Safety across transfer of care: an exploration of insulin management using a Safety-II approach

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Thesis submitted in accordance with the requirements for the degree of

Doctor of Public Health

of the
University of London

DECEMBER 2024

Department of Health Services Research & Policy

Faculty of Public Health & Policy

LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

Funded by NIHR ARC North Thames

I, Catherine Leon, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Dedication

I would like to dedicate this work to my wonderful family who love me unfailingly and unconditionally and who have been my biggest supporters. Grandad Bill, this is for you.

Acknowledgements

I would like to express my deepest thanks to my supervisors Dr Helen Hogan and Dr Yogini H Jani for your incredible kindness, support, patience, guidance and all the time you've dedicated to helping me through this process. Your wisdom and advice have allowed me to find real enjoyment in research, despite the frustrations and pressures involved. Your confidence and belief in me inspired me to continue and keep going. I'm so grateful you chose to give me this opportunity.

I can't ever thank my husband, Henry, or my daughter Sophie enough for your continued encouragement, love, and support. Thank you for bringing so much joy into my life, for helping me take breaks from my studies to dance crazily in the kitchen, cook exotic meals together and by helping me rock climb even when I'm scared. You've been my anchors during the challenging times and my cheerleaders during the exciting ones. Thank you for keeping me laughing and believing in me.

Thank you to the NIHR ARC North Thames who not only funded my studentship, but who provided so many opportunities to learn and develop friendships with other researchers. I especially want to thank Silvie Cooper for her friendship, support, advice, for connecting me with others and helping me through this process. A HUGE thank you to Clare for all your support, advice, mentorship and patient listening as I've gone through this process.

Thank you to Helen, Rustam and Seetal for your ongoing support and for giving me the opportunities to apply what I'm learning in my clinical roles.

To my mother, father, grandmother, grandfather, Liebie, Willie, Bel, Jen, Nanna, and the rest of my family - you always believed in me. Thank you for your unwavering support and encouragement.

Thank you to Abena, Phil and Erin for helping me find the courage to take the leap into the unknown, and to Mitch for giving me such practical and helpful advice.

Thank you to all the people with diabetes, those who care for someone with diabetes, and the healthcare staff who kindly gave their time to speak to me, allowed me to observe how they work and who participated in this research. Without you, this work could never have been undertaken. Your insights provided the rich detail that allowed me to weave the threads of this work together.

Abstract

People with diabetes who use subcutaneous insulin are at risk of harm during Transfer of Care (ToC) due to the challenges of moving between different care settings. Safety is maintained by healthcare resilience, where people and organisations respond, anticipate, monitor, and learn in response to challenges.

To support healthcare resilience and improve safety, real-time data within digital systems has the potential to be used to support monitoring current issues and anticipation of future risks. These data are potentially new leading indicators for safety. The availability and use of a wider array of leading indicators will facilitate proactive safety improvement and enhance current measurement regimes primarily focused on collecting lagging indicators.

This research explored the use of the Functional Resonance Analysis Method (FRAM) to model insulin management during ToC. By examining variability in care processes across ToC linked to outcomes, potential areas where leading indicators could be developed and applied were identified. The findings from the FRAM model were explored in a collaborative way to identify potential leading indicators. These were classified as active leading indicators that could provide real-time information to people with diabetes who use insulin (PWDI), caregivers and staff or passive leading indicators that provide information to organisations about the structural capacity for safe outcomes.

This approach could be adapted and applied to other areas of healthcare to promote safety improvement. Further research will be needed to understand the impact of leading safety indicators on outcomes, workflows and resources.

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List of abbreviations

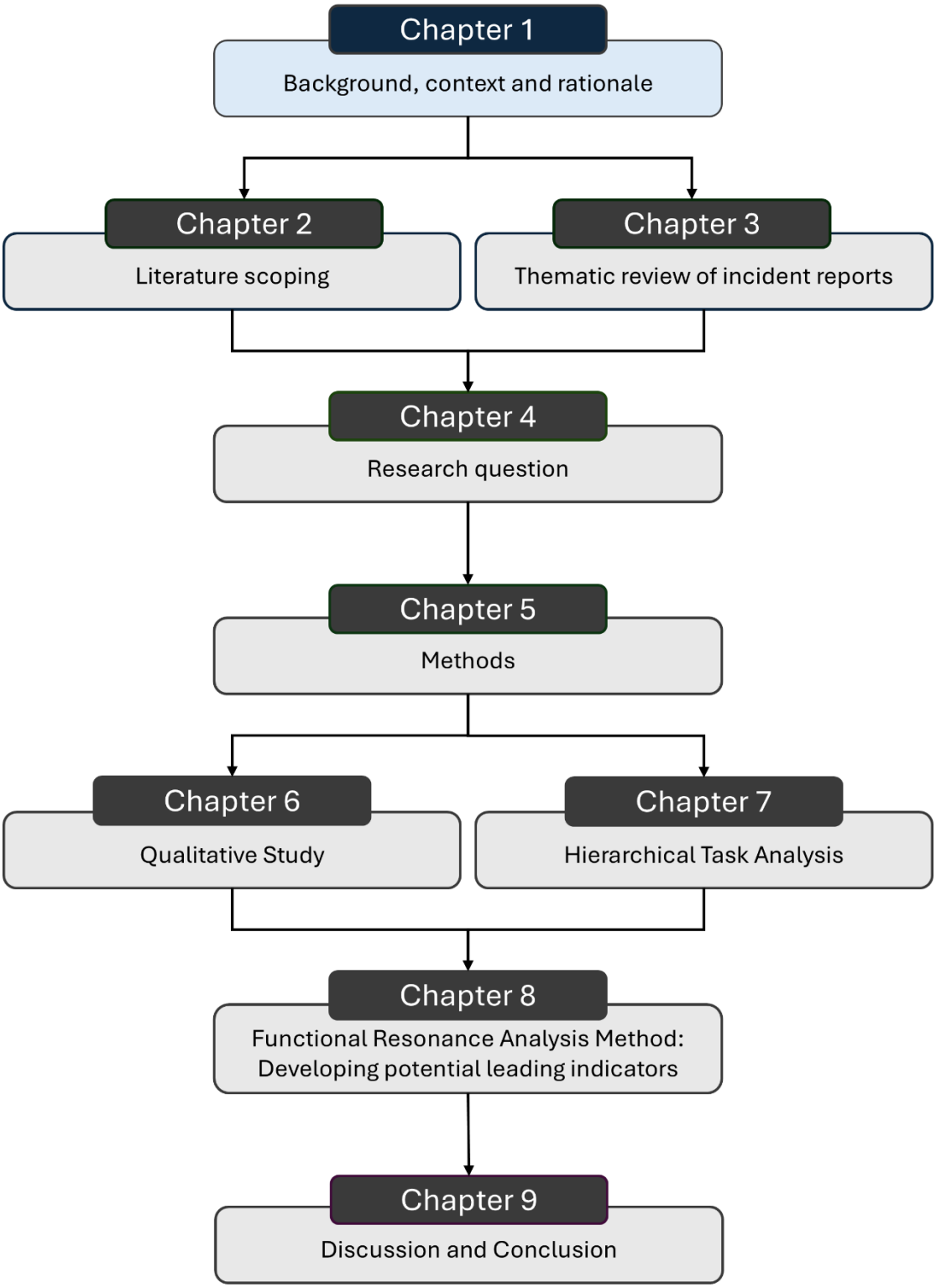
AI	Artificial Intelligence
CARe	Centre for Applied Resilience in Healthcare
CBG	Capillary Blood Glucose
CDS	Clinical Decision Support
CGM	Continuous Glucose Monitor
EHR	Electronic Health Records
EHS	Electronic Health Systems
FRAM	Functional Resonance Analysis Method
GP	General Practitioner
HTA	Hierarchical Task Analysis
NHS	National Health Service
NLP	Natural Language Processing
PWDI	People with diabetes who use insulin
QI	Quality Improvement
RE	Resilience Engineering
SEIPS	Systems Engineering Initiative for Patient Safety
SHERPA	Systematic Human Error Reduction and Prediction Approach
SMS	Safety Management System
STAMP	Systems-Theoretic Accident Model and Processes
T2DM	Type 2 Diabetes Mellitus
ToC	Transfer of Care
WAD	Work-as-done
WAI	Work-as-imagined
WHO	World Health Organisation

Glossary of terms

Activity	Work required to achieve a goal. An activity is made up of multiple tasks.
Centre for Applied Resilience in Healthcare (CARe) Quality Improvement	A method designed to develop improvement activities by understanding how misalignments between the capacity of a work system and the demands required of it are causing adaptations and subsequent outcomes.
Complex system	A work system where the constituent components interact and to produce unpredictable outcomes.
Emergent property	An outcome of a complex system that occurs due to the interaction between its constituent components.
Function	A unit in the Functional Resonance Analysis Method. Each function represents an activity.
Healthcare resilience	Adaptations made by people and organisations within work systems in response to the interactions of different factors.
Plan	A term used in Hierarchical Task Analysis to describe the order and circumstances in which tasks are performed.
Process	A combination of tasks and activities performed by people using technologies within different environments to meet a wider objective.
Resilience Engineering	Understanding the resilient capacity of a complex work system and developing ways to improve safety by supporting and enhancing this capacity.
Resilience potentials or Resilience abilities	The capacity for systems to adapt, monitor, learn and respond to interactions of factors within a work system.
Safety-I	An understanding that safety is an absence of harm. Traditional approaches to understanding and improving safety include

	understanding episodes of harm and exploring ways to prevent future occurrences.
Safety-II	Safety is viewed as an emergent property of a complex system. This means that all outcomes are important for learning and improvement, not just episodes of past harm. Understanding how work is done and the adaptations made to factors within the work system can support improvement efforts.
System	See work system
Task	A task is a piece of specified work to be completed.
Work-as-done (WAD)	How work is performed in everyday situations given the need to adapt to different factors in the work system.
Work-as-imagined (WAI)	How work is performed as defined in policies and guidelines.
Work-system	Defined as a unit of work, can be at different levels, for example an organisation or a clinical area. Incorporates multiple factors including people, teams, tools and technology and the different environments in which work is occurring.

Chapter 1: Background



1.1 Safety in healthcare

1.1.1 Patient Safety Movement

Around the turn of the century, two publications highlighted the prevalence and devastating costs of harm caused by healthcare and the impact on human lives and patient outcomes. These were: 'To Err is Human,' published in 1999 in the United States of America,(1) and, 'An Organisation with a memory' published in 2000 in the United Kingdom.(2) These two reports led to an international patient safety movement and mobilised efforts to improve safety.(3,4) Harm caused by healthcare is widespread and significant resources have been spent trying to reduce this burden to improve safety. It is estimated that nearly one in ten people are harmed during a hospital admission,(5) and as many as 4 to 5% of hospital deaths are potentially avoidable.(6) In primary care, the records of around 2% of consultations contain evidence of healthcare-related harm.(7) Many risks have been identified for people managing their healthcare related activities in their own homes.(8) Despite known risks and improvement efforts, the prevalence of harm has remained static,(3,4) with the NHS Patient Safety Strategy (2019) estimating that up to 1000 lives per year could be saved through improvements in patient safety within the NHS.(9)

1.1.2 Development of current approaches to patient safety

Safety improvement in healthcare has developed over time by seeking to integrate approaches used in other industries, for example aviation. Key concepts in safety management have built on theories of accident causation to recognise that adverse events are the manifestation of problems within an organisation or environment that creates latent conditions (the Swiss Cheese Model)(10) and that accidents within complex systems are unavoidable (the Normal Accident Theory)(11). Rasmussen introduced the concept of how adaptations by individual workers are necessary to achieve goals within constraints, but these actions sometimes result in accidents.(12) While these approaches promoted the understanding, exploration and improvement of safety to be based on challenges within how the environments and factors within them contribute to outcomes, within healthcare use of these tools focused on understanding the contributions of humans and errors.(3)

1.1.3 Safety-I and Safety-II

Traditional applications of safety theory in healthcare have focused on the premise that safety results from the absence of harm, termed Safety-I.(4) Therefore interventions have concentrated on identifying root causes of adverse events and outcomes and fixing these to eliminate harm.(4) Newer conceptualisations of safety (known as Safety-II) focus on

understanding how care continues to be provided safely, despite challenges and changing conditions.(13) All outcomes in healthcare, those that go according to plan and those that do not, are the consequence of the interactions and tensions between the work system and healthcare processes.

1.1.4 Complex systems

It is recognised that healthcare is highly complex. It takes place in constantly evolving, environments, termed 'work systems.'(14) Healthcare work systems are composed of interacting components including the people (among others the person receiving care, informal care-givers, professionals), organisations and their processes, procedures, the tasks required, the tools and technology available and the local setting in which the care is taking place. All these components impact on each other and can affect outcomes for people receiving care, staff, and the organisation. See Figure 1 for a diagram representing the components of a work system, and how healthcare resilience and resilience engineering relate to work systems, care processes and outcomes.

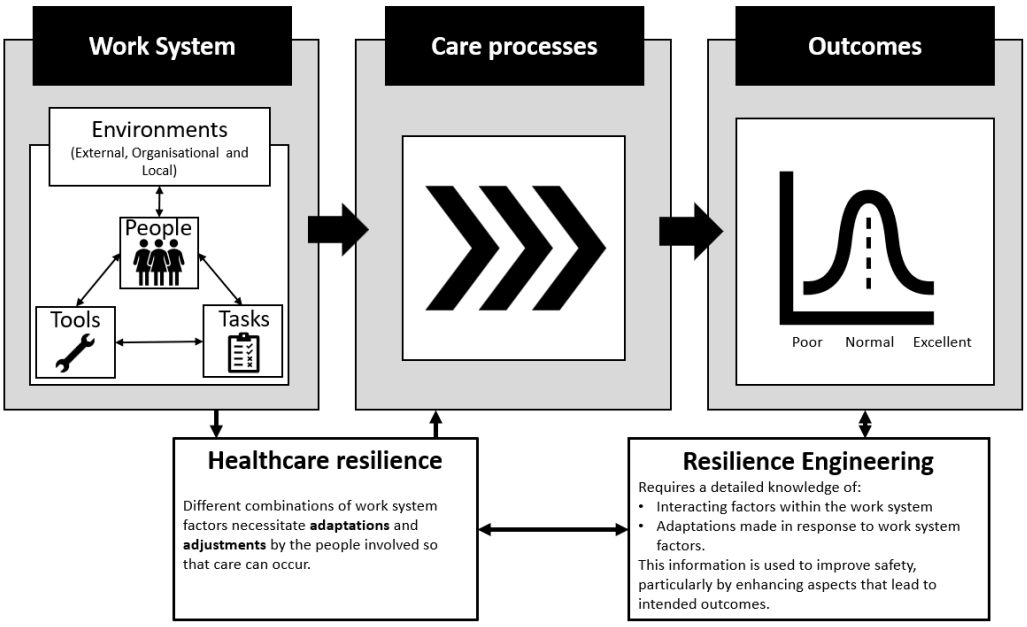


Figure 1: Complex work systems and resilience in healthcare.(15,16)

1.1.5 Healthcare Resilience

Healthcare Resilience is created as work is prioritised, adapted and adjusted to enable the best outcomes in the face of the variable conditions and constraints within the work system.(17,18) The capacity of the work system to provide care is limited, and the demands created by work

system constraints lead to the need to flex how care is provided compared with how it is prescribed in guidelines. How work is provided in real-life situations is known as 'Work-as-done' (WAD). How work should be performed according to guidelines and other official documents is called 'Work-as-imagined' (WAI). People within the work system perform tasks (as specified according to guidelines and procedures (WAI)) and activities (all the work required to achieve a goal, known as WAD). Processes are a group of tasks and activities that must be completed to provide care, performed within and influenced by the work system,(19,20) see Figure 2.

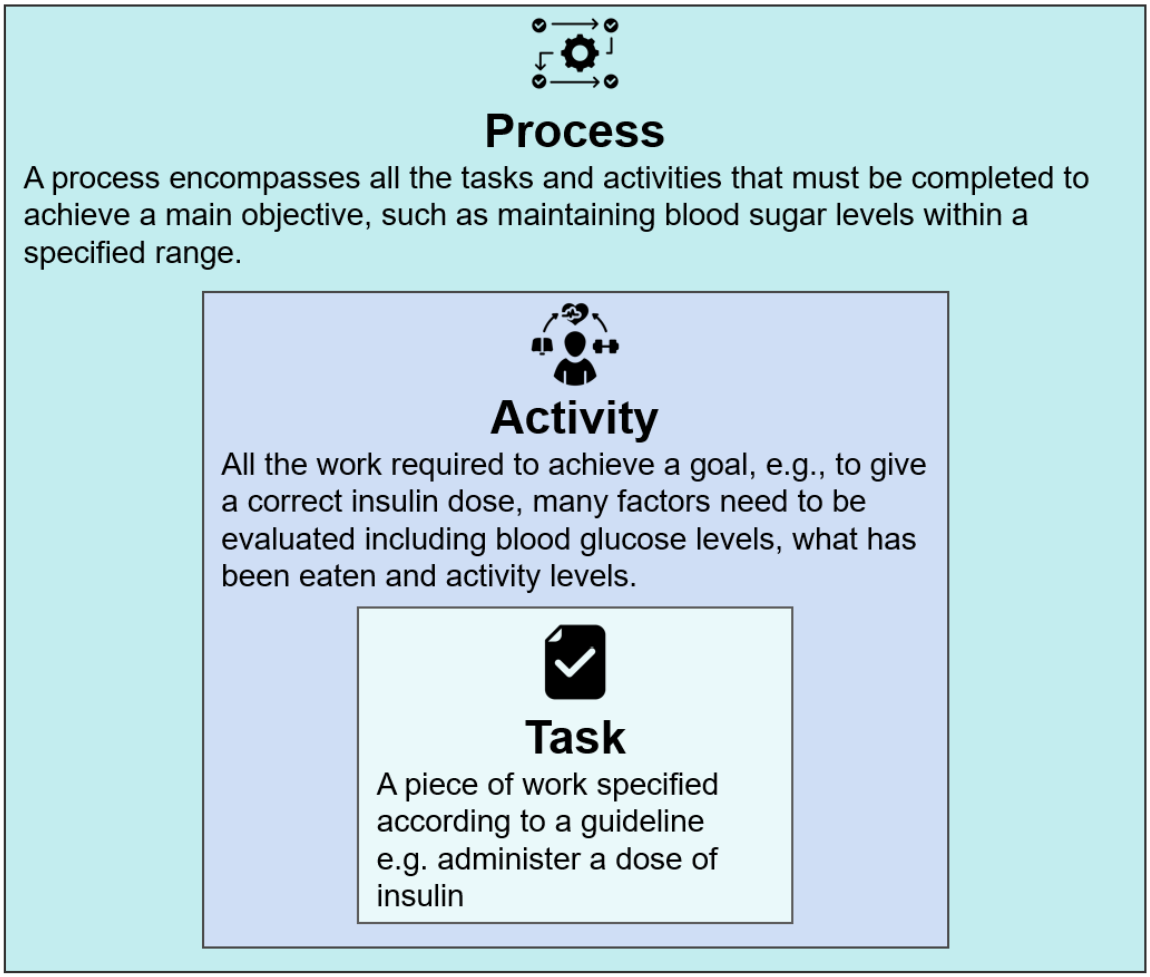


Figure 2: Definition of tasks, activities and processes.

Healthcare outcomes are created through these adaptations made in response to mismatches between demand and capacity.(21) Depending on individual circumstances, the same adaptations can cause both successful and unsuccessful outcomes.(4) The Centre for Applied Resilience in Healthcare (CARe) Quality Improvement model illustrates this tension and resulting adaptations and their impact on outcomes in Figure 3.(21)

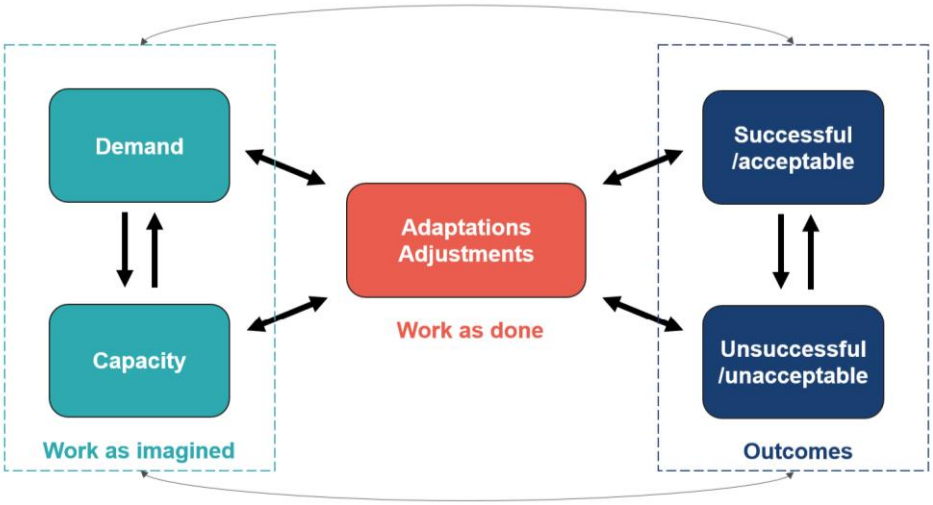


Figure 3: Centre for Applied Resilience in Healthcare Quality Improvement model for healthcare resilience.(21,22)

1.1.6 Approaches to safety improvement

Safety science within healthcare has developed over the last 20 years and has drawn from other industries such as aviation and other high-risk organisations. Incident reporting was used widely in nuclear, industrial and other industries, and was introduced widely in healthcare in the early 2000s.(23) Two approaches to understanding and improving safety in healthcare are Human Factors and Resilience Engineering.(22,24) Human factors aims to understand and optimise how humans interact with all aspects of a system to improve human wellbeing and the system performance.(25) Resilience Engineering has evolved as a concept to counter the dominant approach to safety improvement work that relied heavily on retrospective analysis of poor outcomes.(17,22)

Human Factors/Ergonomics

Human Factors (also known as Ergonomics) in healthcare uses an evidence-based scientific approach to understand the interactions of work systems and how to improve their design for better safety and performance.(26) It aims to identify how work is done, the interactions within the work system and the resulting adaptations being made to WAI. This information is used to design or improve equipment, environments, and tasks to make it easier for people to create successful outcomes.(25) Examining work systems can help identify aspects that are likely to contribute to successful outcomes and aspects that contribute to variability which may reduce the chance of achieving desired outcomes.(25)

Resilience Engineering

Resilience engineering (RE) involves developing mechanisms to support organisations and the people within them to achieve safe and effective performance.(27) RE approaches seek to enhance the ability of organizations, groups, and individuals to anticipate risks and proactively address these before harm occurs. The aim is to support adaptations to ensure safety, while also seeking to ensure adaptations are safe.(13) Such efforts require an in-depth understanding of the work system and the interactions and misalignments necessitating adaptations. RE aligns with a Safety-II approach because it recognises that all outcomes stem from factors and interactions within the work system.(28)

Resilience Engineering defines four aspects of resilience within a system.(29) These known as the resilience potentials or abilities (illustrated in Figure 4). These are the ability of the work system to:

- **Anticipate** future demands.
- **Monitor** for potential problems.
- **Respond** to issues, demands, and needs.
- **Learn** from outcomes.

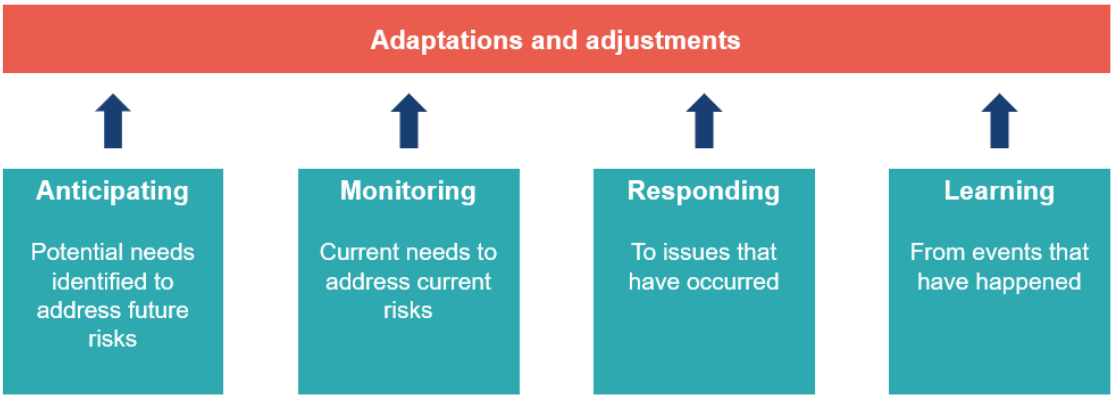


Figure 4: The four resilience potentials that support adaptation.

1.1.7 Measuring safety

While it is universally agreed that improving safety in healthcare is necessary, the challenge of how to measure safety, and therefore determine where improvements can be made or whether improvement has occurred, is an issue that remains incompletely resolved.(30) Finding ways to measure safety is essential to building safe systems.(31)

Measures and indicators

A measure can be calculated to a numerical value, for example the number of people who have been prescribed an anticoagulant during a hospital admission in a specific timeframe. Many aspects of healthcare cannot be measured directly, so other measures are used in proxy or indirect measure, these are called indicators. For example, patient satisfaction is measured using surveys to identify levels of satisfaction patients have with their treatment. A fall in satisfaction levels can identify a deteriorating service, indicating a potential safety or quality issue requiring investigation. As such, indicators can be used to determine the relative levels of certain aspects of safety, enabling comparison, investigation and improvement.(32) Both direct and indirect measures are used to demonstrate the safety of the healthcare system.

Measurement frameworks

Indicator frameworks comprise a group of indicators that together can provide a broader picture of the system being measured. The indicators cover different aspects of the system and its functioning. In other safety-critical industries, safety management systems are used to gather a range of relevant data together to enable a proactive approach to managing safety.(33) The Measurement and Monitoring of Safety Framework has adapted this approach to healthcare and describes five types of indicators that can provide an overview of safety within an organisation. These include outcomes, system reliability, current state of safety, preparedness for challenges and of learning.(34) To address these five areas, different types of measures are required representing safety from multiple perspectives, including those of patients and caregivers, staff, and organisations patients.(16) Care must be taken to ensure that measures reflect the actual work system comprehensively while minimising duplication and/or omissions.(35) Building such a framework requires a robust understanding of the work system alongside knowledge of how it operates in practice.

Safety-I and Safety-II approaches to measurement

Measurement from a Safety-I perspective quantifies risks and harms to develop barriers and other corrective actions in high-risk areas to prevent harm from occurring. A Safety-II approach in comparison, seeks to measure the capacity for safety within a system, in order to enhance and support healthcare resilience.(36) Rather than focusing only on unsuccessful outcomes, which is the mainstay of Safety-I approaches, measures using a Safety-II approach enable learning from both the good and poor outcomes experienced in healthcare.(4) Measures to support healthcare resilience are focused on the system's capacity for learning, responding, monitoring, and anticipating.

Lagging and Leading indicators

Indicators can be lagging (collected after an event has occurred) or leading (collected before an event occurs). Lagging indicators show whether care has been safe in the past, while leading indicators can identify risky situations that could lead to harm in the future. Lagging indicators are often easier to collect,(37) and have been widely used in a Safety-I approach to safety management.(38)

Leading indicators provide the opportunity to intervene to ensure care goes well as often as possible (Safety-II approach).(34) Measurement to support resilient activities, such as anticipation or monitoring requires the use of leading indicators.(27) There are two broad classes of leading indicator, passive and active leading indicators.(39) Passive leading indicators are proactive measures of organisational safety factors, for example safety culture, policies and guidelines and training provision. Active leading indicators are real-time measures that enable action to address issues identified.(39) For example dashboards and digital Early Warning Scores, can proactively identify deteriorating hospital inpatients and enable direct immediate actions to rescue these patients and prevent harm.(40) With the development of electronic health records, the possibilities for real time indicators, and therefore monitoring and anticipation, are expanding. The recently introduced national patient safety alert system is recent example of an active leading indicator.(41) Following reports of harm when people with mechanical heart valves were changed from warfarin (the required anticoagulant) to an alternative, an alert was activated. The alert required GP prescribing records to be searched for people with mechanical heart valves exposed to this change. These patients were sent an urgent message to organise a review, thus providing the opportunity for timely intervention.(41) A combination of lagging, active leading indicators and passive leading indicators facilitate resilient monitoring and anticipation and can provide data to guide decision making to respond to issues. The data from this combination of measures can also be used to identify safety trends over time and to support learning.(34)

1.2 Known patient safety issues

1.2.1 Medications, high-risk medications and patient safety

Medications are the most common healthcare intervention,(42) and are frequently implicated in healthcare-related harm. There are an estimated 237 million medication errors annually in England and approximately 66 million of these (28%) cause clinically significant harm.(43)

Some medications, known as high-risk medications, carry a greater risk of harm when errors occur.(44) Errors are not necessarily more common with these medications, but the consequences of errors are greater. Commonly recognised high-risk medications include anticoagulants, insulin, opioids, sedatives, concentrated electrolytes, anti-infectives and chemotherapeutic agents.(45,46)

Anticoagulants are high-risk medicines that have been the subject of national patient safety alerts in England.(41,47) The consequences of errors with anticoagulants when people transfer between care settings can be fatal. Anticoagulants were found to cause 8% of potentially avoidable admissions(48), and omissions or delays of these medicines – a significant risk at transfer of care (ToC) – contributed to a quarter of the most serious incidents that led to the national patient safety alert "Reducing harm from omitted and delayed medicines in hospital" in 2010.(49) The Institute for Safe Medication Practices highlighted significant anticoagulant-related risks, many of which are associated with ToC, for example, inadvertent provision of multiple anticoagulants due to miscommunication and inadequate counselling.(50)

Insulin is a high-risk medication that has been the subject of national patient safety alerts in England.(51–53) The consequences of incorrect insulin management can be fatal. Delayed and omitted doses of insulin were frequent causes of harm during when people with diabetes who use insulin (PWDI) move between care settings.(54) Despite the vast amount of work undertaken to improve the safety of insulin, it remains a safety challenge, and is one of the key components of the national safety improvement campaign Get it Right First Time.(55)

Both insulin and anticoagulants are medications used for long-term conditions and in multiple care settings, which make them important groups of medications to study during ToC. By contrast, other high-risk medications, such as concentrated electrolytes and sedatives, are largely used for short courses in acute hospital settings. For example, for treating medical emergencies or during surgical procedures.(56–58) Chemotherapeutic agents are overseen by cancer teams and treatment is generally not shared across care settings.(59) Antimicrobial agents are used to treat infections, as opposed to long-term conditions. Many of the risks associated with antimicrobial agents are posed due to inappropriate dosing of injectable preparations in a hospital setting, or the potential development of antimicrobial resistance.(60,61) Opioids are another group of high-risk medications, however many of the risks associated with these agents are due to unsuitable continuation and subsequent dependency.(62)

1.2.2 Transfers of care

When people transfer between care settings, they are at higher risk of medication-related harm.(63) Unintended harm caused by healthcare following transfer from hospital to home is common.(64) Nearly 40% of medication errors occur during transfer of care (ToC), and 20% of those errors are estimated to cause harm.(65) Between 30 to 70% of people experience an error with their medications after ToC.(66,67) Following admission to hospital, there is an 86% chance that an elderly medical patient will be discharged on different medications to those taken before admission,(68) with the risk of unintended harm due to medications increasing with each medication change.(69) The WHO set a Global Safety Challenge in 2017 to reduce severe, avoidable medication-related harm by 50% over 5 years, with 'Medication Safety in Transitions of Care' identified as one of three key areas of focus along with 'Medication safety in polypharmacy' and 'Medication safety in high-risk situations'.(63)

ToC are defined as a person's movement between one care setting and another including:

- Between wards in the same hospital
- Between hospitals
- Between hospital and intermediate care (including ambulatory care, for example where people are given hospital treatments like intravenous medications in their own home)
- Between hospital or intermediate care and primary care settings
- Between community care settings, for example, General Practice, district nursing, the person's home and residential homes(63)

Multiple processes must be undertaken to ensure that people's medications are managed safely during ToC. Poor communication, inadequate person, family and/or carer involvement and lack of supporting services are common barriers to safe transitions.(70)

1.2.3 Developments expected to impact on patient safety during ToC

Empowering patients

Patients play a vital role in creating safe outcomes.(71,72) The patient (and/or their caregiver) is the central and constant person during the ToC journey.(20,63) Patients and their caregivers have essential knowledge about their diabetes and its management that can influence appropriate management.(73,74) Identifying ways to support and empower patients and caregivers to contribute to safety is proposed as a mechanism to improve safety.(73,75,76) In 2023, the NHS began a pilot programme to introduce Martha's Rule.(77) This rule provides

patients and carers to a second opinion if they are worried. This rule has been introduced following the death of Martha Mills who died when concerns about her deterioration raised by her mother were dismissed by the healthcare professionals looking after her.(78)

As central participants in the work system, patients and their caregivers contribute to creating good outcomes through resilience.(71,72,79,80) Co-developing active leading indicators that can support patients and their caregivers to understand their safety provides an opportunity to support this vital role.(73)

Integrated care

When people move between care settings timely and accurate information sharing is crucial to ensure safety.(66) Increasing integration within services is seen as a key step to improving ToC safety by breaking down barriers between different healthcare settings, improving access to information, and enhancing communication across services.(81) Communication issues between healthcare professionals and services were the most commonly cited safety issues identified by patient focus groups.(82) Integrated Care Systems (ICS) were introduced in England in 2022, and 42 ICS have been created with a remit to manage and better coordinate the health and care services within their geographical areas.(83)

Integrated care systems can be horizontal, where providers in the same level of care setting work together (for example different GP practices) or vertical, where services across different levels of care are joined up (for example hospitals and GP practices).(84) Integration can also be at micro level for individual service users through multi-disciplinary team care co-ordination, at meso level, for groups of people with similar need, for example a care pathway for a specific health condition, or at the macro level, through jointly commissioned healthcare services.(84) Engaged and empowered people, supported and equipped to manage their health conditions is a key component associated with successful integrated care.(85) Access to patient health records, clinical information and data through shared or accessible digital systems is also essential and is a core component of the NHS Long Term Plan.(35)

Digital technology

Digital systems in healthcare have the potential to improve patient safety by supporting adherence to guidelines through clinical decision support, real time monitoring of physical and mental health status to enable early intervention, and supporting data collation to assess performance over time.(86) The NHS Patient Safety Strategy recognises the central role that digital technology can provide to improve safety by enabling informed decision making through

greater access to relevant information, the use of technology such as barcode scanners and artificial intelligence, and by providing the ability to access real-time data for monitoring.(9) Digital technology can support the three strategic aims of:

- Insight – by providing access to real-time information to relevant people.
- Involvement – by enabling people to access their healthcare records.
- Improvement – by supporting improvements in the safety and efficiency of healthcare processes, for example through clinical decision support in electronic prescribing systems.

Healthcare services have been slow to harness the full potential of digital technology. The English National Programme for IT (information technology) failed to create an NHS-wide electronic health record despite significant investment of time and money.(87) Progress to increase interoperability has been slow due to the number and complexity of local digital systems in the NHS, which are often old.(88) During the Covid-19 pandemic, the NHS adopted new ways of working with renewed emphasis on joining up digital information,(89) and using digital data to support patient safety initiatives and enable provision of remote care.(41)

Digital technology used in healthcare includes electronic health records (EHR), wearable devices and artificial intelligence.(89) EHR have the potential to incorporate decision support tools to standardise prescribing and improve safety using rules and alerts. Wearable technology is becoming more widely used and has been used to support healthcare activities, for example the management of insulin administration and dosing adjustment via an insulin pump and glucose monitor linked to a smartphone application in patients with Type 1 diabetes.(90) Artificial intelligence has been used largely for diagnostic purposes, however with increasing amounts of electronic data available, the potential for wider use is expanding.(89) There is great potential for digital technology to support and improve safety within integrated care through greater access to the most up to date information for all those who need it to support decision making, across care pathways. Sharing data via up-to-date dashboards can highlight key information (for example outstanding actions required) and improve communication between relevant staff. Where people have access to their own health records, and are supported to understand and use these, they can be empowered to manage their own health conditions, knowing, and agreeing the correct treatments they must take.(91)

1.3 Conclusion

Safety in healthcare is created by the people involved continually adapting to the situations being experienced. Safety improvements can be targeted by understanding how problems arise, allowing changes to be put in place to reduce risks (Safety-I) and by seeking to strengthen the capacity for resilience (Safety-II). Managing high-risk medications safely during ToC is challenging due to the complexity of the healthcare system, the need for monitoring and adjustment during illness and recovery and the need to communicate changes with many people in different organisations. Insulin and anticoagulant medications are two groups of medications that are associated with additional risks during transfer of care. This is because they are both critical medications that are required to be taken for chronic conditions, and if given or taken incorrectly can cause significant harm. During and after transfer of care, safe use of these medications relies on systems and processes for communicating key information with patients and healthcare professionals across many different teams and organisations. Patients and their caregivers have a key role in contributing to safe outcomes. To monitor and measure safety for this cohort of patients, a co-developed framework of indicators that span different components of healthcare is required. A combination of lagging indicators, passive leading indicators and active leading indicators are needed to provide a detailed picture of safety over time along with data that can be used to proactively intervene and improve safety in real-time. Involving people who use insulin for diabetes (PWDI) in managing their own condition during ToC, the creation of integrated care systems, and advances in digital technology provide opportunities for proactive safety measurement.

1.4 Research aims and objectives

1.4.1 Aim

This research aims to explore how insulin is managed within digitally integrated care systems to identify how its safety may be measured using a Safety-II approach.

1.4.2 Objectives

- To scope how insulin safety is currently measured.
- To explore whether factors that support safety and healthcare resilience can be identified from incident reports.

- To identify how insulin is managed when people with diabetes who use insulin (PWDI) move between home and hospital as described in protocols, guidelines, and publications (Work as Imagined).
- To identify and use appropriate methods to identify the key activities driving safety for patients using insulin as they move between home and hospital.
- To undertake a gap analysis with staff and patients to determine the availability of indicators capable of anticipating and monitoring changes in key activities.
- To identify potential targets for leading indicators that could be used to support successful outcomes for managing insulin during transfer of care.

1.5 Research question

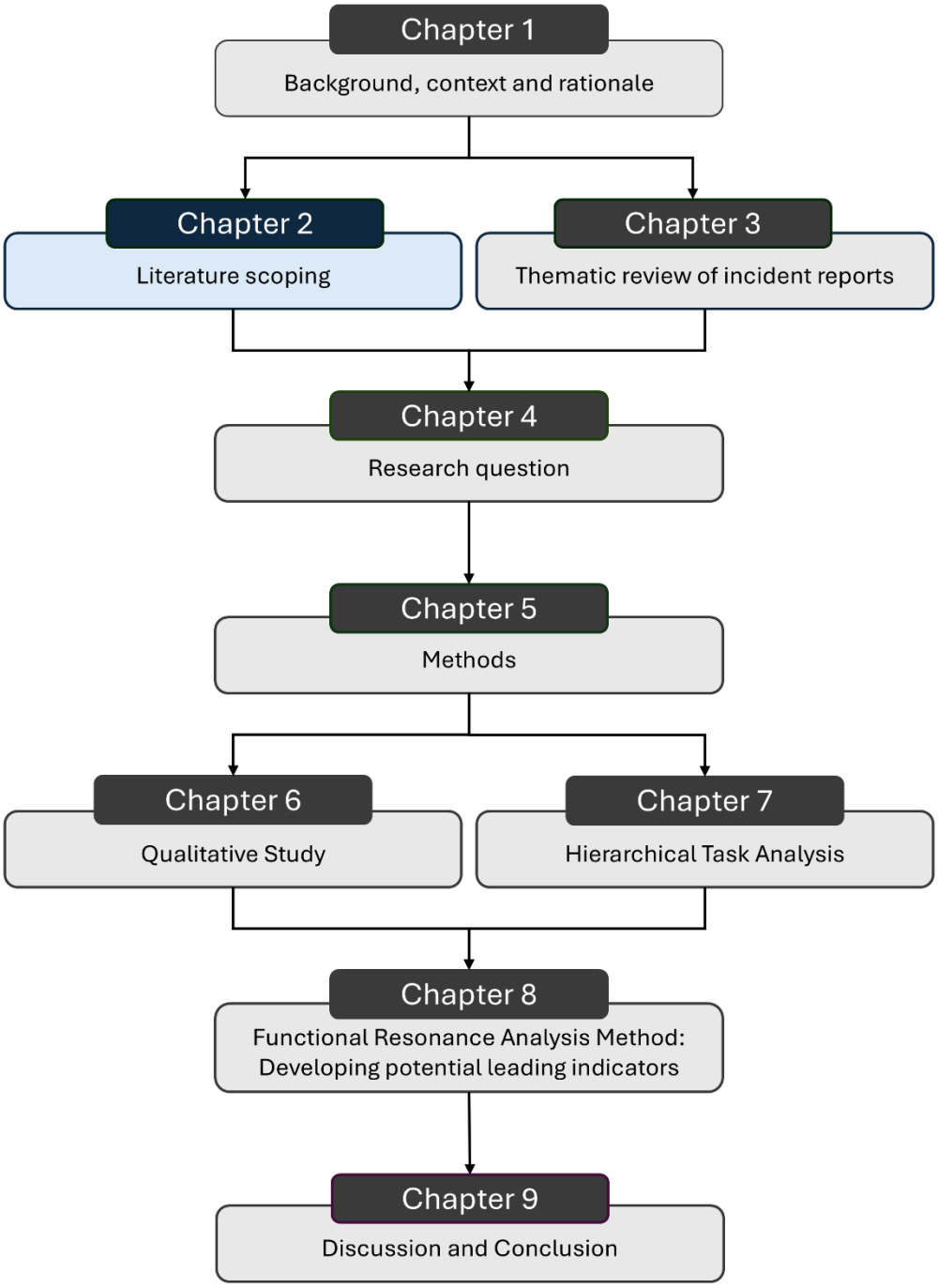
How can a detailed understanding of insulin management within complex digitally integrated care systems be used to create leading indicators that support proactive safety improvements?

1.5.1 Research question chapter

The scoping work presented in the following two chapters will explore how safety is currently measured, how safety is supported and whether healthcare resilience can be identified from incident reports, a current key source of safety intelligence in healthcare.

Chapter 4 will describe how the process of scoping of this information informed the theoretical framework for this research and the rationale for focusing on subcutaneous insulin. The final objectives, informed by the scoping work will be presented. Chapter 4 will then describe how Safety-II, Resilience Engineering and understanding complex systems relate to each other, and how they provide potential targets for developing leading indicators. The method chosen to address the research question, the Functional Resonance Analysis Method (FRAM), will then be introduced.

Chapter 2: Identifying and mapping measures of medication safety during transfer of care in a digital era: a scoping literature review



2.1 Overview

The aim of this literature review was to scope the breadth of indicators that are currently used to measure the safety of high-risk medicines during ToC. Studies that evaluated safety improvement interventions for high-risk medicines (anticoagulants, insulin or high-risk medications as a whole) during ToC and used safety measures for these assessments were included. The measures used in the studied were identified, collated and mapped against three frameworks: the Systems Engineering Initiative for Patient Safety (SEIPS); the Key Components of an Ideal Transfer of Care (KCoIToC); and a framework to review whether the measure was lagging, leading or real-time. Because a time range was not included in the literature search, many of the studies found in the search were conducted before digital systems within healthcare became embedded. Therefore, measures were also considered in terms of their adaptability for digitisation.

Using the three contrasting frameworks allowed different aspects of the measures to be reviewed. The Systems Engineering Initiative for Patient Safety (SEIPS)(14,15,92) framework enabled measures to be assessed as to whether they were of the work system, processes or outcomes. The Key Components of an Ideal Transfer of Care framework(93) describes the different components required for a successful ToC. By using this framework, the measures were assessed to determine whether there were gaps ToC coverage. Finally, measures were examined to determine their spread across leading, real-time and lagging indicators.(34) The potential for measures to be adapted for use with digital technology, was also considered.

There were many lagging measures of processes and outcomes and a dearth of leading indicators and other measures that can highlight how the work system is functioning in real time and provide insight into resilience activities. Only two studies used real-time indicators that enabled proactive review of people at risk. This review identified a need for patient-centred measures that can provide insight into the active role patients and their caregivers play in maintaining safety and managing high-risk medicines during ToC.(16) People with diabetes are experts in their own health, and often have greater understanding of how to manage blood glucose levels than general medical and nursing staff.(94) Developing new indicators that provide a richer picture of the safety of care requires collaboration with PWDI and caregivers to ensure that their perspective and influence on safe insulin management during ToC is captured and represented.

Further research is required to understand how the work system for managing insulin during ToC can be examined and mapped to aid understanding of the activities required to manage insulin for PWDI moving between home and hospital. A method is required that can allow identification of key areas where variability is likely to impact on outcomes as these areas represent potential targets for leading indicators.

Supplementary materials referenced in the study can be found in Appendix I.

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SECTION A – Student Details

Student ID Number	0LSH 2005295	**Title**	Ms
First Name(s)	Catherine		
Surname/Family Name	Leon		
Thesis Title	Identifying and mapping measures of medication safety during transfer of care in a digital era: a scoping literature review		
Primary Supervisor	Helen Hogan		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	BMJ Quality and Safety		
When was the work published?	3 November 2023		
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion	Not applicable		
Have you retained the copyright for the work?*	**Yes**	Was the work subject to academic peer review?	**Yes**

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For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	CL conceived and planned the study. HH and YJ provided advice and guidance on the development of the study plans and protocol. CL performed the data extraction and analyses. HH and YJ supervised the project. CL wrote the first draft of the manuscript and responses to peer review feedback. CL developed the results, and HH and YJ reviewed and made suggestions to the interpretation of results and commented on manuscript drafts.

SECTION E

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Date	08/09/2024

OPEN ACCESS

Identifying and mapping measures of medication safety during transfer of care in a digital era: a scoping literature review

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► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/bmjqs-2022-015859).

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Received 21 December 2022
Accepted 4 October 2023

To cite: Leon C, Hogan H, Jani YH. *BMJ Qual Saf* Epub ahead of print: [please include Day Month Year]. doi:10.1136/bmjqs-2022-015859

ABSTRACT

Background Measures to evaluate high-risk medication safety during transfers of care should span different safety dimensions across all components of these transfers and reflect outcomes and opportunities for proactive safety management.

Objectives To scope measures currently used to evaluate safety interventions targeting insulin, anticoagulants and other high-risk medications during transfers of care and evaluate their comprehensiveness as a portfolio.

Methods Embase, Medline, Cochrane and CINAHL databases were searched using scoping methodology for studies evaluating the safety of insulin, anticoagulants and other high-risk medications during transfer of care. Measures identified were extracted into a spreadsheet, collated and mapped against three frameworks: (1) 'Key Components of an Ideal Transfer of Care', (2) work systems, processes and outcomes and (3) whether measures captured past harms, events in real time or areas of concern. The potential for digital health systems to support proactive measures was explored.

Results Thirty-five studies were reviewed with 162 measures in use. Once collated, 29 discrete categories of measures were identified. Most were outcome measures such as adverse events. Process measures included communication and issue identification and resolution. Clinic enrolment was the only work system measure. Twenty-four measures captured past harm (eg, adverse events) and six indicated future risk (eg, patient feedback for organisations). Two real-time measures alerted healthcare professionals to risks using digital systems. No measures were of advance care planning or enlisting support.

Conclusion The measures identified are insufficient for a comprehensive portfolio to assess safety of key medications during transfer of care. Further measures are required to reflect all components of transfers of care and capture the work system factors contributing to outcomes in order to support proactive intervention to reduce unwanted variation and prevent adverse outcomes. Advances in digital technology and its employment within integrated care provide opportunities for the development of such measures.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ High-risk medications such as insulin and anticoagulants can cause harm if issues occur during transfer of care. Studies to improve the safety of these processes have used many different measures to determine whether these interventions had an impact.

WHAT THIS STUDY ADDS

⇒ This study identifies a range of measures currently used and assesses their comprehensiveness as a portfolio for evaluating the safety of high-risk medications during transfer of care. It identifies where gaps in measurement exist.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The measurement gaps found provide an opportunity to develop indicators which reflect healthcare complexity, real-time risks and can be used to improve safety proactively. Digital systems in integrated care present new opportunities for comprehensive measurement approaches through real-time data collection and analysis spanning the whole patient pathway.

