Investigating inpatient insulin prescribing practice and intervention use in UK hospitals: a mixed methods study and realist synthesis

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Abstract

Insulin prescription errors are a common, costly problem in NHS hospitals in the United Kingdom (UK), and are a consistent source of unintentional harm to inpatients with diabetes. Prompted by the lack of large-scale quantitative and qualitative research conducted in the UK in this area, this research aimed to investigate inpatient insulin prescribing practice and the current use of interventions designed to prevent insulin prescription errors in UK hospitals.

Following the conduct of a systematic review of interventions designed to reduce inpatient insulin prescribing errors, a questionnaire was developed, validated, and used as part of a cross-sectional survey of chief/diabetes pharmacists representing every NHS acute trust in the UK. Information was captured regarding the use, functionality and perceived effectiveness of insulin prescribing systems and interventions. Follow-up qualitative interviews were conducted with survey respondents to further analyse their experiences and opinions regarding insulin prescribing practice and intervention use. Realist synthesis was then undertaken to further understand how insulin self-administration policy interventions worked in different contexts. A participatory health research approach was taken throughout the research to maximise relevance and impact of the research for end-users, and a combination of middle-range theories were used throughout the research to aid the transferability of findings.

Ninety-five hospital trusts responded to the survey (54%), 18 of whom participated in follow-up interviews. Results indicated that a wide range of prescribing systems with varying functionalities were in use, along with a diverse range and combination of error-prevention interventions. Intervention use was positively associated with the availability of specialist diabetes pharmacists (P=0.002), who worked with diabetes teams to improve insulin safety in their organisations. Although mandatory insulin training was used by only 46% of trusts, it was perceived to be very effective at preventing errors. This was due to the perceived lack of understanding and confidence prescribers have with insulin, but the difficulties associated with accessing staff to deliver training in hospital. The insulin passport was perceived to be ineffective and only used by 31% of trusts on account of faults in its design, incompatibility with existing systems, and unreliable use by patients. Self-administration policy interventions were used by 63% hospitals and were described as salient but complex to implement; The use of realist synthesis generated 10 programme theories to further explain how they work, for whom and in what circumstances. Key contexts, outcomes and mechanisms were identified, including hierarchical and blame cultures, patient empowerment, control, shared decision-making, and clarification of roles.

As the first study to investigate insulin prescribing practice and intervention use at a multi-organisational level in the UK, this research contributes to the literature by describing and explaining how interventions may be used to improve the care received by inpatient with diabetes. Actionable findings are included that may help hospitals and policymakers implement interventions that are most likely to result in successful outcomes.

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Without several individuals this research would have not been possible, and I owe them my deepest gratitude. Firstly, I would like to thank my husband, Robbie, who has been my best friend, encourager, and relentless supporter throughout my entire research journey. Without his generosity and sacrifice I would have never been able to undertake this PhD. Also to my children, Micah, Emily and Miriam, who have been a constant source of love, encouragement, and motivation.

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External Outputs

The chapters in this thesis contain material that has been published in peer-reviewed journals and book chapters. Two further publications have been drafted from the thesis, one of which has been submitted for peer-review.

The author of this thesis was the first and corresponding author for all the following publications. Publications were drafted solely (100%) by the first author, and a small number of editorial amendments were made according to the supervisor's (co-authors) feedback (~5-10%). Questions raised by journal editors, peer-reviewers or copy editors were addressed by the author and approved by the supervisory team prior to publication.

Peer-reviewed publications

Bain, A., Hasan, S. S., & Babar, Z. U. D. (2019, August 1). Interventions to improve insulin prescribing practice for people with diabetes in hospital: a systematic review. Diabetic Medicine, Vol. 36, pp. 948–960. https://doi.org/10.1111/dme.13982

Bain, A., Hasan, S. S., Kavanagh, S., & Babar, Z.U.D. (2020). Use and validation of a survey tool to measure the perceived effectiveness of insulin prescribing safety interventions in UK hospitals. Diabetic Medicine, 37(12), 2027–2034.

Bain, A., Hasan, S. S., Kavanagh, S., & Babar, Z.U.D (2020). Strategies to reduce insulin prescribing errors in UK hospitals: results from a national survey. Diabetic Medicine, 37(7), 1176–1184.

Conference abstracts

Bain, Amie, Hasan, S. S., & Kavanagh, S. (2020). Strategies to improve insulin prescribing in UK hospitals: results from a national survey. International Journal of Pharmacy Practice, 28(S1), 44–45.

Other publications

Bain, A., Kavanagh, S., & Babar, Z. U. D. (2019). Prescribing insulin for people with diabetes in secondary care: Recommendations and future direction. In Z. U. D. Babar (Ed.), Encyclopaedia of Pharmacy Practice and Clinical Pharmacy (1st ed., Vol. 3A, pp. 107–116). https://doi.org/10.1016/B978-0-128-12735-3.00082-0

Bain, A., & Fowler, D. (2020). Quality Improvement Methods in Pharmacy Practice Research. In Z. U. D. Babar (Ed.), Pharmacy Practice Research Methods (pp. 75–91). https://doi.org/10.1007/978-981-15-2993-1_4

Bain, A., Babar, Z. U. D., & Hasan, S. S. (2018). Interventions to improve insulin prescribing practice for hospital inpatients: a systematic review. PROSPERO:CRD42018107133. Available from: https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=107133

Bain, A., Jeffries, M., Kavanagh, S., & Babar, Z. U. D. (2020). A realist review of inpatient insulin self-administration policy interventions for people with diabetes in hospital. PROSPERO:CRD42020193351. Available from: https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=193351

Copyright statement

Foreword from the Author

This thesis presents work that I have carried out during my PhD, whereby I have sought to gain an understanding of the strategies used to reduce errors associated with the prescribing of insulin for inpatients with diabetes. Undertaking this work has enabled me to develop skills in research design, conduct and dissemination using a variety of methods and methodologies and has enabled me to make an original contribution of knowledge for the benefit of improving the quality of care that people with diabetes receive in hospital.

My personal and professional background provides an important context to the work presented in this thesis, so I will outline this briefly here. I am currently working as an embedded clinical academic pharmacist at the University of Huddersfield and Sheffield Teaching Hospitals NHS Foundation Trust. This post primarily involves curriculum design and delivery for undergraduate and postgraduate pharmacy students in the areas of applied therapeutics, interprofessional education and prescribing. I am also involved in delivering undergraduate student hospital placements at the hospital, undertaking clinical pharmacy activities on ward areas, conducting practice-based research based at the trust, and supporting other pharmacists in research activities. I have been working in hospital pharmacy since I graduated from my undergraduate MPharm programme in 2009, and have been a proponent of interprofessional working and quality improvement efforts throughout this time. Prior to the PhD, I completed an MSc in clinical pharmacy and an MA in higher education where I developed my skills in quality improvement methods and qualitative research in the areas of insulin prescribing and interprofessional education. In recent years I have contributed to the national assessment of final-year medical students' prescribing competency as a senior author for the national Prescribing Safety Assessment (PSA).

As a clinical pharmacist in a hospital setting, my goal is to always patient safety at the heart of my practice. My motivation for undertaking the PhD is to be able to further my knowledge and skills to become a more advanced pharmacy practitioner for the benefit of the patients that I care for, and to generate and disseminate knowledge that aids wider hospital service improvement efforts. Prior to commencing the PhD, I have worked with colleagues to lead and disseminate quality improvement research regarding insulin prescribing practice at the point of admission and discharge from hospital.

Moreover, following the identification of this topic as being important to both patients and the hospital organisation in which I work. This involved investigating insulin prescribing and administration errors across the trust (Bain, Kavanagh, McCarthy, & Babar, 2019), documenting the impact that medicines reconciliation processes had on insulin errors (Bain, Moussallati, & Kavanagh, 2017), investigating the quality of insulin discharge prescriptions (Bain, Nettleship, Kavanagh, & Babar, 2017), and designing, implementing and evaluating quality improvement interventions to reduce insulin errors and improve patient safety (Bain, Silcock, Kavanagh, Quinn, & Fonseca, 2019). The positive impact that this activity has had on care provision locally, as well as further afield

(e.g. published work being cited by other authors), provided motivation to continue investigating this topic or my PhD.

The research objectives therefore derived from issues I considered important in my own professional practice and experience working in hospital pharmacy, and my prior knowledge of the literature, quality improvement initiatives, and national drivers. The way I have conducted the research reflects both my comfort discussing this topic with members of my own profession, the role I understand pharmacists have in this topic nationally, and the importance I place on involving patients in the care they receive and the research that informs it. As I am the main instrument of data collection throughout the thesis (Bryman, 2012 p405), I have considered how my values, motives and position have influenced how questions are framed, the analysis of the data and the outcomes. I have kept a reflective diary throughout to document how my own background, profession, institutional affiliations, and opinion about the topic may have shaped the design, data collection and analysis.

My journey through the PhD represents something of an epistemological migration from my professional background and training, which was predominantly of a positivist persuasion, towards a more relativist position. To answer the research questions in the most appropriate way, I needed to think more critically about a wider variety of methodological approaches; this resulted in an exploration of paradigms and a deeper engagement with theoretical frameworks and methodological tools that I had not previously encountered. A particular highlight of my journey through this PhD was discovering my methodological 'home' of scientific realism and participatory health research, and having the opportunity to reflect on how these have furthered my understanding of research involving interventions in healthcare settings.

This thesis presents research that furthers our understanding of insulin prescribing practice in the inpatient setting, and the use of interventions that are designed to prevent prescription errors. **Chapter 1** introduces the area of insulin prescribing for inpatients with diabetes in the UK, including insulin prescription error types and proposed improvement strategies to prevent these errors. This chapter incorporates a review of relevant national guidance, policy, and peer-reviewed literature to highlight gaps in what we know that are addressed by the current research. Theoretical models relevant to the research are also introduced, including Reason's human error theory, Human Factors, and Normalisation Process Theory, along with explanations as to why they are particularly suitable to apply to this research.

The review of the evidence to support the research topic provided in the first chapter is followed by a systematic literature review in **Chapter 2.** This review systematically identifies and evaluates the peer-reviewed literature pertaining to the effect of inpatient insulin prescribing interventions on improving insulin prescribing practice. The results are synthesised and presented in a narrative form on account of the diverse methodologies used in the studies identified, and conclusions are drawn that provide a foundation for the original research that follows.

Chapter 3 presents the methodology and methods of the research, including ethical and governance considerations. The chapter starts by outlining the overall design of the research, followed by a discussion of the

chosen methodologies and methods used for each of the studies conducted in the thesis. An explanation as to why mixed methods and realist synthesis were chosen to answer the research questions is provided, including a discussion regarding the compatibility of the methodological approach with my ontological and epistemological position. Details of how the stakeholder groups interacted with the research are also given in this chapter.

The results of the mixed methods study are included in **Chapters 4 and 5.** These relate to the investigation of insulin prescribing practice in UK hospitals and the interventions used to prevent insulin prescription errors. **Chapter 4** describes the development, use and validation of a questionnaire tool based on the findings of the systematic review. The results obtained from using this tool in a national cross-sectional survey of NHS Hospitals in the UK to describe insulin prescribing systems and intervention use are presented. Factors associated with intervention use were extracted from the analysis of results, and conclusions informed the design of the next study.

Chapter 5 presents the development and use of a semi-structured qualitative interview guide to investigate the use of interventions in hospital organisations further, following the national survey results. The results of the qualitative study, which involved interviewing pharmacists who participated in the national survey, are presented as a reflexive thematic analysis, and are interpreted with the aid of a Human Factors model. Conclusions from this study inform the design of the final study of the thesis, which seeks to further explain how one particular intervention works, for whom, in what circumstances and why.

Chapter 6 presents the results of the final study, which is a realist synthesis of self-administration policy interventions. This intervention was chosen as a particularly salient intervention from the results of the mixed methods study presented in **Chapters 4 and 5,** as well as input from the stakeholder groups.

The key results of the mixed methods study and realist synthesis are discussed in their respective chapters. **Chapter 7** includes a general discussion of the quality of the research conducted and how this meets the objectives of the thesis. The implications for practice are also outlined in this chapter as well as opportunities for further work. The thesis concludes with a summary of the research findings and the contribution this work has made to the literature.

I refer to myself as 'the researcher' throughout this thesis. Unless otherwise stipulated, reference to 'the research', 'the study' or 'the present work' refers to the original research designed and conducted by me, presented in this thesis. Where reference to additional researchers, reviewers or team members is made, this is accompanied by some description of who this is: either members of the supervisory team, peer researchers or members of the stakeholder team.

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Abbreviations

ADA – American Diabetes Association

BBCI - Basal bolus correctional insulin

BG – Blood glucose

CF – Cystic Fibrosis

CMG – Clinical management group (hospital-level)

CMOC – Context-mechanism-outcome configuration

CPOE – Computer provider order entry, or electronic prescribing (see also EP and EPMA)

CQC – Care Quality Commission

CQUIN – Commissioning for Quality and Innovation

DISN – Diabetes Inpatient Specialist Nurse

DKA – Diabetic Ketoacidosis

DSN – Diabetes Specialist Nurse

DUK – Diabetes UK

EP – Electronic prescribing

EPMA – Electronic prescribing and medicines administration

FRIII – Fixed Rate Intravenous Insulin Infusion

HbA1c – Glycated Haemoglobin

HHS – Hyperosmolar Hyperglycaemic State

HPC – Healthcare professional

IPT – Initial programme theory

IV – Intravenous

JBDS – Joint British Diabetes Societies for In-patient Care group

LADDER –Lay Advice on Diabetes and Endocrine Research

MMT – Medicines Management Technician

NaDIA – National Diabetes Inpatient Audit

NCEPOD – National Confidential Enquiry in Patient Outcomes and Death

NHS – National Health Service

NICE – National Institute for Health and Care Excellence

NPT – Normalisation Process Theory

PPI – Patient Public Involvement

QI-MQCS - The Quality Intervention Minimum Quality Criteria Set

RCT – Randomised controlled trial

SAM – self-administration of medicines

SEIPS – Systems Engineering Initiative for Patient Safety

SC – Subcutaneous

SCR – Summary care record

SD – Standard Deviation

SSI - subcutaneous sliding scale insulin.

TFA – Theoretical Framework of Acceptability

UBA – Uncontrolled before-after study

VRIII – Variable Rate Intravenous Insulin Infusion

Glossary and Definitions

Blood glucose monitoring – the amount of glucose measured in the blood.

CMO configurations (CMOC) - Heuristic used to generate causative explanations pertaining to outcomes in the observed data. The process draws out and reflects on the relationship of context, mechanism, and outcome of interest of aspects of the intervention.

Context- The 'backdrop' of interventions, which may change over time. These include cultural norms and environment in which the intervention is implemented, the nature and scope of existing social networks, or intervention infrastructure.

CQUIN - Quality improvement goals that are associated with financial incentives for organisations if achieved.

DATIX -a patient safety organization that produces web-based incident reporting and risk management software for healthcare and social care organisations.

Foundation Trainee – otherwise referred to as FY1 or FY2 doctor. Recent graduates of medical school in the initial training stages (junior doctor).

General Practitioner – Primary care physician or doctor.

Hypoglycaemia – low blood glucose levels.

Hyperglycaemia – high blood glucose levels.

Insulin – a hormone produced naturally in the pancreas, which regulates blood glucose.

Inpatient – A person receiving hospital care who requires a bed for an overnight stay.

LADDER panel – Patient public involvement panel dedicated to diabetes-related research, consisting of people with diabetes, based at Sheffield Teaching Hospitals NHS Foundation Trust.

Mechanism - The generative force of resources from the intervention that leads to outcomes. This denotes the reasoning (cognitive or emotional) and responses of the various actors in relation to the work, challenges, and successes of the intervention.

Middle-range theory – theory that is not so specific as to pertain to one intervention but is abstract enough to be connected to the practical workings of interventions.

National Health Service – UK Government-funded medical and health care services.

National Institute for Health and Care Excellence – provides national guidance and advice to improve health and social care. NICE is an executive non-departmental public body, sponsored by the Department of Health and Social Care.

Never Event - Serious, largely preventable patient safety incidents that should not occur in the NHS.

Outcome- Intended or unintended, proximal, intermediate, or final outcomes of the intervention.

Prescription chart – Electronic or paper-based chart that documents and communicates information about a patient's medication that they receive during the course of their hospital admission.

Prescribing error - An error in the prescribing decision-making or prescription writing process.

Prescription error - errors made in the act of writing a prescription or the prescription itself.

Prescription fault – errors made in the decision-making process.

Realist research - Realist research reflects a combination of logical empiricism and constructivism by posing questions that seek out the truth of matters. It operates from the view that human knowledge is context-bound and contingent.

Realist synthesis - A theory-driven approach to synthesizing quantitative, qualitative or mixed methods research in order to answer questions regarding 'what worked, for whom and in what circumstances, how and why?' with respect to interventions.

Retroduction/retroductive theorising - The activity of uncovering hidden mechanisms of action in the deeper 'layers' of reality.

Summary Care Record - An electronic record of important patient information, including current repeat medication, created from GP medical records. This can be accessed by appropriate healthcare professionals working in hospital (e.g. doctors, pharmacists, pharmacy technicians).

Type 1 diabetes – type of diabetes characterised by absolute insulin deficiency due to autoimmune pancreatic beta cell destruction.

Type 2 diabetes – type of diabetes characterised by insulin resistance due to a progressive loss of adequate pancreatic beta cell insulin secretion.

Chapter 1: Introduction

This chapter introduces the topic of inpatient insulin prescribing practice and situates it within the wider literature on inpatient prescribing errors. The importance of the research topic will be outlined, and a rationale for the current research will be established. The following areas will be covered:

- Introduction to insulin use and prescribing practice in the hospital setting.
- Types of insulin errors and their causes.
- Interventions designed to improve inpatient insulin prescribing practice.
- Opportunities for research to improve insulin prescribing practice in UK hospitals.
- The aims and objectives of the research.

1.1 Background

The safe use of medicines is an important and topical issue that has been highlighted by both the World Health Organisation and the Secretary of State for Health and Social care following research estimating that, each year in England, 237 million medication errors are made, costing 1,708 lives and £98 million to the National Health System (BBC News, 2018; Elliott et al., 2018; Elliott, Camacho, Jankovic, Sculpher, & Faria, 2020; WHO, 2019).

One of the top medicines consistently associated with patient harm worldwide is insulin (Amori et al., 2008; Budnitz, Lovegrove, Shehab, & Richards, 2012; Dooley et al., 2011; Geller et al., 2014; Santell, Hicks, McMeekin, & Cousins, 2003). Insulin is a high-risk medication, and as such, it has a greater potential to cause harm than other medicines, and due to the complexities associated with the insulin prescribing process, people with insulin-treated diabetes (of all types) are particularly susceptible to the effects of harmful, avoidable medication errors that occur in the prescribing and administration processes (Cousins, Rosario, & Scarpello, 2011; Institute of Safe Medication Practitices, 2011). To reduce the occurrence of insulin errors and resultant harm to patients, interventions have been designed to improve insulin prescribing practice. These include the use of patient-held medication records and electronic prescribing systems with various functions to restrict or guide the prescribing process.

The work of this thesis focuses on these interventions and their use in the acute hospital setting in the United Kingdom (UK). This chapter introduces the research by first providing an overview of insulin prescribing practice and errors in the hospital setting, with particular emphasis then being placed on the interventions designed to improve the quality of insulin prescriptions. Key terms will be defined, and central theoretical concepts pertaining to the research will be discussed throughout. The aim of this chapter is not to present an extensive or exhaustive critique of the entire literature related to the topic, but rather to explain the relevance of the research and present selected studies that help to explain the rationale for the current work. A thematic funnelling approach will be

taken, where topics and key ideas of increasing specificity to the research question will be discussed successively, prior to the presentation of the systematic literature review presented in **Chapter 2.**

1.2 Insulin use in people with diabetes

Diabetes is a chronic, incurable endocrine condition that is an important cause of mortality, morbidity and associated healthcare costs worldwide (Danaei et al., 2014). Diabetes is characterised by elevated blood glucose (hyperglycaemia) secondary to insufficient insulin production or the presence of insulin resistance. Although there are many types of diabetes, the majority of people would be classified as having either type 1 diabetes (absolute insulin deficiency due to autoimmune pancreatic beta cell destruction) or type 2 diabetes (insulin resistance due to a progressive loss of adequate pancreatic beta cell insulin secretion) (American Diabetes Association, 2020). All people with type 1 diabetes need to inject exogenous prescribed insulin, subcutaneously, to control their blood glucose. Type 2 diabetes is initially managed with lifestyle modification and oral hypoglycaemic agents but for many people, insulin will also be required to control blood glucose levels due to the progressive decrease in insulin secretory capacity over time (Home et al., 2014).

The global prevalence of diabetes is increasing. The International Diabetes Federation (IDF) estimates suggest that there were 463 million people with diabetes in 2019, which is set to rise to 700 million by 2045 (International Diabetes Federation, 2019). In the UK, numbers of people with diabetes have doubled over the last 20 years, with current estimates of around 4.6 million and continue to rise, and associated costs to the NHS are significant; 10% of the overall hospital budget per year (around £5.5 billion) is spent on diabetes treatment (Stedman et al., 2020). Although the majority of this increase involves people with type 2 diabetes, the number of people being diagnosed with type 1 diabetes is also increasing, particularly as a result of COVID-19 (Unsworth et al., 2020).

People with diabetes are more likely to be admitted to hospital, on a more frequent basis, and have longer lengths of stay than people without diabetes (Aro, Kangas, Reunanen, Salinto, & Koivisto, 1994; Comino et al., 2015; De Berardis et al., 2012; Sajjad et al., 2018). Given the increase in incidence of diabetes globally, along with the significant impact that COVID-19 has had on this demographic, the demand for hospital services is likely to increase (Apicella et al., 2020). This increase in incidence of diabetes leads to an increase in demand for prescribed insulin, with current conservative estimates suggesting that there are around 150-200 million insulin users worldwide (Garg, Rewers, & Akturk, 2018).

Insulin is undoubtedly a medication of paramount importance, particularly to people with type 1 diabetes who require insulin injections to survive. It is, however, also classified as a high-alert medication by the Institute for Safe Medication Practices (Institute of Safe Medication Practitices, 2011). High-alert medications confer a heightened risk of causing significant harm when used inappropriately, and require particular safeguards to minimise the risk associated with their use. It is also categorised as a critical medicine that can cause significant

harm to patients if a dose is missed or delayed (e.g. due to a prescribing error). As insulin facilitates glucose movement from the bloodstream into cells, patients receiving excessive insulin may experience low blood glucose levels (hypoglycaemia). Hypoglycaemia can result in impairment of cognitive function, seizures, hemiparesis and even coma. Inpatient mortality rates and length of hospital stay are also higher for people using insulin experiencing hypoglycaemia compared to those who do not use insulin (Akirov, Grossman, Shochat, & Shimon, 2017; Turchin et al., 2009).

Hyperglycaemia can occur when insulin use is under-utilised, or when the dose prescribed and administered is not sufficient to control increased blood glucose levels. Hyperglycaemia, if untreated, may result in diabetic ketoacidosis (DKA) or Hyperosmolar Hyperglycaemic State (HHS) for people with type 1 and type 2 diabetes, respectively. These conditions can result in serious harm and may be fatal if not managed appropriately. People experiencing DKA or HHS during their hospital stay face lengthier admissions, require more intensive nursing input and have an increased chance of requiring intensive care (Joint British Diabetes Societies Inpatient Care Group, 2012; Sinclair-Hammersley et al., 2010).

Unfortunately, such adverse effects associated with inappropriate insulin use are not uncommon. Between 2003 and 2009, there were 16,600 reported patient safety incidents involving insulin use in hospitals in England and Wales, 24% of which involved patient harm (Cousins et al., 2011). In 2017, an estimated 9,600 people required rescue treatment after falling into a coma following a severe hypoglycaemic attack. During the same year, 2,200 people (1 in 25 people with type 1 diabetes) suffered from DKA due to under treatment with insulin (NHS England and Wales, 2018). More recently, a patient who was administered insulin that had been erroneously prescribed at 10 times the correct dose during his hospital admission suffered a tragic fatality as a result (BBC News, 2020).

The adverse effects described above are often a result of suboptimal or erroneous insulin prescribing and administration practices in hospital. These practices are described in the next section, specifically the insulin prescribing process and potential errors that can occur therein.

1.3 Insulin prescribing in the hospital setting

Patients interact with hospital care either on an outpatient basis, whereby they attend a hospital clinic appointment at a specified time (but do not stay overnight), a day patient (day case) basis, where they occupy a hospital bed on a ward for surgery or investigations (but do not stay overnight), or on an inpatient basis, where they occupy a hospital bed for one or more nights to receive medical or surgical treatment (either on an elective or emergency basis) (NHS, 2019). This thesis covers inpatient care, where people with any type of diabetes who use insulin are admitted to hospital for either emergency or elective treatment. The practice of writing insulin prescriptions for patients during their hospital stay is the main topic of interest for the purposes of this research.

1.3.1 Prescribing systems

When patients are admitted to hospital as inpatients, they are assigned a prescription chart for the purposes of communicating information within and across healthcare teams regarding medications given (and to be given) during the course of their hospital stay (Shemilt, Morecroft, Ford, Mackridge, & Green, 2017). These prescription charts often incorporate medication administration records and may be either paper-based or electronic (Z. Ahmed, Garfield, Jani, Jheeta, & Franklin, 2016; Shemilt et al., 2017).

In Wales, Scotland, and Northern Ireland, hospital organisations have developed standardised paper inpatient prescribing charts for use across all hospitals in their respective nations (Healthcare Improvement Scotland, 2014; Medicines Governance Northern Ireland, 2016; Routledge, 2012). In England, despite previous calls for the introduction of a standard drug chart across NHS hospitals (Academy of Medical Royal Colleges, Royal College of Nursing, & Royal Pharmaceutical Society, 2011; Dornan et al., 2009), there is no standardised paper-based or electronic prescribing system in use across hospitals at the time of writing. Rather, individual hospital organisations have developed their own inpatient prescribing systems with varying functionalities and standards (Z. Ahmed, McLeod, Barber, Jacklin, & Franklin, 2013; Dixon, 2017; East Kent Hospitals University NHS Foundation Trust, 2019; Heatherwood and Wexham Park Hospitals NHS Foundation Trust, 2008; Routledge, 2012; Shemilt et al., 2017; Sherwood Forest Hospitals NHS Foundation Trust, 2017).

The incentive to increase the use of electronic prescribing systems in NHS hospitals has been supported by government policy to drive technology use within the NHS (Department of Health, 2000; NHS England, 2019; NHS England et al., 2014). Previous plans for full digitalisation of hospital services by 2020 have not been realised, however; the latest target for all hospitals to implement electronic prescribing systems by 2024 seems equally ambitious considering the substantial work involved in designing and implementing these systems in hospital organisations, as well as the slow uptake of electronic prescribing nationally (Z. Ahmed et al., 2016; Department of Health and Social Care, 2018; Healthcare Safety Investigation Branch, 2019; National Information Board, 2014; NHS England, 2019).

Unlike in Wales, Scotland and Northern Ireland, there seems to be no plan to implement a standardised electronic prescribing record, with many hospitals using electronic prescribing systems heterogeneously across their organisations, and often in combination with supplementary paper prescription charts for complex medicines like insulin (Z. Ahmed et al., 2013; Cresswell, Coleman, Slee, Williams, & Sheikh, 2013; Healthcare Safety Investigation Branch, 2019; Shemilt et al., 2017).

Details regarding how insulin is currently prescribed using available prescribing systems in UK hospitals represents an important line of enquiry that has yet to be investigated. This research can therefore complement previously published work on prescribing system use by focusing on insulin prescribing

systems as more complex systems and processes compared to other medicines. The consistent selection of pharmacists as participants in these studies (on account of their broad and in-depth knowledge of prescribing systems in hospitals) informs the consideration of pharmacists as participants in the current study.

1.3.2 The prescribing process

Prescribing medicines involves the *"identification of the need for a drug and selection of the correct drug, together with the route, form, dose, frequency and duration, for the individual patient"* (Coombes, Stowasser, Reid, & Mitchell, 2009). Most inpatient prescribing is undertaken by junior doctors who are undergoing Foundation training during their first two years of graduating from medical school (P. J. Lewis, Seston, & Tully, 2018). In the UK, these doctors are referred to as Foundation Trainees, or Foundation year one (FY1) or Foundation year two (FY2) doctors, depending on their year of training. Increasingly, non-medical prescribers, such as suitably qualified nurses and pharmacists, undertake the task of prescribing insulin for inpatients with diabetes (Courtenay, Carey, James, Hills, & Roland, 2007), however, the majority of prescribing (around 70-75%) falls on the junior medical staff (Dornan et al., 2010; P. J. Lewis et al., 2018).

In the UK, not all people with diabetes receive insulin as inpatients. This contrasts other countries where it is more common to use insulin to treat hyperglycaemia in all hospitalised people with diabetes during their stay, irrespective of their pre-admission treatment (e.g. oral hypoglycaemic agents only) (American Diabetes Association, 2019). When most people who use insulin to treat their diabetes are admitted to hospital, their pre-admission subcutaneous insulin regimen continues to be prescribed and administered throughout their stay, alongside regular blood glucose monitoring.

Unless patients are being treated for DKA or HHS, or are undergoing surgery or require treatment with corticosteroids, major changes to their insulin are not usually expected during their inpatient stay (Joint British Diabetes Societies for inpatient care, 2019; Joint British Diabetes Societies for Inpatient Care, 2014; Joint British Diabetes Societies Inpatient Care Group, 2012; Sinclair-Hammersley et al., 2010). There are many factors that impact control of blood glucose, however, meaning that the amount of insulin an individual requires each day varies. Many of these factors, including the timing, amount, frequency and carbohydrate content of food, as well as concomitant medical conditions (e.g. infection) and stress levels, are likely to differ in the hospital setting compared to at home (Corsino, Dhatariya, & Umpierrez, 2020). This adds a layer of complexity to the process of prescribing insulin in the hospital setting, and necessitates regular review of capillary blood glucose (BG) levels to ensure doses continue to be appropriate for individual patients (Joint British Diabetes Societies for inpatient care, 2019).

The subcutaneous insulin prescribing process may be delineated as outlined in Figure 1.1. The steps included are based on Barker's model of drug therapy (diagnosis → prescription written → prescription received and processed by a pharmacist → drug dispensed → drug administered → patient receives drug → patient is well) (Barker, Mikeal, Pearson, Illig, & Morse, 1982) and represents the product of personal professional knowledge and experience gained from working in the hospital setting as a pharmacist alongside other members of the healthcare team (doctors and nurses).

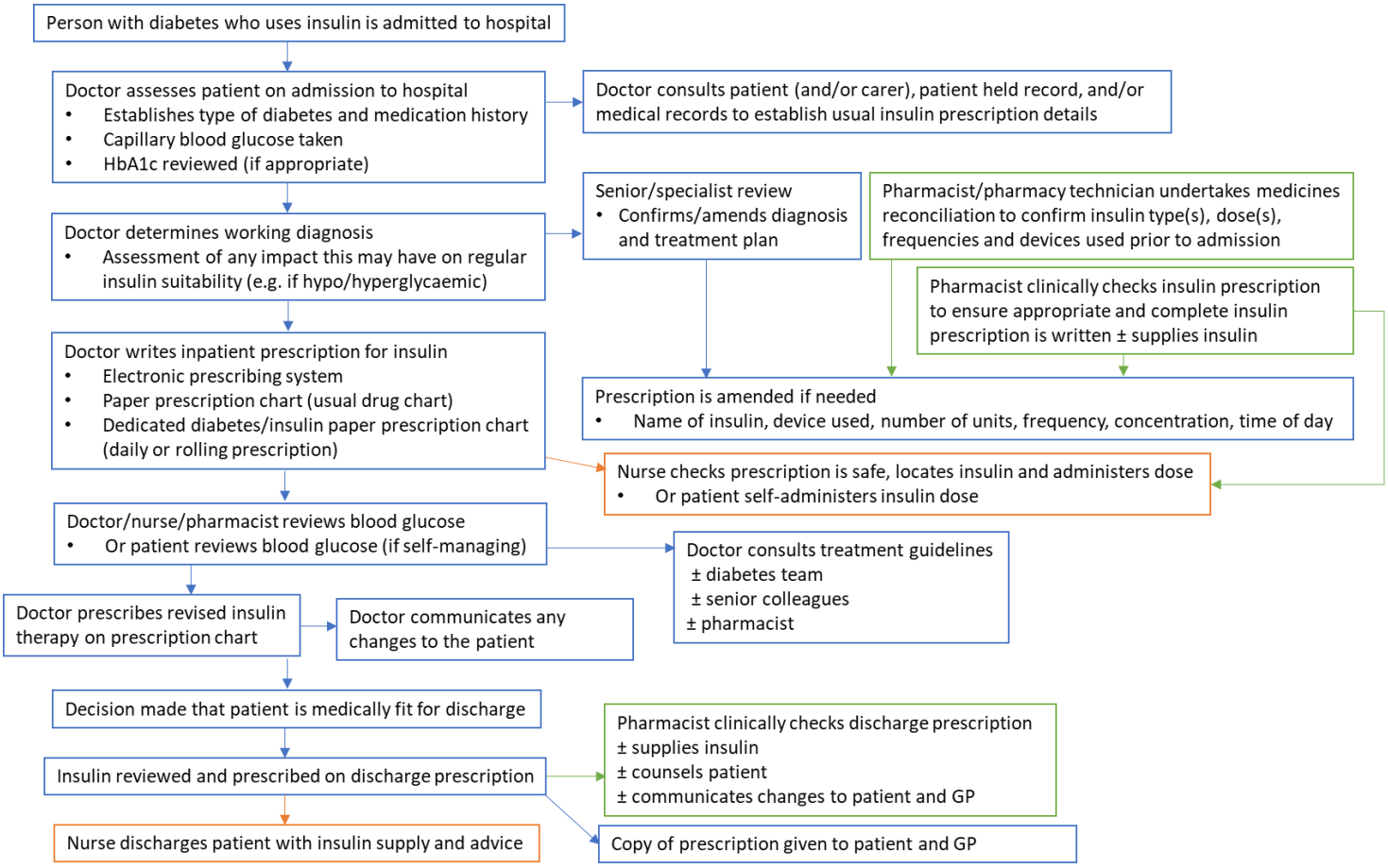


Figure 1.1: Inpatient insulin prescribing process in hospital, based on Barker's model of drug therapy (Barker 1982). Green boxes represent input from pharmacy, orange boxes represent input from nurses.

The process of prescribing insulin on a discharge prescription is distinct from prescribing insulin on an inpatient prescription. Often different systems or forms are used and it serves an additional purpose of communicating information about the care a patient has received in hospital to the General Practitioner (Callen, McIntosh, & Li, 2010; Kripalani et al., 2007). Insulin prescription errors at the point of discharge have previously been investigated prior to the start of the PhD and are not considered in this thesis (Bain, Nettleship, et al., 2017; Bain, Silcock, Kavanagh, Quinn, et al., 2019). The prescription of intravenous (IV) insulin as part of DKA/HHS/peri-operative/hyperkalaemia treatment pathways are also not included due to the clinically distinct situations that these represent. Instead we focus on the process of the routine

prescription of subcutaneous insulin for inpatients with diabetes, irrespective if these prescriptions are new (e.g. as inpatients newly diagnosed with diabetes) or continuations of pre-admission insulin therapy.

Opportunities for error exist throughout the entire subcutaneous insulin prescribing, dispensing, administration and monitoring process, with prescribing errors being one of the most frequently reported types of medication error (Cousins et al., 2011). Only one published study has explored the problems associated with insulin prescribing processes in the hospital setting with original research. Researchers in a Canadian hospital conducted a focus group study with doctors, nurses and pharmacists, which revealed that a lack of access to information, high personnel turnover, and the availability of numerous types of available insulin led to mistakes with insulin prescriptions (Rousseau et al., 2014). This study was bound in the context of a single hospital setting and although thematic analysis was used, the methods for generating and refining themes were not mentioned in the report. The findings were suggestive of a positivistic approach to thematic analysis and were not interpreted considering any theoretical frameworks or models for wider translatability. There have been no qualitative studies that explore inpatient subcutaneous insulin prescribing issues in a UK hospital context, or across multiple organisations.

1.4 Insulin prescription errors

The prescribing stage of medication use is the source of the highest rates of preventable harm in healthcare settings (58%) (Hodkinson et al., 2020), and is the stage at which most medication errors occur, affecting 7% of inpatient medication orders and 52 per 100 hospital admissions (D. King et al., 2014; P. J. Lewis et al., 2009; Velo & Minuz, 2009). For high risk medicines such as insulin, error rates increase to 107-218 errors per 100 admissions (Alanazi, Tully, & Lewis, 2016). Medication errors occurring at the prescribing stage are often referred to as 'prescribing errors'.

The term 'prescribing error' has been defined as:

> *"A clinically meaningful prescribing error occurs when, as a result of a prescribing decision or prescription writing process, there is an unintentional significant (1) reduction in the probability of treatment being timely and effective or (2) increase in the risk of harm when compared with generally accepted practice"* (Dean, Barber, & Schachter, 2000)

The above definition focusses on outcomes of the error rather than the process, and in so doing, may exclude errors that do not result in harm or those resulting from problems in the wider context (Aronson, 2009; Ferner & Aronson, 2006). It also somewhat ambiguously encompasses the whole process of prescribing (as outlined in Figure 1.1), from decision-making to prescription writing, and is less helpful in terms of prevention due to its focus on outcomes rather than causes. When considering prescribing errors, the consensus is that the overall

prescribing process should be categorised into a) the decision-making process, followed by b) the act of writing the prescription. As such, 'prescribing faults' – errors made in the decision-making process (e.g. irrational or inappropriate prescribing) are distinguished from 'prescription errors' – errors made in the act of writing a prescription or the prescription itself (e.g. writing illegibly or omitting information) (Aronson, 2009; Dean et al., 2000; Velo & Minuz, 2009).

With respect to insulin prescribing, much of the literature, practice guidance and national audit metrics for diabetes makes the distinction between an 'insulin prescription error' and an ' insulin-related glucose management error' (Al-Yassin et al., 2013; Hamilton, Nation, Penfold, Kerr, & Richardson, 2013; Joint British Diabetes Societies for inpatient care, 2019; NHS Digital, 2020). Failing to increase the insulin dose following persistently high blood glucose results (e.g. over 11mmol/L) would be classed as an insulin-related glucose management error, in contrast to the doctor erroneously writing "300 units" instead of "30 units" on a prescription (this would be classed as an insulin prescription error). This work focusses on insulin prescribing errors (specifically the act of writing a prescription and the prescription itself) rather than insulin-related glucose management errors, along with the interventions designed to prevent them being made. For the purposes of this thesis, the definition of a prescription error offered by Aronson will be adopted:

> *"A prescription error is 'a failure in the prescription writing process that results in a wrong instruction about one or more of the normal features of a prescription'. The 'normal features' include the identity of the recipient, the identity of the drug, the formulation, dose, route, timing, frequency, and duration of administration."* (Aronson, 2009)

Insulin prescription errors therefore involve wrong or missing information including the normal features described above. For insulin prescriptions, in order to correctly identify the drug, a product name (e.g. as well as or instead of a generic drug name), device and concentration need to be included. As any of these elements may be missing or wrong (resulting in a prescription error) they may be considered separately. In the inpatient insulin prescribing context, prescription errors relating to unintentional omission of insulin from the drug card altogether are described in the National Diabetes Inpatient Audit (NaDIA) and related literature. This is not obviously included in the above definition, which seems to assume that at least one element of the prescription is written. For the purposes of being inclusive and meaningful for the research topic, process-related errors such as omission from the drug chart are included in the definition of a prescription error. Table 1.1 presents examples of insulin prescription errors that may occur in practice. It is the prevention of these errors occurring that the work of this thesis focuses on, rather than preventing harm or the impact on patients once the prescription has been written.

Table 1.1: Types of inpatient insulin prescription error with examples

Prescription error	Example	Reference
Wrong number of units (dosage)	40 units prescribed instead of 4 units	(Dooley et al., 2011)
Wrong insulin product name	Humulin prescribed instead of Humulin I	(Bain, Kavanagh, McCarthy, & Babar, 2019)
Wrong frequency*	Once daily insulin prescribed instead of twice daily	(Bain, Moussallati, et al., 2017)
Wrong concentration of insulin*	Humalog Kwikpen 100units/ml prescribed instead of Humalog Kwikpen 200units/ml	(Segal, Brunner, Burch, & Jackson, 2010)
Wrong insulin device*	Humalog vial prescribed instead of Humalog KwikPen (disposable pen)	(Boparai & Kavanagh, 2015)
Wrong time of day	Biphasic insulin prescribed at night instead of with evening meal	(Bain, Kavanagh, McCarthy, & Babar, 2019)
Incomplete prescription*	Missing name of product, device, time of administration, concentration, signature of prescriber, patient details	(Leech, Johnson, Nayar, Nunez, & Macleod, 2013)
Unclear prescription	Abbreviating 'units' to 'u', which may be misinterpreted for '0'	(Hamid et al., 2016)
Omission of therapy	Patient who usually uses insulin not prescribed insulin	(Cousins et al., 2011)

** Errors that are not currently included in the National Diabetes Inpatient Audit tool for measuring insulin errors*

All the insulin prescription errors included in Table 1.1 have the potential to cause harm to patients due to the high-risk nature of the drug, with consequences ranging from being classified as mild/moderate to severe/fatal (Cousins et al., 2011; Cox & Ferner, 2009). Prescription errors that result in excessive insulin doses being administered may lead to hypoglycaemia, which can result in confusion, seizures, coma or even death (Cohen, 2010). Examples of this include insulin being prescribed twice daily instead of once daily, insulin being prescribed in the wrong device, or the abbreviation of 'units' to 'u', which may be mistaken by the administering nurse as a '0', resulting in in a 10-fold overdose (Lamont, Cousins, Hillson, Bischler, & Terblanche, 2010; Prescrire Editorial Staff, 2014). Prescribing insulin at the wrong time of day may also result in hypoglycaemia due to the need for some insulins to be administered alongside meals (on account of their release profiles). For example, prescribing mixed (biphasic) insulins at night may result in significant nocturnal hypoglycaemia.

Errors that result in a failure to provide an adequate amount of insulin may result in hyperglycaemia, DKA, HHS or even death. This may include not including insulin on the prescription altogether (e.g. following incomplete drug history taking on admission), or failing to provide the insulin concentration on a prescription, which could cause delay in administration or result in a patient who usually receives insulin at a higher concentration of 200 or 300units/ml being given the more commonly available 100units/ml product. Similarly, failure to stipulate the type of insulin device can be a cause of significant confusion, and patients prescribed the wrong device may be unable to receive their insulin dose when needed. The most commonly reported insulin prescription errors

reported include errors of omission, incorrect doses, devices and inaccurate insulin types (Bain, Moussallati, et al., 2017; Boparai & Kavanagh, 2015; James, 2005; Lane & Hunter, 2020; Santell, Cousins, Hicks, & Protzel, 2003).

In the UK, 33 medical negligence claims during 2013-2018 were related to insulin prescription or administration errors (Rayman & Kar, 2020), and between April 2018-19 there were 14 insulin-related NHS Never Events recorded (NHS England & NHS Improvement, 2019). The National Diabetes Inpatient Audit (NaDIA) records insulin prescription error rates each year, along with other insulin errors such as insulin management errors (collectively grouped together in the wider category of 'insulin errors'). On the day of the audit in 2019, 18.2% of inpatient prescriptions for insulin-treated inpatients had one or more insulin error (NHS Digital, 2020). This value has not changed significantly (i.e. P value < 0.05) since 2011, when 20.7% prescriptions were found to contain an insulin error (NHS Digital, 2020). It should be noted, however, that the NaDIA does not include certain types of prescription errors included in Table 1.1, such as wrong device or concentration prescribed, and groups "insulin given/prescribed at the wrong time" as one error type, despite these two processes being temporally and technically distinct in practice. As such, despite the published NaDIA data providing useful information about overall insulin errors, it may not provide a true estimate of the prevalence or incidence of insulin prescription errors in UK hospitals.

As we have found that insulin prescription errors are common, potentially harmful and comprise a significant proportion of medication-related patient safety incidents, our attention must now turn to the causes of such errors, and how these errors may be reduced.

1.4.1 Causes of insulin prescription errors

Identifying and understanding the causes of insulin prescription errors, and the factors associated with them, is important to help develop ways to reduce their occurrence. A systematic review conducted by Tully et al concluded that inpatient prescribing errors were associated with multiple, complex, error-provoking conditions and causes, which often acted together (M. P. Tully et al., 2009). The findings of the review were organised according to Reason's causation of error theory, which is one of the most commonly used theoretical modules when considering medication error (J. T. Reason, 1990).

According to Reason's theory, causal factors are present in a system before an error sequence occurs. These causal factors can include fallible decisions made and implemented by decision-makers and management, and conditions that permit efficient and safe operations (error-provoking conditions). These causal factors are otherwise known as 'latent failures' and can be precursors for unsafe acts. Unsafe acts, otherwise known as 'active failures', can be unintentional or intentional. Unintended active failures include slips (e.g. attentional failures on account of being tired or busy) or lapses (e.g. memory failures). Intentional unsafe acts are classified as either mistakes (e.g. lack of knowledge) or violations (e.g.

conscious decision to ignore procedure, or application of an inappropriate rule). The application to this theory to insulin prescription errors is exemplified in Table 1.2**.**

Table 1.2: Examples of causes of insulin prescription errors categorised according to Reason's human error framework

Error category	Examples	Reference
Latent failure		
Organisational process	• Lack of training in diabetes or insulin use • Insufficient numbers of ward pharmacists • Lack of insulin prescribing guideline (e.g. to specify brand name prescribing)	(Cox & Ferner, 2009) (Almeamar et al., 2018)
Error-provoking condition	• New electronic prescribing system introduced • Numerous available insulin mixtures • Look-alike-sound-alike insulin products (e.g. Humalog and Humulin) in proximity on electronic prescribing system • Numerous descriptors for insulin (e.g. short-acting, basal, mixed, cloudy, clear) • No set dose-range (maximum/minimum) as dosing is highly individual to patient	(Bain, Silcock, Kavanagh, Quinn, et al., 2019) (Cox & Ferner, 2009) (Cornish, 2014) (Ratanawongsa, Chan, Fouts, & Murphy, 2017) (Leech et al., 2013) (Cornish, 2014)
Active failure		
Slip	• Prescriber interrupted when writing prescription • Prescriber writes "Novorapid" instead of "Novomix" • Prescriber mishears dose and writes 15 instead of 50	(Sutherland, Ashcroft, & Phipps, 2019) (Cousins et al., 2011) (Cox & Ferner, 2009)
Lapse	• Prescriber tired and forgets to sign the prescription • Prescriber forgets to prescribe insulin on admission	(Hamid et al., 2016) (Cousins et al., 2011)
Mistake	• Lack of knowledge about what insulins are available	(N. A. A. Kelly, Brandom, & Mattick, 2015)
Violation	• Prescriber does not include details of insulin device on prescription • Adjusting insulin dose not prioritised by doctor • Prescriber incorrectly omits insulin from prescription of person with type 1 diabetes and hypoglycaemia • Prescriber applies outdated guidance/discouraged practice to insulin prescribing	(Boparai & Kavanagh, 2015) (Weiss, 2006) (C. King, Hackett, McKenchie, Higgins, & Gallagher, 2015) (Newsom et al., 2018)

According to Reason, there are two approaches to the problem of human fallibility: the person approach, which focusses on the errors of individuals (e.g. inattention, forgetfulness, carelessness, negligence) and the system approach, which focuses on optimising the working conditions and building defences to avert errors (J. Reason, 2000). The former approach begets strategies, or measures of preventing errors

(otherwise known as interventions), that are targeted at reducing unwanted variability in undesirable individual prescriber behaviour, or making them less fallible, such as poster campaigns, retraining, and policy-writing.

Interventions targeted at modifying human behaviour are often underpinned by behaviour change theories and frameworks such as the Theory of Planned Behaviour (Ajzen, 1991) or more recently, the Theoretical Domains Framework and Behaviour Change Wheel (S. Michie et al., 2005; Susan Michie, van Stralen, & West, 2011). The Behaviour Change Wheel, for example, links intervention functions (restrictions, education, persuasion, incentivisation, coercion, training, enablement) to sources of human behaviour (capability, motivation, and opportunity) to characterise interventions. Previous studies have identified lack of prescriber knowledge and confidence regarding insulin use (Bain, Kavanagh, McCarthy, & Babar, 2019; Derr, Sivanandy, Bronich-Hall, & Rodriguez, 2007; Lee, Liu, Quek, & Chew, 2013). If lack of knowledge is considered to be a causative factor for insulin prescription errors, it follows that interventions designed to remediate this– such as education, training or memory aids – are often implemented (Al-Yassin et al., 2013; N. A. A. Kelly et al., 2015; A. S. Lewis, Mallon, & Cooke, 2018).

The system approach, by contrast, assumes that humans are fallible and that errors are to be expected, and instead focusses on organisational processes that give rise to 'error traps' in the workplace (J. Reason, 2000). As people of all levels of experience and skill can make errors, attention is drawn instead to identifying and changing the error-prone conditions under which humans work. For example, the technologies that prescribers use to write a prescription (either a paper chart or an electronic system) can be designed in ergonomic ways to minimise the potential for prescription errors to occur (D. King et al., 2014).

Reason's Swiss Cheese model depicts this as elements of a system (e.g. a hospital, ward) having layers of barriers, defences, or safeguards to avoid error. These layers may include people (e.g. pharmacists identifying and correcting prescription errors), technologies (e.g. electronic prescribing system alerts when high doses of insulin are prescribed), physical barriers (e.g. pre-printed forms for prescribing insulin that include the word 'units' to avoid abbreviations), and procedures (e.g. nurses checking the prescription prior to administering insulin). The model implies that all of these layers have 'weaknesses' (depicted as holes in the swiss cheese) through which a trajectory of opportunity for error may travel (see Figure 1.2). These holes comprise the active failures and latent conditions described above.

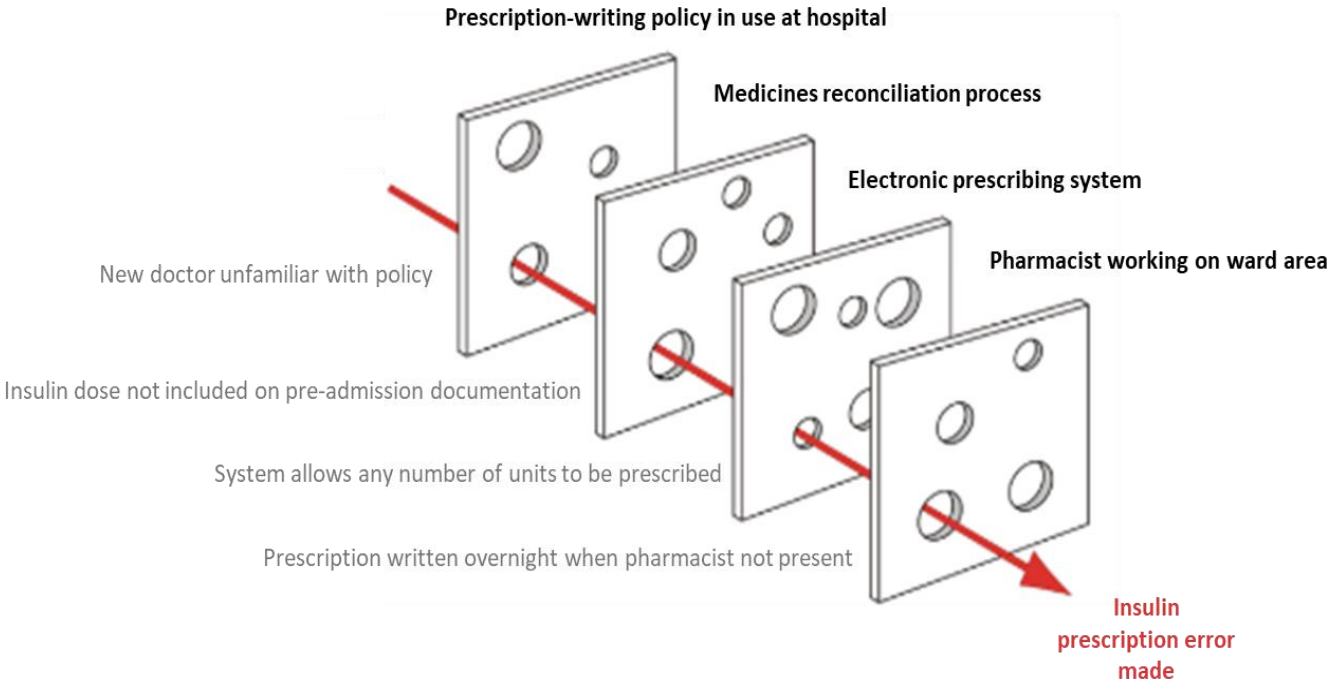


Figure 1.2: The Swiss Cheese Model by James Reason (2000) adapted to exemplify an insulin prescription error trajectory.

This model presents a useful and powerful heuristic for understanding a system approach to error causation, however the systems within healthcare are complex and adaptive. Various features of the work setting (e.g. people, circumstances, activities) combine in multiple ways to bring about (or prevent) an error from occurring, and staff adjust their work according to circumstantial changes as well as their own expertise (Sutherland & Phipps, 2020). As such, the linear and simplistic representation of error causation may not account for the system as a whole, nor provide an understanding of the links between different causal, organisational, local and individual factors (Larouzee & Le Coze, 2020). For example, the systems in which insulin is prescribed in an inpatient setting are 'open', such that interactions with other settings/systems with their own priorities and procedures (e.g. primary care services, community pharmacy services) have an impact on the task at hand (Sterman, 2006). An example of how different

systems interconnect in the process of writing an inpatient insulin prescription, drawn from personal experience and knowledge, is shown in Figure 1.3.

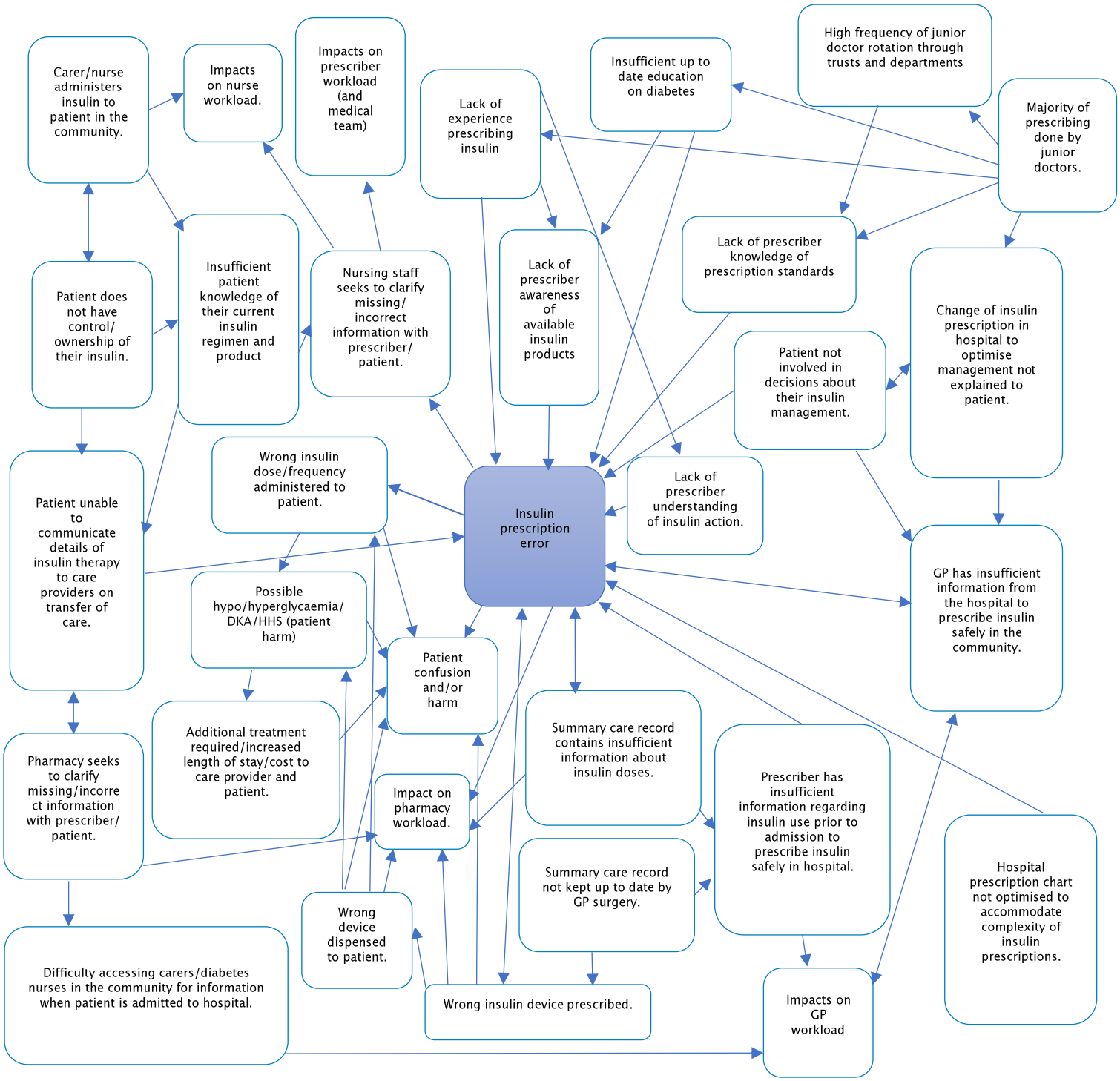


Figure 1.3: Example of systems involved in the safe prescribing of insulin in secondary care.

The combination of human and system approaches is known as Human Factors. Specifically, it is the study of the relationship between the people within a work system and the system itself and its impact on

safety, performance and wellbeing (Hignett et al., 2015; Karsh, Holden, Alper, & Or, 2006). The application of Human Factors to healthcare systems and medication safety research has increased in popularity over recent years and is particularly useful for studying the inherently complex and open systems of healthcare (Weir, Newham, & Bennie, 2020).

The Systems Engineering Initiative for Patient Safety (SEIPS) model, for example, incorporates human factors with Donabedian's widely-used structure-process-outcome model (Donabedian, 1978) to help improve its applicability to healthcare (Pascale Carayon et al., 2014). Donabedian considered quality of healthcare services (e.g. the prescribing of insulin) in terms of structure, process, and outcome. For quality insulin prescribing to occur, for example, assessment of outcomes (e.g. number of prescribing errors) should be considered alongside elements of organisational structure (e.g. availability of staff, presence of insulin prescribing policy) and process (e.g. medicines reconciliation process timely, insulin prescription verification by pharmacist). The SEIPS model (outlined in Table 1.3) has the benefits of accounting for the entire work system and how it interacts to impact on patient safety (P Carayon et al., 2006; Pascale Carayon et al., 2014; Pascale Carayon, Wooldridge, Hoonakker, Hundt, & Kelly, 2020). The benefits of this approach are recognised with respect to investigating inpatient insulin prescription errors within the context of multiple organisations. The application of the SEIPS model will therefore be useful in helping to interpret results for the benefit of various hospitals across the UK and further afield.

Table 1.3: Systems Engineering Initiative for Patient Safety (SEIPS) model. Adapted from Carayon (2014)

Component		**Elements**
Structure	Person	Education, skills, knowledge, motivation, needs
	Organization	Teamwork, communication, culture, management
	Technologies or tools	Electronic prescribing and medicines administration, human factors characteristics of tools
	Tasks	Job content, challenge, workload, control
	Environment	Regulatory, stakeholders
Process	Care processes and other processes	Information follow, improvement activities
Outcome	Employee and organisational outcomes	Burnout, job satisfaction
	Patient outcomes	Patient safety, quality of care

We have recognised that there is a variety of complex and related causes of insulin prescription errors within the open system that is a hospital organisation. Consideration of the underlying psychological mechanisms leading to prescription errors can lead us towards consideration of strategies that help to

reduce their occurrence. The next section discusses the interventions that are designed to prevent insulin prescription errors in the inpatient setting. The section also summarises the current guidance and policy to help improve insulin prescribing practice.

1.5 Preventing insulin prescription errors

Preventing insulin prescription errors from occurring is important to minimise preventable harm to patients. In the hospital setting, pharmacists have an important role in supporting safe prescribing by providing education and training, designing and implementing systems, protocols and guidance to minimise prescription errors and providing accurate drug histories for patients on admission to hospital (Cohen, 2010; Joint British Diabetes Societies for inpatient care, 2019; J. . Kelly, 2010; Patel, Pevnick, & Kennelty, 2019; Szumita, 2009; Ward & Wasson, 2017). Interventions such as these may be targeted at addressing specific causes of insulin prescription errors as described above, using Reason's human error framework. For example, latent failures such as lack of training in insulin use can be addressed with educational interventions, and active failures such as lapses may be addressed with re-design of prescription forms to encourage completion of all necessary aspects of the prescription.

Interventions designed to reduce insulin prescription errors may be categorised according to the Cochrane Effective Practice and Organisation of Care (EPOC) Taxonomy (Effective Practice and Organisation of Care, 2015). Examples include education, clinical practice guidelines, protocols, and the use of information technology. These interventions are the most frequently mentioned in the literature regarding reducing prescribing errors (De Araújo, De Melo, De Bortoli, De Alcântara Bonfim, & Toma, 2019; Manias, Kusljic, & Wu, 2020; The Health Foundation, 2012). Therefore, they will be described further below along with relevant policy and national guidance. The systematic review presented in **Chapter 2** documents and discusses all published interventions designed to reduce inpatient insulin prescription errors.

1.5.1 Educational interventions

Interventions to deliver education and training to prescribers in the hospital setting are designed to reduce insulin prescription errors by addressing prescribers' theoretical and practical knowledge deficits and unfamiliarity with insulin treatment, that contribute to these errors (Hellman, 2004; R. Hansen, Bradley, & Sahm, 2016; Ryan et al., 2014). Various studies indicate that prescribers lack both knowledge and confidence to prescribe insulin in the hospital setting (Al-Yassin et al., 2013; Bain, Kavanagh, McCarthy, & Babar, 2019; Derr et al., 2007; George et al., 2011; Lee et al., 2013; C. G. Taylor, Morris, & Rayman, 2012), although the measures and tools used to assess knowledge and confidence in these studies varied. These knowledge deficits are thought to, in part, be attributed to insufficient

undergraduate medical training on prescribing, particularly with respect to insulin (Brinkman et al., 2018; Hansen, Walsh, Bradley, & Sahm, 2017; N. A. A. Kelly et al., 2015).

Delivering postgraduate education and training to prescribers regarding the safe prescribing of insulin in the hospital setting is currently recommended by the Joint Diabetes Societies for Inpatient Care, who state that hospitals should implement mandatory *"1 hour diabetes prescribing training as part of the induction programme for new doctors and pharmacists joining the Trust"* and "*mandatory insulin safety e-learning annually"* (Joint British Diabetes Societies for inpatient care, 2019). Diabetes UK recommends *"basic training on the safe use of insulin…should be mandatory for all healthcare professionals caring for people with diabetes"* (E. Watts & Rayman, 2018), and the recent Getting it Right First Time National report for Diabetes recommends that *"training should be provided for every healthcare professional who dispenses, prescribes and/or administers insulin, appropriate to their level of responsibility, including an assessment of competency"* (Rayman & Kar, 2020). These recommendations do not stipulate how insulin education and training should be designed or delivered, only that it should be mandatory, and include assessment of competency.

Educational interventions can take a variety of forms and their design may be informed by pedagogical theory, for example Kolb's experiential learning theory informing simulated educational sessions that incorporate reflection and conclusion-drawing (Kolb, 1984; O'connor et al., 2009; Stocker, Burmester, & Allen, 2014). Intervention delivery may include face-to-face teaching (C. G. Taylor et al., 2012), structured educational outreach, for example by pharmacists on ward areas (Hart, Lloyd, Furlong, & Hardy, 2017), and online e-learning modules, which are the most common digital learning resource shown to be effective in teaching prescribers the required knowledge and skills (Bakkum, Tichelaar, Wellink, Richir, & Agtmael, 2019). Other methods include short educational videos (Field, Woodier, Clayton, Plichta, & Teo, 2018) and educational games (Quail et al., 2018).

Studies involving educational interventions to improve prescribing practice more generally have used different outcome measures to demonstrate their effectiveness (Kamarudin, Penm, Chaar, & Moles, 2013). This is the same for studies concerning inpatient insulin prescribing practice. Some have used test performance (e.g. insulin-related knowledge) (Conn, Dodds, & Colman, 2003), self-reported confidence levels (N. A. A. Kelly et al., 2015), or prescribing competence, where prescribers are assessed on their prescription writing skills for theoretical cases (Celebi, Weyrich, Riessen, Kirchhoff, & Lammerding-Köppel, 2009). Others have used prescribing performance, where prescribers are assessed on their 'real world' prescription-writing abilities (Al-Yassin et al., 2013; Clarke & Narendran, 2005). This makes it difficult to make comparisons between interventions, particularly as these studies do not often explicitly relate the findings to pedagogical theory to aid transferability of the findings to different contexts.

1.5.2 Insulin prescribing guidance, protocols, and policy

Prescriber decision-support tools such as guidelines, protocols and policies are designed to reduce insulin prescription errors by providing prompts to prescribers when writing or entering prescriptions. Prescribing guidelines usually include concise instructions on how to prescribe insulin for inpatients in certain circumstances (e.g. peri-operative period, hypoglycaemia), and in so doing, minimise the need for prescribers to rely on their knowledge and memory to write appropriate, complete, and accurate prescriptions for patients using insulin. Guidelines may reassure prescribers about the appropriateness of their practice, and when followed appropriately, improve the consistency of care for patients more widely (Woolf, Grol, Hutchinson, Eccles, & Grimshaw, 1999).

The Joint British Diabetes Societies for Inpatient Care (JBDS) have published a suite of guidelines that address how insulin should be prescribed in a range of clinical conditions (for example in adults undergoing surgery, hypoglycaemia, diabetic ketoacidosis), the latest of which summarises best practice in adult inpatient diabetes care. This is based on all previously published guidance (Joint British Diabetes Societies for inpatient care, 2019) and it also outlines how to write a safe insulin prescription (see Box 1.1)

Box 1.1: Guidance pertaining to writing a safe insulin prescription, taken from the Joint British Societies for Inpatient Care guideline on the Safe Use of Insulin (2019).

Patients self-administering insulins should be assessed daily and this should be documented accordingly
Never use abbreviations e.g. 'U' or 'IU'. Include administration method (e.g. Flexpen, Solostar, cartridges, vials) in 'Device' box. IV insulin should be prescribed on the separate IV insulin medication order and administration chart
Always use full correct name and proprietary name of the insulin
Always give rapid acting analogues (Humalog, Apidra, Novorapid), short acting human insulin (Humulin S, Human Actrapid) and human biphasic (Humulin M3) and analogue biphasic (Novomix 30, Humalog Mix 25 or Humalog Mix 50) with meals
Always give Insulin Glargine (Lantus), Insulin Detemir (Levemir), Insulin Degludec (Tresiba) or insulin Toujeo or other BASAL and intermediate acting insulin at the same time each day, irrespective of meals and even if the patient is receiving intravenous insulin
Confirm any single dose of intermediate/long acting insulin over 50 units and any dose over 25 units of short acting insulin and document
Insulin doses must never be omitted or delayed unless clearly outlined on the prescription and documented in the medical notes by the prescriber
Prescribe 'Insulin as per chart' on the patient's main inpatient prescription chart
Prescribe and review insulin doses on a regular basis according to clinical need
Cross off and re-write the prescription if changes are required
If changes in the patient's insulin regimen are required, as a general rule, alter one insulin prescription at a time by roughly 10% of the dose
Further dose adjustments should be made no less than 48 hourly

The National Institute for Health and Care Excellence (NICE) published a Key Therapeutic Topic called 'safer insulin prescribing' in 2017, which was updated in 2019 (National Institute for Health and Care Excellence, 2017). Unlike the above, this is not a formal clinical guideline, but rather advice that claims to summarise the evidence base on safer insulin prescribing. The advice contained in this document, however, mainly includes what information to give patients being prescribed insulin (e.g. around hypoglycaemia and fitness to drive) rather than the prescription-writing process itself and cites national patient safety alerts rather than peer-reviewed publications on the topic. Where the prescription writing process is mentioned, advice given is included in Box 1.2.

Box 1.2: Advice from the National Institute for Health and Care Excellence Key Therapeutic Topic [KTT20] on Safer Insulin Prescribing (2019)

[Prescribe] insulin doses in units ensuring that the word 'units' is spelled out in lower case.
Healthcare professionals cross-reference available information to confirm the correct identity of insulin products.
Be aware of the differences between insulin products and ensure that people receive appropriate training on their correct use.

In addition to this, NICE also charge hospitals are charged with putting in place systems to allow self-administration of insulin by inpatients to reduce the harmful impact of insulin errors (National Institute for Health and Care Excellence, 2019). Insulin self-administration is where a person who is prescribed insulin and is staying in hospital as an inpatient, administers their own dose of insulin. This occurs with varying degrees of independence depending on the circumstances. Policies to facilitate this practice in the inpatient setting are required because it represents a deviation in the standard practice of nurses administering medicines to patients (Richardson, Brooks, Bramley, & Coleman, 2014).

Hospital organisations often produce bespoke insulin prescribing guidelines, protocols, and policies that take into account their local organisational context, systems, and service provision (Dixon, 2017; Helmle et al., 2017; Jenkins-Liu et al., 2018; Rushmer & Voigt, 2008). These interventions have been shown to demonstrate improvements in error rates and patient harm events when implemented in practice (Donihi, DiNardo, DeVita, & Korytkowski, 2006; Dooley et al., 2011; Noschese et al., 2008; Singh et al., 2018). They are, however, often introduced as part of multifaceted error-prevention strategies or as part of electronic prescribing systems, making it difficult to attribute outcomes to an individual intervention.

In addition to guidelines, policies, and procedures regarding the prescription-writing process, both the Joint British Diabetes Societies for Inpatient Care (JBDS) and the National Institute for Health and Care Excellence (NICE) recommend that hospitals implement insulin self-administration policies to reduce insulin prescribing errors and the consequential impact on patients (Joint British Diabetes Societies for inpatient care, 2019; Joint British Diabetes Societies for Inpatient Care Group, 2012; National Institute for Health and Care Excellence, 2019). This has also been reinforced by the Getting It Right First Time report,

Diabetes UK and the NaDIA results (Rayman & Kar, 2020; E. Watts & Rayman, 2018). There are currently no published studies relating self-administration policy use to insulin error reduction, or that explore their impact, acceptability, or implementation in-depth.

1.5.3 Technologies and tools

The Human Factors approach to error prevention described in **section 1.4** concerns the interface between systems, tools and the people interacting with them (i.e. prescribers). With respect to reducing prescribing errors, tools and technologies that can simplify, standardise and 'force' processes, such as electronic prescribing or standardised prescription charts, may be useful (Etchells, Juurlink, & Levinson, 2008). The introduction of electronic prescribing and standardised prescription charts with respect to insulin prescriptions will be outlined briefly, along with the Insulin Passport, which is a patient-held record containing insulin prescription information designed to help reduce insulin prescription errors on admission to hospital.

Electronic prescribing

Most studies regarding the redesign of technologies and tools to reduce prescription errors address the implementation and outcomes of electronic prescribing systems and computerised decision-support tools (also known as computerised provider order entry (CPOE) systems). The introduction of electronic prescribing systems for inpatient prescribing provides the opportunity to reduce certain types of prescription error, for example abbreviations, missing prescription elements or ambiguities on account of poor handwriting (Prgomet, Li, Niazkhani, Georgiou, & Westbrook, 2017). However, their use is not without its problems, with sociotechnical difficulties, the introduction of new types of prescription error and increased workload also being reported (Brown et al., 2017). A recent overview of systematic reviews concluded that although the use of electronic prescribing resulted in a statistically significant decrease in medication errors, there was considerable variation in the magnitude of their relative risk reduction (Abraham et al., 2020).

With respect to inpatient prescriptions for subcutaneous insulin, the introduction of electronic prescribing has been shown to reduce insulin errors concerning the wrong name or the use of 'u' for units, or insulin not being prescribed (Leech et al., 2016). The latest national audit data suggests that hospitals with electronic prescribing systems have lower insulin error rates than those not using electronic prescribing (17.1% vs 19.5% inpatients with errors, $P<0.05$ (exact p value not stated)), or only partially using electronic prescribing (17.9%, $p>0.05$). (NHS Digital, 2020). It is unclear what impact this has on insulin prescription

errors, however, as the definition of 'insulin error' in the audit also includes glucose management errors with insulin (e.g. when insulin is not reduced if unexplained blood glucose results are <4 mmol/L).

Individual studies have demonstrated improvement in insulin prescription errors following the introduction of electronic prescribing integrated with electronic blood glucose results (24% to 7.7% after 14 months (p=0.017) (Leech, Cook, Cook, & Heed, 2017; Leech et al., 2016). Some insulin prescription error types seem to persist, however, including errors in device, time, and where insulin is omitted altogether (Goble, Sayar, & Pang, 2010; Leech et al., 2017, 2016). Other benefits for insulin prescribing have been demonstrated with electronic prescribing system introduction, including their ability to be manipulated for the purposes of audit and quality improvement more readily than paper systems (Grant, Mustafa, & Malik, 2012; C. King et al., 2015). This benefit has been recognised by a recent report by Diabetes UK, which recommends that "*effective electronic prescribing system for detecting, recording, and avoiding insulin errors should be used across hospitals"* (E. Watts & Rayman, 2018).

Most studies focus on outcomes following the implementation of electronic prescribing systems, rather than the interaction between them and the prescribers. One study, however, explored the impact of the implementation of a new electronic insulin prescribing order set with doctors and nurses across three hospital sites in Canada (Helmle, Edwards, Kushniruk, & Borycki, 2018). Results indicated that although the intervention was perceived to positively impact patient outcomes, there were several barriers to its use, including a lack of initial and ongoing education, lack of availability of information at the time of prescribing, impaired workflow, and lack of communication between care teams. The authors used a chiefly positivistic approach to thematic analysis and did not refer to or use a theoretical framework or model to present their results. The impact of the intervention on insulin prescription errors was also not explicitly mentioned in the study.

The latest national audit figures suggest that around 45% hospitals in England are using electronic prescribing systems for their inpatients (NHS Digital, 2020). It is currently unknown how insulin is prescribed using electronic prescribing in these hospitals. For example, we do not know what controls or functions are in place to restrict, simplify or standardise the prescribing process electronically, how these systems are used and perceived, or how many of these systems are linked to electronic blood glucose results to facilitate workflow.

As there have been no UK based studies regarding inpatient prescribing systems being used for insulin, there is an opportunity to contribute to the existing literature by investigating the use and perception of electronic prescribing on insulin prescription errors at an organisational level. The use of mixed methods and the application of a theoretical framework or model, such as the SEIPS, can further aid transferability of the results for the benefit of hospital organisations.

Insulin prescribing charts

Hospitals prescribing insulin using paper systems (around 55% according to the latest national audit data) may be doing so using standard hospital prescription charts, or bespoke, dedicated insulin prescription charts. The use of these charts aims to help prescribers to write accurate and complete insulin prescriptions by providing decision-support (e.g. summary clinical guidance/protocols/policies) and instructions on how to prescribe insulin safely for people with diabetes. They are also recommended to be designed ergonomically (with human factors in mind) to facilitate workflow and reduce the opportunity for errors by placing critical information and guidance close to the place of prescription (U. Dashora, Castro, Sampson, Stanisstreet, & Hillson, 2015).

The introduction of inpatient subcutaneous insulin prescribing charts has resulted in improvements in insulin prescription errors during audit from 65% to 14% over a period of 3 years in one study (Hamilton et al., 2013) and in another had eliminated them altogether (Wijetilleka, Ahmed, & Patel, 2015), although re-audit was only 4 months after the intervention, and further re-audit would be recommended to demonstrate sustained benefit. A study by Rushmer and colleagues found that although insulin prescription charts improved the accurate recording of insulin device (from 11% to 100% correct), there were no significant reductions in errors concerning dosing, name or time of administration (84% to 87% correct) (Rushmer & Voigt, 2008). There is a distinct lack of qualitative research that explores the impact and acceptability of insulin prescribing chart use, or relates their implementation to human factors approaches to preventing prescription errors. Such research would be timely to conduct considering the sustained insulin prescription errors being reported nationally, despite previous evidence supporting insulin chart use.

The use of insulin prescription charts is not formally recommended, although the Joint British Diabetes Societies for Inpatient Care (JBDS) guidelines stated above recommend that insulin is cross-referenced on the main drug chart, implying that a separate insulin/diabetes chart is preferable. In 2014, the Joint British Diabetes Societies for Inpatient Care launched a national competition to demonstrate the best insulin prescription chart for inpatient use, the results of which were published in 2015 and included recommendations for insulin charts to be practical, appealing, user-friendly, informative, educational, and colour-coded (U. Dashora et al., 2015). It is not currently known how many organisations use insulin prescription charts, or what elements they contain to restrict, standardise, or simplify the process of insulin prescribing. Research that elucidates current practice in this area may help to direct national improvement efforts for insulin prescribing practice.

Patient-held insulin prescription information

A National Patient Safety Alert in 2011 instructed organisations to issue patients with a document containing contemporaneous information about their insulin prescriptions (known as the insulin passport), with the objective of reducing insulin prescription errors due to the unavailability of this information provided to prescribers by patients (National Patient Safety Agency, 2011).

The introduction of the insulin passport was not explicitly based on any evidence of effectiveness, but rather on expert panel consultation and discussions amongst the National Patient Safety Agency (National Patient Safety Agency, 2011). Studies conducted since the instruction for organisations to issue the insulin passports have failed to demonstrate successful use or outcomes. One report demonstrated that out of 50 patients using insulin identified in hospital, only 4% had a completed insulin passport on their person (Walkers & Wilcock, 2014). Concerns have also been raised over uncertainties of who is responsible for ongoing documentation and initial issuing of the passports, as well as time and work constraints and clinical risk being introduced with multiple information sources containing insulin prescription information (Hodgkinson, McFarlane, & Leong, 2013). These findings, however, were presented as conference abstracts relatively recently after the national implementation of the intervention and relate to experiences within a single hospital. The finer details relating to the study methods and findings were unable to be appraised.

Nevertheless, even recent studies have indicated that problems persist with the insulin passport, as they attract little support from patients. An evaluation study conducted in one UK hospital trust found that only 15% of patients issued passports carried them, 30% of whom found it useful and 92% specialist staff surveyed had concerns over its use (Gulati, Oborne, & Babri, 2019). A qualitative study exploring pharmacy staff views on patient handheld medication tools at another UK hospital trust concluded that the insulin passport was not widely implemented across the organisation, was not useful for patients with carers, had design flaws and was not integrated into current systems and workflow (Waly, Garfield, & Franklin, 2018). The wider uptake and regard for this intervention across hospital organisations in the UK is unknown.

Despite the lack of evidence supporting the use of insulin passports, the recently updated NICE key therapeutic topic on Safer Insulin Prescribing reinforces the instructions given by the NPSA in 2011, and advises to *"give adults who are using insulin therapy a patient information booklet and an Insulin Passport"* (National Institute for Health and Care Excellence, 2019). Contemporaneous information about the uptake of the insulin passport and its perceived effectiveness across a range of organisations would be useful to help direct national recommendations regarding its use. This is particularly important in the

context where medication errors on transfer of care are prevalent and resources are scarce (Breuker et al., 2017; Riordan, Delaney, & Grimes, 2016).

1.6 Implementing Interventions

All interventions described above require some sort of change in a behaviour, process or a practice related to insulin prescribing in the inpatient setting. As discussed in **section 1.4**, the insulin prescribing process is part of a wider, interconnected system within (and beyond) the hospital organisation. With respect to implementing insulin prescribing interventions, previous studies have suggested that barriers to uptake are 'complex' and require a multidisciplinary, systems-based approach (Helmle et al., 2018).Johnson and May argue that all interventions that are targeted at healthcare professionals and systems are all complex because they are operationalised in complex organisational and policy contexts, where their implementation depends on collective rather than individual action (M. J. Johnson & May, 2015).

The implementation of interventions is important to consider alongside their design because of the impact of this on intended outcomes. Implementation research is concerned with studying the uptake of the intervention into regular use by practitioners, and has been defined as:

> *"the scientific inquiry into questions concerning implementation — the act of carrying an intention into effect, which in health research can be policies, programmes, or individual practices (collectively called interventions)."* (Peters, Adam, Alonge, Agyepong, & Tran, 2014)

As this thesis is concerned with investigating the use of interventions to reduce insulin prescribing errors, methods and tools that can help us to understand how and why interventions work in the real-world setting need to be considered. For example, context is of rudimentary importance in implementation research in healthcare settings, as complex organisational and social factors can significantly influence the implementation of an intervention, and indeed interact with each other as part of adaptive systems such as hospital organisations (Peters et al., 2014). As such, methods should be chosen that allow for a practical way to understand multiple perspectives, causal pathways and multiple types of outcomes, such as the use of both quantitative and qualitative methods as part of a mixed methods study (Peters et al., 2014).

The application of theories that help us to understand how and why things become routine and normal components of everyday work can also aid implementation research (Kislov, Pope, Martin, & Wilson, 2019; Nilsen, 2015). Relevant theories chosen to aid research should match the level of measurement to avoid erroneous interpretations. For example, in this research, interventions are studied as a unit of analysis at an organisational level (i.e. how well do interventions 'work' to prevent insulin errors in a hospital setting). As such, theories that are concerned with individual level behaviour change, or a seek to explain how individuals interact with

interventions on an inter- or intra-personal level (such as social-cognitive theory and the Theoretical Domains Framework) are less relevant for this work than those that seek to explain how interventions work at an institutional level. The Theoretical Domains Framework, for example, although well-validated and commonly used in studies concerning prescribing practice, does not consider the interactions between diverse domains influencing prescribing practice in the same way as the SEIPs model (R. Hansen et al., 2016).

A systems approach viewed through a human factors lens calls for the application of more systems-level theories. There are several theories that seek to explain how interventions work at an institutional level, including the theoretical framework of acceptability (Sekhon, Cartwright, & Francis, 2017), organisational readiness for change (Weiner, 2009), and normalisation process theory (E. Murray et al., 2010). Normalisation Process Theory (NPT) may be particularly beneficial for understanding implementation processes for insulin prescription interventions. This is because NPT focuses on the collective work and action in a specific context, rather than an individual's beliefs, attitudes, and intentions (as is the case with the Theoretical Domains Framework, or Theory of Planned Behaviour) (E. Murray et al., 2010).

Normalisation Process Theory characterises implementation processes as the product of four social mechanisms (coherence, cognitive participation, collective action, and reflexive monitoring), and in so doing, facilitates and understanding of the contexts, social structure and processes through which interventions are enacted (M. J. Johnson & May, 2015; C. May & Finch, 2009). The application of this theory to the results may therefore facilitate a deeper understanding of insulin prescription interventions and enhance the transferability of findings.

A key principal of implementation research is that researchers work with populations that will use and be affected by an intervention (Peters et al., 2014). Although pharmacists are targeted as participants in this research on account of their role in prescribing system and intervention design and implementation in UK hospitals, insulin prescribing interventions will also impact doctors, nurses, policymakers, and importantly, patients. This research adopts a participatory health research-informed approach that involves co-originating the input of people living with diabetes and members of the multidisciplinary diabetes inpatient care team (doctors, nurses, pharmacy technicians) as well as policy-makers, as members of the wider research team, on account of the importance of co-creating knowledge with stakeholders to improve the relevance, accessibility and impact of the research (Baxter et al., 2016; Gray-Burrows et al., 2018; Ocloo & Matthews, 2016; Tomlinson, Medlinskiene, Cheong, Khan, & Fylan, 2019; Wilson et al., 2015). These stakeholders have been involved in the identification, design and conduct of the research rather than just being targets for dissemination of study results (Peters et al., 2014). Further details of stakeholder involvement are given in **Chapter 3** and throughout the thesis.

1.7 Summary and rationale for the research

Insulin is considered as one of the top medicines associated with serious patient harm worldwide. Errors in the prescription of insulin for inpatients with diabetes are an important cause of poor outcomes and patient injury globally. Despite advances in our understanding of medication error causation in recent years, insulin prescription errors remain a significant and clinically important problem in hospitals, and patients continue to suffer from preventable harm as a result. The consistently unacceptably high insulin error rates identified from national audit data from hospitals in the UK have prompted calls from national bodies for hospitals to further increase efforts from inpatient teams to reduce potentially life-threatening inpatient insulin errors (Joint British Diabetes Societies for inpatient care, 2019; NHS Digital, 2020; Rayman & Kar, 2020; E. Watts & Rayman, 2018).

To make progress in reducing avoidable insulin prescription errors and related harms and costs, it is important to understand the current factors that contribute to these errors in a UK hospital context. This is also vital to critically examine the systems used to prescribe insulin and interventions that are designed to prevent errors. The current thesis seeks to respond to the call for increased efforts to reduce inpatient insulin prescription errors by investigating the use of interventions that are designed to reduce insulin prescription errors in UK hospitals. Although the problem of insulin prescribing safety concerns all healthcare settings (e.g. including primary care and nursing homes), the current thesis bounds the enquiry to the inpatient setting in acute hospitals. This is to allow the requisite depth of enquiry to occur by investigating similar processes and contexts. The process of prescribing in primary care, for example, is markedly different to that occurring in an inpatient setting, and although also prescribing involves risks, these are of a different nature to that of the inpatient setting. Although there would be merit in investigating insulin prescribing errors across care contexts, by bounding the enquiry to the inpatient setting this research can also build on previous work that has focussed on prescribing in the inpatient setting.

There is a paucity of original research investigating the systems used to prescribe insulin for inpatients in UK hospitals. There is also a lack of research that extends our understanding of the factors that contribute to inpatient insulin prescription errors in a UK context, and how interventions may or may not aid the effort to reduce them. The current use of interventions to reduce insulin prescription errors across UK hospitals, including those recommended by national bodies, is also unknown. The existing literature is currently largely limited to UK-based conference abstracts, or published studies in North America, where the healthcare delivery context differs markedly from that of the UK. The absence of theoretical model application in these studies limits the application of results to a UK context. There is, therefore, a significant opportunity to contribute to the literature on this topic by conducting theoretically informed original research that investigates the systems and interventions used to prescribe insulin in UK hospitals.

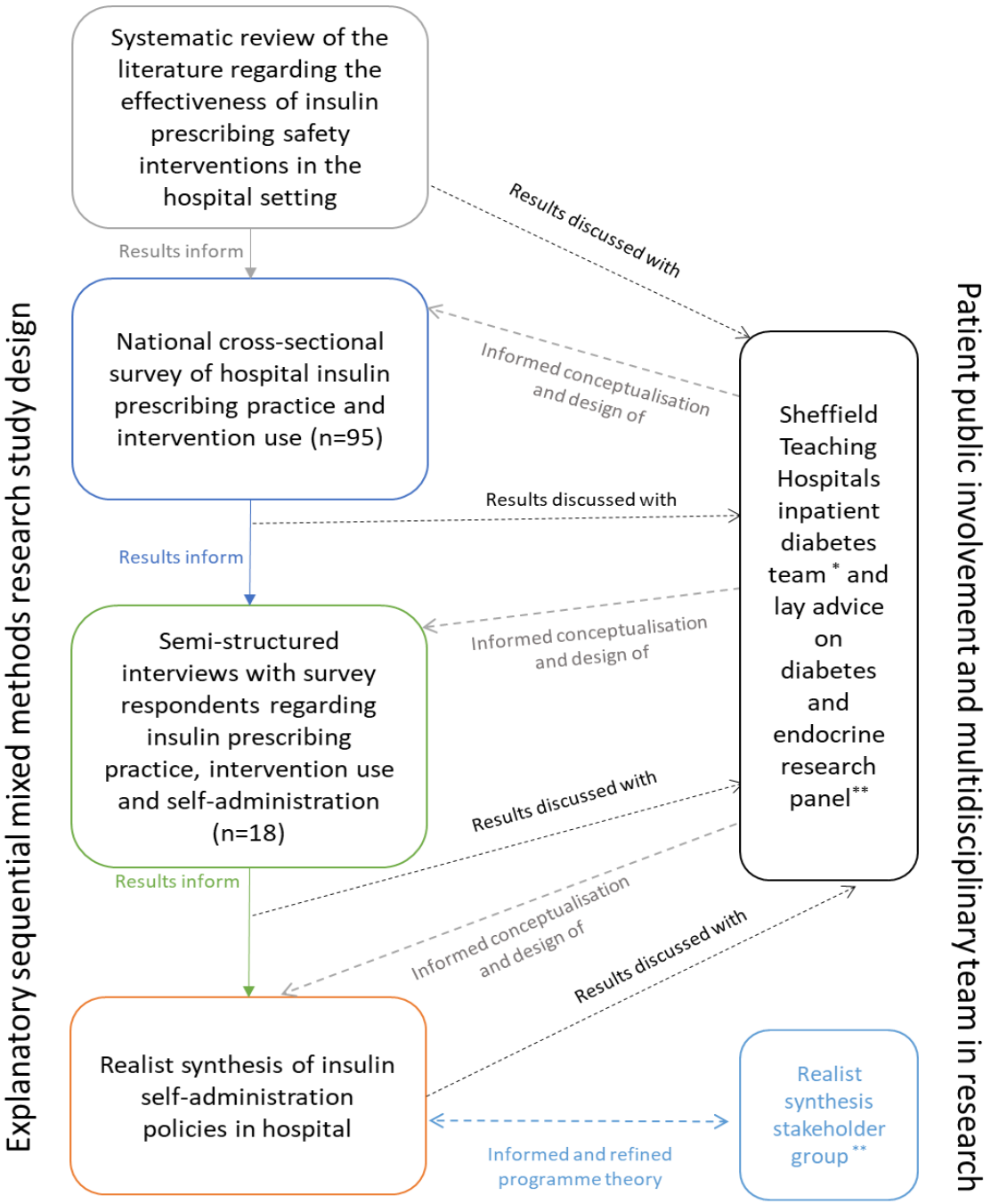
1.8 Aims and objectives of the thesis

The aim of this research is to investigate inpatient insulin prescribing practice and the current use of interventions designed to prevent insulin prescription errors in UK hospitals. This will be achieved by meeting the following objectives, and answering the associated research questions:

1. To undertake a systematic review of the evidence regarding the impact of interventions on insulin prescription errors in the hospital setting.
    - What types of interventions are designed to improve inpatient insulin prescribing practice in the hospital setting?
    - Which interventions are effective in reducing insulin prescription errors?
2. To investigate the current use and perceived effectiveness of interventions designed to improve inpatient insulin prescribing practice across hospitals in the UK using a national cross-sectional survey.
    - What systems are currently used to prescribe subcutaneous insulin for inpatients in UK hospitals?
    - What interventions are currently being used in UK hospitals to improve insulin prescribing practice?
    - Is there an association between hospital characteristics and intervention use?
    - What interventions are perceived to be most effective for improving insulin prescribing practice by those who have a role in designing, implementing and evaluating them?
    - Is there an association between hospital characteristics and perceived effectiveness of interventions?
3. To analyse the experiences and opinions of UK-based hospital pharmacists involved in the design, implementation and evaluation of inpatient insulin prescribing practice interventions using qualitative interviews.
    - What are the current challenges and solutions with respect to improving insulin prescribing practice in the UK hospital setting?
    - What are the contextual factors that may influence the success of insulin prescribing practice interventions in the UK hospital setting?
4. To use realist synthesis methodology to generate evidence-informed theory that explains how a chosen intervention works, for whom, and in what circumstances.
    - What are the mechanisms by which self-administration policy interventions are believed to result in their intended outcomes?
    - What are the important contexts that determine whether or not the identified mechanisms produce either positive or negative outcomes?
    - What are the circumstances in which self-administration policies are most likely to be effective?

1.9 Overview of the research

The overall outline of the PhD project is shown in Figure 1.4.



