Understanding safety differently: developing a model of intravenous insulin infusion use in hospital inpatients

Thesis submitted for the degree of Doctor of Philosophy in Pharmacy Practice

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Declaration

I confirm that this is my own work and the use of all material from other sources has been properly and fully acknowledged.

Mais Iflaifel

Acknowledgement

I would like to pay my special regards and sincere appreciation to my supervisors − **Dr Rosemary Lim, Dr Fran Greco, Dr Clare Crowley** and **Professor Kath Ryan** − who guided and encouraged me to stay the course even when the road got tough. Their immense knowledge and plentiful experience have supported me throughout my research journey. Without their enduring support and encouragement, the goal of this thesis would not have been realised.

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Dedication

I would like to dedicate my work to my wonderful parents, **Hasan** and **Aysha**, who held my hand as a child and in the years since have never hesitated to support me in achieving my dreams. Without their encouragement, this work could certainly not have been completed.

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Abstract

Introduction: Variable rate intravenous insulin infusions (VRIIIs) are very effective in managing hyperglycaemia in hospital inpatients when used correctly. However, if used incorrectly, they can cause harm or even death. Unlike traditional safety approaches that focus on ensuring adherence to predefined standards and identifying errors to prevent their recurrence, Resilient Health Care (RHC) shifts the focus to understanding variability in work, including both successes and failures. RHC achieves this by comparing Work as Imagined (WAI) (what people expect themselves and others to do) with Work as Done (WAD) (what people actually do) with the aim of realigning WAI with WAD in order to reflect reality.

Aim: To develop a model of VRIII use in adult inpatients informed by the RHC framework.

Methods: This mixed methods study was conducted in three phases at a Vascular Surgery Unit in a tertiary teaching hospital in England, UK. **Phase I:** Exploring WAI. Analysis of all documents related to VRIII use, and focus groups with users of VRIII. Documents and transcripts were analysed using inductive/deductive analysis. **Phase II:** Exploring WAD. Video Reflexive Ethnography methodology and quantitative data were used. The qualitative data were analysed using thematic analysis and the quantitative data were used to judge the outcomes of the observed tasks. **Phase III:** Model development. Two separate hierarchical task analyses (HTAs) were produced, one for each phase, to identify similarities and differences and to inform the development of the model of VRIII use.

Results: WAI was perceived as a complex process that involved iterative tasks of producing hospital-specific guidelines and a multi-pronged approach to ensuring implementation of and adherence to guidelines. WAD was accomplished by using standardised practices (adhering to VRIII guidelines) and context-dependent adaptations (assigning blood glucose monitoring to other colleagues during busy shifts). Reflexive meetings revealed that a lack of knowledge in the selection of intravenous fluids and monitoring of blood glucose tasks was the main challenge faced while using VRIII. Suggestions from healthcare practitioners designed to overcome this challenge focused mainly on the need for face-to-face, VRIII-focused training that is tailored to their need. The comparison between WAI and WAD HTAs highlighted that most of the tasks in both

HTAs were mostly aligned. The comparison also assisted in developing a model for the use of VRIII. The model showed that standardisation (WAI) and flexibility (context-dependent adaptations) must complement each other to ensure the delivery of patient care while using VRIII. The model also highlighted two key points to be considered when monitoring and continuously reviewing everyday clinical work and its resultant outcomes: 1) Understanding the permanence status of adaptations is a crucial step in differentiating between work that has long-term and short-term success. 2) Using monitoring tools such as checklists, clinical audits and VRE, corresponding to the type of task being performed is fundamental in reviewing everyday work and designing and implementing effective interventions that help in improving patient care while using VRIIIs.

Conclusion: This research explored safety and complexity in the use of VRIIIs by integrating innovative methodologies inspired by the RHC construct of comparing WAI with WAD and by the VRE principles of exnovation, care, reflexivity and collaboration. The methods employed and findings of this thesis could help researchers as well as healthcare practitioners to better understand the use of VRIIIs in situ and move beyond describing concepts to providing practical recommendations, based on practical data obtained from a Vascular Surgery Unit, for improving safety and patient care delivery while using VRIII.

List of publications

Peer-reviewed journal publications associated with this thesis

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Iflaifel M, Lim R, Ryan K, Crowley C. *Resilient Health Care: a systematic review of descriptions, study methods and factors that develop resilience*. BMC Health Serv Res. 2020;20(1):324.

Iflaifel M, Lim R, Crowley C, Ryan K, Greco F. *A detailed analysis of 'Work as Imagined' in the use of intravenous insulin infusions in a hospital: A Hierarchical Task Analysis.* BMJ Open. 2021;11:e041848.

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List of conferences attended

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Iflaifel M, Lim R, Ryan K, Crowley C. *Developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients.* Ergonomics and Human Factors Doctoral Consortium, April 2018, Birmingham, UK. Oral presentation.

****The presentation won the prize of the most energetic and enthusiastic presentation.**

Iflaifel M, Lim R, Ryan K, Crowley C. *Thinking of safety differently in the use of injectable insulin.* The Doctoral Research Conference, June 2018, University of Reading, UK. Oral presentation.

Iflaifel M, Lim R, Ryan K, Crowley C, Iedema R. *Understanding safety differently: an exploration of the use of intravenous insulin infusions in hospital in-patients.* The Video Reflexive Ethnography Conference, September 2018, Leicester University, UK. Oral presentation.

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International conferences

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Iflaifel M, Lim R, Crowley C, Greco F, Ryan K, Iedema R. *Resilient Health Care in the use of intravenous insulin infusions.* Ergonomics & Human Factors Conference, April 2021, London, UK. Oral presentation.

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List of abbreviations

ADA	American Diabetes Association
ANTT	Aseptic Non-Touch Technique
BCMA	Barcode medication administration
BG	Blood glucose
CARE	Concepts for Applying Resilience Engineering
CAS	Complex adaptive system
CBG	Capillary blood glucose
CGM	Continuous Glucose Monitoring
COVID-19	Coronavirus Disease 2019
DISN	Diabetes Inpatient Specialist Nurse
DKA	Diabetic ketoacidosis
ePMA	Electronic prescribing and medication administration
EPR	Electronic Patient Record
FG	Focus group
FRAM	Functional Resonance Analysis Method
FY1	Foundation year one doctors
FY2	Foundation year two doctors
HHS	Hyperosmolar hyperglycaemic state
HTA	Hierarchical Task Analysis

ICU	Intensive Care Unit
IV	Intravenous
JBDS-IP	Joint British Diabetes Society for Inpatient Care
MMAT	Mixed Methods Appraisal Tool
NA	Nurse assistant
NaDIA	National Diabetes Inpatient Audit
NHS	National Health Service
NPSA	National Patient Safety Agency
NRLS	National Reporting and Learning System
OUH	Oxford University Hospitals NHS Foundation Trust
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis
QI	Quality improvement
RCA	Root Cause Analysis
RE	Resilience Engineering
RHC	Resilient Health Care
SC	Subcutaneous
SpR	Specialist registrar
SRQR	Standards for Reporting Qualitative Research
VIP	Visual Infusion Phlebitis
VRE	Video reflexive ethnography

VRIII	Variable rate intravenous insulin infusions
WAD	Work as Done
WAI	Work as Imagined

Chapter 1

Introduction and thesis outline

1.1 General introduction

The work presented in this PhD thesis is about exploring Resilient Health Care (RHC) surrounding the use of variable rate intravenous insulin infusions (VRIII) in hospitalised adult patients. Specifically, my study focused on understanding how work was expected to be done (imagined) by managers, policy makers and healthcare practitioners in the use of VRIII (phase I), exploring how work was actually performed by healthcare practitioners using VRIII (phase II) and then comparing between phases I and II in order to construct a model of VRIII use to provide in-depth understanding of the conceptualisation of RHC for researchers and healthcare practitioners by illustrating WAI, WAD, and the adaptations used and their resultant outcomes, in the context of VRIII use.

To provide a rationale for this research, this chapter begins with an overview of hyperglycaemia, providing a definition and a discussion of its prevalence (section 1.2.1) and of the treatment options available in hospitals (section 1.2.2). The treatment options focus mainly on the use of VRIII to treat hospitalised inpatients as it is the treatment option that is of particular relevance to this thesis, as well as the associated risks, benefits and main initiatives for enhancing VRIII safety (section 1.2.2.2). The chapter also provides an overview of the safety approaches used to enhance safety in healthcare settings, the problems associated with each approach and a description of new approaches that might be more applicable in complex adaptive systems (section 1.3). Building on these foundations the last part of the chapter outlines the rationale of this study (section 1.4), the scale of the problems in this area, and gaps in the research (section 1.4.2) along with the specific objectives that were developed to address these (section 1.5). Figure 1.1 provides schematic illustration of how the background to my thesis is organised within this first

chapter.

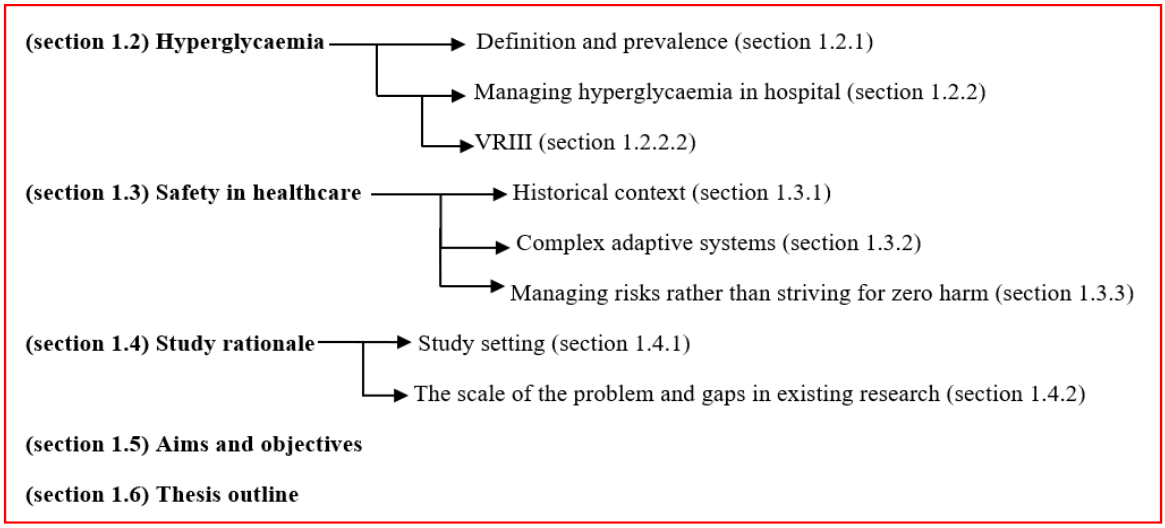

Figure 1.1 Schematic representation of the first chapter of this PhD thesis.

1.2 Hyperglycaemia

1.2.1 Definition and prevalence

Diabetes mellitus is a serious chronic disease in which the body's blood glucose (BG) level becomes too high (hyperglycaemia). Hyperglycaemia is defined as BG value >7.8 mmol/L (140 mg/dL) [1]. The association between hyperglycaemia and adverse inpatient outcomes is widely documented and well established, whether or not the patient has been previously diagnosed with diabetes [2-4]. Hyperglycaemia results in physiological changes that can exacerbate acute illness, increase direct cellular damage, and decrease vascular and immune function [2]. Patients with hyperglycaemia stay longer in hospital for their care, show higher rates of mortality, morbidity and admission to the Intensive Care Unit (ICU), and are more prone to delayed wound healing and surgical site infections [5-7]. Therefore, maintaining BG readings within the target range 6–10 mmol/L (108-180 mg/dL) for most inpatients or up to 12mmol/L (216 mg/dL) for inpatients with comorbidities, is a key goal to prevent complications in hospitalised patients with hyperglycaemia [8, 9]. Hyperglycaemia is common in hospitalised patients and 26% of inpatients with hyperglycaemia have a history of diabetes. Twelve per cent of inpatients with hyperglycaemia either have a diagnosis of diabetes discovered after admission, or develop hospital-related diabetes (stress hyperglycaemia) that spontaneously resolves after the acute illness abates [6, 10]. The 2019 National Diabetes Inpatient Audit (NaDIA) estimated

18% of adult hospital beds in England and Wales were occupied by patients with diabetes, and that by 2030 the prevalence will increase to 30% [11, 12]. As the prevalence of hyperglycaemia among hospitalised patients increases, the treatment of diabetes and hyperglycaemia in hospital becomes part of everyday clinical work. Numerous guidelines have been produced nationally and internationally such as the Joint British Diabetes Society for Inpatient Care (JBDS-IP) and the American Diabetes Association (ADA), to help healthcare practitioners manage diabetes in hospital using various treatment options [13, 14].

1.2.2 Managing acute hyperglycaemia in hospital

Globally, insulin therapy is considered the preferred treatment modality for hospitalised patients with acute, unstable, highly elevated and fluctuating hyperglycaemia [15]. Several studies have shown an association between insulin therapy and improved patient outcomes, not only because of its effect on reducing BG but also because of its pleiotropic effects (producing multiple effects from a single hormone) [16-18]. Such pleiotropic effects include reduced peri/postoperative complication rates [18, 19], decreased blood pressure [16], and improved myocardial perfusion [17]. Insulin can be administered via the subcutaneous (SC) route or as an intravenous (IV) infusion for cases in which rapid titration is the goal e.g. in sepsis and post-cardiac surgery [2].

1.2.2.1 Subcutaneous insulin

SC insulin is the preferred treatment option for patients who are not critically ill and who are able to eat and drink normally [2, 20]. In many countries, scheduled SC insulin (basal or intermediate-acting insulin administered once or twice a day in combination with rapid- or short-acting insulin administered before meals) is widely used because of its effectiveness and safety in controlling BG in non-critically ill patients [21, 22]. This regimen mimics natural physiological insulin secretion as it matches the body's insulin requirements: basal long-acting insulin to control BG in the fasting state, adjusted pre-meal short-acting insulin to control BG following a meal, and supplemental short-acting insulin to control unexpected elevation in BG [2, 23]. Although the scheduled SC insulin regimen is recommended for all non-critically ill medical and surgical patients in the USA and Europe [14, 18], it is not possible to recommend this regimen as first-line therapy for non-critically ill patients in the UK. This could be explained by the fact that 22% of National

Health Service (NHS) hospital sites still have no diabetes inpatient specialist nurses and have low access to diabetes pharmacists, while 65% of hospitals do not fully utilise electronic prescribing technology to facilitate the scheduled SC insulin regimen [24]. SC insulin can also be administered using a twice-daily pre-mixed insulin regimen where rapid- and long-acting insulin are combined. However, it is difficult to control BG under this regimen owing to a number of patient and hospital factors, e.g. co-morbidities, changing medications, variable staff expertise, and changing meal quality and timing [20]. SC insulin is also administered as a correctional 'one-off' or as required, using rapid- or short-acting insulin [25]. However, if repeated doses of the 'one-off' SC insulin are required, the treatment regimen should be re-evaluated as it will not be sufficient to control persistent hyperglycaemia [15]. Compared to SC insulin, IV insulin has a short half-life and decreases BG rapidly, which makes it ideal for controlling BG in acutely ill patients because of the flexibility of dose titration based on the unpredictable changes in patients' health [2].

1.2.2.2 Variable rate intravenous insulin infusions

VRIII is considered the cornerstone treatment and might be the only appropriate option for controlling hyperglycaemia in some situations, as summarised in Box 1 [9, 12, 26].

Box 1 Potential indications for using VRIII to manage hyperglycaemia [9, 12, 14].

1. Patients with diabetes, nil by mouth and missing more than one meal
2. Diabetic ketoacidosis (DKA)
3. Hyperosmolar hyperglycaemic state (HHS)
4. Critically ill patients
5. Post-cardiac surgery
6. Myocardial infarction or cardiogenic shock
7. Uncontrolled hyperglycaemia during high-dose glucocorticoid therapy
8. Perioperative period
9. Stroke
10. Sepsis
11. Parenteral nutrition

VRIII has a narrow therapeutic index and is considered a high-risk medication [27], meaning that if used incorrectly it can cause serious or even fatal harm to the patient. Both underdosing and overdosing may cause severe life-threatening side effects such as hypoglycaemia, rebound hyperglycaemia or ketoacidosis [8]. Four types of challenges

related to the use of VRIII (see Figure 1.2) are described in the scientific literature: medication-related, patient-related, healthcare practitioner-related and hospital-related. These are discussed further in the following paragraphs [12, 28].

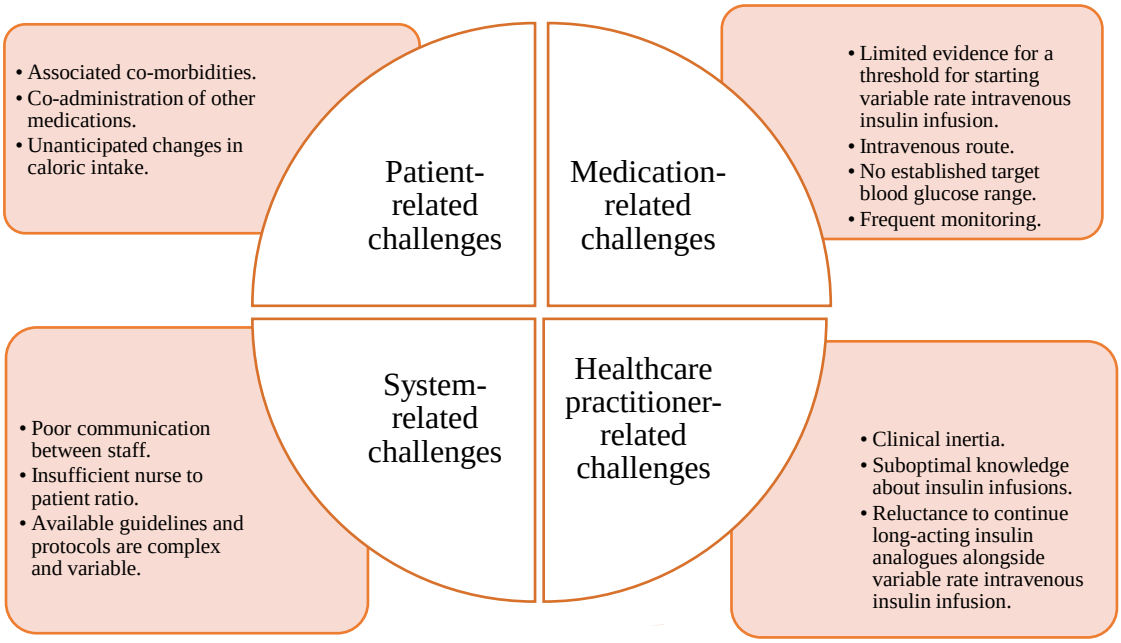

Figure 1.2 Main challenges in the use of variable rate intravenous insulin infusion. [2, 5, 14, 15, 26, 29-34]

Medication-related challenges

Research studies have shown that the IV route of administration poses additional challenges compared to the SC route due to serious errors in prescribing, preparation and administration [2, 20, 35]. VRIII, as an injectable insulin formulation, carries added risk as it might be difficult to alleviate the negative effect of immediate absorption and distribution into the blood circulation [2]. There is limited evidence for a BG threshold to start VRIII. However, there is a consensus view that VRIII should be initiated when BG is >10 mmol/L (180 mg/dL) [12]. Most current guidelines recommend setting BG levels between 6–10 mmol/L (108-180 mg/dL) [12, 14]. However, a more stringent range of 6.1–7.8 mmol/L (110–140 mg/dL) is sometimes the target in selected patients, if this can be achieved in cases of severe hypoglycaemia [14]. Frequent monitoring is another challenge facing healthcare practitioners using VRIII. Recent guidelines recommend frequent BG monitoring for patients on VRIII, ranging from every 30 minutes to every two hours [13, 14, 36].

Patient-related challenges

Each inpatient with hyperglycaemia is unique in their presentation. Associated comorbidities such as renal disease may require frequent adjustment of the VRIII rate as the disease deteriorates and renal clearance reduces [37]. Co-administration of other medications, such as glucocorticoids, which cause hyperglycaemia as a major side effect, is another challenge that can result in worsening glucose control and thus warrant additional BG monitoring and VRIII rate adjustment [30, 31]. Other challenges, such as BG level on admission, outpatient diabetes medications and unanticipated changes in caloric intake, can influence glucose metabolism, increase the risk of insulin resistance and can in turn influence healthcare practitioners' decision-making process while using VRIIIs [30-32].

Healthcare practitioner-related challenges

Clinical inertia is considered one of the key challenges in the use of VRIII which describes healthcare practitioners' reluctance to initiate or intensify the treatment [26, 33, 34]. It could be due to fear of hypoglycaemia [15, 33], lack of confidence [33], complexity of treatment regimens, unfamiliarity with existing hospital guidelines and confusion regarding appropriate BG target [5, 31, 36]. A pilot audit was conducted in 2012 to assess registered nurses' knowledge on diabetes and the use of VRIII in the ICUs. Despite the availability of VRIII hospital guidelines, only 7% of participants were able to identify the correct procedure for stopping VRIII and re-initiating the usual medications [38]. Existing guidelines for the use of VRIII clearly stated the importance to continue the administration of long-acting insulin analogues alongside VRIII [8, 14]. A study conducted to explore diabetes knowledge among registered nurses working in an NHS Trust identified low confidence in their knowledge of insulin therapy, as only 33% of the participants agreed with continuing long-acting insulin analogues while a patient is on VRIII [39].

System-related challenges

Data from several studies suggests potential system-related challenges in the use of VRIII such as lack of multidisciplinary working, poor communication between staff [15, 33] and insufficient nurse to patient ratio [15]. In 2009, Ead found that the initiation of VRIII greatly affected nurses' workload because of increased BG monitoring frequency and

insulin titrations based on BG readings [40]. It is estimated that a nurse needs at least two hours per day for a patient on VRIII, which is considered a tall order in busy, short-staffed hospitals [41]. One of the biggest challenges currently facing the NHS is the shortage of nurses. It is estimated that 80% of nurse and 90% of doctor vacancies are being filled by either agency staff or 'bank' staff (the NHS in-house equivalent of an agency) [42]. Even when vacancies are filled, there could be negative consequences such as inconsistencies in skills and knowledge surrounding VRIII use, the huge financial burden on the NHS budget, and a reduction in the ability to deliver continuous patient care [5, 42].

Although there are available guidelines and protocols for the use of VRIII, they are complex and variable [30]. In the UK, there is a growing body of evidence that recognises wide heterogeneity in VRIII guidelines in terms of indications of use, rate of infusion and duration of use [30]. It is argued that this variability increases the risk of error and makes it more challenging to optimise and to study the efficacy and safety profile of VRIII [26, 36].

1.2.3.3 Initiatives

In order to overcome the challenges associated with the use of VRIII in hospitals, a variety of initiatives have been implemented in hospitals.

VRIII-specific initiatives

Standardised protocols

Several studies recognised the critical role of protocols for the use of VRIII to enhance patient safety and decrease the risk of side effects and errors. A systematic review was conducted to compare the safety and efficacy of protocol-directed insulin infusions therapy with conventional practitioner-directed therapy. Among the studies included, there was a clear link between the use of the protocol-directed insulin therapy, and achieving BG target levels and reducing hypoglycaemic events [43]. According to the National Patient Safety Agency (NPSA), each hospital should have up-to-date protocols for prescribing, preparing and administering injectable drugs in all clinical areas [44]. The JBDS-IP has since 2014 been producing evidence-based guidance on the use of VRIII in order to harmonise practice among hospitals in the UK [8].

Continuous education

Continuous education and learning is another modality used to overcome the challenges faced in the use of VRIII. Initiatives including diabetes and insulin learning sessions have been the subject of many studies. One study assessed the efficacy of a one-hour, case-based educational programme intervention to improve inpatient diabetes care using insulin infusions. After implementing the intervention, there was a 49% reduction in insulin prescription errors in situ and the mean score of confidence in junior doctors' ability to manage hospitalised patients with diabetes increased significantly, from 17.5 to 24.9 ($P< 0.001$) [45]. Another study was conducted to assess a diabetes e-learning module at Barnet and Chase Farm Hospitals NHS Trust in the UK. After participants had undertaken the e-learning module, there was a significant increase in their confidence in managing patients on VRIII and in switching to SC when appropriate ($P<0.001$) [46]. Field *et al.* (2018) assessed the prescribers' knowledge before and after they produced an educational audio-visual podcast to explain the rationale behind their decisions about which fluids are appropriate to prescribe with VRIII. The study showed that producing the podcast had significantly improved the prescribers' knowledge and practice in prescribing the correct fluid with VRIII ($P<0.001$) [47].

There is strong body of evidence to show that a Diabetes Inpatient Specialist Nurse service (DISN) reduces length of stay, excess bed occupancy for people with diabetes [48] and the number of VRIII errors, as well as enhancing staff and patient education and support [38, 49]. Appropriate and effective use of DISN for inpatients is important in ensuring high standards of care. The Think Glucose project was a national initiative, led by the NHS, to improve inpatient diabetes care in the UK. The project developed a comprehensive 'traffic light' system to provide frontline practitioners with guidance about which patients should be referred to the DISN team [50]. The 'traffic light' system strongly recommends that patients on VRIII who have uncontrolled hyperglycaemia or have been on VRIII for more than 48 hours should always be referred to the DISN [50]. The traffic light system was developed to improve the efficiency of DISNs' work; however, the way it is used in practice is not explicitly recorded or defined [51].

Prefilled ready-to-administer insulin infusion syringes

The use of prefilled ready-to-administer insulin infusion syringes for use in VRIII has been introduced in some UK hospitals. Although there is no current evidence showing an increase in patient safety from using the prefilled syringes compared to syringes prepared at the time of administration, their use is advocated by the NPSA guidelines and is also an NHS Trust-wide mandate designed to minimise preparation and administration risks as well as decreasing preparation time [13, 44, 52].

Infusion-specific initiatives

The practice of reducing the range of device types, using centralised equipment libraries and using smart infusion devices, has been advocated to prevent critical medication administration errors. These smart devices require the entering of additional information including patient body weight, name of medication, concentrations and institutionally specified 'soft' and 'hard' dose limits [53]. A number of studies have suggested the benefits of smart infusion devices on improving patient safety and reducing infusion rate errors by using drug error reduction software and providing an electronic double-check to help nurses detect possible prescribing or programming errors [53, 54]. However, more studies are needed to confirm the smart devices' efficacy in reducing infusion errors as the most recent Healthcare Safety Investigation Branch report concluded that this is not yet proven [55].

Other related initiatives

An electronic prescribing and medication administration (ePMA) system is a technological initiative that has had a positive effect on the quality of insulin prescribing [56]. Flanders *et al.* conducted a study to evaluate and compare a glycaemic control initiative as either paper protocol or computer-based protocol with decision support system for intravenous insulin dosing. After implementing the computer-based protocol, it was found that patients were 2.28 times more likely to reach target BG as compared to using paper-based protocols [57].

In England, the Department of Health 'Scan4Safety' project led to the introduction of the barcode medication administration (BCMA) system, by which medications and patient barcodes are scanned and verified before medication is administered [58]. BMCA is becoming more common in other countries, e.g. USA [59] and Canada [60], where it is

often integrated with ePMA systems. A recent study on the impact of using BCMA on patient safety, concluded that the rate and severity of medication administration were reduced using BCMA as well as increasing nurses' time spent in direct patient care [61].

The use of continuous glucose monitoring (CGM) technology has improved dramatically over the past five years. CGM works by inserting a sensor subcutaneously to measure the glucose level in the interstitial fluid, and results are provided every 10 minutes for up to 72 hours. CGM devices reduce the risk of hypoglycaemia and improve HbA1c levels [62]. They incorporate predictive alerts for hypo- or hyperglycaemia which alarm the user before the glucose sensor reaches the low or high threshold [63]. However, the physiological 'lag time' of between 5 and 15 minutes is well reported with the use of CMG because the BG reading reflects glucose level in the interstitial fluid rather than the actual BG level that is found in capillary blood [64]. Unlike the CGM, the Space Glucose Control (SGC) technology is recommended to be used in critically ill adults patients in ICU as it automatically calculates the optimal level of insulin rate based on arterial BG measurements, carbohydrate intake, administered insulin dose and the patient's previous response to insulin [65]. A European multicentre observational study showed that the use of SGC was suitable to achieve excellent BG control in critically ill patients with low variability and a good safety level with low incidence of hypoglycaemia [66].

To date, major initiatives to establish patient safety using VRIII have not convincingly been shown to reduce risk, error or mortality rates [24]. VRIII is still used when not indicated, 7% of the VRIII duration may be unnecessarily prolonged, and 17% of switches from VRIIII to other diabetes medications are mismanaged [8, 67]. Dealing with this situation has proved remarkably difficult, making it important to think about effective new ways of enhancing safety.

1.3 Safety in healthcare

1.3.1 Historical context

Enhancing patient safety is an overarching goal for healthcare systems. The interest in safety, health and environment is as old as civilisation itself [68]. In tracing the historical development of safety, Hale and Hovden distinguished between three ages of safety

(Figure 1.3), namely 'the age of technology', 'the age of human factors' and 'the age of safety management' [68].