INTRODUCTION

Keeping patients safe from harm is a central goal of health services. Despite decades of international effort, improvement is still required.[1] Medication errors are a leading cause of avoidable harm.[2] During transfers of care (ToC) patients move between healthcare settings and are at greater risk of medication-related harm.[3] Adverse events following ToC from hospital to home are common.[4] Nearly 40% of medication errors occur during care transfer, and 20% of those

errors are estimated to cause harm.[5] Between 30% and 70% of people experience an error with their medications after ToC.[6 7] Multiple processes must be undertaken to ensure that people's medications are managed safely during this period. Common barriers to safe transfer include poor communication, inadequate patient, family and/or carer involvement and insufficient provision of supporting services.[8] Failures in these processes or activities can lead to incorrect medications or doses, causing harm from underdosing or overdosing, or through accidental provision of an incorrect medication. Where support systems are not identified and arranged, patients may not be able to obtain or take their medications at all.[3 8 9] The WHO set a Global Safety Challenge in 2017 to reduce severe, avoidable medication-related harm by 50% over 5 years, with 'Medication Safety in Transitions of Care' identified as a key focus for improvement.[3] In developing this safety challenge, a comprehensive review of the literature was performed and the WHO provided some suggested measures that could be used to evaluate the impact of improvement programmes; however, these do not constitute a detailed measurement portfolio.[3] Other systematic reviews of safety during ToC focus on potential strategies for improvement rather than methods for evaluating success.[10 11]

High-risk medications (HRMs) carry a greater risk of harm when errors occur.[12 13] Errors are not necessarily more common with these medications, but the consequences of errors are potentially life threatening. People taking these medications have a heightened risk of medication-related harm during or following ToC.[3 4] Commonly recognised HRMs include insulin, anticoagulants, opioids, sedatives, concentrated electrolytes, anti-infectives and chemotherapeutic agents.[14] These medications continue to cause serious harm despite focused safety improvement work. Insulin and anticoagulants are common HRMs used to treat long-term conditions across all care settings in adults of all ages and are associated with risks during ToC.[15–19] In England, targeted patient safety alerts have aimed to improve access to up-to-date dosing information and related blood tests for HRMs (insulin and anticoagulants) during ToC through patient-held records.[15 17]

To improve safety, it is important to define what safety is. Traditionally, it has been considered as the absence of harm, and improvement efforts have focused on learning from past adverse events.[20] This assumes that poor outcomes are caused by discernible, measurable factors that can be addressed and eliminated to prevent recurrence.[20 21] It is now understood that healthcare takes place in a complex, dynamic system requiring work to be adapted and adjusted in the face of individual circumstances.[20 22 23] The healthcare work system is commonly understood to include people (patients, informal carers, healthcare professionals and other staff), equipment, tasks and the environments in which the healthcare is provided (both locally and more widely).[24–27] The adaptations and adjustments that are necessary to maintain high-quality care in the face of variation and challenges are known as healthcare resilience.[28] Resilient adaptations can be made by individuals or at higher levels, such as in a ward or across an organisation.[28–30] Using this perspective, safety can be conceptualised as the capacity of the system to enable things to go well.[31] Resilience engineering is the study of the work system and healthcare resilience to develop mechanisms to promote successful outcomes; see figure 1 for an illustration of these concepts in relation to ToC.

Measurement and monitoring are required to assess whether safety is improving. As safety cannot be measured directly, measures are used as indicators of safety. Carefully developed portfolios of indicators are required to ensure comprehensive measurement covering multiple aspects of safety including different perspectives of staff, organisations and patients.[32] Traditionally, retrospective (lagging) measures of harm have been employed to provide intelligence around safety and allow comparison over time.[33] Assessing safety, characterised as an emergent phenomenon within a complex work system,[34] requires measures that are collected prospectively (leading) or in real or near-real time which identify areas of variation in work system factors and tasks that make up the processes of care. Capturing variation provides insight into both areas of potential risk where intervention can be made to prevent harm and also system resilience by revealing how challenges are being resolved, and how conditions for successful outcomes are created.[31 35] Resilience engineering approaches can be used to identify these indicators,[21 36] and the advent of digital technology provides opportunities for their collection.

Digital technology is critical for the development of a broader array of safety measures. It enables rapid, targeted sharing of information to promote proactive interventions to improve safety. Advances, such as the introduction of artificial intelligence tools and natural language processing, promise efficient analysis of data gathered across multiple care settings.[37 38] They will facilitate searching for indicators of safety across the vast quantities of textual information held within health records and feedback forums to provide rapid insights around staff and patient experience and outcomes.[39–41] Integration of data from patient portals and wearable technology, such as fitness trackers and continuous glucose monitors, can enable remote monitoring and identification of risks in near real time.[42–45]

The focus of this scoping review was to identify the range of measures that are currently being used to evaluate the safety of insulin, anticoagulants and other HRMs during ToC. The objectives were to establish how well existing measures reflect a comprehensive indicator portfolio for the safety of these medications at ToC, whether they reflect systems, processes or outcomes and whether these may be used for both

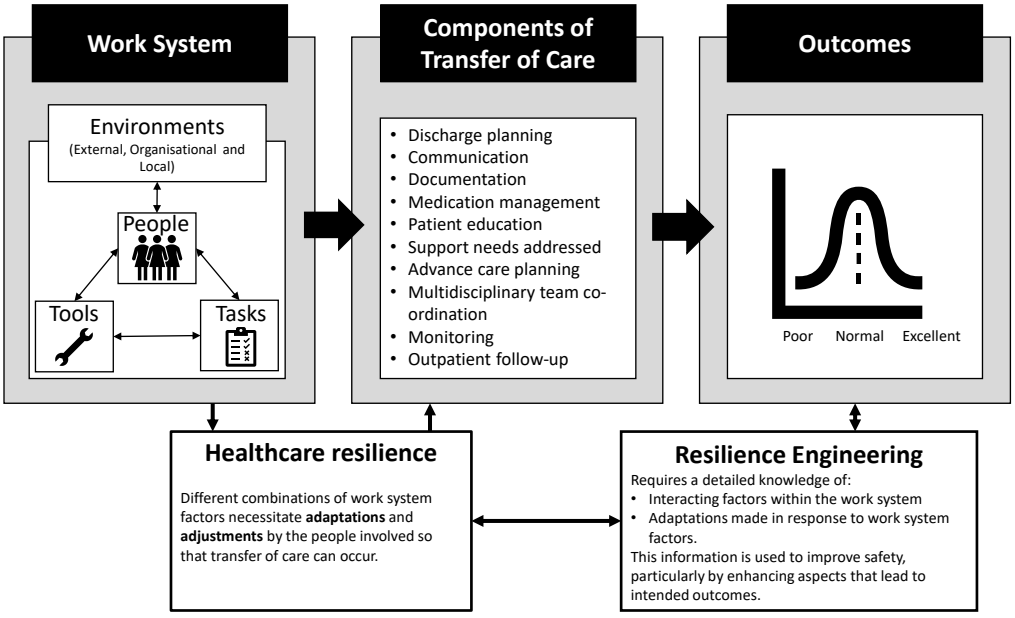

Figure 1 Healthcare resilience and resilience engineering and how these influence the components of transfers of care (ToC) and outcomes.[26 47]

ongoing monitoring of safety and proactive intervention to prevent harm. The secondary aim was to assess the adaptability of the measures for digitisation.

METHODS

Embase, Medline, Cochrane and CINAHL databases were searched using a scoping methodology.[46] This approach allowed the systematic identification and mapping of measures related to safety improvement across a broad literature employing disparate approaches to the evaluation of safety improvement interventions in varying contexts. These measures were then compared, and gaps identified. Selected databases were deemed most likely to contain studies relating to medication safety improvement. Search terms included transfer*, medic* reconciliation, transition, transfer, and insulin*, anticoag*, anti-coag* and high-risk medic*. Full details are included in online supplemental file 1. Searches were performed using the full databases including all years available. Results were limited to English language and human studies. A protocol can be found in online supplemental file 2.

Duplicate references were removed, and titles and abstracts were screened according to the following criteria. To be included, the study had to relate to adults of 18 years or over, involve a ToC (including between wards within a single organisation), focus on anticoagulants, insulin or HRMs as a group and involve evaluation of an intervention designed to improve the safety or quality of the medications involved. Studies where no interventions were performed or where the impact of an intervention on safety or quality was not evaluated were excluded. All measures used to determine the effectiveness of a safety intervention were included provided there was sufficient information to replicate the measure. Randomised and non-randomised controlled trials, before and after studies, interrupted time-series studies, historically controlled studies and research protocols detailing clearly planned measures were included. Case studies, case reports, unpublished studies, opinion pieces and cross-sectional studies were excluded. Conference abstracts were included providing there was sufficient detail to understand the measures used to evaluate the intervention.

The full text of papers that met the inclusion criteria was scrutinised to identify the intervention, whether it targeted anticoagulants, insulin or HRMs as a group, the type of ToC and whether electronic health systems were used, and in what manner. Measures were extracted from the studies and grouped into inductively developed categories according to the overarching aim of the measure. Three frameworks were used to map the measures of the different activities involved in ToC, the extent to which work systems, processes and outcomes were each measured and the spread of these measures in terms of whether they were lagging, leading or real time. By using three frameworks, the different aspects of complexity, potential for proactive measurement and across the care transition, could be explored.

The first framework, the Key Components of an Ideal Transfer of Care (KCoIToC), is a theoretical model capturing the different activities such as discharge

planning or communication required to perform a successful ToC developed by Burke *et al*.[47] The second framework, Systems Engineering Initiative for Patient Safety (SEIPS), was used to determine whether identified measures provided insight into work systems, processes or outcomes. SEIPS is a human factor-based framework 'nested within'[27] Donabedian's quality model of structure, process and outcomes.[24–27] It was created as a tool to support the in-depth understanding of health and care structures (termed work systems) and to identify barriers and facilitators of safety within them. Processes are defined as a combination of tasks and the work system components required to perform them.[24] Variation in processes which drive outcomes stems from the interactions between work system components and tasks. For each process measure, where relevant, the different work system factors that contribute to that process were considered. For example, the process of communication between inpatient and outpatient clinicians involves several different work system factors including people, tasks and tools. The people involved are the patient whose care is being discussed, the inpatient clinician and the receiving outpatient clinician. The tasks include performing the communication (verbal or written), receiving the communication and documentation. The tools required could include communication devices such as telephones, electronic health systems or emails. By considering the range of factors contributing to the process, potential targets for additional measures can be found. These can be used to provide more detailed insight into process variation. The timing of the measures in terms of whether they were lagging, leading or real time[35] was used as the third framework. Considering the measures in this way allows the spread of reactive and proactive measures to be assessed.

Finally, studies were examined to determine whether measures were obtained from digital health systems (DHS) in real time or if they had the potential to be obtained in this way. Real-time measures might be derived from digital systems that identify if a key task has not been completed and alert staff of required action, those that collect real-time information from patients via patient-held digital health records or alerting systems related to extreme blood test results.

One author extracted the data, developed the categories and mapped the measures to the frameworks. The mapping was discussed with the other two authors and consensus reached in cases of disagreement. The measures and the mapping were reviewed at intervals, and any uncertainties were considered and addressed as a team. The team was composed of three healthcare professionals, two with a hospital background and one with a background in primary care. This provided insight into the activities being measured, particularly in mapping according to the SEIPS framework.[24–27]

RESULTS

A total of 8488 studies were identified from the four databases, with a total of 7235 unique studies (see figure 2). An additional six articles were identified by scrutinising the references of included articles.

After applying the inclusion and exclusion criteria, 35 studies were eligible. They were published between

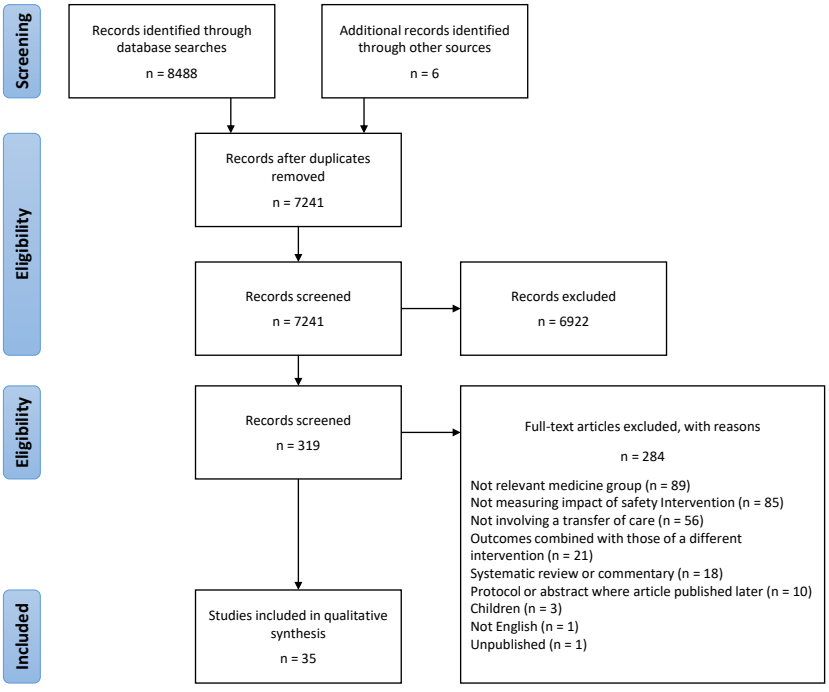

Figure 2 Literature screening process.

2011 and 2022. Most studies took place in the USA (25), with four from Australia and one each from Brazil, China, France, Italy, Saudi Arabia and Spain. The studies principally focused on anticoagulation (21). The remaining studies explored HRMs as a group of medications (10) and insulin (4). Twenty-five were original research reports and ten were abstracts from conference proceedings. See table 1 for an overview of each study. A more detailed table is provided as online supplemental table 1 listing the measures used in each study.

A total of 162 measures were collated and mapped. There were 15 measures identified from studies relating to insulin, 38 for HRMs and 109 from studies relating to anticoagulants. Eight measures were excluded as they were not described in sufficient detail to understand how they were used, for example, 'laboratory ordering practices' and 'medication stopped' with no further information.

Measures were grouped into 29 inductively developed categories. These were adverse events (thrombosis, bleeding, death, hypoglycaemia or hyperglycaemia, readmission rates) (n=61), time in therapeutic range (n=14), medication-related problems (numbers identified (n=12), their potential for harm (n=3), recommendations made (n=2) and recommendations accepted (n=2)), adherence (the extent to which patients follow a medication regimen agreed with their prescribing healthcare professional) (n=7), assessment of patient knowledge, understanding and beliefs (n=7), patient satisfaction (n=6), education and counselling (n=3), outpatient appointments (time to follow-up (n=4), appointment attendance (n=4), enrolment into clinic or appointment made (n=3)), time to reach therapeutic range (n=2), pharmacist time (n=2), protocol adherence (n=4), availability of medicines confirmed (n=2), patients with blood test within 10 days (n=1), therapeutic drug monitoring performed (n=1), baseline laboratory information available (n=1), time outside therapeutic range (n=1), cost of intervention (n=1), documentation of information in discharge letter (n=4), pharmacist coordination documented (n=1), clinician satisfaction (n=1), medication titration frequency (n=1), inadequate follow-up arrangements (n=1), documented communication (inpatient-to-outpatient (n=1) and inpatient-to-anticoagulation clinic (n=1)) and intravenous access obtained (n=1).

Measures identified

Most measures identified were lagging, outcome measures of adverse events and aspects of blood test monitoring. There were process measures that included both leading and lagging indicators. Although many potential specific work system factors were referred to in papers, these were not measured. Only one work system measure (the rate of appointments booked) was identified in the studies.

By far, the most frequently used category of measures were the rates of adverse events such as bleeding or thrombosis (with anticoagulants) or hypoglycaemia (insulin) as well as rates of readmissions and mortality. These were lagging, outcome indicators and related to the 'Medication Safety' component of the KCoIToC. Other medication safety measures included the number of issues identified or rectified and rates of adherence to protocols, all of which were lagging measures counted retrospectively. 'Educating patients to promote self-management' was the second most frequently measured component with measures of patient satisfaction and medication adherence falling into this category. These were often lagging measures for the patients for whom the healthcare experience had been completed but could be used as a leading measure by the organisation. Monitoring and managing symptoms after discharge was another component with many lagging outcome measures and one real-time measure identified. These included aspects of blood test monitoring, particularly for insulin and anticoagulants. Documentation and communication measures were lagging and of processes. They related to the 'Complete communication of information component'. Availability of baseline bloods was measured in one study and related to the component of 'Availability, timeliness, clarity and organisation of information'. Aspects of 'Co-ordinating care among team members' were measured through documentation of pharmacist involvement and clinician satisfaction. These were process and outcome measures, which were all lagging. The 'Outpatient follow-up' component included measures of appointment attendance (a lagging process measure) and the time taken for the follow-up to occur (a lagging outcome measure). No measures were found that covered the components 'Advance Care Planning' or 'Enlisting the help of social and community supports'.

Studies that aimed to improve the safety of anticoagulants and HRMs as a group often focused on measuring specific aspects of prescribing quality and accuracy along with interventions made by healthcare professionals to improve safety. Follow-up arrangements were measured in several studies. Three studies measured aspects of efficiency such as the time involved to undertake the intervention and the cost of the intervention. One study measured staff experience.

Table 2 summarises the range of measures identified, mapped according to KCoIToC component, SEIPS and timing.

DHS use

Only two studies collected real-time (or near real-time) measures and used these to adjust care. Kane-Gill *et al*[48] alerted healthcare professionals of patients at risk of harm via an electronic patient record to facilitate early intervention. Wei *et al*[49] used an internet-based portal to monitor study participants' blood sugar levels,

Table 1 References and key information

Year	Author	Article/ abstract	Study design; number of participants	Medication type	Intervention to improve safety	Care transition
2011	Avanzini *et al*[57]	Article	Observational study; 142	Insulin	Standardised protocol	Intensive cardiac care unit to general ward
2011	Nordenholz *et al*[58]	Abstract	Cohort study; 106	Anticoagulant	Clinical care pathway	Emergency department to primary care
2011	Reger *et al*[59]	Article	Observational study; 207	Anticoagulant	Discharge pathway	Hospital to primary care
2011	Schillig *et al*[60]	Article	Randomised controlled trial; 500	Anticoagulant	Pharmacist involvement	Hospital to primary care
2011	Stafford *et al*[61]	Article	Cohort study; 268	Anticoagulant	Pharmacist involvement	Hospital to primary care
2012	Falana *et al*[62]	Abstract	Cohort study; 88	Anticoagulant	Pharmacist involvement	Hospital to outpatient clinic
2013	Martin III *et al*[63]	Article	Cohort study; not defined	High-risk medications	Pharmacist involvement	Hospital to primary care
2014	Falconieri *et al*[64]	Article	Cohort study; 32	Anticoagulant	Transfer of care programme	Emergency department to primary care
2014	Martins *et al*[65]	Abstract	Randomised clinical trial; 280	Anticoagulant	Outpatient clinic	Outpatient clinic to primary care
2015	Padron and Miyares[66]	Article	Cohort study; 409	Anticoagulant	Anticoagulation stewardship programme	Hospital to outpatient care
2015	Dunn *et al*[67]	Article	Cohort study; 797	Anticoagulant	Information pack	Hospital to outpatient clinic
2015	Quach *et al*[68]	Abstract	Randomised controlled trial; 307	High-risk medications	Medication reconciliation	Primary care to the emergency department
2015	Yilmaz *et al*[69]	Abstract	Randomised controlled trial; protocol only	High-risk medications	Medication reconciliation and discharge counselling	Hospital to primary care
2016	Ha *et al*[70]	Article	Cohort study; 109	Anticoagulant	Standardised protocol	Hospital to primary care
2017	Bryant *et al*[71]	Abstract	Retrospective observational analysis; 220	Anticoagulant	Pharmacist involvement	Emergency department to primary care
2017	Castelli *et al*[72]	Article	Randomised controlled trial; 25	Anticoagulant	Information pack for patients	Hospital to primary care
2017	Chamoun *et al*[73]	Article	Cohort study; 206	Anticoagulant	Standardised protocol	Hospital to primary care
2017	Wei *et al*[49]	Article	Randomised controlled trial; 28	Insulin	Remote glucose monitoring	Hospital to primary care
2017	Zdyb *et al*[74]	Article	Retrospective record analysis; 85	Anticoagulant	Counselling and education	Emergency department to primary care
2018	Herges *et al*[75]	Article	Retrospective record analysis; 1004	High-risk medications	Pharmacist involvement	Hospital to primary care
2019	Dempsey *et al*[76]	Abstract	Observational study; 247	High-risk medications	Pharmacist involvement	Hospital to primary care
2019	Pyrlis *et al*[77]	Article	Randomised controlled trial; 105	Insulin	Transition diabetes team	Hospital to primary care
2020	Kapoor *et al*[56]	Article	Randomised controlled trial; 162	Anticoagulant	Pharmacist involvement	Hospital to primary care
2020	Liang *et al*[78]	Article	Randomised controlled trial; 152	Anticoagulant	Pharmacist involvement	Hospital to primary care
2020	Lim *et al*[79]	Article	Retrospective case series; 120	Anticoagulant	Outpatient clinic	Emergency department to outpatient clinic

Continued

Table 1 Continued

Year	Author	Article/ abstract	Study design; number of participants	Medication type	Intervention to improve safety	Care transition
2020	Tyedin *et al*[80]	Article	Cohort study; 238	Anticoagulant	Pharmacist involvement	Hospital to primary care
2020	Andre *et al*[81]	Abstract	Observational study; 162	Anticoagulant	Medication reconciliation	Primary care to hospital
2022	Bakey and Nguyen[82]	Article	Cohort study; 58	Anticoagulant	Pharmacist involvement	Emergency department to primary care
2021	Bawazeer *et al*[83]	Abstract	Randomised controlled trial; 107	High-risk medications	Medication reconciliation, counselling, follow-up	Hospital to primary care
2021	DeSancho *et al*[84]	Article	Quality improvement; 409	Anticoagulant	Counselling and education	Hospital to primary care
2021	Gurwitz *et al*[85]	Article	Randomised controlled trial; 361	High-risk medications	Pharmacist involvement	Hospital to primary care
2021	Kane-Gill *et al*[48]	Article	Quality improvement; 2127	High-risk medications	Pharmacist involvement	Primary care to nursing home
2021	Magny-Normilus *et al*[86]	Article	Randomised controlled trial; 180	Insulin	Discharge intervention	Hospital to primary care
2021	Zabrosky *et al*[87]	Abstract	Quality improvement; 218	High-risk medications	Standardised protocols for transfer of care	Hospital to primary care
2022	Lázaro Cebas *et al*[88]	Article	Cohort study; 589	High-risk medications	Pharmacist involvement	Hospital to primary care

and where significantly abnormal, the results were reviewed and insulin doses adjusted. Although not described in any studies except Kane-Gill *et al*,[48] many measures had the potential to use DHS to alert staff in real time where tasks have not been documented and therefore may be overdue for completion, as shown in table 2. There were additional lost opportunities to use specific test results and patient-documented adherence information in a real-time manner.

DISCUSSION

Although many measures were identified they did not constitute a comprehensive portfolio for assessing HRM safety during ToC. Measures did not fully represent all components of ToC and were primarily focused on past events. Traditional outcome-based measures were the most used. Although useful for gaining a broad overview of the safety and effectiveness of HRM during ToC, they offer limited insight into where interventions for improvement might be best focused. There were many potential work system factors that could have been measured across studies but there was only evidence of one being measured directly, rates of enrolment to a clinic. Work system factors are key to understanding variation in process measures and ultimately outcomes and providing insight into resilience. This is especially valuable if performance is directly communicated in real time, providing the opportunity for proactive interventions to improve safety.

The KCoIToC are very broad, each consisting of many tasks and influenced by many work system factors. Without a more detailed understanding of each component, the role of adaptations and adjustments in determining outcomes cannot be understood. For example, 'Co-ordinating care among team members' would benefit from a comprehensive understanding of how work system factors such as staff and equipment availability impact on outcomes and drive variability in safety. Such an understanding would identify approaches that could strengthen healthcare resilience.[21]

Comprehensive measurement portfolios can support understanding of how good outcomes are maintained despite varying conditions, providing a window of opportunity for proactive care adjustments to avoid harm. Peñaloza *et al*[50] developed five 'guidelines' to assess whether indicator frameworks can be used to measure the resilience capacities within the healthcare system and therefore be used to improve safety using resilience engineering.[28] These guidelines state that measures must provide insight into the resilient adaptations and complexities of healthcare that are contributing to outcomes. Second, measures should be targeted to the relevant individual who needs to act and should be provided in real time. Third, they should support efforts to learn from what is going well in addition to what is unsuccessful. Fourth, the measures should provide insight into trade-offs between safety and other issues, for example, if safety checks are being omitted due to time pressures

Table 2 Measures identified categorised according to the KCoIToC processes and mapped according to SEIPS, their timing and the potential for real-time use

KCoIToC component	Measures associated with KCoIToC components (SEIPS work system elements involved (people, tasks, tools, environments))	SEIPS framework measured/timing (lagging, leading, real time)	Potential for real time using digital health systems
Discharge planning	Enrolment into clinic/outpatient appointment made[60 84 87] Tasks: booking appointment, documenting appointment	Work system/leading	Documentation and alert.*
	Access obtained for home injections of high-risk medication[87] People: patient, staff Task: performing cannulation Tool: cannulation equipment	Outcome/lagging	Documentation and alert.
	Medication availability confirmed[76 87] People: patient and/or carer, staff Task: determining medication availability Tools: medication, telephone, computer	Process/leading	Documentation and alert.
	Percentage of inadequate warfarin follow-up arrangements[63] People: patient and healthcare professional Tasks: identify follow-up requirements, arrange follow-up Tools: digital health system, telephone, computer, diary	Process/lagging	†
Complete communication of information	Documented inpatient-to-outpatient provider contact[60] People: healthcare professionals Task: documentation Tool: form of communication (paper or electronic)	Process/lagging	Documentation and alert.
	Documented inpatient-to-anticoagulation clinic communication[60] People: healthcare professionals Task: documentation Tool: form of communication (paper or electronic)	Process/lagging	Documentation and alert.
	Information in discharge letter[70 80 82 87] People: healthcare professionals Task: documentation Tool: form of communication (paper or electronic)	Process/lagging	Documentation and alert.
Availability, timeliness, clarity and organisation of information	Baseline laboratory information available[87] People: patient, staff, laboratory staff Tasks: request, take, analyse and report blood test Tools: blood test result (electronic or paper report), patient record	Process/lagging	Alert if baseline blood test results are not available when prescription written.

Continued

Table 2 Continued

KCoIToC component	Measures associated with KCoIToC components (SEIPS work system elements involved (people, tasks, tools, environments))	SEIPS framework measured/timing (lagging, leading, real time)	Potential for real time using digital health systems
Medication safety	Adverse events (hypoglycaemia or hyperglycaemia, venous thromboembolism, readmissions, death, cardiovascular events)[49 57–62 64–66 69 70 72–80 82–84 86–88]	Outcome/lagging	Some, for example, abnormal blood tests.
	Medications managed according to protocol[71 72 74 87] People: patient, prescriber, pharmacy Task: prescribing Tools: medication, prescription, protocol	Process/lagging	†
	Medication discrepancies, errors or issues identified[63 69 75 76 80–83 85 87] People: patient, prescriber, healthcare professional reviewing medications Task: medication review Tools: medications, references (eg, medication information leaflets, reference books)	Process/lagging and real time	Documentation with targeted alert to prompt review.
	Rate of recommendations agreed[63 75] People: patient, staff (recommendation maker and prescriber) Tasks: prescribing, documentation	Process/lagging	†
	Medication safety recommendations made[71 75] People: patient, staff (recommendation maker and prescriber) Tasks: prescribing, documentation	Process/lagging	Documentation and alert.
	Impact of interventions to optimise medications[48 68 81]	Outcome/lagging	†
Educating patients to promote self-management	Measures of adherence[64 69 72 74 84 86] People: patient (and caregiver) Task: taking medication Tools: medication, packaging, compliance aids (eg, tablet cutters)	Process/leading	Through patient-owned digital method, for example, access to their electronic health record or smartphone application.
	Patient satisfaction[56 64 69 72 77 83]	Outcome/lagging for patient Leading for organisation	
	Provision of education and counselling[71 82 87] People: patient, healthcare professional Task: providing education Tools: information leaflets, medication charts	Process/leading	Partially—tasks (eg, education) can be documented and highlighted if outstanding.
	Assessment of patient knowledge, understanding and beliefs[56 72 78 81 84] People: patient, assessor Task: assessment of knowledge Tool: assessment template/quiz	Process/leading	†
Enlisting social and community supports			
Advance care planning			

Continued

Table 2 Continued

KCoIToC component	Measures associated with KCoIToC components (SEIPS work system elements involved (people, tasks, tools, environments))	SEIPS framework measured/timing (lagging, leading, real time)	Potential for real time using digital health systems
Coordinating care among team members	Percentage of patients with pharmacist coordination documented[59] People: patient, pharmacist, multidisciplinary team Tasks: 'co-ordination' tasks, documentation Tool: patient records	Process/lagging	Documentation and alert.
	Pharmacist time per patient[59 87]	Outcome/lagging	†
	Cost of intervention[88]	Outcome/lagging	†
	Clinician satisfaction[67]	Outcome/lagging	†
Monitoring and managing symptoms after transfer	Time in therapeutic range[49 57 61 65 66 70 73 77 78 83 86]	Outcome/lagging and real time	Viewed within patient record.
	Time outside therapeutic range[78]	Outcome/lagging	†
	Time to reach therapeutic range[67 73]	Outcome/lagging	†
	Therapeutic drug monitoring performed[87] People: patient, staff, laboratory staff Tasks: request, take, analyse, report blood test Tools: blood test equipment, laboratory equipment to analyse, blood test result (electronic or paper report)	Process/lagging	Documentation and alert.
	Percentage of international normalised ratio taken within 10 days of transfer of care[67] People: patient, staff, laboratory staff Tasks: request, take, analyse, report blood test Tools: blood test equipment, laboratory equipment to analyse, blood test result (electronic or paper report)	Process/lagging	Documentation and alert.
Outpatient follow-up	Clinic appointment attendance[64 66 67] People: patient, staff Tasks: book, communicate and attend appointment	Process/lagging	Documentation and alert.
	Time to follow-up[60 64 71 83]	Outcome/lagging	†

*Documentation of a specific task with an associated alert targeted to relevant staff prompting action if that task remains outstanding.
†Not applicable.
KCoIToC, Key Components of an Ideal Transfer of Care; SEIPS, Systems Engineering Initiative for Patient Safety.

in a clinic. Finally, the portfolio of measures should evolve as the processes and work changes over time.[50] Without indicators illuminating the complex, interacting factors of the work system and resilient activities performed during ToC of HRMs, the measures obtained from this literature scoping review cannot yet be used for resilience engineering and enhancing capacity for successful, high-quality care. Incorporating these guidelines when developing measurement portfolios will foster the inclusion of indicators that provide insight into the complexity and resilience of healthcare delivery and the underlying causes of variability linked to safety. This enables exploration of factors that contribute to success and focused interventions to improve safety.

Many safety measures would be amenable to real-time measurement if certain tasks were recorded in the electronic patient record. It is essential that all users are involved in the development and testing of such measures as well as the design of electronic health systems so that capturing the required information is not too burdensome for users (healthcare staff and patients).[32 51] As digital technologies are advancing, there is great potential for developing new measures taking advantage of these systems. For example, wearable technology, smartphone applications and data warehouses could all potentially be valuable sources of data if used within appropriate governance arrangements. Machine learning and natural language processing also provide opportunities for identifying measures within unstructured narrative data that have previously been too labour intensive for routine use, for example, from medical notes, compliments and complaints.

Patients and their caregivers contribute greatly to the safety of ToC, adapting their actions to prevent and overcome issues.[52 53] There were very few measures that accounted for the active role that patients perform in the ToC process. Patient contributions are becoming ever more possible with ongoing developments to digital patient-held records and healthcare tools.[54] Within the measurement category of 'Educating the patient to promote self-management', measures included elements of patient involvement, for example, adherence. The patient is key in this process; however, many factors influence their decision to adhere to the medication regimen such as their core beliefs about taking medications, their risk and benefit analysis of the medications and lifestyle factors.[55] Many of these factors are not reflected by the indicators identified in this literature review, with only Kapoor *et al* assessing aspects of patient's beliefs regarding anticoagulation.[56] Evaluating the contribution of patients and the resilience activities they perform will provide valuable ways to include these essential aspects of safety. This will result in a more holistic measurement approach.

Strengths and limitations

The literature review used a systematic approach with clearly defined concepts to explore and identify a wide range of indicators. Inclusion of insulin and anticoagulants along with HRMs in general expanded the breadth of measures identified. Most interventions in the review were aimed at improving discharge from hospital to primary care, with other aspects of ToC less well represented. There may be additional relevant measures that could be detected by including studies of other HRMs, medication safety in general or other potential contexts for ToC. Components of ToC may also vary between countries which potentially limits wider generalisability. Furthermore, the framework of the KCoIToC is designed to assess the transition from hospital to primary care, although many components remain valid for other ToC. The SEIPS framework is a tool that is designed to highlight the impact of interactions between different factors within the work system, processes and outcomes. The limited detail in the literature did not lend itself to in-depth analysis of interacting work system factors using SEIPS. The authors used their prior knowledge and experience to identify some of these factors, but this was not exhaustive. In developing further measures, a more detailed exploration of the relevant work systems is required.

CONCLUSION

This literature review identified a range of measures that can be used as part of a portfolio to evaluate the safety of ToC for people taking anticoagulants, insulin or HRMs. The identified measures were insufficient to provide insight from a resilience engineering perspective. Measures predominantly stemmed from a traditional approach to safety management, providing an overview of general outcomes. There is potential to identify new leading indicators of safety by obtaining a deep understanding of the complex work system interactions and resilience activities that maintain the safety of HRMs during ToC. A comprehensive, patient-centred safety measurement framework for ToC and HRMs should include such leading indicators, targeted in real time to relevant people across care pathways that can enable early intervention. Digital health technology implementation is essential for such an approach.

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Funding This study is independent research funded by the National Institute for Health and Care Research ARC North Thames. The views expressed in this publication are those of the authors and not necessarily those of the National Institute for Health Research and Care or the Department of Health and Social Care.

Competing interests None declared.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information.

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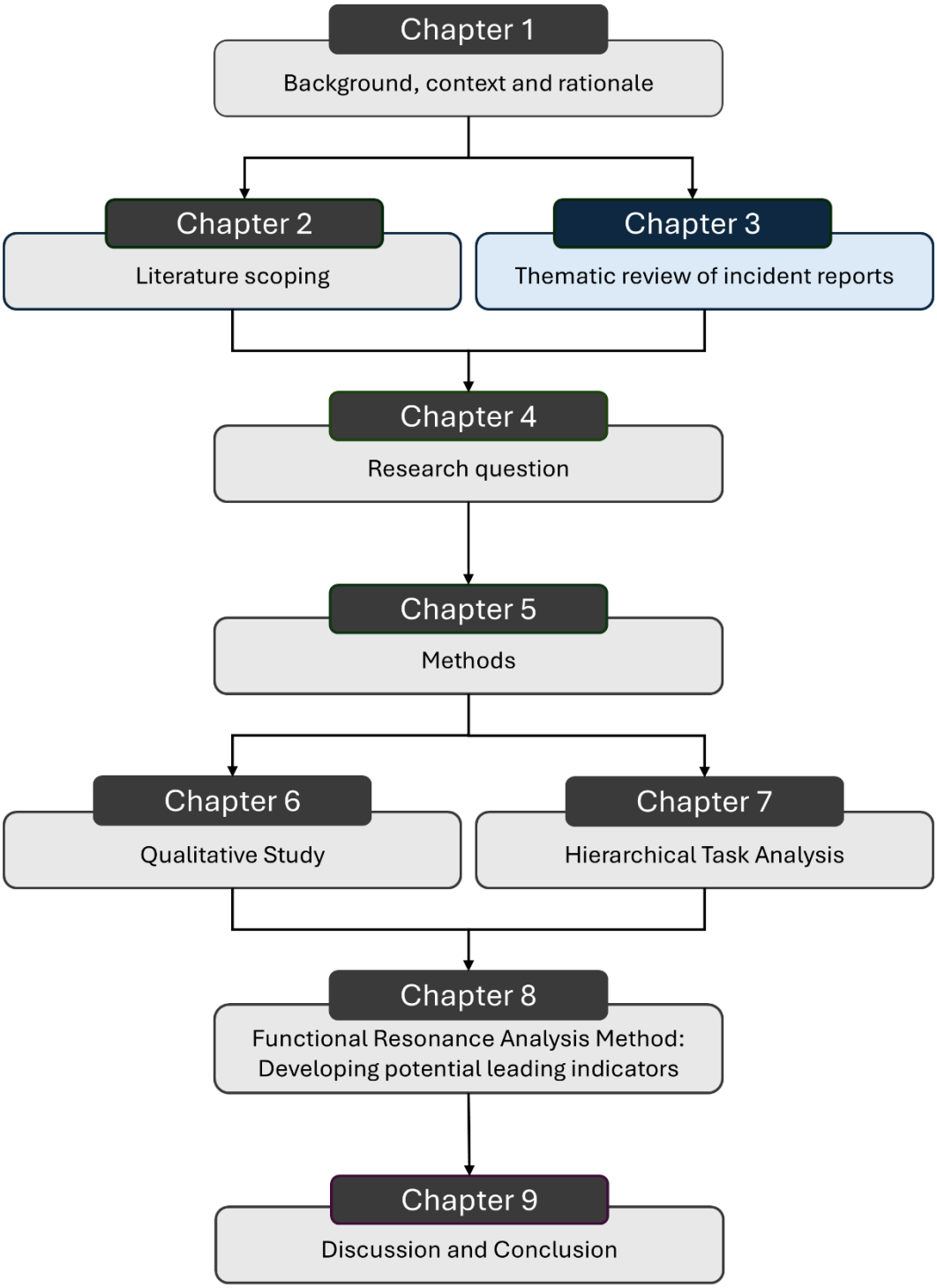
Chapter 3: Seeking systems-based facilitators of safety and healthcare resilience: a thematic review of incident reports



3.1 Overview

This study aimed to use a Safety-II approach to explore whether incident reports could be used to identify facilitators of safety and aspects of healthcare resilience.

Criticisms of Safety-II have been that it is challenging to apply this approach meaningfully in real-life contexts.(95,96) This study aimed to determine whether a common source of safety data, incident reports, could be used to identify information about Safety-II if a different perspective was used when undertaking a thematic review. A Safety-II perspective recognises that all outcomes stem from resilient adaptations due to the changing circumstances being faced.(28) Those involved in healthcare (patients, staff and teams) have to adapt to different combinations of factors including people, the tools available, the tasks required and the surrounding environments (local, organisational and external). Resilient abilities (termed potentials) are defined as the ability to respond, monitor, anticipate and learn in the face of these varying conditions.(97)

A framework approach was applied to identify factors that were facilitating safety according to the Systems Engineering Initiative for Patient Safety work system(15) and the four resilience potentials.(97)

This study found that incident reports contain information about factors within the work system that contribute to successful outcomes. It demonstrated that anticipation and monitoring are occurring, and therefore there are opportunities to facilitate these potentials. Not only do incident reports provide information about where aspects of the work system combined to produce unintended outcomes, they also demonstrate areas where people, teams and organisations are proactively facilitating safety as well as responding to issues.

This study demonstrates the potential benefit of using available safety data to proactively identify and examine how factors within the work system and resilient adaptations that promote safe outcomes can be identified and enhanced for PWDI during ToC.

Supplementary materials can be found in Appendix II.

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SECTION A – Student Details

Student ID Number	LSH2005295	**Title**	Ms
First Name(s)	Catherine		
Surname/Family Name	Leon		
Thesis Title	Seeking systems-based facilitators of safety and healthcare resilience: a thematic review of incident reports		
Primary Supervisor	Helen Hogan		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?	International Journal for Quality and Safety in Healthcare		
When was the work published?	25 June 2024		
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SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I conceptualised the study with the advice of my PhD supervisors. Developed the search criteria and was responsible for data extraction and analysis. I wrote the first draft of the manuscript and undertook revisions following advice from my supervisors.

SECTION E

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International Journal for Quality in Health Care, 2024, **36(3)**, mzae057
DOI: https://doi.org/10.1093/intqhc/mzae057
Advance Access Publication Date: 25 June 2024
Original Research Article

Seeking systems-based facilitators of safety and healthcare resilience: a thematic review of incident reports

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Abstract

Patient safety incident reports are a key source of safety intelligence. This study aimed to explore whether information contained in such reports can elicit facilitators of safety, including responding, anticipating, monitoring, learning, and other mechanisms by which safety is maintained. The review further explored whether, if found, this information could be used to inform safety interventions. Anonymized incident reports submitted between August and October 2020 were obtained from two large teaching hospitals. The Systems Engineering Initiative for Patient Safety (SEIPS) tool and the resilience potentials (responding, anticipating, monitoring, and learning) frameworks guided thematic analysis. SEIPS was used to explore the components of people, tools, tasks, and environments, as well as the interactions between them, which contribute to safety. The resilience potentials provided insight into healthcare resilience at individual, team, and organizational levels. Sixty incident reports were analysed. These included descriptions of all the SEIPS framework components. People used tools such as electronic prescribing systems to perform tasks within different healthcare environments that facilitated safety. All four resilient capacities were identified, with mostly individuals and teams responding to events; however, monitoring, anticipation, and learning were described for individuals, teams, and organizations. Incident reports contain information about safety practices, much of which is not identified by traditional approaches such as root cause analysis. This information can be used to enhance safety enablers and encourage greater proactive anticipation and system-level learning.

Keywords: patient safety; medication safety; risk management; governance; incident reporting

Introduction

Incident reporting and learning systems in healthcare serve as repositories of voluntary reports of events that lead to actual or potential harm to patients, and they are a key source of safety intelligence [1–4]. Learning from these reports may be derived through national, organizational, or local analysis, e.g. by a ward or teams within a hospital [2]. Traditionally, incidents are scrutinized to identify contributory factors and develop interventions to prevent recurrence [4, 5]. However, this approach has been challenged for focusing on unintended outcomes, thus limiting learning opportunities [6, 7]. By seeking to understand what went wrong, learning from incidents can narrow its focus on problems that need to be fixed, often relying on applying remedial strategies to the individuals involved [5, 8].

Healthcare is complex and unpredictable. Safety is maintained by individuals, teams, and organizations adapting to differing circumstances, a concept known as healthcare resilience [9–12]. Healthcare takes place within a work system comprising of interacting components including: (among others) patients, caregivers, and staff, the tasks required to deliver care, available tools and technology, and aspects of the care environments [11]. Safety improvements can be developed by exploring the work system and the resilient adaptations taking place within it [6, 10, 13, 14]. Resilient activities include monitoring for issues that may impact safety, responding to situational changes, anticipating potential issues, and learning from new information [15]. Work system complexities and resilient adaptations contribute to all outcomes experienced in healthcare; therefore, learning should be sought from where care was successful, where harm was prevented (near-misses), and where harm occurred [9, 14, 16]. This understanding of safety has been termed Safety-II [17].

Less attention has been given to whether incident and associated investigation reports can provide information on healthcare resilience and other safety facilitators. Although reports focus on adverse events, they may also describe factors that support safety or resilient activities undertaken. If identifiable within incident reports, these data could expand the use of incident analysis beyond learning from factors contributing to harm towards learning from successful aspects of the system.

This research aimed to determine whether incident analysis can identify aspects of the work system and resilient activities that facilitate safety. Anticoagulants, known to be high-risk medications for patient safety, were used to trial the approach.

Received 18 December 2023; Editorial Decision 15 June 2024; Revised 23 May 2024; Accepted 24 June 2024

The objectives were to explore whether incident reports can be used to identify:

i. Work system factors facilitating anticoagulant safety.
ii. Resilience activities (known as potentials) at individual, team, and organizational levels.
iii. Practical insight into areas for safety improvement.

Methods

A qualitative, thematic review of the narrative content of anticoagulant-related incident reports was undertaken.

The study was conducted in England, using incident report data from two large teaching hospitals reported between August and October 2020. Although reporting systems differed between organizations, both contained the core set of information required by all reporting systems in England [18]. Those used for the analysis included the location of the incident, the type of incident (e.g. medication, staff, or property), the level of harm experienced by the patient, narrative descriptions of the event, and the initial actions taken. Many incident reports included the investigation by the local manager.

Ethics and other permissions

Ethics approval was granted by the London School of Hygiene & Tropical Medicine Ethics Committee (Ref. 22980). NHS ethics approval was not required because the data were anonymized. The project was registered at both hospitals as a service improvement project and followed local data governance requirements.

Sampling strategy

A structured search using medication names, commonly used abbreviations, and keywords was performed in each incident reporting system to identify all incidents relating to anticoagulation between August and October 2020. The full list of search terms is included in the supplementary material.

Extracted incidents were manually checked for anonymity and redacted to remove any reference to patients, staff members, hospital, or location. They were numbered chronologically. The two hospitals used different low-molecular weight heparin (LMWH) products, dalteparin and enoxaparin; therefore, these were anonymized by describing them only as LMWH, with associated doses in each incident changed to Dose A, Dose B, etc.

Inclusion and exclusion criteria

To be included, reports had to relate to patient care and any anticoagulant medication. Incidents were excluded if they did not contain sufficient narrative information to understand the events. All fields in the extracted data, including the local investigation, where available, were included to aid in understanding the narrative and context of the incident.

Data synthesis

A framework approach to coding was used, guided by two frameworks: the Systems Engineering Initiative for Patient Safety (SEIPS) [11, 19–21] and the four resilience potentials [15]. SEIPS was used to categorize different work system components described in the narrative according to people, environments, tools, and tasks (Fig. 1). The second framework was used to identify resilience potentials: respond, monitor, anticipate, and learn. Responding was defined as actions taken in response to an event. Monitoring was defined as the identification of actual events through the knowledge and experience of staff. Anticipation was the identification of potential or future issues by staff, and learning incorporated any reflections on actions taken in response to an event that might prevent similar issues in the future.

Incidents were analysed line by line by one author to identify SEIPS components involved and evidence of anticipation, monitoring, responding, or learning. Where work system factors were identified, those that facilitated safety were listed in a separate column in a spreadsheet. Resilience potentials were recorded in the same way and were further classified according to whether these were at individual, team, or organizational levels. This insight into the context, terminology, processes, and systems within the respective organizations improved the interpretation of what might have otherwise been ambiguous narratives. The coding and themes were discussed with co-authors to enhance data validation. In cases of disagreement, the mapping was reviewed, and consensus was reached.

Results

Overall, 141 incidents were identified, 86 from Hospital A and 55 from Hospital B. After applying the inclusion and exclusion criteria (Figure 2), 60 incidents were included in the analysis. Many incidents were excluded as these were not anticoagulant related, but the ward in which they occurred shared an abbreviation with a search term.

Two-thirds (n = 41) of the incidents involved LMWH, nine warfarin, four apixaban, two edoxaban, and one each involved heparin and rivaroxaban. Incidents occurred in a variety of clinical areas including emergency units, medical and surgical wards, specialist areas, and one in a patient's home. Patients experienced no harm according to 52 reports, with four near-misses, minor harm twice, and moderate harm twice.

The SEIPS work system factors that were identified and how they facilitated safety are described below. A summary is available in Fig. 3. Although reported separately, the combination of factors and interactions between all the people involved, using the tools available to perform tasks within their healthcare environments, impacted safety.

Facilitators of safety

People

People, including patients and staff, facilitated safety using their knowledge, experience, and skills to identify problems. They demonstrated tenacity, communication, and collaboration to resolve issues or adjust plans in response to problems.

For example, staff adapted when they were unable to administer anticoagulants to a patient in her home as intended.

