH INVOLVING CPRD DATA

FEEDBACK TO APPLICANTS

CONFIDENTIAL				<i>by e-mail</i>			
PROTOCOL NO:		18_054RA					
PROTOCOL TITLE:		Meeting the physical healthcare needs of people with serious mental illness in primary care					
APPLICANT:		Katharine Bosanquet NIHR Doctoral Research Fellow Department of Health Sciences University of York kate.bosanquet@york.ac.uk					
APPROVED <input checked="" type="checkbox"/>		APPROVED WITH COMMENTS (resubmission not required) <input type="checkbox"/>		REVISION/ RESUBMISSION REQUESTED <input type="checkbox"/>		REJECTED <input type="checkbox"/>	
INSTRUCTIONS: <i>Protocols with an outcome of 'Approved' or 'Approved with comments' do not require resubmission to the ISAC.</i>							
REVIEWER COMMENTS:							
APPLICANT FEEDBACK:							

DATE OF ISAC FEEDBACK:	09/07/18
DATE OF APPLICANT FEEDBACK:	

For protocols approved from 01 April 2014 onwards, applicants are required to include the ISAC protocol in their journal submission with a statement in the manuscript indicating that it had been approved by the ISAC (with the reference number) and made available to the journal reviewers. If the protocol was subject to any amendments, the last amended version should be the one submitted.

**** Please refer to the ISAC advice about protocol amendments provided below****

Amendments to protocols approved by ISAC

Version June 2015

During the course of some studies, it may become necessary to deviate from a protocol which has been approved by ISAC. Any deviation to an ISAC approved protocol should be clearly documented by the applicant but not all such amendments need be submitted for ISAC review and approval. The general principles to be applied in regard to the need for submission are as follows:

- Major amendments should be submitted
- Minor amendments need not be submitted (but must still be documented by the applicant and should normally be mentioned at the publication stage)

In cases of uncertainty, the applicant should contact the ISAC secretariat for advice quoting the original reference number and providing a brief explanation of the nature of the amendment(s) and underlying reason(s).

Major Amendments

We consider an amendment as major if it substantially changes the study design or analysis plan of the proposed research. An amendment should be considered major if it involves the following (although this is not necessarily an exhaustive list):

- A change to the primary hypothesis being tested in the research
- A change to the design of the study
- Additional outcomes or exposures unrelated to the main focus of the approved study*
- Non-trivial changes to the analysis strategy
- Not performing a primary outcome analysis
- Omissions from the analysis plan which may impact on important validity issues such as confounding
- Change of Chief Investigator
- Use of additional linkages to other databases

- Any new proposal involving contact with health professionals or patient or change in regard to such matters

* N.B. extensive changes in this respect will require a new protocol rather than an amendment - if in doubt please consult the Secretariat

Minor Amendments

Examples of amendments which can generally be considered minor include the following:

- Change of personnel other than the Chief Investigator (these should be notified to the Secretariat)
- A change to the definition of the study population, providing the change is mentioned and justified in the paper/output [NB previously major]
- Extension of the time period in relation to defining the study population
- Changes to the definitions of outcomes or exposures of interest, providing the change is mentioned and justified in the paper/output [NB previously major]
- Not using linked data which are part of the approved protocol, unless the linked data are considered critical in defining exposures or outcomes (in which case this would be a major amendment)
- Limited additional analysis suggested by unexpected findings, provided these are clearly presented as post-hoc
- Additional methods to further control for confounding or sensitivity analysis provided these are to be reported as secondary to the main findings
- Validation and data quality work provided additional information from GPs is not required

To submit an amendment of protocol to the ISAC, please submit the following documents to the ISAC mailbox (isac@cprd.com)

1. A covering letter providing justification for the request
2. A completed and, if necessary, updated application form with all changes highlighted; if new linkages are required the current version of the ISAC application form must be completed. Otherwise, the original form may be amended as necessary
3. **The updated protocol document containing the heading 'Amendment' at the end of it.** Please include all amendments to the protocol under this heading. No other changes should be made to the already approved document.

