The implementation of electronic audit and feedback systems for medicines optimisation in primary care: understandings from a sociotechnical perspective.

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Contents

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List of Abbreviations

ACEI	Angiotensin Converting Enzyme Inhibitor
ADE	Adverse Drug Event
CCG	Clinical Commissioning Group
CDS	Clinical Decision Support System
CPOE	Computerised Physician Order Entry
DCLG	Department of Communities and Local Government
DoH	Department of Health
DQIP	Data Quality Improvement Intervention
EAandF	Electronic Audit and Feedback
eGFR	Estimated Glomerular Filtration Rate.
EHR	Electronic Health Record
EMR	Electronic Medical Record
EPMAR	Electronic Patient Medication and Administration Records
ePMR	Electronic Patient Medical Record
EPS	Electronic Prescribing Service
EPS2	Electronic Prescription Service Release Two
GP	General Practitioner
HSCIC	Health and Social Care Information Centre
HSE	Health and Safety Executive
IT	Information Technology
NHS	The National Health Service
NICE	The National Institute for Health and Care Excellence
NPfIT	National Programme for Information Technology
NOAC	New Oral Anticoagulant Drug
NPSA	National Patient Safety Agency
NPT	Normalization Process Theory
NSAID	Non-Steroidal Anti-Inflammatory Drug
PINCER	Pharmacist-Led Information Technology Intervention for Medication Errors
RCT	Randomised Controlled Trial
SMASH	The Salford Medication Safety Dashboard
SST	Strong Structuration Theory

Researchers' Initials

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DLP	Dr Denham Phipps
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Doctor of Philosophy

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Abstract

Background: Ensuring medicines optimisation is important since medication errors are common and can lead to adverse drug events. Interventions to improve medicines optimisation have made increasing use of information technology (IT). In contrast to traditional approaches that only focus upon technology, sociotechnical approaches to the understanding of the implementation of IT in healthcare settings depict implementation as a social process involving a range of social and organisational factors. The aim of this thesis was to explore, evaluate and understand the socio-technical processes involved in the implementation, adoption and use of two different information technology interventions for medicines optimisation in primary care.

Method: This research adopted a qualitative approach using semi-structured interviews and focus groups with a range of stakeholders in order to understand the use of two electronic audit and feedback (EAandF) systems. Three studies were undertaken each adopting a different sociotechnical approaches. The use of the first system (Eclipse Live) was explored in two studies; the first utilised strong structuration theory, the second adopted a realist evaluation approach. The use of a different EAandF system, the SMASH dashboard, was then explored through normalisation process theory in order to understand how this pharmacist-led intervention was implemented, adopted and embedded into everyday practice.

Results: Strong structuration theory showed how the adoption and implementation of the EAandF system was dependent upon broad institutional contexts, the dispositions of users and the structures embedded in the technology. Differing patterns of engagement and adaptation of work practices, in the use of the EAandF system were highlighted by the realist evaluation. Normalisation process theory illustrated how the SMASH intervention was understood by users, and the ways pharmacists, clinicians and other GP staff worked collaboratively to set-up, operate and sustain the intervention. Implementation and adoption of the two systems was seen to be a dynamic social process that involved social and organisational structures the material properties of the systems, social norms, work practices and divisions of labour. In particular, the interventions involved collaborative processes, requiring communication and cooperation between stakeholders. In contrast systems were often utilised by individual groups of health professionals.

Conclusions: The findings from this work represent an important contribution in understanding how EAandF systems are utilised by different health professionals. The novel use of three different sociotechnical theories was of particular value in understand these interventions for medicines optimisation in primary care. Both systems were seen as beneficial for medication safety activities. The implications from this work suggest a valuable role for information technology and for clinical pharmacists in medicines optimisation in primary care. Further evaluation of such interventions would benefit from drawing upon the insights gained from sociotechnical approaches in order to ensure effective implementation of such initiatives in the future.

Declaration

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Dedication

In memory of my parents

Margaret Jeffries 1929-1985

Brian Allan Jeffries 1934-2014

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In undertaking this PhD I have received a great deal of support, guidance and encouragement from a number of different people. I would firstly like to thank my supervisors, Professor Darren Ashcroft and Dr Denham Phipps who have provided exceptional support throughout the last three years. Their wit, erudition, incites and understanding has expertly guided me through the research and the writing of this thesis. I am enormously grateful for their support.

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I am indebted to friends and family for their support. My children, Jacob and Emily, have put up with my near constant presence in the study and my irritating game of academic "Top Trumps" - a PhD easily beats GCSEs, A levels and undergraduate exams. They have had to cope with much more than a father undertaking a PhD. Their stoicism, strength, resilience, intelligence, energy and striving for success is inspirational. That, and their kindness, love and support, is the reason why this thesis has been completed.

The Author

Mark graduated from Leicester Polytechnic (now De Montfort University) with a lower-second class honours degree in Combined Arts (English and Politics) in 1984. He subsequently trained as a teacher, receiving his PGCE from St. Martin's College, Lancaster in 1985. Mark taught in secondary schools for 12 years and then, after a career break to care for his young children, returned to university to study Psychology at Staffordshire University. He completed a Graduate Diploma (Merit) in Psychology in 2008 and gained an MSc (Distinction) in Health Psychology in 2010 which developed an interest in health research and in qualitative research methodology.

Mark started work at the University of Manchester in 2011 as a Research Assistant in the Centre for Primary Care. Here he worked on two projects; the first exploring the local and community support for individuals with long-term health conditions and the second exploring medication adherence for people with multimorbidity and polypharmacy. The second of these projects led to an interest in medication safety and subsequently to a post as a Research Associate working in the medication safety theme of the NIHR Greater Manchester Patient Safety Translational Research Centre.

Throughout this PhD Mark has developed his interests in the use of information technology in supporting and improving medication safety and in the sociotechnical theories and approaches to the study and evaluation of that. Having started his academic career in psychology, Mark would now describe himself as working from sociological perspectives. Partly as a consequence of that, one aspect that Mark enjoys most about working in applied health research is the collaborations across a range of academic disciplines.

Publications related to this PhD

Journal Articles

Jeffries, M., Phipps, D. L., Howard, R. L., Avery, A. J., Rodgers, S. and Ashcroft, D. M. (2017) Understanding the implementation and adoption of an information technology intervention to support medicines optimisation in primary care: qualitative study using strong structuration theory. *BMJ Open.* **7**:e0148010.

Jeffries, M., Phipps, D. L., Howard, R. L., Avery, A. J., Rodgers, S. and Ashcroft, D. M. (2017) Understanding the implementation and adoption of a technological intervention to improve medication safety in primary care: a realist evaluation *BMC Health Services Research*. 17, 1, p. 196.

Conference Abstracts

Jeffries, M., Keers, R., Phipps, D., Williams, R., Avery, A., Rodgers, S., Kontopantelis, E., Peek, N. and Ashcroft, D.M (2017). Understanding the utilisation of a novel interactive electronic medication safety dashboard by pharmacists and clinicians in general practice: a qualitative study. Informatics for Health, Manchester, 24th-26th April, 2017.

Jeffries, M., Phipps, D.L., Howard, R. L., Avery, A. J., Rodgers, S. and Ashcroft, D.M (2016). Using strong structuration theory to understand the implementation and adoption of a medication safety information technology intervention in primary care: a qualitative case study. BSA Medical Sociology Group Annual Conference, Birmingham, 7th-9th September, 2016.

Jeffries, M., Phipps, D., Howard, R. L., Avery, A. J., Rogers, S. and Ashcroft, D. (2016) Understanding the implementation and adoption of an information technological intervention for medication safety: a qualitative study using strong structuration theory. *International Journal of Pharmacy and Practice.* Suppl. 2 ed. Vol. 24, p. 16-16. International Social Pharmacy Workshop, Aberdeen, 19th-22nd July, 2016.

Conference Poster Presentations

Jeffries, M., Phipps, D., Howard, R. L., Avery, A. J., Rodgers, S. and Ashcroft, D. M. (2015) Understanding the Medication Safety Implications of a Technological Intervention in Primary Care: A Realist Evaluation of Eclipse Live. Poster presented at HSRN Symposium, Nottingham, 1st-2nd July, 2015.

Jeffries, M., Phipps, D., Howard, R. L., Avery, A. J., Rodgers, S. and Ashcroft, D. M. (2015) Medication safety implications of a technological intervention in primary care: a realist evaluation of Eclipse Live. Prescribing and Research in Medicines Management (UK & Ireland) 26th Annual Scientific Conference, London, 23rd January 2015.

CHAPTER ONE: INTRODUCTION

1.1. Background

The prescribing of medicines is one of the most common interventions in healthcare and used to treat or manage many illnesses with over one billion prescription items issued each year in primary care in England (HSCIC, 2015; NICE, 2015) and over 102 million prescription items dispensed in Scotland (ISD Scotland, 2016). Most prescribing of medicines does not lead to harm but at times medication errors will lead to an adverse drug event (ADE) (DoH, 2004). Not all ADEs are preventable since some may be caused by, for instance, an unexpected allergic reaction to a particular medicine (Mcleod, 2016). An ADE that is caused by a medication error is a preventable event (DoH, 2004). More than one in ten of patients have experienced an ADE after receiving prescription medication in primary care (Taché, 2011). A study of over 6000 unique prescriptions over a 12 month period in 15 general practices found medication errors in 4.9% of which 0.2% were classified as severe errors (Avery et al., 2013). Whilst these numbers are low, with the huge volume of prescription items issued each year this could represent a very large number of prescription with serious errors.

Medication errors can carry a huge personal cost to individuals through physical or psychological harm (NICE, 2015; DoH, 2000). Many patients who suffer as a consequence of an adverse event have described profound suffering including permanent disability, long term stress-related ill health and financial hardship (Southwick et al., 2015). Patients who have suffered from adverse events have also been said to lose faith and confidence in health professionals (Southwick et al., 2015).

In addition there is a considerable financial burden to the National Health Service (NHS) with possibly up to £2.5 billion in extra costs (Frontier economics, 2014; DoH, 2004; 2000).

Information technology (IT) has been offered as a solution to health professionals as a way of improving patient safety. However the implementation and adoption of a range of different healthcare IT systems has not been without problems with systems being used differently than planned, used ineffectively or resisted (Greenhalgh et al., 2014; Hayward et al., 2013). Healthcare operates in open complex systems which are contextually dependent upon a range of cultural, social, organisational and political factors, and interventions utilising information technology interventions are complex social programmes (Cresswell and Sheikh, 2014; Greenhalgh et al., 2014; Greenhalgh and Stones, 2010).

Previous interventions utilising IT in healthcare have predominantly occurred within secondary care settings. As a consequence, the bulk of research on IT interventions has focused upon these settings. Primary care is therefore an under researched area. The purpose of this PhD is to evaluate how electronic audit and feedback interventions for medicines optimisation in primary care are implemented and adopted within the complexity of primary care settings. I will explore why and how systems are used and the different ways in which they are implemented and adopted. In doing so I will draw upon a range of theoretical and methodological approaches that have explored how technology is used in practice taking into consideration the complex contextual factors that are implicated in such use. The focus for this PhD is on small scale local interventions of two different IT systems each adopted into general practices across a single Clinical Commissioning Group (CCG).

This PhD draws upon three sociotechnical approaches, which see interventions as not purely about technology but also the way the technology is used within cultural, social, organisational and political contexts (Cresswell et al., 2011). Strong structuration theory (SST) is adopted to explore why an audit and feedback system is used, and how external and internal structures and the material properties of the technology are implicated in the adoption of the technology. The same system is then explored using realist evaluation. Realist evaluation tries to unpick the complexity and inner workings of interventions and seeks to explain the ways the intervention might work for whom and in what circumstances. Normalisation process theory (NPT) is adopted to explore the implementation and adoption of a pharmacist-led information technology intervention that utilises an audit and feedback dashboard system.

1.2. Organisation of the PhD

Chapter Two opens with a detailed review of the literature surrounding patient safety and more specifically medication safety. With the focus of this PhD being primary care settings there follows a review of the literature surrounding patient safety in primary care and an outline of the nature of prescribing in primary care. The remainder of the chapter details the literature relating to the use of IT in healthcare and the key issues involved in previous interventions.

Chapter Three details the programme of work for this PhD. A rationale is given and an overview of the study design. The two interventions are briefly explained. The chapter concludes with the aims and objectives for this PhD.

Chapter Four discusses the theoretical background and methodological approaches taken in this PhD. The theoretical approaches taken to understanding the use of technology in healthcare settings are detailed. There is a particular focus here upon the sociotechnical concepts which inform the evaluation undertaken for this PhD. This is followed by an outline of the approaches taken to the evaluation of the interventions, including detail of how and why a qualitative approach is adopted.

Chapter Five gives a detailed account of the findings from the evaluation of an electronic audit and feedback (EAandF) intervention to support medicine optimisation in primary care using SST. The study aims and methods are expanded upon, including a detailed explanation of SST. In particular, this chapter presents the findings relating to how the use of the system was determined by broad institutional contexts, by the perceptions, dispositions and skills of users and by the material properties embedded in the technology.

Chapter Six revisits the EAandF intervention examined in Chapter Five. This time, realist evaluation is used to explore the mechanisms implicated in the ways in which the system was used by a variety of stakeholders. A detailed outline of realist evaluation is given followed by the findings. This chapter presents findings relating to how the effective use of the system could be dependent upon engagement with the system, the flow of information between different health professionals and upon variably adapting work practices.

Chapter Seven details the findings from the evaluation of the pharmacist-led information technology intervention. This study adopted NPT as the evaluative

framework. A detailed outline of NPT is given. Findings relating to the ways in which the dashboard was understood adopted and used in practice are then presented.

Chapters Eight discusses the significance of the findings from the three studies and reflects upon the programme of work. The first part of Chapter Eight explores common and contrasting themes from across the three studies and relates those to the current literature. The second part of this chapter discusses the strengths and limitations of the programme of work. The value of the interventions is discussed and the value of using sociotechnical approaches in evaluating such interventions is scrutinised. The implications for practice and further research are discussed. Finally this chapter summarises the conclusions of this PhD programme of work and draws the thesis to a close.

CHAPTER TWO: BACKGROUND

2.1. Preface

This chapter outlines the literature relating to patient safety, medication safety and healthcare IT. The intention here is to outline the frequency and nature of the problem concerning medication safety in primary care, the context in which that problem occurs and provide an overview of previous interventions that have been offered as potential solutions to that problem.

In order to do that a scoping review of the literature was undertaking for each of these areas. Searches were undertaken of relevant databases (CINAHL, Web of Science (including MEDLINE), ProQuest and Google Scholar) using combinations of the following search terms: “medication safety”; “prescribing”; “primary care”; “sociotechnical”; “adverse drug event”; “information technology”. Searches were limited to a period from 1999 to capture the last eighteen years. This time period was chosen because it relates to the publication of important and relevant policies relating to patient safety and IT in healthcare particularly the publication in the USA of *“To Err is Human; Building a Safer Health System”* (Kohn et al., 1999) and in the UK of *“An Organisation with a Memory”* (DoH, 2000). These searches revealed a number of key papers. Further hand searches of citations from those papers were conducted. Relevant policy documents were also obtained from the websites of The Health Foundation, The King's Fund, National Institute of Health and Care Excellence (NICE), Department of Health (DoH), NHS England, NHS Scotland and The Scottish Government.

The first part of this chapter, Section 2.2, provides a broad outline of the main issues in patient safety, before discussing more specific issues in medication safety. Section 2.2.1 focuses on what is known about medication safety, including prescribing and monitoring errors, ADEs and the prevalence and causes of these. Section 2.3 focuses on primary care settings and explores the nature of prescribing in primary care given the complexity of primary care settings. Section 2.4 considers potential solutions that have been proposed for medicines optimisation in primary care involving the use of IT. The policy background to IT in healthcare, previous IT-based interventions and key issues in the implementation and adoption of IT are discussed here. This chapter concludes in Section 2.5 with an important discussion of the emerging role of clinical pharmacists in primary care and the ways in which clinical pharmacists might contribute to the success of implementing and adopting interventions for medicines optimisation.

2.2. Patient Safety and Medication Safety

Over the last 20 years or so there has been increasing interest in patient safety across policy makers, health professionals and academics. The publication in the USA of *"To Err is Human; Building a Safer Health System"* (Kohn et al., 1999) and in the UK of *"An Organisation with a Memory"* (DoH, 2000) set out the necessity for the establishment of a patient safety culture within healthcare organisations and paved the way for much research in this area. In the UK this also led to the formation of the National Patient Safety Agency (NPSA), though this was disbanded in 2012 and subsumed into the NHS Commissioning Board. In 2004, the NPSA published "*Seven-Steps-To Patient-Safety"* which set out guidance on how safety for patients in healthcare could be achieved. This was followed by similar guidance for primary care

which described key areas of activity in which primary care health professionals could improve the safety of patients (NPSA, 2006). The NPSA report *"Building a Memory: Preventing Harm, Reducing Risks and Improving Patient Safety"* looked to detail what kinds of patient safety incidents occurred and how they were caused (NPSA, 2005). This was followed by the reports "*Safety in Doses: Improving the use of Medicines in the NHS"* in 2007 and 2009 which detailed medication safety incidents reported to the National Reporting and Learning System (NPSA). Recommendations with regard to medicines optimisation and polypharmacy were made by the King's Fund report *"Polypharmacy and Medicines Optimisation: Making it Safe and Sound"* (Duerden et al., 2013). Similar guidelines were suggested by the Scottish Government report *"Polypharmacy guidance"* which set out a *"7-step"* approach to medication review for patients on multiple medications (The Scottish Government, 2015, p.9). The evaluation of the Health Foundation's *"Safer Clinical Systems"* (Dixon-Woods et al., 2014) programme recommended learning lessons from high risk industry and adopting a more proactive approach to patient safety to prevent errors before they happen. Similarly the NPSA reported how healthcare could draw upon safety in high hazard industries (NPSA, 2010). At a local level, primary care commissioners have operated prescribing financial incentive schemes for many years that are designed to improve the quality of prescribing, respond to the requirements of national guidelines, and reduce excessive prescribing and costs (Ashworth et al., 2003).

2.2.1. Medication safety

2.2.1.1. Medication errors and prescribing errors

There are various stages in the use of medicines from prescription, dispensing, administration and monitoring (Franklin and Tully, 2016). The focus here is specifically on the prescribing of medicines and the monitoring of their use for which the term medication safety will be used. Medication errors therefore would include both prescribing errors and monitoring errors. A prescribing error has been defined as:

> *"[Occurring] when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant reduction in the probability of treatment being timely and effective or an increase in the risk of harm when compared with generally accepted practice."* (Dean et al., 2000, p.235)

Prescribing errors include incomplete information on prescriptions, dosing strength errors (either overdose or under dose), drug-drug interaction, prescribing drugs to which patients are known to be allergic, or when there are specific contraindications to treatment (Avery et al., 2013). Monitoring errors can occur where patients receiving prescribed medicines are not monitored through routine blood tests (Avery et al., 2013; Alldred et al., 2008). A monitoring error has thus been defined as:

> *"[Occurring] when a prescribed medicine is not monitored in the way which would be considered acceptable in routine general practice. It includes the absence of tests being carried out at the required frequency, with tolerance of*

+50%. If a patient refused to give consent for a test then this would not constitute an error." (Alldred et al., 2008, p.318)

In a study of 15 general practices in England, prescribing and monitoring errors have been seen to be associated with a lack of renal and hepatic monitoring through appropriate tests of patients on high risk medicines, failure to provide correct dose instructions and prescription of drugs to which patients had a recorded allergy (Avery et al., 2013). This study also highlighted that monitoring errors were most prevalent in older patients on multiple medications. It has been suggested that high risk prescribing may not in itself cause harm and may be necessary for particular patients, but it does require regular review and monitoring (Howard et al., 2007).

An ADE has been defined as an event that includes "*adverse drug reactions, drug interactions, allergic drug reactions and medication errors that harm the patient"* (Kelly, 2001). It is important to note that not all medication errors lead to harm and not all ADEs are the result of prescribing or monitoring errors (DoH, 2004). However, medication errors are by definition preventable; therefore, an ADE caused by a medication error is preventable (Franklin and Tully, 2016; DoH, 2004). It is important to distinguish between those ADEs that are unpredictable reactions in particular individuals from routine doses of medication and those caused by a medication error, since it is only the latter that are preventable (Franklin and Tully, 2016; DoH, 2004; Hudson and Guchelaar, 2003).

2.2.1.2. Prevalence of errors in primary care

It has been estimated that safety incidents in primary care occur at the rate of between 5 to 80 per 100,000 consultations, which would mean that, across the UK,

approximately 37-600 errors would occur each day (Sandars and Esmail, 2003). In a recent review of the literature Olaniyan et al., (2015) found prescribing error rates of between 5% and 11% of prescription items across thirty three different studies. However, this review focused upon all parts of medicines management including dispensing transcribing and administration errors as well as prescribing and monitoring. As mentioned already, not all errors lead to consequences for patients. It has been estimated that half of all errors have no consequence, but one in five could lead to serious consequences (Vincent, 2004).

In a retrospective study of English general practice prescribing over a period of 12 months in 15 general practices, the prevalence of monitoring or prescribing errors in over 6000 unique prescription items was found to be 4.9%, with 18.7% of patients receiving at least one prescribing or monitoring error (Avery et al., 2013). The most common prescribing errors related to incomplete information, dose or strength errors and incorrect timing of doses. The medicines carrying higher risks of error were those requiring monitoring tests, due to the required tests often being omitted (Avery, et al., 2013). This study assessed also the severity of each error on a scale of 0 (no harm) to 10 (death). Each error was judged by five clinicians (two general practitioners (GPs), two pharmacists and a clinical pharmacologist) and the mean score used as the severity score. Scores of three to seven were moderate and above seven severe. Over half of the errors that occurred were judged in this way as either moderate or severe, although only 1 in 550 was associated with a severe error. However, with a high volume of prescribing in primary care, even a small percentage of errors will lead to a potentially large numbers of patients being affected by an error.

In a cross-sectional study of linked electronic patient records of patients from one hospital and 50 general practices in Salford, the overall prevalence of errors was 5.45% for instances of hazardous prescribing and 7.65% for instances of hazardous monitoring using a core set of 13 prescribing and monitoring safety indicators (Akbarov et al., 2015). In a similar cross sectional study of 526 UK general practices, 5% of patients were found to have received potentially hazardous prescriptions and 12% of patients in receipt of prescription medications had not received adequate monitoring (Stocks et al., 2015). It should be noted that these two studies (Akbarov et al., 2015; Stocks et al., 2015) were focusing upon potentially hazardous prescribing situations, as defined by the core set of prescribing safety indicators they used, not necessarily definite prescribing and monitoring errors. In a similar study of patients defined as particularly vulnerable to an ADE, across 315 general practices in Scotland using a set of fifteen prescribing safety indicators it was found that nearly 14% of approximately 140,000 vulnerable patients received at least one high risk prescription per year (Guthrie et al., 2011).

2.2.1.3. Prevalence of adverse drug events

Approximately 13% of patients have experienced an ADE after receiving prescription medication in primary care, and many of those have been serious enough for patients to seek medical assistance at hospital (Taché et al., 2011; Royal et al., 2006). In a systematic review of 43 studies, Taché et al. (2011) investigated the prevalence of ADEs occurring in ambulatory care settings (primary care and specialist outpatient care). Six of the studies were ambulatory-based and the remaining 37 were hospital-based (patients from ambulatory settings who had presented at hospital). The authors found that for the ambulatory-based studies, ADE prevalence rates were a median of

12.8% of patients identified in ambulatory practice and for hospital based studies a median of 5.1% of patients admitted to hospital were due to ADEs. The median proportion of patients with preventable ADEs was 53% for hospital-based studies and across all of ambulatory care–based studies was 16.5%. As Taché and colleagues (2011) point out, the majority of these studies were hospital based, so making estimates of the prevalence of ADEs in the community is difficult. Similarly, Kongkaew et al. (2013) undertook a prospective observational study in the medical admission units at two hospitals in the UK. Of the 3904 patients screened in the study, they found 439 (11.2%) to have been admitted because of an ADE, of which 209 (47.6%) were judged preventable. In another observational study of patients seen by pharmacists in a hospital medical admissions unit, 6.5% of admissions were judged to be drug related and of those over half were perceived to be preventable; 35% were due to prescribing and 26% due to monitoring (Howard et al., 2007; Howard et al., 2003).

2.2.1.4. Causes of errors

It is important to make the distinction between hazards, errors and risk. A hazard is something that may cause harm (HSE, 1998). A risk is considered the likelihood that someone will be harmed by such a hazard (DoH, 2000). An error is considered to be a failure to complete a planned action as intended (Kohn et al., 1999). In this way errors increase the risk of hazards causing harm. Both *"To Err is Human: Building a Safer Health System"* (Kohn et al., 1999) and *"An Organisation with a Memory"* (DoH, 2000) drew on the work of Reason (2000, 1997, 1990) whose publication *"Human Error"* (1990) set out to explain, amongst other things, the underlying causes of organisational errors, and how, within organisational contexts, the

likelihood of someone being harmed by a hazard could be lessened. There has thus been considerable focus upon the complex causality involving such socio-cultural factors, technological aspects and organisational procedures and weaknesses that might be at the root of the causes of errors in large complex organisations such as healthcare (Reason, 2000). The Bow-Tie model understands risk in terms of how hazards may lead to undesirable consequences (Hudson and Guchelaar, 2003). This describes how events and circumstances may release a hazard. Once the hazard is released various scenarios might act as defences against the hazard to stop it causing lasting harm. Hudson and Guchelaar applied this to clinical pharmacy services in a hospital setting. In the model, the inexperience of a pharmacist might lead to an incorrect drug being dispensed but this might not lead to harm if other systems defended against the hazard, for example an alert in the computer system or intervention from other clinical staff (Hudson and Guchelaar, 2003).

Prescribing is a complex process involving a variety of factors, people and steps that may influence the prescribing decision (Agrawal, 2009). These include the prescriber's knowledge, the patient's medical history and other medications, national and local guidelines and prescribing norms (Lewis, 2016). Prescribing is seen to be *"embedded in social norms and cultures"* (Aarts, 2016 p.102). With such a complex set of processes and the high volume of prescribing, errors are likely (Lewis, 2016). Prescribing errors might occur through insufficient knowledge of the patient, of the patient's clinical condition or inadequate knowledge of the drug being prescribed (DoH, 2004). Studies in hospital settings have suggested that the most common errors involve incorrect dosage (Ashcroft et al., 2015). In a prospective study undertaken in 20 UK hospitals, Ashcroft et al. (2015) found that whilst junior doctors were more

likely to make prescribing errors, there was no significant difference between grades of prescriber in terms of the severity of the errors made. Ashcroft and colleagues suggested that interventions to reduce error need to be targeted at all grades of staff. In a related qualitative study junior hospital doctors were seen to make errors based upon a lack of knowledge or through poor application of knowledge (Lewis et al., 2014). Errors have also been seen to be caused because of physical factors such as tiredness, low mood or hunger (Coombes et al., 2008b). Errors have also been associated with social factors such as teamwork, communication, workload and lack of support (Lewis, 2016; Ross et al., 2012). As has been discussed above, such causal factors might be considered in terms of a person or systems approach; the latter focusing upon workplace conditions, contexts, local infrastructure and work procedures (DoH, 2004). ADEs have been seen to occur for a number of reasons including failures of computerised systems, lack of communication, the organisation and training of staff and deficiencies in drug knowledge (Avery et al., 2002).

Much previous research on the causes of medication errors has taken place in secondary care settings and the causes of prescribing and monitoring errors in primary care is less well researched. One notable exception was a qualitative study of prescribing errors in fifteen English general practices (Slight et al., 2013). Slight et al. conducted 34 interviews and six focus groups with general practice staff to examine the causes of prescribing and monitoring errors. They identified seven *"error-producing conditions"* that included the prescriber, the team, the patient, the working environment, the task, IT, and the secondary-primary care interface. Within these seven conditions, errors could be caused by a clinician's lack of knowledge and

experience, patient characteristics, team dynamics, workload, time pressures and interruptions, as well as IT related problems such as the overriding of alerts.

2.3. Primary care settings

Most research into patient safety over the last fifteen to twenty years has focused upon hospital settings (Esmail, 2013), particularly in the wake of systemic failures at the Mid-Staffordshire NHS Foundation Trust (Francis, 2013). In contrast there has been much less research that has focused upon patient safety in primary care (Esmail, 2103). Reasons for this have included that primary care is considered *"a low technology environment where safety is not a problem"* (Esmail, 2013 p.4). This focus in research upon secondary care has also been evident in the USA where, ten years on from "*To Err is Human"* (Kohn et al., 1999), Wynia and Classen (2011) found that major gaps persist in the literature and that little data outside of studies of hospital settings is available. In trying to build a bridge between policy and the safety activities of health care professionals Kirk et al. (2007) developed a patient safety framework which took into consideration the *"multidimensional and dynamic nature of culture"* (p.318) within primary care organisations.

The challenges for medication safety in primary care are broadly twofold. Firstly, in the UK, the particularly heterogeneous nature of primary care may well make it difficult for patient safety initiatives to be implemented. General practices operate as independent businesses with their own organisational culture and dynamic which may well lead to marked differences in working practices and structure (Esmail, 2013). Secondly, there is a huge volume of medicines prescribed in primary care. With ever ageing populations and the likely associated increases in multimorbidity and

polypharmacy, the numbers of patients receiving prescription medicines in primary care is likely to rise along with the numbers of patients on complex medications regimens (Payne et al., 2014).

2.3.1. Patient safety in primary care

There are many different characteristics of general practices across primary care, with practices in different geographical locations, of varying size, with different personnel and different patient demographics. Furthermore, clinical work in primary care is considered as variable, individual and unpredictable (Daker-White et al., 2015). All of this may mean that such differences and variations in primary care may well impact differently upon interventions in such a way that "*organisational arrangement may not be conducive to top down initiatives*" (Esmail, 2013, p.4). Furthermore, primary care provides individualised care across a very broad range of health and illness, which can lead to further variation in practices (Wilson and Sheikh, 2002).

Key issues for primary care patient safety involve diagnosis, prescribing, communication and organisational change (Wilson and Sheikh, 2002). However, the increasing demands placed upon primary care may impact upon patient safety. A recent meta-ethnography of forty eight qualitative studies of patient safety in primary care found that the reasons why patient safety problems occurred in primary care was attributed to *"the behaviour or characteristics of patients and health care staff, or in organisational or systemic failures"* (Daker-White et al., 2015, p.28). In this review the empirical findings were synthesized into different subsets which included: patients' perceptions of patient safety; professional perspectives; medication safety; systems and organisations; and the primary/secondary care interface. Across a

number of these subsets there were issues of workload and lack of resources which potentially could lead to poor patient safety outcomes. Such issues were considered to be systemically derived from the nature of primary care, which includes busy general practices and healthcare workers caught between bureaucratic healthcare systems, organisational structures and the needs of patients (Daker-White et al., 2015). Moreover, primary care is dynamically evolving and adapting to changes in work practices, the introduction of technology and the shifting of workload from secondary to primary care, all of which has the potential to impact upon organisations' culture (NPSA, 2006). A further complication is that patient safety in primary care is conceptualised differently by patients than by policy makers and healthcare professionals with patients seeing patient safety as fluid, contestable and negotiable as opposed to framed by measurable guidelines, standard rules and checklists (Rhodes et al., 2015). In this study by Rhodes it was found that what patients considered to be safe was not necessarily aligned with the perceptions of health professionals.

2.3.1.1. Nature of prescribing in primary care

Many people are treated in NHS-funded primary care each day, with almost one million people visiting their GP (NPSA, 2006). In the UK over a billion prescription items are issued each year (HSCIC, 2015) which equates to nearly three million a day. This figure has increased annually, with a 55.2% increase since 2004 (HSCIC, 2015). The mean average number of individual prescription items issued per person in 2014 was 19.6 (HSCIC, 2015). With such high volumes of drugs prescribed in primary care, a wide variety of drugs prescribed, the prevalence of repeat prescribing and the increased burden and complexity of complex medication regimens, there is an

increased likelihood that prescribing or monitoring errors can occur (Avery et al., 2013; Alldred et al., 2008; Avery et al., 2002; Dean et al., 2000).

The UK has an ageing population and, as a consequence, increasing numbers of primary care patients have multimorbidity (that is, two or more long-term conditions). Four out of five people aged 75 and over take a prescription medicine and 26% are taking four or more (Naylor et al., 2015; DoH, 2001). A recent study of an adult population in Scotland found that the number of patients prescribed five or more drugs had doubled to more than a fifth of the population studied over a fifteen year period to 2010, and three times as many were in receipt of ten or more drugs (Guthrie et al., 2015). It is important to distinguish between appropriate polypharmacy and inappropriate or problematic polypharmacy since for some patients the taking of multiple medications is necessary and beneficial (Molokia and Majeed, 2017; The Scottish Government, 2015; Duerden et al., 2013). However complex inappropriate polypharmacy is likely to present further issues for patients concerning the potential for side effects, drug-drug interactions and from new treatments that might be prescribed to counter those interactions (Guthrie et al., 2015; Gallacher et al., 2014; Guthrie et al., 2012). Prescribing ten or more medicines for an individual is seen as likely to increase risk with a 50% greater chance of an error occurring (Avery et al., 2013). Polypharmacy has therefore been associated with more hazardous prescribing (Avery et al., 2013; Guthrie et al., 2011). In particular, prescribers face issues concerning the optimisation of medicines for this group of patients and ensuring that these patients are carefully monitored (Guthrie et al., 2015; Wallace et al., 2015). This would also require adequate histories to be taken when prescribing new treatments, since many in this group might be additionally using over-the-counter medicines,

may have been prescribed medicines they are in fact no longer taking and have existing treatments with which the drugs may interact (DoH, 2004). Guthrie and colleagues found that drug-drug interactions increased in excess of two fold over a fifteen year period, with more than one in eight patients dispensed potentially hazardous combinations of drugs (Guthrie et al., 2015). Polypharmacy also presents issues with effective collaboration and communication between health professionals across both primary and secondary care. For instance it has been suggested that specialists, with a specific disease focus, who are treating patients with multimorbidity for single conditions, need to consider the effect of their treatment recommendations in light of the patient's other conditions (Guthrie et al., 2012). In such circumstances collaboration and communication between generalist doctors in primary care and specialist clinicians in secondary care could provide greater continuity of care and avoid medication discrepancies at discharge from hospital (Molokia and Majeed, 2017; Wallace et al., 2015; Duerden et al., 2013).

Many patients with long term conditions will be in receipt of repeat prescribing. Many medicines for this group of patients are prescribed by specialists in secondary care, with repeats initiated in primary care, creating further complexity and the need for effective communication (Wallace et al., 2015; Payne et al., 2014; Duerden et al., 2013). It is thought that 75% of all drugs prescribed in primary care are through repeat prescription, and that half of all patients are on a course of repeat medication (Swinglehurst et al., 2011; De Smet and Dautzenberg, 2004; Avery et al., 2002). Repeat prescribing has been associated with ADEs and drug interaction including the interaction of prescribed medicines with over-the counter medications (Bond et al., 2000). Furthermore, repeat prescribing creates further likelihood of error (Avery et

al., 2002). Repeat prescribing makes the monitoring of patients more difficult because the reauthorisation of the prescriptions may well involve a number of different administrative staff in addition to clinicians, meaning patients may continue to receive medications they no longer require (DoH, 2004). Older patients with many different medicines on repeat prescription have been seen to be at greater risk of hazardous prescribing (Stocks et al., 2015).

A recent ethnographic study of three general practices in Scotland (Grant et al., 2013a) undertook participant observations, semi-structured interviews and reviewed policy documents to understand the influences upon GP's prescribing decisions. General practices were ranked against nine established indicators of prescribing quality which had regularly been used by the local health board. Grant and colleagues found that there were two different prescribing decisions amongst these practices. “Macro” decisions were collective and based upon population-level data and reflected broader policy and research evidence which was used by the practices to formulate their prescribing policies. “Micro” decisions considered the views and preferences of individual patients at the point of consultation. All practices used micro prescribing decisions but for those practices ranked as high quality, they importantly converted the macro decisions that informed policy into practice at the micro level. Practices that only made micro decisions based on patient circumstances were ranked lower. This study highlighted the complex nature of prescribing decisions in primary care and how these two types of prescribing decision-making worked interdependently. Grant and colleagues concluded that:

"Current prescribing quality initiatives that target macro prescribing pay insufficient attention to the delivery and implementation of best research evidence at the micro prescribing level" (Grant et al., 2013a, p.12).

2.4. Information technology in healthcare and medicines optimisation

IT has been seen as a potential solution to the problem of medication errors. Interventions for medicines optimisation have often been focused upon IT and therefore IT systems may well provide benefits for medication safety. A review of the literature on IT in health care, conducted in the USA, found that healthcare IT was associated predominantly with improvements in care (Buntin et al., 2011). The role of clinical pharmacists in medicines optimisation in primary care is becoming increasingly important and interventions have utilised pharmacists alongside IT (Sadler et al; 2014; Avery et al., 2012b; Cresswell et al., 2012a).

Digital health technologies include a huge range of different tools including clinical health technologies, telemedicine and telehealth technologies to assist self-care in patients, social media and mobile applications for the dissemination of health information or health promotion, training systems for health professionals and health informatics systems to assist with healthcare delivery (Lupton, 2015; Llewellyn et al., 2014). The focus, in the discussion and review of the literature that follows, is upon health informatics systems and more specifically those systems that can provide health professionals with easy access to patient information in order to monitor clinical activity, easily transfer patient information or inform clinical decisions either at population or individual level. Whilst the specific and primary focus of this PhD is on healthcare IT systems for medicines optimisation, there are many common factors

in the implementation and adoption of IT for differing purposes across healthcare settings. Therefore the following sections discuss a breadth of different healthcare IT systems.

Initially section 2.4.1 explores the policy background to the implementation of such IT initiatives in healthcare. Section 2.4.2 goes on to discuss the various types of IT systems that have been tried before and the evidence for their effectiveness. The key issues and implications for the implementation and adoption of those IT systems are then discussed in section 2.4.3.

2.4.1. Policy background to information technology in healthcare

IT has been seen as key to the modernisation and transformation of healthcare (Klecun, 2016). One of the recommendations of *"An Organisation with a Memory"* (DoH, 2000) was that the contribution of information systems should be maximised. The launch of the National Programme for Information Technology (NPfIT) in 2002 set out a determination from central government to improve NHS services. A major focus of this was the National Care Record Service which was designed to implement a national shared electronic patient record (Petrakaki et al., 2016; Greenhalgh et al., 2014; Waterson, 2014; Cresswell et al., 2012b; Sheikh et al., 2011). NHS Connecting for Health was launched in 2005 to deliver NPfIT. However after successive delays and problems, the NPfIT and its associated technologies was abandoned in 2011 (Greenhalgh et al., 2014; National Audit Office, 2011) Connecting for Health similarly ceased to exist in 2013.

In terms of medication safety, the Department of Health (DoH) recommendations in the report *"Building a Safer NHS for Patients: Improving Medication Safety"* (DoH,

2004) suggested that steps to safer prescribing may include the implementation of effective IT systems particularly those systems that might highlight and give warnings to medical staff of prescription errors. Highlighting several case studies this report stated that;

> *"The case examples of serious errors contained in this report virtually all involve failure to receive, recognise, interpret or act on drug or patient data. Well-designed and implemented information management solutions therefore offer great potential to reduce the scope for mistakes and lapses."* (DoH, 2004, p.15)

Similar recommendations from The King's Fund report *"Polypharmacy and Medicines Optimisation: Making it Safe and Sound"* (Duerden et al., 2013) have suggested there is a need to develop systems that optimise the use of medicines and that this might include improved electronic decision support for clinicians. The King's Fund report *"Transforming our Health Care System"* (Naylor et al., 2015) recommended the use of IT and decision-support tools to assist health professionals with medicines management activities. In the study of prescribing and monitoring errors, that was part of a larger investigation funded by the General Medical Council, Avery and colleagues also concluded that there was *"considerable scope for GP computer systems to help reduce many [...] prescribing errors"* (Avery et al., 2013 p.9).