* This team includes consultant diabetologists, diabetes registrars, specialist diabetes inpatient nurses and pharmacists, technicians and a diabetes services manager
** This panel consists of 8 members including patients with type 1 and type 2 diabetes, a researcher, and a health economist.
**This group consists of Diabetes UK patient volunteers with various types of diabetes using insulin who have had a hospital admission in the last 5 years. It also contains diabetes pharmacists, technicians, consultant diabetologists, diabetes inpatient nurses, non-diabetes nurses, managers, policy makers and academics

Figure 1.4: Overview of the research

To meet objective 1, a systematic literature review of interventions designed to improve inpatient insulin prescribing quality was conducted. This review is presented in **Chapter 2**, and has also been published in *Diabetic Medicine* (Bain, Hasan, & Babar, 2019). The results of this review were considered and incorporated into the design of a mixed methods study which meets objectives 2 and 3. The underlying methodology and technical details of the methods used for this study are presented in **Chapter 3.** This study incorporates a quantitative cross-sectional survey and follow-up qualitative interviews. The survey results are presented in **Chapter 4**, and have been published across two papers in *Diabetic Medicine* (Bain, Hasan, Kavanagh, & Babar, 2020, 2019). The findings from the qualitative study are presented in **Chapter 5** and have also been submitted for publication. The results of the mixed methods study, and their interpretation with the stakeholder groups, informed the design of the final study. This study meets objective 4 by using realist research methods, and is presented in **Chapter 6**. A discussion of the research relating to the overall objectives and quality is presented in **Chapter 7,** including the implications for practice and further work.

Chapter 2: Systematic review of insulin prescribing interventions in hospital

This chapter builds on the previous chapter by presenting a systematic review of the literature regarding the effectiveness of insulin prescribing safety interventions in the hospital setting. The review will be reported in its entirety in this chapter, including a discussion of the results and implications for the original doctoral research presented in **Chapters 4-6.**

2.1 Introduction

Interventions to improve prescribing practice more generally have been the subject of much study, and are often targeted according to the type of error (Aronson, 2009; Velo & Minuz, 2009). A variety of interventions to improve insulin prescribing practice in the inpatient setting has been recommended by consensus expert panels, including the use of dedicated insulin prescription forms, electronic prescribing, insulin order sets, education, and readily available insulin prescribing guidance/protocols (American Diabetes Association, 2019; Cobaugh et al., 2013; Cornish, 2014). Despite these recommendations to improve the safe use of insulin in hospital, insulin errors persist. In recent years there have been a number of insulin prescribing safety interventions described in the literature, however, there have not yet been any reviews conducted that summarise the available evidence with respect to the success of these interventions.

The aim of this review was to identify and document interventions designed to reduce insulin prescription errors for hospital inpatients with diabetes. To account for the different definitions of 'prescription errors' or 'prescribing errors' in use, all studies that reported on prescription accuracy and completeness were included, as well studies that reported as adherence to national or local insulin prescription guidelines. Insulin-related glucose management errors constitute a separate type of error and were therefore not included (see **Chapter 1, section 1.4**).

2.2 Method

The Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines (Moher, Liberati, Tetzlaff, Altman, & PRISMA Group, 2009) were used to guide and report the systematic review (see Appendix 1). The study protocol was published in advance of the review conduct on the PROSPERO register (CRD42018107133) (Bain, Babar, & Hasan, 2018). The systematic literature review did not require ethical approval as no personal, sensitive, or confidential information was collected. Only publicly accessible documents were used to complete the review.

2.2.1 Identification of studies

A literature search was undertaken between 16th August and 12th November 2018 to identify full-text, original research articles published in English. There were no geographical or date restrictions to maximise the capture of relevant articles. The search strategy used a combination of free-text words and medical subject heading (MeSH) terms targeting 'insulin', 'prescribing', 'interventions', 'medication error', 'quality improvement' and 'hospital' and was tailored to accommodate varying databases (see Table 2.1).

Table 2.1: Example search strategy for the systematic review

Medline	**EMBASE**
# Database Search term Results	# Database Search term Results
1 Medline (insulin).ti,ab 327220	14 EMBASE (insulin).ti,ab 426331
2 Medline (prescri*).ti,ab 174621	15 EMBASE (prescri*).ti,ab 297893
3 Medline (48ypogly*).ti,ab 2017563	16 EMBASE (48ypogly*).ti,ab 2864344
34 Medline (hospital).ti,ab 866517	37 EMBASE (error).ti,ab 200390
4 Medline (1 AND 2 AND 3) 823	36 EMBASE (hospital).ti,ab 1292072
5 Medline (error).ti,ab 167012	18 EMBASE exp "INAPPROPRIATE PRESCRIBING"/ 3933
6 Medline (4 AND 5) 12	19 EMBASE exp "QUALITY CONTROL"/ 344052
7 Medline exp INSULIN/ 176510	21 EMBASE exp INSULIN/ 302730
8 Medline exp PRESCRIPTIONS/ 33632	22 EMBASE exp PRESCRIPTION/ 166546
33 Medline exp INPATIENTS/ 18443	24 EMBASE exp "TOTAL QUALITY MANAGEMENT"/ 50965
9 Medline (7 AND 8) 148	27 EMBASE exp "PATIENT SAFETY"/ 101625
10 Medline exp "MEDICATION ERRORS"/ 15009	29 EMBASE exp "MEDICATION ERROR"/ 17198
	31 EMBASE exp "HOSPITAL PATIENT"/ 145163
11 Medline (7 AND 10) 179	38 EMBASE (14 AND 15 AND 16 AND 37) 55
12 Medline "QUALITY IMPROVEMENT"/ 17576	39 EMBASE (14 AND 15 AND 37 AND 36) 50
	40 EMBASE (14 AND 15 AND 37) 118
13 Medline (7 AND 12) 36	41 EMBASE (18 AND 21) 67
35 Medline (1 AND 2 AND 34) 305	42 EMBASE (21 AND 22 AND 24) 32
42 Medline (1 AND 2 AND 34 AND 5 AND 35) 13	43 EMBASE (21 AND 22 AND 27) 121
	44 EMBASE (21 AND 29 AND 31) 99
	45 EMBASE (21 AND 22 AND 31) 251

Computerised scientific databases, including CENTRAL (Cochrane Central Register of Controlled Trials), PubMed, Medline, EMBASE (Excerpta Medica dataBASE), TRIP (Turning Research Into Practice), and IPA (International Pharmaceutical Abstracts) were searched, as well as hand searches of journals considered to have topic relevance (e.g. Diabetic Medicine, Diabetes Care). Grey literature searches using e-theses online service (EThOS), National Institute for Health and Clinical Excellence (NICE), and Google Scholar

were performed to reduce publication bias. The reference lists of relevant studies were also hand searched to capture studies that may not have been previously identified.

2.2.2 Study Selection

Both randomised and non-randomised studies were included, with no restrictions on research design, sample size, age or follow-up time period. Due to the specific area of interest and the diverse methods and measures included in quality improvement literature, it was felt that a broad and inclusive approach was required.

Inclusion and exclusion criteria

Only studies that examined the effect of inpatient insulin prescribing practice interventions with quantifiable data were included. Interventions targeting any group of healthcare professional or patient were included. The studies reporting the effects of any system-orientated or practitioner-orientated intervention on prescribing compared with no intervention/standard practice were also included (see Table 2.2 for definitions).

Table 2.2. Classification and definition of interventions, adapted from Nuckols et al. (Nuckols et al., 2018)

Classification	Definition
System-orientated Strategies	
Team changes	Changes to the structure or organisation of the clinical health care team, including: adding a team member or "shared care" e.g. routine visits with personnel other than which would be provided as part of 'standard care' like a new diabetes specialist nurse or pharmacist; expansion or revision of professional roles (e.g. non-medical prescribing or increased glycaemic monitoring role)
Continuous Quality Improvement	Interventions explicitly identified as using the techniques of continuous quality improvement, such as plan-do-study-act (PDSA) or any iterative process for assessing quality issues, developing solutions, testing their impact and then reassessing the need for further action.
Dedicated insulin order form/prescription chart	The use of a dedicated form specifically designed for the ordering/prescribing of insulin, either as a template to be completed by adding handwritten prescriptions, or typed and printed.
Electronic insulin order set	Electronic prescribing of insulin whereby a prescription requirements are pre-populated in some capacity, enabling a more standardised, consistent approach.
Restrictive changes	Introduction of a policy or protocol that requires additional validation prior to ordering of insulin.
Practitioner-orientated strategies	

Audit and feedback	Summary of clinical performance of healthcare delivery by an individual or group of individuals over a specified period, which is relayed back to the clinician.
Provider education	Interventions designed to promote increased understanding of principles guiding clinical care are awareness of specific recommendations regarding insulin prescribing. Interventions may include face-to-face lectures, seminars or workshops, e-learning packages or educational outreach visits. This does not include training on how to use a particular intervention (e.g. educating clinicians on how to use a new prescription chart).
Provider decision support tools	Tools designed to help prescribers make decisions on how to prescribe insulin. May include guidelines or algorithms, flowcharts or pocket-guides, reminders to perform certain tasks or include certain information. May be included as part of electronic prescribing software or paper-based.

Studies relating to insulin use in nursing homes, outpatient facilities, community care or long-term care facilities were excluded. Studies focusing on the prescription for intravenous insulin were excluded due to the distinct clinical circumstances in which it is used. Studies focusing on errors in insulin use (e.g. insulin administration errors or not increasing/decreasing insulin doses in response to blood glucose results) were also excluded. Pilot studies for which the complete results were published later were not included.

2.2.3 Data extraction

Titles and abstracts were independently screened to identify potentially relevant articles. Full text review was performed by the researcher using a pilot data extraction form to determine eligibility for inclusion. Uncertainties were resolved by discussion with a second reviewer to achieve consensus.

The researcher extracted all data, which were checked by a member of the supervisory team. Discrepancies were resolved by discussion and where necessary after discussing with a second member of the supervisory team. Attempts were made to contact article authors via email where outcome data were unclear with respect to prescribing practice or insulin errors. Articles were excluded if the data were not obtained.

For each study, the following variables were extracted using a bespoke data extraction form adapted from the Cochrane Handbook (J. Higgins, 2011): study details (authors, date, citation), patient population (numbers of patients, type of diabetes, age, length of stay), number of hospital sites and location (and if stated, institution type and size), intervention characteristics (type of intervention and implementation) and study design.

2.2.4 Assessment of quality and risk of bias in included studies

The quality of the eligible studies was assessed using the Cochrane Risk of Bias Tool (J. P. Higgins, Altman, & Sterne, 2011) for randomised trials and the Newcastle-Ottowa Scale for nonrandomised studies (Wells GA et al., 2012). The Quality Intervention Minimum Quality Criteria Set (QI-MQCS) (Hempel et al., 2015) was used to assess key reported information for all included studies. Studies were not excluded on the basis of risk of bias or quality assessment in order to be as inclusive as possible for the purposes of achieving the aims of the review.

2.2.5 Data analysis

The primary analysis was based on the change in outcomes, for example the difference in insulin prescribing error numbers (%). For studies reporting multiple outcomes, only the outcome of interest was included where the extractable data were available. When studies used controlled designs, the change in numbers of prescribing errors represented absolute differences between the control and intervention groups after the implementation of the intervention. With studies using uncontrolled designs, the change reported represented changes from baseline to follow-up for the intervention group.

As the studies were heterogeneous in terms of methods of analysis, the results are presented in the same manner as in the articles. Statistical meta-analysis was only considered for studies that were similar in terms of settings, interventions, outcome assessments and measures.

2.3 Results

Searches of the main electronic databases led to identification of 32,333 titles (see Table 2.3).

Table 2.3: Databases searched and numbers of hits

Databases/Journals	**Hits**
CENTRAL	8,097
PubMed	503
Google Scholar	2,720
Medline	1,516
EMBASE	6,727
TRIP	10,920
International Pharmaceutical Abstracts	849
Diabetic Medicine	975
EThOS	26
Total	**32,333**

After examination of titles and abstracts, 429 studies were retrieved for more detailed evaluation. Hand searching of reference lists produced 21 new articles. After exclusion of conference abstracts and non-relevant studies, a total of 65 articles were selected for full-text review. After the application of inclusion/exclusion criteria, 35 studies were included in the final review (Figure 2.1). Details of the excluded studies at the final stage are listed in Appendix 2.

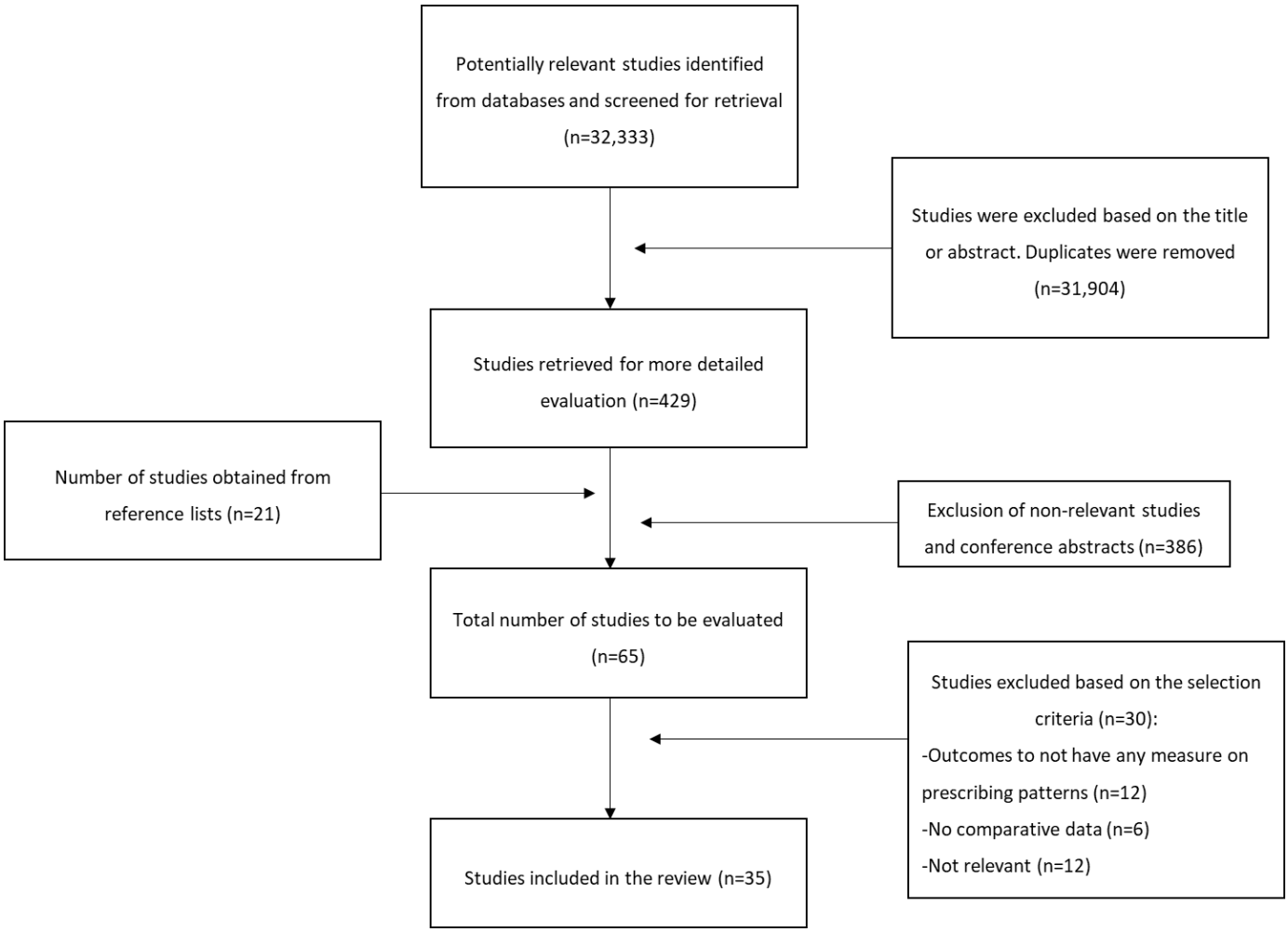


Figure 2.1: Study selection flowchart.

2.3.1 Characteristics of included studies

In total, 35 studies were included: 2 cluster randomised controlled trials (RCTs), 2 cohort studies, and 31 uncontrolled before-after (UBA) studies. The 2 RCTs were at high risk of bias due to lack of blinding and optional use of the intervention. Observational studies were also at high risk of bias due to representativeness of the exposed cohorts and study controls for confounders (see Appendix 3).

The reporting quality of the studies was critically appraised using the Quality Improvement Minimum Quality Criteria Set (QI-MQCS). Many included studies did not include details to satisfy the minimum

reporting requirements according to this tool. For example, more than half of the studies failed to describe the members' shared resolve and belief in their collective ability to implement change (otherwise known as organisational readiness). Descriptions of organisational motivation and the comparator (e.g. practice before the intervention) were also lacking in many studies (see Appendix 3).

All included studies were conducted in hospitals, 6 of which involved multiple sites. The included studies originated from Australia (n=4), Austria (n=1), Canada (n=3), Spain (n=2), the United Kingdom (n=6) and United States of America (n=19). The number of participants ranged from 18 to 4,239 in each individual study. Table 2.4 includes details of the characteristics of included studies.

Table 2.4: Characteristics of included studies. P values are included if they were quoted in the study.

Author and year (citation)	Intervention	Setting and location	Population (n)	Measure of interest	Outcome of interest
Studies reporting insulin prescription error, completeness, clarity or accuracy					
Al-Yassin 2013 (Al-Yassin et al., 2013)	Diabetes e-learning module undertaken by junior doctors	Barnet and Chase Farm Hospitals NHS Trust, UK	Inpatients with diabetes prescribed insulin (49)	Number of patients with insulin prescribing errors	Number of patients with >1 NaDIA insulin prescription errors reduced from 32% to 17% (p>0.05))
Courtenay 2007 (Courtenay et al., 2007)	Diabetes Specialist Nurse Prescriber Service	Six medical and surgical wards in a district general hospital, UK	Inpatients with diabetes treated with insulin and/or oral hypoglycaemic agents (452)	Number of insulin prescribing errors	Reduction in the median number of insulin prescribing errors from 6 to 4 (p<0.01)
Donihi 2006 (Donihi et al., 2006)	Paper insulin prescribing guideline and order form	Non-intensive care units in a tertiary care centre, USA	Inpatients prescribed SSI (unknown)	Number of SSI-related insulin prescribing errors (use of ''U'' for unit or omitted insulin type)	Reduction in the number of insulin prescribing errors from 10.3 per 100 SSI patient-days to 1.2 (p=0.03)
Donsa 2016 (Donsa et al., 2016)	Glucotab® electronic decision support system that gives recommendations for TDD and BB insulin doses	General ward, Medical University of Graz, Austria	Inpatients with type 2 diabetes (79)	Number of insulin calculation errors	Insulin calculation errors reduced from 11.1% to 0%
Dooley 2011 (Dooley et al., 2011)	Implementation of a high dose insulin validation guideline	Three hospitals (a tertiary reaching hospital, a rehabilitation hospital and a	All inpatients prescribed high dose insulin (197)	Number of 'high dose' insulin errors	Reduction in reported errors from 18 to 12, with 8 errors

		community hospital), Australia			being detected and prevented.
Hamilton 2013 (Hamilton et al., 2013)	Redesign of diabetes prescribing chart incorporating prescribing guidelines; diabetes prescription error management pathway and mandatory e-learning	Royal Bournemouth Hospital, UK	All inpatients with diabetes prescribed insulin (unknown)	Number of insulin prescription errors	Reduction in NaDIA insulin prescription errors from 65% to 2%
Kowiatek 2001 (Kowiatek, Skledar, & Potoski, 2001)	New insulin prescribing guidelines involving the wording 'units' and no zeros after whole numbers	University of Pittsburgh Medical Centre Health System, USA	All insulin orders (unknown)	Prescription of insulin dose as 'UNITS' and having no zeros following whole numbers	Compliance with guidelines increased from 30% to 70%
McIver 2009 (McIver, Mitchell, Finn, & Kamp, 2009)	Insulin prescription and administration form redesign	Four Queensland Health tertiary and regional hospitals, Australia	All non-critical, adult inpatients using insulin (199)	Clarity of insulin prescription	Reduction in the opportunity for error as a result of non-standard abbreviations 41.8% to 12.2% ($p < 0.0002$); unclear route 75.5% to 4.9% ($p<0.0002$) and unclear frequency 65.9% to 6.5% ($p < 0.0002$)
Rushmer 2008 (Rushmer & Voigt, 2008)	New insulin prescription chart with guidelines	University Teaching Hospital (900 bed), UK	All insulin prescribing charts (409)	Accuracy and completeness of insulin prescription (details of device)	Prescription accuracy increased from 84 to 87%; completeness improved from 11-100%
Taylor 2012 (C. G. Taylor et al., 2012)	Education programme (1 hour interactive case based)	Four hospitals, UK	All inpatients with diabetes prescribed insulin (494)	Number of insulin prescription errors	Reduction in NaDIA insulin prescription errors from 15.4% to 7.8% ($p < 0.05$)

Tully 2018 (V. Tully et al., 2018)	Medicines reconciliation sticker to capture insulin information	University Teaching Hospital (900 bed), UK	insulin-dependant patients admitted to the acute surgical receiving unit (18)	Completeness of insulin information on medicines reconciliation	Adequate medicines reconciliation with insulin increased from 64% to 91%
Studies reporting adherence to insulin prescribing guidelines					
Wesorick 2010 (Wesorick, Grunawalt, Kuhn, Rogers, & Gianchandani, 2010)	Physician and nurse education and insulin order set	University of Michigan Hospital, USA	Hyperglycaemic, non-critically ill inpatients treated with insulin (245)	Patient days on SSI	23.2% vs 27.6% (p = 0.12) SSI monotherapy; 36.6% vs 15.1% for BBCI (p<0.01)
Lehnbom 2009 (Lehnbom, Welch, Ludington, Brien, & Bryant, 2009)	Introduction of an insulin prescribing chart	Teaching hospital (300 bed), Australia	All inpatients with diabetes prescribed insulin (109)	Prescription of 'regular insulin'	Increase in prescription of regular insulin from 19% to 24%
Harbin 2015 (Harbin et al., 2015)	Pre-printed insulin order sheet	Vasscular surgery unit in an unknown hospital, Canada	Inpatients with diabetes (type 1 or 2) who required insulin prior to admission and were prescribed insulin in hospital (87)	Prescription of BBCI	Increase in BBCI from 51.7% to 83.7% (p<0.0001)
Helmle 2017 (Helmle et al., 2017)	Basal bolus insulin knowledge translation toolkit	Four acute care facilities, Calgary, Canada	All inpatients with diabetes with at least 1 insulin order (2,241)	Prescription of BBCI	Increase in BBCI prescribing from 27% to 40% (p<0.001)
Mamillapalli 2012 (Mamillapalli, Rico, Nallala, Mansuri, & Jakoby, 2012)	Pocket-sized insulin dose guide	Memorial Medical Center, USA	Inpatients with type 2 diabetes admitted to the general medicine (1,163)	Prescription of BBCI	BBCI increased from 16.7% to 41.9% (P < 0.01)
Mulla 2015 (Mulla, Lieb, McFarland, & Aloi, 2015)	Educational campaign with electronic insulin order sets	Integrated health system comprising 7 hospitals, USA	All patients, with or without diabetes (2,866)	Prescription of BBCI	Increase in prescription of BBCI from 20 to 86% (p <0.01)

Wong 2016 (B. Wong, Mamdani, & Yu, 2016)	State-wide subcutaneous insulin prescribing chart	Tertiary hospital, Australia	All inpatients prescribed subcutaneous insulin (118)	Prescription of SSI	Reduction in SSI prescribing from 16.7% to 3.2% (p = 0.014)
Ena 2009 (Ena et al., 2009)	Education involving a 20 minute seminar, pocket guides and posters	Hospital Marina Baixa (280 bed), Spain	Inpatients with type 2 diabetes or BG >200mg/dL on admission (138)	Prescription of SSI	Increase in BBCI prescribing from 17% to 93% (p = 0.004); reduction in SSI from 50% to 3% (p <0.001)
Achtmeyer 2002 (Achtmeyer, Payne, & Anawalt, 2002)	CPOE supplemental insulin only allowed when fasting serum glucoses exceeded 400 mg/dl	Teaching hospital (290 bed) USA	Inpatients with diabetes prescribed insulin (unknown)	Prescription of SSI	Reduction in SSI orders from 978/1007 (97.1%) to 254/398 (63.8%) (P < 0.001)
Guerra 2010 (Guerra et al., 2010)	hospital-wide, CPOE-based, hyperglycemia inpatient protocol	Large public teaching hospital, USA	Medical inpatients with type 1 or 2 diabetes (438)	Prescription of SSI	Reduction in SSI use (22.8% to 0.5%, P<.001)
Horton 2015 (Horton, Weeks, Rhinewalt, Ballard, & Asher, 2015)	Guideline-derived resident educational program	Academic medical centre, USA	All inpatients admitted to two inpatient medicine teams on insulin (125)	Prescription of SSI	Increase in BBCI prescribing (23% vs 8%;P = 0.024); reduction in SSI monotherapy (52% vs 62%; P = 0.289).
Maynard 2009 (Maynard, Lee, Phillips, Fink, & Renvall, 2009)	Insulin order set with management algorithm	University Hospital (400 bed), USA	Adult non-critical inpatients with diabetes or hyperglycaemia (976)	Prescription of SSI	Reduction in use of SSI monotherapy from 72% to 26% (P < .0001)
Newsom 2018 (Newsom et al., 2018)	Glucommander implementation	Large community teaching hospital (581 bed), USA	Hyperglycemic adult patients prescribed insulin, with/without a diagnosis of diabetes (4,239)	Prescription of SSI	Reduction in SSI from 95% to 4%
Noschese 2008 (Noschese et al., 2008)	Pre-printed diabetes order set with prescribing guidelines	Tertiary care academic medical centre (716 bed), USA	All inpatients with an order for a diabetes medication (70)	Prescription of SSI	More orders for BBCI (38% vs 14% p=0.008) and fewer orders for SSI monotherapy (34% vs 42%) on the order set unit than the control

					unit. A trend toward more appropriate orders (91% vs 80%) was observed on the order set unit.
Schnipper 2009 (Schnipper, Ndumele, Liang, & Pendergrass, 2009)	Subcutaneous insulin protocol (pocket guide), education (1 hr) and computerised insulin order set	Large tertiary care hospital, USA	Inpatients with type 2 diabetes or hyperglycaemia (BG > 180mg/dL) (169)	Prescription of SSI	SSI monotherapy use reduced from 29% to 8% (p<0.05)
Schnipper 2010 (Schnipper, Liang, Ndumele, & Pendergrass, 2010)	Computerised insulin order set	Large tertiary care hospital, USA	Inpatients with diabetes or hyperglycaemia (BG > 180mg/dL) (179)	Prescription of SSI	SSI monotherapy use reduced from 58% to 25% (p=0.004)
Thompson 2009 (Thompson et al., 2009)	Subcutaneous insulin order form, automated daily report for BGs, and full-time advanced registered nurse practitioner.	Level-1 regional trauma centre (400 bed), USA	All dysglycemic inpatients in non-critical care wards (subset of 100 from 18,087)	Prescription of SSI	SSI monotherapy use reduced from 16% to 4%
Trujillo 2008 (Trujillo et al., 2008)	Subcutaneous insulin protocol and 1hr education session	Large tertiary care hospital, USA	Inpatients with type 2 diabetes or hyperglycaemia (BG > 180mg/dL) (180)	Prescription of SSI	Increase in basal insulin prescribing from 49% to 64% (p=0.05); nutritional insulin prescribing increased from 0% to 13% (p<0.001); SSI monotherapy prescribing reduced from 49% to 29% (p = 0.01)
Valgardson 2015 (Valgardson, Merino, Redgrave, Hudson, & Hudson, 2015)	Non-compulsory subcutaneous insulin order set (paper, then computerised)	Gallup Indian Medical Center, USA	Adult inpatients with type 2 diabetes (576)	Prescription of SSI	BBCI increased from 10.6% to 27.5% (p<0.001); Reduction in SSI from 36.1% to 28.8% (p=0.6)

Wexler 2010 (Wexler, Shrader, Burns, & Cagliero, 2010)	Non-compulsory use of electronic insulin order set	Massachusetts General Hospital, USA	Inpatients with type 2 diabetes or hyperglycaemia (BG >180mg/dL) (128)	Prescription of SSI	SSI prescribing was 35% in control group vs 38% in the intervention group (p=0.7)
Yeung 2018 (Yeung, Wong, & Wong, 2018)	Computerised hyperglycaemia insulin order set	Veterans Hospital, USA	Inpatients with type 2 diabetes or admission BG >180mg/dL (200)	Prescription of SSI	Reduction in SSI prescribing from 52% to 47% (p=0.48)
Doyle 2014 (Doyle et al., 2014)	Pre-printed insulin orders, decision support tools, education, pocket card	Multicampus tertiary care hospital (1100 beds), Canada	All inpatients with type 1 or 2 diabetes admitted to the pilot unit (unknown)	Prescription of SSI	Reduction of SSI monotherapy from 30% to 4% (ward 1) 32% to 0% (ward 2) – average reduction 29%.
Gomez-Huelgas 2014 (Gomez-Huelgas et al., 2014)	New protocol based on BBCI therapy plus 20 minute seminar, handouts and posters	Tertiary university 1,161 bed hospital, Spain	All non-critical, surgical and medical adult inpatients with diabetes (213)	Prescription of SSI	Increase in adherence to BBCI guideline from 9.6 to 52 %; Reduction in SSI prescribing from 43.5% to 23.5 % (p<0.001)
Vaidya 2012 (Vaidya, Hurwitz, Yialamas, Min, & Garg, 2012)	Department wide computerised educational course	Large tertiary care hospital, USA	All non–critically ill inpatients with diabetes (405)	Prescription of SSI	Reduction in use of SSI monotherapy from 25 to 15% (p=0.1) and increase in BBCI from 35 to 48% (p=0.06)

Note: NaDIA = National Diabetes Inpatient Audit (United Kingdom). SSI = subcutaneous sliding scale insulin. BBCI = basal bolus correctional insulin. BG = blood glucose

Studies described a median of 2 interventions as part of their quality improvement strategy (maximum 7, minimum 1). Twenty-two studies involved the introduction or optimisation of provider decision support tools (such as guidelines and algorithms), 14 studies described the introduction or optimisation of a dedicated insulin order form/prescribing chart, 15 studies involved education of healthcare professionals and 12 involved electronic prescribing interventions such as insulin order sets (involving the automatic population of additional required or supplementary information on electronic prescriptions (e.g. type of

insulin, meal association etc.). Seven studies took a continuous quality improvement approach. Other interventions were used less frequently (see Table 2.5).

Table 2.5: Interventions reported in included studies.

	System-orientated strategies					Practitioner-orientated strategies		
Author and year	**Team changes**	**Continuous Quality Improvement**	**Dedicated insulin order form/prescription chart**	**Electronic insulin order set**	**Restrictive changes**	**Audit and feedback**	**Provider education**	**Provider decision support tools**
Achtmeyer 2002				x	x			
Al-Yassin 2013							x	
Courtneay 2007	x						x	
Donihi 2006			x					x
Dooley 2011					x			
Donsa 2016				x				x
Doyle 2014		x	x				x	x
Ena 2009							x	x
Gomez-Huelgas 2014			x					x
Guerra 2010				x	x			x
Hamilton 2013			x					
Harbin 2015			x					x
Helme 2017		x	x	x	x	x	x	x
Horton 2015							x	
Kowiatek 2001		x			x		x	x
Lehnbom 2009			x					x
Mamillapalli 2012								x
Maynard 2009		x		x				x
McIver 2009		x	x					x
Mulla 2015				x			x	x
Newsom 2018	x			x			x	x
Noschese 2008			x					x
Rushmer 2008		x	x					x
Schnipper 2009				x			x	x
Schnipper 2010				x				
Taylor 2012							x	
Thompson 2009	x		x					x
Trujillo 2008							x	x
Tully 2018		x				x		x
Vaida 2012							x	
Valgardson 2015			x	x				
Wesorick 2010			x				x	
Wexler 2010				x				
Wong 2016			x				x	
Yeung 2018				x				x

Although a few studies described a team approach to the design of interventions, there was a lack of explicit mention of patient or public involvement. Only 2 studies looked at economic or financial sustainability/impact of interventions (Courtenay et al., 2007; V. Tully et al., 2018) and there was a general lack of consideration of the theoretical basis or justification for interventions. Well-reported studies included details of usual care in the control/before group, as well as the organisational characteristics and readiness for change (Helmle et al., 2017; Kowiatek et al., 2001; Newsom et al., 2018; Noschese et al., 2008; V. Tully et al., 2018; V. W. Wong, Ho, Fiakos, Lau, & Russell, 2016).

Compliance with insulin prescribing guidance was measured either by prescription accuracy, completeness, the number of insulin errors on inpatient prescriptions, or the use of basal bolus correctional insulin compared to subcutaneous 'sliding scale' insulin monotherapy. This is the strongly discouraged practice (mainly in North America) of controlling blood glucose in the inpatient setting with correctional doses of short-acting insulin (American Diabetes Association, 2019). As these two measures represent apparent distinct priorities for practitioners based on geographical location, the results are presented based on the aim of each intervention.

2.3.2 Interventions to improve insulin prescribing accuracy and completeness

Eleven studies reported interventions to improve insulin prescription completeness, accuracy or reduction in insulin prescribing errors defined by the individual authors.

There were 6 studies performed in the United Kingdom, 2 in Australia, 1 in Austria and 2 in the United States. All were uncontrolled before-after studies. Four studies were multisite (Al-Yassin et al., 2013; Dooley et al., 2011; McIver et al., 2009; C. G. Taylor et al., 2012), 7 studies involved teaching or tertiary hospitals (Donihi et al., 2006; Donsa et al., 2016; Dooley et al., 2011; Kowiatek et al., 2001; McIver et al., 2009; Rushmer & Voigt, 2008; V. Tully et al., 2018) and 3 involved district general hospitals (Al-Yassin et al., 2013; Courtenay et al., 2007; Hamilton et al., 2013).

Interventions described in the study included the following: structured education sessions (Al-Yassin et al., 2013; C. G. Taylor et al., 2012), insulin prescribing charts (McIver et al., 2009), insulin charts that incorporate prescribing guidance (Donihi et al., 2006; Hamilton et al., 2013; Rushmer & Voigt, 2008), a diabetes specialist nurse prescriber service (Courtenay et al., 2007), a high-dose insulin validation guideline (Dooley et al., 2011), a medicines reconciliation sticker (V. Tully et al., 2018), and the use of electronic software to calculate required total daily and bolus insulin doses (Donsa et al., 2016). None of the studies studied the impact of introducing electronic prescribing software or insulin order sets.

There was a lack of consistency with respect to the methodology and outcome measures used in the studies. Seven studies measured the reduction in insulin prescribing errors (Al-Yassin et al., 2013; Courtenay et al., 2007; Donihi et al., 2006; Donsa et al., 2016; Dooley et al., 2011; Hamilton et al., 2013; C. G. Taylor et al., 2012), 3 studies measured the accuracy, clarity and completeness of prescriptions (Kowiatek et al., 2001; Rushmer & Voigt, 2008; V. Tully et al., 2018), and one measured opportunity for error as a result of unclear prescribing (McIver et al., 2009). The types of intervention varied, as well as the implementation strategies, and measures of improvement between studies (see Appendix 5). Although 3 studies used the United Kingdom's National Inpatient Diabetes Audit (NaDIA) methodology and data collection tool, the follow-up period, interventions, implementation, and the data reported were varied, hence it was difficult to pool data or make meaningful comparisons (Al-Yassin et al., 2013; Hamilton et al., 2013; C. G. Taylor et al., 2012).

The introduction of simple, small focused interventions led to an improvement in the completeness and accuracy of insulin prescribing, particularly when they involved 'hard stops' (such as pre-printing 'units' on dedicated insulin prescription charts to avoid misinterpretation of 'u') (Hamilton et al., 2013; McIver et al., 2009; Rushmer & Voigt, 2008). McIver et al. implemented a standardised insulin prescribing form incorporating pre-printed 'units' and mealtime associations (McIver et al., 2009). As a result, they reported a reduction in the opportunity for error as a result of non-standard abbreviations from 41.8% to 12.2% and unclear frequency from 65.9% to 6.5%. Hamilton et al. saw a reduction in NaDIA-reported insulin prescribing errors from 65% to 14% and later 2%, after making the same changes to their dedicated insulin chart, as well as including practice guidance and using root cause analysis (Hamilton et al., 2013).

Rushmer et al. created a subcutaneous insulin 'care cluster' and used a Plan-Do-Study-Act (PDSA) approach to design and implement changes to their dedicated insulin prescribing chart, involving both a multi-disciplinary team and patients in the process (Rushmer & Voigt, 2008). Prescription accuracy did not increase significantly as a result (84% to 87%); however, by simply dedicating space for insulin device to be documented on the chart, prescriptions improved in their 'completeness' from 11 to 100%. A smaller quality improvement project undertaken by Tully et al. focused on the medicines reconciliation process of insulin on admission to hospital (V. Tully et al., 2018). Using continuous improvement methodology, the design and introduction of a sticker to prompt accurate and complete prescribing of insulin on admission resulted in an increase in insulin medicines reconciliation from 64% to 91%.

Both Taylor et al. and Al-Yassin et al. describe the impact of a single educational intervention involving junior doctors (Al-Yassin et al., 2013; C. G. Taylor et al., 2012). The amount of NaDIA-reported errors reduced from 15.4 to 7.8% ($p<0.05$) and 32% to 17% ($p>0.05$), respectively. Studies more commonly involved a multimodal interventional strategy including a variety of healthcare professionals, which seemed to result in a more substantial improvement in insulin prescribing.

All studies discussed above were non-randomised, hence making it difficult to attribute any quality improvement measures to the impact of interventions alone.

2.3.3 Adherence to national guidelines

None of the studies reported on interventions designed to increase adherence to the UK national recommendations on insulin prescribing safety, for example the implementation of the insulin passport. Twenty-four studies described interventions to improve the adherence to American Diabetes Association guidance, specifically the recommendation that basal bolus correctional insulin regimens are used in non-critically ill inpatients with diabetes instead of subcutaneous sliding scale insulin monotherapy. Two of these studies were cluster randomised controlled trials (Schnipper et al., 2010; Wexler et al., 2010), 2 were cohort studies (Noschese et al., 2008; Wesorick et al., 2010) and 20 were uncontrolled before-after studies. Most studies were conducted in the United States (n=17). Three studies were conducted in Canada (Doyle et al., 2014; Harbin et al., 2015; Helmle et al., 2017), 2 in Australia (Lehnbom et al., 2009; V. W. Wong et al., 2016) and 2 in Spain (Ena et al., 2009; Gomez-Huelgas et al., 2014).

Most studies measured outcomes as the difference in prescribing patterns (change in percentage of subcutaneous 'sliding scale' insulin or basal bolus correctional insulin regimens prescribed); others measured this as percentage patient-days on subcutaneous 'sliding scale' insulin or basal bolus correctional insulin (Wesorick et al., 2010) or percentage of orders for different combinations of insulins (Lehnbom et al., 2009). Results from studies reporting the same outcome measure are shown in Figure 2.2.

Studies mainly described small-scale local change at a microsystem (e.g. ward) level, or single institution level. Three studies described large scale, resource-heavy initiatives involving more than one hospital site (Helmle et al., 2017; Mulla et al., 2015; V. W. Wong et al., 2016).

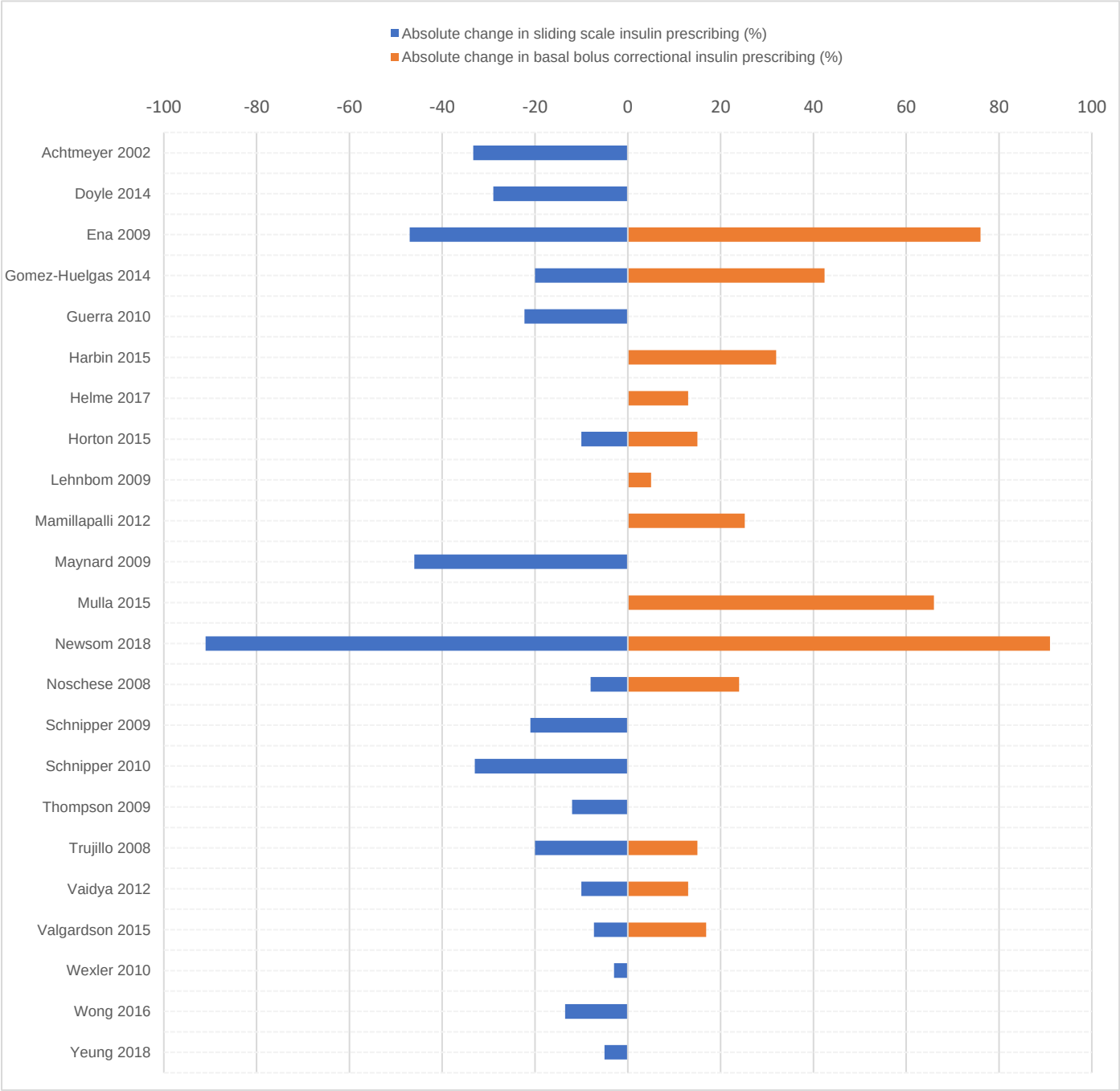


Figure 2.2: Absolute change in prescribing patterns (reduction in subcutaneous 'sliding scale' insulin or increase in basal bolus correctional insulin) reported in studies after implementation of intervention (vs before the intervention), or in the intervention group (vs control group) (%).

Most interventions involved the introduction of insulin order sets using computer physician order entry (CPOE) or a dedicated insulin order form, often including decision support tools such as guidelines or dosing algorithms. Eleven studies described the implementation of electronic insulin order sets (Achtmeyer et al., 2002; Donsa et al., 2016; Guerra et al., 2010; Helmle et al., 2017; Maynard et al., 2009; Newsom et al., 2018; Schnipper et al., 2010, 2009; Valgardson et al., 2015; Wexler et al., 2010; Yeung et al., 2018). Most significant improvements were seen when prescribers were required to use insulin order sets to prescribe insulin (i.e. there was no other option).

Yeung et al. reported only a small, non-significant reduction in subcutaneous 'sliding scale' insulin use from 52% to 47% with the optional use of a new computerised insulin order set containing basal bolus correctional insulin ordering options, where there were previously only subcutaneous 'sliding scale' insulin monotherapy order sets (Yeung et al., 2018). The main limitation was the failure to study uptake/use of the order set, which would have helped to examine the intervention's effect more completely. Wexler et al. implemented a similar insulin order set and also found only a very slight reduction in subcutaneous 'sliding scale' insulin use (35% vs 38%). Authors suggested that this was likely to be due to the optional use of the order set along with minimal support for its implementation (Wexler et al., 2010). Where multiprofessional provider education campaigns supported the implementation of order sets, such as reported by Mulla et al. (Mulla et al., 2015), success of the intervention was greater (e.g. up to 66% absolute increase in use of basal bolus correctional insulin prescribing).

Newsom et al. described the large-scale transition of an entire organisation to the use of an electronic glucose management system integrated with the hospital's electronic health record. The ordering of insulin became simpler and more standardised, and the use of subcutaneous 'sliding scale' insulin monotherapy dramatically reduced from 95% to 4% (Newsom et al., 2018). Wong et al. described the reduction in subcutaneous 'sliding scale' insulin monotherapy use from 16.7% to 3.2% (p=0.014) after the introduction of a mandatory insulin prescribing chart necessitating a doctor's prescription for every single insulin dose in each patient (V. W. Wong et al., 2016).

Educational initiatives mostly complemented the introduction of other interventions and were only described as the sole intervention in 2 studies. Horton et al. reported that face-to-face education of medical residents on the 2009 American Diabetes Association Guidelines for inpatient insulin use alone saw a reduction in subcutaneous 'sliding scale' insulin prescribing from 62% to 52% (p=0.289) (Horton et al., 2015). Details of the session content and delivery were not reported in the sufficient detail to allow for further analysis and conclusion. Vaidya et al. similarly reported statistically non-significant reductions in subcutaneous 'sliding scale' insulin use (25 to 15%) following the introduction of a computerised educational module across the endocrinology department (Vaidya et al., 2012).

Despite the outcome measures being similar across several studies, the difference in characteristics of the organisation, comparators, interventions, their combination, and implementation did not allow for a statistical comparison between studies. Meta-analysis, subgroup analyses and meta-regression were therefore deemed unsuitable.

2.4 Discussion

Although several studies reported on the effectiveness of interventions to increase adherence to insulin prescribing guidelines, the range of heterogeneous study designs, differences in implementation and outcome measures limits the validity and generalisability of conclusions. Despite this, a number of key findings are of interest.

First, the introduction of mandatory, dedicated insulin prescribing documentation can lead to significant improvements in insulin prescribing accuracy and completeness. The introduction of pre-printed 'units' on a dedicated prescription form designed to increase insulin prescribing safety is an excellent example of how a simple intervention reduces the opportunity for a knowledge-based error or writing error. In the United Kingdom, insulin prescription form design to promote insulin safety has been encouraged nationally with the Rowan Hillson Insulin Safety Awards, which enables the sharing of good practice in this area (60, 61).

Second, educational interventions comprise an important part of quality improvement strategies but tend to be less effective when used in isolation. Similar results were found in a review by Kamarudin et al. concerning educational interventions to improve prescribing performance, concluding that multifaceted interventions where education was incorporated into a system-based approach produced more positive results (Kamarudin et al., 2013). Educational interventions targeted at non-medical prescribers and involving feedback to prescribers was missing from the studies included in the review. With increasing numbers of non-medical prescribers being active in the inpatient setting, research into the impact of non-medical prescribers on insulin errors should be encouraged (Cope, Abuzour, & Tully, 2016).

The implementation of electronic insulin order sets had a positive impact on insulin prescribing quality, although the extent of the impact varied. These results echo a previous systematic review that concluded that the implementation of computerised physician order entry (CPOE) reduced medication errors in the hospital setting by around half, although the studies were highly heterogeneous and seldom reported the desired contextual and implementation variables (Nuckols et al., 2014). In the present review, all studies reporting on the implementation of electronic insulin order sets concerned the use of subcutaneous 'sliding scale' insulin versus basal bolus correctional insulin or the calculation of total daily insulin doses. Although the NaDIA has shown that insulin errors are slightly less likely to occur with the use of electronic prescribing compared to paper prescriptions (17.1% vs 19.5%), this is not specific to insulin prescription errors, as NaDIA defines insulin errors as those including insulin management errors (NHS Digital, 2020). There were no included studies showing the impact of electronic prescribing on insulin prescribing errors, accuracy and completeness that could be applicable in the context of hospitals in the United Kingdom.

Applying the results to Reason's error theory (J. T. Reason, 1990), we find that most published interventions are targeted at addressing errors deriving from organisational processes (e.g. education addressing lack of training in

diabetes or insulin use), lapses (e.g. pre-printed prescription proformas prompting prescribers to include all elements of the insulin prescription), mistakes (e.g. validation policies addressing unintentional dosing errors) and violations (electronic order sets addressing prescribers' non-application of insulin prescribing guidance). The results indicate that interventions designed to reduce active errors (such as lapses, mistakes and violations) may be more effective, particularly when they are mandatory. Due to the number of studies reporting on the impact of more than 1 type of intervention (e.g. education plus order set), it is difficult to draw conclusions about which types of error are best to address when attempting to prevent insulin prescription errors.

Improvement strategies involving system change that engage multiple stakeholders at various levels were more likely to be effective and sustainable, which is consistent with principles of total quality management (Pereira & Aspinwall, 1997). None of the studies identified reported taking a whole systems, human factors approach to intervention design and there was a lack of use of models such as the SEIPS that facilitated consideration of the wider organisational factors that can impact on the sustainability of intervention use. Due to the variety of organisational, process and systems contexts described, there is scope to further explore how and why certain interventions work in these different contexts and settings. This level of analysis was missing from included studies, which focussed more on the impact of the intervention rather than exploring issues of design and implementation.

Notably, there was a lack of reported patient involvement in the design, evaluation and reporting of interventions being implemented. The current drive for people with diabetes to self-administer and/or self-manage their insulin in hospital would be further supported by evidence linking this practice to reductions in prescribing errors (Flanagan, Dhatariya, Kilvert, & group, 2018). Although arguably resource-intensive (and not without other limitations described in **Chapter 1**), routine use of the National Diabetes Inpatient Audit (NaDIA) in the United Kingdom can provide organisations with valuable data with which to monitor and benchmark their performance with respect to insulin prescribing errors and patients' experience. Along with other national insulin safety initiatives such as the Rowan Hillson award, these tools can facilitate individuals and organisations to further direct and drive improvement in this area (U. Dashora et al., 2015).

Challenges and limitations

This review aimed to be exhaustive by including all study designs and reporting any outcome of interest. However, only English-language studies were included, which may have excluded studies published in different languages. This review was also conducted prior to the very recently published JBDS guidelines that outlines how insulin should be prescribed in the inpatient setting (see section 1.5.2). It may be anticipated that future studies conducted in the UK may use these guidelines to measure the impact of interventions on insulin prescription quality (absence of errors, accuracy, completeness).

Differences in operational definitions across geographical locations presented difficulties in the initial searching and selection of articles. For example, the use of the term 'sliding scale insulin' in the United Kingdom is mostly reserved for the use of variable rate intravenous insulin infusions due to the non-routine use of 'sliding scale' subcutaneous insulin regimens as described in the American literature. Articles were therefore identified in hand-searches that were not identified or retrieved in the initial stages of searching. A uniformity of terminology would therefore aid future reviews of this nature.

Studies also varied in how they defined an insulin prescribing error. The use of the NaDIA methodology may offer a way of standardising this somewhat, although this is not without its limitations. Documentation of insulin device and concentration, for example, are not included as insulin prescription errors, which may limit the representativeness of the entire range of insulin errors encountered in practice. Standardisation of definitions of insulin prescribing error, along with a theoretical justification for interventions would facilitate evidence interpretation.

Overall, the conclusions drawn are somewhat limited by the quality and heterogeneity of the included studies. The overall risk of bias across studies was high due to the majority of studies adopting uncontrolled before-after study designs. It is appreciated that the design and implementation of interventions will depend on many institution-specific factors such as current practice, structures, culture, staff education, and workflow processes. The difference in organisational behaviour and practice between settings within and between hospitals often means that large randomised studies with effective blinding and controlling for confounding factors is often not possible when it comes to studying prescribing interventions involving inpatients. Nevertheless, studies with more rigorous designs that are powered to detect changes in insulin prescribing errors are needed and should be reported in sufficient detail to facilitate evidence interpretation and uptake. Inclusion of discussions of local context, organisational motivation and readiness, barriers and facilitators, and sustainability issues, including economic evaluations would facilitate assessment of the feasibility, spread potential, sustainability and effectiveness of insulin prescribing interventions.

2.5 Stakeholder group discussions

The results of the systematic review were presented at the Lay Advice for Diabetes and Endocrine Research at Sheffield Teaching Hospitals NHS Foundation trust. A lay summary of the results of the review and the proposed research (mixed methods study) were circulated to the panel prior to the meeting. A number of questions were asked of the panel in preparation for the discussion, including those listed in Box 2.1:

Box 2.1: Example questions asked in the first LADDER panel PPI meeting

- Do you think insulin use in hospital is a problem, and/or one worth investigating?
- Is the research question clear?
- Do you think the project is worthwhile and would you support it in principle?
- Is the reason for the research clear?
- Do you think there is anything that could be done to make the project more acceptable to patients?
- Are incentives are acceptable and adequate?
- Can you think of any ways to improve the research?

The questions were adapted from Patient Public Involvement (PPI) resources available online produced by the National Institute for Health Research (NIHR) INVOLVE group and Diabetes UK. During the meeting, I presented the results and research proposal to the panel, and the above questions were discussed further. Discussions suggested that the topic was important to people with diabetes, and supported the investigation of insulin prescribing practice in the hospital setting. Box 2.2 contains a summary of the verbatim written feedback as circulated by the panel secretary following the meeting:

Box 2.2: Feedback from the LADDER panel regarding the systematic review and proposed original research

- *Yes – it is worth investigating a) to see if it is a problem, b) to find better ways of prescribing/delivering insulin in hospital.*
- *Definitely worthwhile.*
- *Very interesting.*
- *From a personal point of view, I've never been admitted hospital since having diabetes. However, the thought of someone else determining how much and when I get my insulin frightens the life out me, as it takes control away from me (unless that someone is a member of MY diabetic team, e.g. Consultant, Registrar or DSN). So definitely worth investigating.*
- *Yes [the research question is clear] but it needs to be specific that this is about prescribing insulin for in-patients.*
- *Yes [the project is worthwhile and we would support it in principle]*
- *Yes [the reason for the research is clear] – to improve how much/when insulin should be prescribed and reduce errors (which will result in hypo/hyperglycaemia)*
- *Involving patients in all aspects of the project, not just interviewing them for their opinions, but letting them know what issues staff members have, and how staff think these issues can be resolved.*
- *Yes – the biggest potential benefit (and thus incentive) if the project is successful is patients retaining control of their insulin regime (big motivator!)*

2.6 Implications for original research

In general, there is a dearth of literature on the topic of insulin inpatient prescribing practice intervention use and effectiveness in a UK context, particularly at a multi-organisational level. Reflections on the results in relation to the researcher's professional experience lead to the conclusion that many interventions that have been designed and used to reduce insulin prescription errors are not widely reported in the literature. This suggests that the development of a tool that can capture information about the use of interventions across UK hospitals would be useful to help describe current practice and identify areas for future development.

Although there were many studies reporting intervention impact on adherence to American Diabetes Association (ADA) guidance, there were no studies reporting on adherence to UK national guidance. The design of the original research of this thesis should therefore incorporate questions around the use of interventions supported nationally in the UK by NICE – namely the insulin passport, non-abbreviation of 'units' on prescriptions, and the implementation of insulin self-administration policies. Although the practices reported in North American studies are less applicable to a UK context (e.g. interventions to discourage the use of subcutaneous sliding scale insulin monotherapy), the interventions used to do this, for example electronic insulin order sets, may be used in a UK context. No interventions to improve insulin prescribing practice were targeted at inpatients with diabetes. This is perhaps unsurprising considering the types of intervention identified, and would support the design of research that aims to elicit healthcare professionals' opinions on intervention design, use and evaluation.

Studies identified in the review reported effectiveness of insulin prescribing safety interventions by measuring reduction in insulin errors or increased prescription accuracy/completeness. Comparing intervention effectiveness is, however, restricted by differences in implementation and use in different contexts, organisational factors (such as available staffing and resources), and data collection methods. Measuring perceived effectiveness of interventions is also a way of circumventing the above limitations for the purposes of identifying salient strategies nationally (Blendon et al., 2002). Perceived effectiveness - *"the extent to which the intervention is perceived as likely to achieve its purpose"* (Sekhon et al., 2017), can indicate levels of support, acceptability and scepticism towards adopting recommended interventions irrespective of current intervention use (Rosen et al., 2005). Insights of perceived effectiveness from healthcare professionals can be used to garner support for the wider implementation of interventions and focus national insulin improvement efforts.

There is currently no tool to assess the perceived effectiveness of inpatient insulin prescribing safety interventions. An opportunity therefore exists to conduct research that helps us to understand healthcare professionals' perceptions of effectiveness regarding a range of inpatient insulin prescribing practice interventions. This review has enabled the identification of a range of interventions used globally to help improve inpatient insulin prescribing practice, providing a good foundation on which to base the design of original research and associated tools.

2.7 Summary

Evidence-based interventions are required to help tackle the problem of insulin prescription errors that have the potential to cause serious harm. Interventions that are sensitive to the local context and designed to increase adherence to insulin prescribing guidelines are associated with a reduction in insulin prescribing errors. The use of multiple interventions involving various stakeholders at different institutional levels may help to reduce insulin prescription errors. The lack of UK-based studies on insulin prescription error reduction and intervention use prompts the design of original research to investigate insulin prescribing practice and intervention use further in a UK context. The next chapter describes the methodology and methods used in this research.

Chapter 3: Methodology and Methods

This chapter discusses and justifies the approach, study design, and methods used to address the research questions outlined in **Chapter 2**. This chapter includes the following:

- Methodology and research design.
- Patient public involvement and participatory health research approach.
- Study methods, including research ethics and governance.

3.1 Methodology and design

The processes involved in insulin prescribing, and the use of interventions that aim to make these safer, were shown in **Chapter 1** to be inherently complex. The best way of understanding how to make insulin prescribing safer should therefore seek to consider multiple perspectives as well as to explore the context in which they are situated. As the need for this research has arisen in response to a current, real-world problem impacting patient safety, and concerns practical solutions to be implemented, it sits within a pragmatic paradigm. This is where the choice of methodologies is directed by their ability and appropriateness to answer the research questions (Creswell & Clark, 2017, p41).

The methodology chosen also reflects the philosophical, ontological, and epistemological positionality of the researcher. This positionality aligns with that of critical realism, as described by Bhaskar and Sayer (Bhaskar, 1997; R. A. Sayer, 2000), which is grounded in way of understanding society that proposes the existence of a reality that exists independent of our thoughts about it, or our observations of it. This reality exists in layers. Only the surface layer of reality comprises observable events; underneath there are additional layers that are not directly perceivable, and we are unable to empirically capture their essence. These deeper layers contain mechanisms, or causal forces (such as motives and interests) that produce reality at the empirical (observable) level (Bhaskar, 1997; Jagosh, 2019).

Critical realists argue that while interpretative understanding is an important and necessary feature of any social science, there is also scope for causal explanation (Bhaskar, 1997). Critical realism thus sits between positivism and constructivism as it searches for the alignment between reality and our constructions of reality, and therefore lends itself to a relativist epistemology. This is particularly characteristic of the scientific realism described by Pawson and Tilley (1997), Sayer (2000), and Miles and Huberman (1994), who argue that:

> *"social phenomena exist not only in the mind but also in the objective world, and that some lawful and reasonably stable relationships are to be found among them."* (Miles and Huberman, 1994, p4.).

Although a universal truth is assumed, our knowledge of this truth is only partial. Therefore, although we may seek to uncover this objective reality using a variety of methods and techniques, our interpretations should always be tentative and cautious.

Critical realists are interested in generative causation, but cannot escape from their particular positions in the world through the rigorous use of methods (N. King, Horrocks, & Brooks, 2019). This is especially true in the context of this study, where the researcher is studying the use of complex, socially contingent interventions in open and naturalistic systems that they are somewhat 'embedded' in. This is a disparate position to that of positivists, where the study of phenomena must exist in a controlled environment, free from external influences or 'bias' from the researcher and study conditions.

The combination of phenomena being studied that are both 'real' (e.g. insulin errors, intervention use, the act of prescribing) and 'constructed' (e.g. confidence, perceptions of effectiveness, clinical inertia) lends itself to a methodology that can accommodate both inductive and deductive approaches to provide a more complete and corroborated understanding of the research problem. This study conforms to the view of scientific realism, which seeks to combine scientific rigour comparable to positivist approaches with the relativist emphasis on understanding the worldview of the participants.

A methodological approach that can expansively explore contextual factors and engage in complexities of open systems in healthcare is congruent with this ontological and epistemological position. The use of mixed methods approaches facilitates both the quantification and description of insulin prescribing processes and interventions, as well as the exploration of perceptions and insights into the experiences of those for whom this has immediate currency. The additional use of realist synthesis allows a single intervention of interest to be explored in-depth, and the contexts in which it works to be unearthed and theorised. The research design is summarised in Figure 3.1:

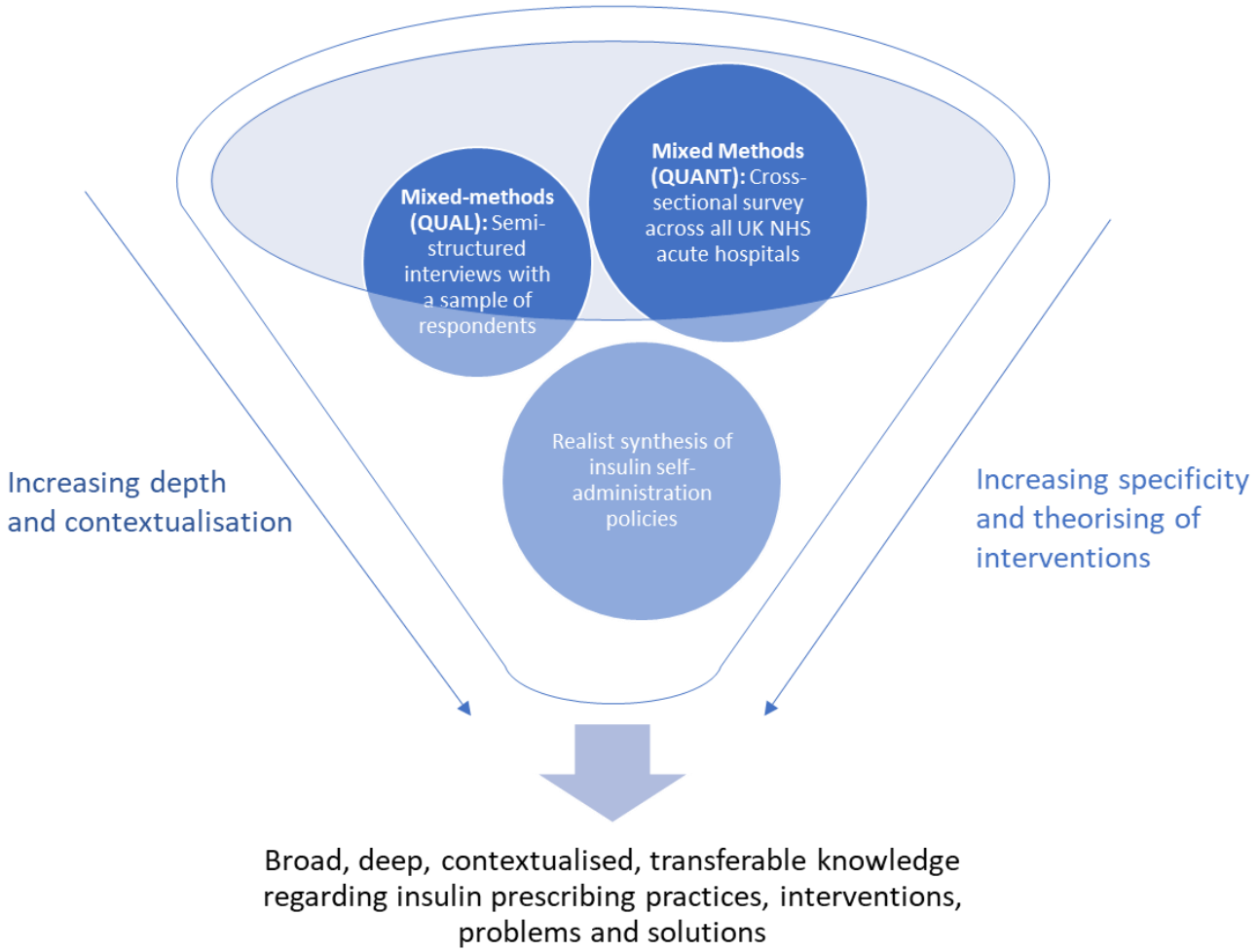


Figure 3.1: Overview of research design.

Using a funnelling approach to the research design enables the investigation of the broader topic of insulin prescribing safety interventions, followed by a more in-depth study of interventions identified as salient by the research and stakeholder team following discussion of results. This has benefits for both transferability and importance of the research findings within a national and local context, both of which are needed to enable impact and change for the benefit of patient safety.

The next section will describe the approaches used and will provide an overview of the study design, which incorporates both a national mixed methods study of insulin prescribing interventions and a realist synthesis of a particular intervention.

3.1.1 Mixed methods research

Mixed methods research design is an approach that involves the collection, analysis and integration of both quantitative and qualitative data in such a way as to provide a better understanding of a research problem than either approach would achieve in isolation (Creswell & Clark, 2017). Originating as a "distinct and self-conscious strategy" in the 1980s-1990s (J. A. Maxwell, Chmiel, & Rogers, 2015), mixed methods research is an evolving methodology that has gained traction in healthcare services and clinical pharmacy research in recent years due to its advantages over mono-method approaches, particularly relating to the study of complex systems and patient-centred care (Hadi & Closs, 2016; Mertens, 2018).

There are multiple definitions of mixed methods research, along with variations in underpinning paradigms, ranging from that which is essentially constructivist in nature to that which is positivist (Teddlie & Tashakkori, 2009). In keeping with the critical realist position of the researcher, it is assumed that both types of data can be integrated in a single paradigmatic position, as proposed by Hall (in Lê & Lê, 2013). This position is important for both the design and the criteria on which the quality of the study is judged. The mixed methods research study design is described below.

Mixed methods study design

The types of mixed methods studies may be categorised based on the timing, interaction and dominance of each component of the study (Creswell & Clark, 2017). These include designs whereby qualitative and quantitative components are conducted simultaneously (convergent parallel design), separately (explanatory sequential or exploratory sequential designs) or where one component is subsidiary to another (embedded design).

This study follows an explanatory sequential design, where the quantitative data is collected and analysed prior to the qualitative data collection and analysis. The quantitative phase provides a general understanding of the research problem and helps to answer descriptive questions about insulin prescribing processes and interventions. The qualitative data and their analysis help to refine and explain the findings of the quantitative component by exploring participants' views in more depth (Ivankova, Creswell, & Stick, 2006). Notwithstanding the strength of this approach, this design is time-intensive and requires the researcher to be familiar in the use of both quantitative and qualitative techniques. A visual model for the mixed methods study design is given in Figure 3.2.

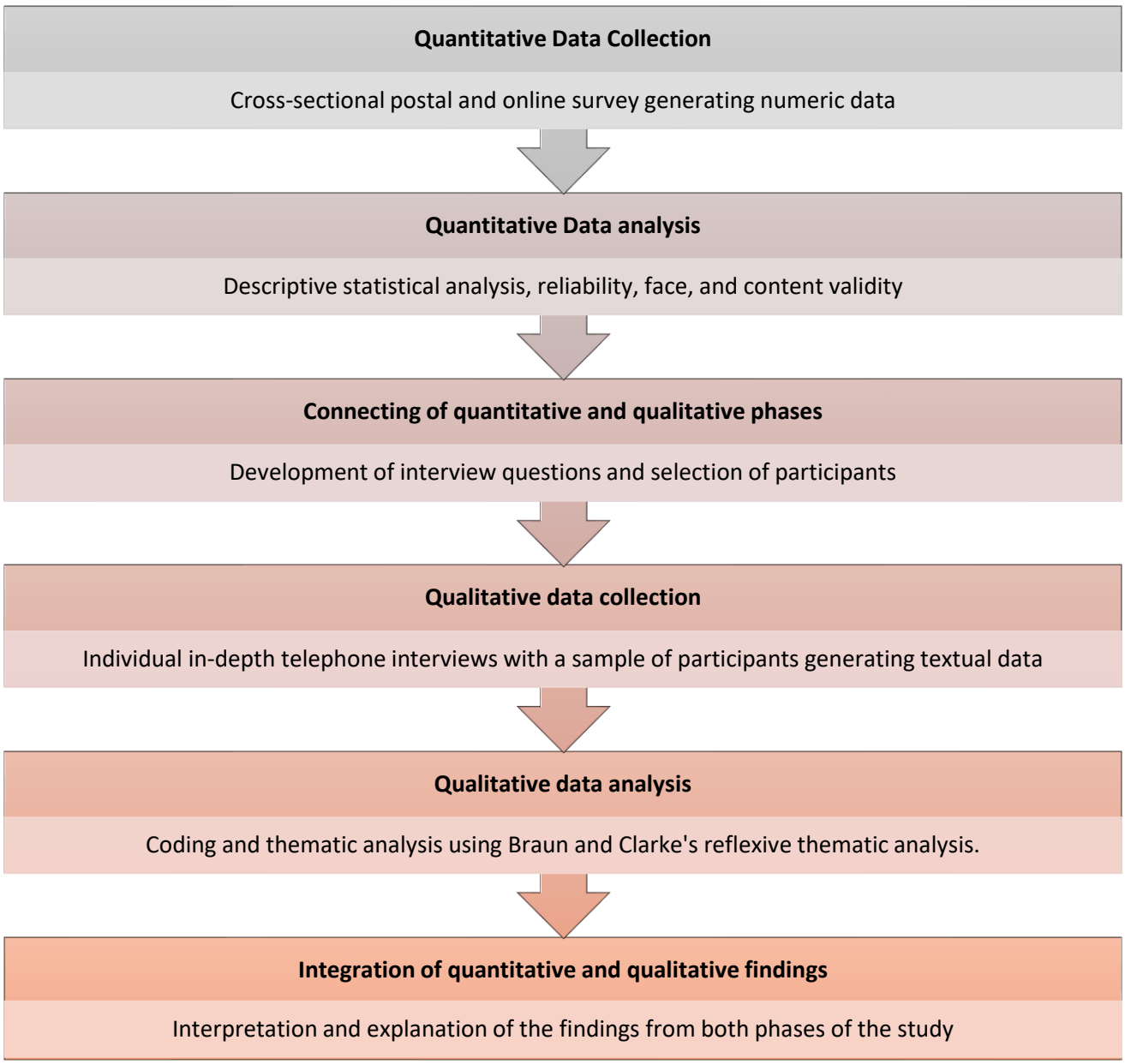


Figure 3.2: Mixed methods study design

Although often in this design, the initial quantitative component is given priority in answering the research question (Hadi & Closs, 2016), this study gives an equal value and weighting to both the quantitative and qualitative phases, which has previously been described by Ivankova *et. al.* (2006). This decision was influenced by the research questions, which involve in-depth exploration of the factors that impede on the success of insulin prescribing interventions, as well as being contingent with the epistemological position of the researcher.

Integration of the quantitative and qualitative components occurs at the beginning of the study in the formulation of the research questions, as well as at the intermediate stage, where the results from the

quantitative study inform the data collection in the qualitative study. The results from the survey inform the development of the interview guide for the qualitative study, such that the results of interest can be explored in greater depth with participants. A variety of participants were included to represent a variety of hospitals, based on organisational characteristics included in the quantitative phase (e.g. presence of diabetes pharmacist at the trust). Data integration at the interpretation level in this study involves a narrative approach that reports both types of data in a staged way, where quantitative results were reported first, followed by qualitative results (Fetters, Curry, & Creswell, 2013). If any conflicting findings were found between the quantitative and qualitative studies, these would be discussed in the respective chapters. The results from both phases were then discussed together in **Chapter 7,** enabling a robust and meaningful treatment of the research questions. The use of alternative data integration approaches that employ quantification of qualitative data, or use qualitative data to verify, dispute or corroborate quantitative data was rejected for this study on the basis that they would not have been epistemologically consistent and would not serve to answer the research questions.

Critical reflections on the findings from the mixed methods directed the design of the subsequent realist synthesis. The focus on a single intervention of significant importance for patients, staff, and policymakers, as well as the study participants, facilitates a greater in-depth exploration and examination of detailed organisational and contextual factors that impact the outcomes of the intervention. This enables the generation of meaningful knowledge regarding a complex and socially contingent intervention that operates in an open system where multiple, diverse healthcare professionals and patients are involved.

3.1.2 Realist Synthesis

"Interventions are theories incarnate." – Pawson and Tilley (1997)

Realist synthesis (otherwise known as realist review) is a theory-driven methodology grounded in the principals of scientific realism, that is concerned with generating an in-depth understanding of an intervention's architecture and the context in which it produces certain outcomes. A realist perspective would argue that an intervention does not simply produce an outcome with an effect size. Instead, it alerts context[1] (e.g. making resources available) that triggers mechanisms that exist in the deeper layers of reality (e.g. trust between patients and pharmacists) which produce both intended and unintended

[1] It should be noted that in realist terms, context refers to specific elements in the backdrop of an intervention, such as cultural norms and environments in which the intervention is implemented, rather than the overall setting (e.g. a large teaching hospital).

outcomes. As such, an intervention may work well in one context but not in another (G. Wong, Greenhalgh, Westhorp, Buckingham, & Pawson, 2013).

The results of the systematic review in **Chapter 2** suggest that an array of factors influence the success of any given insulin prescribing intervention. Particularly in complex organisational settings (such as that of a hospital), intervention outcomes will be somewhat determined by the interplay with organisational factors and socio-cultural influences. These elements of context cannot be 'controlled', particularly in a dynamic environment such as a hospital ward. This makes the use of traditional evaluative methods (using positivistic approaches) limited in their ability to generate transferable knowledge about the design, implementation, and effectiveness of interventions. Indeed, the dynamic interactions and contextual factors often seen as 'confounding factors' in experimental designs should be studied in and of themselves as vital ingredients in relation to attributing causation and facilitating sustainability to any complex intervention (Craig et al., 2008; Greenhalgh & Papoutsi, 2018).

Realist approaches are underpinned by an understanding that there is more to reality than we can perceive (often referred to as 'ontological depth') but we are able to 'unearth' the hidden mechanisms that underpin causal forces (known as 'retroduction' or 'retroductive theorising'). Realist approaches assert that intervention outcomes are the product of particular responses by people (mechanisms), within given circumstances (context) and therefore allow for the exploration of how and why the intervention works, for whom, and in what circumstances (Pawson & Tilley, 1997). This is distinct from the traditional systematic review approach described in **Chapter 2**, which seeks to answer the question 'does the intervention work?' and quantify 'how well?'.

Realist synthesis involves the secondary analysis of multiple primary analyses in an iterative, non-linear process to develop a conceptual model that aims to make explicit (and configure) elements of context, mechanism and outcomes relating to an intervention, and thus create an empirical theory of how and why the intervention works. An illustrative example of how these are defined and presented is given in Figure 3.3 below:

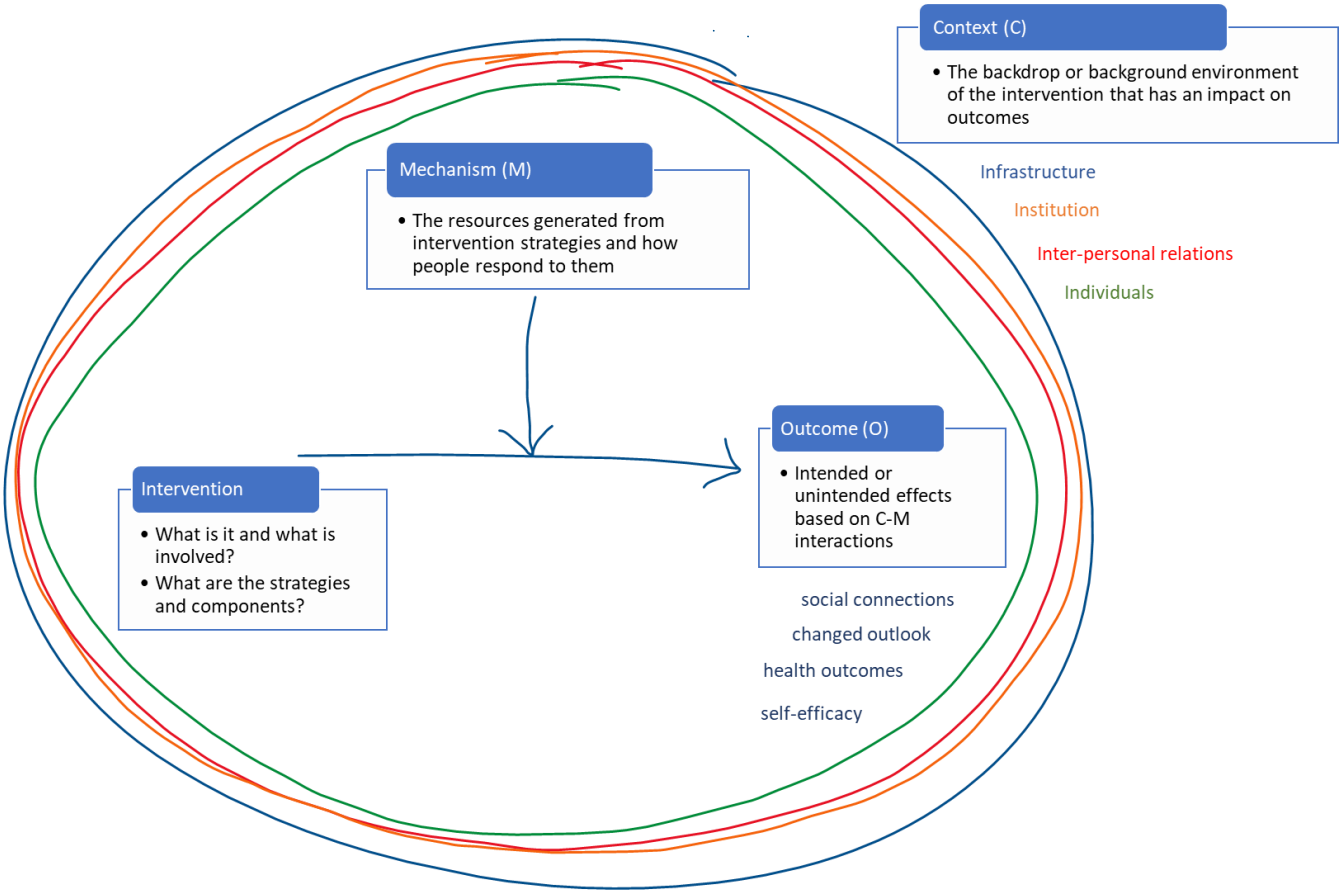


Figure 3.3: Illustrative interaction between context, mechanism, and outcome in realist research. Adapted and expanded from Pawson and Tilley, 1997, p58

The development and refinement of these context, mechanism outcome configurations (CMOCs) into a testable 'programme theory' combined with evidence, are the product of realist synthesis (Pawson, 2002). Programme theories seek to identify the intended outcomes of an intervention and the mechanisms and contexts that affect its success, or lack thereof (Pawson, 2006b). The identified programme theories may then be tested and further refined through the process of realist evaluation, which involves the primary collection and analysis of evidence from intervention users and providers. Realist evaluation is outside of the scope of this thesis but is described briefly in **Chapter 7** (**section 7.5**).

A key feature of realist synthesis is the systematic involvement of stakeholders throughout the process; their expert insider understanding of policy use is documented, formalised, tested, and sometimes arbitrated to produce theories that account for different ways in which the policy is framed across different organisational and professional boundaries (Pawson, Greenhalgh, Harvey, & Walshe, 2005).

Complex interventions

Pawson and Tilley conceptualise interventions as *'theories incarnate'* that are based on hypotheses about how they work (irrespective of if these hypotheses are realised by the intervention designers). Realist synthesis lends itself well to the study of interventions that are inherently complex, which is defined as having 'social contingency', that is, being 'imbedded in social systems' (Pawson, Haley, Greenhalgh 2005). Complex interventions have multiple elements with different aims, or occur within complex adaptive systems consisting of people who adapt behaviour to improve outcomes from their perspective (Greenwood-Lee, Hawe, Nettel-Aguirre, Shiell, & Marshall, 2016; Moore et al., 2015).

The intervention chosen for further investigation in this study is one which is both complex, and has social contingency, because its use and success may depend on trust, relationships, culture, leadership, understanding, perceptions and motivation of both a variety of staff and patients, as well as the characteristics of the intervention itself (what are its components and how is it meant to work?) (G. Wong et al., 2015).

With the use of realist synthesis, some of these contexts and mechanisms pertinent to the success of the intervention under study may be uncovered, which enables knowledge generated to be customisable to different contexts. Knowing how the intervention works within a context also builds capacity to understand why policies might fail in one setting and work in another. This knowledge will be useful in informing, directing, and implementing this intervention and can help develop a more complexity-sensitive process or outcome measures that may be used in future implementation or evaluation studies.

The Medical Research Council's framework for the design and evaluation of complex interventions (Craig et al., 2008) promotes the use of randomised experimental methods but recognises that this is not feasible in situations where the researcher has no influence on the implementation of the intervention. They stipulate the need to evaluate the process of why an intervention works in order to assess fidelity and implementation alongside outcomes, which includes identifying causal mechanisms and contexts that lead to different outcomes. This is the essence and product of realist research.

Critique of realist synthesis

Realist synthesis aims to explain (rather than judge) intervention use and learns from real-world phenomena rather than controlling it. This is a flexible, theory-based approach that can maximise learning across organisational, policy and disciplinary boundaries (Pawson et al., 2005). The critique of realist synthesis is, however, important to consider, in order to anticipate any issues that may occur during the research process, and to critically consider other perspectives on the approach taken.

Realist synthesis aims to understand the mechanisms and contexts behind how interventions produce positive and negative outcomes. Much of this information arises from analysis of narrative information or qualitative data. Pawson advocates inclusion of a wide range of evidence sources with which to conduct realist synthesis (Pawson 2006). These include opinion, unpublished service evaluation and stakeholder views. This has been met with criticism by Dixon-Woods *et. al.* who posit that treating all types of evidence equally can challenge the robustness of the theory generated (Dixon-Woods, Agarwal, Jones, Young, & Sutton, 2005)**.** The quality of the data included are, however, assessed as part of the process of realist synthesis, albeit using different criteria than in systematic reviews. This will be discussed further in **Chapter 6.**

Another criticism of realist synthesis is the operational challenge that is posed, both intellectually and practically, with identifying and differentiating between contexts and mechanisms and thus developing context-mechanism-outcome configurations (CMOCs). Porter (2015) suggests that the confusion between contexts and mechanisms can undermine the explanatory clarity of realist research.

Finally, the way realist synthesis is conducted does not lend itself to reproducibility in the same way as traditional systematic reviews and is not conductive to rigid protocol-driven approaches. The dependence on the individual researcher's ability to be reflective and explicit may also be problematic for some critics. However, conducting a realist synthesis felt like a natural progression for the trajectory of the research. It also fits well with the participatory health research approach that has been adopted throughout this work. This approach is explained in more detail below.

3.2 Participatory approach

The involvement of patients and the public in the design, conduct and dissemination of research is strongly encouraged as best practice in clinical and health services research (Gray-Burrows et al., 2018). Patient and public involvement (PPI) in research helps to improve the quality, relevance and impact of research, particularly when it involves interventions or services that are designed to improve patient outcomes (Tomlinson et al., 2019). Patient public involvement enables research to focus on issues that matter most to patients (and hence more likely to have beneficial impacts), helps to widen accessibility of study materials, and broadens the sphere of dissemination (Baxter et al., 2016; Gray-Burrows et al., 2018; Ocloo & Matthews, 2016). Patients involved in PPI have reported to feel more empowered to share their experiences whilst directly influencing change, and to contribute to society in a positive way (Wilson et al., 2015).

The involvement of PPI in the research in this study seeks to a embody participatory health research approach, whereby the knowledge and action gap is bridged by undertaking the enquiry with those affected by the issues

being studied (Macaulay et al., 1999). This means that stakeholders such as patients and healthcare professionals are involved in setting research goals, objectives, interpreting results and dissemination of findings, and contextualising the results from their unique positions. This facilitates a 'culture of partnership' between academia and practice, and allows the co-production of knowledge that is more context-specific, and therefore more easily incorporated into changes in practice (Vindrola-Padros, Pape, Utley, & Fulop, 2017).

This research therefore tries to ensure that those for whom the benefit is intended (i.e. patients and healthcare professionals) are at the heart of the research decision-making. This ownership and awareness of the research by the stakeholders helps to improve uptake and sustainability of recommendations resulting from the output, and increases the relevance of the research even throughout the project. In this project, integrated knowledge transition is sought, whereby the audience is found first and then the research is done (rather than traditional research to practice knowledge-transition), making 'practice-based evidence' (L. W. Green, 2009).

Despite some of the logistical and financial drawbacks of establishing and maintaining PPI during doctoral studies, the benefits of PPI to positively contribute to the development of doctoral pharmacy and health research studies has been documented (Tomlinson et al., 2019). As a healthcare professional researcher situated within a hospital trust, the researcher draws on an established PPI group that is experienced in reviewing and being involved in diabetes research. In this project, the Sheffield Teaching Hospitals NHS Foundation Trust Lay Advice on Diabetes and Endocrine Research (LADDER) panel was consulted throughout. This panel consists of 8 patients with diabetes (including type 1 and type 2 diabetes) from the Sheffield area, one of whom is also a health economist. The panel have inputted their views and feedback from the conceptualisation of the study and have been consulted at each stage of the project (e.g. the systematic review, cross-sectional survey, qualitative interviews, and realist synthesis). Outcomes from the discussions are presented throughout the thesis and are also discussed in **Chapter 7**.

The research has also had input from the multidisciplinary diabetes inpatient service improvement team based at Sheffield Teaching Hospitals NHS Foundation Trust throughout the project. This team consists of consultant diabetologists, registrars, diabetes specialist nurses, diabetes link nurses, healthcare assistants, service managers, diabetes pharmacists and pharmacy technicians. The team was involved in direction-setting, tool design and sense-checking and interpretation of the results at each stage of the project. This helped to incorporate valuable insights and alternative perspectives from other members of the multidisciplinary team throughout. This is important for this research topic which involves multidisciplinary efforts to implement research recommendations.

In addition to the two panels mentioned above, additional stakeholders were recruited for the purpose of undertaking the realist synthesis. These included people with diabetes who had had a hospital admission within the past 5 years, and healthcare professionals working in an inpatient setting from across the UK. The composition of this additional group is outlined in **Chapter 6**, along with the nature of the input and discussions for the realist synthesis. Throughout

the research, patients and healthcare professionals involved in the research process (not as participants) are referred to collectively as 'stakeholders'.

The above section has outlined the overall design, methodology and approach of the research, which is presented as two distinct but related studies. Details of the study methods employed in both the mixed methods study and the realist synthesis are explained below.

3.3 Study methods

This section describes the study methods of the two studies, including a brief justification of the methods used, how participants were sampled and recruited, and the processes for data collection and analysis.

3.3.1 Mixed methods study

The mixed methods study comprises a national cross-sectional postal and online survey and semi-structed follow-up telephone interviews with hospital pharmacist participants. The details of the research conduct for the mixed methods study are outlined below:

Quantitative component: Cross-sectional survey

The purpose of the quantitative component to the mixed methods study was to describe current insulin prescribing processes and systems in UK hospitals, along with the range and uptake of interventions currently used to improve prescribing practice. This study was also designed to capture current opinion on intervention effectiveness from those who design, implement and evaluate interventions in practice.

Justification of methods

Cross-sectional studies are one of several observational approaches to investigate events or phenomena in a set population or time-period. As inpatient prescribing processes are undergoing mandatory system-level change across hospitals in the UK with the introduction of electronic prescribing and administration systems (see **Chapter 1**), a description and analysis of the current landscape of practice (and potential factors that may be associated with intervention implementation) would enable us to draw conclusions

related to the research questions. As such, a cross-sectional approach was taken as opposed to alternative observational methods such as retrospective cohort or prospective case control studies.

A cross-sectional approach allows the study of a large population in a convenient way within a reasonable time-frame and with limited resources (Von Elm et al., 2007). The main limitation with a cross-sectional research design is that it is not possible to establish causality of exposure with an outcome. This is not an issue for the current study, however, as the research pertains to complex systems and interventions that are not suited well to studies reporting successive causation of factors with outcomes.

Furthermore, due to the results of the systematic review suggesting that no one intervention is outstanding in reducing insulin errors, it was decided that capturing information on a breath of intervention use was most appropriate at this stage. Other observational methods, such as cohort studies and case control studies would, therefore, not have been as appropriate to capture the information required to answer the research questions. A broad dataset was required to capture information about a wide range of hospital trusts to provide currency for national policymakers and individual organisations alike.

For convenience and accessibility, a postal and online survey was identified as the most suitable method to employ for the cross-sectional study. Cross-sectional studies often employ survey methods to generate measurable data regarding phenomena, events, behaviour, or attitudes in a specific population (Calnan, 2013). Surveys are usually disseminated to participants via email or post, or alternatively, administered by researchers themselves in person or over the telephone (Calnan, 2013). Surveys enable the collection of high-level data across a large sample (Bowling, 2009) but are limited by low response rates and obtainable information. As respondents are all registered, practicing pharmacists in this study, recruitment bias due to linguistic problems was not thought to be problematic. Careful attention to the questionnaire design can limit non-response, for example limiting the length and complexity of the questionnaire and allowing participants the flexibility to write responses via open question boxes. The development of the tool to enable accessibility and maximise response rate is described in **Chapter 4.**

Sampling and recruitment

The aim of sampling in cross-sectional surveys is to draw a representative group of participants from the population of interest (Bowling, 2009). As the topic of interest is insulin prescribing practice and intervention use across a national health system, the entire population of UK National Health Service (NHS) hospital organisations was chosen as the sample to maximise representativeness. Probability or random sampling were thus not employed. This was to ensure external validity of the study and to reduce the chance of random error variation in the sample and bias in the study's estimates.

In order to include all NHS hospitals in the UK in our sample, we chose to direct the survey to the main acute hospital within a single hospital trust, on the presumption that prescribing systems are very likely to be homogenous across the organisation (McLeod, Ahmed, Barber, & Franklin, 2014).

A list of all UK NHS hospital trusts and health boards was obtained from NHS webpages (Health and Social Care Online; Health in Wales; NHS; Scotland's Health on the Web) resulting in a total of 175 trusts/health boards at the time of study. A single representative of each hospital trust was asked to complete the questionnaire. Chief hospital pharmacists, lead diabetes specialist pharmacists or medicines safety officers (MSOs) were chosen as the organisation representative due to their broad knowledge of the prescribing systems used in their trust, particularly with respect to subcutaneous insulin and current prescribing safety interventions in place.

An online version of the postal survey was created using Qualtrics© (Qualtrics, Provo, UT) to help improve response rate (T. Taylor & Scott, 2019). Follow-up emails with a link to an online version of the survey were sent to non-respondents after 4 weeks (where email addresses were publicly available via the hospital webpages), as well as promotion via social media, the UK Clinical Pharmacist Association online forums and via the NHS Improvement Medicines Safety Program network.

Data collection

Postal questionnaires were sent during January 2019 to the chief pharmacist (or specialist diabetes pharmacist/MSO if known) at each hospital trust (see Appendix 4). A cover letter was sent in the postal questionnaire as well as a business-franked return envelope to help increase response rate (see Appendix 5).

The respondents were asked to complete the questions with respect to their main acute hospital. As only one response from each hospital trust was required, and concerned the main acute hospital within the trust, duplicate online responses were excluded if received. Any online responses from non-NHS/private hospitals were excluded upon receipt.

All completed postal and online questionnaires returned by May 10th, 2019 were eligible for inclusion. Data from paper questionnaires were manually inputted into Microsoft Excel 2016. Online data were retrieved from the Qualtrics © platform, incorporated into the dataset and exported to SPSS (IBM V24) for descriptive analysis. Data input was checked by a peer-researcher and a joint decision was made regarding interpretation of any unclear responses.