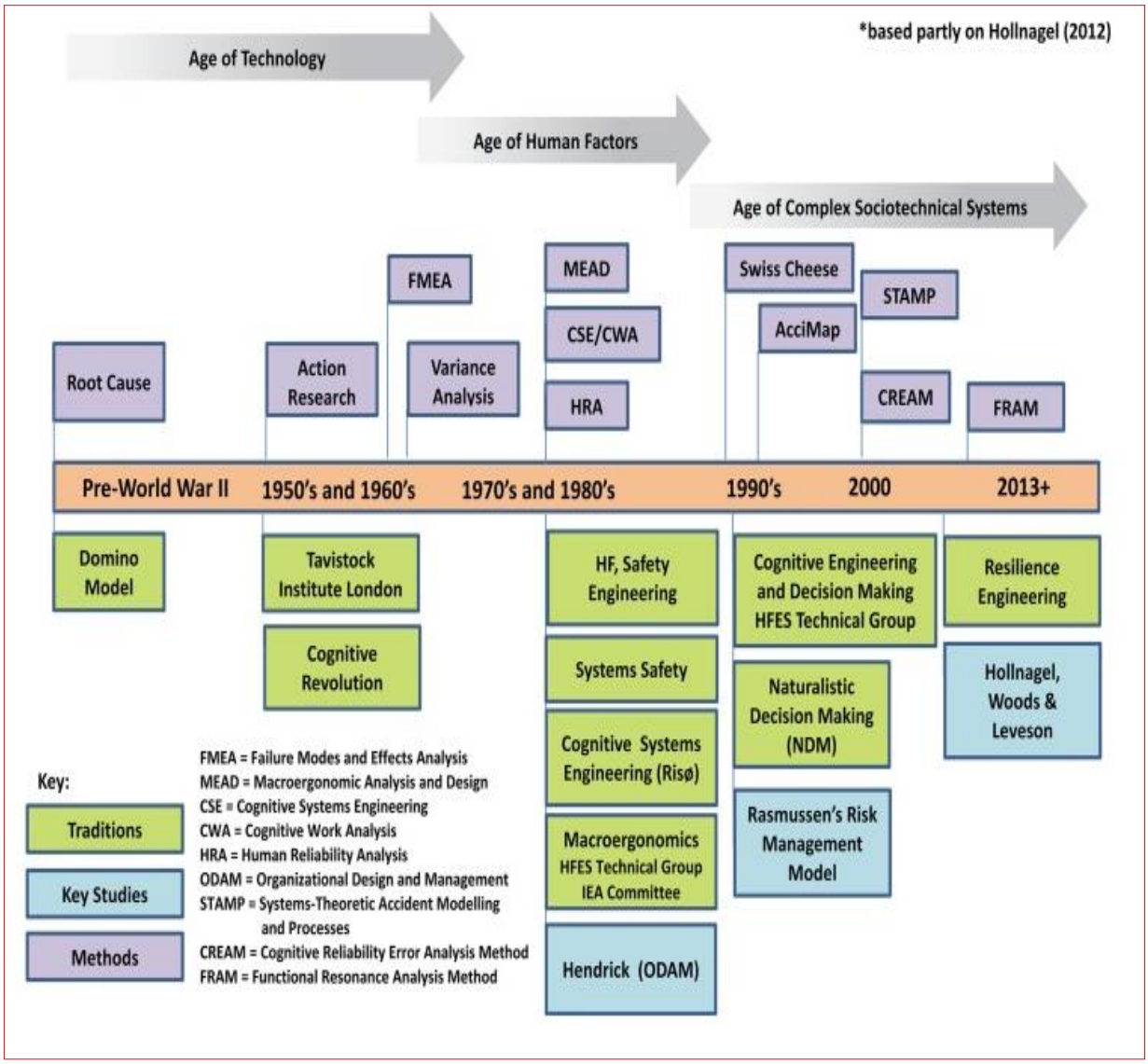

Figure 1.3 Timeline for the three ages of safety evolution (Waterson *et al.* 2015) [69].

The first age started around the beginning of the industrial revolution and it was mainly concerned with the analysis of technological failures. Technology was considered the main threat to safety, not only because the machines of the time were unreliable but also because people had not learned how to systematically avoid its risks [68, 70]. Heinrich (1930) proposed a sequential accident model called the Domino model, which has been influential in safety thinking. The model represents an accident sequence as a causal chain of events, represented as the fall of one domino piece leading to the fall of the next, exemplifying linear causality [71]. Within this period, event analysis is geared towards using the root cause analysis (RCA) approach to discover the underlying causes of accidents in order to formulate appropriate solutions [69].

In 1979 the second age of safety, termed 'the age of human factors', began. This was characterised by a recognition of the potential impact of human performance capabilities and shortcomings on existing risk and safety analyses [72, 73]. This new perspective of the role played by human factors was reflected in developing different methods to address risk and safety issues, including failure mode and effects analysis and hazard and operability analysis [70, 72]. Such methods have also been applied to healthcare systems to perform human reliability and error analysis [74].

Around the end of the 1980s, the third age resulted in a shift in thinking about safety, away from focusing only on technology and human beings, towards placing both within a broader understanding of organisational culture and processes [68]. This new orthodoxy of safety thinking argued that adverse events, errors and risks are mainly attributable to the wider system rather than to individual error. In relation to this age, a so-called 'Swiss cheese model' was developed to explain the occurrence of system failures. It imagined the system, with its series of defences, barriers and safeguards, as slices of Swiss cheese with many holes, arising in the system from a combination of active errors and latent conditions, which if they aligned resulted in system failures [75]. The active failures represent unsafe acts − lapses, slips, mistakes, violations − carried out by practitioners who are in direct contact with the patient or system. Latent conditions are inevitable hazards within the system arising from decisions made by policy-makers and top level management, poor team dynamics, or time pressure [76, 77]. This model informed the development of the framework for analysing risk and safety by focusing on the contributory factors that influence practice [78]. The framework of contributory factors was then adapted to

produce the London Protocol [79], which has been used extensively in healthcare to investigate accidents by attempting to understand how they happen in order to find ways of preventing their recurrence [80, 81].

Although the third age differs in the way in which it identifies the predominant causes of safety and risk, its way of understanding what safety means is the same as the first and second ages of safety [70]. The three ages shared the same understanding of safety as a condition in which the number of errors is as low as possible. In other words, the lack of safety means that something goes wrong or can go wrong [82].

Although much work has been done to enhance patient safety, healthcare systems are not as safe as they could be. It is clear that the logic of the previously mentioned system-oriented approaches focuses on problem-based thinking in reactive or proactive ways, and does not correspond to the complexity of modern healthcare systems or the reality that, most of the time, clinical work results in positive outcomes [77].

1.3.2 Complex adaptive systems

Healthcare systems are regarded as Systems of Systems [83] or complex adaptive systems (CASs), in which "the system's behaviour changes over time and cannot be completely understood by simply knowing about the individual components" [84]. 'Emergence' and 'unpredictability' are considered key characteristics of CASs. In a CAS, interacting processes and individual components operate by following sets of internal rules. However, they respond in different ways to the same input, and outcomes emerge in ways that are not always predictable (non-linear) [85, 86]. 'Interdependence' is another characteristic of CAS where systems and their interacting components learn and adapt their behaviour to new circumstances, and react to and interact with other parts of the same system or new systems, which in turn influences their environment [87]. Healthcare practitioners continually manage tensions and translate these tensions into safe practices through the dynamic adjustments and trade-offs that are part of everyday work [88]. For example, a formal handover from paramedics to clinicians is mandated by the NHS [89]. Usually, paramedics use a structured formal checklist to hand over to the charge nurse then conduct another handover to the bedside nurse. Researchers observed that a second informal handover is usually carried out by the paramedics and the bedside nurses discussing each patient's condition deeply. The informal handover was seen as duplication and time-

consuming by senior nurses but front line clinical staff believed that this provides a clearer and in-depth patient account with less likelihood of missing important information and also improved communication [89]. Another crucial characteristic of CASs is that they are 'indeterministic', meaning that the future cannot be forecast by extrapolating data from the past because the system alters over time [84]. These core characteristics of CASs highlight that for patient-safety advocates, the overarching challenge that must be faced on the road to enhancing safety is that of acquiring a profound understanding of the nature of healthcare systems.

1.3.3 Managing risks rather than striving for zero harm

It is important to pay attention to the methods and approaches used to study safety in CASs. As healthcare systems manifest the properties of CASs, it is crucial to explore approaches that are different to those used to enhance safety in simple linear settings [85].

1.3.3.1 Safety-I

Traditionally, safety was defined as the absence of harm or as few things as possible going wrong (termed 'Safety-I'). The Safety-I approach is predominantly based on the assumption of human culpability, with errors and adverse events being caused directly by things going wrong whether through incompetence, negligence, personal deficiency, or deliberate deviation from standard procedures [90]. It is a bimodal view, where a system's components are viewed as either working correctly, resulting in successful outcomes, or working incorrectly, resulting in failures and adverse events (Figure 1.4). The purpose of safety management is, naturally, to ensure that the system remains in the successful outcomes mode and never slips into the failure mode [70].

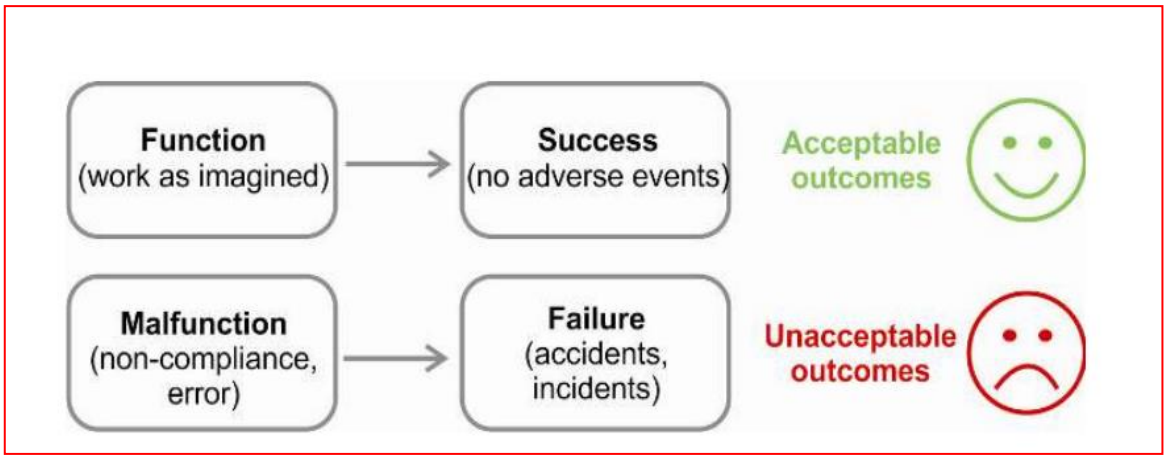

Figure 1.4 Safety-I assumes that things that go right and things that go wrong happen in different ways (Hollnagel *et al.* 2015) [82].

After the World Health Organization (2002) called for urgent action to tackle the problem of patient safety and to better manage healthcare-associated errors, the core mission of healthcare systems became to learn from medical errors and adverse events through learning and incident reporting systems [91]. The assumption was that such an approach would identify systemic errors and enable lessons to be learned which could then be used to prevent future recurrence.

Critics of the Safety-I approach argue that a number of limitations undermine it.

The first is its way of *studying and measuring safety* specifically that an increase in safety is represented by a decrease in the number of adverse events. It is paradoxical that safety is approached by trying to study its subject matter in situations where there is a lack of safety [90], which as de Vos (2018) put it is akin to "trying to understand successful marriage by only looking at divorces" [92].

A second limitation lies in this approach's way of *explaining incidents*. Safety-I assumes at its heart that incidents can be explained by decomposing the problem into its parts then addressing each one separately, using linear cause–effect chains [77, 90]. Techniques such as RCA and incident reporting have been used to identify the multiple factors that have contributed to the harm caused to the patient, bringing a systems science perspective to safety [93]. These techniques explain errors as variability in human performance that could be fixed by introducing interventions to eliminate their distal cause and thus prevent future recurrence [77]. Common examples of interventions for events involving healthcare

practitioners include changes to protocols or policies, the use of warnings [89], and introducing electronic prescribing systems [94]. While such linear approaches to learning from errors have led to some positive results, they have not proved sufficient to enable understanding of the performance variability and the dynamic and non-linear nature of CASs [95].

A third limitation is the people involved in *investigating incidents,* as distinct from those who are directly involved in them. Hollnagel (2008) [96] used the phrase 'What-You-Look-For-Is-What-You-Find' to illustrate the effect of a priori assumptions on the findings of incident investigations. Investigators analyse incidents retrospectively, that is with full knowledge of their outcome. This type of investigation can lead to various biases, including hindsight and attribution error biases, which can negatively impact the validity of investigations' conclusions and in turn produce recommendations that fail to adequately address the external factors combining to contribute to or cause incidents, often in unexpected ways [97]. These biases may also be wasteful, their emphasis on anecdotal accounts leading to precious time, money and other resources being misdirected. For example, additional standard instruction and training may be recommended, in the hope that this will result in 'good behaviour', instead of the same energy being devoted to devising more reliable solutions that focus on system learning and address the factors that led to an undesired outcome [97, 98].

Fourth comes the idealised view referred to as *'Work as Imagined' (WAI).* Safety-I thinking is focused on what regulators, managers and policy makers assume healthcare practitioners should do (WAI) when they design protocols and strategies for improvement. However, individuals/teams in healthcare organisations may resist the introduction of top-down, standardised protocols and linear-style interventions because of the dynamic and emergent nature of CASs, which necessitate individualised responses rather than following standard protocol [99].

Lastly is that *few lessons tend to be learned* from the Safety-I approach. The focus of Safety-I is learning lessons from adverse events affecting patients during their clinical care, but what about the lessons to be learned from those patients who have been correctly treated and experienced no adverse events? Although learning from errors is essential, the knock-on effect of using 'band-aid' approaches which patch areas where there are known issues but are not based on an understanding of the whole system, increases the risk of

fewer and incomplete lessons being learned [100]. A CAS cannot be understood by looking at its individual components – a case of the sum being greater than the parts – and we must instead attempt to understand healthcare systems holistically by learning lessons from both errors (Safety-I) and successes (Safety-II) rather than vainly striving for zero harm.

1.3.3.2 Safety-II

Although the focus of all existing safety approaches is to improve care and safety, firm evidence that patients and healthcare systems are safer as a result of these approaches is lacking [101, 102]. This lack of progress, as has been suggested, is in large measure due to the reliance on approaches to safety that have focused too narrowly on learning from a few extraordinary situations when a system has broken down [86]. Resilience engineering (RE) is a new paradigm for conceptualising how everyday work is accomplished in CASs [95]. It explicitly argues that performance variability is an integral part of how people and systems deal with expected and unexpected situations, and their capacity to successfully adapt is what makes the system work, enabling good outcomes in spite of problems and challenges [103]. In order to understand safety differently, a new safety approach termed 'Safety-II' originated from the RE way of thinking. Safety-II shifts the emphasis from failure to success. It focuses on understanding and strengthening everyday work and adaptations (ordinary) to maximise the number of events with a successful or desired outcome [82].

The fundamental principles that underpin Safety-II approach include:

1- Variability rather than bimodality in performance

In contrast with the Safety-I approach, in which outcomes were seen as either successes or failures, proponents of the Safety-II approach argued that people naturally adapt to their circumstances. These adaptations and variations are necessary for everyday work ('Work as Done', WAD) and interpretations or judgments of such actions as failures or malfunctions should be re-examined [104]. Figure 1.5 illustrates how the occurrence of adverse events may be due to the variability inherent in everyday situations, human performance and complex systems, rather than to malfunctions. This is consistent with the fact that CASs are emergent and interdependent; as a consequence, the work situations are

usually unpredictable. This means that healthcare practitioners on the front line work in resource-constrained, challenging environments, make adaptations to accomplish their tasks to fit with the local context, demands and cultural characteristics, rather than strictly follow top-down policies and protocols [90, 105].

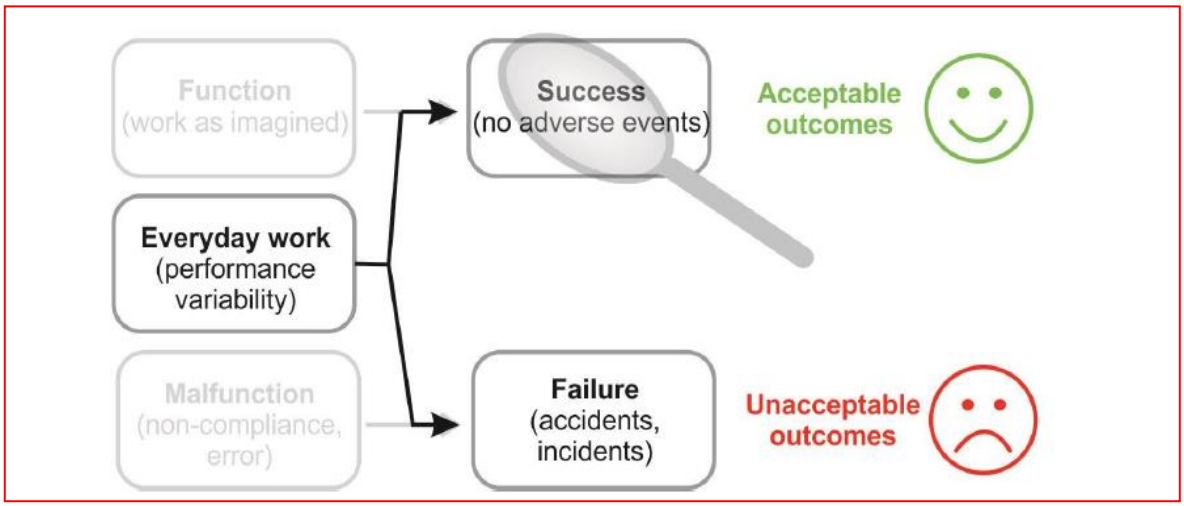

Figure 1.5 Safety based on everyday variability in performance (Hollnagel *et al.* 2015) [82].

2- Emergence rather than causality

The usual way of explaining how outcomes are reached is by tracing back from effect to cause until root causes are reached. By contrast, RE and Safety-II do not aim to identify root causes, since the principle on which they are built depends on the fact that safety is an emergent property of the system and should be seen as residing in the system's ability to succeed under varying conditions [103]. Although there are adverse events that can be attributed to malfunctions or failures of a system, there are also many instances where it is not possible to attribute negative outcomes to definable cause(s); such outcomes are referred to as being emergent rather than resultant [70]. Even when every component of a system functions perfectly, exactly as originally intended, accidents might still occur due to dynamic nature of CAS where outcomes are not always predictable [106].

3- Proactive rather than reactive

Based on the definition of Safety-II, ensuring that things go right in the future cannot rely on responding to negative outcomes after the event, in the hope that this alone will correct what went wrong last time (reactive response). Instead, focusing on understanding

everyday work (WAD) is key in order to replicate and optimise successful practices, to maintain the ability to succeed [86], to understand the context and the tensions within the clinical environment, and to allow different stakeholders to be aware of each other's perspectives [88].

The recent NHS Patient Safety Strategy provides a long-term plan to provide safer and better patient care. The plan focuses on understanding how systems provide the right clinical care and proactively learn from what works, not solely from what doesn't work [107]. For proactive approaches to work, it is important to understand how the system works by understanding both its failures and successes, in order to anticipate what can happen, develop and change within it, and to know how the various components and functions depend on and affect each other.

1.3.3.3 Safety-I and Safety-II

To enhance patient safety, it is crucial that safety advocates integrate the two ways of thinking to gain a more balanced perspective on how things go right and how things go wrong, rather than focusing on the wrong practices [86, 104]. Table 1.1 summarises the key characteristics of the Safety-I and Safety-II approaches [82, 108].

Table 1.1 Key characteristics of Safety-I and Safety-II approaches. Adapted from Hollnagel *et al.* 2015 and Appreciating People 2019.

	Safety-I	**Safety-II**
Definition	That as few things as possible go wrong.	That as many things as possible go right.
Safety management principles	Reactive: respond when a risk happens or is categorised as unacceptable risk (problem-focused approach).	Proactive: continuously trying to anticipate developments and events (appreciative and strength-focused approach).
View of human factor	Human variability is viewed as liability or hazard that needs to be fixed.	Human variability is viewed as a necessary resource for flexibility and resilience. Humans are a source of solutions to various clinical problems.
Explanation of accidents	Accidents are caused by failures and malfunctions. The purpose of the investigation is to find the cause.	Things happen in the same way, regardless of the outcome. The purpose of the investigation is to understand how things usually go right as a basis

	to understand how things might occasionally go wrong.

In order to make the transition to a more adaptive healthcare system, RHC adopts the Safety-II approach and applies RE concepts in healthcare settings, taking a balanced approach to safety by integrating the reactive and proactive approaches and understanding the successes and failures of each approach [86]. RHC is clear that healthcare practitioners are not a problem to be solved or standardised. Instead they are viewed as resources and assets that are able to anticipate, monitor, respond, learn and adapt to threats, all fundamental features of a resilient system [82, 95]. One of the key constructs RHC uses to understand complexity and variability in clinical performance is to compare what people say, think, or assume that they do (WAI), with what people actually do in everyday work (WAD) [109]. Several studies have shown that there are gaps or misalignments between WAI and WAD [110-113]. In practice, patient safety could be enhanced by digging deeper to understand how everyday work and interactions are done and to explore the gap between WAI and WAD. This exploration would direct systems' efforts to realign between the two perspectives by enabling stakeholders at different system levels to better appreciate how work is perceived and how it unfolds in everyday work [114].

A considerable amount of literature has been published on safety improvement in healthcare. These studies have used the terms 'Safety-II' and 'RHC' interchangeably. Safety is an emergent outcome of an RHC organisation. The aim of RHC is beyond 'safety' only: it focuses on all aspects of everyday work, including safety, productivity, quality of care, planning and policy [115]. Throughout this thesis, the term 'RHC' will be used to refer to this approach used to understand the use of VRIII.

After bringing together the main ideas already presented about different safety approaches and the fact that the RHC approach takes a comprehensive perspective in learning from successes as well as failures (which could enhance patient safety in the use of specific medications such as VRIII), certain questions arise. How exactly are RHC principles to be used to enhance patient safety and allow us to learn from everyday work? And what should be studied, how and when?

1.4 Study rationale

To develop a model of VRIII use in a Vascular Surgery Unit based on RHC principles, it is necessary to understand the study setting in which this research took place and what has been done so far to improve patient safety using VRIII. It is also essential to explore the scale of the safety problem faced in the use of VRIII, and gaps in the existing research, in order to highlight the importance of doing this new research.

1.4.1 Study setting

This study took place in the Vascular Surgery Unit of the John Radcliffe Hospital. This is a large tertiary teaching hospital in Oxford, England and is part of the Oxford University Hospitals NHS Foundation Trust (OUH). The Vascular Surgery Unit which is part of the regional vascular network, provides emergency and elective treatment for patients with conditions of the vascular system. One long corridor provides access to the patient bays on one side. The unit has six patient bays and four single patient side rooms (24 beds). On the other side of the corridor, a small nurse station is located between a sisters' office for the nurse manager and a treatment room where the nurses prepare medications and assemble equipment. Computers, delayed discharge and other charts, documents, a printer and a telephone, are housed in the nurse station. Mobile computer trolleys are placed at the entrance of the patient bays. At the end of the corridor is a staff room where staff have their breaks and a room for meetings and training. The hospital has introduced a number of initiatives to support inpatient care and enhance insulin safety such as the use of prefilled ready-to-administer insulin infusion syringes. The ePMA is another initiative that was launched in October 2014 and went live in the Vascular Surgery Unit in February 2015. Bedside BG and ketone monitoring equipment are used in the hospital trust to allow remote access to the BG levels to provide an early alarm if these go outside the target range [116]. The hospital has a multidisciplinary specialist diabetes team including DISNs, Diabetes Link Nurse, specialist pharmacists, podiatrists, and diabetes consultants. DISNs provide regular training for nurses about the safe use of insulin and on the main adverse events and how these can be prevented.

1.4.2 The scale of the problem in the use of VRIII and gaps in existing research

In England and Wales, the 2019 NaDIA report showed that 6.1% of VRIIIs were used inappropriately and 16.1% of VRIIIs were not managed appropriately when switched to SC insulin [116]. The report suggested that better guidance and training surrounding insulin infusions are needed, as is the consideration of processes designed to ensure prompt intervention when hypoglycaemic episodes develop [116]. The 2020 NaDIA report demonstrated that although the prevalence of all hypoglycaemic episode types had decreased since 2010, their relative proportions had remained static since 2017. Almost one patient in four had experienced a severe hypoglycaemic episode (BG <3.0 mmol/L) [11]. An audit was conducted between 2017 and 2018 at the study site to review prescribing, administration and monitoring practice while using VRIII [117]. The audit showed that the most frequent problems were related to the selection of appropriate VRIII regimens and failure to continue or suspend other diabetes medicines [117].

Empirical research on quality improvement in the use of VRIII has mainly involved the quantitative study of adverse events [118, 119], while limited attention has been given to qualitatively defining the safety failures and successes and the characteristics of the healthcare practitioners and the systems that allow these events to arise. However, there are a considerable number of studies on how the RHC approach was used to understand complexity in healthcare systems by exploring systems' adaptive capacities and their ability to adapt under various conditions [110, 120], although no studies to date have researched resilience in the use of VRIII. The question remains about how we can best learn from everyday work (WAD) and compare it with WAI in different contexts in order to enhance and/or create RHC. Previous studies used various methods to understand WAI, among them analysis of documents, reports and protocols, and different methods to understand WAD, such as field observation, interviews and focus groups [33, 110, 121-123]. The methods described can partially capture an approach to understanding WAD. In order to understand *in situ* clinical work, describe the complexity of healthcare, and model specific kinds of recommendations from different perspectives in the use of VRIII, a relatively new methodology, video reflexive ethnography (VRE), was used. In this approach, video footage of real-time practice is shown back to participants in reflexive meeting sessions where they collectively make sense of their work and negotiate

meaningful, context-appropriate ways of improving their practice and thus enhance patient safety [124-127].

1.5 Aims and objectives

This research aimed to develop a model of VRIII use by exploring everyday clinical work (WAD) and comparing it with how work is imagined (WAI). Specific research objectives included:

- To describe and compare WAD and WAI in the use of VRIII in adult inpatients (Chapters 4, 5 and 6).
- To understand how adjustments and adaptations are made in relation to the use of VRIII (Chapters 5 and 6).
- To develop recommendations in collaboration with participants to enhance safety in the use of VRIII (Chapter 5).

1.6 Thesis outline

Figure 1.6 is a graphic representation of an overview of this thesis.

Chapter 1 gives a general introduction and establishes the research context by discussing the main areas covered in this thesis, including hyperglycaemia, VRIII, safety in healthcare and the study's rationale, aims and objectives.

Chapter 2 provides a systematic review and comprehensive analysis of RHC concepts used in research studies, and of methods and tools used to study, and factors used to enhance, RHC. It also proposes a conceptualisation of RHC to be used, and critical questions to be considered, in future studies of RHC.

Chapter 3 builds on the findings of the systematic review of RHC studies in healthcare to provide an overview of the ontological, epistemological and theoretical perspectives that underpin this research. The chapter also describes a published protocol of this thesis.

Chapters 4, 5 and 6 are different studies conducted to develop a model of VRIII use:

Chapter 4 focuses on the first objective of understanding WAI in the use of VRIII. This chapter reports a study on understanding, from different stakeholders'/users' perspectives, how VRIII was thought to be used in practice.

Chapter 5 is a study that focuses on the first, second and third objectives of this thesis with the aim of exploring the use of VRIIIs using VRE, determining what adaptations are made in everyday work, developing realistic solutions to enhance safety in the use of VRIII, and evaluating the feasibility of using VRE in a Vascular Surgery Unit.

Chapter 6 is a comparison study of WAI and WAD using VRIII. The focus here is thus on the overall aim of this study: to develop a model of VRIII use by exploring the everyday clinical work of healthcare practitioners and comparing it with how work is imagined to identify resilient characteristics.

Chapter 7 provides a general discussion of the methods used to ensure methodological rigour, the key research findings, and the potential contribution of the research, as well as identifying future research perspectives.