Appendix 6. 2a ISAC approval of EMERALD amendment

ISAC EVALUATION OF PROTOCOLS FOR RESEARCH INVOLVING CPRD DATA

FEEDBACK TO APPLICANTS

CONFIDENTIAL		<i>by e-mail</i>	
PROTOCOL NO:	17_161RA2		
PROTOCOL TITLE:	EMERALD: Exploring Mental Illness and Diabetes through a Longitudinal Data study		
APPLICANT:	Najma Siddiqi University of York najma.siddiqi@yok.ac.uk		
APPROVED <input checked="" type="checkbox"/>	APPROVED WITH COMMENTS (resubmission not required) <input type="checkbox"/>	REVISION/ RESUBMISSION REQUESTED <input type="checkbox"/>	REJECTED <input type="checkbox"/>
INSTRUCTIONS: <i>Protocols with an outcome of 'Approved' or 'Approved with comments' do not require resubmission to the ISAC.</i>			
REVIEWER COMMENTS:			
APPLICANT FEEDBACK:			
DATE OF ISAC FEEDBACK:	12/02/19		
DATE OF APPLICANT FEEDBACK:			

For protocols approved from 01 April 2014 onwards, applicants are required to include the ISAC protocol in their journal submission with a statement in the manuscript indicating that it had been approved by the ISAC (with the reference number) and made available to the journal reviewers. If the protocol was subject to any amendments, the last amended version should be the one submitted.

Guidance on resubmitting applications, or making amendments to approved protocols, can be found on the CPRD website at <https://cprd.com/research-applications>.

Appendix 6.2b ISAC approval to EMERALD Chief Investigator

8/29/2020

University of York Mail - Fwd: ISAC Protocol 17_161R Amendment Feedback



Kate Bosanquet <kate.bosanquet@york.ac.uk>

Fwd: ISAC Protocol 17_161R Amendment Feedback

1 message

Najma Siddiqi <najma.siddiqi@york.ac.uk>

12 February 2019 at 17:57

To: Simon Gilbody <Simon.Gilbody@york.ac.uk>, Peter Coventry <peter.coventry@york.ac.uk>

Cc: Kate Bosanquet <kate.bosanquet@york.ac.uk>

Just to let you know that it's a yes from CPRD.

Kate already has access to our Emerald dataset so can crack on whilst waiting for the additional linkages in the amendment to be processed. I've asked her to get the ball rolling by completing the linkage request form.

Bw

Najma

----- Forwarded message -----

From: ISAC Secretariat <isac@mhra.gov.uk>

Date: Tue, 12 Feb 2019 at 11:24

Subject: ISAC Protocol 17_161R Amendment Feedback

To: najma.siddiqi@york.ac.uk <najma.siddiqi@york.ac.uk>

Dear Najma,

Please find attached feedback relating to ISAC protocol "EMERALD: Exploring Mental Illness and Diabetes through a Longitudinal Data study". Thank you for your patience whilst waiting to hear back from us.

If your study has been approved to access new linkage data, please complete the attached Linkage Request Form and return this to the CPRD Enquiries at enquiries@cprd.com. Please also provide us with your patient identifiers (in the form of a tab delimited text file) and/or code lists to facilitate the provision of linked data. Once the data extraction team has reviewed your request, you will receive an acknowledgement email with a 10 working-day turn around for data delivery.

If it has not, please disregard the previous paragraph.

Should you require any advice regarding the implementation of your approved study protocol please don't hesitate to contact CPRD Enquiries (enquiries@cprd.com). Please note the CPRD has qualified staff on hand to perform analyses on the data if that level of service is required.

Please do not hesitate to contact me if you require any further information.