Research ethics and governance

Ethical approval for the cross-sectional survey was required and granted by the university research ethics committee (SAS-SREIC 4.1.19-3). The project was deemed to be exempt from requiring Health Research Authority (HRA) and NHS Research Ethics Committee (REC) approvals according to the online HRA tool (http://www.hra-decisiontools.org.uk/ethics/). Exemption was granted on account of answering 'no' to all 4 sets of questions for all UK-member countries using the online tool (England, Wales, Scotland and Northern Ireland). Respondents were informed that all data would be anonymised, and their responses would remain confidential.

Informed voluntary consent was assumed by participation and outlined in the cover letter sent with the postal surveys, or on the front page of the online survey. No sensitive or evocative data were collected, and participants were not financially remunerated for responding. The envelopes were coded to maintain anonymity on receipt of paper responses as well as to keep a record of respondent organisation names.

The back page of the survey, where respondents could volunteer their names and email addresses to register their interest in participating in the follow-up interviews, was separated from the rest of the survey prior to data entry. This was done to maintain anonymity in response. All parts of returned paper surveys were securely locked in a cupboard in the researcher's university office for confidentiality. All data were kept on a password-protected Microsoft Excel files on a university-networked computer. Email addresses were deleted after completion of the follow-up qualitative study.

Data analysis

The main outcome for analysis of sections A-D was a binary variable (yes/no) indicating the use of interventions and system functions relating to inpatient subcutaneous insulin prescribing (see Appendix 4). The main unit of analysis for section E was the average score of effectiveness (out of 5) for each intervention. Missing and 'unsure' responses to individual items were classed as 'unknown'. Individual item non-response was not compensated for with imputation methods or weighted adjustment methods. The analysis was restricted to the recorded responses for each item in accordance with the descriptive univariate analysis performed (Brick & Kalton, 1996).

Descriptive statistics were performed by calculating the frequencies of binary variables (and unknown responses) for each item in section A-D, and the mean scores of items in section E. Subgroup analysis was conducted according to the prescribing system used by hospitals (electronic/paper). Any 'unsure' responses regarding categorial data (e.g. the current use of an intervention) were excluded from the

subgroup analysis. Open question data regarding local interventions were grouped according to intervention categories described in the systematic review and were not subject to quantitative analysis.

The null hypothesis was that there was no association between organisational characteristics (e.g. type or location of hospital) and intervention use or perceived effectiveness. Chi-squared and Fishers Exact tests were used to determine associations between two sets of categorical data. The 2-tailed independent t-test for equality of means was used to determine differences between categorical and continuous data. One-sided Fisher's Exact was used when comparing intervention use between hospital types, based on the assumption that teaching hospitals with more resource will use more interventions than smaller district general hospitals. One-way ANOVA with Tukey's HSD was used to compare means between groups of >2, such as hospital type, size, and country (England, Wales, Scotland, and Northern Ireland). A P value below 0.05 was considered significant.

Content validity was performed using the responses from four specialist diabetes pharmacists and Fleiss Kappa (for level of agreement between raters) was calculated. Internal consistency or reliability was analysed using Cronbach's alpha. Criterion validity was not appropriate for this survey as there was an absence of a measure and criterion with which to find any relationship (Rubio, Berg-Weger, Tebb, Lee, & Rauch, 2003). Construct validity testing was initially conducted, but was ultimately deemed unnecessary for this questionnaire. This was because the tool was not specifically designed to be a psychometric scale that described all of the possible dimensions of the latent concept of 'perceived effectiveness' (DeVellis, 2016). Due to the nature of items (which represented interventions rather than constructs of a phenomenon) it was noted that both exploratory factor analysis and confirmatory factor analysis were not suited to this study. Instead, *a priori* categorisations (based on the systematic review) were used to examine score distributions across the questionnaire.

Qualitative component: Semi-structured telephone interviews

The purpose of the qualitative component was to explain the results of the quantitative component, and to analyse the experiences and opinions of hospital pharmacists regarding the use of inpatient insulin prescribing safety interventions. In line with the epistemology of the research, the various perceptions of intervention effectiveness can be elucidated and explored with the generation and analysis of in-depth qualitative data. The next section justifies and outlines the use of semi-structured telephone interviews as the chosen method for this component of the mixed methods study.

Justification of method

Qualitative research aims to study people in their natural social settings and focuses on the meanings the participants attach to their world. Qualitative research seeks answers to questions about the 'what', 'how' or' why' of phenomena, as opposed to questions about 'how much' or 'how many'? (J. Green & Thorogood, 2004). For example, qualitative research is well-suited to answer questions regarding why healthcare professionals may perceive certain interventions to be ineffective at improving insulin prescribing practice, and the perceived problems and potential solutions regarding insulin prescribing.

The chosen methodology and methods for data collection and analysis in qualitative research should be congruent with the purpose of the qualitative study. If the purpose of the study is to generate an all-encompassing theory of insulin prescribing intervention use, then approaches such as grounded theory may be considered, along with its associated methods of data collection and analysis (Corbin & Strauss, 2012)**.** Despite being a common methodology used by those with a relativist epistemology, a grounded theory approach was not chosen for this study. This is because we do not seek to generate theory about insulin prescribing interventions in general, as multiple overarching theories exist that may be relevant for prescribing interventions (see **Chapter 1**). Furthermore, as an embedded researcher with recent experience researching and working in the topic area, it would not be possible to approach the research completely free from any prior assumptions or knowledge of the literature, which is indeed a requirement of the grounded researcher (Corbin & Strauss, 2012).

Those with more interpretivist, constructivist ontological and epistemological persuasions lend themselves to the use of qualitative approaches such as phenomenology, and their associated methods (open interviews, interpretive phenomenological analysis, and discourse analysis) to generate detailed explanations of personal lived experiences and meaning according to their own ideas and frames of reference. Due to the disagreement with a completely constructivist position of epistemology and its integration within a mixed methods approach, interpretivist approaches were not considered as an appropriate overarching methodology for this study.

Positivist approaches tend to adopt very structured data collection techniques with forced-choice answers imposed on the participants and apply quantitative techniques to sampling and analysis. This was not considered to be a suitable approach due to its limited ability to generate in-depth data of interest to answer the research questions.

Methods that facilitate data integration and triangulation, such as follow-up semi-structured interviews with a sample of respondents from the quantitative component, are more congruent with the overall

research design of a sequential, explanatory mixed methods study. The use of interviews for this study is explained below.

Interviews in Qualitative research

Interviews aim to help the researcher discover the participant's own framework of meanings while avoiding imposing their structures and assumptions as far as possible. By using open-ended, neutral, sensitive, and clear questions, they allow the researcher to help uncover contextually contingent mechanisms by which the causes of specific social phenomena might be plausibly be understood (J. Maxwell, 2012).

Interviews may be either structured, semi-structured or open. Within a relativist epistemology, a semi-structured approach is most appropriate to allow flexibility within a given agenda. Open interviews are more congruent with constructivist methodologies, and structured interviews with more positivistic approaches, both of which would be limited in their ability to answer the research questions of this study. In this study, a semi-structured interview guide was used to help direct the course of the interviews. The development of this tool is outlined in **Chapter 5**.

Due to the geographic diversity of the sample of survey respondents across the UK, face-to-face interviews or focus groups with participants would be logistically, environmentally, and financially problematic. Remote interviewing instead allows participants that otherwise would have been excluded on practical grounds to be interviewed. The general inaccessibility and unavailability of high-quality videoconference equipment and fast internet connection speeds across many NHS hospital sites excluded the use of videoconference interviews, therefore one-to-one telephone interviews were chosen as the method of data collection based on increased flexibility and accessibility for participants.

The use of telephone interviews is not without its limitations. The style of interaction may differ from face to face conversation due to the absence of visual and nuance , although this may allow more focus on the research topic and does not necessarily affect the type or quality of data collected (N. King et al., 2019). Conducting the dialogue in the participant's practice site can also provide a more meaningful context (Deakin & Wakefield, 2014) even if this is done remotely, and would allow participants to access any relevant materials for discussion more easily should they need to.

Sampling and recruitment

In qualitative research, the function of sampling is rarely to represent a given population with large numbers, and is usually strategic and purposive, based on who might most effectively and meaningfully answer the research questions according to specific attributes relating to the phenomena of interest

(Yardley, 2000). Smaller samples are often appropriate for qualitative research (Marshall, 1996) because the aim is to describe information-rich accounts of phenomena rather than to generate generalizable knowledge relating to successive causation.

As this was a mixed methods sequential explanatory study, the primary intention was to acquire a sample of pharmacists from a variety of hospital organisations with a range of experience and specific roles relating to insulin prescribing safety, who had completed the survey such that they could comment further on the topic. The sample was therefore conceptualised around the parameters of breadth of experience and knowledge with insulin prescribing errors and interventions across the trusts they were employed in and was drawn from those who responded to the survey who expressed interest in participating in follow-up interviews.

To account for potential non-recruitment, all survey respondents who had agreed to be contacted for interview (n=53) were contacted directly by the researcher and invited to participate in the study via email. Email invitations detailed the purpose, subject, process, and voluntary nature of the study and included a participant information sheet (see Appendix 6). No remuneration for participation was advertised or offered. Survey respondents were asked to reply to the email if they would like to participate, to arrange a mutually convenient time to undertake the interview directly with the researcher. Twenty pharmacists were initially recruited, and interviews were arranged with 18 of them (2 did not respond to follow-up emails).

The eighteen interviewees represented the maximum practically achievable interview sample from the survey respondents and is consistent with recommendations for interview-based studies (Crouch & McKenzie, 2006; Vasileiou, Barnett, Thorpe, & Young, 2018). This enabled an information-rich complement of cases that represented a variety of organisations across the survey sample (according to type, size, and location across the UK). There was no further process of selection from the sample of 20 respondents. This also helped to avoid any unnecessary selection bias.

Data saturation was not regarded as an appropriate strategy to justify the sample size in this project because it is a concept that is coherent with neo-positivist, grounded theory approaches. Braun and Clarke's reflexive thematic analysis was used in this study (see "data analysis" section below), which has distinct values and assumptions that are not consistent with the concept of data saturation (Braun & Clarke, 2019). Instead, consistent with the theoretical approach and nature of phenomenon under investigation, a practical, information-rich sample that could be analysed interpretatively and provided data adequacy for the purposes of answering the research questions was achieved (Vasileiou et al., 2018).

Data collection

All interviews were conducted via telephone at the researcher's university or remote office at the pre-arranged time and date of convenience to both parties. Participants were encouraged to arrange a time to interview that would not impede on their work schedule, in a location that was suitable to them with respect to convivence and confidentiality. Interviewees were informed that the usual length of interviews was around 30 minutes, but this could be flexible depending on their needs/preference.

Interviews were audio recorded using a recording device with an adaptor allowing connection through the researcher's office or mobile telephone. Audio files were uploaded to the researcher's university-networked drive immediately after recording. Interviews followed a flexible structure, which was adapted for individual participants depending on the topics of interest and flow of the conversation. Interviews started with introductory descriptive questions about the participant's occupation and accounts of experiences, followed by questions about concepts/interventions mentioned in the survey and their evaluation of these interventions.

Explanatory questions were thoughtfully asked as well as probing questions throughout the interview, which helped to demonstrate engagement and emphasise interest in what participants were saying (for example linking to earlier comments directly). The interviewer took field notes during each interview including key points, phrases or topics raised during the interview, which facilitated linking back to earlier comments. The interview concluded with reflections and expectations/ hopes for the future to end the interview positively, along with a thorough debrief, which allowed participants to ask any questions and informed them about how their contribution will help study the topic.

The interviews were conducted in a conversational style in keeping with the interviewer's positionality (as a fellow pharmacist working in the context of a hospital), and ability to respond to the participant's questions regarding the topic and research. In order to be transparent in acknowledging the axiology of the researcher, a reflective diary was kept in order to document ideas, opinions and progression throughout both the collection, transcription and coding of the data.

Research ethics and governance

Ethical approval for the qualitative interviews was required and granted by the university research ethics committee (SAS-SREIC 12.7.19-1). It was deemed to be Health Research Authority (HRA) and NHS

Research Ethics Committee (REC) exempt following use of the online HRA tool (described above) and further discussion with the host NHS trust's research co-ordinator. Careful consideration was given to issues of confidentiality, anonymity, and informed consent.

Participant contact information was self-volunteered by interested survey respondents as described above. Only interested survey respondents were invited to participate over email from the researcher, which included a participant information sheet containing a topic guide and research aims as well as information about the study conduct (see Appendix 7). Fully informed, voluntary consent was implied by pharmacists replying to the email and arranging a date for interview.

Once the phone call was arranged, the researcher checked if participants read and understood the information in the participant information sheet, and consent was verbally obtained again at the start of the phone call. Participants were given an indication of what questions would be asked prior to interview and reminded of the subject area (inpatient subcutaneous insulin prescribing practice and intervention use). All participants were reminded of their right to withdraw at any point, and their permission to be recorded sought, at the start of the telephone conversation. Participants were debriefed about how their data would be used and invited to ask any questions before ending the interview.

Any identifiable data (names of people and organisations) contained in the audio files were anonymised at the point of transcription and were not presented in the results. Audio and text files were stored on password protected folders on a university-networked computer accessible only to the researcher.

Data analysis

Thematic analysis was used to identify themes and patterns of meaning across the dataset in relation to the research questions. Thematic analysis aims to generate an analysis from the data upwards. Although this may be shaped by the researcher's standpoint and disciplinary knowledge, it is not specifically guided by pre-existing theory or theoretical concepts. Thematic analysis is flexible in that it is not paradigm-specific or prescriptive for use within certain epistemological frameworks (Braun & Clarke, 2013). It is therefore a method of analysis that is compatible with a mixed methods explanatory study within a critical realist and relativist epistemology. Other approaches to qualitative data analysis, such as interpretative phenomenological analysis (Smith & Osborn, 2008), constant comparison analysis (with grounded theory) (Henwood & Pidgeon, 2004) and variations of discourse analysis (Potter & Wetherell, 2010) are more specific to particular epistemological positions that are different from the researcher's approach.

The particular approach to thematic analysis taken in this study is the reflexive thematic analysis described by Braun and Clarke (2006). This approach uses a six-stage sequential but recursive process is used to

guide analysis that facilitates a rigorous process of data interrogation and engagement. These steps include data familiarisation, coding, generating initial themes, reviewing themes, defining and naming themes, and writing up. The positionality and reflexivity of the researcher is important to be considered in this approach as the researcher is considered an essential tool that influences the generation of themes.

The use of template analysis with soft *a priori* themes (e.g. those derived from current theory/ideas) was considered to incorporate both deductive and inductive coding in the analysis. However, it was decided that in order to be as consistent as possible throughout the coding process, the analysis remained completely inductive and close to the data in order to stay as true to the participants' accounts as possible (S. Watts, 2014). The incorporation of existing literature and theory may then be incorporated into the discussion of the analysis (rather than the analysis itself), with a view to ensure that the findings of the study are as transferable as possible. This allowed scope for the researcher to actively engage with the analysed data in a way that would not confuse or impose their position on or with the expressed views of the participants.

More details about the stages involved in the reflexive thematic analytical process are given below:

Transcription and data familiarisation

All interview recordings were listened to by the researcher before being fully transcribed via intelligent verbatim, omitting any insignificant non-semantic sounds (such as 'er', 'mm' or 'uhuh') or pauses from the transcript, but including significant paralinguistic features (e.g. laughter, intonation, strong emphasis) in order to not compromise on data quality (N. King et al., 2019). If discourse analysis techniques were to be employed, non-verbal details (e.g. length of pauses, overlapping speakers) would have formed an important part of the paralinguistic transcription due to the need to convey meaning in the spoken word. For the purposes of this study, which seeks to identify broad patterns of common themes in the data, an in-depth level of transcription was not necessary.

The researcher personally transcribed and repeatedly read every transcript to familiarise and immerse themselves in the data, with the aim of understanding the data from the perspective of the participant. Interviews were transcribed using Microsoft Word as soon after the interview as practicable and were aided by the field notes taken where necessary. A bespoke orthographic transcription notation system was constructed to help readers interpret the transcriptions (see Appendix 8). This was based on the system exemplified by Braun and Clarke (Braun & Clarke, 2013). All transcriptions were checked by two independent student researchers for errors of omission, mistaken words/phrases or sentence structure and punctuation errors. A pseudo-anonymised table of participant and organisational characteristics was

constructed, to enhance the potential for transferability of the research. Any identifying information (participant names, organisations) were removed at the point of transcription.

Coding

Transcript documents were imported into NVivo version 12 (QSR International Pty Ltd, 2018) for coding. Coding the data involved assigning a succinct label to sections of text in the transcript to identify important features of the data that might be relevant to answering the research question. In order to thoroughly and systematically identify the key themes, issues and meanings within the data, the entire dataset underwent complete and consistent, open, two-level, inductive, descriptive coding by the researcher, whereby anything of interest of relevance to the research questions were coded. This followed a 'what-how' approach (what is the participant talking about and how is it being described?) as described by Watts (2014). Codes included positive and negative aspects of insulin prescribing interventions (e.g. "electronic prescribing as effective" and "the insulin passport as useless") and the perceived risks and benefits of environmental and systems contexts described (e.g. "staff turnover as a threat to sustainability"). The aim with the coding process was to be as inclusive and close to the data as possible.

To prioritise the participant's words and viewpoints, the researcher attempted to be empathetic to the participants, and set aside their viewpoint and values as much as possible during the coding process. This was applied thoroughly and consistently. Being mindful of the positionality of the researcher, a reflective diary was used throughout the process. This was used to reflect on the researcher's thoughts and feelings following each interview and make explicit any persuasions that may influence data analysis. This process helped to contribute to transparency in the data analysis process.

Throughout the coding process, codes were modified slightly in an iterative and organic way to incorporate the new material. Slightly overlapping codes were merged and similar codes were grouped into superordinate codes where appropriate to answer the research question. The aim was to achieve a comprehensive set of codes that differentiates between different concepts and ideas in the data but captures the patterning within (Braun & Clarke, 2013).

Generating and reviewing initial themes

After coding the data, transcripts were then re-read and the codes, along with their corresponding data segments, were re-examined to identify significant broader patterns of meaning (themes) in the data. For example, codes that related to insulin self-administration intervention design, use, evaluation and implementation were collated under an initial broader theme of 'insulin self-administration'. The

frequency with which patterns occur is not the chief measure of significance here, but rather the identification of meaningful patterns that represent central organising concepts, which are relevant and important in relation to the research question.

These broader patterns in the data (candidate themes), along with their corresponding data, were then reviewed with respect to their viability. This included reviewing themes to decide how they relate to each other, if they have coherence and enough evidence in the data to support them. The candidate themes were then checked against the entire dataset to determine if they *"capture something important about the data in relation to the research question, and represent some level of patterned response or meaning within the dataset"* (Braun & Clarke, 2006). This is an active process, whereby the researcher makes choices about how the data is shaped and crafted, hence the importance of reflexivity and transparency on the part of the researcher. The resulting themes should remain faithful to the data and tell a story that 'rings true' with the data from an objective point of view (Braun & Clarke, 2013).

A member of the supervisory team with a similar background (a practicing clinical pharmacist working across hospital and academia with a background in diabetes) reviewed the generated themes to 'sense check' the analytical structure and provided critical insight into their relevance and contribution. This included asking the following questions:

1. Do you think the codes represent the chunks of interview data they are filed under?
2. Do you think the themes represent the codes within them?
3. Do you think the themes capture something meaningful and interesting about the topic that can add to the literature?

The purpose of this process was not to examine inter-researcher reliability as per positivist approaches, but to enable a greater degree of reflective discussion and reflexivity during the analysis.

Defining themes and write-up

The candidate themes were further developed through detailed analysis, involving working out their scope, boundaries, focus and assigning them informative names. Possible definitions of the themes were explored and evaluated, and then the most plausible explanations were chosen.

A critical realist framework was used to make sense of the accounts given by the respondents. This means that the participant's accounts were considered as 'real' and 'true', yet inextricably shaped by the social and cultural context that may come with their experiences, characteristics, and environment. As such, a chiefly data-driven, semantic approach to analysis was taken to remain close to the data whilst adding value to it. The data were treated illustratively to help tell a story about the interpreted data patterns.

This involved articulating, unpacking and amplifying implicit meanings in the data (S. Watts, 2014). This is in keeping with the relativist positionality, as opposed to constructionist, or interpretivist, whereby data are used more analytically to highlight latent meanings.

Data extracts were used to *"illustrate/support an analysis that goes beyond their specific content, to make sense of the data, and tell the reader what it does or might mean"* (Braun & Clarke 2006, p. 94). In choosing extracts to include, a purposive sample was drawn relative to the identified themes to illustrate the analytic point made about the data. To try and maintain closeness to the data during extract selection, each participant's data was re-read and extracts that were felt to be most representative of the participant's view were selected.

Data extracts were chosen from across the data to demonstrate the breadth of a theme and to avoid too much selectivity (for example over-selecting extracts from more articulate participants). They were also selected based on their capacity to illustrate something distinct and interesting about a theme and make a discernible contribution to the literature. Themes and corresponding data were presented in a logical order respective to the research questions.

After inductive coding and theme generation, additional analyses were conducted whereby codes pertaining to the SEIPS framework were deductively mapped to the model to provide additional findings that have further translatable relevance for hospital teams and policymakers. Data was also re-examined by categorisation according to the participant's current use of the intervention to help further explain salient results from the survey. This is explained further in **Chapter 5**.

The analytic narrative was then woven together with the quantitative findings and contextualised relating to the existing literature in the short discussion section in **Chapter 5**. Key underpinning themes are further discussed in **Chapter 7**. These summarise the evidence from the whole dataset as it relates to the research questions and objectives.

The next section describes the methods involved in undertaking the realist synthesis. This study was conceptualised and undertaken following reflection on the integrated findings of the mixed methods study described above.

3.3.2 Realist synthesis

Justification of method

The primary reason for conducting a realist synthesis of self-administration policies was its ability to explain how interventions work and in what context. Realist synthesis is explanatory and is sensitive enough to account for the complexity of the social world in which the intervention operates (Boaz 2002). The conclusions from the systematic review presented in **Chapter 2**, as well as the findings of the mixed methods study presented in **Chapters 4-5**, pointed to the need to consider these important contextual factors in the investigation of complex interventions. Realist synthesis provides an opportunity to analyse the effects of contextual influences on the function and outcomes of the intervention by extracting and evaluating theories that underpin the intervention (Pawson 2006).

Realist synthesis compares how the intervention was *supposed* to function in relation to the empirical evidence regarding what happens in different situations along the lines of context-mechanism-outcomes. An analysis of the different contingencies that impact the intervention's ability to produce the intended outcome then provides guidance to policymakers or practitioners with respect to resources or contexts required to trigger the mechanisms for the intervention to produce the intended outcomes. The result of a realist synthesis is not a simple answer (e.g. the intervention works) but instead, provides:

> *"a rich, detailed and highly practical understanding of complex social interventions which is likely to be of much more use to them when planning and implementing programmes at a national, regional or local level."* (Pawson et al., 2005).

The decision to focus the review on a single intervention was prompted by the need to carefully define and describe the intervention in-depth to review and theorise the way it functions to produce outcomes. A wider review of all insulin prescribing practice would not be practical or achievable due to the heterogenicity in the types of interventions and the degree to which they are socially contingent. The choice to focus on insulin self-administration policy interventions was directed by careful and collective reflection on the results of the mixed methods study with the stakeholder groups. The process of undertaking the realist synthesis is described below:

Overview of process

Realist synthesis is a non-linear, iterative process due to the nature of identifying, defining, and refining theory from the literature available about the intervention under study. The general process of undertaking realist synthesis, as described by Pawson et al (Pawson et al., 2005), is shown in Figure 3.4.

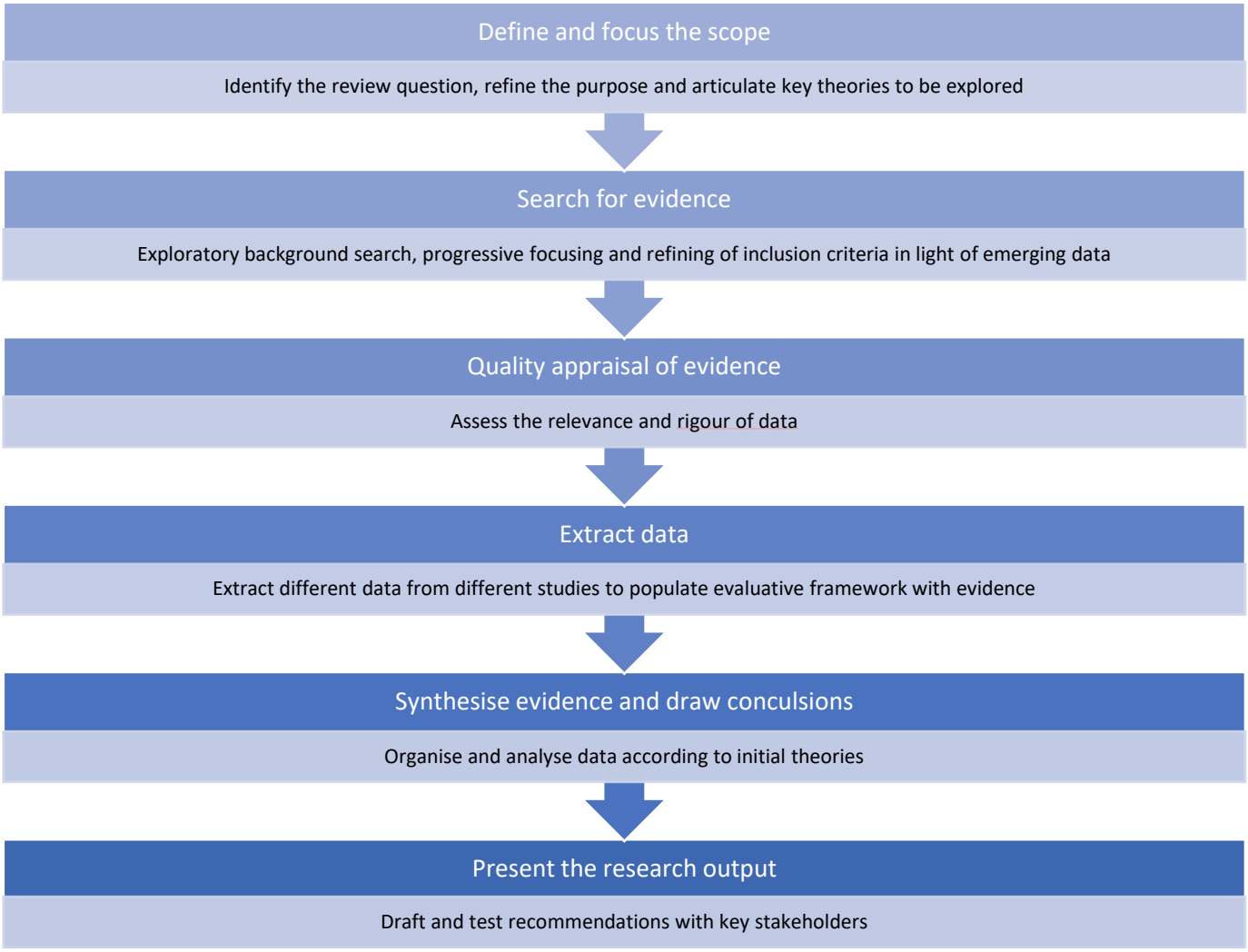


Figure 3.4: Key stages in the realist synthesis process according to Pawson (2005).

The above process was followed to conduct the realist synthesis, which is reported in its entirety in **Chapter 6**. This was aided by the use of the Realist And Meta-narrative Evidence Syntheses: Evolving Standards (RAMESES) training materials for realist synthesis (G. Wong, Westhorp, Pawson, & Greenhalgh, 2013). A modified diagram explaining the iterative literature searches performed is provided in **Chapter 6** (Figure 6.1), along with details of how each step was performed.

Research ethics and governance

The realist synthesis did not require ethical approval as no original, personal, sensitive, or confidential information was collected. It was considerate of the reporting and quality standards produced by the RAMESES I project (G. Wong, Greenhalgh, et al., 2013; G. Wong, Greenhalgh, Westhorp, & Pawson,

2014b) and the study protocol was published in the PROSPERO registry prior to undertaking (CRD42020193351) (Bain, Jeffries, Kavanagh, & Babar, 2020).

3.4 Summary

This chapter discussed the approach, methodology and methods used for the original research in the thesis. A participatory health research approach is taken in this thesis to help increase the relevance of the research output for those whom it is intended and to help generate practice-informed evidence about the research topic.

A mixed methods research methodology is used to enable us to gain a thorough understanding of the research problem, and to enable the initial quantitative results to be explained by more in-depth qualitative data. Methods that are consistent with mixed methods within a critical realist paradigm are used to allow collection of data that can be meaningfully integrated together. Finally, a realist synthesis is conducted to further explain how an intervention works, for whom and in what circumstances. A single intervention is chosen for this purpose to allow a more meaningful and in-depth enquiry within the scope of the thesis. The selected intervention was chosen as a result of careful and collective reflection of the results of the mixed methods study with stakeholder groups. This allowed the research to follow a line of enquiry that was deemed most relevant to both patients and practitioners, in line with following a participatory health research approach.

The next chapter presents the findings of the first phase of the mixed methods study, which is the national cross-sectional survey of UK hospitals.

Chapter 4: Cross-sectional survey of insulin prescribing practice and interventions in UK hospitals

This chapter presents the findings of the quantitative phase of the mixed methods study. This is the first phase of the explanatory sequential mixed methods study and precedes the qualitative stage (**Chapter 5**). This chapter includes the following:

- Development of the questionnaire tool that describes inpatient insulin prescribing systems and intervention use in hospitals and measures their perceived effectiveness.
- Findings from the national cross-sectional survey in which the tool was used.
- Validation of the questionnaire tool.
- Discussion of key findings.
- Discussion of results with stakeholder groups and implications for the next study.

4.1 Background

The safe and appropriate prescribing of subcutaneous insulin in the hospital setting is an important and common goal, with various studies reporting on the implementation and effectiveness of interventions to help achieve this aim. It was evident from the systematic review in **Chapter 2** that although some inpatient teams and researchers have documented the process and outcomes of improvement efforts, particularly in the US and Canada, reporting intervention use and effectiveness in the published literature is not commonplace in the UK. The use of the annual National Diabetes Inpatient Audit (NaDIA) in the UK is useful for tracking the self-reported use of a selection of nationally recommended initiatives (e.g. the insulin passport and combined glucose monitoring/diabetes drug charts), but information about how hospitals are prescribing insulin, and the extent of current interventions in use, is lacking. A detailed examination of insulin prescribing systems and error reduction strategies in current use is therefore needed to make recommendations about the implementation of interventions to reduce insulin prescription errors.

The systematic review also demonstrated that comparing intervention effectiveness is restricted by several important factors that differ between organisations. These include how the intervention was implemented and used in different contexts, organisational factors (such as available staffing and resources), and methods used to collect data and evaluate interventions. Scientific methods seeking to establish intervention effectiveness with any certainty (such as randomised controlled trials) across organisations may also be unsuitable for evaluating complex interventions in the hospital setting due to the inability to control the significant number of 'confounders' existing in open and complex hospital systems.

In the absence of a viable method to measure and compare *actual* effectiveness of interventions across NHS hospitals, it may be useful to use a measure that is universal to all respondents. Measuring *perceived* effectiveness of interventions is a way of circumventing the above limitations for the purposes of identifying salient strategies nationally (Blendon et al., 2002). Perceived effectiveness, as a theoretical construct of intervention acceptability, is defined as *"the extent to which the intervention is perceived as likely to achieve its purpose"* (Sekhon et al., 2017). Measuring perceived effectiveness can indicate levels of support, acceptability and scepticism towards adopting recommended interventions (Rosen et al., 2005). Using this notion also allows responses from hospitals irrespective of current intervention use. Insights of perceived effectiveness from healthcare professionals can be used to garner support for the wider implementation of interventions and focus national insulin improvement efforts.

The objective of this study was to investigate the current use and perceived effectiveness of interventions designed to improve inpatient insulin prescribing practice across hospitals in the UK using a national cross-sectional survey. Research questions included:

- What systems are currently used to prescribe subcutaneous insulin for inpatients in UK hospitals?
- What interventions are currently being used in UK hospitals to improve insulin prescribing practice?
- Is there an association between hospital characteristics and intervention use?
- What interventions are perceived to be most effective for improving insulin prescribing practice by those who have a role in designing, implementing and evaluating them?
- Is there an association between hospital characteristics and perceived effectiveness of interventions?

To answer these questions, a tool was developed and validated to elicit the current practice and opinion of hospital pharmacists and medicines safety officers regarding insulin prescribing safety interventions and their perceived effectiveness. This tool was used as part of a cross-sectional survey of NHS hospitals to determine the systems currently used to prescribe subcutaneous insulin for inpatients with diabetes. The tool also described the range, uptake and perceived effectiveness of interventions currently used to reduce insulin prescription errors and improve insulin prescribing safety. Further details of the methods used to collect and analyse the data presented here are included in **Chapter 3**. The survey has been reported with consideration of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for observational studies (Von Elm et al., 2007). These guidelines are included in Appendix 9 and are discussed further in **Chapter 7**.

4.2 Questionnaire development

Validated survey tools to measure patient perceptions of insulin use are reported in the literature (Anderson et al., 2004; Moock, Hessel, Ziegeler, Kubiak, & Kohlmann, 2010; Snoek, Skovlund, & Pouwer, 2007). However, no such tool exists to measure the service-provider use or perception of effectiveness of insulin prescribing interventions in the hospital setting. Therefore, it was necessary to develop, use and validate a tool to understand healthcare professionals' perceived effectiveness of a range of insulin prescribing safety strategies.

The results of the systematic review of the literature regarding insulin intervention effectiveness (presented in **Chapter 2**) provided the basis for many of the items included in the questionnaire. This was supplemented by the researcher's and supervisor's knowledge of current practice and potential influencing factors (e.g. the presence of a diabetes pharmacist, or specialist diabetes service provision at the trust). The questionnaire included both system-level interventions and prescriber-orientated interventions, including prescribing system functions, guidelines, policy, restrictive measures (such as hard limits on electronic prescribing programs), provider education, and decision support tools.

The Lay Advice for Diabetes and Endocrine Research (LADDER) panel were consulted throughout the conceptualisation and design of the questionnaire, and items regarded as very important for people with diabetes were included in the tool (e.g. self-administration and self-management policies). Additional input from the multi-disciplinary diabetes inpatient group at the host trust (including consultant diabetologists, registrars, diabetes specialist nurses and pharmacists) enabled representation of the views of a range of professions involved in insulin safety.

The questionnaire was developed according to good practice guidance, paying attention to elements of design such as layout, brevity, use of language, clarity of questions and the appropriateness of response formats (Burns et al., 2008; Dillman, Smyth, & Christian, 2014; Kelley, Clark, Brown, & Sitzia, 2003). A cover letter was sent with the postal questionnaires, which were printed on good quality stationary including departmental headers and the researcher's signature to help increase credibility (see Appendix 4 and 5). These stated the objective of the survey an explanation as to why they were selected as potential respondents. Cover letters were personalised with the recipient's name to help increase response rate. Estimates of time taken to complete the survey were included in the cover letter, along with an affirmation that the recipient's participation is imperative to the success of the survey (Kelley et al., 2003).

The questionnaire had five sections: hospital demographics (section A), functionality of electronic prescribing systems with respect to subcutaneous insulin (section B), paper prescribing of insulin (section C), strategies for insulin error reduction (section D) and respondent's opinions on the effectiveness of error reduction strategies (section E). In sections A to D, respondents selected 'yes', 'no' or 'unsure' to the use of system functions and

strategies identified from the systematic review and experience of current practice. An open question allowed respondents to describe any additional initiatives in use that were not included in the list.

In section E, a 5-point Likert scale was used to determine how effective each intervention was perceived to be (or could be, in the case where it was not currently used in their organisation) on a scale of 1 (not effective) to 5 (very effective). Respondents were not asked to explicitly to base their answers on objective local data due to the expected heterogeneity in practice and available measures across hospitals. If respondents used insulin prescribing interventions that were not included on the list, they could describe these in an open-ended question and indicate how effective they were perceived to be on the Likert scale. This enabled the description of a broader range of currently used interventions that could be used in future iterations of the questionnaire.

4.2.1 Pre-testing, sensibility testing, and piloting

The purpose of pre-testing and piloting is to review and revise questions according to whether respondents interpreted questions in a consistent manner as intended by the researcher (Collins, 2003). The tool was pre-tested with four very experienced specialist diabetes pharmacists from four separate acute NHS hospital trusts in England, as well as three members of the research supervisory team and a peer-doctoral researcher at the university. The pharmacists were recruited via the researcher's professional network and were thought to be representative of the target population. The respondents' comprehension of the items may impact the quality of the questionnaire data, therefore these pharmacists and academics were asked to judge the appropriateness of each included question, as well as their salience and relevance.

The pharmacists were also asked to comment on how comprehensive the tool was, and well they thought it addressed the research objective. This was done through individual verbal interviews and written feedback via email. Decisions were made to either accept the original question and meaning, change the question or eliminate it altogether.

Following this process, the tool was re-presented and piloted with the four pharmacists who were representative of the sample population, as well as two additional student-researchers. They were asked to examine the tool with respect to its relevance, flow, arrangement, and administrative ease. Any redundant or unclear question stems, items or responses were identified. They were also asked to time how long it took to complete the questionnaire, such that a realistic timeframe could be stated on the cover sheet for participants. A summary of the changes made following pre-testing, sensibility testing and piloting is presented in Table 4.1.

Table 4.1: Summary of changes resulting from pre-testing, sensibility testing and piloting the survey

Prior to pre-test	**Following pre-test**
"*Are there local hypoglycaemia and hyperglycaemia guidelines in use?*" (Y/N/U)	One question split into two: "*Are there local hypoglycaemia guidelines in use*?" and *"Are there local hyperglycaemia guidelines in use?"*
"*Remote blood glucose monitoring."* (Y/N/U)	Wording amended to *"Electronic system linked to results from remote blood glucose testing"* for clarity.
Blood glucose was abbreviated to *BG* in section C.	*Blood glucose* written in full.
Prior to sensibility test	**Following sensibility test**
"Is there currently a specialist diabetes pharmacist in post?" (Y/N/U)	Addition of an open question immediately following this to capture input of non-specialist pharmacists in diabetes: *"Please describe the grade/role and full-time equivalent (FTE) of the pharmacist(s) overseeing diabetes care."*
"Dropdown menu selection for insulin product(s)"	Amended to *"Dropdown or auto fill menu selection for insulin product(s)"* to account for different systems and terminology.
	"Ability to signpost for self-administration and/or self-management with insulin" and *"Alerts to notify prescriber when a concentrated insulin product is selected"* items added to section B.
Prior to piloting	**Following piloting**
*"Mandatory **annual** insulin safety education for clinical staff."*	*"Mandatory **repeat/booster** insulin safety education for clinical staff"* to account for repeated education that occurs at a different frequency to yearly (e.g. 3-yearly).
"Please go to Section D" written after section B.	This was deleted, as respondents who should be completing both section B and C may see this and skip section C.
"Specific requirements for medicines reconciliation of insulin."	One question split into two for : *"Additional requirements for medicines reconciliation of insulin on admission"* and "*Specific requirements for medicines reconciliation of insulin on discharge"* and a footnote was added to give examples of what this means on the survey.

These processes of pre-testing, sensibility testing and piloting helped to improve the questionnaire by minimising the chance that questions will be misinterpreted, or that respondents will fail to recall what is requested or that the researcher will misinterpret their true response. Factor analysis was not performed following pilot testing due to the nature of the items (which represented interventions rather than constructs of a phenomenon) and purpose of the survey (to describe current use of interventions and opinions on perceived effectiveness).

4.3 Questionnaire use

This section describes the use of the questionnaire tool as part of a national cross-sectional survey of NHS hospitals. The whole population of 175 NHS hospitals across the UK were sent a paper copy of the survey, which was addressed to the chief pharmacist, (or diabetes pharmacist/medicines safety officer if known). Follow-up electronic surveys were sent out via professional networks to increase response rate. The following results pertain to both the paper and online responses received from participants.

4.3.1 Respondent demographics

After excluding duplicate or incomplete responses, 95 NHS hospital trusts (54% of 175 organisations) were Included in the final analysis; 55 (58%) from initial postal responses and an additional 40 (42%) after online follow-up. These included 82 out of 150 hospital Trusts in England (55%), 5 out of 6 hospital health boards

Figure 4.1: map representing geographical locations of survey respondents' hospital organisations across England, Wales, Scotland, and Northern Ireland (n=95)

in Wales (83%), 3 out of 14 health boards from Scotland (21%) and 5 out of 5 health and social care trusts from Northern Ireland (100%) (see Figure 4.1).

Section A of the questionnaire pertained to self-reported demographic information. Most of the 95 respondents represented teaching hospitals (42%) or district general hospitals (40%), with between 200-500 (35%) or 501-1000 (40%) inpatient beds. Eighty-one (85%) organisations provided a specialist diabetes service, but only 28 (29%) employed a specialist diabetes pharmacist. An additional 27 (28%) organisations were able to describe a pharmacist who was overseeing diabetes care, but there was a wide range in their availability and experience (ranging from a part-time newly qualified junior pharmacist to a full-time consultant pharmacist).

4.3.2 Prescribing system use

The systems used to prescribe subcutaneous insulin were described by respondents' answers to sections B and C, which pertained to electronic and paper prescribing systems, respectively. A summary of the findings with respect to systems use is outlined in Figure 4.2. The results pertaining to electronic and paper prescribing are discussed further below.

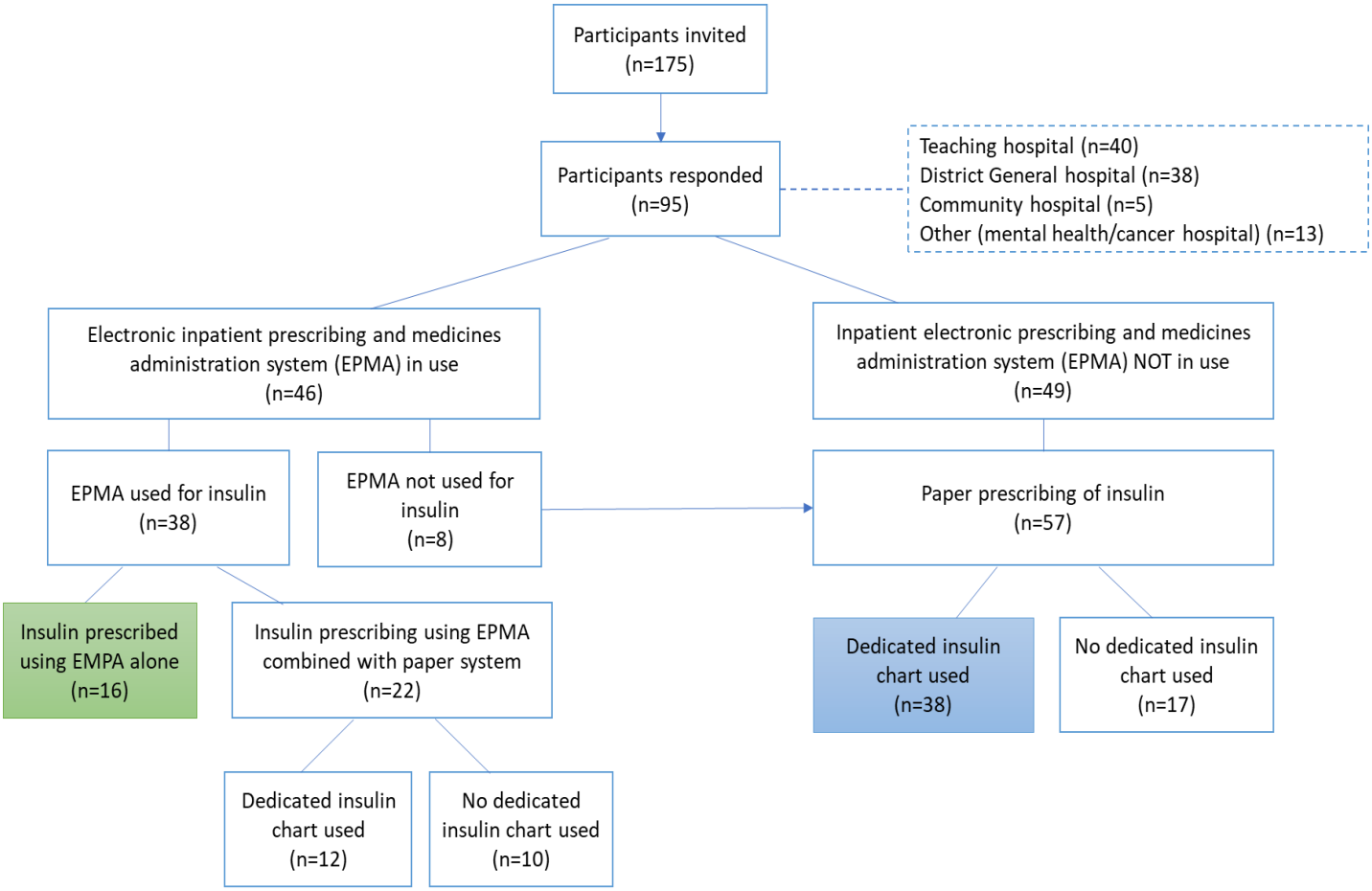


Figure 4.2: Summary of systems used to prescribe insulin in NHS Hospitals as reported by survey respondents. The use of insulin prescribing charts for hospitals not prescribing insulin on paper was unknown in 2 cases.

Electronic prescribing

Forty-six (48%) organisations used inpatient electronic prescribing, all of which were in England. Of these, 38 (83%) used electronic prescribing systems to prescribe subcutaneous insulin. The 8 hospitals (17%) that did not prescribe insulin electronically (e.g. where insulin use was documented electronically but required cross-reference to a paper prescription where further details were given) were excluded from electronic prescribing subset analysis.

The null hypothesis was that there was no association between hospital characteristics (e.g. hospital type, size) and the use of electronic prescribing systems at the organisation. A statistically significant association was found between hospital type and the use of electronic prescribing, with a greater proportion of teaching hospitals using electronic prescribing than district general hospitals (63% vs 39%, $p = 0.035$), and a significantly greater proportion of teaching hospitals prescribing insulin electronically (96% vs 67%, $p = 0.003$). Only 1 out of 5 community hospitals used electronic prescribing, but insulin was excluded from electronic prescribing and was prescribed separately on a paper chart. No significant correlation was

observed between hospital size (number of inpatient beds) and the use of either electronic prescribing systems, or the electronic prescribing of insulin electronic prescribing (p = 0.174).

Figure 4.3 provides an overview of the reported functions of electronic prescribing for subcutaneous insulin at the respondent organ. Although all electronic prescribing systems were linked to the medicines administration record, only 14 (37%) were linked with the patient's electronic medical record, and even fewer were linked to electronic blood glucose results (n=8, 21%). Most electronic prescribing systems included basic forcing functions, such as the mandatory selection of *'units'* as the unit of dose measure (n= 34, 89%) and dropdown/autofill selection of available insulin products (n= 32, 84%). The use of other safety features varied, such as the ability to prescribe variable doses for patients who are carbohydrate counting (n=26, 68%) alerts when prescribers selected high doses (n=10, 26%), or concentrated insulin (n=18, 47%), and prescribing support features such as the ability to check doses are within a reasonable range (n=5, 13%).

Some electronic prescribing systems were limited in their functionality with respect to insulin prescribing. Three systems (8%) could not specify the insulin device used, and only 24 (63%) could associate mealtimes with a prescribed insulin dose. Only 18 (47%) of electronic prescribing systems incorporated the use of insulin order sets (i.e. pre-populated prescription information). Twenty trusts out of 46 (43%) using electronic prescribing systems had electronic systems that could accommodate the prescribing of continuous subcutaneous insulin pumps, two of which were combined with paper insulin pump prescriptions.

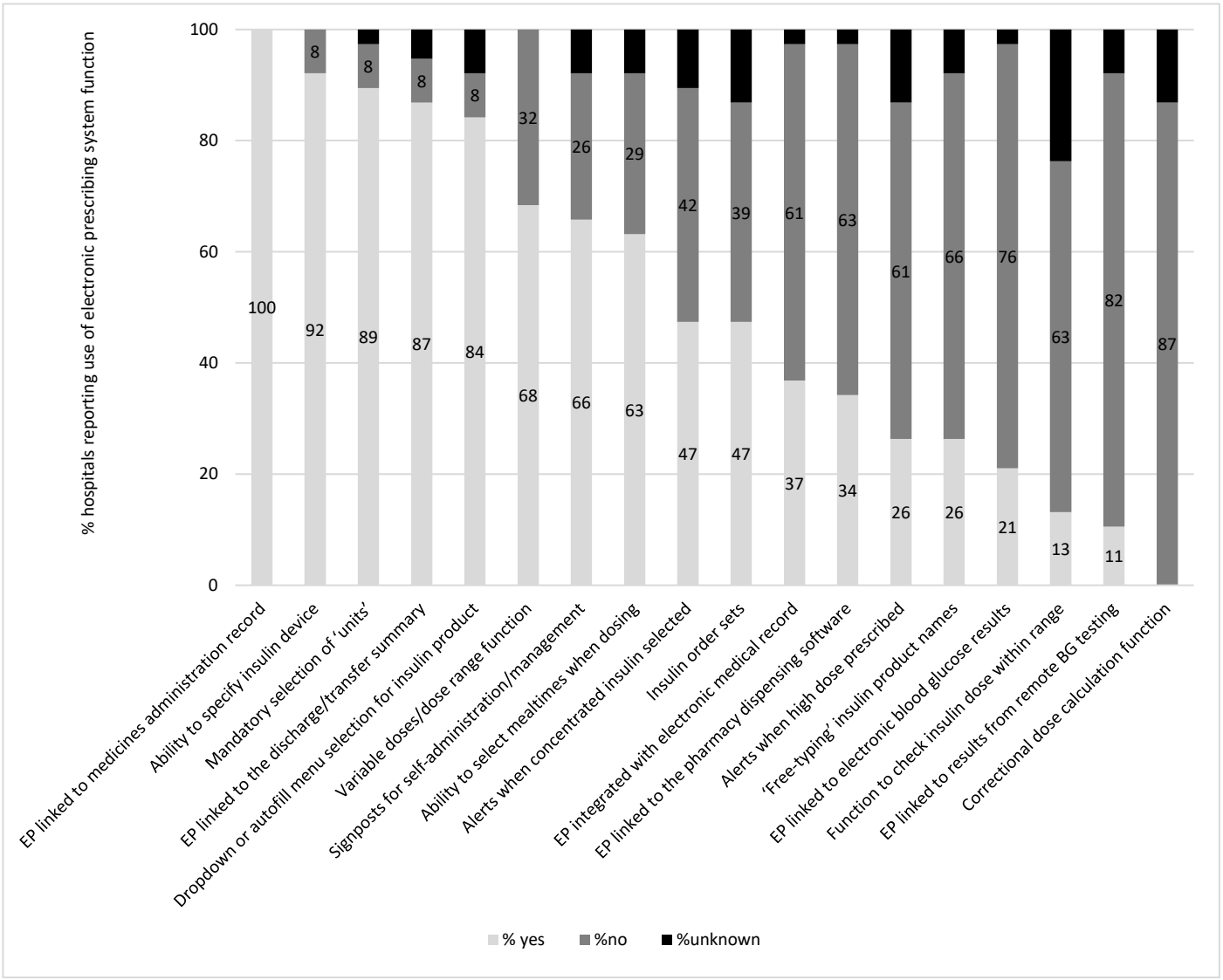


Figure 4.3: Functionality of electronic prescribing systems reported by NHS hospitals using electronic prescribing (EP) systems to prescribe subcutaneous insulin in the United Kingdom (n=38). 'Unknown' comprises responses for 'unsure', 'not applicable', and missing data.

Some respondents described why certain features were included in their electronic prescribing systems using space on the survey (or the open question section - see below), such as removing insulin device from the prescription to reduce mis-selection error from a drop-down list or the ability to regularly interrogate the system to retrospectively review free-text prescribing activity. Others described the use of the electronic prescribing system by pharmacists to identify patients on insulin for priority clinical review, or by other staff to allow referral to the ward pharmacist for verification of one-off or high dose insulin prescriptions. One respondent described the use of an integrated electronic prescription and medical record system that alerts the diabetes team when a high-risk patient is admitted (e.g. where a patient uses insulin and is at risk of DKA/has been a previous DKA risk).

Paper prescribing

A total of 57 (60%) hospitals did not use electronic prescribing for prescribing subcutaneous insulin, and instead prescribed insulin using handwritten paper prescription charts. Thirty-eight (67%) of these used dedicated insulin prescribing charts, or chart sections, for this purpose. Examples of dedicated insulin prescribing charts submitted voluntarily by respondents with their returned surveys are shown in Figure 4.4, below. The remainder of organisations reported using the standard inpatient medication record to prescribe insulin.

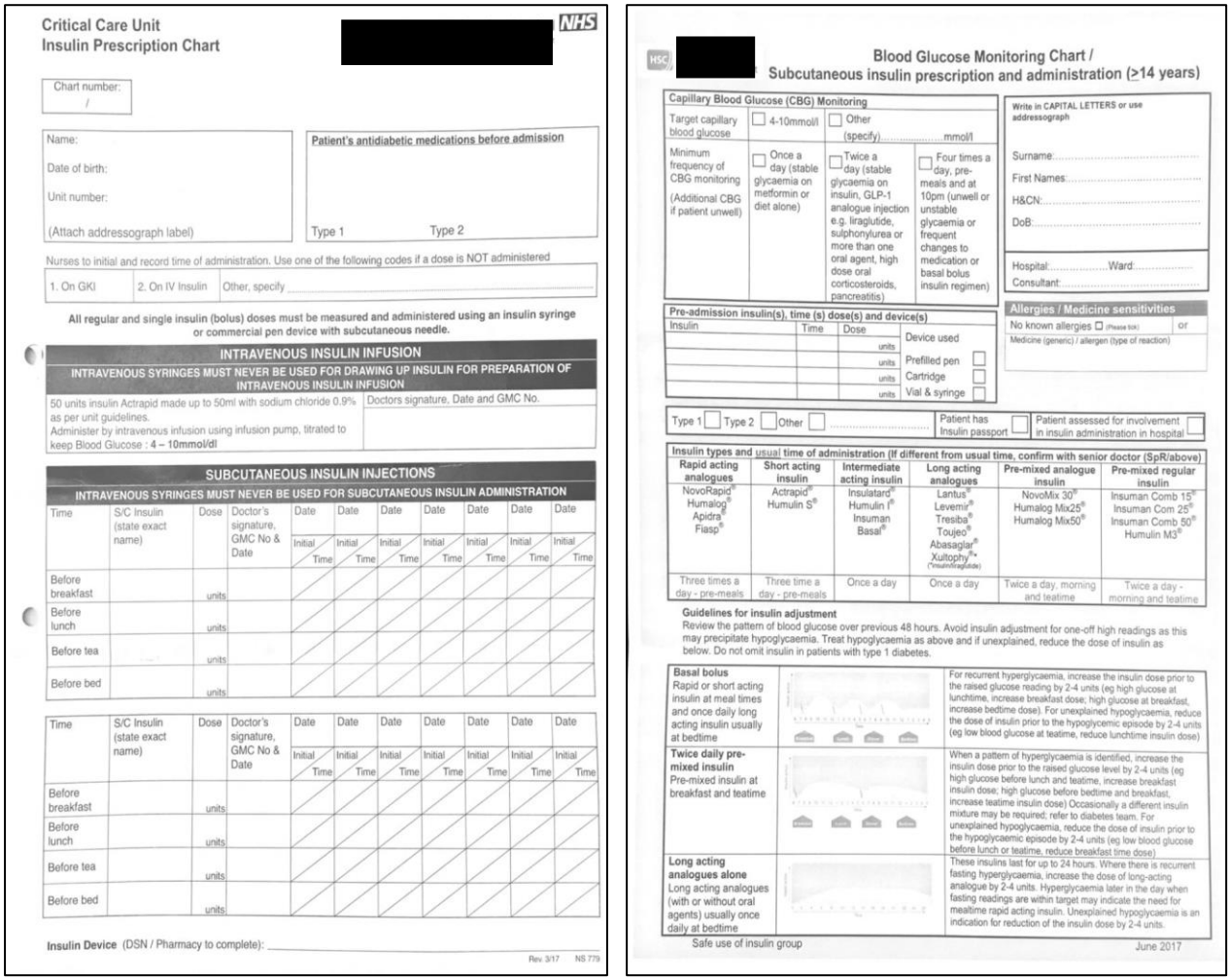


Figure 4.4: Examples of dedicated insulin prescribing charts sent in by respondents. The chart on the left is from an English hospital trust and shows features such as association with mealtimes and pre-printing of 'units'. The chart on the right is from a Northern Irish hospital trust and shows the inclusion of organisation-specific insulin prescribing and management guidelines.

All participating organisations from Scotland and Northern Ireland used dedicated insulin prescribing charts, as did 4 out of 5 (80%) in Wales, and 48 (59%) in England. Thirteen out of 16 teaching hospitals that did not prescribe insulin electronically used dedicated insulin prescribing charts (81%), compared to

19 out of 28 (68%) district general hospitals. Only 1 out of 5 (20%) community hospitals used a dedicated insulin prescribing chart. The remainder prescribed insulin on the normal paper medication chart.

Most charts were designed to reduce prescribing errors by pre-printing *'units'* on the chart (n = 30, 79%) and associated insulin doses with mealtimes (n=27, 71%). Many charts also included a STAT dose section (n=21, 55%) and the ability to prescribe a dose range for those who were carbohydrate counting (n=22, 58%). Other features were less common, such as the inclusion of pre-printed devices (n=11, 29%) to prompt consideration of this often-neglected element of the inpatient insulin prescription. Most charts contained a blood glucose monitoring section to aid management (n=29, 76%) but fewer contained both a monitoring section along with organisation-specific management guidelines (n=17, 5%). Fourteen trusts (25%) had dedicated paper charts for prescribing continuous subcutaneous insulin pumps.

4.3.3 Use of insulin prescribing practice interventions

Section D of the survey pertained to the use of insulin prescribing practice interventions that were designed to reduce insulin prescription errors. An average of 9.0 (SD = 3.1) interventions were used in hospitals to improve insulin prescribing safety, ranging from 2 (one medium-sized mental health teaching hospital in England) to 16 (one large teaching hospital in England). The null hypothesis was that there was no association between hospital characteristics (e.g. hospital type, size) and the number of insulin prescribing practice interventions used at the organisation. The type of hospital did not show a statistically significant association with the mean number of interventions used (9.5 (SD = 3.4) for teaching hospitals vs. 8.9 (SD = 2.6) for district general hospitals (p = 0.42)), but the presence of a specialist diabetes pharmacist did (10.6 (SD = 3.1) with a pharmacist vs. 8.3 (SD = 3.0) without (p = 0.002)). Interventions used by respondents were categorised into intervention types *a priori* as per the systematic review results in **Chapter 2**, and are presented in Figure 4.5. Table 4.2 presents data further categorised by hospital type and includes data on prescribing system use.

Table 4.2: Percentage of hospitals using insulin prescribing systems and interventions, grouped according to hospital type.

Intervention		Teaching Hospitals (%) (n=40)	District General Hospitals (%) (n=38)	Community Hospitals (%) (n=5)	Other (e.g. mental health) (%)(n=12)	Total (%) (n=95)	P value
Provider education	Mandatory insulin education on induction	48	42	20	67	46	0.431
	Mandatory repeat insulin education	28	24	20	33	26	0.391
Provider decision support	Specialist diabetes pharmacist	35	37	0	0	29	0.594
	Local hypoglycaemia guidelines	98	92	100	92	95	0.234
	Local hyperglycaemia guidelines	83	79	80	67	79	0.564
	Correctional dose algorithm	13	21	40	8	17	0.387
	Pocket—sized guideline cards	25	13	0	0	16	0.098
	Insulin discharge checklist	13	11	60	0	13	0.443
	Insulin passport	25	37	0	42	31	0.310
Team changes	Outreach review for patients using insulin	63	50	20	17	51	0.344
	Medicines reconciliation requirements for insulin on admission (e.g. details about self-administration)	40	37	60	42	40	0.404
	Medicines reconciliation requirements for insulin on discharge	23	26	40	25	25	0.500
	Nursing double check of insulin on discharge	33	34	80	0	32	0.332
Policy	Use of patient's own insulin (from home) during hospital	90	95	100	92	10	0.510
	Insulin self-administration policy	63	63	60	67	63	0.434
	Insulin self-management policy	33	26	60	42	31	0.301
	Insulin biosimilar policy	38	37	40	0	33	0.256
	TallMan lettering on prescription	23	16	0	17	18	0.240
Restrictive measures	Hospital formulary limitations	48	63	80	42	55	0.246
	Restrictions on concentrated insulin	33	26	0	25	27	0.225
	High dose validation before supply	8	11	20	8	9	0.583
	Insulin-specific requisition/order form for supply	5	5	0	0	4	0.672
	Limitations of stock/devices on ward areas	68	84	80	83	77	0.158
Prescribing system	Electronic prescribing for inpatients	63	39	20	42	48	0.035
	Electronic prescribing of insulin (for those responding 'yes' to electronic prescribing use)	96	67	0	33	40	0.003
	Insulin prescribing chart (paper-based prescribing)	55	58	20	42	53	0.383
	Insulin pump chart	15	18	0	8	15	0.553

P values have been calculated using Chi squared with Fishers Exact (1-sided) to show differences between teaching hospitals and district general hospitals only, due to heterogeneous group sizes of other hospital types.

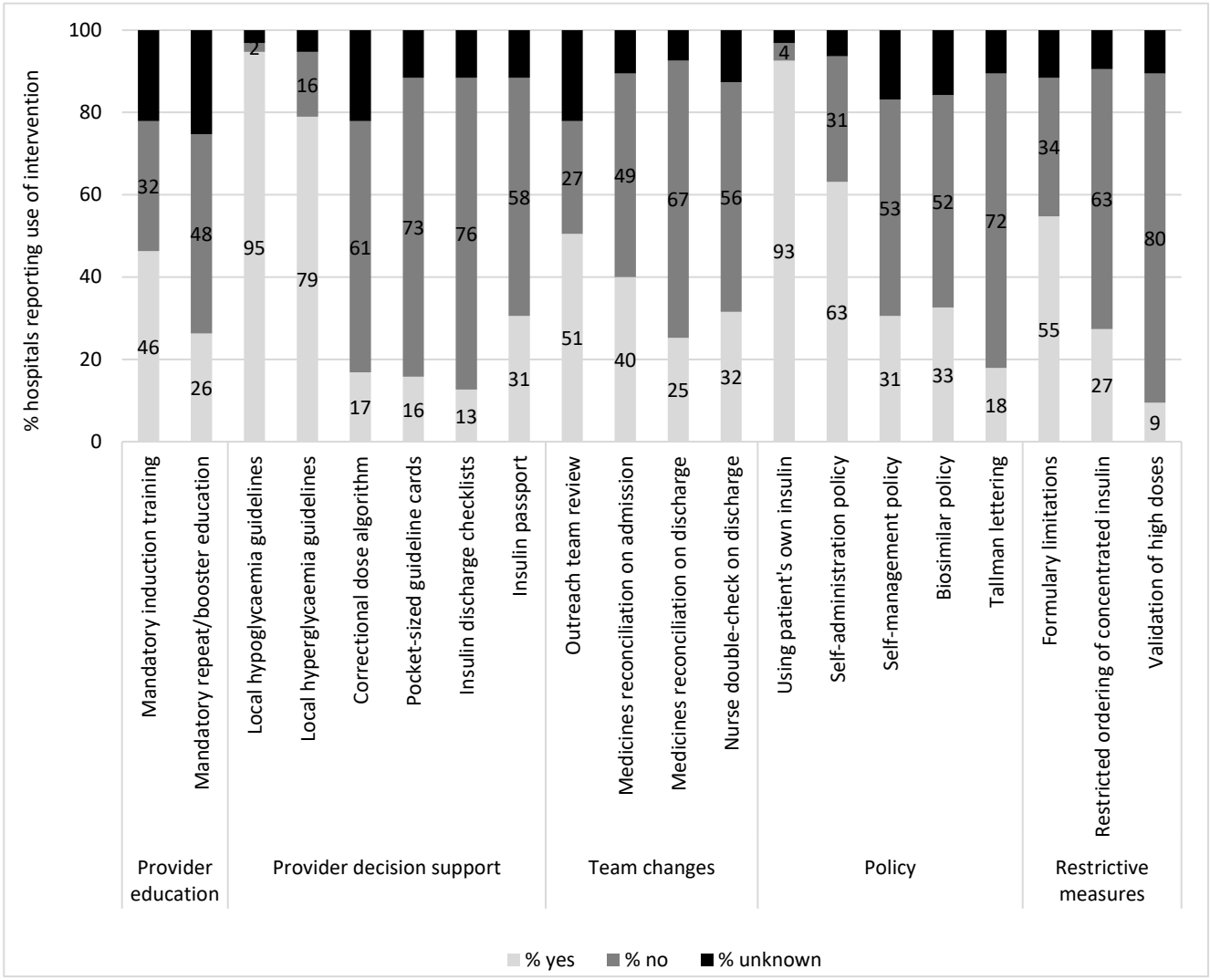


Figure 4.5: Use of insulin prescribing interventions in UK NHS hospitals (n=95). Unknown' comprises responses for 'unsure', 'not applicable', and missing data.

The most common interventions in use include hypoglycaemia and hyperglycaemia guidelines to support appropriate insulin prescribing (n=90, 95% and n=75, 79%, respectively) and the use of the patient's own insulin on admission to minimise product selection error (n=88, 93%). No intervention was used universally by all hospitals, and only 6 interventions were used by more than 50% of organisations surveyed.

The use of policies to encourage self-administration of insulin were reported by 61 (63%) trusts, with self-management policies being less common (n=29, 31%). Hospitals not included in this number were those describing the use of general medicines self-administration policies that were not insulin-specific (n=3, 3%) or who were currently developing insulin self-administration and self-management policies (n= 2, 2%). Insulin self-administration policies were used in hospitals in all countries (70% of respondents in England, 40% in Wales and Northern Ireland and 33% in Scotland) and all types of hospital (68% teaching hospitals, 63% district general hospitals, 60% community hospitals and 67% other hospitals). Self-

management policies were in place in hospitals in England (34%), Wales (20%) and Northern Ireland (20%) and in all types of hospital (35% teaching hospitals, 26% district general hospitals, 60% community hospitals and 25% of other hospitals).

Only 31 (33%) organisations had policies in place to aid the safe and appropriate prescribing of biosimilar insulins, and just 29 (33%) organisations used the insulin passport. The use of other prescriber support interventions was more uncommon. Insulin pocket-guideline cards were used by only 15 organisations (16%) and insulin discharge checklists were only used by 12 (13%) organisations. An example of these interventions submitted by a respondent is shown in Figure 4.6.

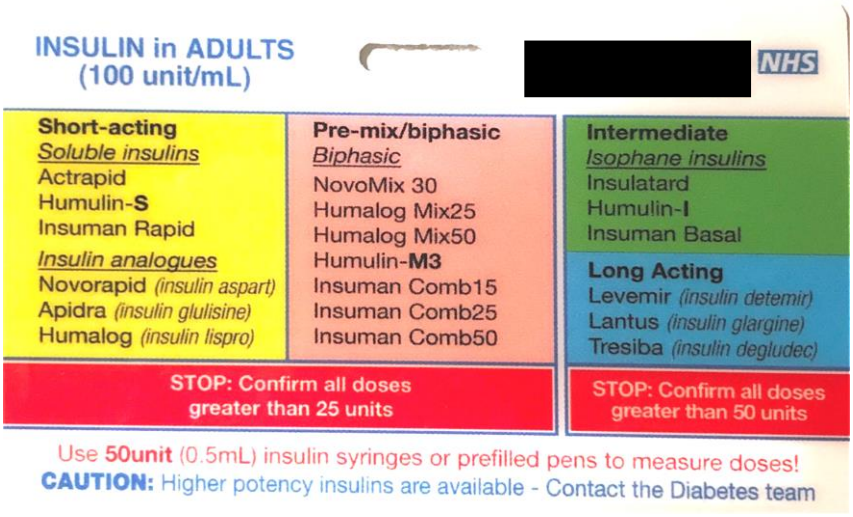


Figure 4.6: Insulin pocket-guideline card voluntarily submitted by one of the survey respondents. The card aids prescribers by categorising insulin into different types and offers advice on confirming doses.

Other insulin prescribing practice interventions that were not included in the list of items in the questionnaire, but were described by respondents are included in Table 4.3. These interventions were not quantified because non-response bias could not be ruled out and may result in unrepresentative results (e.g. there is a possibility that not all trusts using educational outreach would have put this in the free type/open question response section). Table 4.3 therefore serves an illustrative purpose of the range of bespoke and innovative interventions used across the respondent sample, and can be used to supplement the pre-printed list of interventions provided in future iterations of the questionnaire.

Table 4.3: Insulin prescribing practice interventions described by respondents that were not listed as questionnaire items.

Provider education	Educational outreach to ward staff (e.g. on request or when required)
	Individual insulin prescribing feedback delivered by ward pharmacist and monthly group feedback sessions
	Dedicated "Making Insulin Treatment safer (MITS)" funded project
	Participation in the national insulin safety week
	Lunchtime teaching sessions given to foundation doctors annually
	Non-mandatory completion of insulin-specific e-learning packages
	Core training for medical/nursing staff at key points (e.g. progression between foundation year training or core medical training)
Provider decision support	Insulin resource folder (e.g. containing relevant guidelines and policies)
	Posters on wards (e.g. Think Glucose©, details of insulin devices, profile, dosing and administration)
	"Insulin equipment on discharge" sticker
	Additional discharge form for patients receiving insulin from district nurses or care home
	Diabetes team use the same electronic patient record system as the local primary care teams
	Diabetes guideline mobile software application (mobile app)
	Mobile app version of the insulin passport
Team changes	Use of 'in-reach' by community diabetic liaison nurses to support management of patients
	Generalist pharmacist review of those prescribed insulin as priority using prioritisation software
	Specialist diabetes nurses – some of whom are independent prescribers.
	Diabetes link nurses and diabetes champions to upskill clinical areas.
	Pharmacy-led insulin self-administration assessment
	Identifying patients prescribed insulin at nursing handover
	7-day clinical pharmacy service on inpatient wards.
Policy	Insulin prescribing by brand name only
	Therapeutic substitution guidelines if non-formulary insulin/device used by patient
Restrictive changes	Removal of insulin cartridges from use; default use of pre-filled pens unless cartridges specified.
	Use of Apidra [insulin glulisine] for correction doses to reduce mix-ups between Novorapid [insulin aspart] and Novomix 30 [insulin aspart/insulin aspart protamine].
	Limited number of insulin vials in every ward fridge for STAT/first doses.
Audit and feedback	Think Glucose monthly audits reported to ward
	Insulin-related adverse incident report forms reviewed, and trends identified (e.g. monthly)
	Monthly safety /lessons learned meetings to review diabetes related incidents
	Weekly lunchtime meeting involving answering insulin queries
	Wireless monitoring of blood glucose levels - provides alerts to acute inpatient diabetes team when blood glucose results out of range

4.3.4 Perceived effectiveness of interventions

Section E was designed to assess perceived effectiveness of interventions to improve insulin prescribing safety. To do this, respondents were asked to rate the interventions included as questionnaire items in section D using a 5-point Likert scale, with 5 being extremely effective and 1 being not effective. As 3 respondents who completed sections A-D did not complete section E, this section starts by describing the demographics of respondents who completed this section. This is followed by presentation of the descriptive analyses related to perceived effectiveness, and results of the survey validation.

Respondent demographics

After excluding missing responses from 3 hospitals for section E, data from a total of 92 organisations were eligible for analysis. Responses were received from 79 out of 150 (53%) English hospital trusts, 5 out of 6 (83%) health boards in Wales, 3 out of 14 (21%) health boards in Scotland, and all 5 trusts in Northern Ireland (100%). Most of the 92 respondents were from teaching hospitals (n=39, 42%) or district general hospitals (n=37, 40%) and provided specialist inpatient diabetes services (n=79, 86%).

Descriptive analyses

The highest overall mean score for perceived effectiveness was achieved for outreach team review (4.26 out of 5), followed by mandatory education on insulin safety for clinical staff (4.15), and local guidelines on managing hypoglycaemia (4.09). Modest scores were reported for electronic prescribing (3.87) and dedicated insulin prescribing charts (3.76). The lowest scoring strategies included the insulin passport (2.80) and the use of dedicated insulin order forms for dispensing (2.65). The mean scores for perceived effectiveness of all insulin prescribing safety interventions included in the questionnaire are presented in Table 4.4 in descending order of overall score.

Table 4.4: Respondents' opinions on how effective insulin prescribing safety interventions are for promoting insulin safety in their organisations, based on a 5-point Likert scale. N = the total number of respondents answering the item.

	Overall		**Respondents that use intervention**		**Respondents that do not use intervention**		
Intervention	**Average (SD)**	**n**	**Average (SD)**	**n**	**Average (SD)**	**n**	**P value**
Outreach team review	4.26 (0.88)	86	4.38 (0.86)	48	4.18 (0.89)	22	0.396
Mandatory insulin safety education for clinical staff	4.15 (0.89)	87	4.26 (0.75)	43	3.83 (1.08)	29	0.076
Local hypoglycaemia guidelines	4.09 (0.88)	90	4.07 (0.89)	86	5.00 (0.00)	2	0.146
Local hyperglycaemia guidelines	4.06 (0.87)	90	4.04 (0.90)	71	4.00 (0.82)	15	0.868
Insulin self-administration policy	4.06 (0.80)	88	4.03 (0.87)	58	4.11 (0.67)	28	0.701
Use of patient's own insulin on admission to hospital	4.02 (0.86)	89	4.03 (0.84)	86	3.67 (1.25)	3	0.472
Insulin self-management policy	3.99 (0.82)	87	4.11 (0.98)	28	3.98 (0.70)	47	0.552
Requirements for medicines reconciliation of insulin on admission	3.97 (0.88)	86	3.97 (1.00)	37	4.02 (0.80)	42	0.805
Requirements for medicines reconciliation of insulin on discharge	3.96 (0.82)	84	4.04 (0.95)	23	3.93 (0.77)	57	0.584
Algorithm for calculating correctional insulin doses for hyperglycaemia	3.94 (0.89)	85	4.07 (0.77)	15	3.93 (0.94)	54	0.602
Electronic prescribing	3.87 (0.99)	71	3.83 (1.07)	30	3.90 (0.93)	41	0.776
Insulin discharge checklists	3.78 (1.06)	85	4.08 (1.32)	12	3.73 (0.99)	67	0.292
Dedicated insulin prescription chart	3.76 (1.14)	88	4.00 (0.90)	49	3.85 (0.99)	26	0.505
Restrictions on ordering of concentrated insulin	3.71 (1.00)	86	4.08 (0.74)	25	3.51 (1.05)	57	0.007*
Nursing double-check of insulin prescriptions on discharge	3.67 (0.98)	86	4.24 (0.77)	29	3.31 (0.92)	51	0.437

Limitations on variety of ward stock	3.65 (1.13)	89	3.75 (1.10)	72	3.36 (1.11)	14	0.232
Additional validation of 'high doses' of prescribed insulin	3.59 (1.07)	85	4.00 (0.50)	8	3.50 (1.05)	70	0.516
Formulary limitations	3.40 (1.07)	89	3.55 (0.98)	51	3.29 (1.11)	31	0.279
Pocket-sized guideline cards	3.37 (1.23)	84	3.87 (1.20)	15	3.29 (1.21)	62	0.106
Tallman lettering on insulin prescriptions (e.g HumaLOG, HumuLIN)	3.33 (1.09)	85	4.06 (0.80)	17	3.18 (1.07)	65	0.001*
Insulin passport	2.80 (1.31)	87	2.73 (1.35)	26	2.83 (1.25)	53	0.751
Dedicated insulin order form (e.g. for dispensing)	2.65 (1.24)	85	2.67 (1.25)	3	2.65 (1.25)	81	0.987

The factor that best predicted a higher average score of perceived effectiveness of an intervention was its current use by organisations. This was observed for most interventions but was significant for Tallman lettering on prescriptions (p=0.001) and restricting the use of concentrated insulin (p = 0.007). Self-administration policies, extra requirements for medicines reconciliation of insulin on admission, electronic prescribing and the insulin passport were regarded as less effective by organisations currently using them compared to those who were not.

Scores did not vary significantly between hospital types (e.g. teaching hospital, district general, community, mental health), country, or those with a specialist diabetes pharmacist (compared to those without). The only intervention that produced a significantly different score between hospitals of different sizes was outreach team review (4.69 for >1000-bed hospitals, 3.57 for <200-bed hospitals, p=0.034). All interventions returned a minimum score of 1 and a maximum score of 5 amongst

respondents. Figure 4.7 shows the percentage of organisations who classed each intervention as "very effective" (4 or 5 on the Likert scale).

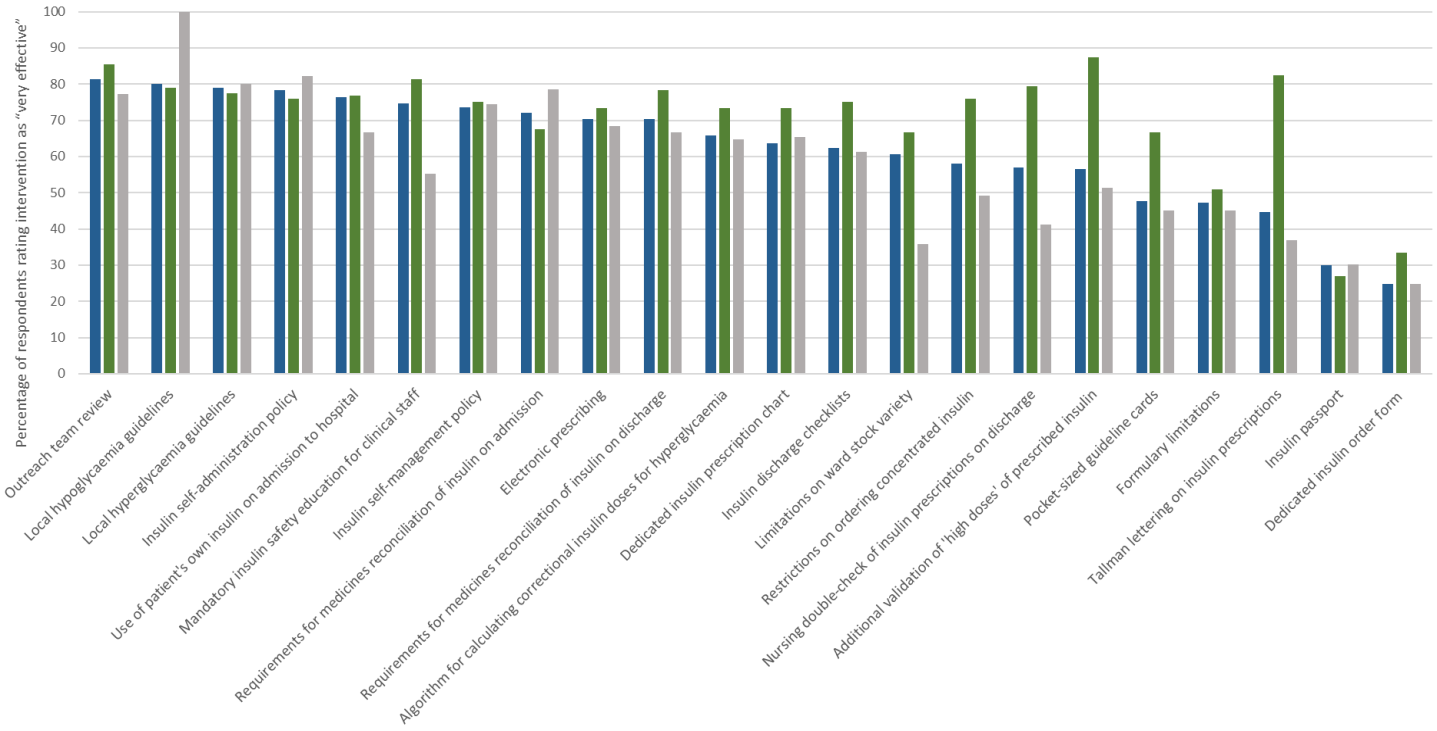


Figure 4.7: Percentage of respondents who consider interventions to be "very effective" for promoting insulin prescribing safety in hospital (score 4 or 5 on the 5-point Likert scale). Blue bars represent overall %. Green bars represent % of respondents who use that intervention in their organisations; Grey bars represent the % of respondents who do not use that intervention in their organisation.

Respondents were given the opportunity to rate the perceived effectiveness of any additional interventions they had described (i.e. in Table 4.3) using a 5-point Likert scale. Highly rated additional self-reported interventions included pharmacist-delivered insulin prescribing feedback, pharmacy-led self-administration assessment, the use of prioritisation software to enable pharmacist review of insulin prescriptions and brand name only prescribing of insulin (all scored 5 out of 5). The lowest rated additional interventions included non-mandatory insulin e-learning and insulin resource folders (both scored 2 out of 5).

4.4 Questionnaire validation

The questionnaire underwent face validity and content validity testing, as well internal consistency reliability testing. Score distributions across *a priori* intervention categories (depicted in Figure 4.5) were also examined. These are described below and discussed further as part of the research quality assessment in **Chapter 7**.

4.4.1 Face validity and content validity

Face validity addresses the issue of whether the questionnaire apparently has validity for survey participants and helps to ensure that the tool measures what it intends to measure (Rubio et al., 2003). In this study, face validity was determined qualitatively using respondents and experts' viewpoints during pre-testing, sensibility testing and piloting of the tool. This process was described in **section 4.2**. As a result of face validity testing some items were changed and added but no items were completely discarded.

Content validity seeks to determine whether questionnaire content accurately assesses all fundamental aspects of the topic, and is best performed with at least 3 content experts (Burns et al., 2008; Rubio et al., 2003). Qualitative content validity was incorporated into the tool development process outlined in **section 4.2.** In this process the recommendations of the four experts (who were also target respondents) were adopted on use of item wording and using explanations where needed.

In addition, the panel of 4 very experienced specialist diabetes pharmacists that represented the target population was asked to score individual items on the questionnaire to specify if it is necessary with a three-degree range of either "*essential"*, *"useful, but not essential", or "not useful".* All 22 items included in the questionnaire were regarded as *"essential"* or *"useful, but not essential"* by panellists (see Table 4.5).

Their opinions on the relevancy of items used in the tool were also quantified using the calculated level of inter-rater agreement using Fleiss Kappa (as there were more than 2 raters). This allowed quantification of agreement using a method that adjusts for chance agreement (Wynd, Schmidt, & Schaefer, 2003). As all items were either fair or excellent, it was considered appropriate that all 22 items could be retained in future iterations of the questionnaire.

Table 4.5: Content validity of the questionnaire. N_E = number of experts who rated the item as essential. N_U = number of experts who rated the item as useful but not essential. N_{NU} = number of experts who rated the item as 'not useful'. Agreement (%) = Pi value calculated using Fleiss Kappa.

Category and item	N_E	N_U	N_{NU}	Agreement (%)
Provider education				
Mandatory insulin safety education for clinical staff	4	0	0	100
Provider decision support				
Local hypoglycaemia guidelines	4	0	0	100
Local hyperglycaemia guidelines	4	0	0	100
Insulin passport	2	2	0	40
Insulin discharge checklists	2	2	0	40
Pocket-sized guideline cards	0	4	0	100
Algorithm for calculating correctional insulin doses for hyperglycaemia	1	3	0	50
Team changes				
Specific requirements for medicines reconciliation of insulin on admission	3	1	0	50
Specific requirements for medicines reconciliation of insulin on discharge	2	2	0	40
Nursing double-check of insulin prescriptions on discharge	0	4	0	100
Outreach team review of patients with hypo/hyperglycaemia (e.g. who have been flagged by an electronic system linked to remote blood glucose monitoring)	2	2	0	40
Prescribing and dispensing system				
Dedicated subcutaneous insulin prescription chart	3	1	0	50
Electronic prescribing of subcutaneous insulin	3	1	0	50
Dedicated insulin order form (i.e. if transcription required to dispense insulin)	0	4	0	100
Tallman lettering on insulin prescriptions	0	4	0	100
Policy				
Use of patient's own insulin on admission to hospital	0	4	0	100
Insulin self-administration policy	4	0	0	100
Insulin self-management policy	2	2	0	40
Restrictive measures				
Formulary limitations on numbers of insulins able to be prescribed	1	3	0	50

Limitations on number of insulins/devices available to order as ward stock	2	2	0	40
Restrictions on ordering of concentrated (200-500 units/ml) insulin	2	2	0	40
Additional validation of 'high doses' of prescribed insulin before dispensing (e.g. over 50 units)	3	1	0	50

4.4.2 Reliability

Reliability testing was undertaken with assessment of the internal consistency of the questionnaire. This was estimated using Cronbach's alpha (α), and examination of score distributions across *a priori* intervention categories. The Cronbach's alpha value of the overall questionnaire tool (n = 58 items) was 0.92 indicating very good reliability. Individual item analysis showed respondents tended to answer all items, and the median response rate per item was 99% (range 84%-100%).

As sections A-D pertained to demographic and binary responses, reliability testing was limited. Section E contained the Likert scale responses (n = 22 items), allowing additional reliability testing to be undertaken. For this section, the Cronbach's alpha value was 0.87, indicating good reliability (see Table 4.6). The Fleiss Kappa value for this section was also calculated using the data retrieved from the content validity test in Table 4.5 (0.35) indicating that there was fair inter-rater agreement (Landis & Koch, 1977).

Table 4.6: Descriptive statistics for the questionnaire (section E)

Items	**Value**
Score, Mean (SD)	82 (10.7)
Score, Median	83
25th Percentile Score	74
50th Percentile (Median Score)	83
75th Percentile Score	89
Possible Score Range	22-110
Actual Score Range	52-109
Alpha Reliability Coefficient (22 items)	0.87

An analysis of the individual items in section E showed that the respondents tended to answer all items and items were well correlated. The number of items, possible range, and number of respondents for each category is presented in Table 4.7.

Table 4.7: Possible range, and score distributions by categories of interventions included in the questionnaire (section E).

Questionnaire domain	**Number of items**	**Possible range**	**Mean ± SD**	**Number of respondents**	**'Floor' effects (worst effectiveness score) n (%)**	**'Ceiling' effects (best effectiveness score) n (%)**
Provider education	1	1-5	4.15 (0.90)	87	1 (1.1)	38 (44)
Provider decision support	6	6-30	22.1 (4.53)	80	1 (1.2)	6 (7.3)
Team changes	4	4-20	15.8 (2.89)	83	1 (1.2)	12 (15)
Prescribing and dispensing system	4	4-20	13.2 (2.62)	63	1 (1.6)	4 (6.3)
Policy	3	3-15	12.1 (2.16)	87	1 (1.1)	20 (23)
Restrictive measures	4	4-20	14.4 (3.45)	85	1 (1.2)	9 (11)

There was no bunching of scores at either extreme. There was a modest ceiling effect for the provider education category (44% respondents selected the highest possible score on the questionnaire), and a slight ceiling effect for the policy category (23% respondents selecting the highest possible score). Negligible floor effects were observed across all categories. This indicated that there was enough variation in the response to justify retaining all items in the tool.

4.5 Discussion of key findings

This is the first survey to focus on subcutaneous insulin prescribing system functionality and safety interventions in NHS hospitals. The results describe the current use of a range of interventions to improve insulin prescribing safety in hospitals, and highlight potential opportunities for safety features to be incorporated in both electronic and non-electronic prescribing systems. In describing the current practice, an important context is provided for those seeking to design, develop or improve interventions to increase insulin safety.

The use of inpatient electronic prescribing systems in English hospitals (particularly teaching hospitals) seems to be increasing in line with recommendations from the NHS Long Term Plan (NHS England, 2019). The results show greater uptake of electronic prescribing in the UK than in previous studies (McLeod et al., 2014; NHS Digital, 2019), but progress remains slow, with more than half of organisations using a combination of both electronic prescribing and paper-based systems, potentially threatening patient safety (Z. Ahmed et al., 2016).

Where electronic prescribing is used to prescribe insulin, the variation in system functionality reflects the wide range of different systems in current use (Mozaffar et al., 2014). This may impact the extent to which electronic prescribing can contribute to insulin prescription error reduction. For example, results show that many electronic prescribing systems do not incorporate various error-prevention features that were identified in the systematic review (such as clinical support tools, order sets, and high-dose alerts). In light of the current drive to implement electronic prescribing across all hospitals, results emphasise the need to carefully design and implement these systems in such a way that the potential benefits on insulin prescribing safety can be maximised, and the shortcomings, such as any negative impacts on healthcare professional working practices, can be minimised (Mohsin-Shaikh et al., 2019).

The modest rating respondents gave for the perceived effectiveness of electronic prescribing would benefit from further explanation, particularly considering the impetus for increased uptake of electronic prescribing system use in NHS hospitals. The lack of evidence for electronic prescribing systems in terms of insulin prescription error reduction, and the higher perceived effectiveness score given by respondents who are using paper-based systems, further contributes to the need to explore this intervention further in future studies.

Results also show a variation in paper-based insulin prescribing, with around one third of hospitals not using a dedicated inpatient subcutaneous insulin chart, and some charts not including some of the beneficial safety features identified in the systematic review (e.g. pre-printing of units). Although insulin prescription charts has been nationally promoted on account of their ability to reduce insulin errors (U. Dashora et al., 2015), respondents only gave this intervention a modest rating for perceived effectiveness. This may also be due to the lack of use of beneficial features of the charts; further exploration of the use of this intervention may help to explain this result.

There was a wide variation in the use of interventions to improve insulin prescribing practice across UK hospitals; a much greater number of interventions were found to be in use than had been identified in the systematic review.

For example, interventions such as outreach team review, prescriber feedback and therapeutic substitution guidelines had not previously been reported in the literature. This may reflect differences in the organisational and departmental support available to design, develop, implement, and indeed publish/report these interventions. The availability of specialist diabetes pharmacists that typically design, implement, and evaluate these interventions, for example, was low (29%), and at comparable levels to those reported in the 2019 NaDIA Hospital Characteristics report (26%). As results show an association between specialist pharmacist employment and number of interventions used, further creation of these posts should be encouraged nationally. This is now being reflected in recent guidance from the JBDS and the GIRFT groups (Joint British Diabetes Societies for inpatient care, 2019; Rayman & Kar, 2020).

Although not widely implemented, respondents regarded mandatory insulin prescribing safety education for healthcare professionals as a very effective intervention. Mandatory education of healthcare professionals is currently recommended for all staff who care for people with diabetes in the hospital setting (E. Watts & Rayman, 2018); results indicate that although this is a welcome recommendation, it is not currently widely followed.

The insulin passport, which has been recommended by NHS Improvement (formally the NPSA) since 2012, and is currently recommended by NICE, had one of the lowest uptake (around 1/3 hospitals) and perceived effectiveness scores. The cross-sectional nature of the survey means that we are unable to determine if perception of effectiveness preceded use, or vice versa. This may be explored further in the qualitative study to help explain why the passport is not used and is thought to be ineffective.

The use of guidelines for prescriber support were, however, perceived by most respondents to be very effective for promoting insulin prescribing safety. Although it is acknowledged that guidelines are not always adhered to, they represent a measurable standard of quality and are often prescriptive in nature, which can modulate prescriber uncertainty. These factors may contribute to their perceived effectiveness in promoting safe insulin prescribing.

Results show national variation in the availability of insulin self-administration and self-management policies despite this being recommended back in 2011 (National Patient Safety Agency, 2011). Further explanation of the result that self-administration policies were regarded as less effective by organizations currently using them (compared to those that were not) would be beneficial to help understand potential issues with its use and implementation. Renewed calls for all trusts to have these policies in use also prompts further investigation of the experiences and opinions of respondents at this time (National Patient Safety Agency, 2011; NHS Digital, 2020; Rayman & Kar, 2020).

Despite results allowing us to identify interventions that are perceived to be more effective than others in general, both the standard deviations and the max/min scores for individual items indicate that opinion varied considerably amongst respondents. This provides support to the conclusions of the systematic review presented in **Chapter 2**, suggesting that several factors may influence intervention effectiveness across different organisations. In order to identify and explain factors that may influence perceived effectiveness of interventions, which may include various social, behavioural and organisational mechanisms, methods that look beyond establishing linear causality should be used (Greenhalgh & Papoutsi, 2018). The use of semi-structured interviews with survey participants would be an appropriate method to help explain the salient results of the survey outlined above.