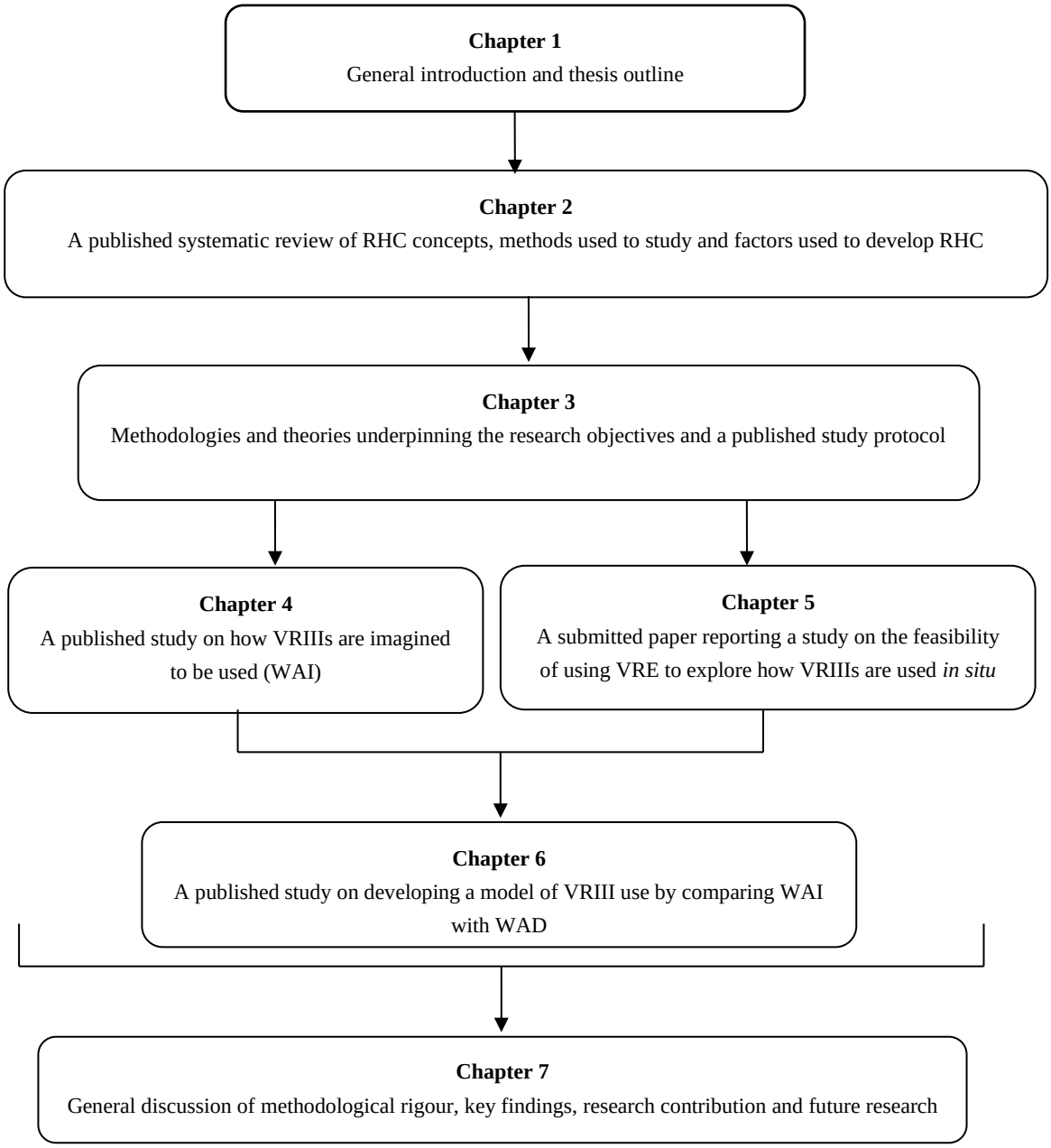

Figure 1.6 Thesis overview.

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Chapter 2

Resilient Health Care: a systematic review of conceptualisations, study methods and factors that develop resilience

Chapter summary: In order to understand the use of VRIII within the RHC framework, it was fundamental to first explore what RHC is and how it is used in healthcare systems. In this chapter is presented a published systematic review of the concepts, methods and tools used to study, and the factors used to enhance, RHC.

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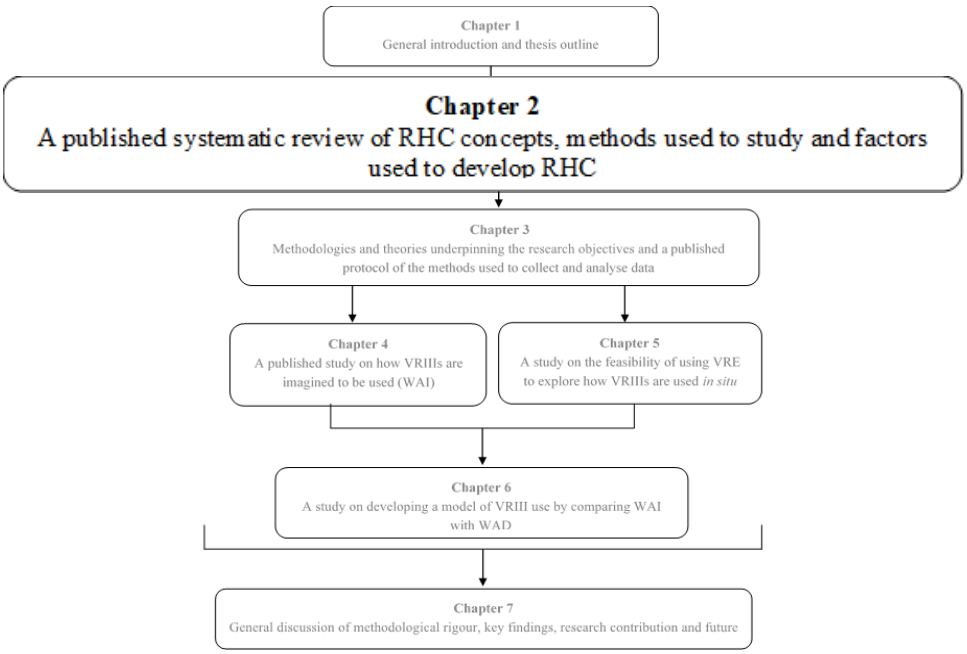

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Resilient Health Care: a systematic review of conceptualisations, study methods and factors that develop resilience

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Abstract

Background: Traditional approaches to safety management in health care have focused primarily on counting errors and understanding how things go wrong. Resilient Health Care (RHC) provides an alternative complementary perspective of learning from incidents and understanding how, most of the time, work is safe. The aim of this review was to identify how RHC is conceptualised, described and interpreted in the published literature, to describe the methods used to study RHC, and to identify factors that develop RHC.

Methods: Electronic searches of PubMed, Scopus and Cochrane databases were performed to identify relevant peer-reviewed studies, and a hand search undertaken for studies published in books that explained how RHC as a concept has been interpreted, what methods have been used to study it, and what factors have been important to its development. Studies were evaluated independently by two researchers. Data was synthesised using a thematic approach.

Results: Thirty-six studies were included; they shared similar descriptions of RHC which was the ability to adjust its functioning prior to, during, or following events and thereby sustain required operations under both expected and unexpected conditions. Qualitative methods were mainly used to study RHC. Two types of data sources have been used: direct (e.g. focus groups and surveys) and indirect (e.g. observations and simulations) data sources. Most of the tools for studying RHC were developed based on predefined resilient constructs and have been categorised into three categories: performance variability and Work As Done, cornerstone capabilities for resilience, and integration with other safety management paradigms. Tools for studying RHC currently exist but have yet to be fully implemented. Effective team relationships, trade-offs and health care 'resilience' training of health care professionals were factors used to develop RHC.

Conclusions: Although there was consistency in the conceptualisation of RHC, methods used to study and the factors used to develop it, several questions remain to be answered before a gold standard strategy for studying RHC can confidently be identified. These include operationalising RHC assessment methods in multi-level and diverse settings and developing, testing and evaluating interventions to address the wider safety implications of RHC amidst organisational and institutional change.

Keywords: Health care, Resilience, Resilient health care, Safety-II, Work as done, Assessment methods, Safety

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Background

Globally, it is reported that about 10% of hospitalised patients experience adverse health care events. Health care organisations may struggle to provide safe and high quality care, and as a result, people might experience unintentional harm [1–3].

The traditional approach to increasing safety has focused on counting incidents, identifying system failures, and understanding the causes of incidents in order to develop strategies to eliminate or reduce them [4]. This is called a Safety-I approach [5]. A Safety-II approach, however, recognises that work can be viewed from different perspectives [5]. The closer the viewer is to the work (whether in space, time or knowledge/experience), the more accurate their understanding about how the work is done. As the viewer moves further from the work, their understanding becomes necessarily more simplified and less accurate. This is often conceptualised as a 'wedge' with a sharp proximal point and a blunt distal edge. In a health care context, health care professionals interact directly with a hazardous process, representing the actual workplace. Regulators, policy makers and managers control and balance the resources, constraints and multiple demands imposed on health care professionals. Safety problems are not always a direct result of a lack of knowledge or effort by health care professionals – they are usually a result of work that is complex, often involving the use of technology [5]. There is often a mismatch, however, between how everyday work is accomplished (Work As Done) and how work is presumed to have happened (Work As Imagined) [6, 7]. These mismatches might sometimes lead to safety problems and there is, therefore, value in learning from the full range of work outcomes, including usual outcomes (when things go right), negative outcomes (for example, errors) and everything in between, despite the inevitable risks and complexity. This is the core concept of the Safety-II approach [5]. Health care professionals often work under varying conditions using principles of both Safety-I and Safety-II, but policymakers, regulators and/or health care managers typically focus their efforts on standardising work practice based on Safety-I principles. For example, safety efforts often focus on counting and tracking events that fail rather than those that succeed [5, 8].

Resilience engineering (RE) has been advocated since the last decade as a new paradigm for safety management in socio-technical systems [9]. RE focuses on a system's capacity to cope with complexity and variable conditions [9, 10]. RE has been applied to various disciplines such as aviation, railways, natural disasters, health care and others [11]. Resilient Health Care (RHC) which applies concepts of RE to health care settings and adopts a Safety-II approach, provides a complementary perspective of learning from incidents and understanding how everyday clinical work is successful [12–14]. RHC acknowledges that health care systems such as a clinic, ward, hospital, or even country, are complex adaptive systems that are constantly changing and can result in unexpected work situations. Because they can anticipate, monitor, respond and adapt to threats, health care professionals are viewed as resources and assets rather than as a problem to be solved or standardised. Therefore, the focus is on how everyday clinical work is performed rather than solely on the unpredictable accidents or incidents [4, 5, 12]. RHC does not focus on an individual's coping and resilience capacity but rather on the factors and methods that enable the workers, team and unit or organisation to adapt and cope effectively in different situations.

RHC is theoretically attractive and recent reviews indicate a growing interest and evidence in operationalising RHC [15, 16] for example in defining models and measurements to understand the effect of trade-offs in operational activities [17]. Ellis et al. (2019) however, reported an increasing shift from studying and understanding RHC to developing resilience in health care settings [18]. There remains, however, conceptual and methodological issues around operationalising RHC. Righi et al. (2015) and Patriarca et al. (2018) highlighted the importance of conceptualising and anchoring resilience to capabilities that characterise resilient systems and explicitly define which capability is under study when describing or modelling resilience, and to develop innovative frameworks that can integrate different existing capabilities to understand in depth their commonalities, differences and relationships [11, 17]. Hollnagel (2006) made a valuable contribution by defining the four capabilities of resilient systems: anticipate, monitor, respond and learn [9]. Other researchers have proposed other resilience capabilities, such as rebound from unexpected events and return to equilibrium, robustness [19], planning, adapting, and noticing [20]. Berg and Aase (2019) conceptualised resilience in healthcare based on four categories: anticipation, sense making, trade-offs and adaptations, and defined it as a set of cognitive and behavioural strategies enacted by individuals within an organisational context [21]. Patriarca et al. (2018) highlighted the importance of developing more advanced safety-oriented models to study resilience in order to overcome the limitations of the traditional safety approaches [17].

Berg et al. (2018) identified methodological issues in the current empirical literature. They found data collection in studies focused primarily on one level, the micro system level for example frontline clinical staff, rather than an integrated understanding of complex, multi-level systems as a whole [22]. They argued for

the need to clearly define the resilient construct to develop theoretical frameworks for empirical testing across different system levels. Berg et al. (2018)'s review was limited to peer-reviewed studies that described the studies' data collection method because they aimed to synthesise methodological strategies [22]. Various models/methods have been developed and used to study resilience, including modelling activities using fuzzy cognitive maps in petrochemical plants [23], the Benefit–Cost–Deficit model to predict car driving violations [15], and the Functional Resonance Analysis Method (FRAM) to analyse the impact of variability on everyday work [24].

As observed by Ellis et al. (2019), the current literature on RHC has reported factors that promote resilience. Examples include training and educating health care professionals to cope with various conditions [4, 25, 26]; encouraging different departments and specialities to communicate about concerns pertaining to work practice [21, 25, 27]; repeated exposure to similar disturbances [4, 26, 28]; enhancing the knowledge and experience of health care professionals to respond to actual work conditions and to enact important trade-offs [4, 21, 28]; reducing the cognitive load on health care practitioners by simulation training to manage expected and unexpected situations [4]; and integrating human factors and health economics in the design process [16].

Despite recent reviews, there is still no 'gold standard' for studying and developing RHC in health care. There is still a lack of understanding of how RHC is conceptualised in empirical studies, for example whether and/or what resilient capabilities are used to conceptualise RHC, the methods/models/frameworks used to study and operationalise RHC, and factors to develop and enhance RHC. It is vital to gather emerging knowledge on applied definitions, methods, models and factors, using a wide range of empirical studies in health care from different sources to provide a robust contribution to the development of RHC research.

As such, the objectives of the systematic review were to: 1. identify how RHC is conceptualised in health care studies; 2. identify and analyse methods and tools used to study RHC; 3. identify and analyse factors that develop and enhance RHC.

Methods

A protocol for the systematic review was registered with PROSPERO (registration number: PROSPERO 2019 CRD42019129049). This systematic review is reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines for reporting of systematic reviews [29].

Ethical approval

Ethical approval was not required as the study was a systematic review of peer-reviewed journal articles and studies published in books.

Inclusion and exclusion criteria

The systematic review was limited to:

1. Scholarly peer-reviewed journal articles and studies published in books, written in English.
2. Studies published in journals and books that described RHC, and/or methods used to study RHC and/or factors to develop and enhance RHC in any health care setting.

Studies were excluded if:

1. They were about resilience in non-health disciplines.
2. They were about individual or community resilience.
3. They were about resilience in disaster.

Search strategy and study selection

Electronic searches of PubMed, Scopus, and Cochrane databases were conducted using the following search terms: (organisational/organizational and/or resilien* or safety or safety I or safety 1 or safety II or safety 2 or "work as imagined" or "work as done" and health care or healthcare or hospital) and/or (tool, measure, strateg*, solution). Other search methods such as hand searching, serendipity/browsing, checking with experts, and searching the specialist website resilienthealthcare.net were also used to identify further relevant peer-reviewed studies and studies published in books. The search covered a time period from January 1982 to April 2019. The titles and abstracts of identified studies were screened independently by two researchers (MI and RL) applying inclusion and exclusion criteria specified a priori. Full-text studies of retained references were then obtained and screened independently by three researchers (MI, RL and KR) using the same inclusion/exclusion criteria. Disagreements were resolved by discussion to achieve consensus.

Data extraction

MI independently extracted the following information: author(s), year of publication, country in which the study was conducted, aim of study, study design and methodology, study setting, sample size, descriptions of RHC, methods used to study RHC and factors that develop RHC where available.

Quality assessment

The quality of the included studies was evaluated using the Mixed Methods Appraisal Tool (MMAT) version 2018 [30], an established tool that enables critical appraisal of quantitative, qualitative, and mixed methods studies. See Additional file 1 for items assessed. An appraisal of all studies (by MI) and a random selection of a third of the studies (by RL) were conducted. Any disagreements were discussed between MI and RL to reach consensus.

Data synthesis

Due to the heterogeneity of study designs, it was not possible to use a meta-analysis approach to analyse the quantitative findings. Data was synthesised using both deductive (question 1) and inductive (questions 2 and 3) thematic approach [31]. This entailed the following steps [32]:

1. Familiarisation: studies were read multiple times to ensure familiarity with the content.
2. Developing a coding framework: data were coded line by line based on the key aims of the systematic review, which were descriptions of RHC, methods used to study RHC and factors used to enhance RHC in health care settings.
3. Indexing: shared categories were developed while reading and comparing between different studies.
4. Charting: the coded data and similar findings were grouped into key themes and subthemes within and across studies.
5. Mapping and interpretation: subthemes were aligned to the main theme to provide explanations for the findings.

Results

Studies included in the review

Eight hundred and seventy-two studies were identified in the initial database searches. Following screening, 74 studies were left for full-text review. From these, a total of 20 studies published in peer-reviewed journals and 16 studies published in books were included in the review. Figure 1 shows the study selection process.

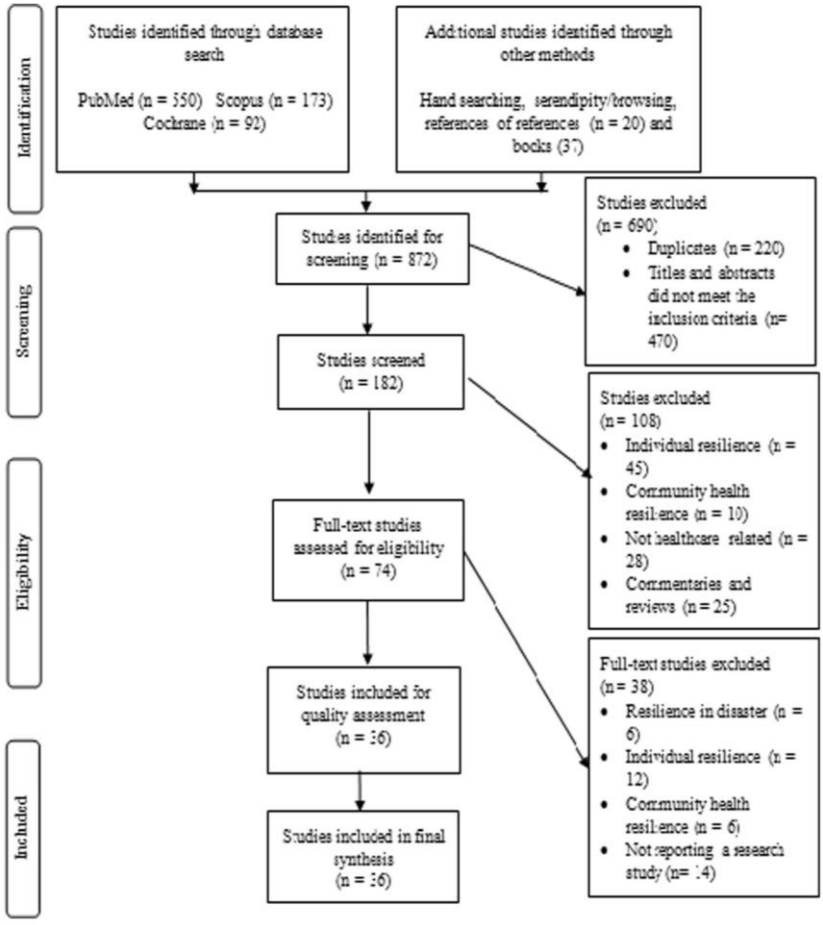

Fig. 1 PRISMA flow chart for study selection process

Quality assessment of studies

Quality assessment of the studies is presented in Additional file 2. Qualitative studies were mostly well designed. Studies using mixed methods had not explicitly explained any inconsistencies between qualitative and quantitative results and/or the risk of non-response bias in the quantitative component [33–39]. Mixed method studies were, however, included in the review as RHC is a relatively 'young' research field and these studies added important insights to the review while addressing at least two of the three research questions.

Study characteristics

The methods used to study RHC varied in the studies: fifteen were qualitative [40–54], and five used mixed methods [33–36, 39]. The methods used in the studies published in books, however, were mainly qualitative [55–68] except two studies that used mixed methods [37, 38].

Studies reported in peer-reviewed journals were mostly conducted in developed countries: the United Kingdom [35, 40, 42, 44, 46, 53], the United States of America [33, 43, 51, 52], Finland [45], Australia [39, 48, 50], Denmark [48–50, 54], Norway [47] and Israel [36]. Two studies were conducted in developing countries: Brazil [41, 51] and South Africa [34]. For studies published in books, all were conducted in developed countries: the United Kingdom [58, 60, 65, 66], New Zealand [62, 67], Norway [57, 61], France [55], Switzerland [56], Australia [59], Denmark [63], Canada [64], the United States of America [68], Japan [38] and one unstated, possibly USA [37].

Descriptions and conceptualisations of RHC

Table 1 shows descriptions of RHC, aims of the included studies, methods used to study and factors that develop RHC. Understanding RHC descriptions and forming concepts are prerequisites to moving from theory level to practical level. Table 2 summarises the underpinning RHC capabilities or categories for describing and conceptualising RHC in empirical studies.

Although the descriptions and conceptualisation of RHC varied across studies, most shared Hollnagel's (2017) [69] four capabilities of RHC: anticipate, monitor, respond and learn [37, 40, 44, 45, 58, 61, 62]. Other studies conceptualised RHC to be about prioritising goals in the midst of competing demands (the quality of trade-offs) [37, 40, 47, 48, 56, 58, 59, 65] or reconciling the gap between Work As Imagined (WAI) and Work As Done (WAD) [38–41, 46, 48, 65–67]. Two studies described RHC as the ability to bounce back from errors by maintaining a positive adjustment to flourish amidst adverse situations [36, 42]. There was one study that illustrated success as a cornerstone capability for RHC. The study found that successful outcomes should be interpreted from multiple perspectives (management, staff, patient, next of kin, hospital and primary care) and that the assessment of successful outcomes depends on what group perspective the focus is on [57]. Interestingly, only one study defined RHC and resilience capabilities as emergent phenomena, which arise from interactions between different variables. Such phenomena might be either desired or undesired and cannot be developed in a fully controlled way, however, it could be influenced [53].

Methods for studying RHC

Data collection methods

Methods were categorised as direct or indirect sources, as described by Hollnagel et al. (2019) [12] (see Table 1).

A *direct source* is one where participants directly express their experience of how work takes place in practice. Direct sources used in included studies included interviews [33, 34, 38, 40, 43–47, 49–51, 53–59, 61–63, 65, 66]; focus groups [41, 42, 49, 52, 59, 61]; surveys and/or questionnaires [33, 34, 36]; process mapping sessions [46, 66]; and an autoethnographic approach in which the author relied on self-reflection to explore his experience while connecting this to a wider context [67].

An *indirect source* is one where participants are observed for a period or the data is collected from non-human resources. Indirect sources drawn upon in included studies were observations [34, 36, 38–41, 43–47, 49, 51, 53, 55, 57–63, 65, 68]; work domain analysis, process tracing, and artefact analysis [43]; simulation [37, 62]; patient charts [36]; document analysis (local or national guidelines, incident reports, minutes of hospital committees and medication supply data) [38, 40, 41, 48, 50, 51, 55, 56, 61]; and The National Aeronautics and Space Administration Task Load Index (NASA-TLX), a widely used multidimensional tool to assess perceived workload [37].

All studies collected data either at the micro and/or meso level (health care practitioners, managers, local guidelines). Only seven reported the use of macro-level data collected from different stakeholders, national surveys, organisation and process design documents, as well as computer software, to assess organisational resilience [35, 38, 48, 50, 51, 56, 66].

Tools for studying RHC

Some studies developed and/or used models, frameworks and quasi-models to study RHC. These are described here under three headings, based on RHC constructs: 1. Performance variability and WAD, 2. Cornerstone capabilities of RHC and 3. Integration with other safety management paradigms.

Table 1 Descriptions, aims and methods used to study and factors that develop RHC

	Study reference	Description of RHC	Aim of study	Methods used to study RHC	Factors used to develop RHC
Peer-reviewed articles					
1.	Gittell, J 2008 (USA) [33]	• Organisational resilience … incorporates insights from both coping and contingency theories. It refers to the maintenance of positive adjustment and the ability to flourish or thrive amid adverse conditions when rigidity might otherwise be expected.	• Explore the role of relationships and organisational practices in enabling workers to respond in a resilient way to external pressures.	• Archival data. • Interviews. • Observations. • Surveys.	• Relational coordination between professionals by sharing goals, knowledge and mutual respect. • Frequent, timely, accurate and problem- solving communication for effective coordination.
2.	Mash B, J, et al. 2008 (South Africa) [34]	• The organisation's ability to remain true to its core values, competencies and vision rather than invest in a specific structure.	• Explore how to create more successful practice teams based on doctors and nurses experience.	• Interviews. • Observations and documentation of changes in progress markers and success of strategies. • Structured questionnaire.	• Staff meeting and discussion with an ongoing exchange of ideas and experiences. • Communication with respect, appreciation and trust. • Teamwork that enables health care professionals to easily interact and commit to each other. • Effective leadership by sharing the vision, and identifying values. • Feedback for reflection and learning.
3.	Brattheim B, et al. 2011 (Norway) [47]	• … process variation related to flexibility is an integral part of how actors deal with uncertainty, variability and high risk, enhancing safety in unpredictable settings. The resilience engineering approach to managing variations centres on attention to essential properties of adaptive behaviours.	• Identify the characteristics and sources of abdominal aortic aneurysm process variability within and between different hospitals. • Develop suggestions for how to design IT-based process support to enhance resilience in this process.	• Observations. • Semi-structured interviews.	• Capability of awareness. • Capability to gain knowledge from experience. • Reduce unintended process variation.
4.	Nemeth C, et al. 2011 (USA) [43]	• The ability of systems to mount a robust response to unforeseen, unpredicted, and unexpected demands and to resume or even continue normal operations. • Resilience is an emergent property of systems that is not tied to tallies of adverse events or estimates of their probability. • Studies how people at all levels of an organization try to anticipate paths that may lead to failure, to create and sustain strategies that are resistant to failure, and to adjust tasks and activities to maintain margins in the face of pressure to do more and to do it faster. • A resilient system can adjust its functioning prior to,	• Develop information and communication technology to support crisis management in healthcare settings.	• Observational study. • Cognitive task analysis. • Interviews. • Artefact analysis. • Work domain analysis. • Process tracing. • Rapid prototyping. • Evaluation.	• N/A

Table 1 Descriptions, aims and methods used to study and factors that develop RHC *(Continued)*

	Study reference	Description of RHC	Aim of study	Methods used to study RHC	Factors used to develop RHC
		during, or following changes and disturbances so that it can sustain required operations, even after a major mishap or in the presence of continuous stress. • The notion of resilience frees safety research from hindsight bias by making it possible to understand how workers anticipate possible adverse outcomes and act in advance to avert them.			
5.	Ross A, et al. 2012 (UK) [44]	• The capacity of a system to adapt safely to changing conditions. Resilience can be defined as the ability of a system to self-correct and adapt to disturbances so that normal operations can be maintained even when unexpected conditions are encountered.	• Investigate how clinical staff deliver inpatient diabetes care. • Identify how resilience is created and/or breaks down. • Provide a basis for designing interventions to improve care.	• Interviews. • Cognitive task analysis.	• Understanding the nature of the gap and how front-line practitioners bridge it and sometimes fail. • Specialist team to coordinate decision making for various medical conditions that open a line for education, detecting problems and managing them early. • Good feedback, communication and monitoring. • Updating knowledge.
6.	Crowe S, et al. 2014 (UK) [35]	• The capability of a health system to mitigate the impact of major external disruptions on its ability to meet the needs of the population during the disruption.	• Explore the feasibility of assessing resilience across local health services and develop a computer software to assess resilience of different service reconfigurations in the NHS in England.	• Computer software modelling tool to assess resilience. • Optimisation and heuristic methods to capture response.	• N/A
7.	Clay-Williams R, et al. 2015 (Australia and Denmark) [48]	• N/A	• Investigate whether FRAM can be used to identify process elements in a draft guideline in order to develop a new guideline that aligned with WAD.	• FRAM. • Meetings.	• Realign WAI with WAD in implementing guidelines.
8.	Drach-Zahavy A, et al. 2015 (Israel) [36]	• Identify, correct and 'bounce back' from errors, with obvious positive consequences for patient's safety.	• Examine the relation between the strategies used during handovers and the type and number of errors in the following shift.	• Observations. • Data extraction from patient's chart. • Surveys.	• Face to face communication between health care professionals and non-professional workers with patients. • Interactive discussion between incoming and outgoing health care professionals that enhances safety through situational awareness. • Exposure to a diversity of opinions.
9.	Sujan M, et al. 2015 (UK) [46]	• The ability of a system to adjust its functioning prior to, during, or following changes and disturbances, so that it can sustain required operations under both expected and unexpected	• Demonstrate how the study of handover's everyday clinical work can contribute novel insights into a common and stubborn patient safety problem.	• Observations. • Semi-structured interviews. • Process mapping.	• Dynamic, and context-dependent trade-offs. • Staff experience. • Intuition. • Reconcile the gap between

Table 1 Descriptions, aims and methods used to study and factors that develop RHC *(Continued)*

	Study reference	Description of RHC	Aim of study	Methods used to study RHC	Factors used to develop RHC
		conditions.			WAI and WAD. • Verbal communications. • Performance variability.
10.	McCray J, et al. 2016 (UK) [42]	• Team Resilience is a team's ability to "bounce back" and "maintain" performance under adverse circumstances. Performance is the team outputs and delivery, and in the case of integrated teams in the health and social care sector, is likely to be linked to service user outcomes.	• Explore the making of resilient team from the perspective of managers in health and social care organisations. • Identify factors that affect team performance.	• Focus groups.	• Effective teamwork. • Team relationship.
11.	Wachs P, et al. 2016 (Brazil, USA) [51]	• The intrinsic ability of a system to adjust its functioning prior to, during, or following changes and disturbances, so that it can sustain required operations under both expected and unexpected conditions. In turn, performance adjustment means filling in the gaps of standardized operating procedures, whatever their extent and reason.	• Investigating resilience skills in emergency departments by understanding how interactions between the elements forming a socio-technical system give rise to resilience skills.	• Observations. • Critical decision method interviews. • Questionnaires. • Documents analysis. • Meetings.	• Individuals and Team Factors: ➢ Collaborative work. ➢ Matching capacity and demand. ➢ Communication. ➢ Recognise the impact of small actions and decisions. ➢ Prioritise actions and decisions. ➢ Identify contextual factors that can hinder performance. ➢ Anticipation of the need for actions. ➢ Managing the trade-off between times allocated to care patients and number of patients seen. ➢ Re-plan the sequence of activities. ➢ Leadership. ➢ Workarounds involving the use of equipment and materials. • Organisational factors: ➢ Contingency plans for crisis management. ➢ Standardisation of managerial and care processes. ➢ Support for collaborative work. ➢ Computerised system. ➢ Management of human and material resources. ➢ Measures to deal with lack of beds for admitted patients.
12.	Back J, et al. 2017 (UK) [40]	• The intrinsic ability of a health care system to adjust its functioning prior to,	• Examine escalation policies in theory and practice using RHC principles.	• CARE model. • Analysis of escalation policies.	• Team work structure. • Awareness of the state of the hospital system based

Table 1 Descriptions, aims and methods used to study and factors that develop RHC *(Continued)*

	Study reference	Description of RHC	Aim of study	Methods used to study RHC	Factors used to develop RHC
		during, or following events (changes, disturbances and opportunities), and thereby sustain required operations under both expected and unexpected conditions.		• Observations. • Interviews.	on experience and expertise.
13.	Larcos G, et al. 2017 (Australia) [39]	• … refines safety by promoting flexibility rather than compliance with protocols, guides and training.	• Identify the rate and nature of interruptions the nuclear medicine technologists experience. • Identify strategies that support safety in the workplace. • Suggest quality improvement strategies in nuclear medicine that may complement those derived from incident reporting.	• Observations. • Linear regression analysis. • Discussions.	• Responsiveness by reacting effectively when a situation changes. • Attentiveness by taking appropriate action considering the situation at hand. • Anticipation. • Experience.
14.	Pickup L, et al. 2017 (UK) [53]	• Refers to how well a system is designed to recognise and respond to such shifts within an organisation and the impact on how a system function. A resilient system would be capable of identifying and adapting to potential vulnerabilities or threats to safety without the need for an incident or accident to occur.	• Understand why performance might vary in blood sampling in acute hospital settings and how a Safety-II approach can inform future safety management programmes.	• FRAM. • Observations. • Semi structured interviews.	• N/A
15.	Raben DC, et al. 2017 (Denmark) [49]	• … focuses on how healthcare systems succeed by rapidly responding and adapting performance in everyday work.	• Asses the feasibility of the LIIM and the challenges or difficulties revealed in the process of blood sampling. • Identifying leading indicators for blood sampling among patients in a Biomedical Department.	• FRAM. • LIIM. • Observations. • Semi-structured interviews. • Focus groups. • Walk-throughs.	• N/A
16.	Damen NL, et al. 2018 (Australia and Denmark) [50]	• N/A	• Understand and compare WAI and WAD in preoperative anticoagulation management. • Examine the utility of FRAM to reconcile WAI and WAD.	• FRAM. • Interviews.	• N/A
17.	Merandi J, et al. 2018 (USA) [52]	• Resilience is an essential part of Safety II. Safety II requires an "adjustment to functioning," which goes beyond "good catches" (situations in which error is avoided by performing an expected task). • Resilient systems require humans to learn from what goes right and develop adaptations and flexibility to incorporate that learning going forward.	• Identify factors in a hospital system and individuals that support increased resilience in delivering patient care.	• Focus groups.	• Individuals and team factors: ➢ Situational awareness. ➢ Experience and expertise. ➢ Recognising the inevitability of error. ➢ Teamwork. ➢ Effective, open and clear communications. ➢ Training.