Despite these policy directives, the implementation of large scale IT within the NHS has been beset by failures (Greenhalgh et al., 2014). It has been suggested that there has been too great a focus upon top down implementation, too little regard for local

characteristics and an emphasis upon the behavioural characteristics of the users of the technology rather than how the technology might work within existing workplace cultural, social and organisational settings (Greenhalgh et al., 2014; Clegg and Shepherd, 2007). In particular NPfIT was criticised for being too technology-centred and failing to understand the organisational contexts in which implementation was going to take place (Clegg and Shepherd, 2007).

2.4.2. Interventions using information technology

Healthcare IT systems have been designed to assist healthcare workers in a number of tasks for example providing accurate, easily accessible and transferable patient records, making clinical decisions, transferring information accurately and monitoring clinical activity in a group of patients or professionals and providing audit and feedback upon clinical decisions. A variety of different IT systems have been utilised in these ways as detailed below.

- **Electronic Health Record (EHR) systems,** (Also variously called Electronic Medical Record (EMR) Electronic Patient Record (EPR) and Electronic Patient Medical Records (ePMR)) have been deemed to provide more streamlined access to patient records in real time, are more easily searchable and avoid errors (Sheikh et al., 2011). Dowding et al., (2015) undertook non-participant observation and semi-structured interviews with nursing staff using an EHR at two hospitals in the USA. They found that the use of the EHR improved communication, ease of access to information and the safety of medicine administration processes.

- **Clinical decision support (CDS)** systems are commonly used to provide support for decision making by clinicians in both secondary and primary care. Silsand and Ellingsen define CDS systems as; *"providing clinicians with computer-generated clinical knowledge and patient-related information, intelligently filtered or presented at appropriate times to enhance patient care."* (2016, p.994)
- **Computerized Physician Order Entry (CPOE)** systems can provide information for clinicians and ensure that the correct drugs and dosage for individual patients are prescribed (Agrawal, 2009). CPOE systems have been suggested to reduce medication errors (Lainer et al., 2013, Agrawal, 2009), to decrease medication turnaround time and to reduce the need for pharmacist intervention (Davis et al., 2013).
- **Electronic Patient Medication and Administration Records (EPMAR)** systems are designed to eliminate errors in prescribing, dispensing and administration of medicines in hospitals (Burgin et al., 2014).
- **Electronic Prescription Service (EPS) and the Electronic Prescription Service Release Two (EPS2)** are designed to reduce error and improve efficiency through the electronic transfer of a prescription (Harvey et al., 2014; Petrakaki et al., 2014).
- **Electronic Audit and Feedback (EAandF) "dashboard" systems.** Within primary care, IT systems can provide linked data from patient records in the GP clinical systems. These can provide GPs with information on prescribing and drug interaction alerts, and in addition can link that data to monitoring tests such as renal, blood pressure and glycaemic results that will be present in the

patient record (Avery et al., 2013). Whilst not specifically a dashboard system, the pharmacist-led information technology intervention for medication errors (PINCER) trial showed the value of IT in drawing from the patient record system so that patients with inadequate monitoring of their medicines could be reviewed (Avery et al., 2012b) Similarly a data driven quality improvement intervention (DQIP), using prescribing safety indicators, was found to reduce potentially hazardous prescribing of non-steroidal anti-inflammatory drugs and antiplatelets in primary care (Grant et al., 2017b; Dreischulte et al., 2016; Dreischulte et al., 2012; Grant et al., 2013a). The DQIP intervention used a web-based informatics tool to identify patients at risk of harm by extracting data from existing GP clinical record systems. This can then allow practices to monitor high risk prescribing, identify those patients requiring review and record decisions about those reviews (Dreischulte et al., 2016; Dreischulte et al., 2012). It has been suggested that primary care CDS systems that can provide information to facilitate a clinical decision about a specific patient and broader audit and feedback systems such as the DQIP and PINCER "dashboard" systems that provide population level information could be combined (Brown et al., 2015).

2.4.3. Sociotechnical approaches and key issues in the implementation and adoption of information technology in healthcare

In recent years it has been seen that the use of IT in healthcare is not merely about the technology but about the social processes which are implicated in the implementation and adoption of IT (Greenhalgh et al, 2014; Bijker and Pinch, 2012; Agrawal, 2009). Such sociotechnical approaches have considered how technology is used by people in

social and organisational contexts (Bijker and Pinch, 2012; Clegg and Shepherd, 2007; Berg, 2001) Sociotechnical approaches developed from sociological studies of technology use in the mid 1980s particularly with the development of Actor-Network Theory (ANT) (Latour 1994; Callon 1986) that considered human and non-human actors as operating within networks, and with social constructionist understandings of the use of technology (Bijker and Pinch , 2012). Within psychology, informatics and organisational studies sociotechnical approaches have been used to describe technology as one part of a system (Waterson, 2009; Orlikowski, 2000). These sociotechnical approaches are discussed in more detail in Chapter Four.

Many healthcare IT systems have been utilised within hospital settings. In primary care, where the bulk of prescribing takes place and where many people with polypharmacy will receive treatment (Guthrie et al., 2015), IT systems have also been seen as potentially beneficial. However, the use of IT in healthcare has not been without problems (Magrabi et al., 2016; Sheikh et al., 2011; Agrawal, 2009). The next three sections explore some key issues for the implementation and adoption of healthcare IT. The first of these sections considers the importance of organisational and social contexts in the implementation and adoption of healthcare IT. The next two sections consider how user acceptance and workflow issues have been seen to be implicated in the successes or failures of healthcare IT interventions.

2.4.3.1. The importance of organisational context

Within healthcare the factors that might influence the safe delivery of care range from institutional context and work environment through to team and individual staff factors (Vincent et al., 1998). Healthcare contexts are open systems that are a

complex entanglement of networks and associations that are collective and collaborative (Green, 2014). A complex system has been defined as;

> *"a collection of individual agents with freedom to act in ways that are not always totally predictable, and whose actions are interconnected so that one agent's actions changes the context for other agents"* (Pslek and Greenhalgh, 2001, p.625).

Healthcare interventions, including those utilising IT, are implemented within a messy, complex, social and organisational world (Cresswell and Sheikh, 2014). This complexity may involve cultural factors, existing work practices and clinical processes that may be dependent themselves upon social, organisational and cultural norms and broader professional, political and economic contexts. This might involve rule-based norms provided by the autonomy and authority of clinicians, professional guidelines and the rules and guidelines issued by policy makers. Furthermore complex systems involve different individuals working within the social norms created by the organisational make-up of the workplace. Therefore professional hierarchies, the interplay of different workforces and different groups of healthcare professionals, and the individual behaviours, experience, attitudes and dispositions of the different users utilising the technology may impact upon how, if at all, it is used (Guarrera et al., 2013; Agrawal, 2009; Clegg and Shepherd, 2007; Berg, 2001; Pslek and Greenhalgh, 2001; Clegg, 2000). In a Norwegian study, Silsand and Ellingsen (2016) found that the process of designing and implementing a CDS tool for assisting clinicians in supporting geriatric patient pathways was implicated by the complex collaborative nature of healthcare. The use of the tool was dependent upon complex organisational, political and behavioural factors and established workplace routines.

Failures of implementation with the NHS National Care Record were attributed to this being seen as a technology project that was implemented from the top down rather than taking into account the provisions of those professionals who would use it and local organisational contexts (Petrakaki et al., 2016; Greenhalgh et al., 2014; Klecun, 2014; Waterson, 2014; Sheikh et al., 2011; Cresswell et al., 2012b; Robertson et al., 2010).

In primary care, the implementation of information technology to general practices will be laden with values not only associated with the interrelation of the technology and the users who operate it but with working practices, organisational values and wider environmental issues associated with policy and national guidelines. Thus as Clegg and Shepherd state;

> *"Organizations are made up of people with various competencies and motivations, pursuing sets of goals, organized in structures and roles, using certain working practices and job designs, working within local, professional and national cultures, and using various technological systems."* (2007, p.214)

This might particularly be pertinent when IT can be seen to constrain behaviour through the application of rules and guidelines derived from evidence-based medicine (Aarts, 2015). Information technology interventions in healthcare have importantly been seen to disrupt existing workflow and require adaptations. Such adaptations, compensations and tailoring of systems suggest a dynamic where system implementation involves utilisation and unintended consequences as systems are interpreted and adapted by users to fit existing work practices and work practices are

developed and changed to adapt to the new system (Peiris et al., 2011, Timmermans and Berg, 2003; Clegg, 2000; Berg, 1997a).

2.4.3.2. User acceptance: Design issues, alert management and cognitive overload.

Where IT systems have not proved successful this has been ascribed to limited user acceptance and use which might be related to the design of the technology or the ways in which it is implemented and adopted. IT systems may be utilised in ways unintended by developers. It has been seen that EPS systems in secondary care settings can lead to new risks to patient safety due to poorly designed systems that make use difficult, create confusion over the mixture of paper and electronic systems or distractions and interruptions to workflow (Redwood et al., 2011). Whilst these systems have been valued by hospital pharmacists they have been linked to unintended changes to work practices. Harvey et al. (2014) undertook non-participant observations and interviews with eight users of EPS2. Pharmacists were found to utilise the system in ways not intended in order to overcome problems with design. It was felt that these issues had occurred because those who were to use the system had not had a role in the development of it (Harvey et al., 2014). In a review of EMR and EHR use, Zahabi et al., (2015) identified four common problems with EHR systems: poor display of information; cognitive overload; navigation issues; and workflow issues. GP computer systems have been seen to provide accurate and relevant information, provide audit trails and enable accurate transfer of information between different systems; however it has been suggested that systems need to be designed so that they are used effectively (Avery et al., 2007).

Systems have been seen to create problems with alert fatigue and failing to tailor alerts so they are not ignored by health professionals. ePMR systems have been seen as effective at alerting users to potential problems but have been inconsistent with alert management for example by giving false alerts (Ojeleye et al., 2013). CPOE systems have been seen to introduce errors (Schiff et al., 2015; Swinglehurst et al., 2011). In a study of error reports across a seven year period in the USA, Schiff and colleagues found that 6.1% of 1 million reported errors were related to CPOE. Many of these errors were further seen as preventable. Systems were seen to over alert physicians and lead to alert fatigue where alerts were then ignored (Schiff et al., 2015). A recent narrative review of eight studies of CPOE and CDS systems concluded that whilst these systems reduced errors there was no evidence they lowered the prevalence of ADEs (Ranji et al., 2014). This was possibly related to warnings not being tailored and consequent alert fatigue. Prescribing errors reduced as users became more experienced with systems, and organisations gained experience in tailoring systems to their needs. Similarly Lainer and colleagues (2013) reviewed ten randomised controlled trials (RCT) of CPOE and CDS systems designed to support medicines optimisation in primary care and concluded that the combining of these two systems was effective at reducing medication errors. However, only half the RCTs revealed a reduction in medication errors (Lainer et al., 2013). Lainer and colleagues also suggested that CDS systems were more effective if they provided targeted and limited information rather than overwhelming clinicians with excessive information leading to alert fatigue.

2.4.3.3. Disruption and failures to integrate with collaborative workflow

The implementation and adoption of IT in healthcare has encountered difficulties because of failures to align with pre-existing work practices including collaboration and communication between different health professionals. Buntin and colleagues (2011) in reviewing 154 studies (predominantly from the USA), found ten studies with overall negative findings. These studies suggested that health IT systems could introduce problems that could impact upon safety. This was ascribed to poor planning of the implementation of the IT and work flow problems, including collaborations and interactions between different health professionals and the altering of responsibilities. Similarly, a study from the Netherlands found that two-way communication between health professionals was not properly facilitated by a CPOE system and as a consequence clinicians, nursing staff and pharmacists reverted to former ways of communicating (Niazkhani et al., 2008). A CPOE system to support the prescribing and dispensing of medication in a paediatric tertiary care centre was seen to be ineffective in that mortality increased after the introduction of the system (Han et al., 2005). In a critique of this study, Greenhalgh and Swinglehurst suggested (2011) that this was because the system was not able to be overridden in an emergency, did not match collaborative work practices and that the electronic system in real-world use was in fact slower than written methods.

Changes in work practices were found in a qualitative hospital based study. Burgin et al. (2014) completed focus groups with pharmacists to discover their perceptions of using both EPR and EPMAR. They found that pharmacists reported that the IT systems changed the relationship and reduced the contact between the pharmacist and the patient. Workarounds adopted by healthcare professionals using an EHR system

were investigated by Ser et al. (2014). They found that factors leading to workarounds included poor integration of the system with workflow, user's competence, and local technical infrastructure.

Within primary care, IT systems have also been seen to introduce further errors related to the disruption to clinical workflow which could affect multiple patients (Magrabi et al., 2016). EPS has been seen to improve safety, time management and relationships between pharmacists and GP staff; however problems with the way the technology was used led to workarounds (Garfield et al., 2013). In a study of community pharmacies, poor utilisation of an EPS system was attributed to a failure to fit the technology with pharmacy workflow (Odukoya and Chui, 2013). Similarly in general practices, Hayward et al., (2013) found that decision support systems did not coincide with GP users prescribing workflow but interrupted it. The CDS system provided alerts but did so too late in the consultation after the GP had made decisions about the prescribing, discussed options for treatment with the patient and possibly given out instructions. As a consequence the system attempted to change decisions that already been made rather than working with the GP to assist with the decision making process. This increased the possibility of the alert being ignored. In a qualitative study of GPs working with a CDS system integrated with the GP clinical record system, Porat et al. (2017) found that whilst GPs valued the system in helping them with diagnosis, they had to adapt their consultation style. Porat and colleagues concluded that the system might require redesigning to accommodate the ways the GPs worked and GPs could benefit from training to use the system in a more patient-centred way. In an ethnographic study of repeat prescribing it was found that practice staff used workarounds to help each other's work and to troubleshoot problems,

changing and adapting what the software was designed to do (Swinglehurst et al., 2011). Repeat prescribing became, as such, a collaboration between doctors, staff and the technology. Such adaptation and transformation of systems was also found by Peiris et al. (2011) where a decision system tool was fashioned by GPs to make it more relevant to the clinical encounter.

2.5. The role of clinical pharmacists in primary care

In the "*General Practice Forward View"* NHS England (2016) committed £112 million to support an additional 1500 clinical pharmacists to be working in general practice by 2020/21. This will mean that one clinical pharmacist will be working in general practice per 30,000 patients and is in addition to the 490 pharmacist working in 650 practices in the pilot scheme started in 2015 (NHS England, 2016). Clinical pharmacists working in general practice are seen as a valuable resource for medicines related problems such as helping patients on multiple medications and providing a resource for general practice staff and patients (NHS England, 2016). Similar recommendations in Scotland have called for primary care to draw upon the skills of pharmacists and suggested that they should be independent prescribers (The Scottish Government, 2014; Wilson and Barber, 2013). The role of clinical pharmacy in general practice is an evolving one; it is however recognised that there is huge potential value in pharmacists working in general practice to improve patient safety, particularly with the rise in polypharmacy linked to increasing multimorbidity and an ageing population (Stone and Williams, 2015; Farrell et al., 2013; Tan et al., 2013). As Avery and colleagues stated:

> *"Pharmacists have a potentially important role to play in medication review in primary care [...] there is considerable scope for this role to develop, particularly in relation to the management of complex patients on multiple medications"* (Avery et al., 2012a, p.175).

The pharmacist-led information technology intervention for medication errors (PINCER) trial provided electronic feedback on hazardous prescribing combined with an educational intervention from pharmacists (Sadler et al., 2014; Avery et al., 2012b; Cresswell et al., 2012a; Avery et al., 2009). The combination of an IT intervention and educational outreach from the pharmacist working together with the general practice team was found to be more effective than simple feedback alone at reducing hazardous prescribing and inadequate monitoring (Avery et al., 2012b; Cresswell et al., 2012a). The use of root cause analysis and educational outreach by pharmacists in the PINCER trial was seen as valuable (Sadler et al., 2014). In the PINCER trial, pharmacists worked across many stages of the intervention including presenting the IT search results to practices, resolving problems, and working with the practice staff to find ways of reducing errors in the future. Pharmacists looked to work with particular clinicians and developed active involvement from the practice staff to discuss their current prescribing behaviours and look to make changes where needed. Sadler et al. (2014) concluded that the successful delivery of the PINCER intervention suggested that pharmacists could deliver other interventions in primary care for medication safety on a day-to-day basis such as helping GP practices identify particular failures in their systems for prescribing.

In addition to the PINCER trial, there are other examples in the literature of pharmacists working in general practice. In a recent review of 38 studies, Tan and

colleagues (2013) found that pharmacists working in general practice clinics were involved in a range of interventions including patient medication review. They concluded that clinical pharmacy had a beneficial effect upon the safety and quality of medicine use and particularly in chronic disease management. Nineteen studies showed positive effects as a result of pharmacist intervention with a number of improvements including blood pressure, glycosylated haemoglobin and cholesterol. Similarly in a study of general practice clinics in Australia, Tan and colleagues (2014) found that pharmacists in general practice could effectively resolve medicine related problems. Stone and Williams (2015) discussed the role of a practice prescriber pharmacist in working particularly with patients with multimorbidity. They found that the pharmacist could help the GPs by freeing them up for other patients, have a positive impact in resolving medicine issues and be a valuable resource for patients. In a Canadian study, Farrell and colleagues (2013) found that pharmacists working in interdisciplinary teams with primary health care adopted different approaches. One approach was to be supportive of clinicians and responding to requests from them. The other was to be more patient centred delivering direct patient care and dealing with system level medicine optimisation issues.

2.6. Summary of Chapter Two

Patient safety has been of increasing importance to researchers, policymakers and practitioners over the last 20 years. Much patient safety research has taken place in secondary care and primary care has been assumed to be a low tech environment which may explain why it is an under researched area (Esmail, 2013). However, the very complex and changing nature of primary care makes patient safety an important consideration (Wilson and Sheikh, 2002). Taking into account the possibility of

prescribing hazards, the prevalence of ADEs and the complexity associated with increasing numbers of patients with complex medication regimens, there is a need for careful attention to be given to prescribing. Furthermore reviewing patients who are on regular medicines for long term conditions and undertaking blood test monitoring of drugs and their potential side effects is considered essential for effective and safe medicines management (Avery et al., 2002).

Information technology has been seen as a potential solution to ensure medication optimisation across both secondary and primary care. However many interventions utilising IT healthcare have not been successful and these failures have been ascribed to top-down implementation and a failure to take into account local organisational, social and cultural contexts. The implementation of IT interventions in primary care to improve medication safety has been aided by the role of pharmacists. The expanding role of clinical pharmacy in primary care has potential to impact positively on medicines optimisation. Sociotechnical approaches to the evaluation of IT in healthcare have sought to understand the relationships between users of the technology, the technology itself and the contextual background, including work practices, socio-organisational structures.

CHAPTER THREE: THE PROGRAMME OF WORK

3.1. Rationale

With high volumes of prescribing within primary care and increasingly complex medicines regimens there is increasing potential for errors and adverse drug events to occur. Information technology is being used more and more widely by health professionals to help them with their work. The use of information technology in primary care has the potential to have an impact upon medication safety. Information technology systems are increasingly being developed to provide feedback and alerts of prescribing activity and potentially hazardous prescribing. The use and utilisation of such systems including how they are implemented and adopted within the complexity of healthcare settings in primary care requires careful evaluation. Such evaluation needs to take into consideration not merely the success or failure of such systems but the ways they are used and the specific mechanisms that might lead to greater utilisation and as a consequence improved medication safety. In doing so, the evaluation needs to consider the social, cultural and organisational factors that might impact upon the implementation of interventions into healthcare systems and and their adoption by a range of stakeholders.

It is important to distinguish between implementation and adoption. Recent guidance on the evaluation of complex interventions has considered implementation as the delivery of an intervention and the ways in which it is enacted upon. This would also include the qualitative nature of the intervention, the intervention design and its fidelity and reach (Moore et al., 2015). Adoption is considered as how interventions

work in everyday use, their utilisation in practice and the mechanisms that are involved in the impact of the intervention (Moore et al., 2015; Peters et al., 2013).

3.2. Overview of the study design

The programme of work presented in this PhD focuses on evaluating two specific intervention that have been implemented to improve medicines optimisation in primary care. (The location of the first intervention is masked here since it was a small Clinical Commissioning Group (CCG) area with specific characteristics and revealing the location could potentially reveal the identities of individual participants).

Part One

A qualitative evaluation of the use of an electronic audit and feedback (EAandF) system in one CCG in the south of England.

Part Two

A qualitative process evaluation of a complex pharmacist-led EAandF information technology intervention in general practices in Salford, Greater Manchester.

The findings for Part One are detailed in Chapters Five and Six. The findings for Part Two are detailed in chapter Seven.

3.3. The two interventions

3.3.1. Eclipse Live: An Electronic Audit and Feedback (EAandF) system

Eclipse Live is an IT system that is able to provide audit and feedback on prescribing activity which can facilitate the identification of patients at risk of ADEs, such as those receiving inappropriate combinations of drugs or not appropriately monitored. It is separately accessed from the GP clinical system and comprises a web-based user interface which securely extracts patient data from general practice patient records. It allows different stakeholders access to real time anonymized patient data including medical histories of diagnoses, prescribed medications and test results. Eclipse Live also allows clinicians and managers in health localities to audit prescribing practices across general practices and make comparisons against national guidelines. Patients can have access to the system through a patient passport which would allow them to view their medications and test results.

3.3.2. The Salford Medication Safety Dashboard (SMASH)

The Salford Medication Safety Dashboard (SMASH) involved of a novel electronic medication safety dashboard providing audit and feedback, combined with a clinical pharmacist linked to the practice. The dashboard was designed to identify and feedback instances of potentially hazardous prescribing in a way which facilitates optimal use in practice. The dashboard interrogated electronic health records using a set of thirteen medication safety indicators. The resulting information, in both aggregated form and as lists of patients, was available to the pharmacist and to clinicians in the practice. The clinical pharmacist worked with the practice to facilitate appropriate action in response to the highlighting of high risk prescribing and to improve the quality of prescribing.

The intervention was conducted in 43 general practices across Salford (Greater Manchester) CCG.

3.4. Aim of this PhD

The aim of this PhD was to explore, evaluate and understand the socio-technical processes involved in the implementation, adoption and use of two different information technology interventions for medicines optimisation in primary care.

3.5. Objectives

- To undertake interviews and focus groups with a range of stakeholders in order to explore the complex social interactions, relationships and collaborations within the general practices where the interventions were implemented and determine the ways the systems were used;
- To critically analyse, using strong structuration theory, transcripts of interviews and focus groups in order to understand the ways in which external, internal and technological structures were implicated in the implementation, adoption and use of the electronic audit and feedback tool;
- To undertake a realist evaluation in order to explore how the electronic audit and feedback tool intervention worked, for whom, in what circumstances;
- To use normalisation process theory to understand how a novel pharmacist-led intervention was implemented and embedded into everyday practice and how if at all, work practice was adapted, changed and sustained.

CHAPTER FOUR: METHODOLOGY AND THEORETICAL CONSIDERATIONS

4.1. Preface

The following chapter describes the methodological approach taken for this PhD. In doing so, the theoretical background to this methodology is explored. The main theories associated with the implementation of IT in healthcare are discussed in Section 4.2. It is felt that it is important to explore and place what is understood about the role of technology and how technology has been seen to operate within social and organisational contexts. Section 4.3 discusses approaches to the evaluation of health care IT focusing upon three theoretical standpoints that inform the empirical work that follows in Chapters Five, Six and Seven: Strong structuration theory (SST); realist evaluation and normalisation process theory (NPT). The chapter concludes with an overview of qualitative ontology and paradigms of enquiry leading to a brief outline of the qualitative methods used in the empirical work.

4.2. Theoretical background: How the programme of work is informed by sociotechnical theory and understandings

A growing number of scholars from health informatics, sociology, organisational science, psychology and related disciplines have considered interventions involving IT, including healthcare IT, from a sociotechnical perspective, which takes into account the cultural, professional, social and organisational values and norms that are embedded within the technology, the ways the technology is used and the social worlds into which it is implemented (Greenhalgh et al., 2014; Petrakaki et al., 2014;

Bijker and Pinch, 2012; Orlikowski and Scott, 2008; Clegg and Shepherd 2007; Berg, 2001; Clegg, 2000). These sociotechnical approaches treat the working practices of people using the IT and the IT itself as inter-related parts of the same system (Clegg and Shepherd 2007; Clegg, 2000). Such an approach would take into consideration the complex nature of healthcare and the organisational aspects of the workplaces in which interventions are implemented (Clegg, 2000). Thus IT interventions, from a sociotechnical point of view, are seen to be dependent upon such interplays of technology, social and organisational processes because they involve open systems that are dependent on context variability and require adaptation to work flow (Oroviogoicoechea and Watson, 2009). In this way, IT therefore requires an interaction between the technology and users (Aarts, 2016; Greenhalgh et al., 2014; Petrakaki et al., 2016; Berg, 2003).

A sociotechnical approach would be critical of IT interventions that are imposed from the top down, whereby the technology is seen as the most important factor in the intervention and implementation is technology-led (Clegg, 2000). It has been suggested that there is a need to move from technology-driven models of implementation to one:

> *"[...] which refocuses attention or adoption as an ongoing working out between staff and technology which thinks of technology as an enabler of improved care rather than an end in itself."* (Sheikh et al., 2011, p.11)

Sociotechnical approaches are more likely to consider local practices and organisational norms, and embed technology into these existing work structures complementing what is already in place. Top-down implementation that has ignored

local needs has been seen to lead to workarounds, resistance from some users and the devising of ways to compensate for time constraints in using the technology and the perceived limitations of it (Waterson, 2014; Cresswell et al., 2013). Systems developed with local users have been seen to be more successfully implemented (Barber et al., 2007). In this way, the technology works for those using it rather than being an addition to their existing work.

One key question discussed across disciplines is whether, and to what extent, technology impacts upon social processes or whether social processes impact upon technology. A further question would be to understand how that occurs. In answering those questions it is important to focus upon how we understand technology itself. Previous research has broadly divided understandings of technology use in organisations in two different distinct ways (Orlikowski and Scott, 2008). Firstly, technology, humans and organisations have been seen as discrete entities with stable and essential properties and characteristics. In this view, it is the impact, moderation or mediation of those discrete variables upon a system that leads to change. Technology in this way would be seen as having fixed material properties. Secondly technology, humans and organisations are viewed as broadly interdependent that shape each other through interactive social processes and affordances (Orlikowski and Scott, 2008; Hutchby, 2001).

4.2.1. Technology use in organisations: approaches, theories and models

Timmermans and Berg (2003) grouped IT healthcare literature into three perspectives: technological determinism (technology is seen to shape societal relations); social essentialism (medical technology is a neutral tool shaped by society

and social processes); and technology-in-practice (in which technology is one actor in a changing and fluid social system to be studied in practice) (Timmermans and Berg 2003; Callon and Law 1982). Greenhalgh et al. (2014) use a more nuanced and developed classification describing four groups of models: behaviourist models (drawing from cognitive psychology and focusing on individual user characteristics and behaviours in the interaction with technology); multi-level models (organisational factors as well as individual ones are considered); interactional models (technology use as part of a system); sociological models (drawing on theories that understand technology use as happening within networks or influenced by social structures). Whilst these are both useful typologies they are not wholly satisfactory. Timmermans and Berg (2003) do not allow for individual determinism where people shape the technology nor does it distinguish between interaction and interdependence. Greenhalgh and colleagues' typology (2014), whilst extremely useful, focuses heavily in the first instance upon multi-level and deterministic models. Therefore, drawing upon both typologies, for the purposes of this PhD, the theoretical understandings of the use of technology are grouped under three broad types: deterministic, interactional and interdependent.

4.2.1.1. Deterministic theories and models

Deterministic models and theories focus on linear causality and the impacts of technology upon individuals and organisations (Orlikowski and Scott, 2008). Technology based models are deterministic in that they focus primarily upon the how the design of technology and ergonomics will lead to better and wider use. In this way, technology is tested in terms of its usability and the social impact of that technology and utilisation and any failures are attributed to design issues with the

technology (Hutchby, 2001). In what have been seen as people determined theories, models that focus upon people using the technology see technology and human agency as discrete entities in which technology is seen as an independent variable and therefore attribute any failure or success to users abilities (Orlikowski and Scott, 2008; Markus, 1983). Social and cognitive psychology have contributed to the understanding of the implementation of technology but have tended to do so from individual perspectives where use is determined by people's attributes such as skills, attitude and perceptions of the technology (Cresswell et al., 2011).

In models such as the Technology Acceptance Model (Holden and Karsh, 2010; Davis, 1989) technology is uncontested and stable, and people (often individuals) are characterized as the problem; the technology is seen as a positive and any issues with its use are attributed to the skills, motivations, aspirations, training or adaptability of users (Greenhalgh et al., 2014; Cresswell et al., 2011). Acceptance of the technology will be optimised through the training of users, training incentives and user participation. User resistance to technology is considered to be an individual deficit that could be overcome with rewards and sanctions (Greenhalgh et al., 2014). Thus interventions, drawing upon cognitive psychology or social psychology, are based upon changing the behaviour of individuals.

Such deterministic approaches see technology, people and organisations as separate things which operate at multiple levels but do not do so through interaction in the way that they are not dynamically changing and adapting each other (Greenhalgh et al., 2014). Whilst extensions of the technology acceptance model have made reference to the differences in users and contexts they have still been seen to focus upon the design of technology and its usability (Greenhalgh et al., 2014).

4.2.1.2. Interactional theories and models

A further focus has been to consider organisational processes such as work flow, organisational culture, rules and regulations and social norms. Clegg (2000) set out sociotechnical principles for system design in which he stated that:

> *"A sociotechnical perspective explicitly embraces the idea that all aspects of a system are interconnected, that none should take logical precedence over the other."* (p.465)

Clegg (2000) argued against technological deterministic approaches, and called for design (and by extension) implementation to be guided by sociotechnical principles that took into consideration users of systems, the ways in which user might interpret, amend or adjust systems, the organisational contexts in which the technology is implemented and wider social and political processes.

Such interactional approaches would be more likely to consider the systems and contexts in which technology was implemented (Berg, 2001). However some models within this approach, whilst acknowledging that technology is implemented in complex organisational contexts, still consider technology, humans and organisations as separate discrete entities and potentially measurable variables. Furthermore technology can still be perceived as a solution against organisational barriers and resistance. Interactional models and theories do however see technology as part of a complex process and see technology use as being dependent upon a dynamic interplay of the social and the technological (Orlikowski and Scott, 2008). In this way, humans, organisations and technology are considered as systems that can shape each other through ongoing interaction (Cresswell and Sheikh, 2014). Such

understandings have been broadly labelled sociotechnical since they incorporate the ways in which technology is implemented in social contexts and understandings of how technology implementation is shaped by cultural, historical and economic circumstances (Creswell et al., 2011).

A cognitive engineering approach (Hettinger et al., 2017; Porat et al., 2017) combines elements from cognitive psychology and human factors to understand the ways technology is designed and evaluated. It focuses upon individual characteristics such as skills and knowledge but does also look at work factors and the complexities of the contexts within which technology is implemented. In this way it understands work places as non-linear and complex. Similarly Waterson (2009) outlines a sociotechnical systems approach which would understand the use of technology as an interacting combination of people, materials and tools. A system is seen to comprise of many parts and in order to understand it needs to be broken down into those parts. Such an approach emphasises the connectivity between the dynamic interrelated parts of the system. It has typically focused upon mismatches between the ways the technology might formally be used and what actually happens informally amongst users at local levels (Berg, 2001). It has also looked at how technology is embedded in social relationships and networks. As a consequence, much emphasis has been placed on work practices and workarounds in the use, usability and interpretation of technology (Leonardi, 2012). As Greenhalgh et al. (2014), drawing upon the work of Brown and Dugoid (2002), have stated:

> *"The detail of how we use, adapt, repair or work around technologies is learned through membership of a community of practice: this social infrastructure, local and specific to an organisation, strongly influences*

whether or not and how particular technologies work in particular conditions of use." (Greenhalgh et al., 2014, p.7)

Interactional models and theories do vary in their understanding of how the dynamic interactions of technology, human agency and social contexts might play out. However system approaches whilst they consider implementation and adoption in light of the interplay and relationships between technology, human agency and social contexts they still regard these as separate entities and unique homogenous elements.

4.2.1.3. Interdependent theories and models

Theories that consider people and technology *"to be related through a reciprocal and emergent process of interaction"* (Orlikowski and Scott, 2008 p.439) see the products and outcomes of the relationships between the social, human agency and technology as interdependent and not simply as the interactions between homogenous unique elements. Such sociotechnical approaches, based upon interdependencies, have emphasised that technology, human agents and contextual factors operate in multiple ways and that people and technology are dynamically connected (Greenhalgh et al., 2016). These interdependent theories and models include those informed by social constructivism, sociomateriality, as proposed by the organisation studies literature, and theories drawn from sociology including structuration theory, actor network theory and strong structuration theory. As Greenhalgh and Swinglehurst have suggested:

"*Technologies shape human action because they make some actions possible [...] some impossible [...] some unimaginable or socially difficult. Technologies are shaped by human action because humans configure them, disable certain*

functionality, decide who may be trained to use them and allocate differential access privileges to different people." (Greenhalgh and Swinglehurst, 2011, p.3)

As Klecun suggests as such interdependent theories do not understand technology as *"a static external change trigger*" (2016 p.66) into a social and human context and thus in that way as a variable, the adoption of which can be measured by the effect of inputting the new technology upon human behaviour in organisational settings. Rather interdependent theoretical approaches move away from determining how technology is adopted, resisted or adapted by individuals or groups to a focus upon the social systems and social processes that include the use of the technology (Leonardi, 2012). This approach sees technological use and adoption as social practices that may involve negotiation and conflict. The introduction of technology occurs within the contexts of social norms, organisational culture, rules, roles and conventions. As a result, new rules and conventions may evolve in a dynamic interaction between the technology, users and contexts that then changes social processes and practices. In this way technology is part of a "*dynamic, networked and potentially unstable system made up of multiple interacting stakeholders*" (Greenhalgh et al., 2016, p.2) within which agents, contexts and technology are contingent upon each other and implementation can be seen as an ongoing dynamic social process (Klecun, 2016). As Greenhalgh and Stones suggest this is a recursive position in which technology and contexts are understood as technologies-in-use:

"...researchers do not study technologies and contexts separately but technologies-in-use. In other words, context is not simply a given external milieu whose properties can be measured [...] rather context is a complex and

emergent outcome of the interplay between social actors and their organisational and technological infrastructures generated and regenerated when actors use technologies in particular ways for particular purposes." (Greenhalgh and Stones, 2010, p.1286)

Greenhalgh et al. (2016) refer to these as fourth generation approaches. Though Greenhalgh and colleagues applied this to assistive living technologies it seems perfectly applicable to other IT in healthcare. They highlight five characteristics of such approaches:

- **Interdisciplinary**: The research takes a multi-disciplinary approach drawing upon social science, nursing and allied health professions, organisational and management studies, informatics and biomedicine.
- **Embracing complexity**: The research seeks to explore organisational social and policy contexts and *"views people and technologies as dynamic, networked and potentially unstable systems made up of multiple interacting stakeholders."* (Greenhalgh et al., 2016, p.2)
- **Recursive:** The research understand**s** the decisions and actions that human agents make as being influenced by wider contexts at organisation (meso) or societal level (macro).
- **Ecological:** The research does not accept that local solutions are transferable or can be generalised to other contexts and situations. This approach favours local collaboratively grown solutions that have been co-produced by end-users.

- **Critical**: interventions involve potential conflicts and power struggles between different stakeholders.

4.2.1.3.1. Constructivist theories, sociomateriality and affordances

Constructivist approaches understand technology as existing through social interactions and thus being socially shaped and reshaped rather than being clearly defined products (Hutchby, 2001; Bijker and Pinch, 2012). Much of the work here does not focus on the technology but is:

> *"...about the complex relationships between technologies and the social and interactional circumstances in which they exist and through which they attain their meaning."* (Hutchby, 2001, p.442)

Constructivist approaches reject realist assumptions of an objective world in which technology has inherent properties. Where interactional approaches emphasize the importance of social processes and organisational contexts it has been suggested that they have paid less attention to the nature of the technology being implemented (Leonardi, 2012). Leonardi suggests that to fully understand the material properties of technology it is important to consider materiality. Materiality is the combination of the form and material of the technology which remains stable over time. The fixed nature of the materiality enables a focus upon the social contexts in which it is used - any differences can then be assigned to those social contexts and processes (Leonardi, 2012). However it has been suggested that material objects are fluid and forever changing and evolving (Orlikowski, 2000). Leonardi does not disagree with this but argues that it is a question of timescale and that the materiality of an object is stabilized for a period of time when different users might interact with it. Furthermore

the way those users interact with the technology defines what features of the technology are important to them. That interaction with the technology can be different for different users; different features of the technology are important to different people (Leonardi, 2012). Focusing upon the term materiality is seen as important as Leonardi states:

> *"The term materiality seems useful if it can direct attention to the properties intrinsic to technological artifacts and remind researchers that those properties are fixed, at least for some short period of time, and encourage them to explore not only how they become fixed [...] but also how their fixedness affects what people deem to be important to their work."* (2012, p.32)

Sociomateriality is seen as a merging of this materiality with social activities, norms and institutions (Leonardi, 2012). Sociomateriality understands technology as having material properties that affect their use by making certain actions possible and others less possible. For Leonardi and others, sociomateriality thus proposes that "*all materiality [...] is social"* (2012, p.32) because it emerges through social processes. This is related to theories of affordances that see technology as being constituted of the possibilities for the actions it makes available (Petrakaki et al., 2016; Petrakaki et al., 2014a; Kallinikos et al., 2012; Zammuto et al., 2007; Hutchby, 2001; Gibson, 1977). Hutchby (2001) drawing on the work of Gibson (1977), proposed an interactional perspective, and a middle way between the two opposing positions of realism and constructivism, that sees technology as offering *"affordances"* in which technology *"can be understood as artefacts which may be both shaped by and shaping of the practices humans use in interaction with, around and through them"* (Hutchby, 2001, p.444). In this way, technology possesses affordances that offer

possibilities for actions by human agents or constrain the way the technology can be used. The attributes of technology that can be considered affordances pre-exist what human agents do to the technology but are only realised through the interaction with those human agents (Hutchby, 2001). Hutchby particular placed emphasis upon interactions which will be governed by rules and conventions about the use of technology. Furthermore the affordances do not govern the ways in which the technology can be used but offer a *"range of possibilities"* (Hutchby, 2001, p.450). Technology is thus not a causal facilitator for change but merely one element of a complex process that allows for organisational and social changes through such interaction (Greenhalgh et al., 2016; Zammuto et al., 2007). Petrakaki and colleagues suggest that these affordances do not pre-exist in the technology in question or within human agents but are *"cultivated and nurtured within a broader cultural-institutional context"* (Petrakaki et al., 2016 p.206). Drawing upon the work of Zammuto et al. (2007), Petrakaki et al. (2016) argue that *"technology is part of the changing fabric of organisation"* and thus it is the interconnection between IT and organisational systems that allows for change to happen (2016, p.208).