4.6 Stakeholder group discussions

The above results were presented to the Lay Advice on Diabetes and Endocrine Research (LADDER) panel and multidisciplinary inpatient diabetes team for discussion. Prior to the LADDER panel meeting, a lay summary of the survey results was circulated and a number of questions were asked of the panel regarding the results. During the meeting, the results were verbally and visually presented and the questions were discussed amongst the group. This allowed the researcher to interpret the results from a different point of view and to direct the focus of the next study in such a way that would be most beneficial for people with diabetes. These questions, along with the written responses from the circulated minutes following the meeting, are included in Box 4.1.

Box 4.1: Questions asked of the LADDER panel after presenting the survey results, and a summary of answers.

How do you think the results might impact people with diabetes?

- *Panel found the results frightening. Members felt that they would not want to give over their insulin when staying in hospital as they would not trust the correct management of their own insulin levels. Group agrees self-administration is the way forward .The panel noted security for medications is also a big issue. They would want a policy allowing them to manage their own insulin but also a security box at the bed side to ensure insulin was not stolen.*

Are there any results you find particularly interesting or feel should be emphasised?

- *Panel agreed self-administration should be emphasised as a solution to minimise errors.*

Are there any ways you might interpret the results that haven't been mentioned?

- *None noted.*

Where do you think the research should go from here?

- *The panel agrees that the next stage would be to look at self-management policies. With alternatives in place when self-administration is not possible. Education of nurses and doctors is another key point.*

Discussion of the survey results with the multidisciplinary inpatient diabetes team – incorporating consultant diabetologists, registrars, diabetes inpatient specialist nurses and pharmacists – centred more around provision of evidence for implementing interventions in the inpatient setting. Members prioritised the generation of data to prove intervention effectiveness in practice, such as a reduction in insulin errors or improvement in the number of 'good diabetes days' with self-administration policies, for example in hospitals that use the policy compared to those that do not. They were also interested in various process and patient-orientated outcomes of organisations using electronic prescribing systems for insulin compared with those that used paper prescriptions.

As a result of the discussions with the LADDER panel and the inpatient diabetes group, it was decided that semi-structured interviews with participants should include questions on self-administration policies and insulin prescribing systems, as these were of particular interest to patients with diabetes and multidisciplinary inpatient teams, respectively. The qualitative study should also seek to provide evidence for generative mechanisms that lead to intervention success/failure in such a way that can help to discriminate between hospitals that use the intervention and those that do not. These reflections were taken forward and helped to design the conduct of the qualitative interview study, which is reported in the next chapter.

4.7 Summary

Effective strategies to improve insulin prescribing quality are needed to reduce harmful and costly insulin prescription errors for people with diabetes in hospital. With the use of a validated, cross-sectional survey tool, we have described the current systems in use to prescribe insulin in NHS hospitals, as well as the uptake and perceived effectiveness of interventions to help improve insulin prescribing safety across a wide range of hospitals throughout the UK.

Inpatient electronic prescribing is increasing, but there are significant differences in the functionality of systems to optimise insulin prescribing safety. The use of insulin prescribing charts is also variable, as are the features included in their design to help prevent insulin prescription errors. There is a wide variation in the uptake of interventions to help improve insulin prescribing quality, including those that are promoted by national bodies such as NICE and the JBDS.

Interventions that are regarded as effective by a large sample of hospitals were identified, such as outreach team review, mandatory insulin education, local guidelines and specific insulin self-administration policies. The insulin passport was not perceived to be effective and is not used by most hospitals. The range of scores received from respondents indicate that perception of intervention effectiveness is likely to be dependent on organisational context. Perceived effectiveness was positively associated with current use for many interventions, except for the insulin passport, electronic prescribing, or self-administration policies. It is recognised that intervention design

and implementation costs time, resource, and effort. The increased use of specialist diabetes pharmacists may facilitate efforts to reduce insulin prescription errors by supporting intervention use to promote safe insulin prescribing.

The salient results from this survey are further explained in the next chapter, which presents the findings of the qualitative phase of the mixed methods study.

Chapter 5: A qualitative study exploring insulin prescribing safety interventions in the hospital setting

This chapter presents the findings of the qualitative phase of the mixed methods study, and includes the following:

- The development of a semi-structured interview guide to analyse the experiences and opinions of hospital pharmacists involved in the design, implementation and evaluation of insulin prescribing practice interventions in the UK hospital setting.
- Presentation of the themes identified from the reflexive thematic analysis of qualitative data.
- The application of the Systems Engineering Initiative for Patient Safety (SEIPS) human factors work systems model to the findings.
- The additional categorisation and analysis of coded data according to intervention use for selected interventions.
- Discussion of key findings.
- Discussion of results with stakeholder groups and implications for the next study.

5.1 Introduction

We have seen from the previous chapter that there are a wide variety of insulin prescribing systems and interventions being used across NHS hospital organisations in the United Kingdom, including those currently recommended by NICE. Despite this, it is clear that some interventions were perceived to be more effective than others; for example the use of outreach team review, mandatory insulin safety training, and guidelines scored much higher than the insulin passport and dedicated insulin order forms for dispensing. Some interventions were perceived to be more effective by participants from organisations where that intervention was not in use, for example insulin self-administration policies, the insulin passport and electronic prescribing systems.

Results in the previous chapter indicated that perceived effectiveness of insulin prescribing practice interventions is likely to depend on various contextual factors. These may include social, behavioural and organisation factors such as prior exposure, experience, and implementation success of the intervention. Exposing and exploring these contextual factors, barriers, and facilitators to intervention success or failure would help to explain and expand on these results, and provide recommendations for the benefit of improving insulin safety in the hospital setting.

In **Chapter 1** we were introduced to the whole systems nature of insulin prescribing practice interventions, and the idea that complex organisational and social factors can significantly influence the success of their

implementation. Few studies have used qualitative methods to explore some of these contextual factors that can hinder or facilitate insulin prescribing intervention success, or the general barriers and facilitators to insulin prescribing safety in the hospital setting (see **Chapter 1, section 1.3**). Findings have suggested that a lack of access to useful information for optimal management of insulin therapy and a lack of communication among personnel on different work shifts are problematic, and that barriers to intervention use are complex and require a systems-based approach (Helmle et al., 2018; Rousseau et al., 2014). Previous studies have been limited to single organizations or interventions, a lack of theoretical underpinning, or limited reporting on the techniques used to generate the findings, and none have been conducted in the UK. The paucity of qualitative research in this area, particularly at an organisation-level of analysis, and the persisting nature of inpatient insulin prescription errors provides a convincing need for transferable qualitative evidence that deepens our understanding of inpatient insulin prescribing errors and interventions, particularly in a UK context.

This study seeks to explore insulin prescribing problems, solutions, and interventions at an organisational level**,** and in doing so, will explain some of the salient findings from the cross-sectional survey discussed in **Chapter 4**. To do this, pharmacists who had completed the survey were invited to participate in follow-up qualitative interviews. These pharmacists occupied a variety of roles depending on the organisational structure of the hospital, such as clinical pharmacy service managers, specialist diabetes pharmacists, and medicines safety officers (typically pharmacists who have a particular role in medicines governance at their organisations). All were involved at some level in the investigation of insulin prescribing errors, insulin prescribing practice intervention design, implementation, or evaluation, and were therefore ideally placed to provide in-depth insights on the topic of study.

The objective of this study was to analyse the experiences and opinions of UK-based hospital pharmacists involved in the design, implementation and evaluation of inpatient insulin prescribing practice interventions using qualitative interviews. Research questions included:

- What are the current challenges and solutions with respect to improving insulin prescribing practice in the UK hospital setting?
- What are the contextual factors that may influence the success of insulin prescribing practice interventions in the UK hospital setting?

First, the development of the interview guides will be discussed, including the contribution of the two pilot interviews. The results of the thematic analysis of the data will then follow.

5.2 Interview guide development and pilot interviews

The interview guide was developed to include a series of questions to guide conversations with the participant (see Appendix 10). It was designed around the research questions and was developed around good practice guidance (Braun & Clarke, 2013; Grbich, 1998; N. King et al., 2019; Ogden & Cornwell, 2010). The content was informed by critical and collective reflections on the systematic review and survey findings with the patient public involvement groups, and included specific topics of particular interest, such as insulin self-administration policies and electronic prescribing.

Questions were designed to be mostly open, positive and framed in the present tense. This was to generate rich data and prompt a fluid discussion of the salient results of the survey, whilst allowing participants sufficient room to discuss areas of particular interest or priority for them. The interview guide aimed to allow the generation of detailed and contextually rich data from a variety of individuals representing a range of hospital organisations. To do this is needed to facilitate a flexible approach to interviewing, such that the researcher could respond appropriately to in-depth personal accounts with unplanned or spontaneous questions (Braun & Clarke, 2013, p79).

Asking directly about insight and causation is said to produce especially rich data on these aspects, particularly later on in the interview (Ogden & Cornwell, 2010). A combination of descriptive and probing questions was therefore included in a logical and funnelling order, starting with more general, descriptive questions, and progressing to more in-depth issues. Descriptive questions enable the participant to talk about something they are familiar with and interested in, such as their life experience or expertise in a particular field (Grbich, 1998, p104). Starting the interviews with these types of questions helped to gain rapport and trust with the participant, which is a key component in interactive data collection (Braun & Clarke, 2013, p81). Subsequent questions explored participants' perceptions and experiences with insulin prescribing practice interventions in the context of their organisations. Closing questions focused on the future hopes and concluding thoughts and allowed participants to raise relevant topics they feel may have been missing from the interview and add any final comments.

Brief prompts were included in the interview guide for reference if the interviewee did not understand the question or required prompting to answer questions. Prompts were not extensively documented in the interview guide to keep the guide brief enough to use with ease during the interviews. The researcher conducting the interviews had prior experiential knowledge of the professional and organisational setting (pharmacy practice in secondary care) as well as the research topic, and the participants were all hospital pharmacists who had a working knowledge and the use of subject and profession-specific terminology. This facilitated a natural conversational style interview with the participants without the need for extensive prompts in the interview guide.

Two pilot interviews were conducted prior to the start of the study to help refine the interview guide and critically examine question wording, sequence, and usefulness. The pilot interviews also helped the researcher to practice the interview delivery and gauge the timescale of the interviews prior to recruitment. One pilot interview was conducted with a diabetes specialist pharmacist and another was conducted with a medicines safety officer. These two interviewees were both female, very experienced in their roles and were colleagues of the researcher working at the same hospital trust. As neither were survey respondents they were not included in the final sample of participants, but they were felt to be representative of the potential participants. The pilot interviews were conducted with fully informed consent in the same manner as the study interviews. They were audio-recorded and transcribed verbatim to help the researcher familiarise themselves with the practicalities of using the recording equipment. The first pilot interview with the specialist diabetes pharmacist lasted just 15 minutes, and the second pilot interview lasted around 45 minutes.

The researcher reflected on each interview successively to review and develop the interview guide. This included assessing if the questions contained in the interview guide helped to generate the required information and help to answer the research questions, and if any questions contained problematic assumptions or ambiguous meanings. The researcher's interview style and input were also reflected on to help identify any areas for improvement. For example, it was noticed that the researcher used some words or phrases to demonstrate engagement with the interviewee that could be leading (e.g. "*that's interesting*"). Awareness of this allowed the researcher to be more careful to choose more neutral phrases or words to demonstrate listening (e.g. *"I see, yes"*).

As a result of the pilot interviews, some question wordings in the interview guide were changed to be more neutral. For example, asking interviewees if patients at their hospital have a "*lack of ability to self-administer"* could lead them to the negative connotations of not having a policy and may reveal a particular viewpoint of the researcher. This was thus changed to the more neutral wording of "*does your trust have a self-administration policy at the moment?"* following which, expanding questions may be asked.

Other minor amendments were made to the guide to make it easier to use, such as colour coding for prompts, and amending question wording for clarity. Additional prompts were also included following pilot interviews, for example with respect to insulin self-administration policies: *"Ideas and assumptions about how it works"* and "*What is necessary to support success?"* The researcher's field note-taking practice during interviews was also reflected on and amended to be more comprehensive. This process allowed the interview guide and the researcher's interview practice to be further optimised to provide a more useful tool with which to obtain more meaningful qualitative data.

Once the interview guide was optimised a total of 18 telephone interviews with survey participants was conducted. Further details regarding the methods employed in this study are outlined in **Chapter 3.** The section below presents the findings of the reflexive thematic analysis of the semi-structured qualitative interviews. The study has been reported with consideration of the COREQ (COnsolidated criteria for REporting Qualitative

research) Checklist for qualitative studies (Tong, Sainsbury, & Craig, 2007). These guidelines are included in Appendix 11 and are discussed further in **Chapter 7**.

5.3 Findings

Individuals were interviewed remotely over the telephone between 12th September and 16th October 2019 using a conversational, semi-structured approach by the researcher, who introduced herself as a hospital pharmacist who has occupied a clinical academic role for the past few years and has an active interest in insulin safety. Interviews lasted between 24-46 minutes (average 35 minutes), with a total of 10.5 hours of interview data being obtained. Interviewees were made aware of the researcher's occupation and gender prior to the interview from the email signature, and the reason for undertaking the research was outlined in the participant information leaflet prior to undertaking the interview.

Further details about the researcher's occupation were disclosed to some participants during the start of the interview on request to help build trust and rapport (e.g. one participant expressed interest in mix of research, practice and teaching involved in the researcher's role at the start of the interview). All participants had previously completed the survey presented in **Chapter 4**; three participants were known to the researcher prior to the interview through professional networks or previous working relationships. There were no obvious power imbalances that was felt to impact the data collection, such as employee-employer or line-manager relationships, positions that were significantly more or less senior than the researcher.

Pharmacists from a variety of backgrounds and representative organisations (see Table 5.1) expressed a clear and patterned set of ideas about insulin prescribing safety risks and interventions in the hospital setting. All participants were able to talk confidently and insightfully about the problems and potential solutions to insulin prescribing practice issues in their organisations, and were able to talk in-depth about the use and effectiveness of interventions to reduce insulin prescription errors.

Table 5.1: Demographics of participants (n=18). Some occupations have been abridged slightly for consistency and/or anonymity.

Gender	Female	12
	Male	6
Country	England	15
	Northern Ireland	2
	Wales	1
Type of Hospital	Teaching Hospital	10
	District General Hospital (DGH)	7
	Other (Mental Health Hospital)	1
Role	Specialist Diabetes Pharmacist	8
	Medicines Safety Officer (MSO)	4
	Clinical pharmacist (managerial)	3
	Clinical Pharmacist (other)	3
Years in post	1-5 years	8
	6-10 years	5
	> 10 years	5
Prescribing system	Paper insulin chart	9
	Electronic insulin prescribing	4
	Electronic prescribing but excluded insulin	3
	Paper chart but no insulin chart	2

The analytic process resulted in the identification of 7 major themes: improving insulin prescribing practice is an important but 'wicked' problem, prescribing insulin is regarded as scary and complex, insulin prescribing safety should be everyone's responsibility, it is an important but uphill battle to educate staff on insulin prescribing safety, a balance must be found between prescribing system control and flexibility to prescribe insulin, interventions to improve insulin prescribing are hard to evaluate in practice, and inpatient insulin self-administration is a problem worth solving. An overview of the main thematic structure is shown in Table 5.2. Example quotes are given to exemplify themes, and are identified by basic demographic information from the participants, along with the participant number in parentheses. The coding tree, which includes the codes generated during the analysis with example quotes, and how these relate to the subthemes, is found in Appendix 12.

Table 5.2: Overall thematic structure derived from inductive reflexive thematic analysis of the interview data, along with theme descriptions and example quotes. DGH = District General Hospital, MHH = Mental Health Hospital MSO = Medicines Safety Officer

Themes	Description	Subthemes	Example quotes
Improving insulin prescribing practice is an important but 'wicked' problem	The perceived need for insulin prescribing quality improvement interventions, organisational and personal drivers for the improvement of insulin prescribing quality locally, and the challenges to making desired changes amongst individuals, teams and organisations.	Insulin prescribing safety is important Improvement is challenging Drivers for improvement Pharmacists as a safety net The importance of team	*"Although we, you know, they've tried. And they will have, they will have, you know, bursts of intervention, if I can call it that where there is increased training, but then it lapses until something else bad happens."* –Male clinical pharmacist (managerial), DGH, Wales (P12)
Prescribing insulin is regarded as scary and complex	The nature of insulin errors in hospital, and the various drug-related and socio-cultural factors that precipitate them. Particular issues and risks around prescribing at the point of care transfer, including access to information, and the perception of interventions that can facilitate this.	Errors are there to be made Insulin prescribing is not easy Prescribers are scared of insulin A 'shot in the dark' on admission Socio-cultural issues with prescribing	*"In terms of prescribing it but they're scared of it. It's two-pronged, they're scared of it because they don't know what to do with it. But then they don't do anything about it."* – Female diabetes pharmacist, DGH, England (P18)
Insulin safety should be everyone's responsibility	The input of diabetes teams, the need for an increased collective responsibility for insulin prescribing safety and the perception of interventions that can facilitate this.	Diabetes teams as a victim of their own success Guidelines for prescriber support	*"And I think part of that is because for so long when the diabetes team has been embedded as "they're the experts" and so a lot of staff on the ward don't take responsibility because they think, "oh, well, you get the diabetes nurse to sort it out", or refer to them."* – Female diabetes pharmacist, Teaching Hospital, England (P5)

It is an important but uphill battle to educate staff on insulin prescribing safety	The perceived need for educational interventions, and the importance of how these are designed and delivered, as well as the factors that make educating the workforce on insulin use difficult, including organisational, employment and political issues.	There is a lack of knowledge and experience with insulin Education is desirable Education alone is insufficient Staff as peer-educators Challenges with educating the workforce The trouble with mandatory training Pedagogy is important	*"So the idea of providing, like, training, and making sure everybody's up to speed with that is a very, very difficult thing to do. And when you line it up with all the other training that sits for a trust to have to undertake, unless, unless you can get these sorts of things into the mandatory category, you generally don't have much success with them."* – Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)
A balance must be found between prescribing system control and flexibility to prescribe insulin	Perceptions regarding the way in which insulin is prescribed in hospital and how this may promote or risk insulin safety in hospital are varied. Restricting prescribing behaviour/actions as beneficial for the sake of insulin prescribing quality on both paper and electronic systems, however flexibility is needed.	Prescribing processes vary Prescribing systems Blood glucose monitoring is tied up with prescribing Opportunities and drawbacks with current prescribing systems	*"And obviously, we've got electronic prescribing, and we've got the ability to put some limits in there. But the regimes are so variable, it's very difficult to put hard limits on them."* – Female MSO, Teaching Hospital, England (P3)
Interventions to improve insulin prescribing are hard to evaluate in practice	The desire to measure the effectiveness of interventions is not met with the ability to reliably do so using audit or error reporting systems, and the use of feedback and anecdotes to evaluate interventions is common.	Anecdotal evidence Audit as a measure for improvement Error reporting Insulin safety achievements as varied Measuring intervention success is desirable but difficult	*"Now can I turn round and tell you that they definitely reduced our error rates? Well I actually couldn't. Because it's very difficult to measure your error rates."* – Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

Self-administration of insulin in the inpatient setting is a problem worth solving	Self-administration policies to promote the independence of people with diabetes in hospital are laudable and encouraged but are often difficult to implement.	Assessment processes Attitudes to self-administration Communication Documentation Implementation Measuring success Self-administration is a risk Self-administration is encouraged Self-management Storage and disposal Suitability of patients Writing the policy	*"And for a whole multitude of those reasons, we're doing it very, very badly. So that if anyone's got - cracked it and got a really good way of doing it, then those are the kind of shared learning we would love to hear from."* – Male clinical pharmacist (managerial), Teaching Hospital, England (P9)

The findings from each of the themes outlined in Table 5.2 are presented in detail below, on a theme-by-theme basis. Subthemes are incorporated into each theme but are not presented as section headings, to facilitate the overall flow of the narrative.

5.3.1 Improving insulin prescribing practice is an important but 'wicked' problem

Problems with insulin prescribing were described by all participants, and were mainly perceived as common, widespread, challenging, and recurrent:

> *"Absolutely, it's the number one drug in our hospital for harm-related incidents."* Female MSO and diabetes pharmacist, Teaching Hospital, England (P11)

> *"So I think when we when we look at our incident reporting, we kind of seeing a whole load of trends coming through, but only sporadic ones for each and, and it's totally so across the board."* Male clinical pharmacist (managerial), Teaching Hospital, England (P9)

> *"I don't know. I mean, you know, there is no one fix. Otherwise we'd have done it."* – Female MSO, Teaching Hospital, England (P13)

> *"Although we, you know, they've tried. And they will have, they will have, you know, bursts of intervention, if I can call it that where there is increased training, but then it lapses until something else bad happens."* –Male clinical pharmacist (managerial), DGH, Wales (P12)

"And that's what we're trying to figure out at the moment is kind of the ways the ways to help prevent these issues from happening, it does tend to be the same sort of issues that happen again, and again." – Female clinical pharmacist, DGH, England (P1)

A need for greater insulin prescribing practice improvement efforts in the hospital setting was expressed, and participants felt this was reflected in their organisations by being high on the local safety agenda:

"I think there's such a lot of improvements to be made in every hospital, because of these errors and issues that happen everywhere... And, you know, is, is quite high on the on the agenda at the hospital, and the medicines safety team as well." - Female clinical pharmacist, DGH, England (P1)

"All trusts care about insulin safety" - Female clinical pharmacist, Teaching Hospital, England (P2)

This perceived need for improvement was often described alongside the difficulties in designing and executing improvement strategies:

"We've been going around in circles for a couple years going, "not entirely sure where to go next"." – Male clinical pharmacist (managerial), Teaching Hospital, England (P9)

"And the thing that she says about insulin safety is that "we've tried everything, and nothing seems to work"." - Male clinical pharmacist (managerial), DGH, Wales (P12)

When these difficulties were explored further with participants, several factors were felt to impede on the success of interventions in general. These mainly included local workforce and organisational factors, including a lack of time, money and staff:

"*But it's just obviously dedicating the time and focusing really on how best to improve what is going wrong."* Female clinical pharmacist, DGH, England (P1)

"But again, it comes down to staffing and money etcetera." - Female diabetes pharmacist, Teaching hospital, England (P10)

"And we don't have many pharmacists in the department, so we all tend to have several wards a day so you don't necessarily have the time to do that." Female clinical pharmacist, Teaching Hospital, England (P4)

For staffing issues in particular, the high turnover of staff through ward areas was thought to be particularly problematic, creating issues related to sustainability of interventions. This resulted in a need for continued momentum for improvement efforts, and a loss of 'organisational memory' with respect to insulin prescription errors and their consequences:

"I think the main problem we have, and must be in all hospitals, is the turnaround of staff... But it's having the momentum to keep - you have to keep that up all the time, or are the new students, the new doctors coming through, the new pharmacists coming through, are they going

to have a better idea now of branding of insulin and, and the importance of - I don't know." Female diabetes pharmacist, Teaching hospital, England (P10)

"But in terms of overall reflection, the problem is we're set in a workforce that's constantly revolving. And as you've been, you're getting somewhere, people move. And you know, even if it's the case of nurses moving on to other things, and you get another batch of nurses in and it used to feel it in work that the sort of the nurse contingent was the steady thing, as well as pharmacists on wards, and now that's not the case anymore. They nearly turn over as quickly as the docs. So it's a real sort of nightmare when it comes what you're trying to do, and instil sort of good practice and get keeping people up to speed." – Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

"Because the NHS, does have a memory, but unfortunately, it tends to be concentrated in people that have been around for a long time. And, as people turn over, then we get more and more worried about how is that memory being passed down to stop us making the same mistakes?" - Male managerial pharmacist, DGH, Wales (P12)

Drivers for intervention use were described by participants. These included both internal (personal) drivers, such as previous experience and professional motivation, as well as external drivers such as national alerts (e.g. from the NPSA), national inpatient diabetes audit (NaDIA) data and recommendations, local quality indicators, audits, and incident reports:

"And then, and then, of course, the alerts came out saying you need to do you know, this, this and this. And on the back of that, well, I'd come from a trust with a separate insulin drug chart, so I devised an insulin drug chart." - Female MSO, Teaching hospital, England (P13)

"I think the driver was at the time it was set up we had a consultant nurse for diabetes that was very keen on progressing those sort of things, and linked in with pharmacy – it was in response to, you know, the number of incidents that were occurring" - Male clinical pharmacist (managerial), Teaching Hospital, England (P7)

"And we've had, unfortunately well I suppose linked to the NPSA and stuff, once you have fatalities associated with administration of insulin and coroners are involved and they get on to the training bodies and get on to the trusts themselves. And once coroners says well all junior doctors should have a mandatory training around the use of insulin it sorts of tends to focus people's minds." - Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

With respect to personal and organisational drivers, it was acknowledged that change was chiefly dependent on individuals embedded within diabetes or pharmacy teams who were enthusiastic about improvement. However, it was necessary to engage senior staff who had the power to implement interventions:

"You need to find one or two people who are dead passionate about it. It's simple, you know, leadership stuff ain't it. If you've got somebody really enthusiastic and picks up on it and you know, pushes it at different fora, then, you know, you'll have more success I think." - Male clinical pharmacist (managerial), Teaching Hospital, England (P7)

"I suppose it's getting buy in from the great and the good, high up the food chain, is excellent as well if you can somehow manage it, sort of aligning it with priorities. Be it with governance

groups and saying that we have a problem with our, you know, our diabetes care or insulin prescribing or NCEPOD you know, using stuff that's out there nationally to say that this needs to improve." - Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

Relationships with the necessary players for action and change were chiefly dependent on individuals, and so were subject to change when staff left or moved on:

"But once the key lead for that stops doing it, it falls." - Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

All participants, who were pharmacists themselves, described the significant input of pharmacists working alongside or as part of inpatient diabetes teams, in the area of insulin prescribing safety.

"I'm employed to pick up on that error, so I am the safety net" - Female clinical pharmacist, DGH, England (P1)

"The pharmacist who was in that role before me, she worked quite closely with the diabetes nurses to sort of develop our current insulin chart and do things around insulin safety" - Female clinical pharmacist, Teaching Hospital, England (P4)

"So I do <u>all</u> of their insulin safety work and their diabetes work basically" - Female clinical pharmacist, Teaching Hospital, England (P2)

Pharmacy teams having a consistent presence advocating for safe insulin prescribing on the ward areas was described as an important element of ongoing improvement efforts, particularly in the context of a high turnover of staff through organisations:

"And again, just obviously increase – we are looking at models of one pharmacist per ward. And again with having that bit more time dedicated to a ward again, we can offer extra, and then extra teaching, etcetera. So that would help also with the doctors coming through, etcetera, you could have a bit more of a role of ensuring that they, you know, you could assess their, you know, insulin knowledge, etcetera, and obviously make sure they do the e-learning and just have these type things." – Female diabetes pharmacist, Teaching hospital, England (P10)

"And that's where pharmacists can make things better because we're on the ward every day. We're consistently there. We should be highlighting when someone isn't having a good diabetes day, and trying to talk to people about why is that happening? Can we do something about it? You don't have to be the person who makes the decision about fixing it." – Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

Although insulin prescribing safety was considered as an important element of the pharmacist's role, participants recognised the multidisciplinary nature of improvement strategies, which was considered to add to the complexities around intervention design, implementation and ongoing sustainability:

> *"And does that collaboratively work at the minute? No, it doesn't. And so actually, you're moving the responsibility from prescribers to our nurses. And is that appropriate? I'm not entirely sure. But that's something we're discussing at this level (interviewer: yes) at the minute. So I guess the chart is a challenge, now, at the minute."* - Female diabetes pharmacist, DGH, England (P18)

> *"So for the past two years, I've been trying to introduce a specific guideline and drug chart. But I need the assistance of the pump teams like specialist nurses and stuff. Getting everyone to sit down together has been a bit of a problem. Because everyone is so busy.* - Female diabetes pharmacist, Teaching Hospital, England (P5)

One method of bringing the necessary stakeholders together to discuss insulin prescribing safety was described by participants as involvement in insulin safety groups. These groups existed either within or across organisations locally and were thought to be beneficial for facilitating the consideration of the multiplicity of systems, cultures and strategies needed to promote the safe use of insulin in hospitals:

> *"There's a local MSOs group that's just been set up in the CCG area. And they're going to try and look at insulin safety across the patch… So we're starting to look at it in a better than one trust organization kind of perspective."* – Male clinical pharmacist (managerial), Teaching Hospital, England (P9)

> *"Obviously creating the insulin safety committee has sort of allowed us to focus more on it."* - Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

> *"We also have as an offshoot of our medicines safety team we have an insulin safety group as well…. I think it meets monthly or bimonthly, but it focusses solely on insulin. Safe prescribing, administration, monitoring, diabetes issues in general... So the work with that group and medicines safety group and EPMA team sort of all pull together to try and make it as safe as possible, but still incidents that happen… But I think the output from that group in particular, tied in with the other stuff that's gone on, we try to tighten it up as best we can."* – Male clinical pharmacist (managerial), Teaching Hospital, England (P7)

The complex nature of insulin prescribing problems and improvement efforts outlined in this theme link to the next theme, which concerns the nature of insulin errors in hospital and the various factors that precipitate them.

5.3.2 Prescribing insulin is regarded as scary and complex

Insulin was often described by participants as a unique risk with respect to prescribing, with reference to complex drug-related, human, socio-cultural and system factors that threatened the safe prescribing of insulin:

> *"And with insulin, it's probably, it's never one thing. It's never just the knowledge. Sometimes it's the environment or the circumstance at the time. And also sometimes it's, it's because there are competing demands maybe, which, which is a little bit different. So not necessarily the physical environment."* – Male managerial pharmacist, DGH, Wales (P12)

"All it takes is one three AM night shift and an inexperienced F1 and an inexperienced nurse and you get an error." - Female clinical pharmacist, DGH, England (P1)

"You know, those sort of errors that you think why on earth would anybody make that mistake? Well, people make it because it's there to be made." - Male clinical pharmacist (managerial), Teaching Hospital, England (P7)

For example, participants cited the complexity, dose-variability, variety, and high-risk nature of insulin as confounders in the prescribing process, making it more error-prone than with most other medicines:

"Like, I suppose, like most medicines, they're a bit you know, there's, there's the same stages where there's the prescribing, the dispensing, the administration, and that's the same for an awful lot of medicines. But I think the difference that insulin is the variability of the dose, and also simply the number of preparations <u>with</u> the fact that so much can go wrong." - Male managerial pharmacist, DGH, Wales (P12)

"I think there's a lot of problems in terms of so many different brand names there's so many different insulin types as well and when you, when ordinarily we encourage prescribing by drug name, but then with insulins say actually "no, it has to be brand name" and then there being so many varieties." - Female diabetes pharmacist, DGH, England (P17)

"Once you take a decision to make a prescription for insulin there are a lot of external factors that will impact on the outcome of your prescription. And that can be things like the nurse forgetting to give the insulin, not giving it at the right time, the patient not eating what they'd usually eat, the surgeon coming and saying "I want the patient to fast" you know the grandchildren coming and bringing an ice cream when granny doesn't usually have an ice cream. <u>All</u> of those things will affect the outcome of your prescribing." – Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

Participants described the resulting fear of insulin and clinical inertia not just from prescribers, but also from nursing and pharmacy staff. This was thought to result in negative consequences for people using insulin in hospital. This is because decisions about prescribing are delayed and hypo- or hyperglycaemia ensues:

"They don't regard that as a critical medicine I don't think, in terms of prescribing it. But they're scared of it. It's two-pronged, they're scared of it because they don't know what to do with it. But then they don't do anything about it." – Female diabetes pharmacist, DGH, England (P18)

"The core trainee was totally frightened to prescribe insulin because they'd never had the opportunity as an F1 do prescribe insulin that often." - Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

"It's interesting is that sometimes, there's a real, I tend to find that it's never in the middle - people either treat insulin as if it's poison and sometimes you have errors of omission because people are so worried about it." - Male managerial pharmacist, DGH, Wales (P12)

"And I think it's because people are scared of insulin, they don't understand it." - Female diabetes pharmacist, Teaching Hospital, England (P5)

A particular area of risk related to insulin prescribing practice was considered to be the process of prescribing insulin on admission to hospital. Participants described their experiences of this in terms of the difficulties associated with the lack availability of requisite information about insulin from primary care, as well as inadequate drug history taking practices during medical clerking:

> *"So then insulin on admission, quite often not prescribing it is probably one of the most common things. So people have missed doses."* - Female MSO and diabetes pharmacist, Teaching Hospital, England (P11)
>
> *"I think the difficulty there is that they don't know what the patient takes."* - Female MSO, Teaching hospital, England (P13)
>
> *"So just the sort of thing of, what dose is the patient on? Primary care sometimes know but are a bit vague, depends who's giving the dose and who is writing it down. Secondary care only knows what primary care know or the patient could tell them."* – Female clinical pharmacist, Teaching Hospital, England (P2)
>
> *"I guess, just generally, with doctors clerking patients in and I think there's a bit of a lack of awareness about how to take a good drug history. They maybe just look at the maybe the GP record, or ask patients, they might do both, but they didn't always marry them up."* – Female clinical pharmacist, Teaching Hospital, England (P4)

With respect to existing interventions to improve insulin prescribing at the point of care transfer, particular disregard was given to the insulin passport. The pervading perception was that this intervention was of little value because it contained insufficient information for prescribing, a lack of clarity on who was responsible for their upkeep, and their redundancy for the few people that would engage with their use:

> *"And you know even the insulin passport doesn't even have the doses on it because they change. Like it's so silly."- Female diabetes pharmacist, Teaching Hospital, England (P5)*
>
> *"You're relying on people updating it and it actually being a contemporaneous record, which, unless somebody takes ownership it never will be."* - Male clinical pharmacist (managerial), Teaching Hospital, England (P7)
>
> *"When I started in the role I said "do we use these?" 'cause we've got a huge big store of them over in pharmacy store and they were like, "no we don't use them because people forget to bring them in or the insulin changes so much or the doses change so much that they don't keep them updated."* - Female clinical pharmacist, DGH, England (P1)
>
> *"It's been, you know, a stone around everyone's foot and we've all drowning because no one updates it, it can't be updated and the only people who use it well are the people who don't need them i.e. the highly invested diabetics. So the passport would never work and everyone kind of made a sort of sighing effort towards having something available and then chose to ignore it because it was never going to happen basically." – Female clinical pharmacist, Teaching Hospital, England (P2)*

Despite the lack of support for the insulin passport, some participants indicated that it remained in their organisations, either physically or through discussions about their potential use:

"It doesn't help anyone. It just creates a lot of work. And everyone keeps chasing it. Everyone keeps saying "we should do more about those passports, do we use those passports? We should definitely use those passports" and everyone else is going "We don't need passports. The passports aren't helpful. Ignore the passports. Do something else." – Female clinical pharmacist, Teaching Hospital, England (P2)

And probably when they first come, they may get sort of an insulin passport, but that doesn't really give any doses. It's never given the doses anyway." - Female diabetes pharmacist, Teaching hospital, England (P10)

Regarding availability of insulin prescription information on admission, participants described how summary care records have superseded the insulin passport as a source of information:

"But to be honest, now we've got the summary care records and they're in fairly routine use. I think that's becoming utilized a lot more frequently than the insulin passport as a source of information" - Female MSO, Teaching Hospital, England (P3)

Despite the positive impact of the summary care record on information availability, participants described the improvements required in the general transfer and communication of information between primary and secondary care. For example, including insulin doses on the SCR was one of the potential solutions raised by participants:

"Exactly, it's just 'inject as directed'. So I'd really love to do something along the lines of improving that, you know, I wondered about, do we try and get on SCR, you know, such and such date the dose was this. And I know that there's problems of people's requirements can change massively, but at least there's a ballpark." – Female diabetes pharmacist, Teaching Hospital, England (P5)

"We wanted to start with at least GPs with something around the, and I know putting a dose on is difficult if your carb counting, but even a dose range would be nice. And a frequency would be really nice. So that's, we've tried to push that for a while at least get the quality of information coming from the GP a bit better." - Male clinical pharmacist (managerial), Teaching Hospital, England (P9)

"It's just stupid like when you speak to primary care people you say "why don't you write the dose on your prescribing system?" Their response is that because it always changes… and when you ask them who changes the dose ninety percent of the time its them so they can write it down." - Female clinical pharmacist, Teaching Hospital, England (P2)

Related to this was the connectedness described between primary and secondary care, and the impact that good prescribing practice in primary care had on patients and process outcomes in hospital:

"So if you've got a brilliant insulin prescribing in community policy, you're likely to see far less errors coming Into secondary care, which then means all secondary care are then doing is maintaining good care." - Female clinical pharmacist, Teaching Hospital, England (P2)

Participants also described the difficulties that junior doctors face when the majority of the inpatient prescribing burden falls on them, combined with the seemingly inherent hierarchical and blame-culture that may pervade ward micro-cultures:

> *"And the really frustrating thing is that if that foundation doctor doesn't do the job right, then everyone feels that they can tear strips off them because you know, "what do you mean you caused a hypo there? Do you not know what you're doing?" It's not like it "actually I don't know what you were doing either. But I'm senior enough to be able to not have to ask you, tell me, you know ask me that question"."* - Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

> *"So it's very much a negative attitude from the top I would say as well from seniors. It's a very much like "oh I haven't done that for years, I don't know anything about it"."* - Female diabetes pharmacist, DGH, England (P18)

Prescribing errors were described as more consequential for junior staff, who are more likely to regard insulin prescribing errors as 'critical incidents' compared to their more senior colleagues:

> *"So those things just sort of brush off them and they go "yeah, I didn't get it right that time. Yeah. You know what, in the grand scheme of things the patient is well and they haven't come to any harm." Whereas the foundation doctor the first time they have the caused a hypo, and they see that as a big disaster. Which it is in their life."* - Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

Considering the above socio-cultural issues with prescribing insulin described, participants highlighted the importance of reflective insulin prescribing practice of foundation doctors before they specialised in their medical training:

> *"And I think people should, if you don't get the opportunity in F1, to start talking and discussing that, then by the time you get to maybe core trainee or registrar, you've totally – it's too late then to say "actually I'm unsure about insulin" because that's totally not acceptable. So, you can then just say, just get the junior doctor to do that, and maybe deep down, you don't actually know the answer to it yourself."* – Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

The pressure on the foundation doctors to bear the burden of insulin prescribing was also said to be relieved by the appointment of the increase in independent (non-medical) pharmacist and nurse prescribers:

> *"We're quite good here in like the DSNs and myself and others in terms of we can act as prescribers so the pressure is not always on juniors in terms of prescribing. Its supporting them and in that in that role, you know?"* - Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

The support that specialist diabetes teams and increased numbers of prescribers can give junior doctors described by participants is included in more detail in the next theme.

5.3.3 Insulin prescribing safety should be everyone's responsibility

The increase in multidisciplinary specialist diabetes teams providing outreach support to clinical teams was regarded as a very positive intervention, and participants described the 'strong presence' of diabetes inpatient specialist nurses (DISNs, or DSNs) as impacting positively on patient care.

> *"Exactly, so, that's been quite useful actually to try and prevent errors in terms of hypos and hypers and as part of that as well sometimes we pick up on inappropriate insulin prescribing and that gets feedback to the team at that time as well"* - Female clinical pharmacist, DGH, England (P1)

Diabetes teams were also perceived as 'victims of their own success', overburdened, and overly relied upon to complete routine tasks:

> *"So we have we obviously have a DSN team we have an in-reach team etcetera. but they can't see every single patient."* - Female diabetes pharmacist, Teaching hospital, England (P10)

> *"Erm, you know, sort of, I think one of the things that diabetes nurses find very frustrating is the fact that they get called to do titrations of doses. When actually we have a policy online, which is really straightforward, it goes, it goes through step by step, is it basal bolus, is it mixed, you know, which one is out, which one do you want to change and it tells them exactly what to do. You know if it is this then change this dose by whatever percentage. And yet it's just not done."* - Female diabetes pharmacist, Teaching Hospital, England (P5)

> *"Maybe the diabetes teams that are there realize now that in a way they're a victim of their own success, in that because they used to treat or work with the people with diabetes, everybody else left them alone. And then when you don't have them, things go really pear-shaped."* - Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

Many participants felt that this over-reliance on specialist input was reflective of a general lack of responsibility for insulin management felt by non-specialist teams, which was described as something that risked patient safety:

> *"And, you know, us as pharmacists, "oh we'll leave it to the doctors, or we'll leave it to the diabetes team, because we don't know any better ourselves". Or, and the nursing staff they just follow the prescription and whatever is said and. You know, we've seen insulins being given at the wrong time for a week, and they've been having hypos and they still haven't responded and recognised that actually the reason they've been having hypos is because you've been giving it at night."* – Female MSO, Teaching hospital, England (P13)

> *"And I think part of that is because for so long when the diabetes team has been embedded as "they're the experts" and so a lot of staff on the ward don't take responsibility because they think, "oh, well, you get the diabetes nurse to sort it out", or refer to them. So yeah, I think I*

want to improve, improve the knowledge of insulin and diabetes for your average staff group." - Female diabetes pharmacist, Teaching Hospital, England (P5)

The participants felt that empowering non-diabetes staff to take collective responsibility for insulin safety was key to improvement efforts. Diabetes link nurses – registered general nurses from diverse clinical areas who routinely linked-in with the diabetes team - were also mentioned as a particularly impactful resource to help achieve this goal:

"So if you highlight people, keep them in different areas to take on the responsibility of diabetes in their care area and continue to update people. I think it's important for different areas to have more ownership of their patients with diabetes, given that it's so rife and so common and numbers are going to increase as the years go on." – Male diabetes pharmacist, Teaching Hospital, England (P14)

"So, I think it's important for the sort of diabetes team when they're there to be very inclusive and to be encouraging as many staff to sort of be getting involved and seeing what their thinking is and helping to come up with sort of solutions for the patients. And opposed to DSNs you know flicking onto the ward, sorting patients out then going off again you know?" - Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

"The diabetes link nurses were brilliant and really did sort of promote an ownership of diabetes on every ward. So their experience of that was very good and that's why they were really keen to re-implement that." – Female diabetes pharmacist, DGH, England (P17)

Some participants described the careful design and dissemination of clinical guidelines to be beneficial for empowering non-specialist teams to manage insulin, but only if these were made easily accessible and were not too cumbersome:

"Then obviously, we have all the other guidelines that are out there and then trying to sort of put them together in one place around our, you know, our trust SharePoint and stuff in our own intranet... Better concise sort of guidelines and documentation is designed with error reduction in mind. They've all sort of helped." - Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

"Obviously it is all in our guidelines but then guidelines are long and people don't have time to read them, and you know that's one of the things that we come across a lot." - Female clinical pharmacist, DGH, England (P1)

"Like, and is there, so we've got a policy that they didn't know about, advice for junior doctors on the ward for hyperglycaemic patients. So it's a flow chart to say, 'is the patient well or is your patient unwell?'" - Female diabetes pharmacist, DGH, England (P18)

Participants described the involvement of non-diabetes specialist staff in the intervention design and implementation processes as beneficial for increasing their accessibility and collective ownership:

"So, anything you're thinking about doing you got to be thinking about the person who's least qualified or least knowledgeable in that area. And making sure they're part of that program. You

know, and if you can get a few people like that in it, and you generally tend to find that it actually works a lot better. Because it's so straightforward then (laughs) you know?"– Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

The idea of engagement and empowerment of non-specialist staff is also linked to the next theme, which involves the education and training of staff regarding the safe use of insulin and its importance in the management of diabetes.

5.3.4 It is an important but uphill battle to educate staff on insulin prescribing safety

A prominent shared opinion amongst participants was that, in general, prescribers lacked knowledge, understanding, confidence and experience with insulin, which participants described as a key risk factor with respect to insulin errors and suboptimal management:

"And to be honest, the lack of knowledge and education is a massive gap for them… I just think education. Making them more confident. I think if we had confident prescribers, then there wouldn't be problems because they would be confident to prescribe the insulin which would be available for the patient." – Female diabetes pharmacist, DGH, England (P18)

"So yes, you can get the wrong drug prescribed. And we still see that. Because I think primarily, there's a lack of understanding in what they're prescribing." - Female MSO, Teaching hospital, England (P13)

"They luckily gave an underdose otherwise it would have been a 'never event'. So, it's that kind of thing, they just don't know what they're doing with it a little bit. Just that complete lack of experience in knowing what they should be doing, which is very worrying." – Male MSO, MH Hospital, England (P15)

Participants often cited the foundational, basic knowledge of diabetes management and insulin pharmacology as insufficient, which when coupled with the inherent risks associated with insulin prescribing described in the theme above, can easily result in patient harm:

"Erm, yeah, I think the issue with diabetes, is that often the simple – its the basics which is going wrong." - Female diabetes pharmacist, Teaching Hospital, England (P5)

"But I think obviously my biggest concern is certainly no awareness of what insulin, not necessarily about what Insulin does. But it is why patients shouldn't miss it." - Female diabetes pharmacist, DGH, England (P6)

"And he had about four hypos on the Saturday. And that was slowly picked up on the Sunday and the Monday and the fact that we weren't allowing the patient to self-administer their own insulin I think was probably the factor in that because he was perfectly fine. He knew exactly what he's doing. What his dose is and he comes into us and we mess it up. And that is about the junior doctor training. They didn't have a clue between short and long-acting treatments. Didn't really know what the basal bolus regime was all about." - Male clinical pharmacist (managerial), Teaching Hospital, England (P9)

A few participants signalled that insufficient undergraduate education may be partially responsible for this, although they appreciated the difficulties in teaching insulin safety as part of the undergraduate curricula:

> *"I just get the feeling that they're coming out of med school with less pharmacology knowledge than they ever used to. But because as you say, things are so complex these days, how do you cover everything?"*– Male clinical pharmacist (managerial), Teaching Hospital, England (P9)

> *"I don't see that it can be occupying the place that it should do in all undergraduate courses for people to be coming out with a level of knowledge that they seem to. And so if it is a priority, it needs to be a priority."* – Male managerial pharmacist, DGH, Wales (P12)

Not all participants felt that there was a lack of prescriber knowledge and education, however. The two participants from Northern Ireland regarded junior doctors as knowledgeable and well-trained with respect to insulin. They perceived that their attitudes towards insulin reflected the experience and appreciation of its risks and importance:

> *"So obviously, there're undergraduates' portfolios and courses and stuff that they're doing are more geared towards what they're actually doing when they get out to practice. So over the last few years we have found them to be a bit more sensible in terms of insulin prescribing."* – Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

> *"I think probably you've, you've probably recognized from your work that people - junior doctors are well educated, they're well trained. And there's lots of training in place, and we're doing a lot of good education, but we're still not making any change to good insulin prescribing."* - Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

Participants were unanimous in their perception that educational interventions were necessary and important, both at undergraduate and postgraduate level:

> *"But I think the biggest one is just around education."* - Male diabetes pharmacist, Teaching Hospital, England (P14)

> *"I think we definitely need more education for junior doctors about the types of product and also the dangers of someone having the wrong product at the wrong dose."* - Female MSO, Teaching Hospital, England (P3)

> *"But it's also about having that repeated training. I don't think its repeated. I think you'd need to have it every three years, like refreshers, for example."* - Male diabetes pharmacist, Teaching Hospital, England (P14)

These educational interventions were often delivered by pharmacists, alongside diabetes specialist nurses:

"I do quite a lot of teaching with the junior doctors and that's something that they identified as, you know, they didn't know how to find what doses people were on." - Female MSO and diabetes pharmacist, Teaching Hospital, England (P11)

"So I've experience at providing FY0 and FY1 supervision and training in relation to insulin prescribing." - Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

"We sort of have diabetes Awareness Week, as well. So where the diabetic nurses will do a lot of on the spot training with doctors and nurses." - Female clinical pharmacist, Teaching Hospital, England (P4)

Despite the perceived need for educational interventions, they were described as a 'weak barrier' by participants:

"Although education is a weak barrier, I think, fundamentally it's a lack of knowledge." Female MSO, Teaching hospital, England (P13)

When the reasons for this were explored further, participants described the restricted access to staff and insufficient time allocated to insulin training as significant limitations to delivering educational interventions:

"And, and you know, when you are teaching, if you get ten junior doctors turn up, then that's probably quite a good number out of the total of them, but I mean, ten, in the scheme of things is a drop in the ocean. So yes, we often do do some teaching. But it's obviously. What, you know, what can you get across in forty-five minutes to an hour to a small number of junior doctors once a year or whatever it may be?" - Female MSO, Teaching hospital, England (P13)

Participants expressed that recipients of education would be quick to forget the messages, and as such repeated training would be beneficial:

"That's because people, you know, can only remember two or three things, and then might only remember that for that week." - Female MSO, Teaching hospital, England (P13)

"But it's also about having that repeated training. I don't think its repeated. I think you'd need to have it every three years, like refreshers, for example." - Male diabetes pharmacist, Teaching Hospital, England (P14)

"I mean, I guess probably you've got to come back to it, at some point after their first induction." - Female MSO, Teaching Hospital, England (P3)

Participants were united in their description of delivering education and training as challenging; obstructed by limitations imposed by lack of time, access to various staff groups, suboptimal communication channels throughout the organisation:

> *"We tried to do some Junior F1 training, but we can't really get more than about ten minutes."* - Male clinical pharmacist (managerial), Teaching Hospital, England (P9)

> *"So we can reach those sort of staff groups but then we've identified that there are others that are much harder to reach - the staff grade doctors, your registrars; consultants get no training.."* - Female diabetes pharmacist, Teaching Hospital, England (P5)

> *"It's a very large teaching hospital. But there are three different sites and we have different specialities at each hospital. So that's a challenge in itself."* - Female diabetes pharmacist, Teaching hospital, England (P10)

> *"But then again it is getting that cascaded down, which I'm not sure how effectively that happens. When people are on night shifts or day shifts or annual leave or you know, so it is trying to get everybody consistently taught about it that's always going to be the issue I think."* - Female clinical pharmacist, DGH, England (P1)

In terms of educational interventions, organisational mandatory training for a range of staff was described as important, but was not without significant challenges. These included the design and delivery of the training whereby staff can share answers, and some pervading negative attitudes to mandatory training that it is a 'tick box exercise':

> *"Some people might share the answers, but at least it will put it on the agenda that insulin is important, especially for people who are actually going to come across it in the day to day. So, you don't always come across a fire where you work but yet you do the annual fire safety training. For insulin its regularly seen so, it will always be on the agenda."* – Male diabetes pharmacist, Teaching Hospital, England (P14)

> *"But you can see that they're attending, thinking, "I've read that policy, I know that policy. I've got twenty scripts to do when I go back to the ward", or you know, and they're on their phones. They're not looking at the screen. They're not interacting in the teaching… They're just there because they sign their name and they get their lunch."* - Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

Other challenges with mandatory training included competing priorities obstructing the prioritisation of insulin training for all clinical staff:

> *"I haven't made it part of the Essential Training because there's so many different things that are on the hospital's agenda that people want as part of the essential training so I think one of our consultants asked a couple of years ago and they were declined to have it as part of the essential training."* - Female clinical pharmacist, DGH, England (P1)

The 'battle' for including insulin safety in mandatory or induction training was also described as politicised, with topics that attract funding (e.g. attached to a CQUIN) or high on the hospital's agenda for other reasons being prioritised over insulin safety:

> *"At the moment there's not a lot of support for mandatory training… So when there was a CQUIN linked to it, it was funded for - everyone had to do a bit of e-learning. But that got pulled the moment the CQUIN went."* - Female diabetes pharmacist, Teaching Hospital, England (P5)

> *"I think we rely on, what happens is we get a potentially serious error and everyone says 'you must put it in the junior doctor's training'. But we have to keep bumping things down. You know, you can't do everything in twenty minutes on their first day."*- Female MSO, Teaching Hospital, England (P3)

Induction training was frequently described as restricted and insufficient for training staff on insulin safety, which did not facilitate engagement or a meaningful learning experience:

> *"There's a slide on a fifteen-minute induction on insulin saying "don't forget units" more or less. Shows them what a prescription looks like, that's about as much as we can get on the induction training."* – Male clinical pharmacist (managerial), Teaching Hospital, England (P9)

> *"Um, but I think at that point, they're getting absolutely bombarded with everything on their first day. They're not really in a position to take it in."* - Female MSO, Teaching Hospital, England (P3)

The pedagogy of insulin education was also discussed with the participants. Experiences with more participant-focused and engaging training were shared, which involved non-judgemental, supportive and reflective discussions with prescribers. These were thought to encourage more meaningful improvements in practice:

> *"We still need to train and we need all those. I think we need to have some way of allowing people to take a space or step back and think about the job that they've done. And how well did it or if they could do it better and not dwell so much on their errors per se."*- Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

> *"So it's about how do you develop the skill of prescribing insulin well, and it's not about having the knowledge on its own, it's about having the knowledge and being able to put that into practice in a safe way and a secure way, you know, you're, you're sort of supported to put that into practice and given the space to, to reflect."* – Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

> *"But sits around the whole real-world things like, what sort of situation did you find yourself in? What other staff are involved in what other pressures are on you in that particular sort of moment in time? And then, you know, what is your experience in this area of prescribing? Who can you go to? Who is there for advice? It's not about textbook right and wrong answers it's more about the real nitty gritty. Everything else going on in the world at that time when you're*

asked to do it." - Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

Active learning pedagogies were also described as beneficial, which included gamification, experiential learning, and peer-feedback from pharmacy colleagues to help prescribers reflect on their prescribing:

"Someone will pretend they were an insulin. And they had to ask questions about it to try and get to the one they were…So I mean I guess it got people looking in the BNF. You know, try and working out in their own heads what the differences between the insulin were." - Female MSO, Teaching Hospital, England (P3)

"Not in a sort of a purely sort of didactic teaching type session but more sort of hands on. Bringing, you know, bringing examples of patients in and case studies and getting them to complete the various cardexes and whatever and getting them to review made-up blood sugar levels. Getting them to tell us what's wrong with those sugar levels? What are we aiming for here, what's the problems and identifying solutions to the problems, you know? So practical things like that have tended to be sort of very beneficial." - Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

The use active and experiential learning also relates to the next section, which concerns prescribing system use to support insulin prescribing safety in the hospital setting.

5.3.5 A balance must be found between prescribing system control and flexibility to prescribe insulin

One of the major themes of participant's accounts was the unique challenge of maintaining safe prescribing systems for insulin within hospital, with restrictive actions being expressed as particularly beneficial for prescribing safety:

"It just stops you making errors. Stops you doing something." - Female MSO, Teaching hospital, England (P13)

You know, the timings are fixed so that if you're prescribing a short acting insulin you can't prescribe it at bedtime, for example, and things like that. - Female clinical pharmacist, Teaching Hospital, England (P2)

"So when that sort of process happened, and those sort of weird errors crop up, we try to build systems to take away that risk. And force – well, take the options away from the doctors so they can't just pick the wrong thing from the list." - Male clinical pharmacist (managerial), Teaching Hospital, England (P7)

Participants represented hospitals that used paper-based, electronic and hybrid systems, and described a range of different processes currently in place – for example daily insulin prescribing and rolling insulin prescriptions:

> *"I mean, we do daily prescribing of it. So our prescriptions are not like a rolling prescription, they are a daily prescription so they have to prescribe insulin each day."* - Female diabetes pharmacist, DGH, England (P18)

All participants using electronic inpatient prescribing that excluded insulin (requiring concomitant paper prescriptions) described the risks associated with using multiple systems and handwritten prescriptions:

> *"I can't wait for us to incorporate into the system and see how we can reduce the sort of errors and disparity. It's probably the discrepancies between the written information and the electronic system."* - Female diabetes pharmacist, DGH, England (P6)

> *"But then again there's issues with that were people don't add that on, or they add it accidently onto JAC rather than onto the paper chart so there are pitfalls in the way that we do it."* - Female clinical pharmacist, DGH, England (P1)

Participants explained that, unlike other medicines, the prescribing system used for insulin was inextricably linked to that used for recording blood glucose monitoring; challenges to moving insulin onto to electronic prescribing were presented where these were not synchronous or proximal:

> *"And do we put it on EP was another discussion that I had yesterday, and move away from a chart completely? And [junior doctors] were very much against that, because they very much like the chart, because it's all in one place. They like because our charts have the blood glucose next to the prescription, and so they can see what the blood glucose is doing and then prescribe, whereas they don't want a separate blood glucose chart to then go and look for that and then prescribe and they just said that if it goes on to electronic prescribing you don't have that nice view to be able to do it straight away."* – Female diabetes pharmacist, DGH, England (P18)

For participants working in hospitals using exclusively paper-based prescribing, specific paper insulin charts were heralded as a very effective and sustainable strategy for improving insulin safety by those who had implemented them, particularly when they were conspicuous (e.g. with colour), designed to support prescribers (e.g. incorporating guidance and blood glucose results), and minimised the input required to generate a safe prescription (e.g. multiple pre-printed elements):

> *"So they said that our charts are white. So they're not very, like obvious. So they'd quite like them to be a brighter colour. Like, the warfarin charts are yellow. So, it's like, "look at me" I need to be doing something about it. So having a white chart it isn't helpful, is what they said."* - Female diabetes pharmacist, DGH, England (P18)

"So I sort of split it into sort of, you know, morning, lunch time, teatime, night-time. And the units were pre-printed. And there was a lot of information as well on that drug chart, although it was only an A4, you know, folded in half, there was a lot of information on there to support them." - Female MSO, Teaching hospital, England (P13)

"So it has units pre-printed, the times of insulin prescribing specified, it says 'brand' at the top so they know they've got to write in brand, you know there's lots of things they've got towards its insulin prescribing. So that was really successful in terms of how insulin was prescribed…the reason it was good was because we did most it for them. The doctor literally just had to write the brand name and the number in the right timed box like it's all they had to do!" - Female clinical pharmacist, Teaching Hospital, England (P2)

Despite this, participants described issues with prescribers circumventing the safety measures designed into the paper charts:

"But saying that, you know, we still managed to have two weeks ago, a doctor write 'units' on an insulin chart where the word 'units' was pre-printed which resulted in a you know, a not unserious overdose." – Male managerial pharmacist, DGH, Wales (P12)

Opinion from participants who did not use insulin paper charts felt they were redundant in their context and may increase the potential for administration errors:

"No, no. I have to say, I'm reluctant to introduce a separate chart for insulin because, I feel like it's not, if it's not on the main chart then there's the potential for missed doses…I don't, looking at the kind of errors that we've had, I'm not convinced that having a separate insulin chart would make a difference." – Female MSO and diabetes pharmacist, Teaching Hospital, England (P11)

The experience of participants using electronic prescribing for insulin was described as beneficial overall, but that benefits were limited by the absence of certain safety features or the introduction of new types of insulin prescription errors:

"Electronic prescribing, I think has helped overall. Because yeah, you might have seen some of those terrible prescriptions where they had no idea the names, the doses, the timings were awful. Yeah, I think it's marginally better." - Female MSO, Teaching hospital, England (P13)

"I mean, it's had some impact on some of the errors that we would get, particularly around units and getting the full details of the prescription specified. But what we're getting now is an increased I would say error rate from mis-selection from drop down menus." - Female MSO, Teaching Hospital, England (P3)

"So we've still had you know, ridiculous doses. It doesn't stop you from doing ridiculous things. It doesn't shout at you. So these things can still happen." – Female MSO, Teaching hospital, England (P13)

Although there was a variety in the functionalities of systems that participants described the use of, common patterns in responses concerned the importance of simplicity, clarity and support for prescribers with electronic prescribing, due to the experience of prescribers circumventing safety features. Electronic insulin order sets, for example, were described as particularly beneficial:

> *"So it's just as dangerous, just a different system creates new errors. So when that sort of process happened, and those sort of weird errors crop up, we try to build systems to take away that risk. And force, well, take the options away from the doctors so they can't just pick the wrong thing from the list... So they pick a regimen, not necessarily pick an individual product, because there is too much choice and they just pick the wrong one basically."* – Male clinical pharmacist (managerial), Teaching Hospital, England (P7)

> *"And that's why I think we need to go back to that insulin prescribing bundle idea from the health foundation. And put the word "insulin" in front of all of these so it is blindingly obvious that some of the new, as you say, things that don't even sound like insulin -."* - Male clinical pharmacist (managerial), Teaching Hospital, England (P9)

> *"So now on EPMA, all insulins are prescribed by protocol. So they've all been assigned…you pick Novomix twice day protocol and it auto populates with the right admin times and then the dose has to be added on basically by the doc."* – Male clinical pharmacist (managerial), Teaching Hospital, England (P7)

Despite the benefits of restrictive functions for insulin prescribing, an appreciation that flexibility, or 'scope for patient individuality' was needed with whatever system was used due to the variety and variability of doses and regimens seen in practice. Rule-based hard limits on prescribing (such as dose ceilings or frequency restrictions), for example, were difficult to apply to insulin compared with most other medicines, which complicated the design of systems to build-in safety for insulin:

> *"And obviously, we've got electronic prescribing, and we've got the ability to put some limits in there. But the regimes are so variable, it's very difficult to put hard limits on them."* - Female MSO, Teaching Hospital, England (P3)

The inclusion and selection of insulin device on electronic prescriptions was an issue of interest for some participants due to the frequent errors associated with mis-selection of device by prescribers. This was particularly associated with electronic prescribing because on paper prescribing, the pharmacist would typically add in the particular device used by the patient onto the prescription form. The consequential challenges pharmacists faced with amending electronic prescriptions and the impact this had on patient care was described:

> *"So have so we did have an instance where the doctor wrote the wrong formulation. The nurse asked, I think they wrote up a pen. And we supplied a pen. And the nurse said, "I don't want a pen." We said, well, that's what's prescribed and then you will have to change the prescription, and then that took almost a whole day for it to change, which resulted in a delay to them*

receiving it. Whereas before, that wouldn't have been an issue." – Female MSO, Teaching hospital, England (P13)

One participant explained that pharmacists annotate the prescription with the insulin device to avoid device-related prescription errors:

"The device isn't part of the prescribing. That is added later, usually by the pharmacist, once they've clarified the device and that kind of thing we add something onto EMPA to clarify that." - Male clinical pharmacist (managerial), Teaching Hospital, England (P7)

With respect to prescribing by brand for insulin, participants perceived this to be beneficial but difficult for prescribers who may be unfamiliar with insulin branding, the large number of products that often sound alike, and the usual convention of prescribing generically for most other medicines:

"And also, there's a number of insulins on the market, which, which a lot of people are simply unfamiliar with, and they don't, a lot of them, the naming is weighted towards the brand as opposed to the different type of insulin or the different effect it would have." - Male managerial pharmacist, DGH, Wales (P12)

"We've noticed they're not prescribing by brand. So we had an incident with glargine because you've got Toujeo, and you've got Lantus haven't you, and you've got Abasaglar and you've got Semglee. So you've got multiple products now with the biosimilars coming on the market. So if you prescribe it as glargine, what are you actually giving?" – Female diabetes pharmacist, DGH, England (P18)

"The manufacturers want a strong brand name where all their product sounds similar. Which is great for establishing a brand, but it's awful for mis-selection." - Female MSO, Teaching Hospital, England (P3)

Participants in Wales and Northern Ireland described the situation and benefits with respect to standardising prescribing systems and guidance regionally and nationally, and expectations that using a single system would facilitate safer prescribing by allowing prescribers to be familiar with the system when rotating through organisations.

"We have adopted that as well in Northern Ireland in that we have the same paper based - we have the same medicines cardex and they can prescribe it across Northern Ireland. And as I said earlier, that has been born out and evolved and sort of helped reduce errors through design and documentation and stuff that helps to really, you know, reduce errors and stuff. So that's regional." – Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

Although there was an appreciation that operational variations amongst hospitals may complicate standardisation, facilitating enhanced familiarity with systems prior to practice (e.g. in undergraduate education) was described:

> *"I would personally like to see a standardization of insulin charts. And that's somebody that I'm not a big fan of standardisation in general…So you know, if we're only teaching people one way within schools, then you'd hope that, you know, if the message is "you're never going to have to write units down. So don't write units down." And that might not necessarily be all-Wales, but that might be a UK-wide thing, I don't see why it wouldn't be."* – Male managerial pharmacist, DGH, Wales (P12)

Often, the prescribing systems described above are interrogated for audit purposes that aid the evaluation of interventions. This links to the next theme, below, which concerns the evaluation of insulin prescribing practice interventions.

5.3.6 Interventions to improve insulin prescribing are hard to evaluate in practice

Participants commonly expressed a desire to be able to evaluate the impact of insulin prescribing interventions that had been designed and implemented, but described their inability to do so due to the difficulties in measuring outcomes:

> *"Now can I turn round and tell you that they definitely reduced our error rates? Well I actually couldn't. Because it's very difficult to measure your error rates."* - Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

Many participants described the routine interrogation of clinical incident reporting software (e.g. DATIX) in order to observe and review trends in locally reported insulin errors. The experience of using these systems to that end was described mainly as challenging and inadequate for measuring the impact on any given intervention, particularly with prescribing errors and incidents, which are often under-reported:

> *"Our incident reporting system is really difficult to interrogate. It comes down to individual drugs. And I can't pull a report very easily at all even just by looking at insulins. So I sort of sometimes have to manually trawl it."* - Female MSO, Teaching hospital, England (P13)
>
> "*We have DATIX but then you know, not everybody then actually reports the errors."* - Female diabetes pharmacist, Teaching hospital, England (P10)

Participants reflected on the reasons why incident reporting systems were under-used, which mainly featured issues with reporting culture, time, and blurred boundaries with respect to professional responsibility:

> *"I think that one of the biggest things is having a proper handle on the true degree of incidents. So it's changing the culture to make sure that say everything was reported. But also it would be about trying to make the reporting systems easier to use, and more intuitive in terms of being*

able to sort of get information from them. So that that would be one big area because we, we genuinely, don't always have a really good handle on what our error rates are for different types of insulin problems and things. And even when we have them, we know they're not a true reflection." – Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

"But because the DATIXing is so underdone and that's because it's a, such a long process to DATIX something but also you know people just don't have time to sit there and DATIX and sometimes the role becomes a bit blurred because as a pharmacist you think well actually it is my role to pick up on these errors and to resolve them." – Female clinical pharmacist, DGH, England (P1)

The use of audit was also described as a commonly used method to evaluate intervention effectiveness and track improvements or changes in insulin prescribing errors. This included the National Inpatient Diabetes Audit (NaDIA) but also bespoke insulin prescribing and administration audits that were locally designed and implemented:

"What we did is we just looked, out of the normal NaDIA we just took out the prescribing and management for subcut insulin and orals. And so every three months, we did that for the whole of the hospital, and reported to back CMGs etc." – Female diabetes pharmacist, Teaching hospital, England (P10)

Limitations with respect to time and labour-intensive data collection, particularly with paper-based systems, along with the unreliability of insulin dose administration documentation, were cited as barriers to the use of audit for evaluative purposes:

"And then the other thing that we're slightly limited about is the fact that we're so paper based. So it's not as if we can pull reports off, you know… But at the moment, that's very hard to do. It's very labour intensive. So we're not really able to do it." - Female diabetes pharmacist, Teaching Hospital, England (P5)

"That's something, I think that actually isn't recorded very well, because no-one documents the time they have their lunch and the time that the insulin was administered, as a pharmacist, you're just checking the dose and that there's a signature next to the lunchtime prescription." - Female MSO and diabetes pharmacist, Teaching Hospital, England (P11)

Participants also described the use of anecdotal evidence and user feedback for attempting to sustain, modify or cease interventions altogether:

"…learn from somebody being able to say to you "you know what, you've written that policy and it's all very good, but practically at two o'clock in the morning, it's not really useful to me. Could you make it a bit easier in this way?" And we need to be able to listen." – Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

"We had a real, real push into teaching the juniors about not repeating Actrapid, because a few years ago, we did have quite a lot of instances where people getting hypo because we're getting

> *repeat doses of Actrapid for hyperglycaemia so regularly. And we've just noticed, that that's not happened so much. So your diabetes nurses who go in and see patients, they're just not seeing it. So we are aware that's worked just because it's stopped. But we've not measured it directly."* – Female diabetes pharmacist, Teaching Hospital, England (P5)

Despite the limitations of tools to measure certain outcomes of interventions in hospital (for example on insulin prescribing errors), participants were able to articulate the improvements, or lack thereof, with respect to insulin prescribing safety over time:

> *"So whatever we've done, it's definitely improved."* - Female diabetes pharmacist, Teaching hospital, England (P10)

The next theme was a substantial theme identified in the dataset that pertained to the design, implementation and use of a particular intervention. The use of self-administration policies in the hospital setting to allow patients to inject their own insulin when required was a salient and timely topic for both participants and our patient representative group. As such, particular emphasis is given to the reporting of findings relative to this intervention below.

5.3.7 Inpatient insulin self-administration is a problem worth solving

Insulin self-administration policies were discussed with all participants due to the saliency of the intervention highlighted by stakeholder group discussions (see **Chapter 4, section 4.6**). Self-administration policies were in varying degrees of use across the organisations represented by the sample of participants. Some organisations had insulin-specific self-administration policies, whereas others worked with a more general self-administration of medicines policy. Eight organisations represented had a self-adminstration policy that was described as currently in use, nine described policies as written but not actively in use (including where policies are being piloted) and one did not have a self-administration policy.

Some participants described insulin self-administration as something that was "ingrained in the culture" of the organisation at ward level. Participants attributed this to satisfying the interests of the patient demographic (e.g. long-term patients) as well as the diabetes team:

> *"I guess, we've got use of patients own medicines on all wards. And we've got, we've got quite a good self-administration policy that's been in use for a number of years (Interviewer: okay.) and because we've got a number of long-term patients, I guess, who are returning to us. We've got, we've got a vested interest in encouraging them to manage their own conditions."* – Female MSO, Teaching Hospital, England (P3)

> *"I think for insulin probably, because it's quite well established and understood and the insulin team have banged on about it quite a lot and we've used it in our sort of CQC inspection, so we have got evidence of self-administration and appropriate documentation."* – Male clinical pharmacist (managerial), Teaching Hospital, England (P7)

Others described self-administration as having not been implemented well or not utilised to its fullest potential, or even adhered to at all:

> *"It was really a matter of the sort of implementation by the nursing staff. And I just think, oh, it was it was, I guess it was too difficult for whatever reason to implement. But yeah, we'd definitely like to look at it again, because it's been a been a while, been a few years."* – Female MSO, Teaching hospital, England (P13)

> *"But its just the timing as I didn't actually manage to do any kind of roll out with it. So it was completed but we didn't do any training or any… yeah. And we've not found it used at all - so people just ignore those pages. Erm, so yeah, I'm trying to do a project around it, because we know that as much as we say, oh it would be great people if people do it, its jut not happening."* – Female diabetes pharmacist, Teaching Hospital, England (P5)

Self-administration of insulin was described by almost all participants as something important that should be encouraged, with many participants describing their involvement with helping to facilitate this in their organisations, either as part of the diabetes team, or the medicines management team:

> *"So, yes, we want to do self-administration. And we'd like to pick it up. And we would hope to sort of start thinking "oh, yeah, we should pick this up again and review it". But we haven't got there yet."* – Female MSO, Teaching hospital, England (P13)

> *"So we haven't moved to total one hundred percent self-administration, but we know we have to, and we know we should do, because that's what patients are demanding."* – Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

One of the key benefits to self-administration described by participants was its potential to prevent harm from insulin prescription errors, thereby acting as a safety net against administration errors and the consequences of prescribing errors:

> *"So I personally do feel that most of our errors would be reduced if the patient is competent and able to self-administer. A lot of the errors I think would come down."* – Male diabetes pharmacist, Teaching Hospital, England (P14)

> *"Because actually probably most of those errors were when the insulin wasn't prescribed and the patient has given it themselves, quite rightly so because (laughs) they're not going to not give themselves insulin when they would always at home just because a prescription isn't there."* – Female diabetes pharmacist, DGH, England (P18)

> *"And actually, when the prescription, when we've had incidents where the prescription has been wrong, fortunately, on most of those occasions, the prescription was wrong, but the patient carried on with their correct insulin."* – Female MSO, Teaching Hospital, England (P3)

This was often related to the idea that patients were best placed to manage their own insulin whilst in hospital. This is due to their greater knowledge and understanding of how their diabetes should be managed, compared to non-diabetes specialist healthcare professionals:

> *"That patients are best at managing their own insulin to be honest! That's it. They're more familiar with what their medication is, what they should be giving at what times and when we start to get involved in it there is always a risk we will get it wrong."* – Male MSO, MH Hospital, England (P15)

> *"With diabetes, patients are very well educated. And they usually they know a lot more about their condition than a non-diabetes specialist would."* – Male diabetes pharmacist, Teaching Hospital, England (P14)

Self-administration was described as empowering for patients, that enabled them to be more involved in their care and promote independence during their hospital stay. This was reinforced by stories of patient complaints regarding the lack of ability to self-administer:

> *"I think just to empower patients to sort of do their own insulin a bit more."* - Female clinical pharmacist, Teaching Hospital, England (P4)

> *"And I don't think we've ever really looked at that other than we know from time to time we would get patients maybe writing to our complaints department to say, "I feel I should be able to control my diabetes myself and administer my own insulin." "* – Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

Nurse administration of insulin, on the other hand, was thought to de-skill the patient, which could result in additional unintended negative consequences:

> *"Because at the end of the day, a patient should be self-administering where they can. They've got to go home and do that. And we, you know, we de-skill them, we take that away whilst they're in hospital."* – Female MSO, Teaching hospital, England (P13)

> *"I think the other thing is that it keeps the patients skilled and doesn't deskill them whilst in hospital. They keep their responsibility for that. Which certainly with our long-stay patients, that can become an issue."* – Male MSO, MH Hospital, England (P15)

The extent to which self-administration was suitable for patients was discussed widely, with perceptions varying on the currency of the intervention considering the patient demographic and perception of 'capacity' or 'competency'. For example, participants described a limited application for self-administration policies where patients are acutely unwell or elderly, and cited elective surgical patients as those for whom the policy would be most beneficial:

> *"And the wards I'm often involved in are quite often more acute and therefore, medical, and it's not necessarily appropriate for the nurse when the patients come in to be doing their insulin because they are too acutely unwell. However, the elective ones. We probably do need to get it on board."* – Female diabetes pharmacist, Teaching hospital, England (P10)

> *"Unfortunately, I've been around for too long than I care to remember, and so having done a self-administration policy, you know, twenty years ago in a previous hospital. Things are completely different now than what they used to be. Patients are far sicker, because actually if they're not very sick, actually we need the bed for the person who is very sick and waiting in A and E, so you have less well patients who could self-administer if you know what I mean."* – Female MSO and diabetes pharmacist, Teaching Hospital, England (P11)

The extent to which the policy was used on account of patient suitability also varied widely across participant's accounts, with one participant representing a mental health trust describing the majority of their inpatients as self-administering, and another representing a district general hospital explaining that very few patients self-administered during a pilot. Of participants who had evaluated the uptake of the policy (e.g. via audit), some cited audit figures of up to 95% of their patients self-administering, and others describing uptake as *"not a high number",* or numbers as *"few and far between".* Some participants reflected on why uptake was low and postulated that the criteria for self-administration was too strict:

> *"And the sort of feedback that we had was the "Oh, the criteria, perhaps was a bit too strict". Because we say obviously, we don't want anybody that's comatose or going for surgery, x, y, z. So the numbers were small."*- Female MSO, Teaching hospital, England (P13)

Some participants described experiences of where self-administration with insulin had resulted in unintended harm to patients, often because of communication breakdown between healthcare professionals and patients, or changes in clinical condition not being reflected contemporaneously in the assessment and documentation, or processes not being followed; These past experiences often resulted in reluctance from healthcare professionals to move forward with the policy implementation:

> *"I think the problem is that as a trust we have been burnt I suppose in the fact that patients refuse to give up their insulin. And we then found that they were probably more confused than they thought they were and they've had crashing hypos because they've given themselves too much insulin. So what's really difficult here, I think, is the fact that people are wary... So that's why, so we were sort of starting it and then ended up being pulled back because of an error, well to be fair it wasn't just one it was a couple of errors from the patient self-medding. But there, they hadn't been through a proper process. They hadn't been assessed properly."* – Female diabetes pharmacist, Teaching hospital, England (P10)

> *"I also think that there have been cases where people have self-admined and it's gone wrong. So like, we had a lady who was on a pump. So she was allowed to continue her pump because we generally say if they're well and able to they can continue it. Yes. But their capacity massively fluctuated in the day. So she ended up having problems."* - Female diabetes pharmacist, Teaching Hospital, England (P5)

> *"So quite often, it wouldn't necessarily be prescribed timely or correctly because they just assumed the patients are self-administering. The patient isn't self-administering and there's nobody monitoring the patient… And yet they've been assessed as self-administering. So, you know."* – Female MSO and diabetes pharmacist, Teaching Hospital, England (P11)

One of the challenges associated with the implementation of insulin self-administration policies was the ambiguity of who oversees and drives the self-administration agenda across the organisation, and who is responsible for ensuring its implementation and success:

> *"And I really didn't want to lead on it. It's like "this is not for me to do" this is, I've provided you with the framework because you know, I'm happy to put something down on paper. But you know, this is for you."* – Female MSO, Teaching hospital, England (P13)

The appetite for driving self-administration of insulin is something that was perceived to be heterogenous, and Influenced by healthcare professionals' personal attitudes, experience, workload, and perception of their role:

> *"Or if you've got a consultant who is keen for it to happen or it's in their head because they've of heard of it or read something, then they're more proactive. Whereas if you've got, say, a bit like you talk to a cardiologist, if you're in a cardiology ward, they're never going to even consider it. They're going they're going to say, "well, I'm not going to assess the patient". So it's not just having the policy and the staff being aware, it's who's pushing, who's driving it, is probably also the thing."* – Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

> *"And sometimes it's a bit like, even in our own work, sometimes other things take priority and some days you might be focused on thinking, "actually, I'm going to try and get the patients on this ward, anybody who can, to self-administer and we'll try and adopt that for this week". You know, that will be this week.'. But then other things get in the way."* – Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

Another factor cited was the lack of awareness about self-administration policies in the hospital setting from both patients and healthcare professionals:

> *"And I just think that a lot of people might not even know that they are able to offer that so were currently also putting together a leaflet for diabetes patients when they come into hospital and within that leaflet it talks about self-administration"* – Male diabetes pharmacist, Teaching Hospital, England (P14)

Solutions to this included the education and comprehensive 'launch' of the policy to staff, and empowering patients themselves to enquire about the ability to self-administer their insulin whilst in hospital, potentially supported by national or local awareness campaigns:

> *"So we're starting (pauses) the wards, so again, we have an e-learning, and then when the wards are up to eighty percent of staff, at least in the E learning."* – Female diabetes pharmacist, Teaching hospital, England (P10)

> *"So maybe it is. It is, you know, the patient trying to, you know, the patient driving it or, I don't know who drives this. And then you get maybe patients who, who aren't aware that it's something they can do so don't ask the question."* – Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

With respect to undertaking the work involved in the intervention, most participants described nurses as the professional group who were responsible for initiating and assessing patient suitability for self-administration at ward-level, although mention was made of pharmacy technicians adopting this role to support the intervention. Diabetes specialist nurse involvement was also discussed, but contextualised by the unsustainability of this group undertaking assessments across an organisation:

> *"It's the nurse. There really isn't much time and I know and other hospitals their MMTs, their techs do some of that. And we just haven't got the staff to do that unfortunately. But yeah. So in my inpatient safety group they say well can't pharmacy do, and I say "we'd love to, but we just haven't got the technicians base to be able to free up their time to be able to do that, unfortunately.""* - Female diabetes pharmacist, Teaching hospital, England (P10)

> *"So a fair chunk of patients self-administer. But there's an assessment process that the nurse has to do, and a proforma that they have to complete and put in the notes, that kind of thing."* – Male clinical pharmacist (managerial), Teaching Hospital, England (P7)

> *"So what's happened in [trust B] is diabetes nurses have started filling it in and I keep saying to them "this is not sustainable. You can't fill this in for every patient in the trust."* – Female clinical pharmacist, Teaching Hospital, England (P2)

Some of the reasons participants gave for not using their self-administration policies included lack of time, motivation and confidence from nurses in undertaking the required tasks. For example completing the pre-requisite patient capacity or risk assessments:

> *"So we have a self-administration policy. It relies on assessing your patient to make sure that they're competent. But then our nurses don't feel they can make that assessment because they don't normally do that kind of capacity assessment. And it makes it a bit long-winded, so that we generally don't do it. But then we got the patients on inhalers and insulins who they recognize that actually would be sensible if they do self-administer so we kind of tacitly allow patients to self-administer their insulins without following our policy. So we kind of shoot ourselves in the foot by trying to be safe for the patients to allow them to do it."* – Male clinical pharmacist (managerial), Teaching Hospital, England (P9)

Risk assessments that were too comprehensive or complex especially disincentivised nurses from using the policy:

> *"I've been brought into [trust B] to have a look at it and they have gone down this classic road and I've seen this so many times, and I've spoken to so many people about it, where the diabetes*

nurses have designed this super complex assessment. "does the patient have lipohypertrophy? Are they doing an air shot? Are they mixing them in?" And requires a huge amount of diabetes knowledge to fill it in. And it's like an A4 side of paper. And of course what happens is the nurses go "I'm not" and they just ignore it. So their self-admin is going nowhere." – Female clinical pharmacist, Teaching Hospital, England (P2)

The participants acknowledged the fact that clinical conditions can change rapidly in hospital, necessitating repeated assessments to be undertaken by the nurse to ensure the patient is safeguarded. This can add to the time-burden of the intervention, but if the assessment process is made simple and easy, to ensure safety rather than complete 'competence', this may be integrated more naturally into the ongoing clinical review of the patient:

"So yeah, I think we need to make sure that within the policy we think of doing the capacity assessments daily and actually if something goes wrong staff will be supported about it." – Female diabetes pharmacist, Teaching Hospital, England (P5)

"It's the classic thing, they fall into this trap of trying to prove perfect diabetes-ness and I keep trying to say to them "patients weren't perfect before they came in but they were safe, and that's all were doing with self-admin". And as long as that patient doesn't give themselves a hypo or DKA, I don't actually care what they are doing. And they don't like it. They don't like it at all. And I'm like "it's up to the primary care team to look after this patient and their ability to inject. Not you. You're here to keep everyone safe.""- Female clinical pharmacist, Teaching Hospital, England (P2)

Attitudes to self-administration interventions were described disparately across the dataset. There were several participants describing nursing staff as wary, resistant, or nervous about self-administration, which was often attributed to a fear of repercussions and led to disengagement with the policy:

"Another bit is that the nurses are sort of a little bit tentative in the context of "well if I let the patient do this and they forget to do it or they're not as competent as they originally thought and they miss their insulin doses and the sugars are sky high. And something happens they'll come back to me on it". You know "why did you let that patient do that?" you know? So there's a little bit of, I would assume, fear. And sort of wanting to protect yourself. So the best way to protect yourself is just to blast on and you know, know that it's done." – Female diabetes pharmacist, DGH, England (P18)

Others described staff as being familiar with the policies which were used frequently on certain wards:

"I think the nurses on there [the endocrinology ward] are much more aware of it anyway because we do get so many younger patients compared with other general medical wards. So we do get an awful lot of diabetics on there who routinely self-administer, so yeah, the nursing staff are more familiar with it and more used to the patients doing it themselves anyway."- Female diabetes pharmacist, DGH, England (P17)

> *"So I think it's very hit and miss as to where they are doing it well. So I know the CF unit. They are using self-admin quite a lot. But then yeah, they self admin all their meds. That's the sort of part of the culture of the ward."* – Female diabetes pharmacist, Teaching Hospital, England (P5)

Linked to this was the perception of burden that self-administration placed on staff nursing time, and the influence this had on uptake of the policy:

> *"And that's one of the things from the nursing staff is that, it's just too time-consuming. Maybe the number – you know, you've got to assess the patient. You've got to get their consent, you've got to ensure this, that and the other, and it's just easier, you know, for them to, to give it to the patient. That's not to say that it's right."* – Female MSO, Teaching hospital, England (P13)

> *"And I think that's, that's probably a challenge for, you know, a busy ward. When the nurses are thinking, "oh, god, and I'm going to have to take that patient off self-administration", or "I have to try and put them on it". And sometimes maybe they just think you know what, it's just easier to just do it all yourself."* – Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

Despite this perceived burden, the need for a shift in paternalistic perspectives to facilitate the implementation and use of insulin self-administration policies in the hospital was also highlighted:

> *"And I think in the past, the sort of de facto position was, we look after everything for you. Whereas, we nearly need to flip that. We really need to say that we expect you to be giving your own insulin unless you can't, providing you do it at home and providing it's safe to do so…"* – Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

Widely discussed with respect to self-administration policies was the difficulty in navigating the complexities around maintaining adequate storage of insulin at ward level and the safe disposal of sharps. The need to satisfy the Care Quality Commission (CQC) requirements for the safe but accessible storage of insulin for people self-administering their insulin was a common theme, with many participants expressing this as a significant barrier to implementation:

> *"The thing that makes us, erm, twitchy, if that's a word, about self-administration of insulin is potentially around how you have to store it to make it available. Actually saying it out loud, it sounds pathetic. But we, I think we, I think we struggle with the infrastructure to allow it in terms of around the keys, you've got to give the patient the keys to the locker in order that they can they can have access as well. And I, I'm not sure we're there yet with that.* – Male managerial pharmacist, DGH, Wales (P12)

> *"And also, some of our wards wouldn't have the facility to allow patients to store their own insulin at the bedside. The newer wards will have that facility but it's hard it's hard actually."* – Female diabetes pharmacist, Teaching Hospital, Northern Ireland (P16)

"And the other side of it, we're never quite sure what the CQC would make of it because their stance is, everything needs to be secured and locked away." – Male clinical pharmacist (managerial), Teaching Hospital, England (P9)

Shared learning across hospital trusts was described with respect to evidencing safe storage requirements for the benefit of ensuring insulin governance and the CQC. This was described as desirable and beneficial, but required the CQC inspectors to have a united stance on how insulin is stored for self-administration:

"So [pharmacist A] did all the work with the CQC to prove you didn't have to lock insulin away so I took that part of it and [pharmacist B] did the risk assessment that the CQC asked for so I took her one and then just [trust A]'d it, submitted it to our medicines governance and they were happy to agree to it not being locked away because we had approval from the CQC so they were happy with that." – Female clinical pharmacist, Teaching Hospital, England (P2)

"And then it was about where do you store the insulin, so if they are able to administer then where do we store it? So it could be lockable? Then we looked at a paper done in [Trust A] and they just used lunch boxes. So we went with that idea that it was they were signing in a contract to say that they would keep it safe." – Female diabetes pharmacist, DGH, England (P18)

"Well, as I say, it's that combination of which locker you buy and what kind of lock you've got it on? How do you manage to get over the coding of cards issue.? Erm, and if anyone's cracked it, it'll be lovely to know exactly what they've done to see whether that's, you know, duplicatable or not…And getting all of the CQC inspectors signed up for that as a collective as well rather than just an individual going "Oh, that's fine." And another one going "No, I don't like that."" – Male clinical pharmacist (managerial), Teaching Hospital, England (P9)

The importance of complete and contemporaneous documentation of insulin self-administration was also widely discussed, with reference made to the fact that the requisite documentation is not always completed when people are self-administering (e.g. completed risk assessments, consent forms). This also had important implications on communication between staff and patients, and the way patients were reviewed at ward level:

"Erm we're also finding interesting that there are sometimes people who are self-admining they haven't filled in the separate paperwork. So we need to make sure that it is properly, erm, done by policy, really, to make sure it's safely done." – Female diabetes pharmacist, Teaching Hospital, England (P5)

"But again, the documentation is very vague, because what I find between the self-administration policy again is a disparity between the electronic system and what is on the BM chart and particularly as well, with self-administration you can imagine how relaxed the nurses are about "oh self-administer, ppft, don't even care how much he's given himself'." – Female diabetes pharmacist, DGH, England (P6)

"And I think because sometimes the medics they may do a ward round and may not know that a patient is self-administering, so they'll just change it on the chart for example, walk asway and leave. And then the patient's still self-administering the units they were always using, and it's not being changed. So, I think it's important from both angles that both the teams that are

prescribing and the patient are having great communication to know, "okay, we're changing this so, now start injecting this dose"." – Male diabetes pharmacist, Teaching Hospital, England (P14)

Designing the documentation to be simple, easy to complete and reducing the number of extra forms was also considered an important way to aid completion of the paperwork. This included integration with electronic prescribing systems or prescription charts where possible to ease the burden on staff time:

"So we put the words exactly as they appeared on JBDS at the bottom of our chart and then a signature at the bottom that said "is the person self-admining?" get them to sign it, get you to sign it, job done. Because it's obviously a hospital chart its part of patient record so it goes in their record so it meant that nothing else had to be written in the notes and it was all great." – Female clinical pharmacist, Teaching Hospital, England (P2)

"So whereas obviously I've got a lot of paperwork. There's a consent form. There's an assessment form, an information form, leaflet form for the patient. And all the other documentation, I was thinking, you know, if you can put some of that on, on the EPMA system. That could be you know, quite helpful." – Female MSO, Teaching hospital, England (P13)

An important pattern in the description of designing self-administration policies was the need to be able to take the shared learning from other institutions but appreciate that they will need to be carefully tailored to the specific needs of the organisation:

"And then so there's that importance of designing it around, that's sympathetic to your environment. And because I think quite often, we're all for a one-size-fits-all, you know, the whole 'do once' thing but it's not gonna work." – Female MSO and diabetes pharmacist, Teaching Hospital, England (P11)

The exception to this was participants representing countries that are seeking to achieve a more standardised approach. For example, participants from Northern Ireland described the development of a Northern Ireland- wide self-administration of insulin protocol:

"And one of my actual key tasks sitting on the regional inpatient group is within a subgroup of that is, is developing a Northern Ireland-wide self-administration of insulin protocol." - Male diabetes pharmacist (managerial), Teaching Hospital, Northern Ireland (P8)

Participants also described the multidisciplinary input required in designing the policy, which involved both pharmacists and nurses at the minimum, with others extending this to patients. This was described as crucial due to the understanding needed regarding the scope, feasibility, and degree of input from each professional group involved in enabling insulin self-administration:

"And that's what we found, so we were really surprised, we did a lot of teaching on the patient self-admin at one point. And we kind of just assumed, you know, took it for granted that they [nurses] do these kind of capacity assessments all the time. And they basically, they turned round

and said "No, we never do them. The OTs do them occasionally, physios sometimes, the medics do them, but we don't". And we went "Oh."" – Male clinical pharmacist (managerial), Teaching Hospital, England (P9)

"I can't see any resistance from them I think its key to get nurses on board. For anyone that wants to implement it in the hospital you need to get your nursing on board." - Male diabetes pharmacist, Teaching Hospital, England (P14)

The above thematic findings represent a data-driven approach to analysis of the qualitative data by the researcher and will be discussed in relation to the survey results below, and also in **Chapter 7**. The next section presents an additional deductive treatment of the data, whereby the findings are mapped to an established model of patient safety from a human factors engineering approach.

5.4 A systems approach to insulin prescribing safety

To further present the findings in a theoretically informed but empirically driven way, the thematic analysis was re-examined with reference to the components of the Systems Engineering Initiative for Patient Safety (SEIPS) work system model (person, organization, tools/technology, tasks, environment). This allowed the researcher to be alerted to further systems-related explanatory factors contained in the framework, and brought these to the foreground. The findings and inferences from the reflexive thematic were summarised and aligned with components of the SEIPS in a deductive process to provide an explanation of the human factors systems issues related to insulin prescribing practice in the hospital setting. The presentation of findings in this way is included in Table 5.3 along with example quotes.

Table 5.3: Summary of subthemes aligned according to the Systems Engineering Initiative for Patient Safety model. Example quotes contain participant numbers but not demographic information for brevity.