Table 1 Descriptions, aims and methods used to study and factors that develop RHC *(Continued)*

	Study reference	Description of RHC	Aim of study	Methods used to study RHC	Factors used to develop RHC
					➢ Careful examination and feedback after errors. ➢ Double- check. ➢ Prioritising work. ➢ Commitment to standard procedures. ➢ Bridging experience from other microenvironments. • Structural and environmental factors: ➢ Familiarity and proximity. ➢ Shift resource availability.
18.	Raben DC, et al. 2018 (Denmark) [54]	• N/A	• Investigate how complex processes produce positive outcomes despite variability in the early detection of sepsis using FRAM.	• Document reviews. • Focus groups. • Observations. • Interviews. • FRAM.	• Experience. • Ability to multi-task.
19.	Rosso C, et al. 2018 (Brazil) [41]	• The ability of the health care system to adjust its functioning prior to, during, or following changes and disturbances, so that it can sustain required performance under both expected and unexpected conditions. • Resilience in health care … shed light on the gap between WAI and WAD, as well as on new approaches for patient safety, which rely on learning from every day work, instead of only from adverse events.	• Develop and test a framework design, which combines insights from lean production and RE.	• FRAM. • Stream mapping. • Notes from observations, focus groups and other documents.	• Creation of conditions to design and construct systems that have the capacity of resilience. • Modelling designs by developing innovative artefact to solve practical problems and make scientific contribution.
20.	Wahlström M, et al. 2018 (Finland) [45]	• The intrinsic ability of a system to adjust its functioning prior to, during, or following changes and disturbances, so that it can sustain required operations under both expected and unexpected conditions.	• Explore surgeons' adaptations to situational demands within robotic surgery.	• Core-task analysis. • Action-perception-cycles. • Observations. • Video analyses. • Interviews. • Self-confrontation video sessions. • Workshops.	• Mindfulness characterises: anticipation, backups, holistic consideration of patient anatomy, and thoughtful damage minimisation. • Technical developments and medical knowledge. • Situational interpretation.
Book chapters					
21.	Cuvelier L, et al. (France) [55]	• The intrinsic ability of a system to adjust its functioning so that it can sustain required operations under both expected and unexpected conditions. • It is not only the system's ability to cope with unforeseen variability that fall outside the expected areas of	• Identify strategies used by anaesthesiologists to avoid negative consequences of variability in everyday work.	• Open-observations. • Incidents. • Interviews.	• Care protocols. • Experience. • Making situations more predictable. • Increase knowledge. • Vocational training. • Cognitive trade-off. • Mobilisation of additional resources.

Table 1 Descriptions, aims and methods used to study and factors that develop RHC *(Continued)*

	Study reference	Description of RHC	Aim of study	Methods used to study RHC	Factors used to develop RHC
		adaptations, but also looks at its ability to operate in foreseen conditions. • A resilient system is the one capable to detect that the conditions have changed, to assure transition to another state and to operate in the new state of resilience achieved.			
22.	Pariès J, et al. (Switzerland) [56]	• The ability to make sacrificing decisions, such as accepting failures to reach an objective in the short term to ensure another long-term objective, or 'cutting one's losses' by giving up initial ambitions to save what is essential. • The ability to acknowledge the need to shift from one mode to the other. It measures the quality and robustness of trade-offs; their stability in the presence of disturbances.	• Observe how the ICU in the University Hospital of Geneva was functioning after the merger of two hitherto separate units. • Understand how and why the merger units succeeded or failed in controlling variations.	• Observation grid.	• Anticipation capacity. • Skills and accuracy of team's perception. • Trade-offs. • Diversity of experiences. • Interactions with patients. • Intuition. • Sacrificing decisions. • Functional reconfiguration. • Collaboration between different job profiles. • Strong team spirit. • Leadership mechanisms. • Flexible delegation.
23.	Laugaland K, et al. (Norway) [57]	• The ability of health care system to succeed under varying conditions to increase the proportion of intended and acceptable outcomes. • Adjustments could be deemed successful from one perspective but not from the viewpoint of others. • Different outcomes thus represent different judgement of values that need to be explored and acknowledged in order to be able to share a common ground on what constitutes acceptable, successful outcomes.	• Explore how different wards and units in hospital and primary care adjust their functions to sustain new demands imposed by system reforms.	• Observations. • Interviews.	• Multi-faceted outcomes from different perspectives. • Interconnections between systems.
24.	Stephens RJ, et al. (USA) [68]	• Capacity for manoeuvre.	• Analyse strategies taken by staff for regulating capacity for manoeuvre in terms of RE concepts.	• Observations.	• Coordinate adaptive capacities across units. • Regulate the capacity for manoeuvre. • Reduce the risk of decompensation in hospital units. • Reciprocity.
25.	Anderson JE, et al. (UK) [58]	• The ability of the health care system to adjust its functioning prior to, during, or following events (changes, disturbances and	• Investigate how care of older people was delivered, how decisions were made and how people adapted to pressure in clinical	• Interpretive approach. • Observations. • Interviews.	• Balance different goals during discharge process. • Plan and co-ordinate the different tasks for discharge across different staff groups,

Table 1 Descriptions, aims and methods used to study and factors that develop RHC *(Continued)*

	Study reference	Description of RHC	Aim of study	Methods used to study RHC	Factors used to develop RHC
		opportunities), and thereby sustain required operations under both expected and unexpected conditions. • … ability or capacity for adaptation, rather than a state of the system. • Understands the complexities of the whole system rather than focuses on a discrete part.	environment. • Design and implement interventions to increase the safety and quality of care.	• CARE model.	agencies, and families and carers.
26.	Debono D, et al. (Australia) [59]	• Adapt, flex and navigate competing demands so as to adjust under expected or unexpected conditions in order to sustain required operations. • The shifting and jostling demands of delivering care that prioritise one goal over another in a continually changing way, the role of context in influencing that process, and ongoing judgements about when to use [or not use] primary and secondary workarounds.	• Explore nurses' role and explanations of workarounds when using electronic medication management systems to understand the gap between WAI and WAD.	• Comparing WAI (process mapping) with WAD (observations, interviews and focus groups).	• Workarounds.
27.	Deutsch E, et al. (Unstated) [37]	• Reinforcing appropriate actions and resources making the margins and constraints of the system visible, and developing team behaviours that have the potential to improve the adaptive capacity of the team.	• Explore the role of simulation to understand and support the emergence of RHC.	• Simulation. • NASA-TLX score. • Debriefing. • Analyse the simulation performance from the perspective of four abilities for resilience.	• N/A
28.	Furniss D, et al. (UK) [60]	• It can adjust its functioning prior to, during, or following events (changes, disturbances, and opportunities), and thereby sustain required operations under both expected and unexpected conditions.	• Investigate if the RMF can be used to extract resilience strategies during interviews. • Explore resilient strategies in anaesthetic's environment.	• RMF. • Semi-structured interviews.	• Provide an alternative means for clinicians to access relevant medical information. • Take time for mental preparation. • Take drugs and equipment to emergency calls. • Maximise information extraction.
29.	Heggelund C, et al. (Norway) [61]	• N/A	• Explore the resilience mechanisms used in maternity services in two Norwegian hospitals.	• Theoretical framework using the four cornerstones of resilience: anticipation, monitoring, learning, and response. • Qualitative interviews, focus group interviews, field notes from observations (meso and micro level) and analysis of national documents (macro level).	• Identify the content and evaluate the variability in the four cornerstones of resilience. • Flexible organising. • Cultural factors (openness, support, communication, cohesion and trust). • Mixing experienced and inexperienced people. • Knowledge and experience. • Buffer of staff familiar with the services.

Table 1 Descriptions, aims and methods used to study and factors that develop RHC *(Continued)*

	Study reference	Description of RHC	Aim of study	Methods used to study RHC	Factors used to develop RHC
					• Procedures and the use of checklists and protocols. • Simulation. • Multi and inter disciplinary training. • Teamwork. • Statistics available for employees.
30.	Horsley C, et al. (New Zealand) [62]	• The ability of the health care system to adjust its functioning prior to, during or following events (changes, disturbances, opportunities) and thereby sustain required operations under both expected and unexpected conditions. • The ability to adapt over multiple timescales that marks the concept of resilience as different from concepts of robustness or rebound, in which temporary stressors on the system (i.e., patient admissions, acute events, disasters) must be absorbed without overt failure. • RHC should expand its aspiration beyond safety or even 'sustaining operations' to seeing the potential for this approach to advance health care towards the long-held goals of safe, patient-centred care delivered by engaged staff.	• Assess aspects of team functioning in a Critical Care Complex, describe elements of a functional team and how this forms a foundation to adapt to different situations using a Team Resilience Framework.	• Team Resilience Framework. • Simulation. • Interviews and in-practice observations.	• Shared understanding of current situation. • Allocate or self-nominate roles to team staff. • Efficient communication. • Explicit about expectations. • Know what to monitor. • Flexible response to events. • Learn why things go right. • Open and productive team climate. • Debriefings. • Checklists. • Team training. • Human factors teaching. • Shared team concept. • Psychological safety.
31.	Hounsgaard J,et al. (Denmark) [63]	• N/A	• Elucidate the impact of variability on everyday work in a spine centre.	• FRAM. • Interviews.	• Mnemonic systems.
32.	Hunte G, et al. (Canada) [64]	• The ability of a system to adjust its functioning prior to, during, or following events (changes, disturbances and opportunities), and thereby sustain required operations under both expected and unexpected conditions. Central to this proactive approach is the understanding that safety is dynamic, emerges from everyday practice, and is something a system does. • In a resilient system, large increases in work processed contribute to only small increases in recovery, and the system is able to keep pace.	• Evaluate the RAG to develop a context-specific framework to be used by emergency care providers and ancillary staff and leaders to assess and monitor over time.	• Dialogue workshop. • RAG.	• Team-environment. • Exploitation of resources. • Systematic (re)prioritisation. • Effective linkages, communication and attention to cross-scale interactions.

Table 1 Descriptions, aims and methods used to study and factors that develop RHC *(Continued)*

	Study reference	Description of RHC	Aim of study	Methods used to study RHC	Factors used to develop RHC
33.	Nakajima K, et al. (Japan) [38]	• To promote resilient health care, it is essential to understand how health care professionals actually work in a given environment. One way to understand everyday clinical work is based on the concepts of work-as-imagined and work-as-done.	• Understand how work is actually done for handling KCL concentrate injection solutions in Japanese hospitals.	• Direct and indirect approaches to represent WAD (minutes and memoranda of hospital committees, medication supply data, observations, interviews, and expert opinions).	• Resource allocation. • Systemic approach.
34.	Ross A, et al. (UK) [65]	• … to study responding, monitoring, anticipation and learning at all levels.	• Explore how delivery of care happened in inpatient diabetes care by using the CARE model to guide their interpretation.	• CARE model. • Interviews using cognitive task analysis techniques.	• Inpatient care cycle. • Workarounds and outcome trade-offs. • Distributing expertise at the ward level.
35.	Sujan M, et al. (UK) [66]	• RHC is able to reconcile the gap between the way everyday clinical work unfolds WAD with the way managers and administrators think about clinical practice WAI.	• Evaluate how safety cases are used in health care systems. • Understand the gap between WAI and WAD in clinical handovers in emergency care.	• Process map and FMEA. • FRAM.	• Communication and building trust between stakeholders. • Proactive and mindful.
36.	Zhuravsky L, (New Zealand) [67]	• The ability of the health care system to adjust its functioning prior to, during, or following events (changes, disturbances and opportunities), and thereby sustain required operations under both expected and unexpected conditions.	• Demonstrate the practical application of RHC approach on sustained nursing performance after the Christchurch earthquake in New Zealand in 2011.	• Autoethnographic methodology.	• Leadership (individual and shared). • Simulation and debriefings. • Training. • Workarounds. • Proactive monitoring of signs of stress, fatigue and anxiety. • Utilise technical capabilities. • Handovers. • Double-loop approach to learn. • Realignment of WAI with WAD.

Note: N/A is used when studies did not report methods used to study and/or factors to develop resilience
CARE Concepts for Applying Resilience Engineering, *FRAM* Functional Resonance Analysis Method, *FMEA* Failure Mode Effects Analysis, *ICU* Intensive Care Unit, *IT* Information Technology, *KCL* Potassium Chloride, *LIIM* The Leading Indicators Identification Method, *NASA-TLX* The National Aeronautics and Space Administration-Task Load Index, *RAG* Resilience Analysis Grid, *RE* Resilience Engineering, *RMF* Resilience Markers Framework, *UK* The United Kingdom, *USA* The United States of America, *WAD* Work As Done, *WAI* Work As Imagined

Performance variability and WAD

Ten studies developed and/or evaluated tools for studying RHC based on understanding variability in everyday clinical work, and how health care practitioners adapt and cope in response to varying conditions [40, 48–50, 53, 54, 58, 60, 63, 65]. The Concepts for Applying Resilience Engineering (CARE) model developed by Anderson et al. (2016) [70] was used in various studies to examine escalation policies used in emergency departments [40], to develop practical tools to study resilience and identify potential quality improvement initiatives [58], and to explore the misalignment between demand and the ways in which clinical staff adjust their work to be able to perform as needed [65]. The Resilience Markers Framework (RMF) was used to uncover resilience strategies used by anaesthetists, and to allow participants to reflect on their work demands and to contrast routine and non-routine aspects [60]. Different studies used the FRAM method to differentiate between WAI and WAD and to develop context-specific models in different clinical settings such as a preoperative anticoagulation management [50], blood sampling [49, 53], clinical guidelines implementation [48] early detection of sepsis [54] and a Medical Department's daily variations and adjustments [63]. Models developed in these studies were used to elucidate the complexity of everyday clinical work, understand the variability in daily routines and suggest new perspectives to improve safety.

Table 2 Underpinning RHC capabilities or categories used to conceptualise RHC in the included studies

RHC capabilities or categories/ study reference	[34]	[35]	[36]	[37]	[38]	[39]	[40]	[41]	[42]	[43]	[44]	[45]	[46]	[47]	[48]	[49]	[51]	[52]	[53]	[54]	[56]	[57]	[58]	[59]	[60]	[61]	[62]	[63]	[65]	[66]	[67]	[68]	[69]	Total
Respond/cope	√		√								√														√									**4**
Anticipate/foresee											√																							**1**
Learn/recover									√												√													**2**
Monitor, respond, anticipate and learn.					√		√	√				√	√		√									√			√	√						**9**
Adjust/adapt to variability								√	√				√	√				√	√	√	√			√		√		√	√		√		**13**
Create shared vision and collective values		√																																**1**
Maintain robust response											√																							**1**
Bounce back				√						√																								**2**
Re-align between Work As Imagined and Work As Done						√		√	√					√		√	√	√												√	√	√		**10**
Trade-offs					√			√							√	√						√		√	√				√					**8**
Succeed																							√											**1**
Sustain system capacity for manoeuvre																																	√	**1**

Note: Three studies [49, 54, 63] were not included as they did not include relevant information to conceptualise RHC

Cornerstone capabilities for resilience

While the notion of the four capabilities of RHC, anticipate, monitor, respond and learn, is not presented as a theory, Hollnagel et al. (2019) suggested using it as a generic model or quasi-model for resilience performance [12]. Five studies were based on these four capabilities [51, 56, 61, 62, 64]. The Observation Grid Model was developed to observe how an Intensive Care Unit (ICU) functioned after the merger of two hitherto separate units, and to understand how and why the merger units succeeded or failed in controlling variations [56]. A theoretical framework based on the four capabilities of resilience was used to identify what mechanisms shaped resilience in maternity services in two different hospitals [61]. The Team Resilience Framework was designed to retrospectively assess aspects of team functioning in a Critical Care Complex, describe elements of a functional team, and determine how this forms a foundation to adapt to different situations [62]. The Resilience Analysis Grid (RAG) was adapted to a context-specific framework for an urban Emergency Department in Canada and then evaluated to find discrepancies, coherence and complementarity with reference to RAG [64]. A model for describing resilience skills was proposed to identify the origin of resilience skills, contextual factors that could affect them, and leverage points that support their development in emergency departments in two different countries [51].

Integration with other safety management paradigms

In order to operationalise RHC, three studies highlighted the benefits from the integration between RHC and other management concepts and theories. For example, the Model of Relationships and Resilience was developed based on coping and contingency theories arguing that resilience responses require both psychological and organisational resources [33]. The framework for supporting a work system design was developed and tested in a health care system involving patient flow from an Emergency Department to an ICU. Insights from lean production (improving efficiency) and resilience engineering (improving safety) were combined in an approach to system design inspired by complexity theory [41]. When operationalising RHC, researchers will be confronted with both what goes right and what goes wrong. Sujan and colleagues (2019) combined Safety-I and Safety-II ways of thinking to ensure that stakeholders appreciated the current safety position by understanding the gap between WAI and WAD [66].

There was one tool not assigned to any category: a computer software tool to assist in decision-making concerning services' reconfiguration in the National Health Service (NHS) in England. They used operational research techniques such as mathematical optimisation and heuristic methods to capture responses and to assess the impact of a given disruption on the capability of the health care system to respond [35]

Factors to develop and enhance RHC

Operationalising RHC aims to find measures that reliably capture the concept under study [21]. Based on the analysis of the included studies, seven key factors were used at different levels (individual, team, and organisation) to develop RHC:

1. **Teamwork** was considered a factor in developing and sustaining resilience in the health care sector [19, 36, 40, 42, 44, 46, 51, 52, 61, 62, 64, 66, 67]. Aspects of teamwork included:

- *Effective and frequent team meetings* involving active listening, disagreement resolution and decision-making [34, 36, 42].
- *Effective communication*, characterised by respect, building trust between health care professionals, enhancing staff satisfaction to exchange information and ideas before and after the implementation of new practices [34, 36, 44, 46, 51, 52, 61, 62, 64, 66].
- *Effective leadership*, keeping the organisation focused on key objectives while also remaining open to feedback from clinical staff to create a shared vision, and revise decisions if required [19, 34, 42, 51, 66].
- *Effective involvement of clinicians* as top-down leaders to look for positive work practices [42].
- *Effective team working structure* between doctors, nurses and patient flow-coordinator roles to enhance the ability to expedite patient transfer to manage crowding in an emergency department [40, 51].

2. **In-situ practical experience** was a core factor in building resilience by providing a deep knowledge of how the system works and how the organisation adapts to and copes with expected and unexpected situations. Experienced health care professionals may teach novices how the health care system works and how to perform work. Managing different situations and cases will provide health care professionals with knowledge and experience that allows development of the resilient behaviours of anticipating, learning, monitoring and responding when facing similar situations [39, 40, 45–47, 56, 61, 65]. Another example of building resilience is in-situ simulation training and debriefings, which provide opportunities for experts and novices to

understand practice and adapt to routine and unexpected situations [44, 61, 62, 67].

3. **Exposure to diverse views and perspectives on the patient's situation** provided the fundamental advantage of understanding the patient's situation thoroughly while decreasing the likelihood of cognitive bias and maintaining the previous level of performance. One example was face-to-face verbal communication in handovers, with interactive questioning and a summary written by the outgoing nurse helping to decrease the probability of bias that might occur through inappropriate assumptions of an incoming nurse [36, 52, 56, 57, 61, 62].
4. **Trade-offs:** The clinical staff dynamically used their subjective assessment of the current situation to resolve stressors and tension. Being mindful and acting proactively to shift from one mode to another in the presence of disturbances is one of the key reported factors in developing RHC [39, 46, 51, 55, 56, 58, 64–67].
5. **The value of using protocols and checklists:** Protocols and checklists are valuable ways of defining potential variabilities and situations that are well known in the clinical practice and well described in the literature of speciality. [52, 53, 56, 63].
6. **System design:** One empirical study developed and tested a framework in a health care environment by adopting insights from resilience engineering to create conditions that supported resilient performance. Eight design propositions were developed which can contribute to the redesign of socio-technical systems to be safe and efficient at the same time [41].
7. **Workarounds:** These facilitated practice to continue by enabling staff to cope with challenges and maintain effective delivery of patient care [59, 65, 67]. One study considered that intended workarounds were necessary activities to mitigate risk and enhance safety [47].

Discussion

The aim of this systematic review was to identify and understand how RHC is conceptualised and operationalised including methods used to study and factors identified to develop RHC. Most studies conceptualise RHC based on Hollnagel's (2017) [69] four capabilities of RHC: anticipate, monitor, respond and learn. Methods for studying RHC include the use of a variety of data sources (direct and indirect, and mainly qualitative) and existing or new tools/frameworks. Factors that develop and enhance RHC include effective team relationships, trade-offs and health care 'resilience' training of health care professionals.

Conceptualisation of RHC

Concept formation is essential to inform and guide operationalisation efforts. Recent studies have conceptualized RHC by understanding the gap between WAI and WAD, which shifts the focus to everyday clinical work instead of adverse events only, and the importance of reconciling this gap to enhance RHC [38, 40, 41, 46, 48, 50, 65–67]. Perhaps unsurprisingly for a research area that has only developed in the last half a decade, most studies assessed shared the same definition for RHC, i.e. that developed by Hollnagel and colleagues. We share the perspective of Ellis et al. (2019) that RHC would benefit from more research of an international nature, to overcome this conformity of ideas and over-reliance on the founding authors [18]. Although the four cornerstones of RHC capabilities defined by Hollnagel have contributed to a deeper understanding of the RHC concept, and provided insights into how to operationalise in health care systems, the four capabilities affect and are affected by the environment [69]. Consistent with other systematic reviews [11, 17], this review found that other capabilities such as flexibility, trade-offs, and robustness should be taken into consideration to conceptualise RHC.

Methods for studying RHC

A health care system is viewed as a complex adaptive system comprising networks of components (hospitals, health care professionals, families and patients) that interact in non-linear and evolving ways [71]. All included studies indicated that researchers acknowledged the complexity in health care settings – they triangulated data from different data sources (documents, reports, interviews and observation). Few studies, however, have used methodological triangulation (quantitative and qualitative) to study RHC.

Most of the studies included in this systematic review used qualitative data to study everyday clinical work that explained frontline practitioners' contribution to RHC and kept patients safe despite pressure. Although interviews and focus groups are widely used in qualitative research, the assumption that participants' words are indicators of their inner experiences may be questionable [72]. Observational research reports what people do or say, rather than what they say they do. Observation, however, can include a high degree of researcher bias as the method relies on interpretation of what has been observed. The researcher cannot 'see' attitudes and memories, so it can be difficult to create an accurate analysis from observation alone. One study used self-confrontation video sessions in which participating surgeons were encouraged to explain what took place while they were conducting surgery [45]. To understand in-situ practices, describe the complexity of health care,

and model and test specific kinds of recommendation to improve safety and resilience, more innovative approaches should be used to explore WAD in-situ from the perspective of frontline practitioners. Video reflexive ethnography (VRE), developed by Iedema and colleagues [73], could be used to explore WAD. Video footage of real-time practices is shown back to participants in small groups where they collectively reflect to make sense of their work and negotiate meaningful, context-appropriate ways of improving their practices [73–76].

While the extensive use of qualitative methods is one of the strengths of RHC, deepening understanding of everyday clinical work rather than merely measuring system behaviour [18], other methods have been under-explored. Quantitative methods such as surveys, mathematical methods and computer software modelling tools could have fruitful implications. Mixed method approaches could be used to determine the outcomes of applying RHC principles and to investigate the extent to which RHC principles have been used at the various organisational levels (staff, patient, team, managers and organisation) [11, 18].

Several of the studies included developed models/frameworks based on predefined resilient constructs. The performance variability and WAD construct brings resilience closer to an empirical ground by facilitating understanding of how everyday situations and uncertainties are successfully managed [12]. This construct has been shown to be relevant in identifying and assessing ways in which performance variability can be monitored and managed, e.g. in the Vessel Traffic Service system [77] and in the Air Traffic Management System which has been used to analyse a mid-air collision over the Amazon [78]. Various studies included in this systematic review used FRAM to develop models that were essential in understanding system functions, performance and variability [48–50, 53, 54, 63]. Consistent with the literature [79], this systematic review found that it is imperative to combine FRAM models with quantitative data to quantify functions and measure outputs of functions in order to assess distributions of variability.

Patriarca et al. (2018) found that the RAG model, which comprises questions related to the four cornerstone capabilities has not been used widely [17]. However, the findings of the current systematic review showed that four studies used the generic principles of RAG as the basis on which more context-specific grids or questions were developed and tailored [56, 61, 62, 64]. The Resilience Engineering Tool to Improve Patient Safety (RETIPS) tool developed by Hegde et al. (2019) used RAG as an initial framework to guide the development of a more specialised tool to build the resilience profile of a system. The tool was validated and revised based on feedback from clinicians, resulting in a version customised for anaesthesia residents. RETIPS has been developed to operationalise the Safety-II paradigm by learning how things go well in everyday clinical work [80].

Despite the importance of the complementary perspective to learn from incidents and to understand how everyday clinical work is successful, few studies have used studied RHC from both perspectives [55, 56, 66]. In order to operationalise RHC, researchers need to bridge between RHC and other safety paradigms to enhance patient and organisational safety. Our recommendation is consistent with other studies that advocate combining data from the RHC perspective with others such as accident analysis, risk assessments, grand rounds, and electronic health report data to enhance system safety through the identification of visible outcomes, unnoticed deficiencies and longitudinal implications of certain adaptations [81, 82]. Some models used to study RHC had not incorporated sufficient details to enable problems to be understood and/or resolved in meaningful and comprehensive ways [35]. Current methods for studying RHC represent efforts to improve the understanding of RHC. Health care settings are constantly experiencing turnover of staff, policies and equipment, so future studies will need to investigate the practicality and feasibility of the methods, enhance their applicability and evaluate interventions for generalisation across organisations.