4.2.1.3.2. Structuration theory

Structuration theory, as proposed by Giddens (1984), understands agency (human actions and choices) and structures (social norms, political and economic institutions) as operating as a duality where neither can exist independently of the other. Structures can be found in social norms, rights and obligations, and in rules and resources (Stones, 2005). Such structures place constraints and provide resources for the possibilities for action. Agents draw upon their knowledge of their environment and structural properties. In this way, social structures are continually developed from

agents interpretations, meanings and choices and their consequent actions within social practice (Rodiguez and Pozzebon, 2011; Jones and Karsten 2008). Consequently, structures are then shaped and re-shaped by those agents in social processes. As Hardcastle comments in structuration theory, the messiness of human life is because *"a person's 'reality', 'truth' and 'knowledge' are constantly being structured and restructured, produced and reproduced"* (2005, p.225). In applying structuration theory to technology it has been suggested that technology is therefore "*only active through human action*" (Rodiguez and Pozzebon, 2011, p.2).

4.2.1.3.3. Actor network theory

Latour (1994) suggested that to understand the use of technology, it was necessary to move beyond the notion of a dualism between human and non-human actors where such actors are considered separate entities. Drawing from philosophy and sociology, Latour argues that both human and non-human actors can occur within a system. The process in which technology is used is one that both the human and the technology shapes (Latour, 1994). This draws away from understandings of technology as merely tools for human agents to operate. Latour argues for a rejection of a subject-object dichotomy, where human and non-human actors are separate, for a subject-object symmetry in which action is co-produced by both human and non-human actors. Goals of action are achieved through what Latour calls the *"technical mediation"* of actors, in which both the properties of the human and the properties of the technology shape outcomes (Latour, 1994 p.29). What the technology *is* will shape what the human actor does and how the human actor *uses* that technology will shape what is achieved. In this way, action is not simply a property of human beings but the combination of human and non-human agents - what Latour refers to as associations.

Furthermore, these associations, and the consequent actions, are woven into a complex social order, since objects are part of institutions. Consequently there are groups of association and sequences of interrelated actions that might lead to outcomes. (Latour gives the example of a plane; neither planes nor people fly, but a complex series of interactions and associations involving an array of human and non-human actors, leads to people being able to travel across continents).

Actor Network Theory (ANT) (Latour, 1994; Callon, 1986) is built upon this theoretical background. One main consideration of actor network is that objects can have agency (Cresswell et al., 2010). In this way technologies and human actors are equal within a network. In ANT, it is the positions of people and things within a network that are considered important (Greenhalgh and Stones, 2010). Actor-networks are dynamic but can become stabilised and aligned by a process of translation in which problems are defined and solutions found by engaging others and defining roles and practices (Greenhalgh and Stones, 2010).

4.3. Evaluation

4.3.1. The evaluation of complex interventions

IT interventions in healthcare have been considered as complex social programmes (Green, 2014; Walshe, 2007). Such interventions may be considered as heterogeneous across the domains of context, process and content; they are complex programmes delivered in complex settings involving complex processes (Walshe, 2007). It has been suggested that considering this, such programmes should be evaluated on why and how they work, how the intervention might be implemented and to explore contextual factors (Walshe, 2007; Oakley et al., 2006). An evaluation needs to take

into account the contexts and circumstances in which interventions might work and to unmask "*the fine nuances that characterize this complexity*" (Cresswell et al., 2010, p.1). In doing so, an evaluation might not simply look for whether the intervention is successful or not, but at the reasons for the successes or failures, the circumstances in which the intervention might work, the unintended consequences and for whom it is most successful. It has been suggested that *"intervention is a social interaction, and its effects are realised not just through linear causal pathways, but through interactive exchanges in the system"* (Green, 2014, p. 250). Therefore, evaluation of healthcare IT based on outcomes alone might be seen to ignore these contextual factors and the processes involved in its implementation and adoption and over simplify the social settings in which technology might be implemented (Greenhalgh and Swinglehurst, 2011). Furthermore, the experimental approach may miss meaning, power and other social factors that might influence whether technology is used or not (Greenhalgh and Swinglehurst, 2011). An evaluation might therefore consider methodologies that uncover how change might occur and how practices are routinized into practice (Swinglehurst et al., 2010).

It has been argued that the knowledge used in the process of evaluation is in itself a contestable area, with potential contests concerning the autonomy and authority of that knowledge (May and Ellis, 2001). Evaluation itself may be viewed as a social practice (Greenhalgh and Russell, 2010). It might therefore be that the *"assumptions, methods and study designs of experimental science...may be ill-suited to the particular challenges of evaluating ehealth programs"* (Greenhalgh and Russell, 2010, p. 2). Furthermore simply adding in social elements to the evaluation (often as facilitators or barriers) misses the importance and complexities of the relationships

and networks in a system and evaluative research has to be open to such complexity (Green, 2014).

4.3.2. Strong structuration theory

Strong structuration theory (SST) is built upon both Giddens's structuration theory (Giddens, 1984) and Actor Network Theory (Callon, 1986; Latour, 1994). It has been proposed as a way of examining the sociotechnical aspects of healthcare IT implementation (Stones, 2005). SST understands external structures being built through social positions, practices and networks of social relationships (Greenhalgh and Stones, 2010; Greenhalgh et al., 2014). These could include hierarchical relationships between employers and employees, professional roles, local and national guidelines, governance measures, regulations, professional codes of practice, as well as local work practices and interactions among groups of stakeholders (Greenhalgh and Stones, 2010; Stones, 2005). Internal structures inform how one is supposed to act in specific situations in the here and now, and are considered in two ways. Firstly, they are found in the skills, dispositions, ambitions, attitudes, values, past experiences of actors and ways of viewing the world of actors; Secondly as the actors' knowledge of rules, conventions, obligations and social norms, which may involve partial understandings and past experiences (Hinder and Greenhalgh, 2012; Greenhalgh and Stones, 2010; Stones, 2005).

Greenhalgh and Stones (2010) added a further technological dimension to SST. In contrast to Latour's (1994) theoretical position, discussed above, which sees technology as working in symmetry with human agents, SST sees humans and technology as separate entities that may act in different ways (Greenhalgh and Stones

2010; Stones 2005). Similarly to constructivist and other interdependent theories discussed previously in section 4.2.1.3.1 above, SST understands technology as incorporating procedures, codes, material properties and standards that can enable or constrain use and therefore seen as shaping human actions by making certain actions possible (Greenhalgh and Swinglehurst, 2011; Hutchby, 2001). A further expansion on SST is given in Chapter Five.

4.3.3. Realism and realistic evaluation

Realism understands reality as existing outside people's representations of it (Astbury and Leeuw, 2010; Sayer, 2000). Actions only make sense if they are considered as part of social reality with the associated rules, social norms and regulations (Marchal et al., 2012; Pawson and Tilley, 1997). Within social reality people are limited in their choices, since the social conditions that confront them are not wholly of their making. In this way, social actions are an interplay of structure and agency; of human action understood *"in terms of its location within different layers of social reality"* (Pawson and Tilley, 1997, p.64). Whilst human action is constrained by structures, adaptation of those structures is possible and new structures are developed. In this way *"structures shape actions, which shape structure, which shape actions and so on*" (Dalkin et al., 2015, p.2).

Realist evaluation draws upon realist explanations of the causes of change as a way of unpicking the internal features of a social programme that may then explain the ways that inputs to a programme may lead to outcomes (Dalkin et al., 2015; Pawson and Tilley, 1997). Within a realist evaluation it is the inner workings of the evaluation that are of importance (Kazi, 2003). As Porter and O'Halloran (2011) state;

> *"Its adoption of a realist ontology and particularly of the generative causality, means that realistic evaluation is able to provide, as it claims, a more realistic conception of the factors involved in the introduction and maintenance of complex healthcare interventions than experimental methods that confine themselves to artificial notions of unilinear causality. In turn, this means that realistic evaluation can shed light on the processes essential to the success and sustainability of those interventions; processes that remain in the dark to the experimental scientist."* (p.26)

Realist evaluation considers outcomes as the result of particular responses derived from the choices made by humans and actors (Pawson and Tilley, 1997). These are considered as "mechanisms". Mechanisms are not part of the programme activity but a human response to its introduction into a specific context which will then lead to an outcome (Dalkin et al., 2015; Astbury and Leeuw, 2010; Weiss, 1997) and are therefore considered in terms of agency and structure and social embeddedness (Marchal, et al., 2012). Realist evaluation asserts that interventions always and only work through such mechanisms and thus the identifying of them is crucial to the approach. In this way *"we take a step from asking whether a program works to understanding what it is about a program which makes it work"* (Pawson and Tilley, 1997). Mechanisms are often considered as hidden or underlying that requires realist evaluation to go beneath the surface of an intervention (Astbury and Leeuw 2010; Pawson, 2008; Pawson and Tilley, 1997). Mechanisms are not considered as additional variables but as an account of how the intervention might work (Astbury and Leeuw 2010; Pawson and Tilley, 1997).

Mechanisms are considered to be sensitive to particular contexts and can be only activated under specific circumstances (Astbury and Leeuw, 2010). Contexts are the set of pre-existing conditions in which the programme or intervention may be introduced. They are the prevailing social conditions that go beyond the spatial, physical, historical and temporal conditions of an intervention, to include the sets of rules, regulations, social norms, cultural values, relationships, power dynamics, policy and politics which might set limitations upon the programme (Pawson and Tilley, 1997).

The process of a realist evaluation is to identify responses from actors to specific elements of the program ("mechanism") and in what circumstances that mechanism might be triggered ("contexts"). Such groups of contexts and the mechanisms lead to outcome(s) (Pawson and Tilley, 1997). Realist evaluation considers these groupings of contexts, mechanisms and outcomes as theory which can then be further tested. Realist evaluation thus provides a detailed understanding of what makes an intervention work, rather than a simple cause-and-effect relationship between an intervention and its outcome(s). The latter can indicate whether or not an intervention has worked, but provides limited insights into how or why the identified outcomes were obtained (Dalkin et al., 2012; Byng et al., 2005; Pawson and Tilley, 1997). The logic of realist evaluation is thus summed up by Pawson and Tilley as:

> *"The basic task of social inquiry is to explain interesting, puzzling, socially significant regularities (R). Explanation takes the form of positing some underlying mechanism (M) which generates the regularity and thus consists of propositions about how the interplay between structure and agency has constituted the regularity. Within realist investigation there is also investigation*

> *of how the workings of such mechanisms are contingent and conditional, and thus only fired in particular, local historical or institutional contexts (C)"* (1997, p.71).

When a change occurs in a regularity it is said to be an outcome. A realist evaluation thus presents findings as an explanation in terms of a pattern of contexts, mechanisms and outcomes (so-called "CMO configurations").

A limited number of studies have utilised realist evaluation to evaluate how and why interventions might work across a variety of healthcare settings. Many of these studies have been of large, complex, multidisciplinary projects involving different groups of stakeholders. Realist evaluation is said to be particular suited to complex health systems (Marchal et al., 2012). These have included nursing (Oroviogoicoechea and Watson, 2009), mental health services (Wand et al., 2011; 2010; Byng et al., 2005; McEvoy, 2000), health service delivery through protocol based care (Rycroft-Malone et al., 2010), health service organisation (Sheaff et al., 2014; Greenhalgh et al., 2009), public health interventions such as smoking cessation (Douglas et al., 2010) and palliative care (Dalkin et al., 2012; Tolson et al., 2007). In a recent review, Marchal et al. (2012) found a diverse application of realist evaluation principles across eighteen different studies. Of these studies seven were of healthcare programmes, seven based on health service organization and four on clinical care.

The application of realist evaluation has been criticised for its different interpretations and lack of methodological guidance. Specifically there appears to be an inadequate definition as to what constitutes mechanisms and contexts (Dalkin et al., 2015; Marchal et al., 2012; Byng et al., 2005). Mechanisms are often considered as

constituent parts of the intervention programme rather than identified in different layers of social reality. In addition greater clarity is needed over what is a mechanism as opposed to a context (Marchal et al., 2012). It has been seen that it is difficult to make decisions on how processes might impact contextually or mechanistically (Dalkin et al., 2015). Byng and colleagues (2005), as previously discussed, found mechanisms or outcomes could provide interaction with other mechanism in a process of feedback. They also found it difficult to distinguish as mechanisms those that were more overt as against those that were more hidden. Realist evaluation will be revisited in Chapter Six, in relation to the empirical work in this PhD.

4.3.4. Normalisation process theory

Normalisation process theory (NPT) can highlight the ways in which an intervention is integrated and adopted into everyday practice. This has particular utility in examining how individuals and groups understand the intervention through processes of sense-making (Murray et al., 2010, May and Finch, 2009). NPT seeks to examine the social processes involved in implementation and the work people do to make the intervention happen in a process of adoption (May, 2013). Interventions are also understood as complex and multiple. NPT rejects implementation theory that over emphasizes either contexts or individual behaviours and focuses more upon the social processes of implementation. Contrary to SST, it rejects the concept that technology can be an actor in the network favouring a focus on what human agents accomplish in achieving the intervention; it is about what people actually do and how they work (May et al., 2009). It thus focuses upon the interactions between users and the intervention.

NPT is built upon four constructs: Coherence, Cognitive Participation, Collective Action and Reflexive Monitoring (May, 2013; Murray et al., 2010; May and Finch 2009.) These constructs demonstrate how an intervention is understood and operationalised in practice and sustained. Tables 4.1 and 4.2 give further explanation of these four constructs, the individual components that make up each construct and an explanation of those. Table 4.1 details the coherence and cognitive participation constructs which might be thought of as broadly the ways the intervention is implemented. Coherence is about the ways in which the intervention is defined, how people make sense of it and how they distinguish it from other practices. Coherence is conceptualised as four components; differentiation, communal specification, individual specification and internalization. These components are used to describe the work people do to understand how the intervention might a different set of practices, the work people do together to understand the intervention and to integrate it into a healthcare setting, the individual tasks involved in the intervention and what people do to attribute worth to that new practice. Cognitive Participation is about how people organise themselves and others through relational work to build a community of practice around the new intervention. This construct is conceptualised in four components; Initiation, enrolment, legitimation and activation. These components are used to describe the work people do to set up the new intervention. This involves working together to collectively contribute to the new ways of working that the intervention requires, the work people to validate their and others involvement in the intervention and how the actions and procedures that will be needed to sustain the intervention are defined. Table 4.2 details the Collective Action and Reflexive Monitoring constructs which might be thought of as broadly the ways in which the

intervention is adopted. Collective Action is how the intervention is operationalised and enacted in practice. Collective Action is described through four components: interactional workability, relational integration, skill set workability and contextual integration. These components describe the collective and interactional work that people do with each other in order to adopt the new intervention into practice. This might involve knowledge work to build confidence in the new practice, divisions of labour and allocation work including the tasks people do and how those tasks are related to their existing skill sets. The contextual integration component describes how existing and new resources including protocols and policies are managed in the adoption of the intervention. Reflexive Monitoring is how other individuals and groups evaluate and the intervention and look to sustain it Reflexive Monitoring is conceptualised through four components: systemization, communal appraisal, individual appraisal and reconfiguration. These are used to describe the work that participants do individually and collectively to evaluate and determine how effective the intervention is for them and for others and what the impact of the new practices is upon their own work. This may include attempts to modify the intervention. NPT will be revisited in Chapter Seven, in relation to the empirical work for this PhD.

Table 4.1 - Normalisation process theory: Constructs and components - Coherence and cognitive participation (May, 2013)

NPT Construct	Corresponding Component	Explanation
Coherence Sense-making work: understanding and conceptualisation of interventions and their work.	**1.1 Differentiation**	What people do to understand how a set of practices and their objects are different from each other. What they do to organise the differences.
	1.2 Communal Specification	People working together to build a shared understanding of the aims, objectives, and expected benefits of a set of practice. How a team works out how to integrate an innovation into their healthcare setting.
	1.3 Individual specification	Individuals' understanding of their specific tasks and responsibilities around a set of practices.
	1.4 Internalization	Work to understand the value, benefits and importance of a set of practices. The *w*ork people do to attribute worth to a new way of working.
Cognitive Participation Relational work that people do to build and sustain a community of practice around a new technology or complex intervention: notions of legitimation and buy-in, both in terms of the individuals involved and involving others.	**2.1 Initiation**	The work people do to drive forward the new or modified practice. Setting things up and working with others to make things happen.
	2.2 Enrolment	How participants organise and reorganise themselves and others in order to collectively contribute to the work involved in new practices. This is complex work that may involve rethinking individual and group relationships between people and things.
	2.3 Legitimation	The work ensuring that other participants believe it is right for them to be involved, and that they can make a valid contribution to it.
	2.4 Activation	The work of keeping the new practices in view and connecting them with the people who need to be doing them. Collectively defining the actions and procedures needed to sustain a practice and to stay involved.

Table 4.2 - Normalisation process theory: Constructs and components - Collective action and reflexive monitoring. (May, 2013)

NPT Construct	Corresponding Component	Explanation
Collective Action Operational work that people do to enact a set of practices: organisational resources, training, division of labour, confidence and expertise as well as the workability of the intervention in clinical interaction.	**3.1 Interactional workability**	The interactional work that people do with each other, with artefacts, and with other elements of a set of practices, when they seek to operationalise them in everyday settings. The impact the new practice has on interactions with each other and/or service users.
	3.2 Relational integration	The knowledge work that people do to build accountability and maintain confidence in a set of practices and in each other as they use them. The impact the innovation has on relationships between different groups of professionals e.g. trust, accountability and responsibility.
	3.3 Skill set workability	The allocation work that underpins the division of labour that is built up around a set of practices as they are operationalised in the real world. Who gets to do/did what, and how the tasks relate to their existing skill sets.
	3.4 Contextual integration	The resource work - managing a set of practices through the allocation of different kinds of resources and the execution of protocols, policies and procedures. Fit between the new practice and overall organisational context, including organisational goals, morale, leadership and distribution of resources (e.g. funding, policy, priorities).
Reflexive Monitoring Appraising and monitoring implementation work. The appraisal work that people do to assess and understand the ways that a new set of practices affect them and others around them.	**4.1 Systematization**	The work of collecting information in a variety of ways to determine how effective and useful the new practice is for them and for others.
	4.2 Communal appraisal	Participants work together - sometimes in formal collaboratives, sometimes in informal groups to evaluate the worth of a set of practices.
	4.3 Individual appraisal	Individuals appraising the new practice in relation to their own work; the impact it has on their tasks. Actions through which individuals express their personal relationship with the innovation.
	4.4 Reconfiguration	The appraisal work by individuals or groups which may lead to attempts to redefine procedures or modify practices - and even to change the shape of the innovation itself.

4.4. Methodology

4.4.1. Qualitative research

This research adopts a qualitative approach. The specific methods used are semi-structured interviews and focus groups. It has been suggested that, *"the purpose of qualitative research is to gain an appreciation of how people's experiences are shaped by their subjective and socio-cultural perspective"* (Wilkinson et al., 2004 p.39). Qualitative methodology is concerned with meaning and the quality and texture of experience rather than the identification of variables (Willig, 2001). Qualitative research is particularly valuable for open complex systems (Willig, 2001) such as those that could be found in primary care health settings. Thus qualitative research explores variation, inconsistencies, multiple understandings and subjective accounts; what Giddens (1984) referred to as the *"messiness of social life"* (Hardcastle et al., 2005, p.225).

4.4.2. Ontological and epistemological considerations in qualitative research

Guba and Lincoln (1994) highlighted four competing paradigms of qualitative inquiry within the social sciences; positivism, post positivism, critical theory and constructivism. These paradigms are considered to be distinct in that they provide separate answers to three fundamental questions: the ontological question; the epistemological question; and the methodological question. Ontology is concerned with the nature of reality and what can therefore be known about that reality. Epistemology is concerned with knowledge and how that knowledge might be known (Guba and Lincoln, 1994). If the first of these considers that there is a real world the

second assumes that by some objective detachment that real world can be known. The third question that of methodology, concerns how a researcher might discover what they believe to be known. For Guba and Lincoln the four competing paradigms thus represent four different ontological, epistemological and methodological positions.

In ontological terms: positivism assumes an objective reality; post positivism would take a critical realist position of believing that a reality exists but that it is imperfectly discoverable and tending to subjectivity; critical theory assumes that reality has been shaped by social, cultural political factors over time into what we consider to be real structures; and for constructivist positions, realities are purely relative being multiple, fluid, context dependent and constructed by the social world (Guba and Lincoln, 1994). In epistemological terms: for positivism it is possible to know and measure the objective reality; post-positivist and critical realist positions would assume that the reality is measurable but since that is an imperfect reality it is not wholly possible to undercover truths; for critical theory's historical realist position knowledge is value dependent; and for constructionists or relativists knowledge is created in interaction. These ontological and epistemological positions inform methodological approaches which range from that of the empirical experiment for positivism, to constructionist understandings of the plurality of discourses and interactions (Guba and Lincoln 1994). Social constructionist or relativist positions such as this are drawn from the understanding that since the social world is determined by the limitations of contexts it would not be possible for a value free neutral perspective to be taken by researchers. Such approaches are at odds with experimental approaches because they ignore process and the socio-historical context (Murray and Chamberlain, 1999; Danziger, 1990).

In drawing from understandings of these paradigms (Greenhalgh and Swinglehurst, 2011; Greenhalgh and Russell, 2010; Murray and Chamberlain, 1999; Pawson and Tilley, 1997; Guba and Lincoln, 1994) Table 4.3 details the ontological position of each paradigm and how each position understands the nature of reality and knowledge. This table also details the methodological positions of these paradigms, the types of enquiry that methodology might lead to and further explains how these methodological positions might frame possible research questions in medication safety research.

Table 4.3 - Paradigms of enquiry as applied to medication safety research

Paradigm	**Positivism**	**Post-Positivism**	**Critical-Theory**	**Constructionist**
Ontology - nature of reality	A real and material world exists	Reality can be subjective	Real world is shaped by social and cultural factors	Reality is fluid, relative and context dependent
Epistemology - nature of knowledge	Knowledge is to be found in objective reality	Not wholly possible to uncover truths	Knowledge is value laden	Knowledge is created in interaction
Methodological positions	Experimental	Realist and Critical realist		Relativist
Types of enquiry	The objective testing of variables	Subjective social enquiry to uncover the interplay of structure and agency		Descriptive accounts of experiences - often focused upon language and interaction
Possible research in medication safety	Does an intervention reduce the prevalence of ADEs?	What are the circumstances and ways in which an intervention might reduce the prevalence of ADEs?		What are the experiences of patients who suffer an ADE?

The position that Guba and Lincoln (1994) take that suggests constructivist research is based upon relativist ontology has recently been challenged by Willig (2016). Willig suggests that constructivist approaches can be combined with realist views. Willig gives as an example Charmaz's approach to constructivist grounded theory which sees people's interpretations and subjective accounts operate within wider social processes (Charmaz, 2006). Willig (2016) suggests that subjective experience is, in constructivist terms informed by discourses and interaction but it is also subject to the constraints of a material world that makes some things possible and constrains other actions.

4.4.3. Qualitative methods used in this PhD

The research methods used throughout the three studies for this PhD draw upon this qualitative ontology and epistemology. Interviews and focus groups were used to capture the perceptions, attitudes and dispositions of users of the systems and of health professionals within practices where interventions were implemented and adopted. It was also hoped that this would reveal participants understandings and knowledge of the networks of relationships and the social structures related to the contexts in which the interventions were implemented. The intention was that these interviews and focus groups would provide thick description of the ways in which the interventions were operationalised in everyday practice. It has been suggested that focus groups may uncover variation in views and insights into conflict and consensus. Interviews have the potential to explore participants' understandings in depth (Moore, 2014).

These qualitative methods suited the theoretical methodological approaches utilised in this PhD. Whilst Pawson and Tilley (1997) suggest no specific methods in undertaking a realist evaluation it is probable that mechanisms, since they are hidden, will not be uncovered by quantitative methods alone and the use of semi-structured interviews and non-participant observation will be more likely to reveal what is previously unknown. Such qualitative methods have been adopted across the realist evaluation literature (Rycroft-Malone et al., 2010; Tolson et al., 2007; Byng et al., 2005). Similar SST has utilised a qualitative approach. Greenhalgh and colleagues undertook qualitative analysis of computer use in general practice through observations, field notes, interviews and background documents (Greenhalgh et al., 2014). NPT understands implementation *"as a social process of collective action"* (May, 2013, p.1). Since it is aiming to understand the process of implementation of interventions qualitative methodology is perfectly suited to this. NPT has been used in a range of qualitative research and complex interventions (McEvoy et al., 2014)

4.5. Chapter summary

Sociotechnical perspectives take into consideration the ways technology is used and the social worlds in which it is implemented. Theoretical understandings have seen the relationship between humans, objects and the social world in different ways. Technology, humans and organisations have been understood as discrete entities. Alternatively it has been suggested that people, technology and the social world are interdependent and shape each other. This chapter explored these different theoretical perspectives in a typology that understood theories as deterministic, interactional or interdependent. The evaluation of complex social programmes has drawn upon this theoretical background. SST, realist evaluation and NPT are three contrasting

evaluative and theoretical approaches that can be utilised in the evaluation of complex interventions in healthcare. Qualitative research methodology is a valuable approach for exploring the thick descriptive accounts of participants and in adopting these methods participants understandings and perceptions of the interventions and the contexts in which they were implemented would be uncovered.

CHAPTER FIVE: UNDERSTANDING THE IMPLEMENTATION AND ADOPTION OF AN INFORMATION TECHNOLOGY INTERVENTION TO SUPPORT MEDICINES OPTIMISATION IN PRIMARY CARE: QUALITATIVE STUDY USING STRONG STRUCTURATION THEORY

5.1. Preface

As described in Chapter Two, a high volume of medicines are prescribed to patients in primary care and the potential for medication errors mean there is a need for the monitoring of patients in receipt of prescription medication. Healthcare IT systems designed for medicines optimisation might offer ways to reduce medication errors. This chapter outlines the use of SST to examine the implementation and adoption of a new EAandF system, Eclipse Live (Eclipse Solutions) that was implemented in a primary care locality. This is the first of two studies of Eclipse Live the second of which, using the same data set, and utilising realist evaluation is outlined in Chapter Six.

Firstly, the aims and objectives of this study are detailed. The chapter then outlines the methods adopted in the study including a detailed explanation of the methodological approach that informed the study. This is followed by a presentation of the findings from the study and a brief summary. The implications of these findings for the implementation of IT in healthcare settings, for further research and for practice are discussed in Chapter Eight.

5.2. Aims and objectives of the study

The aim of this study was to explore, using strong structuration theory, the adoption and implementation of an electronic clinical audit and feedback tool to support medicines optimisation in primary care.

Objectives

Semi-structured interviews and focus groups were undertaken with a range of stakeholders in order to:

- Understand the ways in which external, internal and technological structures were implicated in the implementation, adoption and use of the EAandF system;
- Explore the complex social interactions within general practices where the intervention was implemented and the ways the system was used by a range of health professionals and GP staff;
- Understand how the contextual background, including work practices, socio-organisational structures and behaviours might influence the various ways in which the intervention was achieved in everyday use.

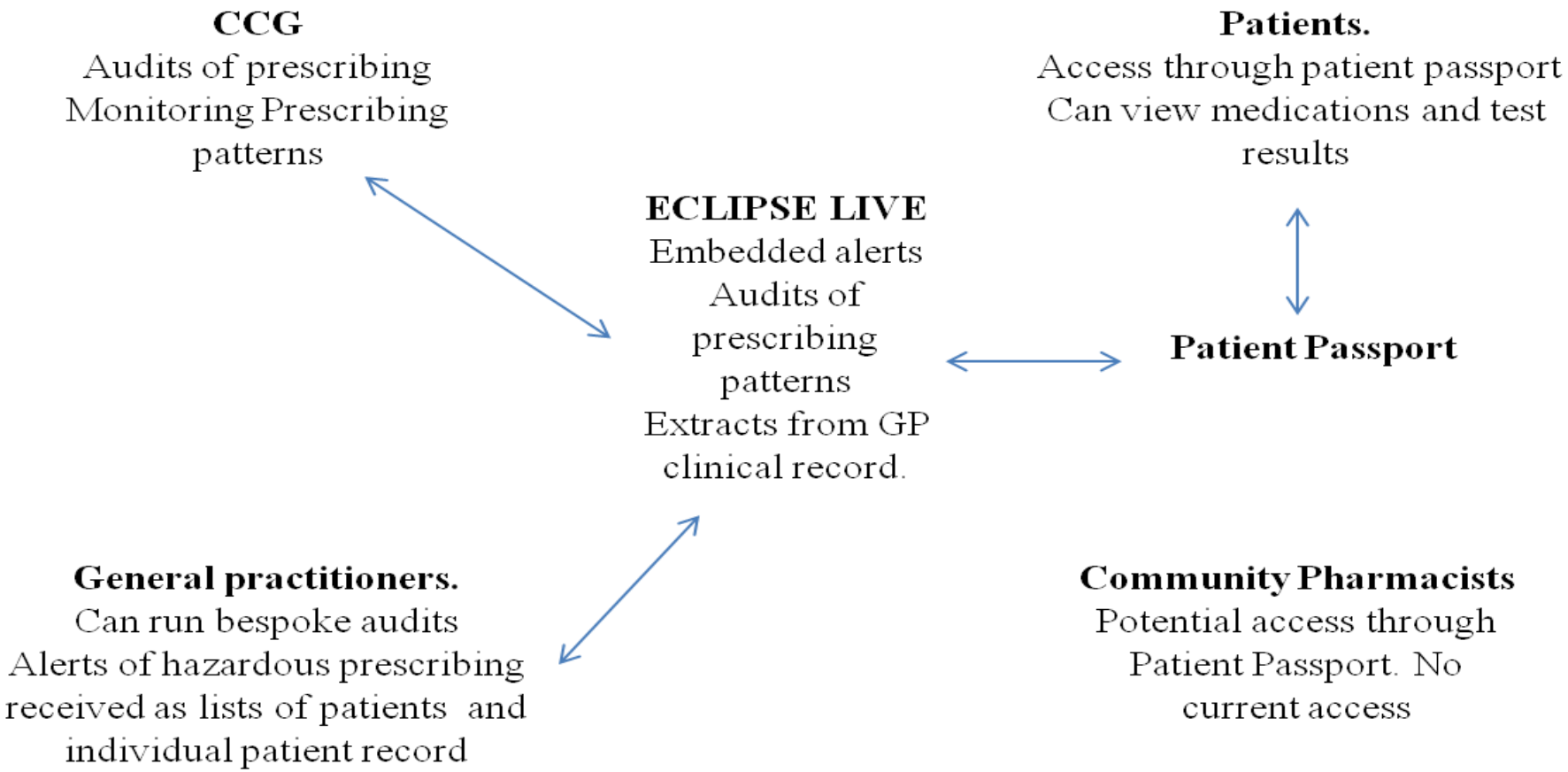
5.3. Methods

5.3.1. The Intervention: Eclipse Live

As described in Chapter Three Eclipse Live (Eclipse Solutions) is an electronic audit and feedback system that can facilitate the identification of instances of hazardous prescribing and thus patients at risk of ADEs. It is a secure web based system that draws an extract from the general practice clinical system of patient data including

diagnosis, recent test results, and prescribed medications. It therefore gives access to real-time clinical data. This data is available in a number of formats. Clinicians and managers are able to search populations at practice or CCG level of particular medications or particular groups of patients in order to audit and monitor prescribing behaviours across a locality and make comparison between practices or against national guidelines. In this way patterns of prescribing can be monitored and recommendations made to practices. Either centrally or at practice level bespoke searches of particular medications or patient groups can be made and used to identify instances of hazardous prescribing. The system also provides alerts based upon national or local guidelines. Clinicians area able to visualise these as red amber or yellow alerts with red as the most important or presenting the highest level of risk and yellow presenting the least severe. These alerts are presented in the system in three ways. Firstly as a list of different alerts relating to different prescribing or monitoring. Secondly each of those alerts can be looked at in more detail to see all those patients the alert is affecting and finally as individual patient records. Clinicians will be alerted through the system and can then respond as to how they have reviewed the patient. In addition to override the potential for clinicians not accessing the system alerts are emailed to a nominated email address at each practice. A small number of patients have access to their own record via a patient passport which provides them with a log in to a patient area of the system. At the time of the study the CCG was trialling access for a small number of patients with diabetes or hypertension. Community pharmacists have the potential for access to the system via this patient passport. A visual description of these users and uses of the system is detailed in figure 5.1.

Fig 5.1 Eclipse Live Users and Utilisation



5.3.2. Study design and setting

This study used a qualitative design. The study setting was a CCG in the South of England, which was chosen because it was an early adopter of Eclipse Live, the EAandF system, and had all general practices signed up to use the system. All practices used the same GP clinical IT system (In Practice Systems Vision). The CCG was relatively small in size (17 separate general practices, and approximately 140,000 patients). Medicines management activities at the CCG were undertaken by three clinical pharmacists (including participants CCGP1 and CCGP2) and two pharmacy technicians. Additionally one GP (participant GP1) operated as prescribing lead for the CCG. The sampling frame was people within the CCG's geographical area who represented the stakeholder groups. This included doctors, pharmacists, general practice managers and patients.

5.3.3. Recruitment and data collection

The author undertook a preliminary visit to the study site in July 2014 to discuss recruitment to the study with CCG managers, community pharmacists and patient groups. Individual participants were recruited on a purposive basis via the CCG, through community pharmacy networks, or through direct contact from the author via telephone or email to represent the different stakeholder groups and a range of different users of the system, as outlined in Table 5.1. Potential interview participants were identified by the CCG and then contacted directly by the author via telephone and email. The study site CCG acted as a gatekeeper and arranged for focus group participants for the patient and GP focus groups. This was deemed a practical way of recruiting participants considering the researchers' distance from the study site.

Table 5.1 – Eclipse Live EAandF system - Interview and focus group participants.

Participants	Role	How they used the EAandF system
Interviews		
GP1-INT	General Practitioner	In general practice and prescribing lead for the CCG. Worked with the medicines management team in supporting the adoption of the EAandF system by the CCG. Used the EAandF system to send alerts to GPs.
GP2	General Practitioner	In general practice and respiratory lead for the CCG. Utilised the EAandF system to undertake audits of prescribing relating to respiratory conditions.
GP3	General Practitioner	In general practice
CCGP1 (additional observation as part of interview)	CCG Pharmacist	Utilised the EAandF system to undertake medication reviews with care home patients
CCGP2	CCG Pharmacist	CCG medicines management team. Used the EAandF system to run audits centrally at the CCG and then alert clinicians locally
Focus group A - General Practitioners		
GP4	General Practitioner	In general practice
GP1-FG	General Practitioner	In practice and as prescribing lead for the CCG
Focus group B – Community Pharmacists		
CP1	Community Pharmacist	Aware of, but no access
CP2	Community Pharmacist	Aware of, but no access
CP3	Community Pharmacist	Aware of, but no access
CP4	Community Pharmacist	Aware of, but no access
Focus Group C – Patients		
Pt1	Patient	Access through patient passport
Pt2	Patient	Access through patient passport
Pt3	Patient	Access through patient passport
Pt4	Patient	Access through patient passport
Focus Group D - General practice managers		
GPM1	General Practice Manager	In general practice
GPM2	General Practice Manager	In general practice
GPM3	General Practice Manager	In general practice
GPM4	General Practice Manager	In general practice

Potential participants for the community pharmacists' focus group were identified by local community pharmacy networks and then contacted directly by the author. General practice managers were recruited directly by telephone and email to their place of work by the author.

Five semi-structured interviews (lasting between 20-50 minutes) were conducted with three GPs and two CCG pharmacists who were known to be using the system and had specific roles that required the use of the EAandF system, between August and December 2014. Four homogeneous focus groups (lasting between 57-112 minutes) were also conducted between September and December 2014, each with a specific group of stakeholders: GPs (2); community pharmacists (4); patients (4); and general practice managers (4). Whilst the first of these focus groups only included two participants and could have been considered a joint interview it was felt that their was enough interaction, discussion and debate between the participants for it to be considered a focus group. CCG Pharmacists, community pharmacists, patients and general practice managers were reimbursed with £20 shopping vouchers for their time. GPs received £40 shopping vouchers. These differences in reimbursement reflected in normal hourly pay for these groups. No repeat interviews were conducted, although one GP was both interviewed and participated in a focus group. Assigning each type of stakeholder to a specific group was felt to facilitate free, uninhibited and open discussion.

Data collection continued until saturation was reached and no new themes emerged from the interviews and focus groups. Four interviews were conducted by telephone and one at the CCG offices. The focus groups were conducted at the CCG offices or at a local hotel. The interviews were conducted by the author. The focus groups were

conducted by the author and co-facilitated by a research pharmacist (RH). All participants gave written informed consent to take part in the study, and for the interviews and focus groups to be audio recorded and transcribed verbatim. Ethical approval for the study was granted by the Preston NHS Research Ethics Committee (reference 14/NW/0113). Participant information sheets and consent forms are detailed in Appendices 1a and 1b.

5.3.4. Interview and focus group

Interviews and focus groups were both conducted in order to capture both individual perceptions of the use of the system and to understand and contextualise the collective use by stakeholder groups. The four telephone interviews helped to inform the focus groups with some broad, generalised and anonymized initial findings fed back to the focus group participants to initiate discussion. Topic guides for the interviews and focus groups (see Appendices 2 and 3) were developed by reading relevant literature examining the implementation of information technology in healthcare settings (Burgin et al., 2014; Hayward et al., 2013; Swinglehurst et al., 2011; Clegg, 2000; Berg, 1997). In the interviews and focus groups, the following areas were explored: experiences of working with the EAandF system, perceptions of the system, benefits and drawbacks, the organisational structures and roles required for its use and the circumstances under which it was considered most effective. Interviews and focus group audio recordings were transcribed verbatim by an approved university transcription service.

5.3.5. Methodological background: Strong structuration theory

SST has been proposed as a way of examining the sociotechnical aspects of healthcare IT implementation (Stones, 2005). It is based on Giddens' structuration theory, which proposed a relationship between structures (such as social norms, political and economic institutions) and agency (people's actions and choices) (Giddens 1984). According to Stones (2005), SST extends this structure-agency relationship to include the following elements:

- *External structures*, which are the physical, social or economic context in which action is contemplated. External structures are built through social positions, practices and networks of social relationships (Greenhalgh et al., 2014; Greenhalgh and Stones, 2010).These could include hierarchical relationships between employers and employees, professional roles, local and national guidelines, governance measures, regulations, professional codes of practice, as well as local work practices and interactions among groups of stakeholders (Greenhalgh and Stones, 2010; Stones, 2005).

- *Internal structures*, which are manifest in two ways. Firstly, as the skills, dispositions, ambitions, attitudes, values, past experiences of actors and ways of viewing the world; secondly, as the actors' knowledge of rules, conventions, obligations and social norms, which may involve partial understandings and past experiences. These inform how one is supposed to act in specific situations in the here and now, based upon the agents understanding of external structures (Hinder and Greenhalgh 2012; Greenhalgh and Stones, 2010; Stones, 2005).

- *Agency*, which is how and why agents draw upon internal structures to act in particular ways in specific situations (Greenhalgh and Stones, 2010).

- *Outcome*, which is the way agency impacts on external or internal structures and how they are maintained or changed (Greenhalgh and Stones, 2010).