Elements		**Summary of inferences from data**	**Example quotes**
Person	**Education, skills and knowledge**	There is a lack of education, experience, confidence, knowledge, and skills with respect to insulin use in hospital.	*"Although education is a weak barrier, I think, fundamentally it's a lack of knowledge. They don't really know the difference between the different insulins and how they work and what the impact is." – P13*
		Experienced practitioners may also require increased knowledge and skills with respect to insulin.	*"One of the other I think, it must have been twelve units, but it looked like one hundred and twenty. And a nurse had actually drawn up one hundred and twenty. And this is like an experienced nurse and didn't think that was a high dose to be giving." - P4*
		There is a lack of appreciation from prescribers about the	*"They'd prescribed Insulatard but actually, they've recently been switched from insulartard to Levemir…*

	Motivation and needs	importance of getting insulin prescribing right first time.	*but I think the doctors, I spoke to the doctors about it and they weren't really that bothered about it, they didn't see the problem." – P4*
		There is a need for widespread, accessible insulin safety training that is based on sound pedagogical principals (such as active, experiential learning and reflective practice) and can translate to positive insulin prescribing outcomes.	*"I think my biggest thing would be, just people's knowledge of insulin to be better" – P5* *"So I mean I guess it got people looking in the BNF. You know, try and working out in their own heads what the differences between the insulin were." - P3*
		Facilitating prescriber feedback and reflective practice is beneficial and motivational.	*"And it's even, for junior doctors to be able to be told, and pharmacist prescribers, "You've done a good job." And you can learn as much from that as you can from "let's start dissecting this error that you had". So I think that's where we need to be looking at how we can get people to start thinking about, "would I have done something differently" or "where could I have got more information" or "who could have helped me with that?" - P16*
	Psychological characteristics	Improvement efforts require physical and psychological momentum.	*"But it's having the momentum to keep - you have to keep that up all the time, or are the new students, the new doctors coming through, the new pharmacists coming through, are they going to have a better idea now of branding of insulin and, and the importance of - I don't know?" P10*
		Insulin invites prescriber clinical inertia, fear and therapeutic misadventure.	*"I tend to find that it's never in the middle - people either treat insulin as if it's poison and sometimes you have errors of omission because people are so worried about it. Or you have the other types of errors where people maybe don't treat it with the respect that it needs, or the care that it needs and then you have therapeutic misadventure." - P12*
Organisation	**Teamwork, coordination, collaboration and communication**	Insulin safety teams comprising a broad membership is important for sustainability of interventions.	*"But having that ownership and representation from those teams hopefully can be more effective and bring about more permanent change."* – P14
		Communication and collaboration between diabetes teams and usual care teams at ward level impacts on insulin safety.	*"Maybe the diabetes teams that are there realize now that in a way they're a victim of their own success, in that because they used to treat or work with the people with diabetes, everybody else left them alone. And then when you don't have them, things go really pear-shaped."* – P8

		Clear communication between primary and secondary care is critical for insulin safety in hospital.	*"Communication of doses gets lost sometimes or misunderstood."* – P2
		Sharing learning between organisations can facilitate local improvement.	*"So they published that. And I'm thinking oh, that's really interesting. That's useful. And they use JAC, the same as us for electronic prescribing. And I took that to the diabetes team and was like "oh look what they do"."* – P13
		Insulin safety is an interprofessional issue and a sound understanding of each other's roles is necessary to devise and implement interventions and policies to make this safer.	*"And we kind of just assumed, you know, took it for granted that they do these kind of capacity assessments all the time. And they basically, they turned round and said "No, we never do them. The OTs do them occasionally, physios sometimes, the medics do them, but we don't". And we went "Oh."* - P9
	Organizational culture and patient safety culture	Hierarchical structure in medicine prohibits the development of the relationships needed to build a positive safety culture.	*"… you start to open up a bit more about, you know, it's difficult to, you know, find a registrar at three o'clock in the morning, and we feel worried that we have to ring them or..."* – P16
		Reporting prescribing safety incidents is time-consuming, perceived as unnecessary, and rarely occurs unless it impacts on administration.	*"But because the DATIXing is so underdone and that's because it's a, such a long process to DATIX something but also you know people just don't have time to sit there and DATIX and sometimes the role becomes a bit blurred because as a pharmacist you think well actually it is my role to pick up on these errors and to resolve them." - P1*
	Work schedules	Organisation size and working patterns of staff can impact effective communication about insulin safety messages.	*"I think the problem is it is in a large organization. Lots of docs involved. Getting that messages out to all of them."*– P9
		High turnover of staff in organisations is prohibitive to insulin safety efforts.	*"But in terms of overall reflection, the problem is we're set in a workforce that's constantly revolving."* – P8
		Enabling a stronger, more consistent clinical pharmacy presence on the ward would aid insulin safety efforts.	*"I think that I personally feel that twenty-four-hour pharmacy services would do wonders for it."* – P12
	Social relationships	Relationships between pharmacy teams and nursing and medical staff are key to facilitating their role in insulin safety efforts.	*"And when I do get across, because I don't know the teams, as well, it feels like I'm sort of interfering."* – P10

	Supervisory and management style	Senior staff attitudes impact on junior doctor confidence with insulin.	*"So it's very much a negative attitude from the top I would say as well from seniors. It's a very much like 'oh I haven't done that for years, I don't know anything about it'"* - P18
Technologies and tools	**Electronic health record, computerized provider order entry and bar-coding medication administration**	Electronic prescribing minimises handwritten insulin prescribing errors but has a limited impact on other prescribing errors such as wrong product and/or device (e.g. mis-selection).	*"I mean, it's had some impact on some of the errors that we would get, particularly around units and getting the full details of the prescription specified. But what we're getting now is an increased I would say error rate from mis-selection from drop down menus."* - P3
		Electronic prescribing that enables direct transfer of drug history records from pharmacist medicines reconciliation is beneficial.	*"And another good thing about the prescribing system is if a pharmacist comes along and does the drug history, so puts it on, doctors can, what they can do is they can reconcile it, so they just click on the electronic prescription what the pharmacist has put on and it just transfers it automatically... So, we do see less discrepancies from meds rec with electronic prescribing compared to the paper one."* - P14
		Electronic prescribing systems that direct prescriber choice based on local insulin availability, alerts prescribers when they choose 'high strength' insulins and prompts them to prescribe hypoglycaemia order sets/protocols is beneficial.	*"So, we also make a distinguish in our electronic system of what is formulary with what is not. So, by entering basically a symbol on the system then you are you able to identify all those insulins that we don't keep but we could prescribe. So, there is a better, probably is more clear at what is available."* - P6
		The restrictive benefits of electronic prescribing are limited due to the flexibility needed to prescribe individualised insulin regimens.	*"And obviously, we've got electronic prescribing, and we've got the ability to put some limits in there. But the regimes are so variable, it's very difficult to put hard limits on them."* - P3
		Auto labelling and dispensing linked to electronic prescription reduces human error.	*"But once that order's been picked it flags up things like device and all that kind of thing. And then when you do the label it auto-labels so you can't pick the wrong label, or the wrong drug from the label, it all ties back to the electronic prescription."* - P7
		Insulin charts are particularly useful when incorporating blood glucose monitoring results and prescriber support/guidelines, but their usefulness may be dependent	*"And that, I think, again, worked in many respects. Because, similar to sort of EPMA, it was laid out better for you. So I sort of split it into sort of, you know, morning, lunch time, teatime, night-time. And the units were pre-printed. And there was a lot of information as well on that drug chart, although it*

		on the design of other prescribing systems in use (paper or electronic).	*was only an A4, you know, folded in half, there was a lot of information on there to support them." – P13* *"So it's already an all-encompassing book really. I think adding another separate page or a separate chart would probably start to overcomplicate things." - P11*
		Multiplicity of prescribing systems, where insulin is only partially prescribed electronically (e.g. simultaneous use of paper chart and electronic system), or where an organisation uses multiple electronic systems, is a risk.	*"So I think that's still our main challenge at the moment is the fact that there are two charts, and therefore they didn't necessarily tie up. And then so you have you have a beautiful prescription on electronic because obviously it's electronic. But then you still get the handwriting problems on your green chart." - P10*
		A unified, accessible integrated electronic health record and prescribing system that works across primary and secondary care would minimise inefficiencies and reduce error-prone processes currently in place (e.g. at the point of care transfer).	*"It probably does need a combined effort, primary, secondary care. I mean, ideally, what would be the solution, ideally, is you have one patient record that has all the information on for each patient in the NHS. So it has DN records, it has GP records, has hospital – all on one record as opposed to the multitude that we have."* - P7
	Medical devices	Data extracted from electronic blood glucose monitoring records enable easier prioritisation and review of patients.	*"We also put our glucose monitoring chart electronically on our e-noting so our electronic noting system so it's easy to access as a visible graph, to see your patient on the ward and see how they've been. And it's colour coded."* - P14
		Duplication of blood glucose monitoring records (e.g. on a paper chart and electronically) can introduce risk.	*"So at the moment, we have a separate diabetes chart to the main chart…And so there's that potential risk that a blood sugar can be recorded in two places."* - P5
	Other technologies and tools	Prescriber support cards for insulin may be helpful as a quick and accessible reference but use is unknown.	*"I give them some pocket cards, you know, with the common insulins and things like that. Whether they use them, look at them, I don't know."* - P13
		Diabetes dashboards may enable quick review and prioritisation of at-risk patients and provide data for measuring patient outcomes	*"So, like having a diabetes dashboard electronically so each ward can see how many patients on their ward are hypo or hyper or within their target range, because that's on the electronic system that were currently implementing at the moment."* - P14

		(e.g. hypoglycaemia) from interventions.	
	Human factors characteristics of technologies and tools (e.g. usability)	Highlighting key messages on guidelines may aid more appropriate prescribing.	*"One of the safety issues we've done is pretty much on all the guidelines is putting advice, putting in bold and you know, quite clear, capital letters "basal must not be omitted"."* - P6
		Guidelines need to be conspicuous, convenient, accessible, clear and succinct.	*"Obviously it is all in our guidelines but then guidelines are long and people don't have time to read them, and you know that's one of the things that we come across a lot."* – P1
		Colour-coding of insulin charts enables more efficient identification and more prompt review.	*"So they said that our charts are white. So they're not very, like obvious. So they'd quite like them to be a brighter colour. Like, the warfarin charts are yellow. So, it's like, "look at me" I need to be doing something about it. So having a white chart it isn't helpful, is what they said."* - P18
		Prescribing systems that minimise prescriber input are effective at improving the quality of insulin prescribing.	*"The reason it was good was because we did most it for them. The doctor literally just had to write the brand name and the number in the right timed box like it's all they had to do! Takes away all the thinking! But as a result of taking away all the thinking, so basically, I just assumed they were all idiots which is a shame to start with, but what that resulted in was great insulin prescribing."*- P2
		Blood glucose monitoring records should be accessible and proximal to insulin prescribing records to enable more contemporaneous and appropriate prescribing.	"*They like because our charts have the blood glucose next to the prescription, and so they can see what the blood glucose is doing and then prescribe, whereas they don't want a separate blood glucose chart to then go and look for that and then prescribe and they just said that if it goes on to electronic prescribing you don't have that nice view to be able to do it straight away."* - P18
		Treatment algorithms (e.g. for hyperkalaemia or hyperglycaemia) may aid prescribing but their use without the requisite knowledge about insulin may confer risk due to lack of a 'sense-check'.	*"And we actually had one patient who got administered one thousand units, because a doctor wrote up ten mils of Actrapid, instead of units. And they transcribed and you can actually see from the initial one, how it could have been mistook from the units. And then obviously you've got the calcium gluconate which is ten mils, so within the treatment algorithm your head knows there's a ten mil there. And then there was a, you know, we did the risk assessment, and there was a disconnect."* - P5

		The process and time required to undertake incident reporting is prohibitive to its use, and the system is not easy to interrogate, which limits it's ability to monitor trends in insulin errors.	*"Our incident reporting system is really difficult to interrogate. It comes down to individual drugs. And I can't pull a report very easily at all even just by looking at insulins. So I sort of sometimes have to manually trawl it."* - P13 *"And the staff have got a finite ability to report DATIXs because they take so long to do..."* - P15
Tasks	**Job content, challenge and utilization of skills**	Non-medical prescribers have the opportunity to improve insulin prescribing safety by altering and initiating insulin prescriptions rather than making recommendations for the usual care team to action.	*"I think it's getting better 'cause like the diabetes nurses push quite well for sort of education, and also now they're both prescribers so when they see patients, they can actually make changes themselves."* – P4
	Autonomy, job control and participation	Non-prescribing diabetes outreach teams making recommendations to usual care teams can improve care outcomes and empower them to make changes, but this requires sufficient communication between teams.	*"So we go and we say "actually Mr Smith is having loads of hypos and we've had a look and actually we think you need to reduce his insulin so we've done that but we need you to monitor it and if it does this then we need you to do this" and that's all documented and we're feeding that back to the consultants and the members of the medical team that are with them at that time."* – P1
		Junior doctors are expected to independently prescribe insulin.	*"Yeah, what do we do with the doctors? Not a lot really. I mean, yeah, you see them at induction, I tell them a bit about prescribing and the system, we do a sort of a teaching session for them. And then then they're on their own. And they can ask for, for help, or look at the guidelines."* - P13
	Job demands (e.g. workload, time pressure, cognitive load, need for attention)	Daily prescribing of insulin places a higher burden on prescribers and nursing staff (e.g. when prescriptions aren't written on time or the prescriber is not available), but rolling prescriptions may shift the onus onto nursing staff to review blood glucose results and alert prescribers.	*"But my worry with moving to a rolling prescription is that you need buy-in from the nurses because they are the ones are going to have to alert the prescribers to highs or lows. And does that collaboratively work at the minute? No, it doesn't. And so actually, you're moving the responsibility from prescribers to our nurses. And is that appropriate? I'm not entirely sure."* – P18 *"You just get a bigger prescribing onus on junior staff. And the more times you prescribe things, the bigger the risk of even simple transcription errors, and omissions and all the rest of it. So that's one thing that we need to change."* – P8

		Increased input from clinical pharmacy teams verifying prescriptions would require significant resource but has the potential to significantly reduce insulin errors	*"But something along the lines of as soon as it's prescribed, it has to be clinically verified by a pharmacist before administration. And I know the resources that would well, he says, I can have a guess at that the amount of resource that would take, but I think you put that in then you're starting to get to a point where you would see a fundamental decrease in the problems that we experience with insulin."* – P12
		Out-of-hours working confers particular risk with respect to insulin safety	*"We have occasionally missed it at meds rec when the pharmacists haven't done it and weekends."*- P9
Environment	**External environment (political, regulatory stakeholders)**	National safety campaigns can help facilitate insulin safety efforts, but messages must be reflective of 'real-world' situations.	*"Once it starts to hit the arena, of sort of NPSA alerts and things being sort of sent to the Chief Executive Office and asking them to be actioned. They tend to have then a greater force and a greater drive behind them, you know"* – P8 *"That's somebody sitting in an ivory tower really who has no clue what goes on in the ground."* – P11
		National recommendations can facilitate pharmacist involvement in insulin safety at a directorate and organisational level	*"And with GIRFT, the getting it right first time, they're all pushing. You know, [person C] has released his "inpatient diabetes teams should have a pharmacist" and all stuff like that. All of the words now are saying "you need a pharmacist to do this" so if you are in that position where you can do it, just get on with it."* - P2
		Lack of funding for diabetes pharmacists inhibits organisations' ability to tackle insulin safety	*"And but obviously, at the moment, I'm still only doing two days a week until we get some sort of funding approved."* - P1
		Hospital performance incentivises driving insulin safety efforts	*"As part of what we were doing this year as one of our quality on the back of obviously CQC one of the quality markers was to improve our insulin safety."* – *P10*
Care processes	**Information flow**	Information transfer between community and hospital settings is suboptimal and poses a risk to insulin safety	*"I do quite a lot of teaching with the junior doctors and that's something that they identified as, you know, they didn't know how to find what doses people were on."* – P11

	Improvement activities	A culture of resistance to change impacts on continuous quality improvement efforts	*"The problem with all quality improvement projects, from what I can work out in my years of doing it, is everyone wants to cling to what they did before or the trust has a bit more history."* - P2
		Dedicating time and effort to focus on insulin prescribing efforts is challenging	*"And, you know, is, is quite high on the on the agenda at the hospital, and the medicines safety team as well. But it's just obviously dedicating the time and focusing really on how best to improve what is going wrong."* - P1
Employee or organisational outcomes	**Job satisfaction and other attitudes**	Pharmacist involvement in diabetes teams is a rewarding and fulfilling role with the opportunity to positively impact on insulin safety	*"So, you know, I think it's, it's quite an exciting avenue to go into, because I think in terms of being able to elicit change is probably one of the big areas to be able to do that in. And yeah so for me, and my personal progression, and, you know, professional growth, I think, that's quite good."* – P1
		Prescribing outcomes with insulin are felt more acutely by junior doctors compared to more senior doctors	*"You know, so those are the challenges that they have because they haven't done it as many times as a, you know, as a consultant whose been a consultant for twenty years. So those things just sort of brush off them and they go "yeah, I didn't get it right that time. Yeah. You know what, in the grand scheme of things the patient is well and they haven't come to any harm." Whereas the foundation doctor the first time they have the caused a hypo, and they see that as a big disaster. Which it is in their life."* - P16
	Job stress and burnout	Prescribing outcomes are rarely observed by prescribers with respect to insulin due to time constraints and work patterns	*"And I think that's the hard thing for junior doctors, they don't get time to go back and check the outcome, especially when you prescribe insulin." – P16*
Patient outcomes	**Patient safety**	Insulin prescribing improvement efforts are often a reactive response to clinical incidents affecting patient safety in an organisation	*"To be honest, it feels a bit like a knee-jerk reaction to an incident."* - P5
	Quality of care	Self-administration of insulin can improve the shared-decision making and prevent harm from erroneous insulin prescribing	*"And we absolutely would agree and support the idea that patients need to have a bigger input into the decision making. And if they can give it, they should be giving it."* - P8 *"And actually, when the prescription, when we've had incidents where the prescription has been wrong, fortunately, on most of those occasions, the prescription was wrong, but the patient carried on*

			with their correct insulin. There was no harm to the patient for that very reason." - P3

The above table highlights important human factors systems components of insulin prescribing practice interventions, deduced from the thematic analysis of qualitative semi-structured interviews.

The next section presents an additional 'subgroup' analysis of the qualitative data regarding 3 specific interventions: the insulin passport, mandatory insulin training, and insulin self-administration policies. This analysis aimed to provide a comparison between hospitals where interventions were in use and those where it was not, to give further explanatory power to findings from the cross-sectional survey presented in **Chapter 4.**

5.5 Perceived effectiveness of interventions

Differences in organisational contexts and implementation strategies, as well as other factors, may explain the heterogenicity in the perceived effectiveness of interventions. To explain these results further for interventions identified following results of the survey and stakeholder group discussions, an additional analysis was undertaken whereby qualitative data pertaining to the use of selected interventions were further categorised according to the participant's current use and/or implementation stage of the intervention, as described by the participant. This was to compare between data from hospitals that used the intervention and those that did not, as prioritised by the multidisciplinary inpatient group (see **Chapter 4, section 4.6**). It also facilitated explanations regarding whether perceived effectiveness preceded use, or vice versa.

Data did not undergo re-coding for this analysis, as complete and inductive coding had occurred as part of the overall thematic analysis. This additional analysis therefore re-examined the codes presented in Appendix 12, along with the associated data in NVivo, considering participants' self-reported use of the intervention. The results presented here complement the 7 major themes identified above and are consistent with the narrative presented in **section 5.3**.

Interventions selected for further explanation of perceived effectiveness were the insulin passport, mandatory training, and insulin self-administration policies. Detailed descriptions of these interventions are included for reference in Appendix 13. These interventions were selected due to the differences in their perceived effectiveness found in the survey, as well as the specific role of pharmacists in designing, modifying and/or implementing these interventions. They were also all discussed in the interviews but were not used unanimously amongst participants, therefore allowing comparisons to be made.

5.5.1 Insulin passports

Qualitative data pertaining to experiences and perceptions with the insulin passport were categorised and re-examined according to participants' use of the intervention. All accounts related to current or previous use of the intervention; no participant expressed views about adopting the intervention in the future. Quotes to support the formation of the statements presented in Figure 5.1 are found in Appendix 14.

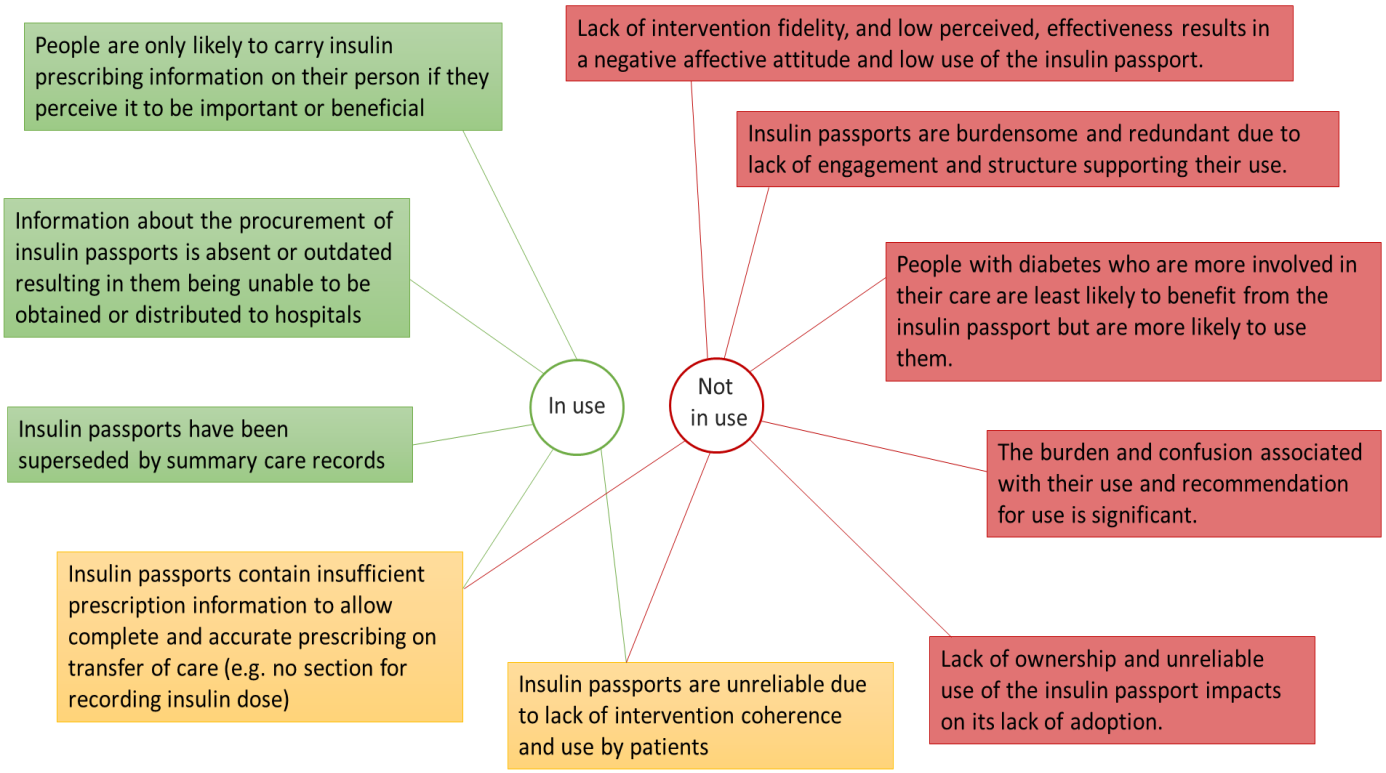


Figure 5.1: Statements relating to participant's experiences and perceptions of the insulin passport, derived from data categorised according to current intervention use. Statements from participants representing organisations currently using the insulin passport are presented in green, those representing organisations where it is not used are presented in red. Statements in yellow were identified across both categories.

There were no significant patterns found that distinguished generative mechanisms for perceived intervention effectiveness between participants who used the passports and those who did not. The limitations with the use of the passport were the main topic of discussion in both groups, although those who did not use them seemed to feel more strongly about their limited effectiveness than those who did. All participants who did not use the passports expressed their persuasions against their use, citing a lack of intervention coherence, ownership, fidelity, and uptake as reasons for not adopting them locally. Participants who did use the insulin passport expressed the limitations and redundancy in their use and

described the lack of benefit of the insulin passports over summary care records, mainly due to the lack of sufficient information needed for prescribing on the passports.

5.5.2 Mandatory training

Data regarding the use of mandatory training was categorised according to participants' descriptions of its current use at their organisation. Where insulin training was optional, this was regarded as not using mandatory training. Example quotes to support the formation of the statements presented in Figure 5.2 are found in Appendix 14.

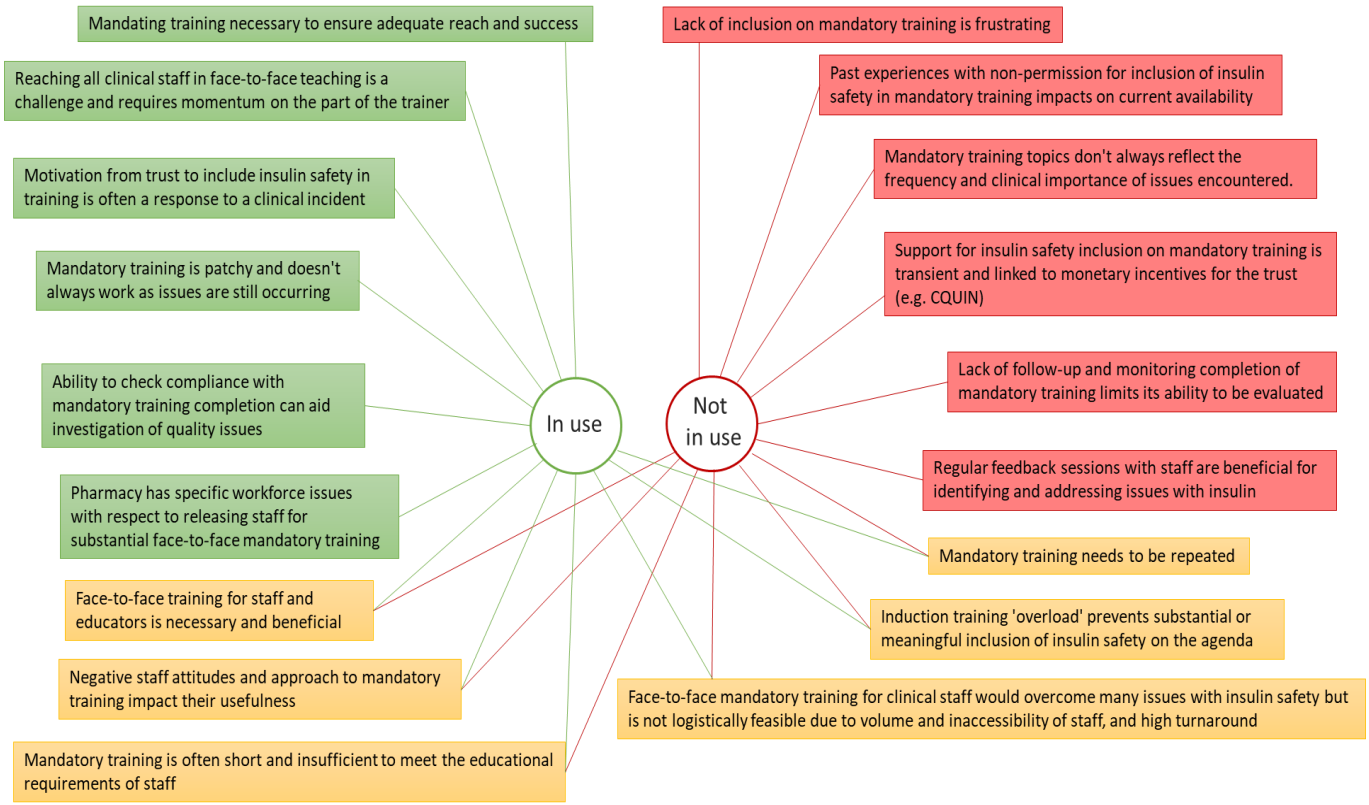


Figure 5.2: Statements relating to participant's experiences and perceptions of mandatory insulin safety training. Statements are derived from data categorised according to current intervention use. Statements from participants representing organisations where insulin safety training is mandatory are presented in green, those representing organisations where it is not are presented in red. Statements in yellow were identified across both categories.

The categorised data shows that participants who represented trusts that did not include insulin safety on their mandatory training felt that this was not a positive outcome, often describing frustrating limitations on accessing staff training programmes. Others that delivered optional training expressed the benefits of doing so face-to-face, especially when it incorporated regular feedback with prescribers, but

reach and sustainability was problematic. Those who had mandated training described the requirement for it not to be optional to help solve these issues. Of note was the discussion of e-learning as an accessible medium for delivering mandatory training, with the ability to monitor completion, which was expressed and an important factor across both groups.

The categorisation also highlighted several sentiments that were consistent across both groups, highlighting and reinforcing the overall finding that both the benefits and challenges with delivering mandatory insulin training are appreciated across participants, particularly with respect to face-to-face training. Most participants also recognised that although training was important to address deficiencies in understanding and knowledge, it was described as only a partial solution, and efforts to improve insulin safety needed to be accompanied by other system-wide interventions.

5.5.3 Insulin self-administration policies

Qualitative data pertaining to experiences and perceptions with the use and implementation of self-administration policies were categorised and re-examined according to participants who had no policy in place, those who had a policy in place but did not actively use it, and where policies were in place and used. Example quotes to support the formation of the statements presented in Figure 5.3 are found in Appendix 14.

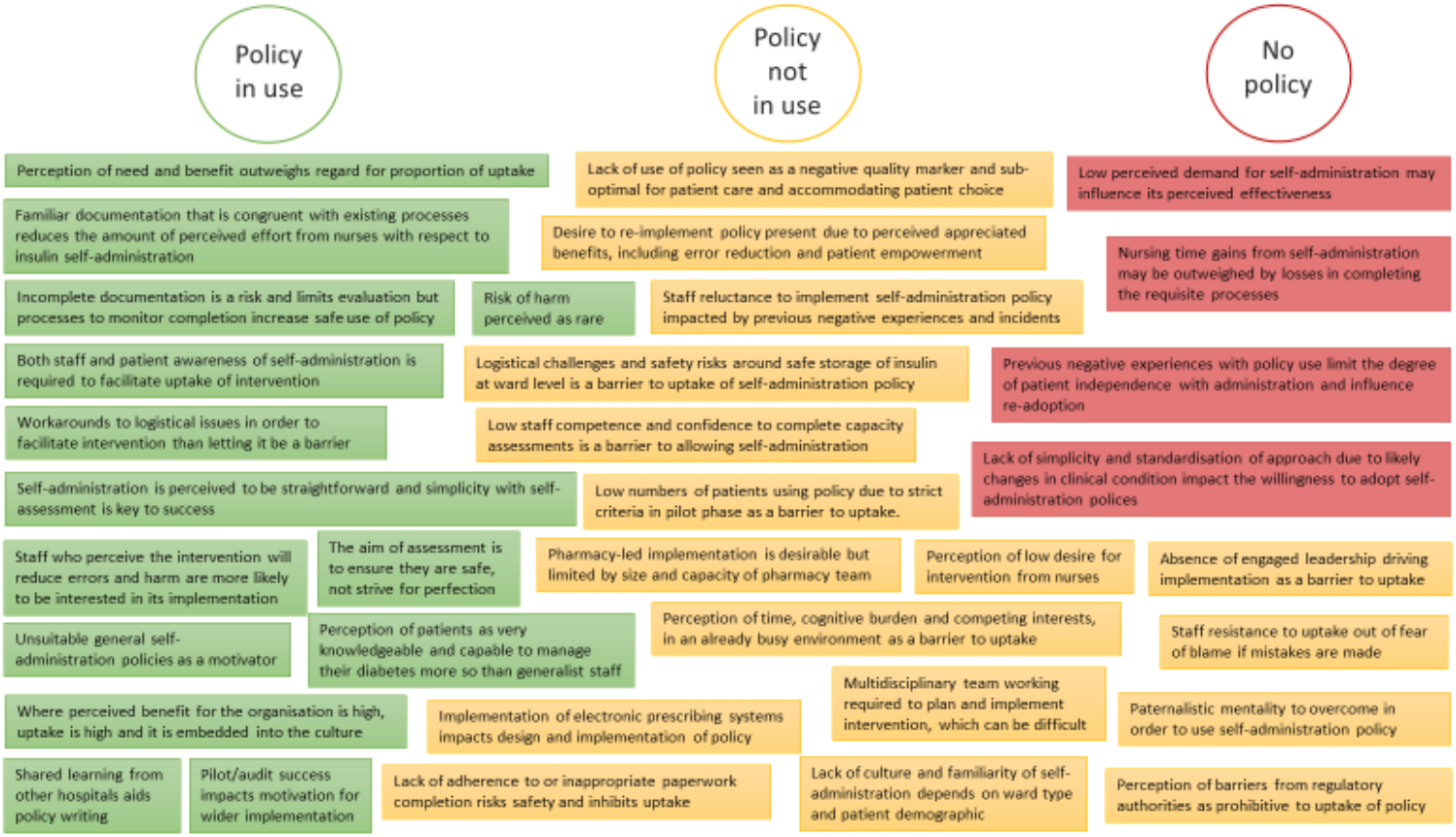


Figure 5.3: Statements relating to participant's experiences and perceptions of insulin self-administration policies. Statements derived from participants using the intervention are in green. Statements identified from participants with no policy in place are in red. Those from participants who had a policy that was not being actively used are in yellow.

Impressions from the categorised data suggest that previous negative experience with self-administration policy use is the main limiting factor for hospitals re-introducing self-administration policies. This is also accompanied by a perception that low numbers would benefit, and nursing burden would increase, therefore resulting in a low motivation to pursue the intervention.

Statements derived from data from participants who have a policy that is not being used include issues around implementation, including lack of leadership, low desire from nurses and logistical issues around storage and documentation. Most participants in this group, however, described a desire to reinvigorate or drive policy use because they related its use to greater quality of care and experience for patients.

Participants from organisations who had a self-administration policy in use described the need to overcome logistical issues, describing 'workarounds' and practical solutions to satisfy needs of both patients and regulators, and had a positive view of the intervention due to perceived benefits for both patients (e.g. empowerment), staff (time and injuries) and the organisation (reduction in errors). Data also included the benefits of professional networks for shared learning, perception of the intervention as simple and safe, and high regard for the knowledge and abilities of patients to self-care. A few sentiments

were common across all groups, including the need for communication and documentation to be complete and accurate and the need to carefully consider and work through logistical issues.

It is clear from the data that self-administration policy design and implementation was a topic of interest to participants, and that the intervention was perhaps the most complex to implement. As such, this intervention is explored in greater depth with complexity-sensitive realist methods in the next chapter. Self-administration policies are more socially contingent than many other interventions mentioned and the data suggest that a greater range of contexts are present that may be explored and theorised further for the benefit of improving patient care.

5.6 Discussion of key findings

This is the first qualitative study to focus on subcutaneous insulin prescribing system functionality and safety interventions in NHS hospitals. The results describe the opinions and experiences of hospital pharmacists involved in insulin prescribing practice intervention design, use and evaluation across UK hospital trusts. Important contextual information is given to aid understanding of the survey results presented in **Chapter 4**, specifically around why interventions are perceived to be effective or not, and the circumstances and factors impacting this. The successful application of a human factors systems model demonstrated the importance of considering intervention use for insulin prescribing practice in relation to the wider systems and ergonomics.

All participants were able to describe the important roles pharmacists have in the design, implementation or evaluation of insulin prescribing error reduction interventions in their respective organisations. For some participants, this involved working across multiple organisations, including membership of regional insulin safety panels. The consistent presence of pharmacists on the ward was also key to facilitating insulin prescribing safety improvement efforts. This helps to explain the survey findings of significant associations between the number of interventions used and the employment of specialist diabetes pharmacists at the organisation. This evidence also supports the national drive to incorporate pharmacists in the multidisciplinary inpatient diabetes team to help to reduce inpatient insulin errors (Joint British Diabetes Societies for inpatient care, 2019; Rayman & Kar, 2020; E. Watts & Rayman, 2018).

Findings regarding the perceived lack of staff knowledge support results from other studies indicating insulin-related knowledge is lacking amongst healthcare professionals in the hospital setting (Bain, Kavanagh, McCarthy, & Babar, 2019; Derr et al., 2007; Lee et al., 2013). The role of complex socio-cultural factors impacting on the prescribing process found in this study have also been reported in other studies regarding antibiotic prescribing practice in secondary care (Papoutsi et al., 2018). Findings regarding the need for further education and training of clinical staff explain the high regard for educational insulin prescribing safety interventions found in the national

survey in **Chapter 4**. This is despite educational interventions more generally being described in the literature as having limited effectiveness for improving patient safety (Cafazzo & St-Cyr, 2012; Woods et al., 2008).

With respect to the design and delivery of educational interventions, results support the systematic review findings in **Chapter 2** that educational interventions are most effective when they are mandatory rather than voluntary. Findings also indicate that the use of active and experiential pedagogies and incorporating individual and peer- reflections on current prescribing practice is more beneficial than tokenistic, brief, tick-box training packages received by staff on induction. These results concur with the positive results found with the use of these types of pedagogies, and link to well-known pedagogical theories (such as Kolb's experiential learning theory) that explain the benefits of these approaches (Derr et al., 2007; Kolb, 1984; Lee et al., 2013; M. Lloyd, Watmough, O'Brien, Furlong, & Hardy, 2018; Stocker et al., 2014). In Northern Ireland, for example, where the national 'Making Insulin Treatment Safer' programme (The Health Foundation, 2019) has been implemented to facilitate prescriber situational awareness and reflection around insulin prescribing, participants provided more positive descriptions of prescriber skills and knowledge, compared to their English counterparts. Increased exposure of undergraduates and trainees to insulin prescribing systems and safety issues (for example in simulated learning) is also likely to facilitate improvement efforts by increasing prescriber familiarity with processes (Pichardo-Lowden, Haidet, & Umpierrez, 2017).

Findings regarding the insulin passport explain why it is scarcely used and perceived as ineffective by the national survey respondents. Participants described incompatibilities with both human and system-level contexts related to insulin use and prescribing, which are consistent with previous qualitative studies investigating the use of patient handheld tools for information transfer (Waly et al., 2018). These results suggest that the concerns around the insulin passport outlined in **Chapter 1** are sustained and are raised across multiple organisations. The findings of this study go further than previous studies on the use of the insulin passport, however, by suggesting that the greater utilisation of existing technology systems (e.g. the summary care record), supported by an appreciable national patient safety agenda would enable consideration of wider systems issues impacting on the success of the intervention and would likely be more successful in enhancing information transfer at the care interface than the passport.

Around 17% of hospitals using electronic prescribing that did do so for subcutaneous insulin was further explained by a lack of system flexibility for the needs of prescribing insulin and the issues with proximity/integration with other systems necessary for insulin prescribing (e.g. recorded blood glucose results). Participants in Wales and Northern Ireland also explained the national standardised approach to electronic prescribing system introduction in their respective countries, which was planned to be implemented after the survey and interviews had been conducted (Downey, 2020; Hoeksma, 2020). Findings regarding the limited benefits of electronic prescribing for insulin and the introduction of new error types helped to explain the survey results demonstrating that electronic

prescribing systems were more highly regarded by trusts yet to implement it, and that it was only modestly effective overall.

The socio-technical issues associated with electronic prescribing systems (e.g. lack of flexibility resulting in workarounds, clinical workflow and communication changes) and their impact on medication errors have been widely studied in the literature (Z. Ahmed et al., 2016; Brown et al., 2017; Mohsin-Shaikh et al., 2019). This study argues that insulin presents unique challenges with respect to electronic prescribing systems with respect for the need for flexibility and limited benefits of 'hard stops' incorporated into prescribing systems. In order to realise the full potential of electronic prescribing systems to reduce insulin errors, consideration of a human factors approach to prescribing system design is therefore encouraged. This involves consideration of the proximity of blood glucose results to the insulin prescription, as well as targeted, appropriate, accessible prescriber decision support tools that are integrated into the prescribing workflow (Bell, Garfield, Khosla, Patel, & Franklin, 2019; Nirantharakumar, Chen, Marshall, Webber, & Coleman, 2012). This is particularly important in light of the number of hospitals with electronic prescribing systems that currently use paper prescriptions for insulin (as found in the national survey) and the lack of prescriber confidence and knowledge with insulin and diabetes management in the hospital setting (George et al., 2011).

This study also explained the survey findings regarding insulin self-administration policies: specifically that insulin self-administration policies were perceived to be more effective by organisations that did not have these policies in place compared to those that did. Results elucidated the complexities of designing and implementing these policies within organisations in practice, with several hospitals not utilising the policies that they had developed as a result. Contextual factors that impacted intervention successes, such as workforce support/collaboration and ability to integrate the use of simple policy documentation into existing workflow, were highlighted, along with socio-cultural issues, such as ward culture, practice norms, and fear of repercussions if things went wrong. Some of these issues have been described anecdotally in a previous single-centre reports on self-administration (Rowse, 2018a) but most reports are limited to small-scale audits reporting measurable quantitative outcomes such as patient self-administration status and documentation completion (Alabraba, Floyd, Morgan, Kelly, & Wallymahmed, 2014; Gangopadhyay et al., 2008; Hodgson & Voigt, 2013; S. Kavanagh & Boparai, 2015). It was clear from the study findings that the success of this intervention was socially contingent; Due to the widespread problems reported by participants regarding its implementation – despite good intentions – it was decided that this would benefit from further investigation using complexity-sensitive realist research methods.

5.7 Stakeholder group discussions

The results of the thematic analysis were presented to the LADDER panel via a group meeting on Microsoft Teams. This was the first meeting to be conducted virtually and was a result of new restrictions imposed by the COVID-

19 pandemic. A lay summary of results was circulated prior to the meeting to allow panel members the opportunity to process the results and devise questions in advance of the meeting. During the same meeting, a lay proposal of the final study was also presented for comment from the panel. Similar questions were posed to the panel in this meeting to the previous meeting and are included in Box 5.1.

Box 5.1: Questions and discussion points from the patient panel meeting following presentation of the study results.

How do you think the results might impact people with diabetes?
Are there any results you find particularly interesting or feel should be emphasised?
Are there any ways you might interpret the results that haven't been mentioned?
Are there any other comments you have about the research?

After presenting the results of the thematic analysis virtually, discussions with the panel gravitated towards the topic of self-administration interventions and how the results of the qualitative study could be explored in further depth. It was clear from discussions with the panel that self-administration interventions remained an important and evocative topic, with much of the meeting being given over to answering questions on the results regarding this intervention. Circulated feedback from the secretary is included verbatim in Box 5.2.

Box 5.2: Written feedback from the panel regarding the qualitative results and further exploration with realist synthesis

The results were interesting as they showed either of two extremes with no middle ground
Group suggested those capable should be allowed to sign a waiver or disclaimer to self-administer; those incapable a set of steps should be put in place to ensure correct administration
It should be communicated to ward staff should that nothing can go too significantly wrong over a few days whilst in hospital
Some members suggested a strict policy throughout all hospitals
The policy should be clearly communicated to patients
Consideration should be given to BAME communities
Suggested patients should be asked whether they usually receive help with insulin administration
Suggested that an outcome for the project should be that patients are made aware that each hospital should have a policy in place
The option to self-administer should be discussed throughout the hospital stay, not just on admission
Suggested a dedicated project manager for each hospital to ensure the policy is put in place

The results of this study were unfortunately not able to be discussed with the multidisciplinary inpatient diabetes team at the host site due to the pressures that were occurring at the time due to the COVID-19 pandemic.

5.8 Summary

Insulin prescribing is a complex and difficult task for prescribers in the hospital setting, and is commonly associated with medication errors and patient harm. With the use of qualitative interviews, the challenges and solutions with facilitating the safe prescribing of insulin were articulated and explored to reveal important mechanisms underpinning intervention success or failure.

A rich set of qualitative data was obtained and analysed to explain salient results from the survey regarding the use of interventions to improve insulin prescribing safety. Findings suggest that current opinion and practice is influenced by several contextual factors. These include organisational factors such as staff turnover, organisational size, availability and capacity of diabetes and pharmacy teams, as well as socio-cultural factors such as hierarchy, fear, and perceived burden of interventions.

A greater understanding was provided regarding why the insulin passport has a low uptake and perceived effectiveness, and why educational interventions are thought to be needed and effective. Interventions that are more complex in their design and implementation, such as electronic prescribing and self-administration policies were also explored, and contextual factors that impress on their perceived success were articulated.

The use of the SEIPS model enabled the description of salient human factors systems elements of insulin prescribing practice and intervention use in the hospital setting, which increased transferability of the results. The categorisation of data based on current intervention use also provided further contextualised results for the benefit of readers from various hospital organisations.

The next chapter builds on these results and focuses on self-administration policies as one of the more widely discussed and socially contingent complex interventions. This is also supportive of the priorities of the patient stakeholder group. As we have found in this chapter, some interventions work for some people, some of the time, to some extent. The next goal of enquiry should therefore be to discover “what works, for whom, under what circumstances and why”.

Chapter 6: Realist Synthesis of insulin self-administration policies

This chapter presents the in-depth analysis of insulin self-administration policy interventions using realist synthesis. This synthesis is presented in its entirety, including the following:

- Explanation of the initial stages of the synthesis process.
- Development of preliminary programme theories.
- Theory refinement with stakeholder consultations and three iterative literature searches.
- Presentation of the resultant programme theories in the form of context-mechanism-outcome configurations, using two established middle range theories as a conceptual framework.
- Discussion of key findings.

6.1 Introduction

Insulin errors in the hospital setting are prevalent, costly, and harmful to people with diabetes. Some progress has been made to address this in recent years, with the introduction of a range of interventions to improve insulin prescribing practice. However, we have found that interventions are used inconsistently and heterogeneously across different hospitals, and the success of implementing interventions relies on a complex combination of various organisational, personal, technical, and socio-cultural factors, making intervention success difficult to measure. We found insulin self-administration policy interventions to be regarded as one of the most complex, important and timely interventions used in hospitals to reduce insulin errors, both by interview participants and also by our patient stakeholder group.

Self-administration of medicines (SAM) is considered to be an important aspect of patient self-management, which healthcare professionals are encouraged to promote to patients as part of the goal to promote self-care (Vanwesemael, Boussery, & Dilles, 2020). During hospitalisation, medication administration is usually the responsibility of nurses, which disrupts the continuity of the patient's usual self-management (Vanwesemael et al., 2020). Self-administration of medicines (SAM) is defined as the practice of inpatients administering their own medications in hospital, and denotes a significant change to normal practice and shift in responsibility from nurses to patients (Richardson et al., 2014). As such, interventions such as policies or guidelines are needed in order to facilitate this in the hospital setting (Vanwesemael et al., 2020).

Self-administration of insulin policies have important distinctions from SAM policies more generally, and are often separated in practice. This is due to additional factors that need to be considered with insulin, including the disproportionate amount of medication errors associated with the use of insulin in the hospital setting, its

association with clinical inertia and the lack of staff knowledge, the relative clinical risks associated with maladministration of insulin, and the fear that many people with diabetes feel when insulin is taken away from them on admission to hospital.

The results of the mixed methods study suggest that insulin self-administration policies are often developed by hospital teams, but their use is highly variable due to problems with implementation. As the successful implementation of insulin self-administration policies is important for people with diabetes across all hospitals, as well as hospital teams and the wider NHS, the factors associated with success were chosen as the subject of further study (Joint British Diabetes Societies for Inpatient Care Group, 2012; National Institute for Health and Care Excellence, 2016; National Patient Safety Agency, 2011; NHS England, 2018; E. Watts & Rayman, 2018).

The use of theory may help to explain the factors associated with successful implementation. Middle range theories (such as Normalisation Process Theory) give conceptual currency to analyse studies involving the use of interventions such as self-administration policies. Whilst previous reports have identified barriers and facilitators to self-administration policies in the hospital setting (A. Murray, 2011; Richardson et al., 2014; Rowse, 2018a, 2018b; Vanwesemael et al., 2020), these have not been explicitly underpinned by theory in such a way to facilitate translatability across diverse hospital settings. In keeping with one of the objectives of the thesis, this study links contextual factors with underlying generative mechanisms to form hypotheses about how these policies work, for whom and in what circumstances.

This 'reality test' of the intentions of the intervention can help to form recommendations for hospitals and policymakers regarding the implementation and design of insulin self-administration policies. It can also uncover mechanisms to develop more complexity-sensitive measures to use in future effectiveness or implementation studies. Unlike in systematic reviews, the goal is not to determine *if* insulin self-administration policy interventions work and to what extent, but to uncover *how* they work. To achieve this objective, the following research questions were asked:

- What are the 'mechanisms' by which self-administration policies are believed to result in their intended outcomes?
- What are the important 'contexts' that determine whether or not the identified mechanisms produce either positive or negative outcomes?
- In what circumstances are self-administration policies likely to be effective?

To answer these questions, a realist synthesis was conducted, which enables the production of a series of theories about how insulin self-administration policies work, presented as configured context-mechanism-outcome (CMO) hypotheses. These theories, known as programme theories, were developed iteratively throughout the synthesis by a combination of retroductive theorising, literature searching and stakeholder group consultation. Programme

theories were then analysed using two substantive middle-range theories (Normalisation Process Theory (NPT) and Kanter's theory of structural empowerment) as a conceptual framework to aid understanding of the results.

The protocol for the realist synthesis was published in the PROSPERO register (CRD42020193351) (Bain, Jeffries, et al., 2020) prior to reporting. The RAMESES (Realist And MEta-narrative Evidence Syntheses: Evolving Standards) training materials were used to guide the synthesis conduct, and the RAMESES publication standards was used to guide reporting (G. Wong, Greenhalgh, et al., 2013; G. Wong, Westhorp, et al., 2013) (see Appendix 15). An overview of the conduct of the realist synthesis is given in Figure 6.1.

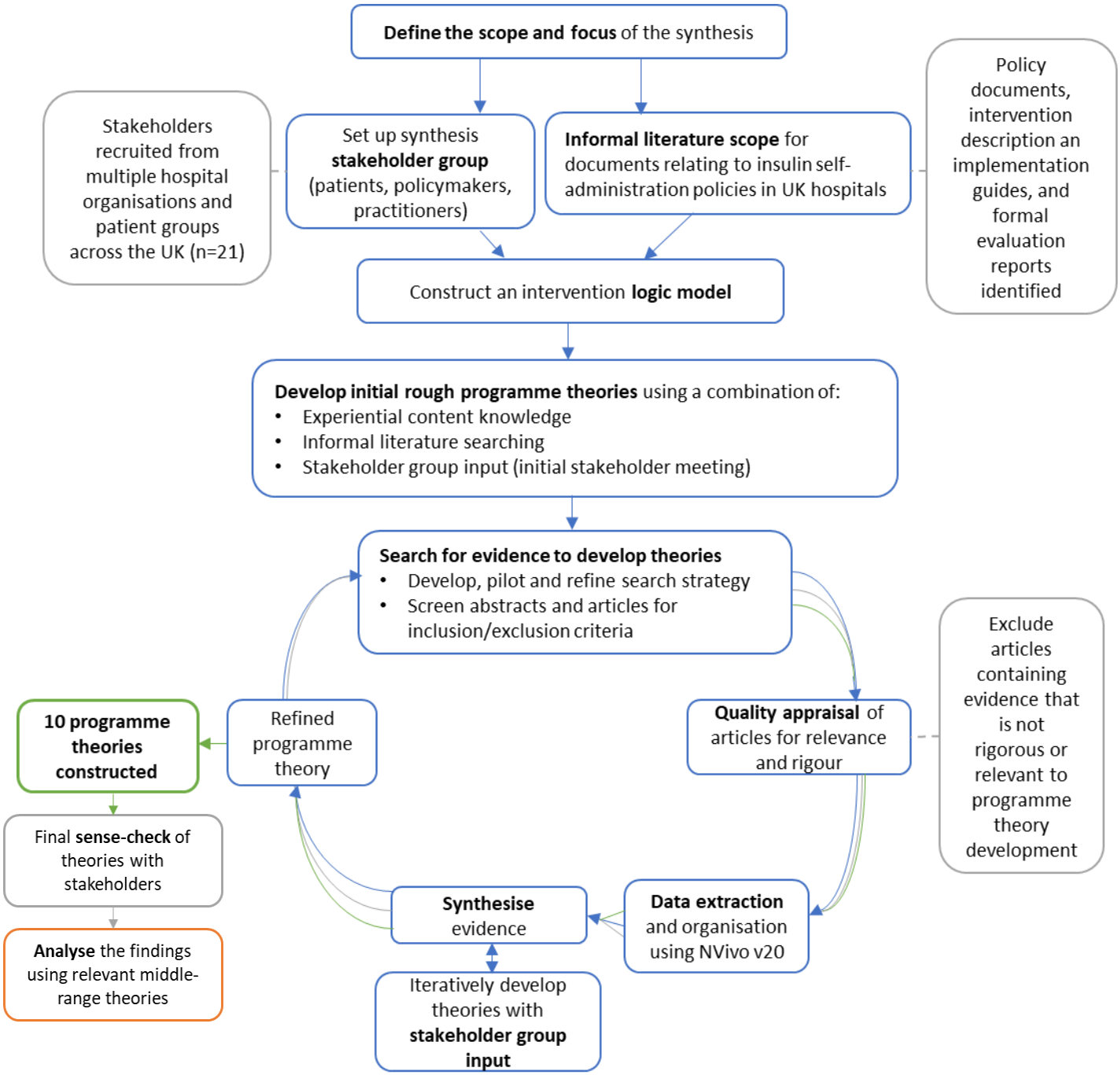


Figure 6.1: Realist synthesis process. Three separate literature searches were conducted as part of the cycle to generate the 10 programme theories.

Although the process of conducting the realist synthesis was iterative and non-linear, it is presented in this Chapter in order of the key stages outlined above (see also **Chapter 3**, Figure 3.4). First, the initial stages of clarifying the scope and developing initial theories is presented. This is followed by details of the 3 iterative literature searchers, quality appraisal and data extraction processes. Finally, the results of the synthesis are presented; the resultant 10 programme theories are outlined in the context-mechanism-outcome configurations (CMOCs) and are analysed according to middle range theories.

6.2. Defining and focusing the scope

The initial stages of the synthesis involved informally scoping the literature to identify formal policy documents or descriptions of insulin self-administration policies, implementation guides and research or evaluation reports regarding the intervention. This was done using electronic databases (Google and PubMed) and a combination of the terms 'self-administration' 'insulin' and 'hospital'. Only documents relating to insulin self-administration policies in UK hospitals were included at this stage, with no date restrictions. These documents were read and examined in such a way to attempt to become accustomed to retroductive theorising – the process of uncovering the hidden mechanisms of action in the deeper 'layers' of reality. This process is shown in Table 6.1

Table 6.1: Documents identified in the initial scoping literature, along with reflective questions asked when reviewing the documents. Reflective questions are taken from the RAMESES training materials for realist synthesis (G. Wong, Westhorp, et al., 2013)

Documents identified in scoping process	**Questions asked when reading and reflecting on the documents**
• Wessex Academic Health Science Network, (2017). *Self Administration of Insulin in Hospital*. • Rowse, V. L. (2018a). Implementing self-administration of insulin in hospital: a journey of discovery and innovation. Part 1: Culture and storage. *British Journal of Diabetes*, *18*(1), 18–21. https://doi.org/10.15277/bjd.2018.160 • Rowse, V. L. (2018b). Implementing self-administration of insulin in hospital: a journey of discovery and innovation. Part 2: Implementing change. *British Journal of Diabetes*, *18*(2), 66–68. https://doi.org/10.15277/bjd.2018.159 • Alabraba, V., Floyd, E., Morgan, C., Kelly, C., & Wallymahmed, M. (2014). "My diabetes, my insulin": Self-administration of insulin in hospital. *Journal of Diabetes Nursing*, *18*(7), 296–299. • Gangopadhyay, K. K., Ebinesan, A. D., Mtemererwa, B., Marshall, C., McGettigan, A. T., Cope, A., & Narendran, P. (2008). The timing of insulin administration to hospital inpatients is unsafe: Patient self-administration may make it safer. *Practical Diabetes International*, *25*(3), 96–98. https://doi.org/10.1002/pdi.1217 • Joint British Diabetes Societies for Inpatient Care Group. (2012). *Self-management of diabetes in hospital*. (March)	• How or why is this outcome expected to be achieved? • Who is expected to do what differently, in order for this outcome to be achieved? • What different choices or decisions would they need to make, in order to do that? • What will the program do or provide to assist them to do that? • What is the logic of the intervention? • How or why does each link in the chain work? • What assumptions are built into the programme theory? • What assumptions am I (the reviewer) making? • What assumptions are there in the data, and which of these do we need to challenge, and why?

As a result of this scoping process, a flow diagram was constructed to outline the general architecture of insulin self-administration policies (Figure 6.2)**.** Although the scoping process (and results from **Chapter 5**) revealed that details regarding finer sociotechnical elements of the intervention differ between settings, it was concluded that all insulin self-administration policies share the same logic. That is, they all aim to empower patients to take control of their own insulin injections to improve patient satisfaction and health outcomes, and reduce occurrence and adverse consequences of insulin prescribing and administration errors in hospital.

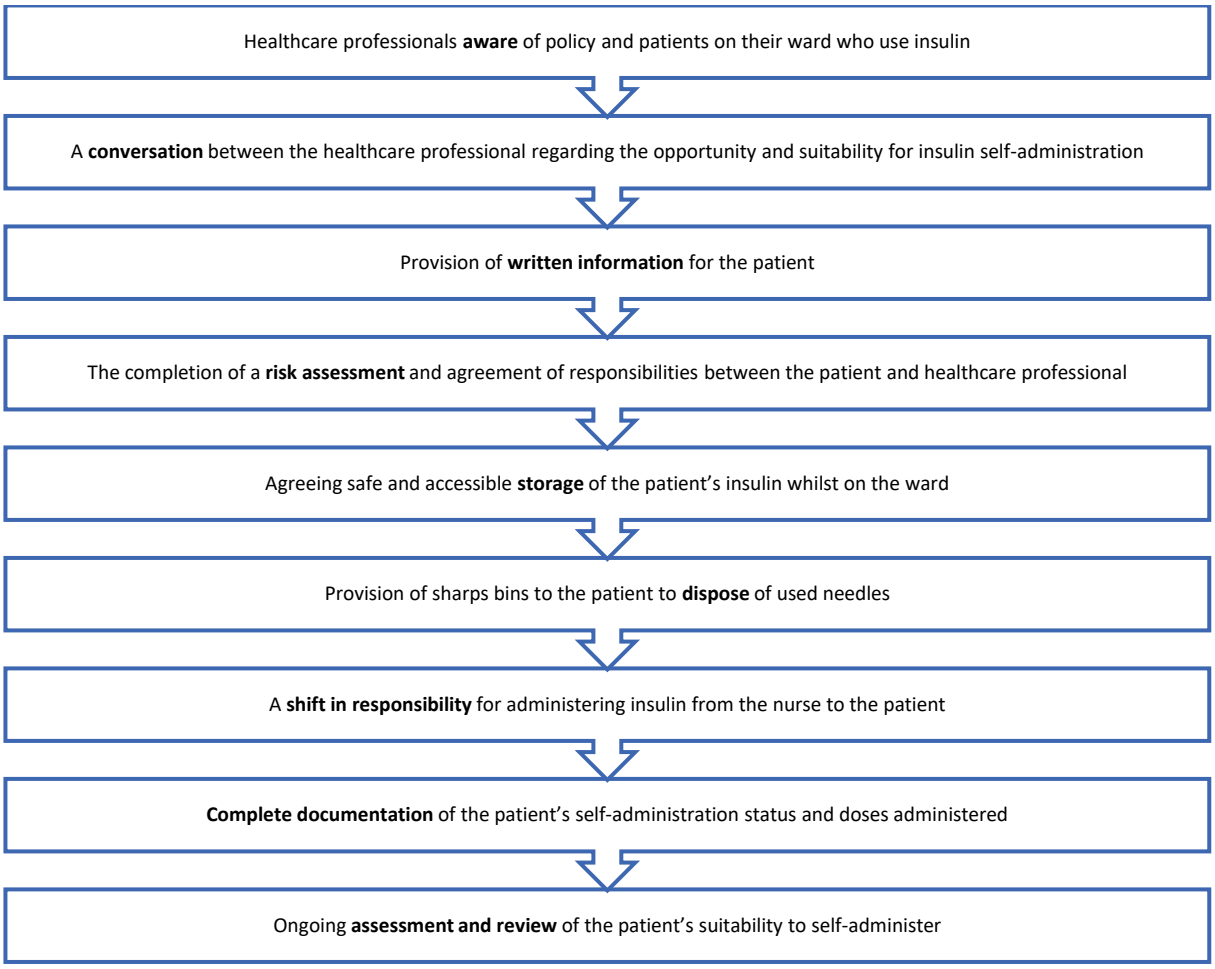


Figure 6.2: Flow diagram outlining the general architecture of inpatient insulin self-administration policies, constructed from reflective consideration of the scoping literature and results from Chapter 5.

Following the creation of this logic model, stakeholder groups were recruited and consulted to co-produce a set of initial, rough programme theories that could be taken forward for development as part of the synthesis process.

6.2.1 Stakeholder involvement

A diverse stakeholder group was recruited to provide content expertise for the development and refinement of insulin self-administration programme theories. This was to drive the focussing process to

achieve maximal end-user relevance (G. Wong, Westhorp, et al., 2013). Juxtaposing primary data from stakeholders alongside the literature enables a more powerful interpretative lens through which to explore real-word problems and solutions, and offer authentic data for realist research (Carey et al., 2015; in Emmel et al., 2019). This is consistent with the recommendations put forth by Lavis et al. to create *a 'dialogue that allows the data and research evidence … to inform and be considered alongside the views, experiences, and tacit knowledge of those who will be involved in, or affected by, future decisions about the health system problem'* (2012).

Stakeholders were recruited via professional networks and via the charity Diabetes UK. Unlike selection for inclusion in qualitative research, there is no formal sampling strategy for involvement in a stakeholder group for realist research. This is because the aim is not to achieve proportional representation, but rather to have an appropriate variation in the complement of individuals to help achieve the research aims. Individuals were considered for inclusion based on their current or previous employment or position as a healthcare professional or person with diabetes who had experience in designing, implementing or using insulin self-administration policies in the UK hospital setting. People with any type of diabetes were considered if they used insulin and had been admitted to hospital for any reason in the past 5 years. The stakeholder panel included a variety of healthcare professionals, including diabetes specialists and non-specialists, from several hospital organisations in the UK, including some of the authors on articles relating to insulin self-administration policies in UK hospitals. The group also included people with type 1 and type 2 diabetes, to represent those who would be most impacted by the implementation of insulin self-administration policies (see Table 6.2). Selection was checked with a member of the supervisory team in order to be critical about the inclusion of individuals involved**.**

Table 6.2: Stakeholder group for realist synthesis (n=21)

Role	**Recruited from (organisation)**
Nurses	
Diabetes inpatient specialist nurse	Large teaching hospital in Yorkshire and the Humber
Diabetes inpatient specialist nurse	Large teaching hospital in the South of England
Diabetes nurse consultant	CCGs and hospital in London
Deputy sister – elective orthopaedics	Large teaching hospital in the East Midlands
Medical Doctors	
Consultant diabetologist and clinical lead for diabetes	Large teaching hospital in the North of England
Pharmacists	

Consultant diabetes pharmacist and clinical lead for diabetes	Large teaching hospital in the South of England
Specialist pharmacist	Large hospital in the South West of England
Pharmacist	Large teaching hospital in the North West of England
Specialist Diabetes Pharmacist	Large teaching hospital in the North of England
Policymakers and programme managers	
Senior Programme Manager	Academic Health Science Network in the South of England
Policy manager, Getting It Right First Time	NHS England, NHS Improvement
People with diabetes	
Lay member with type 1 diabetes, patient representative for 'making insulin treatment safer' and Antrim hospital self-administration projects, co-lead the Diabetes UK Research Network in Northern Ireland	Diabetes UK
Lay member with type 1 diabetes	
Nurse with type 1 diabetes	
Junior doctor with type 1 diabetes	
Lay member with type 2 diabetes, type 2 clinical champion in the London Clinical Network	
Lay member with type 1 diabetes	
4 Lay members with diabetes	Sheffield Teaching Hospitals NHS Foundation Trust LADDER Panel

Consultations with the stakeholder group took place periodically over the course of the study, via email and several group and individual videoconferences. A total of 3 virtual group meetings and 5 individual virtual meetings were held, each lasting around 60 minutes. The combination of stakeholders at group videoconference meetings varied on each occasion, and two stakeholders were consulted via email instead. This non-uniform approach was not originally anticipated, but the researcher soon realised that it allowed for increased input of stakeholders throughout the project.

The first stakeholder group meeting comprised a programme manager, a nurse and 3 people with diabetes. Additional individual meetings were had with a diabetes nurse consultant and a lay member with diabetes, and a specialist pharmacist. Stakeholders were initially asked about the following areas in the first meeting to help generate the initial rough programme theories:

- The challenges and solutions to self-administration of insulin in hospital (with a focus on their personal experiences)

- Their perceptions about the role of social dynamics and informal influences regarding the uptake/use of self-admin policies.
- The gap between expectations and what happens in practice
- What do they think the answer is?

Notes were taken from these discussions and used to build the rough programme theories using retroductive theorising. Subsequent meetings enabled further refinement of programme theories and (see **section 6.3**). The involvement of stakeholder opinion ensured that the synthesis remained grounded in the practical reality experienced by a range of participants, and enhanced the usability of actionable findings.

6.2.2 Development of initial programme theories

The process of designing interventions makes use of theories about why certain components to the intervention are required in order to achieve the desired outcomes, whether this is done knowingly or not (Pawson & Tilley, 1997). For example, the basic theory underlying the introduction of mandatory training would be that a lack of knowledge leads to poor prescribing practice and the solution is to educate prescribers. The goal of realist synthesis is to identify these theories to explain how self-administration policy interventions work and under what circumstances. This process starts with the development of rough programme theories.

Initial rough programme theories attempt to explain and 'make sense' of activities involved in self-administration policies (as described in Figure 6.2) and the responses of individuals to those activities. Initial rough programme theories were devised from a mixture of experiential, professional and content knowledge, qualitative data from the mixed methods study (see **Chapter 5**), stakeholder group discussions, and insights from reflection on the scoping literature outlined in Table 6.1. This process was messy, iterative and complex, whereby the 'inner workings' of the intervention were sought to be exposed and unpicked.

First, intervention outcomes relating to insulin safety and patient satisfaction (e.g. insulin errors, hypoglycaemic events, number of people wishing to self-administer being able to) were identified and selected from the scoping literature. Then, 'working backwards' from these outcomes using a process of retroductive theorising, insights from stakeholders were incorporated with experiential, professional and content knowledge from the research group, as well as relevant qualitative data from **Chapter 5** to form

a rough theories about how elements of the intervention work to achieve these outcomes (G. Wong, Westhorp, et al., 2013). An illustrative example of this process is given in Figure 6.3.

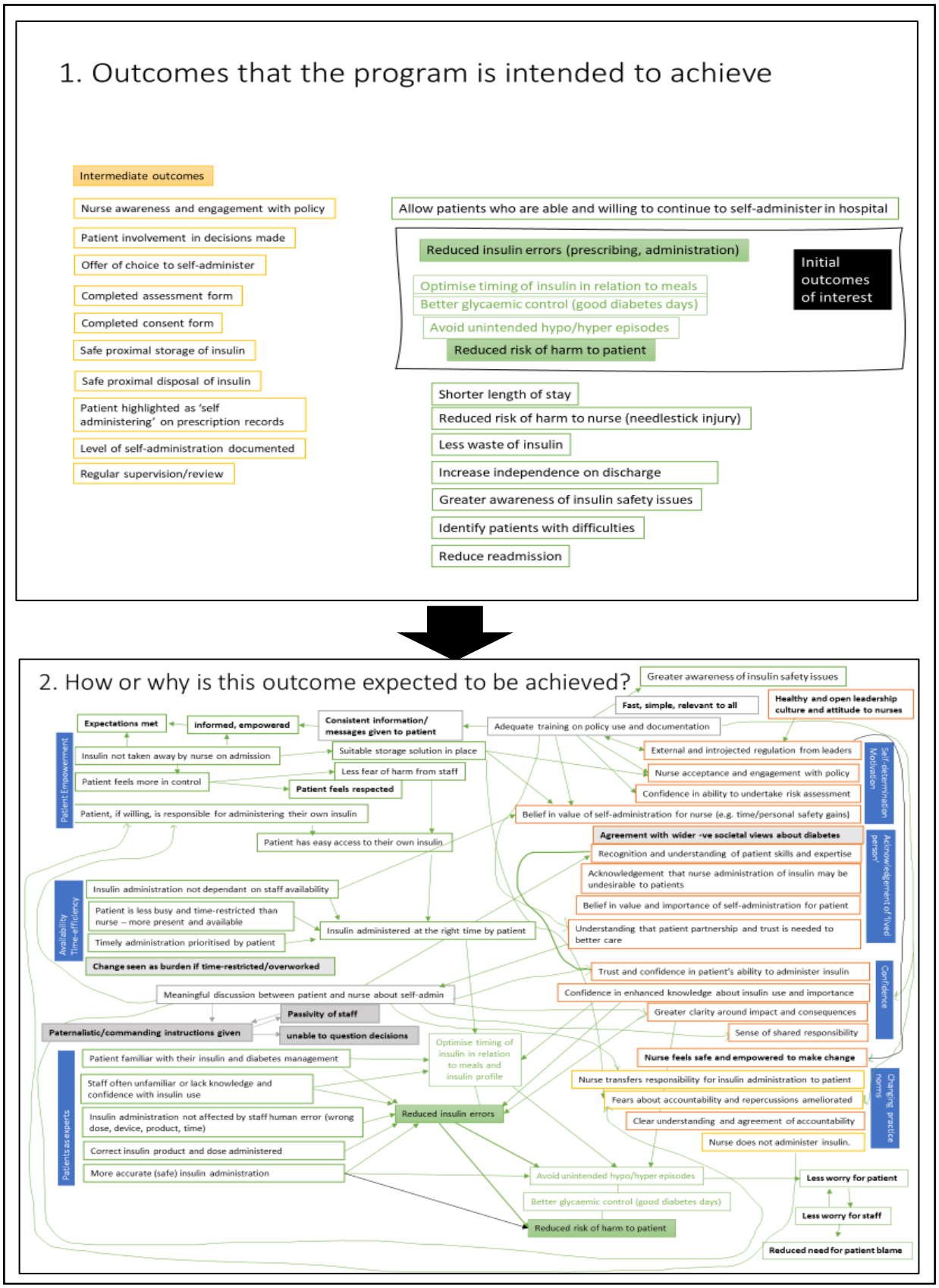


Figure 6.3: Initial rough programme theory development. First, key outcomes were identified, then a complex process was used to help uncover how and why these outcomes are achieved with the interventions. Bold text represents the additional insights from stakeholders.

In a process of linearizing the complex, three-dimensional and fluid thinking about how these interventions work exemplified above, the initial rough programme theories were organised into initial sets of contexts, mechanisms, and outcomes. This aimed to capture a broad set of ideas about self-administration policies (see Table 6.3 for an example).

Table 6.3: Excerpt from initial rough programme theory organised into contexts, mechanisms and outcomes, prior to further refinement and development with stakeholders.

Context	**Mechanism**	**Outcome**
Inpatients retaining possession of their insulin as 'the norm'	Empowerment, greater control and confidence felt by patient	Inpatients are able to accurately administer their own correct insulin product(s) on time
	Levelling power relationships	Insulin dosing optimised according to insulin type and meals
	Greater patient independence maintained	Reduced insulin errors
	Reduced reluctance to change nurse-administration norms	Fewer episodes of hypo/hyperglycaemia
		Reduced risk of harm to the patient
		Greater patient satisfaction
		Greater efficiencies in team processes around medicines administration, greater productivity
		Correct insulin product and dose administered at an appropriate time
		Insulin administration not impacted by staff human error
Open and honest communication and shared decision-making process between patients and healthcare team	Staff acknowledgement of 'lived person'	Increased patient awareness of opportunity for self-administration
	Motivation to support self-administration due to greater trust and confidence in patient's expertise	Patient feels respected and involved
	Recognition and understanding of each other's skills and knowledge around insulin	Patient is empowered to question decisions
	Opportunity for conversation prompted by integration of self-administration into clerking process	Patient is more in control
A culture of respect and understanding the importance of insulin being near to the patient at all times	Information and explanations given to patients regarding what is achievable with respect to insulin storage and use whilst in hospital	Patient is empowered and their opinions are respected
	Increased understanding that patient partnership and trust is needed to achieve better care	

6.3 Revised programme theories

Although the scope of the review was clarified and focused, the initial rough programme theories were extensive and required refinement and prioritisation for review. The theories were therefore discussed with the stakeholder group (via email and videoconferencing) so that theories with particular relevance for influencing practice and importance for people with diabetes could be selected for further development.

Stakeholders were shown the initial programme theories (which they helped to develop previously) and were asked to give their perspectives regarding the following:

- Do the programme theories match their experience and not, and how?
- Do the programme theories match their ideas about self-administration?
- Are the identified mechanisms were important and/or relevant?
- Is the terminology used in the programme theories appropriate?

Meetings with the stakeholders were engaging and overall, stakeholders agreed that the theories represented their experiences and insights with policy use and the important contexts in which they worked. Some important areas of development were also elicited through these meetings, including the focus on shared decision-making and partnership, as well as the impact of power differentials and consistency of communication.

The stakeholder group also identified mechanisms with particular salience and value. These included the opportunity for open and honest communication, the acknowledgement of the 'lived person' with diabetes, reducing the perceived burden of the intervention and increasing clarity of governance requirements. These revised theories, exemplified in Table 6.4, contained the key mechanisms identified by the stakeholder group, which may work to both hinder or facilitate insulin self-administration policy implementation.

At this point in theory development, mechanisms were separated into resources that the intervention provides (e.g. information, opportunities, change in practice) and responses from agents involved in the intervention use/implementation (feelings or actions). This disaggregation of mechanisms into its constituent parts helps to understand the difference between the resources offered by the intervention and the ways in which this changes the reasoning of participants, and helps to distinguish mechanisms from contexts, which is cited as a common difficulty in realist research (S. M. Dalkin, Greenhalgh, Jones, Cunningham, & Lhussier, 2015)**.**

Table 6.4: Excerpt of revised programme theories following stakeholder discussion, prior to literature searching.

Context	Mechanism (resource)	Mechanism (response)	Outcome
Staff unaware of patient's needs or wishes with respect to insulin self-administration Culture of patients receiving care as 'passengers'	Provides opportunity for open and honest communication between patient and staff	Gaining perspective on each other's needs, wishes and abilities which inspires trust, corrects misconceptions, acknowledgement of 'lived person' and reassurance	Highlights potential issues Improved patient satisfaction and service delivery Maintained patient autonomy, independence, and health engagement Increased understanding that staff-patient partnership is needed to achieve better patient care
Patients are unaware of hospital self-administration policy Cultural norm of being a passive recipient of inpatient care	Patient informed about self-administration policies and processes	Patient empowered to speak up and be involved in their own care and attenuation of fears over lack of control and potential harm as a result of not being able to self-administer	Increased numbers of people (staff and patients) aware of policy Increased numbers of people who wish to/are able to self-administer doing so Patient expectations managed
Doctors regarded as the 'expert' Mistrust of doctors Wider negative societal views around people with diabetes	Opportunity for shared decision-making between patient and staff and more even power dynamics	Fostering trust between patient and staff Staff feeling of being undermined or threatened	Improved staff-patient relationship, improved self-management Reduced propensity for conflict

The revised theories were then further refined during a process of evidence identification, synthesis, and configuration from studies in the literature. This is described further below.

6.4 Evidence searching

In order to develop the programme theories using realist logic of analysis (i.e. the context-mechanism-outcome (CMO) heuristic), data from documents need to be gathered, scrutinised and used. This is an interactive and interactive process which differs from that of a systematic review. For example, complementary and snowball searching, or cluster searching, were used in this synthesis.

The first formal literature review was undertaken in September 2020 to locate a relevant body of literature with which to refine the programme theories. A broad criterion of studies matching the keywords 'insulin' 'self-administration' and 'hospital' was used. Terms were tailored and indexed to individual databases (e.g. MEDLINE and EMBASE) as well as using free-text searching (see Table 6.5). Searching was undertaken in September and October 2020 using the following databases: The Cochrane Library, PubMed, MEDLINE, EMBASE, CINAHL, Google Scholar, NICE Evidence, and Google (to identify policy documents, hospital information websites, newspaper articles, blogs). Conference abstracts were excluded because they did not contain sufficient extractable detail about contexts or mechanisms. Non-English language publications were excluded because there was insufficient time and resource to translate them.

Table 6.5: Initial search strategy for the realist synthesis.

Database	Search terms	Hits
PubMed	Insulin AND hospital AND self-administration	617
PubMed	Insulin AND hospital AND self-administration AND policy	16
MEDLINE	exp INSULIN/ AND (hospital).ti,ab AND exp "SELF ADMINISTRATION"/	9
EMBASE	exp HOSPITAL/ AND *INSULIN/ AND exp "DRUG SELF ADMINISTRATOIN	3
EMCARE	exp HOSPITAL/ AND *INSULIN/ AND exp "DRUG SELF ADMINISTRATOIN	0
CINAHL	exp INSULIN AND exp HOSPITALS/ AND "SELF CARE"/ OR "SELF ADMINISTRATION"/	11
PsycINFO	*INSULIN/ AND exp HOSPITALS/OR "HOSPITAL ENVIONMENT"/ AND exp "DRUG SELF ADMINITRATION"/	0
Google Scholar	Insulin AND self-administration AND hospital	4420
NHS Evidence	"Self-administration of medicines in hospital"	4161
Google	"Insulin self-administration hospital policy"	~8,290,000

Citations of relevant articles were also manually searched, as well as relevant grey literature. Inclusion criteria remained broad to enable the examination of evidence from studies of all designs that reported on the design, implementation, or evaluation of insulin self-administration policies in the inpatient setting, either on patients, staff or organisations. All outcome measures focussing on patient satisfaction and safety were included. Studies were excluded if they did not concern self-administration policy intervention, or concerned self-administration policies in settings other than the acute hospital setting (e.g. care homes, community). Studies were not excluded on the basis of date of publication.

Two additional searches were performed in October 2020 to further illuminate the theorised mechanisms of the rough programme theories. This involved searching more specifically for wider literature on the concepts identified, due to the dearth of literature to explain this relating to insulin self-administration in the hospital

setting. These included “patient empowerment” and “shared decision-making”, thereby reflecting the priority areas identified from stakeholder consultations. Inclusion criteria for these searches were widened to include studies reporting on self-administration of medicines more generally (i.e. not just insulin-specific) in an inpatient setting, to understand and explain the wider socio-cultural context in which insulin self-administration policies are implemented.

It was decided that it was not necessary to search as wide a selection of databases for the purpose of these iterations (a general Google search was not performed). Search terms for these were tailored to the database searched (see Table 6.6). Only studies from economically developed nations were included due to the particular cultural and medico-legal distinctions that exist between this setting and others (e.g. quality of care, liability, roles and responsibilities of different professionals).

Table 6.6: Additional iterative search strategies used in the realist synthesis.

Database	Search terms	Hits
Search 2 (patient empowerment)		
PubMed	Empowerment AND hospital AND self-administration AND diabetes	17
PubMed	Empowerment AND hospital AND self-administration	152
MEDLINE	(Patient Empowerment). ti, ab AND INPATIENTS/ AND "SELF CARE"	3
MEDLINE	(Patient Empowerment). ti, ab AND INPATIENTS/	21
MEDLINE	(Patient Empowerment). ti, ab AND (hospital). ti, ab AND DIABETES MELLITUS/	7
EMBASE	EMPOWERMENT/ AND "DRUG SELF ADMINISTRATION"/AND "HOSPITAL PATIENT"/	0
EMBASE	EMPOWERMENT/ AND "HOSPITAL PATIENT"/	223
EMCARE	EMPOWERMENT/ AND "DRUG SELF ADMINISTRATION"/AND "HOSPITAL PATIENT"/	2
CINAHL	EMPOWERMNENT/ AND SELF ADMINISTRATION/	9
PsycINFO	EMPOWERMENT/ AND HOSPITALIZATION/ OR "HOSPITAL ADMISSION"/ AND "DRUG SELF ADMINISTRATION"/	0
Google Scholar	Patient empowerment AND self-administration AND hospital	4250
NHS Evidence	Empowerment AND self-administration	86
Search 3 (shared decision-making		
PubMed	(shared decision making). ti, ab AND (inpatient). ti, ab AND (diabetes). ti, ab	3
PubMed	(shared decision making). ti, ab AND (inpatient).	208
MEDLINE	"DECISION MAKING, SHARED"/AND INPATIENTS/	1
MEDLINE	"DECISION MAKING, SHARED"/AND exp" HOSPITAL MEDICINE"/	0
MEDLINE	"DECISION MAKING, SHARED"/AND "DIABETES MELLITUS"/	1
EMBASE	"SHARED DECISION MAKING"/ AND exp "HOSPITAL PATIENT"/	106

EMCARE	"SHARED DECISION MAKING"/ AND exp "HOSPITAL PATIENT"/	53
CINAHL	("DECISION MAKING, SHARED"/ AND (INPATIENTS/ OR "DIABETIC PATIENTS"/)) AND exp "HOSPITAL UNITS"/"	8
CINAHL	"DECISION MAKING, SHARED"/ AND (INPATIENTS/ OR "DIABETIC PATIENTS"/)"	39
PsycINFO	(shared decision-making).ti, ab AND HOSPITALIZATION/ OR "HOSPITAL ADMISSION"/ AND "DRUG SELF ADMINISTRATION"/	0
Google Scholar	Shared decision-making AND inpatient AND diabetes	69200
NHS Evidence	Shared decision making AND diabetes AND hospital	3432

After the initial screening of titles and abstracts, a total of 69 articles were excluded based on irrelevance to the review question, not satisfying inclusion criteria, or being irretrievable/conference abstracts. Details of excluded articles, along with reasons for exclusion, are listed in Appendix 16. Articles included after the initial full-text screen underwent additional in-depth screening to determine their applicability and appropriateness (to contribute to theory development) using Pawson's criteria of relevance and rigor (Pawson, 2006; G. Wong, Westhorp, et al., 2013). Details of this process are included in the section below.

6.5 Quality appraisal

As with traditional systematic reviews, realist syntheses require quality appraisal and filtering of evidence based on that quality. A quality review process was conducted prior to decision to include evidence in the final synthesis. Unlike systematic reviews, however, which are selective based on methodological quality (e.g. based on traditional hierarchies of evidence), realist syntheses require a broad range of evidence relating to the intervention to illuminate the richer picture. Selecting based on methodological quality would therefore impoverish the synthesis and is inappropriate because the study is not the main unit of analysis in realist review. Methodological checklists (e.g. the Newcastle Ottowa Scale, QI-MCQS and the Joanna Briggs Institute checklist) are therefore also inappropriate because synthesis calls on impact evaluations, documentary analysis, opinion pieces, audit results, theses, policy documentation, and all their permutations.

Both qualitative and quantitative evidence were therefore considered for the development of programme theories, in line with realist methodology. Quality of evidence included in studies or documents was judged according to its relevance (did it address the theory under test?) and rigor (does the inference have sufficient weight to make a methodologically credible contribution to the theory refinement?) relative to the programme theory (Pawson et al., 2005; G. Wong, Greenhalgh, et al., 2013). The assessment of relevance was answered as a yes/no response with justification, and the assessment of rigour was a brief description of limitations of the method used in the article to generate data (either qualitative or quantitative). This meant that elements of

evidence could be considered from studies even if the study's overall quality would not be considered 'strong' according to traditional quality criteria (e.g. risk of bias assessments).

The relevance of studies was discussed with members of the supervisory team if necessary, and rigour was assessed by judging the plausibility and coherence of the method used to generate data (G. Wong, Westhorp, et al., 2013). The relative contribution of each source was weighed using this criteria, and a total of 24 articles were excluded across the 3 searches as a result. Evidence from studies that were regarded as not relevant to theory development were not included and therefore did not get assessed for rigour. Inclusion of articles often followed any uncertainties, as to avoid missing valuable contributions to theory. Appendix 17 documents the quality appraisal for the synthesis, and includes details of excluded articles, along with reasons for exclusion at this stage.

6.6 Data extraction

The revised programme theories were added as individual nodes in NVivo (QSR International Pty Ltd, 2018), using shortened subsection names (e.g. "CMOC 1 – empowers patients and highlights problems"). The qualitative data from the mixed methods study was imported to NVivo along with the literature passing quality appraisal. The included documents were then read in full, and evidence within these interviews and studies were coded to these theories as described by Dalkin et. al. (S. Dalkin, Forster, Hodgson, Lhussier, & Carr, 2020). Data were prioritised for coding if they were able to elucidate or refute causal claims, or could support/refute programme theories. Evidence included results from qualitative and quantitative primary studies, insights from discussion sections, information from the introduction sections, and the primary data from the qualitative interviews conducted with pharmacists in the mixed methods study.

Evidence from studies that supported or helped to develop more than one programme theory were coded to multiple theories in NVivo. This occurred regularly in the initial stages of coding on account of the interactivity between mechanisms contained in the different theories. For example, empowerment and control were often discussed together in the literature, and were therefore difficult to untangle for the purposes of developing programme theories. Several versions of the programme theories and corresponding supporting or refuting evidence was retained on separate dated word documents to demonstrate theory development over time. This 'audit trail' helped to aid transparency in the process.

6.7 Middle-range theories

In order to help to explain how insulin self-administration policies work at a more general, overarching level, substantive middle-range theories were sought to be identified from the included literature resulting from the iterative literature searches (Jagosh, 2019). Middle range theories, which lie in between the smaller hypotheses

that are required for “day to day research” and the larger “all-inclusive” unifying theories of social behaviour, serve to provide a level of abstraction that is specific enough to explain a particular case but general enough to apply across a range of cases (Merton, 1968; G. Wong, Westhorp, et al., 2013).

No complete substantive middle-range theories were identified in the literature, therefore the researcher attempted to identify relevant theories from the wider implementation science and healthcare disciplines. Although many theories were considered, Normalisation Process theory and Kanter’s Theory of Structural Empowerment were selected as middle-range theories that, together, had the most relevance for explaining programme theories. Whilst neither of these theories individually explain how insulin self-administration policies work through the refined programme theories, they do support specific contexts or mechanisms that predict intervention outcomes. The two theories were therefore used together as tools to help frame and explain the analysis. The CMOCs were mapped onto the constructs of the theories to help analyse and explain the results and highlight any gaps that may have been missed through the coding process alone. These two theories are outlined below:

6.7.1 Normalisation Process Theory

Normalisation Process Theory (NPT) is useful in identifying factors that promote or inhibit the routine incorporation of complex interventions (such as self-administration policies) into clinical practice (C. May & Finch, 2009; C. R. May et al., 2009). Normalisation Process theory proposes that complex interventions become routinely embedded and normalised in their contexts as the result of people working to implement them; that this work is operationalised through four dynamic generative mechanisms (coherence, cognitive participation, collective action and reflexive monitoring) and that the work of integration requires continuous investment by people in ensembles of action that carry forward in time and space (E. Murray et al., 2010).

Coherence involves the sense-making work (differentiation, communal and individual specification, and internalisation), cognitive participation involves relational work to sustain the community of practice around the intervention (initiation, enrolment, legitimation, and activation), collective action involves the actual operational work involved in the intervention (interactional workability, relational integration, skill set workability and contextual integration), and reflexive monitoring pertains to the appraisal work (systemisation, communal and individual appraisal, and reconfiguration). Further definitions and examples of these mechanisms and constructs may be found in the work of May, Finch and Murray (C. May & Finch, 2009; C. May et al., 2011; C. R. May et al., 2009; E. Murray et al., 2010).

6.7.2 Kanter's Theory of Structural Empowerment

Kanter describes opportunity and power as two primary empowerment structures in organisations (Kanter, 1977). The structure of opportunity to learn and grow relates to job conditions that enable employees to advance their knowledge and skills, which enables individuals to take a more proactive approach to problem solving and change. The structure of power, where power is defined as the ability to *"mobilise information, resources and support to get things done"* requires access to information, support, and resources (Kanter, 1977). These two structures of empowerment are facilitated through formal and informal power systems: informal power derives from job activities that allow flexibility and discretion in decision-making (such as skill-development and participative management) and formal power derives from forming alliances or relationships with others (such as establishing partnerships with patients and networking with colleagues).

The components of Kanter's theory of structural empowerment are therefore access to information, access to support, access to resources, access to opportunity to learn and grow, informal power and formal power. Kanter argues that empowered people are more likely to share power with others, which in this setting, entails healthcare professionals sharing their power with their patients, resulting in more empowered patients, who experience a greater sense of self-determination, self-efficacy and control (Spence Laschinger, Gilbert, Smith, & Leslie, 2010).

6.8 Results

The overall search and screening process resulted in the identification of 49 references for inclusion in the realist synthesis (see Figure 6.4). Articles comprised literature reviews (n=5), systematic reviews (n=2), observational studies (n= 7), qualitative interview studies (n=12), quality improvement project reports (n=8), surveys (n= 5), patient information resources (n=2), implementation guides (n=2), opinion pieces (n=2), conceptual piece (n=1), audit (n=1) and best practice guidance (n=2). Studies reporting original data originated in the UK (n=19), USA (n=7), Australia (n=5), Belgium (n=2), Denmark (n=2), Germany (n=2), Canada (n=1), Singapore (n=1), and Sweden (n=1).

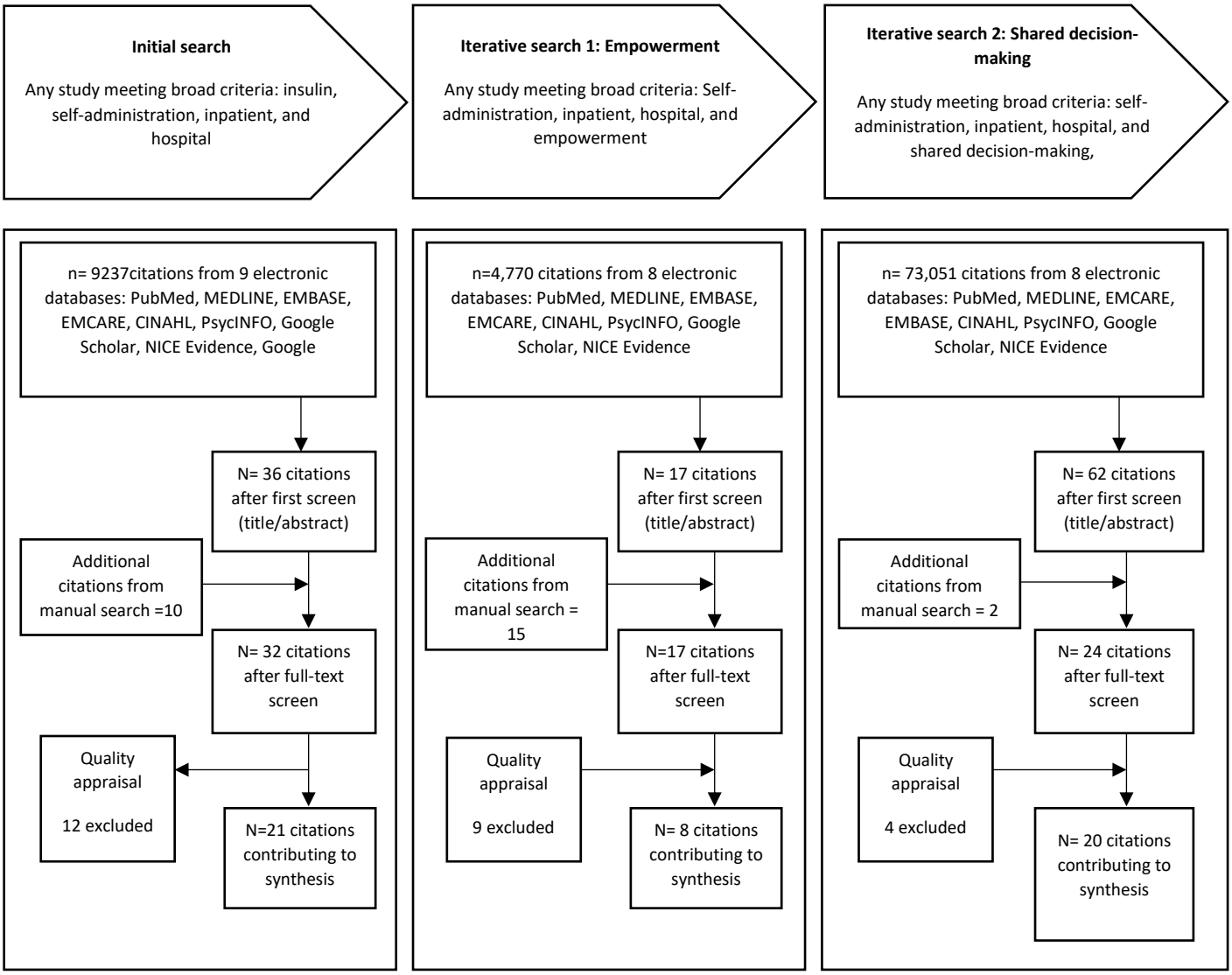


Figure 6.4: Literature searching and review process. The hits from the initial google search are not included due to their inaccuracy and number (around 8,290,000).