Factors to develop and enhance RHC

Recognising that the health care environment is complex and unpredictable, whilst also understanding how the system works in everyday and unexpected situations, is a starting point for improving patient safety. Few studies have taken a whole-system approach to developing resilience in health care. These results reflect those of Berg et al. (2018), who also found that multi-level mechanisms for studying RHC are not well established [22]. Almost all the included studies did not assess how the factors used by individuals and teams affect the resilience of the whole system. The identified factors that were used to enhance safety could make sense locally, but the outcomes are not necessarily successful at the higher levels. Indeed, resilient performance and adaptations could lead to negative outcomes at the organisational level [17, 57]. Laugaland et al. [57] found that adjustments could be deemed successful from one perspective (hospital) but poor from the viewpoint of others (patients). This review supports evidence from previous reviews [18, 21, 22] to suggest that the focus should be on how resilience is distributed throughout the entire system at different levels, in different settings, cultures and countries, to help better understanding of RHC. The move from research to practice is still nascent. More work is needed to design interventions based on the identified factors and then to measure their effectiveness

in different health care contexts, investigate the implementation of designs and artefacts, and explore how to operationalise the changes.

Future work

Several questions remain to be answered before a gold standard for studying and developing RHC can confidently be identified. We propose the following conceptualisation of RHC for consideration to underpin future research - the ability of the whole system (individual, team and organisation) to manage the gap between WAD (what goes wrong and what goes right) and WAI proactively and in response to situations while achieving patient and system safety goals. The focus of future studies should consider the following:

- Explore whether the adaptations and adjustments used are appropriate to maintain usual work, and how resilient adaptations on a system level could affect resilience on other system levels. Explore WAD by using the Integrative Learning approach [82], exploring what goes right and what goes wrong, factors that contributed to success or failure, challenges that threatened patient safety or hindered successful intervention, etc.
- Explore WAD and WAI for each system level e.g. micro, meso and macro, and integrate findings to form a robust understanding of the work system. Insights into WAD depends on the angle and system level the research has focused on and may not always reflect the everyday work of health care practitioners.
- Explore the variability in everyday work in more depth using mixed method approaches. For example, using methods that enhance reflexivity such as VRE to reflect on invisible aspects of work and also applying quantitative methods for measuring work outcomes.
- Develop and use tools and/or frameworks including integrating those from other safety paradigms capable of describing factors and mechanisms occurring at different system levels that enhance or hinder resilience.
- Explore RHC in multi-level, diverse settings (long-term care facilities such as nursing homes, outpatient clinics, ambulatory care, home health care and emergency medical services) and in different countries to build on current knowledge and guide the operationalisation of RHC to different settings and cultures.

Review limitations

First, relevant data might be missed from unpublished studies. To counteract this limitation, a broad search was conducted to include both peer-reviewed studies published in journals and relevant studies published in books. Second, most of the studies included were conducted in developed countries and more studies are needed to investigate whether the findings are applicable to other countries. Third, resilient factors reported were derived from specific case scenarios and this might affect their influence in different settings. Fourth, mixed method studies were included in the review despite the quality of the studies as they added insights to the review. Lastly, the results of this systematic review represented the researchers' interpretation and other researchers might have different perspectives and reach different conclusions.

Conclusion

Most studies shared similar characteristics in their descriptions and conceptualisations of RHC. Although methods to study and factors that develop RHC currently exist, it is vital to understand how RHC works within existing health care systems, how to enhance RHC and how it can be sustained. In addition, it important to understand and explore how to develop RHC effectively in order to devise innovative interventions and to evaluate and design resilient socio-technical systems. Future research is needed to address the wider safety implications of RHC amidst organisational and institutional change.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s12913-020-05208-3.

Additional file 1: Mixed Methods Appraisal Tool **(**MMAT) checklist items [20].

Additional file 2: Quality assessment of included studies.

Abbreviations

CARE: Concepts for Applying Resilience Engineering; FRAM: Functional Resonance Analysis Method; ICU: Intensive Care Unit; MMAT: Mixed Methods Appraisal Tool; NASA-TLX: National Aeronautics and Space Administration-Task Load Index; NHS: National Health Service; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analysis; RAG: Resilience Analysis Grid; RE: Resilience Engineering; RETIPS: Resilience Engineering Tool to Improve Patient Safety; RMF: Resilience Markers Framework; RHC: Resilient Health Care; VRE: Video Reflexive Ethnography; WAD: Work As Done; WAI: Work As Imagined

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Authors' contributions

RL conceived the study; MI extracted study data and drafted the article. MI, RHL and KR screened studies for eligibility for the study. MI and RHL assessed the quality of the included studies. MI, RHL, KR and CC contributed to the study design and data synthesis. MI, RHL, KR and CC revised the manuscript critically for intellectual content, agreed and approved the final version to be published.

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The data used in the study are available from the corresponding author on request.

Ethics approval and consent to participate
Ethical approvals were not required as the study was a systematic review of peer-reviewed journal studies and studies published in books.

Consent for publication
Not applicable.

Competing interests
Dr. Rosemary Lim is an Associate Editor of the journal *BMC Health Services Research*. All other authors declare that they have no competing interests.

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Publisher's Note

Supplementary information

Resilient Health Care: a systematic review of conceptualisations, study methods and factors that develop resilience

Additional File 1: Mixed Methods Appraisal Tool (MMAT) checklist items

	Methodological quality criteria
1. Screening questions (for all types)	**1.1.** Are there clear research questions? **1.2** Do the collected data allow to address the research questions?
2. Qualitative studies	**2.1.** Is the qualitative approach appropriate to answer the research question? **2.2.** Are the qualitative data-collection methods adequate to address the research question? **2.3.** Are the findings adequately derived from the data? **2.4.** Is the interpretation of results sufficiently substantiated by data? **2.5.** Is there coherence between qualitative data sources, collection, analysis and interpretation?
3. Quantitative descriptive studies	**3.1.** Is the sampling strategy relevant to address the research question? **3.2.** Is the sample representative of the target population? **3.3.** Are the measurements appropriate? **3.4.** Is the risk of nonresponse bias low? **3.5.** Is the statistical analysis appropriate to answer the research question?
4. Mixed method studies	**4.1.** Is there an adequate rationale for using a mixed methods design to address the research question? **4.2.** Are the different components of the study effectively integrated to answer the research question?

	4.3. Are the results adequately brought together into overall interpretations? **4.4.** Are divergences and inconsistencies between quantitative and qualitative results adequately addressed? **4.5.** Do the different components of the study adhere to the quality criteria of each tradition of the methods involved?

Additional File 2: Quality assessment of included studies

Study reference	Screening questions		Qualitative studies					Quantitative descriptive Studies					Mixed methods studies				
	1.1	**1.2**	**2.1**	**2.2**	**2.3**	**2.4**	**2.5**	**3.1**	**3.2**	**3.3**	**3.4**	**3.5**	**4.1**	**4.2**	**4.3**	**4.4**	**4.5**
Studies published in journals																	
1. Gittell J. (2008)[1]	Ö	Ö	Ö	Ö	Ö	Can't tell	Ö	Ö	Ö	Ö	Can't tell	Ö	Ö	Ö	Ö	Can't tell	Ö
2. Mash BJ, *et al.* (2008)[2]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Can't tell	Ö	Ö	Ö	Ö	Can't tell	Ö
3. Nemeth C, *et al.* (2011)[3]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
4. Ross A, *et al.* (2012)[4]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
5. Crowe S, *et al.* (2014)[5]	Ö	Ö	N/A	N/A	N/A	N/A	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Can't tell	Ö
6. Drach-Zahavy A, *et al.* (2015)[6]	Ö	Ö	Ö	Ö	Can't tell	Ö	Ö	Ö	Ö	Ö	Can't tell	Ö	Ö	Ö	Ö	Can't tell	Ö

7. Anderson JE, *et al.* (2016)[7]	Ö	Ö	Ö	Ö	Ö	N/A	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
8. McCray J, *et al.* (2016)[8]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
9. Back J, *et al.* (2017)[9]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
10. Rosso C, *et al.* (2018)[10]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
11. Wahlströma M, *et al.* (2018)[11]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Studies published in books																	
12. Cuvelier L, *et al.*[12]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13. Pariès J, *et al.*[13]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
14. Laugaland K, *et al.*[14]	Ö	Ö	Ö	Ö	Can't tell	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
15. Stephens RJ, *et al.*[15]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
16. Anderson JE, *et al.*[16]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
17. Debono D, *et al.*[17]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

18. Deutsch E, *et al.*[18]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	X	Ö	Ö	Ö	Ö	Can't tell	Ö
19. Furniss D, *et al.*[19]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
20. Heggelund C, *et al.*[20]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
21. Horsley C, *et al.*[21]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
22. Hounsgaard J, *et al.*[22]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
23. Hunte G, *et al.*[23]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
24. Nakajima K, *et al.*[24]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Ö	Can't tell	Ö
25. Ross A, *et al.*[25]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
26. Sujan M, *et al.*[26]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
27. Zhuravsky L.[27]	Ö	Ö	Ö	Ö	Ö	Ö	Ö	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Chapter 3

Understanding safety differently: developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients—a feasibility study protocol

Chapter summary: Building on the findings and insights gained from the systematic review of RHC in healthcare systems presented in Chapter 2, this chapter presents my philosophical perspective as the PhD and main researcher in this thesis, followed by a published study protocol of the main data-collection and analysis methods.

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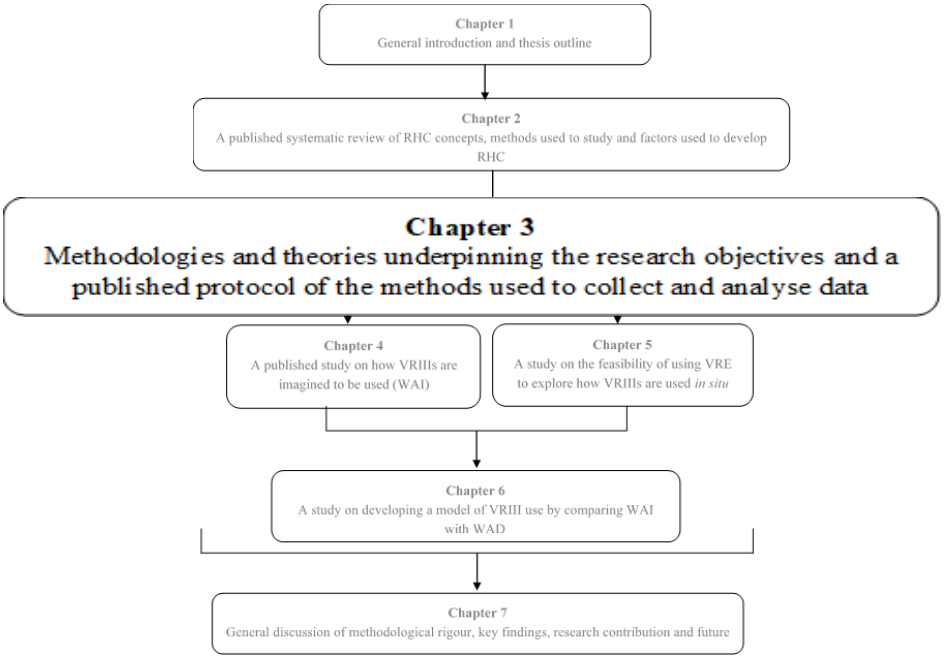

3.1 Introduction

The aim of this thesis was to explore the use of VRIII *in situ* and develop a model of its use. An interpretive theoretical perspective was used to explore the research aim. The philosophical positioning of the researcher is explained in section 3.2. The methodological perspectives that underpin the type of data collected, the methods used for its collection, and how the data was interpreted, are presented as a published study protocol in section 3.3.

3.2 Philosophical perspective

3.2.1 Relativist ontology (beliefs about the nature of reality)

Understanding the use of VRIII in a CAS can be subjective in nature because relativism argues that there are multiple realities that are shaped by the context where truth evolves and changes constantly [1]. How VRIII is assumed to be used or how it is actually used *in situ* may thus be expressed differently by various stakeholders and users. In addition, the use of VRIII to treat a patient's condition may be influenced by the current context, with different issues arising at other points in time for that patient or in the case of other patients. Additionally, the use of VRIII in a complex, adaptive environment requires exploration of the perspectives of multiple agents − healthcare practitioners, patients, managers and the researcher − who are interacting with each other and distributed in complex ways, in order to accomplish work and goals in both expected and unexpected conditions. My ontological stance is that patient safety must be created and recreated every day because of the dynamic nature of CASs, which needs to be reflected in our understanding of them.

This relativist ontological perspective of understanding the subjective experience of reality and multiple truths, shaped what kind of data would be appropriate in exploring the use of VRIII (epistemology) [2].

3.2.2 Constructivist epistemology (theory of knowledge)

Constructivist epistemology maintains that truth or meaning are not discovered, but constructed [3]. In this way of understanding knowledge, constructivism is underpinned by the assumption that all people, including researchers, construct realities and meanings in

different ways, even when dealing with the same phenomenon [1, 4]. My constructivist epistemological stance was fundamental in the process of distinguishing between WAI and WAD and the development of a model for the use of VRIII [5]. Therefore, studying the use of VRIII entails being cognisant of various perspectives by understanding how the use of VRIII is described in hospitals' protocols and clinical guidelines, how different stakeholders/users perceive these guidelines and how the work is coordinated, delivered and accomplished in various situations.

3.2.3 Interpretivist theoretical perspective

Interpretivism is a theoretical perspective which focuses on how humans construct meaning as they engage with the world they are interpreting [1]. It addresses the interpretation or understanding that how humans attach to their work is shaped by their own experiences and background [6]. This thesis aimed to understand safety differently. That is, instead of the key to improving patient safety lying in counting the number of hyper/hypoglycaemic episodes and trying to prevent their occurrence, the researcher focused on gaining a comprehensive understanding of how and why most of the time these episodes do not happen and what adjustments and factors might contribute to their occurrence in a specific context. From the RHC perspective, WAI and WAD are different; an in-depth understanding and interpretation of how participants perceive the use of VRIII (WAI) and how they use VRIII *in situ* (WAD*),* were thus required. In order to achieve this, a qualitative approach employing ethnographic methodology was used to understand WAI, while a VRE methodology along with quantitative data was used to explore WAD. As a result, the development of the model of VRIII use was interpretive in nature as it was based not on a single reality but on the ethnographic and VRE research output. The next section will present a published study protocol, with further emphasis on the specific methodologies, data-collection methods, sample size, recruitment methods, and analytic and ethical considerations used to conduct this research.

3.3 Published protocol

Open access Protocol

BMJ Open

Understanding safety differently: developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients—a feasibility study protocol

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ABSTRACT

Background Intravenous insulin infusions are considered the treatment of choice for critically ill patients and non-critically ill patients with persistent raised blood glucose who are unable to eat, to achieve optimal blood glucose levels. The benefits of using intravenous insulin infusions as well as the problems experienced are well described in the scientific literature. Traditional approaches for improving patient safety have focused on identifying errors, understanding their causes and designing solutions to prevent them. Such approaches do not take into account the complex nature of healthcare systems, which cannot be controlled solely by following standards. An emerging approach called Resilient Healthcare proposes that, to improve safety, it is necessary to focus on how work can be performed successfully as well as how work has failed.

Methods and analysis The study will be conducted at Oxford University Hospitals NHS Foundation Trust and will involve three phases. Phase I: explore how work is imagined by analysing intravenous insulin infusion guidelines and conducting focus group discussions with guidelines developers, managers and healthcare practitioners. Phase II: explore the interplay between how work is imagined and how work is performed using mixed methods. Quantitative data will include blood glucose levels, insulin infusion rates, number of hypoglycaemic and hyperglycaemic events from patients' electronic records. Qualitative data will include video reflexive ethnography: video recording healthcare practitioners using intravenous insulin infusions and then conducting reflexive meetings with them to discuss selected video footage. Phase III: compare findings from phase I and phase II to develop a model for using intravenous insulin infusions.

Ethics and dissemination Ethical approvals have been granted by the South Central—Oxford C Research Ethics Committee, Oxford University Hospitals NHS Foundation Trust and University of Reading. The results will be disseminated through presentations at appropriate conferences and meetings, and publications in peer-reviewed journals.

Strengths and limitations of this study

- This study will test the feasibility of using a novel combination of methods to understand the clinical work of managing intravenous insulin infusions to understand Resilient Healthcare.
- In collaboration with healthcare practitioners, this study will result in the development of practice recommendations to improve the management of patients requiring intravenous insulin infusions.
- This study will produce a model of the use of intravenous insulin infusions.
- Although there are criticisms with the use of a video approach in that it might affect the behaviour of participants, a recent review challenged this assumption and found no evidence that video recording causes significant alteration to the usual way participants behave.

INTRODUCTION

Healthcare organisations are now highly complex and staff are becoming more stressed due to rising pressures and the high risk nature of their work.[1] Globally, it is reported that about 10% of hospitalised patients experience adverse events.[1 2] Medications can present a considerable risk to patients due to their potency and the systems in which medicines are used are one of the main causes of harm and errors in healthcare. Prescribing medication is the most common intervention in healthcare and medication errors are considered to be the most preventable.[3]

Insulin is a high-risk medication that can cause significant patient harm or death when used incorrectly.[4] Although intravenous insulin is extremely effective at reducing blood glucose levels quickly for hospitalised patients, this characteristic also carries the risk of causing patient harm due to errors in how it is used. Insulin requires additional measures to ensure safe prescribing, monitoring and administration.[4 5] Based on the National Diabetes Inpatient Audit (NaDIA)

(2018),[6] four out of 10 insulin-treated inpatients experienced a medication error during their hospital stay. Inappropriate intravenous insulin infusion rates, inappropriate duration, inappropriate transfer to subcutaneous insulin and infrequent monitoring are examples of problems with the use of intravenous insulin infusions.[6]

Traditional approaches to increase safety have focused on identifying systemic weaknesses that contribute to errors, for example, through incident reporting,[7] audit[8] and complaints.[9] These initiatives then result in solutions to prevent future recurrence. Common solutions have included double checking,[10] standardisation of intravenous insulin infusion guidelines and education and training of healthcare staff.[11] Such approaches do not always take into account the complex nature of healthcare systems, which cannot be controlled solely by standards or procedures. Yet, major investments to enhance patient safety have focused on these and have not resulted in convincing reductions in risk, error, harm or death due to incidents.[12]

This disappointing track record of safety improvement informed by traditional approaches has led to a call for a change in thinking about safety. An emerging approach called Resilient Healthcare proposes that although it is necessary to understand what goes wrong, there is also value and lessons to be learnt from what goes right.[13]

BACKGROUND

Resilient Healthcare is defined as 'the ability of the healthcare organisation to adjust its functioning prior to, during, or following events and thereby sustain required operations under both expected and unexpected conditions'.[13] It proposes that the complexity and variability in the healthcare environment is key to understanding how errors occur.[13] This approach considers healthcare practice not as a problem to be solved or requiring standardisation. Instead, existing practices are 'assets' because they show an organisation's ability to adapt to changing situations.[13–16]

Capturing the dynamic nature of complex work is a methodological challenge. Previous research has focused on assessing resilience in healthcare settings and implementing resilience engineering for healthcare quality improvement.[17–22] Researchers compared how work is proposed to be done (Work-As-Imagined (WAI))—that is what people say, think or assume they do—with how work is actually done by healthcare practitioners (Work-As-Done (WAD))—that is what people actually do in practice. The core concept of Resilient Healthcare directs attention to the importance of studying how work is actually done in practice because clinical work does not unfold according to prespecified policies and guidelines.[13]

There is currently limited information on how intravenous insulin infusions are used in hospitals. Additionally, although current methods for studying WAI and WAD have been documented, there are limitations to these. For example, methods to understand WAI include the analysis of documents, reports and protocols.[17 19] WAI is not limited to what is written in a document and can include professionals' perceptions and expectations of work.[23] Methods to understand WAD include field observation, interviews and focus groups[17 19 21 22] but these rely primarily on the researchers' view or lens of how work is performed and poses a risk of researcher bias.

In this study, WAI will be explored using two approaches: (1) analysing intravenous insulin infusion guidelines and (2) analysing transcripts of focus group discussions with guideline developers, managers and healthcare practitioners.

A relatively new methodology called video reflexive ethnography (VRE),[24] whereby healthcare practitioners can review and reflect on their in-situ practices, will be used to understand the interplay between WAI and WAD. As the core concept of Resilient Healthcare is to understand how work is actually done in practice and to understand how adaptations and adjustments are created and how outcomes emerge from the interplay of misalignments between WAI and WAD, video observations will show how people address their own and others' habituated activities as well as their interpretations of policies and guidelines. Video footage of real-time practices will be shown back to participants in reflexive meeting sessions where they collectively make sense of their work and negotiate meaningful, context-appropriate ways of understanding practice and enhancing work.[24–28] The collaboration between researcher and healthcare practitioners in the reflexive sessions will result in the development of workable and realistic recommendations and solutions to increase resilience in the use of intravenous insulin infusions.

Aim and objectives

The overall aim of the research is to test the feasibility of methods to understand the clinical work of managing intravenous insulin infusions to understand Resilient Healthcare.

Objectives

1. To describe and compare WAI and WAD in the use of intravenous insulin infusions in adult inpatients.
2. To understand how approximate adjustments and adaptations are made in relation to the use of insulin infusions.
3. To develop a model of the use of intravenous insulin infusions in adult inpatients.

METHODS

Setting

The study will be conducted at a single site—the Vascular Surgery Unit at the Oxford University Hospitals (OUH) NHS Foundation Trust.

Study design

This feasibility study will take place from December 2018 to December 2019 and will involve three phases (see figure 1).

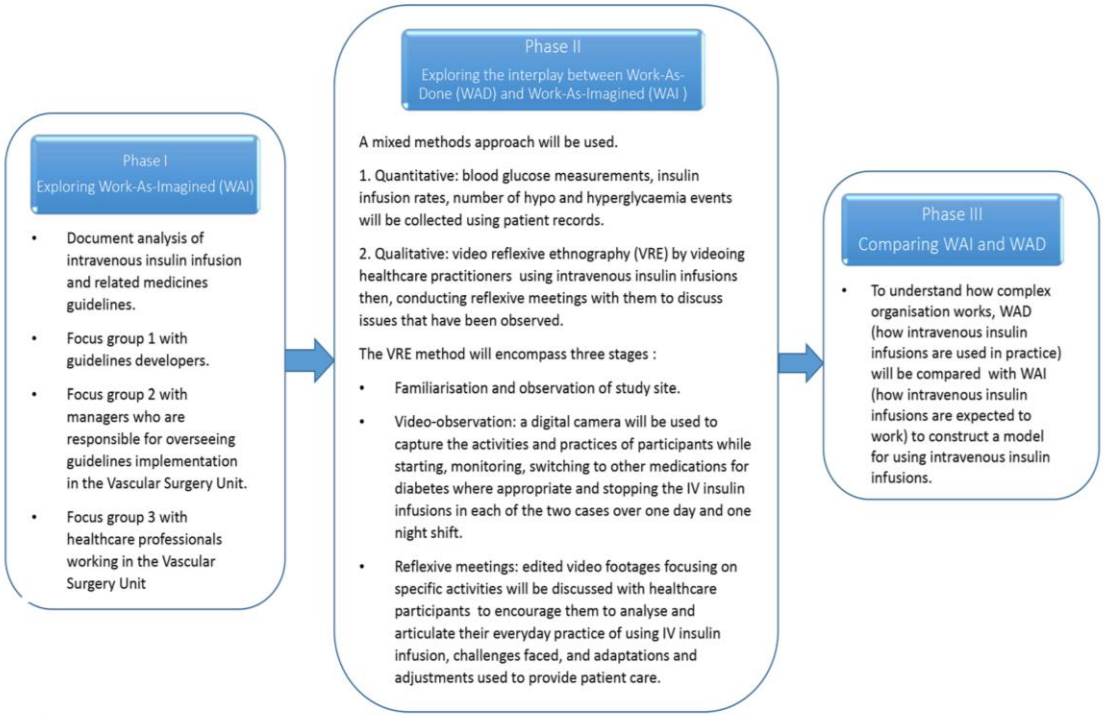

Figure 1 Flowchart of outlined study.

Phase I: exploring WAI

Phase I will consist of (1) document analysis of guidelines for the use of intravenous insulin infusions and (2) focus groups with guidelines developers, managers and healthcare practitioners.

1. Document analysis

To develop understanding and discover insights relevant to what is expected when using intravenous insulin infusions, hierarchical task analysis[29 30] will be used to analyse the documents as outlined below:

- Define the task under analysis—which is the use of intravenous insulin infusions in hospitalised patients for glycaemic control.
- Collect intravenous insulin guidelines and all related documents.
- Determine the overall goal—which is treating elevated blood glucose in hospitalised patients.
- Determine the subgoals that are required to achieve the overall goal. An inductive thematic analysis[31 32] of the intravenous insulin infusion guidelines and related documents will be conducted to identify subgoals such as indications, prescribing, administration, monitoring, adjusting infusion rates and transition to other medication for diabetes where appropriate.
- Deconstruct subgoals: each subgoal will be broken down to further subgoals and operations.
- Analyse the plans (steps) required to achieve each goal.

2. Focus groups

Sample

Three different groups of participants will be invited to take part in separate focus groups. A purposive sample of guidelines developers (five participants), managers (five to seven participants) and healthcare practitioners working at Vascular Surgery Unit (five to seven participants) will be recruited. The inclusion and exclusion criteria for participants are presented in box 1.

Box 1 Eligibility criteria for phase I focus group participants

Inclusion criteria

- Guideline developers responsible for developing and implementing local guidelines in Oxford University Hospitals (OUH) on the use of intravenous insulin infusions.
- Managers responsible for controlling resources and staffing and overseeing the implementation of intravenous insulin infusion guidelines in the Vascular Surgery Unit.
- Healthcare practitioners without a management role who care for patients requiring intravenous insulin infusions in the Vascular Surgery Unit.

Exclusion criteria

- Any participant not willing to be audiorecorded.
- Any healthcare practitioners not working in the Vascular Surgery Unit at OUH.
- Guidelines developers other than the Adult Inpatient Diabetes Specialist Team.

Recruitment and informed consent

An email invitation letter and participant information sheet outlining the purpose of the study will be sent to potential focus group participants. On the day of the focus group, signed informed consent will be obtained.

Data collection

A focus group guide, informed by hospital guidelines, policies and protocols related to the use of intravenous insulin infusions will be used throughout the discussion (online supplementary Appendix 1). A case study will be presented in the last 10 min of the session aimed to contextualise ways of working within a plausible patient case.

The discussions with healthcare practitioners will be essential to establish relationships with the researchers because they are potential participants for phase II of the study in which work practices in-situ will be observed.

The three focus group discussions will enable comparison between WAI as described by the healthcare practitioners who are in direct contact with the patients and the guideline developers and managers who have limited direct patient contact. To the best of our knowledge, this will be the first study that compares the understanding of WAI between guideline developers and healthcare practitioners.

Focus groups will be audiorecorded and audiorecordings transcribed verbatim. Any identifying information will be removed from the focus group transcripts.

Data analysis

An inductive thematic approach will be used with the aid of NVivo 12, a qualitative data management software.[33]

Phase II: exploring the interplay between WAD and WAI

Phase II will include analysis of patients' records, video observation of WAD and reflexive analysis of the recordings with participating healthcare practitioners. The inclusion and exclusion criteria for participants are presented in box 2.

A mixed-methods approach using qualitative and quantitative methods will be used.

1. Qualitative approach: VRE

This phase will use an innovative method, VRE[24] that has not been applied before in this study setting. As such, this study will test the feasibility of using the VRE method along with quantitative methods to understand how healthcare practitioners work and interact as part of a system while using intravenous insulin infusion. VRE is a qualitative research methodology that depends on collaboration between the researcher and the participant to film specific work performed by the participant.

The aim of using VRE is to improve healthcare delivery from the bottom up (WAD in practice) by directly involving healthcare practitioners in collaboration with the researcher in understanding the complexity of healthcare delivery.

Box 2 Eligibility criteria for phase II participants

Healthcare practitioners

Inclusion criteria
- Willing to be observed by video recording.
- Working in the Vascular Surgery Unit at Oxford University Hospitals.
- Managing patients on intravenous insulin infusions.

Exclusion criteria
- Not involved in the use of intravenous insulin infusions.

Patients

Inclusion criteria
- Aged ≥18 years old.
- Receiving intravenous insulin infusion for at least 24 hours to treat hyperglycaemia.
- Under the care of healthcare practitioners who have consented to participate in this study.
- Able to provide informed consent.

Exclusion criteria
- Not willing to be observed by video recording.
- Not prescribed intravenous insulin infusions.
- On intravenous insulin infusion to treat hyperkalaemia
- Non-English speakers.

A key concern with using video approaches is the effect of videoing on the practices and communications between the participants and the patients. A recent review found no evidence that video recording causes significant alteration to the usual way participants behave.[34] However, there is a possibility that changes to working practices may occur at the initial stages of video recording. To address this, the researcher will familiarise herself with the workflow of participants in the wards, she will observe and consult with participants about where she should best 'locate' herself during videoing. The researcher will ensure video recording is not intrusive to the daily routines of participants and will stop recording if appropriate for example, medical emergency.

Sample

In this feasibility study, two patient cases receiving intravenous insulin infusion will be observed to provide a clear understanding of actions and tasks that should be performed while managing patients on intravenous insulin infusion. The sample size of two cases was determined by time and resource constraints and Uncertanties about the quantity and quality of the data to analyse.