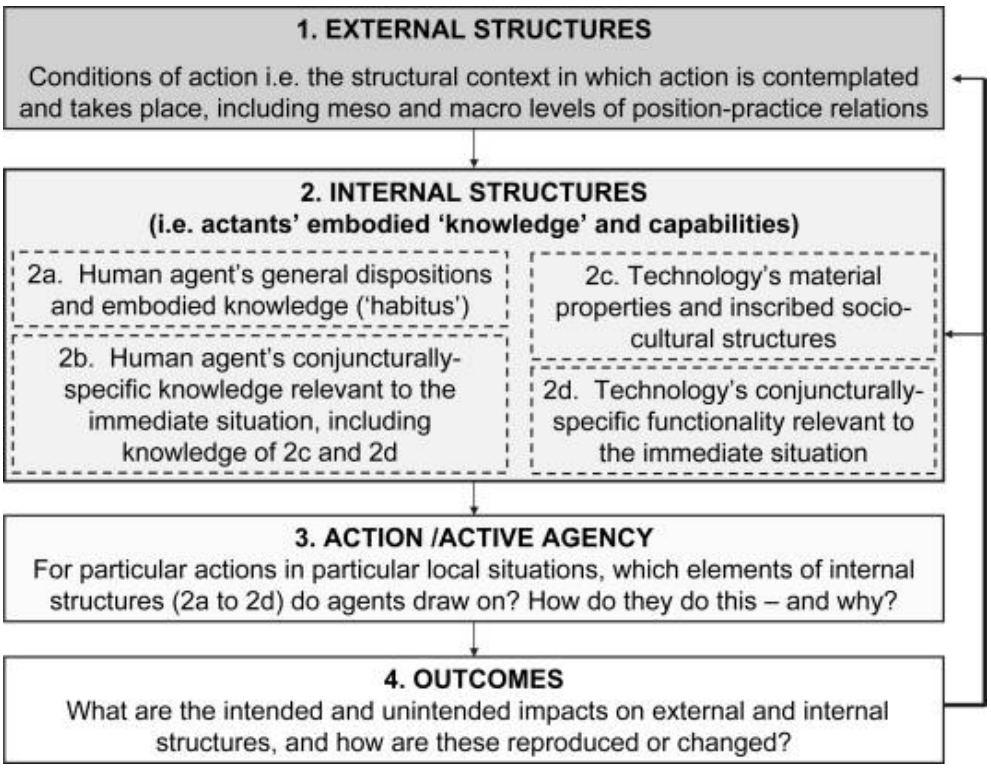


Figure 5.2. Strong structuration theory incorporating a technology dimension (adapted from Stones, 2005; Greenhalgh and Stones, 2010).

Stones and Greenhalgh (2010) further explained the role of technology in SST: rather than there being symmetry between technology and human actors, they are instead separate and may act in different ways (see Figure 5.2).Technology incorporates procedures, codes, material properties and standards that can enable or constrain use (Greenhalgh et al., 2014, Garfield et al., 2013; Hinder and Greenhalgh 2012; Greenhalgh and Stones, 2010). It is therefore seen as shaping human actions by

making certain actions possible (Greenhalgh et al., 2014). Previously it has been suggested that SST can illuminate the implementation and adoption of information technology by understanding how people *"take action with respect to technologies"*; in other words, what people actually do with the systems and to what effect (Greenhalgh et al., 2014). SST has been previously used to understand the ways a large scale healthcare IT intervention, designed to assist patients and General Practitioners (GPs) to book hospital outpatient appointments, was resisted or adopted by users (Greenhalgh et al., 2014).

For this study it was felt the use of SST would help to understand the ways in which users of the EAandF system drew upon their dispositions, attitudes, skills and ambitions and upon their knowledge and understanding of external structures to engage with the technology.

5.3.6. Analysis

The analysis was thematic, using a template approach (King, 2012). Template analysis involves the summarising of themes through a coding template. Often, template analysis begins with an *a priori* set of themes. New themes are then added, or existing themes revised, as data is iteratively analysed in a process of developing the template (King, 2012).

An *a priori* set of thematic codes based upon SST was developed from the literature (Greenhalgh et al., 2014; Greenhalgh and Stones 2010; Hardcastle et al., 2005; Stones 2005). These included: external structures such as national or local policies, guidelines and governance; interactions, including relationships, conflicts and communication; the internal structures of agents including dispositions, skills,

attitudes and cognitive demands; rules and contextuality including routines, social norms and regulations and technological structures including the social structures built into the technology. This set of codes was applied to the transcripts and documented using the QSR NVivo 10 application. The coding template was then modified through successive readings of the data. Coding and analysis of the data was lead by the author with regular discussions with DA and DP about codes and emerging themes in order to provide verification of these themes. The first and last iterations of this coding framework are detailed in appendices 4 and 5.

5.4. Findings

The ways in which the EAandF system was implemented and adopted were conceptualised in five broad thematic categories related to the external, internal and technological structures identified through SST. These were:

- Infrastructures and dispositions of users allows for information gathering;
- Technological structures and dispositions of actors: Perceptions of the system as new;
- Roles and contextuality: workplace routines and work practices;
- Specific knowledge of users: perceptions of the EAandF system as requiring technical competence;
- Interactions, communication and relationships: Allocations of access, divisions of labour, shared and collective use of the technology.

5.4.1. Infrastructures and dispositions of users allows for information gathering

The EAandF system facilitated the efficient acquisition of information relating to the appropriateness of prescribing for individual patients. External structures provided the conditions for the use of the technology; specifically through the requirements of national policies relating to safe medicines use as set down by national governance and guidelines and the CCG's responses to those requirements. The CCG was motivated to carry out audits of prescribing, and much of the data extracted through such audits were used to benchmark the CCG against these national policies and targets. This auditing was in turn determined by the policy and institutional climate that required the reporting of such auditing, the setting of certain guidelines and targets, and the adherence to those. This further led to the CCG utilising the technology in a local context to monitor prescribing behaviour in practices in response to local initiatives. External structures such as national or local "initiatives" worked with the internal structures (in this specific instance the motivations of the CCG to report in response to these "initiatives") and the material properties of the technology, to more swiftly identify patients registered with general practices that met the relevant prescribing safety audit. The material properties of the system shaped the ability to conduct extensive searches of electronic health records across multiple general practices in a relatively short space of time. According to the following extract from an interview with a CCG pharmacist, the technological structures enabled the collection of data in a more efficient and timely fashion.

> *"[...] it's a way of being able to gather pseudo-anonymised individual patient data and relate it to ideas and thoughts around initiatives that CCG or the*

medicines management team are looking at that perhaps has been identified or highlighted nationally, or locally and it can all be done relatively quickly within a few seconds if necessary. So you don't have to trawl round 17 different practices." (CCGP2)

Centrally, in a form of pay for performance initiative, the CCG made the EAandF system part of a *"GP incentive scheme to engage with alerts in a meaningful way" (GP1-INT)* and this was conceptualised as *"trying to sort of get some more traction" (GP1-INT).* Guidelines and documents concerning strategies for prescribing framed the possibilities for use *"to actually monitor the progress against a sort of target outcome*" *(GP1-INT).* The functionality within the EAandF system allowed for benchmarking across the CCG. This in turn provided for structures that could be utilised by the CCG to encourage practices to use the system, and an infrastructure that supported their own activities in monitoring prescribing behaviour and to *"reward good prescribing" (GP1-INT).*

"If there are some practices that are demonstrating very good prescribing, then we've picked those out as well and highlighted those to act as a kind of beacon of hope for everybody else". (CCGP2)

The system also allowed for communication channels and feedback, between different health professionals, where contact with practices was through the system or as a result of alerts being sent out by email. Such communication, between the clinicians placed centrally at the CCG and the individual GP practices, enabled the CCG to monitor prescribing as *"a way of looking at the map" (GP2)* as well as the use of the system by *"tracking our advice in those practices" (GP1-INT).* The codes

and material properties of the system facilitated monitoring in that logging on to the system indicated engagement with it. This in turn allowed the CCG to further monitor and audit prescribing patterns since they could swiftly see which practices had responded to alerts and *"[could] have some kind of objective measure that [gave them] some idea as to who's perhaps even more engaged than others" (CCGP2).* The ambitions and motivations of the CCG to monitor prescribing acted as an internal structure to work *"very hard to get the uptake of that better" (CCGP2)* and in "*trying to persuade our clinicians to use it so that we get a much more real time feedback." (CCGP2).* Furthermore, this combination of technological infrastructure and the ambitions of the CCG created a new internal structure in the form of a convention for using the system.

> *"(When) the GP logs onto the Eclipse system and there's a little tick box to say patient reviewed [...]. Now some practices are doing that as a regular routine exercise, so that means that tracking our advice in those practices is very easy and what it does allow you to do as well is not to send the same alert out to the same practice again" (GP1-INT).*

In this way, there were patterns of agent-technology relationships, through the CCG using the system to track prescribing activities that reinforced a hierarchical agent-agent relationship within the network. The CCG managers were interacting with the technology to monitor prescribing since engagement at local clinician level with the system was encouraged by the CCG. Since this then provided further feedback to them, agent-technology relationships could build through the system use as new agent-agent relationships between managers centrally at the CCG and local GPs.

5.4.2. Technological structures and dispositions of actors: Perceptions of the system as new

Using the EAandF system was characterised as a new practice that would require new approaches. Resistance towards the system was thus justified by characterising existing behaviours as ingrained. Here, habits and ways of doing things that were presented by one GP as "*the old fashioned way" (CCGP2),* provided for a limited use of the system. One such disposition was around their prescribing habits, which they described as "*conservative" (CCGP2).* This allowed for a limited use of the EAandF system, in which most alerts would not require action because prescribing behaviour was already "*protective of patients*" *(CCGP2).* Similarly, as the following extract illustrates, non-use of the system resulted from habitual accustomed practice of using other systems, pre-existing routines and repetitive ways of doing things.

> *"I think the trouble is Eclipse is another thing you have to log into along with the other 20 things you log into every day, and you're so used to using your other clinical system all the time."(GPM3)*

In a further example of agent-agent relationships, and in contrasting professional roles, associated with the use of the system, the CCG pharmacists were concerned that GPs would otherwise avoid using the system. It was assumed that GPs, in addition to training on the system, needed persuasion in order to "*just [get] them to use it as habit" (CCGP1).*

> *"but we have had a situation where the GP said, oh, I'm not sure if I'll have time to look on Eclipse, but you can't spoon feed them everything."(CCGP1)*

There were thus perceived differences in different stakeholder groups to how the system should be used and who should use it.

5.4.3. Roles and contextuality: Workplace routines and work practices

Social structures could shape the ways things were done. Workplace routines and practices, such as the prioritisation of work schedules, acted as constraints or enablers to the use of the new system. One GP highlighted contingencies within the structures associated with the *"special circumstances of my workplace" (GP4)* which allowed for a range of actions from side-lining the alert through to reviewing the patient. In this way, the duality of structure (the specific demands of his work) and his agency (his interaction with the alerts in the EAandF system) both governed his act of utilising the system and the extent and character of that utilisation.

> *"[...] it can depend on the nature of the alerts, how urgent it seems, and the special circumstances of my workplace [...] some things might actually get side-lined for a few weeks if they're not clinically urgent, but [...]the next time I catch up with my paperwork then I'll dig up that alert[...]and review the situation." (GP4)*

For the CCG pharmacist, undertaking medication reviews in care homes, the system changed the way they worked because *"if necessary if there's something that comes up on Eclipse whilst we're there we can, rather than having to go back to the surgery first, check it and then make a decision" (CCGP1).* In this way, the technology shaped their actions enabling them to undertake medication reviews more efficiently. Furthermore the technological structures in the EAandF system and the internal structures led to

new shared decision making, use and outcome, whereby using the system and communication between the pharmacist and the GP resulted in medication changes.

> *"We can look on Eclipse and most of the time it's on Eclipse and we can answer the question there and then. For example, we had a patient who was on Memantine, who was a really not very well gentleman, [...] so we phoned the GP straightaway; we (the pharmacist and the GP) stopped it."(CCGP1)*

5.4.4. Specific Knowledge of Users: Perceptions of the EAandF system as requiring technical competence

The EAandF system was conceptualised as a "clever" system that could conduct complex searches, but would require technical knowledge on the part of users in order to do so. This allowed for GP4's limited use of the system when combined with an understanding of his own abilities to use the system;

> *"That's how I become accustomed to doing things, which is perhaps why I then don't use Eclipse, because I do think I might not have the ability and the power of making the use of a more powerful tool. But, perhaps I have also then learned useful habits with the old fashioned way." (GP4)*

Non-use of the system was associated with the cognitive and physical demands associated with using the EAandF system and finding time to learn how to get the best out of it. This further conceptualised the system as complex requiring time, training and *"proper teaching" (GPM2)* to gain the expertise required to utilise it.

> *"And if you had the time to log into it and go oh, what does this do? What does that do? […]You train your audit clerk who runs all sorts of searches and does*

all sorts of audit work, you could have the time to show her and teach her,[…] I'd love to have the time to tinker with,(the system).[…] You'd need time to play with it and time to…proper teaching, proper (training) showing us what it does" (GPM2)

This also relates to agent-agent relationships and interactions in that the requirements of the system would require interactions in order to train others. The conceptualisation of the EAandF system as requiring technical competence was related to structures embedded within the technology that allowed for or constrained its use. This conceptualisation could either empower users, and thus facilitate further use, or could undermine that agency.

"And also I'm computer literate and I can work out, I can problem solve because I'm reasonably well educated, if you were talking about average population here, they would either give up, they would probably have given up when they couldn't log in" (Pt2)

This service user conceptualises the system as difficult and one that required their abilities as a "*computer literate"* to use it. In other words, usage required an interaction of their capabilities with structures within the system, and difficulties with logging in were perceived to be a potential constraint for other users.

5.4.5. Interactions, communication and relationships: Allocations of access, divisions of labour, shared and collective use of the technology

There were variations in the ways the technology was used within collaborative networks of social relations. In a division of labour, based upon professional roles,

different general practice staff took responsibility for using the technology; use depended upon shared or collective roles, or upon a hierarchical allocation of access.

For service users, using the technology was determined by networks of social relations. This was expressed as having support from medical professionals to understand the system.

> *"But I think the important thing is before you sort of almost start using it, you do need that kind of intervention from a medical practitioner in some way to actually help you with the things you need to know" (Pt1)*

Within general practices, there was variation, and a division of labour, in who took responsibility for the EAandF system. On receiving an alert through the system one practice manager would then *"pass it on to the GP and get them to respond to me" (GPM 2)* and that *"the doctors don't access it at all. […] I'm the only one that, yeah, has anything to do with it."(GPM 2)* Another remarked:

> *"I get the alert the same way through the email, I identify the patient [...] then mine goes to the GP. But the GP actions it, I don't have any more responsibility for it after that […] They go into Eclipse, they do it, […] my job is just to literally give them the information and they do the rest." (GPM1)*

Such variation was driven by the conventions and norms associated with work practices. In different general practices, individuals were assigned to different roles and responsibilities often based on what worked best for the practice.

> *"one of the GPs has been nominated within our practice to take that lead in the same way that we break our workload down in other areas; you be the lead for*

this and tell us if there's anything we all need to know and share the workload." (GPM4)

The preferential allocation of access to the EAandF system limited its use. Community pharmacists did not have access to the system. Perceived social norms associated with contrasting professional roles were seen as *"historically a barrier" (CP2)* that perpetuated that lack of access. Community pharmacists attributed this barrier to GPs seeing themselves as "*as the custodians of the patient record" (CP2).*

"I think there always has been a conflict because GPs often see themselves as the custodians of the patient record and even though the information in that patient record, even abbreviated information is incredibly useful for community pharmacists, they've never successfully managed to allow us access and this is going back to EPS [Electronic Prescription Service], this is what EPS promised and it's never happened." (CP2)

There was a perception that the system was a tool for the CCG. This differential access meant that the system had not been used in some general practices. There were, however, perceptions that the system had *"evolved"*.

"I think that's what it was […] originally purchased…or the agreement with Eclipse was originally for the meds management team to use it as a tool for them […] And I think Eclipse has evolved since that happened […] And I don't think any of us have kept up with how Eclipse has evolved and what else it can now do."(GPM3)

Such changes were related to social norms around ownership and conventions concerning how the system would be used; centrally by the CCG to look at prescribing patterns across practices, and by individual practices to carry out their own prescribing audits. As the system evolved there were perceptions that it could do more. Hence, perceptions of the technological structures and material properties of the technology drove the ambitions of some users to learn more about the potential uses of the system which opened up access to different users.

5.5. Chapter summary

The adoption and implementation of the EAandF system was dependent upon a dynamic mix of external structures, internal structures and the material properties embedded in the technology. Using SST highlighted the ways that these structures and human agents interacted.

External infrastructures, the motivations of users and the material properties of the EAandF system facilitated information gathering. External structures involving guidelines and policy provided the conditions of use for the technology. This policy landscape worked with the internal structures of the CCG managers and the technological properties in the EAandF system to allow the CCG managers to audit and monitor prescribing and to benchmark prescribing in the practices and across the CCG against national targets and guidelines. Communication through the system provided agent-technology relationships and reinforced agent-agent hierarchical relationships between the CCG and clinicians in general practices since the system allowed for the CCG to monitor and track their advice.

Perceiving the system as new could lead to resistance and the maintenance of habitual behaviours. Users resisted the technology through internal structures and dispositions that characterised their own behaviours as conservative and old fashioned. The material properties within the EAandF system were thus utilised as part of this resistance since the technology was seen as new and thus at odds with the dispositions of the actors. Similarly the use of the system could be further constrained by conceptualising the system as requiring technical competence. Technological knowledge, training and expertise were seen to be prerequisites for the system use. Use was also dependent upon interactions and relationships between users. Workplace and social structures shaped the ways things were done. Whilst workplace demands and time pressures could lead to resistance in other ways the material properties of the system, and the way that the system enabled pharmacists to adapt their workplace routines, meant that the technology shaped new actions.

Collaborative networks were implicated in the use of the system. There were divisions of labour based upon professional roles that led to different use of the system. Different ways of operationalising the system were driven by conventions and norms of differing general practices. The preferential allocation of access and perceptions of ownership of the system could lead to a lack of use.

These findings and their implications are further discussed in Chapter Eight.

CHAPTER SIX: UNDERSTANDING THE IMPLEMENTATION AND ADOPTION OF A TECHNOLOGICAL INTERVENTION TO IMPROVE MEDICATION SAFETY IN PRIMARY CARE: A REALIST EVALUATION

6.1. Preface

Chapter Five detailed the analysis of an EAandF intervention using strong structuration theory. By identifying the structures implicated in the use of the system and the different motivations, ambitions, aims and attitudes of a range of stakeholders SST was found to be particularly valuable for unpicking why an electronic audit and feedback tool designed for medicines optimisation was used. This chapter details a realist evaluation of the same EAandF system using the same data set. Utilising realist evaluation enabled an exploration of the mechanisms relating to the use of the EAandF system and thus how it was used. The aims of this study are given and the methodological approach adopted here is then outlined in detail. The findings from this realist evaluation are then presented.

6.2. Aims and objectives of the study

This study aimed, by undertaking a realist evaluation, to understand, evaluate and explore the implementation and adoption of an electronic audit and feedback tool to support medicines optimisation for patients in primary care.

Objectives

To undertake semi-structured interviews and focus groups with a range of stakeholders in order to:

- Explore the ways the EAandF system was used by a range of health professionals and GP staff;
- Understand how the EAandF system was used by exploring what worked for whom and in what circumstances;
- Understand how the contextual background, including work practices, socio-organisational structures and behaviours might influence the various ways in which the intervention was achieved in everyday use.

6.3. Methods

6.3.1. Study design and setting

Our research used a qualitative case study design, informed by the realist evaluation methodology. As outlined in Chapter Four, the study case was a clinical commissioning group (CCG) in the South of England that was an early adopter of Eclipse Live.

6.3.2. Methodological approach: Realist evaluation

Complex interventions, such as those involving the implementation of healthcare IT, can be understood from a "realist evaluation" perspective which seeks to explain the ways the intervention might work, for whom and under what circumstances (Wand et al., 2010; Pawson and Tilley, 1997). As has been described in chapter four, realist evaluation asserts that a set of outcomes is the product of particular responses from

human and technological actors within the system ("mechanisms"). Mechanisms are seen as being a combination of the resources made available by the intervention and the reasoning of human actors in that context (Dalkin et al., 2015). These mechanisms are activated in a given set of organisational or social circumstances ("context") (Dalkin et al., 2012; Pawson and Tilley, 1997). A combination of contexts and the associated mechanisms leads to outcome(s) for a given intervention (Pawson and Tilley, 1997). Given the complexity of healthcare interventions, (Grant et al., 2013b; Westhorp, 2012; Berg, 2001) realist evaluation provides a detailed understanding of what makes an intervention work, rather than a simple cause-and-effect relationship between an intervention and its outcome(s). The latter can indicate whether or not an intervention has worked, but provides limited insights into how or why the identified outcomes were obtained (Dalkin et al., 2012; Pawson and Tilley, 1997). Realist evaluation presents these findings as a set of links between contexts, mechanisms and outcomes (so-called "CMO configurations"). "Context" refers to pre-existing organisational, social or cultural circumstances. "Mechanism" refers to specific and particular responses from human actors to the delivery of the intervention. "Outcome" refers to the product of mechanisms activated within the specific context. The relationship between these three elements is shown in Figure 6.1).

6.3.3. Analysis

Consistent with qualitative realist evaluation, the analysis was cumulative and iterative with data analysis occurring alongside data collection (Dalkin et al., 2012; Wand et al., 2011; Marchal et al., 2012; Wand et al., 2010; Byng et al., 2005; Pawson and Tilley, 1997). The analysis was lead by MJ with discussions at all stages across the research team with DA, DLP, RH, TA, and SR. The data were analysed using a

thematic approach, with each final theme representing a set of CMO configurations (CMOs). The analysis was undertaken in a number of steps. The first step, consistent with previous realist evaluations (Dalkin et al., 2012; Rycroft-Malone et al., 2010), developed an a priori set of CMOs deductively from available literature (Ranji et al., 2014; Hayward et al., 2013; Avery et al., 2012; Cresswell et al., 2012a; Dalkin et al., 2012; Greenhalgh and Russell 2010; Oroviogoicoechea and Watson 2009) and informal discussions with users of the EAandF system. These included ways in which the intervention led to changes in work practices (Ranji et al., 2014), changes to the flow of information (Hayward et al., 2013; Greenhalgh and Russell, 2010) and the goals of the system.

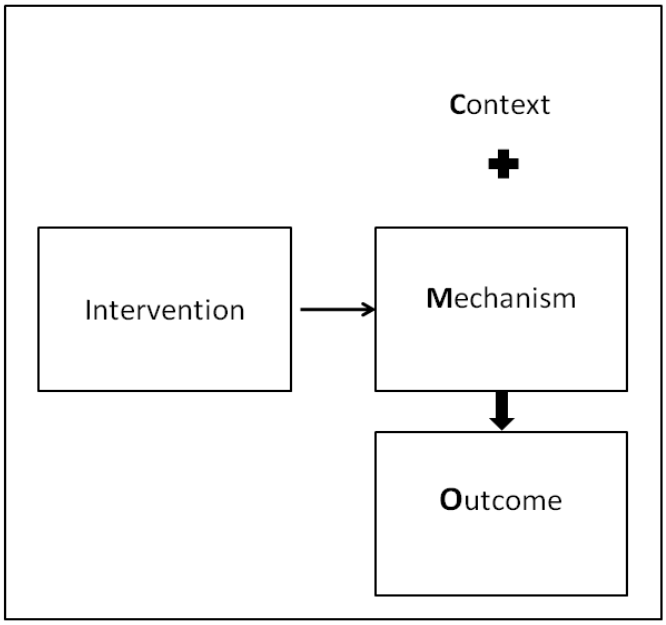


Figure 6.1 - Context-Mechanism-Outcome Configurations in Realist Evaluation *(developed from Dalkin, et al., 2012; Wand et al., 2011; Marchal et al., 2012; Wand, et al., 2010; Byng et al., 2005; Pawson and Tilley, 1997)*

These provided the initial thematic framework for data analysis. In a second step early findings were discussed in subsequent focus groups in an iterative approach consistent with realist evaluation (Pawson and Tilley, 1997). Transcripts of the interviews and focus groups were then read and reread by MJ in a process of familiarization and immersion and discussed with DA, DP and RH. A set of thematic codes, based on the initial framework and from these readings of the early interviews, was then applied to the transcripts by MJ using the QSR Nvivo 10 application to organise the data. This iteration of the coding framework is outlined in Appendix 6.

Consistent with realist evaluation the next step of the analysis was to identify outcomes (Dalkin et al., 2015). The set of thematic codes had identified an initial set of outcomes which were then grouped under new themes that emerged from the data as outlined in Appendix 7. Having determined the final group of outcomes, the data was interrogated further for the mechanisms and contexts that might have led to these. Hence, CMO configurations were generated from the data. These CMOs were further discussed with DA, DP and RH. The first iteration of these CMOs is detailed in Appendix 8. Finally these CMOs were then further organised thematically into the three groups detailed in the results below.

6.4. Findings

Consistent with a realist evaluation the findings were conceptualised as CMO configurations; the circumstances and ways in which the EAandF system was used were perceived to lead to a number of medication safety outcomes. These CMOs were organised into three groups based upon the ways the system was utilised: access; engagement or disengagement with the system; the monitoring of prescribing;

and work practices. Within each group we identified mechanisms, and contexts within which these mechanisms were activated, that led to given medication safety outcomes such as patients' electronic health records being screened to identify potentially hazardous prescribing events.

6.4.1. Engagement and disengagement

The first group of CMOs concerned access, engagement and disengagement (Tables 6.1 and 6.2). In the first of these CMOs, the EAandF system focused healthcare users' attention on medication rather than on disease. Engagement with the system by GPs could therefore lead to more focused patient reviews. Increased engagement with safer prescribing could be sustained by voluntary engagement with the EAandF system on the part of the practices; this was said to reduce a *"big-brother" (GP1-INT)* hierarchical relationship with the CCG, challenge the belief that it was a tool primarily for the CCG pharmacists, and give a greater sense of ownership of the system within general practice.

> *"Say you are monitoring renal function and you look and the eGFR [patient's filtration rate] has gone down to 29 and it was 31 the month before. You're thinking, well that's okay, we'll just monitor that, you fail sometimes, [...] one fails to think, ah, I need to review the allopurinol, I need to renew the metformin , because it is so, so, easy to focus on a disease and that's, I think, where Eclipse can come in." (GP1-INT).*

However, GPs could instead end up relying upon the medicines management team to send out alerts, disengaging them from proactively using the system and reinforcing CCG ownership. Engagement was to be encouraged financially in the future by

building a requirement to use the EAandF system into the *"prescribing incentive scheme" (CCGP2).* In contrast, engagement was discouraged by blocking mechanisms in the context of IT use in general practice. One GP (GP2) stated that they and only one other colleague used the EAandF system. Such task allocation meant that within their practice they operated as a prescribing lead where they took responsibility for auditing and monitoring the prescribing within their practice, and therefore were the only ones expected to use the system.

Table 6.1 Context-Mechanism-Outcome configurations concerning access and engagement

<table>
<tr><th>Context</th><th>Mechanism</th><th>Outcome</th></tr>
<tr><td>General Practitioner monitoring individual patients</td><td>Focuses attention on medications</td><td>Attention focused on patients most in need of review</td></tr>
<tr><td>General Practitioner prescribing audited and monitored in practices</td><td>Proactively conducting own audits</td><td>Practice prescribing patterns benchmarked against each other across the Clinical Commissioning Group</td></tr>
<tr><td>Communication between Clinical Commissioning Group and General Practitioner</td><td rowspan="2">Real time feedback</td><td>Patients reviewed to ensure appropriate monitoring, to optimise medications, or to avoid dangerous combinations of drugs</td></tr>
<tr><td>Clinical Commissioning Group conducting searches of prescribing based upon "projects" and "initiatives"</td><td>Prescribing patterns and trends benchmarked against national targets and guidelines</td></tr>
<tr><td rowspan="3">Clinical Commissioning Group encouraging clinicians to be engaged in more proactive safety management</td><td>Engagement of practices in using the system for feedback</td><td rowspan="3">The effectiveness of safety initiatives audited more quickly

Improved engagement with safety monitoring of prescribing</td></tr>
<tr><td>Voluntary engagement by clinicians</td></tr>
<tr><td>Audits conducted as a means of support to General Practitioners</td></tr>
</table>

Table 6.2 Context-Mechanism-Outcome configurations concerning disengagement

Context	Blocking Mechanism	Outcome not achieved
Communication between Clinical Commissioning Group and general practitioners	Feedback on alerts requires logging in	Potential delays in patients being reviewed
	Reliance on alerts being sent out centrally	
Information technology use in General Practice	Lack of use/not logging in to the system	Potential delays in review of patients
Community pharmacists conducting medicine use reviews with patients	No access to additional information	Opportunity for more appropriate and directed medication review lost
Community Pharmacy	Perceived conflict and lack of ownership	Limits potential improvements in quality of care for patients
Patients using the electronic medicines optimisation system	Facilitated use by healthcare professional	Lack of direct access to information to benefit shared care and self-management
	Difficulties obtaining passwords and logging on	

Another GP remarked, in terms of seeing alerts in the system, *"I don't commonly open the software full stop" (GP4)* a barrier that was related to time pressures:-

> *"a third of my time (is) seeing patients, two-thirds of my time doing paperwork and an extra mystical 10 or 20 per cent of time [...]Eclipse fits into that last 10, 20 per cent of time that doesn't really exist." (GP4)*

Other health professionals were also disengaged from the system. The lack of access for community pharmacists that had been seen in the previous study using SST outlined in Chapter Five, worked in this way as blocking mechanisms. The perception that there was a denial of access both inhibited the use of the system by community pharmacists and created conflict over ownership. Community pharmacists had been

involved in patient passport initiatives that could have given them access to the EAandF system but issues of confidentiality, delays and poor communication with the CCG and general practices had led to them being "denied access".

A limited number of patients had access to the EAandF system through the patient passport. They saw this as potentially valuable in giving access to information about medications and their conditions, which would in turn have a positive bearing on self-management and shared care. However, this was prevented by a blocking mechanism concerning access: *"The first problem I had was I couldn't log in at all" (Pt2).* Patients also felt that they would get best use out of the system if this was facilitated and interpreted by a health professional.

> *"I think that's why it's important to, it's not just to be used on its own, it's to be used with, to be used with a clinician of some kind to actually help you to interpret some of that stuff, because some of it is, I mean when you look at high haemoglobin levels or the glucose levels, [...] Which are the bad ones? Which is this? What does this mean?" (Pt1)*

6.4.2. The monitoring of prescribing

The monitoring of prescribing across general practices (see Table 6.3) was undertaken by pharmacists and GPs placed centrally at the CCG. The SST analysis conducted on the intervention and outlined in Chapter Five highlighted external structures related to this policy background that determined why the system was used. The contexts identified by this analysis were a product of those structures.

Table 6.3 – Context-mechanism-outcome configurations concerning the monitoring of prescribing.

Context	Mechanism	Outcome
Clinical Commissioning Group engagement with prescribing alerts	Alerts designed and results fowarded to practices	Prescribing patterns and trends benchmarked against national targets and guidelines
	Identify specific patients	Pre-emptive or timely review of individual patients
Monitoring prescribing by conducting searches based upon local "initiatives"	Efficient use of time	Prescribing patterns benchmarked across the Clinical Commissioning Group
	Highlight suboptimal prescribing	Reduction of knowledge gaps to optimise use of medicines
	Reward good practice	

Building upon this, two overriding contexts were identified within which mechanisms were activated. The first of these concerned the engagement with prescribing alerts issued by the CCG. Alerts that related to the implementation of national guidance were designed and disseminated to general practices. These allowed for bespoke searches of prescribing data to be run across all general practices within the CCG. This in turn allowed for benchmarking against criteria set by national guidelines. One respondent (GP1-INT) acknowledged that the existing alerts embedded within the system could be used, but that they were unwieldy because of their large number so

were not commonly used. Similarly, one CCG Pharmacist (CCGP2) said there was a lack of confidence in these alerts, because of a lack of knowledge about the content of the underlying algorithms used to generate the existing alerts, so they were seldom used. The engagement with prescribing alerts also allowed the activation of a mechanism for identifying specific patients, which was seen as more likely to lead to a timely review of patients.

> *"You [can] pin [the alert] to [specific patients]. So if you say […] metformin shouldn't be prescribed with an eGFR less than 30 and these are the patients who you need to consider in this category it's such a more meaningful event." (GP1-INT)*

The second context concerned the CCG setting up their own searches based upon local initiatives. Within this context one mechanism allowed for searches to be conducted speedily across all practices within the CCG. This was a change in working, where in the past *"trawling round all […] practices" (CCGP2)* had *"[taken] us about three to four weeks" (GP1-INT).* Since the introduction of the intervention, *"we ran the same search and literally [...] 90 minutes without actually leaving your desk, you've got the results" (GP1-INT).* Using the system helped to identify prescribing patterns and *"to have the ability to look at the prescribing by practice […] so we could compare […] the prescribing of a drug one practice to another" (GP1-INT).* Participants saw this as leading to prescribing patterns being benchmarked across the CCG. Additionally, the EAandF system was seen as an educational tool that could reduce knowledge gaps and change prescribing behaviour by highlighting suboptimal prescribing within and across practices *"because we could identify those patients receiving whatever strength, notify GP within the system*

and […] got 100% adherence to this safety thing"(GP1-INT). This educational outcome was further enhanced by rewarding good practice: *"if there are some practices that are demonstrating very good prescribing, then we've picked those out as well and highlighted those" (CCGP2).*

6.4.3. Work Practices

The final group of CMOs concerned the effect of the EAandF system on work practices (Table 6.4). This involved a number of different stakeholders in general practices: GPs; practice managers; and practice-based pharmacists.

The first context here concerned administrative work practices. Some practices relied on alerts being sent to them by email rather than proactively seeking the alerts by logging on to the EAandF system. The process of responding to alerts varied, but often involved transferring information from email to paper in addition to logging on to the system, causing a delay.

> *"The alert is printed off on a piece of paper which [then] sits in my in-tray with 500 other items of equal urgency, and [...] it might be that I have to work my way down through that pile over a period of a few months." (GP4)*

Reviewing the patient through the system was a more successful mechanism that gave immediate feedback to the CCG, avoided the delays, and provided clear and speedily accessible information in a readable form where: *"you can plot the graphs [and] quickly eyeball 100 patients in a couple of minutes." (GP1-INT)*

Table 6.4 – Context-Mechanism-Outcome configurations concerning work practices

<table>
<tr><th>Context</th><th>Mechanism</th><th>Outcome</th></tr>
<tr><td>Multiple administrative work practices</td><td>Logging on, responding to alert, and reviewing patients through the system</td><td rowspan="2">Patients reviewed to ensure appropriate monitoring, to optimise medications, or to avoid hazardous combinations of drugs</td></tr>
<tr><td>Pre-existing division of labour within General Practices</td><td>Task allocation</td></tr>
<tr><td>General Practice workload</td><td>Task Prioritisation</td><td>Pre-emptive or timely review of individual patient</td></tr>
<tr><td>Pharmacist workload</td><td>Existing work practices developed and adapted</td><td rowspan="4">Can result in a more focused medication review</td></tr>
<tr><td rowspan="3">Pharmacist undertaking reviews in care homes</td><td>Accessing easily readable and informative data</td></tr>
<tr><td>Necessary workarounds to overcome technical issues</td></tr>
<tr><td>Necessary workarounds to find patient details</td></tr>
</table>

Within the context of pre-existing divisions of labour within practices, the EAandF system was seen to require a specific task allocation which would be *"certainly led by a clinician and most likely performed by a clinician" (GP4).* There was variation

in the ways the EAandF system was used by either practice managers or GPs. One practice manager said that once an alert was received they took responsibility for it:

> *"I pass it on to the GP and get them to respond to me, and then I update Eclipse […] the doctor's don't access it at all." (GPM2)*

Whereas in another practice the responsibility for accessing the system was the GP's:

> ***"****The GP actions it, I don't have any more responsibility for it after that […] They go into Eclipse, they do it, […] I had to remind one GP today, I just wanted to check they had actually reviewed this patient." (GPM1)*

If the system was used effectively then patients would be reviewed but, as noted by the general practice manager above, it was possible that the task allocation could act as a blocking mechanism (that is, inhibiting the effect of the system) if GPs had to be reminded to review patients.

Within the GP workload context, mechanisms associated with task prioritisation could lead to the timely review of patients. To utilise the system effectively, GPs had to juggle competing tasks and prioritise. If GPs were *"getting pertinent alerts that they feel are relevant"* these alerts were seen with *"virtually no negativity" (GP1-FG).*

For pharmacists undertaking medication reviews in care homes, the system saved time by giving more speedy access to information, *"there and then in front of you"* (CCGP1) allowing for a more focused review. The system gave the pharmacist the opportunity to send recommendations to the GP based on information about

medications, test results, conditions and demographic factors. This information was easily accessed through the EAandF system and findings easily interpreted.

> *"The benefit of Eclipse is you can log on and look at the graph and you can see the basic trend of blood pressure, of cholesterol, of weight etcetera, on a beautiful graph which is so easy to read with the red/amber/green bits, it's so clear what's going on."*(CCGP1)

Effective use of the system required some adaptations and improvisation on the part of the users. For example participant CCGP1, whilst carrying out tasks in a care home, had to adapt ways of obtaining passwords for the system to deal with limited internet access. Pharmacists, *"beforehand were trying to look up all the stuff on Eclipse whilst we were in the care home" (CCGP1)* but had adapted their activities in order to have, *"more information to start off with (and) use Eclipse for less time in the care home, but in a more directed manner" (CCGP1).* Limitations to the information available in the system, necessitated workarounds in order to obtain further patient details; *"because it doesn't list actual allergies" (CCGP1)* and *"we can't look at letters" (CCGP1).* This meant finding out more information from the general practices before the visit to the care home or returning to general practices to obtain *"any relevant letters from consultants or anything like that" (CCGP1).*

6.5. Chapter summary

This study highlighted the ways in which the EAandF was utilised across primary care for medicines optimisation. The capacity to audit prescribing across practices allowed for the practices to be benchmarked. One particular benefit of the EAandF system is the ability to swiftly review specific patients and groups of patients to

ensure they have appropriate monitoring, to optimise dosages or to avoid hazardous combinations of medicines, which may result in safer prescribing. This study has identified variations in stakeholders' experiences of the IT intervention across primary care, which potentially affects its successful implementation.

There was differing patterns of engagement with the system highlight by the CMO configurations. Whilst engagement with the system could lead to more focused reviews disengagement was found with a number of stakeholder groups. GPs were disengaged from the system relying upon CCG managers place centrally to send them alerts. Access to the system had been denied to community pharmacists. Patients found logging on to the system difficult or requiring assistance from a health professional. This latter CMO configuration limited the potential for improved quality of care for patients.

As outlined in Chapter Five strong structuration theory had identified the structures associated with the monitoring of prescribing. Here groups of CMOs based upon two contexts were identified. One particular CMO was that by conducting searches based upon local initiatives CCG managers were able to highlight suboptimal prescribing which lead to an educational effect of reducing knowledge gaps in practices. The system was also valued by the clinicians and pharmacists placed centrally at the CCG because it could be utilised to access prescribing information and could lead to the timely review of patients at risk of adverse drug events.

There was a range of CMOs associated with work practices. These were at times adapted to make best use of the system particularly by the CCG pharmacist

conducting medication reviews with care home patients. Administrative work practices were more successful if they utilised the system.

The CMOs developed here represent middle range theory that could be applied to further exploration of the use of this system in other locations. This would help to build a wider picture of the use of the system and develop further CMOs that be applied more broadly to further use of the system as Pawson and Tilley (1997) describe, in a process of cumulation, theory building and a cycle of evaluation. This could then inform healthcare professionals, policy makers and developers for further development of the system and its use.

These findings and their implications are further discussed in Chapter Eight.

CHAPTER SEVEN: UNDERSTANDING THE IMPLEMENTATION AND ADOPTION OF A COMPLEX IT-BASED INTERVENTION FOR MEDICINES OPTIMISATION IN PRIMARY CARE: A QUALITATIVE STUDY USING NORMALISATION PROCESS THEORY

7.1. Preface

Chapters Five and Six outlined the use of an EAandF system, Eclipse Live, in primary care. This system was able to provide audit and feedback to clinicians and others to facilitate the identification of patients at risk of ADEs as a result of prescribing or monitoring errors. This system was explored from sociotechnical perspectives firstly using SST to uncover the ways in which the system was utilised and then through realist evaluation to unpick the mechanisms involved in the implementation and adoption.