The available data concerning insulin self-administration policies in the UK hospital setting was mostly limited to best practice guidance, audit or project reports. Although data presented in these reports was specific to the intervention being studied, methodological detail was often lacking. Project reports were often written by those responsible for designing/implementing the intervention and included valuable discussion that contributed to theory building, however, and were therefore included in the review. Some articles presented duplicate information, for example the project described in the insulin self-administration implementation guide (Wessex Academic Health Science Network, 2017) was also presented in an additional article (Rowse, 2018b). Similarly, the project included in the article by Dashora et al was also presented as a report by Kavanagh (Umesh Dashora et al., 2018; Sallianne Kavanagh et al., 2016).

Johnston reported their hospital's insulin self-administration project in two articles, (Johnston, 2019; Johnston & Newland-Jones, 2017), as does Hendrieckx and Litterbach for their qualitative study (Hendrieckx, Holmes-Truscott, & Speight, 2020; Litterbach, Holmes-Truscott, Pouwer, Speight, & Hendrieckx, 2020). Articles that reported duplicate data were included if they made unique contributions to the development of programme theories (i.e. if papers had different emphasis/discussion). This was not thought to be problematic because results were not quantified or pooled as in systematic review/meta-analysis, and the aim was to develop theory rather than measure effect size.

Due to the paucity of original data regarding this specific intervention, identified articles that concerned diabetes medication self-administration (SAM) in an inpatient setting more generally were included, and judgements were made regarding the relevance and applicability to insulin self-administration on a case-by-case basis. In order to gather evidence to refine proposed mechanisms, searches were widened further to include more general discussions inpatient empowerment and shared decision-making with respect to medicines administration in a hospital setting. These searches resulted in the inclusion of articles with a higher methodological quality (e.g. qualitative interview studies, cross-sectional surveys), which helped to support theory development.

Refined Programme Theories

The process of theory development, refinement and focus theory resulted in ten overall programme theories (in the form of CMO configurations) that help explain how insulin self-administration policies work, for whom, and under what circumstances (Table 6.7). These theories expose the mechanisms by which self-administration policies are believed to result in their intended outcomes, as well as the contexts that determine whether the identified mechanisms produce either positive or negative outcomes. Each theory was examined in light of the literature, with data from included publications being used to develop the individual theories.

The ten theories represent distinct elements of how insulin self-administration policy interventions work for different groups of people, namely individual healthcare professionals, teams within the organisation, and patients. For individual healthcare professionals, the programme theories identify mechanisms such as clarity of responsibility, and increased motivation to challenge norms. For wider teams within the organisation (e.g. a multidisciplinary ward team), collaborative working practices, ward culture and integration with current workflow and systems were identified as important explanatory factors. Finally, for patients, important mechanisms were identified such as empowerment, control and shared decision-making. A couple of these mechanisms fired in more than one context to produce outcomes, and as such appeared in more than one theory, such as altered perception of burden on staff and greater appreciation of each other's contribution to self-administration.

Prior to writing up, the revised ten theories were presented to the stakeholder group for a final 'sense check'. Stakeholders confirmed the theories encapsulated the key and salient topics with respect to intervention use from

their multiple perspectives. Individual videoconference meetings and email exchanges were conducted with three of the stakeholders (a nurse with type 1 diabetes, a specialist pharmacist and programme manager) and minor changes were made to the wording as a result (e.g. “consistent information given to patient” was changed to “consistent information given to patient throughout organisation” in theory 10).

Table 6.7: Summary of programme theories resulting from the realist synthesis

Subsection	**Context**	**Mechanism (resource)**	**Mechanism (response)**	**Outcome**
1. Empowers patients and highlights problems	Staff awareness of patient’s needs or wishes with respect to insulin self-administration, patient uncertainty regarding hospital processes and policies regarding self-administration	Patient and care team informed about self-administration policies and processes, which prompts a conversation regarding self-administration of insulin on admission	Helps motivated patients feel empowered to communicate their needs, abilities and expectations and be involved in their own care, leading to the care team having greater awareness and understanding of the patient’s situation, abilities and wishes	Increased numbers of people (staff and patients) aware of policy, Increased numbers of people self-administering that are willing and able to do so. Patient expectations and potential issues highlighted and managed
2. Facilitates shared decision-making	Model of healthcare delivery (e.g. paternalistic, hierarchical) and healthcare professionals’ regard for patient's ‘lived experience’ of diabetes	Patient offered a choice to self-administer and given the opportunity (and permission) to participate in shared decision-making.	Patients feel listened to. More even power dynamics. There is an increased appreciation of each other’s contribution to their care which inspires trust and corrects misconceptions, and encourages mutual respect and understanding. This may also be met with a feeling from staff as being undermined or threatened	Improved patient satisfaction and service delivery quality Increased patient perception of care as more individualised Increased understanding that staff-patient partnership is needed to achieve better patient care Improved staff-patient relationship Reduced propensity for conflict
3. Allows patients to maintain control	Cultural norm of being a passive recipient of inpatient care, multiple competing	Patients are responsible for their own insulin administration	Helps alleviate the patient’s fear of harm or mismanagement due to perceived lack of	Greater patient satisfaction and maintained skill whilst in hospital,

	priorities of staff, level of trust of healthcare professionals' ability to manage diabetes whilst in hospital		availability or competence of staff. Patients feel more empowered and in control of their diabetes. This can also lead to reluctance of the nurse to share control due to their values or understanding of professional responsibility and identity.	greater percentage of people who feel they can maintain control of their own diabetes management in hospital
4. Reduces insulin errors and improves efficiency	Staff familiarity with insulin therapy or diabetes management and presence of competing tasks for staff	Patients administer insulin themselves instead of nurse	Reduced burden on nursing and medical staff and patents feel reassured that they are receiving the right dose of the right insulin at the right time	More accurate and timely insulin administration. More nursing time released. Reduced insulin errors. Reduced risk of harm to patient as a result of maladministration of insulin
5. Changes attitudes and culture	Staff awareness and appreciation of benefits of self-administration Powerful cultural norm of nurse administration of medication. Perception of change (e.g. as a burden/opportunity)	Staged implementation allows increased observability and attribution of self-administration policy to outcomes by staff	Correcting misconceptions, belief in value and importance of self-administration for patient and staff, fears around safety implications and workload/service provision ameliorated and increased motivation and confidence to challenge norms.	Improved understanding of policy process, impact, Increase in motivations and policy use
6. Alleviates fears and clarifies roles	Staff inertia and fear of repercussions or blame if things go wrong Understanding of organisational and professional regulatory positions	Clarity regarding application of information regarding staff/patient responsibilities, processes and professional/organisational	Staff feel protected, supported, and reassured, leading to an increased confidence and motivation to engage with policy and a sense of reassurance for the patient	Improved service delivery, involvement in policy development and decision-making and work satisfaction Improved staff-patient relationship

	with respect to personal liability surrounding insulin self-administration	regulatory positions/liability and signed disclaimer		Clarity of role
7. Integrates with work processes and systems	Busyness of ward environment perception of burden resulting from intervention	Simple and quick training and assessment process integrated into current workflow and systems	Increased self-assessed ability and confidence to engage with risk assessment and reduced anticipated psychological and physical work burden/effort	More risk assessments completed appropriately
8. Satisfies governance requirements	Compliance with regulatory and governance requirements regarding secure patient-accessible bedside insulin storage	Clarity regarding the interpretation of storage requirements	Altered perception of burden required for change and reduced fear or worry regarding patient safety, blame or reprimand	More timely insulin administration Increased compliance with external regulations
9. Encourages collaborative working	Self-administration policy implementation requires the input and representation of a range of healthcare professionals	Opportunity for collaboration between nursing, medical and pharmacy teams (and patients) in policy development, implementation, and practice Clear definitions of responsibilities / task allocation amongst different professions	Increased appreciation of each other's expertise and skills and reduced perception of extra burden and feeling of shared responsibility Power dynamics can lead to tensions if unresolved issues	Increase team working and collaborative behaviours to innovate and problem-solve
10. Reduces burnout and ensures consistency	Improvement efforts often taken on as additional to day job by motivated individuals	The presence of a dedicated project manager to aid implementation, manage incremental changes and gradual roll-out of policy across organisation.	Reduced burden and burnout felt by motivated individuals and patient reassurance of consistency	Clarity regarding project leadership and management Consistent information given to patient throughout organisation

		Improves capacity to focus on trust-wide engagement of non-diabetes specialist staff.		

Theory 1: Empowers patients and highlights problems

Publications that specifically described the design, implementation or evaluation of insulin self-administration policies in hospital commonly described the intervention as aiming to achieve greater "patient empowerment" (Umesh Dashora et al., 2018; Joint British Diabetes Societies for Inpatient Care Group, 2012; Pearce, 2019; Rowse, 2018a). Patient empowerment is not a well-defined construct but most definitions relate to the process by which patients gain more control over their health by participating in their own care as self-determining agents with self-efficacy (McAllister, Dunn, Payne, Davies, & Todd, 2012; WHO, 2013).

This theory hypothesises that insulin self-administration policies work to empower patients by increasing staff and patients' awareness of the ability to self-administer insulin whilst in hospital. This involves the provision of timely, accessible, consistent and relevant information about insulin self-administration of insulin (to both patients and staff), as well as providing the opportunity for open and honest conversations between patients and healthcare professionals about a patient's individual needs and preferences regarding insulin administration, early on in the patient's hospital admission, and throughout their stay. It is important that patients feel listened to and respected during these conversations, and that they feel able to speak up and be involved in their own care:

> *"We'd had negative feedback about their sense of disempowerment and feeling uninvolved in their own care... In extreme circumstances, some even felt a little bit insulted."* (Pearce, 2019)
>
> *"A lot of people don't know their rights as a patient, like, oh I have to do that, or oh, well I forgot to ask the doctor that . . . a lot of times I find myself explaining that you have the right to refuse too, you have the right to monitor everything that goes into or out of your body . . . To some people that's like a revelation . . . a lot of people aren't used to advocating for themselves"* (Jerofke-Owen & Bull, 2018)
>
> *Patient preferences need to be established on admission to hospital and where appropriate, mechanisms to include patients more effectively and consistently in their own medication management need to be identified and implemented.* (Bucknall et al., 2019)
>
> *Further, nurses described how they empowered patients by surrendering some of their own power to the patients, as they willingly shared information with patients, updating them on plans detailing options.* (Oxelmark, Ulin, Chaboyer, Bucknall, & Ringdal, 2018)

These conversations between patients and healthcare professionals also had the effect of highlighting pre-existing problems with insulin self-administration. This also allows healthcare professionals to have an increased understanding of the individual abilities of the patient and provide appropriate support:

> *"So we get a lot more referrals into our diabetes team…and they're coming and assessing and finding problems and fixing them, that actually need fixing…But that's brilliant because obviously the nurses would have been doing it [administering the insulin] assuming the patient would do it when they go home, and we would never have found the problem until like the day they're walking out of hospital or something else goes on."* (Interview data, Pharmacist 2)
>
> *More significantly, beyond the primary aim of empowering patients, the SAM program had also enabled us to identify the "hidden threat": a significant number of patients who have entered our program could not progress to independent SAM (i.e. SAM 3) during our inpatient assessments, even though they are expected to be responsible for self-administration post-discharge. Many of these patients would not have been picked up, had they not entered into our program and attempted self-administration, thus significantly predisposing them to the risk of medication errors post-discharge, with its myriad of potentially serious sequelae.* (Meng, Chao, & San San, 2020)

This theory proposes that the above mechanisms fire in the context of variable staff awareness of a patient's needs or wishes, or where there is uncertainty regarding hospital policy or procedure regarding self-administration, to result in an increase in awareness and number of willing and able patients self-administering their insulin:

> *"Our project suggests that raising healthcare professionals' awareness of self-administration can greatly increase the proportion of patients who wish to self-administer who are actually able to do so…Many healthcare professionals, particularly doctors, junior nurses and therapists, indicated that they knew very little of the policy and that increasing training and making the key components more accessible would be helpful."* (Garfield et al., 2018)

Box 6.1

Context	**Mechanism (resource)**	**Mechanism (response)**	**Outcome**	**Evidence**
Staff awareness of patient's needs or wishes with respect to insulin self-administration, patient uncertainty regarding hospital processes and policies regarding self-administration	Patient and care team informed about self-administration policies and processes, which prompts a conversation regarding self-administration of insulin on admission	Helps motivated patients feel empowered to communicate their needs, abilities and expectations and be involved in their own care, leading to the care team having greater awareness and understanding of the patient's situation, abilities and wishes	Increased numbers of people (staff and patients) aware of policy, Increased numbers of people self-administering that are willing and able to do so. Patient expectations and potential issues highlighted and managed	(S. H. Ahmed, Chiran, & Chattington, 2013; Bucknall et al., 2019; Umesh Dashora et al., 2018; Garfield et al., 2018; Hendrieckx et al., 2020; Jerofke-Owen & Bull, 2018; Joint British Diabetes Societies for Inpatient Care Group, 2012; Manias, Beanland, Riley, & Baker, 2004; Meng et al., 2020; Oxelmark et al., 2018) Interview 2

These identified mechanisms may also be explained by Kanter's Theory of Structural Empowerment, both for patients and for staff. Kanter proposes that access to information, support and resources are empowering for employees, which in turn, results in individuals that motivate and empower others by sharing the sources of power (Kanter, 1977).

Access to information about the ability to self-administer insulin and what that entails, in the form of timely provision of written and/or verbal information and communication, empowers both patients and staff to act on the information and engage with the policy. Access to support for patients may be achieved by maintaining open communication with staff regarding their abilities, feelings, needs and wishes regarding insulin self-administration throughout their hospital stay. Staff may also give patients access to support by encouraging their autonomy; this may come as a result of greater understanding of their individual circumstances. The conversation that occurs between the healthcare staff and the patient maps well to the construct of informal power, where relationships are built in order to facilitate empowerment; in this instance, the relationship between the patient and healthcare professional (e.g. nurse).

Theory 2: Facilitates shared decision-making

Shared decision-making between patients and healthcare professionals is a hallmark of patient-centred care, and involves the open communication and information-sharing activities described above (Charles, Gafni, & Whelan, 1997; Waldron et al., 2020). Shared decision-making requires a balanced relationship between healthcare professionals and patients whereby information exchange and discussion results in a mutually agreed decision regarding elements of their care, and promotes greater patient involvement. In this respect, shared decision-making as a mechanism is an extension of the empowerment mechanism outlined in the previous theory.

The process of making decisions about insulin use in the acute inpatient setting is traditionally practitioner-led (Griscti, Aston, Warner, Martin-Misener, & McLeod, 2017; Munt & Hutton, 2012). This theory hypothesises that insulin self-administration policies work to improve patient satisfaction and staff-patient relationships by providing the means for greater shared decision-making, which inspires trust, respect and aids mutual understanding:

> *The choice to continue to self-manage during admission, if well enough to do so, should be that of the patient… Whenever possible, the patient should be involved in decisions and, as with all other aspects of their care, should be allowed to make the final decision about self-management* -(Joint British Diabetes Societies for Inpatient Care Group, 2012)

> *Their subjective experiences of being respected, encouraged and enabled (or not) were important influences on their sense of involvement (or otherwise) in treatment decisions* (Entwistle, Prior, Skea, & Francis, 2008)

> *Having a better understanding of the person's perspective facilitates shared decision-making, and will very likely impact the person's motivation to engage with the agreed action plan. This affects the therapeutic relationship, to the satisfaction of both parties.* (Hendrieckx et al., 2020)

For this to work, the policy must provide opportunities for ongoing dialogue and connectedness between patients and the healthcare team, which, like in theory 1, involves the provision of information. Information exchange and dialogue between healthcare professionals and patients should be continuous, and seek to promote mutual understanding, respect and connectivity in the relationship:

> *Other observational data related to power and control were that nurses sometimes limited patients' choices. For example, nurses did not involve patients in decision-making, and when asked about this at interview, most of the evidence related to nurses considering that patients had enough information…Some patients also noticed that they were not involved in decision-making.* (Crispin, Bugge, & Stoddart, 2017)

> *It is crucial to recognise that some degree of responsiveness to and accommodation of patient perspectives is essential if involvement is to be more than 'lip service' and also to see that responsiveness to patients' lifeworlds can - just as with patient education – serve intrinsic and not merely instrumental purposes* (Cribb & Donetto, 2013)

> *It is vital for providers to identify patient preferences regarding engagement early on and educate the patients on the benefits of being active in healthcare decisions. Patients reported that their engagement in health care changed over time based on their situations, highlighting the need for repeated assessments of patient preferences for engagement throughout the continuum of care.* (Jerofke-Owen & Dahlman, 2019)

> *I think this (discussion about self-management of medication) opens more possibilities for improving the connection between the patient and the team, not patient and doctor but patient and care team. - Physician 2* (Vanwesemael, Boussery, Manias, et al., 2018)

A 'space of trust' in which patients and the care team could exchange perspectives openly with one another is needed. This may sometimes present challenges to the ingrown notions of the roles of patients and professionals, which can sometimes serve to hinder the relationship between patients and healthcare professionals (Cribb & Donetto, 2013). This is particularly when the patient is considered to be an 'expert' in the management of their own condition:

> *Both patients and professionals have incentives to fall back upon transitional scripts sometimes, with patients sometimes not wanting to assume responsibility and professionals sometimes being more familiar with 'prescription' (even when it is ineffective), than with the 'messy' and potentially compromising process of negotiation and support.* (Cribb & Donetto, 2013)

> *Nurses found those wanting to have discussion to be a hindrance to their relationship with the expert patient… and their professional confidence and years of experience were questioned and diminished by*

the expert patient's knowledge, further hindering their relationship with the expert patient (Wilson et al., 2006 in Munt & Hutton, 2012).

The contexts relating to these mechanisms relate to the ideological model and culture of healthcare delivery, which has an impact on the value that healthcare professionals place on the contribution of experiential knowledge that people with diabetes can bring to the decision-making process. This, in turn, impacts the extent of the collaborative approach taken with respect to decision-making (Schultz, Maaegaard, Hamid, & Qvist, 2019):

> *The findings under this study revealed that hospitals are still embedded in a patriarchal system, which privileges expert knowledge over patient's wisdom about the management of their condition.* (Griscti et al., 2017)

> *Participants' narratives confirmed the importance that patients attach to practitioners eliciting, listening empathetically to and taking seriously the patient's own view of their symptoms, of how their diabetes affected their life (and not just how their life affected their diabetes) and of their current treatment regime… Third, and most frequently, involvement was associated with practitioners recommending rather than ordering particular treatments, phrasing treatment proposals as suggestions, asking patients for their opinions and in some sense giving them an option.* (Entwistle et al., 2008)

> *Variation among services remained very influential after adjusting for team and patient characteristics, which suggests that "climate" or service culture should be targeted by an intervention, rather than individual attendings or subgroups defined by team or patient characteristics* (Blankenburg et al., 2018)

Box 6.2

Context	**Mechanism (resource)**	**Mechanism (response)**	**Outcome**	**Evidence**
Model of healthcare delivery (e.g. paternalistic, hierarchical) and healthcare professionals' regard for patient's 'lived experience' of diabetes	Patient offered a choice to self-administer and given the opportunity (and permission) to participate in shared decision-making.	Patients feel listened to. More even power dynamics. There is an increased appreciation of each other's contribution to their care which inspires trust and corrects misconceptions, and encourages mutual respect and understanding. This may also be met with a feeling from staff as being undermined or threatened	Improved patient satisfaction and service delivery quality Increased patient perception of care as more individualised Increased understanding that staff-patient partnership is needed to achieve better patient care Improved staff-patient relationship Reduced propensity for conflict	(S. H. Ahmed et al., 2013; Asimakopoulou, Newton, Sinclair, & Scambler, 2012; Baysari, Westbrook, & Day, 2011; Blankenburg et al., 2018; Cribb & Donetto, 2013; Crispin et al., 2017; Umesh Dashora et al., 2018; Entwistle et al., 2008; Griscti et al., 2017; Health Foundation, 2012; Hendrieckx et al., 2020; Hughes et al., 2018; Joint British Diabetes Societies for Inpatient Care Group, 2012; Joseph-Williams, Elwyn, & Edwards, 2014; Köberich, Feuchtinger, & Farin, 2016; Litterbach et al., 2020; Milky & Thomas, 2020; Munt & Hutton, 2012; Ommen, Thuem, Pfaff, & Janssen, 2011; Oxelmark et al., 2018; Pearce, 2019; Scholl, LaRussa, Hahlweg, Kobrin, & Elwyn, 2018; Schultz et al., 2019; Vanwesemael, Boussery, Manias, et al., 2018; Weingart et al., 2011)

This theory may be explained by constructs of both Kanter's Theory of Structural Empowerment (access to support, informal power) and Normalisation Process theory, as there is work to be done, both individually and collectively, to normalise the change in practice required to embed shared decision-making processes into practice. Specifically, coherence, or the sense-making work necessary to implement the intervention, requires a shared and individual understanding of the benefits of the intervention component, that is, the opportunity for shared decision-making. It also requires staff understanding on how the practice of shared decision-making is different, if at all, to current practice.

Theory 3: Allows patients to maintain control

Another mechanism identified in the process of the synthesis that is related to patient empowerment and shared decision-making, is the concept of patient control over elements of their care in the inpatient setting. In an inpatient setting, many activities that would usually be within the patient's control (e.g. washing, eating) are now dependent on the care team or hospital services' schedule. Allowing patients to be responsible to self-administer their insulin allows them to maintain control of this important activity, which is particularly important due to the consequences of not being able to have timely access to their insulin (Johnston & Newland-Jones, 2017):

> *Twenty-one of 25 patients in Group 1 returned the questionnaire of whom 15 patients preferred to self-inject their insulin whilst in hospital, and, of these, the vast majority (13 patients) felt that they had a lack of control over their diabetes while in hospital because they were not allowed to self-inject* (Gangopadhyay et al., 2008)

> *Also, because I have more control. Which they (nurses) give me, because as I have a lot of medication, it causes a lot of difficulties for the nurses, with, what is that now and what is that now. They have trouble understanding it while I know all about it… if I am in charge I know that I have taken them correctly and yes, that gives me peace of mind. - Patient 5* (Vanwesemael, Boussery, Manias, et al., 2018)

> *They [patients] felt that they could be sure that they took the right medication at the right time and felt more in control about their health... the big advantage is that what people could do before, you hand back to them. In fact, this is about independence and autonomy, and respect for that autonomy - Nurse 6* (Vanwesemael, Boussery, Manias, et al., 2018)

By allowing the patient to self-administer, the 'skill' of self-administration is maintained, which may otherwise be lost (Rowse, 2018a). In addition, allowing patients to self-administer facilitates diabetes management in a context where this may not be of immediate or primary importance to the healthcare team (e.g. if the admission is elective or not diabetes-related) and where healthcare professionals' knowledge of diabetes is lacking (Cohen et al 2007 in Munt & Hutton, 2012).

Because at the end of the day, a patient should be self-administering where they can. They've got to go home and do that. And we, you know, we de-skill them, we take that away whilst they're in hospital. (Interview data, P13)

"In my experience and that of some of my colleagues, with select patients, usually type 1's, patient self-management (with physician oversight) yields better glycemic results (and less patient and physician anxiety) than if insulin dosing is left to the vagaries of the busy floor staff…In past years, as surgeons and cardiologists tended to their more immediate tasks, my diabetes was often relegated to a secondary and sometimes seemingly non-existent concern. I was frustrated and angered by substitution of the sliding-scale for my normal insulin regimen, especially as my blood glucose spiralled out of control…(Weiss, 2006)

"In that sense, the patient often knows all his (self-managed) medication better than the nurses or the treating physician, because it often involves something completely different to the disease for which he is being treated" - Hospital pharmacist 1 (Vanwesemael, Boussery, Manias, et al., 2018)

The transference of responsibility and control from the care team to the patient represents a shift in role and potentially professional identity, which may take time to change and be met with resistance, particularly from members of the care team who did not initially train under a patient empowerment participant ideology, with an increased focus on patient autonomy (Schultz et al., 2019).

Box 6.3

Context	**Mechanism (resource)**	**Mechanism (response)**	**Outcome**	**Evidence**
Cultural norm of being a passive recipient of inpatient care, multiple competing priorities of staff, level of trust of healthcare professionals' ability to manage diabetes whilst in hospital	Patients are responsible for their own insulin administration	Helps alleviate the patient's fear of harm or mismanagement due to perceived lack of availability or competence of staff. Patients feel more empowered and in control of their diabetes. This can also lead to reluctance of the nurse to share control due to their values or understanding of professional responsibility and identity.	Greater patient satisfaction and maintained skill whilst in hospital, greater percentage of people who feel they can maintain control of their own diabetes management in hospital	(Alabraba et al., 2014; Booth, n.d.; Gangopadhyay et al., 2008; Houlind et al., 2018; Johnston & Newland-Jones, 2017; Pearce, 2019; Schultz et al., 2019; Vanwesemael, Boussery, Manias, et al., 2018; Vanwesemael, Boussery, van den Bemt, & Dilles, 2018; Weiss, 2006) Interviews (P13,15)

In Kanter's Theory of Structural Empowerment, formal power systems that lead to empowerment are linked to greater feelings of trust and respect between the individual agents (which here would be patients and healthcare professionals). The relationship between the patient and healthcare professional can be viewed as a formal power

structure; where healthcare professionals are empowered, they are more likely to share power with their patients (Spence Laschinger et al., 2010). Furthermore, as per Kanter's theory, where patients are given access to support to self-administer, they are empowered to maintain control of their health.

The mechanism relating to professional roles and identity can be explained by the cognitive participation and collective action constructs of Normalisation Process Theory, namely the process of legitimisation, whereby healthcare professionals need to believe that they should be involved in the intervention (allowing patients to control their insulin administration), and skill set workability, where there is a division of labour that is required to operationalise the work of the intervention (transference of the act of injecting from the nurse to the patient).

Theory 4: Reduces insulin errors and improves efficiency

One of the key drivers for self-administration policies in the inpatient setting are the numbers of avoidable and harmful errors that occur as a result of insulin prescribing and administration errors. Allowing patients to self-administer insulin shifts the work of administering insulin from nurses to patients. This reduces the need to rely on staff who are less familiar with insulin and diabetes treatment, and can safeguard patients against the consequences of insulin errors, such as hypoglycaemia, hyperglycaemia or diabetic ketoacidosis (Johnston, 2019). For patients, this provides reassurance of insulin safety whilst staying in hospital, and is linked to being able to maintain control as outlined in Theory 3:

> *Thorne and Paterson (2001, p. 87) found their participants experienced terror at delegating their T1DM management to health professionals in hospital and therefore suggested the patients need to be their own advocate during hospitalisation to ensure errors aren't made* (Munt & Hutton, 2012)

> *It was thought that 40% of incidents could have been prevented if the patient had been self-administering whereas 12% (6) incidents occurred in patients who were self-injecting…A patient focus group identified some of the concerns patients had when coming to hospital, including not having access to their insulin and doses not being given at the correct time in relation to meals with resulting hypoglycaemia.* (Umesh Dashora et al., 2018)

> *When the insulin was self-administered by the patient, it was appropriately timed in 78% of cases. Though not perfect, this is significantly better than when administered by hospital staff ($p<0.0001$)… Though some self-administration was still inappropriate, many of these instances appeared to be due to factors beyond the patient's control. Aside from patients' failure to bring their own insulin pen, these included waiting for hospital staff to check insulin doses, retrieving insulin from the fridge, and the food trolley arriving without warning.* (Gangopadhyay et al., 2008)

> *"If you look at your many numbers of administration errors by being given the wrong insulin, or the wrong dose, or been using the wrong needle, for example, whichever it is. If your patient is able to manage their own insulin at home usually, there's no reason for them not to then in hospital, then I guarantee I'm quite sure that that number of administration errors will come down, if they're self-administering themselves.- P14*

And actually, when the prescription, when we've had incidents where the prescription has been wrong, fortunately, on most of those occasions, the prescription was wrong, but the patient carried on with their correct insulin. There was no harm to the patient for that very reason. – P3

Patients also suggested that self-administration would result in an increased compliance after their discharge (68%) and it would even increase their own safety while in hospital (65.4%). A smaller percentage of the patients indicated that, self-administration would make them more satisfied about their hospital stay (62.4%). Over half of the patients were convinced self-administration would lead to patients taking their medication more correctly compared with administration of medication by nurses (56.7%). (Vanwesemael, Boussery, van den Bemt, et al., 2018)

By allowing patients to administer their own insulin, nursing time is also released, which provides benefits for workload and efficiency. One observational study showed that an average of 12 minutes of nursing time per patient per hospitalisation was saved with self-administration compared to nurse administration (Houlind et al., 2018):

"Once the new process was implemented they were happy with electronic documentation at each drug round and bedside storage of the insulin as it reduced the time they had to spend walking around the ward, releasing their time to care…The early outcomes are timely insulin injections; safer, happier patients; and nurses' time released to care." - (Rowse, 2018a)

It takes a long time to administer drugs and I can see the interruptions on the ward during the drug administration period…People get called away to handle something that's cropped up in the middle of it, and they have to leave…If you were given control of the thing, the problem…of mistakes would be small. (P3) (Manias et al., 2004)

Box 6.4

Context	**Mechanism (resource)**	**Mechanism (response)**	**Outcome**	**Evidence**
Staff familiarity with insulin therapy or diabetes management and presence of competing tasks for staff	Patients administer insulin themselves instead of nurse	Reduced burden on nursing and medical staff and patents feel reassured that they are receiving the right dose of the right insulin at the right time	More accurate and timely insulin administration. More nursing time released. Reduced insulin errors. Reduced risk of harm to patient as a result of maladministration of insulin	(Umesh Dashora et al., 2018; Gangopadhyay et al., 2008; Houlind et al., 2018; Johnston, 2019; Joint British Diabetes Societies for Inpatient Care Group, 2012; Manias et al., 2004; Munt & Hutton, 2012; Pearce, 2019; Rowse, 2018a; Schultz et al., 2019; Vanwesemael, Boussery, Manias, et al., 2018; Vanwesemael, Boussery, van den Bemt, et al., 2018; Weingart et al., 2011) Interviews (P1, 11, 14, 3, 9)

Skill set workability as a quality of collective action in Normalisation Process Theory describes the distribution and conduct of work that distributes a practice in a division of labour (May et al., 2009). Insulin self-administration

policies affect the ways that the work of injecting insulin is allocated, and the way skills are defined. For patients injecting insulin appropriately prior to admission, the task of self-injecting whilst in hospital may be more appropriate for their skills than for some staff (providing no clinical deterioration impacting this skill is present).

Theory 5: Changes culture and beliefs

The shift in practice away from traditional nurse administration and control of medicines in hospital described above is not a straightforward or insignificant one. Such a change to job responsibilities and roles requires a change in the wider culture surrounding administration of medicines in the hospital setting. The culture of a ward environment has been described in the form of values, beliefs and norms which influence the behaviour of people as members of an organisation. This is also linked to how a team is managed (Schneider & Barbera, 2014)**.** The pervading culture on many ward teams is that of nurse control of the medication administration process, which has assumptions about medication safety and 'right practices' underpinning them:

> *There is what Watson (2006, p. 935) describes as a 'ritual confiscation' of medication, where the nursing staff remove an individual's medication and store it in a locked medicine cupboard or trolley...Risk adverse practices prevail, with severe reluctance to relinquish control to the patient in areas such as medicines management. Fears for the maintenance of personal safety within the assessment unit continue to be the factors that perpetuate the lack of patient autonomy, decision-making or self-determination* (A. Murray, 2011)

This theory suggests that insulin self-administration policies work to challenge this culture (and underlying assumptions), and indeed, this shift in culture is needed in order for them to work on many ward settings:

> *And I think in the past, the sort of de facto position was, we look after everything for you. Whereas, we nearly need to flip that. We really need to say that we expect you to be giving your own insulin unless you can't, providing you do it at home and providing it's safe to do so… the traditional feeling or sort of understanding that we look after patients in hospital. You know, if you're a nurse you'll be giving their insulin because you're giving them their medicine and insulin is a medicine. (*Interview data P8)

> *The theory-based construct most frequently associated with intention was subjective norm…This conclusion is consistent with a recent study that showed that intention to engage in SDM behaviours is most effectively changed by implementations that target subjective norm and perceived behavioural control.* (Thompson-Leduc, Clayman, Turcotte, & Légaré, 2015)

This change in culture also needs to be supported by leaders that impact culture, including professional and regulatory bodies and senior leaders, to provide reassurance to staff and facilitate change (Johnston, 2019; Pearce, 2019; Rowse, 2018a; Wessex Academic Health Science Network, 2017).

The beliefs and practice norms of staff that contribute to ward culture are important elements that are hypothesised to impact how the intervention works. In a context where staff are sceptical or wary of the change and implications of insulin self-administration (e.g. on workload or patient safety), it is important that concerns are addressed and promptly resolved, and the intervention is appraised (e.g. with outcome data). This will help to ensure sustainability and buy-in from the many staff members across the organisation required for success (Pearce, 2019; Rowse, 2018a).

> *And I think that's, that's probably a challenge for, you know, a busy ward. When the nurses are thinking, "oh, god, and I'm going to have to take that patient off self-administration", or "I have to try and put them on it". And sometimes maybe they just think you know what, it's just easier to just do it all yourself.* (Interview data P16)
>
> *There was also a perceivable, but not quantified, ambivalence among the staff on this policy. A major limitation quoted as a hindrance to the execution of the policy was time constraint, as risk assessment for self-administration in the acute setting can be time consuming. It must also be reviewed regularly as the clinical condition of any patient can change over time.* (S. H. Ahmed et al., 2013)
> *Teams that routinely monitored new SDM practices could demonstrate impact, which increased motivation for sustained implementation.* (A. Lloyd, Joseph-Williams, Edwards, Rix, & Elwyn, 2013)
>
> *The main challenge was overcoming the preconceptions of the governance teams about the potential risk of a patient or visitor misappropriating insulin and causing harm to themself or another patient. This was overcome by analysing the incident reporting system and communication with the national medicines safety officers. The confirmation that their concerns had not been a reality appeased this misconception.* – (Sallianne Kavanagh et al., 2016)

Box 6.5

Context	**Mechanism (resource)**	**Mechanism (response)**	**Outcome**	**Evidence**
Staff awareness and appreciation of benefits of self-administration Powerful cultural norm of nurse administration of medication. Perception of change (e.g. as a burden/opportunity)	Staged implementation allows increased observability and attribution of self-administration policy to outcomes by staff	Correcting misconceptions, belief in value and importance of self-administration for patient and staff, fears around safety implications and workload/service provision ameliorated and increased motivation and confidence to challenge norms.	Improved understanding of policy process, impact, Increase in motivations and policy use	(S. H. Ahmed et al., 2013; Garfield et al., 2018; Sallianne Kavanagh et al., 2016; A. Lloyd et al., 2013; Munt & Hutton, 2012; Pearce, 2019; Sorensen, Olesen, Lisby, Enemark, & De Thurah, 2020; Thompson-Leduc et al., 2015)

This theory can be further understood with Normalisation Process Theory, which proposes that *"the production and reproduction of a practice requires that actors collectively invest effort in its understanding."* This involves formal and informal appraisal and evaluative work (both collectively and individually), known as reflexive monitoring, that is required for an intervention to be embedded in practice. This may also result in

reconfiguration, whereby ideas about the use and utility of the policy are modified in a way that promotes further coherence and meaningfulness of the practice associated with the intervention. The active involvement of staff and the importance of receiving and acting on feedback (which may result in iterations of the policy) are therefore important elements for the success of insulin self-administration policies.

Theory 6: Alleviates fears and clarifies roles

Following on from the contexts and mechanisms exposed in Theory 5, it is also hypothesised that successful implementation of insulin self-administration polices relies on staff feeling supported and being empowered by being given information about individual responsibilities, accountability and repercussions for specific situations relating to insulin self-administration (Johnston & Newland-Jones, 2017; Rowse, 2018a; Vanwesemael, Boussery, Manias, et al., 2018). The actions required to alleviate any fears associated with the change in practice required (e.g. information giving and appropriate documentation/processes to support staff) are thought to result in staff clarity around how to apply the policy, and subsequent reassurance and confidence, which impacts the outcomes that the policy can have:

> *Following the training, the staff in the diabetes and endocrinology ward felt confident to take on the role of assessing the patients' ability to administer their insulin.* (Alabraba et al., 2014)

> *"And yes, sort of staff worry, staff resistance is one of the main ones. 'Cause I know I've had a look at various patients and stuff. And I know staff can worry if the patient takes the wrong dosage they'll be held responsible for it and all of that. So yeah, I think we need to make sure that within the policy we think of doing the capacity assessments daily and actually if something goes wrong staff will be supported about it."* (Interview data, P5)

> *A much-debated obstacle during the interviews, and one about which all healthcare providers were unanimous about, was the absence of a clearly defined legal context in which responsibilities were determined* (Vanwesemael, Boussery, Manias, et al., 2018)

> *The other barrier that has been faced was concern from nurses about 'what if the patient gives the wrong dose', this is covered in the policy which details the action to be taken, and states that the responsibility does not lie with the nurse if the correct procedures for ensuring competence had been followed.* – Rowan Hillson Insulin Safety Award

> *Information for nurses about accountability and what their regulatory body says is vital in changing the beliefs of nurses that they can't support patients to self-administer, as is endorsement from matrons and chief nurses. Commonly, nurses believe they will be disciplined if a patient makes a mistake under their care…nursing teams were made aware of the Nursing and Midwifery Council (NMC) Standards for Medicines Management and their responsibilities… as lead for both quality and patient experience, she was able to support the change of thinking on the wards and provide access to senior nursing forums to ensure everyone was aware of the change and correct information* - (Rowse, 2018a)

Box 6.6

Context	Mechanism (resource)	Mechanism (response)	Outcome	Evidence
Staff inertia and fear of repercussions or blame if things go wrong. Understanding of organisational and professional regulatory positions with respect to personal liability surrounding insulin self-administration.	Clarity regarding application of information regarding staff/patient responsibilities, processes and professional/organisational regulatory positions/liability and signed disclaimer.	Staff feel protected, supported, and reassured, leading to an increased confidence and motivation to engage with policy and a sense of reassurance for the patient.	Improved service delivery, involvement in policy development and decision-making and work satisfaction. Improved staff-patient relationship. Clarity of role.	(Alabraba et al., 2014; Johnston & Newland-Jones, 2017; Pearce, 2019; Rowse, 2018a; Vanwesemael et al., 2020; Vanwesemael, Boussery, Manias, et al., 2018) Rowan Hillson Insulin safety award 2016 Interviews p10, 16, 5 8

In the same way that Kanter's theory helps to further explain the patient empowerment mechanisms in Theory 1, here we see that the idea of access to information regarding application of the policy, support to encourage autonomy and provide protection (if things do go wrong), and resources (e.g. signed disclaimer) through formal power structures can help empower nurses to use the policy. In Normalisation process theory, cognitive participation is the relational work required to sustain a community of practice around the intervention, and involves legitimation, whereby staff 'buy in' to the practice in relation to institutionally shared beliefs (e.g. about repercussions of the policy and its propriety). This leads to activation, whereby the materials and means are brought forth to effectively operationalise the policy in a clinical setting – here this would involve any documentation and support structures for staff to feel reassured and able to use the policy.

Theory 7: Integrates with work processes and systems

An important mechanism identified in the theory building and refinement process was relating to perceived ability, confidence and effort required to undertake the risk assessment component of the self-administration policy. This was particularly pertinent in the context of a busy ward environment, where any tasks that are allocated on top of existing workloads may be perceived as burdensome.

The process whereby staff assess the individual risk and appropriateness (sometimes termed competence) of a patient to undertake insulin self-administration is an extra task in many settings, and therefore requires careful consideration with respect to how it should be integrated into existing processes and systems.

Where changes are made to existing processes, that require documentation and 'extra steps' to processes, these should be made in such a way that causes the least disruption to existing processes, and integrates with current systems as much as possible (Garfield et al., 2018; Rowse, 2018a):

> *We suspect that if the assessment could be better integrated into current electronic prescribing workflow in a more user friendly way, completion may increase and we are working on this within our organisation. Healthcare professionals were of the view that they did not have the time for an additional process but that most of the information required would be gathered as part of their current workflow and that it was a question of prompting them at the correct times to consider self-administration. Ideally, an automated process could be created where the electronic system draws together information from different records and identifies patients who may be suitable for self-administration.* (Garfield et al., 2018)

> *So whereas obviously I've got a lot of paperwork. There's a consent form. There's an assessment form, an information form, leaflet form for the patient. And all the other documentation, I was thinking, you know, if you can put some of that on, on the EPMA system. That could be you know, quite helpful –* (Interview data, P13)

> *But what happened is that the chart didn't look any different. It was always there to be used but we just force anyone to use it. And what we did is put the assessment, we followed the JBDS guidelines exactly which was we assumed competence, and then temporary exclusion and definite exclusion. So we put the words exactly as they appeared on JBDS at the bottom of our chart and then a signature at the bottom that said "is the person self-admining?" get them to sign it, get you to sign it, job done. Because it's obviously a hospital chart its part of patient record so it goes in their record so it meant that nothing else had to be written in the notes and it was all great.* (Interview data, P2)

Risk assessments should be accessible and easily retrievable (Garfield et al., 2018) and simple and quick enough that any appropriate staff member can complete them (e.g. RGN, pharmacist, pharmacy technician). Risk assessment processes should be designed in such a way that they prioritise safety over the need to evidence perfection in a patient's injection technique (Johnston, 2019; Pearce, 2019):

> *Previous policies on self-administering medications were rigid, with patients needing to prove they knew what they were taking, and nurses observing them counting out doses. 'My feeling, as a patient and a professional, was that it was never done, because it made everyone's lives so miserable and was far too complicated,' she says. 'Here the question is: are you competent or are you not?' – Pearce 2019*

Box 7.7

Context	**Mechanism (resource)**	**Mechanism (response)**	**Outcome**	**Evidence**
Busyness of ward environment perception of burden resulting from intervention	Simple and quick training and assessment process integrated into current workflow and systems	Increased self-assessed ability and confidence to engage with risk assessment and reduced anticipated psychological and physical work burden/effort	More risk assessments completed appropriately	(S. H. Ahmed et al., 2013; Umesh Dashora et al., 2018; Garfield et al., 2018; Johnston, 2019; Pearce, 2019; Rowse, 2018a; Vanwesemael et al., 2020; Vanwesemael, Boussery, Manias, et al., 2018; Walsh & Swain, 2011) Interviews P13, 2, 7

Normalisation Process Theory helps us to understand the above theory with its concept of collective action, which addresses how the intervention affects the work of healthcare professionals, division of labour, resources and responsibilities, and how compatible it is with existing work practices. Work is required to define and operationalise a practice, which may involve reshaping behaviours or actions and employing objects, which in this case would involve the additional practice of conducting a risk assessment and documenting this in the medical notes. Integrating and streamlining these actions as much as possible within existing structures aids the activation of this practice to help operationalise it in the clinical setting.

Theory 8: Satisfies governance requirements

Similar to the mechanisms involving perception of burden and reprimand presented above, this theory exposes how the policy works in relation to insulin storage requirement adherence in order to alleviate fears of breaching regulatory standards.

Typically, insulin needs to be locked away in a safe, secure locker, either by the patient's bedside or on a ward medication storage unit. Although this seeks to ensure patient safety in one respect, it can lead to problems with insulin accessibility for patients, who must rely on nurses being available to retrieve their insulin to receive a timely dose. This can disrupt the correct administration schedule in relation to meals and may result in hypo/hyperglycaemia (thereby risking safety). The perceived effort and cost needed to solve this problem by providing secure but accessible storage is commonly reported as a barrier to insulin self-administration:

> *And the other side of it, we're never quite sure what the CQC would make of it because their stance is, everything needs to be secured and locked away… So practically, I'm not sure that the technology for self-administration is that good. If the CQC have a patient with their insulin sitting on the side, they won't like it. So you then have to go down a locker for the insulin. If you do that, you might as well do it for the rest of the medicines. And you can't do it for the locker because it's the sort of technical issues in getting specific patient access to their medicine locker… And getting all of the CQC inspectors signed up for that as a collective as well rather than just an individual going "Oh, that's fine." And another one going "No, I don't like that."* (Interview data, P9).

Self-administration policies that apply clear and consistent information from external regulators (such as the Care Quality Commission) regarding workable, suitable, safe and affordable bedside storage solutions are therefore needed in order to alleviate fears from staff regarding the misappropriation of insulin on the ward and the need to satisfy regulatory requirements (Garfield et al., 2018; Johnston, 2019; Johnston & Newland-Jones, 2017; Joint British Diabetes Societies for Inpatient Care Group, 2012; Rowse, 2018a):

So [pharmacist A] did all the work with the CQC to prove you didn't have to lock insulin away so I took that part of it and [pharmacist B] did the risk assessment that the CQC asked for so I took her one and then just [trust A]'d it, submitted it to our medicines governance and they were happy to agree to it not being locked away because we had approval from the CQC so they were happy with that. – P2

The CQC supports SAFE patient self care. We asked the pharmacy advisor who said: Key is being able to demonstrate that the organisation has identified the risks and put in place systems to mitigate the risks whilst promoting independence and better care. Where it is being done well we have seen clear risk assessments, policies, SOPs, care plans, and there is secure patient access storage. - (Wessex Academic Health Science Network, 2017)

Box 7.8

Context	**Mechanism (resource)**	**Mechanism (response)**	**Outcome**	**Evidence**
Compliance with regulatory and governance requirements regarding secure patient-accessible bedside insulin storage.	Clarity regarding the interpretation of storage requirements.	Altered perception of burden required for change and reduced fear or worry regarding patient safety, blame, or reprimand.	More timely insulin administration. Increased compliance with external regulations.	(Garfield et al., 2018; Johnston, 2019; Johnston & Newland-Jones, 2017; Joint British Diabetes Societies for Inpatient Care Group, 2012; Rowse, 2018a; Wessex Academic Health Science Network, 2017) Interviews – P12, 14, 16, 2 Rowan Hillson Insulin Safety Award

Here, the theory of structural empowerment helps to explain how organisations more generally may be empowered by the provision of information and resources needed to apply the regulatory and governance requirements to the context of insulin self-administration in a hospital setting. Clear, consistent information from the CQC that is disseminated and appropriately interpreted and applied in inpatient settings can empower teams who would otherwise regard insulin self-administration to be incompatible with insulin storage requirements. Similarly, readily accessible storage (resources) for insulin for patients can empower teams to implement the policy. As has been shown from the literature, this may be cost-effective, with creative and inexpensive solutions being shown to satisfy regulatory requirements (Umesh Dashora et al., 2018; Johnston, 2019).

Theory 9: Encourages collaborative working

Insulin self-administration policy implementation requires multidisciplinary input in order to work. An understanding of project management, insulin governance, nursing work and diabetes is required for the policy to be coherent, and as such, it promotes collaborative working between nursing, pharmacy and medical professionals:

> *And that's what we found, so we were really surprised, we did a lot of teaching on the patient self-admin at one point. And we kind of just assumed, you know, took it for granted that they do these kind of capacity assessments all the time. And they basically, they turned round and said "No, we never do them. The OTs do them occasionally, physios sometimes, the medics do them, but we don't". And we went "Oh."* - (interview data, P9)

By providing the opportunity for collaborative working, it is hypothesised that an increase of role appreciation, innovation and collegiality will follow:

> *Collaboration between pharmacy and nursing in the management of this project enabled innovative thinking.* (Rowse, 2018a)
> *'We have shared goals and passion and that's important…But we come at it from different angles. As a project, it means it's more holistic because we're doing different aspects – and it usually means we've covered everything between us.'* (Pearce, 2019)

Where individual responsibilities amongst a multidisciplinary team are indicated in the policy, it will reduce burden on a single professional group (Johnston, 2019; Rowse, 2018a):

> *Our findings suggested that rather than self-administration assessment being solely nurses' responsibility, it should be multi-disciplinary. The majority of healthcare professionals interviewed were of the view that their profession could contribute to advising on patients' suitability for Increasing self-administration but few were comfortable with their profession taking sole responsibility* (Garfield et al., 2018)

Box 6.9

Context	**Mechanism (resource)**	**Mechanism (response)**	**Outcome**	**Evidence**
Self-administration policy implementation requires the input and representation of a range of healthcare professionals.	Opportunity for collaboration between nursing, medical and pharmacy teams (and patients) in policy development, implementation, and practice. Clear definitions of responsibilities / task allocation amongst different professions.	Increased appreciation of each other's expertise and skills and reduced perception of extra burden and feeling of shared responsibility. Power dynamics can lead to tensions if unresolved issues.	Increase team working and collaborative behaviours to innovate and problem-solve.	(Garfield et al., 2018; Johnston & Newland-Jones, 2017; Pearce, 2019; Vanwesemael, Boussery, Manias, et al., 2018) Interview - P9

Both Kanter's theory and Normalisation Process Theory help explain the above programme theories. In Kanter's Theory of Structural Empowerment, informal power is derived from alliances or relationships with people at different levels in the organisation (e.g. interdisciplinary networking and collegiality), which enable staff to get the required co-operation to achieve their goal (which here would be the successful use of the policy). The collective

action construct of NPT also explains how relational integration is required for successful intervention implementation. Here, a practice affects the ways that people understand the actions of others around them, which in this case, explains how the work that people do to build accountability and maintain confidence in each other leads to a greater appreciation of each other's roles as they relate to the practice of insulin self-administration. This may however, conversely result in loss of confidence in each other, particularly where there are uneven interprofessional power dynamics and unresolved problems in workload allocation, which has been reflected in the above theory.

Theory 10: Reduces burnout and ensures consistency

Following on from Theory 9 which exposes mechanisms around multidisciplinary interactions, this theory hypothesises that the allocation of a project leader, who has protected time to dedicate to policy design and implementation, will further reduce the perception of burden on individuals and burnout experienced by the individuals driving the policy implementation on top of their regular clinical duties.

The complexity and scale of implementing the policy consistently across large organisations requires engagement of leaders and staff at various levels. This is, however, unlikely to be achieved without dedicated time. There is a risk of burnout individuals are attempting to achieve organisation-wide change in addition to usual job tasks (Garfield et al., 2018; Rowse, 2018a):

> *Initially, we thought we could do it within our team, alongside our day jobs. But it quickly became apparent that it would take dedicated time to achieve. I was seconded to work on the project three days a week, funded by pharmacy. It took 18-24 months to implement at our trust and we are rolling it out to the remaining final areas.* (Johnston, 2019)

> *And sometimes it's a bit like, even in our own work, sometimes other things take priority and some days you might be focused on thinking, "actually, I'm going to try and get the patients on this ward, anybody who can, to self-administer and we'll try and adopt that for this week". You know, that will be this week.'. But then other things get in the way.* (Interview data, P16)

The presence of a dedicated project manager to lead the project can also help ensure that the policy is implemented consistently and successfully across the organisation and that issues are highlighted and resolved (Sorensen et al., 2020; Wessex Academic Health Science Network, 2017):

> *The lack of progress made initially with the diabetes team trying to fit the project in with their day job made us decide that a dedicated project manager with time, the right skills and connections/relationships in the trust was vital to the success of the project… Implementation of self-administration of insulin is complex and requires dedicated project management and trust wide engagement* (Rowse, 2018a)

Box 6.10

Context	Mechanism (resource)	Mechanism (response)	Outcome	Evidence
Improvement efforts often taken on as additional to day job by motivated individuals	The presence of a dedicated project manager to aid implementation, manage incremental changes and gradual roll-out of policy across organisation Improves capacity to focus on trust-wide engagement of non-diabetes specialist staff	Reduced burden and burnout felt by motivated individuals and patient reassurance of consistency	Clarity regarding project leadership and management Consistent information given to patient throughout organisation	(Garfield et al., 2018; Jerofke-Owen & Bull, 2018; J. K. Johnson et al., 2012; Rowse, 2018a; Sorensen et al., 2020; Wessex Academic Health Science Network, 2017) Interview – P16

This theory may be further explained by the NPT construct of cognitive participation, specifically the initiation component, where key participants are working to drive the new set of practices forward. Commonly, implementation strategies (e.g. communication, education) are curtailed by time and resource constraints, and the impact of this is emphasised in the absence of a project leader.

6.9 Discussion

The aim of the realist synthesis was to generate evidence-informed theory that explains how insulin self-administration interventions works, for whom, and in what circumstances. This was achieved by an analytic process that involved iterative testing and refinement of theoretically based explanations using empirical findings in data obtained from literature (G. Wong, Greenhalgh, et al., 2013). Contexts, mechanisms, and outcomes pertaining to intervention use were configured in explanatory sequences (CMOCs) to produce realist programme theories.

Theory development, which involved amending wording, reviewing the proposed relationships between contexts and mechanisms, and how the evidence supports this, was discussed with stakeholders and with the research team throughout the synthesis. This was an iterative process that was not always straightforward, particularly where concepts were inter-related in the literature and were not clearly discrete. Designations of concepts between theories were therefore made according to how best to describe what the policy does with respect to the responses described. A wider set of studies were drawn on to comprehensively explain the professional, socio-

cultural, and organisational dynamics in which inpatient insulin self-administration policy intervention use by healthcare professionals is situated.

Findings confirm that insulin self-administration policy interventions are complex and socially contingent, with their success depending on many personal, socio-cultural, organisational, and technical factors. For example, key contextual factors included staff awareness and appreciation of diabetes and the importance of shared decision-making, cultural norms of the organisation (e.g. nurse administration and control of medicines), staff familiarity with insulin therapy, and the presence of motivated individuals to oversee and lead policy implementation. These contexts, amongst others, were thought to lead to outcomes that included patient satisfaction, increased self-management and collaborative behaviours, reduced insulin errors and consequential harm to patients and increased consistency of information given to patients.

These outcomes consider a wider variety of measures compared to previously published studies, which tend to focus on more easily quantifiable outcomes such as percentage of documents completed or patients self-administering insulin (Alabraba et al., 2014; Johnston & Newland-Jones, 2017; S. Kavanagh & Boparai, 2015). Findings encourage the consideration of these wider outcome measures in future studies seeking to examine the impact and effectiveness of insulin self-administration policies in the hospital setting.

Of particular interest is the mechanisms that were identified during the course of the realist synthesis, which gives contextually sensitive explanatory power to how insulin self-administration policy interventions work. These included how particular resources offered by the policies facilitate patient empowerment, shared decision-making, mutual respect and understanding, alleviation of fear, confidence and motivation and altered perception of burden required for change.

These results both echo and extend the findings from the qualitative study in **Chapter 5** regarding self-administration. For example, the qualitative study results indicated that insulin errors would be reduced by the implementation of self-administration policies. The findings of the synthesis enable this to be supported with other evidence and explain that this is achieved by reducing the burden on nursing staff and increasing patient reassurance. The description of self-administration interventions being empowering in the qualitative study was also explained further with the realist synthesis findings; policies inform patients and prompt them to communicate their abilities, needs and expectations with staff, and staff gain awareness and understanding of the patient's situation as a result. Also, the paternalistic perspective described by interview participants was delineated further in the synthesis to expose related mechanisms including patients feeling listened to, power differentials, appreciation, respect and understanding and correcting misconceptions.

The use of a combination of Normalisation Process Theory (NPT) and Kanter's theory of structural empowerment was useful in helping to further explain the programme theories generated in the realist synthesis. All four constructs of NPT were identified in the analysis of the 10 CMOCs. Taken together, the 10 CMOCs demonstrated that self-administration polices focus more on the constructs of collective action and cognitive participation than

coherence and reflexive monitoring. This means that when operationalised in complex interventions such as hospital environments, insulin self-administration policies need to lead to normative and relational restructuring, and the legitimation of new working practices through experience.

All but one construct of Kanter's theory was identified in being able to help interpret the results of the synthesis. The construct of 'access to opportunities to learn' was not identified as one that had relevance for helping to explain how insulin self-administration policies worked in the inpatient setting. It may be presumed, however, that to empower people with diabetes to self-administer their insulin on initiation of therapy, access to opportunities to learn and grow in skills such as injection technique and self-management of diabetes more generally should be offered (e.g. by the diabetes nurse specialist in the community). Arguably this may not be so relevant for acute inpatient settings that this theory pertains to. Similarly, providing opportunities for staff to access training on self-administration and inpatient diabetes care, and giving them new challenges (e.g. acting as a diabetes link nurse between the ward and the specialist diabetes team), would also help empower them through formal power structures. This theory focuses on policy implementation, which although requires staff training (on use of the policy), did not quite fit as an empowerment construct for staff in and of itself.

The findings of the realist synthesis highlight important circumstances that impact on the success of policy use in organisations. These include the extent to which patients are (and feel) listened to, shared decision-making is practiced, and the powerful cultural norms of nurse control and expected passivity of inpatients. Findings also suggest that when staff feel adequately informed, protected, and supported regarding self-administration, these are more likely to result in successful use of the policy. This also links to the absence of a blame culture, which remains a wider problem in the NHS despite efforts to promote a more 'just' culture (Stretton, 2020). Considering these complex and multiple factors that contribute to the success of policy interventions, it is likely that a combination of multifaceted intrinsic (bottom-up) and extrinsic (top-down) solutions would be required to support implementation across NHS hospitals.

As realist synthesis places primary emphasis on actionable findings that can lead to context-sensitive change, a number of high-level principals that can be tailored to different environments to suit different needs are outlined:

- All hospitals should devise policies that facilitate the self-administration of insulin for people with diabetes staying in hospital. This requires multidisciplinary collaboration between nurses, pharmacists, doctors, and patients.
- All staff should be aware of the policy and know how to access the relevant information and documentation. Staff should inform people who use insulin about self-administration on admission to hospital (or before, in the case of elective admissions).
- Healthcare staff (e.g. nurses, pharmacists) caring for patients using insulin should listen to the patients to help understand their individual needs, expectations and abilities regarding insulin administration.

- Healthcare staff should offer patients a fully informed choice to self-administer their insulin and participate in shared decision-making.
- Healthcare staff should be educated (e.g. by diabetes teams) regarding the importance of timely insulin administration and the benefits of allowing patients to control their own insulin administration. Outcomes of policy implementation should be shared with staff and any questions/concerns should be addressed.
- Healthcare staff should be given clear and consistent information regarding their responsibilities and positions from their regulatory/professional bodies regarding insulin administration, storage, and associated regulations.
- Healthcare staff should feel supported and protected by senior leadership teams with respect to facilitating self-administration. Completion of associated documentation (e.g. risk assessments, disclaimers) should be accessible, simple and integrated into normal workflows.
- A dedicated project manager should be appointed to oversee the design and implementation of the policy across the whole organisation.

Overall, the use of realist synthesis was appropriate to uncover the underlying mechanisms that cause the intervention to work in different ways in different settings. This enabled a rich description of how the self-administration policies work, for whom and in what circumstances.

6.10 Summary

Insulin self-administration policies to promote insulin safety in the inpatient setting are a complex intervention that requires careful implementation to successfully achieve their intended outcomes. Existing literature on insulin self-administration policy interventions in the UK hospital setting is limited to short audit reports or implementation commentaries. Although these are useful to understand elements of policy implementation in given settings, a theory-driven approach to uncover generative mechanisms that can lead to intervention success was needed given the timeliness and importance of this intervention. This realist synthesis exposes the underlying logic behind self-administration policy interventions, as well as identifying the mechanisms by which these interventions result in their intended outcomes. The important contexts that determine whether or not the identified mechanisms produce either positive or negative outcomes were also identified, and as such, the circumstances where insulin self-administration policies are likely to be effective are explained.

These contexts, mechanisms and outcomes were configured to produce programme theories that were refined with a combination of expert, professional and content knowledge, stakeholder input, re-examination of

qualitative interview data and a series of iterative literature searches. The analysis of the theories was aided with the use of existing, substantive middle-range theories as conceptual frameworks.

The function of insulin self-administration policies in the hospital setting was found to include patient empowerment, diagnosis of existing/potential administration problems, shared decision-making, patient autonomy and independence, as well as insulin error reduction. It was found that consideration of the necessary governance issues was essential, as was a significant shift in organisational culture and perception of the staff-patient relationship. Certain features of intervention implementation and change management, such as the designation of a dedicated project lead and the collaboration of professionals, as well as work to clarify roles and alleviate staff fears, were also highlighted as important elements of making insulin self-administration successful.

The next chapter discusses quality of the realist synthesis along with the quality of the overall research programme. The extent to which the overarching aims and objectives of the research were met with the methods employed is also discussed. This is along with suggestions for further work and implications for policy and practice.

Chapter 7: General Discussion

This chapter discusses the overall research programme in terms of its outcomes, process, quality, and implications for policy and practice, and is presented according to the stated objectives and research questions presented in **Chapter 1**. The discussion presented here complements the discussions presented in each chapter on how the key findings relate to the literature and triangulate each other. Sections include:

- Discussion of the outcomes of the research
- Discussion of stakeholder groups at each stage of the project
- Strengths, limitations, and quality assessment
- Implications for practice
- Future research
- Impact of the research on the researcher

7.1 Discussion of study outcomes

The overall aim of this thesis was to investigate the current use of interventions designed to prevent insulin prescription errors in UK hospitals. This research fulfilled this aim by describing the current use of interventions in hospitals across the UK, determining the perceived effectiveness of those interventions on reducing insulin prescribing errors and exploring the opinions and insights of hospital pharmacists involved in the design, implementation and/or evaluation of these interventions in practice. The identification of insulin self-administration policy interventions as a particularly complex and salient intervention to explore further – both through reflection on the results of the mixed methods study discussions with the PPI stakeholder groups – led to the generation of evidence-informed testable theory of how this intervention works to achieve various outcomes in different contexts.

Summary of key findings

The systematic review identified the published interventions used to improve insulin prescribing in the inpatient setting, both in the UK and further afield. The mixed methods study allowed quantification of issues relating to the use of interventions to improve inpatient insulin prescribing practice followed by in-depth exploration of key issues with the survey participants. The cross-sectional survey stage identified that most insulin is prescribed for inpatients with diabetes using paper charts, or a combination of paper and electronic prescribing systems in hospital, with important safety implications. Only 30% of respondents considered the insulin passport to be effective at improving insulin prescribing safety, whereas around 80% respondents considered guidelines and self-

administration policies to be effective. The highest scoring interventions in terms of perceived efficacy were outreach team review and mandatory insulin safety education for clinical staff. The only organisational characteristic that was associated with increased number of interventions used was the presence of a specialist diabetes pharmacist at the trust.

On exploring the use and perceived effectiveness of interventions with survey respondents during qualitative interviews, key themes were identified that included: insulin prescribing safety being an important but 'wicked' problem, fear and complexity of the prescribing process, the battle to educate staff on insulin safety, the need to broaden responsibility for insulin prescribing safety, the difficulty of evaluating interventions, the need to find a balance between prescribing system control and flexibility and insulin self-administration in the inpatient setting being a problem worth solving.

The realist synthesis exposed the explanatory mechanisms of insulin self-administration interventions further, and presented evidence-informed theory about how the intervention leads to outcomes in different contexts. The theories addressed how insulin self-administration policies work to empower patients and highlight problems, facilitate shared decision-making, allow patients to maintain control, reduce insulin errors and improve efficiency, change attitudes and culture, alleviate fears and clarify roles, integrate with work processes and systems, satisfy governance requirements, encourage collaborative working, reduce burnout and ensure consistency across the organisation.

How the research objectives were achieved throughout the thesis are discussed below, including how key findings contribute to the existing literature in this field.

Objective 1: Systematically review evidence regarding the impact of interventions on insulin prescription errors in the hospital setting.

The systematic review enabled the comprehensive identification of published interventions designed to reduce inpatient insulin prescribing errors using a proven methodology that was well-suited to this aim. The types of interventions designed to improve inpatient insulin prescribing practice were documented, and the impact on insulin prescription error reduction, completeness or accuracy of prescription, or adherence to prescribing guidelines was analysed to reveal the types of interventions that were associated with positive outcomes. Aspects of intervention implementation that were associated with more favourable outcomes in the studies were also described.

Despite this, it is appreciated that systematic reviews are, by nature, summative, and judge interventions in terms of change in outcome measures to give a generalised view. In this sense they are limited in their ability to more fully explain the context in which an intervention is successful in one setting and a failure in another. The use of the Quality Intervention Minimum Quality Criteria Set (QI-MQCS) tool as part of the quality assessment process

in the systematic review was helpful to give an overview of the general reporting quality of the included studies, and to encourage future original studies in this area to include sufficient contextual information when reporting on intervention use.

Although the heterogenicity of study design, reporting standards and definition and measurement of insulin prescribing error limited the ability to draw quantifiable conclusions, the research questions were answered using systematic review methodology, and results highlighted opportunities for research and provided a helpful framework to guide the development of tools used in the mixed methods study.

Stakeholder discussions

Following discussions with the LADDER panel regarding the systematic review results and implications for research (see **Chapter 2**), it was clear that the investigation of insulin prescribing practice was important to people with diabetes to reduce insulin errors and harm. It was also evident that the panel prioritised investigation of interventions that were perceived has having a high impact on people with diabetes, for example self-administration policies. As these policies were not reported in the studies identified in the systematic review, but featured in various UK national guidance recommendations, it was decided that these interventions should be included in the questionnaire tool. This decision was an example of shared-decision-making and co-production, directed by the priorities of patients, as the researcher's personal thought was that self-administration policies are more targeted at the impact of insulin prescription errors (as well as other aims, such as patient empowerment), rather than preventing the prescription error itself.

Discussing the research with a variety of stakeholders at this early stage helped to achieve a greater understanding and appreciation of the issues from the patient's perspective. This is of particular value when studying interventions to improve patient safety with insulin, and especially interventions to enable insulin self-administration in hospital (Wilson et al., 2015).

Objective 2: Investigate the current use and perceived effectiveness of insulin prescribing interventions.

Investigating current intervention use and perceived effectiveness across UK hospitals at an organisational level involved answering the following questions:

1. What systems are currently used to prescribe subcutaneous insulin for inpatients in UK hospitals?
2. What interventions are currently being used in UK hospitals to improve insulin prescribing practice?
3. Is there an association between hospital characteristics and intervention use?

4. What interventions are perceived to be most effective for improving insulin prescribing practice by those who have a role in implementing and evaluating them?
5. Is there an association between hospital characteristics and perceived effectiveness of interventions?

To answer these questions, a questionnaire tool was developed, validated and used in a national cross-sectional survey of UK hospitals. The self-administered questionnaire tool was designed to capture information about hospital characteristics, prescribing system use, intervention use and perceived effectiveness of interventions. Results from the systematic review were incorporated into the tool design, including the list of documented interventions, and some of the contextual information identified from the studies (e.g. local prescribing practice, prescribing systems used, organisation size, presence of diabetes pharmacist, type of hospital). The tool was developed according to good practice guidance and piloted with content experts and those representing the target population of survey respondents, namely hospital pharmacists who are responsible for designing, implementing, and evaluating insulin prescribing practice interventions in UK hospitals.

The survey was conducted as the first phase of the mixed methods study, and was the first of its kind to capture information on the functionality of systems used to prescribe subcutaneous insulin and the use of interventions to prevent insulin prescription errors, both in the UK and worldwide. The current use of a range of interventions to improve insulin prescribing safety in hospitals was described, and potential opportunities for safety features to be incorporated in both electronic and non-electronic prescribing systems were highlighted.

How the research questions above were answered with the use of the research method are discussed below.

Prescribing system and intervention use

Research questions 1-3 pertain to the description of insulin prescribing system and intervention use, and the existence of any association between hospital characteristics and intervention use.

Prescribing systems were able to be described with the use of the survey, as a range of functionalities were included as items that were informed by both the systematic review results and co-design with content experts and representative respondents. The tool was limited in that it may not have been sensitive enough to capture the breadth of information for organisations that used multiple electronic systems (each with different functionalities), although the tool could describe the use of concomitant paper and electronic systems.

Comparing the results of the survey with the most recently published NaDIA data, which was collected a few months after the survey was administered, confirmed that the tool was able to capture accurate information about prescribing system use. For example, the results of the survey indicated that around

48% hospitals are using electronic prescribing systems, but just under 17% hospitals are prescribing insulin using electronic prescribing systems alone (i.e. not in combination with paper charts). The NaDIA found that result that a total of 55.8% of sites are at least partially using electronic prescribing is similar to our finding of 48%. The difference may be explained by the NaDIA only including hospitals in England, whereas this survey included hospitals in other parts of the UK, none of which were using electronic prescribing systems at the time of data collection. There are also no accompanying definitions of what 'partial' or 'full' utilisation means in the NaDIA audit results, and the NaDIA did not measure what proportion of sites using electronic prescribing used it for insulin.

The survey built on the results of the systematic review by enabling the capture of all currently used interventions by enabling respondents to document bespoke interventions in use in their hospital. This facilitates the shared learning of organisations and also provides a broader picture of the interventions in use compared to what the NaDIA used to report in terms of care improvement initiative use (NHS England and Wales, 2018), for example use of mandatory training and the insulin passport and self-administration policy use. Although the bespoke interventions self-reported by survey respondents could not undergo statistical analyses, some may be incorporated into future versions of the survey.

Results show that despite the recommendation by NICE and JBDS (2012) for trusts to implement systems to allow insulin self-administration of insulin by inpatients, only 63% stated they had policies to enable insulin self-administration and only 31% had a policy to enable self-management. This is roughly similar to the reported figures from the NaDIA, where 65.2% sites stated they allowed self-administration of diabetes medication, and 45.9% had a policy to enable self-management of diabetes (NHS Digital, 2020). The difference in the self-management figure may be due to some hospitals allowing self-administration of oral medicines, but not insulin, as the wording in the NaDIA was not specific to insulin.

The usefulness of the survey for reporting pharmacist input into diabetes care was limited by the variation of job titles self-reported by respondents, as well as difficulties in interpreting this. For example, pharmacists may be covering diabetes wards but not have the title of specialist diabetes pharmacist, and these roles and titles may depend on organisational practices and norms. Nevertheless, the data retrieved was able to be analysed to find associations between the number of interventions used and the presence of a specialist diabetes pharmacist, as well as other characteristics such as hospital type, size and location.

The anonymous nature of the survey at the point of data input meant that it was not possible to externally verify self-reported descriptive information about the organisation. Although no unclear responses were received, non-anonymity may have been useful to clarify responses that were classed as 'unknown' responses and to enable purposive sampling of respondents based on maximum variation for the follow-up interviews. It would also enable characteristics of non-respondents to be described so that any differences between respondents and non-respondents could be further analysed. However, a wide

variety of hospitals from across the UK responded, which provided a broad and generalisable insight into current opinion at an organisational level. The survey response rate was reasonable, and comparable to other similar surveys of healthcare professionals (Cook, Dickinson, & Eccles, 2009).

Perceived Effectiveness of interventions

Research questions 4 and 5 pertain to the measurement of perceived effectiveness of listed interventions and the identification of any associations between hospital characteristics and these perceptions. The questionnaire used as part of the survey was developed and validated to describe the perceived effectiveness of a range of insulin prescribing interventions with good reliability.

The survey enabled the reporting of clear distinctions between interventions that were perceived to be highly effective, and those that were not. Results indicated that there was support for certain national recommendations, such as mandatory insulin training for clinical staff and self-administration, but not others, including the insulin passport.

Whilst the intervention list included in the tool was obtained from the systematic review results in **Chapter 2**, as well as input from frontline staff from multiple hospitals, the open question responses show that it was not completely exhaustive. Other interventions, such as insulin safety campaigns, prescriber feedback, insulin safety huddles and other bespoke strategies described by respondents were not included in the item list and were therefore unable to be represented in the statistical data analysis.

Despite the benefits of using perceived effectiveness of insulin prescribing interventions as a concept to measure for the purposes of a national survey, it also has its limitations. For example, the effectiveness of an intervention may be perceived differently between two members of the same organisation, neither of which may be identical to a quantitative measure indicating functional effect of the intervention (e.g. percentage reduction in insulin prescription errors at the trust). Perceived effectiveness may be influenced by experience, context, cognition and perceptual biases filtering individual observations (Ohrens, Santiago-Ávila, & Treves, 2019; Slovic, 1987; Starr, 1969) and may not be static. Sekhon et al comment that use and experience of an intervention may change one's perception of its effectiveness, which the analysis of survey results would support (Sekhon et al., 2017). It is also acknowledged that perceived effectiveness is just one element of the overall acceptability of an intervention. Other elements, or constructs, include affective attitude, burden, ethicality, intervention coherence, opportunity costs, and self-efficacy (Sekhon et al., 2017). These constructs may be also be important when considering the overall use of interventions to reduce insulin prescribing errors and may be worth investigating in future studies.

Stakeholder discussions

The discussions with the patient panel following the results presentation was useful in appreciating the patient's concerns over the safety of people with diabetes in hospital. The participants used words like 'frightening' and 'shocking' to describe their reaction to the results. These wouldn't have been terms I would have identified with as a person who does not have diabetes, and a healthcare professional used to viewing data regarding prescribing errors.

The meeting enabled me to be critically reflective and examine my assumptions about the research results; for example being able to view the results through the lens of someone who would be on the receiving end of such a statistic, with all the implications that may have on their wellbeing and safety helped me to appreciate the impact of the results.

The panel clearly identified the variation in self-administration and self-management policies as something that required further investigation due to the perceived benefits from them that this intervention can bring to their experience in hospital. These insights gave further support for the need to include discussion of this intervention in the interviews, and as such, it was included in the interview guide. The survey results regarding this intervention would benefit from further explanation, so it was easy to agree to include discussion of self-administration policies in the next study. The decision to retain questions on wider topics in the interview guide (i.e. to not make the qualitative interview study exclusively about self-administration policies) was made to balance the interests of the panel with that of the research team.

The prioritisation of quantitative data from the multidisciplinary inpatient group was an interesting difference in perspective to that of the patient group. Although this could not be achieved within the study design, exploring 'actual' intervention effectiveness further between a limited number of organisations with complexity-sensitive methods may be worthwhile.

Objective 3: Analyse the experiences and opinions of hospital pharmacists involved in insulin prescribing intervention design, implementation, and evaluation.

Analysing the experience and opinions of hospital pharmacists involved in the design, implementation and/or evaluation of insulin prescribing interventions involved answering the following research questions:

1. What are the current challenges and solutions with respect to improving insulin prescribing practice in the UK hospital setting?

2. What are the contextual factors that may influence the success of insulin prescribing practice interventions in the UK hospital setting?

This was achieved by in-depth, collective examination of insulin safety issues across multiple UK hospitals using thematic analysis of qualitative interview data collected from survey participants. The survey respondents were well positioned to discuss insulin prescribing practice interventions in their hospital setting, and results were able to further our understanding of contextual factors that threaten insulin safety and influence the success of interventions designed to reduce insulin prescribing errors in the hospital setting.

This was the first study of its kind to analyse the collective experiences and opinions of pharmacists (or any healthcare professional) involved in insulin prescribing safety in the hospital setting across multiple organisations both in the UK and worldwide. It was also the first study to collect qualitative data in this field in the UK, with the use of a well-known and thoughtfully considered approach to data analysis (Braun and Clarke's reflexive thematic analysis). Studies conducted prior to this were limited to single site studies and did not report qualitative analyses methods in requisite detail to critically appraise. It was also the first study to interpret findings relating to insulin prescribing safety using a human factors systems approach using the SEIPS model, with previous literature focusing on the outcomes of a small number of interventions being implemented at single sites.

It is also recognised that although coding was done inductively, there was also some level of deduction on account of the identification of topics to discuss in the interview guide. For example, insulin self-administration policy use was chosen as a topic for discussion prior to the interviews and consequently appeared as the topic of one of the themes.

Current challenges and solutions for improving insulin prescribing practice

The use of semi-structured interviews allowed participants to freely discuss a range of the challenges and solutions regarding current insulin prescribing practice in the hospital setting. The generation of deep contextual data was valuable in generating descriptions of the various organisational, personal, technological, environmental and socio-cultural factors that contribute to insulin prescribing errors.

Existing theoretical frameworks were not used to design the interview guide or code the transcribed data. This decision was to help widen the lens through which insulin prescribing problems and interventions were viewed during the interview and coding process. Although this enabled the identification of important mechanisms that lie outside of 'off the shelf' theoretical frameworks, it may have been beneficial to include more prompts in the interview guide that were based on elements contained in the SEIPS framework or consideration of Normalisation Process Theory (NPT) or the Theoretical Framework

of Acceptability (TFA) constructs to stimulate discussion further, or to enable additional deductive analyses to be undertaken using the dataset in the future.

Although interview data were not mapped to Reason's error theory categories in the same way as the SEIPS, consideration of the results suggests that both latent and active failures contribute to insulin prescription errors in current practice, including organisational processes (e.g. lack of training), error-provoking conditions (e.g. look-alike-sound-alike products), slips (prescriber writes 80 instead of 8), lapses (prescriber writes 'units' on a chart with pre-printed 'units' on), mistakes (lack of knowledge of long-acting vs short-acting) and violations (adjusting insulin prescription not prioritized by doctor).

The complex and widespread problems with insulin prescribing processes in hospitals are not bound by a single organisational setting; wider issues regarding staff retention and rotation, insulin branding, primary care systems and communication across settings, as well as undergraduate and postgraduate education all impact on the ability of prescribers to generate safe and appropriate insulin prescriptions for people with diabetes in the hospital setting. Solutions, therefore, need to be able to consider these wider systems issues. Evidence of this include recent calls from the UK Clinical Pharmacists Association Diabetes and Endocrinology group for manufacturers to change the name of biosimilar insulins coming onto the market to avoid mis-selection (Jelley, 2019).

Contextual factors that influence intervention success

The integration of the qualitative data with the quantitative data from the survey enabled further explanation of the salient survey results regarding perceived effectiveness of interventions. Many factors align closely with human factors associated with prescribing errors more generally outlined in the literature, such as reduction of prescriber cognitive 'work' required to generate prescriptions, proximity to other tools (e.g. prescription chart and blood glucose results), and conspicuousness (Coombes, Stowasser, Coombes, & Mitchell, 2008; Sutherland et al., 2019; M. P. Tully et al., 2009). The application of the findings to the SEIPS model alerted the researcher further to a range of components at multiple levels of social reality that should be accounted for when designing and evaluating interventions (Kislov et al., 2019). This enabled the more evaluative findings to be further translatable, to increase the relevance and significance of results. This also provided further clarity with respect to uncovering generative mechanisms behind why and in what contexts, interventions were perceived to work by participants.

All components of the model were able to be populated, often with multiple inferences made from the thematic analysis. These inferences mapped to specific domains aids the development of interventions that are likely to be more effective than those developed without reference to theory. Consideration of

the results with reference to NPT would be difficult due to the disparate categories of interventions discussed. However, all four constructs of NPT (coherence, cognitive participation, collective action and reflexive monitoring) can help further explain findings in general. For example, reference was made to *"aligning priorities"* (coherence - communal specification), individuals driving interventions (cognitive participation – initiation), the division of labour required for self-administration policies (collective action – skill set workability) and collecting feedback on prescription charts from prescribers (reflexive monitoring – communal appraisal).

This collection of feedback on interventions and being inclusive in their design in particular may enable a more proactive approach to safety management (Braithwaite, Wears, & Hollnagel, 2015; Sujan, 2015). Overall, results suggest that a chiefly reactive method of strategy implementation which prioritises consideration of local safety trends is taken, which may be problematic (Carson-Stevens, Donaldson, & Sheikh, 2018; Macrae, 2016).

The additional 'subgroup' analyses undertaken to categorise the data according to intervention use may be limited as the study was not designed to include equal numbers of representatives from organisations with those characteristics. Results should therefore be taken with caution. Despite this, the presentation of data in this way was thought to have utility for inpatient diabetes and pharmacy teams, as it communicated 'lessons learned' from those who had implemented interventions. Future studies designed for the purpose of comparing between organisations may benefit from careful purposive selection of participants and more structured questioning.

Although electronic prescribing was of particular interest to the multidisciplinary stakeholder team, this was not chosen for subgroup analysis due to the complexity of the intervention. For example, participants described many variations of system use (as outlined in the survey) which would obfuscate the categorisation process. The important human factors systems elements of electronic prescribing use for subcutaneous insulin were, however, contained in the SEIPS model to help hospitals implementing electronic prescribing consider salient issues when designing or implementing these systems.

Stakeholder discussions

The discussion with the patient panel following the presentation of the results was conducted virtually due to the COVID-19 restrictions on in-person meetings. This did not seem to impact discussions but there were noticeably less panel members in attendance compared to usual (4 compared to the usual 6-8). In contrast to previous meetings, the questions posed were not answered straightforwardly as the panel quickly entered into a lively discussion about self-administration of insulin in hospital. As this had been a theme throughout the panel discussions this was unsurprising, but it was difficult on this occasion to direct

discussions towards how the research may uncover how the interventions work. Participants vivaciously gave their different opinions about how interventions should be designed and delivered to patients in hospital (see Box 2 in **Chapter 5**) but it was difficult to conduct the deeper discussions around potential mechanisms that generate outcomes. Despite this, the meeting did confirm that researching self-administration interventions in more depth with realist methods was an appropriate way to conclude the body of work.

Objective 4: Generate evidence-informed theory to explain how an intervention works, for whom, and in what circumstances.

Following the identification and exploration of self-administration policies as a salient and complex intervention from the mixed methods study and patient/multidisciplinary team consultation, a realist synthesis was chosen to examine "what works, for who, in what circumstances and why?" with respect to intervention design, implementation and use. Realist synthesis exposes and links contextual factors with underlying generative mechanisms to form hypotheses about how organisations can successfully implement insulin self-administration policies. The paucity of published literature evaluating insulin self-administration interventions and providing a theoretical grounding to implementation and design confirmed the need for such a study to contribute to improvement efforts. The realist synthesis answered the following research questions:

1. What are the 'mechanisms' by which self-administration policies are believed to result in their intended outcomes?
2. What are the important 'contexts' that determine whether or not the identified mechanisms produce either positive or negative outcomes?
3. What are the circumstances in which self-administration policies are most likely to be effective?

This is the first study that studies self-administration intervention implementation in a hospital context using realist review methods. Prior to this study, implementation designers had written commentary pieces on their experience and used audit methods to report outcomes of policy use (Johnston, 2019; Johnston & Newland-Jones, 2017; Pearce, 2019; Rowse, 2018b, 2018a). Although there has been qualitative research investigating inpatient self-administration of medicines more generally, often this concerns oral medication use in the hospital setting and excludes the self-administration of injectable medicines with additional governance considerations such as insulin (Schultz et al., 2019). This study adds to the literature by using evidence-informed theory to uncover the generative intervention mechanisms that lead to outcomes of insulin self-administration policies (both positive and negative).

The decision to use realist research methods for this final study was prompted by careful reflection on the qualitative analysis and the importance of context in contributing to intervention effectiveness highlighted by the

studies conducted so far (perceived or real). It was also important to continue the theme of including patients in the research, and as insulin self-administration in hospital was such an important topic to the panel, it was felt that working with a wider stakeholder group to co-produce a theory of how they work was an appropriate way to finish the current programme of research.

All three research questions were answered by the collaborative, iterative and evidence-informed generation of 10 context-mechanism-outcome configurations (CMOCs) that explained how insulin self-administration policies worked in what circumstances, and why. Insulin self-administration interventions are inherently complex and socially contingent, meaning that this intervention was particularly well-suited to realist research methods.

The process of undertaking the realist synthesis was, however, very challenging, and required familiarisation and understanding of the underpinning realist logic as well as the use of more specialist terminology. For example, the cognitive task required to linearise the messy, 'three-dimensional' and fluid thinking process, and distinguish between realist-defined contexts and mechanisms was complex, and has been cited as a criticism of the method by some (Porter, 2015). For example, some of the outcomes included in the theories (e.g. patient empowerment and control) may become new contexts over time as the policy becomes embedded, in what has been described as a 'ripple effect' (Jagosh et al., 2015). The iterative process with which the realist synthesis was conducted differed markedly to other research methods used in this thesis, for example the systematic review and cross-sectional survey. However, spending sufficient time to develop rough programme theories early on helped to identify the type of data needed at context, mechanism or outcome level in the later stages.

It is recognised that the synthesis relies on available evidence, which is limited in the specific area of inpatient insulin self-administration policies in the UK hospital setting. A key strength of the synthesis was the additional literature searches conducted once key influencing factors were identified (empowerment and shared decision-making). These searches were not limited to inpatient insulin self-administration policies in the UK hospital setting, which increased the validity and plausibility of the findings. For example, more literature was available regarding general self-administration of medicines and in non-UK settings, which could be used to help further develop theories for transferable learning.

The co-creation of theories with stakeholder groups also presented an increased commitment to participatory health research approaches; the administrative task of conducting, documenting, processing, and synthesising stakeholder input was considerable. The stakeholder involvement was significant and useful throughout the review, however, both in theory creation early in the review, and later in confirming and refining programme theories. Although the literature searching was undertaken solely by the researcher, the in-depth, reflective discussions with various stakeholders throughout the project added to the validity of findings. Keeping records of meetings, notes and versions of programme theories as they developed added to the transparency of the process, along with following a systematic approach as outlined in the publicly available study protocol.

The creation of 'non-academic' actionable findings from the realist review should also help hospital teams improve the design and implementation of insulin self-administration policies. These findings are planned to be disseminated along with the per-reviewed publication of the review, via professional networks and national diabetes fora (e.g. Diabetes UK).

The CMOs are not exhaustive, that is, there were more candidate CMOs than were prioritised for refinement with the literature. Realist programme theory is not designed to be exhaustive, however, unlike other theory-based approaches like certain types of grounded theory (Pawson et al., 2005). As such, there is scope for further work to generate other theories focusing on different intervention outcomes (such as reduction in medicines wastage and increase cost saving). Realist theories are also tentative, designed to be testable, and not absolute, so results should be interpreted with caution (Blamey & Mackenzie, 2007). Further refinement of theories is expected, for example through realist evaluation methods (see **section 7.5,** below).

The application of both NPT and Kanter's theory in the healthcare setting is well documented, and have been used in previous studies that were multi-perspectival with involvement of healthcare professionals and patients (C. May et al., 2011; McEvoy et al., 2014; Spence Laschinger et al., 2010). By framing the analysis with substantive middle-range theories, the resulting product of the realist synthesis can be applied across different settings and can help to shape implementation journeys.

Stakeholder discussions

The additional stakeholder group recruited for the realist synthesis provided valuable 'insider knowledge' with respect to advice and insight into the use of self-administration policies from a range of perspectives at different points throughout the study. There was much interest in being part of the realist synthesis stakeholder group at the early stages, and it was not a struggle to recruit an appropriate variation of stakeholders that could add legitimate voices to the development of the theory from both patient and multidisciplinary healthcare professional angles. This also confirmed the salience of the topic for a wider range of healthcare professionals and patients than previously consulted.

The decision to facilitate both synchronous and asynchronous discussions with stakeholders throughout the project was taken to accommodate the diverse availabilities of the group, many of whom were working in hospitals as front-line clinicians during the COVID-19 pandemic. Individual meetings were arranged where stakeholders could not attend group meetings, and email conversations were had with others. This also helped individuals' voices to be heard, which can be difficult when conducting group discussions that tend towards producing consensus opinion, especially in diverse groups such as this where professionals and patients – each with their own preconceptions, values and understanding of each other (Somekh & Lewin, 2005, p43).

The composition of members attending the group discussions varied, with a combination of healthcare professionals and patients attending the first group meeting, and with patients being the majority in the second meeting. The third meeting comprised mainly healthcare professionals. This may have impacted the theory development by disproportionately including patients' input in the early 'formative' stages of theory refinement. The consideration of the interview data from the qualitative phase early on helped to redress what may have been an imbalance, as well as multiple healthcare professionals inputting into theory refinement during the later stages. The purpose of stakeholder involvement in realist research is not to get a proportionate sample of representative voices, however, but to add relevance and value to the theory development.

Group meetings comprised between 4-6 individuals, which was an ideal size for group discussions (Liamputtong, 2011). Although power differentials between group participants was anticipated due to the heterogeneous nature of the groups (patients, nurses, pharmacists, programme managers), there were no conflicts or apparent difficulties resulting from differences in participant characteristics. The group dynamics resulted in productive and positive discussions, and all members contributed unique insights. This may have been due to group members being motivated and educated enough to feel confident to volunteer for participation, and united in their desire to contribute to the research agenda on account of it being an important topic to them personally. Future studies may benefit from efforts to recruit 'harder to reach' representatives or those that could provide additional insights from a different perspective (i.e. those opposed to or wary of inpatient insulin self-administration).

In summary, the research objectives were able to be met with the use of mixed methods and realist synthesis, although results should be interpreted with caution. The next section discusses the quality of the overall research, starting with general strengths and limitations of the thesis, followed by quality assessment of the individual studies.

7.2 Strengths and limitations of the research

The mixed methods study followed by the realist synthesis allowed quantification of issues relating to insulin prescribing practice interventions followed by in-depth exploration of key issues and interventions. Overall, this body of work extends our knowledge and understanding of current practice and experience with respect to insulin prescribing practice in the hospital setting, which is important to aid much-needed improvement efforts both in the UK and worldwide.

A mixed methods approach is utilized to provide a rich and contextualised dataset for the purposes of answering the research questions. In doing so, a more comprehensive understanding of the research problem is gained compared to the use of qualitative or quantitative methods alone. The sequential order of the studies aided the explanation of salient issues pertaining to insulin prescribing safety in the hospital setting as they were identified and discussed with stakeholders throughout the work. The list of identified interventions generated from the systematic review was further developed by cross-sectional survey results, generating a comprehensive documentation of current strategies for the benefit of shared learning and improvement of care across hospitals. The qualitative study results were able to explain the variation in the use and perceived effectiveness of interventions by discovering that these are influenced by the success of current implementation, individual organisational contexts, and respondents' experiences. The use of reflexive thematic analysis to identify patterns of shared meaning across the dataset, as well as the application of a theoretical human factors framework, aids transferability of the findings. The scientific realist position and pragmatic approach to the research was congruent with the methodologies chosen. Although the studies produced somewhat different 'types' of knowledge, these were complementary, allowing tentative conclusions to be drawn relative to research questions that had arisen from the need to solve a common practice-based problem.

Dissemination of results that identify salient interventions to improve insulin prescribing practice has further facilitated improvement efforts across NHS hospitals since publication, which is increasingly important where resources and capacity are increasingly limited (The Health Foundation, 2013). For example, results from the mixed methods study were discussed in person to policy makers at the NHS Getting It Right First Time (GIRFT) programme for diabetes ahead of the publication of the national report, particularly those relating to the association between specialist diabetes pharmacists and the greater use of insulin prescribing safety interventions (Rayman & Kar, 2020).

Results from **Chapters 2** and **3** have so far been disseminated via peer-reviewed publications, conference abstracts, professional networks and locally via hospital patient and professional forums. Following publication, individual clinicians, pharmacists, and medicines safety officers from trusts across the UK, including national speciality advisors, and clinical directors, have contacted the researcher to discuss local improvement efforts further. Survey participants have received copies of the peer-reviewed publications for more targeted dissemination of the findings (in their respective organisations), and it is intended that results will be shared with national patient groups via the charity Diabetes UK, specifically to help empower patients who are admitted to hospital to ask about insulin self-administration policies. This will also help to bring about one of the desired contextual factors impacting intervention success from the realist synthesis (i.e. patient empowerment by provision of information) on a national level.

Although sometimes challenging, there have been many benefits to using a participatory health research approach throughout this thesis, including a sense of 'closing the gap' between research, policy, and practice.

Such approaches should be therefore considered for research that seeks to describe and investigate healthcare professional practices that impact on patient care and safety. Although the need to include patient public involvement in much research that is funded, it is appreciated that this may sometimes be 'tokenistic' and not always be in the spirit of participatory health research. If the researcher had not adopted a participatory approach in this work, it would likely have been to the detriment of themselves, their colleagues, and the stakeholders with whom they were working throughout the project.

In summarising the evidence for interventions, along with reporting their current implementation status and perceived effectiveness, policymakers and practitioners can critically reflect on the suitability of initiatives being used locally and driven nationally. The use of human factors systems theory in exposing the contextual factors impacting on insulin prescribing practice in the hospital setting also enables policymakers and practitioners to take more of an evidence-informed and theoretically grounded approach to intervention use. The evidence-informed theory generated from the realist synthesis will also facilitate the successful implementation of self-administration interventions for the benefit of patients and practitioners. The product of the synthesis can also function as a set of contextually-sensitive measures for future evaluation studies.