Recruitment and informed consent

Healthcare practitioners:

Three different ways will be used to recruit potential participants:

1. The researcher will join various existing meeting(s) to meet as many healthcare providers working in the Vascular Surgery Unit as possible, and to explain the VRE study.
2. A poster with details about the study will be placed in the staff room and on the door of the toilets until the completion of data collection for phase II.

3. An invitation letter and participant information sheet outlining the purpose of the study, the methodology and the design will be sent to all potential participants working in the Vascular Surgery Unit.

On the day of the videoing and prior to switching on the camera, informed consent will be obtained for observing the participant while using intravenous insulin infusion by video recording and participating in video reflexive meetings. In cases where the researcher is unable to obtain written consent before videoing, verbal consent will be obtained, and written consent sought as soon as possible afterward (posthoc consent).

Patients

The patient will be provided with an invitation letter and participant information sheet to explain the purpose and objectives of the study, which includes videorecording and the use of medical records. The patient will be given time to ask any questions about the study before giving written informed consent. To ensure that patients do not feel obliged to participate, we have included information in the participant information sheet and consent form that participation is entirely voluntary. The patient will also have information, in the participant information sheet, about their right to withdraw, how to withdraw and what will happen to any study data collected. Prior to taking informed consent, the researcher will also verbally explain the voluntary nature of participation and their right to withdraw from the study. Files with participant's identifiers (videos and quantitative data) will be immediately deleted if a participant decides to withdraw from the study.

Data collection

Data will be collected in three stages:

Stage 1: familiarisation and observation of study site

The researcher will familiarise herself with the healthcare environment in the Vascular Surgery Unit by initially using data from focus group 3 (phase 1) to identify key areas of practice using intravenous insulin infusion to focus on during the video observation stage. Then, the researcher will familiarise herself with the environment by finding areas other than the bed space to be videoed such as the treatment room where infusions are stocked and the electronic patient records are completed. The researcher will also speak informally with staff working in the Vascular Surgery Unit; conduct two general observations of the use of intravenous insulin infusions and record the observation in a notebook. These observations will be conducted for short periods of 30–60 min during normal working hours (day shift) and night shift.

Familiarisation will be accomplished by observing actual work practices and by reviewing the electronic patient record for historical usage of intravenous insulin infusions.

Stage 2: video-observation

A digital video camera will be used, and another one will be available on site as a backup camera in the event of technical failures. The researcher will video the activities and practices of participants while starting, monitoring, switching to other medications for diabetes and stopping the intravenous insulin infusions. Each case will be observed over 24 hours (one day shift and one night shift). The research team will review the video footage collected and mask all identifiers using a video cartooniser software (Adobe Premiere Pro) that turns videos to cartoons. To reduce any potential bias, the research team consisting of those with different expertise and roles will select 3–4 short video clips of interest lasting around 1.5–3 min for use in the reflexive meeting. Clips of interest might include set-up of intravenous insulin infusions, treatment decisions to increase/decrease infusion rates and to stop intravenous insulin infusion and any additional unique aspects of the use of intravenous insulin infusion observed by the researcher.

Stage 3: reflexive meeting

Each participant will attend one arranged small group reflexive meeting to allow them to watch selected video footage, explore issues identified in observations and propose different solutions and recommendations to enhance patient safety in the use of intravenous insulin infusions. The researcher will be in the reflexive meeting discussions to facilitate the discussion, to indicate some issues identified through video observation, to prompt questions and to elicit innovations (online supplementary Appendix 2).

All reflexive meetings will be held in a private room in the OUH for 30–60 min and will be audiorecorded and then transcribed verbatim. The transcripts will provide the researchers with an essential record of the discussions and the potential solutions and plans provided by the participants.

Analysis

Non-identifiable codes will be used to refer to the participants in the written materials. An inductive thematic approach will be used with the aid of NVivo 12 to analyse the recordings of the reflexive meetings. Initial themes derived from the analysis of data will be discussed within the wider research team. Master themes will be developed following identification of cross-cutting patterns and themes within and across the data from the video reflexive meetings.

To ensure trustworthiness, two members of the research team will independently code transcripts and differences in interpretation will be resolved through discussion between coders.

2. Quantitative approach: analysis of patients' records

Electronic patient records of two patients whose care will be observed through VRE will be accessed retrospectively after videoing, to identify extra relevant quantitative data

covering the 24 hours of recording such as blood glucose measurements, and infusion rates, and monitoring frequency for the intravenous insulin infusion.

Analysis

Descriptive statistics (actual numbers and percentages) will be used to compare blood glucose, infusion rates and monitoring frequency for intravenous insulin infusion against the hospital's standard protocols.

From the data, the number of hyperglycaemic (>12.0 mmol/L) and hypoglycaemic (<4.0 mmol/L) events, the cumulative time that the insulin infusions were held for hypoglycaemia, and the number of times that the patient required an intravenous 'rescue' 20% glucose infusion to treat hypoglycaemia will be calculated to determine the efficiency and safety of using intravenous insulin infusions.[35 36]

The quantitative data are complementary to the qualitative as it is an objective measure of WAD and qualitative data from VRE will provide context and meaning of the measured data in patients' records.

Data storage and security

All storage of data will adhere to the General Data Protection Regulation 2016 and the Data Protection Act 2018. Participant identifiable data will be stored on a password-protected project shared drive. The final study data set (focus group and reflexive meeting discussion transcripts' with non-identifiable codes and cartoonised videos for the video observation stage) and data that directly underpins the research findings will be stored on the University of Reading Research Data Archive.

Phase III: developing a model for using intravenous insulin infusions

A comparison of discursive descriptions of findings from phase I and phase II will be performed to produce a model showing concepts that represent misalignments between WAI and WAD. Findings will be analysed and interpreted within the context of Resilient Healthcare theories. The model will be supplemented by summaries of underpinning data used to identify and categorise misalignments, and the outcome of work performed. We will interpret the outcome of work by comparing descriptions by healthcare practitioners in the reflexive meetings against quantitative data from patient records.

Developing a systems model based on our study data brings together disparate sources of information to provide an evidence-base for future intelligent redesign of the system. The model will provide a systems view of how intravenous insulin infusions are used; highlighting and providing nuanced insight into interactions between and among key parts of the system such as people, tasks, technology and environment, that can influence processes and outcomes, to explain how mismatches between WAI and WAD occur.

Patient and public involvement

Patients will be actively involved in the dissemination of the study findings through interactive workshops with patient representatives, healthcare providers and policy-makers to influence attitudes and behaviours surrounding the use of intravenous insulin infusions within hospitals.

DISCUSSION

This study is designed to evaluate the feasibility of methods to understand the clinical work of managing intravenous insulin infusions and functionality of constructing a model of the use of intravenous insulin infusion using a Resilient Healthcare approach. Although many research studies have focused on the use of Resilient Healthcare to improve safety by comparing WAI with WAD,[17 19 21 22] no study to date has examined and strengthened resilience in the use of specific medications such as intravenous insulin infusions.

To understand WAD, interviews and focus groups have been used in previous qualitative research to improve quality of care and resilience in an emergency department[17 19] clinical handovers[21 37] and inpatient diabetes care.[22] The assumption that participant's words are reliable indicators of what happens in actual practice may be questionable. Interviews and focus groups, usually convened by the researcher, focus on a particular issue or problem. Interviewees may choose to withhold certain information or change it, particularly if the 'truth' is inconsistent with their preferred self-image.[38] Focus group data are the product of context-dependent group interactions, and participants might or might not disclose certain information during the focus group discussion.[39] Observational research establishes what people actually do or say, rather than what they say they do. Observations can, however, include a degree of researcher bias as the method relies on the interpretation of observations. The researcher cannot 'see' attitudes and memories and so it can be difficult to create an accurate analysis from observation alone. To overcome problems using these approaches in understanding WAD and describing the complexity of healthcare, VRE will be used to capture how work with intravenous insulin infusion is actually done, what complexities healthcare practitioners encounter, what creative adaptations are made, and how they deal with expected and unexpected conditions. As a form of reasoning, reflexive discussions with healthcare practitioners will draw attention to aspects that remained taken for granted before witnessed on video, but which are critical in understanding why work was done in such ways. This will allow healthcare practitioners to think of ways to reshape their practices to improve their work and patient safety.

CONCLUSION

This study will test the feasibility of a mixed-methods approach designed to explore and strengthen resilience

in the use of intravenous insulin infusions by comparing WAI from different perspectives (guideline developers, managers and healthcare practitioners alongside analysing intravenous insulin infusion guidelines) with WAD. It will explore and develop understanding of the actual work in the use of intravenous insulin infusion through videoing practices and then discussing the resultant footage with the healthcare practitioners to identify how they do their work. This way of understanding resilience in healthcare will introduce different views on what actually happens in the use of an intravenous insulin infusion. It will help in understanding why and when there are misalignments between WAI and WAD, what creative adaptations may be performed to overcome misalignments and assist in the development of a model for the use of intravenous insulin infusion in hospitalised in-patients.

DISSEMINATION

There are different key audiences for this research, including healthcare practitioners, patients and the public, the Joint British Diabetes Societies for Inpatient Care Group (JBDS-IP), The Getting It Right First Time (GIRFT) Programme, developers of diabetes guidelines at OUH, Diabetes UK and academia. The findings of the study including recommendations, solutions to enhance the safety in the use of intravenous insulin infusions and the model for intravenous insulin infusion use will be presented to healthcare practitioners, guideline developers and managers at the study site. In addition, presentations will be given at national and international conferences and seminars, and workshops with patients' representatives. Findings will be published in peer-reviewed journals. Participants and interested parties can request a copy of the Final Study Report. Findings will be of interest to those involved in safety and resilience of intravenous insulin infusions such as the Patient Safety Team NHS Improvement, GIRFT and JBDS-IP.

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Supplementary appendices

Understanding safety differently: developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients-a feasibility study protocol

Appendix 1: Focus group discussion guide

Introduction:
1. Welcome
2. Ground Rules
3. Turn on audio-recorder

Focus group 1 (guideline developers):

Let's begin:

- How did you develop the guidelines for IV insulin infusions?
  Prompts: personnel, process, purpose, materials/content/policies, did anybody lead this development
  - ✓ If they only mention one guideline… can you discuss why this guideline?

- What factors were taken into consideration?
  Prompts: patients, healthcare providers, availability
- How do you think the guidelines to be used?
- Who will oversee the implementation of the guidelines?
  Prompts: roles, each ward
- Are there any circumstances where you expect staff might deviate from the guidelines?
- How do you evaluate the use of the guidelines?
  Prompts: reporting systems
- How will you refine them?
  Prompts: personnel, process, materials

In the last 10 minutes, the researchers will provide a case scenario for the focus group to discuss how they would use the IV insulin guidelines to the case.

Case scenario
AA, a 55-year-old, obese woman, admitted to the hospital with a sudden, severe headache which was described as the "worst headache" ever experienced associated with nausea, vomiting and blurred or double vision. After examination, she was diagnosed with brain aneurysm and admitted for emergency surgery BUT it is weekend, so she was on the emergency list and was prepared for surgery.

Past medical history
Hypertension, type1 diabetes, peripheral vascular disease, dyslipidaemia.

Admission blood test:
Glucose (11.7 mmol/L)
Haemoglobin A1c (HbA1c 8.6%).

K 4mmol/L

Diabetes medications:
Lantus 22 units subcutaneously at bedtime
Novorapid 2-4 units with each meal

Vital signs: BP 135/85 mm Hg, HR 80 bpm, temperature 37 C, weight 99.8 kg, BMI 32.5

AA is euvolaemic and last ate lunch; it is now 4:30pm.

Let's focus on glycaemic control. How do you think healthcare practitioners will treat this patient? (Target BG, home medications, type of insulin, using fluids, monitoring, conversion to SC.)

Focus group 2 (managers):

Let's begin:

- How do you know about the new guidelines?
  Prompts: meetings, email, courses
- When there is a new guideline, what do you do with it?
  Prompt: Who does this and when? How do you introduce the guidelines to your staff?
  Prompts: one to one, meetings, training days, email, ward handover meeting
- Is there a given timeline to introduce the new guidelines or to do something about it?
- How do you ensure the guidelines are being used by the staff?
  Prompt: Can you give examples?
  Prompts: monitoring, reporting, training, understandable
- What has been your experience of using the guidelines?
  Prompts: successes, good practice, incidents, accidents, concerns, non-conformities, complaints

In the last 10 minutes, the researchers will provide a case scenario for the focus group to discuss how they would use the IV insulin guidelines to the case.

Case scenario
AA, a 55-year-old, obese woman, admitted to the hospital with a sudden, severe headache which was described as the "worst headache" ever experienced associated with nausea, vomiting and blurred or double vision. After examination, she was diagnosed with brain aneurysm and admitted for emergency surgery BUT it is weekend, so she was on the emergency list and was prepared for surgery.

Past medical history
Hypertension, type1 diabetes, peripheral vascular disease, dyslipidaemia.

Admission blood test:
Glucose (11.7 mmol/L)
Haemoglobin A1c (HbA1c 8.6%).
K 4mmol/L

Diabetes medications:
Lantus 22 units subcutaneously at bedtime
Novorapid 2-4 units with each meal

Vital signs: BP 135/85 mm Hg, HR 80 bpm, temperature 37 C, weight 99.8 kg, BMI 32.5

AA is euvolaemic and last ate lunch; it is now 4:30pm.

Let's focus on glycaemic control. How do you think healthcare practitioners will treat this patient? (Target BG, home medications, type of insulin, using fluids, monitoring, conversion to SC.)

Focus groups 3 (healthcare practitioners working in the Vascular Surgery Unit):

Let's begin:

- Are you aware of any OUH guidelines for IV insulin infusions?
- What do you think of the OUH guidelines for IV insulin infusions?
  Prompts: language, training, content
- When do you use IV insulin infusions guidelines?
  Prompts: presentation of patients
- How do you use the guidelines?
- Are there any challenges with the use of these guidelines?
  Prompts: gaps, barriers, understanding
- What are the challenges you encounter when treating patients on IV insulin infusions?
  Prompts: knowledge, time, staffing

In the last 10 minutes, the researcher will provide a case scenario for the focus group to discuss the treatment plan using IV insulin infusions based on their understanding of IV insulin infusions guidelines in their hospital.

Case scenario
AA, a 55-year-old, obese woman, admitted to the hospital with a sudden, severe headache which was described as the "worst headache" ever experienced associated with nausea, vomiting and blurred or double vision. After examination, she was diagnosed with brain aneurysm and admitted for emergency surgery BUT it is weekend, so she was on the emergency list and was prepared for surgery.

Past medical history
Hypertension, type1 diabetes, peripheral vascular disease, dyslipidaemia.

Admission blood test:
Glucose (11.7 mmol/L)
Haemoglobin A1c (HbA1c 8.6%).
K 4mmol/L

Diabetes medications:
Lantus 22 units subcutaneously at bedtime
Novorapid 2-4 units with each meal

Vital signs: BP 135/85 mm Hg, HR 80 bpm, temperature 37 C, weight 99.8 kg, BMI 32.5

AA is euvolaemic and last ate lunch; it is now 4:30pm.
Let's focus on glycaemic control. How do you think healthcare practitioners will treat this patient? (Target BG, home medications, type of insulin, using fluids, monitoring, conversion to SC.)

That concludes our focus group. Thank you so much for coming and sharing your experience with us.

Appendix 2: Reflexive meeting discussion guide

1. Welcome
2. Ground rules
3. Turn on audio-recorder
4. Let's begin:

- Introductory question: Thinking back to your recent work, can you write down on the white paper on the desk three things that you liked and three things that you dislike about your experience in the use of IV insulin infusions? You have 5 minutes to write. Prompts: access to the guidelines, clarity of the guidelines, availability of pumps, monitoring frequency, etc.…
- Thank you. I would now like us to watch a few short videos (approximately 3-6) of you using IV insulin infusions.
- What are your thoughts on what you saw? Prompt: what was happening in the clip shown? Please take a few moments to write down on the paper provided what your initial thoughts, then feel free to discuss with your colleagues the practices in the use of IV insulin infusions in the video that you have seen.
- Here is a summary of the main recommendations that you mentioned. Do you think that this is an adequate summary? Have I missed anything?
- Of all the things that we have discussed today, what do you think is the most important?

I want to thank you all for taking time out of your busy schedules to be here today.

Chapter 4

A detailed analysis of 'Work as Imagined' in the use of intravenous insulin infusions in a hospital: A Hierarchical Task Analysis

Chapter summary: Following on from the previous chapter in which the protocol presented the methodologies and analysis methods required to explore WAI and WAD, the current chapter explores WAI in the use of VRIII. WAI was investigated drawing on the analysis of hospital-specific guidelines and accounts from different stakeholders' on how they think VRIII is used in practice.

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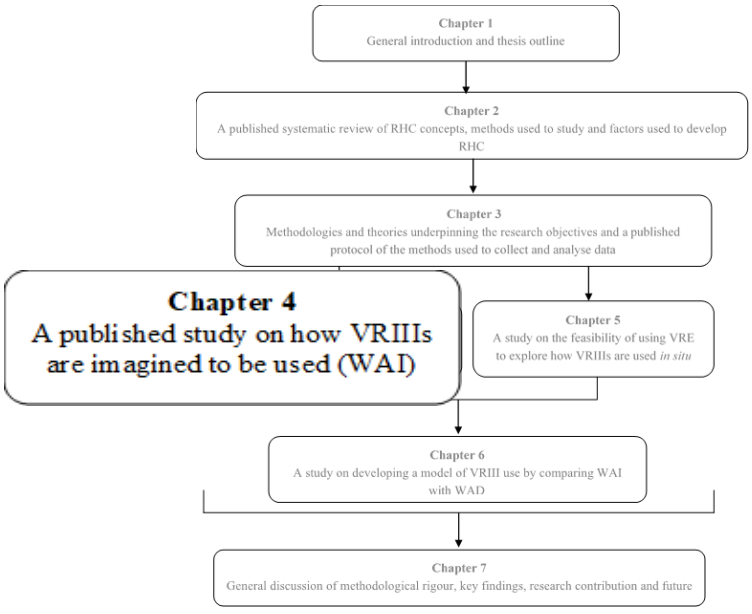
Author contributions: MI, RL, KR, CC and FG conceived and designed the study. CC and MI facilitated the recruitment of the participants. MI was responsible for data collection with support and guidance from RL, CC and KR. MI, RL and KR coded and analysed the data. MI drafted the initial manuscript and the HTA. All authors edited the HTAs and CC extensively reviewed and commented on the HTA. All authors extensively edited drafts of the manuscript and accepted the final version of the manuscript.



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Detailed analysis of 'work as imagined' in the use of intravenous insulin infusions in a hospital: a hierarchical task analysis

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ABSTRACT

Objective Variable rate intravenous insulin infusions (VRIII) is a high-risk medication that has a potential to cause significant patient harm if used in error. Complex preparation of VRIII in clinical areas and the need for frequent monitoring and adjustment increase the complexity of using VRIII. An emerging approach, called Resilient Healthcare, proposes understanding complexity of work by exploring how work is assumed to be done and compare it with everyday work. This study aimed to explore how VRIII is perceived to be used by healthcare practitioners, focusing on one aspect of Resilient Healthcare: understanding how work is assumed to be done, using a method called hierarchical task analysis (HTA).

Design A qualitative study using document analysis and focus groups.

Setting A vascular surgery unit in an acute National Health Service teaching hospital in the UK.

Participants Stakeholders/users in different professional roles involved in the process of using VRIII.

Results The HTA showed the complexity of using VRIII and highlighted more than 115 steps required to treat elevated blood glucose. The process of producing hospital-specific guidelines was iterative. Careful consideration was taken to coordinate the development and implementation of guidelines. Documents provided detailed clinical instructions related to the use of VRIII but practitioners selectively used them, often in deference to senior colleagues. Intentional adaptations, for example, proactively asking for a VRIII prescription occurred and were acknowledged as part of providing individualised patient care.

Conclusion Using VRIII to treat elevated blood glucose is a complex but necessary process mediated by a range of factors such as organisational influences. Adaptive strategies to mitigate errors were common and future research can build on insights from this study to develop a broader understanding of how VRIII is used and to understand how adaptations are made in relation to the use of VRIII.

Strengths and limitations of this study

- ► To the best of our knowledge, this is the first study to explore Work As Imagined in relation to the use of variable rate intravenous insulin infusions (VRIII).
- ► Multiple data sources, that is, document analysis and focus group meetings were used to understand how work is imagined while using VRIII.
- ► This is the first study that used hierarchical task analysis to illustrate the tasks that were expected to be done while using VRIII.
- ► The low number of focus groups participants might not represent the perspectives of all the staff who might have given different views on the tasks of using VRIII.
- ► Discussions with focus groups participants about the guidelines that were implemented a few years ago may have been a potential source of recall bias.

INTRODUCTION

Controlling blood glucose (BG) in hospitalised patients is very important for optimal patient outcomes. Globally, variable rate intravenous insulin infusions (VRIII) is considered the treatment of choice to achieve optimal BG levels in hospital inpatients who are not eatingand those with some acute illnesses, for example, sepsis.[1 2] Studies reported in the scientific literature describe benefits from using VRIII to control elevated BG levels, including reduced mortality, less time spent in hospital and improved wound healing.[3 4] However, if used incorrectly, it can result in patient harm from hypoglycaemia, rebound hyperglycaemia and diabetic ketoacidosis.[5]

Complex systems and clinical complexity

Contemporary healthcare systems have been described as complex adaptive system (CAS) where components in a system act in a dynamic network, constantly react in unpredictable and non-linear ways resulting in the emergence of outcomes [6 7] The level of complexity in healthcare systems has increased exponentially with each new diagnostic, therapeutic and technological discovery.[8] The use

of VRIII is also complex and can result in unpredictable outcomes. A range of factors such as medication-related factors, for example, the limited evidence for a threshold for starting VRIII[1]; patient-related factors, for example, associated comorbidities[9]; provider-related factors, for example, fear of hypoglycaemia[10]; task-related factors, for example, frequent (hourly) BG monitoring[1] and hospital-related factors, for example, complex and variable guidelines and staff shortages,[9] contribute and influence the clinical complexity of using VRIII.

Safety in the use of VRIII

A variety of national and international interventions and initiatives have been reported to improve the safety of using VRIII, including using advanced glucose monitoring technology that measures BG continuously and alerts for hypoglycaemia or hyperglycaemia episodes,[11] specialist diabetes nurses,[12] the Think Glucose campaign,[13] double checking, standardisation of VRIII guidelines, providing ready-to-administer injectable medications and extra education and training for healthcare staff.[14] In the UK, the Joint British Diabetes Societies for Inpatient Care (JBDS-IP) was established in 2008 to improve inpatient diabetes care through standard setting and clinical guidelines development.[15] A recent audit assessed the breadth of the JBDS-IP guidelines' adoption in the UK.[15] It was found that 88% of the surveyed hospitals adopted the VRIII guidelines for medical inpatients, and around 58% of healthcare practitioners in these hospitals felt that the guidelines' adoption had improved clinical outcomes and patient safety.[15] Despite the high adoption of the VRIII guidelines and other safety initiatives, the 2018 National Diabetes Inpatient Audit (NaDIA) revealed that the percentage of inappropriate use and duration of use of VRIII have not changed significantly since 2011 and that errors still persist.[5] A possible explanation for this is that some traditional safety approaches, for example, standardised practice do not always take into account the constantly changing and complex nature of healthcare systems. Greenhalgh and Papoutsi illustrated the need to design and implement research methods that appreciate dynamic interactions and emergence in CASs, and understand from different perspectives how the whole system works.[16] Recent safety literature shows a growing interest in what is called Safety-II, which advocates investigating how things go right instead of only focusing on how a particular failure had happened (Safety-I). Resilient Healthcare (RHC) acknowledges that variability in performance is inevitable. It does not argue for a total replacement of Safety-I with Safety-II, rather proposes that it is necessary to focus on how everyday work can be performed successfully (what goes right) as well as how work has failed (what can go wrong) in order to improve safety.[17 18] Various data collection methodshave been used to study RHC, including using the four capabilities of RHC, that is, respond, monitor, anticipate and learn, investigating performance variability and Work As Done (WAD) and integrating RHC with other safety paradigms.[17]

Modelling 'work as imagined'

Work is defined as a physical or cognitive effort/activity directed toward achieving a specific goal or task.[19] This study is part of a wider project for which there is a published protocol.[20] There have been many research studies discussing the quality of different process modelling approaches.[21 22] Although a sequential flow diagram is considered the most commonly used process mapping approach in healthcare, there have been precedents for using hierarchical task analysis (HTA) for analysing and mapping complex healthcare systems.[23 24] An HTA is known as a prerequisite task analysis that is developed from general to specific. HTA answers what must the user know or do to achieve the goal.[25] However, the sequential process map is developed step by step and linearly to answer what are the methods that the user must go through in order to complete a specific activity.[26] Colligan *et al* conducted a study to examine the effect of a sequential flow diagram and HTA on the healthcare practitioner's judgement. The results of that study found that HTA was easier to produce graphically and review as the mapping progressed, flexible in representing specific goals which did not correspond to specific acts or times, and encompassing unpredictability of healthcare activities with a focus on goal rather than the precise method. HTA is one of the most commonly used task analysis techniques[27] to understand and analyse the complexity of the work. In this study, HTA was used to investigate work is imagined (WAI) in the use of VRIII from different perspectives. HTA was developed based on the theory of performance and has been used to describe system dynamics and human-system interfaces.[28] HTA is a flexible and generic tool and has been applied in different domains[25 27] such as in the process control and power generation industries and recently in medication administration and management.[29 30] The use of VRIII is driven by the need to identify and achieve the goal of patient care despite the variability in patients, availability of staff and the demands on the system.

Study aim

In this study, we aimed to systematically explore WAI when using VRIII from multiple perspectives. The findings of this study may be the first step for healthcare practitioners and policy makers to create robust understanding of the reality of WAI to improve patient safety in relation to the use of VRIII.

METHODS

Study design

This research drew on the constructivism paradigm, which emphasises the importance of the context in the process of knowledge construction and accumulation.[31] This

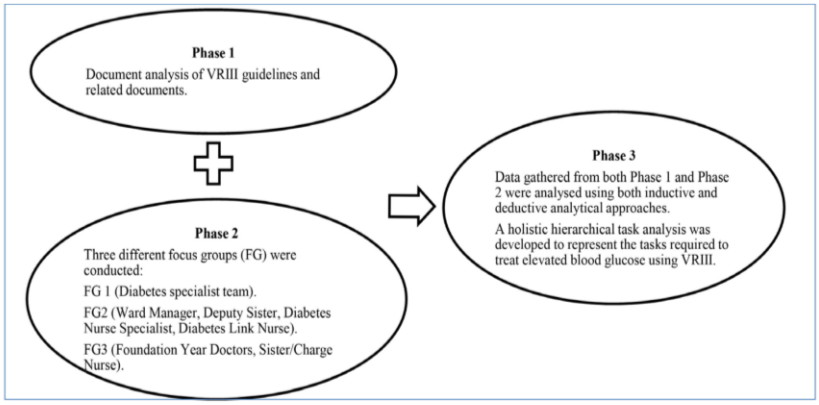

Figure 1 Diagram summarising the three different phases of the study. VRIII, variable rate intravenous insulin infusions.

paradigm shaped our view of what type of knowledge about WAI would be of value.[32] For the purpose of this study, a descriptive, systematic approach was applied to establish empirical data with a view to exploring how WAI in the use of VRIII.[33] The researchers interpreted and analysed data from documents and focus groups (FGs) drawing on their own experiences, in order to construct a deep understanding of WAI as it is described in the guidelines and how practitioners think they use the VRIII guidelines. This study was conducted in three phases: (1) document analysis; (2) FG discussions; (3) the development of the HTA by merging of the data from both sources. Figure 1 illustrates the study phases to represent WAI in the use of VRIII.

Study setting

The study was conducted at the vascular surgery unit of an acute National Health Service (NHS) teaching hospital in the UK.

Phase 1: document analysis

All current hospital-specific documents that described key tasks related to the use of VRIII to treat elevated BG in adult in-patients, such as indications for use, prescribing, administration, monitoring, adjusting infusion rates and transition to other medication, and were readily available on the hospital's intranet (see box 1), were included. These documents were used to develop understanding and discover insights relevant to what is expected when using VRIII.

Box 1 Documents related to the use of variable rate intravenous insulin infusions (VRIII)

1. Guidelines for VRIII in adults.
2. Guidelines for management of diabetic ketoacidosis in adults.
3. Guidelines for management of hyperosmolar hyperglycaemic state in adults.
4. Managing diabetes in adult inpatients before, during and after operations and procedures.
5. The management of hypoglycaemia in adult inpatients.
6. Hand hygiene policy.
7. Aseptic non-touch technique (peripheral and central access intravenous therapy).
8. Recording Line Insertion and Visual Infusion Phlebitis Score.
9. Patient identification policy.
10. Visual Infusion Phlebitis Score.
11. Procedure for preparing and administering injectable medicines.

Phase 2: FGs

Sample

A purposive sample of stakeholders/users with different key responsibilities (guidelines developers, managers and healthcare practitioners) involved in treating elevated BG using VRIII were recruited. There is no definite sample size for qualitative research. It depends on a range of factors including the underpinning methodology, the scope of the research question, and the resources available.[34] Summary information about FG participants' characteristics can be found in Table 1.