This chapter explores the use of a different EAandF intervention designed to improve medicines optimisation in primary care. Eclipse Live provided feedback on hazardous prescribing but this was dependent upon some users, predominantly those placed centrally at the CCG, co-ordinating searches through the system and then providing feedback for clinicians. The Salford Medication Safety Dashboard (SMASH) is a medication safety intervention implemented in general practices across Salford (Greater Manchester) CCG that is designed to identify, audit and feedback instances of potentially hazardous prescribing by presenting practice results for an established set of prescribing and monitoring safety indicators. Using the dashboard local users

could immediately access practice level data relating to the indicators in contrast to Eclipse Live where they responded to alerts sent to them. Having such access to the data through the SMASH dashboard facilitated the role of the pharmacist assigned to the general practices. A clinical pharmacist therefore worked with and supported clinicians and other practice staff in responding to the information provided in the dashboard. The evaluation of this intervention utilised NPT which focused upon the ways in which the intervention was implemented, adopted and sustained in practice through the actions of the people involved in the intervention.

The first part of this chapter outlines a brief rationale and aim of the study. This is followed by a more detailed description of the intervention. The methods for the study are then outlined. The findings are then presented followed by a brief summary. Further implications of these findings are discussed in Chapter Eight.

7.2. The Salford Medication Safety Intervention (SMASH)

The intervention consisted of two parts: The dashboard and the work of a clinical pharmacist in practice

7.2.1. The SMASH dashboard

The SMASH dashboard draws from an integrated clinical record to interrogate electronic health records for instance of hazardous prescribing and presents the resulting information to its users in both aggregated form and as lists of individual patients with potential safety hazards. The dashboard was developed and designed around the needs of users with GPs and CCG Pharmacists involvement and consultation (Keers et al., 2015). The dashboard uses a suite of thirteen prescribing

and monitoring safety indicators. Prescribing safety indicators describe prescribing or monitoring events or patterns that may place patients at risk of harm and should generally be avoided. The indicators featured in the dashboard focussed on situations of potentially hazardous prescribing that could result in patients experiencing: a gastro-intestinal bleed; exacerbation of asthma; exacerbation of heart failure; acute kidney injury; and the monitoring of patients in receipt of amiodarone and methotrexate. The full set of thirteen indicators is described in Tables 7.1, 7.2 and 7.3.

Five different types of pages are available within the dashboard (examples of these pages, based upon fictitious data to preserve patient anonymity, are shown in Appendices 9a-9e):

- Practice summary: practice size, number and percentage of patients affected by at least one indicator, and number of patients affected by multiple indicators.

- Tables: listing for each indicator the practice's current performance (i.e. number and percentage of affected patients), and comparisons with the CCG average.

- Charts: same information as the table but represented using bar and line charts.

- Patient numbers (indicator-specific): a list of NHS numbers of patients affected by the selected indicator, including other indicators they are affected by and duration that the patient has been exposed.

Evidence summaries (indicator-specific): explanation and evidence of the selected safety indicator and suggestions for taking corrective action; supported by references outlining the existing evidence-base to support these decisions.Once patients at potential safety risk are identified, participants can investigate their records in the local electronic medical record system and solve the risk (e.g., prescribe gastro-protective medicine). Two pathways exist to navigate to a page displaying patient numbers: via the practice summary (to view patients affected by multiple indicators) and via the overview table (to view patients affected by the selected indicator).

7.2.2 Clinical pharmacist working in practice.

Clinical pharmacists were aligned to participating practices to assist practice staff in resolving safety hazards identified by the dashboard for a period of 12 weeks (intervention period), and were free to continue using the dashboard (follow-up period). There were a range of different pharmacists assigned to practices; practice pharmacists already working at individual practices, pharmacists assigned as part of the intervention to one or more practice to work exclusively on SMASH and pharmacists who were employed centrally by the local NHS trust to work as neighbourhood pharmacists in one or more practices. Pharmacists utilised the dashboard to indentify instances of hazardous prescribing and then worked with the practice to take actions as a result.

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Table 7.1 Salford Medication Safety Dashboard - Prescribing Safety Indicators - Patients at risk of Gastro-Intestinal Bleed

Description of indicator	Eligible patients at risk (denominator)	Patients flagged by system (numerator)
Prescription of an oral NSAID without co-prescription of an ulcer-healing drug in a patient aged ≥65 years.	Patients aged ≥ 65 years on the audit date without prescription of an ulcer-healing drug within the 3 months leading up to the audit date.	Patients prescribed at least one oral NSAID within the 3 months leading up to the audit date.
Prescription of an oral NSAID without co-prescription of an ulcer-healing drug to a patient with a history of peptic ulceration.	Patients aged ≥ 18 years on the audit date with a history of peptic ulceration at least 3 months before the audit date without co-prescription of an ulcer-healing drug within the 3 months leading up to the audit date.	Patients prescribed an oral NSAID within the 3 months leading up to the audit date.
Prescription of an antiplatelet drug without co-prescription of an ulcer-healing drug[5] to a patient with a history of peptic ulceration.	Patients aged ≥ 18 years on the audit date with a history of peptic ulceration at least 3 months before the audit without co-prescription of an ulcer-healing drug within the 3 months leading up to the audit date.	Patients prescribed an antiplatelet drug within the 3 months leading up to the audit date.
Prescription of warfarin or NOAC in combination with an oral NSAID.	Patients aged ≥ 18 years on the audit date prescribed warfarin or NOAC within the 3 months leading up to the audit date.	Patients prescribed an oral NSAID within the 3 months leading up to the audit date.
Prescription of warfarin or NOAC in combination with and an antiplatelet drug without co-prescription of an ulcer-healing drug.	Patients aged ≥ 18 years on the audit date prescribed warfarin or NOAC within the 3 months leading up to the audit date without co-prescription of an ulcer-healing drug within the 3 months leading up to the audit date.	Patients prescribed an antiplatelet drug within the 3 months leading up to the audit date and within 28 days of the prescription for Warfarin or NOAC
Prescription of aspirin in combination with another antiplatelet drug without co-prescription of an ulcer-healing drug.	Patients aged ≥ 18 years on the audit date prescribed aspirin within the 3 months leading up to the audit date without co-prescription of an ulcer-healing drug within the 3 months leading up to the audit date.	Patients prescribed another antiplatelet drug within the 3 months leading up to the audit date and with 28 days of the prescription for aspirin.
NOAC - New oral anticoagulant drug NSAID- Non-steroidal anti-inflammatory drug		

Table 7.2 Salford Medication Safety Dashboard Prescribing Safety Indicators - Exacerbation of Asthma; Heart failure; Acute Kidney Injury

Description of indicator	**Eligible patients at risk (denominator)**	**Patients flagged by system (numerator)**
Prescription of a non-selective beta-blocker to a patient with asthma.	Patients aged ≥ 18 on the audit date with a Read code for asthma at least 3 months before the audit date and no Asthma resolved code.	Patients prescribed a non-selective beta-blocker within the 3 months leading up to the audit date.
Prescription of a long-acting beta-2 agonist inhaler (excluding combination products with inhaled corticosteroid) to a patient with asthma who is not also prescribed an inhaled corticosteroid.	Patients aged ≥ 18 on the audit date with a Read code for asthma at least 3 months before the audit date and no Asthma resolved code, who have been prescribed a long-acting beta-2 agonist inhaler (excluding combination products with inhaled corticosteroid) within the 3 months leading up to the audit date.	Patients who have not been prescribed an inhaled corticosteroid within the 3 months leading up to the audit date.
Prescription of an oral NSAID to a patient with heart failure.	Patients aged ≥ 18 on the audit date with a Read code for heart failure at least 3 months before the audit date.	Patients prescribed an oral NSAID within the 3 months leading up to the audit date.
Prescription of an oral NSAID to a patient with chronic renal failure (eGFR <45)	Patients aged ≥ 18 on the audit date an eGFR <45 at least 3 months before the audit date.	Patients prescribed an oral NSAID within the 3 months leading up to the audit date.
Prescription of an ACE inhibitor, loop diuretic and oral NSAID to a patient with chronic renal failure (eGFR < 45)	Patients with chronic kidney disease stage 3B, 4, or 5 (or eGFR < 45) and prescribed ACEI and loop diuretic	Patients prescribed an oral NSAID within 3 months leading up to audit date
NSAID- Non-steroidal anti-inflammatory drug eGFR- Estimated Glomerular Filtration Rate. ACEI - Angiotensin Converting Enzyme Inhibitor		

Table 7.3 Salford Medication Safety Dashboard - Prescribing Safety Indicators - Monitoring of patients in receipt of Amiodarone or Methotrexate

Description of indicator	**Eligible patients at risk (denominator)**	**Patients flagged by system (numerator)**
Missing thyroid function test in the past 6 months/patients receiving repeat amiodarone	Patients prescribed amiodarone 6-12 months before audit date and again within 6 months leading up to audit date	Patients who have NOT had thyroid function test in 6 months leading up to audit date
Missing full blood count or liver function test in the past 3 months/patients receiving repeat methotrexate	Patients prescribed methotrexate 3-6 months before audit date and again within 3 months leading up to audit date	Patients who have NOT had liver function test or full blood count in 3 months leading up to audit date

7.3. Rationale and aims of the study

Increasingly, electronic dashboard systems are being utilised in healthcare to support clinicians and others by providing feedback on data on predefined metrics (indicators) (NHS England, 2015). As described in Chapter Two, the PINCER trial demonstrated how a pharmacist working collaboratively with primary care clinicians was effective at reducing the numbers of medication errors (Avery et al., 2012b). Whilst the PINCER study identified factors which were implicated in the successful implementation of the intervention (Sadler et al., 2014) exactly how the system was accessed and used by pharmacists, clinicians and other GP staff and how they interacted was not thoroughly investigated. Additionally PINCER trial was not specifically based upon a dashboard. A report was provided based on the findings of a search of the GP clinical system that was run at a particular time point. In contrast the Salford medication safety dashboard is continually updated every day drawing on an integrated health record (Salford Integrated Record - SIR) covering primary and hospital data resources.

As described in Chapter Four a sociotechnical approach to the implementation of IT in healthcare focuses upon how the technology is used. It was therefore assumed that the use of the dashboard might be dependent upon the range of structures, different work practices and varied organisational and social norms that operated within the complexity of primary care settings.

7.3.1 Aims and objectives

This study, using NPT, aimed to explore the ways in which a complex pharmacist led EAandF dashboard intervention was implemented, adopted and embedded into everyday practice.

Objectives

Semi-structured interviews were undertaken with a range of pharmacists, CCG managers and general practice staff in order to:

- Understand the processes by which the pharmacist-led intervention was understood by stakeholders;
- Explore the contextual background, including work practices, socio-organisational structures and behaviours which might have influenced the various ways in which the intervention was achieved;
- Understand the interactions, relationships and collaborations between a range of health professionals and others that were implicated in establishing, operationalising and sustaining the intervention;
- Understand how, if at all, work practices were adapted, changed and sustained in a process of normalizing the intervention into everyday practice.

7.4. Methods

7.4.1. Study design and setting

This was a qualitative process evaluation of the SMASH intervention, using semi-structured interviews. The study ran parallel to the implementation of the SMASH intervention.

The study was carried out during the implementation of SMASH in 44 general practices across Salford Clinical Commissioning Group in Greater Manchester which has a population of approximately 250,000 people. Each individual general practice in Salford CCG was eligible to participate in the study. As practices were consented and began to receive the SMASH intervention, participants were recruited from practices purposefully to reflect different contexts across Salford in which SMASH was implemented, including variations in practice size, social deprivation and clinical systems used within the practice (EMIS Web; InPractice systems VISION). Participants were recruited from 18 different practices across all eight neighbourhoods within Salford CCG. Of these, 11 practices used the InPractice Systems Vision clinical system and the remainder used EMIS web. Practice list size ranged with seven practices having fewer than 4000 patients registered and three with greater than 12000. Based upon the indices of multiple deprivation (DCLG, 2015) practices were located within the 18th least deprived area and the 2nd most deprived (see table 7.4).

7.4.2. Recruitment and data collection

Within each practice, GPs, practice nurses, practice administrators and managers and pharmacists working at those practices were eligible for inclusion in the study. Practice managers initially gave written consent to receive the SMASH intervention and participate in the evaluation. Individual participants were then recruited to take part in interviews on a purposive basis, through direct contact with the pharmacist delivering the SMASH intervention at the practice(s) in question or through direct contact with practice managers. Potential participants at practices were contacted by MJ by telephone or email and invited to take part in an interview.

A range of different pharmacists working in different practices were recruited to the study. These included pharmacists employed by the CCG, those employed by individual practices and those employed by the local NHS trust as part of a neighbourhood practice pharmacist scheme. Two pharmacists worked exclusively on the SMASH intervention; the remaining pharmacists worked on SMASH as one part of their duties. I also included staff members within Salford CCG who worked directly with the SMASH intervention in order to provide perspectives relating to how the SMASH intervention would fit in to broader medicines safety and quality and improvement activities that were taking place across the CCG. Two of these staff members had quality and improvement roles. One CCG staff member was also a pharmacist who worked part-time with the SMASH intervention in practices so could provide a perspective that was both an overview from a CCG perspective and an understanding of how the dashboard worked at a local level in practices. Participant information is detailed in Table 7.5. Ethical approval for the study was granted by the North West - Greater Manchester East NHS Research Ethics Committee (reference

15/NW/0792) and from the local NHS research and development board. Written informed consent was obtained from all participants upon entry into the SMASH intervention study.

Table 7.4 General practices from which participants were recruited.

Practice	GP Clinical system	Practice List Size[1]	Neighbourhood rank for multiple deprivation across Salford 1= most deprived 20 = least deprived[2]
A	EMIS Web	4000 to 7999	12th
B	Vision	Less than 4000	18th
C	Vision	8000 to 11,999	13th
D	Vision	More than 12,000	10th
E	Vision	More than 12,000	14th
F	EMIS Web	4000 to 7999	2nd
G	Vision	More than 12,000	15th
H	EMIS Web	8000 to 11,999	10th
I	EMIS Web	4000 to 7999	12th
J	Vision	Less than 4000	2nd
K	Vision	4000 to 7999	2nd
L	Vision	Less than 4000	2nd
M	Vision	Less than 4000	2nd
N	Vision	4000 to 7999	2nd
O	Vision	Less than 4000	2nd
P	EMIS Web	4000 to 7999	12th
Q	EMIS Web	Less than 4000	3rd
R	EMIS Web	Less than 4000	12th

[1] Approximate list sizes only can be given to avoid unmasking the identity of the practice

[2] The twenty wards in Salford are ranked according to deprivation (DCLG, 2015). These areas are located within the eight different neighbourhoods that the CCG uses to group the practices. The ranking score here is therefore an approximation of the rank for neighbourhood based upon the wards located in that neighbourhood. Practices in the same neighbourhood will each therefore have the same ranking.

Table 7.5 Interview participants by gender, employment role, role in SMASH and practice assigned to.

Participant	Gender	Role	Role within SMASH Intervention	Practice
CCG1	F	CCG Quality and Improvement manager	Aligning SMASH with other quality and improvement initiatives across CCG	n/a
CCG2	M	CCG Quality and Improvement manager	Aligning SMASH with other quality and improvement initiatives across CCG	n/a
CCG3	M	CCG Pharmacist	Overview of medicines optimisation activities across the CCG Implemented SMASH in three different practices	A, B and C
GP1	F	GP	Prescribing Lead for Practice	D
GP2	M	GP	Prescribing Lead for Practice	E
GP3	F	GP Admin- Booking clerk	Administered recall system for patients requiring monitoring	E
GP4	M	Practice manager	Overview of medicines safety and Q and I initiatives for the practice	G
GP5	F	Practice Nurse	Involved in Q and I initiatives for the practice	G
GP6	F	GP	No direct involvement with dashboard - communicated with pharmacist	H
GP7	F	GP	No direct involvement with dashboard - communicated with pharmacist	H
P1	F	Practice Pharmacist	Employed by practice - SMASH intervention only one part of their role	F
P2	F	Practice Pharmacist	Employed by practice - SMASH intervention only one part of their role	G
P3	F	Practice Pharmacist	Employed for the specifically to implement SMASH intervention	E
P4	F	Practice Pharmacist	Employed by practice - SMASH intervention only one part of their role	D, H
P5	M	Practice Pharmacist	Employed for the specifically to implement SMASH intervention	B, E, I
P6	M	Neighbourhood Practice Pharmacist Lead	Neighbourhood Integrated Practice Pharmacist	J, K, L, M, N, O
P7	M	Practice Pharmacist	Employed by practice - SMASH intervention only one part of their role	H
P8	F	Practice Pharmacist	Employed by practice - SMASH intervention only one part of their role	G
P9	F	Practice Pharmacist	Neighbourhood Integrated Practice Pharmacist	J, K, L, M, N,
P10	F	Practice Pharmacist	Neighbourhood Integrated Practice Pharmacist	Q, R, S, T
P11	F	Practice Pharmacist	Neighbourhood Integrated Practice Pharmacist	N, O
P12	F	Practice Pharmacist	Employed by practice - SMASH intervention only one part of their role	P

7.4.3. Interviews

Twenty-five semi-structured face-to-face interviews were conducted by MJ between April and December 2016 with 22 participants including twelve practice-based pharmacists and a range of practice staff (four GPs, one practice nurse, one practice administrator and one practice manager) working in 18 different general practices. Three interviews were conducted with CCG staff including a pharmacist and quality improvement managers (see Tables 7.4 and 7.5). Interviews lasted between 14 and 62 minutes. Each of the participants was interviewed once individually with the exception of GP4 and GP5 (Practice nurse and practice manager) who took part in a joint interview since they were part of a team who were using the dashboard alongside other quality and improvement initiatives in practice. Repeat interviews were conducted with three pharmacists and one GP to see what changes were made in the intervention across a three month period. Interviews were audio recorded and then transcribed verbatim by a university approved transcription service

The interview schedule drew upon NPT to examine how participants made sense of the intervention, the interactional work involved in its adoption and implementation, the ways the intervention worked in practice and how it was appraised. The interviews initially explored participant experiences of working with the dashboard and their expectations of the intervention. The interviews further explored how the intervention had worked in practice including what had changed in terms of roles and work practices as a consequence of the intervention. Interviews also explored the participants' perceptions of the role of the clinical pharmacist in primary care (full interview schedules are detailed in Appendices 10-12). Eighteen of the interviews were conducted at the general practice where the participant was working, four were

conducted at university premises, one at the CCG offices and two at the local NHS hospital trust. Pharmacists, CCG staff and GP staff were reimbursed with £20 shopping vouchers for their time. GPs received £40 shopping vouchers. These differences in reimbursement reflected in normal hourly pay for these groups. All participants gave written informed consent to take part in the study, and for the interviews to be audio recorded and transcribed verbatim. The participant information leaflets and consent forms that were used in this study are provided in Appendices 13a to13f.

7.4.4. Methodological approach: Normalization process theory

It is has been suggested that evaluations need to consider the fidelity and quality of implementation, understand the mechanisms associated with how and why the intervention might lead to outcomes and to identify contextual factors (Moore et al., 2010). Interventions are considered complex social processes that are implemented into complex systems and as such dependent upon a range of organisational and social factors (Aarts, 2016; May, 2013). Interventions are not set apart from the dynamic social world in which they are implemented but are shaped by *"their associated ensembles of individual and collective beliefs, behaviours and activities"* (May, 2013 p.26). NPT can highlight the ways in which an intervention is integrated and adopted into everyday practice (May, 2013; May and Finch, 2009). This has particular utility in examining how individuals and groups understand the intervention through processes of sense-making and how they work to enable the intervention to happen (Murray et al., 2010; May and Finch 2009). Interventions, it has been suggested, become part of everyday practice only through the work that people, individually or in groups, undertake (May, 2013).

NPT focuses on the process of implementation and the ways in which agents dynamically engage in those processes (May, 2013); it was therefore considered particular valuable in this process evaluation that was conducted alongside the implementation of the intervention. Using NPT in this study had the potential not only, therefore, to uncover the ways in which the dashboard was made sense of and how people worked together to implement it, but would also be valuable at unpicking exactly how that occurred as the intervention was rolled out across the various practices.

7.4.5. Analysis

MJ lead on the coding and data analysis which was thematic and iterative and conducted concurrently with data collection. After the first six interviews had been conducted the transcripts for these were read and reread in a process of immersion to uncover emerging themes. These were then discussed by MJ, RK and DLP and from this initial analysis a thematic coding framework was developed (see Appendix 14) which was then applied to the transcripts by MJ using the QSR NVivo 11 application. As data collection continued, further transcripts were added to the dataset and coded alongside the initial interviews by MJ. In this way, a clear picture of the emerging themes was developed and discussed by MJ, DLP and RK. In a further stage of the analysis, a framework developed using the sixteen components from the four NPT constructs (Murray et al., 2010; May and Finch 2009) as described in Tables 4.1 and 7.6 (and detailed in Appendix 15) was applied to the full data set. This two-step process in the analysis was undertaken in order that important emerging themes were uncovered and additionally to allow for the data to be organised alongside the NPT constructs and components. In the final stage of analysis independent analysis by MJ

RK and DP of the coded extracts for both the emerging themes and the NPT components was undertaken and consensus reached. These themes were found to align with 14 of the NPT components. These were then grouped around the four NPT constructs (coherence, cognitive participation, collective action, and reflexive monitoring).

7.5. Findings

The findings are presented in line with the four NPT constructs thus detailing how people made sense of the intervention, worked collectively to implement it and sustain it in everyday practice. Table 7.6 summarises the ways in which the intervention was made sense of, implemented and adopted in relationship to NPT.

7.5.1. Coherence: Making sense of, and setting up, the intervention in the context of pharmacist and GP working practices

Pharmacists, GP staff and managers understood and attributed worth to the SMASH intervention. Pharmacists and managers saw the potential for the dashboard to provide quick and easy solutions. Users found the dashboard easy to use describing it as "*very user-friendly, very easy to log [...] easy to navigate around*" *(CCG 1);* "*very clean and very simple and very straightforward*" *(CCG 2),* "*dead easy to use*" *(P1).* The user-friendliness was seen as an advantage if the system was to be used by multiple users *"it's very user friendly and I think that's good when you're having to have multiple people, different types of people all using it, it's definitely easy for anybody to use" (P3).* The simplicity of the dashboard was particularly noted in comparison to the way *"general practice as a whole is becoming ever more complicated with systems and*

processes" (CCG2). The dashboard was further seen to present a solution to *"workloads of an existing practice" (CCG2).*

Pharmacists also attributed worth to the dashboard because it streamlined the way they worked. The dashboard was differentiated by pharmacists and GPs from running clinical audits of prescribing patterns through the GP clinical system. It was seen as a potential time saver since it provided real-time information and did not require manually running long and laborious audits and searches of patient records using the GP clinical system or require other staff involvement by *"asking the practice managers to do big searches" (P1).* In contrast using the dashboard, where such searches and audits had already been completed, allowed the patients highlighted as at risk to be visible when the pharmacist logged on in the morning:

> *"I think the main benefit is that it's just how quick and easy it is to access these patients [...] running the searches on that software [GP clinical system] I think is a nightmare [...] For me, I literally go in, in the morning, and I open up SMASH and I have all my patients straightaway and I think it's just the ease of that. Also, there's less room for human error in running your searches as well for these patients, because it's already made for you..." (P11)*

Table 7.6 Normalisation process theory: Constructs and components adapted for the SMASH study

COHERENCE : Making sense of, and setting up, the intervention in the context of pharmacist and GP working practices	
Differentiation What people did to understand how SMASH was different to other ways of working.	Pharmacists, GP staff and managers saw potential for the dashboard to provide quicker and easier solutions to previous audit and feedback approaches. The ease of use of the dashboard changed the way people worked.
Individual specification How pharmacists and others understood their specific role and tasks in relation to SMASH	The pharmacists understood their specific tasks and responsibilities in using the dashboard in the context of reviewing patient's medications and ensuring that patients were safer as a consequence. The SMASH intervention was understood in the context of wider medicines safety activities.
Communal Specification How people worked together to build a shared understanding of the aims, objectives, and expected benefits of SMASH	Pharmacists were largely responsible for setting up the intervention and integrating it into the GP practice.
Internalization What people did to understand the value of SMASH	Pharmacists overcame any resistance to the intervention through sense-making work in small groups.
COGNITIVE PARTICIPATION.Enrolment and engagement to establish the intervention	
Initiation The work people did to set up SMASH. How people worked with others to make things happen**.**	Pharmacists led the intervention, demonstrating the dashboard and setting things up within the practice setting.
Enrolment How people organised themselves to work together on SMASH.	There was varied access and engagement from different stakeholders
Legitimation How people gain trust in SMASH	Trust and confidence in the dashboard and in the work of the pharmacists was important in establishing the intervention and in developing the professional role of clinical pharmacy.
Activation How people connected and worked together to sustain the practice	The intervention helped to establish and develop the role of a clinical pharmacist in general practice.

Table 7.6 (Continued) Normalisation process theory constructs and components adapted for the SMASH study

COLLECTIVE ACTION The work undertaken to adopt and sustain the SMASH intervention: Communication, building relationships and divisions of labour**.**	
Interactional workability How was SMASH operationalised through interactions between participants.	Communication and collaboration between pharmacists and clinicians was important for the intervention. The dashboard helped to build relationships
Relational integration Trust and confidence in the collaborations between different people working on SMASH. How relationships were built	Pharmacists becoming integrated into practice team. Collaborations between pharmacists and clinicians based upon agreement and planning.
Skill set workability How the work on SMASH was allocated. What divisions of labour were in place.	Pharmacists mostly worked with the dashboard separate from other GP staff. Pharmacist skill-set made them the most appropriate people to work with the dashboard. Such division of labour drew upon the pharmacists' skill set.
REFLEXIVE MONITORING How pharmacists and clinicians reflected upon and appraised the intervention and the potential for sustaining long-term system change	
Systematization How people determined how effective and useful the SMASH was for them and for others.	Value of the data presented in the dashboard and ease of access to information seen as beneficial to improve medicines safety
Individual appraisal Individuals appraising SMASH in relation to their own work.	The dashboard built confidence and understanding of the value of clinical pharmacists' professional role in general practice.
Reconfiguration How SMASH was modified and developed by pharmacists and others. Changes to wider medicines safety work as a consequence of SMASH.	Pharmacists met together and gave feedback which led to improvements in the dashboard Pharmacists broadened their actions from attending to high risk prescribing cases to undertaking full medicine reviews with patients. The dashboard was seen as presenting opportunities for further medicines safety work.

The simplicity of the system was seen to allow for greater impact in a short space of time:

> *"...it's just quick and easy isn't it? You can turn up at a surgery, log on the dashboard, 'cause you'll have access to that surgery, and within an hour you could have made several safety interventions, from just turning up at a random doctor's surgery, [...]you can just walk in, and you could have made quite an impact." (P3)*

Particular sense making work was undertaken in order to understand and then implement the intervention. Pharmacist P9 understood and undertook their specific tasks and responsibilities in using the dashboard in the context of reviewing patient's medications. This pharmacist felt that this was ensuring that patients were safer as a consequence. That the dashboard was able to help them complete these tasks in this way gave value to that work, which in turn motivated them to continue to use it.

> *"It's very simple to use and it motivates me. Because the practice that I've been in for the longest, I can open the dashboard at any given time and go, those (have been solved). At the moment, there's seven interventions, patients that have fallen off in the time that I've been there that I know that I have personally reviewed. They're safer now. And also I've done a full medication review and I know that I'm satisfied with their treatment at the moment. To have that, for it to be quantifiable like that, is really nice" (P9)*

The SMASH intervention was also understood in the context of wider medicine safety activities. Pharmacists and clinicians were more likely to use the dashboard if it helped to fulfil the requirements of other incentivised schemes. General practices were

described as busy and under pressure from competing priorities such as the constant flow of such new initiatives.

> *"...from what I understand in GP land, they get...every year they get something new thrown at them, something new, something exciting, something that is basically going to change the way they get paid." (P2)*

Whilst one GP talked of taking responsibility for doing a "*a medicines management update from time to time in the practice meetings"* he highlighted that business obligations mean that the focus in general practice is upon *"things you get paid for"(GP2).*

People worked together to build an understanding of the intervention but this often involved the pharmacists educating others and sharing their own interpretation of the dashboard. It was assumed that there would need to be *"buy-in"* from the practice *(CCG3)* and that *"for anything to be sustainable, it's got to be owned by the practice" (CCG1).* Another pharmacist *(P2)* talked of the difficulty and challenge of *"getting everyone on-board"*. In order to integrate the intervention into the practices, pharmacists demonstrated and explained the dashboard to clinicians and other GP staff. This sometimes involved identifying and highlighting the evidence summaries for the dashboard indicators to help practice staff to understand the benefits of the tool.

> *"I alerted the GP verbally. So, showed them the dashboard, where I had got the information from, because it was a good way to get his buying into the dashboard, to say, oh, look what this can do, look what it has found. So, I showed them the dashboard, how I had found that patient and then we went through the evidence of the potential harm that that could cause together." (P1)*

There was some perceived resistance from clinicians and GP staff to working with the dashboard and a need to build awareness and understanding that the intervention could "*save problems in the future" (P11).* Similarly one pharmacist felt there was potential resistance, sometimes related to a perception that it would involve extra work that had to be overcome in order for the benefits of the dashboard to be understood. This pharmacist therefore adopted a practice of working with individuals and small groups in a process of sense making.

> *"Generally speaking, I kind of have just been…I've been logging on to it regularly just because I've been showing other clinicians. So each time I sit down with a clinician I explain what this whole thing is. I do it with obviously the SMASH in front of me just to show them and get them to have a look at it, get them to play with it and put them in the seat so that they then are forced to kind of look at it as opposed to you just showing them. I found if you just show them they just nod and agree and pretend to engage when nobody does." (P2)*

7.5.2. Cognitive participation: Enrolment and engagement to establish the intervention

The process of establishing the intervention involved collaborations and interactions between stakeholders. Pharmacists led on the implementation of the intervention; as well as demonstrating and presenting the dashboard, they would often set up access to the dashboard for the clinicians. Clinicians and other GP staff were seen as important to the intervention in that they provided a way of linking the work the pharmacist was doing to the wider prescribing activities in the practice. Pharmacists spoke of needing *"a clinician to go to regularly" (P2)* partly because prescribing changes could be

carried out by that clinician. Giving clinicians access to the dashboard and showing them the tool was perceived as important to get practice staff "*on board"*.

> *"So I got involved in a lot of the setup in the practices that I'll be working in and also showing them [practice staff] the dummy [version of the dashboard], and then getting them on board with it. And the initial feedback we got was all very positive. A lot of the GPs are on board. The practice manager is completely on board and excited for it. And [...] most of the GPs have access now as well." (P9)*

Having the pharmacist lead the intervention meant that it was perceived to be owned by them. One pharmacist reflected that clinicians saw the dashboard as something for the pharmacist to use and that GPs were not accessing it.

> *"I think it's been well received. I don't know if any of them are looking at the dashboard themselves. I think the dashboard is seen as my thing. I don't think they're looking at the dashboard. We've got them set up with log-ins but I think it could be that they don't really know how to use it." (P5)*

There was thus a sense in which it was not something for clinicians or GP staff, which led to a lack of involvement across these staff groups. Such a lack of involvement was legitimised by suggestions that pharmacists were experts in medicines, with the appropriate skill-set, and was therefore the ideal people to use the system. As one GP stated; *"pharmacists have got that constant focus on the prescribing and so it fits within their remit" (GP4).* It was assumed that pharmacists were much more likely to engage with the system than clinicians because; "*they know*

what they're looking for and what they've already actioned and what still needs actioning." (GP5).

Access and engagement with the system by GPs appeared be very much decided by GPs on an individual autonomous basis. GPs were reported to make decisions based on whether they thought the dashboard was useful for them, with some GPs wanting to use the dashboard for their "*own education.*" *(GP1).*

> *"I think we've got about five or six people that have got logins for the dashboard – not huge numbers because other people have just said, well I'm never going to look at it so there's no point [...] Then a couple of people have said I want to be able to get these [...] I want to be able to get the evidence for the educational point of view." (GP1)*

Whilst therefore the day to day use of the dashboard was mostly a role for the pharmacist GPs did value the dashboard as *"an educational tool" (GP1),* particularly for the evidence summaries for each indicator.

As part of the relational work in setting up the intervention it was important that clinicians trusted the intervention both in having confidence in the dashboard and confidence in the work that the pharmacist was doing. Trust was thus important in establishing the intervention. Such trust and confidence could be achieved as one pharmacist reflected by *"proving our worth" (P1)* through their work with the dashboard and thus adding value and allowing the pharmacists to develop their professional role in general practice. Trust and an understanding of the benefits of the intervention could be achieved by changes made to patient's medication because of the

dashboard. Trust and confidence in the intervention was also achieved in that the feedback was seen to be depersonalised:

> *"Yeah, it does (improve things in practice) and having this tool depersonalises (feedback), because it is...this system has picked up that you have prescribed this. It's not...you know, you've done this and I don't think it's safe...it's the system has picked this up, so it depersonalises everything [...]so it's a good way of getting feedback without making it personal." (GP1)*

Similarly this pharmacist felt the practice knowing their expertise helped to establish that confidence.

> *"I personally feel that because we are new to the practice I don't want to go in and start making interventions myself without them knowing my expertise, me getting a feel for what they want to me to do, me getting a feel for what they are comfortable with." (P10)*

Pharmacist P1 also saw the dashboard as helping develop the role of the pharmacist and as a consequence improving trust and developing relationships with GPs.

> *"So, almost give me an "in" to say, this is what my role is here [...]And then when we were talking about the GPs, kind of, saying, oh, so you can see what I am doing, I think it developed that personal relationship and that professional relationship. [...]So, I think it built that respect between me and the GPs as well, having that tool to support them." (P1)*

Many pharmacists saw the dashboard as an opportunity to demonstrate their skills and to progress the role of a clinical pharmacist working within general practice.

"But as far as the role is concerned, I think getting [...] just being here and being available and looking…even though only looking at 13 different things, I'm still on hand getting a presence, getting the staff to understand what you can do, so I think it's good for pharmacists in general to get exposure and show your skills." (P3)

7.5.3. Collective action: The work undertaken to adopt and sustain the SMASH intervention; Communication , building relationships and divisions of labour

The communication of messages regarding the dashboard and the intervention was primarily initiated and led by the pharmacists. This was important work in order to establish how the intervention was going to be adopted and operationalised in the practices. It could be through regular practice meetings, through email or through more opportunistic contact. Pharmacists adopted different ways of communication with clinicians and other GP staff in order to engage them with the intervention. This involved many pharmacists modifying and adapting their own ways of working from their previous places of work in hospital settings to the different context of primary care, as well as building an understanding of the complexities of working in primary care where group meetings and getting everybody together was perceived as difficult.

"It's difficult, one thing I find awkward is that I don't want to have to channel everything through one doctor,[…]it's quite difficult to get your head around when's the best time to approach doctors to discuss things in tracking one thing, because they go into home…when the surgery is not on, they're on home visits or they're in meetings, it's quite a different way of working. So that's probably one

barrier is getting free time, so it'd be difficult probably to get everybody together unless you went to the practice meeting on another day." (P3)

Communication and collaboration were seen as important for the intervention. Most pharmacists relied upon clinicians to make changes to patients' medication based upon the data from the dashboard. The majority of pharmacist participants were not prescribers so they were reliant on GPs to change prescriptions. One CCG pharmacist talked of providing clinicians with "*simple messages"* if needed and described communication as only driven from necessity.

"So, yeah, that's how I've been using it [dashboard] within (name of practice), hands on approach, not bothering the GP too much if they don't need to be, just trying to get, for those patients [...] just simple messages and where patients do need acting on, just passing the NHS number to the GP and getting that acted upon. So that's how I've been using it." (CCG3)

The collaboration between pharmacists utilising the dashboard and other GP staff was characterized by agreement and planning. Pharmacists discussed how they worked with GPs to decide *"the best course of action" (P5)* and *"to have agreed an action plan" (P10).* The pharmacist worked through lists of patients flagged by prescribing or monitoring indicators but *"action plans"* were sent to/discussed with the relevant person. There was therefore some division of labour happening whereby pharmacists undertook specific tasks in highlighting patients at risk and suggesting a suitable plan of action but then these would be dealt with by clinicians who took *"appropriate action"(P3).*

"So, at the minute, I spend my time working my way through each indicator, from that I look at each patient, find out the ins and outs of it, work out an action plan and then I will send that to the relevant person or take the appropriate action. So I might do things like ringing a patient up, getting doctors to write prescriptions, sending a letter for somebody to come in, documenting everything that I've found in the notes and then keep moving on to the next indicator." (P3)

In contrast GP1 described how they used such linear feedback in a way that was beneficial in getting medication reviewed and in providing prescribers with feedback on high risk issues.

"Really like using the dashboard, it's very easy to use and what we do is use it to identify the new cases and so we've got a practice pharmacist. At least once a month she'll go through the new cases, have a look at them, see who's prescribed it, signs an internal message to the prescribing person saying, you have prescribed this, are you aware it's a high risk combination, get them to review it. Then that means it's the prescribing person that reviews the medication and gets feedback that it's a high risk prescribing issue." (GP1)

Participants thought practice level feedback designed to change prescribing behaviour –so that pharmacists could get "*engagement with the wider clinical team" (GP4),"so you can get other people to change their practices" (P2)* was seen as better than one–to-one feedback.

"So we have weekly clinical meetings for each site. It could well go back to those. We also have monthly mandatory training where we switch the phones

off and everyone gets actual dedicated time to do their training. So, if it's a site-specific problem [...] and probably in the first instance it will go back to the clinical meetings and then if it's still not getting through then take that up a level. There's also the pharmacy bulletin we're putting positive feedback in there as well." (P8)

Whilst pharmacists worked to a degree in isolation communicating messages back in this way to the clinicians, they reflected on how it was important to be integrated and become "*identified as like a member of their staff and part of their team" (P11)* in the practices in which they worked in order for the intervention and their work to be valued. It was also seen as important that the pharmacist developed and built relationships with practices in order to make the intervention more successful. Relationships between the pharmacist and others were perceived to be built through the use of the dashboard;

"So, I am using it as an exercise, really, in way of building a relationship with the GPs as well and for them to see what the SMASH dashboard can do for them. So, I know, potentially, not everyone is using...taking that approach, but I just think it, one, gets SMASH, the dashboard some PR and is also, yeah, helping me to build some relationships."(P10)

Such allocation work was often characterized by the pharmacist tasked to look for new cases of high risk prescribing whilst the final decisions on actions would be made by the GP.

"Then what we decided as a practice is that we want our pharmacist to look at the new initiations. On the dashboards the new cases, we wanted (name) to look

at them and look at the new cases. Then she is going to send a message to the prescribing doctor that that's a high risk prescribing area and then leave it to the doctor to decide whether to contact the patient, whether to action it or not." (GP1)

This division of labour was attributed to GP workload and to the particular skills of the pharmacist since *"they know what they're looking for" (GP4)* and *"were the right person to be tasked with the right job" (GP5)*. This role allocation and division of labour did have the benefit of improving value to the intervention. Pharmacists valued the dashboard in that it was perceived to potentially *"lead on to making general practitioners confident in what pharmacists can do within general practice" (P10).* GPs valued the additional presence of the pharmacist since it was seen to ensure *"things don't get missed" (GP7).*

"Well that's the benefit of having it pharmacist led, isn't it that you know somebody is going to follow it up and make sure it's done and keep checking and keep going back and, you know. Sometimes you give GPs work and they're just so overloaded that it's just another thing for them to be looking at and to be doing..." (P12)

This division of labour therefore could have been said to be drawing upon the particular skills of the pharmacist and providing through them a way of getting the dashboard used within practice.