> Patient attended ED and was diagnosed with both Covid pneumonia … and a new [pulmonary embolism (PE)]. The plan was for the patient to go home and self-isolate, and

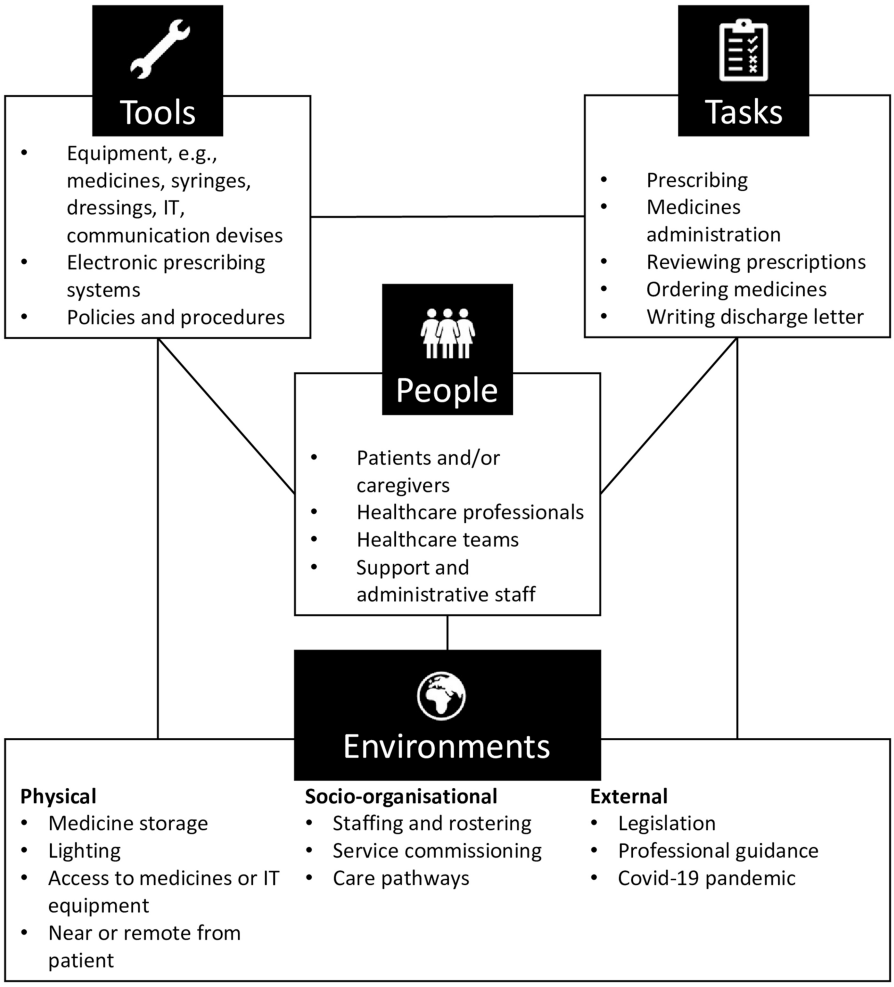

Figure 1 The SEIPS 101 work system with examples of each factor [21]

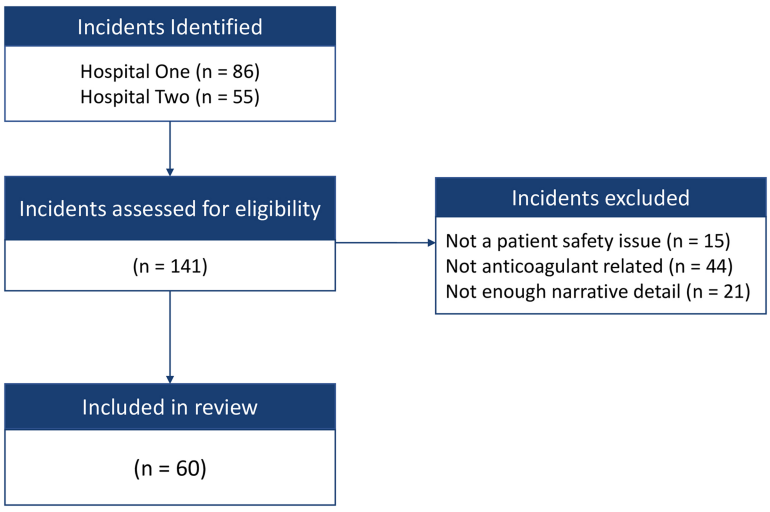

Figure 2 Incident selection following the application of inclusion and exclusion criteria

for ambulatory care to counsel patient and initiate anticoagulation therapy for the PE; ambulatory care cannot do this whilst the patient is housebound with Covid. She was discharged with a single dose of [LMWH] …. We have had to organise a courier to deliver [LMWH] to her home to continue her treatment until the quarantine is over.

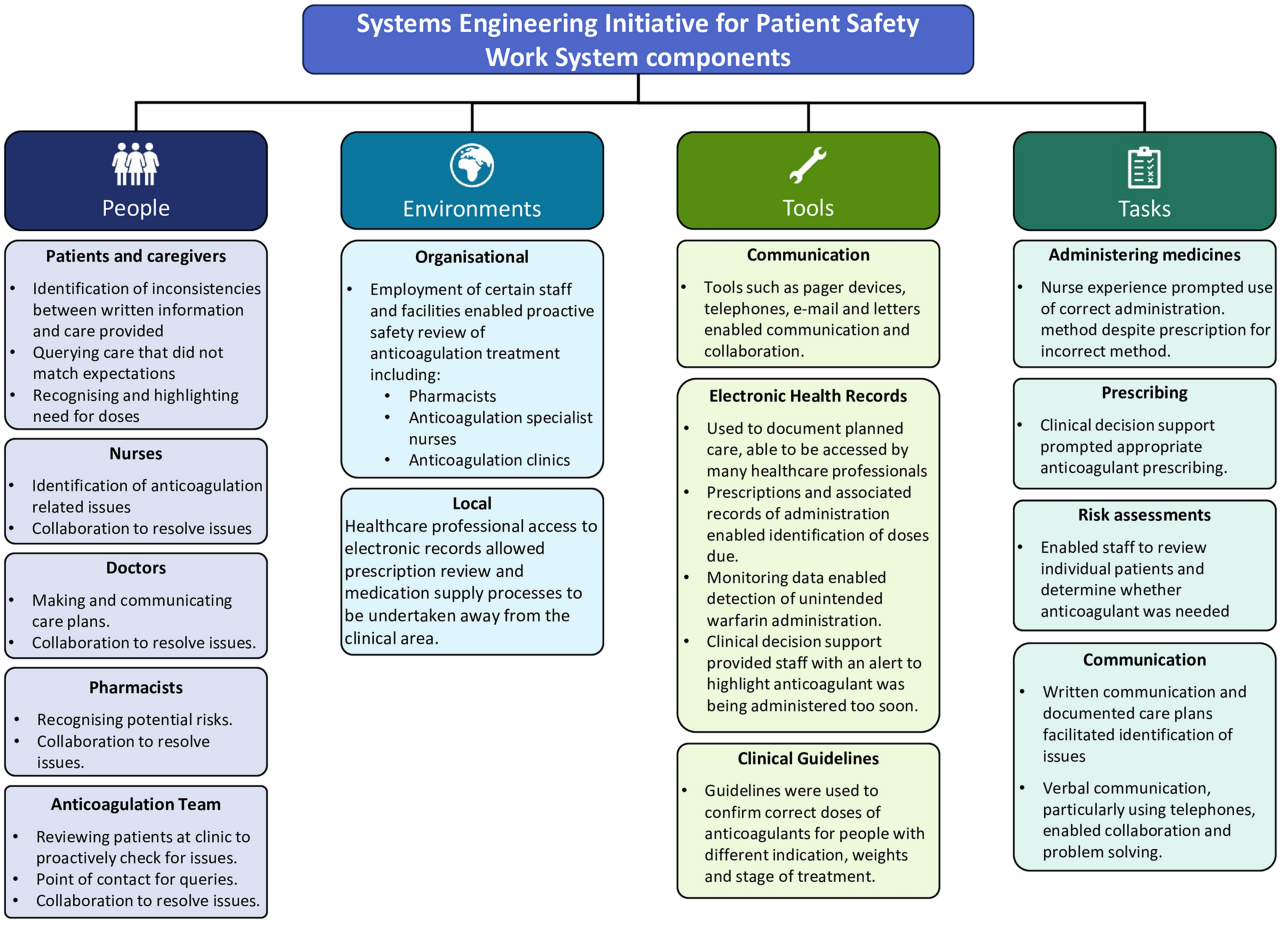

Figure 3 Work system components and their role in facilitating safety

Environments

Organizational resources supporting safety were identified. Follow-up processes, such as clinic appointments or healthcare professional reviews, allowed monitoring of at-risk patients to prevent problems. The pharmacist's clinical review of the medication chart allowed confirmation that medications were prescribed safely.

Communication channels enabled the escalation of potential issues and prevented harm.

> Telephone call from out-of-area GP to anticoagulation service … regarding patient discharged on warfarin and lack of handover and discharge information.

Organizational enablers supported such communication, e.g. by providing contact details for the specialist anticoagulation team.

Tools

Clinical guidelines and electronic health records (EHRs) were the most frequently described tools enabling anticoagulation safety. Guidelines were used to influence individualized prescriptions and aid their review to prevent or identify potentially life-threatening incorrect dosing.

EHRs facilitated safety both in terms of the information they contained (patients medical notes, prescriptions, and administration records) and the availability of clinical decision support. EHR rules and alerts supported guideline-based prescribing and highlighted potential errors to users, often in real-time. In one report, a pharmacist identified a patient with an incorrectly documented weight based on an estimate and the higher than indicated LMWH dose prescribed consequently. EHR clinical decision alerts highlighted issues, enabling staff to act swiftly to prevent or mitigate adverse events.

> Patient … had been prescribed … [LMWH] prophylaxis. After giving the medications and signing them it popped up with a message to say [LMWH] had already been given at 0852 ….

Tasks

Communication was the most frequently described task promoting safety. Examples included querying prescriptions, clarifying, and collaborating to update plans following unintended events. This example captures the complexity of such communications across secondary, primary, and home care settings.

> Patient attended outpatients' area to be seen in our clinic however we were not on site. Full bloods taken - noted INR to be high as patient no longer on warfarin. Contacted

> patient's GP for more details. Medications managed by care assistants according to GP.
>
> Contacted patient's care assistant - she states that the patient has several boxes of different medications at home including [warfarin] which he had been taking since discharge alongside prescribed [direct oral anticoagulant].

The clinic attendance provided the opportunity to review this man's care. Remote access to EHR notes and blood tests enabled the anticoagulation team to identify the unintended continuation of warfarin. Subsequent communication took place the General Practicitioner, community pharmacist, anticoagulation team, and care assistants to develop a plan to support the patient in taking his medications safely.

Resilient activities identified

Respond

Incident reports, by their nature, describe an individual's actions to resolve or manage situations that are encountered. Therefore, many demonstrate responding, particularly at an individual level. Here, a member of the anticoagulation team provided advice to avoid harm.

> Patient was given [higher dose A LMWH] instead of [lower dose B]. Informed the nurse in charge, on call doctor and on call pharmacy. Recheck patient vital signs and monitor patient for any bleeding.

Learn

Learning was identified at individual, team, and organizational levels.

> Reflected on my own practice - when I had a phone call with the patient I asked if he was on any 'blood thinning' medication and perhaps I didn't make this clear what I meant. Also was during a phone call when I had given the patient a lot of information about stem cell transplant plans so he may have felt overwhelmed etc. Spoke to [patient's] usual haematology team at [another hospital] and we have discussed how we can improve communication going forward.

Team learning was observed in reports that described reviews of system processes such as EHR use.

> This was an unusual scenario …. The patient had such an effective diuresis that he lost over 30kg, which placed him in a different dosing category for [LMWH]. The team as a whole have reflected upon this and whether using the 'ward round' feature of EPR might mitigate in the future.

Organizational learning was demonstrated where whole pathways or clinical guidelines were updated in response to issues raised, e.g. changes to ambulatory care provision to ensure that treatment was available to those self-isolating due to COVID-19.

Anticipate

Team-level anticipation was demonstrated when automatic email replies were used to highlight the correct referral method.

> Patient seen … with suspected [deep vein thrombosis (DVT)]. He was referred to the DVT clinic for investigation, however the doctor emailed the anticoagulation clerical team email address which (as per the out-of-office reply the doctor would have received) is not checked out of hours.

At an organizational level, evidence of anticipation was seen by clinical decision support alerts designed to highlight the known risk of duplicate dosing.

Monitor

Individuals used their knowledge, experience, and/or skills to monitor for issues. For example, a pharmacist identified that an anticoagulant medication was not kept in the clinical area and would need to be supplied by the pharmacy. A patient contributed to his safety by letting the staff know that he had missed a dose of his usual anticoagulants before admission.

> Patient came…to have some bloods taken …. Whilst here he asked me to give his Filgrastin injection and a dose of Tinzaparin as his district nurse had not been able to get to him before he left for the hospital.

Discussion

Statement of principal findings

Incident reports can provide insight into interacting factors that promote safety and aspects of healthcare resilience that can be used for safety improvement. People identified and responded to safety issues through communication and collaboration. Organizational resources, such as staff with responsibility for reviewing anticoagulants (anticoagulation teams and pharmacists), supported safe care. Clinical guidelines, EHRs, and communication devices were tools for enhancing anticoagulation safety. The initial investigations undertaken by the local manager provided additional descriptions of many system-based factors. Incident reports are subjective accounts, written after events, and therefore the most resilient activities identified were of individuals responding to unanticipated events; however, aspects of monitoring, anticipation, and learning were also detected.

Our analysis identified system factors frequently associated with safer care. For example, communication channels often enabled issues to be resolved. Opportunities therefore arise to improve safety at a system level by supporting these key areas, an example of proactive learning from successful outcomes. The approach also highlights where staff are regularly adapting to situations because of suboptimal factors in the work system. These adaptations provide insight into where safety risks exist and where potential interventions to prevent harm might be needed. Multiple incident reports described staff recognizing incorrect anticoagulation doses for specific patients. Repeated resilient adaptations for this recurring risk highlighted the need to evaluate how other safeguards, such as clinical decision support tools and guidelines, could enable systems to anticipate this issue and prevent it in the future. In England, the introduction of the Patient Safety Incident Response Framework [22] and the Learning from Patient Safety Events (LFPSE) system [1] supports a systems-based approach to learning for patient safety. The former encourages staff to use SEIPS as a key tool for analysing work system factors that both support and threaten safety. LFPSE is designed

to provide incident-related data in a format that supports the use of tools such as SEIPS.

Interpretation within the context of the wider literature

Current approaches to incident analysis often focus on what went wrong because What-You-Look-For-Is-What-You-Find [8]. Exploring healthcare resilience and factors promoting safety within incidents provides a more comprehensive picture of healthcare work systems. Identifying how safety was facilitated uses a different lens to interpret incident report data and can highlight where systems and resilient activities are maintaining safety. This balances the negative and stigmatizing effect of a focus on errors, failures, and unsafe acts [14, 17, 23]. Exploring what went well when performing incident analysis can improve staff morale, support learning, and promote a positive organizational safety culture [24–27].

Implications for policy, practice, and research

Thematic analysis of the narrative content of incident reports is time-consuming. Due to the volume of incidents reported, those resulting in severe harm or death are often prioritized [2]. Machine learning tools to efficiently gather information from the textual content of incidents are being introduced in England with LFPSE [28]. Natural language processing can efficiently analyse vast quantities of such data and shows promise for learning based on newer concepts of healthcare safety, making a broader approach to incident analysis more feasible [14, 29]. Although systematic use of a Safety-II lens may benefit from machine learning or natural language processing, we have shown that it is possible to extract meaningful data manually whenever incident reports are investigated or analysed. Our study provides early evidence that using a Safety-II lens for reviewing incident report data can offer additional insights.

Strengths and limitations

This study used a systematic approach to identify facilitators of safety and healthcare resilience within incident reports. Analysis was undertaken by medication safety pharmacists whose clinical insight allowed the interpretation of the narrative descriptions. Anticoagulants were chosen as the focus of the study because they are high-risk medications associated with patient harm and their use involves all aspects of the work system. This allowed insight into a wide range of activities undertaken by staff, patients, and caregivers to maintain safety. Although the study took place using data from the incident reporting system in England, this approach is likely to work in different reporting systems.

There remain challenges in adopting this approach to analysis. Incident reports are written using standard forms and often require knowledge of the clinical and organizational context for interpretation. Furthermore, these are not designed to capture information about the work system or healthcare resilience. Information quality in reports is variable [30, 31], and this analysis depended on the reviewers' knowledge to draw out information on work-system factors and resilience potentials. Our method would benefit from further testing in a larger study of a contrasting subject area, employing additional reviewers.

Conclusion

Incident reports can provide vital insight into how safety is facilitated and the role of healthcare resilience. This approach allows the identification of a broader range of potential areas to intervene, complementing traditional incident analysis. Information about resilient activities and the work system factors facilitating safety can be used to proactively highlight and explore opportunities for improvement. Natural language processing and machine learning have the potential to develop this approach, given the greater efficiency for incident analysis these tools can provide.

Acknowledgements

None declared.

Author contributions

Catherine Leon, Yogini H. Jani, and Helen Hogan (Conceptualization, Methodology), Catherine Leon (Project administration, Data curation, Data analysis, Writing—original draft, Writing—review & editing), Helen Hogan and Yogini H. Jani (Supervision, Validation, Writing—review & editing).

Supplementary data

Supplementary data is available at *IJQHC* online.

Conflicts of interest

None declared.

Funding

This article is independent research funded by the National Institute for Health and Care Research ARC North Thames. The views expressed in this publication are those of the authors and not necessarily those of the National Institute for Health Research and Care or the Department of Health and Social Care.

Data availability

The data underlying this article cannot be shared publicly due to the information governance requirement of the participating organizations. The data will be shared on reasonable request to the corresponding author.

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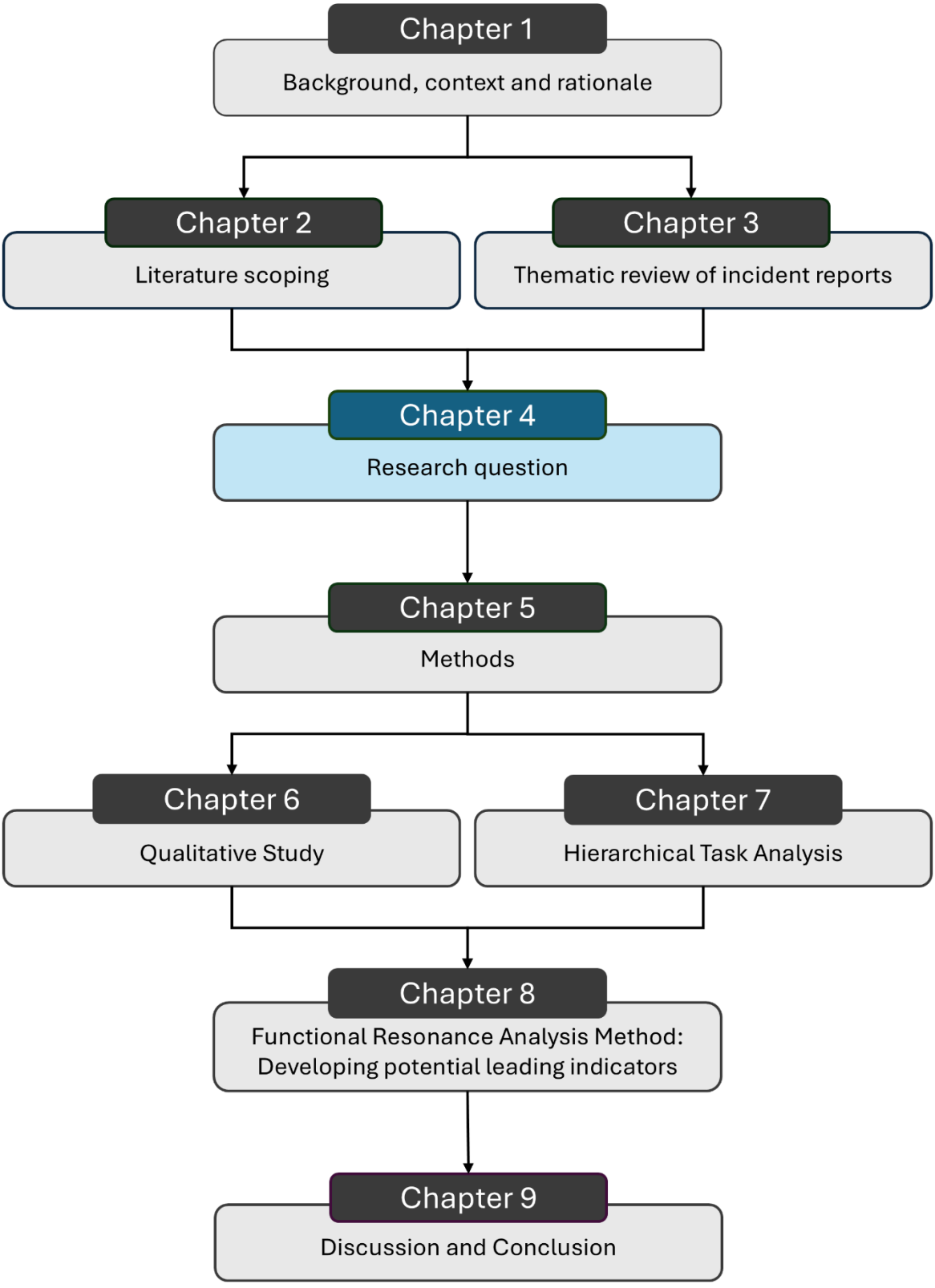
Chapter 4: Research Question



4.1 Research question

How can a detailed understanding of insulin management within complex digitally integrated care systems be used to create leading indicators that support proactive safety improvements?

4.2 Objectives

The scoping work presented in the previous chapters was used to develop and refine the initial objectives. The objectives to address the research question are:

- To identify measures currently being used to understand the safety of high-risk medications during transfer of care.
- To explore whether factors that support safety and healthcare resilience can be identified from incident reports.
- To map insulin management for PWDI across their journey through healthcare immediately before, during and after a hospital admission.
- To identify the factors in the work system that influence the success of insulin management for PWDI moving between home and hospital.
- To develop a detailed map of insulin activities involved during admission and discharge from hospital, based on the lived experiences of patients and the healthcare professionals involved in their treatment (Work as Done).
- To identify how variability during these care transfers is associated with outcomes.
- To identify whether areas of variability can be used as potential targets for leading indicators.

4.3 Rationale

People with diabetes who use subcutaneous insulin are at risk of harm during Transfer of Care (ToC) due to the challenges of moving between different care settings. Safety is maintained by healthcare resilience, where people and organisations respond, anticipate, monitor, and learn in response to challenges.

Real-time data within digital systems can be used to improve safety, by enhancing the monitoring of care processes and facilitating early identification of potential risks to safety before harm occurs. Such data could indicate possible future states and allow proactive adjustments based on likely need and risk and could be considered for use as leading indicators for safety. The availability and use of a wider array of leading indicators will facilitate proactive safety improvement.

The scoping review of the literature (Chapter 2) presented a summary of indicators currently used to measure the safety of high-risk medicines following ToC. There were many lagging measures of processes and outcomes and a dearth of leading indicators and other measures that can highlight how the work system is functioning and provide insight into resilience activities. It also identified a need for patient-centred measures that can provide insight into the active role patients and their caregivers perform in maintaining safety and managing high-risk medicines during ToC.(16) People with diabetes are experts in their own health, and often have greater understanding of how to manage their blood glucose levels than general medical and nursing staff.(94) Developing new indicators that provide a richer picture of the safety of care requires collaboration with PWDI and caregivers to ensure that their perspective and influence on safe insulin management during ToC is captured and represented.

The thematic review of anticoagulation incident reports presented in Chapter 3 demonstrated that resilient healthcare activities can be identified from this source of data. One of the most common resilient adaptations identified was the need to rescue situations caused by a misalignment in demand and capacity. Determining how variation in the work system contributed to these misalignments and their outcomes can generate potential targets for real-time leading indicators. Such indicators might signal where proactive interventions to rebalance the work system might be most effective in preventing harm. Applying this understanding to insulin management during ToC, exploration of resilient adaptations could be used to identify how successful outcomes are achieved and how variation because of these adaptations can change outcomes.

The development of leading safety indicators that can be used for proactive prevention of harm is less advanced than the development and use of lagging indicators. Definitions are still being strengthened, with some concepts, such as passive and active leading indicators only emerging recently.(39,98) The Functional Resonance Analysis Method (FRAM), a Resilience Engineering method for mapping complex systems and their interactions has been used to develop safety indicators,(99) including leading indicators, in a healthcare setting.(38,100) The FRAM approach can be used to identify areas of the work system contributing to variable outcomes.(19) If variation has the potential to lead to harm and can be highlighted to the right person in the right way then such harm may be averted. For those involved in healthcare, monitoring and anticipating potential threats by tracking leading indicators allows them to make proactive changes in real time to reduce risks. This represents an advance in patient safety over today's approach to learning and change in the aftermath of patient harm. FRAM also allows the identification of overarching systems and supporting infrastructure that influence successful outcomes. These are potential targets for passive leading indicators, which can highlight the

wider organisational capacity for managing insulin safety during transfers of care (ToC). To date, no studies have used FRAM to identify and distinguish active and passive leading indicators separately.

This research aims to apply FRAM to insulin management across ToC to identify leading indicators and to determine the capacity of FRAM to identify both active and passive indicators. The study will also explore how patients, caregivers and staff can contribute to the FRAM approach and what these contributions can add in terms of the scope of potential indicators identified and their feasibility for use.

4.4 Theoretical framework

The concepts of Safety-II and resilient healthcare form the basis for the theoretical framework for this research.

Using a Resilience Engineering approach, leading indicators would provide people at all levels of the work system with the data they need to consider potential future outcomes and current and future risks to safety. Real-time data highlighting where demand is outstripping capacity can provide insight into areas of potential risk, where resources could be provided to increase capacity or actions could be taken proactively to reduce demand, see Figure 5. Such data could support individual, team and organisational monitoring and anticipation to enable adaptations and adjustments to improve the likelihood of successful outcomes, see Figure 6.

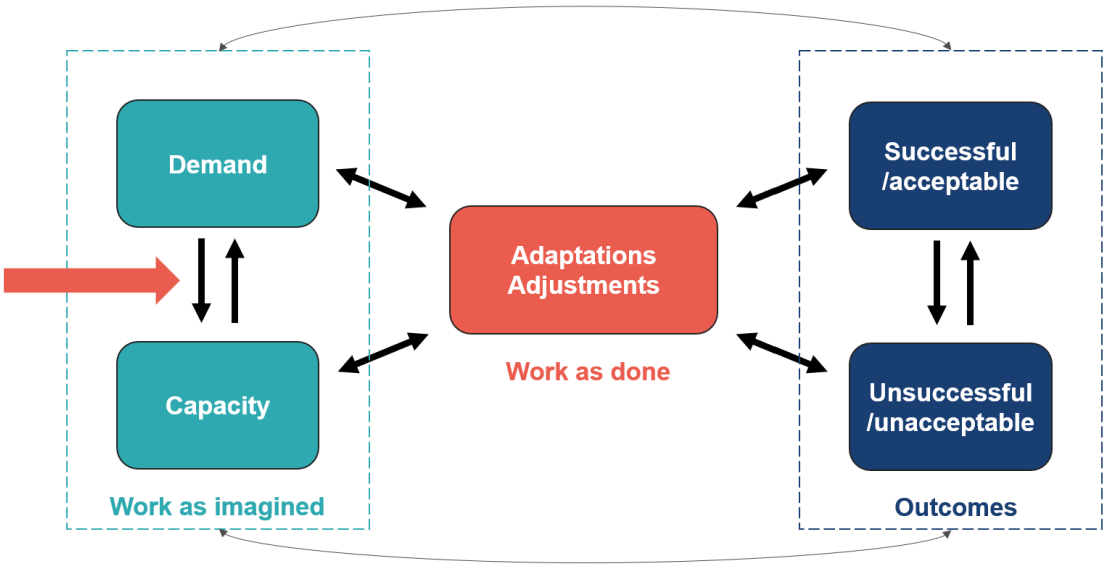


Figure 5: Potential target for real-time data to support proactive safety interventions.(21,22)

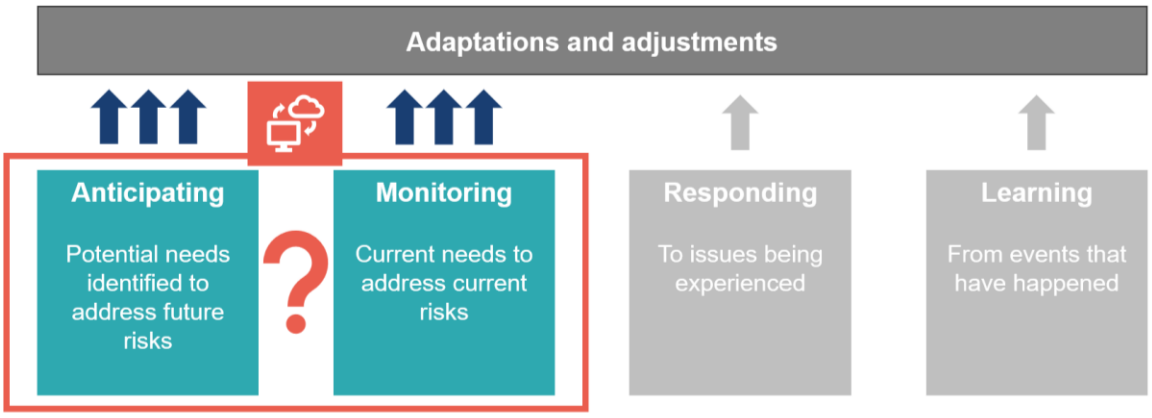


Figure 6: Potential target for real-time data to provide insight to support proactive interventions to address safety risks.

4.4.1 The Functional Resonance Analysis Method (FRAM)

The Functional Resonance Analysis Method (FRAM) is a Resilience Engineering method by which complex systems, such as healthcare, can be modelled. The key activities involved in the delivery of an aspect of health care are examined and mapped, in this case, the management of insulin when people are admitted and discharged from hospital. The time constraints for each activity are considered, the factors that regulate the activity (such as policies and procedures), what needs to be in place before the activity can occur, what resources are required (for example staff, equipment), and then what triggers the activity and what happens once the activity is performed, see Figure 7. The links and connections between all the activities are explored and mapped, and the factors that contribute to variability and different outcomes can be identified. By using the FRAM, factors that contribute to the successful management of insulin when people are admitted and discharged from hospital can be identified, and mechanisms to measure and monitor these in digital systems can be explored.

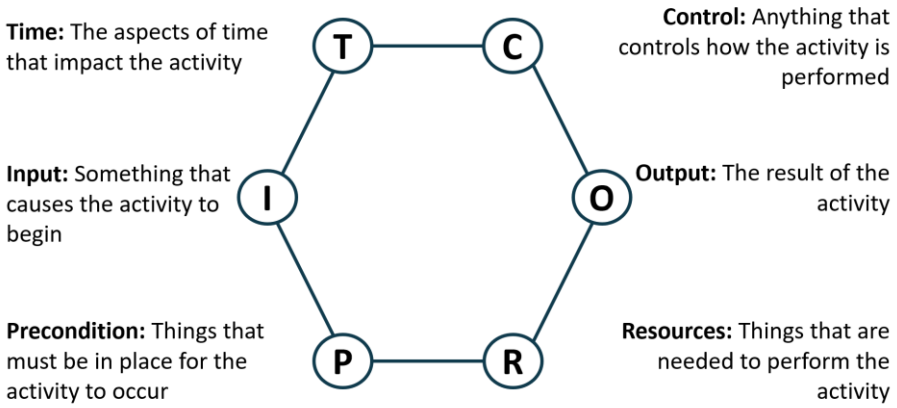
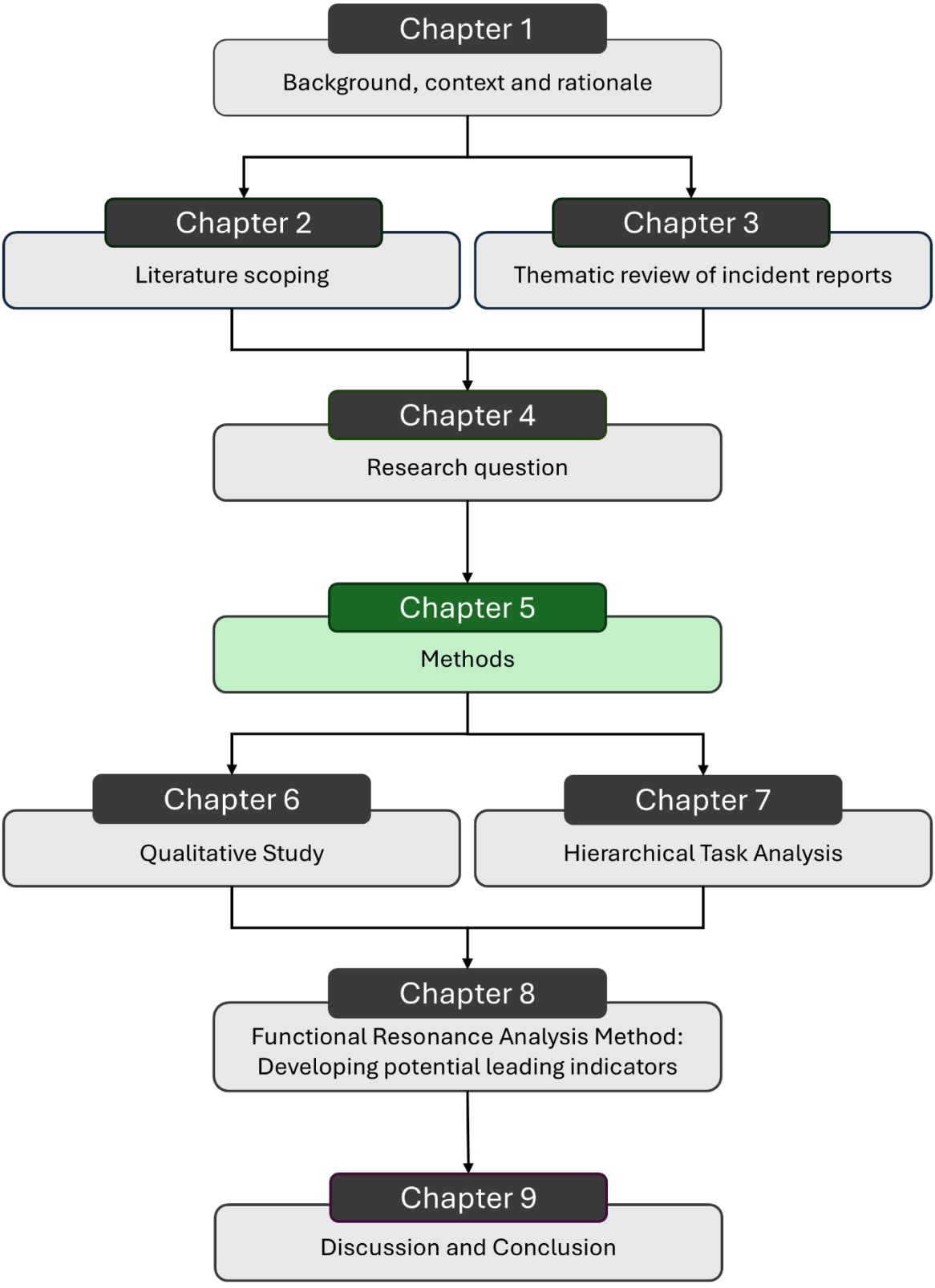


Figure 7: An activity and its six aspects in the Functional Resonance Analysis Method, adapted from Hollnagel (2012).(19)

Chapter 5: Methods



5.1 Introduction

This chapter will outline the conceptual model for the approach taken to address the research question. It will describe the study design, recruitment strategy and nine work packages that contributed to answering the research question along with ethical considerations and sampling strategy. I reflect on how my background as a medication safety pharmacist influenced this research. The final section of the chapter will describe the multiple adaptations made in response to challenges faced during the fieldwork, and their impact on the methods.

5.1.1 Approach

The Safety-II approach is based on the premise that all outcomes (both intended and unintended) stem from the same need to adapt to interacting factors within a work system. Therefore, to use a Safety-II approach a detailed investigation and understanding of the care pathway and work system being examined is required. This requires comparing how work is described based on guidelines and procedures (WAI), with how people are working in real life settings where adaptations and adjustments are necessitated by the misalignments between demand and capacity (WAD). To gather these different perspectives to map the process of managing insulin safely during transfer of care between hospital and home and the factors that influence outcomes, multiple qualitative methods were used.

5.1.2 Choice of subject

The research question is 'How can a Safety-II approach be used to identify effective leading indicators that support proactive improvements for safe insulin management within digitally integrated care systems?'

The initial aim was to identify potential leading indicators for anticoagulation safety, however during the Covid-19 pandemic, there was a drive to change to the newer oral anticoagulant medications that no longer require frequent blood test monitoring. This meant clinical oversight of these medications was owned by either primary care or secondary care and as a result the care of these agents was not transferred between care settings to the same extent. Another high-risk medication, insulin, was therefore chosen as the focus of this work. Insulin is a lifesaving, long-term mediation that requires careful co-ordination, planning and communication across different care settings, particularly when used for Type 2 Diabetes Mellitus (T2DM). For T2DM, it is usually given as subcutaneous injections. It requires regular monitoring of blood glucose levels, and the amount administered needs to be adjusted based on these results and other factors that can influence blood glucose levels (for example, the amount of carbohydrates eaten, illness, activity levels, and some other medications). When

people with diabetes who use insulin (PWDI) are admitted to hospital, it is often for conditions or illnesses unrelated to their diabetes. Managing insulin safely is essential for preventing unintended harm due to hypoglycaemia or hyperglycaemia. During ToC, challenges to safe insulin management are heightened due to the need to adjust insulin frequently during acute illness and during recovery and clearly communicate these changes with the many people involved. ToC is known to be a time where issues can occur which can lead to poor outcomes.(63)

The Functional Resonance Analysis Method (FRAM) is a Safety-II method. It is used to explore and model complex systems and identify how variability affects outcomes.(19) FRAM has been used to develop potential leading indicators for detecting sepsis.(38) Other methods to develop leading indicators have largely been based on Safety-I data, for example, using incident report data or accident analysis.(39)

5.2 Study design

Multiple qualitative methods were used to explore how subcutaneous (SC) insulin therapy is managed when people who use insulin (PWDI) for T2DM move between primary and secondary care settings. These took the form of several work packages which were used to develop a comprehensive map of insulin use during ToC, a Hierarchical Task Analysis (HTA). Alongside this, framework thematic analysis was performed using the Systems Engineering Initiative for Patient Safety (SEIPS) 101 work system components to identify factors that impacted ToC.(15) These were the people involved, the tasks being performed, the equipment and the environments (local, organisational, and external).

An overview of the different work packages and how they contribute to the different research outputs is demonstrated in Figure 8.

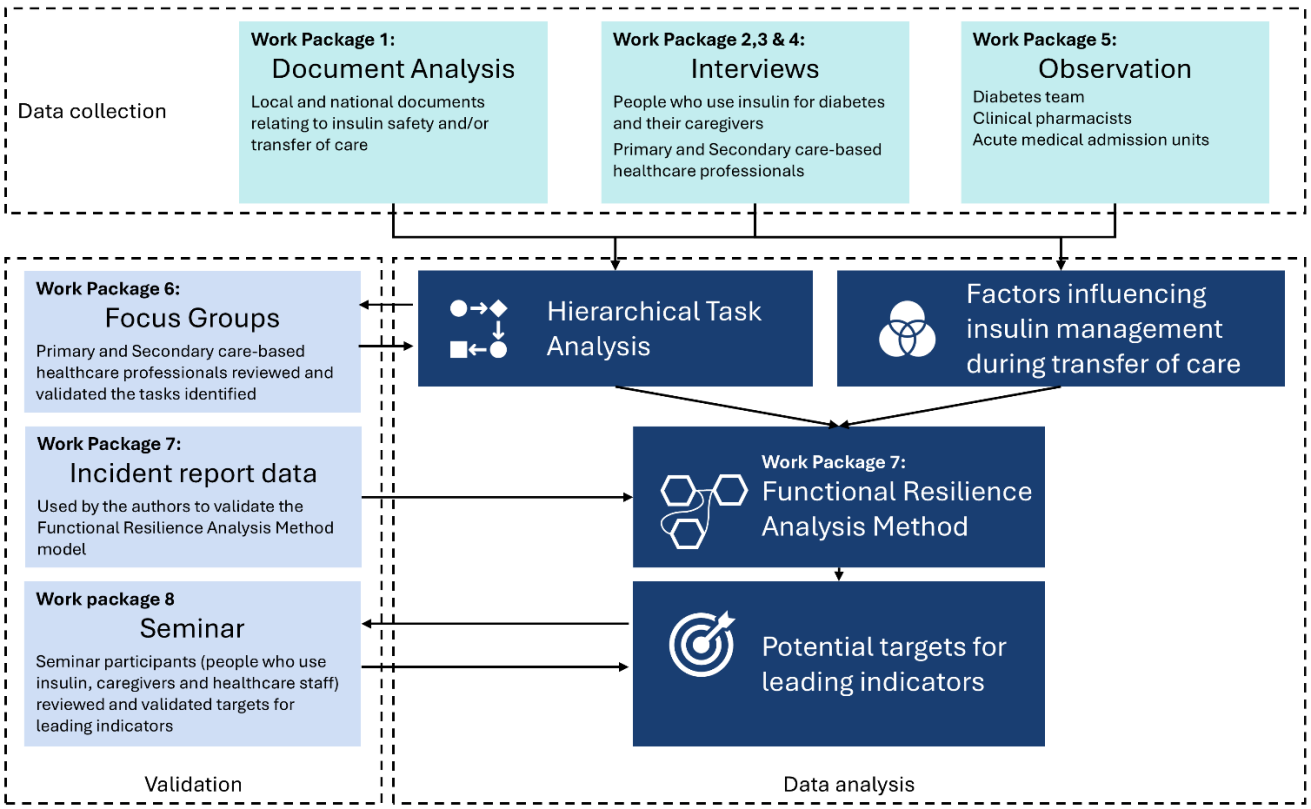


Figure 8: Work packages and their contribution to research outputs.

Work Package 1: Documentary Analysis

National guidelines were identified from the relevant professional bodies (including Diabetes UK, Joint British Diabetes Societies for inpatient care, National Institute for Clinical Excellence). Participating stakeholders were asked to provide any local policies, procedures, guidelines, or other documents relating to insulin.

A framework analysis was performed using the SEIPS 101 work system components(15) to identify tasks and factors that impact insulin management.

Work Package 2:Interviews with PWDI and/or their caregivers

Interviews were undertaken with people with diabetes who use insulin, or their caregivers. Initially, PWDI were recruited during their stay in hospital. To be included in the study, the participant had to be:

- Using insulin to treat T2DM or caring for a PWDI with T2DM
- Registered with a GP in the local integrated care system
- Able to participate in an online call through Zoom or Microsoft Teams

Due to significant challenges recruiting PWDI, the inclusion criteria were expanded to those who use insulin for T2DM or their caregivers who live in England and who have had a hospital admission. In addition to recruiting PWDI during their hospital admission, national Diabetes charities were approached, and invitations were shared on social media via X (formerly Twitter). Interviews by telephone call were also added to ethics amendments to allow those unable to participate in online video calls to be included in the study.

Interviews were 30 minutes in duration and took place with the PWDI following their return home. They were contacted at least a week after discharge to arrange a time and date for the interview, to allow them to recover from their hospital stay. The interviews were semi-structured in format to enable participants to share and explore those issues that were most important to them. A topic guide (included in Appendix III) was used to direct the interview, exploring with open ended questions, the participant's lived experiences of using, or supporting someone to use, insulin during their journey to and from hospital. The focus of the interview was on understanding their journey and the positive experiences, challenges, and safety issues they encountered during this time. Any activities were noted where the patient or their caregiver had to make sure that their insulin was safe during the journey through hospital to home, for example, contacting the GP to inform them of changes to insulin made by the hospital.

The healthcare professionals and/or services who were involved in managing the patient's insulin were also identified.

Work Package 3:Interviews with health care professionals who are involved with the management of insulin

Healthcare professionals or services who were identified during the patient and carer interviews as being involved in supporting insulin activities were invited by letter or e-mail (with the permission of the individual) to participate in further interviews.

Unfortunately, this method of identifying healthcare professionals did not result in any healthcare professionals agreeing to participate in the study. Therefore, ethics permission was updated to allow healthcare professionals known to the researchers who take part in providing care for people who use insulin before or after hospital admissions to be invited to participate by email.

These 30-minute interviews were semi-structured in format and aimed to explore the experiences of the healthcare professionals in managing insulin safely when patients move between hospital and home. The interviews examined the activities and processes involved, and factors that impacted insulin management. An adapted topic guide (included in Appendix

III) was used to direct the interview to explore issues, challenges, positive experiences, and resilient adaptations relating to insulin safety. Including the healthcare professionals allowed a wider perspective of the challenges being faced by patients and carers to be explored. Healthcare professionals were sought to represent different settings and professions to ensure a comprehensive range of perspectives were included.

Work Package 4: Interviews with professionals who manage or are involved with digital health systems

Interviews were performed with professionals who were involved in the programming or managing digital health systems (for example the programmers who manage how insulin is prescribed, recorded, and documented in electronic prescribing systems along with those who were responsible for the analytics that enable data to be extracted and used). A topic guide was used to guide the interview using open ended questions (included in Appendix III).

These interviews used a semi-structured format to explore how insulin management is captured in digital health systems within the ICS, what measures are currently available, and how digital health systems can be used to measures different aspects of insulin management.

Work Package 5: Observation

The researcher spent 85 hours between October 2022 and July 2023 in a large teaching hospital with the diabetes specialist team, pharmacists in acute medicine and on an acute admission unit. The aim was to become familiar with the layout, staff roles, processes, and situational context of the areas observed.

The researcher observed activities involved in managing insulin, for example taking a medication history when a patient was admitted to hospital, adjusting insulin dosages, diabetes specialist nurse review, prescribing insulin for discharge and supplying insulin. Photographs of relevant information, such as posters, PWDI insulin records and others were taken using a digital camera, making sure that no people or confidential information were included in the images.

The researcher took the role of a minimally active participant, aiming to be a detached observer, but questioning and seeking clarification to understand the activities being performed where required. This was done sensitively to minimise any disturbance to the clinical workflows and patient care.

Detailed field notes were taken by the researcher during and/or immediately after each day of observation. The work system components of SEIPS 101 work system(15) were used to prompt

identification of different including the people involved (patient, teams, healthcare professionals), the tasks performed and in what order, equipment used and environmental factors that impact on insulin management (for example if lighting affected the ability of reading doses on the insulin pens). These were recorded on paper and digitally transcribed at the end of the session. Episodes of care observed were documented with intention of capturing chronologically the activities being performed including any interruptions, contents of discussions (while maintaining confidentiality) and any challenges or issues encountered. Adjustments to planned actions made in response to issues and challenges were carefully recorded, along with the outcome of these adjustments.

A field diary of the researcher's experiences, challenges, thoughts, and feelings was kept alongside this work, ensuring no identifiable information was recorded.

The HTA was updated to include the additional activities and processes observed in the real-life settings and from interviews with PWDI, their caregivers and healthcare professionals.

Work Package 6: Focus groups

Two focus groups were held to explore the draft HTA developed to represent the tasks involved in managing insulin during ToC. One focus group included participants from a hospital setting and was held in-person, and one with participants from primary care was held online. Due to recruitment challenges, only two people participated in each group. The HTA was shared in a paper format or electronically and focus group participants commented and recommended changes to the HTA based on their expertise and experiences. The researcher guided the conversation by asking questions, highlighting unexplored areas, allowed participants to develop and share ideas, and ensured the focus remained on finalising the HTA where the conversation stalled or went on a tangent. A topic guide was used to support the focus groups discussion is included in Appendix III.

Work Package 7: FRAM analysis

The key activities required for insulin management during ToC from hospital to home were identified from the HTA. These were then used to perform the Functional Resonance Analysis Method (FRAM). The factors that impact insulin management during ToC that were identified by the thematic analysis were also used to develop the FRAM model.

Once the FRAM was performed and the model was drafted, anonymous patient safety incident report data from the National Reporting and Learning System (NRLS) was obtained. One hundred reports were randomly selected from a bespoke NRLS data search. A search was run for incidents involving insulin, transfer of care, admission, and discharge (full search terms

available in Appendix IV). Of the incident reports identified from this process, a random sample of 100 reports were provided, with 60 reported by healthcare professionals in hospital settings, 39 from primary care and one from a nursing home. The incident reports were reviewed, and ten of these were selected according to the detail available in the reports and the stages and activities described so that as many parts of the FRAM could be reviewed as possible.

Additional activities identified through the incident analysis were added to the FRAM map as functions, and their variability assessed as described previously.

Those functions that impacted the most other functions or had the greatest potential consequences for safe insulin management were identified as the key activities that contribute to safe outcomes for insulin management.

Work Package 8: Seminar

Contributors to the research and other key stakeholders in insulin management, patient safety, Integrated Care Systems, and electronic health records, were invited to attend and participate in a seminar. The key areas of variability identified from the FRAM model were considered as targets for potential leading indicators for managing insulin safely across ToC. These were shared and seminar participants were asked to provide feedback on their face validity.

The twelve participants of the seminar were then given an opportunity to reflect on what measures are currently used to understand two example indicators, what are the measurement gaps and what information or data would allow proactive identification of potential variability or risks for insulin management. From the findings of this seminar, along with the results of the FRAM, potential measures for these two example indicators were drafted.

5.2.2 Completion of the study

The final product of the research was the evaluation and reflections of the feasibility, acceptability, and potential application of this method of identifying leading indicators that can support healthcare resilience and proactively improve safety.

5.2.3 Data Analysis

Framework analysis

Data from work packages 1 to 5 were used to develop a hierarchical task analysis and were used for a framework thematic analysis. Documents, field notes and interview transcripts were uploaded to NVivo and were analysed line by line. As the work packages were performed concurrently, the analyses were performed iteratively while data collection continued.

The SEIPS 101 work system components(15) were used to categorise:

- Tasks involved in the management of insulin during the ToC between primary and secondary care.
- Other factors in the work system (relating to people, equipment, local, organisational, and external environments) that impact insulin management.

Hierarchical Task Analysis

The tasks were mapped using a Hierarchical Task Analysis (HTA). A HTA is a method used to map processes where the overall goal, in this case insulin management during admission and discharge from hospital, is broken down into the smaller tasks required to fulfil this goal. Each task can be further broken down into sub-tasks, and explained in further detail, until all the relevant information is described. The HTA developed described the steps involved in the management of insulin when individuals move between primary and secondary care. It was validated and updated during Work Package 6, the focus groups. Further detailed description of HTA and the method used to develop it are described in Chapter 7.

The Functional Resonance Analysis Method (FRAM)

The thematic analysis and the HTA were then used to as the basis for developing the FRAM model, as described above and according to the method described by Hollnagel (2012)(19). Framework thematic analysis was then undertaken to explore and understand the factors that impact safe insulin management during ToC. To perform the FRAM, the first step is to look at each activity, called 'functions.' Each function has six aspects that must be considered, which are described in Figure 9.