Kind regards,

Sam Speer
ISAC Secretariat

 17_161RA2_ISAC feedback.docx
37K

Appendix 6.3 EMERALD data specification

EMERALD: Exploring Mental Illness and Diabetes through a Longitudinal Data study

Data-set specification for an ISAC-approved study

Protocol 17_161R

Version	Description	CPRD Author	Summary of Changes	Date
0.1	Initial Draft	Jessie Oyinlola	n/a	08/01/2018
0.2	Modified	Sonia Cotton	Quality Assurance	10/01/2018
0.3	Modified	Najma Siddiqi	Comments following review	16/01/2018
0.4	Modified	Jessie Oyinlola	Updates to Data specification following review and further comments	22/01/2018
0.5	Modified	Najma Siddiqi	Comments regarding matching and cohort identification	04/02/2018
0.6	Modified	Jessie Oyinlola	Updates following comments	05/02/2018
1.0	Final	Jessie Oyinlola	Final	07/02/2018
1.1	Modified	Jessie Oyinlola	Update of patient numbers and matching file	02/03/2018
1.2	Modified	Jessie Oyinlola	Updated patient numbers following re-matching	16/03/2018

Prepared by: Jessie Oyinlola [CPRD]

Distribution: Najma Siddiqi [University of York]

Date: 7th February 2018

Objective

The overall aim of our research is to improve diabetes outcomes for people with Serious Mental Illness (SMI). The present study contributes to that goal, and specifically aims to understand the

determinants of diabetes and variation in diabetes outcomes for people with SMI, in order to identify potential healthcare interventions that can be tested further.

The study has the following objectives:

1. In people with SMI, to identify which socio-demographic, illness, family history and lifestyle factors are associated with the development of diabetes.
2. In people with SMI and diabetes, to identify which socio-demographic, illness, family history and lifestyle factors are associated with variation in diabetes and mental health outcomes.
3. In people with SMI, to compare healthcare interventions, physical and mental health outcomes in those with diabetes with those without diabetes.
4. In people with diabetes, to compare healthcare interventions, physical and mental health outcomes in those with SMI and those without SMI.
5. To compare diabetes care provision for people with and without SMI, and estimate costs for these.
6. To identify which healthcare interventions (e.g. medication, referrals and care pathways) may be associated with better diabetes outcomes for people with SMI and diabetes.

Study design:

A retrospective cohort study

Source Population

The extraction population will comprise of all acceptable patients in CPRD (from the most recent snapshot available; December 2017)

Data to be supplied:

Primary Care (GOLD) data with ONS Death Registration, Full HES, Practice Level Index of Multiple Deprivation and Patient Level Index of Multiple Deprivation data (from Set 15)

Cohort definition in CPRD GOLD

From the source population in CPRD GOLD:

- 15,160,693 patients are acceptable¹
- 15,160,196 patients meet gender criterion (Male and Female Only)
- 7,985,853 patients are eligible for the linkages required (this also means that patients will only be registered at a practice in England)

Case definition

Dataset A

Inclusion Criteria

From the cohort population in CPRD GOLD:

¹ Acceptable patients are identified within the CPRD using pre-defined criteria (see Glossary Terms - Acceptable & UTS.pdf)

² Up-to-standard (UTS) follow-up is the period of good quality data from the practice (see Glossary of terms).

- Inclusions
 - 70,622 patients had a record of SMI recorded in their Clinical or Referral File based on specific medical codes (See Appendix 1).
 - 48,408 patients had a record of SMI so that at least one event occurs within the study period (01/04/2000– 31/03/2016). Patients could have a record for SMI prior to the start of the study period.
 - 47,742 patients were aged 18 and above on the date of their diagnosis of SMI.
 - 32, 759 patients had the above events within their up-to-standard (UTS²) follow-up period

- Exclusions
 - None

The total number of patients in Dataset A was 32,759.