There was variation in the utilisation of the pharmacist in practice. Some pharmacists were employed directly by the practice others had been assigned to practices for the duration of the project. This led to different expectations from the practices and to

different approaches. Some of these could act as barriers to using the dashboard such as asking the practice pharmacist to undertake a range of different tasks not directly associated with the intervention such as repeat prescription requests, and medicine reconciliations of patients discharged from the hospital. Pharmacists who had been assigned to practices specifically for the SMASH intervention could feel a sense of isolation and separation from the rest of the practice team which could potentially undermine collaborative working.

> *"So I suppose, I do feel a bit weird sometimes because like, if I don't turn up, they'll just presume I'm somewhere else, they don't really know where I am or what I'm doing. […] I just roll up and do a bit of tinkering and roll off again. […], I do feel, a bit like I've come in through the back door. I sneak upstairs, sit at that desk, do what I do, nobody knows what I'm doing, to a point, 'cause nobody's checking on me are they? And then I just go home again.*" *(P3)*

7.5.4. Reflexive monitoring: How pharmacists and clinicians reflected upon and appraised the intervention and the potential for sustaining long-term system change

Participants reflected upon the SMASH intervention and appraised its worth but in this context did so primarily as individuals rather than groups. They reflected upon the worth and value of the data in the dashboard where it was seen that "*having that at your fingertips is really useful*" *(GP1).* Having easy access to such information was seen as a positive reinforcement of the intervention because the numbers of patients at risk due to prescribing was seen to fall and such feedback was valued by clinicians "*since they were all saying we want to be told if we are prescribing unsafely" (GP1).* The value of

the data in the dashboard was therefore related to safer prescribing since the implication here is that if clinicians wish to have feedback on unsafe prescribing they want to prescribe more safely in the future. Similarly perceived outcomes in terms of changing prescribing for this GP showed the value of the dashboard to them:

> *"...they (other GPs) come to me and say they've noticed these changes. Actually I have seen doctors prescribing more PPIs with NSAIDs, which probably they weren't doing before. But I was working on the disease modifying drugs for arthritis and the monitoring before that and that is changing as well. But that is part of the dashboard too, so that's why I think we're probably scoring very well on that..." (GP2)*

The pharmacists who worked on the intervention also met regularly in a process of sharing good practice and developing different approaches to working with the dashboard and within their various practices. One such meeting led to a change to the dashboard in the development of a 'note feature' that allowed users to give reasons for the actions that had been taken in response to the highlighting of patients at risk. This was valued by one pharmacist:

> *"The fact that now you've added the notes system, so I can flag up if we have reviewed somebody, just to avoid duplication, works good." (P6)*

The SMASH intervention was seen as a tool that could lead to system changes in practices, and make long term changes through prescriber education and awareness. The role of the practice pharmacist within the intervention was to engage in such educational outreach within the practices but in some practices this was seen as

opportunity to "*broaden the remit a little bit" (P6)* and develop the intervention to include a fuller medication review for patients:

> *"So, what we've been doing is, we've actually broadened the remit a little bit, because obviously when you have a patient with one thing that's up with them, or something that's identified on the dashboard, there often may be other things, and our view is holistic care, with Salford standards, we do a few medication reviews on the patients. [...]but when we look at those patients, we're obviously looking at the indicator that flags, but also making sure we look at the wider patient as well, because we don't want to go in and just fix something, like order a blood test, and realise there's other issues, that might [...] need resolving. So, we're using it as a way of catching the patients, but then looking at the whole patient not just one particular indicator." (P6).*

Several respondents discussed education for individual clinicians and prescribers, for instance, *"if you feedback to the individual prescriber, then the person that makes the mistake learns from it and then hopefully doesn't do it again" (GP1)* or about changing "*the systems and processes in the future*" (*CCG3).* It was acknowledged that working on high risk prescribing cases then needed to lead to education in order to maintain the quality of prescribing;

> *"I think because we have not done too much, because we have not had massive indicators to […] go through, it has been very much a bit of a reactive, oh, I have opened the dashboard this week, this patient needs sorting this week, let's do it. But, that has then lead to education" (P1)*

Pharmacists spoke of the need for education and awareness as part of "*a personal development as well*" *(P4)* and for the need for clinicians to "*take more of an ownership" (P3)* in order to bring about change and to" *sustain the difference*" *(P2).* Such change and education of clinicians was often initiated by pharmacists;

> *"But that was something I came up with...it was group effort and my idea was that they shouldn't think of an NSAID without a PPI, they should think of it as like they just go together like salt and pepper. I did the salt and pepper cards, I even stole a salt and pepper from a good sandwich vendors to put in the envelope so that they've got the novelty, a bit of a fun thing" (P2)*

The SMASH dashboard was also seen as presenting opportunities for the further quality and medicines safety programmes in the future. One CCG manager reflected that;

> *"I think it'll give us a useful tool to be able to perhaps design our programmes of work, and also thinking about if we're going to run any quality programmes in the future, it will hopefully help us to design what we're working on because it will give us that information, give us that baseline that we need so often." (CCG1)*

7.6. Chapter summary

This chapter explored the implementation and adoption of a novel medication safety dashboard in primary care through NPT. The processes involved in the implementation of the SMASH dashboard were understood through the four NPT constructs.

Pharmacists, GP staff and managers attributed worth to the intervention and understood it in the context of wider medication safety work. The ease of use of the dashboard changed the ways in which they had previously undertaken work to highlight high risk prescribing. Pharmacists were largely responsible for the setting up of the intervention and whilst people worked together to understand the dashboard it was often the pharmacist who took on the lead role. Communication and collaboration was important for the intervention and allowed clinicians to receive feedback on high risk prescribing instances. Whilst the pharmacists thought integration into the general practice team was important there was some division of labour. Pharmacists felt clinicians were important to the intervention but at times there was a lack of involvement from GPs and other GP staff. However this was because the pharmacists' skill-set made them the most appropriate person to work with the dashboard and provide feedback to clinicians who could then facilitate changes if needed.

A specific focus was on the role of the clinical pharmacist both in their utilisation of the dashboard and their relationship with the general practice staff. The dashboard was implicated in helping to develop the role of clinical pharmacy in general practice. Of importance here was trust and confidence in the role of the pharmacist. Many pharmacists felt the dashboard presented an opportunity to demonstrate their worth and value. Pharmacists reflected upon the worth of the intervention and worked to suggest improvements to the dashboard. The dashboard and intervention were utilised as a spring board to extend medicines safety work.

The following chapter presents a full discussion of all study findings. This focuses upon the common and contrasting themes across the three empirical studies and considers the implications for practice and future research.

CHAPTER EIGHT: DISCUSSION

8.1. Preface

The aim of this PhD was to explore, evaluate and understand the socio-technical processes involved in the implementation, adoption and use of two different information technology interventions for medicines optimisation in primary care. This was a novel study in that it explored healthcare IT systems in primary care settings and it utilised three different and complementary, sociotechnical theoretical approaches. This chapter reflects upon the programme of work for the PhD and discusses the significance of the findings across the three studies outlined in Chapters Five, Six and Seven.

The first part of this discussion (Section 8.2) looks at the significance of the findings and the relationships to previous studies, exploring in particular the most important findings in this PhD and the common and contrasting themes across the three studies. The second part of this discussion (Section 8.3) is a reflection upon the programme of work for this PhD. This explores strengths and limitations of the work including a discussion of the value of sociotechnical approaches to the evaluation of IT systems in healthcare, specifically focusing upon the value of the three theoretical approaches applied in this thesis. This section continues to consider the implications of this research for practice, for future interventions and for future research.

8.2. Significance of the findings

The most important finding of this PhD was that the successful implementation and adoption of interventions involving IT in healthcare is dependent upon the people

who may use that IT and upon the interactions collaborations and cooperation between different healthcare professionals. As has been described in Chapters Five, Six and Seven, users of the two IT-based systems attributed worth to them and considered them valuable for improving medication safety, but there were considerably varied patterns of utilisation, access and engagement between different stakeholder groups. The EAandF system Eclipse Live was described as being more utilised by CCG managers centrally than by clinicians at individual general practices though some GPs took active roles. CCG pharmacists used the system to conduct medication reviews for care home patients but community pharmacists had no access to the system. Within practices there was a variation in use with different practice staff taking responsibility for interacting with the system. Similarly the SMASH dashboard was used more readily by pharmacists than by GPs or other GP staff. Some GPs were actively involved with using the dashboard whilst others were disengaged from it.

Previous literature has established the role of social, organisational and work practices in the adoption of IT (Burgin et al., 2014; Hayward et al., 2013), whilst others have focused upon functionality of design and tailoring to users (Harvey et al., 2014; Cresswell et al., 2012b). Other research has indicated that emphasis upon training might also construct end-users as the problem (Waterson, 2014). With notable exceptions (Greenhalgh et al., 2014; Hinder and Greenhalgh, 2012), much of this earlier literature has highlighted the importance of work practices and how technology needs to be embedded into pre-existing routines, but has not seen how those work practices and organisational routines are dynamically linked to wider contexts, particularly in the context of medication safety in primary care. The

findings presented in this thesis have shown that, within primary care, wider external structures could impact upon local organisational routines. This was seen in the ways in which policy and national and local initiatives impacted upon the use of the systems. Of particular importance were the relationships between stakeholders. These could foster collaborations that enhanced implementation and adoption and could involve divisions of labour which enabled some groups to focus their skills upon the intervention but created disengagement elsewhere.

Primary care settings are governed by institutional norms, measures, rules and traditions, habits and behaviours (Daker-White et al., 2015; Greenhalgh et al., 2014). Some of these are embedded in local rules and conventions associated with the different working dynamics of individual general practices, while others are found in regulations and governance associated with wider economic and institutional contexts (Greenhalgh et al., 2014; Winthereik et al., 2007). The three studies outlined in this PhD highlight how the healthcare IT interventions were implemented and adopted in the complex social and organisational contexts of primary care. Across the three studies it was found that social and organisational structures shaped the way the interventions were implemented.

Four key, interrelated, themes that cover the three studies are discussed below. These themes are: social processes of implementation and adoption; organisational norms, work practices and routines in primary care; divisions of labour; and external structures and wider context.

8.2.1. Social processes of implementation and adoption

Across the three studies, interactions and relationships were clearly noted to affect use of the systems. This finding fits with what Klecun has described as a *"sociotechnical network"* in which *"implementation is an ongoing social process influenced by stakeholders' needs, interests, norms and ways of doing things"* (2016, p. 66). Across the studies, relationships between health professionals, communication and collaboration were important in the use of the systems and in how the interventions were implemented, adopted or sustained. This could involve the flow of information between health professionals, interactions that involved shared or collective use and collaborative work practices. Different health professionals took responsibility for both the interventions so communication between them was important. This was particularly so in the case of the SMASH intervention where communication in the form of feedback from the pharmacist accessing the system to the GPs ensured that medication safety actions were taken.

There were also patterns of relationships between agents and the technology that were related to different responses to the material properties within the technology. Therefore, of importance were both the agent-agent relationships and the agent-technology relationships, and how those relationships were embedded into social structures. For instance, the material properties of Eclipse Live facilitated the CCG to communicate with practices by sending out alerts through the system and also to track practice response to those alerts. In this way there were both agent-agent communication and agent-technology relationships that worked dynamically together to allow actions to take place. This fits with understandings of technology use through the concepts of affordances and of sociomateriality outlined in Chapter Four (Leonardi,

2012; Orlikowski and Scott, 2008; Zammuto et al; 2007; Hutchby, 2001). Since these patterns of relationships occurred within social practices they cannot be considered in isolation. In previous research there has been a focus upon interoperability, work practices and system usability, suggesting that poor adoption of IT is related to users or the system (Garfield et al., 2013; Cresswell et al., 2012b). This misses how interactions and relationships between contexts, users and the technology might work and how the adoption of IT is a social practice (Greenhalgh and Russell, 2010).

Of particular importance to the interventions and these social processes was that they were taking place in primary care settings. As was described in Chapter Two, primary care is a complex and dynamically evolving landscape (Rhodes et al., 2015; Daker-White et al., 2015; Esmail, 2013). The findings in this thesis similarly highlighted the difficulties associated with interventions in primary care where workload, resources, business obligations, financial incentives and divisions of labour could all impact upon how these interventions were adopted into everyday practice. The workload in primary care was seen as particularly important, and as such was a significant part of the contextual landscape into which the interventions were implemented. This was particularly apparent in the realist evaluation of the Eclipse Live EAandF system, where GPs discussed needing to juggle competing tasks and prioritise workloads. What was also apparent in these studies was the multi-disciplinary nature of primary care and how the social processes of the interventions were interconnected with the patterns of relationships between different stakeholder groups across primary care. There were important relationships between the CCG managers and GPs, between pharmacists and GPs, and between administrative staff and GPs. In the SMASH study this was important as part of the process of embedding the intervention.

8.2.2. Organisational norms, work practices and routines in primary care

Previous research has suggested that interventions utilising information technology can facilitate new working practices and collaborations between health professionals (Petrakaki et al., 2016). Across the studies in this thesis, the organisational structures and the work practices across primary care settings were implicated in the use of systems. This included fitting the system in with work routines, work schedules or workloads, or in changing work practices in response to using the system. Also of significance were the competing priorities of other initiatives. Such findings are consistent with much of the literature relating to IT in healthcare outlined in Chapter Two (for example: Greenhalgh et al., 2014; Hayward et al., 2013; Lainer et al., 2013; Crowe et al., 2010; Oroviogoicoechea and Watson, 2009). As has been seen, this previous literature has generally suggested that IT systems have not fitted with pre-existing work practices leading to resistance, abandonment, the ignoring of alerts and disengagement with systems or in the creation of workarounds and adapted work practices (Porat et al., 2017; Peiris et al., 2011; Swinglehurst et al., 2011).

There were similar descriptions of changes to work practices across the three studies presented in this thesis. In the findings outlined in Chapter Six it was perceived that the flow of information between the CCG and individual practices facilitated engagement with the system. Practices were more engaged when the system was trimmed down to relevant alerts based on local projects, rather than using a whole catalogue of embedded alerts within the system. Consistent with previous research, this tailoring of alerts allowed for time saving and avoided alert fatigue (Ranji et al., 2014) and so encouraged greater engagement. Ojeleye et al. (2013) have likewise found that the tailoring of alerts maximised the likelihood of action being taken.

The combination of perceptions of the Eclipse Live system as new and of ingrained behaviours and set patterns of work amongst GPs, allowed for limited use of the system. As seen in Chapter Six varied administrative practices could impact differently upon how effectively the EAandF system was used. For CCG pharmacists, some adaptations of pre-existing work practices were required for efficient and effective use of the system. Whilst prioritising tasks and enacting workarounds contributed to effective use of the system, some work practices acted as blocking mechanisms; for instance, underutilising the system by making paper copies of alerts that were designed to be read and responded to on screen. In a study of GP practices' handling of secondary care information, (Crowe et al., 2010) delays were seen to be caused by similar sub-optimal work practices. In the first study of this system adopting SST outlined in Chapter Five, the prioritisation of work schedules could also constrain use of the system.

However, whilst the three studies for this PhD have revealed some instances of workarounds and the adaption of work practices, some of the findings have been in contrast to this previous literature and have highlighted a more positive adoption of the technology where work practices have not required adaptation or have been changed in a positive manner; in other words, changes to work practices as a result of the technology improved the way people worked. In the study of the SMASH dashboard outlined in Chapter Seven the system was seen by pharmacists as a solution to workload and something that improved work practices by saving time. The simplicity of the system was seen to allow for a greater impact (upon medication safety for patients) in a shorter space of time than the previous more laborious work practices. So whilst the system did change work practices, this was seen in a positive

rather than a negative light. There were similar positives with the evaluation of Eclipse Live. In the realist evaluation outlined in Chapter Six, a pharmacist undertaking medication use reviews with patients in care homes found the Eclipse Live saved time and helped with a more focused review. Similarly the CCG pharmacist found this system useful when conducting audits across the health locality, and GPs found the system helpful if it provided relevant alerts.

A common position across the sociotechnical literature is that *"IT that does not fit with organizational culture, professional values and practices are likely to be resisted"* (Klecun, 2016, p. 72). The variations in the relationship between work practices and system utilisation found in the findings here is interesting in that it may well highlight how systems can work effectively in one organisational and social context, and lead to positive use and potentially positive outcomes, but be less effective in other contexts. Thus whilst, as Klecun suggests, systems that do not fit with pre-existing contexts may be resisted, if systems do fit with organizational culture, professional values and practices they may well be more likely to be successfully adopted. Possibly the most important factor in adoption of the intervention could be the specific stakeholder group that is using the system in a specific context. So in the examples given above, where the system fitted into organisational norms and workplace routines it was in the context of use by a specific professional group. The system worked for the pharmacist conducting medication reviews in care homes because it provided them with the necessary information in a way that had been more difficult to access previously; the system gave access remotely at the care home to the patients' electronic health record and avoided having to visit the general practice to access the clinical record there. Similarly for the

SMASH pharmacists, the dashboard was seen as a solution to previous laborious manual searches of GP record systems. It may well therefore be that such IT systems do not necessarily require adaptation of pre-existing work practices when they are utilised in a focused way by specific groups and that work practices might require adaptation more frequently when the system is then used in wider contexts by other health professionals.

Furthermore successful adoption may well not be determined by the IT intervention fitting with pre-existing contexts but about how the intervention interacts with those existing contexts and thus the interplays between existing structures and the new ones that the intervention creates. This was seen in both the Eclipse Live studies and the SMASH intervention where new ways of working emerged from this interaction. The SMASH dashboard led to new roles, identities and working practices for pharmacists working in the general practices and Eclipse Live allowed facilitated new ways of working for the CCG managers in their auditing of prescribing across the CCG.

8.2.3. Divisions of labour: ownership and professionalism

Utilisation of the systems was also associated with divisions of labour, with different specific groups of stakeholders more likely to use systems than others. These divisions of labour could be explained across the two interventions in different ways. Firstly, social norms and organisational practices could undermine use across groups by instilling a sense of ownership of the systems which could lead to a lack of involvement from other stakeholder group. Secondly, the use of systems by different stakeholders could be dependent upon the individual expertise and skill-sets of specific groups of health professionals.

In Chapter Six, it was found that similar to previous research (Sheikh et al., 2011) greater ownership of the system across the workforce, and more embeddedness within existing work practices could lead to better utilisation across primary care, with potential benefits for medication safety. The use of the system was undermined by a perception amongst several stakeholders that the EAandF system was owned by the CCG. Partly this perception related to the design of the system as a tool to be used for audit and feedback centrally. The value and potential for the system to be more widely used locally within a general practice, was undermined by the perceived ownership of it by the CCG and by the understanding that it was a population level audit tool. Utilisation was further undermined by time pressures in general practice, a lack of access to and a lack of knowledge and awareness of the potential benefits of utilising the EAandF system which meant that there was a lack of ownership of the system at the local practice level. Participants in this study speculated that general practices more engaged in the use of the system might have dedicated prescribing leads that were more likely to run their own audits and as such were more proactive in managing medication risks.

Similarly in the SMASH study, the dashboard was seen as something belonging to and for the pharmacists and not necessarily for clinicians or other GP staff. Practice pharmacists clearly engaged with the dashboard more than it was used by clinicians and other GP staff. As a consequence of this, pharmacists particularly felt at times a sense of isolation in terms of how they worked with other members of the practice team. A similar intervention to improve prescribing in primary care found variations in implementation and differences in practice engagement (Grant et al., 2017a; Grant et al., 2017b). These studies found that collective engagement within practices,

particularly from clinicians, led to more successful implementation (Grant et al., 2017b).

The second of these divisions of labour concerned skills and professionalism. There were two interrelated ways in which skills and professionalism were implicated in the use of the systems. Perceptions of the Eclipse Live system, examined in Chapters Five and Six, as requiring technical competence could undermine use by those who believed themselves insufficiently skilled to do so. Health professionals were, partly as a consequence of that, able to resist using the technology by suggesting that others had professional skill-sets which were more readily applicable to the use of the systems. The pharmacists in the SMASH study were considered by general practitioners and others to have the skill-set most appropriate to highlight instances of high risk prescribing and to deal with medication safety issues and would thus be the most appropriate people to engage with the system. This enabled the general practitioners to distance themselves from the system and legitimised their own disengagement from it. In the SMASH study outlined in Chapter Seven, GPs and others were more remote from the system and were said to only engage with the system when they made autonomous decisions that deemed it useful for them. In the first two studies GPs were said to require training and persuasion to use the Eclipse Live system. This is similar to previous research that found that doctors rejected using systems in a process of differentiating their professional identities from other health professionals who were using them (Petrakaki et al., 2016).

Whilst GPs distanced themselves from systems, pharmacists working in practices and for the CCG were able to demonstrate their professional skills through the use of both the systems. This was itself at least partly dependent upon other stakeholders having

trust and confidence in the expertise of the pharmacists using the system which helped to build respect. Further to this, the SMASH dashboard helped to support the developing professional role of clinical pharmacists in general practices. As outlined in Chapter Seven, the SMASH intervention brought worth and value to the role of the pharmacist. The dashboard was seen to help in developing this role of clinical pharmacy, in that it provided objective evidence of improvements in medication safety following review of patients by the pharmacists. Therefore, this division of labour not only fulfilled tasks regarding medication safety but also strengthened the professional value of clinical pharmacy in general practice. This runs somewhat counter to previous literature that has seen IT in healthcare systems as reducing the autonomy and professional discretion of health professionals (Greenhalgh et al., 2014, Petrakaki and Kornelakis, 2016). It may well suggest that when IT does fit with the professional norms and values of a specific group of health professionals it is more likely to be accepted and use sustained.

These ways in which the technology in this research afforded both opportunities for pharmacists to demonstrate their professional skills and allowed other professionals to resist in using the dashboard, is similar to that found by Petrakaki et al. (2016). Petrakaki and colleagues explored how affordances embedded in the material properties of a patient record system could redistribute clinical work and lead to certain health professionals utilising the technology, whilst others resisted and rejected (Petrakaki et al., 2016). Petrakaki and colleagues drew upon the understanding of affordances in technology espoused by Zammuto (2007) which suggests that for changes to occur in work organisations, technology has to be understood as one part of a system rather than a facilitator. The findings presented in

this thesis suggest there may have been pragmatic and practical reasons for this division of labour based upon perceptions of the usefulness of the system in fulfilling a specific role for a specific health professional. It may also have been related to the ways in which the technology was utilised when the perception of the affordances the technology offered aligned with a health professional's sense of self (Petrakaki et al., 2016).

As with the adaptation of work practices discussed above, these findings, related to division of labour could suggest that systems might be more effectively implemented, adopted and utilised when they are tailored to the professional values and norms of specific groups of health professionals. In the SMASH intervention there were many positive examples of successful working arrangements that evolved between pharmacists and GPs where the pharmacist took a lead and then filtered cases through to GPs that required their specific input for corrective action. There were also examples of feedback being provided within practices – either one-to-one or as group meetings. It is possible that expectations that systems will work across healthcare teams are unrealistic, particularly with narrowly focused systems targeted at specific areas of healthcare such as medicines optimisation. However there may also have been issues of power here. The separation of pharmacists and clinicians in both studies reinforced an unequal hierarchy in which the clinicians retained power. Within SMASH, pharmacists partly had contact only with specific GPs with whom they raised issues for the clinician to then action and handle. GPs exercised autonomy in making decisions about their own use of the systems and whilst this was legitimised through discourses of workload and time pressure, habitual practices or

through a valorising of the pharmacists work, it allowed for the maintenance of a hierarchical division of labour.

8.2.4. External structures, wider contexts and power differentials.

External structures were implicated in the interventions and the use of the systems. These were related to policy guidelines from both local and national contexts and, specifically to the Eclipse Live system, to the requirements of guidelines related to audits of prescribing. External structures provided the conditions of use for the technologies. In Chapter Five, it was seen that the contextual background was shaped by policy relating to medication safety and the requirement to benchmark against national prescribing and safety targets. SST proposes that in order to act, agents draw upon internal structures. These internal structures include dispositions and knowledge of the *"strategic terrain"* of external structures (Greenhalgh and Stones, 2010, p.1291). It has been suggested that to understand the implementation and adoption of IT from a SST standpoint it is important to understand the context in which the IT is being introduced, the networks of people and technologies, the dispositions of actors in those networks, the material properties of the technology and how those shape human action (Greenhalgh et al., 2014). In the findings outlined in Chapter Five, it was seen that CCG managers' knowledge of the external structures relating to that policy background, and their own skills and ambitions, led to actions around the monitoring of prescribing behaviours across the CCG area. This was facilitated by the material properties in the system. The outcomes from the monitoring actions were not just that prescribing data was gathered and reported to other institutions but that the external structures, the dispositions of the CCG managers and the material properties of the system allowed for governance and monitoring of clinicians' behaviours through tracking engagement with

the system and processes of persuasion and reward. This could therefore have been said to reinforce hierarchical relationships between the CCG and local GPs. Hence the use of the system created new internal structures concerning such social rules and conventions. Similarly, in previous literature, information systems have been seen to enable managers to capture information, place local clinicians under surveillance and make their actions quantifiable (Greenhalgh and Russell, 2010). Furthermore, an effect of such surveillance is for individuals to adapt their own behaviour to ensure they act legitimately (Doolin, 2004).

Allocation of access led to system usage being distributed unevenly across stakeholder groups either by preferential access decided by one group over another or through decisions by particular groups of stakeholders to not access or engage with systems. In Chapter Six, it was seen that centrally the CCG encouraged access to general practices but could limit the engagement for others. There was therefore a "top down" implementation that was dependent upon soft governance from the CCG in the form of incentives and permission for access. Such preferential allocation of access as was seen here could be seen to be related to the ways power has been seen to be unevenly distributed across stakeholder groups in healthcare settings (Petrakaki et al., 2016). This lack of involvement from a broader range of stakeholders, including community pharmacists and patients, prevented the exploitation of potential benefits of the EAandF system in enhancing shared care, self-management and medication reviews; all of which could have an impact upon medication safety. Some disengagement from the Eclipse Live system was also related to power differentials, particularly with the reaction of general practice staff to a system that they perceived

to be imposed upon them by the CCG for the purposes of monitoring their prescribing behaviours.

8.3. Reflections on this programme of work

8.3.1. Value of the three methodological approaches: Strong structuration theory, realist evaluation and normalisation process theory.

This PhD utilised three different theoretical and sociotechnical perspectives. Where such frameworks and methodologies have been utilised individually before (Grant et al., 2017a; Greenhalgh et al , 2014; Byng et al., 2005) to draw upon three different perspectives was a novel approach to the evaluation of IT in healthcare The value of each of these methodological approaches is discussed below. Whilst these were different approaches with different theoretical backgrounds, using the three methodologies helped to understand different aspects of the implementation of IT in primary care. SST was particularly useful for exploring wider contexts and for understanding how these worked with technological structures. Realist evaluation was useful for unpicking the mechanisms of the intervention. NPT was useful in understanding the complex social processes involved in implementation. The strengths and limitations of the three individual theoretical approaches are detailed below.

8.3.1.1. Strong structuration theory

SST would argue that individual agency is dependent upon knowledge of rules and conventions. Using SST may be particularly valuable in primary care research since general practices operate with their own organizational culture and dynamic, which may well lead to marked differences in working practices and structure (Esmail, 2013).

In applying SST in this PhD research it was possible to reveal the differences in motivations, ambitions, aims and attitudes of different actors from different stakeholder groups towards the EAandF intervention. SST also revealed the complex contextual backgrounds in which the EAandF system was implemented and how the implementation was informed by wider contexts particularly those associated with national guidelines that informed the actions of the CCG. SST was also valuable, therefore, in unpicking how this wider context facilitated an uneven power differential and hierarchical relationship between the CCG and local general practices. Hence it was possible to understand that the successful adoption of Eclipse Live was not merely dependent upon agents but upon the complex contextual terrain in which it was implemented. Previous studies using this approach have focused upon large national IT projects where institutional contexts might be considered to have more impact (Greenhalgh et al., 2014, Cresswell et al., 2013). It was found, however, that in a smaller scale project, wider policy institutional contexts did impact upon the implementation and adoption of the IT for example through the CCG's response to the requirements of national policies. In this way the use of the system depended on other factors alongside the dispositions of the users.

8.3.1.2. Realist Evaluation

Whilst SST was particularly useful for revealing this contextual background and the wider background to the use of the EAandF system Eclipse Live, and therefore was particularly useful for understanding why it was used, the novel use of a realist evaluation allowed the different ways Eclipse Live was used to be explored in more detail. Recent guidelines advise that evaluation should examine in detail how the intervention works and the interactions of different stakeholders (Moore et al., 2014).

In this PhD realist evaluation was particular valuable at revealing the ways the intervention worked but also the ways in which it did not work. The findings outlined in Chapter Six revealed a pattern of engagement and disengagement from Eclipse Live. These findings contributed additional insights about how the system was used in practice.

The realist evaluation approach has been criticised because its pragmatism has the potential to ignore wider societal and individual benefits at the expense of the mechanics of a programme and therefore not take a critical enough perspective (Porter, 2015; Porter and O'Halloran, 2011). Furthermore, realist evaluation has been criticised for its adherence to the inner workings of a programme at the expense of considerations of wider social concerns and consequences in that it *"tends to narrow its vision to immediate concerns"* (Porter and O'Halloran, 2011, p.22). In this way it is espoused that critical realism should be adopted to consider wider utopian goals and values beyond what is considered to be the overly pragmatic approach of the scientific realism that is the basis for realist evaluation (Porter and O'Halloran, 2011).

Whilst these criticisms of realist evaluation are important what they do highlight is how by using SST and realist evaluation together it was possible to unpick the inner workings of Eclipse Live and to consider the wider social contexts. These two methodological approaches can be further understood in the context of the paradigms of qualitative enquiry (Guba and Lincoln, 1984) as outlined in Chapter Four. By using the two different methodological approaches, to study the same IT system, it was possible to do so from realist position that considered the technology and its use in terms of a subjective reality and additionally from a more critical lens that considered technology and its use as shaped through social and cultural processes. In

other words SST allowed for the exploration of the social processes that were implicated in *why* the system was used and the realist evaluation allowed a more pragmatic understanding of *how* the system was used.

8.3.1.3. Normalisation process theory

The NPT constructs (May et al., 2009) proved useful particularly for understanding the ways in which the SMASH dashboard was accessed and how pharmacists and others responded to the data in the dashboard. The coherence construct was particularly valuable for unpicking how the participants recognised that the dashboard changed the way they worked in relation to conducting audits of high risk prescribing. Pharmacists led the intervention and encountered some resistance from other GP staff however they countered this by finding different ways of communicating and collaborating. From the initial plan for pharmacist-led practice level feedback they instead gave individual and small group feedback in differing ways. This evolution, adaptation and development of the implementing of the intervention were readily captured by the NPT constructs.

Some of the NPT constructs and components pointed towards collective actions. In this research it was found that there was a variable pattern of collaboration. There were collaborations, negotiations over role definitions and there was communication between the pharmacists and the clinicians but the intervention was primarily led by the pharmacists, often working alone. Other components, particularly those within the collective action construct, were useful for drawing out the multifaceted nature of the intervention which included the dashboard itself, the negotiation of roles, the fitting the intervention into general practice, the wider considerations of the CCG and the

pharmacist role. This construct was also able to reveal how the dashboard meant different things to different people; pharmacists using it to feedback instances of high risk prescribing; GPs using it for their own education. This fits with an extended version of NPT that focuses upon the complexity of contexts, the changes in roles and plasticity of the intervention (May et al., 2016).

Using NPT was particularly useful in unpicking what McEvoy et al., have described as the *"implementation journey"* (2014, p.10). Following the intervention from its outset and using the NPT analysis concurrently with the intervention as a process evaluation was particularly beneficial as has been seen in previous literature (Grant et al., 2017a; Grant et al., 2017b; Nordmark et al., 2016; Grant et al, 2013a). This helped to focus on the various ways in which the intervention was understood, the ways in which the dashboard was used and how people worked out the ways in which it could help them in practice. NPT could then help reveal the ways pharmacists, clinicians and other GP staff how the dashboard fitted in to the work of general practice and what their role was within this. The pharmacists in particular negotiated how they were to communicate and feedback to prescribers. The collective action construct was particularly valuable in illuminating these important aspects of the pharmacists' role. Within this construct it was possible to see how the pharmacist developed their role alongside the intervention by extending it to undertake full medication reviews and in negotiating changes and development to the dashboard tool.

8.3.1.4 Reflections upon utilising the three methodological approaches.

Each of the three methodological approaches used in this PhD represented different challenges. Whilst SST has a depth of theoretical perspective (Stones 2005) it has

been used infrequently to evaluate IT in healthcare (Greenhalgh et al 2014). Therefore exactly how to operationalising the theoretical approach is challenging. Greenhalgh and Stones (2010) do suggest a series of questions that may guide an SST approach and how it might be used to unpick implementation and adoption at macro, micro and meso levels and how a recursive relationship between structure and agency evolves to impact upon that implementation and adoption. Whilst this gave a theoretical lens to understand both the structural background of Eclipse Live and the ways agents adopted the system exactly how to operationalise the methodology was less clear. This difficulty was overcome in part by trying to explore the data to understand the policy background and the dispositions of individuals using the system. SST proved useful but it required successive steps in the analysis as described in Chapter Five above. SST is particularly useful for understanding the recursive relationships between infrastructures, people and technology but in using SST it would be useful to consider policy documents as well as conduct interviews and focus groups as part of the data collection in order to build a clearer understanding of those relationships.

The biggest challenge and difficulty in undertaking realist evaluation is defining mechanisms and contexts (Dalkin, et al., 2015; Byng et al., 2005). In order to do this in the present study a number of steps in the analysis process were undertaken. This uncovered a large number of potential CMO configurations which then required further analysis and discussion to unpick the most important CMOs that highlighted how the intervention worked in practice. A further challenge with realist evaluation is that data collection should be an iterative process of presenting middle-range theory to participants for them to comment upon (Pawson and Tilley, 1997). Whilst in this

PhD I presented interim findings from a limited range of interviews to focus group participants, this approach of presenting middle range theory could have been used more widely in data collection.

NPT provided two distinct challenges. Firstly NPT is about people's actions not their attitudes and about the work they do to accomplish implementation, adoption and sustaining of an intervention (May and Finch, 2009). As will be explored below data collection using observation of the work that people do would have been very useful. Data analysis for NPT was difficult in that a thematic approach might not fully uncover the processes involved in implementation and adoption as defined by the NPT constructs and components whilst an analysis using the constructs and components could be said to be forcing the data into the framework. To try to overcome this challenge I undertook various stages in the analysis where initial thematic coding and analysis was then absorbed into an analysis utilising the NPT components.

8.3.2. Strengths and limitations of this work

8.3.2.1. Reflections upon the research process

There were a number of difficulties and challenges through the research process. Of particular difficulty was recruiting participants to the two studies. In both of these recruiting GPs was difficult mainly because of their lack of engagement with the systems and their workload. In both the studies ideally a greater number of GPs would have been recruited to provide a broader cross section of and variation in perceptions and views. Furthermore some of those GPs who did take part in the studies could have been said to have been enthusiast for the IT system. The second

issue with recruitment was the necessary use of gatekeepers. This was important in finding contacts and potential participants but it possibly undermined some of the trustworthiness and integrity of the research in that gatekeepers could have had a stake in the implementation of systems and could have potentially selected participants who were favourable to the benefits of the systems. This however was not seen in the data where participants in, for instance focus groups organised through CCGs included participants with a range of views and opinions.

Coding and data analysis was conducted by MJ. This potentially could undermine the trustworthiness of the analysis process. To overcome this discussions were held at various stages and steps, as detailed in the methods sections for each study, with other researchers and my supervisors. This ensured that findings were agreed and consensus about themes was reached.

8.3.2.2. Primary care

A major strength of this research is that it has explored IT interventions for medicines optimisation implemented and adopted within primary care settings. Whilst there has been other similar studies including the PINCER trial (Avery et al., 2012b) and DQIP study (Grant et al., 2013a), healthcare IT in primary care is a relatively under researched area. Whilst other studies have looked at EAandF systems, few have explored, as with the Eclipse Live and SMASH interventions, the complex work of a range of different stakeholders working in general practice and utilising those systems. Of particular value in this research was exploring these relationships in the contexts of the implementation of the technology. This research was able to explore

the breadth and variation of different interactions with the systems and the different agent-agent relationships and agent-technology relationships that occurred.

One particular strength in this research in relation to primary care is the understanding of how different groups of health professionals engaged with the systems. Previous research has suggested IT systems can be an actor within the *"complex collaborative working practices of primary care"* (Swinglehurst et al., 2010, p.7) but as Swinglehurst and colleagues suggest, communication between different health professionals is sometimes challenging. In previous research of GP administrators undertaking coding and data entry into the GP clinical record, Swinglehurst and Greenhalgh (2010) found that whilst work and duties were shared hierarchies were maintained. This suggested a complex negotiation of roles in general practice. In the studies for this PhD there were, as has been stated above, divisions of labour and a distribution of roles. This research would suggest that primary care whilst multidisciplinary is also compartmentalised by role. This is important when considering IT interventions in primary care and may well counter expectations of how the IT could be used collaboratively.

8.3.2.3. Variation between the two interventions

An additional strength of this research was that it focused upon two different interventions that had the potential to improve medicines optimisation. There were some similarities in that both provided alerts on high risk prescribing. However, the ways in which the systems operated were different. The Eclipse Live system was predominantly a system through which audits were run, often centrally from the CCG, and then alerts were sent to practices. Whilst practices could access the system

the day to day use of it was in a cascading down of alerts from the CCG pharmacists and managers, which were then dealt with by GPs or GP staff. In contrast, the SMASH dashboard was an ongoing audit of prescribing data related to the thirteen prescribing safety indicators. The dashboard was then predominantly accessed from within the practice by pharmacists. In looking at these two EAandF systems it was possible to compare and contrast the different ways they were used in practice. It was also useful to be able to explore the breadth of use across primary care from centrally based CCG managers through to administrative staff in practice.

8.3.2.4 Possibilities of ethnography

It has been suggested that studies could also explore wider social contexts through analysis of relevant documentary data and through ethnographic observation (Greenhalgh et al., 2011; Swinglehurst et al., 2010). Although one observation was conducted with a CCG pharmacist for the Eclipse Live system, this was only as an extension of the interview with that participant to elicit some further understanding of how they used the EAandF system and the field notes were not part of the data set. Three observations of meetings between the pharmacists and practice staff were undertaken for the SMASH study, whilst these provided the author with valuable background information, field notes were not used in the analysis because it was felt that they did not add anything further to the data set than the material in the interview transcripts. Further observations were not undertaken primarily for pragmatic reasons including resources to undertake the study, the distance from the researcher's base to one of the study sites and workload of the participants which could have made recruitment difficult. Observations were impractical because some health care professionals used the systems intermittently for short periods of time. The nature of

the IT systems meant it was difficult for it to be used in collaborative settings where interactions would be dynamically happening in real time during the observation. If these difficulties could have been overcome in both the studies observations may well have been valuable. Naturalistic observations would have been useful in unpicking contexts and agents' choices and actions in using the systems. In particular NPT is focused upon what people do and ethnography has been usefully employed in NPT studies in the past (Grant et al., 2013). Similarly video recording of GP computer use has previously been utilised in studies of the influence of IT on consultations between GPs and patients (Milne et al., 2016; Hayward et al., 2015; Hayward et al., 2013). However, as has already been stated, the ways in which both systems were utilised did not lend themselves to non-participant observation.

Alternative ethnographic methodologies drawn from participatory research could have been explored, and could be useful for similar research in the future research. The researcher-in-residence model has been adopted to understand how interventions are successfully implemented and delivered in local contexts (Eyre et al., 2015; Marshall et al., 2014). In this model there is a cooperation and collaboration between researchers and practitioners, through which a researcher is part of the team delivering the intervention. As such there is a co-creation, between researcher and participants, of the knowledge about the intervention being studied. One way in which this model could have been adopted for the current research could have been through a pharmacist delivering the intervention being either part of the research team or operating along the researcher-in-residence model. This could have reflected the longitudinal process of the intervention and the specific perspective of the pharmacist, although it would have only captured that process as it happened in one specific local context.