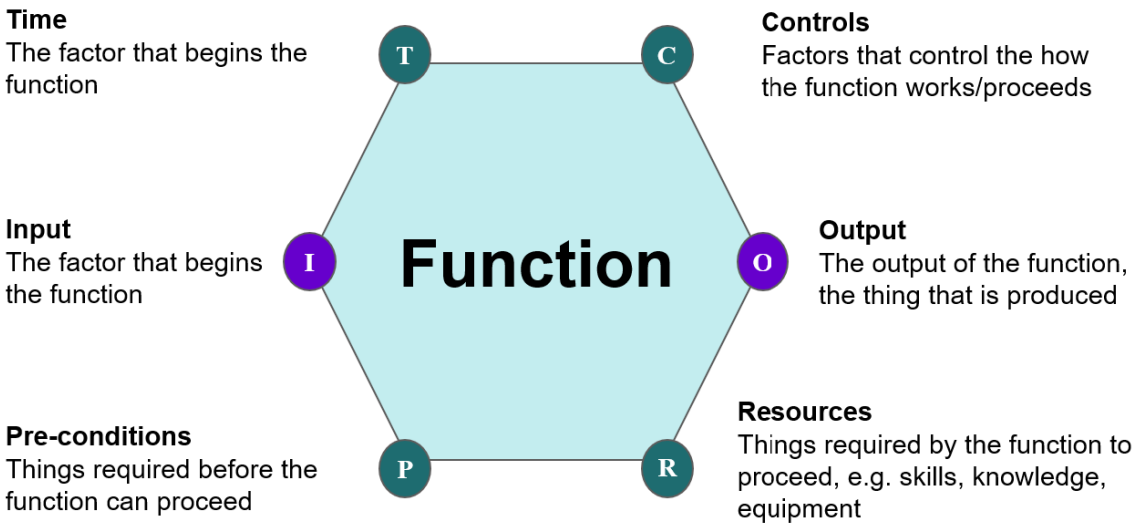


Figure 9: A Functional Resonance Analysis Method (FRAM) function and its aspects.

Each key task identified in the HTA was evaluated and considered according to each of the six aspects. Functions were added to the FRAM model visualiser. This software allowed the links and connections between the functions to be modelled and studied. Each function was then considered according to potential variability in terms of timing and accuracy, and the consequences of variability on other functions.

Key areas of variability were then identified and proposed as potential targets for leading indicators. These were then shared at a seminar to review their validity. Two example functions were explored in depth to consider current measures, gaps and potential future measures. The findings of this seminar were used to draft potential measures for these two potential leading indicators.

A more detailed description of the development of the FRAM model and identification of key areas of variability is provided in Chapter 8, and Chapter 9 provides an illustrative example of developing two potential targets for indicator development.

5.3 Researcher bias and assumptions

My background as a pharmacist specialising in medication safety provided me with a baseline understanding of the subject. With my hospital-based background, I have often supported insulin management when PWDI are admitted or are being discharged from hospital. I have encountered issues and challenges in ensuring safe ToC in my clinical practice. These experiences allowed me to understand and explore some of the issues described by interview participants and during periods of observation. My professional background contributed to my desire to undertake this research, as I was very aware of the need for improvement in this challenging area. It also fed my desire to look at safety from a wider perspective and consider how new measures can be developed by exploring all outcomes, both successful and unsuccessful. It allowed me to inform interview participants that I could understand technical terms, and that they do not need to explain these, saving time for discussion of the aspects of insulin management that mattered to them.

5.4 Study Setting

The study took place in England. The initial setting for the fieldwork was the North Central London (NCL) Integrated Care System (ICS). This partnership includes the University Hospitals London NHS Foundation Trust and GP surgeries across Barnet, Camden, Enfield, Haringey, and Islington. Recruitment through NCL ICS was challenging, and there was insufficient uptake

within the ICS. Recruitment was therefore expanded to allow for involvement of PWDI and healthcare professionals from across England.

5.5 Sampling and Recruitment

Following amendment, people with diabetes were eligible if they lived in England and had had a hospital admission and discharge within the last 5 years. Healthcare staff were identified through pre-existing professional contacts of the researcher and supervisory team.

5.6 Inclusion criteria

Patients or their caregivers were eligible to participate in the research if they or the person they provide care for met all the criteria below:

- Aged over 18 years.
- Used subcutaneous insulin for diabetes.
- Have had an admission to hospital and returned to their usual place of residence.
- Able to access and use video conferencing software or receive a telephone call.
- Able to understand and speak English and
- Able to consent to participating in the research.

Healthcare staff were eligible to participate in the research if they:

- Provided care for individuals who use insulin.
- Were:
    - Known to the researchers through pre-existing professional relationships or
    - Referred by a healthcare professional recruited to the study.
- Worked:
    - In a community pharmacy, GP surgery, community health services, ambulance service, or hospital or
    - In a role that influenced the management of insulin during periods of ToC for example commissioners, digital programmers or data analysts, mangers and
- Were able to participate in internet-based video conferencing.

Key stakeholders were eligible to participate in the seminar to hear and provide feedback on the face validity of the research findings if:

- They had a personal or professional interest in the use of insulin or
- They were an advocate for people who use insulin or

- Were involved in the management of insulin through developing strategies, policies and/or guidelines for insulin or
- They impacted how insulin is managed within digital health systems and
- They could participate in an online seminar using video conferencing software.
- They could speak and understand English.
- They were over 18 years.

Participants were selected to cover a range of ages, genders, ethnicities as widely as possible within the inclusion criteria.

5.7 Ethical approvals

Ethics approvals were obtained from the NHS Ethics Committee and NHS Health Research Authority on 26 July 2022 (Rec ref 22/EE/0155). LSHTM Ethics approvals were granted on 15 August 2022 (28148).

Amendments were approved for:

1. Widening the recruitment of patients.
2. Advertising the study on social media.
3. Expanding inclusion criteria to healthcare professionals known to the researchers.
4. Extending the deadline for the research.

Informed consent was obtained from all participants in the research, including interviews, focus groups and the seminar. Consent was obtained to observe healthcare professionals, and from PWDI or their caregivers if the activity being undertaken directly involved their input (for example, administering a dose of insulin). Consent was confirmed before recording was started for online or telephone-based interviews, focus groups and the seminar.

Confidentiality was maintained for all study participants. During observation, no identifiable information was recorded in field notes or photographs. During interviews, focus groups and seminars, recordings were taken to allow transcripts to be taken. Once the transcription generated by the built-in software was reviewed, the recording was deleted. All references to names and locations were removed from the transcripts. Participants were given a code name for the file storage.

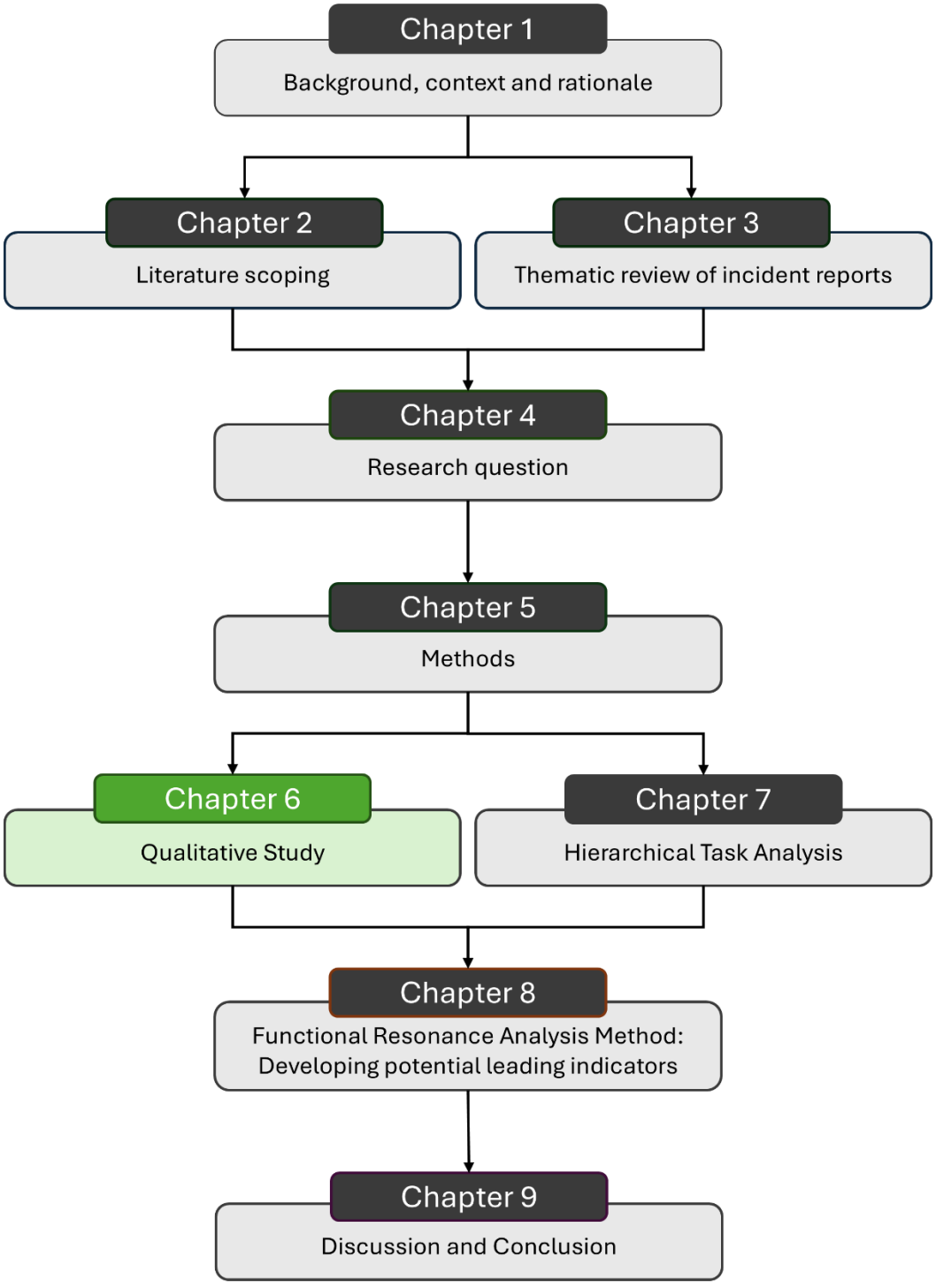
5.8 Conclusion

The use of multiple qualitative methods incorporating a wide range of perspectives, allowed the development of a very detailed map of insulin management during ToC and the identification of

the factors that impact this process. The voice of the PWDI and their caregiver was central to developing this work, reflecting their pivotal and central role in managing insulin during ToC. The contributions of all participants allowed the picture of insulin management during ToC to be built and developed collaboratively.

Participants for interviews, focus groups and seminars were recruited from across England. Due to the breadth of the ToC process, the FRAM focuses on quite high-level key activities for safe ToC for insulin management. Therefore, these are likely to be similar across England, however consideration of local context would be required before applying the findings of this work in other areas, particularly outside England.

Chapter 6: Exploring the complexity of safe insulin management during transfer of care using qualitative methods



6.1 Overview

The article presented in this chapter describes the findings of a thematic analysis of qualitative data collected to support the development of the FRAM model. The study aimed to identify the factors that impact on the safety of insulin management during ToC and explore how these factors interacted to influence outcomes.

Framework analysis was performed on the following data sources:

- Documents relating to insulin or medication management during ToC identified from the local hospital intranet and relevant organisational websites.
- Field notes taken during 85 hours of targeted observation performed in an acute hospital setting.
- Transcripts from interviews with PWDI, their caregivers and healthcare professionals in primary and secondary care.

The Systems Engineering Initiative for Patient Safety (SEIPS) work system categories(15) were used as a framework to map factors related to people, tools, tasks and environments (local, organisational and external).

Six stages of ToC were identified:

1. Preparing for admission
2. Admitting to hospital
3. Adjusting insulin during acute illness
4. Planning for discharge
5. Handing over medical care back to primary care
6. Resuming insulin management in the community

Four key areas of complex interactions with the potential to influence outcomes were identified. The first of these was 'recognising and incorporating the expertise of PWDI in identifying diabetes management needs and ongoing insulin adjustments'. Linked to this was 'enabling PWDI to manage their diabetes while in hospital'. The third area was 'the lack of confidence of healthcare staff in managing insulin'. The fourth area described 'the extent to which PWDI and their diabetes management team were involved in anticipating and proactively addressing potential challenges.' Managing these four areas required frequent adaptations to challenges experienced by PWDI, their caregivers and staff.

This analysis demonstrated the complexity of interacting factors from across all aspects of the work system. Current safety improvements are often only targeted at the people involved but

this study highlights how a systems-based approach can identify a wider range of factors that impact safety and additional opportunities to target safety improvement interventions.

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RESEARCH PAPER COVER SHEET

Please note that a cover sheet must be completed for each research paper included within a thesis.

SECTION A – Student Details

Student ID Number	LSH2005295	**Title**	Ms
First Name(s)	Catherine		
Surname/Family Name	Leon		
Thesis Title	Exploring the complexity of safe insulin management during transfer of care using qualitative methods.		
Primary Supervisor	Helen Hogan		

If the Research Paper has previously been published please complete Section B, if not please move to Section C.

SECTION B – Paper already published

Where was the work published?			
When was the work published?			
If the work was published prior to registration for your research degree, give a brief rationale for its inclusion			
Have you retained the copyright for the work?*	Choose an item.	Was the work subject to academic peer review?	Choose an item.

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SECTION C – Prepared for publication, but not yet published

Where is the work intended to be published?	Diabetic Medicine
Please list the paper's authors in the intended authorship order:	Catherine Leon, Helen Hogan, Yogini H Jani, Clare Crowley
Stage of publication	**Submitted**

SECTION D – Multi-authored work

For multi-authored work, give full details of your role in the research included in the paper and in the preparation of the paper. (Attach a further sheet if necessary)	I conceptualised the study with the advice of my PhD supervisors. I performed the fieldwork, undertook observations, wrote field notes, interviewed participants and conducted focus groups. I coded the data and analysed this thematically, using a framework approach and the Systems Engineering Initiative for Patient Safety framework to guide analysis. I wrote the initial draft of the paper, and amended and updated this following critical review from the co-authors.

SECTION E

Student Signature	Catherine Leon
Date	08/09/2024

Supervisor Signature	Helen Hogan
Date	08/09/2024

Title Page

Exploring the complexity of safe insulin management during transfer of care using qualitative methods.

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Word counts

Manuscript: 4000

Abstract: 237

Conflicts of interest

None to declare

Novelty Statement

- **What is already known?** Transfers of care for people with diabetes are known to be challenging for safe insulin management.
- **What has this study found?** Many complex factors combine and impact insulin management during transfers of care. People, including those with diabetes and healthcare professionals, circumvent issues to maintain safety.
- **What are the implications of this study?** Understanding the factors that impact on safe management can identify additional opportunities to target safety improvement interventions. Empowering people with diabetes is pivotal for improving safety.

Funding and acknowledgements:

This report is independent research funded by the National Institute for Health and Care Research ARC North Thames and was supported by the NIHR Oxford Biomedical Research Centre. The views expressed in this publication are those of the author(s) and not necessarily those of the National Institute for Health Research and Care or the Department of Health and Social Care.

We would like to offer our sincere thanks to Dr Rustam Rea for his advice while preparing this manuscript.

Abstract

Background

Managing insulin during care transfers requires improvement. Understanding factors that impact insulin management during this process improves the likely effectiveness of interventions.

Aims

To map the processes involved in managing insulin during transfers of care and the factors that affect them to identify potential areas for safety improvement interventions.

Methods

A qualitative, case study approach was used to undertake documentary analysis, interviews, focus groups and observation. Participants included people with diabetes who use insulin, caregivers, and primary and secondary care healthcare professionals. A framework approach guided analysis and subtheme categorisation under the domains of people, tools, tasks, or environments.

Results

Insulin management during transfers of care was mapped across hospital admission and discharge along with factors that impact this process. Six stages of the care transfer process were identified. Workforce pressures and demand impacted safe insulin management. Four themes were identified 1) People with diabetes hold vital information not otherwise available 2) their ability to manage their diabetes care in hospital was limited 3) healthcare staff lacked confidence managing insulin, 4) people acted proactively to prevent issues.

Conclusions

A detailed picture of factors impacting insulin management during transfer of care was developed. Incorporating the PWDI expertise and removing barriers to insulin self-management across the care pathway, ensuring staff have adequate knowledge, skills, and confidence in the management of insulin and promoting proactive interventions to support safe outcomes represent key interventions to improve safety for PWDI.

Key words

Diabetes; drug safety; complications; insulin.

Main Text

Introduction

When people with diabetes who use insulin (PWDI) move between different parts of the healthcare system, there are many challenges to managing insulin safely. Insulin is a critical and high-risk medication. It is critical because for many PWDI if not managed correctly, it can cause significant harm, for example hyperosmolar hyperglycaemic state. It is high-risk because where an incorrect dose is used unintentionally, the resulting harm can be life threatening.(101,102) Safety challenges with insulin are well documented. There are a multitude of insulin types and brands that look and sound like each other, which can lead to incorrect insulin prescriptions and administration.(103) Insulin delays and omissions, more likely on admission and discharge from hospital, can lead to harms such as hyperglycaemia.(104–106) If an incorrect device is used to administer insulin, there is a risk of severe hypoglycaemia due to an unintentionally high dose.(52,106) Challenges arise due to issues with communication, inadequate involvement of PWDI or their caregivers and failure to provide support following discharge.(107) Ensuring insulin is given on time without delays or omissions is also challenging in these transitional periods.(63,105) Transfer of Care (ToC) occurs when a PWDI moves between different care settings and responsibility for the practical and medical management of insulin is transferred. The World Health Organisation global safety campaign aimed to reduce harm from high-risk medications such as insulin during ToC by 2024.(63) There is a need for further research into mechanisms to improve the safe management of insulin during ToC.(108)

Previous safety philosophies have focused on identifying the root cause of harms and introducing policies and fixes to prevent these recurring.(4) Newer conceptualisations of safety recognize that healthcare is provided within a complex, interacting tangle of factors, known as the work system. These work system factors include people interacting with the tasks they must perform, the equipment being used and the different settings, organisations and legislation under which healthcare is provided.(14,15,20,92) It is now understood that safety is not just as the absence of harm. Instead, safety is thought to be created and maintained by people making necessary adaptions to changing situations created by varying combinations of work system factors.(13) PWDI and healthcare professionals adjust their activities due to a mismatch between the demands placed on them and the resources available to meet those demands. These resources include time, skills, knowledge and equipment.(29)

To improve the safe management of insulin during ToC, strategies must be targeted effectively to minimise mis-alignments between the demand and resources, and enhance successful

adaptations.(29,109) Therefore, it is essential that the work system is examined in detail to understand how different factors are contributing to outcomes.(110,111) The aim of this study is to map the processes of insulin management during transfers of care between primary and secondary care and the work system factors that impact them.

Methods:

Study design

We used qualitative, embedded case study approach,(112) focusing on different organisations within an Integrated Care System (ICS). Fieldwork was undertaken over 17 months to map the processes involved in managing insulin during admission and following discharge for adults with Type 2 diabetes mellitus (T2DM). The focus of T2DM was due to the greater involvement of primary care teams in managing insulin for people with T2DM compared with Type 1 diabetes. Relevant local and national documents were identified and included in the analysis. Approval was obtained from the NHS research ethics committee (Reference 22/EE/0155) as the study involved NHS patients and staff, and the university ethics committee (Reference 28148) for sponsorship. Informed consent was obtained for all participants including for interviews, observation and focus groups.

Data collection and analysis

Purposive, opportunistic observation was undertaken in a large teaching hospital during 2022 and 2023. Eighty-five hours were spent observing diabetes specialist nurses, nursing staff, clinical teams, pharmacists, discharge coordinators and PWDI undertaking insulin-related activities within a large acute teaching hospital. Detailed field notes focussing on the people, tools, tasks, and environments were taken and typed up as soon as possible.

Semi-structured online interviews were held with 20 participants, see Table 1 for a breakdown of their roles in managing insulin. Participants represented different social and ethnicities, however this data was not formally collected, and therefore quota sampling was not achieved. Healthcare professionals were initially recruited from a single ICS, however due to the low number recruited, this was expanded across England. PWDI were identified during their time in hospital by referral from the diabetes specialist nurses or pharmacists, or through invitations shared on national diabetes forums and on X (formerly Twitter). PWDI or their caregivers were eligible if they were over 18, had T2DM, used insulin and had a hospital admission and discharge within the last two years. Healthcare professionals were selected to represent a range of roles across care settings. Interviews were held online for 30-minutes, and participants were asked to describe their experiences of managing insulin during admission and following

discharge from hospital, to consider what helps safe insulin management, and what challenges present during these times of transition. Interview transcripts were captured using video conferencing tools (Zoom and Microsoft Teams) and were updated for accuracy by the first author.

Table 1: Participants, role in insulin management and care setting

Participant number	Role in managing insulin	Care setting at time of recruitment	Geographical Location
1	Caregiver of person who uses insulin	Secondary Care	London
2	Person who uses insulin	Primary Care	South of England
3	General Practitioner	Primary Care	London
4	General Practitioner	Primary Care	London
5	General Practitioner	Primary Care	London
6	Diabetes Specialist Nurse	Primary Care	London
7	Diabetes Specialist Nurse	Secondary Care	South Central England
8	Medication safety pharmacist	Secondary Care	South Central England
9	Emergency surgical unit pharmacist/Community pharmacist	Secondary Care/Primary Care	South Central England
10	Surgeon	Secondary Care	Midlands
11	Surgeon	Secondary Care	Midlands
12	Diabetes specialist and Emergency Department nurse	Secondary Care	London
13	Paramedic assistant	Primary Care	South Central England
14	Primary Care Network Pharmacist/Community pharmacist	Primary Care	South Central England
15	Primary Care Network Pharmacist	Primary Care	South Central England
16	Person who uses insulin	Secondary Care	London
17	Person who uses insulin	Primary Care	South Central England
18	Person who uses insulin	Primary Care	Not disclosed
19	Person who uses insulin	Primary Care	Midlands
20	Person who uses insulin	Primary Care	Not disclosed

Local and national guidance relating to insulin management during ToC were identified using hospital intranet searches and through exploration of relevant organisational websites, including the Joint British Diabetes Societies for Inpatient Care Group, the National Institute for Health and Care Excellence, the Royal College of General Practitioners, and the Royal Pharmaceutical Society.

Thematic analysis was undertaken using a framework approach. Field notes from observations, interview transcripts and documents were uploaded into NVivo 12 and analysed line by line. Key components of the ToC process were identified inductively. These key components were confirmed using two hour-long focus groups. These were held in July 2023, one in-person with secondary care-based staff and one online with primary care-based staff.

The Systems Engineering Initiative for Patient Safety (SEIPS 101)(15) tool was then used as a framework to develop four sub-themes relating insulin management during ToC and to explore how work system factors impacted these themes. Work system factors were categorised as people, tasks, tools and equipment and environments (local, organisational, and external).

The fieldwork and data analysis were performed by one author, a medication safety pharmacist. The co-authors included a second medication safety pharmacist who was also digital clinical safety lead and a general practitioner. The healthcare backgrounds of the authors allowed contextual insight into terminology and issues being observed and described. Themes and sub-themes were developed iteratively through discussion with the co-authors to enhance data validation.

Results

Processes involved in ToC from home to hospital and back again and the system factors that influence insulin management were identified from policies and guidelines. These were supplemented with processes identified from observation and from interviews with PWDI, their caregivers and healthcare professionals. Six key stages of ToC were identified: preparing for admission, admitting to hospital, adjusting insulin during acute illness, planning for discharge, handing over medical care back to primary care and resuming insulin management in the community. Many system factors impacted how these processes were managed, see Figure 10 for a summary of SEIPS work system factors identified across the different stages of ToC. Four key themes were identified as having the greatest potential to improve the safety of insulin as PWDI journeyed between health settings and home. The first was the challenge around identifying, understanding, and adapting the PWDI's diabetes management plan. The second was recognising and incorporating the expertise of the PWDI into insulin management. The third

was the need for staff to be equipped with or have access to someone with the skills, knowledge, and confidence to manage insulin. The final theme was the anticipation of potential issues after admission or following discharge and actions taken to prevent these.

Overarching factors that impacted all ToC stages

The SEIPS components identified included: External environment (winter pressures, industrial action), Organisational environment (staffing, training), Tools (Electronic Health Records, IT hardware)

During the study period, across the case study site and more widely in the NHS, there were intense pressures on staff due to the impact of winter respiratory infections which led to high demand for hospital treatment at a time of seasonal increases in staff absence due to illness. This was compounded by ongoing industrial action across England, both within the NHS and also impacting national infrastructure including railways and schools which also reduced staff availability. Healthcare professionals' capacity to meet the demands of safe insulin management was consequently reduced, and activities were balanced against the urgency of clinical needs. For example, when the specialist diabetes team were short staffed, requests for advice were prioritised and other non-urgent activities ceased to allow the team to manage their workload safely. Decisions about starting insulin or doses for discharge were made earlier, often based on more limited information, to allow education to be provided ahead of anticipated service disruption.

Electronic health records (EHR) were used extensively to manage insulin and communicate between healthcare professionals within and across different settings. The ICS Health Information Exchange (HIE) allowed read-only access to medical notes from different care settings, for example hospital-based staff could view general practice records and vice versa. Information on the type of insulin being used by the PWDI was generally available but dosing information was usually absent within these records. On numerous occasions, malfunctioning hardware or software led to staff spending considerable time locating alternative computers to document plans, prescribe insulin, and communicate with other staff members. Observation also highlighted the diversity of PWDI who were being admitted to hospital, and how multiple factors at individual, family and community levels had to be taken into consideration when optimising insulin management.

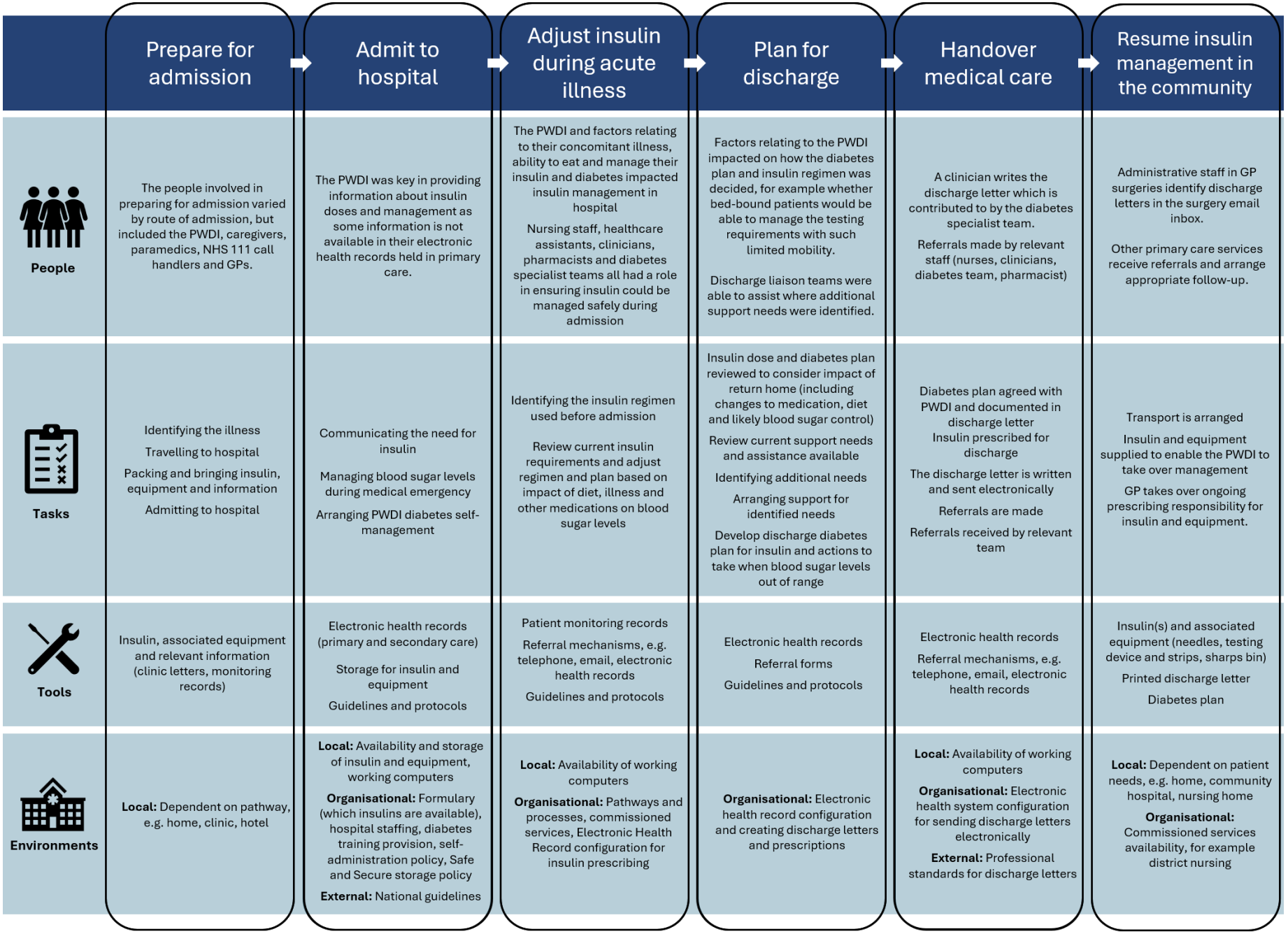


Figure 10: Work system factors identified for the different stages of insulin management during transfer of care.

Information only available to PWDI

The SEIPS components identified included: People (presenting illness, co-morbidities, ethnicity, and religion); Tasks (identifying need for admission, communicating); Tools (electronic health records, telephones, emails, insulin and diabetes records)

Once admitted to hospital, it was necessary to identify the insulin used by the PWDI and manage blood glucose levels in the context of the clinical situation. Understanding not only the PWDI's usual insulin regimen was required, but also their diabetes management plan. These plans should include typical blood glucose ranges, and any adjustments or treatments used when levels are outside these ranges, or when the individual is unwell. During the admitting process, the PWDI was often the only person who had this information. Depending on the presenting illness, their ability to share this information could be variable. PWDI were not observed bringing in written diabetes plans, however interview participants described keeping information in a wallet or on medical alert bracelets. One PWDI was using a record of blood glucose levels and insulin doses that he had designed himself, however staff were unable to decipher the information it contained (see Figure 11).

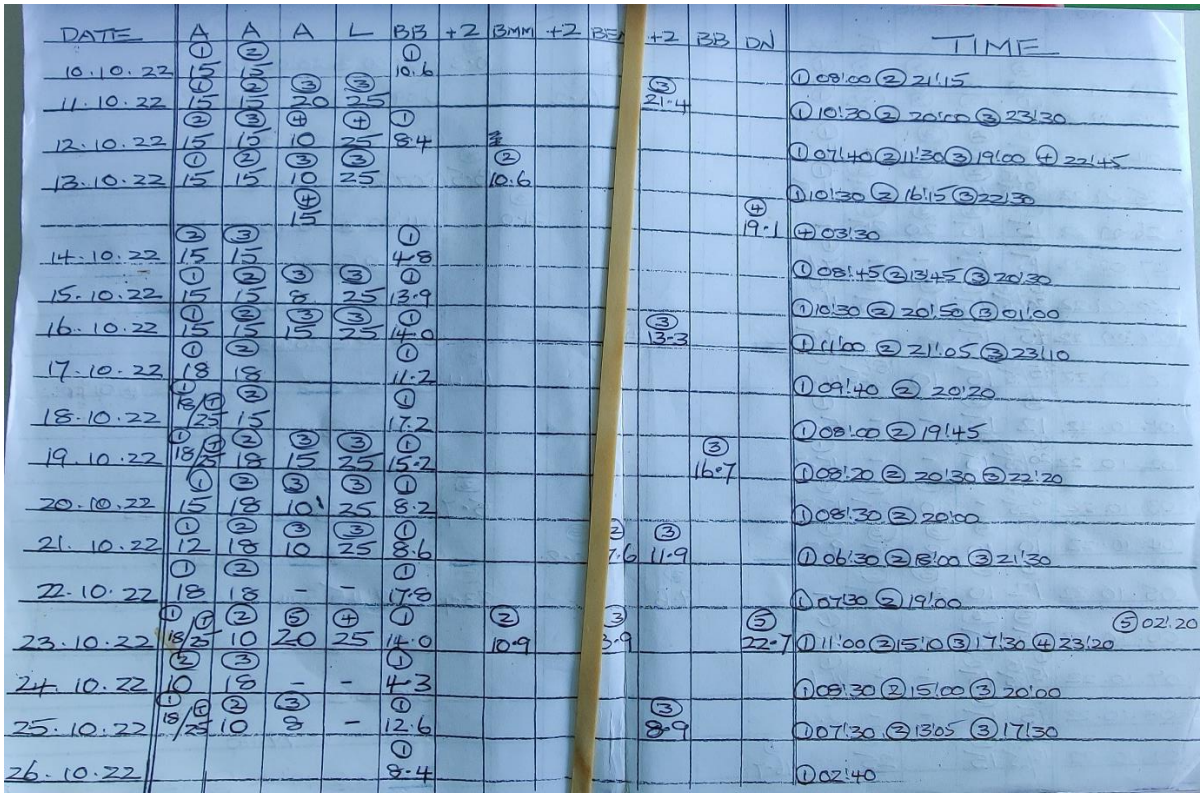


Figure 11: A patient developed insulin dosing and monitoring record.

Challenges in identifying the PWDI's usual insulin regimens were described by interview participants.

> *"The patient always feels to be the best source of information…for insulin, [digital] medical records are…very good at the brand, the device. [But] the major issue though for all of us is really the lack of information on dosing." Hospital Pharmacist*

National guidelines recommend the use of patient-held Insulin Passports. These were not in wide use in the hospital setting but were referred to by a Community Diabetes Nurse

> *"So insulin passports, haven't seen them for a long time, really not really being used or don't know how well when they first come out, they were used. I don't know." Hospital-based diabetes nurse*

Where PWDI brought information about their current diabetes plan, insulin regimen and monitoring records to hospital there was opportunity for the safe transfer of information to secondary care staff. PWDI expressed frustration that this key information was often not acted on or dismissed.

> *"At the point I started having [a hyperglycaemic] episode…I was telling them 'Something doesn't feel right and the last time that happened my blood glucose was all over the place.' And …they were like, 'maybe it's just the anaesthesia wearing off', and…they weren't listening to me. They assumed, they felt they knew better…and by the time I finally you know, got a nurse to check my blood sugar. It was skyrocketing, like it was critically high." PWDI*

PWDI also identified factors relating to their race and religion that impacted on how healthcare professionals behaved towards then, and on the likelihood of their requests and or their individual expertise in self-management being acknowledged.

> *"From my judgment it felt like as a person of colour, the attention I was given wasn't as much as I should have gotten. They just looked down, repulsively, I don't know. I try not to think about it much, it wasn't very pleasant of an experience." PWDI*

> *"I know it's occupational hazard of what I wear [a religious headscarf], but sometimes it's like, I do not feel I get the empathy or the listening ear that I deserve, because I look or dress a certain way." PWDI*

Self-management while in hospital

The SEIPS components identified included: People (PWDI skills, knowledge, nursing staff); Tasks (risk assessments, administering, recording, monitoring); Tools (insulin and administration and monitoring equipment, electronic health records, insulin storage facilities), Environments (national policy, organisational policies).

Responsibility for managing diabetes and insulin during admission was generally held by nursing and medical staff. National guidelines recommend self-management by PWDI in hospital as a key mechanism for improving safety. Enabling PWDI self-management across ToC was viewed as challenging, requiring additional tasks for staff. Both assessing the ability of PWDI to self-manage during intercurrent illness and putting in place practical arrangements to ensure insulin, monitoring

equipment and hypoglycaemia treatments were accessible were seen as key obstacles. These activities often did not happen. Staff and PWDI reported frustration with the situation.

> *"I actually felt safer doing it myself than having a nurse do it, which is very odd. You should feel safer with the person that has more training, but ironically, your experience makes you feel safer than the person who has gone 3 or 4 to 6 years of like nursing school." PWDI*

Hospital staff highlighted organisational policies requiring insulin be stored securely in a locked cupboard or refrigerator often prevented self-administration.

> *"Patients are getting frustrated that their insulin is being taken away from them, it's been locked away." Diabetes specialist nurse, hospital.*

Furthermore, there were challenges getting PWDI administration records uploaded onto the EHR with the result that staff were required to spend time transcribing this information onto the system on behalf of PWDI.

Confidence of staff in managing insulin

The SEIPS components identified included: People; Tasks (reviewing insulin in the context of illness and adjusting dose, creating plans); Tools (guidelines and electronic health records); Organisational factors (availability and provision of staffing and specialist roles, provision of training and supervision).

Optimising insulin dosage to reflect the stage of the current illness, concurrent medications, and diet is critical for safety. With PWDI often excluded from this process either because of their condition or by organisational factors acting as barriers to self-management, decision-making mainly falls to healthcare staff. Frontline staff described 'fear' and 'under-confidence' in managing insulin and often relied on the expertise of specialist diabetes teams to make decisions around suitable adjustments. Specialist teams struggled to cater for staff support needs due to their limited availability.

> *"But there's a knowledge gap in that aspect…there was a bit of levity on their end, like, okay, they knew they have to [administer insulin], but they do not know why it's so serious." PWDI*

> *"We always, always, get the diabetic team involved…to review the patient and tell us exactly what we need to prescribe or not prescribe." Surgeon*

National and organisational guidelines exist to support insulin adjustment decisions during acute illness, but specialist diabetes teams felt these were not always used in practice.

> *"We've got these really good guidelines…but sometimes it's not followed. I don't know if it's because they ask the advice of the doctor, and the doctor just makes a number up or they think this is what should be or they don't read our notes [which explain the guidelines]." Hospital-based diabetes specialist nurse*

Anticipation and prevention of potential ToC issues

The SEIPS components identified included: People (skills, experience, and knowledge); Tasks (planning admission needs, identifying discharge needs, making referrals); Tools (patient held records, electronic health records, referral forms); Organisational factors (availability and provision of staffing and specialist roles).

Safe management of insulin across ToC required input from both the PWDI and a multidisciplinary team including community and hospital nursing staff, general practitioners, hospital doctors, diabetes specialists and pharmacists among others. Many of those involved demonstrated their ability to recognise potential issues and take action to avoid adverse outcomes. PWDI often informed their GP practice about changes to their diabetes management. One PWDI was so concerned about a delay to his insulin when admitted to hospital, he arranged for his friend to bring his own supply from home.

> *"Eventually I had to ask for insulin from home, and that took a while, but due to the delay and everything I had to do that." PWDI*

The specialist diabetes team frequently used their skills and experience to proactively prevent problems occurring. They arranged their work commitments to ensure education and training for staff and PWDI could be provided during their service hours. They also used their expertise to predict the impact of improving health, altered diet, changes in medication on PWDI blood glucose levels when deciding on insulin dosing for discharge.

Diabetes specialist nurses also identified any potential support needs PWDI might have after discharge and put in place plans to meet these. This was particularly important when needs changed during the admission. In one case, for a PWDI who had become bed bound during admission, the nurses considered whether insulin was still a suitable option given the challenges of administration and monitoring.

Once back in their own home, PWDI are likely to require adjustments in their insulin requirements, however referral to the community diabetes team was not automatic. Generally, it was up to the GP to identify the potential need for such follow up. One primary care pharmacist described proactively following up PWDI following discharge:

> *"Some patients…ask for their insulin…fairly soon after being discharged cause they understand how important it is…I think our role as a [primary care] pharmacist…where there is new medication, especially things like insulin, [is to] ask them if they…understand how they're…meant to be using their insulin…Their needs change as soon as they…come out of hospital…generally I'll always…check if they're under the diabetes nurses locally… so they can have their insulin monitored." Primary Care pharmacist*

Discussion

Many system factors impact insulin management during ToC. By mapping these in detail, potential areas for interventions to improve safety can be explored. Four themes that impacted the safe management of insulin during ToC were identified. The first of these was recognising and incorporating the expertise of PWDI in identifying diabetes management needs and ongoing insulin adjustments. Linked to this was enabling PWDI to manage their diabetes while in hospital. The third theme was the lack of confidence of healthcare staff in managing insulin. The fourth theme described the way in the PWDI and their management team are involved in anticipating and proactively addressing potential challenges. We identified six processes as being key components of ToC for PWDI. These were, preparing for admission, admitting to hospital, adjusting insulin during acute illness, planning for discharge, handing over medical care and resuming insulin management in the community. For each of these, multiple work system factors influenced how well these processes worked to ensure the PWDI were safely managed.

Much research around safe insulin management has been undertaken in hospital settings, and consequently interventions to improve safety have been mainly targeted in this sector.(55,113,114) Maintaining safety for PWDI during ToC is an under-researched area and this gap in evidence has been highlighted over many years.(108,115,116) Using a complex work systems lens to identify the processes that impact insulin management in this context allows a detailed picture of the multiple interacting work system factors to be developed and, in doing so, presents new opportunities to improve and strengthen safety. Key work system factors that drive unsafe care include inadequate staffing, poor IT infrastructure, and the organisational and cultural factors that inhibit the expertise of the PWDI being recognized and applied. The mismatch between the demand placed on the system by ever increasing numbers of PWDI with complex needs and availability of skilled, knowledgeable staff to manage the needs of PWDI is significant. This mismatch was demonstrated by the general lack of confidence staff expressed in managing diabetes and the over-reliance on the limited capacity of the specialist diabetes teams to provide this expertise. Maintaining safety is challenging when demand outstrips capacity.

Empowering PWDI throughout ToC is essential for safe diabetes management.(63) PWDI potentially play a pivotal role in bridging safety gaps created by factors in the work system.(71) Our study showed that there is scope for improvement in incorporating their self-management expertise during ToC. Supporting PWDI to provide sufficiently detailed information about their insulin and diabetes

management in a format healthcare professionals can access could reduce the information gap during ToC. Patient held diabetic records have been proposed in the past. The Diabetes 'Getting It Right First Time' report states that 'electronic insulin passports, electronic patient records which include information on insulin needs, and electronic prescribing may also be effective in reducing insulin errors.'(55) There is currently no standard template for such documents and previous attempts to introduce insulin passports have not been widely taken up.(117) With the ongoing development of the NHS app(118), there may be potential for developing a shared diabetes records in the future.

Ensuring staff involved in managing insulin during ToC have access to the skills, knowledge and competency required is challenging. Current mechanisms to address this are aimed at the people within the work system through training and competency assessments and strengthening the support of specialist diabetes teams across organisations. Understanding how other aspects of the work system could be modified or re-designed to support safe insulin management provide additional opportunities for improving safety.(119) Guidelines and procedures could be developed using human design principles to reduce the need to rely on memory.(120)

Strengths and limitations

PWDI and a range of healthcare professionals were interviewed and observed to map work system factors influencing the safe management of insulin during ToC in real-life situations whilst documentary analysis of relevant guidelines provided insight into the context of insulin management during ToC. The findings were validated through discussions within the study team which brought together healthcare professionals from a range of backgrounds and in two focus groups held with primary and secondary care staff. Quota sampling for interview participants was not achieved, therefore findings may not represent some aspects of healthcare inequalities.

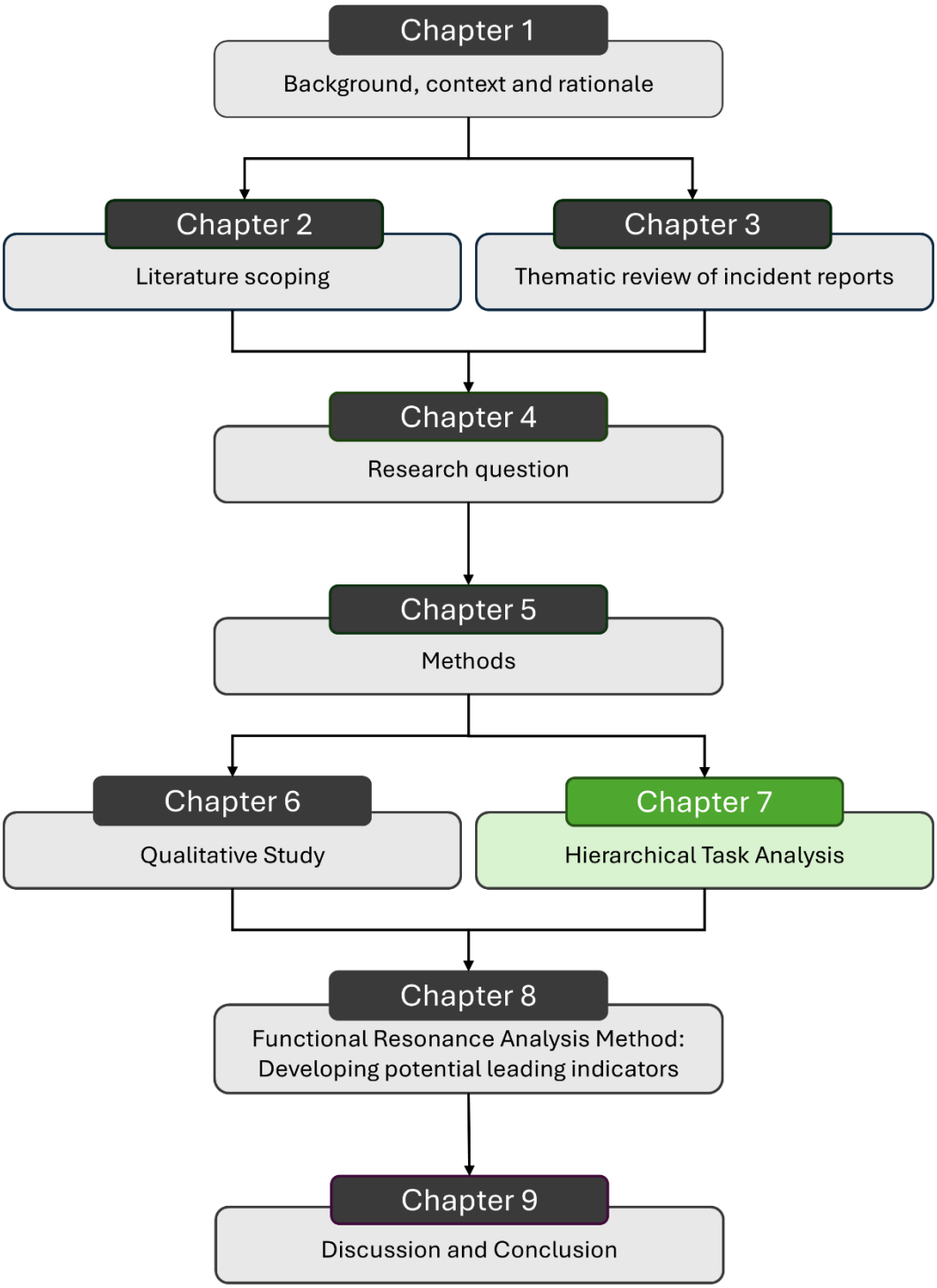
Observation took place in one hospital within a single ICS, and resources, processes and guidelines will differ across the country. It was not possible to undertake observation within primary care, therefore the factors that impact insulin management were not seen directly and were gathered indirectly from interviews with both PWDI and healthcare professionals working in this setting. Observation of how tasks are performed in primary care would have strengthened understanding of the complexity of insulin management during ToC. Due to recruitment challenges, study participation had to be broadened to include NHS staff and PWDI from across England. However, all participants described similar challenges and opportunities to those observed in the original ICS selected for the case study. This study focused on PWDI with Type 2 diabetes. Our findings are likely to apply to any person with diabetes who uses subcutaneous insulin. For people with Type 1 diabetes, there are even

more factors likely to impact management due to additional technologies and more complex insulin regimens.

Conclusion

Managing insulin safely for PWDI during ToC is challenging due to the complexity introduced by all aspects of the work system. Current safety improvement mechanisms are often targeted at the people involved. Using a systems-based approach to discover the factors that impact safe management can identify additional opportunities to target safety improvement interventions for other aspects of the work system.

Chapter 7: Mapping insulin management during transfer of care using Hierarchical Task Analysis.



7.1 Introduction

Managing insulin during transfer of care (ToC) is a complex process involving many people across different care settings. To design measures that can guide improvement, and leading indicators that can provide insight into safety, a detailed understanding of how insulin is managed during ToC is required.(16,38,121,122) This requires exploration of the work system to understand how these processes are performed by those involved. One method of mapping complex processes is by using a Hierarchical Task Analysis (HTA). This technique is a frequently used tool by Human Factors practitioners across many fields of work, for example manufacturing, space exploration and healthcare.(123)

HTAs have been widely used in healthcare research. The technique has been used to explore healthcare resilience by identifying WAI (for example, as described in procedures) and contrasting this with WAD.(124–126) It has also been combined with other tools, such as the systematic human error reduction and prediction approach (SHERPA) to understand medication errors.(127,128) It is a task analysis method recommended as a step in using the Functional Resonance Analysis Method (FRAM).(19) The key advantage of using an HTA is that processes are considered in terms of the tasks required to achieve goals, with the ability to include the required level of detail to describe all relevant tasks.(129) They are used to represent WAD and are developed collaboratively with healthcare professionals.(121) Focusing the analysis on the goals of the processes allows representation of the context of work, and detailed plans can allow for non-sequential and non-linear processes to be described.(121,129) The output form an HTA is a detailed, visual representation of the tasks involved in processes which can be used as the basis for further analysis.