Dataset B

Inclusion Criteria

From the Dataset A population in CPRD GOLD:

- Inclusions
 - 3,296 patients had a record of Type 2 Diabetes recorded in their clinical or referral file based on specific medical codes (See Appendix 2).
 - 3,296 patients were registered during the study period (01/04/2000– 31/03/2016).
 - 3,295 patients were aged 18 and above on the date of their diagnosis of Type 2 Diabetes.
 - 2,805 patients had the above events within their up-to-standard (UTS) follow-up period

- Exclusions
 - 44 patients had a record (in their clinical or referral file) for Type 1 Diabetes after the date of their diagnosis of Type 2 Diabetes (Appendix 3).

The total number of patients in Dataset B was 2,761.

Follow-up definition

The start of follow-up will be defined as the latest of the patient registration date, the practice UTS date and 01/04/2000. The end of follow-up will be defined as the earliest of the patient transfer out date, the practice last collection date, the CPRD GOLD derived death date and 31/03/2016.

Index date

The index date is defined as the first record of a clinical diagnosis of Type 2 Diabetes between 01/04/2000– 31/03/2016.

² Up-to-standard (UTS) follow-up is the period of good quality data from the practice (see Glossary of terms).

Control definition and matching (Dataset C)

Up to four matched controls will be provided for each case in Dataset B. The controls (Dataset C) will comprise of patients from the source population who:

- Had a record of Type 2 diabetes recorded in their clinical or referral file based on specific medical codes (See Appendix 2) (287,399 patients)
- Had a record of Type 2 diabetes so that at least one event occurs within the study period 01/04/2000– 31/03/2016 (243,859 patients)
- were aged 18 and above on the date of their diagnosis of Diabetes (243,619 patients)
- had the above events within their up-to-standard (UTS) follow-up period (197,716 patients)

Exclusions

- had a record of SMI (ever) in their clinical or referral file (4,191 patients)
- had a record (in their clinical or referral file) for Type 1 Diabetes (Appendix 3) after the date of their diagnosis of Type 2 Diabetes (2,914 patients).

The total number of potential controls in Dataset C was 190,611. Data will only be provided for controls who are matched to a case.

Controls will be matched based on:

- Year of birth (within +/- 2 years)
- Gender and
- GP practice

Matching method

Age at study start Matching

CPRD will be using Age at study start matching. In this algorithm, the age of the case patient at the study start an event occurred, must match the age of the control patient at the study start within a given range.

Criteria not applied by CPRD

None

Limitations

- The clients are aware that their codelists for Type 1 and Type 2 diabetes does not contain any of the generic diabetic codes (codes without a specific diagnosis of Diabetes e.g. “diabetic retinopathy”) nor are they identifying/ excluding patients based on prescriptions for anti-diabetic drugs. Therefore they may not capture all Type 2 Diabetic patients or exclude all Type 1 Diabetic patients as there may be instances where a patient will not have a specific diabetes diagnosis (e.g. “Type 2 Diabetes with diabetic retinopathy”) recorded but

may have other forms of evidence for the type of diabetes they have (e.g. the medications they may have been prescribed). They wish to proceed with their current codelists and method.

Data Delivery

A single dataset will be supplied containing all of the data for the patients of interest. This will contain no more than 42,332 patients. The full suite of primary care (GOLD) data will be supplied for the patients of interest and the linked data.

Please note, a request for re-extraction of data will incur data costs.

Data to be supplied

1. Case file (see below)
2. Matching file (See below)
3. Practice list (See below)
4. Primary care data (see CPRD GOLD Full Data Specification.pdf)
5. Full HES APC (see Data_Dictionary_HES_Full_set15_v2.0)
6. ONS Death Registration data (see Documentation_Death_set15_v1.7.pdf)
7. Patient level deprivation data in 2010 in twentiles (see Documentation_SmallAreaData_Patient_set15_v2.3.pdf)
8. HES Outpatient (see Documentation_HES_OP_set15_v1.6.pdf)
9. Practice Level Deprivation data (see Documentation_SmallAreaData_Practice_set15_v2.4.pdf)

Case file

<i>Column name</i>	<i>Field name</i>	<i>Description</i>
Patient identifier	patid	The encrypted unique identifier given to a patient in CPRD
SMI date	smidate	The date of an SMI diagnosis
Medical Code	medcode	The CPRD medical code associated with the event of interest
Start of follow-up	Start	The latest of the practice up-to-standard date, 01/04/2000 and the patient first registration date
End of follow-up	End	The earliest of the practice last collection date, the patient transfer out date, the CPRD GOLD derived death date and 31/03/2016.
Medical Code	medcode	The CPRD medical code associated with the event of interest

The Matching file (17_161R_Matching_file.txt) contains the details of which cases (in Cohort B) match which controls.