7.2.1 Limitations

Despite this, it is recognised that the work has some limitations and therefore results should be interpreted cautiously. Data retrieved in the mixed methods study was limited to the views and experiences of pharmacist intervention designers and implementors in NHS hospital organisations. Although the project has benefitted from multidisciplinary input throughout, including medical prescribers, nurses and patients as participants in future studies would enable the consideration of alternative viewpoints and thus add value to results. As in all self-reported surveys, it was not possible to validate the data.

Surveys were anonymised which limited the ability to do an in-depth analysis on individual cases (as interviewees were also survey respondents). This could have enabled additional analyses to be conducted on the overall mixed methods dataset, where a focus is on cases rather than themes (e.g. comparing a respondent's interview data with survey data).

Interventions were also not associated directly with reported organisational insulin error rates to generate results on 'actual effectiveness' of interventions. This was due to the diversity and complexity of organisations, systems and error measurement that would present significant confounders threatening the ability to draw any meaningful conclusions for investigations being conducted at a multi-organisational level. The product of this research does, however, aid the design of future evaluation studies by outlining contextual factors that influence intervention success, as well as relevant human

factors measures that extend past insulin error measurement (such as extent of integration with current prescribing systems, pedagogic design of educational interventions, and patient empowerment).

7.3 Quality Assessment

To assess the quality of the work produced one must apply quality criteria that is coherent with the overall philosophical and methodological approach to the research. This research was conducted under a pragmatic view, such that the most appropriate methodology was used to answer the research questions. A combination of mixed methods and realist research was used, which, within a critical realist ontology and relativist epistemology, calls for the application of different quality criteria to assess each study, rather than one general criteria. For example, in this research, it would be inappropriate to assess the quality of the qualitative research with quantitative criteria (reliability, validity, generalisability, objectivity), as a relativist-informed reflexive thematic analysis was conducted from a non-positivist epistemology that did not seek to quantify qualitative data. Quality criteria therefore emerge from the specifics of a study, and are discussed below in order of the studies presented in the thesis.

7.3.1 Systematic review

The systematic review aims to conduct a literature review with the same rigour that should be used when conducting original research. As the aim is to minimise bias and random error in systematic review, the use of transparent and objective methods is required to allow the review to be reproducible. The systematic review was conducted according to the PRISMA guidelines, which enabled the generation and peer-reviewed publication of a high-quality review. A protocol that was externally peer-assessed and published on the PROSPERO database increased the quality and transparency of the review.

The literature search was comprehensive, with a wide range of electronic databases being used to search the literature, including grey literature and hand searches of reference lists and journals. This enables a greater proportion of the literature to be captured, although it is possible that some papers may be missed. Selection criteria were discussed with the supervisory team (including a topic expert) and applied consistently to all papers. The studies were assessed independently by two researchers using a combination of three verified quality assessment tools appropriate to the study type, which strengthened the rigour of the review. Data extraction forms were developed based on those provided by the Cochrane Handbook and piloted to ensure that no relevant data were missed (J. Higgins, 2011)

Although publication bias was minimised by including grey literature searches, it was not formally assessed (e.g. with a funnel plot) as it was deemed unnecessary in the absence of meta-analysis. As meta-analysis was not possible due to the diverse methodologies, methods, and definitions of prescription error in the studies, a narrative synthesis of findings was conducted.

7.3.2 Mixed methods study

Currently there is a lack of consensus in the description of quality for mixed methods studies, as well as a lack of consensus guidelines on how to evaluate mixed methods research designs (Ramzan, Hadi, & Babar, 2019). Some of the current frameworks for conducting mixed methods research recommend justifying the use of mixed methods, describing the design, methods and integration, as well as identifying limitations, insights and discussing how disagreements between components will be dealt with (Creswell & Clark, 2017; Hadi, Alldred, Closs, & Briggs, 2014; NIH Office of Behavioral and Social Sciences, 2018; O'Cathain, Murphy, & Nicholl, 2008). These considerations have been discussed in **Chapter 3 (section 3.1.1).** Due to the differences in mixed methods designs, approaches and typologies (Teddlie & Tashakkori, 2009), the application of individual quality criteria appropriate to the individual components of the studies was also undertaken. This will be discussed for the quantitative and qualitative phases below.

Quantitative phase: cross-sectional survey

Quality of quantitative research is considered in terms of validity and reliability, replicability, and generalisability. Although replicability and generalisability are understandably important in clinical studies quantifying effectiveness of treatments, they are considered less relevant for social research, with criteria such as explicitness and transparency being more valued (Alan Bryman, Becker, & Sempik, 2008). The range of quantitative study designs and purposes calls for the application of specific quality criteria relevant to the research being conducted. The cross-sectional survey was conducted and reported according to the STROBE guidelines for reporting observational studies (see Appendix 9), which was deemed the most appropriate criteria to apply for this cross-sectional survey according to the EQATOR network (EQUATOR network, 2016). The use of these guidelines facilitated the transparent and explicit reporting of the survey, and included consideration of generalisability. The measures taken to address validity and reliability are described in **Chapters 3 and 4** but will be discussed further below.

Validity

In survey research, validity refers to the extent that the measure used accurately reflects the concept we are interested in (Cowles & Nelson, 2019). Although there is debate about what constitutes instrument validation, the minimum requirement of tool validation is thought to be face validity (Burns et al., 2008; Menold, Bluemke, & Hubley, 2018). For the questionnaire tool used in this survey, face validity and content validity are the most relevant. Construct and criterion validity are important to consider when developing psychometric scales but were not applicable to this survey, which aimed to describe the use of systems and interventions across multiple organisations (a fact-based measurement) and report on respondent's perceptions of effectiveness of multiple interventions, rather than generate constructs of perceived effectiveness of a single intervention (see also **Chapter 3, section 3.3.1**).

Face validity assesses the presentation and relevance of the questionnaire such that the goals of the survey are met; that is, questions can be interpreted by participants, who are then willing and able to respond accurately (Dillman et al., 2014). To this end, due consideration was given to ensure item wording was specific, clear and of appropriate length and complexity (Cowles & Nelson, 2019). The use of an external expert panel allowed for the face validity to be assessed and the content and wording to enable the collection of relevant information. All expert panel reviewers were female diabetes pharmacists from larger teaching hospitals in England with involvement in diabetes research and healthcare professional education on a national level. It is therefore recognised that although they represented the target population, face validity may have been further improved by consulting additional target respondents from Wales, Scotland and Northern Ireland who represented other pharmacist respondents such as chief pharmacists or clinical pharmacy service managers.

Content validity refers to the extent to which the items in the questionnaire are fairly representative of the entire domain it seeks to measure (Salkind, 2012). To address this, items were initially derived from the systematic review conducted in **Chapter 2** as well as the literature identified in **Chapter 1,** the expert content knowledge from the supervisory team, external face validators and personal professional knowledge of interventions used in practice. Inter-rater reliability of judgements made on the usefulness of each item was also calculated as recommended by Wynd et al. (Wynd et al., 2003). This increased the chances of any important intervention items being omitted from the questionnaire tool design. The panel consisted of four target respondents who were also considered experts in the area; if a larger number of panellists was able to be recruited, additional quantitative validity testing may have been performed, such

as content validity index or content validity ratio, which is widely reported in tool development studies (Lawshe, 1975; Rubio et al., 2003; Zamanzadeh et al., 2015).

Although questions were limited in scope (i.e. use, functions and perceived effectiveness of interventions), this was on account of due consideration being given to minimising the burden on respondents. Future iterations on the survey may benefit from limiting the number of interventions being investigated, and using the results of the qualitative study to inform development of more detailed questions regarding respondents' understanding of intervention effectiveness.

Although the survey was reviewed by a multidisciplinary diabetes team, and involved mainly fact-based questions that could be answered with reference to protocols or colleagues in the organisation, the possibility that some responses may have been different if answered by another individual at the hospital cannot be ruled out. As respondents were asked to describe current practice, recall bias is unlikely to impact results, although non-response bias could have affected the results. This was not formally assessed, however, due to the lack of readily available relevant demographic information for non-responding hospital organisations (e.g. type, size of hospital, presence of diabetes service and diabetes pharmacist). Sample size estimates were not conducted on account of the whole population of NHS hospitals being surveyed. It is recognised that those with an interest in insulin prescribing safety may have been more inclined to respond to the survey, although this was not directly investigated.

Reliability

In surveys, reliability refers to the consistency in responses across different respondents in the same situations. Perceptions on the individual questions asked in may impact reliability of the questionnaire; this is minimised by asking questions that are likely to have a shared meaning. In this tool, the individual items have a high probability of being understood by the respondents, all being hospital pharmacists who are familiar with prescribing practice intervention design, use and evaluation and associated terminology. Most questions in the tool were fact-based and were therefore likely to be reliable. Different individuals' understanding of the concept of perceived effectiveness may vary, however this is a common concern with self-administered questionnaires.

Test-retest reliability was not undertaken in this study, due to time and resource constraints, as well as the unfavourable ethical and financial implications of requesting front-line healthcare professionals' time to complete additional surveys, when the likelihood that response rate for re-tests would be low. Split half reliability was not undertaken due to the absence of factor analyses,

however internal consistency reliability was undertaken using Cronbach's Alpha. This test showed that the items were highly correlated across both the overall tool and the Likert scale section. It is understood, however, that alpha is also sensitive to the number of items in a test, with larger number of items resulting in a larger alpha.

Qualitative phase: semi-structured interviews

There is no absolute criteria for judging whether a piece of qualitative research is good (Braun & Clarke, 2013), and different types of qualitative research employ varying theoretical approaches stemming from with diverse philosophical assumptions. The quality criteria described above (namely reliability and validity) stem from more positivist approaches that seek to minimise error and bias in research studies originating from the researcher. Some qualitative research that is conducted within this paradigm may employ techniques such as inter-rater reliability for data coding that researchers seek to quantify, but these are based on the assumptions that coding can and should be objective (Braun & Clarke, 2013).

This study is underpinned by the researcher's assumption that truth is context-bound, and that data are thus produced (rather than passively collected) by the researcher who inevitably influences the research process. Techniques such as inter-rater reliability assessments were therefore not considered for this research as they are not consistent with the approach taken. The qualitative phase was conducted with reference to the criteria for reporting qualitative research (COREQ) checklist, which facilitates quality assessment of how elements of reflexivity, methods, context, findings, analysis, and interpretations are reported (Tong et al., 2007). It is recognised, however, that checklists such as this do not ensure quality in a qualitative project (Amin et al., 2020; Braun & Clarke, 2013) and are not always completely relevant for the type of qualitative research undertaken. For example, although most of the items on the COREQ checklist were relevant to the qualitative phase of the mixed methods study, the requirement for data saturation included in the checklist was not compatible with the methodological approach used (Braun and Clarke's reflexive thematic analysis). Braun and Clarke argue that data saturation is a concept that is not compatible with reflexive thematic analysis where codes (and coding) are context-dependent, and the meaning of themes derive from the interpretative process of data analysis, which is an ongoing and organic process (Braun & Clarke, 2019). This supports Richer's position that it might not be possible to develop a single set of guidelines that apply to all forms of qualitative research, and that each study should be judged on its own terms (Braun & Clarke, 2013; Reicher, 2000).

Therefore, in addition to the COREQ checklist, a 15-point checklist for a good thematic analysis produced Braun and Clarke (the authors of the approach used in this study) was also considered (Braun & Clarke,

2006, 2013). This checklist covers the different processes involved in thematic analysis, including transcription, coding, analysis and writing.

To reflect on the overall rigour of the qualitative phase is described below, the general quality criteria of trustworthiness and authenticity are discussed briefly below. These criteria are the original and widely accepted criteria outlined by Lincoln and Guba (Lincoln & Guba, 1985, 1986) recently developed for pharmacy research by Amin et al. (Amin et al., 2020).

Trustworthiness

Trustworthiness involves establishing the credibility, transferability, dependability, and confirmability of the research. My background as a hospital pharmacist and previous research into inpatient insulin prescribing quality (prior to and during the PhD) enabled prolonged engagement with the research topic and the 'culture' that I was researching, as well as development of trust with the research participants, who are from the same pharmacy profession and sector and had expressed interest to participate following their completion of the cross-sectional survey.

The sequential nature of this study following analysis of the survey, as well as discussions with stakeholder teams and keeping a reflective diary after each telephone interview, facilitated persistent observation, and a more critical reflection on contextual factors, salient issues and my own presumptions, ideas, doubts and thoughts throughout the study. The combination of prolonged engagement and persistent observation serve for a thick description to be presented in the analysis, to advance our knowledge of the topic and enhance transferability (Amin et al., 2020)

Member checking, where participants are given their transcripts, data interpretations or codes to review and confirm, is recommended by Lincoln and Guba to enhance the confirmability of the research (Lincoln & Guba, 1985). This was not undertaken due to the resource and time constraints of both the researcher and the pharmacist participants, as well as potential problems over non-response, or the impact of partial response and how to manage the analysis if accounts were changed or redacted.

Triangulation is another technique recommended by Amin to enhance trustworthiness of the data by establishing its credibility. This qualitative study benefits from methodological triangulation with the cross-sectional survey and investigator triangulation by the involvement of 2 undergraduate student researchers to ensure the analysis is rich, comprehensive, and inclusive

of others' insights and interpretations. Theoretical triangulation was also achieved with the use of both reflexive thematic analysis and the application of human factors theory to the data.

Peer debriefing was also undertaken with a fellow pharmacy practice PhD researcher studying diabetes medication use, whereby questions were asked about the research process, question formation, study design, analysis and data interpretation that enabled reflection on biases that may remain implicit. Negative case analysis, where elements in the data that deviated from the 'norm' was also conducted to a limited degree. For example, one participant described how insulin prescribing charts were not helpful in their organisation during the interview, which was contrary to the majority opinion. This was explored further in order to amplify the understanding of the data, for example why the predicted response did not occur, and strengthen trustworthiness (Amin et al., 2020).

Finally, although not included in the thesis, an audit trail was kept throughout the study, in which records of the raw data, recordings, interview notes, iterations of data analysis on serial dated NVivo file versions, pilot forms of interview guides and dated reflective diary entries were kept. Lincoln and Guba promote this practice as the examination of the research process can corroborate its dependability (Lincoln & Guba, 1985). The inclusion of reflective diary accounts also demonstrate reflexivity as a mark of trustworthiness, as preconceptions and biases are accounted for during the conduct of the research as well as in the choosing of topic and research questions (as discussed in the **Foreword**).

Authenticity

Authenticity refers to the fair and faithful presentation of a range of the different realities expressed by the participants, and involves an assessment of the meaningfulness, usefulness and impact of interactive inquiry processes (Shannon & Hambacher, 2014). The concept of authenticity stems from a more constructivist positionality, which recognises the existence of multiple 'truths' or 'realities' and seeks to ensure these are represented in the work produced. As this is not congruent with the scientific realist position, which claims the existence of one universal truth that cannot be completely known, this criteria may have limited applicability here. However, the concept of fairness is applicable due to the recognition of value-pluralism. The use of fully informed consent processes, member checks, thick description, audit trails, a reflective diary, and peer-debriefing helped to avoid a situation where some participants' values were suppressed or enhanced depending on their agreement with my own. Also, excerpts were chosen that were felt to best represent the participants' views, rather than serve the purpose of

confirming/refuting my assumptions. The same semi-structured interview guide was used with each participant, which gave each participant the opportunity to make their opinion heard on different aspects of the issue. It was also flexible enough to allow discussion of issues that participants felt were important to the topic area.

Taken altogether, the above considerations should provide the reader with greater confidence in the qualitative study results. It is recognised, however, that this confidence is not guaranteed and complete evidence to inspire confidence is not possible to demonstrate, therefore the results should be interpreted with caution.

7.3.3 Realist synthesis

Unlike the mixed methods study, the assessment of quality of the realist synthesis benefits from the publication of a universally accepted quality criteria outlined by the Realist And Meta-narrative Evidence Syntheses: Evolving Standards (RAMESES) group (G. Wong, Greenhalgh, Westhorp, & Pawson, 2014a). The RAMESES quality criteria involve 8 core components, with associated sub-criteria that enable researchers to appraise elements of the work as either inadequate, adequate, good, or excellent. These components include due consideration of the appropriateness of the research problem for realist synthesis, demonstration of understanding and application of the underpinning principals of a realist philosophy of science, along with elements of how the synthesis was undertaken (programme theory development, search strategy, document appraisal, data extraction). These quality standards were considered in addition to the publication standards referred to in **Chapter 6,** and enabled the enhancement of methodological rigour by aiming to achieve the 'excellent' standard for each criterion. A brief discussion of how these criteria were met is provided below:

The research problem

The study of insulin self-administration policies was identified as suitable for realist research methods as it is a complex intervention that involves human decisions and actions. This was confirmed with consultation with a realist methodology specialist during attendance at a training conference prior to the start of the study. The results from the mixed methods study prompted further explanation of the 'why' question, which is paramount concern of realist synthesis. The research question was structured to reflect the elements of realist explanation, and was simple and focused enough to be achieved with realist synthesis methods.

Understanding and applying the underpinning principals

To apply the underpinning principals of realist synthesis, I took time to wrestle with and understand the realist philosophy and logic of enquiry. This included familiarising myself with the work of social science methodologists Pawson and Tilley (Pawson, 2006; Pawson & Tilley, 1997), as well as their forerunners (Bhaskar and Sayer) and others advancing (and criticising) the use of the method (S. Dalkin et al., 2020; S. M. Dalkin et al., 2015; Emmel et al., 2019; Luetsch, Twigg, Rowett, & Wong, 2019; Porter, 2015), as well as participating in a specialist realist methodology training course.

The realist synthesis presented in **Chapter 6** demonstrates the iterative testing and refinement of theoretically-based explanations of how and why self-administration interventions work, which is the key analytic process in realist synthesis.

Focussing the review

The initial stages of the synthesis generated many potential avenues for exploration and explanation, on account of the complexity of the intervention and the diversity of stakeholders included. The process of focusing the breadth and depth was considered from the start on account of resource and time limitations to undertake the synthesis. The second round of stakeholder meetings were dedicated to prioritising issues to focus the review, which achieved maximal end-user relevance. This was documented as part of the review.

Constructing and refining a realist programme theory

The initial programme theories were elicited according to the structure recommended in the RAMESES training materials, by starting with outcomes of interest, and 'working back' to uncover why the intervention was thought to work to generate these outcomes. This was then iteratively recast in realist terms as the synthesis progressed, first using the CMO heuristic outlined by Pawson (Pawson & Tilley, 1997) and later as multiple CM(response + reasoning)O configurations, as per Dalkin (S. M. Dalkin et al., 2015). The relationship between programme theories and substantive theory (NPT and Kanter's theory of structural empowerment) is also identified.

Developing a search strategy

The search strategy was guided by the objectives and focus of the review and was directed at retrieving evidence from documents from a wide range of sources in order to refine the programme theory. No restrictions were placed on the study or documentation type, and further searchers were undertaken to seek out data from situations related to the intervention under study (general inpatient self-administration policies) to find additional data to enable further theory refinement (e.g. search 2 and 3 described in **Chapter 6**).

Selection and appraisal of documents

All documents were appraised and selected based on their relevance (their contribution to theory development), and rigour (the credibility of the method used to generate the piece of data). The limitations of the methods used to generate data were identified, considered, and documented in Appendix 17. This ran in parallel with the analysis stage and was based on explanations of this process given by Pawson (Pawson, 2006) in accordance with realist synthesis methodology.

Data extraction

Data were extracted from documents in such a way that prioritised theory refinement. Unlike in the systematic review presented in **Chapter 2**, data concerned contexts, mechanisms, outcomes, demi-regularities and theories. This was facilitated by the use of NVIVO, which allowed elements of papers to be coded. The extraction process was refined to progress from coding data to individual contexts, mechanisms and outcomes, to overall CMO configurations. This improved the clarity of theory development and refinement.

Reporting

The final component of quality assessment pertains to reporting the synthesis, where adherence to the items listed in the RAMESES Reporting standards for realist synthesis is prioritised along with the availability of additional materials for external readers to investigate aspects of the review in further detail. The reporting standards were followed and additional material pertaining to the theory development, assessment and selection is available for review in the thesis Appendices.

7.4 Implications for policy and practice

The importance of the implementation of evidence-based policy cannot be underestimated. In the context of a national health system with scarce resource, one may argue that there is an ethical imperative to only commit resources to interventions where there is sound reason to believe that they will bring about effective change (Hawe, 2015). Resources should be targeted towards interventions that target mechanisms that have the most leverage, and away from those which are minimal in their effects. In investigating the interventions that are perceived to be the most (and least) effective for improving insulin prescribing safety nationally, this research provides policymakers with evidence with which to direct efforts. For example, our results would support a move away from the national recommendation and resources directed towards the insulin passport in the UK, in favour of interventions such as pedagogically sound and meaningful insulin safety training for healthcare professionals.

The use and development of theory allows the deeper influences that impact on intervention use and outcomes to be uncovered, rather than focusing on surface-level barriers and facilitators to insulin prescription error reduction in the hospital setting. The wider contextual and human factors are considered to allow policymakers and practitioners to consider the sustainability issues around how interventions work within the wider system prior to implementation and during formal or informal evaluation.

The annual national diabetes inpatient audit (NaDIA) in England and Wales has been used to benchmark and measure improvements in insulin prescribing practice both nationally and locally. Although this study did not include the NaDIA as an intervention *per se*, the use of the NaDIA data for promoting improvements in insulin prescribing may be improved by reports separating insulin errors into insulin prescription errors and insulin administration errors. At present they are reported together, either as insulin errors – incorporating insulin prescription and management errors, or prescription errors – incorporating other types of diabetes medication. Also, as our results show that not all trusts using electronic prescribing do so for subcutaneous insulin, the routine collection of more detailed data on how insulin is prescribed may help to interpret associations between electronic prescribing systems and prescription errors reported in their results.

Our results suggest that the intrinsic motivations of frontline staff to improve insulin prescribing practice are substantial, but limited to what is enabled and prioritised by leadership, both in the trust and wider. This leads to the persuasion that, in keeping with the Health Foundation's position, a combination of both top-down 'extrinsic' and bottom-up 'intrinsic' approaches lead to more sustainable improvements in inpatient insulin prescribing. This needs to involve and engage all members of the healthcare team, not just diabetes specialists in the hospital setting.

With respect to the implications for the use of individual interventions in organisations, recommendations for trusts following consideration of the research results are presented in Table 7.1.

Table 7.1: Recommendations for practice following consideration of the results from the thesis.

Inpatient insulin prescribing practice improvement	All trusts should have a dedicated insulin safety team that comprise a broad membership to facilitate sustainability and spread of interventions. Inclusion of primary care representation would further promote insulin safety efforts and continuity of safe care across the interface.
	All inpatient care teams (with or without specialist diabetes inpatient services) should benefit from the input of a pharmacist to help design, implement and evaluate interventions to improve inpatient insulin prescribing practice.
	The implementation of insulin prescribing safety interventions requires dedicated time and a systems approach across all hospital teams to be effective. These should be designed with generalist staff in mind, to empower non-diabetes specialist staff to make safe decisions with respect to insulin prescribing. This may help relieve the burden of responsibility for insulin safety falling onto specialist diabetes teams, particularly where capacity is an issue.
Prescribing systems	Well-designed prescribing systems (paper or electronic) can help to reduce insulin errors. These should reduce the 'work' of prescribing (e.g. electronic insulin order sets linked to trust formularies, pre-printed paper insulin prescribing charts) and be easily identifiable (coloured paper charts/inclusion of the word 'insulin' next to the product name on the electronic system/avoidance of device/product selection errors).
	Insulin prescriptions should be proximal to readily accessible blood glucose results. Design of electronic systems need to be flexible enough to be able to prescribe insulin appropriately, particularly as safety features (restrictive functions/limits) are not easily applicable to insulin.
	Local guidance regarding insulin prescribing, particularly in special situations (e.g. peri-operative/dose titrations/hyperglycaemia etc.) needs to be up-to-date, brief, easy to follow, and readily available for prescribers.
Care transfer	Availability of current and complete insulin information at the point of care transfer is a problem. The insulin passport has incompatibilities with wider systems and mechanistic flaws in its design and is not supported as an effective intervention.
	Current systems/technology that span the care interface (e.g. the summary care record) should be utilised to include current insulin prescribing information (including doses). Inclusion of a well-staffed pharmacy team at the front door would facilitate the timeliness and accuracy of insulin prescribing and administration at the point of admission.
Education and training	Although mandatory insulin safety training is recommended, brief sessions or training packages completed on induction are unlikely to be effective. Active learning strategies utilising simulated and experiential pedagogies, and individual/group reflection on practise is likely to be more effective. Well-designed, mandatory, repeated e-learning packages that incorporate individual reflection and discussion are alternatives where in-person education is problematic.
Insulin self-administration policies	Most hospitals have the intention of creating and using insulin self-administration policies, but multiple problems arise in the implementation phase, often due to complex socio-cultural issues. A supportive culture is needed to reassure staff that they will not be 'blamed' or 'chastised' if things go wrong. Open and honest communication, a culture of listening to patient's concerns and opinions, and shared decision-making between the nurse and the patient is needed.

	Risk assessments for insulin self-administration need to be simple and quick to complete, prioritising safety over perfection of technique. These should be integrated into existing review processes and documentation to ease the perceived burden on nursing staff time.
	Within-organisation communication and documentation needs to be consistent and reliable, so that patients are empowered to ask about self-administration and get a unified response irrespective of ward/directorate.
	Staff should have a forum to discuss and contribute to policy development/implementation with dedicated project leads to respond quickly to challenges and concerns. Strong supportive professional relationships are needed between diabetes specialists and non-specialists in order to facilitate shared ownership and responsibility for self-administration.

7.5 Future research

Following the consideration and discussion of the key outcomes of this research, as well as the strengths and limitations of the work, research areas that may be proposed for future work could include:

1. Analysis of the experiences and perceptions of foundation doctors and nurses regarding the perceived effectiveness of inpatient insulin prescribing practice interventions in UK hospitals. This could be done nationally (like the present study) or in a bounded case study to triangulate with other data sources (such as local incident reporting analysis and prescribing error data)
2. Assessment of the effectiveness of individual interventions to improve inpatient insulin prescribing practice in a UK hospital setting. This may be achieved using a multi-site bounded case study approach to allow for cross-comparisons.
3. Investigating the overall acceptability of individual insulin prescribing practice interventions using other constructs included in the theoretical framework of acceptability (e.g. burden, intervention coherence). This could be conducted using similar methodology to the present study but incorporating psychometric scale development for these constructs.
4. Investigating the implementation outcomes of individual insulin prescribing practice interventions amongst a larger number of healthcare professionals in a single organisation (e.g. acceptability, adoption, feasibility, sustainability). This may be done using a mixed methods approach.
5. Investigating the challenges and solutions to inpatient insulin prescribing practice and use of interventions in low-and-middle-income countries (LMICs). This could be conducted using similar methodology to the present study, following examination of the individual care systems and context of inpatient diabetes care in the countries of interest.
6. Investigating the perceptions of patients on insulin self-administration using qualitative interview studies and incorporating a diverse sample of patients from different backgrounds. This may allow for the

identification and exploration of patient-factors that may impact the use of insulin self-administration interventions.

7. Further testing and refinement of the insulin self-administration policy programme theories using primary data collection methods within a realist approach. This could be done with realist evaluation using a single or multi-site, mixed methods, bounded case study approach.

7.6 Impact of the research on the researcher

Prior to this research project I had not thought critically or in-depth about the design and implementation of interventions that are used to improve insulin prescribing practice in hospital, despite having been a pharmacist, whose role it is to ensure safe prescribing in this setting for many years. I have grown in my understanding of the various ways that pharmacists work with specialist inpatient diabetes teams to improve patient safety and care for people with diabetes. I have also been encouraged by the increased visibility that pharmacists have in this area amongst the multidisciplinary team, which has been reflected in national guidance and reports that have been published during the conduct of this PhD (Joint British Diabetes Societies for inpatient care, 2019; Rayman & Kar, 2020). I feel more confident and responsible to take a proactive approach to assist in the design, implementation and evaluation of prescribing interventions more generally in the trust. I have also gained valuable experience with using human factors and implementation theories to help approach problem identification and solving for issues wider than insulin prescribing in practice.

Throughout conducting the research it has become increasingly apparent that the work many pharmacists do in hospital goes unpublished. I also feel a responsibility to share my learning in this area to support the conduct and dissemination of good quality practice-based research, both locally in my new trust and working with colleagues further afield. This will help to demonstrate the positive impact pharmacists have on patient care for the ongoing health, growth and standing of our profession. I feel the skills I have learnt during the course of the PhD will benefit me as a pharmacist going forward, and are very relevant to my practice as a hospital pharmacist.

By co-producing work with patients and other members of the inpatient care team, particularly in the realist synthesis, I have also grown in my awareness of the need to be patient-centred, both in research and in practice. Key skills of communication, partnership, shared decision-making and empathy have been developed during the course of this work. Being able to incorporate different viewpoints and value positions into the research agenda was a challenge, but it enabled me to realise how important these skills are to be able to provide good patient care.

7.7 Conclusion

Insulin prescribing is a common but risky process that has the potential to cause unintentional harm to people with diabetes in the hospital setting. The use of effective interventions to improve insulin prescribing quality are needed to reduce harmful and costly insulin errors for people with diabetes in hospital. Prompted by the lack of large-scale quantitative and qualitative research conducted in the UK in this area, this research aimed to investigate inpatient insulin prescribing practice and the current use of interventions designed to prevent insulin prescription errors in UK hospitals.

The research findings indicate that inpatient electronic prescribing use is increasing, but there are significant differences in the functionality of systems to optimise insulin prescribing safety, which may limit the abilities of these systems to prevent errors. Both electronic and paper prescribing systems that reduce prescriber cognitive work and input during the prescribing process are likely to be more effective, such as the use of electronic insulin order sets or pre-printed 'units' and associations of doses with mealtimes. Restrictive functions may also be useful but these are limited for insulin due to the variability in doses and regimens required. Socio-technical factors that should be considered in system design include simple, obvious, accessible prescriber support for insulin prescribing in close proximity to the prescription (e.g. blood glucose results, local hypo/hyperglycaemia management guidelines).

There is a wide variation in the use of recommended strategies to help improve insulin prescribing quality including prescriber education, decision-support tools, and policies. The implementation of nationally recommended strategies varies across hospitals, with only 46% using mandatory training, 31% using the insulin passport and 63% using self-administration policies. Interventions that were desirable and perceived to be effective included mandatory training, outreach team review and self-administration policies. The insulin passport was not perceived to be effective on account of flaws in its design and reliability; results suggest that efforts should be directed away from the passport and towards the optimisation of other systems such as summary care records to improve information transfer on admission to hospital.

The implementation of interventions relies on a combination of personal, organisational and socio-cultural factors, such as staff turnover, availability and capacity of diabetes and pharmacy teams, hierarchy, fear, and perceived burden of interventions. This suggests that a multifactorial strategy is needed to prevent insulin prescription errors, including both bottom-up and top-down approaches. With respect to insulin self-administration policies, the creation of programme theories enabled the circumstances in which these are likely to succeed was unearthed. These included promoting shared decision-making and more even power dynamics, simple documentation and integration with current workflow and systems, and the presence of a dedicated project lead to ensure consistent implementation and messages given to patients across the organisation.

With the use of systematic review, mixed methods and realist synthesis methods, this body of work extends our knowledge and understanding of current insulin prescribing practice and intervention use across NHS hospitals in the UK. The research has resulted in a comprehensive review of the evidence for such interventions, determined current intervention use and perceived effectiveness in UK hospitals, highlighted the current challenges and solutions to insulin prescribing practice improvement and has produced programme theories regarding how insulin self-administration policy interventions work, for whom and in what circumstances. The application of middle-range theories and a human factors systems model will enable practitioners and policymakers to design, implement and evaluate interventions in a more evidence-informed and contextually sensitive way, which is especially important in the climate of restricted resources and capacity. The use of a participatory health research approach enabled the research to be designed and interpreted with its end-users throughout; this resulted in increased relevance and impact, and enabled a greater degree of reflexivity from the researcher.

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Appendices

Appendix 1: PRISMA checklist

Section/topic	#	Checklist item
TITLE		
Title	1	Identify the report as a systematic review, meta-analysis, or both.
ABSTRACT		
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.
INTRODUCTION		
Rationale	3	Describe the rationale for the review in the context of what is already known.
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).
METHODS		
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g. Web address), and, if available, provide registration information including registration number.
Eligibility criteria	6	Specify study characteristics (e.g. PICOS, length of follow-up) and report characteristics (e.g. years considered, language, publication status) used as criteria for eligibility, giving rationale.
Information sources	7	Describe all information sources (e.g. databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.
Study selection	9	State the process for selecting studies (i.e. screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).
Data collection process	10	Describe method of data extraction from reports (e.g. piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.
Data items	11	List and define all variables for which data were sought (e.g. PICOS, funding sources) and any assumptions and simplifications made.
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.
Summary measures	13	State the principal summary measures (e.g. risk ratio, difference in means).
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g. I^2) for each meta-analysis.
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g. publication bias, selective reporting within studies).

Additional analyses	16	Describe methods of additional analyses (e.g. sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.
RESULTS		
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g. study size, PICOS, follow-up period) and provide the citations.
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).
Additional analysis	23	Give results of additional analyses, if done (e.g. sensitivity or subgroup analyses, meta-regression [see Item 16]).
DISCUSSION		
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g. healthcare providers, users, and policy makers).
Limitations	25	Discuss limitations at study and outcome level (e.g. risk of bias), and at review-level (e.g. incomplete retrieval of identified research, reporting bias).
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.
FUNDING		
Funding	27	Describe sources of funding for the systematic review and other support (e.g. supply of data); role of funders for the systematic review.

Appendix 2: Details of excluded studies (systematic review)

Excluded article	**Reason**
Arif, Sally A., and Alisa K. Escaño. "Barriers to Implementing an Insulin Order Form in a Non-ICU Medical Unit." *P and T*, vol. 35, no. 1, 2010, pp. 30-42.	No comparative/before data for prescribing
Breuker, Cyril, et al. "Patients with Diabetes are at High Risk of Serious Medication Errors at Hospital: Interest of Clinical Pharmacist Intervention to Improve Healthcare." *European Journal of Internal Medicine*, vol. 38, 2016;2017;, pp. 38-45.	No data regarding prescribing of insulin
Cani, Catarina G., et al. "Improvement in Medication Adherence and Self-Management of Diabetes with a Clinical Pharmacy Program: A Randomized Controlled Trial in Patients with Type 2 Diabetes Undergoing Insulin Therapy at a Teaching Hospital." *Clinics (Sao Paulo, Brazil)*, vol. 70, no. 2, 2015, pp. 102-106.	Outpatient setting
Carey, Nicola, et al. "An Evaluation of a Diabetes Specialist Nurse Prescriber on the System of Delivering Medicines to Patients with Diabetes." *Journal of Clinical Nursing*, vol. 17, no. 12, 2008, pp. 1635-1644.	Pilot study for which results later published
Chen, Helen J., et al. "Intensive Insulin Protocol Implementation and Outcomes in the Medical and Surgical Wards at a Veterans Affairs Medical Center." *The Annals of Pharmacotherapy*, vol. 44, no. 2, 2010, pp. 249-256.	No data regarding prescribing of insulin
Cheung, N. W., et al. "Implementation of a Dedicated Hospital Subcutaneous Insulin Prescription Chart: Effect on Glycaemic Control." *Diabetes Research and Clinical Practice*, vol. 92, no. 3, 2011, pp. 337-341.	Does not measure adherence to guidelines
Clemens, Evan, et al. "Prescriber Compliance with a New Computerized Insulin Guideline for Noncritically Ill Adults." *Annals of Pharmacotherapy*, vol. 45, no. 2, 2011, pp. 154-161.	No comparative/before data for prescribing
Conn, Jennifer J., Agnes E. Dodds, and Peter G. Colman. "The Transition from Knowing to Doing: Teaching Junior Doctors how to use Insulin in the Management of Diabetes Mellitus."*Medical Education*, vol. 37, no. 8, 2003, pp. 689-694.	Measures post-test knowledge, no prescribing data
Singh A, Adams A, Dudley B, et al Making surgical wards safer for patients with diabetes: reducing hypoglycaemia and insulin errors BMJ Open Qual 2018;7:e000312. doi: 10.1136/bmjoq-2017-000312	Insulin management errors rather than prescribing errors
Sinha, Gregory, Naina, et al. *Decreased Rates of Hypoglycemia Following Implementation of a Comprehensive Computerized Insulin Order Set and*	No data regarding prescribing of insulin

Titration Algorithm in the Inpatient Setting. vol. 44, , England, 2016, doi:10.1080/21548331.2016.1250603.	
Hamid, Tahir, et al. "Prescription Errors in the National Health Services, Time to Change Practice." *Scottish Medical Journal*, vol. 61, no. 1, 2016, pp. 1-6	Does not exclusively target insulin
Harada, Saki, et al. "Reduction of Medication Errors Related to Sliding Scale Insulin by the Introduction of a Standardized Order Sheet." *Journal of Evaluation in Clinical Practice*, vol. 23, no. 3, 2017, pp. 582-585.	Data regarding insulin administration and communication errors
Heatlie, Jeanne M. "Reducing Insulin Medication Errors: Evaluation of a Quality Improvement Initiative." *Journal for Nurses in Staff Development (JNSD)*, vol. 19, no. 2, 2003, pp. 92-98.	No data regarding prescribing of insulin
Helmle, Karmon E., et al. "Qualitative Evaluation of the Barriers and Facilitators Influencing the use of an Electronic Basal Bolus Insulin Therapy Protocol to Improve the Care of Adult Inpatients with Diabetes." *Canadian Journal of Diabetes*, vol. 42, no. 5, 2018, pp. 459-464.e1.	Qualitative data only
Herring, R., et al. "Can an Interprofessional Education Tool Improve Healthcare Professional Confidence, Knowledge and Quality of Inpatient Diabetes Care: A Pilot Study?" *Diabetic Medicine*, vol. 30, no. 7, 2013, pp. 864-870.	Unclear outcome data with respect to prescribing
Hodges, Angela, et al. *Implementing a Pharmacist Consultation Model for Multimodal Insulin Therapy.* vol. 74, , England, 2017, doi:10.2146/ajhp150941.	No data regarding prescribing of insulin
Khalil, Viviane, et al. "Antidiabetics' Usage in Type 2 Diabetes Mellitus: Are Prescribing Guidelines Adhered to? A Single Centre Study." *Diabetes & Metabolic Syndrome: Clinical Research & Reviews*, vol. 12, no. 5, 2018, pp. 635-641.	Does not address insulin prescribing
Kopanz, Julia, et al. "Limited Documentation and Treatment Quality of Glycemic Inpatient Care in Relation to Structural Deficits of Heterogeneous Insulin Charts at a Large University Hospital." *Journal of Patient Safety*, 2018, pp. 1.	No intervention
Lee, JaeHo, et al. "Impact of a Clinical Decision Support System for High-Alert Medications on the Prevention of Prescription Errors." *International Journal of Medical Informatics*, vol. 83, no. 12, 2014, pp. 929-940.	Does not exclusively target insulin
Mader, J. K., et al. "Efficacy, Usability and Sequence of Operations of a workflow-integrated Algorithm for basal–bolus Insulin Therapy in Hospitalized Type 2 Diabetes Patients."*Diabetes, Obesity and Metabolism*, vol. 16, no. 2, 2014, pp. 137-146.	Does not measure adherence to guidelines

Monroe, P. S., Wendy D. Heck, and Stacey M. Lavsa. "Changes to Medication-use Processes After Overdose of U-500 Regular Insulin." *American Journal of Health-System Pharmacy*, vol. 69, no. 23, 2012, pp. 2089-2093.	Case study, no data presented
Murphy, Donna M., et al. "Reducing Hyperglycemia Hospitalwide: The Basal-Bolus Concept."*Joint Commission Journal on Quality and Patient Safety*, vol. 35, no. 4, 2009, pp. 216-223.	No data regarding prescribing of insulin
Najjar, Muath F., et al. "The Impact of a Combined Intervention Program: An Educational and Clinical Pharmacist's Intervention to Improve Prescribing Pattern in Hospitalized Geriatric Patients at King Abdulaziz Medical City in Riyadh, Saudi Arabia." *Therapeutics and Clinical Risk Management*, vol. 14, 2018, pp. 557-564.	Concerns intravenous (IV) insulin infusions
Neubauer, Katharina M., et al. "Standardized Glycemic Management with a Computerized Workflow and Decision Support System for Hospitalized Patients with Type 2 Diabetes on Different Wards." *Diabetes Technology & Therapeutics*, vol. 17, no. 10, 2015, pp. 685-692.	No comparative/before data for prescribing
Poppy, Amy, et al. "Reduction of Insulin Related Preventable Severe Hypoglycemic Events in Hospitalized Children." *Pediatrics*, vol. 138, no. 1, 2016, pp. e20151404-e20151404.	Does not measure adherence to guidelines
Rozich, John D., et al. "Standardization as a Mechanism to Improve Safety in Health Care."*The Joint Commission Journal on Quality and Safety*, vol. 30, no. 1, 2004, pp. 5-14.	No data regarding prescribing of insulin
Wong, Bertha, MD, Mamdani, Muhammad M., PharmD, MPH, and Yu, Catherine H., MD, MHSc. "Computerized Insulin Order Sets and Glycemic Control in Hospitalized Patients."*American Journal of Medicine, the*, vol. 130, no. 3, 2016, pp. 366.e1-366.e6.	No comparative/before data for prescribing
Yong, Alice, Eileen Power, and Geoffrey Gill. "Improving Glycaemic Control of insulin-treated Diabetic Patients – a Structured Audit of Specialist Nurse Intervention." *Journal of Clinical Nursing*, vol. 11, no. 6, 2002, pp. 773-776.	Outpatient setting
Yu, Catherine H.Y., MD, MHSc, et al. "Insulin Order Sets Improve Glycemic Control and Processes of Care." *American Journal of Medicine, the*, vol. 125, no. 9, 2012, pp. 922-928.e4.	No comparative/before data for prescribing
Zhao, Rui-Yi, et al. "A Stewardship Intervention Program for Safe Medication Management and use of Antidiabetic Drugs." *Clinical Interventions in Aging*, vol. 10, 2015, pp. 1201-1212.	No comparative/before data for prescribing

Appendix 3: Risk of Bias and Quality Assessments (Systematic review)

QI-MQCS

Study	Organisational motivation	Intervention rationale	intervention description	Organisational characteristics	Implementation	Study design	Comparator	Data source	Timing	Adherence/ fidelity	Health outcomes	Organisational readiness	Penetration/ reach	Sustainability	Spread	Limitations
Achtmeyer 2002	0	1	1	1	1	1	1	1	1	1	0	0	0	0	0	1
Al-Yassin 2013	0	1	1	0	1	1	0	1	1	1	1	0	1	0	1	1
Courtneay 2007	0	1	1	1	1	1	1	1	1	0	0	0	0	1	0	1
Donihi 2006	1	0	1	1	0	1	1	1	1	1	1	0	0	0	0	0
Dooley 2011	1	1	1	1	1	1	0	1	1	1	0	1	1	1	1	1
Donsa 2016	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	0
Doyle 2014	0	1	1	0	1	1	1	1	1	1	1	0	0	0	0	1
Ena 2009	1	0	1	1	1	1	1	1	1	0	1	0	1	0	0	1
Gomez-Huelgas 2014	0	1	1	1	1	1	1	1	1	0	1	0	1	0	1	1
Guerra 2010	0	1	1	1	1	1	0	1	1	1	1	0	1	1	1	1
Hamilton 2013	1	1	1	0	1	1	1	1	1	1	0	0	1	1	0	0
Harbin 2015	0	1	1	0	0	1	1	1	1	1	1	0	0	0	1	1
Helmle 2017	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Horton 2015	0	0	0	0	0	1	0	1	1	0	1	0	0	0	0	1
Kowiatek 2001	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	0
Lehnbom 2009	1	0	1	1	1	1	0	1	1	0	1	0	1	0	1	1
Mamillapalli 2012	1	0	1	0	1	1	0	1	1	0	1	0	1	1	1	0
Maynard 2009	0	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1
McIver 2009	0	1	1	0	1	1	0	1	1	0	1	0	1	1	1	1
Mulla 2015	0	1	0	0	1	0	0	1	1	0	1	1	1	0	1	0
Newsom 2018	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Noschese 2008	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1
Rushmer 2008	1	1	1	1	1	1	0	1	1	0	0	1	1	1	1	1

Schnipper 2009	0	1	1	1	1	1	0	1	1	0	1	0	0	0	0	1
Schnipper 2010	0	1	1	0	1	1	1	1	1	1	1	0	0	1	1	1
Taylor 2012	0	1	1	0	1	1	0	1	1	1	1	0	0	0	1	0
Thompson 2009	1	0	1	1	1	1	0	1	1	0	1	0	0	0	0	1
Trujillo 2008	0	1	1	1	1	1	0	1	1	1	1	0	1	1	1	1
Tully 2018	1	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1
Vaidya 2012	0	0	1	0	1	1	0	1	1	1	1	0	1	0	0	1
Valgardson 2015	1	0	1	1	0	1	0	1	1	1	1	1	1	0	0	1
Wesorick 2010	0	1	1	0	1	1	1	1	1	1	1	0	0	0	0	1
Wexler 2010	0	1	1	0	1	1	1	1	1	0	1	0	0	0	0	0
Wong 2016	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Yeung 2018	1	1	1	0	0	1	1	1	1	0	1	1	1	1	0	1

Cochrane Risk of Bias

Study	Study design	Sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective outcome reports	Other issues
Schnipper 2010	Cluster RCT, single site (n=179 patients)	Unclear risk. "Two of the 4 GMS teams were randomly chosen to receive the intervention"	Unclear risk	High risk	High risk	Low risk	Low risk	High risk. Use of the intervention was optional.
Wexler 2010	Cluster RCT (n=128 patients)	Low risk. "Using a computerised coin toss, we randomly assigned seven teams of providers (42 internal medicine residents)..."	Unclear risk	High risk	High risk	Low risk	Low risk	High risk. Use of the intervention was optional.

Newcastle-Ottowa Scale

	Selection				Comparability		Outcome		
Study	**Representativeness of exposed cohort**	**Selection of non-exposed cohort**	**Ascertainment of exposure**	**Demonstration that outcome of interest was not present at study start**	**Study control for most important confounder**	**Study controls for any additional factor**	**Assessment of outcome**	**Follow-up long enough to capture outcomes**	**Adequacy of follow-up cohorts**
Achtmeyer 2002	*	NA	*	*	*	NA	*	*	*
Al-Yassin 2013	*	NA	*	*	NA	NA	*	*	*
Courtneay 2007	*	*	*	*	NA	NA	*	*	*
Donihi 2006	*	*	*	*	NA	NA	*	*	*
Dooley 2011	*	NA	*	*			*	*	*
Donsa 2016		NA	*	*		NA	*	*	*
Doyle 2014	*	NA	*	*	NA		*	*	*
Ena 2009		NA	*	*		NA	*	*	*
Gomez-Huelgas 2014	*	NA	*	*	*	*	*	*	*
Guerra 2010	*	NA	*	*	*	*	*	*	*
Hamilton 2013	*	*	*	*			*	*	*
Harbin 2015	*	*	*	*	*	*	*	*	*
Helmle 2017	*	*	*	*	*	*	*	*	*
Horton 2015	*	*		*			*	*	*
Kowiatek 2001	*	*		*				*	*
Lehnbom 2009	*	*	*	*	*	*	*	*	*
Mamillapalli 2012			*	*			*	*	*
Maynard 2009	*	*	*	*			*	*	*

McIver 2009	*	*	*	*			*	*	*
Mulla 2015	*	*	*	*			*	*	*
Newsom 2018	*		*	*	*		*	*	*
Noschese 2008	*	*	*	*	*	*	*		*
Rushmer 2008			*	*			*	*	*
Schnipper 2009			*	*	*	*	*	*	*
Taylor 2012	*	*	*	*			*	*	*
Thompson 2009	*	*	*	*			*		*
Trujillo 2008			*	*			*	*	*
Tully 2018	*	*	*	*			*		*
Vaidya 2012	*	*	*	*			*		*
Valgardson 2015			*	*			*	*	*
Wesorick 2010	*	*	*	*			*	*	*
Wong 2016	*	*	*	*			*	*	*
Yeung 2018			*	*			*	*	*

National survey of insulin prescribing in UK NHS hospitals

We are conducting a cross-sectional survey that aims to describe how insulin is currently prescribed for inpatients in National Health Service hospitals throughout the United Kingdom.

Despite various measures to help improve insulin safety, medication errors involving insulin remain a problem. Your valuable responses will help us to understand how to focus efforts to improve insulin prescribing safety and reduce insulin errors.

Please answer the following questions to the best of your ability and as fully as possible. Feel free to ask colleagues for help as appropriate. Any information you provide will remain strictly confidential.

If you are answering on behalf of a Hospital Trust in England, please answer according to the **main acute hospital** in the Trust. The survey should take approximately **15 minutes** to complete. Please send your completed survey back to us using the pre-paid envelope provided by **Thursday 31st January 2019.**

Once the survey is complete, a copy of the results will be sent to you as a token of our appreciation.

If you have any questions about this survey, or require any help, please do not hesitate to contact the research team lead, Amie Bain, at a.bain@hud.ac.uk

THANK YOU for your time and for contributing to this valuable piece of work

Section A About your hospital

Please answer the following questions about your hospital.

1. Where in the UK is your hospital situated? *(please circle one)*

   England Wales Scotland Northern Ireland

2. How would you best describe the hospital you work in? *(please circle one)*

   Teaching Hospital District General Hospital Community Hospital

   Other (please state): _____

3. How many inpatient beds does your hospital have? *(please circle one)*

   <200 200-500 501-1000 >1000

	YES	NO	Unsure
4. Does your hospital provide specialist diabetes services?	☐	☐	☐
5. Is there currently a specialist diabetes pharmacist in post?	☐	☐	☐

6. Please describe the grade/role and full-time equivalent (FTE) of the pharmacist(s) overseeing diabetes care
   (e.g. 1 band 8a diabetes specialist pharmacist 0.5FTE, 2 band 7 medicine pharmacists both 1 FTE)

   _____

	☐	☐	☐
7. Are there current, local hypoglycaemia guidelines in use?			
8. Are there current, local hyperglycaemia guidelines in use?	☐	☐	☐
9. Is inpatient electronic prescribing used at your hospital?	☐	☐	☐
10. Is subcutaneous insulin prescribed electronically for inpatients?	☐	☐	☐

*If you answered **YES** to **question 10**, please go to **Section B***
*If you answered **NO** to **question 10**, please go to **Section C***
*If your hospital currently has both electronic **AND** non-electronic prescribing of insulin, please complete **both sections B and C***

Section B Electronic prescribing of subcutaneous insulin

11. How long has subcutaneous insulin been prescribed electronically at the hospital? *(please circle one)*

<1 year 1-2 years 3-5 years >5 years not sure

Please indicate if any of the following are currently used in the <u>electronic prescribing of subcutaneous insulin</u> at your hospital *(please tick one box per question)*

	YES	NO	Unsure
12. Electronic prescribing system integrated with medicines administration record system	☐	☐	☐
13. Electronic prescribing system integrated with electronic medical record	☐	☐	☐
14. Electronic prescribing system linked to electronic blood glucose results	☐	☐	☐
15. Electronic prescribing system linked to the pharmacy dispensing software	☐	☐	☐
16. Electronic prescribing system linked to the discharge/transfer summary	☐	☐	☐
17. Mandatory selection of 'units' (as opposed to u, iu, mg, ml)	☐	☐	☐
18. Function to check that the insulin dose is in a 'normal' range	☐	☐	☐
19. Alerts for when insulin is prescribed at particularly high doses	☐	☐	☐
20. Alerts to notify prescriber when a concentrated insulin product is selected	☐	☐	☐
21. Dropdown or auto fill menu selection for insulin product(s)	☐	☐	☐
22. Ability to specify insulin device (e.g. vial, pen-fill, disposable pen)	☐	☐	☐
23. 'Free-typing' insulin product names for insulin prescribing	☐	☐	☐
24. Ability to select mealtimes instead of clock times for dosing	☐	☐	☐
25. Insulin order sets*	☐	☐	☐
26. Function to automatically calculate correctional insulin doses for hyperglycaemia	☐	☐	☐
27. Ability to prescribe variable doses/dose range(s) (e.g. for patients who dose-adjust according to carbohydrate intake)	☐	☐	☐
28. Ability to signpost for self-administration and/or self-management with insulin	☐	☐	☐
29. Electronic prescribing of insulin pumps (continuous subcutaneous insulin infusions)	☐	☐	☐
30. Electronic system linked to results from remote blood glucose testing	☐	☐	☐

** Automatic population of additional required or supplementary information on electronic prescription (e.g. type of insulin, meal association etc.)*

Section C Non-electronic prescribing of subcutaneous insulin

Please indicate if any of the following are currently used in the non-electronic prescribing of subcutaneous insulin at your hospital *(please tick one box per question)*

	YES	NO	Unsure
31. Dedicated subcutaneous insulin prescription chart	☐	☐	☐
32. Dedicated subcutaneous insulin prescription chart incorporating a blood glucose monitoring section	☐	☐	☐
33. Dedicated subcutaneous insulin prescription chart incorporating a blood glucose monitoring section **AND** management guidelines?	☐	☐	☐
34. Pre-written 'units' to minimise the use of alternatives (e.g. u, iu, mg, ml)	☐	☐	☐

	YES	NO	Unsure
35. Mealtimes specified rather than clock-times	☐	☐	☐
36. Device specified (e.g. prescribers may select from pre-printed devices)	☐	☐	☐
37. Dedicated subcutaneous insulin prescription chart incorporating a section for STAT doses of insulin	☐	☐	☐
38. Ability to prescribe variable doses/dose range(s) (e.g. for patients who dose-adjust according to carbohydrate intake)	☐	☐	☐
39. Dedicated chart for prescription of insulin pumps (continuous subcutaneous insulin infusions)	☐	☐	☐
40. Electronic system linked to results from remote blood glucose testing	☐	☐	☐
41. Does the hospital intend to prescribe subcutaneous insulin electronically in the near future?	☐	☐	☐

*Please continue on to **Section D***

Section D Other insulin prescribing interventions

Please indicate if any of the following are used in your hospital *(please tick one box per question)*

	YES	NO	Unsure
42. Additional requirements for medicines reconciliation of insulin on admission*	☐	☐	☐
43. Insulin passport	☐	☐	☐
44. Use of patient's own insulin on admission to hospital	☐	☐	☐
45. Insulin self-administration policy	☐	☐	☐
46. Insulin self-management policy	☐	☐	☐
47. Formulary limitations on numbers of insulins able to be prescribed	☐	☐	☐
48. Limitations on number of insulins/devices available to order as ward stock	☐	☐	☐
49. Dedicated insulin order form (i.e. if transcription required to dispense insulin)	☐	☐	☐
50. Restrictions on ordering of concentrated (200-500 units/ml) insulin (e.g. restricted policy/extra checks required before dispensing)	☐	☐	☐
51. Additional validation of 'high doses' of prescribed insulin before dispensing (e.g. over 50 units)	☐	☐	☐
52. Tallman lettering on insulin prescriptions (electronic or paper)	☐	☐	☐
53. Specific requirements for medicines reconciliation of insulin on discharge*	☐	☐	☐
54. Nursing double-check of insulin prescriptions on discharge	☐	☐	☐
55. Insulin discharge checklists	☐	☐	☐
Pocket-sized guideline cards	☐	☐	☐
56. Algorithm for calculating correctional insulin doses for hyperglycaemia	☐	☐	☐
57. Mandatory insulin safety education for clinical staff **on induction**	☐	☐	☐
58. Mandatory **repeat/booster** insulin safety education for clinical staff	☐	☐	☐
59. Outreach team review of patients with hypo/hyperglycaemia (e.g. in conjunction with remote blood glucose monitoring)	☐	☐	☐
60. Local policies/recommendations addressing the use of biosimilar insulins	☐	☐	☐

**Such as insulin administration and monitoring arrangements, management plans, recent dose/device changes, details of last dose given etc.*

61. If your hospital currently uses other interventions or strategies (not listed above) to improve insulin prescribing safety, please describe them below:

_____

_____

_____

_____

_____

*Please continue on to **Section E***

Section E Effectiveness of insulin prescribing interventions

How effective do you think the following interventions are (or could be) for promoting insulin safety at your hospital? *Please give your answer on a scale of 1 to 5, with 1 being not effective and 5 being very effective.*

	Not effective				*Very effective*
	1	2	3	4	5
62. Electronic prescribing of subcutaneous insulin	☐	☐	☐	☐	☐
63. Dedicated subcutaneous insulin prescription chart	☐	☐	☐	☐	☐
64. Local hypoglycaemia guidelines	☐	☐	☐	☐	☐
65. local hyperglycaemia guidelines	☐	☐	☐	☐	☐
66. Specific requirements for medicines reconciliation of insulin on admission*	☐	☐	☐	☐	☐
67. Insulin passport	☐	☐	☐	☐	☐
68. Use of patient's own insulin on admission to hospital	☐	☐	☐	☐	☐
69. Insulin self-administration policy	☐	☐	☐	☐	☐
70. Insulin self-management policy	☐	☐	☐	☐	☐

**Such as pre-admission insulin administration and monitoring arrangements, management plans, recent dose/device changes, details of last dose given etc.*

	Not effective				*Very effective*
	1	2	3	4	5
71. Formulary limitations on numbers of insulins able to be prescribed	☐	☐	☐	☐	☐
72. Limitations on number of insulins/devices available to order as ward stock	☐	☐	☐	☐	☐

73. Dedicated insulin order form (i.e. if transcription required to dispense insulin)
74. Restrictions on ordering of concentrated (200-500 units/ml) insulin
75. Additional validation of 'high doses' of prescribed insulin before dispensing (e.g. over 50 units)
76. Tallman lettering on insulin prescriptions
77. Specific requirements for medicines reconciliation of insulin on discharge*
78. Nursing double-check of insulin prescriptions on discharge
79. Insulin discharge checklists
80. Pocket-sized guideline cards
81. Algorithm for calculating correctional insulin doses for hyperglycaemia
82. Mandatory insulin safety education for clinical staff
83. Outreach team review of patients with hypo/hyperglycaemia (e.g. who have been flagged by an electronic system linked to remote blood glucose monitoring)

**Such as post-discharge insulin administration and monitoring arrangements, recent dose or device changes, diabetes management care plans.*

84. If you described any other insulin safety measures at your hospital in **Q62**, please comment on their effectiveness below

	Not effective 1	2	3	4	*Very effective* 5
_____	☐	☐	☐	☐	☐
_____	☐	☐	☐	☐	☐
_____	☐	☐	☐	☐	☐
_____	☐	☐	☐	☐	☐

End of Questions

You are welcome to enclose anonymised copies of your hospital's insulin prescribing charts or educational materials should you wish to. These may be included in the published report as appendices.

If you are enclosing any additional documentation with this survey, please tick here ☐

Thank you for completing this survey

Your valuable responses will help inform evidence-based strategies to improve insulin safety in hospital.

If you are interested in being involved in the next stage of our research, which will seek to further explore insulin prescribing safety in hospital, please provide your details below:

Name:

Role/position:

Hospital:

Email address:

This page will be removed by the administration team prior to data analysis.

***Providing your details will not compromise the anonymity of your responses**. Your expression of interest information will be transferred to the research team once the survey has been completed. If you wish to withdraw your interest at any point, please let us know via email (a.bain@hud.ac.uk).*

Thank you.

Thank you again for your participation in this survey.

Please return your completed survey to the research team using the prepaid self-addressed envelope provided by **Thursday 31st January 2019.**

Appendix 5: Accompanying letter to cross-sectional survey

Mrs Amie Bain
School of Applied Sciences
University of Huddersfield
HD1 3DH
Email: a.bain@hud.ac.uk
Tel: 01484 471476

10th January 2019

Dear

You are invited to participate in a national survey regarding the prescribing of subcutaneous insulin in hospital. The study is being conducted by a team of researchers at the University of Huddersfield, which includes undergraduate MPharm students, and has been approved by the University's Research Ethics Committee (REF: SAS-SREIC 4.1.19-3).

The purpose of the study is to describe how insulin is currently prescribed in hospitals across the United Kingdom, along with any measures taken to improve insulin prescribing safety. Your participation in the survey will help us to better understand how to focus efforts to improve insulin prescribing for inpatients with diabetes. This is particularly pertinent following both the 2017 WHO Global Patient Safety Challenge on Medication Safety and National Inpatient Diabetes Audit (NaDIA) report, which urges hospitals to take measures to considerably reduce insulin errors.

We have contacted you as either the chief pharmacist, pharmacy manager or specialist diabetes pharmacist for your hospital. If you feel there is a more suitable member of the team to complete this survey on behalf of your hospital please feel free to redirect accordingly. We estimate that it will take about **15 minutes** of your time to complete the survey.

Your participation in the survey is voluntary. You may decline to answer any question you wish and you have the right to withdraw from participation at any time. Please feel free to contact us at the above address if you would like to discuss the survey further.

Responses given in this survey are anonymous and will remain confidential. Identification codes included on the self-addressed envelopes will be kept by a member of the university administration team during the data collection phase for tracking and follow-up purposes only.

If you agree to participate please complete the attached survey and post it back to us using the included pre-paid envelope by **Thursday 31st January 2019**.

Thank you for your valuable time in helping us with this important work.

Yours sincerely

Amie Bain

Academic Practitioner, University of Huddersfield/Sheffield Teaching Hospitals NHS Foundation Trust

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NHS Foundation Trust

Appendix 6: Email invitation to participate in telephone interviews

Dear _____

Thank you for expressing interest in our research, which aims to explore insulin prescribing safety in hospitals across the UK. Your participation in the National Insulin Prescribing Survey earlier this year was very much appreciated; the report is currently undergoing peer-review and we will send you a copy as soon as it is published.

We would like to invite you to participate in a short, semi-structured telephone interview in order to further explore some of the results from the survey. More information is included in the attached information sheet, but briefly, we would like to talk about the following topics:

- Your experiences and opinions regarding insulin prescribing safety strategies at your hospital.
- The impact of any strategies on insulin errors and patient experience.
- Challenges and possible solutions to the safe prescribing of insulin in hospital.

If, after reading the attached information sheet, you would like to participate, please reply to this email and we can arrange a suitable time to call. We would love to hear from you – your responses are really valuable in helping to shape future strategies and interventions to help achieve safer use of insulin in hospital. If you have any questions, please do not hesitate to get in contact.

We look forward to hearing from you soon.

Best wishes,

Amie Bain

Appendix 7: Participant information sheet for telephone interviews

Improving the safety of insulin prescribing in hospital

Information sheet for participants

Introduction

We would like to invite you to participate in this project, which is concerned with the safe prescribing of insulin for people with diabetes in hospital. We are interested in exploring the challenges and solutions with respect to safe insulin prescribing at different hospitals throughout the United Kingdom. Please read the following information before deciding to participate in this study.

Why am I doing this project?

Despite various interventions to help improve insulin prescribing safety, insulin errors persist. The 2017 National Diabetes Inpatient Audit showed that 4 in 10 patients using insulin experience an insulin error, and urged pharmacy teams to work with diabetes teams to support the safe use of insulin in hospital.

As part of this project, people who responded to the National Insulin Prescribing Survey earlier on this year will be invited to participate in a telephone interview with the lead researcher and pharmacist, Amie Bain. These interviews aim to explore some of the results of the survey, and will be audio-recorded and the information will be transcribed and analysed and the results published for wider dissemination. This study forms part of a PhD project at the University of Huddersfield and Sheffield Teaching Hospitals NHS Foundation Trust and has had ethical approval from the university (ref: SAS-SREIC 12.7.19-1).

What will you have to do if you agree to take part?

Your consent to take part will mean the following will happen:

We will arrange a time when we can talk over the phone about your experience of insulin prescribing at your hospital. This should take around 30 minutes and will be at a time that is convenient to you.

The interview will be semi-structured with open questions designed to facilitate an in-depth discussion. I am particularly interested in discussing the following, although we can talk through any related topics that are important to you:

- Your experiences and opinions regarding insulin prescribing safety strategies at your hospital.
- The impact of any strategies on insulin errors and patient experience.
- Challenges and possible solutions to the safe prescribing of insulin in hospital.

Will your participation in this project remain confidential?

All identifiable information about yourself or your organisation will not be transcribed or disclosed to third parties. Your responses will remain anonymous and used for the purposes of this project only. Transcribed information will remain secure on a password-protected networked computer at the university, accessible only to myself.

What are the advantages of taking part?

This interview will help explore the current challenges and solutions to the safe use of insulin in hospital. The results from this study could inform strategies to improve insulin prescribing in hospitals across the country. The interview process may also help facilitate reflection on related issues affecting your organisation locally.

Are there any disadvantages to taking part?

You may not feel comfortable talking about current practices or your experiences at your hospital, but you can be assured that any data will remain fully anonymised.

Do you have to take part in the study?

Participation in this study is completely voluntary, and you can withdraw at any point should you wish to do so.

What happens now?

If you are interested in being interviewed, please reply to the email from Amie Bain (a.bain@hud.ac.uk) and we can arrange a phone call at a time convenient for you - my intention is to not impede on your working day so I can be as flexible as possible. Feel free to ask any questions you may have. You can contact me (Amie) or another member of the research team as detailed below.

Thank you once again for your help with this important work.

Contact details:

Lead Researcher:
Amie Bain
School of Applied Sciences
University of Huddersfield
Queensgate
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HD1 3DH
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Appendix 8: Transcription Notation system

Feature	Notation and explanation of use
The identity of the speaker	The speaker's pseudonym or role, followed by a colon, or with their speech on the following line. E.g: Interviewer Hello, how are you? Or Interviewer: how are you? Where one person is mid-way through a phrase and the other verbally signals agreement or similar, this is included in parenthesis and italics with a colon after the speaker's name in the text. E.g.: P1 Don't you think, yeah *(interviewer: yeah)* that it happens this way because
Laughing	(laughs) signals a speaker laughing during their turn of talk
Reported speech	Where the interviewer or participant is quoting themselves or someone else in their phrase, this is indicated with speech marks. E.g.: she said "why not, it's only a biscuit?" when I started in the role I said "do we use these?"
Pausing	(pauses) signals a significant pause (a few seconds or longer).
Spoken abbreviations	Abbreviations are included as given (e.g. DKA) but abbreviations will not be included unless a participant does so.
Inaudible	(inaudible) used where speech and sounds are inaudible on the audio. Where the phrase is uncertain, use a question mark before it is written in parenthesis (e.g. (?abasaglar))
Non-verbal utterances	Common non-verbal sounds such as 'erm' 'mm' 'uhuh' will not be included unless it is deemed critical to interpret the phrase.

Spoken numbers	All spoken numbers are spelled out rather than using numerals. The exception to this is when referring to job titles e.g. FY1 doctor, years e.g. in 2012, or paper sizes e.g. on an A4 sheet of paper.
Emphasis on particular words	Emphasis is indicated by italicising words in the transcript (e.g. I think it really *is* a waste of time)
Expression	Where phrases are said in an expressive way, this is indicated by the use of exclamation marks as would be in written text. E.g. Interviewer Absolutely, I bet!
Identifying information	Where information has been redacted or replaced due to anonymity this is presented in brackets (e.g. I worked at [Hospital A] for 5 years with [person A] where [details redacted due to confidentiality])
Accents, abbreviations, mispronunciation	Participants' speech will be as closely represented as possible and not 'corrected' in the transcript to correct pronunciation or 'standard English'.
Cut-off sounds	The phonetic sounds heard will be transcribed followed by a dash (e.g. I went to eat my breakf- oh, I forgot to mention)
Non-transcription of sections of data	Denoted by the use of three full-stops (…)

Appendix 9: STROBE Checklist of items that should be included in reports of cross-sectional studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram

Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
Outcome data	15*	Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for exposed and unexposed groups.

Appendix 10: Semi-structured telephone interview guide

Improving the safety of insulin prescribing in hospital

Semi-structured telephone interview

Start of interview

- Introduce yourself and thank for participation
- Explain reason for interview – *to explore your opinions and experiences with respect to challenges and solutions of [the design, implementation and use of] insulin prescribing improvement strategies and their impact.*
- Agree time limits
- Inform conditions of confidentiality- as stated in participant information sheet
- Ask for consent to use tape recorder

Examples of questions to be asked:

- Can I start by asking what your role is?
- How long have you been in your current role?
- What kind of organisation do you work for?
- As part of your role, are you involved with helping the trust to safely prescribe insulin?
    - If not, is there anyone within pharmacy with this responsibility?
- What does your/their role involve with respect to insulin prescribing safety?
    - Prompts – some of the things we asked about in the survey were around medicines reconciliation/ prescribing systems/guidance/education
- What do you feel the main challenges are at the moment in your hospital with respect to insulin prescribing safety?
- What strategies are currently in place to try and optimise the quality of insulin prescribing at your trust?
    - **Why have these specifically been used?**
- What do you feel has been the most impactful strategy that has been put into place in this area?
    - Why is that?
- How do you go about reflecting on [this strategy]?
- Have any strategies not worked particularly well?
    - What factors do you feel contributed to this?
- When we discussed the results of the survey with our patient panel, one of the main issues raised was around self-management and self-administration of insulin in hospital.
    - Could you describe what happens in your hospital with respect to this?
    - What are your reflections on this?
        - Ideas and assumptions about how it works
        - What is necessary to support success?
- One of the main things we looked at in the survey was electronic prescribing. Does your trust use electronic prescribing?
    - What are your perceptions with respect to how effective this is at reducing prescribing errors with insulin?

- Is there any advice you would give someone who is wanting to improve insulin prescribing safety at their hospital?
- Are there any desired changes or improvements that you'd like to see with respect to insulin prescribing in hospital?

Closing

- Any other factors that you think might be important that we haven't covered?
- Is there anything you would like to add, or ask me?

You can choose to stay updated about the project in which case I will add you to a regular mailing list and inform you regarding the progress of the study. Alternatively, you can opt out of any further communication too

Thanks once again for your time

Appendix 11: COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

Topic	Item No.	Guide Questions/Description
Domain 1: Research team and reflexivity		
Personal characteristics		
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?
Credentials	2	What were the researcher's credentials? E.g. PhD, MD
Occupation	3	What was their occupation at the time of the study?
Gender	4	Was the researcher male or female?
Experience and training	5	What experience or training did the researcher have?
Relationship with participants		
Relationship established	6	Was a relationship established prior to study commencement?
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic
Domain 2: Study design		
Theoretical framework		
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis
Participant selection		
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email
Sample size	12	How many participants were in the study?
Non-participation	13	How many people refused to participate or dropped out? Reasons?
Setting		
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace
Presence of non-participants	15	Was anyone else present besides the participants and researchers?
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date
Data collection		
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?
Field notes	20	Were field notes made during and/or after the inter view or focus group?
Duration	21	What was the duration of the inter views or focus group?
Data saturation	22	Was data saturation discussed?
Transcripts returned	23	Were transcripts returned to participants for comment and/or

Appendix 12: Explanations of codes and example quotes

The codes provided below are exported from NVivo and appear in alphabetical order, which may differ slightly from the logical order presented in Chapter 5.

1. Improving insulin prescribing practice is an important but 'wicked' problem

The perceived need for insulin prescribing quality improvement interventions, organisational and personal drivers for the improvement of insulin prescribing quality locally, and the challenges to making desired changes amongst individuals, teams and organisations.

Name	Description and example quotes	Files (n=17)	References (n=270)
Drivers for improvement	**Organisational and personal drivers exist for the improvement of insulin prescribing quality locally. Factors that facilitate the desire to improve insulin prescribing quality.** "*The reason was I suppose on the back of a CQC where we had quite a negative report around diabetes." P10* *"And then, and then, of course, the alerts came out saying you need to do you know, this, this and this. And on the back of that, well, I'd come from a trust with a separate insulin drug chart, so I devised an insulin drug chart." P13* *"I think the driver was at the time it was set up we had a consultant nurse for diabetes that was very keen on progressing those sort of things, and linked in with pharmacy – it was in response to, you know, the number of incidents that were occurring" P7*	14	60
Data as a driver		8	12
Interventions as designed around causes of error		2	3
Research as a tool for improvement		3	3
Experience as a driver		6	19
Independent prescribing as positive		6	10
Individuals driving insulin safety		2	3
Action as dependant on individuals in power		2	4
Engaging senior staff as important to improvement		6	11
Diabetes team infrastructure as longstanding		1	1
Enthusiasm as important for success		1	1
Relationships as dependent on individuals		1	1
Regulation and recommendations as a driver		8	16
Care Quality Commission as a driver for improvement		1	2
Never event as just avoided		1	1

Name	Description and example quotes	Files (n=17)	References (n=270)
NPSA as removed from practice		2	3
Quality markers as a facilitator		1	1
Improvement is challenging	**The challenges and barriers to making desired changes amongst individuals, teams, and organisations. Factors that make the process and sustainment of improvement difficult.** *"Absolutely, it's the number one drug in our hospital for harm-related incidents". – P11* *"And, you know, is, is quite high on the on the agenda at the hospital, and the medicines safety team as well. But it's just obviously dedicating the time and focusing really on how best to improve what is going wrong." P1* *"Although we, you know, they've tried. And they will have, they will have, you know, bursts of intervention, if I can call it that where there is increased training, but then it lapses until something else bad happens." – P12* *"Yeah. I don't know. I mean, you know, there is no one fix. Otherwise we'd have done it." – P13*	17	70
Funding as needed		2	3
Insulin errors as common		9	15
Insulin errors as recurrent		3	4
Insulin errors as widespread		2	3
Insulin improvement as ongoing		1	1
Intervention design as contextual		3	4
Intervention efforts as needing reviving after time		1	1
Lack of staff as a barrier to improvement		1	1
Lack of time or capacity as a challenge		5	9
Problem as difficult to fix		8	17
Risk reduction as territorial		1	2
Staff turnover as a barrier to improvement		6	10
Insulin safety is important	**The perceived need for insulin prescribing quality improvement** *"I think there's such a lot of improvements to be made in every hospital, because of these errors and issues that happen everywhere." P1* *"All trusts care about insulin safety" P2*	12	24
Implementation of interventions as important		5	11
Insulin prescribing as poor		3	3
Insulin prescribing improvements as necessary		2	4

Name	Description and example quotes	Files (n=17)	References (n=270)
	"Yeah, so I think there was a large focus on insulin safety, they realized they recognize that there's a lot of work to be done." P5		
Pharmacists as a safety net	**The role of pharmacists in the area of insulin prescribing safety**	14	43
Diabetes pharmacy teams as desirable	"*I'm employed to pick up on that error, so I am the safety net" P1*	10	26
Diabetes pharmacists as improving insulin prescribing	*"What we do when we're doing it well, in pharmacy, I think is we, in terms of having an organizational responsibility for insulin is we try and shoulder as much of the risk as we can." P12*	8	20
Diabetes pharmacists as reviewers of medicines safety incidents		4	7
Diabetes pharmacists running insulin clinics		2	3
Diabetes pharmacy as a positive role	*"And that's where pharmacists can make things better because we're on the ward every day. We're consistently there." P16*	1	3
Specialist diabetes pharmacists as recently accepted		1	1
Increased pharmacy ward cover as necessary		2	4
Medicines safety officer as a point of contact		1	1
Pharmacy team awareness of insulin errors as important		1	2
The importance of team	**The role of the wider team, and how is this composed, when conceiving and implementing insulin prescribing improvement strategies.**	15	46
Discussion forum as important		2	3
Governance board as a forum for improvement	*"So what we've just started now is we've got support from our trust directors to implement a trust-wide diabetes group. And that has representation from each directorate." P14*	8	13
Insulin group as beneficial		6	10
Insulin safety as multidisciplinary		11	14
Patient involvement in insulin prescribing as important		2	4

Name	Description and example quotes	Files (n=17)	References (n=270)
	"We also have as an offshoot of our medicines safety team we have an insulin safety group as well." P7		

2. Prescribing insulin is regarded as scary and complex

The nature of insulin errors in hospital, and the various drug-related and socio-cultural factors that precipitate them. Particular issues and risks around prescribing at the point of care transfer, including access to information, and the perception of interventions that can facilitate this.

Name	Description and example quotes	Files (n=17)	References (n=204)
Errors are there to be made	**The nature and types of insulin prescribing errors in hospital.** *"And with insulin, it's probably, it's never one thing. It's never it's never just the knowledge. Sometimes it's the environment or the circumstance at the time. And also sometimes it's, it's because there are competing demands maybe, which, which is a little bit different. So not necessarily the physical environment." P12* *"All it takes is one three AM night shift and an inexperienced F1 and an inexperienced nurse and you get an error." P1*	10	23
Causes of insulin error as complex		4	5
Errors as inadvertent		1	1
Errors resulting from environment as common		1	2
Failure as inevitable		2	3
Insulin errors as happening with experienced nurses		1	1
Lapses as main error types		1	1
Mistakes as there to be made		1	1
Not thinking as a risk		2	2
Out of hours working as a risk		4	7
Insulin prescribing is not easy	**The range of factors that make insulin prescribing errors likely in hospital.** *"Once you take a decision to make a prescription for insulin there are a lot of external factors that will impact on the*	8	23
Complexity of insulins as a risk		2	3
High-strength insulins as a risk		6	9
Insulin terminology as confusing		1	3

Name	Description and example quotes	Files (n=17)	References (n=204)
Variability of dose as a risk	*outcome of your prescription" P16* *"I think there's a lot of problems in terms of so many different brand names there's so many different insulin types as well and when you, when ordinarily we encourage prescribing by drug name, but then with insulins say actually "no, it has to be brand name" and then there being so many varieties." P17*	2	4
Variety of insulins as a risk		7	16
Consequences of prescribing as difficult to know		1	2
Hospital food as a risk		5	11
Impact of errors as more consequential to junior doctors		1	2
Insulin as a unique risk		2	3
Prescribers as alone		1	1
Prescribing as complex		1	1
Socio-cultural issues with prescribing	**The social and cultural issues around the prescribing process in hospital.**	5	19
Being a junior doctor as hard	**"**And the really frustrating thing is that if that foundation doctor doesn't do the job right, then everyone feels that they can tear strips off them because you know, "what do you mean you caused a hypo there? Do you not know what you're doing?" It's not like it "actually I don't know what you were doing either. But I'm senior enough to be able to not have to ask you, tell me, you know ask me that question". P16 "So it's very much a negative attitude from the top I would say as well (interviewer, okay. Yeah.) from seniors. It's a very much like 'oh I haven't done that for years, I don't know anything about it'"P18	1	1
Challenging prescribing as rejected		1	1
Hierarchy as a barrier		2	5
Prescribing as a FY1 job		1	1
Seniority as a veil		2	4
Vulnerability and humility		1	2
Ward culture as a barrier		4	5
Prescribers are scared of insulin	**The fear that doctors sometimes experience when prescribing insulin for inpatients with diabetes**	4	7

Name	Description and example quotes	Files (n=17)	References (n=204)
Clinical inertia as a risk	*"They're coming back to me and saying, "I don't want to be involved in that because I don't know anything about insulin. And that's too, that's too dangerous for me"." P16* *"In terms of prescribing it but they're scared of it. It's two-pronged, they're scared of it because they don't know what to do with it. But then they don't do anything about it." – P18*	3	4
A 'shot in the dark' on admission	Issues and risks around prescribing at the point of care transfer, including access to information and interventions designed to improve this.	13	132
Prescriber support on admission		11	37
Algorithm for admission doses as useful		1	3
Insulin passport		8	27
Insulin passport as undesirable		7	16
Insulin passports as dead		2	3
Insulin passports as feasible		1	1
Mobile apps as problematic		1	1
Patient handheld app as new		1	1
Patient handheld information as dependent on patient's engagement		3	5
Medicines reconciliation as beneficial		4	7
Patients as a source of information		2	3
Transfer of care issues		13	95
Access to shared database as important		5	12
Role of primary care as important		3	12
Insulin dose changes as misunderstood		2	5
Primary care mentality as irrational		1	2

"And you know even the insulin passport doesn't even have the doses on it because they change. Like it's so silly." P5

"So obviously we all cheer when a patient knows exactly what they're doing and tells us exactly how many units etcetera, etcetera. But that doesn't always happen." P10

"I think the difficulty there is that they don't know what the patient takes." P13

"So just the sort of thing of, what dose is the patient on? Primary care sometimes know but are a bit vague depends whose giving the dose and who is writing it down, secondary care only knows what primary care know or the patient could tell them" P2

"I guess, just generally, with doctors clerking patients in and I think there's a bit of a lack of

Name	Description and example quotes	Files (n=17)	References (n=204)
Transfer of care as a risk	*awareness about how to take a good drug history. They maybe just look at the maybe the GP record, or ask patients, they might do both, but they didn't always marry them up.'' P4*	13	71
Accessing information on admission as difficult		10	34
Care home transfers as not bad		2	2
Discharge letters as a risk		2	2
Maintaining clarity on insulin as difficult		1	1
Medical clerking as poor		3	15
Miscommunication of doses changes as risky		2	3
Omission of insulin on admission as common		4	5

3. Insulin prescribing safety should be everyone's responsibility

Diabetes teams make a positive contribution, but this may result in an over-reliance on them to manage people with diabetes. The need for an increased collective responsibility for insulin prescribing safety and the perception of interventions that can facilitate this.

Name	Description and example quotes	Files (n=14)	References (n=79)
Diabetes teams as a victim of their own success	**Diabetes teams make a positive contribution, but this may result in an over-reliance on them to manage people with diabetes. The need for a collective and increased responsibility for insulin prescribing safety from all staff involved in patient care, including pharmacists.** *"So we have we obviously have a DSN team we have an in-reach team etcetera. but they can't see every single patient.'' P10*	13	52
Diabetes teams as positive		4	13
Diabetes link as important		1	3
DSN presence as strong		1	1
Lack of specialist support as a risk		1	1
Outreach teams as a safety net		1	5
Outreach teams as a multidisciplinary effort		1	1

Name	Description and example quotes	Files (n=14)	References (n=79)
Outreach teams as interacting with care teams	*"And I think part of that is because for so long when the diabetes team has been embedded as "they're the experts" and so a lot of staff on the ward don't take responsibility because they think, "oh, well, you get the diabetes nurse to sort it out", or refer to them." – P5* *"I think empowering non-diabetes specialists to have an understanding of what to do with their insulin and how to manage it I think is quite key." – P14*	1	2
Passing the buck		12	38
DSNs as overloaded		3	4
Generalist staff as over-reliant on DSNs		3	3
Involving and empowering non-specialist staff as key		3	9
Lack of responsibility as a risk		5	9
Responsibility for insulin as needed		8	11
Risk aversion as a barrier		1	1
Guidelines	**The benefits and risks with the use of guidelines as a tool to help empower staff to make more appropriate decisions with respect to prescribing insulin in hospital.** **"***Obviously it is all in our guidelines but then guidelines are long and people don't have time to read them, and you know that's one of the things that we come across a lot." P1* *"Then obviously, we have all the other guidelines that are out there and then trying to sort of put them together in one place around our, you know, our trust SharePoint and stuff in our own intranet. So there's far more information out there for you. Better concise sort of guidelines and documentation is designed with error reduction in mind. They've all sort of helped." P8*	9	27
Algorithms as a risk		1	1
Guidance as de-skilling		1	1
Guidance on high-strength insulins as effective		1	2
Guideline length as a barrier		1	1
Guidelines as available		4	10
Guidelines as instruction		2	2
Guidelines as new		2	3
Insulin cards as prescriber support		3	3
Pharmacists as guideline producers		3	3
Prescriber support toolkits as desirable		1	1

4. It is an important but uphill battle to educate staff on insulin prescribing safety

The perceived need for educational interventions, and the importance of how these are designed and delivered, as well as the factors that make educating the workforce on insulin use difficult, including organisational, employment and political issues.

Name	Description and example quotes	Files (n=17)	References (n=293)
Challenges with educating the workforce	**The factors that make educating the workforce on insulin use difficult, including organisational, employment and political issues.**	11	47
Access to staff for training as difficult		2	3
Communicating with nurses as difficult	*"So the idea of providing, like, training, and making sure everybody's up to speed with that is a very, very difficult thing to do. And when you line it up with all the other training that sits for a trust to have to undertake, unless, unless you can get these sorts of things into the mandatory category, you generally don't have much success with them." – P8*	1	3
Competing agendas for essential training as a barrier		5	7
Complexity of care as difficult to teach		1	1
Education as a challenge		5	13
Information sharing as ineffective		1	2
Keeping momentum as a challenge		1	1
Nurse turnover as recent	*"For our staff nurses when they come in and you know, and they leave and start and doctors leave and start. And so it's trying to keep on top really, people being aware of the incidents that we've had, and how we're trying to overcome these." P1*	1	1
Size of organisation as a challenge		3	5
Staff turnover as a barrier to training		4	5
Time for training as difficult		2	2
Variety of staff as a barrier to education		2	4
Education alone as insufficient	**Education in its current form and delivery as insufficient to tackle the issues around insulin prescribing in hospitals.**	7	14
Education as requiring improvement		1	1
Repeated training as important	*"I think our education and training needs improving" P17* *"So yes, we often do do some teaching. But it's obviously. What, you know, what can*	3	5

Name	Description and example quotes	Files (n=17)	References (n=293)
	you get across in forty-five minutes to an hour to a small number of junior doctors once a year or whatever it may be?'' P13 *''But it's also about having that repeated training. I don't think its repeated. I think you'd need to have it every three years, like refreshers, for example.'' P14*		
Education is desirable	**The desire and benefits for educating staff on insulin prescribing safety.**	11	28
Education as inspiring confidence	"I just think education. Making them more confident. I think if we had confident prescribers, then there wouldn't be problems because they would be confident to prescribe the insulin which would be available for the patient." P18 "I don't see that it can be occupying the place that it should do in all undergraduate courses for people to be coming out with a level of knowledge that they seem to." P12	2	3
Educational packages as desirable		1	1
Standardised education as desirable		2	2
Raised awareness campaign as needed		2	4
Undergraduate insulin education as necessary		5	7
Staff as peer-educators	**The various members of staff who have a role in educating the workforce about insulin.**	12	22
Diabetes pharmacist as a teacher	*''I know the diabetic nurses as well do some teaching to, to the nurses and the consultants do and teaching to the junior doctors'' P1* *''I do quite a lot of teaching with the junior doctors and that's something that they identified as, you know, they*	7	10
Diabetologists as teachers		1	1
DSNs as teachers		3	5
Outreach teams as teachers		1	2
Pharmacists as teachers		4	4

Name	Description and example quotes	Files (n=17)	References (n=293)
	didn't know how to find what doses people were on.'' P11		
The trouble with mandatory training	**The use and issues around mandating insulin training in hospital, and how this is delivered, for clinical staff.**	11	33
Induction training as not optimal	*''So for example, I know that insulin safety is not mandatory training for people who prescribe, administer or supply insulin when it's our number one high risk drug as well.'' P14* *''So when there was a CQUIN linked to it, it was funded for - everyone had to do a bit of e-learning. But that got pulled the moment the CQUIN went.'' P5* "And when you line it up with all the other training that sits for a trust to have to undertake, unless, unless you can get these sorts of things into the mandatory category, you generally don't have much success with them." P8	2	3
Induction training as patchy		2	2
Mandatory training as desirable		5	11
Mandatory training as important		3	6
Mandatory training as inadequate		1	1
Mandatory training as lamented		3	3
Mandatory training as not supported		1	2
Restrictions on mandatory training as negative		3	4
Too much information on induction as a barrier		1	1
Pedagogy is important	**The way in which insulin education is designed and delivered is important.**	10	38
Active learning as beneficial	*''And I think the doctors – they can either do face to face or they can do e-learning, the doctors. And they definitely benefit from face to face.'' P10* *''So it's about how do you develop the skill of prescribing insulin well, and it's not about having the knowledge on its own, it's about having the*	3	4
Assessment as a tool		2	2
Errors as not the focus		1	1
Experiential learning as beneficial		1	1
Face-to-face education as desirable		3	3
Feedback with foundation doctors as a tool for improvement		4	8
New junior doctors as more exposed to insulin		1	2

Name	Description and example quotes	Files (n=17)	References (n=293)
Pedagogy as important	*knowledge and being able to put that into practice in a safe way and a secure way, you know, you're, you're sort of supported to put that into practice and given the space to, to reflect.''* P16 *''So I mean I guess it got people looking in the BNF. You know, try and working out in their own heads what the differences between the insulin were.'' P3*	1	3
Reflective practice as beneficial		4	13
Opportunity for reflection as challenging		1	1
Reflecting as informal		1	1
Reflection perceived as unimportant		1	1
Reflective motivation as necessary		1	1
There is a lack of knowledge and experience with insulin	**The lack of knowledge, experience and familiarity with insulin and the need for educational interventions.**	16	111
Attitudes towards insulin as polarised	*''To be honest, just because we had an open and honest forum with the twenty-ish or so F1s that we have. And to be honest, the lack of knowledge and education is a massive gap for them.'' – P18* *''I just get the feeling that they're coming out of med school with less pharmacology knowledge than ever used to.'' P9* *''But I think obviously my biggest concern is certainly no awareness of what insulin, not necessarily about what Insulin does. But it is why patients shouldn't miss it.'' P6* *''I think my biggest thing would be, just people's knowledge of insulin to be better. So I just find it really frustrating. The fact that the wrong insulin is still prescribed at the wrong time of day. It's literally that basis of which is*	1	1
Basics as going wrong		3	5
Consequences of errors as unappreciated		4	8
Consultants as non-specialists in diabetes		2	3
Control of BG as an aim of education		1	1
Diabetes knowledge as lacking		2	2
Education as patchy		3	3
Fundamental knowledge as lacking		1	2
Importance of insulin safety as unappreciated		1	1
Increased awareness of risk as important		3	3
Insulin prescribing risks as understood		2	2
Lack of confidence as a risk		1	3
Lack of education as a risk		6	8
Lack of experience as a risk		7	10

Name	Description and example quotes	Files (n=17)	References (n=293)
Experience with insulin as beneficial	*long-acting, which is a short-acting, and therefore, you know, what would be a rough dose of it?'' P5*	1	1
Lack of knowledge about insulin as a risk		9	17
Lack of knowledge as embarrassing		1	1
Lack of knowledge as frustrating		1	1
Lack of understanding as a risk		5	11
Medical clerking process as a target		3	15
Staff unaware of historical events as a risk		2	4
Undergraduate education as inadequate		2	6
Understanding clinical picture as important		2	3

5. A balance must be found between prescribing system control and flexibility to prescribe insulin

Perceptions regarding the way in which insulin is prescribed in hospital and how this may promote or risk insulin safety in hospital are varied. Restricting prescribing behaviour/actions as beneficial for the sake of insulin prescribing quality on both paper and electronic systems, however flexibility is needed.