HTA is a systematic method used to analyse processes.(19,123) Processes are a group of tasks that must be completed to reach a specific goal. In this case the goal is to use insulin(s) correctly to maintain blood glucose levels within a defined range throughout admission and discharge. The tasks that must be carried out to achieve the goal are systematically identified by reviewing guidelines and procedures and identifying additional work described in interviews or during observation. Each task can be further divided into sub-tasks, and this process repeated until the map provides enough detail to understand how goals are achieved. Once sub-tasks have been described to a level at which variation in undertaking the tasks is unlikely to impact the goal, a line is drawn underneath the box to demonstrate that this is the final level of description for that task. Because of the hierarchical nature of this map, goals (also termed ‘operations’) are superordinate to their subordinate tasks. Subordinate tasks then become the goal or superordinate task for further subordinate tasks, see Figure 12 for an example demonstrating the tasks that contribute to the goal of ‘Wash clothes,’ and

how the terms are applied. The sequence in which tasks should be completed is also considered and described using plans. Although presented linearly, plans allow for non-sequential and variable task sequences to be represented.(123)

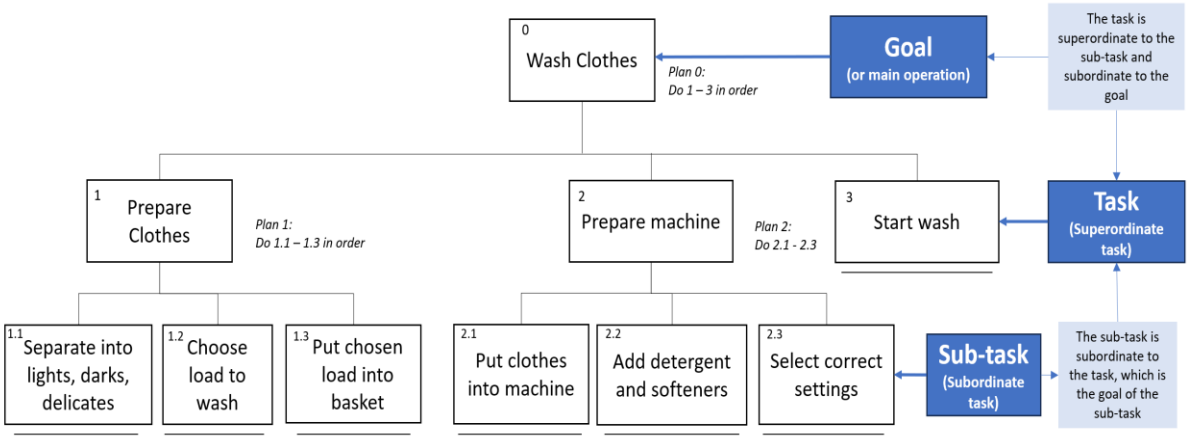


Figure 12: A hierarchical task analysis for washing clothes.

Multiple perspectives are required to develop a comprehensive and accurate HTA, incorporating procedures, guidelines and feedback from those involved in performing the tasks.(123) This ensures that all tasks involved in achieving the goals are represented, even where some may not be written down.

The aim of this work package was to develop an HTA to map the tasks involved in managing insulin from the time when the need for hospital admission for a PWDI was identified, through to their return home following discharge.

7.2 Method

Information was gathered from multiple sources including documents, field notes from observations, and interviews. Interviews were held with PWDI, their caregivers and a range of healthcare professionals who are involved in managing insulin during ToC.

Fieldwork was undertaken over 17 months, between October 2022 and March 2024 during which time 85 hours of observation were performed in an acute hospital. The specialist diabetes team were observed managing referrals, seeing patients, adjusting insulin plans, providing education, and collaborating with other healthcare professionals. Pharmacy staff were observed identifying insulin doses on admission, discussing insulin with patients, planning and preparing insulin for discharge and resolving challenges and queries about dosing. Nursing staff were observed identifying insulin use with patients and families, confirming doses, locating insulin for administration, administering

insulin, testing blood glucose levels, highlighting and escalating issues with glucose management, querying doses, contacting specialist teams and preparing PWDI for discharge. Field notes were written up as soon as possible after the observation took place.

Twenty interviews were held online using either zoom or Microsoft teams. Interview participants included three PWDI, one caregiver, and healthcare professionals across primary and secondary care. They included pharmacists, nurses, diabetes specialists, paramedic assistants, general practitioners and surgeons. Transcripts were taken using the built-in software and were manually confirmed and anonymised.

Local and national guidance relating to insulin management during ToC were identified using hospital intranet searches and through exploration of relevant organisational websites, including the Joint British Diabetes Societies for Inpatient Care Group (JBDS), the National Institute for Health and Care Excellence (NICE), the Royal College of General Practitioners (RCGP), and the Royal Pharmaceutical Society. The documents identified are included in Table 2.

Table 2: Documents identified for analysis

Name of document	Published by	National/ Organisational or Local
Simple steps to keep you safe during your hospital stay**(130)**	NHS England	National
Keeping patients safe when they transfer between care providers – getting the medicines right.**(66)**	Royal Pharmaceutical Society	National
Perioperative management of the adult surgical patient with diabetes.	Local organisation	Local
Diabetes at the front door**(131)**	Joint British Diabetes Societies for Inpatient Care Group	National
Discharge planning for adults with diabetes**(132)**	Joint British Diabetes Societies for Inpatient Care Group	National
Insulin essentials	Diabetes UK	National
Help with Hypos**(133)**	Novo Nordisk	National
Organisational procedures for prescribing insulin on the electronic health record	Local organisation	Organisational

The HTA was developed using the recommended steps:

Step 1. Define the purpose of the analysis.

The aim of this HTA was to identify all the tasks involved in managing insulin safely during ToC. The ToC of interest was hospitalisation of PWDI from the community and their return home after recovery involving transfer of responsibility of care from primary care to secondary care, admission of PWDI to hospital from home, discharge of PWDI back home after recovery and transfer of responsibility for care back to primary care. The goal was defined as 'use insulin(s) correctly to maintain blood glucose levels within a defined range throughout admission and discharge.' Conditions that describe the inclusion criteria for the HTA (termed pre-conditions) were defined as:

1. The patient had to have a known diagnosis of Type 2 diabetes and be using insulin.
2. The target range for insulin had to be known by relevant people (patient, caregiver, managing healthcare teams).

Step 2. Define the boundaries of the process description.

The boundaries of the process were from the point where the need for hospital admission was identified, through to when the PWDI returned home, and medical care was resumed by their GP. This process included the tasks to be performed by PWDI, GPs, paramedics, administrative staff, nurses, clinicians, pharmacists, and discharge co-ordinators.

Step 3. Access a variety of sources of information about the process.

Documents, field notes, and interview transcripts were uploaded into NVivo and analysed line by line to identify all the tasks that were required to use insulin(s) correctly to maintain blood glucose levels within a defined range throughout admission and discharge.

Step 4. Describe the goals and tasks (keep sub-goals between 3 and 10).

The tasks identified from the documents were used to begin to develop the HTA, with complex tasks broken down into sub-tasks as required to ensure that they were clearly described. The tasks subordinate to the goal were developed inductively, by considering the different stages of ToC and grouping tasks together where they applied to each stage. As the field work and interviews progressed, the tasks identified from these sources were incorporated where appropriate. Each task was then explored to determine the relevant sub-tasks required to complete it. This analysis was applied, in turn, to each sub-task where additional detail was required to ensure that the related superordinate task could be described clearly.

The hierarchy and links between the goals, tasks and sub-tasks were added at this stage. The identification of sub-tasks was stopped when further exploration was deemed not likely to impact the

goal. For example, managing insulin while in hospital was not expanded, as this did not impact management of insulin during admission or discharge.

Step 5. Develop plans to outline when each task is undertaken and in what order.

Each task was reviewed and the order and circumstances in which the sub-tasks were performed were documented.

Step 6. Confirm the HTA with subject-matter experts.

Following the development of the HTA, two focus groups were conducted to confirm face validity in terms of accurately capturing the ToC process. The first focus group was held live and consisted of staff working in secondary care. The second group included staff in primary care and was conducted online, the HTA being shared on screen. The HTA was subsequently updated. The HTA was also shared informally with other healthcare professionals who had subject matter expertise for feedback.

7.3 Results

Six key tasks were identified as necessary to achieve the goal of 'Using insulin(s) correctly to maintain blood glucose levels within a defined range throughout admission and discharge' (Figure 13). The sub-tasks for each key task are described below apart from the task of 'adjusting insulin during acute illness'. This task does not influence the ToC process, so exploration of sub-tasks was not undertaken.

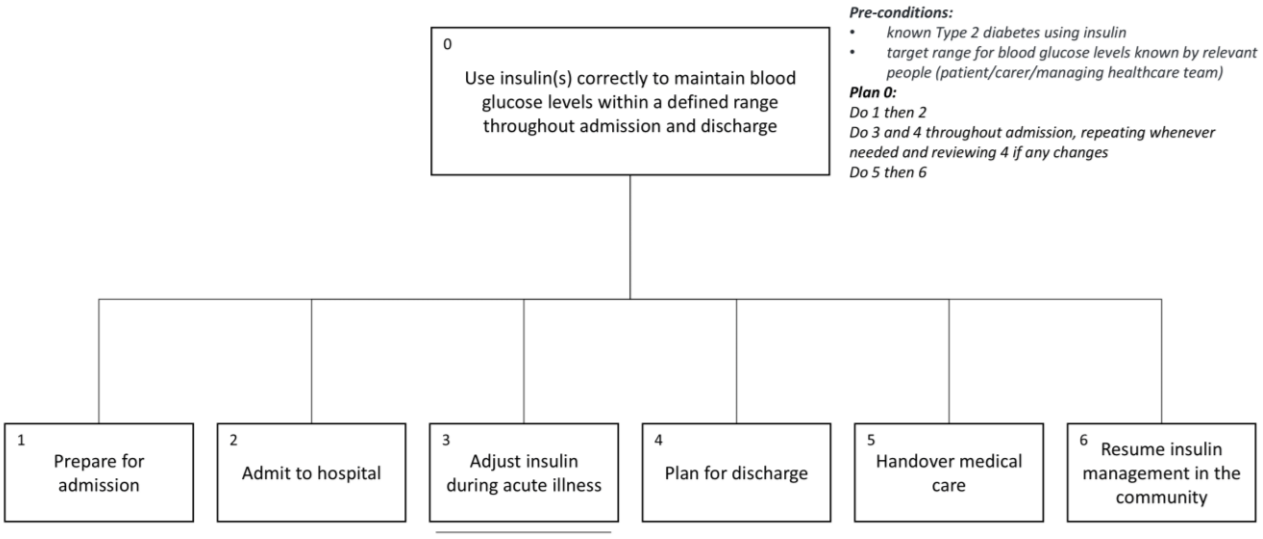


Figure 13: High-level hierarchical task analysis showing overall goal, pre-conditions and six key tasks.

Task 1: Prepare for admission

Preparing for hospital admission included five key sub-tasks which were: identifying the need for a hospital admission, packing belongings, fasting at the time advised if being admitted for surgery, monitoring for symptoms of hypoglycaemia, and travelling to hospital. (These can be seen in Figure 14).

There was little documentation related to pre-admission tasks to be undertaken while planning for admission. Required tasks will vary depending on the illness being experienced by the PWDI. For example, a PWDI being admitted for planned surgery compared to someone experiencing an emergency admission due to a collapse while out shopping.

As demonstrated in the HTA shown in Figure 14, many of the tasks and sub-tasks involved were not described in these documents and were identified during interviews or by observation.

Task 2: Admit to hospital

The task 'Admit to hospital,' involved seven sub-tasks, as shown in Figure 15:

- PWDI to attend the receiving area (for example the emergency department or pre-admission unit)
- Settle PWDI on ward
- Take baseline observations including blood glucose and ketones
- Confirm medical history
- Achieve safe blood glucose levels
- Complete medication reconciliation
- Perform discharge assessment

These sub-tasks cover the administrative work involved in checking the patient into the hospital, assigning a bed or chair and safely storing their belongings, including their insulin and equipment. Healthcare professionals are required to undertake initial clinical assessments gathering information about the patient's diabetes and insulin history as well as details on current health issues and using this information to plan and administer treatments. Identifying relevant issues that might impact on discharge planning such as support needs for insulin administration in the home are also best identified at this early stage. Capillary Blood Glucose (CBG) monitoring and monitoring for signs of hypoglycaemia are ideally conducted throughout the whole ToC with intensive monitoring of CBG at the time of admission to determine the impact of acute illness. For example, gastrointestinal symptoms such as vomiting leading to hypoglycaemia.

Although there was more comprehensive documentation of the tasks involved in this ToC step, many tasks were only identified through other methods, particularly observation, but also interviews and when confirming the drafted HTA in focus groups.

Task 3: Adjust insulin during acute illness

Adjusting insulin during acute illness involved identifying the PWDI's diabetes needs, consideration of carbohydrate intake, and whether other medications are being used that may lead to changes in blood glucose levels. For example, steroids could lead to raised blood glucose levels, and insulin doses needed to be reviewed as these medications are added, then tailored off or stopped abruptly. In this HTA, the task of adjusting insulin during admission relates specifically to the hospital admission only. The tasks associated with identifying relevant information to prescribe insulin are described in Task 2: Admit to hospital. Evaluation of the insulin doses needed during admission to plan for discharge, are described in Task 4: Plan for discharge. As the adjustment of insulin during acute illness relates only to the inpatient stay, this task was not expanded into sub-tasks, as those sub-tasks would not further impact the goal of using insulin(s) correctly to maintain blood glucose levels within a defined range throughout admission and discharge.

Task 4: Plan for discharge

Four sub-tasks were identified that enabled planning for discharge to be completed. These are shown in Figure 16. The first sub-task was deciding the appropriate insulin regimen and diabetes management plan for discharge, the second was arranging for supplies of insulin and equipment for the PWDI to take home with them. The third step was to provide education and information to enable the PWDI or their caregiver to manage the insulin and diabetes at home. The final step was to arrange transport.

Task 5: Handover medical care

Handing over medical care, the fifth task, includes sharing the information about insulin and diabetes management with the relevant healthcare professionals in primary care. It also includes making relevant referrals for follow-up in primary care. Finally, follow-up from the secondary care diabetes team is provided through a phone call once the PWDI has returned home to gauge understanding of the insulin management plan, check that CBG levels are remaining within an appropriate range and to answer any questions the PWDI might have. These sub-tasks are displayed in Figure 17.

Task 6: Resume insulin management in the community

The final key task in the ToC HTA is the resumption of insulin management by healthcare providers in primary care (see Figure 18). Sub-tasks include identifying a new discharge of a PWDI to home from hospital, reviewing the information in the discharge letter, performing medication reconciliation for insulin, supplying insulin and CBG monitoring equipment as required and arranging further follow-up as needed. Medication reconciliation is the process by which a person's medication list is reviewed following a ToC, and all changes are identified, discrepancies resolved, and the records updated.(134)

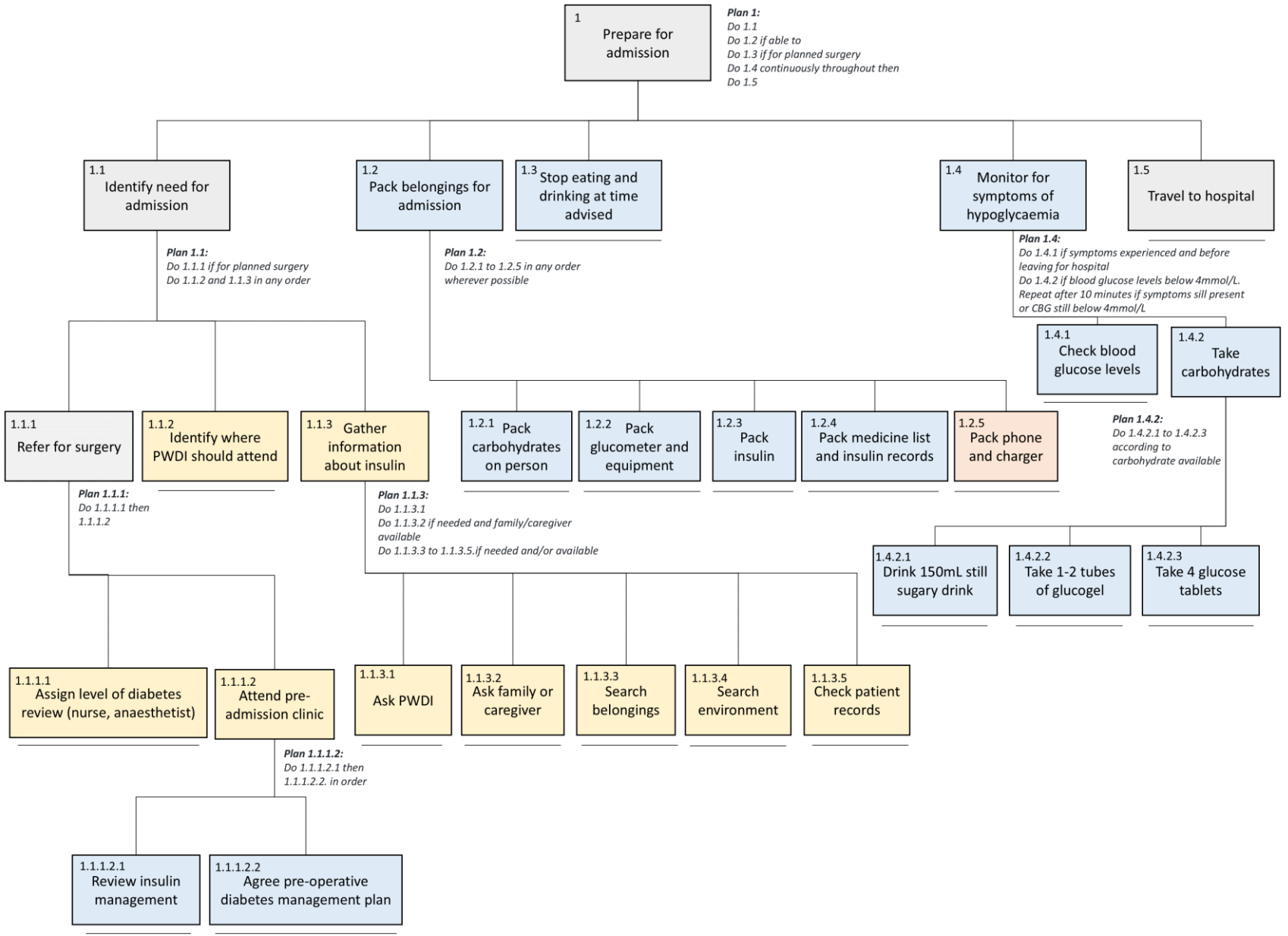


Figure 14: Hierarchical task analysis for Prepare for hospital admission.

Key:

Information identified from: Documents | Interviews | Observation | Focus groups | Identified by researcher

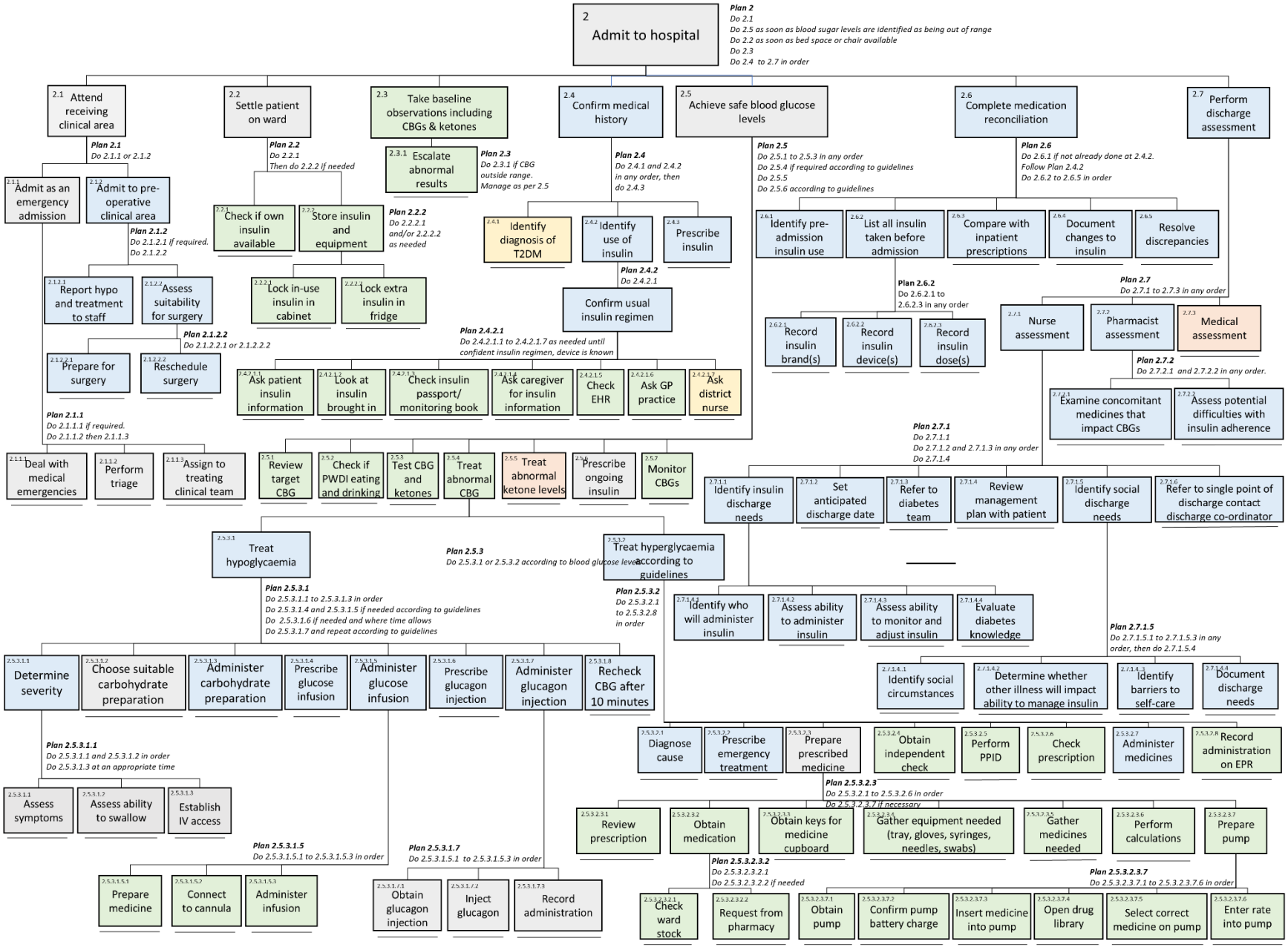


Figure 15: Hierarchical task analysis of admission to hospital.

Key:

Information identified from: Documents | Interviews | Observation | Focus groups | Identified by researcher

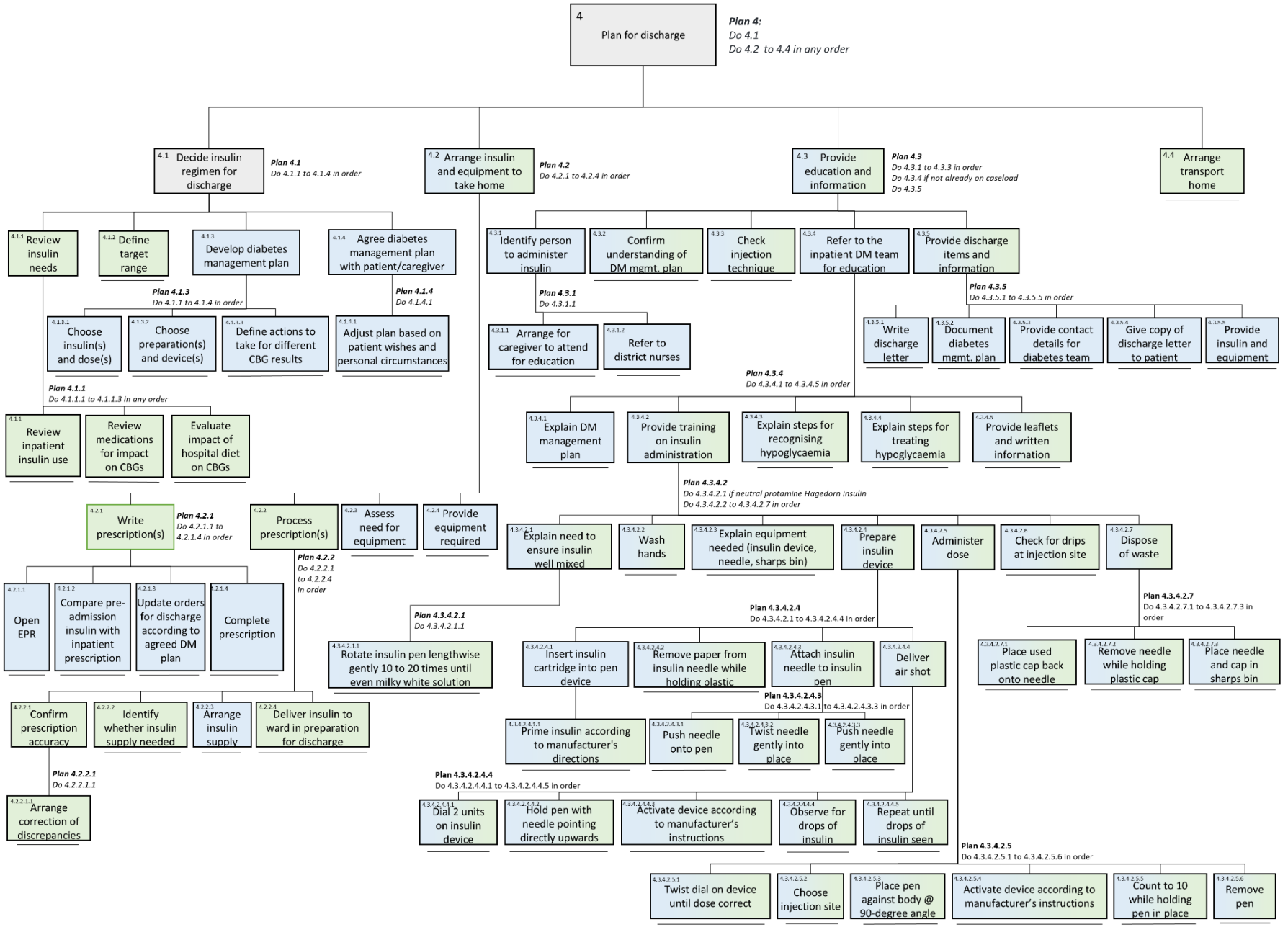


Figure 16: Hierarchical task analysis of planning for discharge.

Key:

Information identified from: Documents | Interviews | Observation | Focus groups | Identified by researcher

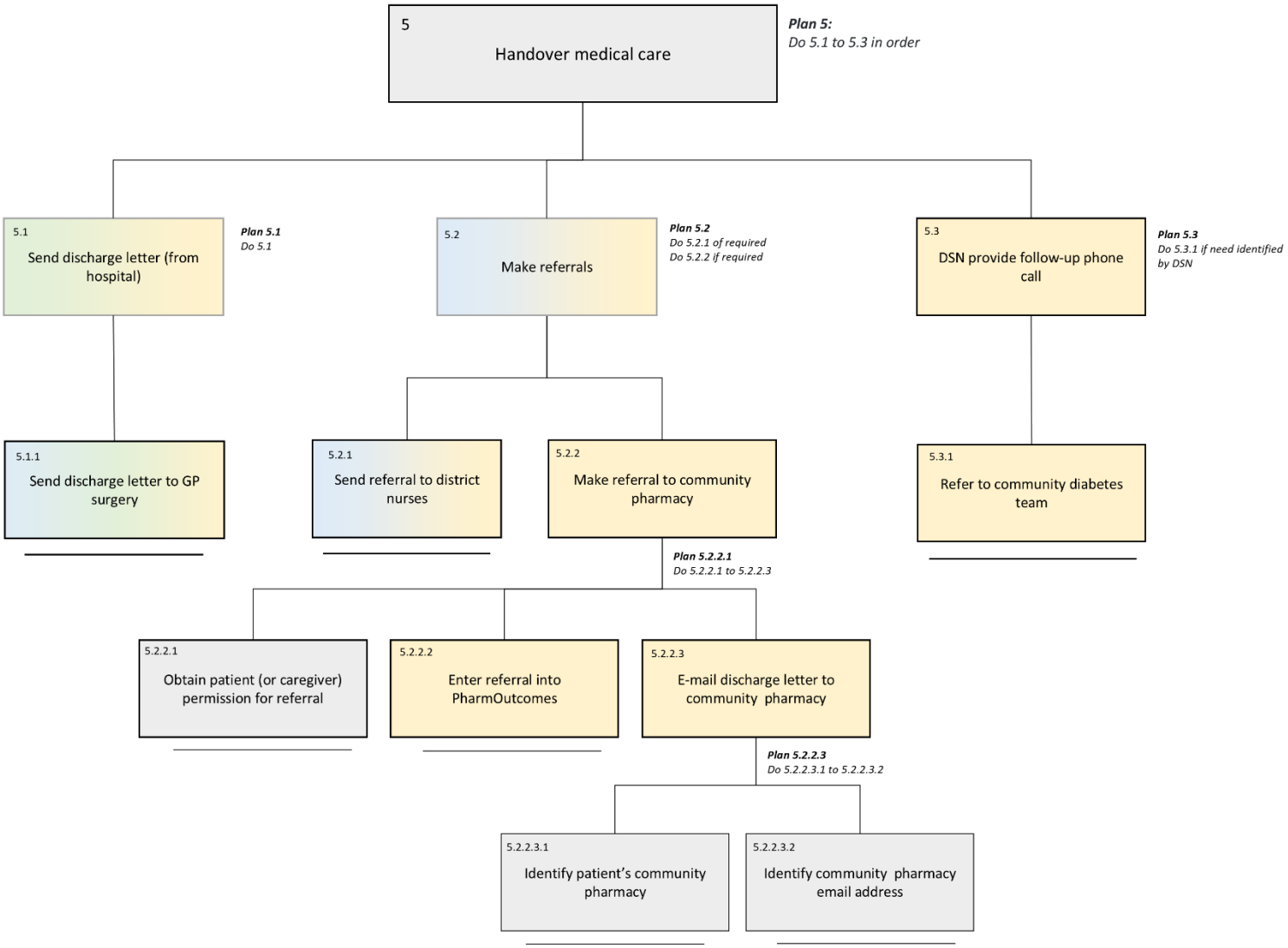


Figure 17: Hierarchical task analysis of handing over medical care.

Key:

Information identified from: Documents | Interviews | Observation | Focus groups | Identified by researcher

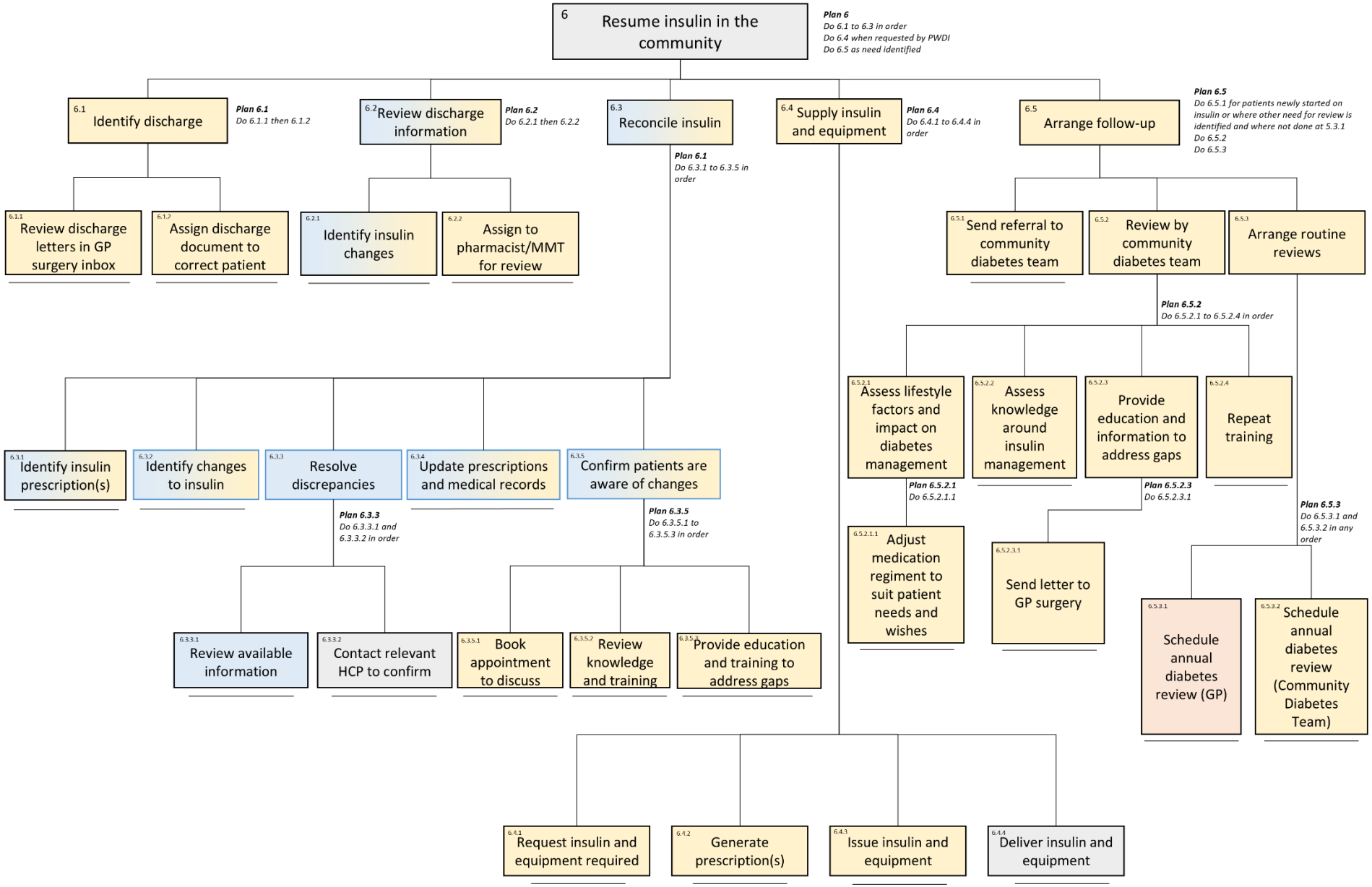


Figure 18: Hierarchical task analysis of resuming insulin the community.

Key:

Information identified from: Documents | Interviews | Observation | Focus groups | Identified by researcher

7.4 Discussion

The development of this HTA has drawn together information from multiple sources across the whole ToC pathway from home through admission and after discharge home. Six key tasks have been identified that allow the goal of using insulin correctly to maintain blood glucose levels within a defined range throughout admission and discharge to be achieved. There are many sub-tasks involved in each of these key tasks. The high level of complexity involved in managing insulin during ToC is demonstrated by the number of tasks and sub-tasks identified, the number of options within the plans, and the many factors that influence how they are performed. Documents relating to insulin management were more readily available for hospital-based tasks, while many tasks in primary care appeared to rely on local processes and staff knowledge. Tasks occurring in primary care were identified largely through interviews. The two focus groups highlighted additional tasks, and suggested changes to the ordering of tasks and plans.

HTAs are useful tools for representing complex processes, and by including goals and plans they can allow incorporation of more contextual information compared with other process mapping techniques.(121) They are a valuable tool that can be used to incorporate multiple perspectives, information sources and be used to explore system level processes, such as transfer of care.(125) They are able to display complex information concisely,(135) and provide detailed description of tasks at macro and micro levels.(126) The National Patient Safety Syllabus Level 3 and 4 in the NHS includes the use of HTA as a tool to identify and explore systems issues. Training to use this tool is being provided to all Patient Safety Specialists in England during 2024.(136)

This HTA provides detailed information that can be used as a basis for exploring how variability can occur during ToC, and how this can contribute to different outcomes for organisations, patients, and staff. HTA is a method recommended to identify the key tasks that form the functions for analysis using the Functional Resonance Analysis Method (FRAM).(19) FRAM is a tool that can be used to identify which aspects of tasks can vary and how and the impact of this variation on other tasks.

The steps undertaken predominantly in primary care had relatively few sub-tasks compared with those in secondary care. This could be due to the challenges involved in obtaining information about these tasks, for example the lack of national guidance for referring to hospital or post-discharge processes. Alternatively, the high number of sub-tasks involved in

admitting a PWDI to hospital and planning for discharge represent times where a PWDI is experiencing changes in their health and many tasks are required to ensure safe insulin management compared with their time in primary care. Further validation and exploration of the HTA will be undertaken as part of the FRAM analysis which will aim to address these gaps.

Strengths and limitations

The HTA was developed using multiple sources of information and provides a comprehensive map of tasks involved in managing insulin during ToC from before admission until after discharge. Using multiple sources of information enabled tasks that are not well described in national documents to be identified and included. Observation allowed identification of factors that influenced how work was done that were not picked up through other methods. Reviewing the draft HTA using focus groups enabled feedback from practitioners who undertake these tasks to be incorporated and the HTA improved to reflect their experience.

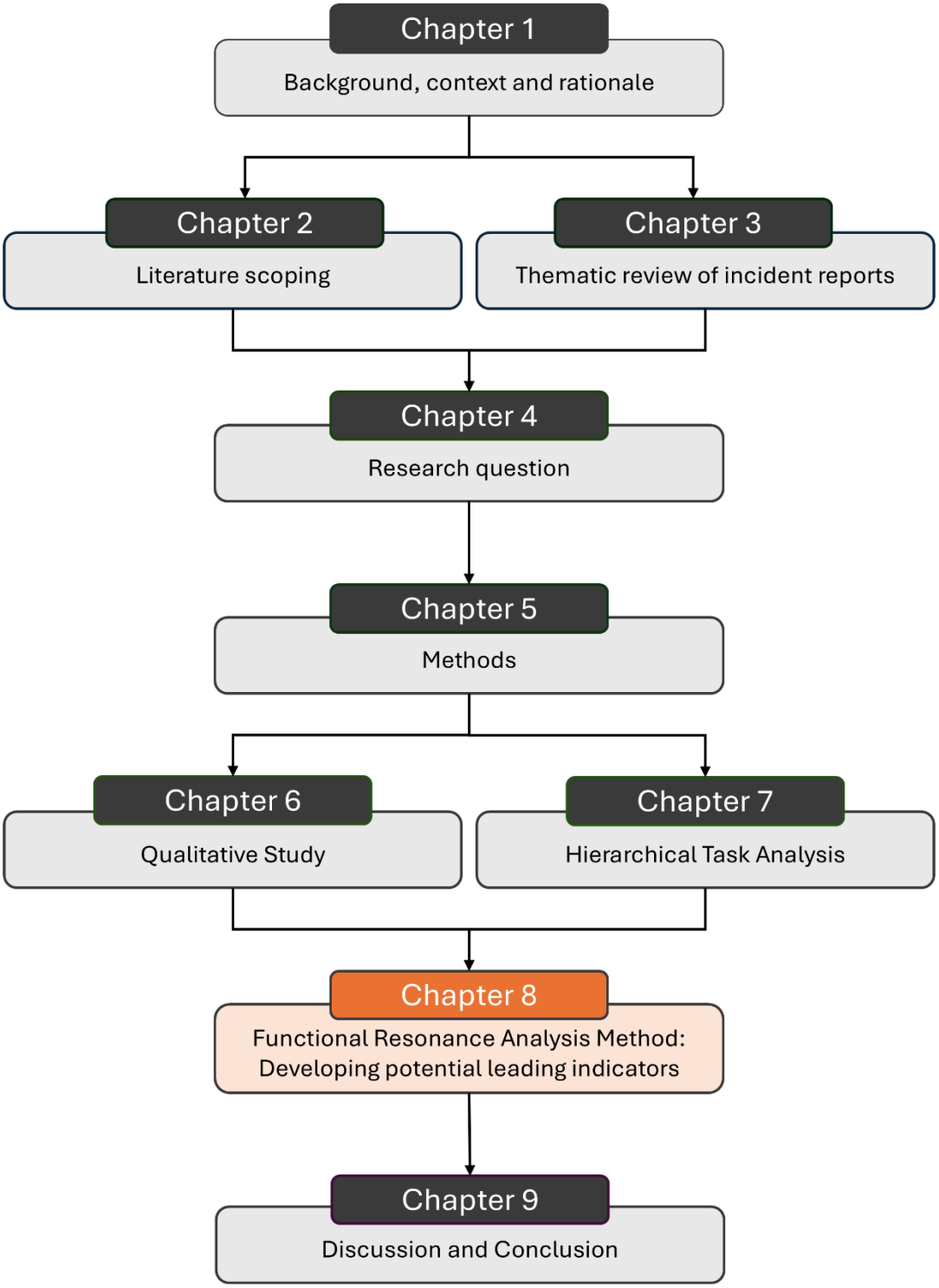
Less information was available from primary care, including in published or available documents, such as guidelines or pathways. It was also not possible to undertake observation in any primary care settings. Good representation from primary care based interview participants allowed details of primary care processes to be included.

There were few participants in the focus groups which could have limited the feedback provided. This limitation was addressed in future work, where the FRAM model developed from this data underwent further validation using incident reports from both primary and secondary care and with a wide range of stakeholders in a seminar.

7.5 Conclusion

The HTA developed represents an overarching view of the tasks that contribute to managing insulin safely during admission and discharge for PWDI. The map has been created through combining multiple sources of information and has been reviewed and updated following feedback in focus groups. This map provides a basis for identifying the functions for analysis using FRAM.

Chapter 8: Functional Resonance Analysis Method: Developing potential leading indicators



8.1 Introduction

This chapter describes the development of the Functional Resonance Analysis Method (FRAM) model representing insulin management during ToC. It demonstrates how this model was used to identify key areas of variability and subsequently to predict how and where variability can impact outcomes. These key areas of variability were explored as targets for developing safety leading indicators.

The FRAM is a way of modelling complex systems using a Safety-II approach. This is achieved through modelling care based on a detailed understanding of how care is provided. WAI is explored through guidelines, pathways and protocols and contrasted with WAD, how care is provided in real-life contexts. An understanding of WAD is developed by studying and understanding causes of variability and subsequent resilient adaptations. A Safety-II approach recognises that all outcomes, both intended and unintended are the result of these adaptations made to provide care in the face of constantly varying circumstances in the work system.(28)

Activities involved in a care pathway are developed into functions for the model, with each function having an output that causes other functions to begin. Variability can be introduced into care pathways through work system factors that may cause the output of functions to vary, and how interdependent functions can impact each other, termed coupling. A function can be impacted by an earlier function, or variability in its output can impact later functions. These linked functions and their variability are termed upstream and downstream coupling. Functions may also vary due to the direct impact of factors within the work system.

Leading indicators proactively highlight areas where adjustments may be required allowing those involved in healthcare to monitor for issues that may need to be addressed and anticipate potential problems and seek to prevent them occurring or minimise their impact.

There are two types of leading indicators, active and passive.(39) Active leading indicators for use by people directly involved in providing and receiving care, such as the National Early Warning Sign scores, can highlight people at risk of deterioration in real time prompting timely review.(137) Passive leading indicators provide information to organisations about how well the systems and processes are designed.(39)

This study aimed to model the care pathway for managing insulin across ToC and to identify key areas of variability that impact on patient safety. These areas of variability were then

considered as potential targets for leading indicators that can highlight opportunities for those involved in providing care to support safe outcomes.

8.2 Method

Study design

Multiple qualitative methods were used to explore and understand WAI and WAD for insulin management during ToC. People with Type 2 diabetes who use insulin were chosen as the target population, as their care is often provided collaboratively between primary and secondary care. An overview of the components of the study are shown in Figure 19. ToC was defined as being from when the need for hospital admission was identified through to routine follow-up after discharge. The development of the FRAM model followed the method described by Hollnagel, (2012).(19) The identification of potential leading indicators is based on the method described by Raben et al.(2018)(38)

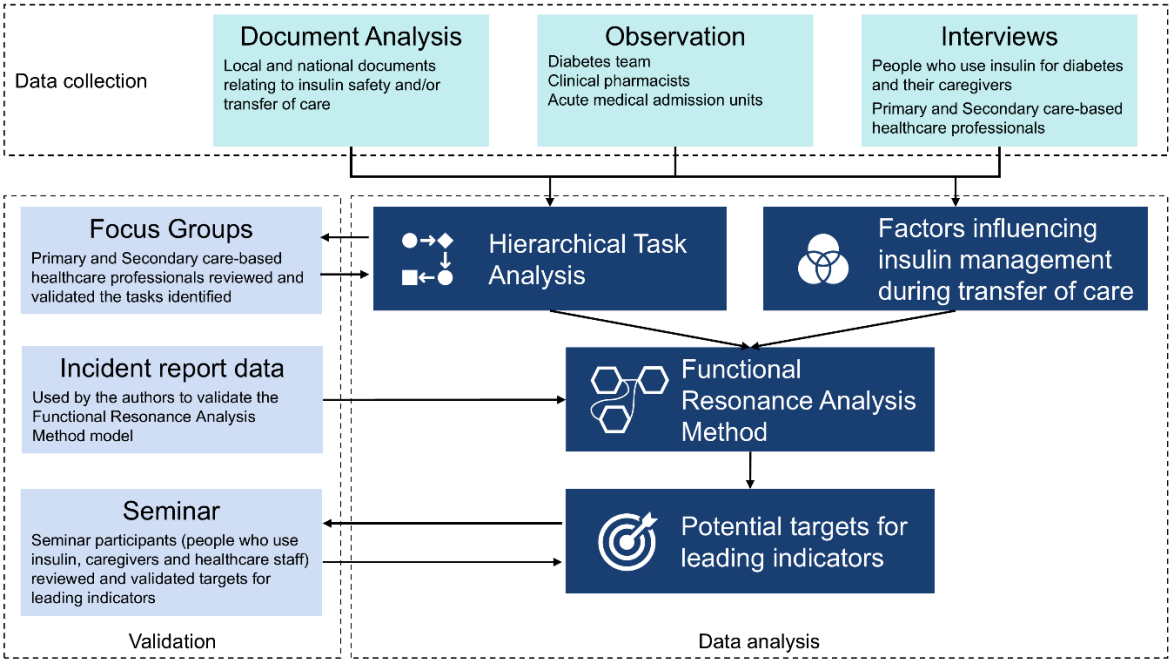


Figure 19: Data sources and components of research.

Setting and sample

Fieldwork was undertaken over 17 months between October 2022 and March 2024. The initial setting was within a single integrated care system in England. Recruitment was widened to allow participants from across England to increase participant numbers for interviews, focus groups and the seminar.

Data collection

Documentary analysis was performed on national and local documents relating to insulin safety and/or transfer of care. Documents were identified using hospital intranet searches and through exploration of relevant organisational websites, including the Joint British Diabetes Societies for Inpatient Care Group, the National Institute for Health and Care Excellence, the Royal College of General Practitioners, and the Royal Pharmaceutical Society.

A total of 85 hours of purposive observation was performed in a large, acute teaching hospital. Activities relating to insulin management were observed, such as confirming insulin use, doses, PWDI knowledge and providing education, adjusting doses and planning for discharge. Staff observed included members of the diabetes team and clinical pharmacists. Opportunistic observation of PWDI admitted to an Acute Medical Admissions unit was undertaken to witness activities relating to admission and discharge. Extensive field notes were written during and immediately following the period of observation, guided by the Systems Engineering Initiative for Patient Safety 101(SEIPS) work system categories.(15) Written consent was gained from staff members and patients being observed. Verbal consent from the patient and clinical team was obtained to observe inpatients. Written consent was obtained from PWDI where they were directly involved in the care process, for example explaining their insulin regimen.

Online interviews were undertaken with people involved in managing insulin during ToC using a semi-structured format. Inclusion criteria were:

- PWDI (or their caregiver) over 18 years with Type 2 diabetes who use subcutaneous insulin
  AND
- Have had a hospital admission within the last 5 years
  OR
- Healthcare professionals working either in primary or secondary care who are involved in insulin management for PWDI

Participants, including PWDI, their caregivers and healthcare professionals, were identified during the periods of observation and invited to participate in interviews. PWDI were recruited for interviews by referral from healthcare professionals during observation, and through invitations shared on national diabetes forums and on X (formerly Twitter). PWDI recruited during periods of observation were contacted approximately two weeks following their return home to ensure they were well enough to participate in the interview. Healthcare professionals

were recruited through introductions by the diabetes and pharmacy teams. Additional healthcare professionals were invited through pre-existing professional relationships with the researchers. A total of 20 participants were interviewed. They were asked to describe their experiences with managing insulin during ToC, what went or generally goes well and where challenges have been or are commonly involved. Written consent was obtained from all participants before the interviews, which was confirmed prior to recording. At the time of consent, participants were also invited to participate in the focus groups and seminar.