Matching file

<i>Column name</i>	<i>Field name</i>	<i>Description</i>
Patient identifier	case_patid	The encrypted unique identifier given to a patient in the CPRD GOLD: Listed for cases
Practice identifier	case_pracid	The encrypted unique identifier given to a specific practice in CPRD GOLD: Listed for cases
Patient Gender	case_gender	Patient's gender: Listed for cases
Birth year	case_birtheyear	Patient's birthyear: Listed for cases
Start of follow-up	case_event	The latest of the practice up-to-standard date, 01/04/2000 and the patient first registration date: Listed for the cases
Age at event	case_ageatevent	The age of the patient in the year of their start of follow up: Listed for cases
Number of matches	match	Number of matches per case.
Patient identifier	control_patid	The encrypted unique identifier given to a patient in the CPRD GOLD: Listed for controls. Where a control could not be matched to a case this field is empty.
Practice identifier	control_pracid	The encrypted unique identifier given to a specific practice in CPRD GOLD: Listed for controls. Where a control could not be matched to a case this field is empty.
Patient Gender	control_gender	Patient's gender: Listed for controls. Where a control could not be matched to a case this field is empty.
Birth year	control_birtheyear	Patient's birthyear: Listed for controls. Where a control could not be matched to a case this field is empty.
Start of follow-up	control_event	The latest of the practice up-to-standard date, 01/04/2000 and the patient first registration date: Listed for the controls. Where a control could not be matched to a case this field is empty.
Age at event	control_ageatevent	The age of the patient in the year of their start of follow up: Listed for controls. Where a control could not be matched to a case this field is empty.

The Practice list file (17_161R_Practice_list_file.txt) contains the number of patients registered at each practice included in the study.

Practice List file

<i>Column name</i>	<i>Field name</i>	<i>Description</i>
Practice identifier	pracid	Encrypted unique identifier given to a specific practice in CPRD GOLD
Practice list size	list_size	The number of patients registered at the practice

Appendix 7.1 Data preparation

Summary of the processes involved in the preparation of data for analysis:

- Cleaning and coding the dataset
- Check data for missing values and data entry errors
- Ascertaining participant eligibility
- Source relevant read codes for each health check
- Import clinical test files to merge each with readcode/medcode files
- Append all clinical and test files for each health check
- Convert wide patient data file to long format – reshape command in Stata
- Merge each complete clinical and test file with long format patient file

Abbreviations

BMI: Body Mass Index

BMA: British Medical Association

COPD: Chronic Obstructive Pulmonary Disease

CPRD: Clinical Practice Research Datalink

CRN: Clinical Research Network

CVD: Cardiovascular Disease

DNA: Did Not Attend

DSM: Diagnostic and Statistical Manual of Mental Disorders

EHR: Electronic Health Record

GP: General Practitioner

HES: Hospital Episode Statistics

HSCIC: Health and Social Care Information Centre

ICD: International Classification of Diseases

IT: Information technology

ITS: Interrupted Time-Series

NHS: National Health Service

NICE: National Institute for Health and Care Excellence

OECD: Organisation for Economic Cooperation and Development

ONS: Office of National Statistics

PN: Practice Nurse

QOF: Quality and Outcomes Framework

RCT: Randomised Controlled Trial

SMI: Serious Mental Illness

THIS: The Health Improvement Network

UCL: University College London

UNSW: University of New South Wales

UK: United Kingdom

US: United States

WHO: World Health Organisation

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