Name	Description and example quotes	Files (n=17)	References (n=208)
Blood glucose (BG) monitoring is tied up with prescribing	**The importance of being able to access and review BGs when prescribing insulin, and the risks of multiplicity of systems for monitoring BGs.**	3	4
Monitoring technology as less risky	*''obviously with our glucose monitors, it all goes electronic, so we get a report for high INRs, sorry blood glucose levels and low blood glucose levels, so if we can see that someone is having hypos or hypers, then we go and assess those patients as part of the ward round in the morning and feed back to the medical team looking after them as well.'' P1*	2	2
Diabetes dashboard as helpful		2	2
Integrated prescribing and monitoring notes system as hopeful		2	2
Monitoring technology as a risk		2	3
Review of BG as prescribers' role		1	1
Reviewing BG as nurse responsibility		1	1

Name	Description and example quotes	Files (n=17)	References (n=208)
Prescribing processes vary	**The process of prescribing insulin and how this may promote or risk insulin safety in hospital, including what is required on prescriptions and daily prescribing.** *"I think that's definitely a challenge as well. Even though we encourage everybody to prescribe by brand, that's in all our guidelines. But it doesn't happen both in primary and secondary care." P11* *"I mean, we do daily prescribing of it. So our prescriptions are not like a rolling prescription, they are a daily prescription so they have to prescribe insulin each day. Well, when I say that they have to prescribe it each day, they don't have to, they can prescribe in advance for patients that are stable, but for unstable patients, they may change, they would prescribe each day. So it's not, in our trust, it's not a rolling prescription." P18*	14	52
Biosimilars as a challenge		1	6
Brand vs Generic		10	19
Brand and generic as useful		2	4
Brand name prescribing as beneficial		1	1
Brand naming as a risk		5	9
Generic prescribing as a risk		4	5
Considering prescribing options as risk management		1	1
Daily prescribing		3	11
Daily prescribing as a risk		2	3
Ineffective handover as a risk		1	2
Daily prescribing of insulin as a challenge		3	7
Daily prescribing of insulin as positive		1	1
Devices on prescriptions		2	3
Insulin pumps as a challenge		2	3
Strength of insulin on prescription		3	9
Opportunities and drawbacks with current prescribing systems	**The benefits and risks with using current paper-based or electronic systems to prescribe insulin, including explanations around functionality and opportunities for improving insulin prescribing quality.**	17	145
Electronic Prescribing		13	49
Alerts		1	2
Electronic prescribing as a challenge		5	8

Name	Description and example quotes	Files (n=17)	References (n=208)
Electronic prescribing advances as dependant on regional plans	*"I mean, it's had some impact on some of the errors that we would get, particularly around units and getting the full details of the prescription specified. But what we're getting now is an increased I would say error rate from mis-selection from drop down menus." P3* *"Electronic prescribing, I think has helped overall. Because yeah, you might have seen some of those terrible prescriptions where they had no idea the names, the doses, the timings were awful. Yeah, I think it's marginally better." P13* *"So I think that's still our main challenge at the moment is the fact that there are two charts, and therefore they didn't necessarily tie up. And then so you have you have a beautiful prescription on electronic because obviously it's electronic. But then you still get the handwriting problems on your green chart." P10* *"But saying that, you know, we still managed to have two weeks ago, a doctor write 'units' on an insulin chart where the word 'units' was pre-printed which resulted in a you know, a not unserious overdose." P12* *"And obviously, we've got electronic prescribing, and we've got the ability to put some limits in there. But the regimes are so variable, it's very difficult to put hard limits on them." P3*	1	1
Influencing technology companies as challenging		1	1
Understanding drugs when designing electronic prescribing systems as necessary		1	2
Electronic prescribing as desirable		10	23
Default fields as desirable		1	2
Electronic prescribing alerts as desirable		2	3
Protocol prescribing as effective		1	1
Electronic prescribing of insulin as undesirable		2	6
Benefits of electronic prescribing as limited		3	3
Electronic prescribing as a risk		6	12
Electronic prescribing as impacting the type of errors		5	8
Flexibility as needed		4	10
Prescribing insulin as rule-based		3	4
Paper charts		16	77
Carb counting chart as absent		1	1
Handwritten prescriptions as a risk		5	8
Insulin Charts		16	65
Colour-coding as helpful		3	3
Documentation as improved		1	1
Insulin chart as effective		5	8
Charts as sustainable		1	1

Name	Description and example quotes	Files (n=17)	References (n=208)
Insulin charts for prescriber support		5	5
Insulin charts as a risk		2	5
Insulin charts as not necessary		1	1
Insulin charts as requiring improvement		2	3
Insulin prescribed on normal prescription chart		1	1
Insulin prescribing chart and BG chart together		9	11
Multiplicity of prescribing systems as a risk		5	16
Pre-printed prescribing charts as a safety net		3	4
Removing prescribing steps as effective		2	3
Uniformity in prescribing charts as needed		3	10
Standard prescription charts		2	4
Use of charts as outdated		1	2
Visual markers on charts as effective		1	1
Medication charts as limited		1	3
Restrictive measures as beneficial		4	19
Electronic prescribing as a restrictive measure		2	5
Safety measures as circumvented		1	1
Simplicity as important		3	5

6. Interventions to improve insulin prescribing are hard to evaluate in practice

The desire to measure the effectiveness of interventions is not met with the ability to reliably do so using audit or error reporting systems, and the use of feedback and anecdotes to evaluate interventions is common.

Name	Description and example quotes	Files (n=16)	References (n=90)
Anecdotal evidence	**The use of feedback and anecdotes to evaluate the efficacy of interventions.**	3	5
Evaluating effectiveness as anecdotal	*"I guess the diabetes nurses have probably got quite a good idea from when they go around and see patients. It's like a town that we're in. So they know a lot of the patients that come in and out of hospital anyway, they're probably like 'oh I know that patient. I see them in clinic'." P4*	2	2
Feedback on interventions as important		1	1
Feedback as unreliable measure		1	1
High dose rule as contentious		1	2
Audit as a measure for improvement	**The use of audit to collect data on intervention efficacy, and the issues with this.** "so I think its difficult, you want to be able to audit, but I'm not sure you're ever going to be able to audit to see if it has improved and that's the problem really." – P10	9	18
Audit as difficult		1	1
Paper-based systems as difficult to interrogate		1	2
Recording of insulin doses as unreliable		2	3
Education as a predictable outcome of audit		1	1
Error reporting	**The use of error reporting systems in order to evaluate intervention efficacy and the problems associated with this.**	11	50
Error reporting as a challenge		4	4
Error reporting as a feedback tool	"I think that prescribing is under-reported generally. So I think what tends to happen with prescribing is that unless it ends up being administered, nothing gets reported. If it's	6	10
Error reporting as a tool for measuring effectiveness of interventions		5	5
Error reporting as an unreliable measure		6	18

Name	Description and example quotes	Files (n=16)	References (n=90)
Interventions implemented as a response to incident types	just picked up as an error, it just gets sorted. And we don't necessarily hear about it.'' – p15	6	13
Insulin safety achievements as varied	**The variability in insulin prescribing intervention effectiveness in different hospitals.**	4	5
Interventions as effective	*''So whatever we've done, it's definitely improved.'' P10*	1	1
Progress as gradual		3	4
Interventions as unsuccessful	*''So, my colleague, who works next to me is, has a greater role within medicine safety, whereas I kind of focus on service. But we spend a lot of time talking about incidents. And the thing that she says about insulin safety is that ''we've tried everything and nothing seems to work''. That that was her take.'' P12*	2	3
Measuring intervention success is desirable but difficult	**The desire to measure the effectiveness of interventions in hospital but the lack of ability to do this reliably.** *''Now can I turn round and tell you that they definitely reduced our error rates? Well I actually couldn't. Because it's very difficult to measure your error rates.'' – P8* *''so I think its difficult, you want to be able to audit, but I'm not sure you're ever going to be able to audit to see if it has improved and that's the problem really.'' P10*	7	11

7. Inpatient insulin self-administration is a problem worth solving

Self-administration policies to promote the independence of people with diabetes in hospital are laudable and encouraged but are often difficult to implement.

Name	Description and example quotes	Files (n=18)	References (n=322)
Assessment processes	**The process and oversight of assessing patients as 'competent' or 'safe' to self-administer their insulin during their hospital stay.** *"We will try for pharmacy and technicians to also support that role if we, if we have the availability. So yes, they need to know about it as well. But predominantly, it would be, also because the nurses are more likely to be on the ward twenty-four seven." P10* *"So yeah, I think we need to make sure that within the policy we think of doing the capacity assessments daily and actually if something goes wrong staff will be supported about it." P5* *"I think I suppose the hard part about that is getting someone to assess the patient to make sure that they are safe to self-administer." P16*	14	42
Administration technique assessment as not a DSN job		1	1
Assessment as needing to be simple and easy		2	5
General self-administration assessment		5	6
Self-administration assessment as a nurse job		7	8
Self-administration assessment as cautious		2	2
Self-administration assessment as formal		1	2
Self-administration assessment as necessary		10	14
Self-administration process as stratified		4	4
Attitudes to self-administration	**Staff perceptions, attitudes and beliefs around the processes, policy and consequences of insulin self-administration in the inpatient setting.** *"Number one is the traditional feeling or sort of understanding that we look after patients in hospital. You know, if you're a nurse you'll be giving their insulin because you're giving them their*	8	20
Change as psychological		1	3
Fear from nurses		1	1
Nurse familiarity as an enabler to self-administration		1	1
Nurses as not conscious of self-administration consequences		1	1
Nurses as relaxed about self-administration		1	1
Past approaches as flipped		1	2

Name	Description and example quotes	Files (n=18)	References (n=322)
Patients as protective of self-administration	*medicine and insulin is a medicine.'' P8*	2	2
Perceived consequences of self-administration as a barrier		1	1
Self-administration policy as not desired		1	2
Staff as wary of self-administration		2	4
Staff resistance as a barrier		1	1
Traditional understanding as paternalistic		1	1
Burden of self-administration	**The burden of work and change processes associated with implementing insulin self-administration policies.**	6	23
Burden of work for self-administration as a challenge		1	1
Nurse administration as easier than self-administration	*''So, you know, you've got to consider obviously, the security arrangements and disposal arrangements. The monitoring, the documentation, the consent. And the assessment of the patient. You know there's an awful lot to consider.'' P13* *''And I think that's, that's probably a challenge for, you know, a busy ward. When the nurses are thinking, ''oh, god, and I'm going to have to take that patient off self-administration'', or ''I have to try and put them on it''. And sometimes maybe they just think you know what, it's just easier to just do it all yourself.'' P16*	3	5
Self-administration as requiring nurse oversight		3	6
Self-administration is time-consuming		2	5
Self-administration policy as complex		3	6
Communication	**Issues around how communication between healthcare professionals and patients, and between ward teams impacts self-administration policy implementation and use.**	1	3

Name	Description and example quotes	Files (n=18)	References (n=322)
	"The issue with that, though, is that if any medical team changes the patient's dose its key that they let patient know so they are able to change what they're using as well." P14		
Documentation	**The systems and processes involved in documenting decisions made as part of insulin self-administration policy use.**	9	23
Electronic prescribing impacts self-administration		5	7
Patients documenting BG on charts as inappropriate	*"It didn't really feel appropriate for patients to be using our insulin charts because all they wanted to do is tell you what their blood sugar was and how much they gave themselves." P18*	1	1
Recording BG as patient job		1	1
Self-administration document as a safety net		1	1
Self-administration documentation as accessible	"Erm we're also finding interesting that there are sometimes people who are self-admin-ing they haven't filled in the separate paperwork. So we need to make sure that it is properly, erm, done by policy, really, to make sure it's safely done." P5	3	4
Self-administration documentation as important		4	9
Implementation	**Issues around the implementation of self-administration policies in practice, including how this process is overseen and its integration into normal workflows.**	13	31
Adherence to intervention		6	11
Oversight of self-administration intervention		5	12
Competing priorities as a barrier to self-administration	"But we haven't managed to roll it out as successfully as we've wanted to. And I think, again, that's probably on the back of staffing really?" P10	1	1
Lack of staff as a barrier to self-administration		1	2
Self-administration as a pharmacy job		1	4

Name	Description and example quotes	Files (n=18)	References (n=322)
Self-administration policy as not a pharmacy job	"And I really didn't want to lead on it. It's like 'this is not for me to do' this is, I've provided you with the framework because you know, I'm happy to put something down on paper. But you know, this is for you." P13 "So it's not just having the policy and the staff being aware *(interviewer: exactly)*, it's who's pushing, who's driving it? *(interviewer: yes)* is probably also the thing." P16	1	1
Who is driving self-administration as important		4	4
Self-administration as difficult to implement		2	2
Self-administration as ingrained in workflow		1	1
Self-administration as established		3	3
Supporting staff		2	2
Self-administration provider education as pre-requisite		1	1
Staff as requiring support		1	1
Measuring success	**Issues around how the success of insulin self-administration policy interventions are measured and evaluated.** *"We looked at a variety of things then and we did find actually most patients who wanted to self-administer were self-administering following that proforma being filled in." P17* *"So its difficult to see uptake but there was definitely a need for it there and its now there so helping patients to self-administer so it's a valid process that they can go through to be able to do that." P1*	9	25
Patient feedback on interventions as important		1	2
Self-administration as not perfect		1	2
Self-administration as successful		4	9
Self-administration as unsuccessful		6	10
Self-administration interventions being pulled		2	2
Uptake of self-administration policy as difficult to measure		2	2
Self-administration as a risk	**The negative elements of insulin self-administration practice** *"I think the problem is that as a trust we have been burnt I*	4	7

Name	Description and example quotes	Files (n=18)	References (n=322)
	suppose in the fact that patients refuse to give up their insulin. And we then found that they were probably more confused than they thought they were and they've had crashing hypos because they've given themselves too much insulin. So what's really difficult here, I think, is the fact that people are wary." P10 *"But Yeah. I also think that there have been cases where people have self-admined and it's gone wrong." P5*		
Self-administration as encouraged	**The positive elements of insulin self-administration practice** *"One of the key benefits of self-administration would be to actually get it at the right time." P11* *"Because at the end of the day, a patient should be self-administering where they can. They've got to go home and do that. And we, you know, we de-skill them, we take that away whilst they're in hospital." P13* *"So, within the mental health service, we don't see a lot of it and where we do see it, we very much encourage patients to self-administer." P15* *"And we absolutely would agree and support the idea that patients need to have a bigger input into the decision making. And if they can give it, they should be giving it." P8*	15	63
Patients as being empowered		5	6
People with diabetes as knowledgeable about diabetes		2	2
Self-administration as a safety net		11	20
Administration errors as common		1	1
Nurse administration as a risk		3	3
Nurse unavailability as a risk		1	1
Nurse workload as a risk		2	2
Self-administration as a vested interest		2	2
Self-administration as beneficial to patients		3	4
Self-administration as important		6	10
Self-administration as patient prerogative		2	6
Self-administration as satisfactory for patients		1	1
Self-administration policy as a respite for nurses		4	4
Self-management		3	9

Name	Description and example quotes	Files (n=18)	References (n=322)
Self-administration as different to self-management	**The discussion of insulin self-management in hospital, where people with diabetes measure their blood glucose levels and self-adjust their insulin dose.** *"It was to say that we are only able to do self-administration. We can't do self-management, because our point of care team insists that we use our meters" P5*	2	3
Self-management as a safety net		1	2
Self-management as restricted by policy		1	2
Self-monitoring as deemed insufficient		1	2
Storage and disposal of sharps	**Practical issues around how insulin paraphernalia is stored and disposed of safely at ward level and the impact this has on policy use.** *"But we, I think we, I think we struggle with the infrastructure to allow it in terms of around the keys, you've got to give the patient the keys to the locker in order that they can they can have access as well." P12* *"So, just about the self-administration the key thing that we kind of had a hiccup was around sharps bins in that you can overlook but it's quite key that if they are going to be self-administering and wards they will need access to sharps bins." P14*	13	30
CQC approval for storage as required		1	1
Safety needles as problematic in self-administration		1	2
Sharps bins as an issue		3	4
Storage for self-administration as necessary		12	13
Storage of insulin as a problem		7	10
Suitability of patients for self-administration	**The factors impacting how suitable self-administration policies are for different groups of patients in the hospital setting, and the impact this has on policy use.**	15	31
Criteria for self-administration as strict		1	1

Name	Description and example quotes	Files (n=18)	References (n=322)
Patient capacity and competence as needed		10	22
Uptake of self-administration as varied	**"***So obviously if someone comes in acutely confused or they've got some sort of cognitive impairment then we would take over control of doing the insulin as we wouldn't want them to be at risk of administering it incorrectly.'' P1* *''And we sort of piloted it for a little while, but it didn't really sort of come off. The numbers were really small. And the sort of feedback that we had was the ''Oh, the criteria, perhaps was a bit too strict''. Because we say obviously, we don't want anybody that's comatose or going for surgery, x, y, z. So the numbers were small.'' P13*	6	8
Writing the policy	**The nature and processes involved in designing and formulating insulin self-administration policies for use in the inpatient setting.** *''So as I say I'm in the next couple of weeks I've already talked to the sort of nurse, lead nurse in our assessment unit. And the DSN and myself and some of the pharmacists and some of the technicians are going to sit down and work through a sort of a quality improvement sort of model to try and get the whole sound piece tied up a little bit, you know.'' P8* *''And because I think quite often, we're all for a one-size-fits-all, you know, the whole 'do once' thing but it's not gonna work.'' P11*	8	13
Assumptions about HCP role as problematic		1	1
Insulin as unique for self-administration		1	1
Self-administration policy as collaborative		6	7
Self-administration policy as standardised		1	1
General self-administration policy as useless		1	1
Uniformity in approach as ineffective		1	2

Appendix 13: Descriptions of the insulin passport, mandatory insulin training and insulin self-administration policies

Interventions are described using the Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann et al., 2014). Descriptions are provided by the researcher with reference to relevant supporting literature as outlined in **Chapter 1**. As this study is looking at an organisational level across a range of hospital settings, descriptions provided are more generic compared to those pertaining to individual specific system or modification of an intervention.

Brief name	**Insulin passport**	**Mandatory insulin training**	**Insulin self-administration policy**
Why?	Designed to minimise insulin errors by providing readily available information on each patient's insulin product(s) to help ensure that the insulin products that patients use are correct, that the dose is right and that patients self-administer insulin in hospital whenever appropriate. Enables patients and healthcare professionals to check the accuracy of prescribing, dispensing and administering of insulin as well as providing a mechanism for transferring patient safety information across all healthcare interfaces.	Healthcare professionals lack knowledge and confidence with diabetes management and insulin. Inpatient perception of staff awareness of diabetes is declining. Pre-registration training doesn't always support a sound knowledge in diabetes and post-registration training is challenging due to ward pressures and high staff turnover. Basic mandatory training on the safe use of insulin and the main diabetes harms and how they can be prevented should be provided for all healthcare professionals caring for people with diabetes.	Self-administration empowers patients to take more control of their care whilst in hospital, and can avoid nurse administration errors (such as untimely, erroneous or omitted doses, wrong insulin) that lead to patient harm.
What materials?	The Insulin Passport is a single, double-sided sheet that folds up to credit-card size with cardboard covers. It contains the necessary information for emergencies and safe use of insulin as patients transfer across healthcare providers. Accompanied by a patient information booklet designed for adults who are 18 years or older. Insulin passports are obtained via telephone or	Insulin safety training is aimed at a wide range of healthcare professionals and to varying degrees. Training may take many forms, for example at induction only, or repeated, linked to staff personal development plans. It may involve manipulation of placebo insulin devices, gamification, and/or hard copies of training material. A range of insulin safety	Patient information about self-administration may be given to patients on admission to hospital. Self-administration training materials may be provided to hospital staff (nurses, pharmacists, doctors). Materials required include bedside insulin storage facility (e.g. locker), self-administration assessment form, consent form,

	email (nhsforms@spsl.uk.com). An appendix is available to support healthcare professionals in advising patients about the Insulin Passport	training packages exist and are available nationally or created locally. An example of an open-access package is the Six Steps to Insulin Safety (https://www.diabetesonthenet.com/course/the-six-steps-to-insulin-safety/details)	documentation of patient's self-administered doses. Examples include https://wessexahsn.org.uk/projects/58/self-administration-of-insulin-in-hospital#:~:text=Self%20Administration%20of%20Insulin%20in,admitted%20to%20hospital%20require%20Insulin.
What procedures?	Adult patients on insulin therapy receive a patient information booklet and an Insulin Passport from their prescriber. Healthcare professionals and patients are informed how the Insulin Passport and associated patient information can be used to improve safety. When prescriptions of insulin are prescribed, dispensed or administered, healthcare professionals cross-reference available information to confirm the correct identity of insulin products.	Activities may include completing an online e-learning package, or attending a face-to-face session. Topics may include understanding the action of insulin, risks involved, common errors, range of insulin profiles and devices, understanding insulin regimens, safeguarding patients, quality of prescribing and administration	Provision of written information to explain responsibilities of self-administration to people with diabetes and hospital staff. Nurse and patient to agree if and when self-administration is appropriate. Agreement/consent form to be signed. The patient has free access to their own insulin whilst in hospital and self-injects their usual insulin when required. Documentation outlining the patient's self-administration status and recorded doses should be completed. The patient's ability to self-administer should be assessed on a regular basis. Safe storage and disposal facilities should be suitably available. Support activities for staff should be provided.
Who provided?	The NPSA designed and provided the insulin passports to organisations from 2011, accompanied by a national 'Patient Safety Alert' (NPSA/2011/PSA003). "Healthcare professionals who prescribe insulin" are responsible for issuing patients with a patient information booklet and an Insulin Passport, and their	Providers may include local diabetes teams: nurses, pharmacists, doctors. National providers include TREND UK, the Primary Care Diabetes Society and Health Education England. The University of Southampton and the University of Leicester (EDEN) also offer	The nurse, pharmacist or pharmacy technician working on the ward prompts and completes the self-administration assessment and consent forms with the patient. All staff involved in self-administration should be supported and trained accordingly in its aims, risks, benefits and procedures.

	replacement. Healthcare professionals must be available to assist patients in completing the Insulin Passport, and specifically in how to describe their insulin products so that there is no ambiguity in what they are using.	insulin online/distance learning education packages.	
How?	Face-to-face provision of a hard copy of the insulin passport by healthcare professionals to patients.	Depending on the training provided, this may be face-to-face or online, either individually (e.g. e-learning) or group (e.g. face-to-face).	face-to-face discussion about self-administration and completion of documentation (electronic or hard copy depending on local systems used). Intervention provided individually to patients at ward level.
Where?	Although not specified directly, presumably both primary and secondary care (GP surgeries, diabetes outpatient clinics, hospital wards). The organisation must themselves order, store and ensure an adequate supply of the passports for dissemination.	The main anticipated site would be at the hospital, either in a dedicated training space or at ward level. E-learning would be completed at any appropriate, available workspace.	Inpatient ward facility. Depending on 'level' of self-administration and type of inpatient facility, individual lockers or containers may be provided at the patient's bedside, or insulin may be stored centrally for patients to request access.
When and How much?	Since March 2011 when the NPSA alert was disseminated, the intervention was intended for initial use for every patient using insulin currently and henceforth any patient newly prescribed insulin. Thereafter, the passport was updated anytime there was a change in patients' circumstances, their insulin products, other drug therapy (if recorded) and information that needed to be communicated. Anytime insulin was prescribed, dispensed and administered across any care setting the intervention was intended for use.	Mandatory training may involve induction training only (when new staff members commence employment at the trust), or may be required to be repeated every 1-5 years.	Initial assessment to be conducted at the point of admission or transfer to inpatient ward area. Subsequent assessment to b e completed periodically (e.g. daily). Patient self-administers according to their individualised insulin regimen. Nurse to record that patient has self-administered their dose each time it is due. The intervention may cease if patient clinical status declines throughout patient stay, or on request.

Tailoring	The NPSA permitted providers of diabetes services to tailor the insulin passport, in conjunction with patients, but stipulated that the result must facilitate patients receiving the correct insulin products and allow for details of concurrent medications. The developer then takes full responsibility for the amended version of the intervention	Training is often tailored to include insulin prescribing information that is most relevant to the organisation (e.g. particular prescribing charts/electronic systems). Training may also be tailored to the professional group (e.g. HCAs would receive a different type and level of training than junior doctors) according to their role and requirement for information. Local errors and incident trends may also be incorporated into training.	Self-administration policies are usually locally created by the hospital trust to tailor to their prescribing/administration systems, ward set-up, staff capacity and governance arrangements. Regional policies may be created if similarities in systems/procedures allow, and any national policy created must take into account any differences in organisation facilities, staff and structures. Any tailoring must take into account the requirements for safe medicines storage and disposal by the relevant governance agencies, professional regulations and standards (e.g. medicines code, CQC, NMC).
Modifications	Modifications to the insulin passport have been described, including electronic versions and addition of doses and diabetes team contact details. Regional medicines management teams and CCGs have developed clearer guidance for the use of insulin passports more locally.	Modifications may be made to locally designed and delivered training may be expected based on changes to policy, procedures and systems, as well as local evaluation and organisational requirements.	Modifications may be made in light of staff and patient feedback or more formal evaluation, as well as any changes made at an organisational level to systems, policies and procedures.
How well (planned)?	Use of the Insulin Passport is recommended but is not mandated. Local protocols and policies should describe clear processes and audit benchmarks for cross-checking information in the Insulin Passport during the prescribing and dispensing processes, and to identify and document if patients decide not to follow the	Staff adherence to e-learning and face-to-face training may be measured by register keeping and electronic e-learning completion records. Impact of training on staff knowledge/confidence/satisfaction may be measured and evaluated with feedback and test scores. Impact of staff training on patients may be tracked by question	Intervention uptake, appropriateness and compliance with policy (e.g. completion of requisite documentation) may be audited locally by prospective or retrospective interrogation of medical documentation. Feedback from staff and patients may be obtained for evaluation purposes.

	recommendations in this Patient Safety Alert.	response to the National Diabetes Inpatient Audit.	
How well (actual)?	Local audits have demonstrated varying degrees of acceptability and adherence to the insulin passport from both staff and patients. The National Diabetes Inpatient Audit monitors trust-wide use of the insulin passport (%) each year.	Previous local evaluations have included self-reported changes in confidence and knowledge and/or impact on insulin prescribing quality. The National Diabetes Inpatient Audit monitors the proportion of hospital trusts who provide insulin safety training (%) each year.	Previous local audits have demonstrated varying degrees of adherence to self-administration policies and disparate uptake of the intervention. The National Diabetes Inpatient Audit monitors the proportion of hospital trusts who use self-administration policies (%) each year.

Appendix 14: Qualitative data supporting theme identification for individual interventions

Inferences - respondents using the intervention	**Example quotes**	**Inferences - respondents not using the intervention**	**Example quotes**
Insulin Passport			
Importance of carrying insulin prescribing information may depend on an individual's perception of benefit.	*I mean, I'm personally not diabetic, but carrying round an insulin passport doesn't, I would defiantly, and I'm not young but I'm of the era where I would have my phone with me all the time and it would be on there – if I'm a diabetic it would be on there. But then is that because I'm a diabetes pharmacist and therefore I know how important it is? It's difficult isn't it. - P10*	Lack of intervention fidelity, and low perceived, effectiveness results in a negative affective attitude and low use of the insulin passport.	*So the passport would never work and everyone kind of made a sort of sighing effort towards having something available and then chose to ignore it because it was never going to happen basically. - P2*
Insulin passports contain insufficient information to aid with complete prescribing on	*And probably when they first come, they may get sort of an insulin passport, but that doesn't really give any doses. It's never given the doses anyway. All it ever did is tell you hopefully the actual insulin that they're on. But there's never been anything which says, "this is the dose that I take at the moment" - P10*	Insulin passports contain insufficient information to aid with complete prescribing	*And you know even the insulin passport doesn't even have the doses on it because they change. Like it's so silly. - P5*

transfer of care		on transfer of care	
Insulin passports appear to be unobtainable and information about their supply to organisations is absent or outdated	*Yeah, the insulin passport seems to have died a death. In fact, I tried to order some more recently and the details on the original alert to get more supplies, that route of ordering them doesn't even exist anymore. And I've been asking another trust, you know, where are you getting them? And no one seems to be able to give me an answer. So we're actually at the point where we can't get any more of the product, although we could obviously start photocopying them ourselves. - P3*	Insulin passports are burdensome and redundant due to lack of engagement and structure supporting their use.	*it's been, you know, a stone around everyone's foot and we've all drowning because no one updates it, it can't be updated and the only people who use it well are the people who don't need them i.e. the highly invested diabetics. - P2*
Insulin passports have been superseded by summary care records	*But to be honest, now we've got the summary care records and they're in fairly routine use. I think that's becoming utilized a lot more frequently than the insulin passport as a source of information (interviewer: yeah) because obviously, when you do meds reconciliation you've got other drugs as well. - P3*	People with diabetes who are less involved in their care are most likely to benefit from the insulin passport but are least likely to use them.	*The problem with the passport is that it relies on the patients being engaged and the engaged patients can tell you what dose they're on. - P2*
Insulin passports are unreliable due to lack of intervention coherence and use by patients	*And even if they had an insulin passport, they would probably come without it. Yeah. And then we end up going to things like summary care records. – P3*	Insulin passports are unreliable due to lack of intervention coherence and use by patients	*We don't use them because a, people forget to bring them in or the insulin changes so much or the doses change so much that they don't keep them updated - P1*
		The burden and confusion associated with their use and recommendation for use is significant.	*It doesn't help anyone it just creates a lot of work. And everyone keeps chasing it everyone keeps saying "we should do more about those passports, do we use those passports? We should definitely use those passports" and everyone else is going "We don't need passports. The passports aren't helpful. Ignore the passports. Do something else." - P2*

		Lack of ownership and unreliable use of the insulin passport impacts on its lack of adoption.	*Insulin passport isn't the answer. I know locally it's not been adopted. You're relying on people updating it and it actually being a contemporaneous record, which, unless somebody takes ownership it never will be. - P7*
Mandatory training			
Lack of inclusion on mandatory training is frustrating	*Yeah, so we've not gone down that route. Which is, which is irritating because you know, it's such a big a big clinical area. - P1*	Motivation from trust to include insulin safety in training is often a response to a clinical incident	*I think we rely on, what happens is we get a potentially serious error and everyone says 'you must put it in the junior doctor's training'. But we have to keep bumping things down. You know, you can't do everything in twenty minutes on their first day. - P3*
Past experiences with rejection for inclusion on mandatory training impact on current availability	*I haven't made it part of the Essential Training because there's so many different things that are on the hospital's agenda that people want as part of the essential training so I think one of our consultants asked a couple of years ago and they were declined to have it as part of the essential training. Yeah, so we've not gone down that route. - P1*	Mandatory training is patchy and doesn't always work as issues are still occurring	*So even though they have these mandatory training days - some of the issues still don't seem to get through. - P12*
Induction training 'overload' prevents substantial or meaningful inclusion of insulin safety on the agenda	*I know that for medics, when they start new, on induction it's very difficult to get within five minutes on their induction timetable, it's basically an overload. But there's nothing that I know specific in regard to insulins. - P14*	SAME	*Um, but I think at that point, they're getting absolutely bombarded with everything on their first day. They're not really in a position to take it in. - P3*
Support for insulin safety inclusion on mandatory temporal is transient and linked to	*And then we've also had – at the moment there's not a lot of support for mandatory training. So when there was a CQUIN linked to it, it was funded for - everyone had to do a bit of e-learning. But that got pulled the moment the CQUIN went. Yeah. I think we have*	Reaching all clinical staff in face-to-face teaching is a challenge and requires momentum	*And, and you know, when you are teaching, if you get ten junior doctors turn up, then that's probably quite a good number out of the total of them, but I mean, ten, in the scheme of things is a drop in the ocean. So trying to get the numbers*

monetary incentives for the trust (e.g. CQUIN)	*trouble within the trust because there are so many competing things which are important. Erm, and because it's not actually linked to any money. We were finding more often bumped.- P5*	on the part of the trainer	*and teach them is just an ongoing battle. You'd have to be doing it all the time really. - P13*
Face-to-face mandatory training for clinical staff would overcome many issues with insulin safety but is not logistically feasible due to volume and inaccessibility of staff, and high turnaround	*it would be great to have some mandatory training for every staff nurse which isn't necessarily logistically feasible but that would be one of the ways, you know like a half-day training event or something like that that was set up for staff nurses and doctors to go on to learn about the correct prescribing of insulin, the risks with insulin, so they do it a little bit more in-depth than perhaps they'd do with other medicines. That, I think, would overcome a lot of the issues but again it's the logistics of trying to get that arranged to get people to come to it and as I said with staff coming and going you'd continually have to be giving that training to people so its not necessarily going to fix everything but trying to get the message out there is the big thing. - P1*	SAME	*And you know, even if it's the case of nurses moving on to other things, and you get another batch of nurses in and it used to feel it in work that the sort of the nurse contingent was the steady thing, as well as pharmacists on wards, and now that's not the case anymore. They nearly turn over as quickly as the docs. So it's a real sort of nightmare when it comes what you're trying to do, and instil sort of good practice and get keeping people up to speed. So the idea of providing, like, training, and making sure everybody's up to speed with that is a very, very difficult thing to do. - P8*
Lack of follow-up and monitoring completion of mandatory training limits its ability to be evaluated	*And that's then got to be agreed with your line manager that's specific to your role, and there's no real follow up to see whether you've done it or not. So even if we go down the e-learning the assurance on whether people do it is going to be a bit lacking. - P9*	Ability to check compliance with mandatory training can aid investigation of quality issues	*But that's again something else we can check if we have problems. - P10*
Face-to-face training for staff and educators is necessary and beneficial	*And if its, that's one aspect of the training, the mandatory training. Then I think another aspect is going to be still face to face training does help and then implementing 'train the trainer'. - P14*	SAME	*And I think the doctors – they can either do face to face or they can do e-learning, the doctors. And they definitely benefit from face to face. - P10*

Mandatory training is often short and insufficient to meet the educational requirements of staff	*I mean, not even the teaching trust, but trying to teach all of those staff members who will be involved in diabetic care, which is pretty much everybody on every ward, about how important it is a really difficult challenge. You know, and we spoke about, "do we get it as part of the central training?", but then actually, you know, half an hour of a video isn't enough to teach somebody all the skills that they're gonna need to look after diabetic patients. - P1*	SAME	*So, yeah, I did a number of things. One of which was the drug chart and, and, and some teaching, but I mean, teaching is a very weak barrier really...That's because people, you know, can only remember two or three things, and then might only remember that for that week. Then they're not always going to take that with them (interviewer: yes, yeah) throughout. And, and you know, when you are teaching, if you get ten junior doctors turn up, then that's probably quite a good number out of the total of them, but I mean, ten, in the scheme of things is a drop in the ocean. So yes, we often do do some teaching. But it's obviously. What, you know, what can you get across in forty-five minutes to an hour to a small number of junior doctors once a year or whatever it may be? - P13*
Mandatory training needs to be repeated	*Yeah, so, yeah nursing wise, everyone who's a new nurse to the trust, they have an induction with our diabetic specialist nurses and that does cover some form of diabetes as a whole training. But it's also about having that repeated training. I don't think its repeated. I think you'd need to have it every three years, like refreshers, for example. - P14*	SAME	*I mean, I guess probably you've got to come back to it, at some point after their first induction. - P3*
Regular feedback sessions with staff are beneficial for identifying and addressing issues with insulin	*And then I do regular sessions with the F1 and the F2 doctors. In terms of just twenty minutes a month, just at the beginning of their sessions of learning from common prescribing errors. And, and it's really helpful because they feed back to me what the issues are. - P11*	Mandating training necessary to ensure adequate reach and success	*And when you line it up with all the other training that sits for a trust to have to undertake, unless, unless you can get these sorts of things into the mandatory category, you generally don't have much success with them. - P8*
Mandatory training topics don't always reflect the frequency and	*Some people might share the answers, but at least it will put it on the agenda that insulin is important, especially for people who are actually going to come across it in the day to day. So, you don't*	Pharmacy has specific workforce issues with respect to	*Although nurses do manage to carve out time for training, which we struggle with in pharmacy, because of the availability of bank or locum staff for nursing, whereas they can*

clinical importance of issues encountered.	*always come across a fire where you work but yet you do the annual fire safety training. For insulin its regularly seen so, it will always be on the agenda. - P14*	facilitating staff completing face-to-face mandatory training due to shift patterns	*say "these six people are not going to work on that day, because they're going to have their mandatory day's training", which they do do here, I don't know if they do it elsewhere, and they will fill the ward then with bank or locum staff. Whereas we simply do not have that within pharmacy. - P12*
Negative staff attitudes and approach to mandatory training impact their usefulness	*I know mandatory training doesn't always work if you think of things like hand washing or fire training. It's a tick-box exercise, everyone does it. - P14*	SAME	*But you can see that their attending, thinking, "I've read that policy, I know that policy. I've got twenty scripts to do when I go back to the ward", or you know, and they're on their phones. They're not looking at the screen. They're not interacting in the teaching. Yeah, they're not [engaged]. They're just there because they sign their name and they get their lunch. But if you ask them questions, nobody speaks. P16*

Self-administration policy					
Inferences - respondents using the intervention	**Example quotes**	**Inference - respondents not actively using existing policy**	**Example quotes**	**Inferences - respondents not using the intervention**	**Example quotes**
Familiar documentation that is congruent with existing processes reduces the amount of perceived effort from nurses with respect to insulin self-administration	*But what happened is that the chart didn't look any different... Because it's obviously a hospital chart its part of patient record so it goes in their record so it meant that nothing else had to be written in the notes and it*	Pharmacy-led implementation is desirable but limited by size and capacity of pharmacy team	*"There really isn't much time and I know and other hospitals their MMTs, their techs do some of that. And we just haven't got the staff to do that unfortunately. But yeah. So in my inpatient safety group they say well can't pharmacy do, and I say we'd love to, but we just haven't got the technicians base to be able to free up*	Previous negative experience with policy use limit the degree of patient independence with administration and influence re-adoption of intervention	*I think with maternity patients, we had self-administration of medicines policy that I think the midwives used to think "well then they're managing their insulin themselves". So quite often, it wouldn't necessarily be prescribed timely or correctly because they just assumed the patients are self-administering. We've now stopped that. So*

	was all great. - P2		*their time to be able to do to do that, unfortunately." – P10*		*that was an issue. - P11*
Perception of need and benefit is stronger than regard for proportion of uptake	*So its difficult to see uptake but there was definitely a need for it there and its now there so helping patients to self-administer so it's a valid process that they can go through to be able to do that. And it gives our nurses some respite as well from having to give medicines as well. Some time respite. - P1*	Lack of use of policy seen as a negative quality marker and sub-optimal for patient care and accommodating patient choice	*Because at the end of the day, a patient should be self-administering where they can. They've got to go home and do that. And we, you know, we de-skill them, we take that away whilst they're in hospital. - P13*	The perceived demand for self-administration may influence its perceived effectiveness	*But I think the problem that we've got … is that a lot of it is down to the assessment of the patient's ability to self-administer. And the group of patients that you've got, presumably as your kind of advisory group or whatever are presumably fit and healthy people (interviewer: Yes. Yes, exactly) who would be absolutely mortified to think that somebody else could do their medicines better than them. Whereas actually, the kind of people that we've got acutely ill in our hospital (interviewer: yeah,) are generally really ill. - P11*

Staff who perceive the intervention will reduce errors and harm are more likely to be interested in its implementation	*Okay. So, I have a personal interest in this area, in self-administration. So I personally do feel that most of our errors would be reduced if the patient is competent and able to self-administer. A lot of the errors I think would come down. - P14*	Staff reluctance to implement self-administration policy impacted by previous negative experiences and incidents	*I think the problem is that as a trust we have been burnt I suppose in the fact that patients refuse to give up their insulin. And we then found that they were probably more confused than they thought they were and they've had crashing hypos because they've given themselves too much insulin. So what's really difficult here, I think, is the fact that people are wary. - P10*	Lack of simplicity and standardisation of approach due to likely changes in clinical condition impacts the willingness to adopt self-administration policies	*I think the difficulty with self-administration in general, is that there isn't a one-size-fits-all. And if you could write the policy that, you know, sensible people can self-administer, and we're going to give them the keys to their lockers, and you know, anybody who's dependent isn't going to be. But actually, for all of us, that can change. And so I think, for me, I think that's the challenge and the difficulty. Unfortunately, I've been around for too long than I care to remember, and so having done a self-administration policy, you know, twenty years ago in a previous hospital. Things are completely different now than what they used to be. Patients are far sicker, because actually if they're not very sick, actually we need the bed for the person who is very sick and waiting in A and E, so you have less well patients who could self-administer if you know what I mean. - P11*

Perception of patients as very knowledgable and capable to manage their diabetes moreso than generalist staff	*That patients are best at managing their own insulin to be honest! That's it. They're more familiar with what their medication is, what they should be giving at what times and when we start to get involved in it there is always a risk we will get it wrong. So I think that's why it works well. I think the other thing is that it keeps the patients skilled and doesn't deskill them whilst in hospital. They keep their responsibility for that. Which certainly with our long-stay patients, that can become an issue. - P15*	Logistical challenges and safety risks around safe storage of insulin at ward level is a barrier to uptake of self-adminsitration policy	*The thing that makes us, erm, twitchy, if that's a word, about self-administration of insulin is potentially around how you have to store it to make it available. Actually saying it out loud, it sounds pathetic. But we, I think we, I think we struggle with the infrastructure to allow it in terms of around the keys, you've got to give the patient the keys to the locker in order that they can they can have access as well. And I, I'm not sure we're there yet with that. Which is a shame, because what I perceive to be the vast majority of patients who would be able to self-administer. - P12*	Nursing time gains from self-administration are balanced with losses completing the requisite processes	*The nurses haven't got time to do it. One of the key benefits of self-administration would be to actually get it at the right time. Dinners are all put out and if the nurse has got like five patients on insulin to do. Someone's not gonna get it at the right time invariably. So if you've got someone that can self-administer it pre-meal, and you know, that would be a key benefit. - P11*
Need to address staff and patient awareness of the ability to self-administer insulin whilst in hospital can	*And I just think that a lot of people might not even know that they are able to offer that so were currently also putting together a leaflet for diabetes patients when they come into hospital and within that leaflet*		Staff competence and confidence to complete capacity assessments is a barrier to allowing self-administration	*And they do implement the self-administration policy. But I still don't think its clear cut in regards to okay who's appropriate who's not because I don't know necessarily that the nurses are really conscious of the consequences of you know, using self-administration on the ward. - P6*	

be supported with literature	*it talks about self-administration. P14*		
Risk of harm from insulin self-administration on account of patient characteristics perceived as rare	*Certainly on our community wards that's true. On the mental health wards that's true as well. On the rare occasions we have people that are either confused and not knowing what dose to dial up or potentially at risk of harming themselves with the insulin then that takes a little bit more supervision. - P15*	Absence of engaged leadership driving implementation as a barrier to uptake	*And then when I was on mat leave it just got stopped because nobody really took it forward. - P18*
Logistical restrictions with storage of insulin and disposal of needles limits the independence patients have with self-administration	*The only problem with it though is it, sorry (interviewer: no, go ahead) is that to self-administer at level three you need to have a key to your locker, on most wards what you'll find what you find is it's the same key for every single locker on the ward. It's the same code because no one's going to purchase thirty different keys. Sometimes it won't be level three it will be level two. So, it will just be supervised self-administration because they can't actually give you a key, not to say that a patient going to go to another person locker in the night and steal their medicines, but it's just that risk. - P14*	Perception of low desire for intervention from nurses	*Because I think that the people that would probably really want it, are nurses because it would decrease administration time for them, which, bearing in mind the rest of the stuff that they've got going on. They could, where it was safe, offload it, but I don't feel a support for it. But then I might not be in the position to feel that. - P12*
Perception of usefulness of general self-admin policies as a motivator	*So what I then I did was write the hospital policy, and again we came up against a problem, because they had, every hospital has a self-admin policy and they all vary in degrees of utterly useless, basically. - P2*	Low numbers of patients using policy due to strict criteria in pilot phase as a barrier to uptake.	*And we sort of piloted it for a little while, but it didn't really sort of come off. The numbers were really small. And the sort of feedback that we had was the "Oh, the criteria, perhaps was a bit too strict". Because we say obviously, we don't want anybody that's comatose or going for surgery, x, y, z. So the numbers were small. So it's like okay, well, we'll, we'll adjust it, and we came back to it. And I don't know, for one reason or*

			another, it didn't really sort of take off. - P13
Self-administration is perceived to be straightforward and simplicity with self-assessment is key to success	*But patients basically have to do some kind of NVQ in giving themselves a drug before they're allowed to have a key, you know, it's incredibly complex, incredibly complicated. - P2*	Desire to re-implement policy present due to perceived appreciated benefits, including error reduction and patient empowerment	*So it's like they're shocking figures. And I think it seems like that which was hopefully going to help get people on board and improving the self-admin. Because Yeah, we we definitely have issues with it being given at the wrong time of day. - P5*
Shared learning from other hospitals aids policy writing	*so [pharmacist A] did all the work with the CQC to prove you didn't have to lock insulin away so I took that part of it and [pharmacist B] did the risk assessment that the CQC asked for so I took her one and then just [trust A]'d it, submitted it to our medicines governance and they were happy to agree to it not being locked away because we had approval from the CQC so they were happy with that. - P2*	Perception of time and cognitive burden and competing interests in an already busy environment as a barrier to uptake	*Not that much, no. But and I think it is, even with the self-administration under supervision, there has to be, there's still some, still some, you know, tick-boxes that are needed. And I think sometimes it's easier for nursing staff just to do it themselves and just get on with it. - P16*
Measurable success with pilot motivates wider implementation	*And so what we did, we piloted it in like cardiology and renal were all your diabetics are, and it worked a treat and then we took it to the admissions unit and obviously I was admissions pharmacist so that made it a little bit easier as well and they were like "yeah no that's cool" and so what we're doing, and so the nurses were just kind of like "yeah cool" and obviously what we say to them is "go and do this and the patient gets on with it". So we've had it where the nurses are just doing it, they're happy to sign it off, the patient signs it and off they go. - P2*	Implementation perceived as difficult	*So you they had a, you know, a whole booklet really on how to do it. And I just lifted it from that. The consent and stuff like that. So again, the sort of templates were there. It wasn't difficult to do, it was really a matter of the sort of implementation by the nursing staff. And I just think, oh, it was it was, I guess it was too difficult for whatever reason to implement. - P13*

Workarounds to logistical issues as more important to facilitate intervention than letting it be a barrier	*Now, we had this thing were they had to put everything into boxes and no one ever did, but I was like "look, just make sure it's in the locker out of the way, you know, like in their bedside locker out the way, off the table and you're fine" and they kind of went "okay then". - P2*	Implementation of electronic prescribing systems as a factor in timing and design of policy	*But again, it goes hand in hand with maybe devising a new chart and maybe putting it on EP because we're moving to a whole new EPMA system. - P18*
The aim of assessment is to ensure they are safe, not strive for perfection	*So we've lots of conversations about it. It's the classic thing, they fall into this trap of trying to prove perfect diabetes-ness and I keep trying to say to them "patients weren't perfect before they came in but they were safe, and that's all were doing with self-admin". And as long as that patient doesn't give themselves a hypo or DKA, I don't actually care what they are doing. And they don't like it. They don't like it at all. And I'm like "it's up to the primary care team to look after this patient and their ability to inject. Not you. You're here to keep everyone safe." - P2*	Lack of adherence to paperwork completion risks safety	*Erm we're also finding interesting that there are sometimes people who are self-admin-ing they haven't filled in the separate paperwork. So we need to make sure that it is properly, erm, done by policy, really, to make sure it's safely done. - P5*
Where the perception of benefit of self-administration for the organisation is high, uptake is high and it is embedded into the culture	*And we've got, we've got quite a good self-administration policy that's been in use for a number of years and because we've got a number of long-term patients, I guess, who are returning to us. We've got, we've got a vested interest in encouraging them to manage their own conditions. - P3*	Staff resistance to uptake out of fear of blame if mistakes are made	*Another bit is that the nurses are sort of a little bit tentative in the context of "well if I let the patient do this and they forget to do it or they're not as competent as they originally thought and they miss their insulin doses and the sugars are sky high. And something happens they'll come back to me on it". You know "why did you let that patient do that?" you know? So there's a little bit of, I would assume, fear. And sort of wanting to protect yourself. So the best way to protect yourself is just to blast on and you know, know that it's done. - P8*

Incomplete documentation is a risk and limits evaluation but processes to monitor completion increase safe use of policy	*It's quite formal that. The diabetes nurses pick up on if patients haven't got the forms filled in and they're self-meding, self-administering they will actually do that as an incident. We have some robust kind of systems to ensure that patients who are self-administering that the appropriate documents and assessments have been done. - P7*	Lack of culture and familiarity of self-administration depends on ward type and patient demographic	*So I think it's very hit and miss as to where they are doing it well. So I know the CF unit. They are using self-admin quite a lot. But then yeah, they self admin all their meds. That's the sort of part of the culture of the ward. And again on maternity they can self-admin, which isn't - they're not doing it as per policy, but because actually the vast majority of women there are healthy they're just in because they've had a baby. - P5*
		Multidisciplinary team working required to plan and implement intervention that is workable	*And that's what we found, so we were really surprised, we did a lot of teaching on the patient self-admin at one point. And we kind of just assumed, you know, took it for granted that they do these kind of capacity assessments all the time. And they basically, they turned round and said "No, we never do them. The OTs do them occasionally, physios sometimes, the medics do them, but we don't". And we went "Oh." - P9*
		Paternalistic mentality to overcome in order to use self-administration policy	*A couple of different things with it. Number one is the traditional feeling or sort of understanding that we look after patients in hospital. You know, if you're a nurse you'll be giving their insulin because you're giving them their medicine and insulin is a medicine. So they need to let go of that a little bit. - P8*
		Perception of barriers from regulatory authorities as prohibitive to uptake of policy	*And getting all of the CQC inspectors signed up for that as a collective as well rather than just an individual going "Oh, that's fine." And another one going "No, I don't like that." - P9*

Appendix 15: RAMESES Checklist: List of items to be included when reporting a realist synthesis

TITLE	
1	In the title, identify the document as a realist synthesis or review
ABSTRACT	
2	While acknowledging publication requirements and house style, abstracts should ideally contain brief details of: the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice.
INTRODUCTION	
3. Rationale for review	Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area.
4. Objectives and focus of review	State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review.
METHODS	
5. Changes in the review process	Any changes made to the review process that was initially planned should be briefly described and justified.
6. Rationale for using realist synthesis	Explain why realist synthesis was considered the most appropriate method to use.
7. Scoping the literature	Describe and justify the initial process of exploratory scoping of the literature.
8. Searching processes	While considering specific requirements of the journal or other publication outlet, state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the review. Where searching in electronic databases has taken place, the details should include, for example, name of database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected.
9. Selection and appraisal of documents	Explain how judgements were made about including and excluding data from documents, and justify these
10. Data extraction	Describe and explain which data or information were extracted from the included documents and justify this selection.
11 Analysis and synthesis processes	Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process
RESULTS	
12 Document flow diagram	Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). You may

	consider using the example templates (which are likely to need modification to suit the data) that are provided.
13 Document characteristics	Provide information on the characteristics of the documents included in the review.
14 Main findings	Present the key findings with a specific focus on theory building and testing.
DISCUSSION	
15 Summary of findings	Summarize the main findings, taking into account the review's objective(s), research question(s), focus and intended audience(s).
16 Strengths, limitations and future research directions	Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the review process and (b) comment on the overall strength of evidence supporting the explanatory insights which emerged. The limitations identified may point to areas where further work is needed.
17 Comparison with existing literature	Where applicable, compare and contrast the review's findings with the existing literature (for example, other reviews) on the same topic.
18 Conclusion and recommendations	List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice.
19 Funding	Provide details of funding source (if any) for the review, the role played by the funder (if any) and any conflicts of interests of the reviewers

Appendix 16: Details of excluded studies (Realist synthesis)

Excluded article	**Reason**
Abrahams, N., Gilson, L., Levitt, N. S., & Dave, J. A. (2019). Factors that influence patient empowerment in inpatient chronic care: early thoughts on a diabetes care intervention in South Africa. *BMC endocrine disorders*, *19*(1), 133. https://doi.org/10.1186/s12902-019-0465-1	LMIC context
Ahmed Atalla, Hanan Ramzy. (2016). Effectiveness of nursing intervention regarding self insulin administration among diabetic patients. Clinical Nursing Studies. 4. 10.5430/cns.v4n2p57.	Assessing patient's knowledge of insulin
Aujoulat, I., Young, B., Salmon, P. (2012) The psychological processes involved in patient empowerment. Orphanet Journal of Rare Diseases , 7(Suppl 2):A31	Abstract only
Baicus, C., Balanescu, P., Zeh, S., Oprisan, E., Lapadatu, R., Gurghean, A., Padureanu, V., Rezus, C., Mitu, F., Jurcut, R., Balanescu, A. R., Daha, I., Balanescu, E., Bojinca, M., Pinte, L., Constantin, A. M., Dima, N., Floria, M., Leon-Constantin, M. M., Roca, M., … Badea, C. G. (2019). Characteristics of shared decision making in Romania from the patient perspective: A cross-sectional multicentric study. *Journal of evaluation in clinical practice*, *25*(6), 1152–1159. https://doi.org/10.1111/jep.13257	LMIC context
Berger A. (2019). Shared decision-making. *BMJ sexual & reproductive health*, *45*(2), 168. https://doi.org/10.1136/bmjsrh-2018-200257	No access
Beyene, L. S., Severinsson, E., Hansen, B. S., & Rørtveit, K. (2019). Being in a space of sharing decision-making for dignified mental care. *Journal of psychiatric and mental health nursing*, *26*(9-10), 368–376. https://doi.org/10.1111/jpm.12548	Mental health context
Bjønness, S., Viksveen, P., Johannessen, J. O., & Storm, M. (2020). User participation and shared decision-making in adolescent mental healthcare: a qualitative study of healthcare professionals' perspectives. *Child and adolescent psychiatry and mental health*, *14*, 2. https://doi.org/10.1186/s13034-020-0310-3	Adolescent context
Buhse, S., Heller, T., Kasper, J., Mühlhauser, I., Müller, U. A., Lehmann, T., & Lenz, M. (2013). An evidence-based shared decision making programme on the prevention of myocardial infarction in type 2 diabetes: protocol of a randomised-controlled trial. *BMC family practice*, *14*, 155. https://doi.org/10.1186/1471-2296-14-155	Intervention protocol only
Burn, E., Conneely, M., Leverton, M., & Giacco, D. (2019). Giving Patients Choices During Involuntary Admission: A New Intervention. *Frontiers in psychiatry*, *10*, 433. https://doi.org/10.3389/fpsyt.2019.00433	Involuntary admission context
Daniel, K. , Takatori, K. , Fiore, A. , Neto, A. , Pavin, E. , Minicucci, W. , & Parisi, M. (2015). Evaluation of the insulin administration technique in a tertiary hospital. Diabetol Metab Syndr, 7 (Suppl 1). doi: 10.1186/1758-5996-7-s1-a176	No intervention, considers technique only

Das Choudhury, S., Das, S. K., & Hazra, A. (2014). Survey of knowledge-attitude-practice concerning insulin use in adult diabetic patients in eastern India. *Indian journal of pharmacology*, *46*(4), 425–429. https://doi.org/10.4103/0253-7613.135957	Outpatient setting
Devi, Sarungbam & Kumari, Vinay. (2015). Effectiveness of Structured Teaching Programme on Self-administration of Insulin in terms of Knowledge and Skill of patients with Diabetes Mellitus. 10.13140/RG.2.2.27242.36802.	Concerns patient skills
Dungan, K., Lyons, S., Manu, K., Kulkarni, M., Ebrahim, K., Grantier, C., Harris, C., Black, D., & Schuster, D. (2014). An individualized inpatient diabetes education and hospital transition program for poorly controlled hospitalized patients with diabetes. *Endocrine practice : official journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists*, *20*(12), 1265–1273. https://doi.org/10.4158/EP14061.OR	Educational intervention
Dunning, Trisha; Martin, Peter; Orford, Neil and Orellana, Liliana.(2018) Diabetes, palliative and end of life care: Information to support shared decision-making [online]. Australian Nursing and Midwifery Journal, 26 (1): 40. Availability: <https://search.informit.com.au/documentSummary;dn=663363800769899;res=IELHEA> ISSN: 2202-7114.	Palliative care context guidance only
Dy, S. M., & Purnell, T. S. (2012). Key concepts relevant to quality of complex and shared decision-making in health care: a literature review. *Social science & medicine (1982)*, *74*(4), 582–587. https://doi.org/10.1016/j.socscimed.2011.11.015	Systematic review, and not hospital based
Fabio, Macchi & Pravettoni, Gabriella & Lucchiari, Claudio & Gorini, Alessandra. (2015). Patient empowerment and quality of life: a qualitative study on the doctors' perspective.	Abstract only
Frosch, D. L., May, S. G., Rendle, K. A., Tietbohl, C., & Elwyn, G. (2012). Authoritarian physicians and patients' fear of being labeled 'difficult' among key obstacles to shared decision making. Health affairs (Project Hope), 31(5), 1030–1038. https://doi.org/10.1377/hlthaff.2011.0576	Primary care based
Gawand, K.S, Gawali, U.P. and Kesari, H.V. (2016). A STUDY TO ASSESS KNOWLEDGE, ATTITUDE AND PRACTICE CONCERNING INSULIN USE IN ADULT PATIENTS WITH DIABETES MELLITUS IN TERTIARY CARE CENTRE. Indian Journal of Medical Research and Pharmaceutical Sciences, 3(9), 36–40. http://doi.org/10.5281/zenodo.61778	Assessing patient's knowledge of insulin
Gerada, Y., Mengistu, Z., Demessie, A., Fantahun, A., & Gebrekirstos, K. (2017). Adherence to insulin self administration and associated factors among diabetes mellitus patients at Tikur Anbessa specialized hospital. *Journal of diabetes and metabolic disorders*, *16*, 28. https://doi.org/10.1186/s40200-017-0309-3	LMIC context
Getachew, F. and Solomon, D. (2019). Knowledge, Attitude, Practice and associated factors towards Self-Insulin Administration among Diabetic Patients in Hawassa Referral Hospital, Southern Ethiopia, Recent Research in Endocrinology and Metabolic Disorder, 1(1) 10-17. http://dx.doi.org/10.33702/rremd.2019.1.1.3	Assessing patient's knowledge of insulin
Giacco D, Mavromara L, Gamblen J, Conneely M, Priebe S. Shared decision-making with involuntary hospital patients: a qualitative study of barriers and facilitators. BJPsych Open. 2018;4(3):113-118. Published 2018 Apr 17. doi:10.1192/bjo.2018.6	Involuntary admission context

Guzman S. J. (2020). A Behavioral Perspective of Therapeutic Inertia: A Look at the Transition to Insulin Therapy. *Diabetes spectrum : a publication of the American Diabetes Association*, *33*(1), 38–43. https://doi.org/10.2337/ds19-0024	Concerns starting insulin therapy
Hadgu, Gerensea. (2015). Knowledge and Attitude on Insulin Self Administration Among Type One Diabetic Patients in Mekele Hospital,Tigray, Ethiopia, 2015. Advances in Surgical Sciences. Volume 3, , October 2015,. Pages: 32-36. 10.11648/j.ass.20150305.11.	Assessing patient's knowledge of insulin
Hamann, J., Holzhüter, F., Stecher, L., & Heres, S. (2017). Shared decision making PLUS - a cluster-randomized trial with inpatients suffering from schizophrenia (SDM-PLUS). BMC psychiatry, 17(1), 78. https://doi.org/10.1186/s12888-017-1240-3	Concerns intervention to increase SDM
Hamersky, Carol Mahler, (2017) Exploring Autonomy Support in Shared Decision Making and Patient Activation of Diabetes Self-Care Behaviors. Seton Hall University Dissertations and Theses (ETDs). 2243.	Outpatient setting
Harman, S. M., Blankenburg, R., Satterfield, J. M., Monash, B., Rennke, S., Yuan, P., Sakai, D. S., Huynh, E., Chua, I., Hilton, J. F., & Patient Engagement Project (2019). Promoting Shared Decision-Making Behaviors During Inpatient Rounds: A Multimodal Educational Intervention. Academic medicine : journal of the Association of American Medical Colleges, 94(7), 1010–1018. https://doi.org/10.1097/ACM.0000000000002715	Intervention does not involve policy
Hiley, J., Homer, D., & Clifford, C. (2008). Patient self-injection of methotrexate for inflammatory arthritis: a study evaluating the introduction of a new type of syringe and exploring patients' sense of empowerment. *Musculoskeletal care*, *6*(1), 15–30. https://doi.org/10.1002/msc.114	Concerns methotrexate injection
Jaensch, D., Baker, N., & Gordon, S. (2019). Contemporaneous patient and health professional views of patient-centred care: a systematic review. *International journal for quality in health care : journal of the International Society for Quality in Health Care*, *31*(10), G165–G173. https://doi.org/10.1093/intqhc/mzz118	No access
James, J. T., Eakins, D. J., & Scully, R. R. (2019). Informed consent, shared-decision making and a reasonable patient's wishes based on a cross-sectional, national survey in the USA using a hypothetical scenario. BMJ open, 9(7), e028957. https://doi.org/10.1136/bmjopen-2019-028957	Survey tool development
Johansson, K., Leino-Kilpi, H., Salanterä, S., Lehtikunnas, T., Ahonen, P., Elomaa, L., & Salmela, M. (2003). Need for change in patient education: a Finnish survey from the patient's perspective. *Patient education and counseling*, *51*(3), 239–245. https://doi.org/10.1016/s0738-3991(02)00223-9	Educational intervention
Kärner Köhler, A., Tingström, P., Jaarsma, T., & Nilsson, S. (2018). Patient empowerment and general self-efficacy in patients with coronary heart disease: a cross-sectional study. *BMC family practice*, *19*(1), 76. https://doi.org/10.1186/s12875-018-0749-y	Coronary heart disease context
Kavanagh, S. and Boparai, P (2015), Does the current self-administration policy enable self-administration of insulin at a large teaching hospital? Diabetic Medicine, 32 p160-161	Abstract only

Leey, J, Acord, C., James, L.K., Pratt, E, Tobin, G.S. (2014) Inpatient management of diabetes: Assessing perceptions and barriers among nurses, Diabetes. Jun; 63(Supplement 1): A170-A212	Abstract only
Liebherz, S., Härter, M., Dirmaier, J., & Tlach, L. (2015). Information and Decision-Making Needs Among People with Anxiety Disorders: Results of an Online Survey. *The patient*, *8*(6), 531–539. https://doi.org/10.1007/s40271-015-0116-1	Concerns anxiety disorders not hospital based
Lipkin M. (2013). Shared decision making. *JAMA internal medicine*, *173*(13), 1204–1205. https://doi.org/10.1001/jamainternmed.2013.6248	No access
Madsen, C., & Fraser, A. (2015). Supporting patients in shared decision making in clinical practice. *Nursing standard (Royal College of Nursing (Great Britain) : 1987)*, *29*(31), 50–57. https://doi.org/10.7748/ns.29.31.50.e8570	No access
Martins (2017) Martins, P. F., & Perroca, M. G. (2017). Care necessities: the view of the patient and nursing team. Revista brasileira de enfermagem, 70(5), 1026–1032. https://doi.org/10.1590/0034-7167-2016-0197	Survey tool development
McAlearney, A. S., Fareed, N., Gaughan, A., MacEwan, S. R., Volney, J., & Sieck, C. J. (2019). Empowering Patients during Hospitalization: Perspectives on Inpatient Portal Use. *Applied clinical informatics*, *10*(1), 103–112. https://doi.org/10.1055/s-0039-1677722	Intervention not relevant
McCarter, S. P., Tariman, J. D., Spawn, N., Mehmeti, E., Bishop-Royse, J., Garcia, I., Hartle, L., & Szubski, K. (2016). Barriers and Promoters to Participation in the Era of Shared Treatment Decision-Making. Western journal of nursing research, 38(10), 1282–1297. https://doi.org/10.1177/0193945916650648	Cancer specific context
Melis, R. J., Makai, P., & Perry, M. (2014). Actual involvement vs preference for involvement as an indicator of shared decision making. *JAMA internal medicine*, *174*(4), 643–644. https://doi.org/10.1001/jamainternmed.2013.12866	No access
Meltzer, D. O., Ruhnke, G. W., & Tak, H. J. (2014). Actual involvement vs preference for involvement as an indicator of shared decision making-reply. *JAMA internal medicine*, *174*(4), 644. https://doi.org/10.1001/jamainternmed.2013.12840	No access
Mendel, R., Traut-Mattausch, E., Frey, D., Bühner, M., Berthele, A., Kissling, W., & Hamann, J. (2012). Do physicians' recommendations pull patients away from their preferred treatment options?. Health expectations : an international journal of public participation in health care and health policy, 15(1), 23–31. https://doi.org/10.1111/j.1369-7625.2010.00658.x	Hypothetical decision-scenario not relevant to topic
Mitsis (2017), Shared decision making for cancer treatment: Patient preferences at a comprehensive cancer center, Psycho-Oncology 2017; 26: 47–104	Abstract only
Modic, M. B., Sauvey, R., Canfield, C., Kukla, A., Kaser, N., Modic, J., & Yager, C. (2013). Building a novel inpatient diabetes management mentor program: a blueprint for success. *The Diabetes educator*, *39*(3), 293–313. https://doi.org/10.1177/0145721713480246	Concerns nurse empowerment rather than patients
Muhammad, K., Khan, T., Rehman, N-U, Khan, Z. and Subhan, F. (2020), Knowledge and attitude regarding insulin self-administration among diabetic patients: a cross-sectional	Assessing patient's

study in a teaching hospital of Khyber-Pakhtunkhwa, Pakistan Drugs & Therapy Perspectives (2020) 36:266–272	knowledge of insulin
Olasoji, M., Plummer, V., Shanti, M., Reed, F., & Cross, W. (2020). The benefits of consumer involvement in nursing handover on acute inpatient unit: Post-implementation views. *International journal of mental health nursing*, *29*(5), 786–795. https://doi.org/10.1111/inm.12709	Acute mental health unit setting
Parchman, M. L., Zeber, J. E., & Palmer, R. F. (2010). Participatory decision making, patient activation, medication adherence, and intermediate clinical outcomes in type 2 diabetes: a STARNet study. *Annals of family medicine*, *8*(5), 410–417. https://doi.org/10.1370/afm.1161	Primary care based
Phillips, Anne. (2019). Recognising the importance of self-management for people with diabetes. British Journal of Healthcare Management. 25. 224-229. 10.12968/bjhc.2017.0030.	No access
Redley (2019), Redley, B., McTier, L., Botti, M., Hutchinson, A., Newnham, H., Campbell, D., & Bucknall, T. (2019). Patient participation in inpatient ward rounds on acute inpatient medical wards: a descriptive study. BMJ quality & safety, 28(1), 15–23. https://doi.org/10.1136/bmjqs-2017-007292	Ward round context
Sande-Meijide, M., Lorenzo-González, M., Mori-Gamarra, F., Cortés-Gago, I., González-Vázquez, A., Moure-Rodríguez, L., & Herranz-Urbasos, M. (2019). Perceptions and attitudes of patients and health care workers toward patient empowerment in promoting hand hygiene. *American journal of infection control*, *47*(1), 45–50. https://doi.org/10.1016/j.ajic.2018.07.002	Concerns hand hygiene promotion
Scheel-Sailer, A., Post, M. W., Michel, F., Weidmann-Hügle, T., & Baumann Hölzle, R. (2017). Patients' views on their decision making during inpatient rehabilitation after newly acquired spinal cord injury-A qualitative interview-based study. Health expectations : an international journal of public participation in health care and health policy, 20(5), 1133–1142. https://doi.org/10.1111/hex.12559	Spinal injury context
Seale, H., Chughtai, A. A., Kaur, R., Crowe, P., Phillipson, L., Novytska, Y., & Travaglia, J. (2015). Ask, speak up, and be proactive: Empowering patient infection control to prevent health care-acquired infections. American journal of infection control, 43(5), 447–453. https://doi.org/10.1016/j.ajic.2015.01.007	Concerns healthcare acquired infections
Sengupta R.; Indihar M.V.; Joseph P.M.; Eckman M. (2017) Patient education tools to improve shared decision making in CF, Pediatric Pulmonology, The 31st Annual North American Cystic Fibrosis Conference	Abstract only
Sharma, R. K., Cameron, K. A., Zech, J. M., Jones, S. F., Curtis, J. R., & Engelberg, R. A. (2019). Goals-of-Care Decisions by Hospitalized Patients With Advanced Cancer: Missed Clinician Opportunities for Facilitating Shared Decision-Making. *Journal of pain and symptom management*, *58*(2), 216–223. https://doi.org/10.1016/j.jpainsymman.2019.05.002	Concerns cancer patients
Shay, L. A., & Lafata, J. E. (2015). Where is the evidence? A systematic review of shared decision making and patient outcomes. *Medical decision making : an international journal of the Society for Medical Decision Making*, *35*(1), 114–131. https://doi.org/10.1177/0272989X14551638	Systematic review not inpatient context
Shrestha, D. & Basnet, S. & Parajuli, P. & Baral, Dharanidhar & Badhu, Angur. (2018). Knowledge Regarding Self-Administration of Insulin Among the Diabetic Patient Attending	Assessing patient's

the Diabetic Clinic of Tertiary Care Center of Eastern Nepal. Journal of Diabetes and Endocrine Association of Nepal. 2. 9. 10.3126/jdean.v2i1.21194.	knowledge of insulin
Southern, L. and Bielawski, C. (2013) Timely administration of anti-parkinson's medications: A multi-disciplinary project to improve knowledge, drug availability and patient empowerment, Age and Ageing, Volume 42, Issue suppl_2, March 2013, Pages ii5–ii16,	Abstract only
Tariman, J. D., Katz, P., Bishop-Royse, J., Hartle, L., Szubski, K. L., Enecio, T., Garcia, I., Spawn, N., & Masterton, K. J. (2018). Role competency scale on shared decision-making nurses: Development and psychometric properties. *SAGE open medicine*, *6*, 2050312118807614. https://doi.org/10.1177/2050312118807614	Tool validation
Tariman, J. D., Mehmeti, E., Spawn, N., McCarter, S. P., Bishop-Royse, J., Garcia, I., Hartle, L., & Szubski, K. (2016). Oncology Nursing and Shared Decision Making for Cancer Treatment. *Clinical journal of oncology nursing*, *20*(5), 560–563. https://doi.org/10.1188/16.CJON.560-563	Cancer specific context
Theeranute, Ampornpan & Methakanjanasak, Nonglak & Surit, Pattama & Ruisungnoen, Wasana & Sawanyawisuth, Kittisak & Saensom, Donwiwat. (2018). The individual empowerment program improves glycemic and lipid controls in admitted type 2 DM patients. Diabetes mellitus. 21. 113-117. 10.14341/DM8339.	Educational intervention
Thornton, L (2013) Educating nurses for person-centered care, Middle east journal of nursing, Vol 7 (4): 38-42	Concerns long-term residential care for older people
Torres, A., Kunishige, N., Morimoto, D., Hanzawa, T., Ebesu, M., Fernandez, J., Nohara, L., SanAgustin, E., & Borg, S. (2015). Shared governance: a way to improve the care in an inpatient rehabilitation facility. *Rehabilitation nursing : the official journal of the Association of Rehabilitation Nurses*, *40*(2), 69–73. https://doi.org/10.1002/rnj.143	Concerns rehabilitation nursing
Trief, P. M., Cibula, D., Rodriguez, E., Akel, B., & Weinstock, R. S. (2016). Incorrect Insulin Administration: A Problem That Warrants Attention. *Clinical diabetes : a publication of the American Diabetes Association*, *34*(1), 25–33. https://doi.org/10.2337/diaclin.34.1.25	Assessing patient's knowledge of insulin
van der Kluit, M. J., Dijkstra, G. J., & de Rooij, S. E. (2018). The decision-making process for unplanned admission to hospital unveiled in hospitalised older adults: a qualitative study. BMC geriatrics, 18(1), 318. https://doi.org/10.1186/s12877-018-1013-y	Concerns decision-making prior to hospitalisation
Wallach, A., Plaskin, J., Pavlishyn, N et al (2016) Developing a patient empowerment program (PEP) to achieve better patient outcomes by preparing patients to participate in medical encounters, Journal of General Internal Medicine, 31 (2)	Abstract only
Winkley, K., Upsher, R., Polonsky, W. H., & Holmes-Truscott, E. (2020). Psychosocial aspects and contributions of behavioural science to medication-taking for adults with type 2 diabetes. *Diabetic medicine : a journal of the British Diabetic Association*, *37*(3), 427–435. https://doi.org/10.1111/dme.14214	Narrative review of medicines-taking behaviours

Wittmann-Vieira, Rosmari, & Goldim, José Roberto. (2018). Decision-making ability of patients undergoing invasive medical procedures. Acta Paulista de Enfermagem, 31(5), 497-503. https://doi.org/10.1590/1982-0194201800070	Concerns invasive procedures
Wijetilleka, S., Ahmed, M., Patel, N. (2015) Improving patient safety by reducing inpatient subcutaneous insulin prescription errors and the promotion of inpatient self-management in patients with diabetes. Diabetic Medicine, 32 p102	Abstract only
Yosef T. (2019). Knowledge and Attitude on Insulin Self-Administration among Type 1 Diabetic Patients at Metu Karl Referral Hospital, Ethiopia. *Journal of diabetes research*, *2019*, 7801367. https://doi.org/10.1155/2019/7801367	Assessing patient's knowledge of insulin

Appendix 17: Quality Appraisal (Realist synthesis)

Author, year	Study design	Study aim	Sample population	Relevance: does it address the theory under test?	Rigour: credibility and trustworthiness	Included in final review (Y/N)
Search 1						
Ahmed 2013	Audit	Examine adherence to the SAM policy for diabetes medicines (including insulin) and patient attitudes to SAM	Inpatients at Warrington General Hospital NHS Foundation Trust, UK (n=50)	Yes, discusses diabetes SAM in a UK hospital with people with diabetes	Inferences not backed by qualitative data but patient preferences backed with audit data	Y
Alabraba 2014	Insulin self-administration project description and audit	Shared learning for insulin self-administration policy implementation	Inpatients at Aintree University Hospital NHS Foundation Trust, UK (n=30)	Yes, discusses implementation of insulin SAM in a UK hospital	Audit data and 'lessons learnt'	Y
Booth (no date)	Opinion piece	Criticism of lack of ability to self-administer whilst in hospital	NA	Yes, discusses diabetes SAM in a UK hospital context	Personal opinion / experience only	Y
Dashora (2018)	Retrospective incident report review, patient focus-group and audit	Initiate insulin self-administration in hospital	Inpatients at Sheffield Teaching Hospitals NHS Foundation Trust, UK (n= 51 reports)	Yes, discusses insulin SAM in a UK hospital	Data presented support inferences but methodological detail lacking in report	Y
Diabetes UK and University Hospitals Southampton NHS Foundation Trust	Patient Information Resource	Promote insulin self-administration in a hospital setting	UK NHS Hospitals	Yes, explains the process of insulin SAM to patients	No data presented but useful for refining theories relating to patient-staff relationship and activities in the intervention	Y
Gangopadhyay (2008)	Observational study and audit	Evaluate patient preference and accuracy of timing of insulin	Inpatients at University Hospital Birmingham	Yes, discusses insulin SAM in a UK hospital	Audit data plus patient survey. Lacks detail on method of	Y

		administration by staff compared with patients	NHS Foundation Trust, UK (n=35)		direct observation during study	
Garfield (2018)	Quality improvement project report	Make self-administration more easily available to patients who wanted it	Inpatients at Imperial College Healthcare NHS Trust, UK (n=155, 118)	Yes, SAM in general but in a UK hospital setting. Discussions regarding 'lessons learned'	Audit and interview data, well reported.	Y
Grant (2012)	Commentary	Shared learning about setting an insulin safety group up	Inpatient diabetes team in Kings College NHS Hospital, UK	No, SA only mentioned briefly – not intervention specific	Personal opinion/experience only	N
Healthcare Safety Investigation Branch (2020)	National patient safety incident report bulletin	Patient safety investigation report into an insulin prescription error	NHS hospital Trust, UK	Not sufficient information regarding mechanisms or SA	NA	N
Houlind (2018)	Observational study, cost analysis and questionnaire	To assess hospital medication costs and staff time between SAM and nurse administration and evaluate patient perspectives	Inpatients at Hvidovre Hospital, Copenhagen, Denmark (n=148)	Yes, supports outcomes of increased satisfaction, perceived safety and responsibility, and staff time saved, although not insulin specific	Yes, uses questionnaire data and observational data to support inferences	Y
Joint British Diabetes Societies for Inpatient Care Group (2012)	Best practice guidance for self-management of diabetes in hospital	Improve the safety of the in-hospital management of diabetes	UK NHS Hospitals	Yes, discusses insulin self-administration in hospitals and implementation	Expert opinion and guidance on a national level, but no original data included	Y
Johnston (2019)	Quality improvement project report	Shared learning in implementing insulin self-administration in a UK hospital setting	University Hospital Southampton NHS Foundation Trust, UK	Yes, discusses the challenges and solutions of implementing insulin SAM in the inpatient setting	Personal experience and reflection of project lead, brief inclusion of audit data but no supporting methodology or qualitative data	Y
Johnston (2017)	Quality improvemen	Shared learning in implementing	University Hospital	Yes, discusses processes and	No comprehensive	Y

NB: reports findings from the same project as Johnston (2019)	t project report	assessment processes for insulin SAM	Southampto n NHS Foundation Trust, UK	lessons learned from implementing insulin SAM in the inpatient setting	data reported but brief feedback comments from staff and patients included	
Manning (2005)	Observation al study	Investigates the incidence of timing problems with insulin administration by nursing staff	Sub-acute inpatient unit in Broadmeado ws Health Service, Melbourne, Australia	No, no intervention and although concerns insulin administration in hospital, doesn't address SAM	NA	N
Miller (no date)	Patient Information and empowerme nt Resource	Guide to managing diabetes in the hospital setting to empower patients to share decisions and improve outcomes (satisfaction/safety)	UK NHS Hospitals	Yes, addresses self-administration from a patient's point of view including empowerment, shared decision making and safety	Guidance formed by collaboration between healthcare professionals and people with diabetes, no original data	Y
Munt (2012)	Literature review	Review the published literature on self-management of type 1 diabetes in hospital between 1998-2008 (n=16)	NA	Yes, addresses decision making, control and power imbalances in inpatients with type 1 diabetes	Thematic analysis of qualitative studies included, details of all studies included	Y
Pearce (2019)	Quality improvemen t project report	Shared learning in implementing insulin SAM	North Bristol NHS Trust, UK	Yes, includes lessons learnt and discussion of challenges and solutions to implementation	Yes, from first hand commentary	Y
Kavanagh (2016) NB: reports same project as Dashora (2018)	Quality Improvemen t project report	Rowan Hillson Insulin Safety award 2016 winner's project description	Sheffield Teaching Hospitals NHS Foundation Trust, UK	Yes, discusses insulin SAM in a UK hospital	Data presented support inferences but methodological detail lacking in report	Y
Rowse (2018a) NB: reports same project as Rowse (2018b) Wessex Academic	Quality improvemen t project report	Describes insulin SAM project	NHS Hospital Trust, UK	Yes, discusses insulin SAM in a UK hospital	Descriptive of issues rather than intervention. Mechanisms unclear.	N

Health Science Network (2017)						
Rowse (2018b) NB: reports same project as Rowse (2018a) and Wessex Academic Health Science Network (2017)	Description of implementation guide	Describes a guide developed to help trusts through the change process required to implement patient self-administration of insulin and the experience of doing so in one trust	NHS Hospital Trust, UK	Yes, discusses insulin SAM in a UK hospital	Personal reflections of project lead. Project methodology described but not supported by qualitative data	Y
Rutter (2012)	Cross-sectional questionnaire	To measure in-patient diabetes treatment satisfaction and its relationship to in-patient diabetes care. Methods	Inpatients in UK hospitals (n=1319)	No, does not concern insulin SAM in any detail	NA	N
Shultz (2019)	Observational study with qualitative interviews	To investigate the perspectives of healthcare professionals on self-administration of medication for patients admitted to a general surgical ward	Staff at Odense University Hospital, Denmark (n=14)	Yes, not insulin specific but contributes to discussion of relevant areas of control and ideological contexts	Qualitative data and observations using phenomenological-hermeneutic approach described in detail	Y
Specialist Pharmacy Service (2020)	Guidance document on inpatient SAM in general	To assist hospitals in identifying when SAM should be used and present examples of best practice	NHS Hospitals, UK	No, useful for programme strategy only, insufficient detail presented regarding insulin	NA	N
Shah (2015)	Commentary	Case report to argue against self-management of diabetes in hospital	Inpatient facility in California, USA	No, USA setting and no intervention	NA	N
Sorensen (2020a)	RCT cost-consequence analysis	Evaluate the costs and consequences of introducing SAM during hospitalisation	Randers Regional Hospital, Denmark (n=632)	Not insulin specific, cost and dispensing error outcomes not relevant	NA	N
Sorensen (2020b)	Randomised pilot study	Pilot test of SAM intervention	Inpatients on a cardiology unit,	Not insulin specific but discusses relevant lessons learnt and patient	No qualitative data to support relevant areas of discussion	N

			Denmark (n=60)	satisfaction of intervention		
Vanwesemael (2017)	Qualitative interview study	To explore healthcare providers' and patients' perspectives on self-management of medication during the patients' hospital stay	Staff and patients in a hospital setting, Belgium (n=30)	Not insulin specific but discusses relevant areas of SAM in general in hospital	Methods clearly described, qualitative data presented	Y
Viasuso (2007)	Commentary	Discusses challenges of implementation of SAM in hospital	Northwick Park Hospital, UK	No, not insulin-specific, and elderly care context	NA	N
Wallymahmed (2012)	Editorial	Journal editorial, no aims stated	NHS hospital, UK	Concerns insulin SAM but very brief editorial relevant to programme strategy only	No data presented, personal opinion/ summary of issues	N
Weiss (2006)	Commentary	Patient account of experiences with insulin self-management	Virginia, America	Yes, concerns insulin SAM but in a USA setting	No data presented, personal experiences as a patient only but concerns relevant issues for theories	Y
Wessex Academic Health Science Network (2017)	Implementation guide	Help trusts through the process of setting up safe and robust arrangements for routine self-administration of insulin for patient safety	NHS Hospitals, UK	Yes, implementation guide for insulin self-administration provides support for outcomes and contexts	No original data presented	Y
Wright (2006)	Literature review	Discover if benefits of self-administration programmes are supported in the literature in relation to risk and resource implications	NA	Not insulin specific but concerns inpatient setting and issues relevant to theories (e.g. empowerment, highlighting issues, errors)	Details of included studies and outcome reported	Y
Search 2						

Asimakopoulou (2012)	Qualitative interview study	Examines what healthcare professionals understand by 'empowerment' and their attitudes towards it	Diabetes healthcare professionals from an NHS Hospital and GP clinic, England, UK (n=13)	Yes, discusses empowerment issues in diabetes care	Methods described in detail, ethnomethodological approach and thematic analysis	Y
Bucknall (2019)	Qualitative interview study	Identify patient preferences for involvement in medication management during hospitalisation	Inpatients on medical and surgical wards in Melbourne, Australia (n=20)	Yes, discusses patient experiences and perceptions of self-administration, including issues of control, although not insulin specific	Qualitative data presented and methods described in detail to support conclusions	Y
Dei Cas (2020)	Workflow creation and domain relationships	To build a tool to assess the management of inpatients with diabetes mellitus and to investigate its relationship, if any, with clinical outcomes	Inpatients in hospital, Italy (n=678)	Not relevant to theory, concerns tool development and clinical guideline adherence	NA	N
Faulkner (2001)	Scale development of empowerment in the hospital	Develop a valid and reliable measure of patient empowerment and disempowerment in hospital environments catering for older people	Older inpatients (n=102)	No, tool development and older people context	NA	N
Griscti (2017)	Qualitative interviews with patients	To explore how social and institutional discourses shape power relations during the negotiation process.	Inpatients with chronic illness in hospital in Nova Scotia, Canada (n=8)	Yes, contributes to relevant theory on staff-patient relationships and empowerment from patient perspective	Use of discourse analysis and qualitative approach well described	Y
Jerofke-Owen (2018)	Qualitative study with nurses	Explore acute care nurses' experiences empowering patients and the facilitators and barriers they encountered during the process	Nurses in 4 hospitals in the Midwest, USA (n=34)	Yes, contributes to relevant theory on empowerment from nurse perspective	Yes, quotes included support inferences made	Y

Kelly (2011)	Literature review	To identify current trends in readmissions and practices for preventing readmissions in client populations with chronic disease.	NA	No, concerns hospital readmission rather than inpatient care	No	N
Liu (2010)	Tool development and telephone survey	Describes care quality attributes of the experience desired by patients and application of visualisation tools	Patients who received care at 6 hospitals in St Louis, USA during 2005 (n=1800)	No, describes tool development	NA	N
Meng (2020)	QI project implementing SAM	To describe the process of establishing a SAM program in a local rehabilitation inpatient ward.	Changi General Hospital, Singapore	Yes, supports outcomes and describes lessons learnt from implementation and issues of empowerment and identifying issues	Yes, supported by survey data	Y
Murray (2011)	QI project implementing SAM	Report on the literature related to SAM programmes that contributed to the development of an Older Persons Mental Health (OPMH) specific pathway for a self-administration of medication (SAM) programme.	Nurses in Solent Health Care NHS Trust, Portsmouth, UK (n=5)	Yes, provides relevant review and discussion on SAM but project applied to older persons Mental Health services	Qualitative data only summarised and only small number of respondents	N
Manias (2004)	Qualitative interviews with patients	Determine patients' perspectives about self- medication in the acute care setting.	Inpatients in Melbourne, Australia (n=10)	Yes, discusses patient perspectives on SAM, including diabetes, but not insulin-specific	Interview data presented in detail to support inferences	Y
Prey (2014)	Systematic literature review	To systematically review existing literature regarding patient engagement technologies used	NA	No, regarding engagement technologies	NA	N

		in the inpatient setting				
Selman (2017)	Ethnographical study: interviews and fieldwork	To explore challenges to and facilitators of empowerment among older people with advanced disease in hospital, and the impact of palliative care	6 hospitals in England, Ireland and the USA	No, concerns patients with advanced/palliative disease	NA	N
Vanwesemael (2020)	Literature review	Theoretical interpretation of literature on self-administration in the hospital setting	NA	Yes, discusses interventions to aid SAM, but not insulin-specific	Conclusions supported by cited literature but lack of detail regarding methods for review	Y
Vanwesemael (2018)	Cross-sectional questionnaire study	To describe patients' willingness towards self-administration of medication while in hospital	Inpatients in 3 hospitals in Belgium (n=125)	Yes, supports outcomes and theory regarding safety and satisfaction	Yes, survey data included to support conclusions	Y
Wang (2020)	Cross sectional study	To explore the relationships of self-care behaviours and glycaemic control and the differences in patient preference for medical decision-making	Outpatients with type 2 diabetes in Taiwan (n=316)	No, concerns outpatients	NA	N
Zimmer (2015)	Focus group study	To investigate patients' perceptions of self-injection and how nurses can improve the training given to patients	Nurses and patients from France, Germany, Canada, USA (n=9)	No, focuses on injection technique	NA	N
Search 3						
Baysari (2011)	Observational study at one hospital	To determine when and with whom medications were discussed, and in particular, whether shared decision making (SDM)	Doctors in a hospital, Syndey, Australia (n=46)	Yes, involves medicines SDM on ward rounds	Qualitative data presented not extensive but example observations	Y

		occurred on ward-rounds.			support conclusions	
Blankenburg (2018)	Observational study and interviews	To assess overall quality, provider behaviors, and contextual predictors of SDM during inpatient rounds on medicine and pediatrics hospitalist services	Inpatient teams across 2 hospitals in Stanford, USA (=35)	Yes, involves inpatient SDM on ward rounds but included paediatric as well as adult encounters	Validated tools used to measure team-level SDM behaviours, qualitative interview data not included	Y
Coulter (2011)	Report	King's Fund report to inform and promote shared decision-making between individual patients and clinicians	NA	No, useful background information but does not contribute to theory	NA	N
Cribb (2013)	Conceptual piece	Indicative summary of the research base relating to SDM	NA	Yes	Author's reflections on evidence synthesis but lacks details on methods of review	Y
Crispin (2017)	Observational study and interviews	To explore the sufficiency of, and intentions behind, information exchanged by patients and nurses	Nurses and patients in an NHS hospital, UK (n=41)	Yes, concerns SDM in an inpatient setting relevant to information exchange, power and control elements of theory	Recognised model of SDM used to frame analysis, interview data included	Y
Entwistle (2008)	Interview study	Investigate the meaning of involvement in treatment decision-making for people with diabetes	Outpatients with diabetes in Scotland (n=18)	Yes, outpatient setting, although concerns diabetes and patient's experiences in hospital	Interview data presented as well as participant characteristics	Y
The Health Foundation (2012)	Literature review	Provides evidence of impact of SDM on quality (e.g. safety, effectiveness)	NA	Yes, includes hospital-based literature	Review methods included	Y
Hendrieckx (2020) NB: reports the same project as	Description of MILES-2 study and application to practice	Translation of qualitative study data to best practice guidance for consultations	Australian adults with type 1 or type 2 diabetes (n > 1000)	Yes, people with diabetes, no setting described	Presents themes and subthemes as well as interview quotes	Y

Litterbach (2020)						
Hughes (2018)	Survey	Evaluate the impact of perceived SDM on patient-reported outcomes, healthcare quality, and healthcare utilization.	Patients in the USA (n=63,931)	Yes, looks at SDM in relation to patient-reported outcomes but not diabetes or hospital specific	Quantitative data presented support inferences made	Y
Jerofke-Owen (2019)	Interview study	To examine patients' experiences and preferences for engaging in their healthcare while hospitalised. Background:	Inpatients in Wisconsin, USA (n=17)	Yes, contributes to theories regarding control and SDM	Qualitative data included and methods described in detail	Y
Joseph-Williams (2014)	Systematic review	To systematically review patient-reported barriers and facilitators to SDM and develop a taxonomy of patient-reported barriers.	NA	Yes, contributes to theories regarding knowledge, power imbalances	Yes, detailed results provided and methods described	Y
Koberich (2016)	Cross sectional survey	To identify the individual and organisational factors influencing hospitalised patients' perception of individualised care.	Patients from 5 hospitals across Germany (n=606)	Yes, supports outcomes of patient perceptions of individualised care and SDM	Uses validated score and detailed quantitative data presented	Y
Legare (2018)	Systematic Review	To determine the effectiveness of interventions for increasing the use of SDM by healthcare professionals.	NA	No, concerns evidence for effectiveness of interventions and doesn't contribute to theory	NA	N
Legare (2013)	Commentary	Description of essential elements of SDM	NA	No, non-specific to patients in hospital and USA context	NA	N
Litterbach (2020) NB: reports the same project as	Interview study	To explore what people with diabetes wish their health professionals	Adults with type 1 or type 2 diabetes in	Yes, although not inpatient focused, results did include discussion of hospital care	Detailed methods and results provided with qualitative	Y

Hendrickx (2020)		understood about living with diabetes	Australia (n=1316)		data to support inferences	
Lloyd (2013)	Interview study	Healthcare professionals' experiences of SDM interventions	Healthcare professionals from hospital teams, Cardiff, UK (n=31)	Yes, contributes to SDM and culture elements of theory	Interview data included supports inferences	Y
Milkey (2020)	Retrospective study	Examine factors associated with SDM and whether SDM was associated with satisfaction with care or with adherence to anti-diabetic medication.	People with diabetes in the USA (n=797)	Yes, supports outcomes related to SDM and patient satisfaction, diabetes-specific but not inpatient-specific	Quantitative data supports results with statistical significance	Y
Ommen (2011)	Cross-sectional survey	Investigate the relationship between social support, SDM and inpatient's trust in physicians in a hospital setting	Patients who were treated in 6 hospitals in Germany in the year 2000 (n=2197)	Yes, contributes to theory building around trust and SDM in an inpatient setting but not diabetes specific	Methods and tools well described and results support inference made	Y
Oxelmark (2018)	Interview study	To describe Registered Nurses' experiences with patient participation in nursing care including their barriers and facilitators for participation	Registered nurses in 2 hospitals in Sweden (n=20)	Yes, contributes to theory concerning staff-patient relationships	Interview data support inferences made	Y
Rennke (2017)	Literature synthesis and adaption	Inductive construction of a novel SDM model appropriate for the inpatient setting	NA	No, model building for process of SDM, doesn't contribute to theory	NA	N
Scholl (2018)	Scoping review	Compile a comprehensive overview of organizational- and system-level characteristics that are likely to influence the	NA	Yes, organisational level factors considered to contribute to level of theory-building	Details of included literature support findings	Y

		implementation of SDM, and to describe strategies to address those characteristics described in the literature				
Thompson-Leduc (2015)	Systematic literature review	Explore how the theory of planned behaviour is used to explain influences on SDM intentions and/or behaviours	NA	Yes, helps to develop theory concerning culture and beliefs, and uses middle-range theory	Methods and results support inferences made	Y
Walsh (2011)	Focus groups, interviews and workshops with healthcare professionals and patients	Progress SDM as the norm as set out in the Government's 2010 Equity and Excellence White Paper	NHS, UK	Yes, but not exclusive to diabetes or inpatient settings	Interview data included supports inferences	Y
Weingart (2011)	Survey and record review	Measure the extent of patient participation in the hospital inpatient setting and its relationship to adverse events or quality	Inpatients in acute care hospitals, USA (n=2025)	Yes, supports outcomes relating to SDM, satisfaction and safety	Yes, quantitative data support inferences made	Y