Performing the FRAM

Step 1. Identifying and describing the functions

The HTA presented in Chapter 7 was used to identify the initial FRAM functions, according to the method defined by Hollnagel.(19) The tasks required to manage insulin during ToC and the factors that influenced them were identified through framework analysis of documents, field notes from observations and transcripts from interviews. SEIPS 101(15) work system categories were used to guide analysis. Factors that impacted insulin management were categorised according to whether they involved tasks, people, tools, or environments (local, organisational, or external). The six broad tasks to achieve successful insulin management across ToC were: 'Prepare for admission,' 'Admit to hospital,' 'Adjust insulin during acute illness,' 'Plan for discharge,' 'Hand over medical care' and 'Resume insulin management in the community.' Two focus groups were held with four healthcare professionals from primary and secondary care to agree the completeness and accuracy of the HTA for managing insulin safely during ToC identified through documentary analysis, observation, and qualitative interviews.

The six tasks and their immediate subordinate tasks were used as the initial functions. Other sub-tasks contributed to their definitions. Figure 20 provides an example for how this was done for the key task (or goal) to 'Prepare for admission'.

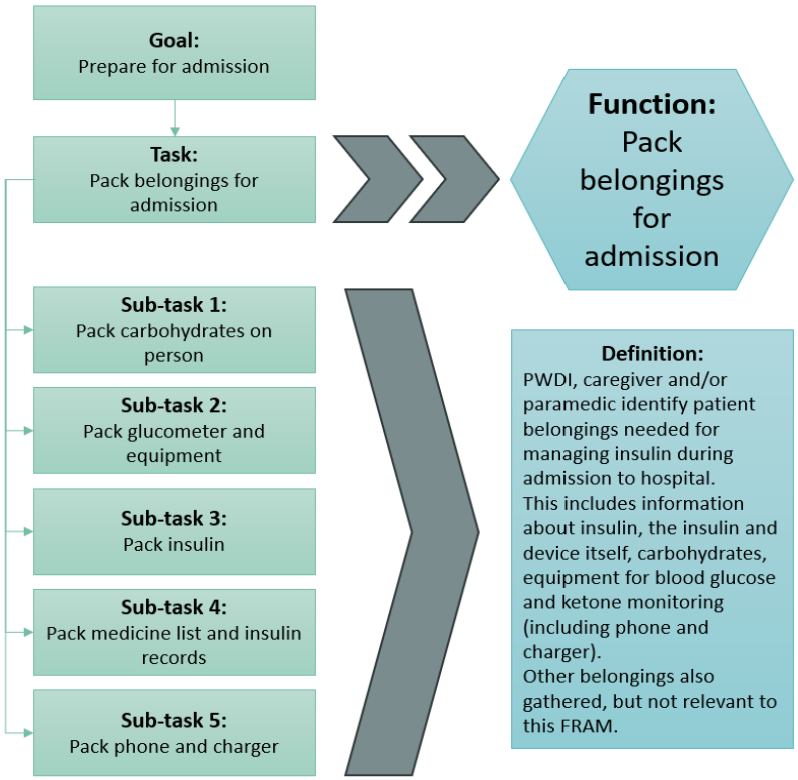


Figure 20: Example of how an example task extracted from the hierarchical task analysis was used as a function, with the sub-tasks contributing to its definition.

FRAM modelling focused on the emergency admissions to hospital element of the ToC pathway. Emergency admissions are a particularly high-risk time for safety due to their unpredictable and unplanned nature and a fruitful area for identifying potential new areas of safety measurement using FRAM. Widening the FRAM to include planned admissions would make the final model too unwieldy and had the potential to obscure the impact of variability within the high-risk emergency admissions pathway.

There are two types of FRAM function – foreground and background functions. Foreground functions are the activities that are carried out as part of the care pathway being modelled. Background functions are the supporting activities that are part of the organisational or wider structural environment. For example, providing adequate staff and other resources to enable functions to be performed.

Once the functions were identified, each one was evaluated according to six aspects(19):

1. **Input** – the prompt for the function to begin.
2. **Output** – the outcome of the function.
3. **Pre-conditions** – anything that must be in place for the function to begin.

4. **Resources** – resources needed for the function, for example, skills, equipment, and guidelines.
5. **Controls** – the aspects of the system that control the output of the function, for example, IT programming or regulations.
6. **Time** – how time influences how the function is performed, for example, whether it needs to be before other functions, or how long the function may take to process.

The FRAM model was built iteratively. The qualitative findings described in Chapter 6 were used to help populate the function aspects. During the process of developing the FRAM model additional activities were identified and added, including background functions. These functions were required for the care pathway to work in the model. Detailed information on the functions and how they were identified is included in Table 3.

Once developed, the FRAM model was tested for completeness using incident reports from the National Reporting and Learning System (NRLS). Permission was obtained from the NRLS data team to obtain incidents relevant for insulin management during ToC. A structured search was developed including terms relating to insulin with associated terms, admission, discharge, and transfer of care (see Appendix IV for full details). The NRLS data team ran the search and provided a random sample of 100 anonymous incident reports, covering both primary and secondary care. From these reports, ten incidents that provided the most comprehensive narratives and represented different sections of the patient journey were selected and used to check the completeness of the model (a summary of these incidents is included in Appendix V). Additional functions identified through this process were added to the model. See Figure 21 for an example function.

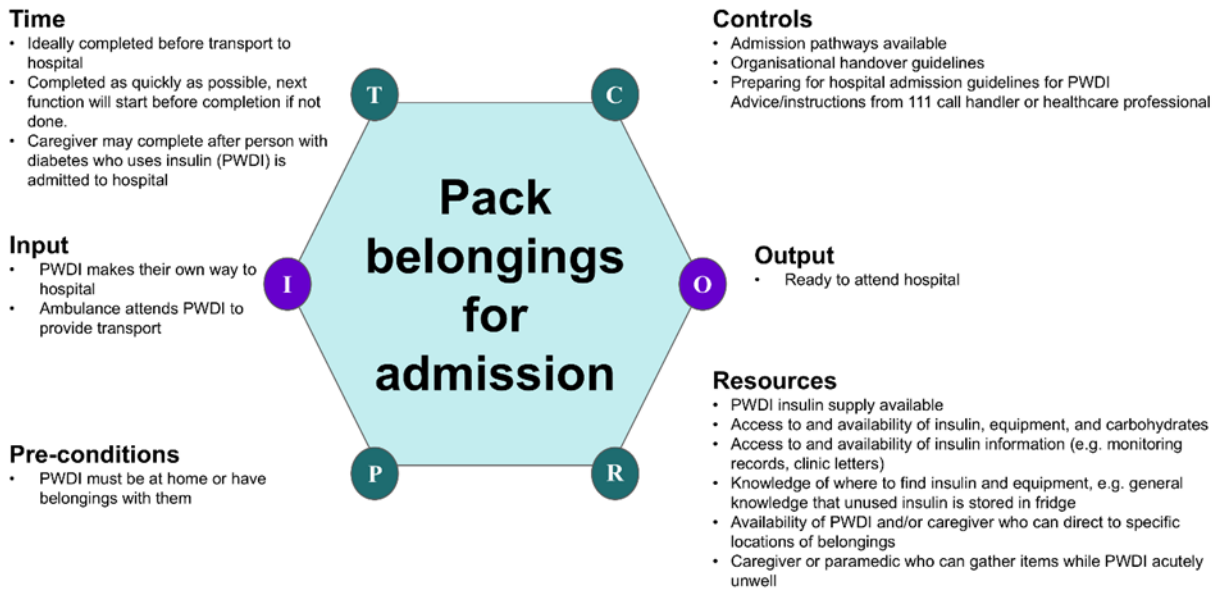


Figure 21: An example function demonstrating the aspects identified.

Step 2. Identifying the variability

Once the functions were identified, each foreground function was reviewed to explore how and when it might vary. For variability to affect insulin management during ToC, it must impact the potential outcomes of the function. Variation could be due to the accuracy of the function, or the timing. For example, the function could be incomplete or incorrect, performed too early, too late or omitted. Factors within the work system can impact the timing and accuracy of functions. The potential variability and the consequences of this variability on other functions were then described and recorded in a spreadsheet. The qualitative findings presented in Chapter 6 supported the identification variability and impact on functional output.

Step 3. Determining how variability may be impacted by other functions

Each foreground function was considered in terms of:

- The impact of other functions on the foreground function being examined
- How variability in this function's output could impact other functions

Controls governing the performance of functions were considered using the Hierarchy of Controls tool.(138) This tool describes different types of control and how effective they may be in controlling risks. The five different types of control are:

1. Elimination (the most effective control) – this type of control removes the risk from the situation completely. An example of elimination is where an anticoagulant that requires frequent monitoring and adjustment to maintain safety is replaced by newer

anticoagulant that does not require monitoring. The risks posed by problems with monitoring and adjustment are removed as the new agent no longer has these associated risks.

2. Substitution (second most effective control) – uses a safer alternative to reduce risks. For example, to reduce the risk of incorrect doses and staff injury, hospitals provide insulins to be administered by pen devices instead of using insulin vials and syringes wherever possible.(139)
3. Engineering (third most effective control) – the equipment or environments are adapted to reduce risks and support intended actions. An example of this type of control would be the use of EHR to incorporate clinical guidelines into prescribing and administration tasks, for example, clinical decision support.
4. Administrative controls are the second least effective controls. These include providing training and guidance for how to perform processes.
5. Personal Protective Equipment is the least effective control, however this relates more to occupational health and safety, for example using safety needles when staff administer insulin to PWDI to prevent needlestick injuries.

Step 4. Considering how the areas of variability can be used as potential leading indicators of safety for insulin management across ToC

Functions that were identified as having high levels of variability, either in their output or through their influence on other functions, were identified as potential targets for developing leading indicators.

In a mixed participation online seminar with twelve PWDI, caregivers and health professionals, two representative functions with significant variability were interrogated in detail. These functions were selected to be relevant to the wide range of stakeholders who would be attending the seminar, PWDI, their caregivers and healthcare professionals from both primary and secondary care. The potential for these functions as sites for development of new safety leading indicators was explored. The chosen functions represented one background function (*Empower PWDI to manage diabetes*) related to the structural factors required for successful outcomes, and one foreground function (*Arrange self-management of diabetes while in hospital*) related to supporting PWDI as care is being provided. During the seminar, structured discussions of the functions and their variability elicited suggestions for potential measures related to these functions. Comparisons with measures currently available and measurement gaps were also discussed. The participants considered what data would be needed to enable monitoring for issues in real-time and anticipation of potential risks.

Validation

Validation of the model occurred throughout the research project. The initial HTA was validated in two focus groups with healthcare professionals from primary and secondary care. Comments, suggestions and feedback were used to update the HTA, and this was used to identify the initial FRAM functions.

The FRAM model was tested using incident result data to ensure that journeys described in representative incident reports were reflected. The model was updated to incorporate additional steps identified in this data source.

An online seminar was held with PWDI, caregivers and primary and secondary health professionals and managers to present the findings of the analysis and to gauge consensus on the key background and foreground functions associated with safe insulin management during ToC. Suggestions for missing activities or factors and comments were requested. Two representative functions (one background and one foreground) were reviewed as potential targets for leading indicators.

Ethics

Ethics approval was obtained from the United Kingdom NHS Health Research Authority and Ethics Committee (22/EE/0155) and the University Ethics committee (28148). Amendments were obtained from both ethics committees to widen the recruitment of patients, healthcare professionals and to extend the deadline. All participants provided informed consent for participation.

8.3 Results

The boundaries of the FRAM model were defined during the HTA development, and the pathway began with the decision that a hospital admission was required. The pathway ended once the PWDI was transferred back home, initial reviews and referrals were made, and they were listed for routine follow-up.

A total of 59 functions were identified and modelled using the FRAM model visualiser software. This included 50 foreground functions and 9 background functions. The 59 functions identified are listed in Table 3. The model is included in Figure 22. The stages of ToC are separated to simplify the model; however, the pathways are non-linear. FRAM functions can occur in different sequences, concurrently, repeatedly and/or may not occur during the defined stages. For example, the function *Gather insulin information*, might not be performed before the PWDI

is admitted to hospital due to the severity of the illness or if the PWDI is not at home when they become ill. Caregivers, friends or relatives may subsequently retrieve insulin information on behalf of the PWDI and bring it to hospital after the PWDI has been admitted. *Monitor blood glucose levels* is performed repeatedly across the whole ToC pathway, however for pragmatic reasons this was included as part of the 'Admit to hospital' stage in the visual representation of the model.

Detailed tables for each function which include the definition and the components of each of the six aspects are included in Appendix VI. Further tables listing the functions, their definitions, how they vary, and functional couplings are included in Appendix VII.

Key factors impacting the variability of functions were related to the PWDI themselves, their individual needs and circumstances and the impact of their illness on their diabetes management. It was also introduced through organisational and environmental factors that impacted staffing and workload, and the level of diabetes knowledge of the staff providing healthcare. Further details about the variability of functions, and their coupling are described below for each of the six stages of ToC.

Table 3: The Functional Resonance Analysis Method functions identified, type of function and how they were identified.

Stage of transfer of care	Name of function	Type of function	How function was identified	Proposed target for leading indicators?
Preparation for admission	Decide hospital admission is needed	Foreground	HTA sub-task	No
	Pack belongings for hospital admission	Foreground	HTA sub-task	No
	Travel to hospital	Foreground	HTA sub-task	No
	Arrange ambulance	Foreground	During modelling	No
	Refer person with diabetes who uses insulin (PWDI) to hospital	Foreground	During modelling	No
	Handover diabetes care to hospital	Foreground	During modelling	Yes
	Gather insulin information	Foreground	HTA sub-task	Yes
Admit to hospital	Monitor blood glucose levels	Foreground	HTA sub-task	No
	Admit PWDI to hospital	Foreground	HTA sub-task	No
	Provide orientation to clinical area	Foreground	HTA sub-task	No
	Hospital-based clinical team accept patient	Foreground	During modelling	No

Stage of transfer of care	Name of function	Type of function	How function was identified	Proposed target for leading indicators?
	Confirm diabetes history	Foreground	HTA sub-task	Yes
	Arrange self-management of diabetes for PWDI	Foreground	During modelling	Yes
	Prescribe insulin	Foreground	HTA sub-task	Yes
	Check baseline observations	Foreground	HTA sub-task	No
	Treat presenting illness	Foreground	During modelling	No
Adjust insulin during acute illness	Develop diabetes inpatient treatment plan	Foreground	HTA sub-task	Yes
	Assess blood glucose levels	Foreground	HTA sub-task	No
	Treat hypoglycaemia	Foreground	HTA sub-task	No
	Treat hyperglycaemia	Foreground	HTA sub-task	No
	Source insulin(s) for inpatient use	Foreground	During modelling	No
	Refer to inpatient diabetes team	Foreground	HTA sub-task	No
	Assess and treat high ketone levels	Foreground	HTA sub-task	No
	Adjust insulin during acute illness	Foreground	HTA Task	No
	Administer routine insulin	Foreground	During modelling	No
Plan for discharge	Perform discharge assessment	Foreground	HTA sub-task	Yes
	Identify insulin needs for discharge	Foreground	HTA sub-task	No
	Create insulin plan for discharge	Foreground	HTA sub-task	Yes
	Identify equipment needs for discharge	Foreground	During modelling	No
	Arrange discharge supply of insulin & equipment	Foreground	HTA sub-task	No
	Provide education to PWDI or carer	Foreground	HTA sub-task	Yes
Handover medical care	Provide discharge letter	Foreground	HTA sub-task	Yes
	Discharge to primary care	Foreground	During modelling	No
	Make primary care referrals	Foreground	HTA sub-task	Yes
	Travel home	Foreground	HTA sub-task	No
Resume insulin management in the community	Secondary care diabetes team make follow-up phone call	Foreground	HTA sub-task	No
	Manage diabetes at home	Foreground	During modelling	Yes
	Primary care team accept referral	Foreground	During modelling	No
	Identify hospital discharge	Foreground	HTA sub-task	No
	Reconcile insulin in primary care	Foreground	HTA sub-task	No

Stage of transfer of care	Name of function	Type of function	How function was identified	Proposed target for leading indicators?
	General Practice surgery review diabetes	Foreground	During modelling	No
	PWDI follow-up in primary care	Foreground	HTA sub-task	No
	Review discharge letter in primary care	Foreground	HTA sub-task	Yes
	Request insulin/equipment prescription in primary care	Foreground	During modelling	No
	Supply insulin and equipment in primary care	Foreground	HTA sub-task	No
	Prescribe insulin and equipment in primary care	Foreground	During modelling	No
	Seek assistance after discharge	Foreground	During modelling	Yes
	Adjust insulin following discharge	Foreground	During modelling	Yes
	Provide authority to administer insulin for district nurses	Foreground	During validation	No
	Review referral in primary care	Foreground	During validation	No
Background functions	Provide diabetes framework	Background	During modelling	Yes
	Empower PWDI management of diabetes	Background	During modelling	Yes
	Healthcare organisational capacity	Background	During modelling	No
	Manage workload	Background	During modelling	No
	Provide transfer of care infrastructure	Background	During modelling	Yes
	Maintain information technology infrastructure	Background	During modelling	Yes
	Manage stock of insulin and equipment	Background	During modelling	Yes
	Provide appropriate competent staff	Background	During modelling	Yes
	Train staff around diabetes and insulin use	Background	During modelling	Yes

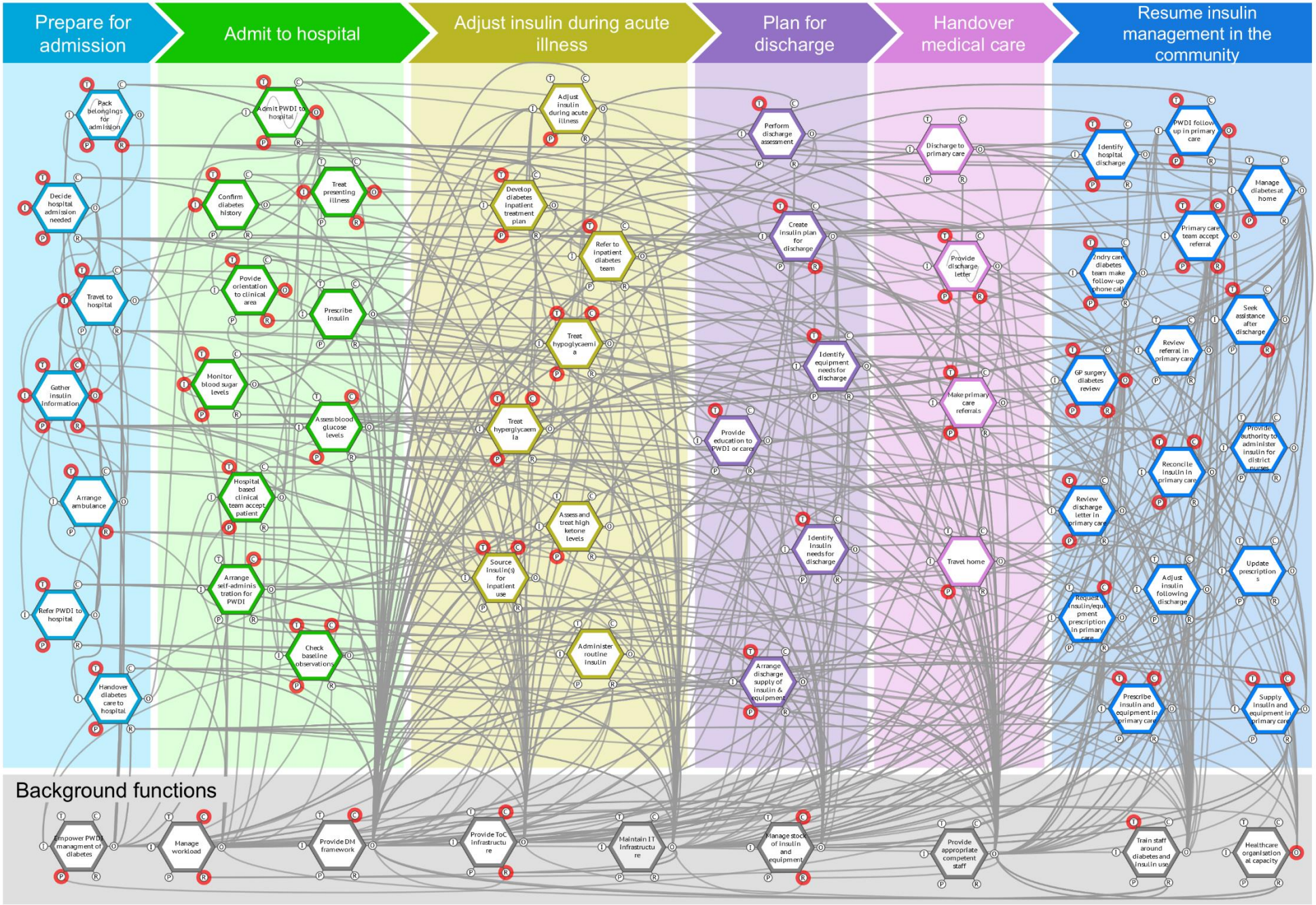


Figure 22: The full Functional Resonance Analysis Method (FRAM) model of insulin management during transfer of care including background functions.

8.3.1 Background functions

The nine background functions identified (see Table 3) provided the infrastructure to enable insulin management during ToC. These functions underpinned the whole process, and gaps in these background functions will impact the performance of foreground functions across the ToC pathway. Outputs of these functions were often controls or resources required for other tasks, therefore they were fundamental to safe outcomes. Gaps in background functions may have an amplified effect across the whole ToC pathway due to their widespread impact on the outcomes of foreground functions.

Empower PWDI management of diabetes

Empowering the PWDI to manage their own diabetes was essential for safe ToC. Once trained, the PWDI or their caregiver can take ongoing responsibility for managing diabetes. The PWDI's self-management of their diabetes and insulin was a key factor and resource for the success of many functions across the whole ToC journey.

Healthcare organisational capacity* and *Manage Workload

These two background functions are closely linked. *Healthcare organisational capacity* allows sufficient staff, hospital beds and appointments for PWDI to be seen when needed. As hospital capacity is limited or when demand exceeds the capacity, the function *Manage workload* is necessary to support staff within the organisation to manage and prioritise their work to ensure that urgent needs are met, and care is provided.

Provide appropriate competent staff

Linked to *Healthcare organisational capacity* is *Provide appropriate competent staff*, which requires staff to have the right skill mix and credentials to perform their tasks, for example prescribing and providing expert advice on diabetes management.

Train staff around diabetes and insulin use

The function *Train staff around diabetes and insulin use* provides staff with the competency to understand the requirements for managing insulin during ToC and make the adjustments needed to ensure care was provided safely. This function was key in providing the output 'Staff diabetes knowledge,' which was an administrative control for the successful outcomes for many functions across the whole ToC pathway.

Provide diabetes framework

Another background function, *Provide diabetes framework,* represents the development and implementation of guidelines, processes and directives for how insulin should be managed

across ToC, including how diabetes specialist teams should be included. For example, this framework outlines the provision and components of both inpatient and outpatient diabetes teams, and how they function together. One of the outputs of this function is the implementation of diabetes policy and guidelines. These guidelines act as an administrative control for many foreground functions across ToC.

Manage stock of insulin and equipment

Manage stock of insulin and equipment represents how the use of these items is prescribed through formularies which guide choice of agents and products. Organisations within the region must have systems in place to make sure these items are available. An example of variability in this function is where a national shortage of a particular insulin preparation requires an organisation to make changes to their choice of agents and/or devices.

Provide ToC infrastructure

This function describes the infrastructure required to support ToC, for example through admission pathways, acute admission units, triaging systems and mechanisms to request ambulances, or advice telephone call centres.

Maintain IT infrastructure

Providing and maintaining IT infrastructure underpins prescribing and communication within and across care settings. Staff require access to multiple IT systems and devices, and delays in performing functions can occur when there is poorly functioning hardware. An output of this function, EPR configuration, acts as a control for some functions during ToC.

8.3.2 Foreground functions by ToC stages

Preparing for Admission

Functions

This stage of the FRAM model begins with the recognition that the PWDI is unwell and needs admission to hospital. In preparing to go to hospital, relevant information and belongings are gathered to be taken to the hospital.

Functions related to this stage rely on the resources produced by the background functions including ToC infrastructure, and competent, trained staff who prioritise sick patients to ensure that the most ill are seen soonest. In terms of foreground functions, PWDI who are empowered to manage their own diabetes, and well enough to do so, can bring relevant knowledge, documentation and belongings with them to hospital. In contrast, where PWDI are unable to

provide information about their diabetes management, hospital staff either must find this information from other means, or use guidelines to make alternative arrangements, such as weight-based doses or variable rate intravenous insulin infusions[1].

Controls in place intended to support functional outputs related to preparing for admission include ToC guidelines and pathways and training, both administrative controls. The responsibility for performing each activity in this phase of ToC depends on the pathway being followed, and often there are no written guidelines to follow. GPs tend to have knowledge of the admission pathways to local hospitals gained through experience and mentorship. They may direct people to attend the Emergency Department, arrange an ambulance or speak to an acute admissions unit over the telephone. PWDI have the option to attend the Emergency Department directly, call an ambulance or seek advice from NHS 111, the online or telephone triaging and advice service.

Variability

Variability in preparing for admission arises from the multitude of different circumstances that may lead to a decision to attend hospital. Therefore, many of the functions shown in Figure 22 can be omitted or delayed, or not completed accurately depending on the specific situation and who is available to gather and provide information. The individual situation of the PWDI, their illness and who makes the decision that a hospital admission is required will all impact on later functions, such as arranging ambulances, handing over diabetes care or admitting the PWDI to hospital. For example, a sudden illness when outside the home may necessitate attendance by an ambulance and emergency admission without any belongings. Moreover, the PWDI may not be able to provide information about their diabetes and insulin management. Conversely, a PWDI may be reviewed by a GP in their home with a caregiver or family member present to assist in gathering belongings. The GP may be able to provide information to the ambulance and hospital about diabetes and insulin management.

Functional coupling

The functions of *Packing belongings for admission*, *Handover medical care to hospital* and *Gather insulin information* impact the later functions of *Confirm diabetes history* and *Develop an inpatient diabetes plan*. Successful identification that a PWDI has diabetes and how to

[1] A variable rate intravenous insulin infusion is an infusion of insulin given alongside glucose and other fluids, with regular measurement of blood glucose levels. The amount of insulin administered per hour is guided by blood glucose levels.

manage this is supported by these pre-admission functions, see Figure 23 for the functions involved in this stage of ToC.

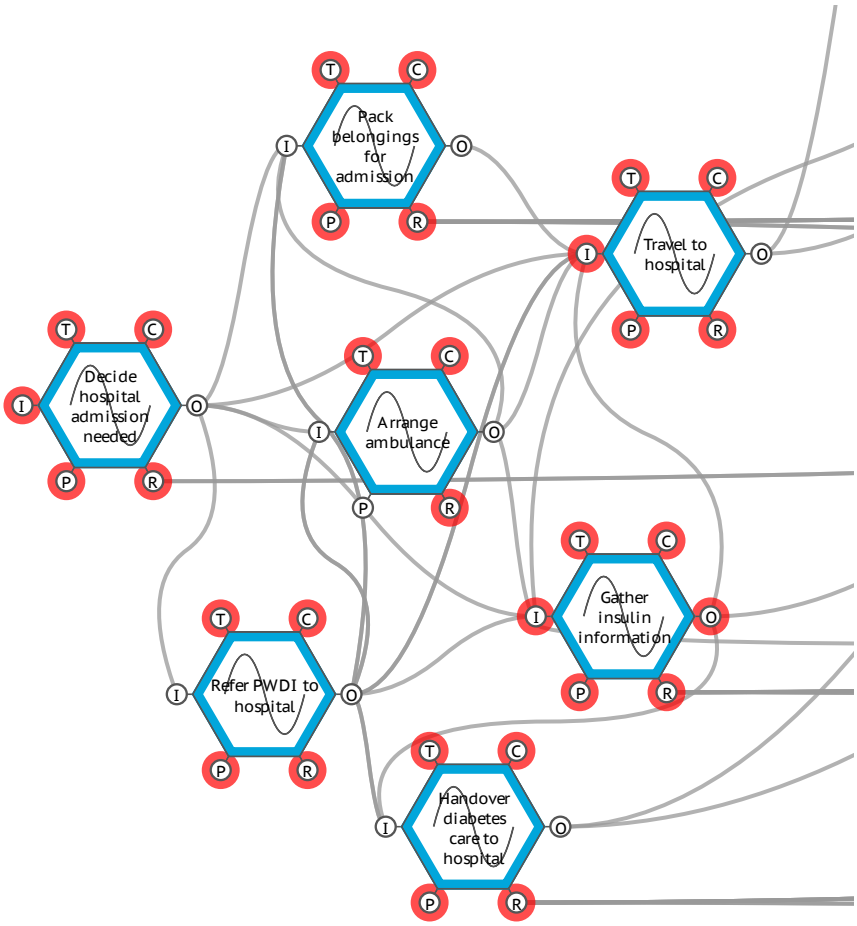


Figure 23: Section of Functional Resonance Analysis Method (FRAM) model representing preparation for admission.

Admit to hospital

Functions

During this stage of ToC, the PWDI is formally admitted to hospital and baseline investigations are done. The presenting symptoms are managed with treatment of life-threatening illness taking priority over all other activities. Staff identify key information about the PWDI, including diabetes history and management and current glucose control. Ongoing treatment requires a hospital-based team to take over medical responsibility for treatment and care. To ensure diabetes is managed safely, insulin is prescribed, and where possible and appropriate, the PWDI enabled to self-manage their diabetes during their admission, see Figure 24 for an overview of this stage.

Background functions required for successful admission to hospital include providing trained staff who can prioritise their workload and Electronic Health Records (EHR) containing

information about diabetes treatment. The skills and knowledge of PWDI and healthcare professionals are also critical resources.

EHR can function as an engineered control, supporting intended outcomes, where programmed prescribing and nursing care packages are available to guide healthcare staff to treat high-risk conditions such as hypoglycaemia. Other administrative controls for how these functions are performed include the provision of protocols, guidance, and diabetes training.

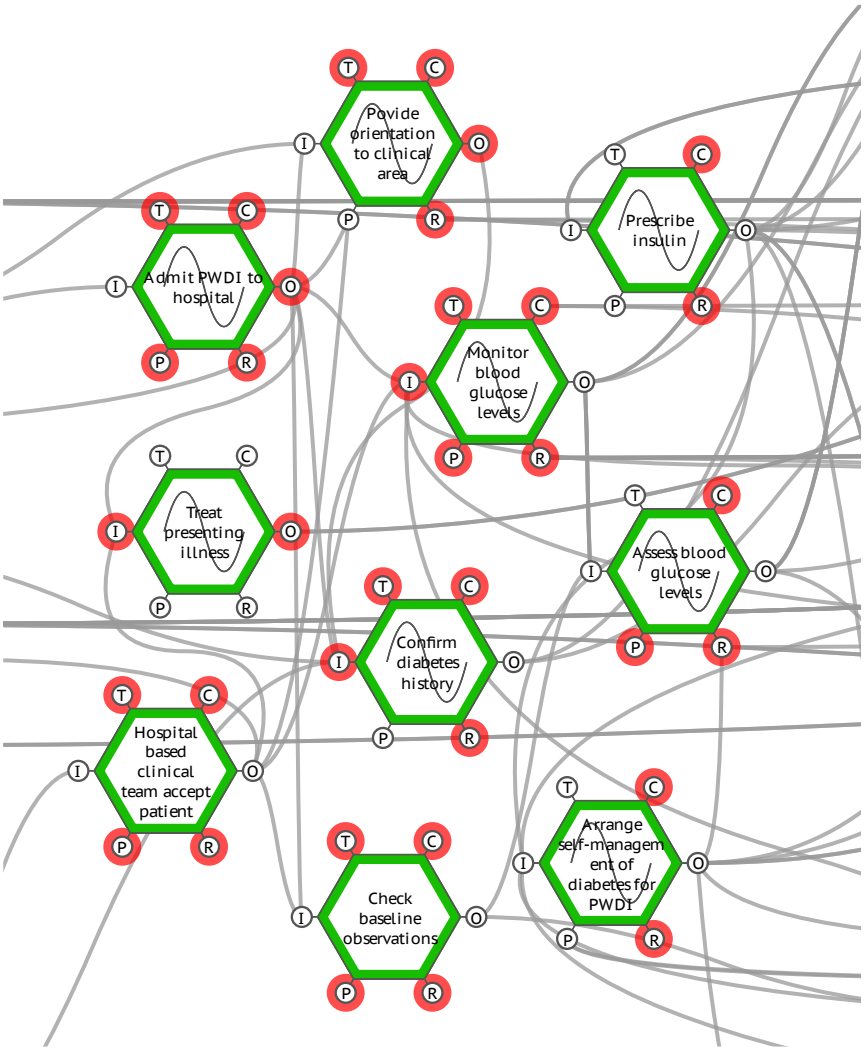


Figure 24: The admission to hospital section of the Functional Resonance Analysis Method (FRAM) model.

Variability

Many of the functions in this stage of ToC can vary. The two functions *Confirm diabetes history* (including identifying usual doses of insulin), and *Prescribe insulin* for inpatient administration may be delayed, omitted or inaccurate. Similarly, monitoring of blood glucose levels and identification of abnormal results may also vary. The function *Arrange self-management of diabetes for PWDI* may be delayed or omitted.

Functional coupling

The functions to *Admit to hospital*, *Confirm diabetes history* and *Prescribe insulin* are all impacted by the upstream functions that occur during preparation for admission. The ability for the admission activities to be completed successfully is greatly enhanced by the successful completion of earlier functions, such as *Handing over diabetes information*, *Gather insulin information* and where the function *Refer PWDI to hospital* has been performed by another healthcare professional. With greater information available, the hospital-based healthcare professionals can more accurately perform the functions *Confirm diabetes history, Prescribe insulin* and *Develop diabetes inpatient treatment plan*. This can be seen in Figure 25. *Develop diabetes inpatient treatment plan* is a function that is repeated throughout the PWDI admission and must be done before insulin is prescribed. It is included in the third phase of ToC, 'Adjust insulin during acute illness', because as the PWDI's illness progresses and more information becomes available, this is the time when the plan can become better informed.

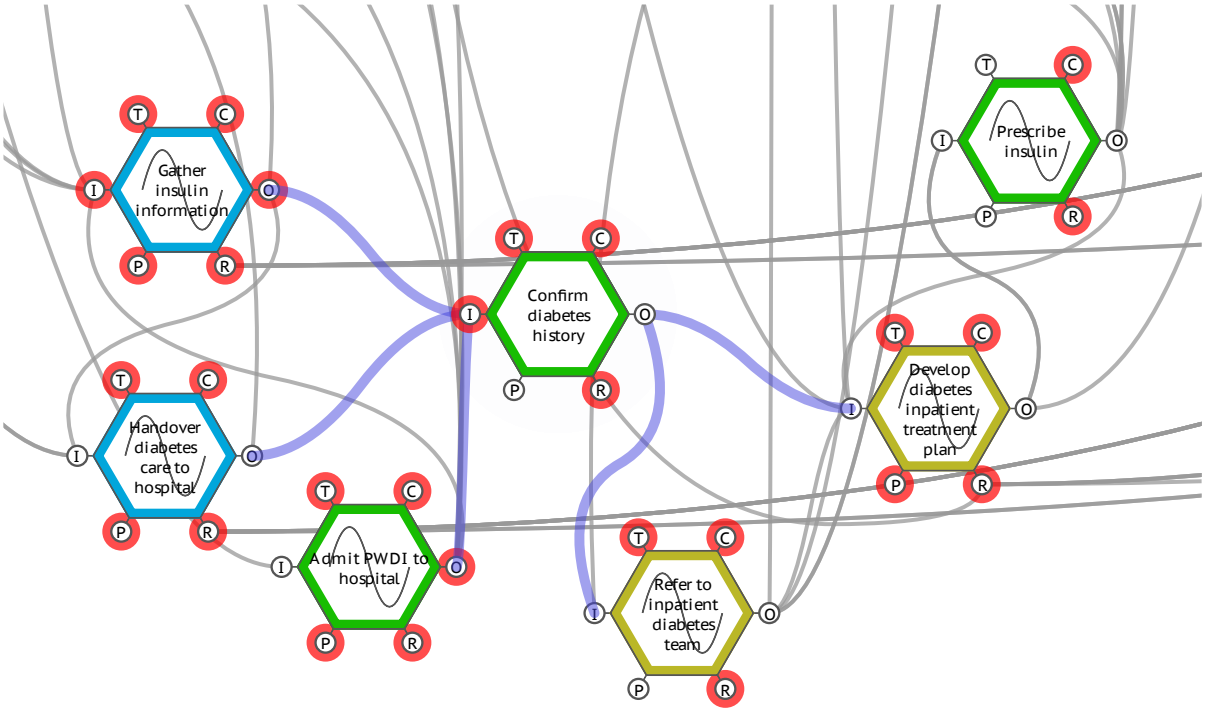


Figure 25: Functional couplings between functions impacting confirmation of diabetes history, and how this impacts some later functions.

Arrange self-management of diabetes for PWDI while in hospital promotes the success of later functions, as it acts as a resource for several later functions. Where formal processes to prescribe and arrange self-management of insulin and diabetes do not occur, this may still happen informally when the PWDI gives themselves an insulin dose to prevent harm from delayed administration.

Adjust insulin during acute illness

Functions

This stage of ToC, illustrated in Figure 26, requires those involved to develop an understanding how the PWDI usually manages their diabetes. This information is then used to support adjustment of insulin doses to account for changes in blood glucose levels related to illness, activity levels and changes in diet (for example, limited carbohydrates consumed due to symptoms of illness such as vomiting or where a PWDI must fast before surgery). The impact of other medications on blood glucose levels is also considered, for example corticosteroid medications used in the treatment of some infections, inflammation and cancer can lead to significant increases in blood glucose levels for the duration of treatment. As the doses of corticosteroids change to reflect the stages of treatment, glucose levels can fluctuate, and insulin doses require adjustment.

To manage these factors an inpatient diabetes plan is developed and adjusted. Often assistance is sought from the inpatient specialist diabetes team.

The availability of trained staff is a key resource for these functions, as they require skills in reviewing diabetes management in the context of blood glucose levels and the various factors impacting diabetes control and developing a plan for insulin doses. The PWDI's level of empowerment and ability to self-manage is an additional resource, as they often have knowledge and ability to adjust their own insulin appropriately.

Administrative controls in place to support the success of this stage of ToC include training to provide skills and knowledge for staff. Policies and guidelines provide additional administrative controls as they describe how to manage insulin during acute illness and promote self-administration. EHR systems can act as engineered controls if protocols or policies are programmed into the system to guide prescribing or nursing activities.

Variability

Successful outcomes in this stage are heavily influenced by the outcome of background functions including the availability of staff, levels of diabetes training and the diabetes frameworks in place. These three factors are key to supporting staff to identify insulin needs and facilitating development of diabetes plans by having staff available with the right skillset, and by providing guidelines to support decision making. For example, a key group of staff with specialist and extensive knowledge in managing diabetes and providing education are the diabetes specialist team. The availability of the diabetes specialist team varies with the day of

the week and time of day, and the team accept referrals based on criteria within the organisation's diabetes framework. Therefore, at some times of the day or week, staff may have limited access to this resource for advice or support for managing PWDI diabetes.

The functions in this stage are repeated as often as needed, and often across multiple stages of the ToC pathway. In particular, the diabetes treatment plan must be reviewed as the PWDI's treatment progresses, and whenever blood glucose levels are reviewed.

It is possible for all these activities to be delayed or omitted, and they can be performed inaccurately, which will impact the output of each function.

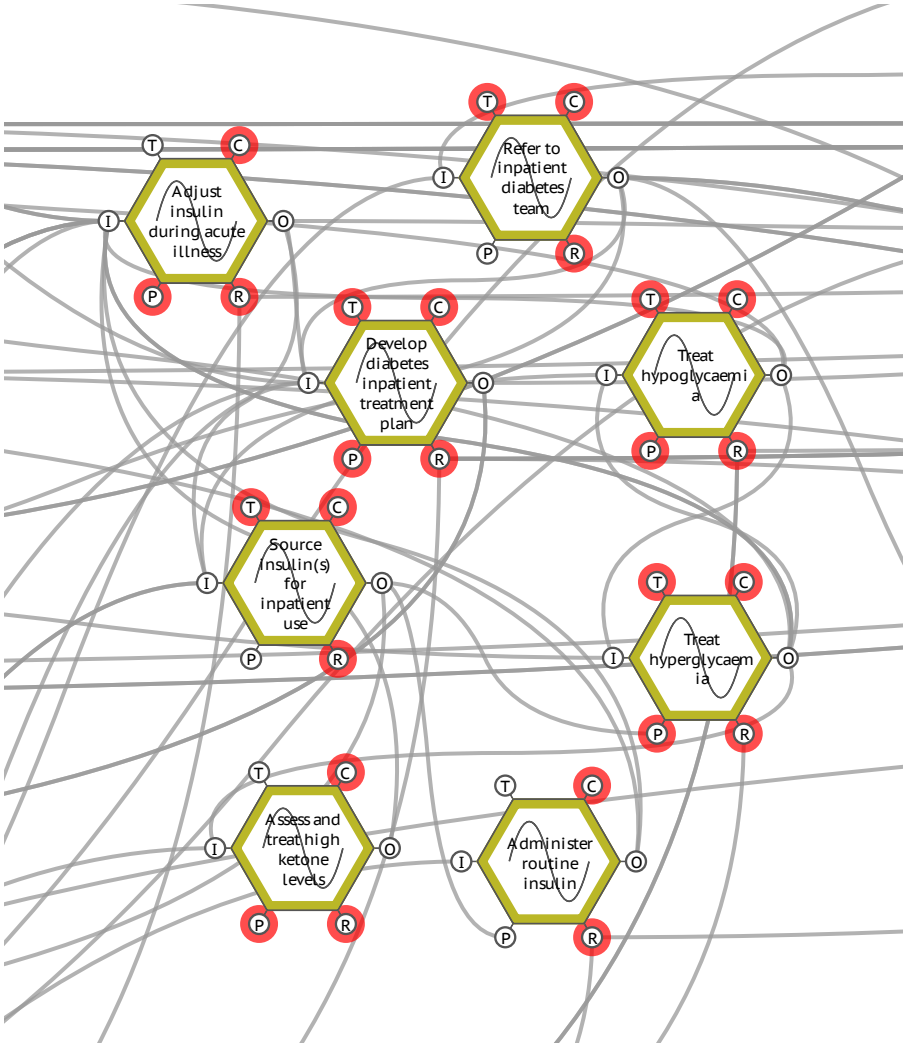


Figure 26: The 'adjust insulin during acute illness' section of the Functional Resonance Analysis Method (FRAM) model.

Functional coupling

The function *Develop diabetes inpatient treatment plan* is a key function for the performance of many other functions. It is closely linked to *Prescribe insulin*, which then impacts many other later functions involved in ToC, see Figure 27. The link between the two functions is circular,

with the prescribed insulin and its impact on blood glucose levels contributing to the diabetes plan that is developed, which in turn impacts what is prescribed.

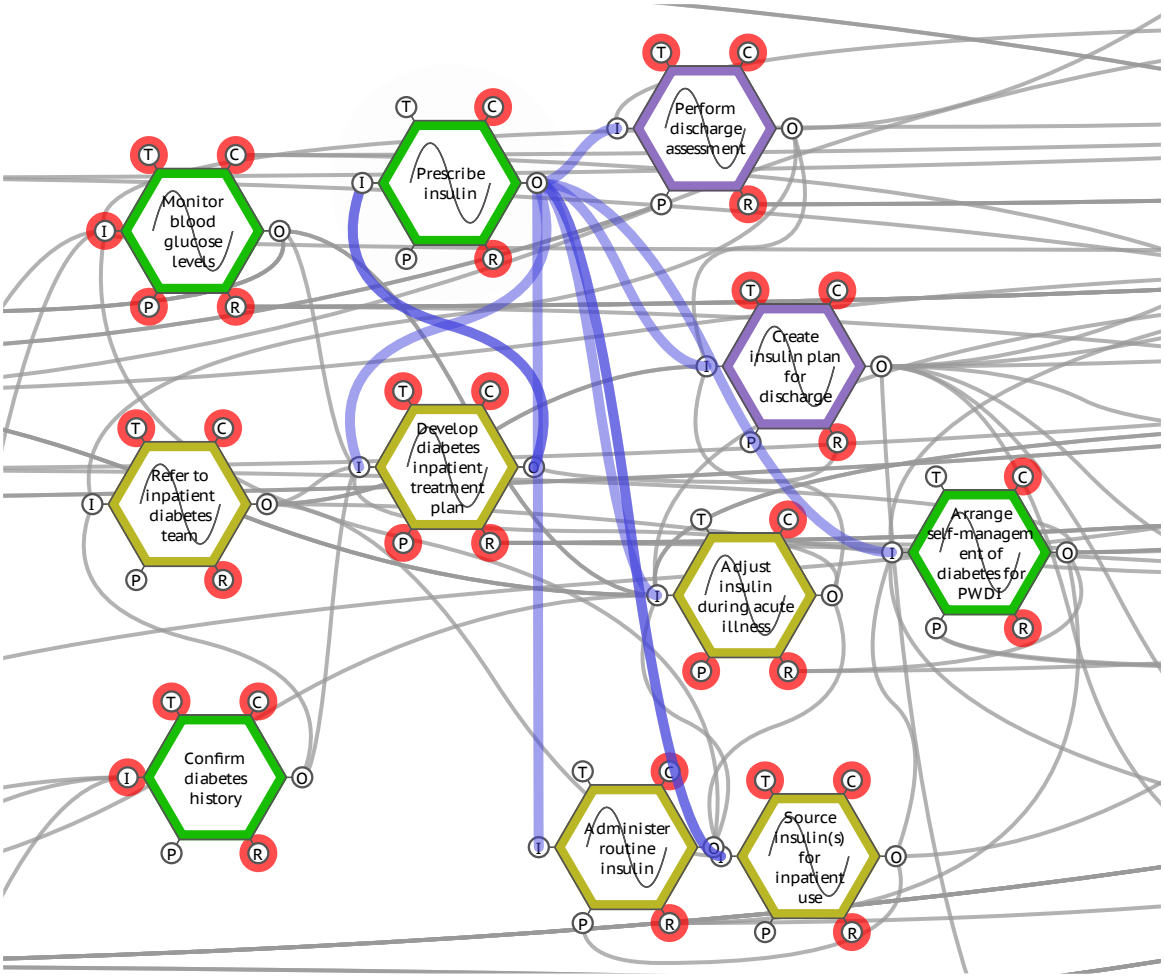


Figure 27: Close coupling between 'Prescribe insulin' and 'Develop diabetes inpatient treatment plan'.

The success of the inpatient diabetes treatment plan may be improved if the inpatient diabetes team have been involved. Team availability directly impacts the function *Prescribe insulin* and is a resource that impacts on the success of the later function *Create insulin plan for discharge* (Figure 28). As previously mentioned, the functions associated with the admission to hospital provide key information to hospital-based healthcare staff and are important factors in the successful performance of *Develop diabetes inpatient treatment plan*. In addition, another two functions *Refer to the inpatient diabetes team*, and *Assess blood glucose levels*, also support the success of the function *Develop diabetes inpatient treatment plan*.

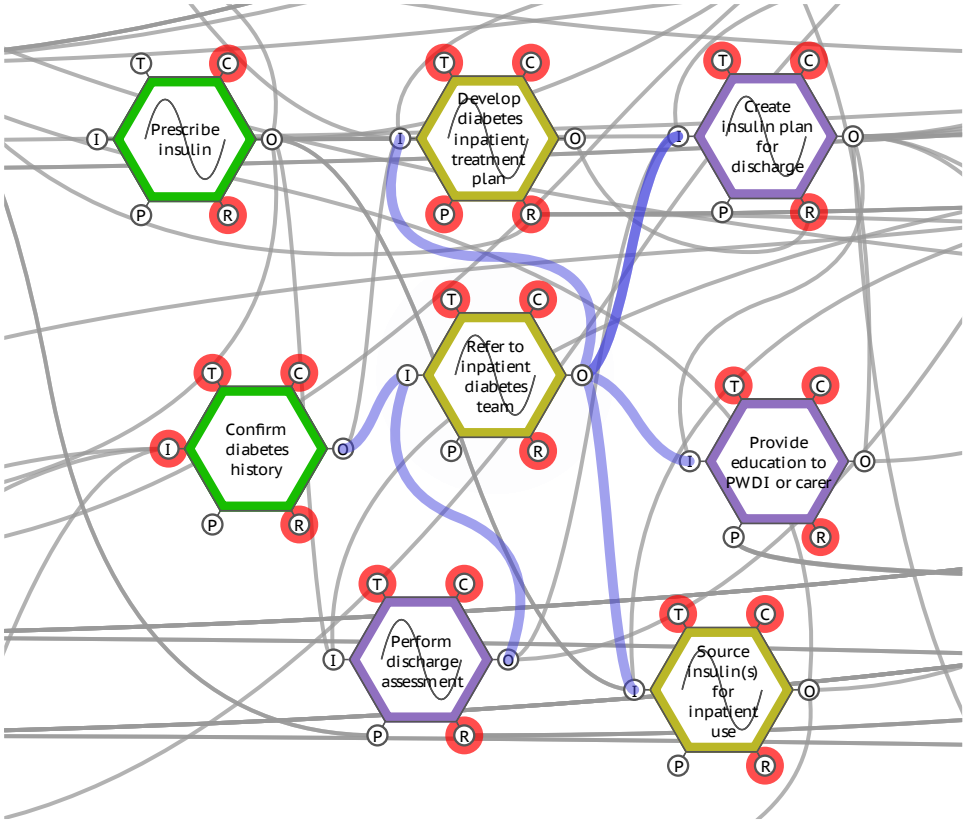


Figure 28: Coupling of referral to diabetes team and impact on the other functions of 'Developing diabetes inpatient treatment plan' and 'Create insulin plan for discharge'.