8.3.2.5. Small case studies

A potential limitation of each study was that it focused upon one a single CCG. Whilst there was inclusion of all relevant stakeholders, the number of participants in focus groups for the first study was small given the size of the case study site. In the first intervention the CCG had been an early adopter of Eclipse Live but it was used less widely than anticipated. This limited our understanding of how the system could be used by the widest range of stakeholders and in different contexts within primary care, particularly since the use in community pharmacy and among patients was limited. Due to the cross-sectional and self-report nature of the study design, there was reliance upon respondents' subjective accounts and it was difficult to assess the medication safety outcomes directly. One further limitation of small case studies was that it limited the number of potential participants. Though the participants were fairly representative of different stakeholder groups across the two CCGs, there were fewer participants from certain groups - namely GPs and GP staff - than would have been ideal. Time constraints and the difficulty of recruiting busy general practitioners made it difficult to achieve this.

8.3.3. Implications for medication safety and practice

The research presented in this thesis was focused upon the ways that two interventions were implemented and adopted so was not able to report any patient safety outcomes. However there were significant elements to the implementation of the two systems that might have had implications for medication safety. The first of these was that whilst there was, as the findings have shown, some disengagement from the systems and a variation in use, the two systems were used to different

degrees for medication safety activities. Furthermore there was a range of health professionals using the systems. This was thus likely to lead to instances of high risk prescribing being identified and medication for patients at risk being reviewed.

One important implication, for both primary care and medication safety, arising from this work would be the potential for clinical pharmacy in general practice. As was discussed in Chapter Two, having clinical pharmacists work in general practice is an new and evolving strategy that has broad implications for medicines optimisation and patient safety. As the findings in this PhD have shown, pharmacists partly valued the dashboard because it could demonstrate the value and worth of clinical pharmacists working directly in primary care. The SMASH intervention utilised clinical pharmacists in general practice but this in turn allowed then to define their roles. The diverse backgrounds of pharmacists led to different approaches to working in primary care. Pharmacists gave examples of how they utilised the dashboard to optimise the safety of prescribing by reviewing patients and providing feedback and education to prescribers. To do this, pharmacists negotiated their role within the complexities of general practice. These roles emerged very differently, with some pharmacists having more autonomy than others. Role definition required communication, the evolution of professional identity and building new relationships with clinicians and GP staff. Such variation in pharmacist professional identities has been seen in previous research (Elvey et al., 2013). This development of the pharmacist role has clear implications for general practice and medicines optimisation. In the SMASH study only one of the pharmacists was an independent prescriber. As the role of clinical pharmacy in general practice expands it is likely that nonmedical prescribing, which has been seen to make better use of the skills of a variety of health professionals, will

also expand (Stewart, et al., 2017; Weeks et al., 2016). The professional autonomy of pharmacists and opportunities to apply skills, as seen here in the SMASH intervention, has previously been seen to facilitate nonmedical prescribing (Stewart, et al., 2017).

As has been discussed in Chapter Two, primary care is variable, multidimensional and individual. This variability may well have allowed for the variability in approaches to the SMASH intervention. In the SMASH intervention, the dashboard was designed to highlight instances of high risk prescribing related to the thirteeen prescribing safety indicators. Once patients flagged by the dashboard had been reviewed, ideally clinicians would be advised and systems would be put into place to reduce such high risk prescribing in the future in the manner of the PINCER trial (Avery et al., 2012b). Whilst some pharmacists focused upon ensuring that patients highlighted as at risk were dealt with at an individual patient level by, for instance, changing particular instances of prescribing or agreeing patient-specific action plans with clinicians and patients themselves, others focused in addition to that upon education and system change to avert further instances of that high risk prescribing in the future. Some pharmacists, in the SMASH intervention, discussed how their response to the instances of high risk prescribing for specific patients was to use that as a starting point to then conduct full medicines reviews on all of the patient's medicines and treatment. This was considered a holistic approach by those pharmacists. To utilise the dashboard as a starting point for reviewing patients' medications involved a considerable amount of time and was in effect an extension of the work required to address the high risk prescribing event highlighted by the dashboard. In this way, the dashboard, and the work of the pharmacist in practice,

was changing the ways in which medicines optimisation activities were conducted from addressing single one off events, through to education for clinicians and prescribers and delivering a more holistic patient-centred approach. Such variability of approach was arguably available to the pharmacists because the SMASH intervention allowed different pharmacists to operate in different ways. This highlights potential ways in which IT interventions for medicines optimisation can be utilised beyond the narrow remit for which they were designed.

8.3.4. Recommendations for IT implementation and adoption

As was evident in the findings presented in this PhD, collaborations and cooperation between stakeholders was important for the interventions. Equally as discussed earlier in this chapter the utilisation of systems by one group of stakeholders can enhance the adoption of systems and mean that there use is sustained in practice. It may well be that in the design of systems for primary care in the future there should be careful consideration given to who will be utilising the systems and if communication, co-operation and collaboration is required, how that is to be achieved. One of the most important considerations in this PhD across the studies is that these IT systems themselves only provide information for health professionals. Subsequently clinical actions by health professionals are required to either respond to the medication safety issue for a particular patient or to work with others to change systems, norms, culture and behaviours that might have led to the high risk prescribing. As such the IT presents a starting point and whilst it might afford the change the role of people is paramount. Therefore considering how systems will be used is crucial in both implementation stages when the system is being delivered into a healthcare setting and in the adoption stages when users are interacting with the technology. Further

consideration should also be given when implementing IT in healthcare settings that the adoption of that IT will be impacted upon by the structures associated with that setting be that the policy backgrounds or the organisational culture and norms.

8.3.5. Recommendations for future research

There are wider implications for the evaluation and implementation of other IT systems in primary care. IT systems in healthcare are often interrelated, and their interactions with users vary and evolve over time (Barber et al., 2007). This creates complexity in the way that healthcare organisations operate (Cresswell et al., 2012b; Greenhalgh and Russell, 2010). To capture this complexity and change over time, more longitudinal qualitative studies of IT interventions may well be of benefit. This would particularly be useful for studies utilising NPT which could begin the evaluation at the outset of the intervention and continue through successive time periods as it is gradually embedded into everyday practice. Additionally, the complexity of IT in primary care could be explored. Research has tended to explore the implementation of single and new systems. In the research presented within this thesis, the two IT systems were separately accessed from the GP clinical system. Whilst CDS systems embedded in GP clinical systems have been previously researched (Hayward et al., 2013) more research around such systems may be valuable. It has however been found that many CDS systems do not fit with clinical workflow and often clinicians override alerts (Hayward et al., 2013 Avery et al., 2007). New CDS systems integrated into GP clinical systems, such as for instance Optimise Rx (First Databank Europe Ltd) have been widely adopted but as yet not fully evaluated. It would be of significant benefit to understand the ways in which such a system was utilised and to unpick the contextual factors that influenced the

implementation and sustained use of the system. Within the findings for Eclipse Live, participants talked of an underutilisation of the system because it was not embedded in the GP system. General practice also has multiple IT systems and software. Further research that explores this complexity and unpicks how health professionals and other GP staff interact with this host of different systems may be of benefit. It would be of particular benefit to understand the utilisation of systems where systems which offer a range of alerts and messages including prescribing safety indicators in order to understand how health professionals prioritise use and for what purposes the systems are used. It may also be of value to understand how different systems might be used in complementary fashion. The PINCER intervention is now to be widely implemented across many different practices. There is potential for evaluating how this intervention might integrate with other CDS systems.

Further research to understand the implementation and adoption of IT for medicines optimisation in primary care could benefit from utilising the sociotechnical approaches used here. Of particular benefit would be to, as in this research, adopt a pragmatic and pluralistic approach that uses different theoretical models and approaches in studying the same intervention. In this research, as has been seen, SST was found useful to unpick the wider contexts and strategic terrain in which the interventions were adopted, realist evaluation could reveal the mechanisms of interventions and NPT could help an understanding of the ways in which the interventions were adopted into everyday practice. Therefore utilising different models to uncover different aspects of the implementation process could be beneficial.

Realist evaluation suggests that CMOs are middle range theory that can then be further tested. The CMO configurations conceptualized in Chapter Six here would be valuably applied to further evaluation of the EAandF system Eclipse Live in use in other CCG areas, in a process of cumulation and further theory testing (Wand et al., 2010; Pawson and Tilley, 1997). This would build upon how the system could be further implemented. A realist evaluation of Eclipse Live might also be run in a longitudinal manner, alongside the implementation of the intervention. This would help to track changes to work practices as the intervention was embedded into existing work behaviour (Cresswell et al., 2013; Tolson et al., 2007).

Qualitative research such as this looks to understand the social processes involved in interventions and is not focused upon outcomes. Whilst that position was central to this research it is acknowledged that there could be potential for other quantitative data to enhance findings in qualitative studies of this type. For instance quantitative metric data of the user interaction with systems could lead to further understandings of which groups of health professionals were using the systems, for how long they were engaged and the specific data they were looking at. This could build a wider and broader picture of use that would complement the depth of understanding that could be achieved through focus groups and interviews. Whilst this would only reveal data around the agent-technology interaction it might also have the benefit of informing the interviews and providing some background for the discussion which could then explore the processes behind those interactions.

One of the important findings from this research has been the developing and emerging role of clinical pharmacy in primary care. Further examination of the professional identity of this role and the ways in which it is evolving within primary

care would be beneficial. Within this it would be interesting to understand how clinical pharmacists engage with other health professionals. This research saw that there was a negotiation and demarcation of roles between different health professionals particularly with GPs suggestion that medicines safety and use of the EAandF systems was more something for the pharmacists. As other medicines optimisation systems are rolled out in primary care it would be interesting to see how the implementation and adoption of these works alongside the developing role of clinical pharmacy in general practice.

8.4 Conclusions

This research aimed to explore, evaluate and understand the socio-technical processes involved in the implementation, adoption and use of two different information technology interventions for medicines optimisation in primary care. As was described in Chapter Four, to understand technology as one part of a dynamic system with multiple interdependent stakeholders is a recursive position in which actors' use of technology occurs within wider dynamically changing contexts (Klecun, 2016; Greenhalgh and Stones, 2010). The findings of this research highlighted a complexity and variation in the use of the technology that reinforced the understanding of IT use in healthcare as a dynamic social process. Implementation of the two systems involved social and organisational structures, norms, work practices and divisions of labour. There was variation in patterns of utilisation and engagement. Much of this was related to wider structures such as external policy backgrounds. Work practices were similarly linked to wider contexts. Use of the two systems occurred within networks of interaction and relationships and within different patterns of collaboration and communication between different health professionals. There was

also variation in how work practices were adapted or changed with in some instances the technology improving the ways in which people worked.

Adopting a sociotechnical approach was valuable in unpicking these social processes that were involved in the implementation, adoption and use of the two systems. SST, realist evaluation and NPT were therefore found to be valuable for examining interventions for medicines optimisation in primary care. The use of these three theoretical approaches allowed for the capturing of different aspects of the two interventions particularly in the novel use of SST and realist evaluation to explore the same system. Utilising these three approaches allowed for a plural view which drew upon different perspectives and highlighted different aspects of the implementation and adoption processes. Such plurality may be useful because it aligns with the complexity of the use of IT in primary care settings.

Both systems evaluated here were seen as beneficial for medication safety activities within primary care settings. Further evaluation of such interventions would benefit from drawing upon the insights gained from sociotechnical approaches in order to ensure effective implementation of such initiatives in the future. In doing so, future research might valuably draw upon ethnographic approaches. This research highlighted the complex and multidisciplinary nature of primary care and how IT interventions need to take that into consideration.

This work suggests there is a valuable role for information technology in medicines optimisation in primary care. However it is likely that IT systems will be used differently by different professionals in different contexts. Of particular interest here was the growing and evolving role for clinical pharmacy. Aligning IT systems with

the role of clinical pharmacists may be of significant benefit in the future. This research suggests that interactions, collaborations and communication between professionals are important for successful implementation of healthcare IT. Furthermore if systems fit with the organisational culture norms and professional values found within primary care they are more likely to be used effectively.

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Appendices

Appendix 1 Information and Consent forms for Eclipse Live studies

Appendix 1a Participant Information Sheet: Interview / focus group

Participant Information Sheet: Medication safety implications of a technological intervention (interview / focus group)

Introduction

You are being invited to take part in a research study by The University of Manchester and The University of Nottingham. In order to help you decide whether or not to take part, this information sheet provides you with further details about the study. The sheet is in two parts: Part One explains the purpose of the study and what it will involve; Part Two gives more detailed information about the conduct of the study. You may keep this sheet for future reference, along with a copy of the consent form.

Part One

What is the purpose of the study?

The aim of our study is to examine how Eclipse Live is used to support medicines management in (name of place) The study is being conducted by the University of Manchester, and is independent from the NHS.

Why have I been chosen?

We would like to learn from the experiences of those who have already used Eclipse Live, and the (name of place) is one of the first areas in the United Kingdom to do so.

We have invited you to take part in the study because we understand that you have used Eclipse Live in (name of place).

Do I have to take part?

You do not have to take part in the study. If you do decide to take part and then later change your mind, either before, during or after the study, you can withdraw without giving any reason.

What will I be asked to do if I take part?

You will be asked to take part in either a one-to-one interview or a focus group. During an interview, you would be asked to discuss your experience of using Eclipse Live; for example, the purposes to which you put it. During a focus group, you would take part in a group discussion with other users (including healthcare professionals and service users) about the best ways of working with Eclipse Live. Interviews will be conducted over the telephone, and will last for approximately half an hour. Focus groups will be carried out at a location that is convenient for you, and will last for approximately two hours. During an interview or focus group, you can take a break at any time.

The researchers involved in the study are:

- Mark Jeffries (Research Associate)
- Dr Rachel Howard (Research Pharmacist)
- Dr Denham Phipps (Research Fellow)
- Dr Sarah Rodgers (Senior Research Fellow)
- Prof. Tony Avery (Professor of General Practice)
- Prof. Darren Ashcroft (Professor of Pharmacoepidemiology)

Expenses and payments

We will reimburse any reasonable out-of-pocket expenses incurred as a result of taking part in our study. This will be in the form of vouchers at a maximum of £40 per hour for GOPs and £20 for pharmacists and service users.

What are the benefits of taking part?

There are no direct benefits to you from taking part in this study. However, by taking part you will help us to understand how healthcare professionals and service users,

whether in (name of place) or elsewhere, can get the best out of Eclipse Live. The study findings will also help us to understand how Eclipse Live and similar systems should be designed in order to be effective.

What if there is a problem?

We have made provision for any queries or complaints you may have to be addressed, either by the research team or by an independent body. Further details are given in Part Two.

Will my taking part in the study be kept confidential?

We will take steps to ensure the confidentiality of any data you provide. Further details are given in Part Two.

Where can I obtain further information if I need it?

If you need further information or are interested in taking part then you are welcome to contact Mark Jeffries on 0161 275 3680 or mark.jefferies@manchester.ac.uk.

This completes part one of the information sheet. If Part One has interested you and you are considering participation, please continue to read the additional information in Part Two before making any decision.

Part Two

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researcher, who will do his best to answer your questions. If he is unable to resolve your concern or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Co-ordinator on 0161 275 7583 or 0161 275 8093 or by email to research.complaints@manchester.ac.uk

What data will you collect, and what will happen to it?

Provided that you give consent for us to do so, we will audio record the interviews and focus groups. These recordings will be transcribed, and the transcripts used for the data analysis. Both the recordings and the transcripts will be used only for the purposes of this study, and will be destroyed five years after the final report is

released. During the interview or focus group, you may request that the recording is stopped at any point. You may also request that any part of the transcript is deleted or rephrased.

Will my taking part in this study be kept confidential?

Yes. During analysis of interview and focus group transcripts, any information that may lead to specific individuals being identified will be removed. While direct quotes may be reproduced to illustrate particular points when reporting the research, these will be made anonymous as necessary. Any discussions that take place during the study are confidential. However, if you were to tell us something new that could put you or someone else at risk of harm, or reveal unsafe practice, we may have to report this information to a clinical supervisor. If so, we would discuss this with you and tell you what we intend to do.The data will be used only by us, and for this study only. However, relevant sections of data may be looked at by responsible individuals from the University of Manchester, regulatory authorities or the NHS Trust who are monitoring our research practice.

What will happen to the results of the research study?

The results of the study will be published in reports to be held at the University of Manchester. It is our expectation that the results will also be published in reports to be released into the public domain. These reports will be provided to participants on request. No participant will be identified in any publication unless he or she has given specific consent for such information to be released.

Who is organising and funding the research?

The University of Manchester is providing sponsorship for this study, with funding coming from the National Institute for Health Research.

Who has reviewed the study?

This study was approved by the National Research Ethics Service (reference 14/NW/0113).

We would like to thank you for considering participating in this study, and for taking the time to read this information sheet.

Appendix 1b Consent form: Interview / focus group

Participant Identification Number:

Consent form

Title of Project: Medication safety implications of a technological intervention (interview/focus group study)

Researchers: Mark Jeffries, Denham Phipps, and Darren Ashcroft (University of Manchester); Rachel Howard, Sarah Rodgers and Tony Avery (University of Nottingham)

Please sign each of the boxes below if you agree to each point

Sign here

1. I have read and understood the information sheet (Version 2.1 28th July 2014) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.		
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without any detriment to me.		
3. I consent to being audio recorded as detailed in the Participant Information Sheet.		
4. I consent to the researchers using anonymised verbatim quotations from the interview or focus group.		
5. I understand that relevant sections of data collected during the study may be looked at by responsible individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in the research. I give permission for these individuals to have access to this data.		
6. I agree to:	*Be interviewed*	
	Take part in a focus group	

Name of participant: …… **Signed:** ..... **Date:** .....

Consent taken by: …… **Signed:** ..... **Date:** .....

Appendix 2. Interview Topic guide - Eclipse Live Study

INTERVIEW SCHEDULE

Interviewer introduction:

I am [….] and I am a researcher at the University of Manchester. We are carrying out a project looking at the use of Eclipse Live in medicines management. We would like to find out more about the views of healthcare professionals and service users who have used this system.

This interview will last for approximately half an hour, and during that time I'd like to discuss your experience of using Eclipse Live. I should remind you that the interviews are confidential and will be used only for our own research. I'd like to record the discussion if that is okay with you; this is simply to help me capture all of the information that comes out of it. Before we begin, I'd like to provide some ground rules for the discussion:

- You are being digitally recorded, so speak clearly;
- We will anonymise the transcript so that nobody can be identified by name. However, please try to avoid naming specific healthcare professionals or locations;
- Everything discussed here is confidential. However, if you were to reveal anything that would place you at somebody else at risk of harm, we may have to report this to a clinical supervisor.

Unless you have any questions for me, then we can begin.

Interview questions:

1. What is your experience of working with Eclipse Live?
2. How do you use Eclipse Live?
3. What do you see as its benefits?
4. What problems do you encounter with it?
5. How do you get the best out of Eclipse Live?
6. Is there anything else that you think should be discussed given our research topic?

Appendix 3. Interview Topic guide - Eclipse Live Study

FOCUS GROUP SCHEDULE

Facilitator introduction:

I am [….] and I am a researcher at the University of Manchester. We are carrying out a project looking at the use of Eclipse Live in medicines management. We would like to find out more about the views of healthcare professionals and service users who have used this system.

This group will last for approximately two hours, and during that time I'd like to firstly talk about the findings of an interview study involving users of Eclipse Live, and then discuss your own experience of using it. I'd like to record the discussion if that is okay with you; this is simply to help me capture all of the information that comes out of it. [Check that group is happy to tape record].

Before we begin, I'd like to provide some ground rules for the discussion:

- You are being digitally recorded, so speak clearly and do not speak over one another;
- Please respect each other's right to express a view, even if it differs from yours;
- We will anonymise the transcript so that nobody can be identified by name. However, please try to avoid naming specific healthcare professionals or locations;
- Everything discussed here is confidential. However, if you were to reveal anything that would place you at somebody else at risk of harm, we may have to report this to a clinical supervisor.

Unless you have any questions for me, then we can begin.

Part 1 – Discussion of interview findings

- What are your experiences of working with Eclipse Live?
- What is your reaction to the findings?
- Do they reflect your experiences? How are your experiences similar/different?

Part 2 –Further discussion

- Describe medicines management in (XXX) CCG using the following headings:

    - Vision (how it works)
    - Logic (why it works in the way it does)
    - Organisational structure (what supports it working this way)
    - Roles required
    - Benefits of working this way
    - Costs of working this way
    - Implications of having the pharmacy work this way
- Now consider alternative ways in which medicines management could work. Compare these with how it currently works, using the headings listed above
- How can Eclipse Live support the different ways of carrying out medicines management in your trust? Does Eclipse Live allow you to do things differently?

Appendix 4. First iteration of the coding framework for the SST Study

Coding Framework - informed by Strong Structuration Theory/Structuration Theory - Interplay of Agency and Structure

External Structures - Perpetuated or changed as position-practices/communities of practice				Internal structures - Agents draw routinely and strategically upon these	Agency
Infrastructure/Expert Systems - shape monitor and standardise	Imposed Conventions		Interactions		
	Contextuality - Local Practices	Roles/Social Positions			
National Infrastructure - NHS, NICE, National guidelines	Pre-existing work practices	Change agents/followers	Relationships -General Practice/CCG MMT relationships; internal relationships in practices	Dispositions of users - skills; attitudes; ambitions; values; past experience. Interpretative frames of actors - built up over time and informed by durable socialised dispositions.	Constraints to use - What agents do that constrains use: - abandonment; limitations to use; limitations to functionality; alternative use of other IT; practicality
CCG/MMT decisions re EL:- translation, enrolment of practices, prior negotiation, implementation, allocations of access	Pre-existing routines - repetitiveness, ways of doing things,	Obligations/social norms	Communication - How tech makes possible new communication; how communication constrains use of technology	Specific knowledge of users	Enablers to use - How agents enable use - including:- workarounds, adaptations; training; allocation of users
Eclipse Live - what it does as an enabler; social structures built into technology; Technology shaping human action	Rules and regulations/Conventions that describe the way things are and can enable or constrain	Privileges	Co-operation	Physical and cognitive demands including time	
Routinisation of EL into practice		Divisions of labour	Conflicts	What do people know about Eclipse Live?	
		Role identity/role perception - self positioned against others	Power - influence; authority; hierarchies; incentives; sanctions		

Appendix 5. Final iteration of the coding framework for the SST Study

Strong Structuration Theory - New Framework

External Structures – Perpetuated or changed as position-practices/communities of practice		**Internal structures – Agents draw routinely and strategically upon these**		**Technological Structures**
Infrastructure/Expert Systems - shape monitor and standardise	**Interactions**	**Dispositions of Actor-Habitus**	**Roles and contextuality**	
National Infrastructure - NHS, NICE, National guidelines	Relationships - General Practice/CCG MMT relationships; internal relationships in practices	Dispositions of users - skills; attitudes; ambitions; values; past experience. Interpretative frames of actors - built up over time and informed by durable socialised dispositions.	Pre-existing work practices	Eclipse Live - what it does as an enabler; social structures built into technology; Technology shaping human action
CCG/MMT decisions re EL:- translation, enrolment of practices, prior negotiation, implementation, allocations of access	Communication - How tech makes possible new communication; how communication constrains use of technology	Specific knowledge of users	Pre-existing routines - repetitiveness, ways of doing things,	Routinisation of EL into practice
	Co-operation	Physical and cognitive demands including time	Rules and regulations/Conventions that describe the way things are and can enable or constrain	What do people know about Eclipse Live?
	Conflicts	Knowledge - What do people know about Eclipse Live? Of IT systems?	Change agents/followers	
	Power - influence; authority; hierarchies; incentives; sanctions		Obligations/social norms	
	Privileges		Role identity/role confusion/role perception - self positioned against others	
	Divisions of labour			

Appendix 6. First iteration of the coding framework for the realist evaluation

Realistic Evaluation Components	Broad Themes	Description (and relationship of themes to background lit)	Detailed Themes	Some examples (Not exclusive)
Outcomes	Benefits of EL	Policy - implementation of national guidelines. Clinical significance. Improvements in patient care. Timely interventions. Unintended consequences.	Monitoring Prescribing	Avoiding prescribing of dangerous interactions
				Adherence to guidelines
				Changing Prescribing at Practice or Island level - qulity of care
			Reviewing Patients	GPs reviewing individual Patient
				Medicines Use reviews in care homes
				Prospective use in MURs with Community Pharmacists
			Shared Care	Patient empowered by knowledge and information
			Self-management	Diabetes manager - targeting patients most in need of review (HbA1c flux)
				Patient uploading and reviewing test results
Mechanisms	Work Practices	Intervention is systemic and requires changes to working practices roles, structures etc across multiple users and multiple task allocations	Systems of work that facilitate or act as a barrier to using EL	Responding to alerts - logging on
				Responding to alerts -Email > paper > in-tray > to email
				Targeted alerts do not cause alert fatigue
				Web-based system not logged into and run side-by-side with Vision
				Vision used instead of EL
				Time and workload
			Technical issues with system as facilitator or barrier	Difficulties logging on - obtaining passwords etc
				Remote access at care home requires passwords and wi-fi
				No two way communication with Vision
				Allergies not coded. No directions for meds
Contexts	Relationships	Change agents, innovators or followers. Collaboration or conflict over use. Contested ownership and goals.	Ownership and stake holding	Meds Management using to control prescribing habits -
				Use and engagement in GP (GP, PM admin staff) responding to alerts and running own Audits - proactive v. reluctant users
				Patient Passport as patient empowerment - level playing field with HCP
			Conflict	Non-use in community pharmacy - perceived conflict with GPs +MMT
			Co-operation	Facilitated use - Patients/HCAs or Diabetic Nurse
				MUR in Care home
				Self-management targets and shared care

Appendix 7. Eclipse Live - Interim outcomes developed from coding

Monitoring Prescribing

Possible functions this impacts on – monitoring use and consumption of resources; cost effectiveness; maintaining well-being of patients; medicines audits, medicines supply; medication safety.

1. *Can track the prescribing of a particular drug already included in the formulary*
2. *Can help to inform choices for drugs in the formulary*
3. *Audit the effectiveness of safety initiatives*
4. *Practice prescribing patterns benchmarked against each other across the CCG*
5. *Prescribing patterns and trends benchmarked against national targets and guidelines*
6. *Reports show how well practices are managing quality indicators*
7. *Practices receive feedback on the auditing of their prescribing*

Appropriate Monitoring and Review of Patients
Possible functions this impacts on - medication supply; medication safety; monitoring patients; maintaining well-being of patients; patient consultation

8. *Patients reviewed to optimise medications where patients not receiving treatment or optimal dose*
9. *Patients who haven't had appropriate monitoring are reviewed*
10. *Patients who are on a dangerous combination of drugs that's affected their likelihood of serious adverse event are reviewed*
11. *Pre-emptive or timely review of individual patient*
12. *Screening of multiple patients*
13. *Attention focused on patients most in need of review*
14. *Can have a more focused review of medicines use*
15. *Care Homes have more appropriate and tailored care*

Changing Prescribing and Medicine Supply
Possible functions this impacts on - medication supply; maintaining well-being of patients; cost effectiveness; clinician education and training

16. *Change and improve the safety of prescribing across the CCG (avoids serious adverse events)*
17. *Safer supply of medicines*
18. *Informs a decision to sell a medicine or supply a medicine*
19. *Cost savings*
20. *Improved quality of care for patients*

Appendix 8. Eclipse Live - Realist Evaluation -First iteration of CMO configurations

Targeting and prioritising

Context	Mechanism	Outcome
CCG MMT Pharmacist and GP prescribing lead looking at national alerts	Alerts put together by MMT and sent to practices	Prescribing patterns and trends benchmarked against national targets and guidelines
CCG MMT monitoring prescribing by conducting searches of based upon “projects" and “initiatives”	Speed of the system allows for efficient use of time searches done centrally and information collated relatively quickly rather than "trawl(ing) round practices"	Practice prescribing patterns benchmarked against each other across the CCG
	Identify patterns of prescribing with certain prescribers	
MMT sending out relevant alerts	System used to “pin” alerts to particular patient	Pre-emptive or timely review of individual patient
MMT monitoring the prescribing of specific medications	Use EL to identify pts receiving incorrect of less than optimal doses	Change and improve the safety of prescribing across the CCG

Engagement

Context	Mechanism	Outcome
CCG and MMT encouraging clinicians to be engaged in safety process and culture	Engagement of practices in using EL responses as feedback system	Audit the effectiveness of safety initiatives (much more quickly)
CCG MMT conducting searches of prescribing based upon “projects" and “initiatives”	Real time feedback if clinicians use the system	Prescribing patterns and trends benchmarked against national targets and guidelines
GP prescribing audited and monitored in practices	Proactively conducting own audits through EL	Practice prescribing patterns benchmarked against each other across the CCG
Communication between MMT and GPs – Centrally rolling out initiatives	EL allows for feedback on alerts but requires logging in and persuading GPs to use the system	Patients reviewed to ensure appropriate monitoring, to optimise medications, or to avoid dangerous combinations of drugs
	Reliance on MMT to send out alerts	
CCG and MMT encouraging clinicians to be engaged in safety process and culture	Engagement of practices in using EL responses as feedback system	Increased engagement with safety culture and safer prescribing
	Voluntary engagement by clinicians reduces "big-brother" relationship with CCG	
	Audits looking at trends in prescribing as a means of support to GPs	

Work Practices

Context	Mechanism	Outcome
GP monitoring individual patients	Clinician support from EL focuses attention on medications	Attention focused on patients most in need of review
Pre-existing Division of labour within GP practices	Complexity of EL requires specific task allocation (e.g. –" I think a lot of the more clever things that Eclipse does is more likely something that would be certainly lead by a clinician and more likely performed by a clinician")	Patients reviewed to ensure appropriate monitoring, to optimise medications, or to avoid dangerous combinations of drugs
	Used by either practice managers or GPs	
GP workload	Prioritising tasks	Pre-emptive or timely review of individual patient
	Pertinent relevant alerts (are acted upon – no alert fatigue)	
Use of multiple administrative work practices – email, paper, in-trays, computer systems	Logging on, responding to alert, and reviewing patient *through* Eclipse Live	Patients reviewed to ensure appropriate monitoring, to optimise medications, or to avoid dangerous combinations of drugs
CCG Pharmacist workload	EL saves time – do not have to visit surgeries for information can get that by logging on	Can have a more focused review of medicines use
CCG Pharmacist undertaking reviews in care homes	Accessing easily readable and informative data in EL	Can have a more focused review of medicines use
	Necessary workarounds to overcome technical issues (WiFi and phone signal)	
	Necessary workarounds to find patient in Eclipse - Vision numbers obtained from surgeries	

Appendix 9 - Screenshots of pages from the SMASH dashboard (fictitious data)

Appendix 9a - Practice summary

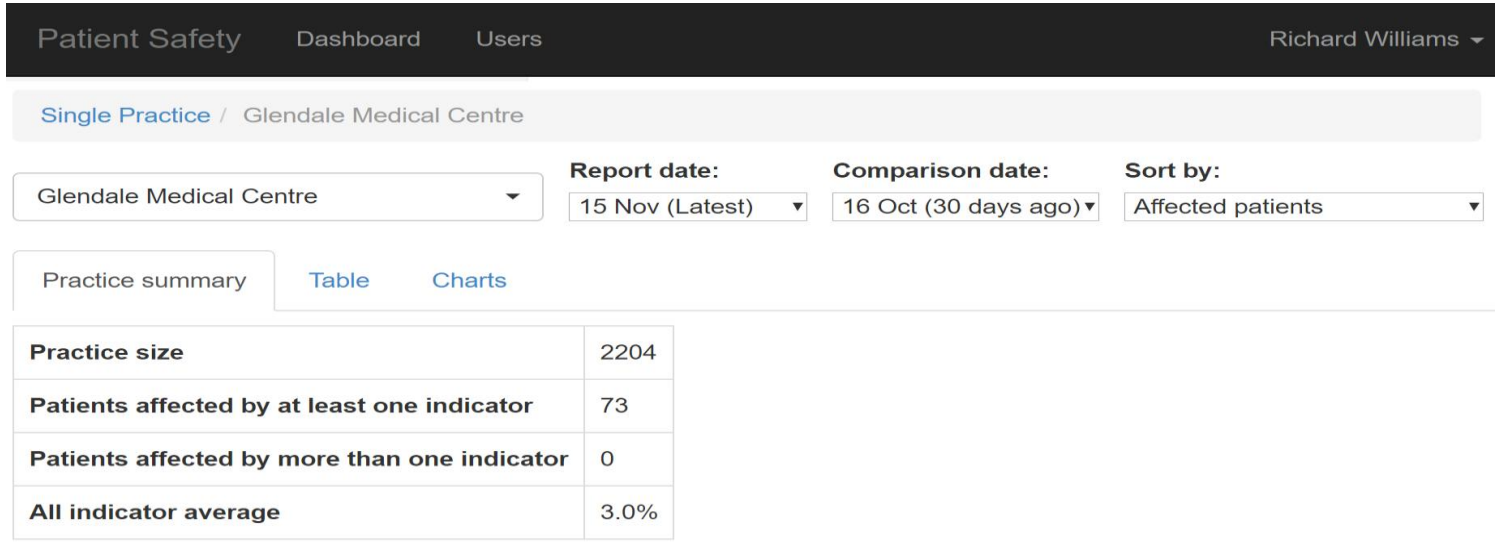
Appendix 9b - Table view

Appendix 9c - Chart view

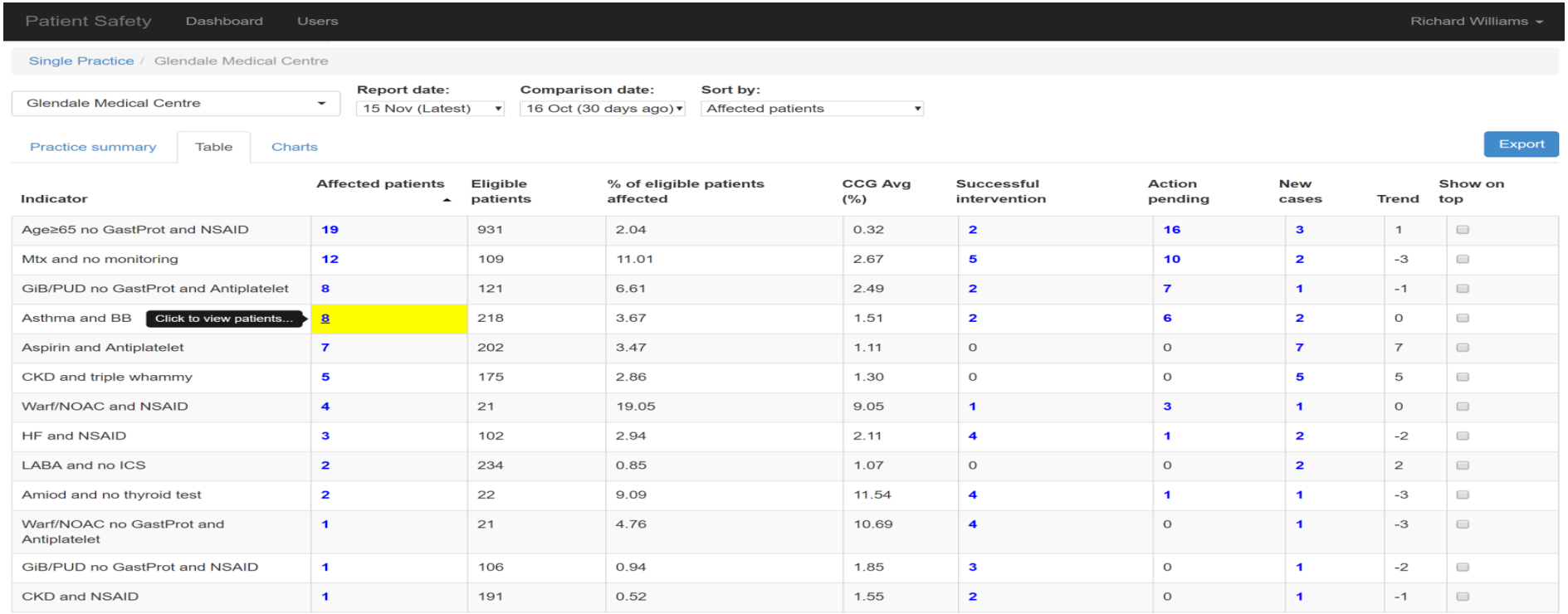
Appendix 9d -Patients affected

Appendix 9e- Evidence summary

Appendix 9a - Practice summary

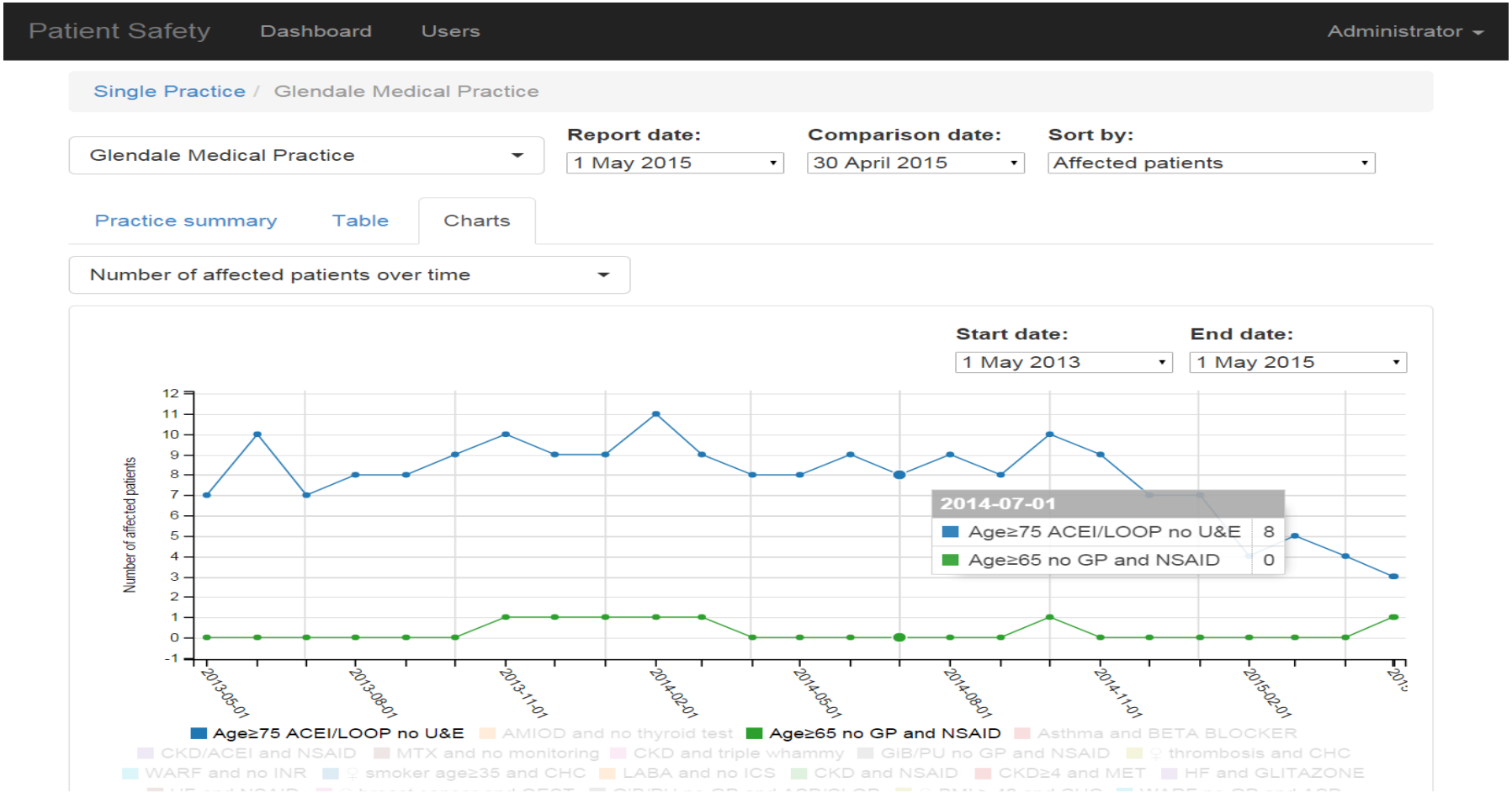


Appendix 9b - Table view

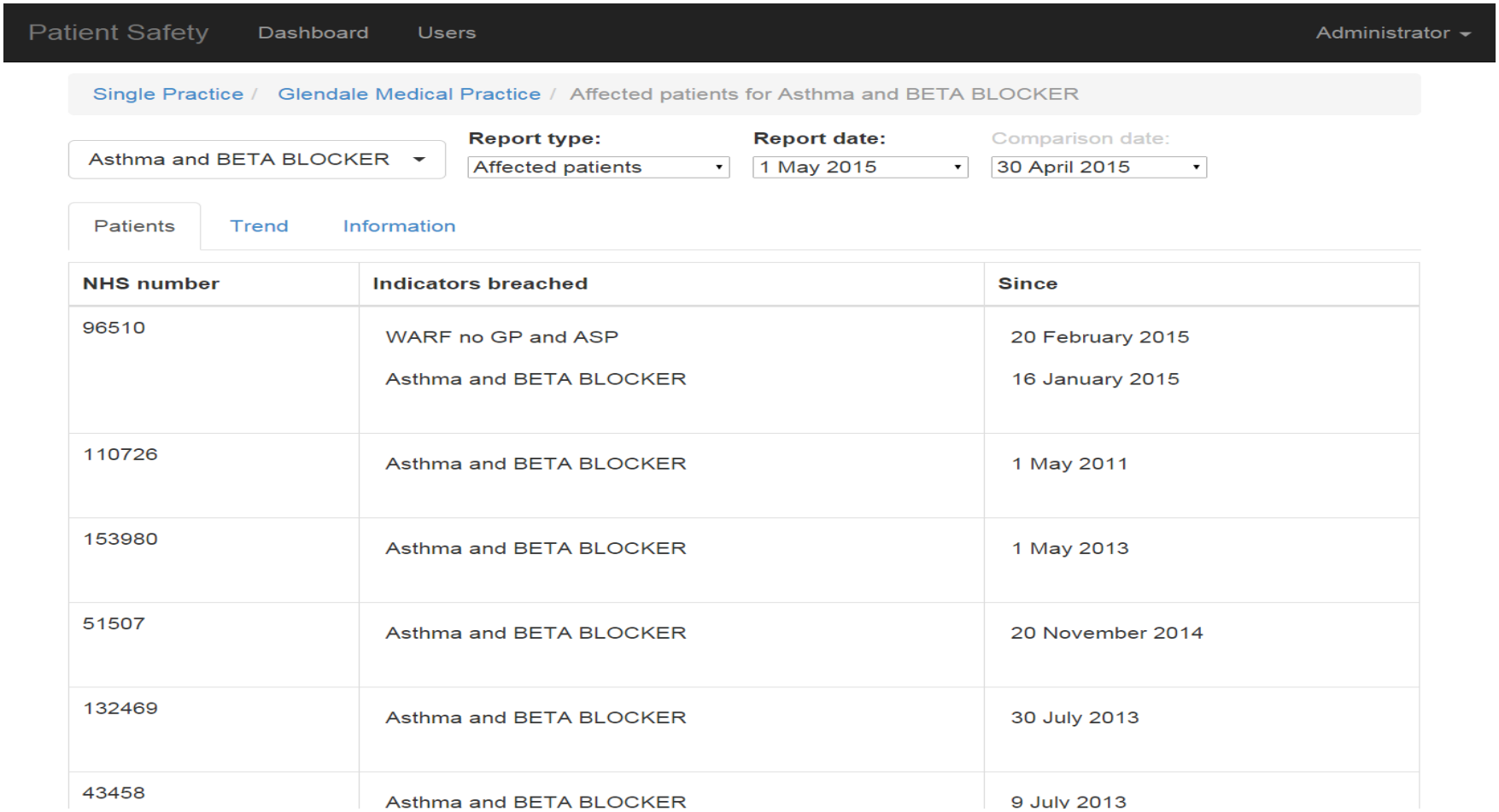


Indicator	Affected patients	Eligible patients	% of eligible patients affected	CCG Avg (%)	Successful intervention	Action pending	New cases	Trend	Show on top
Age≥65 no GastProt and NSAID	19	931	2.04	0.32	2	16	3	1	
Mtx and no monitoring	12	109	11.01	2.67	5	10	2	-3	
GiB/PUD no GastProt and Antiplatelet	8	121	6.61	2.49	2	7	1	-1	
Asthma and BB	8	218	3.67	1.51	2	6	2	0	
Aspirin and Antiplatelet	7	202	3.47	1.11	0	0	7	7	
CKD and triple whammy	5	175	2.86	1.30	0	0	5	5	
Warf/NOAC and NSAID	4	21	19.05	9.05	1	3	1	0	
HF and NSAID	3	102	2.94	2.11	4	1	2	-2	
LABA and no ICS	2	234	0.85	1.07	0	0	2	2	
Amiod and no thyroid test	2	22	9.09	11.54	4	1	1	-3	
Warf/NOAC no GastProt and Antiplatelet	1	21	4.76	10.69	4	0	1	-3	
GiB/PUD no GastProt and NSAID	1	106	0.94	1.85	3	0	1	-2	
CKD and NSAID	1	191	0.52	1.55	2	0	1	-1	