Recruitment

Participant recruitment for the three FGs was undertaken over 6 months (December 2018–May 2019). Specifically, the hospital collaborator sent an email invitation letter and participant information sheet outlining the purpose of the study to potential participants for FGs 1 and 2. The clinical and managerial leads sent an email invitation letter and participant information sheet for FG3. The researcher attended two ward meetings to meet as many healthcare practitioners as possible to explain the aim and methods of the study. Interested participants contacted the researcher directly via email. On the day of the FG and prior to the session, the researcher explained the study to the participants again, allowed time for any other questions they may have about the study and took informed consent.

Data collection

The three FG meetings took place in a quiet meeting room at the vascular surgery unit and lasted approximately 30–45 min, each. The research team, including the hospital collaborator, developed the FG topic guide (see online supplemental file 1). The topic guide was informed by the results of the document analysis. A topic guide included open-ended questions, and a case scenario

Table 1 Characteristics of focus groups (FG) participants

	FG1 guidelines developers	FG2 managers	FG3 healthcare practitioners
Sample	Diabetes consultants, pharmacist and diabetes specialist nurses.	Nurses (ward manager, deputy sister, diabetes nurse specialist and diabetes link nurse that is, registered nurse with an expressed interest in diabetes and a formal link to diabetes specialist team).	Foundation year doctors (medical graduates entering the medical workforce as 'junior doctors' on a 2-year work-based training programme) and Nurses (Sister/ Charge Nurse).
Role	Develop and disseminate guidelines for the use of IV insulin infusions.	Implement guidelines, allocate resourcesand staff training. Diabetes Link Nurse acts as a conduit between front line practitioners and the inpatient diabetes specialist team.	Work at the vascular surgery unit using intravenous insulin infusions and do not have a management role.
No of potential participants	4	10	20
No of recruited participants (%)	4 (100)	3 (30)	4 (20)

of treating elevated BG was used in all FG meetings to discuss the treatment plan based on their understanding of the VRIII guidelines used in their hospital. MHI (PhD candidate, pharmacist) moderated all the FG meetings. All meetings were audiorecorded, and the recordings transcribed verbatim.

Phase 3: data analysis

Data gathered from both documents and FG meetings were analysed using both inductive and deductive analytical approaches. The analysis began by analysing documents deductively, codes were determined based on the literature to provide details on the key tasks in the process of treating elevated BG using VRIII. Coding for the documents was conducted by a single researcher (MHI) with the aid of NVivo V.12, a qualitative data management software. Initial codes were then discussed within the research team (MHI, RL and KR) and mutually refined until they reached consensus.

After the initial stage of document analysis was completed, FG transcripts were analysed using both inductive and deductive analytical approaches. To enhance credibility, three of the authors participated in analysing the transcripts. MHI, RL and KR independently coded the transcripts. The three researchers discussed their codes until they reached consensus. Then codes from documents and FGs were constructed into candidate categories. For example, initial codes relating to preparing guideline were identified as 'best practice' (MHI), 'consensus, no robust evidence' (KR), and 'contextualise the national guidelines' (RL). Working together, MHI, RL and KR reinterpreted these codes into 'understand the context'. The categories from both document analysis and FGs were combined and refined according to the HTA objectives of identifying the overall goals, subgoals, subtasks, operations and analysing plans to explain how goals were obtained. HTA development comprised various steps, including defining task under analysis, determining the overall goal, determining task subgoals, breaking down subgoals until an appropriate operation was reached, and analysing plans to explain how goals were reached.[27] The HTA was constructed using the Microsoft Visio Professional 2019 software.

Developing the HTA was an iterative process. The researchers identified and agreed on the task under analysis and the overall goals. Three key subgoals from both the documents and FG transcripts were identified, reflecting important patterns in helping to answer the research question. Descriptions of subgoals were used to explain how goals were achieved. The draft HTA was validated with the wider research team and healthcare practitioners from the study hospital to establish the fit between the participants' views and the researchers' representation of the final HTA.[35]

Patient and public involvement

Patients and the public were not involved in the development of the research question, study design, recruitment and conduct of the study.

RESULTS

The final HTA diagram is presented in Figure 2. The overall HTA goal resulting from our analyses and interpretation of the hospital documents and FG participants' perspectives on how work was imagined in the use of VRIII, was to treat elevated BG in hospitalised patients using VRIII. Three key subgoals were identified: produce hospital-specific VRIII guidelines, implement the guidelines and use the guidelines. Each of these subgoals is presented individually, below. For clarity, representative quotations from participants are reported below; additional quotations can be found in online supplemental files 2 and 3.

Produce hospital-specific VRIII guidelines

A multidisciplinary team, composed of diabetes/acute medicine consultants, pharmacists and adult diabetes inpatient nurse specialists, was responsible for preparing hospital-specific VRIII guidelines. Producing guidelines took place in several iterative stages. 'Preparing a first draft' sub-goal was based on several resources such as the relevant JBDS-IP guidelines,[2] the NaDIA,[5] local incident reports, feedback,

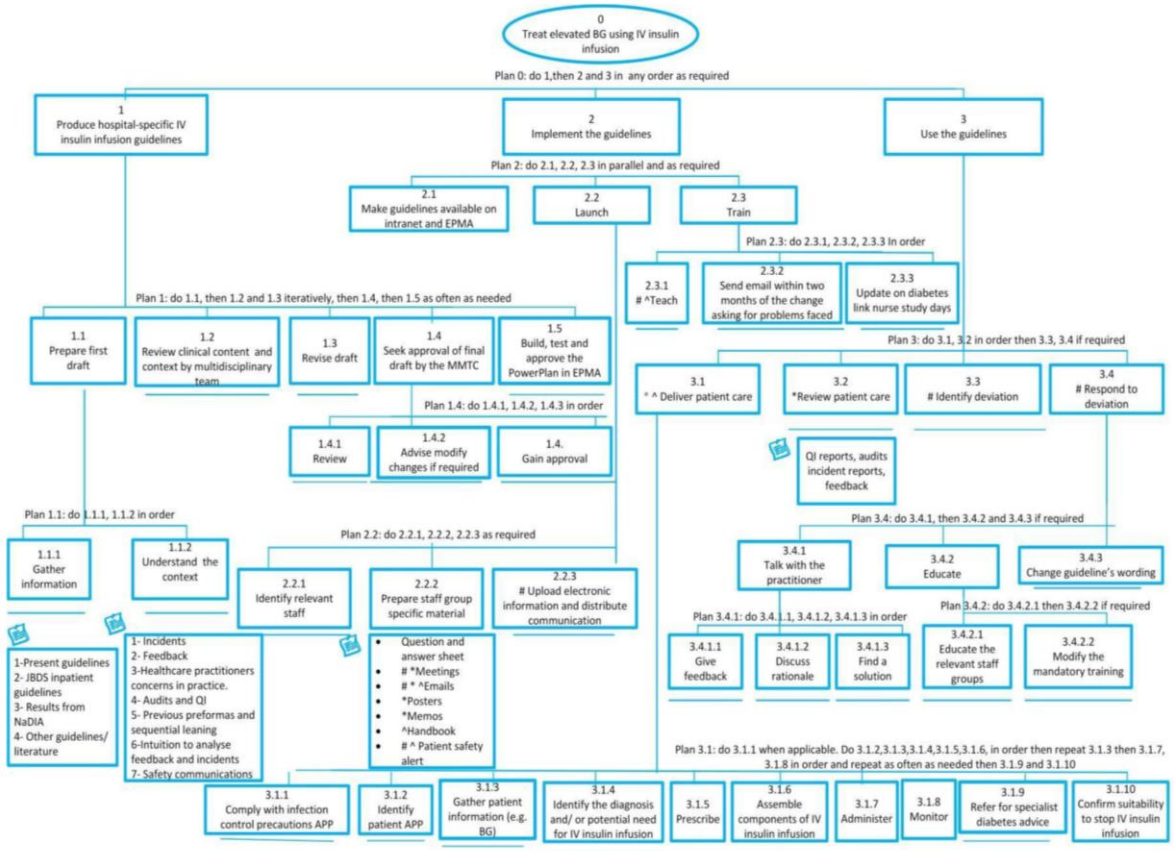

Figure 2 Hierarchical task analysis diagram of the process of treating elevated BG using VRIII. #FG1; *FG2; ^FG3. APP, as per policy; BG, blood glucose; EPMA, Electronic Prescribingand Medicines Administration; IV, intravenous; JBDS, Joint British Diabetes Societies; MMTC, Medicine Management Therapeutics Committee; NaDIA, National Diabetes Inpatient Audit; PowerPlan, Electronic prescribing and laboratory testbundle based on the local hospital guidelines; QI, Quality Improvement.

audits, quality improvement (QI) projects and intuition. FG1 data showed that all participants perceived 'reviewing the clinical content and context by multidisciplinary team' to be vital. Although the JBDS guidelines were used as the standard as they are considered best practice, it was clear that the hospital did not solely rely on these guidelines.

> 'That draft was based on loads of previous proformas and sequential learning and then when we done that we initially sent it round our Think Glucose…. So there is not necessarily a really a robust evidence base or, if you look at the JBDS… some of the ones where we could not just follow the template guidelines verbatim'. FG1

The hospital used different resources (eg, consulting the Think Glucose Group, which is a multidisciplinary group of healthcare professionals at the study hospital concerned with inpatient diabetes, an inpatient specialist nursing team who have extensive hands-on experience, and junior doctors) to adapt the national guidelines to make it relevant to their hospital. The guidelines were 'live' documents and underwent review, revision and then approved by a committee when required, in appropriate situations.

Implement the guidelines

Second, implement the guidelines started from a formal 'launch' of the electronic prescribing and laboratory test care bundle (PowerPlan). This progressed in parallel with widespread communication by 'making the guidelines available on the hospital intranet' and accessible to all practitioners, followed by 'training' relevant staff about the new guidelines. The importance of informing relevant staff was recognised where 'launch' consisted of several subgoals. The subgoal 'prepare staff group-specific material' was described by participants in all three FGs. This involved, for example, the adult diabetes inpatient nurse specialists providing a fact sheet to the link nurses, inviting them to explain the rationale of changes made to other nurses. Matrons also sent memos and emails to ward sisters requesting they inform all staff of the new changes.

> '… so he [link nurse] would go to the ward meeting and say this is happening…., the ward sister, may get a memo from her matron saying please can you get all your staff to revisit this policy? We'd also have ward-based training. So it isn't just one thing, it's different methods of reinforcing a change of practice or a change of policy'. FG2

'Train staff how to use the guidelines' was another major subgoal in the task of implementing guidelines. To accomplish this subgoal:

- The guideline developers ensured that new junior doctors were taught how to prescribe VRIII. As the task of prescribing VRIII is complicated, the junior doctors were asked to use the PowerPlan, which was based on the local hospital guidelines. In addition, the doctors sometimes followed a hyperlink on the PowerPlan to access the full guidelines.
- Healthcare practitioners indicated that doctors were provided with a generic induction handbook not specific to VRIII as part of the training process when they joined the vascular surgery unit.
- Diabetes Link Nurses and ward sisters provided a brief (10 min) ward-based training covering three main points on a topic related to in-hospital diabetes management.
- The consultant body used medical grand round meetings to inform doctors about the latest changes and to discuss the rationale of new guidelines (eg, Hyperosmolar Hyperglycaemic State) and provide further information around them.
- Feedback was sought within 2 months of implementing the new guidelines, to identify any problems that had arisen, with responses being provided in separate communications.
- Update on Diabetes Link Nurse study days: the Diabetes Link Nurses were asked general questions and specifically probed about areas such as how often they managed to complete BG monitoring, where compliance might be difficult and to ascertain whether it was achievable, such as how often they managed to complete BG monitoring.

This way of training was used to gather as much feedback as possible in order to gain awareness of the problems practitioners faced and to devise solutions to them. It was clear from the three FGs that practitioners learnt by observing the practice of senior practitioners. The training and teaching relating to new practices happened through cascading—the 'chain of influence' technique[36] by which staff influenced one another in making decisions and resolving disagreements.

> '…I think we found out that we don't have the time or the staff to sit down for an hour and provide in-depth teaching to someone so [they've] started this what they call espresso teaching'. FG3

Use the guidelines

To accomplish this subgoal, almost all participants stated that staff are expected to follow the guidelines to 'deliver appropriate patient care'. As delivering patient care was perceived to have a direct consequence on patients' BG treatment, deliver patient care was further decomposed to ten sub-goals, using data from analysing the 11 documents related to the use of VRIII. The ten subgoals were 'complying with infection control precautions', 'identify patient', 'gather patient information', 'identify the diagnosis', 'prescribe', 'assemble components of VRIII', 'administer', 'monitor', 'refer for specialist diabetes advice' and 'confirm suitability to stop VRIII'. HTA diagrams for each sub-goal can be found in online supplemental file 4. The documents were clear and comprehensive and contained details about the aim, scope, responsibilities, training and monitoring compliance with precautions relating to specific tasks. There were, however, a lack of clarity in a couple of documents. In 'The Management of Hypoglycaemia in Adult Inpatients Guidelines', for example, when and at what rate to restart VRIII after managing hypoglycaemia was unclear. In 'Guidelines for VRIII in Adults', there was inconsistent guidance for example, it was stated to 'continue VRIII for one hour after the subcutaneous insulin (SC) has been administered to allow time for the insulin to be absorbed', while in the summary page it was recommended to 'stop intravenous insulin at time of first prescribed dose' of SC insulin. One of the guideline developers was contacted and this inconsistency was rectified. Participants in each FG discussed a variety of ways that are used to review patient care, such as QI projects, audits, comments and feedback from practitioners, and local incident reports.

Almost all participants agreed that the number of deviations from prescribed practice in the hospital was low. FG1 participants highlighted various situations in which healthcare practitioners might deviate, such as new doctors coming from a different Trust that have different guidelines, intentional deviations based on specialist advice related to a patient's case, difficulty with hourly monitoring for VRIII (resulting in monitoring being done every 2 hours instead of every hour), and the active choice to discontinue long-acting insulin when using VRIII. Unintentional deviation might occur because of challenges within the Electronic Prescribing and Medicines Administration (ePMA). For example, the FG1 participants highlighted that nurses were unclear about the order that prescribed intravenous fluids should be administered. As the ePMA system is not designed to show the order in which fluids are to be administered, FG1 participants emphasised the importance of a separate flow sheet to remind practitioners of the order in which to administer intravenous fluids. FG1 participants respond to deviations by having conversations and asking questions to identify the reasons behind the deviation, giving feedback, finding a compromise, providing immediate informal education, and finally changing the wording of guidelines if required. If deviations become a pattern, the Diabetes Specialist Team would conduct localised education in the ward and modify the content of mandatory training materials.

> 'So the insulin, you know the safe use of insulin is mandatory. Training has been modified based on incident and patterns that we see, so serious incidence and patterns that we see'. FG1

DISCUSSION

The HTA showed the complexity of using VRIII by highlighting more than 115 steps required to achieve the key goal of treating elevated BG using VRIII. While HTA is typically applied to represent what people do,[29 37] HTA was used in this study to explore the process of treating elevated BG using VRIII. The HTA illustrated how the use of VRIII was expected to be done, and how practitioners use VRIII in a wider system in a hierarchy of goals. The study highlighted three key subgoals.

Produce hospital-specific VRIII guidelines

Producing hospital-specific VRIII guidelines was iterative and inclusive, with different specialities and committees included. Almost all participants described the documents as very practical, clear and user-friendly. The documents contained clear details about the aim, scope, responsibilities, training and monitoring compliance for specific tasks but the documents were written in a technical way that not every novice can understand unless they are very well experienced in hospital work generally and insulin use specifically. The comprehensive documentation could inadvertently result in a negative effect, as the large number of documents related to VRIII could confuse healthcare practitioners. Consistent with previous studies,[38 39] however, the importance of this comprehensiveness should not be underestimated; it serves as a backup and has a positive effect on patient safety by providing practitioners with all the information they need for using VRIII.

Implement the guidelines

The training and teaching around new changes to guidelines happens by cascading the 'chain of influence' technique, in which members influence one another in making decisions and resolving disagreements.[36] This way of training can be expressed as applying tacit knowledge, including skills, experiences, intuition and judgement, that is difficult to transfer to another person by means of writing it down or verbalising it.[40] While there was agreement that the hospital environment was very supportive in terms of training and education, there was a mix of proactive and reactive approaches to training new staff. If new staff did not know how to use VRIII, senior staff would train them. Senior staff would inform front-line practitioners about new changes or the training they needed with front-line practitioners often taking on a passive role. The current study showed that specific teaching sessions for junior doctors on using PowerPlan to prescribe VRIII were an essential part of the guidelines' implementation process to ensure patient safety while using VRIII. Lack of knowledge is one of the key barriers in delivering appropriate diabetes care.[41 42] An interventional controlled multicentre study was conducted to assess the impact of a strategy focused on educating healthcare practitioners. The strategy's impact on the quality of care was limited and there was no significant difference between controlled and interventional hospitals' education strategies for changing practitioners' behaviour.[43] Similarly, a systematic review conducted by Bain *et al* concerning educational interventions to improve prescribing performance, concluded that education was an important part of QI strategies in insulin prescribing; however, it was less effective when used in isolation.[44] It can thus be suggested that further work is needed that directly evaluate the effectiveness of the educational strategies used in the study hospital by exploring how challenging it is to achieve and sustain behaviour change.

Use the guidelines

The majority of the FG participants highlighted the importance of following the guidelines in order to deliver appropriate patient care while using VRIII. This finding is consistent with that of Sampson and Jones who concluded that the growing use of the JBPD-IP guidelines since 2011, has resulted in harm reduction related to the number of hypoglycaemic events and the unnecessary use of insulin infusions.[15] Many studies described various challenges with the use of VRIII such as the risk of hypoglycaemia, frequency of monitoring, insufficient nurse-to-patient ratio and confusion about the target BG level.[9 10 45] In contrast to previous studies, participants only mentioned two main challenges: sequence of administering intravenous fluids, and frequency of BG monitoring. On the one hand, the findings might not represent all the challenges healthcare practitioners face at hospital; on the other, the results are not necessarily transferable to all the vascular surgery unit healthcare practitioners and the whole Trust.

The general conclusion of earlier evaluations of ePMA systems in hospitals has been that they can improve quality, not least by reducing medication prescribing and administration errors.[46–48] However, one recent study found that although pharmacists valued a number of safety features associated with ePMA, they also perceived an overall increase in medication risk.[49] In a retrospective audit of VRIII comparing ePMA with bespoke paper proforma, there was improved completion of tasks where prompts were inbuilt but in other areas, completion rates were inconsistent.[50] This study found that nurses do not usually refer to the guidelines and doctors use the PowerPlan feature within the ePMA when prescribing. The fact that doctors usually rely on the ePMA might have mixed consequences. On one hand, it might save time in prescribing, as doctors are busy. On the other, if the ePMA system is not working for example, freezes, safety challenges might rise such as delaying patients receiving their medications and affecting the efficiency of ward rounds.

Prescribing intravenous fluids is a complex and an ever changing situation in which indication, fluid type, volume and rate depend on the pathophysiological changes that affect fluid balance in disease states.[51 52] In this study, prescribing intravenous fluids on the ePMA found another layer of complexity which was the lack of clarity about the order in which prescribed intravenous fluids should be administered. This result is in line with one study which found that some medications, such as insulin and intravenous fluids, were not safely prescribed using the system

because their protocols did not fit easily into the structures embedded in the software.[53]

The availability of a fully staffed diabetes inpatient team is recommended to enhance patient safety and reduce insulin prescribing errors.[54] It has been suggested that the introduction of specialist diabetes pharmacists can support the implementation of insulin-prescribing interventions and decrease the percentage of insulin prescribing errors.[55] In this study, although the role of specialist diabetes nurses was reported in all the activities required to treat elevated BG using VRIII, nothing was mentioned about the role of specialist diabetes pharmacists in treating elevated BG using VRIII.

Adaptations to work was part of everyday work. Although the general thinking between participants was about errors and how to avoid them (Safety I), guideline developers explicitly acknowledged the occurrence of intentional deviation from guidelines, as patients' treatment should be individualised based on their situation. Nurses usually anticipate the needs of patients prior to surgery and sometimes proactively ask for a VRIII prescription, but doctors do not always provide such prescriptions as doing so may not be appropriate for the patient. There seems to be a need for careful thinking about flexibility and trade-offs in practice, and to set and define patient safety boundaries. These results reflect those of Vos *et al*, which showed that some behaviours that might be considered deviations from best practice when administering intravenous infusions resulted from reasoned clinical judgement by nurses with the aim of improving patient care.[56]

The HTA provided a better understanding from multiple perspectives of the use of VRIII, and of organisational influences such as how policies and guidelines were written, what was permitted, and how mandatory training was expected to be conducted. These results are broadly consistent with those of Raduma-Tomàs *et al*, who found that the application of the HTA provided a detailed description of the doctors' handover process, enabled the identification of strengths and weaknesses in the performance of handover activities, and allowed for specific problems to be targeted for improvement.[57] HTA has been used in health information technology by modifying existing designs or creating new ones.[58 59] Roosan *et al* used HTA and interactive infographics to develop a mobile prototype designed to deliver the patient package-insert information for the medication risperidone in an interactive way that helped patients gain an improved overall knowledge of the medication.[58] Another study used HTA to assess the effect of implementing new health information technology on the workflow of the medication administration process.[60] Its analysis of the HTA diagrams resulted in providing 15 recommendations for healthcare facilities to facilitate the transition to the new health information technology system.[60] The developed HTA could serve as an effective form of system documentation, enable guidelines developers to redesign guidelines and protocols based on the developed HTA, and help software engineers to gain familiarity with the tasks required while using VRIII in a systematic way which may enhance the design and usability of electronic systems as well as their ability to support individual/organisational contexts of use.

Clinical implications

WAI surrounding the use of VRIIIs was mainly related to the production, implementation and use of VRIII guidelines used in the study hospital. As the guidelines were implemented and used as part of the ePMA system, system designers in the study site may be able to use the developed HTAs to understand which trigger point of clinical care they can use to change and improve patient safety. For example, the study found that the ePMA system was not designed to show nurses the order in which fluids need to be administered—which makes it difficult for nurses to make the appropriate decisions. System designers might reduce the confusion by redesigning the ePMA system in a way that would enable doctors to prescribe intravenous fluids in a certain order and nurses to receive intravenous fluids prescriptions as graphs plotted from a timeline perspective.[61] Data visualisation can reduce cognitive load and the amount of information needed to be searched before making decisions.[62 63] A recent study found that developing a web-based timeline software, that graphically displays administered medication (y-axis) against time (x-axis), improved healthcare practitioners' interactions with the medical record system.[63] The graphical timeline software allowed healthcare practitioners to click on a medication name to display specific dosing and timing which resulted in reducing the time spent on medication review and easing the viewing of medication administration.[63] In the study site, developing an intravenous fluids graphical timeline software that shows the order of administering the prescribed intravenous fluids may reduce the confusion in administering intravenous fluids and improve confidence in deciding the order of intravenous fluids administration without delay.

Another example of a trigger point of care that might be improved is the task of frequent BG monitoring, especially given the growing challenges facing the NHS, for example, the shortage of healthcare practitioners and the current pressure forced on healthcare practitioners by the Coronavirus (COVID-19) pandemic,[64 65] which makes it difficult for this task to be conducted hourly. Evidence suggests that in-hospital use of continuous glucose monitoring (CGM) provides a practical alternative to frequent inpatient fingerstick testing. CGM works by inserting a sensor subcutaneously to measure the glucose level in the interstitial fluid, and results are provided every 5–10 min, 24 hours a day.[64] CGM incorporates predictive alerts for hypoglycaemia or hyperglycaemia which can be directly integrated into the electronic health record to alert the healthcare practitioners before the glucose sensor reaches the low or high threshold.[66] Considering the implementation of this technology may decrease the burden of glucose monitoring for healthcare practitioners and decrease the risk of hypo/hyperglycaemia events.

Strengths and limitations

The application of HTA revealed the importance of in-depth understanding of how WAI and how guidelines are used to treat elevated BG using VRIII. Methodologically, this is the first study to explore WAI in relation to the use of VRIII using the HTA. Future research can build on insights from the study findings, and indicate how and where within the BG treatment process safety challenges might occur, thus allowing for specific challenges to be targeted and extraordinary work/adaptations to be highlighted to improve patient safety when using VRIII. Limitations associated with this study include the subjectivity of the healthcare professionals who participated in the FGs. The low number of staff who participated, especially in FGs 2 and 3, means that this analysis may not represent the perspectives of all the staff who use VRIII. Other participants might have given different views on the process of using VRIII. However, by purposive sampling of a diverse range of practitioners, this risk may have been somewhat mitigated. The purpose of qualitative studies is not to replicate or generalise the findings, however, qualitative studies are concerned with credibility and transferability.[67] Although the results from qualitative studies of small sample size may not always statistically represent the whole population of interest; they are qualitatively transferable. In this study, credibility and transferability were ensured by using a member check technique to confirm the accuracy of the developed HTAs, data triangulation using two data sources (documents and FGs) and thorough, detailed description of the contexts relating to the use of VRIIIs and the participants' accounts. Finally, it is necessary to acknowledge that guidelines discussed in this study were implemented a number of years ago and participants were not given a topic guide prior to the discussions hence there could be recall bias. In hindsight, it would be better to provide participants with key discussion topics, so they have time to consider past events before the FG meetings.

CONCLUSION

This study set out to understand from various perspectives how VRIII were expected to be used to treat elevated BG in the clinical environment. Using the HTA methodology, a detailed and systematic description of the tasks needed to use VRIII was successfully developed. The novel exploration of WAI within this context has important implications, revealing that the tasks required to treat elevated BG using VRIII are far more complex than merely implementing and adhering to national guidelines. Specifically, the complexity was found in various tasks/subtasks including understanding the context, prescribing intravenous fluids using ePMA and BG monitoring frequency. These complexities have been shown herein to play a key role and have possible broader implications in different healthcare context with similar challenges. Various strategies were expected to be used to enhance safety while using VRIII, among them training and intentional deviations/adaptations. However, further work is required to extend the scope for understanding how VRIII is used by assessing the impact and efficacy of the reported strategies on the actual process of using VRIII. The study results provided a deep understanding of the reality of WAI. The next stage is to conduct video observations[20] in order to understand how guidelines are used in practice, situations where the guidelines could not be delivered as written, type of challenges and context-dependent adaptations and to explore the gap/misalignments between WAI and WAD in order to find strategies to minimise the gap to improve patient care delivery.