Plan for discharge

Functions

Planning for discharge begins early after admission but is included visually in this latter part of the model. For successful outcomes for this stage of ToC, the social and physical needs of the PWDI, their support networks and ability to manage insulin following discharge are considered and planned for. This stage of the ToC model can be seen in Figure 29.

A diabetes discharge plan is developed, taking into consideration inpatient blood glucose control, potential changes in diet after discharge, and changes to medications. The diabetes plan outlines doses of insulin after discharge and a target blood glucose range. It includes planned actions for how to manage low or high blood glucose levels.

Supplies of the insulin(s) and equipment required to support administration and blood glucose monitoring are arranged.

Education is tailored to the PWDI's previous experience with insulin. The aim of education is to empower self-management of all aspects of diabetes and insulin administration after discharge and usually includes the following topics:

- Confirming agreement with and understanding of the diabetes plan
- How to monitor glucose levels
- How to identify and treat hypoglycaemia
- When and how to seek advice if blood glucose levels are outside the desired range (as per diabetes plan)
- How to use the insulin device to administer doses
- How to adjust doses according to the diabetes plan
- How to maintain sufficient insulin and equipment supplies
- The need to attend appointments for review
- How to store insulin appropriately in fridge until cartridge/pen is in use
- What action to take if the PWDI becomes unwell (known as sick day rules)
- How to dispose of needles and empty devices

While planning for discharge, any needs for primary care support are identified and the feasibility of diabetes plans are considered. Insulin doses and the diabetes plans are adapted to enable district nurse administration by changing insulins so that the doses can be given once a day if possible, or if unavoidable, twice a day.

The administrative controls in place to support these functions are guidelines, formularies and the availability of competent and trained staff. Education leaflets provide resources to support staff and to provide education to PWDI or carer.

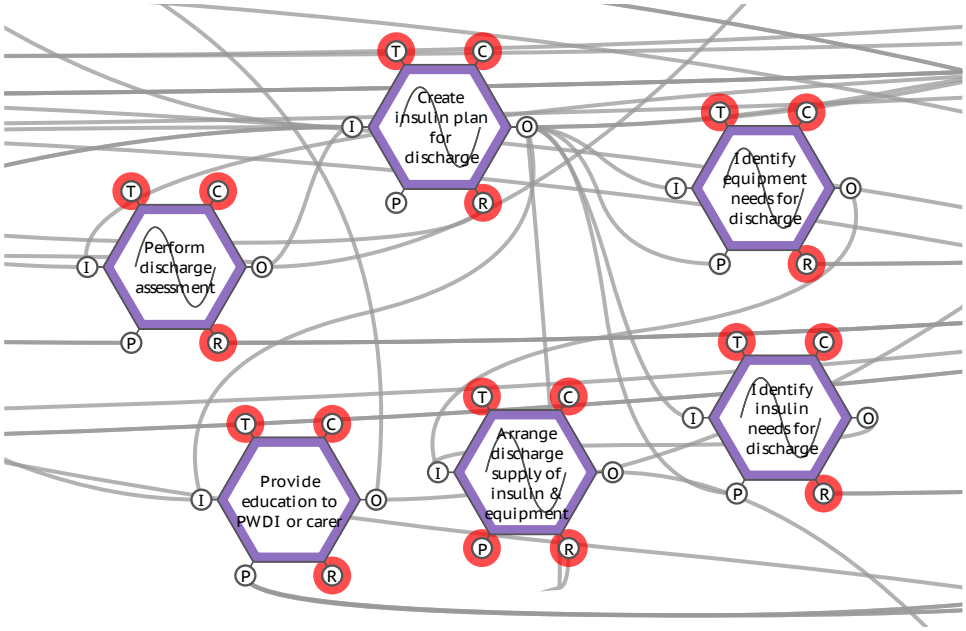


Figure 29: The 'Plan for discharge' section of the Functional Resonance Analysis Method (FRAM) model.

Variability

The functions within this stage can vary due to the availability of trained staff. Delays may develop when workload prioritisation shifts staff away to deal with the most urgent healthcare needs. The level of PWDI empowerment and their knowledge of diabetes management can influence how successfully these functions are performed. Where PWDI can provide detailed information about their diabetes management and discharge needs, this can support the success of other functions to prepare for discharge.

Inaccurate performance of these functions may mean that the post discharge needs of the PWDI are not recognised and/or planned for.

Functional coupling

The functions *Create insulin plan for discharge*, and *Identify insulin needs for discharge* and *Provide education to PWDI or carer* were all linked to the success of other functions. Creating an insulin plan for discharge is dependent on the success of multiple previous functions, including those to adjust insulin during admission, referral to the inpatient diabetes team, the inpatient diabetes plan and the results of the discharge assessment.

The discharge insulin plan developed impacts multiple other functions later in the process, including *Provide education to PWDI or carer*, *Identifying Insulin* and *equipment needs for discharge*, and is key in enabling the PWDI to manage their diabetes at home, see Figure 30. The provision of education to PWDI or carer impacts the successful outcomes in the subsequent stages of ToC.

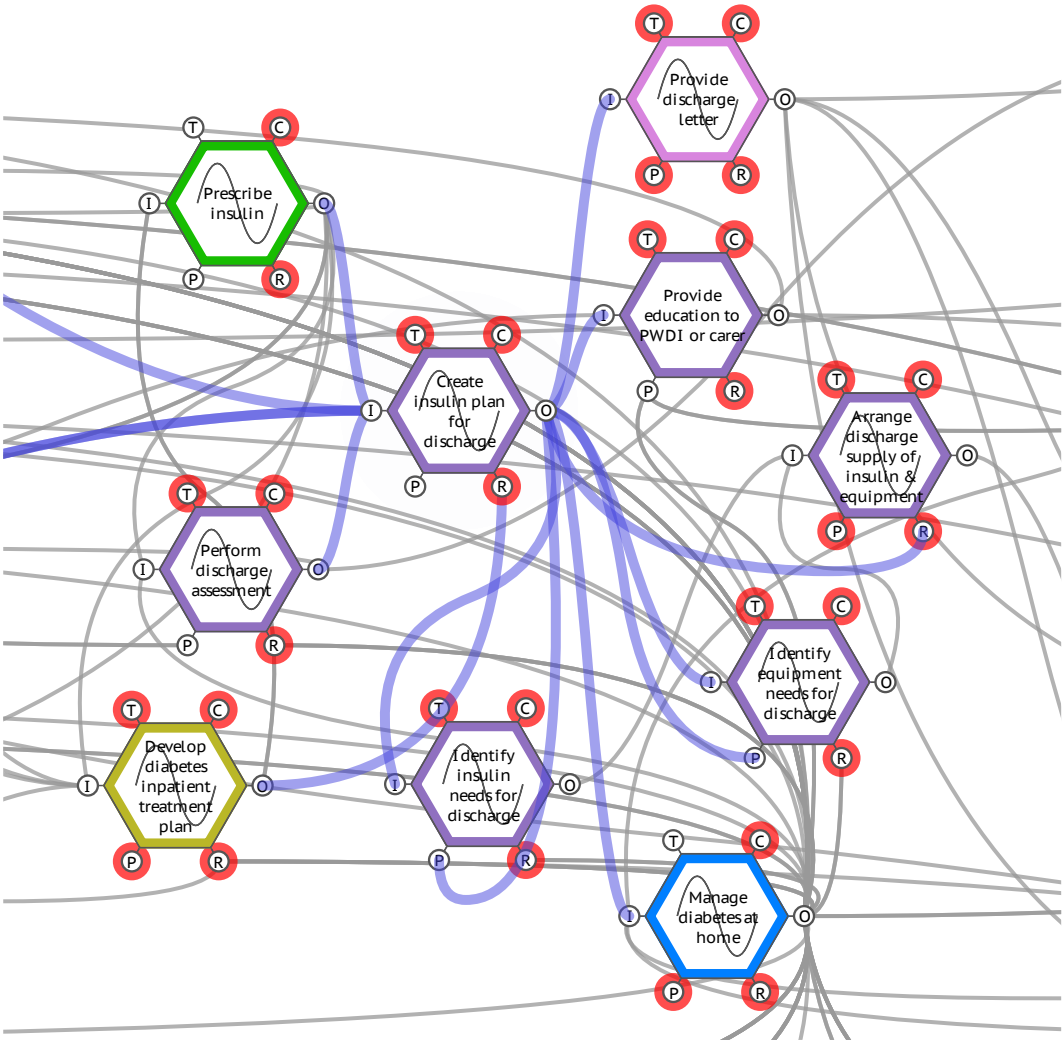


Figure 30: Functional couplings for 'Create insulin plan for discharge'.

Handover Medical Care

Functions

The process of handing over medical care involves writing and sharing the discharge plan and prescription along with making relevant referrals. It also includes providing the PWDI and/or their caregivers with insulin and equipment and a copy of the discharge letter, see Figure 31.

Discharge systems that enable the discharge letter to be shared, and the systems in place to support referrals are key engineering controls to ensure this stage of ToC is successful. IT systems and communication channels are resources that support these functions.

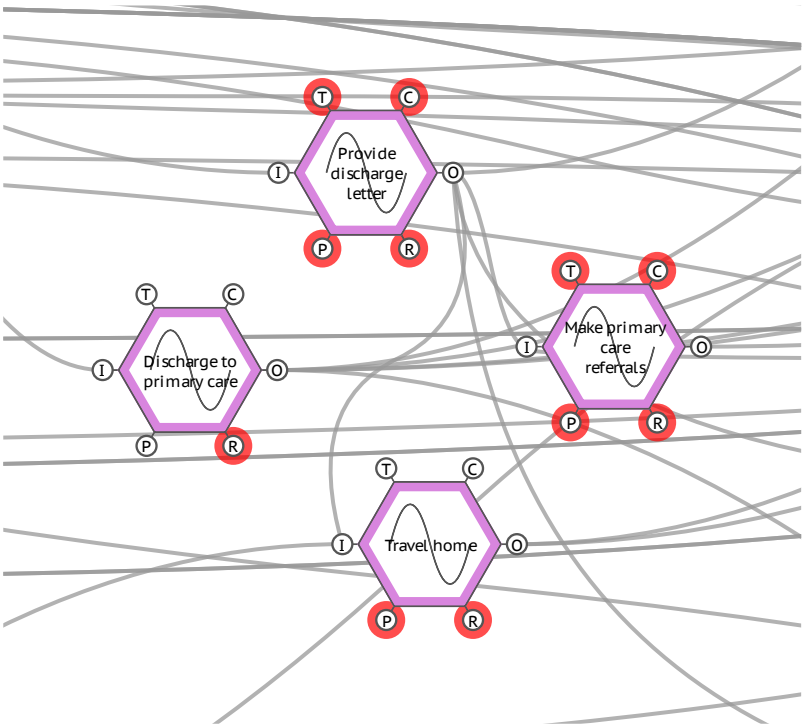


Figure 31: The 'Handover medical care' section of the Functional Resonance Analysis Method (FRAM) model.

Variability

Variability in the output of these four functions largely relates to the background functions that create the right conditions for them to succeed. This particularly relates to ToC infrastructure which guides discharge pathways, communication of information and how referrals are made.

Sufficient provision of well-functioning IT infrastructure supports this stage as communication and referrals are predominantly made electronically.

Provide discharge letter and *Discharging PWDI to primary care* were supported by EHR programming which can result in less reliance on staff to remember or know how to perform these tasks. The quality, accuracy and timeliness of discharge letters may vary which can impact the subsequent stage of ToC.

Primary care referrals may also be unsuccessful or delayed. This is more likely with this function than the others, as performing referrals requires staff to identify that a referral is needed, identify the correct mechanism for creating the referral and perform this task accurately.

Functional coupling

The function *Make primary care referrals* is impacted by the success of previous functions including *Perform discharge assessment* and the two functions to identify insulin and

equipment requirements on discharge. It is during the performance of these functions that the need for referral may be detected. Therefore, these are key to initiating the referral process.

The function of providing the discharge letter is required for many subsequent functions, and it is the key mechanism for GP surgeries to identify that a PWDI has been in hospital.

Resuming insulin management in the community

Functions

To resume insulin management in the community, the PWDI must return home equipped with the knowledge, ability and supplies to manage their diabetes and insulin. The GP becomes once more clinically responsible for diabetes management and the diabetes plan is shared with the GP electronically within the discharge letter.

The discharge letter is received by the GP surgery, and an administrative assistant identifies it, links it to the relevant persons medical record and assigns a clinical member of staff to review the contents, for example a doctor or a pharmacist. The clinical member of staff then updates the PWDI's medical record with the details from the hospital discharge letter, querying with the discharging team where there are discrepancies.

Follow up needs are identified, and arrangements made to address these. For district nurses, the GP provides a document containing the authority for the nurses to administer the insulin doses. The doses are updated to match those prescribed on discharge from hospital.

Where other referrals have been made by secondary care, for example to the primary care diabetes team, these are identified and arranged.

When the PWDI requires further supplies of insulin and/or equipment, these are requested from the GP who generates a prescription that is sent to a nominated community pharmacy to supply.

If the PWDI, caregiver, community pharmacist or diabetes team identify issues with the PWDI's diabetes management, the GP will be contacted to adjust the diabetes plan and insulin doses after reviewing the patients plan and blood glucose monitoring results.

This section of the care pathway is shown in Figure 32.

There are few effective controls in place to support these functions. There are guidelines (administrative controls) that describe how medication reconciliation should be performed following discharge from hospital. The knowledge and experience of trained staff (another

administrative control) are key resources for identifying PWDI who have been discharged from hospital and their follow-up requirements.

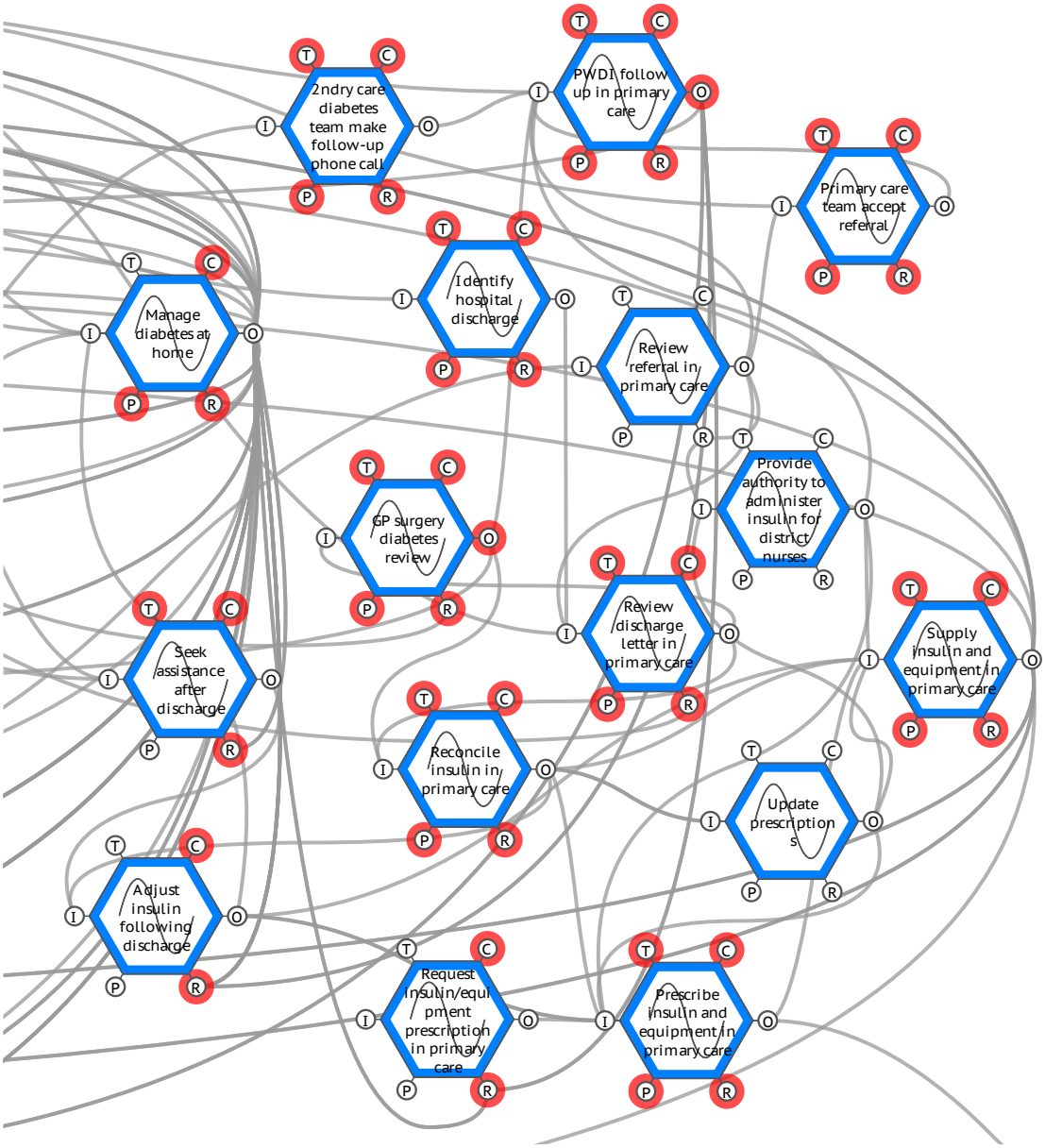


Figure 32: The 'Resuming insulin management in the community' section of the Functional Resonance Analysis Method (FRAM) model.

Variability

Variability can occur in the timing and precision of many of these functions, for example, there may be a delay in receiving or identifying the discharge letter or referrals in primary care. Such delays may be due to the output of background functions for the provision of sufficient, trained staff who can prioritise their workload. Staff require the skills to perform the functions accurately and the opportunity to perform them on time. If there are insufficient staff, there is a

danger that functions may be omitted or delayed due to prioritisation of other work. If staff do not have sufficient training, then the accuracy of tasks could be impaired, for example the task *Reconcile insulin in primary care*, requires a staff member to compare the pre-admission insulin prescriptions with those on the discharge documentation, clarify any undocumented discrepancies and update the PWDI's medical record with the new information. Staff who have not been trained to perform this activity may miss changes in therapy inadvertently.

Functional coupling

Post discharge functions require successful completion of earlier functions, particularly accurate and timely completion of *Provide discharge letter*, and *Make primary care referrals*. The function *GP surgery diabetes review* is key to later functions (*PWDI follow up in primary care* and *Reconcile insulin in primary care*) and provides an opportunity to make primary care referrals if this has not yet been performed.

The function *Manage diabetes at home*, is central to the success of many other functions across the ToC pathway, see Figure 33. In the 'Resume insulin management in the community' stage of ToC, it is coupled with *Adjust care after discharge*, which is key for safe insulin use after a hospital admission and is required for the function *Seek assistance after discharge* to proceed. Key upstream functions that impact on the success of this function include *Provide education to PWDI or carer*, *Create insulin plan for discharge*, and *Discharge to primary care*.

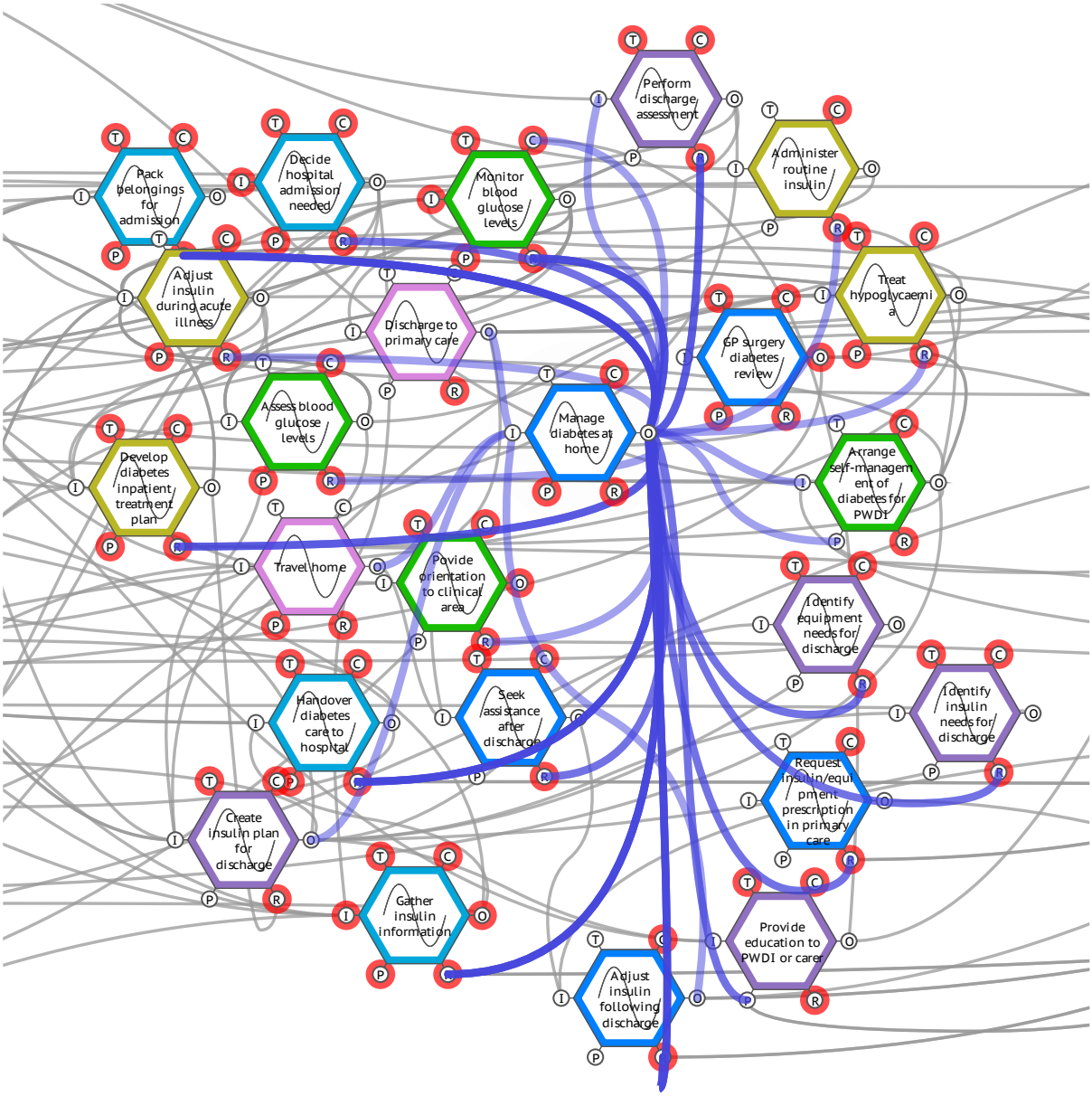


Figure 33: Functional couplings for 'Manage diabetes at home'.

8.3.3 Key areas of variability

There were fifteen functions identified where variability in their outcomes (due to lack of effective controls or through coupling) were key to successful outcomes for insulin management during ToC. These functions are highlighted in Figure 34, the functions and their definitions can be seen in Table 4. Six background functions were identified that had the greatest impact on the variability of the foreground functions.

These 21 functions were shared during an online seminar with twelve key stakeholders who agreed that these are essential for safe management of insulin during ToC. Two representative functions, one foreground and one background were then used as examples to explore whether

they can be developed into leading indicators. These two functions *Arrange self-management of diabetes for PWDI* (foreground function) and *Empower PWDI management of diabetes* (background function), were chosen to be relevant to the widest number of seminar participants, particularly PWDI and their caregivers, along with hospital and primary care-based staff. An example of a function demonstrating the potential causes and consequences of variability is demonstrated in Figure 35.

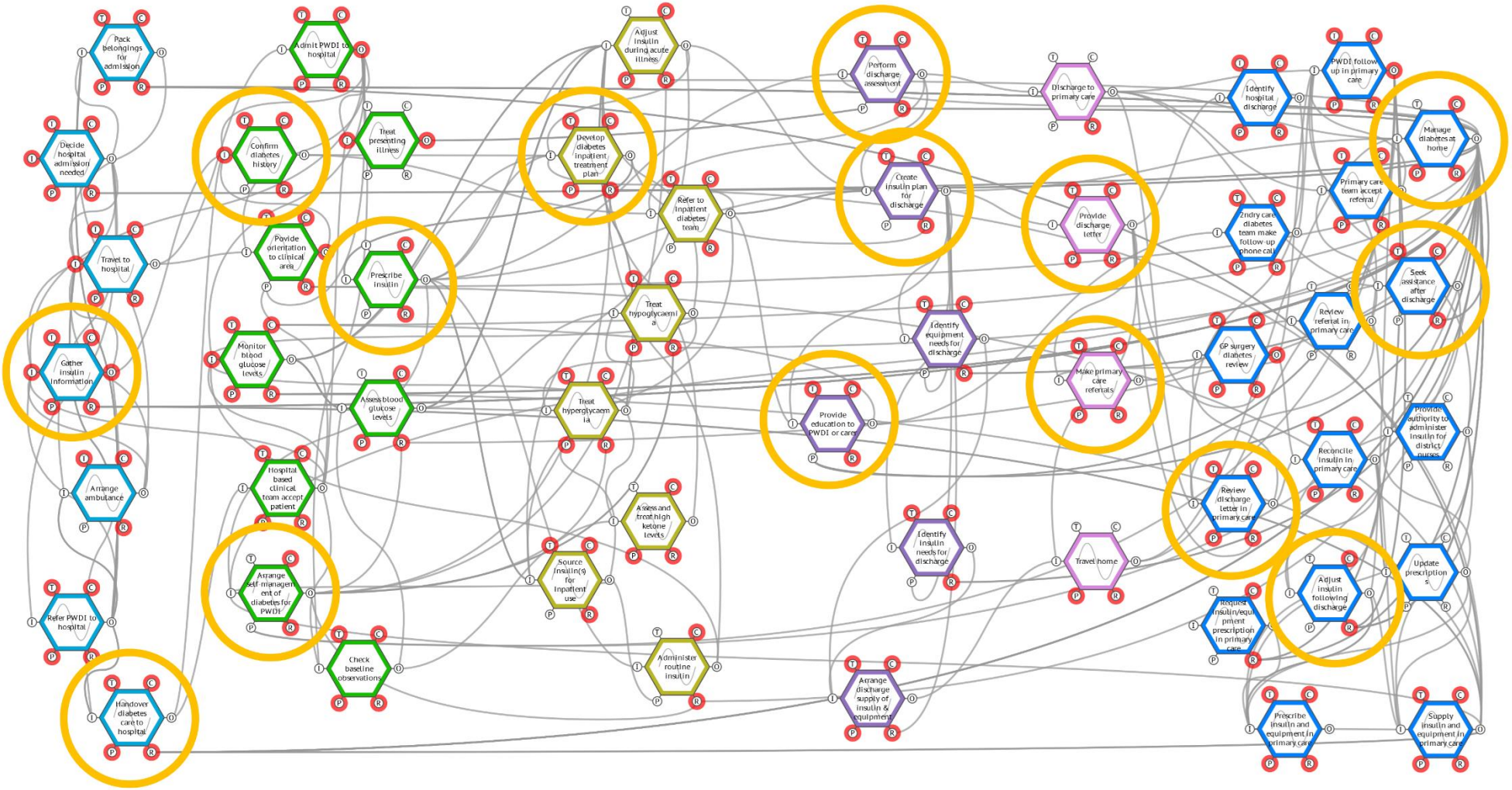


Figure 34: Fifteen key foreground functions contributing to variability in outcomes for insulin management during Transfer of Care within the Functional Resonance Analysis Method (FRAM) model.

Table 4: Functions considered as potential leading indicators and their definitions

Type of function	Name of function	Definition
Foreground	Manage diabetes at home	Managing all aspects of diabetes care including: • Collaborating to develop and update diabetes plan • Monitoring glucose levels and identifying and treating hypoglycaemia • Seeking advice if blood glucose levels are problematically outside of range (as per diabetes plan) • Administering insulin and adjusting doses • Maintaining sufficient insulin and equipment supplies • Attending appointments for review • Undertaking training to understand how to manage diabetes according to plan • Storing insulin appropriately in fridge until cartridge/pen is in use
	Handover diabetes care to hospital	Communication of information: • Includes the person with diabetes who uses insulin (PWDI)s current illness, medical and diabetes history and insulin information • May be shared by the paramedics or by the general practitioner (GP) • May be performed over the telephone, by email or by printed report
	Gather insulin information	Identify all relevant information about insulin that is available at the time depending on: • The location of the PWDI • The consciousness level of the PWDI • Available resources (e.g. pen device and record book availability)
	Confirm diabetes history	Identify presence of diabetes: • Identify past medical history and presence of diabetes • Consider diabetes and glucose levels alongside signs and symptoms of illness • Medication history and identify insulin use
	Develop diabetes inpatient treatment plan	Plan should describe an appropriate insulin regimen prescribed for current situation based on: • Pre-admission diabetes management • Lifestyle factors • Impact of current illness and concurrent medications reviewed Plan may include withholding insulin (for example if PWDI has hypoglycaemia), changing to intravenous insulin, or reducing the dose if unable to eat.
	Prescribe insulin	Insulin is prescribed for inpatient administration along with rescue treatments using Electronic Health Record (EHR).

	Arrange self-management of diabetes for PWDI while in hospital	Staff perform assessments, paperwork, and organisational requirements to enable PWDI to administer their own insulin. This includes:
		• Assessing capacity and understanding
		• Obtaining written consent
		• Arranging suitable insulin and equipment to allow them to:
		  ○ Administer insulin doses
		  ○ Monitor blood glucose levels

Type of function	Name of function	Definition
		○ Manage hypo or hyperglycaemia.
Foreground	Perform discharge assessment	Evaluate PWDI's insulin needs for discharge and consider: • Whether any support is likely to be required given social circumstances and potential impact of illness on ability to manage insulin. • Impact of illness and concomitant medications
	Create insulin plan for discharge	Develop plan with PWDI for managing diabetes after discharge considering: • Insulin requirements during admission and blood glucose levels • Diet in hospital and likely diet following discharge • Other medications and their potential impact on insulin dosing • Discharge assessment for social and other support needs • Develop a plan that includes all the above plus: ○ Details about which insulin(s) and device(s) to use ○ What to do when unwell (sick day rules) ○ Plan for who will administer insulin ○ Monitoring requirements
	Provide discharge letter	Letter from hospital to GP including details of: • Diabetes management during admission • Changes to diabetes management and diabetes care plan for discharge • List of medicines and insulin prescribed • Other equipment not routinely prescribed at most hospitals (although some do) Discharge letters are written on electronic health records (EHR) and: • Sent electronically to GP surgery email inbox • A printed copy is given to the PWDI and/or caregiver
	Provide education to PWDI or carer	Provide education to PWDI or their caregiver including: • How to monitor blood glucose levels • How to administer insulin • How to adjust insulin doses as needed • What to do when unwell • How to dispose of sharps • Implications for driving
	Make primary care referrals	Referrals made to relevant outpatient teams where needed including: • District nurses to help with insulin administration • Community pharmacy for review of discharge medications
	Review discharge letter in primary care	Administrative staff in GP surgery: • Identify hospital discharge letter • Assign to task list of relevant clinical staff for review (e.g. clinician for review of diabetes, pharmacist, or Medicines Management Technician if medicines/insulin involved).

Type of function	Name of function	Definition
	Seek assistance after discharge	If an issue with diabetes or insulin occurs after discharge: • PWDI, caregiver, GP or other healthcare professional seek help or advice to manage • Advice could be sought from primary or secondary care
	Adjust insulin following discharge	Healthcare professional in collaboration with PWDI or caregiver: • Review blood glucose levels and insulin doses • Adjust insulin to ensure blood glucose levels stay within desired range as much as possible • Update diabetes plan
Background	Provide diabetes framework	Provider strategies include organisational: • Staffing policies including specialist teams • Training provision • Equipment and medication formulary • Standard operating procedures and guidelines • Commissioned pathways, their oversight and assurance.
	Empower people who use insulin to manage their diabetes	Providing the training and support to enable PWDI (or their caregivers) to manage diabetes at home (see foreground function for included components).
	Maintain IT infrastructure	Provide and maintain a functional IT system and associated software and hardware that: • Allows access to healthcare records across organisations • Enables recording of and access to medical history, medications, appointment details, clinical letters, pathology, and laboratory results etc. • Includes the wireless connection between the monitoring devices and the hospital EHR system

	Manage stock of insulin and equipment	Ordering system in place within hospital or primary care pharmacies to:
		• Ensure that insulin is ordered, stocked and stored appropriately
		• Manage stock on wards
		• Management and adjustment of guidelines where supply issues occur
		Insulin equipment is managed by:
		• Community pharmacy when prescribed by GPs in primary care
		• In hospital the manage provision of:
		  ○ Diabetes specialist nurses provide insulin equipment for the PWDI
		  ○ Hospital stock systems provide a supply of needles, syringes, sharps bins and monitoring devices etc

	Provide appropriate competent staff	Organisations provide adequate healthcare professionals with appropriate skills to match demand of patient population.
	Train staff around diabetes and insulin use	Training for staff enables non-specialist diabetes staff to be equipped with the competencies to care for PWDI using insulin.

*PWDI = people with diabetes who use insulin

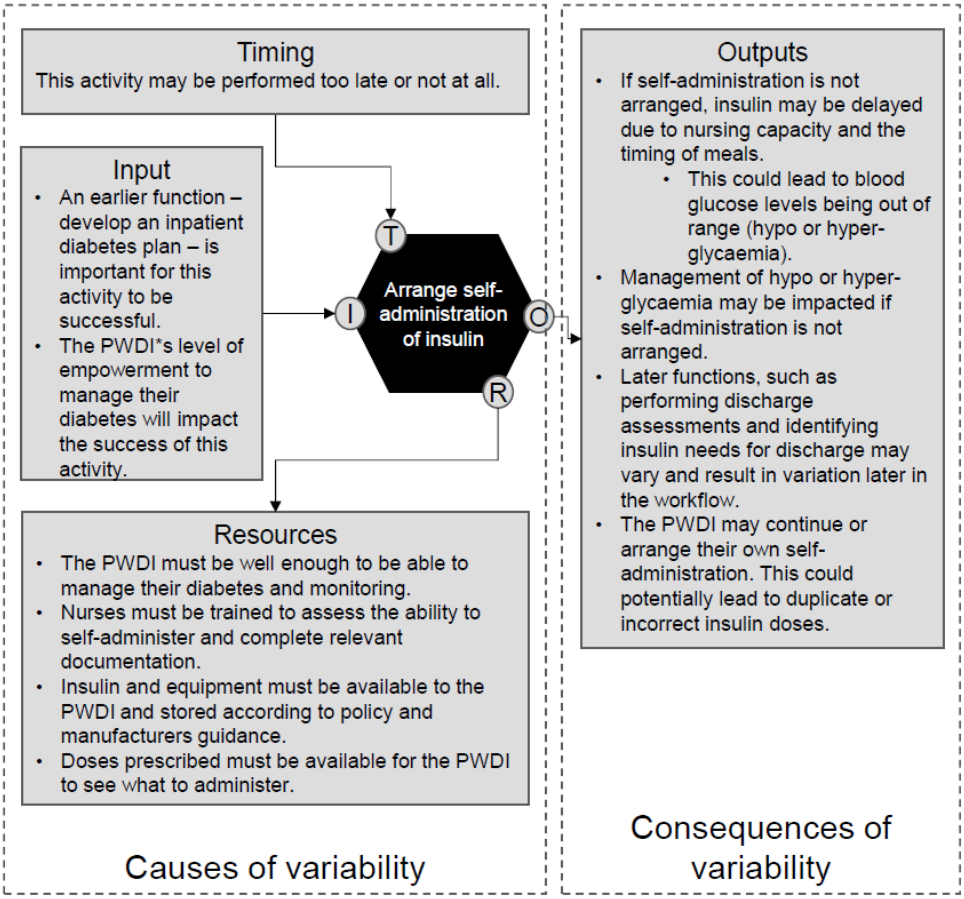


Figure 35: Potential causes and consequences of variation for the function 'Arrange self-administration of insulin (during hospital admission).

Seminar findings

Discussions at the seminar focused on assessing the six background functions and fifteen foreground functions. The participants agreed that these were strong targets for developing indicators of safe insulin management across ToC. Multiple challenges to measuring safety were highlighted. Participants described the many different admission and discharge pathways across organisations. Data available currently was described as limited and variable and access to key information not readily available to all who need it. Information governance arrangements could act as obstacles to appropriate and timely access to view and input relevant data.

Participants agreed that safe ToC should be supported by real-time data that included information on blood glucose levels, insulin doses administered, diet, activity levels and any treatments taken for hypo or hyperglycaemia. This information would be required across the care pathway and accessible to PWDI and healthcare staff.

Measures indicating *Empower PWDI to manage diabetes* (background function) were limited. Glycated haemoglobin (HbA1c) is a test currently relied on as a lagging indicator to understand blood glucose levels over time. This acts as a proxy for PWDI empowerment. Seminar participants agreed proactive measures require development and must include qualitative data. PWDI knowledge, belief and attitudes represented important person centric areas for developing indicators. Facilitating access for PWDI to shared EHR systems would be required to allow information on diabetes to be recorded and proactively shared with the healthcare team. Insulin self-administration requires accurate recording on hospital records to support measurement of the foreground function *Arrange self-management of diabetes for PWDI*. Participants highlighted that there were currently no measures to capture PWDI self-management of diabetes and PWDI are unable to record relevant information into the hospital EHR themselves, often relying on staff to do this on their behalf.

The seminar participants felt that data on blood glucose levels and dosing information from continuous glucose monitors (CGM) and pen device recordings should be integrated with EHR as a matter of urgency to allow sharing across the healthcare system.

Development of potential leading indicators

Seminar findings were combined with the FRAM model to develop a list of potential measures for each of the two example functions (Table 4). To demonstrate how measures could be developed for each function so it could act as a leading indicator, the function's definition was broken down into the discrete tasks that are required for the function to be completed, see Figure 36 for an illustration of this process. Each component task of the two functions was assessed to consider how specific measures could provide data to support monitoring current risks and anticipation of future risks. The audience for each measure was defined by considering who would need to act in response to highlighted risks. Indicators were classified as passive indicators where they highlight the capacity and functioning of structural and organisational aspects of ToC. Active indicators were those that would provide real-time insight into specific needs of individual PWDI for either individuals, teams or groups of PWDI for organisations. At an organisational level, the indicator is more likely to be a passive indicator highlighting areas where further implementation of self-administration policies and training may be required.

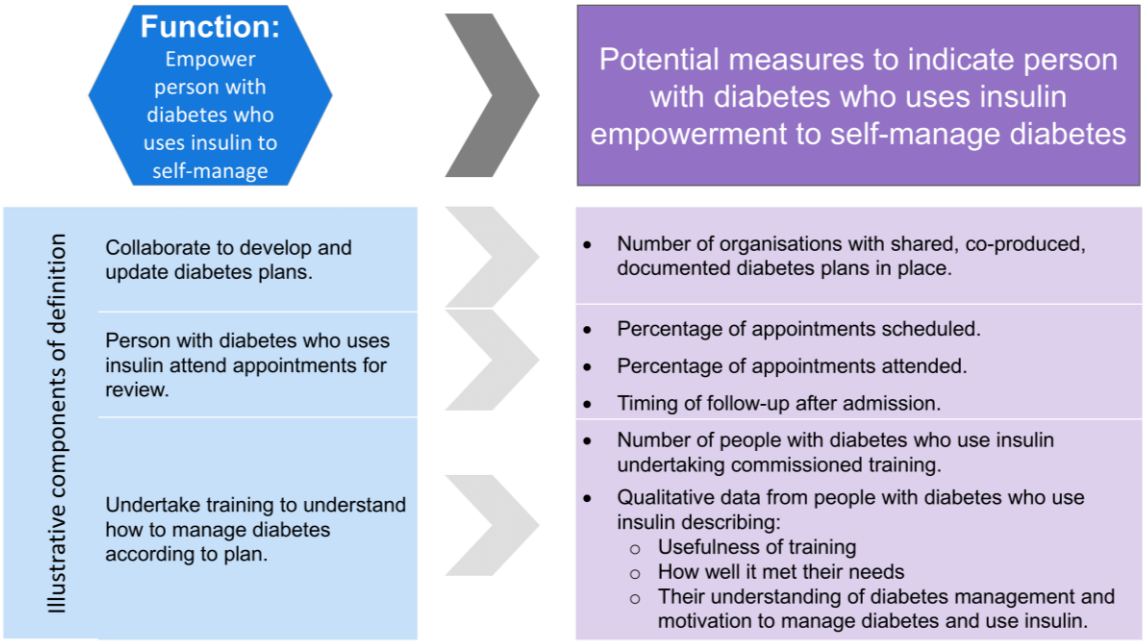


Figure 36: Illustrative example of using the components of a function's definition to identify potential measures.

Table 5: Potential measures for proposed leading indicators

Proposed leading indicator	Activities involved	Potential measures	Target audience	Indicator type
Empowering People With Diabetes who use Insulin (PWDI) to self-manage	Collaborate to develop and update diabetes plans.	• Number of organisations with shared, co-produced, documented diabetes plans in place.	Integrated Care System	Passive
	PWDI attend appointments for review.	• Percentage of appointments scheduled. • Percentage of appointments attended. • Timing of follow-up after admission.	Organisation PWDI Healthcare teams	Passive (Active for PWDI and healthcare teams)

	Undertake training to understand how to manage diabetes according to plan.	• Number of PWDI undertaking commissioned training.
		• Qualitative data from PWDI describing:
		  ○ Usefulness of training
		  ○ How well it met their needs
		  ○ Their understanding of diabetes management and motivation to manage diabetes and use insulin.
			Organisation and Integrated Care System	Passive

	Monitor glucose levels	• Percentage of PWDI with diabetes regular prescriptions for monitoring equipment. • Population level HbA1c data (percentages of population within different ranges).	Organisation	Passive
	Take insulin and adjust doses based on test results and other factors such as carbohydrate intake.	• Percentage of PWDI with a documented, up-to-date, co-produced, shared diabetes plan.	Organisation	Passive
	Treat hypoglycaemia and seek help or advice where blood glucose levels are problematically outside of range (as per diabetes plan).	• Number of documented diabetes plans with directions for when to seek help or advice. • Number of contacts to diabetes teams or GP surgeries seeking advice for blood glucose levels.	Organisation	Passive
	Maintain sufficient insulin and equipment supplies to continue to administer and monitor insulin	• Insulin and equipment formularies agreed across region. • Regularly reviewed and updated. • Escalation plans and alternative options defined in case of supply shortages.	Organisation	Passive
	Store insulin appropriately in fridge until cartridge/pen is in use.	• Evidence that insulin initiation guidelines and education programmes review and consider PWDI's ability to store insulin according to manufacturer directions.	Organisation	Passive

Proposed leading indicator	Activities involved	Potential measures	Target audience	Indicator type
	PWDI knowledge, belief and attitudes around diabetes and insulin management	• Qualitative surveys and responses	Organisation Healthcare teams	Passive (Active for teams)
Arranging self-management of diabetes for PWDI	Recognition person uses insulin and should self-administer unless there is a reason not to.	• PWDI and diabetes self-management status highlighted on Electronic Health Records (EHR). ○ Measure percentage of PWDI who are self-managing their diabetes.	Healthcare professional, teams and Organisation	Active (Passive for organisation)
	Risk assessments performed to ensure self-administration appropriate	• The number of task(s) outstanding for completion highlighted on EHR.	Healthcare professional and teams	Active
	Paperwork and other organisational requirements completed including: • Assessment of insulin administration technique • Arranging informed consent with PWDI • Completing forms and documentation	• The number of task(s) outstanding for completion highlighted on EHR.	Healthcare professional and teams	Active
	Insulin and equipment provided to allow: • Insulin administration • Blood glucose monitoring • Carbohydrates to treat hypoglycaemia	• The number of task(s) outstanding for completion highlighted on EHR.	Healthcare professional and teaks	Active
	Identification and documentation of insulin doses taken on electronic health record	• Number of doses documented on EHR. • Real-time data for blood glucose levels. • Insulin doses or blood glucose levels outside normal range highlighted on EHR.	PWDI, Healthcare professional and teams	Active
	Identification and documentation of any blood glucose levels outside desired range and any carbohydrates taken to treat hypoglycaemia	• Real-time data for blood glucose levels. • Insulin doses or blood glucose levels outside normal range highlighted on EHR. • Carbohydrates consumed by PWDI documented on EHR. • Carbohydrates consumed by PWDI to manage hypoglycaemia highlighted on EHR.	PWDI, Healthcare professional and teams	Active
	PWDI highlighting any issues to nurses or doctors	• Number of queries from PWDI about diabetes or insulin management	Healthcare professional and teams	Active
	Insulin doses adjusted in agreement with PWDI	• Number of dose changes highlighted in EHR. • Number of PWDI signatures highlighting agreement for dose change. • Real-time data on accuracy of dose documented compared with dose prescribed on EHR.	PWDI, Healthcare professional and teams	Active

8.4 Discussion and conclusion

A detailed model of insulin management during ToC was developed using FRAM, a Safety-II approach. The model enabled a visual representation of the impact of variability across the pathway and highlighted how functions across ToC were performed in a non-linear manner, and how, through interlinkage, they influence outcomes. Fifteen foreground functions and six background functions were identified where extensive variability in their outcomes impacted on the performance of other functions and on the overall safety of ToC. These were explored as potential targets for leading indicators designed to support monitoring for potential threats and anticipation of future needs. Several specific measures were developed that would provide insight into the performance of each of the two example leading indicators. Data derived from measures for the background function 'empowering PWDI to self-administer', would provide insight into the performance of organisations and their capacity for safe outcomes by illustrating how well the different aspects this function of were implemented. Potential real-time measures for supporting front-line staff, teams and PWDI to anticipate and monitor whether self-management of diabetes was being undertaken were identified. Such data would enable those involved to take action to address issues highlighted. The application of FRAM provided a method to identify potential indicators based on understanding how work is performed and how variability can impact outcomes later in the pathway. It contrasts with other approaches to indicator development that rely on analysis of past harm. Applying this method is challenging without the input of an experienced practitioner, and given the extensive variation identified across almost all functions, it was necessary to focus on representative functions or the model would become overwhelming. Those wishing to use this method would benefit from the development of training materials and mentorship models which should support potential users to understand how and when to use this method to get the most benefit.

For safety improvement interventions to be effective, the causes of variability influencing successful outcomes must be understood. Leading indicators can highlight this variability, providing opportunities to intervene and evaluate improvement. Potential real-time measurement is limited by the technology and integration of current systems. As EHR and wearable technologies such as continuous glucose monitors (CGM) become more compatible and connected within and across care settings, the opportunities for active leading indicators and real-time measures will expand. Insulin management is undergoing significant transformation with the advent of CGM. CGM allows glucose levels to be monitored through a device attached to the skin, and results are sent to an application automatically. Such devices

are not currently routinely integrated into electronic health records (EHR) and are not universally used for all people with diabetes who use insulin, however researchers are exploring the safety and potential benefits of this approach.(137,138) As such technology becomes more widely used and more integrated across health care systems, the FRAM model developed in this process will require adaptation.

Future research will be required to co-develop, test and validate these measures with stakeholders. Due to the number of potential measures, if the approach was widened across all key areas of variability identified, additional efforts would be required to test and refine the list of measures to those that have the greatest predictive ability. Proactive collaboration with software providers and digital professionals is key to ensuring required real-time data is available for future measures.

This approach provided a mechanism to explore the role of resources and controls on outcomes. Many of the controls currently in place to support successful outcomes were ineffective. Most were administrative controls related to having trained staff, policies and guidance in place. Therefore, functions relied on the people involved understanding what was required, knowing the appropriate guideline and performing the activity correctly. The lack of effective controls contributed to variability in function output, and subsequent outcomes during ToC.