Appendix 9c - Chart view



Appendix 9d -Patients affected



Appendix 9e- Evidence summary

Appendix 10. Interview schedule SMASH - CCG Pharmacist or manager

INTERVIEW SCHEDULE – CCG Pharmacist or Manager

Interviewer introduction:

I am [….] and I am a researcher at the University of Manchester. We are carrying out a project looking at the use of a medication safety dashboard in Salford. We would like to find out more about the views of healthcare professionals and managers who have used this system.

This interview will last for approximately forty minutes, and during that time I'd like to discuss your experience of using the dashboard and engaging with pharmacists and general practice staff. I should remind you that the interviews are confidential and will be used only for our own research. I'd like to record the discussion if that is okay with you; this is simply to help me capture all of the information that comes out of it. Before we begin, I'd like to provide some ground rules for the discussion:

- You are being digitally recorded, so speak clearly;
- We will anonymise the transcript so that nobody can be identified by name. However, please try to avoid naming specific healthcare professionals or locations;
- Everything discussed here is confidential. However, if you were to reveal anything that would place you at somebody else at risk of harm, we may have to report this to a clinical supervisor.

Unless you have any questions for me, then we can begin.

Interview questions: (supplementary questions)

1. What is your role?
2. How did you come to use the dashboard? (What were your expectations of it? What are your motivations to use it?)
3. What is your experience of working with the medication safety dashboard?
4. What benefits or disadvantages do you see in using the dashboard in your role? (What particular things have helped? What particularly things have not helped?)
5. What are the benefits or disadvantages of the dashboard to the CCG as a whole? (How do you see this in the future?)
6. Have you worked with others who are using it? (What interactions have there been between yourself and those people? Why have those people been involved?)
7. What is your understanding of how the dashboard will work in the GP practices? (How do you see the role of the clinical pharmacist as they go into the practices?)
8. Is there anything else that you think should be discussed given our research topic?

Appendix 11. Interview schedule SMASH - GP staff interviews

INTERVIEW SCHEDULE – GP Staff

Interviewer introduction:

I am [….] and I am a researcher at the University of Manchester. We are carrying out a project looking at the use of a medication safety dashboard and clinical pharmacist-led education and feedback in Salford. We would like to find out more about the views of healthcare professionals who have worked with this system. This interview will last for approximately forty minutes, and during that time I'd like to discuss your experience of using the electronic dashboard and engaging with the clinical pharmacist. I should remind you that the interviews are confidential and will be used only for our own research. I'd like to record the discussion if that is okay with you; this is simply to help me capture all of the information that comes out of it. Before we begin, I'd like to provide some ground rules for the discussion:

- You are being digitally recorded, so speak clearly;
- We will anonymise the transcript so that nobody can be identified by name. However, please try to avoid naming specific healthcare professionals or locations;
- Everything discussed here is confidential. However, if you were to reveal anything that would place you at somebody else at risk of harm, we may have to report this to a clinical supervisor or manager.

Unless you have any questions for me, then we can begin.

Interview questions: (supplementary questions)

1. What is your experience of working with the medication safety dashboard?
2. What were your expectations of the intervention (the dashboard and the work of the pharmacist)? (What was your understanding of it?)
3. Can you describe how the intervention has worked in your practice? (Who has used the dashboard? What interactions have there been with the pharmacist? Why have those people been involved?)
4. What particular things have helped make the intervention work in your practice?
5. What things have meant that the intervention has not worked in your practice?
6. How, if at all, have things changed from the way you worked before? (What are those changes? What adjustments have been made to work practices? Have there been any role changes? Are things done differently? Why have those changes been made?)
7. Is there anything else that you think should be discussed given our research topic?

Appendix 12. Interview schedule SMASH - Clinical Pharmacist

INTERVIEW SCHEDULE – Clinical Pharmacist

Interviewer introduction:

I am [….] and I am a researcher at the University of Manchester. We are carrying out a project looking at the use of a medication safety dashboard in Salford. We would like to find out more about the views of healthcare professionals who have used this system.

This interview will last for approximately forty minutes, and during that time I'd like to discuss your experience of using the dashboard and engaging with general practice staff. I should remind you that the interviews are confidential and will be used only for our own research. I'd like to record the discussion if that is okay with you; this is simply to help me capture all of the information that comes out of it. Before we begin, I'd like to provide some ground rules for the discussion:

- You are being digitally recorded, so speak clearly;
- We will anonymise the transcript so that nobody can be identified by name. However, please try to avoid naming specific healthcare professionals or locations;
- Everything discussed here is confidential. However, if you were to reveal anything that would place you at somebody else at risk of harm, we may have to report this to a clinical supervisor.

Unless you have any questions for me, then we can begin.

Interview questions: (supplementary questions)

1. What is your experience of working with the medication safety dashboard?
2. Can you describe how the intervention has worked in this practice? (Who has used the dashboard? What interactions have there been between yourself and practice staff? Why have those people been involved?)
3. What particular things have helped make the intervention work in this practice?
4. What things have meant that the intervention has not worked in this practice?
5. Is there anything else that you think should be discussed given our research topic?

Appendix 13.

SMASH study-Practice and Participant information sheets and consent forms

Appendix 13a. Practice Cover Letter

Appendix 13b. Practice Information sheet

Appendix 13c. Practice Consent

Appendix 13d. Participant Information Sheet- GP Staff

Appendix 13e. Participant Information Sheet- Pharmacist

Appendix 13f. Participant Consent Forms

Appendix 13a. Practice Cover Letter

Name of practice manager or senior partner
Address
Postcode

Date

Dear [letter sent to a named practice manager/senior partner in each practice]

The Salford MedicAtion Safety dasHboard (SMASH) Trial

I am writing to ask if your practice would be willing to participate in a research project that has been funded by the National Institute for Health Research (NIHR) Greater Manchester Primary Care Patient Safety Translational Research Centre (PSTRC).

Whilst the majority of medicines are prescribed and monitored safely in primary care, research from the Universities of Manchester and Nottingham has shown that some patients are placed at risk from hazardous prescribing or infrequent therapeutic monitoring. In the landmark PINCER trial, pharmacist-led feedback on potentially inappropriate prescribing and monitoring data obtained from electronic dashboards which searched GP patient records was shown to successfully reduce the number of patients exposed to hazardous prescribing.

In this SMASH study, we will be utilising pharmacists in the same way as the PINCER trial but with the addition of our new and expanded electronic medication safety dashboard of hazardous prescribing and monitoring indicators. Specifically, we want to evaluate the effects of the PINCER pharmacist-led intervention with our dashboard on hazardous prescribing and monitoring when compared to standard care provided in primary care in Salford. We would also like to explore how SMASH is implemented and used in practice, using interviews with stakeholders and observation of pharmacist activities.

The study is being conducted by the Universities of Manchester and Nottingham, and we hope to recruit as many practices as possible within Salford CCG. The study has been granted ethical approval by [NHS Ethics Committee details here] and organisational approval by Salford Royal Research and Development Unit.

Please find enclosed an information sheet which explains more about the SMASH trial, requirements for participation and what would be expected of the practice during the study. We would be grateful if you would read the information sheet and return the enclosed reply slip in the pre-paid envelope provided, indicating whether or not you might be interested in participating.

If you are interested in participating and return the reply slip, a member of the research team will telephone you to arrange a meeting to discuss the study in more detail and address any questions or concerns you may have. If we don't hear from you within two to three weeks a researcher will give your practice a ring.

Yours sincerely

Dr Niels Peek, Principal Investigator, SMASH Trial

Appendix 13b. Practice Information sheet

Practice Participant Information Leaflet
The Salford MedicAtion Safety dasHboard (SMASH) Trial

(A trial to determine the effectiveness and acceptability of a pharmacist-led, updated medication safety dashboard-based intervention in reducing rates of potentially hazardous prescribing and monitoring in general practice)

Your practice is being invited to take part in the above study. Please take time to read this information leaflet and discuss it with other practice members before returning the reply slip on behalf of your practice to indicate whether you are interested in taking part.

Thank you for taking the time to read this leaflet.

Purpose of the study
The purpose of this study is to determine the effectiveness of a pharmacist-led information technology-based intervention in reducing the incidence of potentially hazardous prescribing in primary care, when compared with existing practice.

Why has my practice been chosen?
We are approaching practices that are part of Salford CCG, due to their being linked to the Salford Integrated Record. Your practice has been chosen because it is within Salford CCG.

Does my practice have to take part?
It is up to you and your colleagues to decide whether you wish to take part. If you decide to take part you are still free to withdraw at any time and without giving a reason, with no detriment to you or your practice. Please return the reply slip attached to your cover letter using the pre-paid envelope to indicate whether you are interested in taking part. If your slip indicates that you are interested in participating, you will then be contacted by the research team to sign a consent form on behalf of other staff within your practice.

What will happen if we decide to take part?
If you are interested in taking part please return the reply slip attached to your cover letter using the pre-paid envelope. You will then be contacted by the research team to sign a consent form on behalf of your practice. Don't worry if you lose your reply slip or forget to send it; you can contact the research team using the details in this

leaflet to register your interest, and a researcher will also call your practice after 2-3 weeks if we don't hear from you after receiving this leaflet.

1. The pharmacist-led, medication safety dashboard-based (SMASH) intervention
Once you have signed the study consent form, you will work with the research team to identify a suitable date to receive the SMASH trial intervention. On the agreed date, your practice staff will be given access to the electronic medication safety dashboard tool using a secure login. Using this dashboard, staff will be able to view individual patients who may be affected one or more potentially hazardous prescribing and monitoring indicators (for example, prescribing non-steroidal anti-inflammatory drugs to patients with a history of peptic ulcer without co-prescribing gastro-protective drugs). Staff will also be able to identify those indicators which are most commonly occurring in the practice for targeted action. Along with the dashboard, practices will also be visited by a clinical pharmacist during a 12 week period, who has been trained to work collaboratively with practice staff in understanding and solving potentially hazardous prescribing and monitoring indicators that have been identified with the dashboard. It is very important to stress that the SMASH intervention is not designed to replace clinical judgements regarding individual prescribing and monitoring decisions; these decisions remain the sole responsibility of relevant practice staff (i.e. GPs, practice nurses).

2. Understanding the effectiveness of the SMASH intervention
In order to assess the effect of the SMASH pharmacist and medication safety dashboard intervention on safe prescribing and monitoring, we will compare the numbers of patients at risk of avoidable harm in each practice before and after the intervention is introduced. In addition, we will use log files of the electronic dashboard to investigate the frequency with which the electronic dashboard is used, who its primary users are (e.g. pharmacists or GPs), which feedback modalities provided by the electronic dashboard (table, benchmark charts, trend charts, patient lists) are typically accessed by users and which areas of medication safety (i.e. which indicators) users tend to focus when they access the electronic dashboard.

3. Understanding how the SMASH intervention is delivered, and what stakeholders think of it
In order to find out what practice staff (managers, GPs, practice nurses) think of the SMASH intervention and how it is implemented and used in practice, we plan to undertake a number of face-to-face and telephone interviews with clinical and administrative staff from a select number of those practices involved in the trial. Staff in your practice may be approached to ask if they are willing to participate in these activities, and if they agree to take part each member of staff will be interviewed a maximum of two times, totalling approximately 1 hour of their time. These interviews will be audio-taped and transcribed, and we will ask for written consent from each individual staff member involved. We are also aiming to observe pharmacists as they deliver the SMASH intervention in a select number of general practices, which may last between 4-8 hours per session. We are specifically looking to understand how pharmacists interact with practice staff during these observations. For practical

reasons we will not ask for written consent from each member of practice staff involved in these observations; instead we ask for you to give permission by reading this information sheet and signing a consent form on behalf of your practice colleagues.

What are the possible disadvantages or risks of taking part?
This pharmacist-led medication safety dashboard-based intervention does not expose patients to any medical risks that would not exist otherwise. The intervention targets prescribing and monitoring behaviour of practice staff; there is no intervention at patient level. Practice staff and pharmacists will be explicitly instructed that advice generated by the electronic medication safety dashboard should not replace clinical judgment. Therefore we do not foresee potential adverse effects for patients.

Involvement in the study will take up some time for members of your practice when working with the pharmacist or being interviewed. However, our previous research indicates that it should not be too time-consuming for most practices and we will reimburse members of staff for their time conducting the interviews. Observation of staff working with pharmacists to deliver the intervention is not expected to take up more time as practice staff will be conducting normal duties without interference from the researcher.

What are the possible benefits of taking part?
For GPs, participation in the study will allow quick and easy identification of patients to whom potentially hazardous medication has been prescribed, or whose medication may not have been properly monitored. In addition, they will receive support (including visits) from a pharmacist in understanding and solving these issues. All practices involved in the study will have the opportunity to check these patients and to decide whether to take corrective action.

For pharmacists, participation in the study will help to reduce the number of potentially hazardous medication prescriptions and improve medication monitoring. The study will also facilitate better collaboration with practice staff in improving patient care.

Will the practices' participation in the study remain confidential?
All data for the analysis of prescribing will be anonymised using a link code at patient-level, GP-level, pharmacist-level and general practice-level. Individual patients, GPs, pharmacists and practices will not therefore be identifiable in any reports or publications produced by the research team.

Any discussions that take place during the study are confidential. However, if you were to tell us something new that could put someone at risk of harm, or reveal unsafe practice, we may have to report this information to a clinical supervisor or using an incident reporting system. If so, we would discuss this with you first.

The data will be used only by us, and for this study only. However, relevant sections of data may be looked at by responsible individuals from the University of

Manchester, regulatory authorities or the NHS Trust who are monitoring our research practice.

What will happen to the results of this study?
The results of this study will be published in relevant peer reviewed journals and presented at professional conferences. A summary report of the main findings will also be distributed at CCG and practice level.

Who is organising and funding this research?
The research is funded by the National Institute for Health Research (NIHR). It is organised by the NIHR Greater Manchester Primary Care Patient Safety Translational Research Centre (PSTRC) based at The University of Manchester, in collaboration with the Division of Primary Care, University of Nottingham.

What if there is a problem?
If you have a concern about any aspect of this study, you can speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact the University of Manchester's Research Practice and Governance Co-ordinator on 0161 275 8093 or by email to research.complaints@manchester.ac.uk

Who has reviewed the study?
This study has been approved by [NHS Ethics Committee details] and the Research and Development office of Salford Royal NHS Foundation Trust.

Contact Details
For further information about this study please contact the Principal Investigator:
Dr Niels Peek
Centre for Health Informatics
Vaughan House, Portsmouth St
Manchester, M13 9GB
Tel: 0161 306 0674 Email: niels.peek@manchester.ac.uk

Appendix 13c. Practice Consent

The Salford MedicAtion Safety dasHboard (SMASH) Trial

Principal Investigator: Dr Niels Peek

Name and address of general practice:
…….....

……
…

General Practice Consent to Participate in SMASH Trial

Please complete the following:

Please delete as applicable

Have you read and understood the information sheet [version _, date dd/mm/yy]?

YES / NO

Have you had an opportunity to ask questions and discuss this study? YES / NO

Have you received satisfactory answers to all your questions? YES / NO

Have you received enough information about the study? YES / NO

Do you understand that participation in this study is voluntary and that the practice is free to withdraw from the study at any time, and without giving a reason?

YES / NO

Do you give permission for responsible individuals from the University of Manchester, from regulatory authorities or from Salford NHS to look at relevant sections of data collected during the study, where it is relevant to your practice taking part in the research?

YES / NO

Do you agree for a researcher to observe your practice staff whilst they work with pharmacists as part of this study?

YES / NO

Who explained the details of this study to you?

…….....

The practice agrees to take part in this study. YES / NO

Name of practice representative:
……..……..…….....

Designation of practice representative:
…….....

Signed: ……..……..……..

Date: ……..

Name of researcher:
……

Signed: .....…….. ……...….

Date: ……..….

Appendix 13d. Participant Information Sheet- GP Staff

Participant Information Sheet: Salford Medication Dashboard –

Qualitative Evaluation (Interviews - GP staff)

Introduction

You are being invited to take part in a research study by The Universities of Manchester and Nottingham. In order to help you decide whether or not to take part, this information sheet provides you with further details about the study. The sheet is in two parts: Part One explains the purpose of the study and what it will involve; Part Two gives more detailed information about the conduct of the study. You may keep this sheet for future reference, along with a copy of the consent form.

Part One

What is the purpose of the study?

This qualitative work will seek to explore and understand the ways in which a pharmacist-led electronic medication safety dashboard intervention might optimise improvements in medication safety in primary care. The intervention involves a novel interactive medication safety dashboard tool and visits to the practice by a clinical pharmacist. The study is being conducted by the Universities of Manchester and Nottingham, and is independent from the NHS. The research is funded by the National Institute for Health Research (NIHR).

Why have I been chosen?

GPs and other practice staff will likely have interactions with the pharmacist and access to the electronic medication safety dashboard tool. We would therefore like to learn from the experiences of those who are involved in the intervention in general practices in Salford.

Do I have to take part?

You do not have to take part in the study. If you do decide to take part and then later change your mind, either before, during or after the study, you can withdraw without giving any reason.

What will I be asked to do if I take part?

You will be asked to take part in two interviews. During the interviews, you would be asked to discuss your experiences of the intervention (the pharmacists visit and the medication safety dashboard);

The first of these will be during the pharmacists visit to your practice - this will be conducted either be face-to-face or by telephone and will last approximately 40 minutes. The second will be at a later date after the pharmacist has stopped working at your practice; this interview will be by telephone and may last approximately 20 minutes. With your permission the interviews will be audio-recorded. During an interview you can take a break at any time.

The researchers involved in this qualitative study are:

- Mr Mark Jeffries (Research Associate)
- Dr Richard Keers (Clinical Lecturer)
- Dr Denham Phipps (Research Fellow)
- Dr Sarah Rodgers (Senior Research Fellow)
- Prof. Tony Avery (Professor of General Practice)
- Prof. Darren Ashcroft (Professor of Pharmacoepidemiology)

Expenses and payments

We will reimburse any reasonable out-of-pocket expenses incurred as a result of taking part in our study. This will be in the form of vouchers at a maximum of £40 per hour for GPs and £20 for other general practice staff.

What are the benefits of taking part?

There are no direct benefits to you from taking part in this study. However, by taking part you will help us to reflect and learn how healthcare professionals, whether in Salford or elsewhere, might optimise working practices to improve quality, and how

new ways of working can be integrated into local circumstances. The study findings will also help us to understand how similar interventions should be designed in the future in order to be most effective.

What if there is a problem?

We have made provision for any queries or complaints you may have to be addressed, either by the research team or by an independent body. Further details are given in Part Two.

Will my taking part in the study be kept confidential?

We will take steps to ensure the confidentiality of any data you provide. Further details are given in Part Two.

Where can I obtain further information if I need it?

If you need further information or are interested in taking part then you are welcome to contact Mark Jeffries on 0161 275 3680 or mark.jefferies@manchester.ac.uk.

This completes part one of the information sheet. If Part One has interested you and you are considering participation, please continue to read the additional information in Part Two before making any decision.

Part Two

What data will you collect, and what will happen to it?

Provided that you give consent for us to do so, we will audio record the interviews. The recordings will be transcribed, and the transcripts used for the data analysis. Both the recordings and the transcripts will be used only for the purposes of this study, and will be destroyed five years after the final report is released. During the interview, you may request that the recording is stopped at any point. You may also request that any part of the transcript is deleted or rephrased.

Will my taking part in this study be kept confidential?

Yes. During analysis of interview transcripts, any information that may lead to specific individuals being identified will be removed. While direct quotes may be

reproduced to illustrate particular points when reporting the research, these will be made anonymous.

Any discussions that take place during the study are confidential. However, if you were to tell us something new that could put you or someone else at risk of harm, or reveal unsafe practice, we may have to report this information to a clinical supervisor or manager. If so, we would discuss this with you and tell you what we intend to do.

Relevant sections of data may be looked at by responsible individuals from the University of Manchester, regulatory authorities or the NHS Trust who are monitoring our research practice.

The data collected during this study could be used to support research in the future. We may use the anonymous data in future studies or share it with other researchers working on other studies. All of the data used for future research will be anonymised and so no-one will be able to identify you.

What will happen to the results of the research study?

The results of the study will be published in reports to be held at the University of Manchester. It is our expectation that the results will also be published in reports, journal articles and in conference presentations that will be released into the public domain. These reports will be provided to participants on request. No participant will be identified in any publication unless he or she has given specific consent for such information to be released.

Who is organising and funding the research?

The University of Manchester is providing sponsorship for this study, with funding coming from the National Institute for Health Research.

Who has reviewed the study?

This study was approved by the National Research Ethics Service (details) and Research and Development Unit, Salford Royal NHS Foundation Trust.

We would like to thank you for considering participating in this study, and for taking the time to read this information sheet.

Appendix 13e. Participant Information Sheet- Pharmacist

Participant Information Sheet: Salford Medication Dashboard –

Qualitative Evaluation (Interviews - Pharmacist)

Introduction

You are being invited to take part in a research study by The Universities of Manchester and Nottingham. In order to help you decide whether or not to take part, this information sheet provides you with further details about the study. The sheet is in two parts: Part One explains the purpose of the study and what it will involve; Part Two gives more detailed information about the conduct of the study. You may keep this sheet for future reference, along with a copy of the consent form.

Part One

What is the purpose of the study?

This qualitative work will seek to explore and understand the ways in which a pharmacist-led electronic medication safety dashboard intervention might optimise improvements in medication safety in primary care. The intervention involves a novel interactive medication safety dashboard tool and visits to the practice by a clinical pharmacist. The study is being conducted by the Universities of Manchester and Nottingham, and is independent from the NHS. The research is funded by the National Institute for Health Research (NIHR).

Why have I been chosen?

We would like to learn from your experiences as the pharmacist involved in the intervention within general practices in Salford.

Do I have to take part?

You do not have to take part in the study. If you do decide to take part and then later change your mind, either before, during or after the study, you can withdraw without giving any reason.

What will I be asked to do if I take part?

You will be asked to take part in an interview at each of the general practices you visit as part of the intervention. During the interview, you would be asked to discuss your experiences of the intervention at that particular practice.

The interview will be conducted either be face-to-face or by telephone and will last approximately 40 minutes. With your permission the interview will be audio-recorded. During an interview you can take a break at any time.

The researchers involved in this qualitative study are:

- Mr Mark Jeffries (Research Associate)
- Dr Richard Keers (Clinical Lecturer)
- Dr Denham Phipps (Research Fellow)
- Dr Sarah Rodgers (Senior Research Fellow)
- Prof. Tony Avery (Professor of General Practice)
- Prof. Darren Ashcroft (Professor of Pharmacoepidemiology)

Expenses and payments

We will reimburse any reasonable out-of-pocket expenses incurred as a result of taking part in our study. This will be in the form of vouchers at a maximum of £20 per hour.

What are the benefits of taking part?

There are no direct benefits to you from taking part in this study. However, by taking part you will help us to reflect and learn how healthcare professionals, whether in Salford, or elsewhere, might optimise working practices to improve quality, and how new ways of working can be integrated into local circumstances. The study findings will also help us to understand how similar interventions should be designed in the future in order to be most effective.

What if there is a problem?

We have made provision for any queries or complaints you may have to be addressed, either by the research team or by an independent body. Further details are given in Part Two.

Will my taking part in the study be kept confidential?

We will take steps to ensure the confidentiality of any data you provide. Further details are given in Part Two.

Where can I obtain further information if I need it?

If you need further information or are interested in taking part then you are welcome to contact Mark Jeffries on 0161 275 3680 or mark.jefferies@manchester.ac.uk.

This completes part one of the information sheet. If Part One has interested you and you are considering participation, please continue to read the additional information in Part Two before making any decision.

Part Two

What if there is a problem?

If there are any issues regarding this research you should contact the researcher in the first instance – Mark Jeffries by telephoning 0161 275 3680. If you wish to make a formal complaint about the conduct of the research you can contact a Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 8093

What data will you collect, and what will happen to it?

Provided that you give consent for us to do so, we will audio record the interview. These recordings will be transcribed, and the transcripts used for the data analysis. Both the recordings and the transcripts will be used only for the purposes of this study, and will be destroyed five years after the final report is released. During the

interview, you may request that the recording is stopped at any point. You may also request that any part of the transcript is deleted or rephrased.

Will my taking part in this study be kept confidential?

Yes. During analysis of interview transcripts, any information that may lead to specific individuals being identified will be removed. While direct quotes may be reproduced to illustrate particular points when reporting the research, these will be made anonymous.

Any discussions that take place during the study are confidential. However, if you were to tell us something new that could put you or someone else at risk of harm, or reveal unsafe practice, we may have to report this information to a clinical supervisor. If so, we would discuss this with you and tell you what we intend to do.

Relevant sections of data may be looked at by responsible individuals from the University of Manchester, regulatory authorities or the NHS Trust who are monitoring our research practice.

The data collected during this study could be used to support research in the future. We may use the anonymous data in future studies or share it with other researchers working on other studies. All of the data used for future research will be anonymised and so no-one will be able to identify you.

What will happen to the results of the research study?

The results of the study will be published in reports to be held at the University of Manchester. It is our expectation that the results will also be published in reports, journal articles and in conference presentations that will be released into the public domain. These reports will be provided to participants on request. No participant will be identified in any publication unless he or she has given specific consent for such information to be released.

Who is organising and funding the research?

The University of Manchester is providing sponsorship for this study, with funding coming from the National Institute for Health Research.

Who has reviewed the study?

This study was approved by the National Research Ethics Service [details] and the Research and Development Unit, Salford NHS Foundation Trust.

We would like to thank you for considering participating in this study, and for taking the time to read this information sheet.

Appendix 13f. Participant Consent Forms

MANCHESTER 1824
The University of Manchester

The University of Nottingham
UNITED KINGDOM · CHINA · MALAYSIA

Participant Identification Number:

Consent form for qualitative interview

The Salford MedicAtion Safety dasHboard (SMASH) Trial

Researchers: Mark Jeffries, Denham Phipps, Richard Keers & Darren Ashcroft (University of Manchester); Sarah Rodgers & Tony Avery (University of Nottingham)

Please initial each of the boxes below if you agree to each point

Initial here

1. I have read and understood the information sheet (version _ dated dd.mm.yyyy) for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without any detriment to me.	
3. I consent to being audio recorded as detailed in the Participant Information Sheet.	
4. I consent to the researchers using anonymised verbatim quotations from the interview.	
5. I understand that relevant sections of data collected during the study may be looked at by responsible individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in the research. I give permission for these individuals to have access to this data.	
6. I understand that the data collected during this study could be used to support research in the future. All of the data used for future research will be anonymised and so no-one will be able to identify me.	
7. I agree to take part in this study	

Name of participant: ……………..……..…… **Signed:** .... **Date:** ....

Consent taken by: ……………..……..…… **Signed:** .... **Date:** ....

Appendix 14. First iteration of the thematic coding framework for SMASH

GROUP A - THE DASHBOARD		
Perceived benefits or disadvantages of the dashboard	Access and functionality of the dashboard	Perceived outcomes
CCG Strategic overview	Access to	Prescriber education
Role of dashboard in medicines optimisation	Who uses it?	What changes are users trying to make?
Patient safety	Ease of Use	What changes clinical decisions?
"Fit" with other initiatives	Functionality	System changes
Identifying high risk prescribing	Numbers	Medication review
Educational value – evidence summaries	Time	Changes to patient medication
Importance and impact of practice demographics to benefits and disadvantages of SMASH		
GROUP B - WAYS OF WORKING IN RESPONSE TO SMASH DATA		
Divisions of labour/role allocation	Reactive /Opportunistically	Proactive
How the work is divided	Affected patients	Prioritising specific indicators of groups of indicators
Role allocation decisions	Individual Patient Intervention	Feedback on prescribing and education for individual doctors
One GP takes a lead v. multiple GP involvement	New cases	Systems developed, adapted or evolved as a result of the dashboard
Pharmacist role v. GP role		
Admin role		
GROUP C - EVOLVING MODELS OF PHARMACY IN PRIMARY CARE		
Role definition	What work the pharmacist does	Relationships with GPs
SMASH dedicated pharmacist v. not SMASH dedicated	Patient focused - e.g. review patients, direct contact with patients	Engagement with practice/position in practice
How SMASH work fits into other pharmacist work	Practice focused - e.g. give feedback to GPs who review patients	Contact and Communication
Different approaches to pharmacist work in primary care	Affected patients or new cases	Who decides the "how" and "when" of communication?
Role of the practice pharmacist outside of SMASH	Clinical decisions - How are these made? Why? By whom? What difference is the pharmacist making?	Individual contacts
Who defines the role?	Boundaries to work	Practice meetings
Line management	Embedding into the complexities of general practice	Fitting contact around GP work
Contractual obligations/business obligations	Adding work for clinicians or easing clinician workload	Formal v Informal
Relationship with CCG	Patient safety	Professionalism

Appendix 15. Final iteration of the coding framework for SMASH

NPT Construct	Corresponding Component	Explanation	Possible examples from SMASH Emerging themes and observations during data collection/analysis
1. Coherence Sense-making work: understanding and conceptualisation of interventions and their work.	1.1 Differentiation	What people do to understand how a set of practices and their objects are different from each other. What they do to organise the differences.	• How SMASH work fits into and is different from other pharmacist work • "Fit" with other CCG initiatives • Differences between SMASH and other initiatives • Importance and impact of practice demographics to benefits and disadvantages of SMASH
	1.2 Communal Specification	People working together to build a shared understanding of the aims, objectives, and expected benefits of a set of practice. How a team works out how to integrate an innovation into their healthcare setting.	• CCG strategic overview • What changes are users trying to make? • Practice based decisions • Defining the pharmacist role • Who defines the role • Different approaches to pharmacist work in primary care
	1.3 Individual specification	Individuals' understanding of their specific tasks and responsibilities around a set of practices.	• Pharmacist role v GP role • Single GP v multiple GP involvement • Patient safety • Role of dashboard in medicines optimisation • Changes to patient medication • Medication review
	1.4 Internalization	Work to understand the value, benefits and importance of a set of practices. The *w*ork people do to attribute worth to a new way of working.	• Identifying high risk prescribing • System changes • Prescriber education • Educational value – evidence summaries
2. Cognitive Participation Relational work that people do to build and	2.1 Initiation	The work people do to drive forward the new or modified practice. Setting things up and working with others to	• Access to the dashboard • Functionality • Ease of use • Line management • Contractual

sustain a community of practice around a new technology or complex intervention: notions of legitimation and buy-in, both in terms of the individuals involved and involving others.		make things happen.	obligations/business obligations
	2.2 Enrolment	How participants organise and reorganise themselves and others in order to collectively contribute to the work involved in new practices. This is complex work that may involve rethinking individual and group relationships between people and things.	• Who uses it? • Different plans for how SMASH will be used. • Who defines the (pharmacist) role? • Different approaches to pharmacist work in primary care • Contact and communication
	2.3 Legitimation	The work ensuring that other participants believe it is right for them to be involved, and that they can make a valid contribution to it.	• Relationship with CCG • Embedding into the complexities of general practice • Professionalism - professional identity
	2.4 Activation	The work of keeping the new practices in view and connecting them with the people who need to be doing them. Collectively defining the actions and procedures needed to sustain a practice and to stay involved.	• One GP takes a lead v. multiple GP involvement • Pharmacist role v. GP role • Admin role • Boundaries to work • Patient focused - e.g. review patients, direct contact with patients
3. Collective Action Operational work that people do to enact a set of practices: organisational resources, training, division of labour, confidence and expertise as well as the workability of the intervention in clinical interaction.	3.1 Interactional workability	The interactional work that people do with each other, with artefacts, and with other elements of a set of practices, when they seek to operationalize them in everyday settings. The impact the new practice has on interactions with each other and/or service users.	• Prioritising specific indicators of groups of indicators • Individual patient intervention - contacting patients • Feedback on prescribing and education for individual doctors • Adding work for clinicians or easing clinician workload • Systems developed, adapted or evolved as a result of the dashboard • Contact and communication • Who decides how and when of communication • Formal v informal relationships
	3.2 Relational	The knowledge work	• Confidence in the

	integration	that people do to build accountability and maintain confidence in a set of practices and in each other as they use them. The impact the innovation has on relationships between different groups of professionals e.g. trust, accountability and responsibility.	robustness and credibility of the dashboard data • Numbers • Engagement in practice /position in practice
	3.3 Skill set workability	The allocation work that underpins the division of labour that is built up around a set of practices as they are operationalized in the real world. Who gets to do/did what, and how the tasks relate to their existing skill sets.	• How the work is divided • Role allocation decisions • SMASH dedicated pharmacist v. not SMASH dedicated • Practice focused - e.g. give feedback to GPs who review patients • Patient focused - e.g. review patients, direct contact with patients
	3.4 Contextual integration	The resource work - managing a set of practices through the allocation of different kinds of resources and the execution of protocols, policies and procedures. Fit between the new practice and overall organisational context, including organisational goals, morale, leadership and distribution of resources (e.g. funding, policy, priorities).	• Systems developed, adapted or evolved as a result of the dashboard • Engagement with practice/position in practice • How SMASH work fits into other pharmacist work
4. Reflexive Monitoring Appraising and monitoring implementation work. The appraisal work that people do to assess and	4.1 Systematization	The work of collecting information in a variety of ways to determine how effective and useful the new practice is for them and for others.	• Clinical decisions - How are these made? Why? By whom? What difference is the pharmacist making?
	4.2 Communal appraisal	Participants work together - sometimes in formal collaboratives, sometimes in informal	• Embedding into the complexities of general practice • Informal v formal

understand the ways that a new set of practices affect them and others around them.		groups to evaluate the worth of a set of practices.	• Engagement with practice
	4.3 Individual appraisal	Individuals appraising the new practice in relation to their own work; the impact it has on their tasks. Actions through which individuals express their personal relationship with the innovation.	• Adding work for clinicians or easing clinician workload • Professionalism • Formal v Informal
	4.4 Reconfiguration	The appraisal work by individuals or groups which may lead to attempts to redefine procedures or modify practices - and even to change the shape of the innovation itself.	• Embedding into the complexities of general practice