The contributions of those involved in ToC were essential to building the model. The perspectives of PWDI, their caregivers and healthcare professionals from primary and secondary care provided detailed insight into how work was performed, and the challenges and opportunities for managing insulin safely across the ToC journey. They highlighted the circumstances where adaptations to provide care occurred and why. PWDI contributed information that was not always recorded in healthcare records. This information was essential in building a model that captured the complexity of WAD. The model itself became too large and complicated to share in the online seminar, so key areas were discussed with stakeholders to check they represented their experiences. FRAM is a method that is being increasingly used to model ToC across different care settings.(72,140–142). Other methods have also been employed to explore complex systems and identify elements within the system contributing to outcomes including the Systems Theoretic Accident Model and Process (STAMP)(143), AcciMap(12) and SEIPS(14,15,92). The SEIPS 3.0 model is particularly designed to represent a patients journey through different healthcare settings.(20) AcciMap and SEIPS methods are limited to providing snapshots of system interactions in time, or multiple snapshots across a

patient journey (SEIPS 3.0). STAMP is a tool developed for Engineering and uses complex systems theory; however, it is based on examining and enhancing controls and constraints, rather than seeking to understand how variability can create successful outcomes.(144,145) In contrast, the FRAM model allows interactions between the stages of the pathway to be viewed visually and explored across timeframes, to see how these different parts interact and contribute to variability and both successful and unsuccessful outcomes. Understanding interdependencies between functions enables prediction of the impact on outcome of changing aspects of functions. The model illustrates not only where factors and interactions contribute to poor outcomes but also where they are enhancing safety.

Alternative methods for identifying leading indicators include machine learning and natural language processing to quantify risks.(39) These techniques use accident investigation reports and retrospectively collected safety data to identify areas where potential leading indicators could be developed.(39,143) STAMP has also been used to identify leading indicators in other industries. The mechanism for identifying potential leading indicators using this approach is to identify safety-critical controls at risk of failing.(143) Given that the FRAM model demonstrated a widespread lack of effective controls across the ToC pathway for PWDI, STAMP would be challenging to apply in this context. FRAM has benefits over the other methods for identifying leading indicators through its capture of WAD and the ability to explore factors that contribute to successful outcomes.

Using FRAM to develop leading indicators across ToC allows a proactive perspective of safety improvement that provides a strong foundation for indicator development. This method meets many of the Global Principles for Measuring Patient Safety(146): It seeks to target key areas for improvement, the process requires full involvement of PWDI and their caregivers, it considers the whole journey across different care settings and it aims to identify real-time data. Further work to develop specific measures should strive to meet the other aims of ensuring equity, and that they can be continuously adapted to changes in care pathways. In addition, the burden of data collection for staff must be minimised.

A FRAM model allows potential outcomes in a care pathway to be anticipated. It can demonstrate how functions promote successful outcomes (for example enabling self-administration in hospital) and how others can cause adverse outcomes if omitted or delayed (create insulin plan). Several challenges limit the opportunities for FRAM to be used more widely within the NHS and other healthcare systems. The first is the limited training opportunities to learn how to use and apply FRAM. There are currently few (if any) courses

available to learn how to develop a FRAM model in England. Guidance is based on written materials and/or ad hoc peer support from those who have already used the method. Given the lengthy process and multiple steps involved, opportunities for training and formal mentoring would support those who wish to use FRAM to develop the skills and knowledge to get the most out of the process. In England, the NHS has introduced the role of the Patient Safety Specialist,(9) who may be a suitable target audience for such training. Another practical challenge is the resource implications for gathering and analysing data, then performing and validating the FRAM. Each of these steps requires input from stakeholders to ensure that findings represent how work is performed in real-life settings. Given the financial, workforce and workload pressures facing the NHS and other healthcare systems, the use of FRAM will need to be carefully targeted to care pathways that will obtain the most benefit. Finally, FRAM models may be large and difficult to interpret, and therefore presenting information meaningfully to influence change may be challenging.(147,148)

8.4.1 Strengths and limitations

The development of the FRAM model and the identification of key areas of variability were performed systematically and involved key stakeholders throughout the process. The model developed provides a visual representation of the whole ToC journey and represents the perspective of multiple stakeholders, including the PWDI, their caregivers and health professionals in both primary and secondary care. Wide recruitment of interview and seminar participants from across England allowed multiple perspectives and experiences to be included. Most functions involved in managing insulin across ToC could have variable outcomes. Focusing on two example functions to consider specific measures allowed rich discussions within a limited time. Future research could follow a similar approach to explore additional functions.

The model produced is visually complex, and challenging to share key findings visually in a succinct and meaningful way. This was addressed by using selected data that would be meaningful for stakeholders at the seminar, and by using excerpts of the overall model to demonstrate points discussed. Careful planning is required when using FRAM models to influence policymakers and non-technical stakeholders to ensure that findings presented are impactful. A key area of research is to explore mechanisms for impactfully communicating findings from FRAM models.

The challenges in observing WAD in primary care were offset by including stakeholders from primary care in the interviews and seminar, and by exploring journeys and issues occurring in primary care through the incident reports to ensure these were reflected in the FRAM model. The incident reports highlighted the need for further exploration of the roles and activities of district nurses following a PWDI's discharge from hospital using observation, interviews and focus groups to understand WAD during this component of ToC.

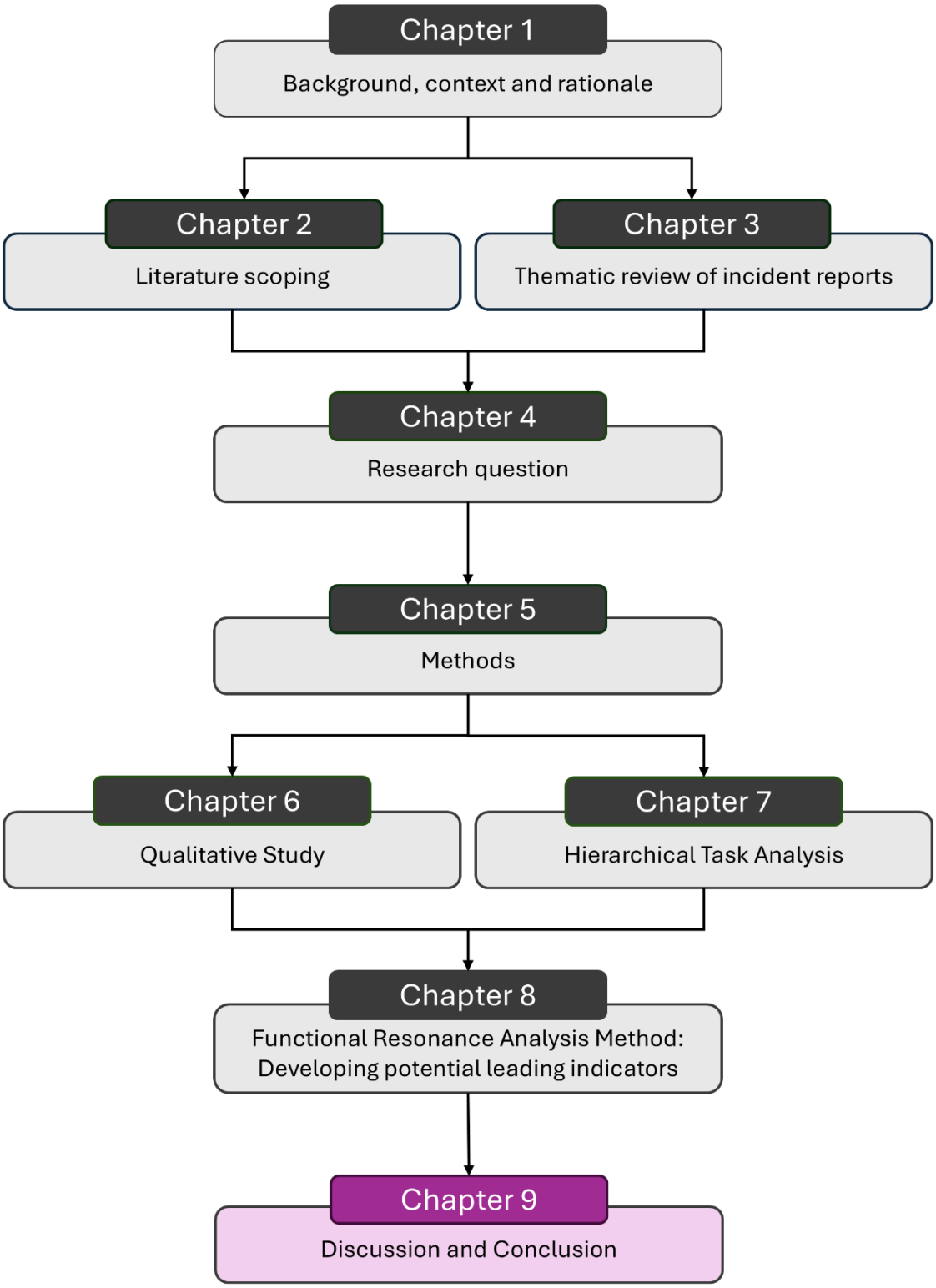
The FRAM method was challenging to apply, and this study benefited from the mentorship of a practitioner experienced in using this approach. There are currently very few training opportunities for using FRAM, and the method described by Hollnagel (2012)(19) is recognised as being under-developed for exploring variability.(147) Exploring different methods and approaches to teaching FRAM is a promising area for future research.

Due to the focus on understanding WAD, the findings of the model are specific to the area studied. To transfer findings, adaptations will be required for local areas. Local stakeholders would need to confirm the model represented care pathways and WAD, and adjustments would be required based on stakeholder feedback. As PWDI, caregivers and healthcare professionals were involved from across England, the overarching model is likely to be generally transferable within this country, however other health systems would need to adapt to local pathways.

8.4.2 Conclusion

The FRAM is a powerful method for exploring care pathways and identifying how and where variability can occur using a Safety-II philosophy. Using this approach, key targets for potential leading indicators were developed, along with possible measures. These need further development and validation with key stakeholders. FRAM allowed factors that promote both successful and unsuccessful outcomes to be explored and understood visually and the model was used to explore potential impacts of variation on outcomes.

Chapter 9: Discussion and conclusion



9.1 Introduction

9.1.1 Improving safety of complex care across ToC pathways

People who use insulin for diabetes are at risk when they move between care settings. Incorrect, delayed or omitted doses of insulin can cause significant harm. Many interventions have aimed to improve the safety of insulin management during ToC; however, problems remain. Integrated care systems providing joined-up care pathways and underpinning connected digital systems are anticipated to improve ToC, however, to understand if these and other safety interventions are having an impact, we need suitable measures.

This research sought to explore safe insulin management across ToC using a Safety-II approach to develop potential leading indicators for supporting proactive safety improvements within digitally integrated care. An overview of the components of the research, how the concepts and analysis fit together and the key findings from each component can be seen in Figure 37.

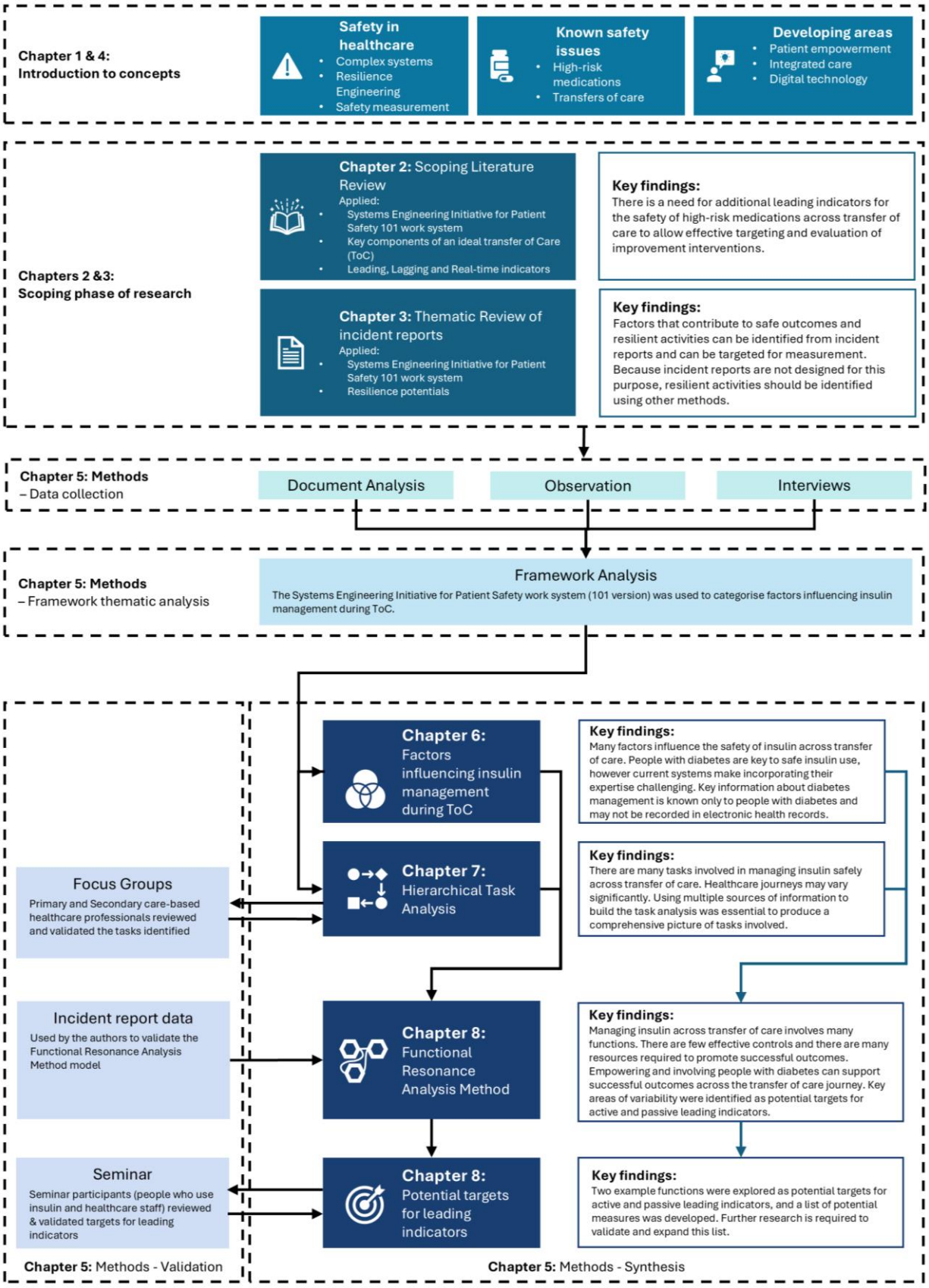


Figure 37: Overview of the components of the research and associated findings

9.1.2 Identifying leading indicators using a Safety-II approach

Current measures for safety during ToC rely heavily on outcome measures, which represent episodes of past harm. Understanding safety by looking at past harm to prevent future occurrences is known as Safety-I. By contrast, a Safety-II approach recognises that healthcare is provided in a complex system composed of people, the tasks they perform, the equipment they use and the environments they are interacting with. In this view, safety is created by adapting to changing conditions. All outcomes are the product of the adaptations made in response to interactions of the components of the complex system, therefore both intended and unintended outcomes are important for understanding safety. Rather than seeking to strengthen controls and regulation, a Safety-II approach seeks to understand the causes of variability and support safety improvement by understanding and strengthening safe adaptations and increasing capacity within the work system.

There is a need for proactive indicators of safety that consider the complex system in which care is provided and the interacting factors that are contributing to different outcomes, both successful and unsuccessful. Such indicators, if provided in real-time, could support those involved in providing care, and their organisations to monitor for potential risks, anticipate potential issues and adapt and adjust care to improve outcomes. This would enable teams and organisations to move resources to increase capacity in critical areas or take action to address risks.

The aim of this thesis was to determine how a Safety-II approach could be used to identify leading indicators for managing insulin safely within digitally integrated care systems. In this chapter, I summarise the findings of the research included within this thesis. I will then describe the strengths and limitations of the work and the potential implications for practice, policy and research.

9.2 Summary of findings

The findings of the research are presented against each objective to demonstrate how these have been met.

9.2.1 To identify measures currently being used to understand the safety of high-risk medications during transfer of care

In Chapter 2, I shared the findings of a scoping review of the literature. Embase, Medline, Cochrane, and CINAHL databases were searched for any study that aimed to improve the

safety of insulin, anticoagulants or high-risk medications as a group. The measures used within these studies were extracted and evaluated against three frameworks to determine how comprehensively they reflected: 1) The Key Components of an Ideal ToC(93), 2) systems, processes, outcomes (using the SEIPS framework)(14,15,92), and 3) whether they were leading, lagging and/or real-time measures.(34) As real-time measures are becoming progressively viable with advancing digitisation in the NHS, the potential for each measure to be provided in real-time was also assessed.

The measures identified from the 35 studies reviewed were predominantly Safety-I orientated, outcome-based measures of past harm. There were few measures illuminating the complex interactions that maintain safety during ToC. A need for further leading and real-time indicators based on a detailed understanding of the complex work-system was identified.

9.2.2 To explore whether factors that support safety and healthcare resilience can be identified from incident reports.

The aim of this work, presented in Chapter 3, was to determine whether voluntarily reported accounts of incidents could be used to explore and identify aspects of Safety-II. A Safety-II perspective recognises that the people in healthcare create safe outcomes by adapting to changing situations and factors within the complex work system (including tools, tasks, environments and the people involved). There are four commonly recognised categories of adaptation, known as resilience potentials; the ability to anticipate, monitor, respond and learn. The aim of the study, presented in Chapter 3, was to explore whether factors within the system that were facilitating safety could be identified, particularly those reflecting the resilience potentials.

From this study, it was possible to identify not only factors that supported successful outcomes, but also examples of each of the four resilience potentials. Resilience was demonstrated at multiple levels, by individuals, teams and organisations. A key limitation with this approach was that it used a source of data not designed for Safety-II analysis and therefore much of the information on resilient adaptations is likely to be missing. The main conclusion of this study was that identifying future indicators associated with resilient adaptations during ToC would require interrogation of a wider range of data.

9.2.3 To identify the factors in the work system that influence the success of insulin management for PWDI moving between home and hospital.

The qualitative study described in Chapter 6 provided information about how tasks involved in managing insulin during ToC were influenced by factors within the work system. A framework approach using the SEIPS work system categories(15) was used to map work system factors related to people, tools, tasks and environments (local, organisational and external). Four key areas of complex interactions with the potential to influence outcomes were identified. The first of these was 'recognising and incorporating the expertise of PWDI in identifying diabetes management needs and ongoing insulin adjustments'. Linked to this was 'enabling PWDI to manage their diabetes while in hospital'. The third area was 'the lack of confidence of healthcare staff in managing insulin'. The fourth area described 'the extent to which PWDI and their diabetes management team were involved in anticipating and proactively addressing potential challenges.' Managing these four areas required frequent adaptations to challenges experienced by PWDI, their caregivers and staff.

9.2.4 To develop a detailed map of insulin activities involved during admission and discharge from hospital, based on the lived experiences of patients and the healthcare professionals involved in their treatment (Work as Done).

Data obtained through documentary analysis, observation and interviews allowed the development of a Hierarchical Task Analysis (HTA), presented in Chapter 7. The HTA provides an overview of the tasks involved in managing insulin across Transfer of Care. Six main tasks were identified to meet the overarching goal of 'Using insulin(s) correctly to maintain blood glucose levels within a defined range throughout admission and discharge.' The six tasks were to:

1. Prepare for admission
2. Admit to hospital
3. Adjust insulin during acute illness
4. Plan for discharge
5. Hand over medical care
6. Resume insulin management in the community.

Five of the six tasks were then broken down into sub-tasks, which further detailed the steps involved to fulfil that task. Detailed plans were created to describe the order in which the tasks were performed. The relevance of the HTA was assessed in two focus groups.

The HTA and the findings of the qualitative analysis were then used to perform the Functional Resonance Analysis Method (FRAM). The use and development of the FRAM model is described in Chapter 8. The detailed model developed using FRAM was produced represents how ToC occurs for PWDI who use insulin. It encompasses from when a need for admission is recognised through to discharge and follow-up in the community. The FRAM model identified 59 overall functions that were required in the workflow of insulin management across ToC. These included functions relating to preparing for admission, those involved in the admission process, functions for managing and adjusting insulin during acute illness, for planning for discharge and for returning to primary care and seeking or providing follow-up care. Nine of the functions were background functions representing structural components that contribute to the ability of all other functions (foreground functions) to succeed. Background functions included the availability of trained staff, adequate functioning IT equipment, healthcare provider organisation diabetes strategies, and clinical pathways. The FRAM was validated using ten representative journeys identified from national incident report data.

9.2.5 To identify how variability during care transfers is associated with outcomes.

Chapter 8 describes how each function in the FRAM model was explored to assess its potential for variation, and how the function could both impact and be impacted by the performance of other functions. This assessment provided rich information on how and where variation occurs when managing insulin during ToC and the potential of this variation to impact on outcomes.

Variability in output of individual functions was often the consequence of ineffective or insufficient controls. The controls identified in the FRAM analysis were predominantly guidelines and policies directing care, and diabetes training for staff and patients. According to the hierarchy of controls,(138) such measures are considered administrative controls and are generally regarded as poorly effective in controlling outcomes. Elimination, substitution or engineering controls to support functions to perform correctly are considered stronger controls. Some stronger controls were in place, for example where EHR programming supported discharge processes, for example by automatically sending the discharge letter to GP systems.

Other variability potentially affecting outcomes arose due to interactions between functions. Variability in the outcome of one function could impact other functions within the pathway creating a ripple effect. Some functions, such as *Handover diabetes care to hospital, Arrange*

self-management of diabetes for PWDI and *Empower PWDI management of diabetes* were particularly important in ensuring successful outcomes for later functions.

Fifteen areas of high variability were identified as having the greatest impact on the success of other functions later in the ToC journey and consequently were judged to have significant impact on overall outcomes. Six background functions were also identified as having the greatest impact on outcomes. These 21 areas of variability were validated in a seminar with key stakeholders, including PWDI, caregivers, and healthcare professionals from primary and secondary care. Participants at this seminar agreed that these were key areas for insulin safety during ToC.

9.2.6 To identify whether areas of variability can be used as potential targets for leading indicators.

Findings from the seminar presented in Chapter 8, describe how stakeholders explored whether the key areas of variability could be used as foci for the development of potential leading indicators. Facilitated discussions and an online survey tool were used to identify current measures, measurement gaps and targets for real time measures. Two exemplar functions *Arrange self-management of diabetes for PWDI while in hospital* a foreground function, and *Empower PWDI management of diabetes* a background function, were interrogated during the seminar to facilitate consideration of types of indicators and data collection requirements. Findings from the seminar and the FRAM model were combined to produce a list of potential leading indicators for each of the two functions. This provides a strong foundation for future work to develop definitions of potential measures, refine data sources and undertake further testing for validity, feasibility, and accuracy using a collaborative co-design process.

9.3 Comparison with published literature

9.3.1 Approaches to leading indicator development

Safety-II philosophy

This study aimed to explore how leading indicators for safe insulin management can be developed across the whole ToC pathway from before admission until after discharge using a Safety-II approach. There is a paucity of research on using the Safety-II perspective to develop safety indicators. More commonly indicators have been derived based on Safety-I using expert consensus (Delphi method) or machine learning methods.(39) These indicators generally draw

on data from accident reports describing harm events or near misses, or are based on standards set out in guidance documents either alone or in combination.(39,99) The Systems-Theoretic Accident Model and Process (STAMP) method(143) has also been used to develop targets for leading indicators by identifying areas where controls are at risk of failure.(143) The focus on strengthening controls to prevent harm in the STAMP approach relates more to a Safety-I perspective, although it takes a systems-based approach. Given the extensive number of weak controls across the whole ToC pathway for PWDI, STAMP would be challenging to apply in this context. In contrast, FRAM can identify factors that both support safe outcomes as well as those that contribute to risks and offers the possibility of identifying measures that allow proactive interventions to prevent harm. Indicators derived using this tool enable anticipation of risk and facilitate real time monitoring to prevent undesirable outcomes at both individual patient level and organisation level. As such, FRAM supports a Safety-II approach promoting resilient anticipation and monitoring to improve safety. The advent of improved digital systems in the NHS will facilitate use of such leading indicators.

Comparison with other studies using FRAM to develop leading indicators

FRAM has been used to identify leading indicators in other industries but its use for this purpose is relatively rare in healthcare. This study applied FRAM to a new area, insulin management during ToC using the tool to systematically explore and understand variability and its impact on outcomes.(38,99) FRAM is particularly useful for understanding complex systems such as ToC for PWDI because FRAM models can be used to predict the impact of variability at different points in a care pathway. Previous studies have used FRAM to model ToC processes but not in this area. (72,141) Furthermore, by incorporating the voice of PWDI and healthcare staff into the FRAM process, many additional activities required to ensure safe ToC for people who use insulin were identified than found in these studies.

Raben et al. (2018) used FRAM to identify broad areas that were defined as leading indicators for the early detection of sepsis, for example 'Receiving and obtaining the necessary and sufficient information on the patient from the referring doctor.'(38) While this research demonstrated that these areas were precursors for successful outcomes, further work would be required to develop mechanisms to make these broad activities measurable. This study went further by using the seminar discussions and feedback to develop a list of potential measures for two target leading indicators.

This study was novel in distinguishing between active indicators (enabling real-time anticipation and monitoring by frontline staff and PWDI) and passive indicators (capacity of organisations

for creating safe outcomes) as defined by Bayramova et al (2023).(39) By using this distinction, it enabled the target audience of PWDI, front-line staff, teams or organisations and resilient mechanisms for potential measures to be defined.

9.3.2 Insulin safety improvement activities

Insulin safety has been the target of multiple improvement efforts over many years and is currently a focus in the national Get it Right First Time (GIRFT) Diabetes campaign in England.(55) This study explored insulin management across the entire pathway of ToC. Findings from this work align with recommendations from the GIRFT campaign. This campaign recommends two key areas for supporting safe outcomes: supporting PWDI to self-manage diabetes during hospital admission; and providing access to staff who have knowledge and competency in managing diabetes, particularly specialist diabetes teams.

This study demonstrates additional factors that are important in managing insulin safely. It highlights the significant resources and underpinning organisational and cross-system requirements for facilitating safe insulin management across ToC. These include the provision of diabetes frameworks, organisational capacity and maintaining IT systems. It also demonstrates the key role that empowered PWDI, and their caregivers, play in safe insulin management, and the considerable impact this can have in supporting safe outcomes across the whole ToC pathway. The lack of insulin information in a central, digital location where all can access it to inform decision making was highlighted as a significant challenge for safe ToC. Providing a mechanism for recording PWDI insulin information and integrating this into EHR systems across both primary and secondary care is another key area for supporting safety. Previous safety initiatives have attempted to address this issue through provision of insulin passports, however their use has not been sustained in the UK.(113)

Mechanisms to incorporate continuous glucose monitoring (CGM) data into EHR are being developed.(149) Such data are available through CGM devices that are attached to the skin as a patch and measure and send blood glucose levels to a smartphone application. Insulin delivery devices are also available that can record dosing data and provide bespoke information to PWDI.(150) The availability of these data within EHR systems would facilitate access to real-time safety information for people who use insulin and would enable earlier detection and management of glucose levels outside the desired range. Mechanisms for PWDI to submit their own monitoring and insulin information directly into a central health record has the potential to improving safe insulin management by supporting empowerment of PWDI.

These areas represent important areas for targeting of future safety measures.

9.3.3 Integration of care

A key aim for integrated care systems (ICS) introduced in England, and other efforts to integrate care is to make healthcare more patient centred and improve experience and safety by reducing silos between different healthcare providers.(151,152) ICS are still in their infancy and connected pathways remain a key area for improvement.(151) Healthcare remains fragmented and disjointed, and electronic health records are not connected either within organisations or across different organisations within ICS and more widely. Many patients who were considered for inclusion as interview participants were excluded from the study as they did not live within the ICS. Consequently, PWDI recruitment was challenging and required an amendment to the ethics approval to allow inclusion of PWDI from across England, irrespective of the ICS boundary they live within. This demonstrates that integration of care at an ICS level is insufficient to provide connected healthcare for such a large cohort of patients. Work is currently underway to create large regional care records, such as the London Care Record(153) and the Greater Manchester (GM) Care Record(154), however nationwide electronic health record access or integration is required.(155) Information governance considerations will require addressing in the development of such a system.

9.3.4 Patient empowerment

There is a powerful body of research that highlights the importance of empowering patients and the impact on outcomes.(71,72,156,157) Despite this, the patient voice is not always well represented in healthcare services.(158,159) The findings from the fieldwork in this study demonstrated the how PWDI and their care givers felt disempowered and key information they were seeking to share about their diabetes management was not acted on by healthcare staff. Key information about insulin management was often held only by the PWDI or their carer and was not documented in the GP records. Other research has demonstrated that patient held medication records can support safe information sharing about medication use between patients and healthcare professionals, however patients may not share such records, assuming healthcare professionals have access to this information.(160) Additionally, patients own medication records may be in a range of formats, and the information recorded within them may vary.(160) Opportunities remain to enhance and promote mechanisms for patients own insulin and medication records to be shared with healthcare professionals across all care settings.

The introduction of the Patient Safety Partner role in healthcare organisations is a step towards listening to the patient voice, however a wider cultural change and further actions are required to ensure patients are empowered and considered key members of their healthcare teams.(161)

9.4 Implications for practice, policy and research

9.4.1 Implications for PWDI

Opportunities

The FRAM model developed in this study demonstrated the widespread potential for supporting successful outcomes if PWDI are empowered to manage their diabetes. This aligns with other research showing the integral role patients have in supporting their own safe outcomes in healthcare.(71,72,156,157) Developing a measurement system that supports the role of PWDI by providing real-time information about key aspects of their care would enable such empowerment. These systems would elevate PWDI to become full members of their care team, enhancing their autonomy and ability to contribute to their own safety. This approach aligns with a key guiding principle for improving patient safety found in the World Health Organization's Global Safety Action Plan.(162) The NHS Patient Safety Strategy also emphasises the need for empowering patients and their advocates to play an active role in safety, including by providing access to their own data.(9) There is growing evidence that developing and empowering patients to be active partners in their care can reduce healthcare costs.(163) By co-developing real-time indicators collaboratively with healthcare staff, the partnership approach is supported, and indicators developed will reflect key issues of concern that relate to the needs of PWDI and those supporting them. As little real-time data is currently available to those involved in receiving and providing care, developing such indicators will provide visibility into safety issues that are currently hidden.

Despite the advantages of digital integration, advances may contribute to inequalities. There remain some significant challenges to engaging PWDI and caregivers in an inclusive and equitable manner. Patients with Type II diabetes usually commence insulin after three to four previous hypoglycaemic medications have failed to reduce blood glucose levels below the target range. New medications such as tirzepatide and glucose responsive (or smart) insulins mean that in the future daily subcutaneous insulin is likely to be less frequently used.(164,165) As a consequence, those people who require subcutaneous insulin for T2DM are likely to have more complex needs and/or more established, difficult to control diabetes.(164) This patient

population may face more barriers to digital enablement than other populations due to age, disabilities, or other barriers including language.(166) Ensuring such patients are equally empowered to participate and be partners in their care where they are able and willing will require careful planning, consideration and co-design. It is equally important to provide equitable safe care for those unable to contribute in this way.

9.4.2 Implications for organisations and healthcare systems

The NHS Patient Safety Strategy and use of FRAM

A FRAM model enables visualisation of care pathways using a Safety-II perspective. It highlights where potential safety risks are greatest, and where current controls are ineffective (Safety-I). It can also demonstrate factors that enhance safety that could be developed (Safety-II). This detailed and broad view can support targeted investment to improve safe outcomes. The NHS Patient Safety strategy is seeking to incorporate Safety-II thinking and methods within their approach to patient safety management in the NHS.(9) The Patient Safety Incident Response Framework (PSIRF) has been introduced, which details how organisations should respond to safety events within their organisations. An additional component of the patient safety strategy is to embed a cohort of trained Patient Safety Specialists within NHS organisations to understand human factors approaches to improving patient safety, including tools such as SEIPS(14) and HTA(129). While these tools are useful for understanding complex systems, Patient Safety Specialists would benefit from the additional insights that FRAM can provide to understand those systems over time, to model changes and predict their impact on outcomes, and to understand causes and consequences of variability. Patient Safety Specialists are a key audience who would benefit from understanding how and when to use FRAM and how to obtain the most benefit from their analysis as they explore and seek to improve patient safety within and across their organisations and networks. The NHS Patient Safety Strategy also seeks to involve patients and their caregivers and make them partners in their care.(9) Developing a FRAM model collaboratively with patients and their caregivers allows a model that represents their needs and experiences to be incorporated. This model can inform the development of patient centred safety interventions, particularly across care boundaries.

Using FRAM to explore care provision is a powerful method for organisations to develop patient-centred care pathways. It allows a collaborative approach to exploring current systems, identifying key activities and understanding the different perspectives and experiences of all involved. The resources required for a pathway to succeed can be clearly identified and demonstrated to support planning, including business case development and funding

applications. Areas that may be vulnerable to variability and pressures due to misalignments between demand and capacities can be proactively identified and mitigations put in place. Such an approach could support ICS to meet their core purposes of enhancing productivity and value for money, improving healthcare outcomes, and tackling inequalities.

This study demonstrated the impact that empowering PWDI to manage their diabetes and enabling self-management of diabetes while in hospital were key areas that can support safe outcomes during ToC. By investing in, supporting, and promoting these two activities, organisations have the potential to improve safe outcomes for PWDI.

Further application of FRAM in healthcare

New models of care including Hospital at Home services (also known as Virtual Wards) services provide traditionally hospital-based care to people who are unwell in their own homes, for example by providing intravenous medications at home rather than as an inpatient in a hospital bed.(167) For such services to be successful, they require collaboration between patients and their caregivers and healthcare staff across sectors. Proactive monitoring of key vital signs has played a part in maintaining safe care, for example, monitoring of oxygen saturation levels at home for people with Covid-19 during the pandemic.(168,169) For this model of care provision, access to shared, integrated electronic records highlighting real-time indicators for people receiving treatment would be hugely beneficial in supporting decision making and ensuring safety is maintained. Deterioration in clinical condition or other factors influencing safe outcomes requires identification in real-time to prompt assessment and intervention. Co-developing leading indicators using FRAM would ensure that patients are partners in this process and their priorities and needs are included in the measurement frameworks developed. It would allow insight into the key activities that promote safe outcomes for Hospital at Home and the often hidden structural factors that are required to ensure safe outcomes (background functions), that may be missed or assumed.

Alijaafari et al. (2024) have developed proactive disease modelling and predictive algorithms that can guide diabetes management in virtual wards through artificial intelligence supported analysis of clinical data such as key blood test results, age, weight and blood pressure.(170) This innovation included decision support tools for clinicians and patients to guide care. Integration of FRAM findings with such machine learning models could potentially ensure more user friendly and informative outputs for PWDI, caregivers and healthcare professionals.

Implications

There are practical challenges to the wider use of FRAM especially as a means of developing leading indicators. The collaborative approach integral to developing a representative FRAM model is resource intensive for front-line staff. Given the financial, workforce and workload pressures the NHS is facing, dedicating the amount of time to fully explore issues in this manner is likely to limit wider use. Secondly, the model produced is highly specific to the setting in which it is developed. Therefore, it will not be possible to directly transfer knowledge gained from this approach to a general audience without some adaptation to local systems and pathways. It will also require review over time as practices change and develop to ensure findings remain applicable.

Developments in digital health technology and associated advanced analytic capacity may mitigate resource challenges. For example, other research has applied automation to aid the feasibility of WAD scoping.(99) Technological advances will support adoption of this approach within healthcare systems that are facing multiple pressures on capacity.

Digital maturity and readiness in the NHS

Current digital systems in healthcare remain siloed and fragmented.(171) NHS-wide investment in digital integration of EHR and patient access is required for improving safe ToC and for the wider development and use of real-time indicators. A connected health record joining data across community, primary care and secondary care and integrating patient-held data is required. This would provide those who need it with up-to-date information to guide decision making at all stages of the ToC journey. Developing an integrated care record would enable real-time indicators to be available to those who need them to guide decision making.(155) Artificial Intelligence (AI) using Machine Learning and Natural Language Processing are likely to provide opportunities for wider implementation of this approach including by enabling faster and more intelligent data processing of large volumes of textual data.(172) The Darzi report into the state of the NHS recommends that digital investment is essential for improving productivity and using a more proactive approach to providing healthcare.(173) Successful development of connected digital health systems connecting wearable and patient-held data and integrating AI will require central funding and a unified, collaborative approach between patients, clinicians, digital providers, software companies and medical device companies.

9.4.3 Implications for policymakers

Using a Safety-II approach to identifying potential leading indicators provides a more holistic understanding of safety that spans care pathways and system boundaries. While

understanding and monitoring rates of adverse events remains an important tool for ongoing assessment of the impact of improvement work, supplementing these indicators with those developed using a Safety-II approach can promote a deeper understanding of where to best focus efforts. This is important for the prevention of unintended outcomes that are more likely when interventions are based on analysis of harm without adequate understanding of contributing interactions within complex systems. By contrast, by encouraging and supporting the use of Safety-II tools such as FRAM, light can be thrown on WAD and ongoing adaptations in response to interacting factors within the work system. This can enable the efficient direction of resources that best support reduced risks and improved safety. FRAM can also highlight structural issues that require policy-level interventions. Investing in recruitment and expanding the capacity of healthcare is a key component for improving safety. This can be done through better recruitment and retention, developing new models of care and enhancing IT infrastructure. It also requires support for cultural changes across the service that promotes patient and family engagement and empowerment. The NHS Long Term plan, published in 2019, sought to reduce the need for hospital admissions by supporting 'out of hospital' care, reforming emergency hospital care and providing people with more personalised support.(35) The independent investigation into the state of the NHS highlighted the need to empower and involve patients to improve services, invest in digital technology and move more care into community settings, for example through programmes like Hospital at Home (also known as Virtual Wards).(173) This provides an opportunity to build further on the aspirations of the NHS Plan particularly in consideration of how automation and engineering can reduce reliance on people's adaptations to maintain safety in the face of overwhelming demands. The need for further development and integration of digital health systems to meet needs of patients across care boundaries is recognised as a key area for development internationally.(174,175)

This research demonstrated the impact that the foundational elements of the healthcare system, such as IT infrastructure, frameworks, staffing, and education and training have on successful outcomes in transfer of care for PWDI. Due to the challenges involved in measuring safety, these foundational elements provide evidence for where capacities for safety lie. Policy makers can use this approach to identify how well resourced and effective these elements of their healthcare systems are as a proxy for understanding the capacity for safety within a system.

9.4.4 Implications for research

Safety-II focuses on how to create the capacity for safety within healthcare(109), while Safety-I seeks to prevent harm by introducing safety barriers.(36) The need for the Safety-II perspective to drive enhanced resilience, learning and safety improvement across complex health systems, is widely accepted in the international safety-focused research community.(36,97,176) There have been practical challenges relating to demonstrating the impact of such an approach.(36,95,177) Safety-II and similar safety philosophies have been criticised for being largely theoretical without practical tools to apply them in real-world situations.(95,96,178) FRAM is a key tool that can be used to apply a Safety-II perspective to safety improvement.(147) This study has shown how the method can be used to identify targets for potential leading indicators, however there is a need to develop an approach to testing the validity and feasibility of indicators developed in this way. Implementation science approaches and frameworks can support the adoption of knowledge into practice.(179) Drawing on research designs from this discipline will be helpful in promoting an understanding of the implications and barriers of moving from a safety system based on measuring past harm to one that focuses on anticipation and monitoring and how real time measures might be integrated into workflows to ensure staff have the capacity to act on them. Implementation science-based evaluation frameworks could be used to determine the best way to implement leading indicators and the impact on resources and outcomes.(179)

This study highlights the broad scope and complexity of ToC workflows for PWDI. The resulting model is challenging to display simply with much detail lost if only presented at a high level. Sujan et al. (2024) describe FRAM as 'a tool for the analyst.'(147) It is common for FRAM to become too cumbersome to easily share and explain with wider, non-technical audiences.(147) Future research might consider how findings and recommendations developed using FRAM might be better presented to ensure that they are impactful and understandable for a range of audiences including policy makers. Careful use of examples and extracts of the model may be one way to demonstrate key points.

The key findings of this study are summarised in Figure 38. These have been shared with the national Specialist Pharmacy Service(180) who are introducing a workstream to improve insulin safety.

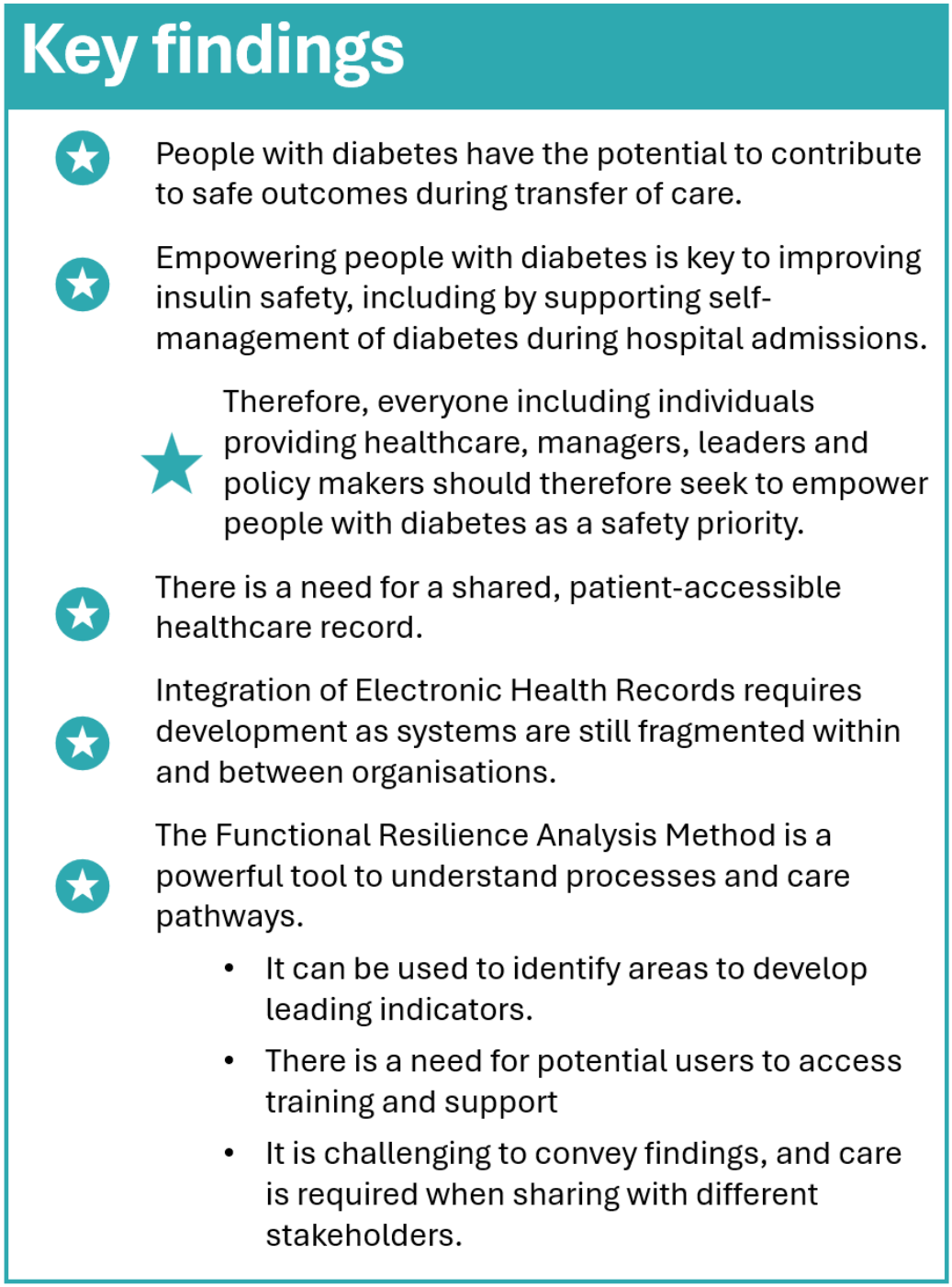


Figure 38: Summary of key findings.

9.5 Strengths and limitations

9.5.1 Strengths

This study applied a Safety-II perspective to a new area to develop potential areas for the development of leading indicators. The FRAM model of ToC for PWDI was developed using a detailed understanding of WAI and WAD obtained through multiple methods. The SEIPS tool is

well established in healthcare for exploring interacting factors within complex systems and was used consistently through the work packages to analyse and interpret factors that contribute to safety. The detailed analysis of qualitative data and the HTA allowed the FRAM functions to be developed, and the model built and examined to understand variability. The potential targets for developing leading indicators and example measures identified provide a strong basis for future work to develop and validate these potential indicators. The FRAM model development benefited from the mentorship and advice of a Chartered Human Factors practitioner.

A range of stakeholders were actively engaged throughout the study. Understanding how insulin was managed in real-life settings was gathered directly from the people involved in these processes through interviews and/or observation. Stakeholders actively contributed to the development and validation of the findings. When there were challenges to recruitment, recruitment methods were adapted, to ensure participation of a wide range of stakeholders. Widening recruitment criteria for PWDI and healthcare professionals to include those located across England, ensured the model developed may be more representative of ToC, and findings applicable to a wider audience than the single ICS. This stakeholder involvement meant the model developed included the priorities, needs and perspectives of those who deliver and receive frontline care, as did the potential targets for leading indicators identified. Intended users of new real-time indicators were able to reflect on and suggest measures they would find meaningful.

National incident reporting data was obtained and used to validate the model. Furthermore, for areas where observation had not been possible, for example in primary care, incident reports shed light on key risks arising in this context.

This study took a proactive view of how digital technology might enable real-time data capture and response to support monitoring and anticipation in the future. Diabetes is an area where real-time digital data is already available, and there is real potential to expand its use in maintaining and improving safety through the development of leading indicators.(29)

9.5.2 Limitations

While the research aimed to be patient-centred and sought to include the patient experience in all aspects of the work packages, a Patient and Public Involvement and Engagement (PPIE) panel were not involved in the design of the research protocol. The PPIE Virtual Document Review Panel(181) contributed to the development of the plain language summaries, participant information leaflets and consent forms. The research would have benefited from the

active collaboration with a PPIE panel during the design of the protocol and throughout the research. Multiple PWDI contributed to all stages of the research as participants to ensure their experiences and values were represented in the findings. The PWDI who participated in the study were recruited using a convenience sample and their demographics were not reported.

The process of developing the model was time consuming and despite focusing on emergency admission pathways, the result was visually complicated and challenging to explain in lay terms to stakeholders. This was mitigated by using two example functions which enabled a mixed seminar audience to explore in detail their potential for use as leading indicators. It was challenging to identify specific measures for these potential indicators when current access to real-time data is limited, there was uncertainty about how such data would be presented, who would be required to intervene, and what resources would be needed to respond. Further work is needed to co-develop, test and validate the example measures and evaluate their effectiveness as leading indicators for safe care.

Understanding and comparing WAD with WAI requires a detailed look at a specific work system. This study took place in England, and because PWDI, caregivers and healthcare professionals contributed from across England, the results are broadly applicable to insulin management during ToC across the country. Adaptation to local contexts will be required whenever the model is applied. To apply the findings in other countries, additional work would be required to understand WAD in these contexts. For developing nations, the differences between workflows are likely to be particularly significant, and the model will require substantial adaptation.

This study aimed to explore how current digital systems could be used to support real-time indicators and intended to use interviews with professionals involved in digital health systems to identify current capabilities and the potential to develop measures. Despite multiple attempts to engage with digital professionals, this offer was not taken up. Scoping conversations with people involved in digital systems highlighted the need for additional integration across services and sectors, and with patient held data. The potential for current systems to be harnessed to support use of real time indicators of safety requires further exploration, and a proactive approach to collaborating with software developers, insulin and device manufacturers to develop and incorporate the required functionality.

9.5.3 Reflexivity

My clinical background and concurrent clinical roles in patient safety throughout the study provided me with insight into the processes, terminology used, and safety issues being described. I was able to interpret the implications of insulin issues that may not be apparent to someone without a pharmacy background. Working in a patient safety role, I was also able to apply the knowledge and skills I gained from undertaking this research directly to other scenarios. I have applied my knowledge of SEIPS, ability to perform HTAs and thematic reviews to explore patient safety issues and contribute to developing a patient safety incident response plan. This demonstrates the practical value of the study findings as well as the tools and techniques which can be applied widely for investigating healthcare safety issues and identifying improvement opportunities.

Although my background as a pharmacist and patient safety specialist was a strength in terms of allowing additional insight, my experiences and biases will have influenced my findings. I sought to mitigate these biases by actively seeking feedback from stakeholders throughout the study.

9.6 Conclusion

This study has applied a Safety-II approach to identifying potential targets for developing leading indicators for managing insulin safely within digitally integrated care systems. It has highlighted a gap in current measures of safety for high-risk medications across ToC. Additional leading indicators that highlight the functioning of the work system are needed to provide opportunities to proactively intervene to improve safety.

The multiple qualitative methods used to understand WAI and WAD and develop the FRAM model were inclusive and allowed collaboration with PWDI, their caregivers and multiple healthcare professionals across different sectors. The resulting model therefore incorporated key users' needs and perspectives. The findings from the FRAM model were built on in a collaborative way to identify potential leading indicators. These were classified as active leading indicators that could provide real-time information to PWDI, caregivers and staff or passive leading indicators that provide information to organisations about the structural capacity for safe outcomes. This approach could be adapted and applied to other areas of healthcare to promote safety improvement.

For this approach to be applied more widely, collaboration between software developers, manufacturers, PWDI, caregivers and staff from all care settings is required to develop and

proactively consider the potential for real-time indicators and how these can be integrated in a single unified record accessible to all who need it. Further research will be needed to understand the impact of leading safety indicators on outcomes, workflows and resources.

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