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Supplementary information

A detailed analysis of 'Work as Imagined' in the use of intravenous insulin infusions in a hospital: A Hierarchical Task Analysis

Supplementary File 1: Focus group topic guide

See Appendix 1, Chapter 3 page 76

Supplementary File 2: Categories, codes and illustrative quotes for focus groups

Categories	Codes and examples of focus groups' quotes
Preparing the 1st draft	**Using different resources to collect data** *"We took what we had before, we looked at the Joint British Diabetes Society's template guidelines and learning from incidence and from feedback and from nurses about concerns in practice and the other audit and quality improvement work we'd done and we sort of stuck it all together and came up with a draft. That draft was based on loads of previous proformas and sequential learning and then when we done that we initially sent it round our Think Glucose which is our operational group". (FG) 1* **Contextualising the national guidelines** *"So there isn't necessarily a really a robust evidence base or, if you look at the JBDS there is a guideline for surgical patients and a guidelines for medical patients, so took that to the group particularly for the consultants to help with some of those decisions about ... some of ones where we couldn't just follow the template guidelines verbatim". (FG) 1* **Rationale for using The Joint British Diabetes Societies (JBDS) guidelines** *"The key thing about the JBDS guidelines is there has been a general attempt to standardise things in terms of best practice nationally because there was quite a bit of variability in practice across the country". (FG) 1*

Reviewing the clinical content and context	**Multidisciplinary team** *"Then we thought we got a reasonable draft we shared it with a wider inpatient adult specialist nursing team". (FG) 1* *"..these were all designed by and using junior medical staff. So specifically, to try and use design and sort of a flow sheet as a quick reminder for them to follow. And so in a way they gave us sort of fresh eyes on how they reviewed or interpreted it". (FG) 1* **Iterative process** *"And we can see sort of see from the staff if they feel they are user-friendly. if they have many issues in reading and using them because we are obviously around the wards all the time". (FG) 1* *"And I was going to say, you get honest feedback because people give you real time feedback of what it is like to use now. That is, you are seeing, getting day in day out". (FG) 1*
Approving the final guidelines	**Identifying inconsistencies** *"So it [the Medicines Management Therapeutics Committee] is a generalists' review and so if there are things that are unclear or inconsistent, I think we picked up most of the inconsistencies but things that feel clear to us because we know what the language means, its the language we use every day and potentially shorthand language then gets reviewed and get sent back". (FG) 1* **Seeking approval** *"..it went to our Medicines Management Therapeutics Committee which is the committee that has to approve any of these types of documents". (FG) 1*

Making guidelines available for staff	**Availability of the guidelines** *"The MIL has the information and everything that is in the MIL essentially has been digitalised so you don't have to think too much about it, so you just tick the boxes". (FG) 2* *"There's the, it's the MIL, it's called the MIL that's on the intranet that's accessible". (FG) 3* **Implementation strategy** *"If you mean is there a Trust process for MIL implementation, the answer is not really. Once they are approved they can tend to get stuck on the intranet but we didn't do that with this one". (FG) 1* **Big process** *"Because variable rate is something that is used so much in this acute hospital, when it came to implementing the new changes and we had to take on change management really because nurses are very good at making changes if they see the advantages. They are really good. If they see it is going to affect their patient, I bet they are very good". (FG) 1*

Informing changes	**Ways to inform new changes** *".. so he would go to the ward meeting and say this is happening..., the ward sister, may get a memo from her matron saying please can you get all your staff to revisit this policy? We'd also have ward-based training. So it isn't just one thing it's different methods of reinforcing a change of practice or a change of policy". (FG) 2* **Interdisciplinary, proactive approach** *"I would have share them with all of the pharmacist going out to the clinical areas. We did also for some of them do an alert on the intranet. We have a safety alert". (FG) 1* *"...so we catch the new junior doctors as they come in and make them aware that these exist, we don't have enough time so this is even before they have started". (FG) 1* **Distance between TRUST and the frontline** *"The Trust have objectives. Yeah, and I'm sure…We don't get told. They have a timeline but I don't know exactly what it is". (FG) 2*
Training staff	**Strategies to teach new changes** *"So staff are encouraged to do eLearning, so we all have to do an insulin and diabetes management type eLearning and that's a mandatory requirement of a qualified nurse". FG 2* *"There's an induction booklet that tells you in terms of when patients are going to theatre if they're diabetic this is how you do it, this is what you do, that is in the vascular handbook for [juniors] when we joined". (FG) 3* **Tacit knowledge** *"That thinking was developed here and so it was already in the kind of culture, the organisational consciousness actually". (FG) 1* **Modifying training to meet the needs** *"They been having diabetes training once every a couple of months and variable rate is part of that*

	but we discussed that we don't think that has the impact that we would wish, so for 2019 we are talking about doing one subject a week, a month that the link nurses have little target teaching, make more express huddles so variable rate probably would be the very top of the list so the link nurse would be given that topic and told they need to train each member staff in the ward over that month, 5 minutes". (FG) 1

How participants perceive and use the guidelines	**Description of the guidelines** *"I like the MIL, I think it's quite clear, I like them...". (FG) 3* *"..it's [protocols] overruled by consultants, by doctors". (FG) 2* **Flexibility and adaptations** *".. we would have put it up thinking that patient's going to be nil-by-mouth whereas now it's like you can go two meals without it before we put it up. So we're sort of waiting those six/eight hours, to the afternoon, before we're putting them up sometimes". (FG) 3* **Resilient practices** *"You're like, okay, my patient's going to theatre tomorrow, he'll need a sliding scale and you mention it to the doctor the day before so it's like I'm mentioning it but I'm not planning on putting it up right now but I know he's going to need it come the morning so you're trying to get that prescription there already so that then the night staff in the morning can just set it up". (FG) 3* **Safety-I thinking** *".. so there's lots of support structures in place to make sure that we adhere to policy. So on the ward it's very… this ward is very, very… I would say that we're very familiar with diabetes management because we're vascular so I would say that our practices we really do try to adhere to the policies because we understand the importance of doing hourly blood sugars, for example if somebody's on sliding scale, we understand about prompt management of hypoglycaemia, prompt action of hypoglycaemia". (FG) 2* **Challenges** *"I need to monitor it every hour…But I still have other patients". (FG) 3* *"The nurses really struggle with the flow of the fluids I mean which bag to give next. It is actually within the electronic prescribing system that we are working". (FG) 1*

Monitoring practice	**Personnel** *"Like if it's a change in the way it's prescribed then it would be the pharmacist who polices that [monitoring]". (FG) 2* **Incident reporting system** *"The Trust monitors everything, so if there's incidents we Datix them". (FG) 2* **Feedback** *"We have got different rafts of them that have tended to go on sequentially feeding back from different things and also really from the incidence and the comments and the, you know, the feedback from the people live in the area. These are the brains, there are the knowledge and there are the feel of, they are the link of what's happening in reality and what isn't and the disconnect and so what you are particularly after is either something that's gone markedly out of how one would expect or the things they are seen all the time". (FG) 1*
Responding to deviation	**Acknowledging intentional deviation** *"The one case we would specifically expect them to appropriately deviate would be if they would have tailored specialist advice, so because this is guidelines we acknowledge this may not fit every patient all of the time". (FG) 1* **Situations when staff might deviate** *"Some of the old guidelines are quite different on variable rate and sometimes you will get doctors come from a different Trust that might be using slightly different ones. So sometimes they prefer to use those to these". (FG) 1* **Dealing with deviations** *"So it is having that conversation and giving that feedback, and I think negotiating a compromise with them which maybe about doing something you know in terms of reducing basal insulin". (FG) 1* *"And if it [deviation] becomes a pattern, then we look at 2 things. One is localised education on the ward and the other thing that we have done is modify the mandatory training, so the insulin, you know*

	the safe use of insulin is mandatory training has been modified based on incident and patterns that we see so serious incidence and patterns that we see". (FG) 1

Supplementary File 3: Categories, codes and illustrative quotes for document analysis

Categories	Codes and quotes
Infection control precautions	**Bare below the elbow** *"The 'Bare below the elbows' initiative was introduced as part of the government's Clean Safe Care Strategy to reduce infection risks by improving the ability to clean the hands effectively in order to perform effective hand decontamination". 6* **Hand hygiene** *"In most routine clinical situations decontaminating hands with an alcohol based hand rub or soap and water is sufficient". 6* **Dress code** *"All wrist and hand jewellery should be removed at the beginning of each clinical shift before regular hand decontamination begins. Only one plain wedding band ring may be worn on the finger when in clinical areas. No other rings or rings with stones or ridges may be worn as they harbour micro-organisms and will impede adequate hand hygiene". 6*
Patient identification process	**Wrist band** *"The use of printed, barcoded wristbands forms an essential part of the integrated process for PPID in relation to the safe collection of specimens, the safe administration of medications and the safe administration of blood products". 9* **Positive patient identification** *"It is the responsibility of every health care professional to check the patient's identity before carrying out any procedure or treatment, using positive patient identification". 9*

	Ensuring the identification *"Should a member of staff identify a patient without a wristband or with discrepancies they must take responsibility for ensuring the correct identification of the patient using the above safe checking procedure and attachment of a wristband without delay and before any procedures are carried out". 9*
Indications for VRIII	**Ward- based medical inpatients** *"Capillary Blood Glucose (CBG) above 12 mmol/L plus:* • *Severe illness or sepsis* • *Recurrent vomiting* • *Nil by mouth (missing two or more meals) plus:* ✓ *Insulin treated & awaiting procedure* ✓ *Prolonged starvation". 1* **Ward-based surgical inpatients** *"Nil by mouth (missing two or more meals) plus:* • *Insulin treated & awaiting surgery* • *CBG above 12 mmol/L for 2 hours* • *HbA1c greater than 69 mmol/mo (8.5%) and surgery cannot be delayed* • *Acute severe pancreatitis and CBG persistently above 12 mmol/L". 1&4* **DKA** *"In patients presenting with ketosis (ketone (β-OHB) levels above 3mmol/L), but without significant acidosis, treatment with variable rate intravenous insulin infusion (Variable-RIII) can prevent the onset of acidosis". 2* **HSS** *"Post-acute phase... if the patient is not eating and drinking by 24 hours start a variable rate insulin infusion (see Variable Rate Intravenous Insulin Infusion MIL)". 3*

Prescribing VRIII	**Electronic Prescribing and Medicines Administration (ePMA)** *"The 'Insulin-Adult Variable Rate Infusion PowerPlan' should be used to prescribe intravenous insulin infusions in adults". 1* **Concomitant medications** *"Continue long-acting subcutaneous insulin. Suspend all other subcutaneous insulin and other diabetes medication". 1* **Dose and rate** *"Prescribe continuous intravenous insulin infusion according to patient's normal total daily insulin usage". 1* **Avoiding hypoglycaemia** *"Rescue glucose infusion (75 mL of 20% intravenous glucose PRN for hypoglycaemia)". 1* **Fluids and electrolytes** *"The preferred fluid for administration alongside variable-RIII is 4% glucose & 0.18% sodium chloride with potassium 20 mmol per litre (0.15%) to run at 100 mL/hr, rate adjusted according to clinical requirements". 1* **Checking intravenous access** *"Ensure the patient has dedicated IV access for variable-RIII". 1&11* **Checking initial infusion rate** *"Two registered professionals must set up and check initial insulin infusion rate and for each rate change. This is recorded by both signing the prescription for administration". 1*
Assembling and setting up VRIII	**Syringe pump type** *"Administer insulin and glucose containing infusion via a single cannula via a Y-connector with dual anti-reflux valves (NHS code FKA322) and a syringe pump extension set with integral anti-syphon valve (NHS code FKA040) to connect to the insulin". 1*

	Aseptic Non Touch Technique (ANTT) *"Administration sets must be changed using an Aseptic Non Touch Technique (ANTT) and observing standards precautions and following manufacturers' recommendations". 11* **Visual Infusion Phlebitis score** *"Assess and document the Visual Infusion Phlebitis (VIP) score every shift and prior to and following administration of any intravenous medicine on EPR". 11* **When to change administration set** *"Administration sets must be changed if they are disconnected from the intravascular device and a new infusion commenced". 11*
Administering VRIII	**Independent check** *"If the two professional have differing results then they should each review their process to see if they can detect any error. If there is any uncertainty of a discrepancy remains then this should immediately be escalated to the nurse in charge and/or prescriber". 11* **ANTT** *"Again, a non touch technique here is an essential safety net. It must not be relaxed even if the user is wearing sterile gloves. (Because once open to air and worn they are no longer sterile.)". 7* **Precautions** *"Do not dilute or reconstitute injectable medicines with a pre-filled 0.9% sodium chloride syringe as it is not licenced for this use". 11* **Cleaning** *"It is essential that the post procedure hand clean is performed immediately after glove removal because the hands will have sweated deep and low lying organisms to the surface of the skin". 7*

Adjustment and monitoring	**Injection site** *"Ask the patient to inform a nursing member of staff promptly any soreness at the injection site or discomfort of any kind". 11* **CBG target** *"Where tight glycaemic control is appropriate, target capillary blood glucose (CBG) is 6-10 mmol/L, but readings in the range 4-12 mmol/L are acceptable". 1* **Titration** *"Titrate insulin infusion according to CBG". 1* **Checking ketones** *"If CBG over 12 mmol/L, then check capillary ketones". 1* **Urea and electrolyte** *"Essential measures for the safe maintenance of a variable-RIII:... Daily urea and electrolytes (more frequent if unstable)". 1* **Anaphylaxis reaction** *"Observe the patient for signs of adverse reaction including anaphylaxis and/or circulatory overload". 11* **Frequency of monitoring** *"Measure and record CBG hourly (day and night); adjust infusion rates accordingly. This is vital to ensure the prompt treatment of hypoglycaemia". 1*
Ending VRIII	**Assessment of suitability** *"The switch from IV to SC meal-time insulin should be delayed until the patient is able to eat and drink normally, without nausea or vomiting". 1* **Timing** *"This should happen preferably at breakfast, but no later than 5pm". 1*

	CBG monitoring after ending VRIII *"After discontinuation of variable-RIII monitor CBG 2 hourly for first 6 hours, then every 4-6 hours for the first 24 hours". 1* **Transition to subcutaneous insulin** *"Restart subcutaneous meal-time insulin at previously established dose(s). Doses may need to be adjusted according to clinical condition and/or calorific intake". 1* **Restarting oral medications** *"Other diabetes medication should be restarted, if still appropriate, when patient is eating and drinking normally". 1* **Hypoglycaemia** *"If CBG less than 4 mmol/L (hypoglycaemia): Stop infusion and treat for low blood glucose according to the hypoglycaemia MIl. Recheck CBG 15 minutes later". 5*

1 Guidelines for Variable Rate Intravenous Insulin Infusions in Adults. 2 Guidelines for Management of Diabetic Ketoacidosis (DKA) in Adults. 3 Guidelines for Management of Hyperosmolar Hyperglycaemic State (HHS) in Adults. 4 Managing Diabetes in Adult Inpatients Before, During and After Operations and Procedures. 5 The Management of Hypoglycaemia in Adult Inpatients. 6 Hand Hygiene Policy. 7 Aseptic Non-Touch Technique (peripheral and central access intravenous therapy). 8 Recording Line Insertion and Visual Infusion Phlebitis (VIP) Score. 9 Patient Identification Policy. 10 Visual Infusion Phlebitis Score. 11 Procedure for Preparing and Administering Injectable Medicines.

Supplementary File 4: Hierarchical task analysis diagrams for deliver patient care sub-goals

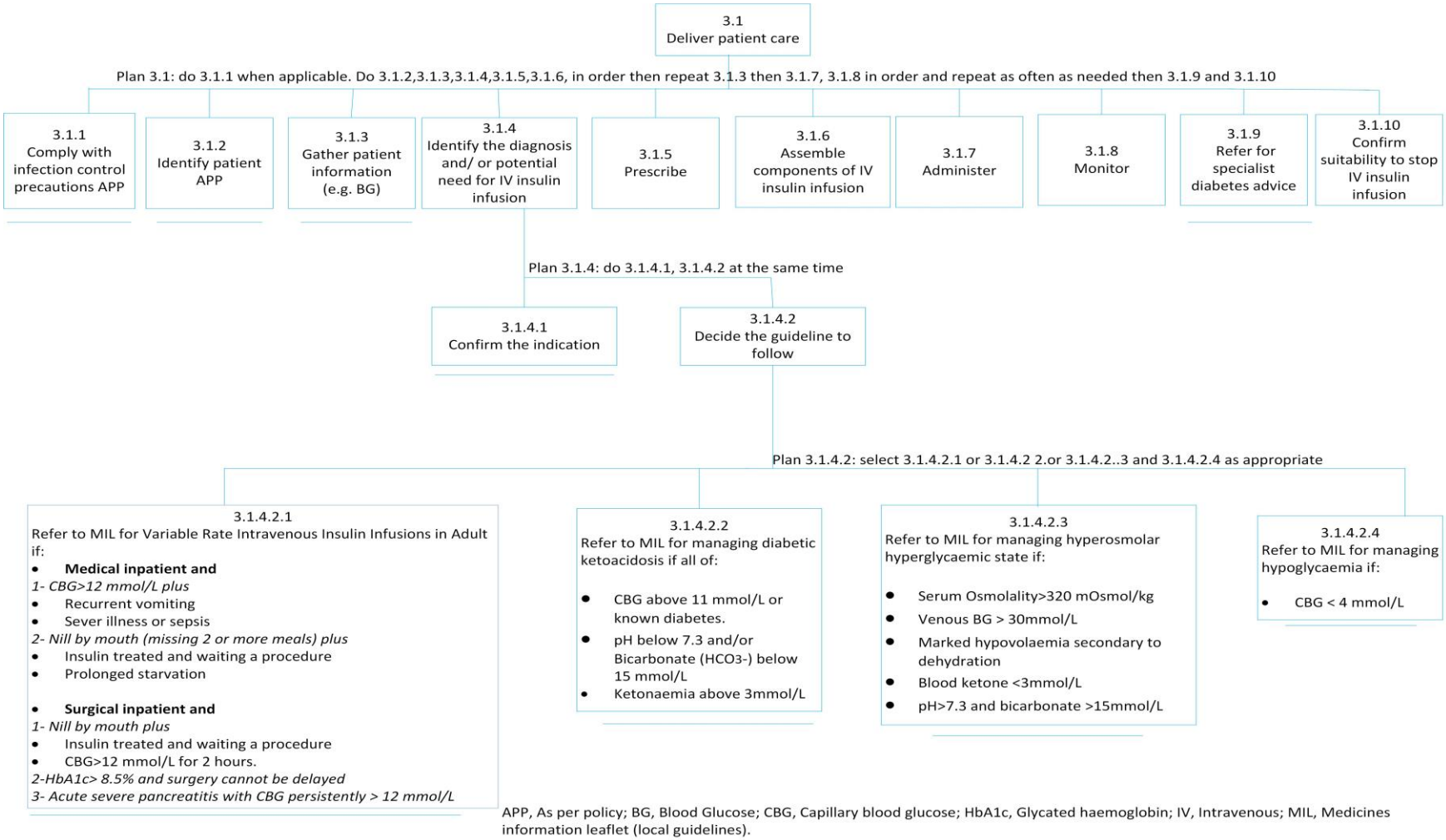
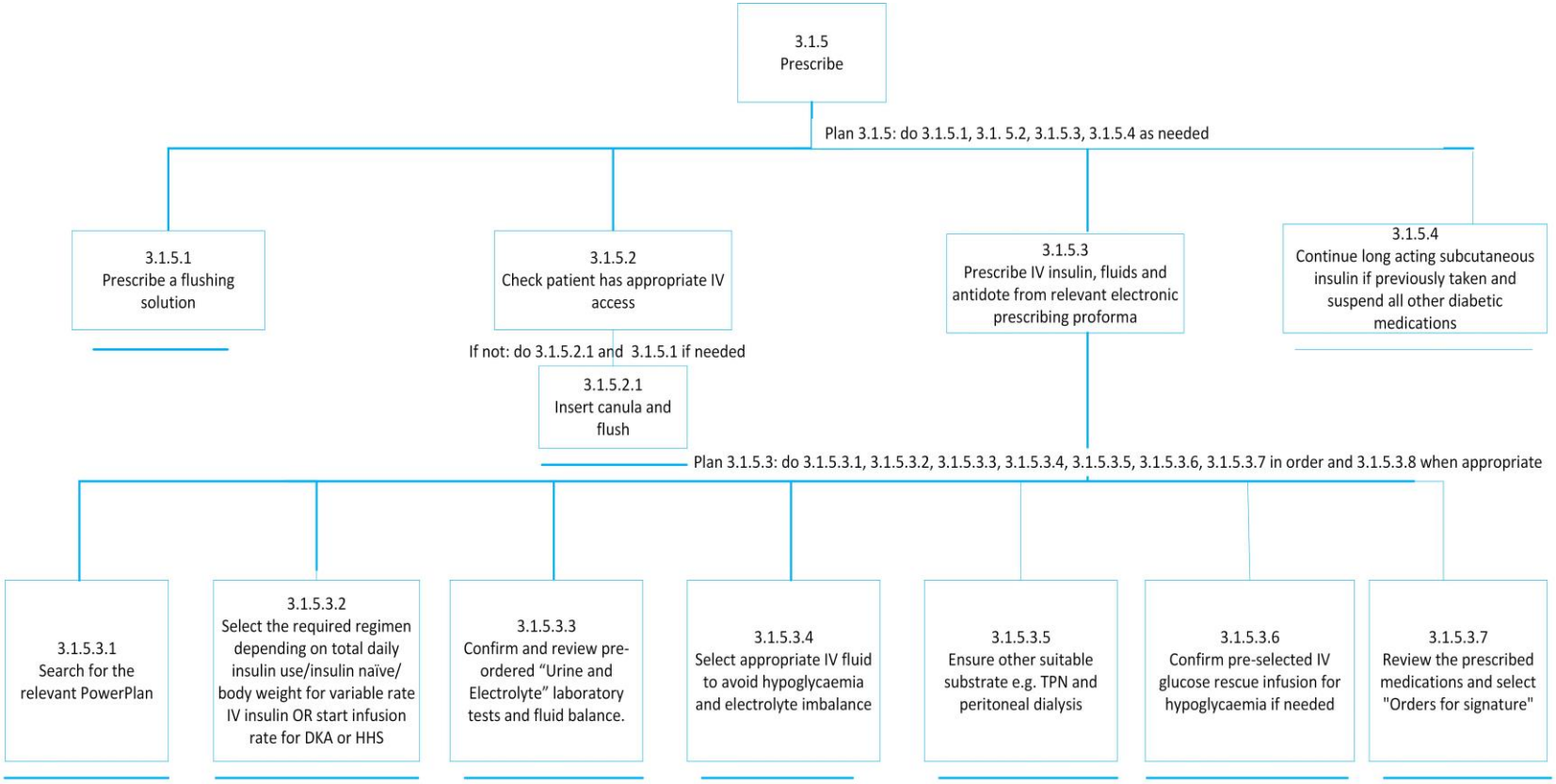
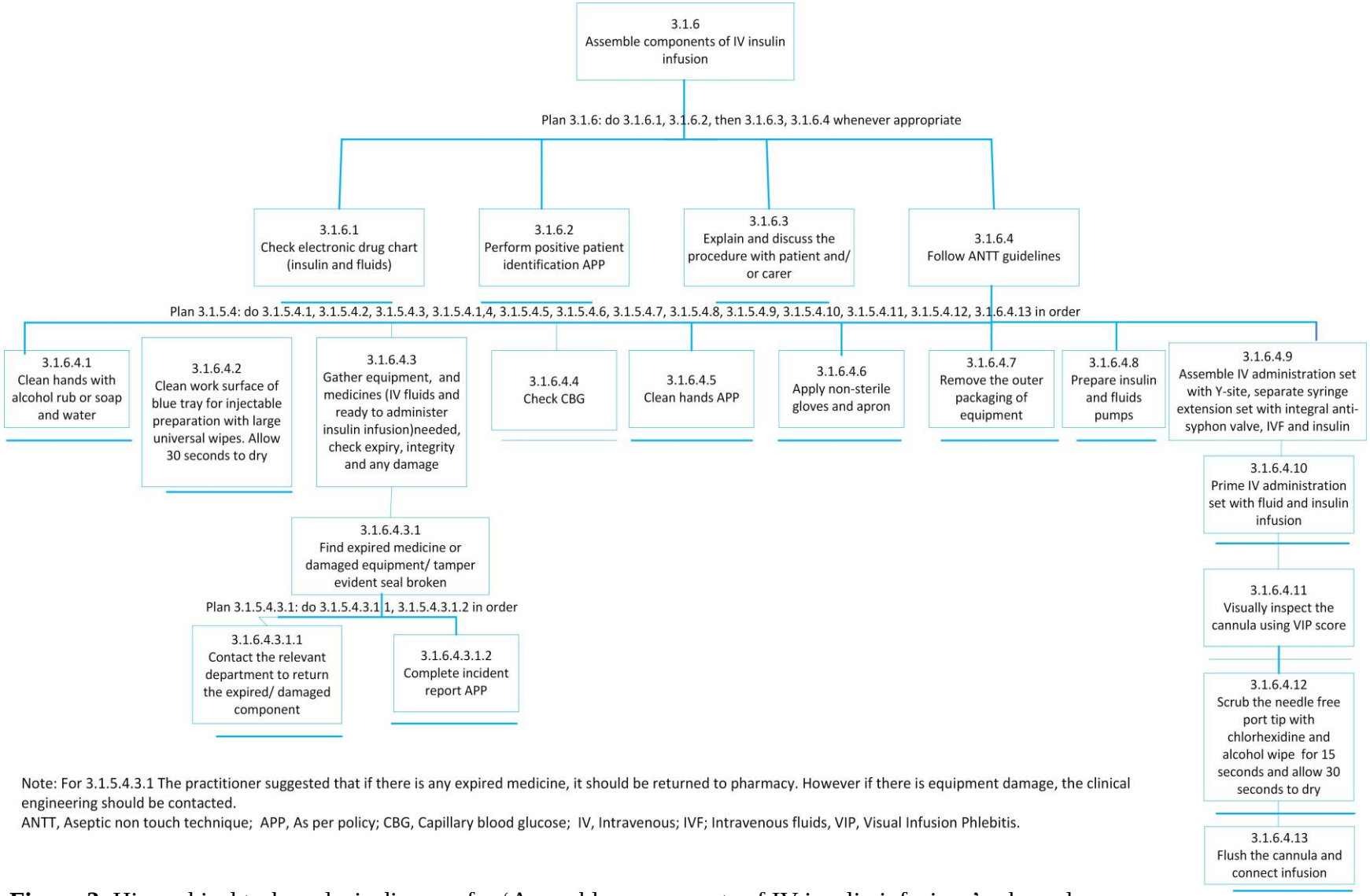


Figure 1: Hierarchical task analysis diagram for 'Deliver patient care' sub-goal.



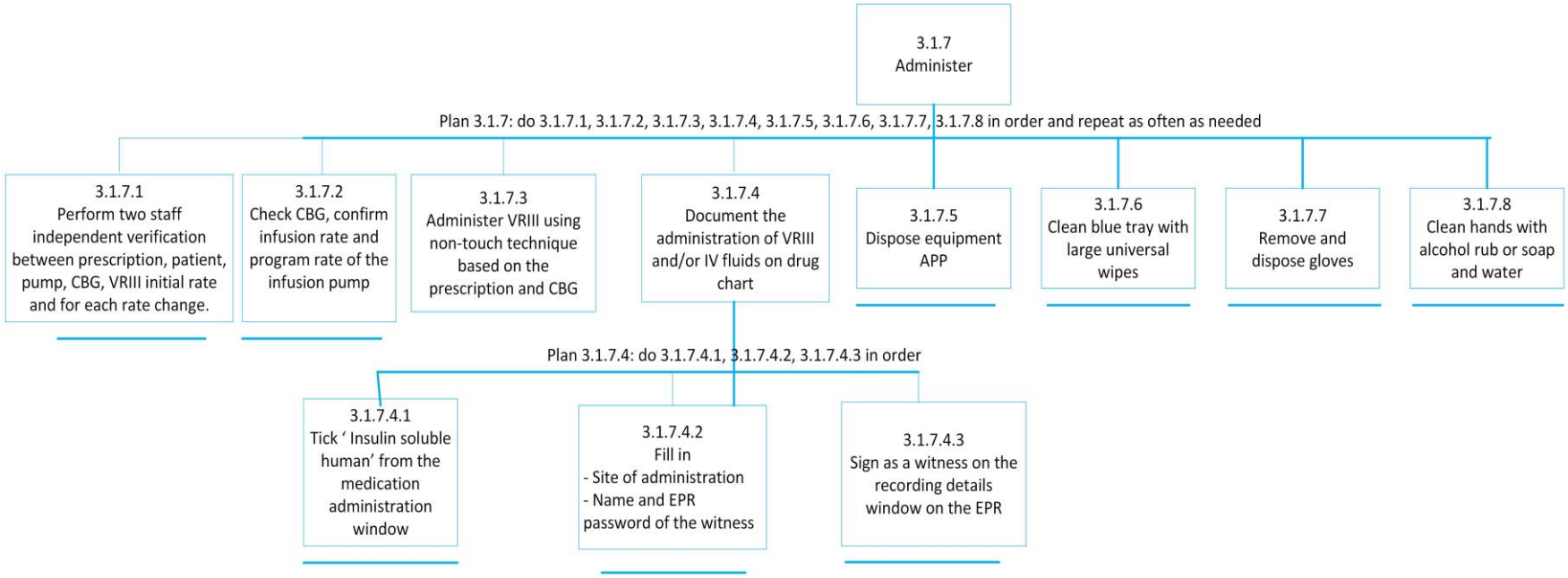
Note: 3.1.5.2.1 is suggested by a practitioner
DKA, Diabetic Ketoacidosis; HHS, Hyperosmolar hyperglycaemic state; IV, Intravenous; PowerPlan, Electronic prescribing and laboratory test care bundle based on the local hospital guidelines; TPN, Total parenteral nutrition.

Figure 2: Hierarchical task analysis diagram for **'**Prescribe' sub-goal.



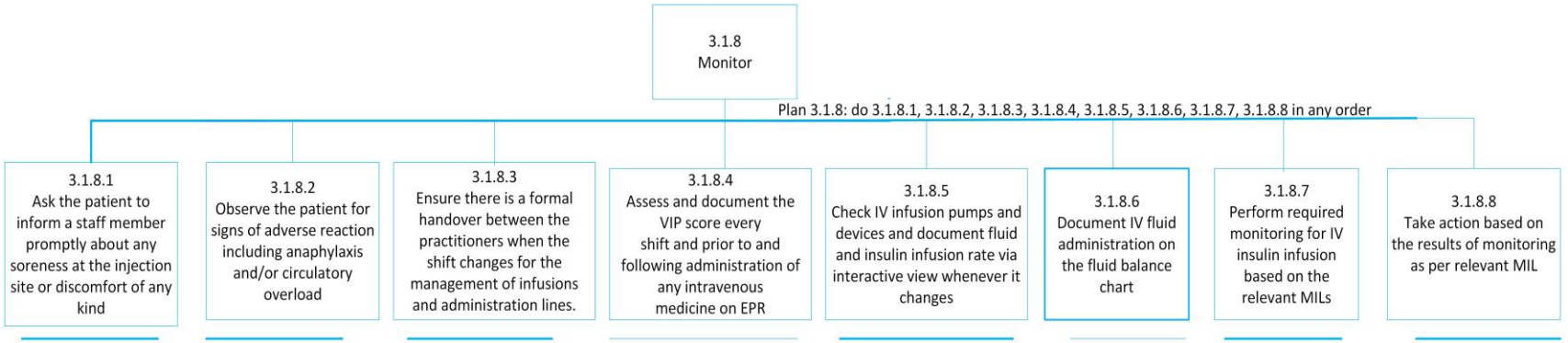
Note: For 3.1.5.4.3.1 The practitioner suggested that if there is any expired medicine, it should be returned to pharmacy. However if there is equipment damage, the clinical engineering should be contacted.
ANTT, Aseptic non touch technique; APP, As per policy; CBG, Capillary blood glucose; IV, Intravenous; IVF; Intravenous fluids, VIP, Visual Infusion Phlebitis.

Figure 3: Hierarchical task analysis diagram for 'Assemble components of IV insulin infusions' sub-goal.



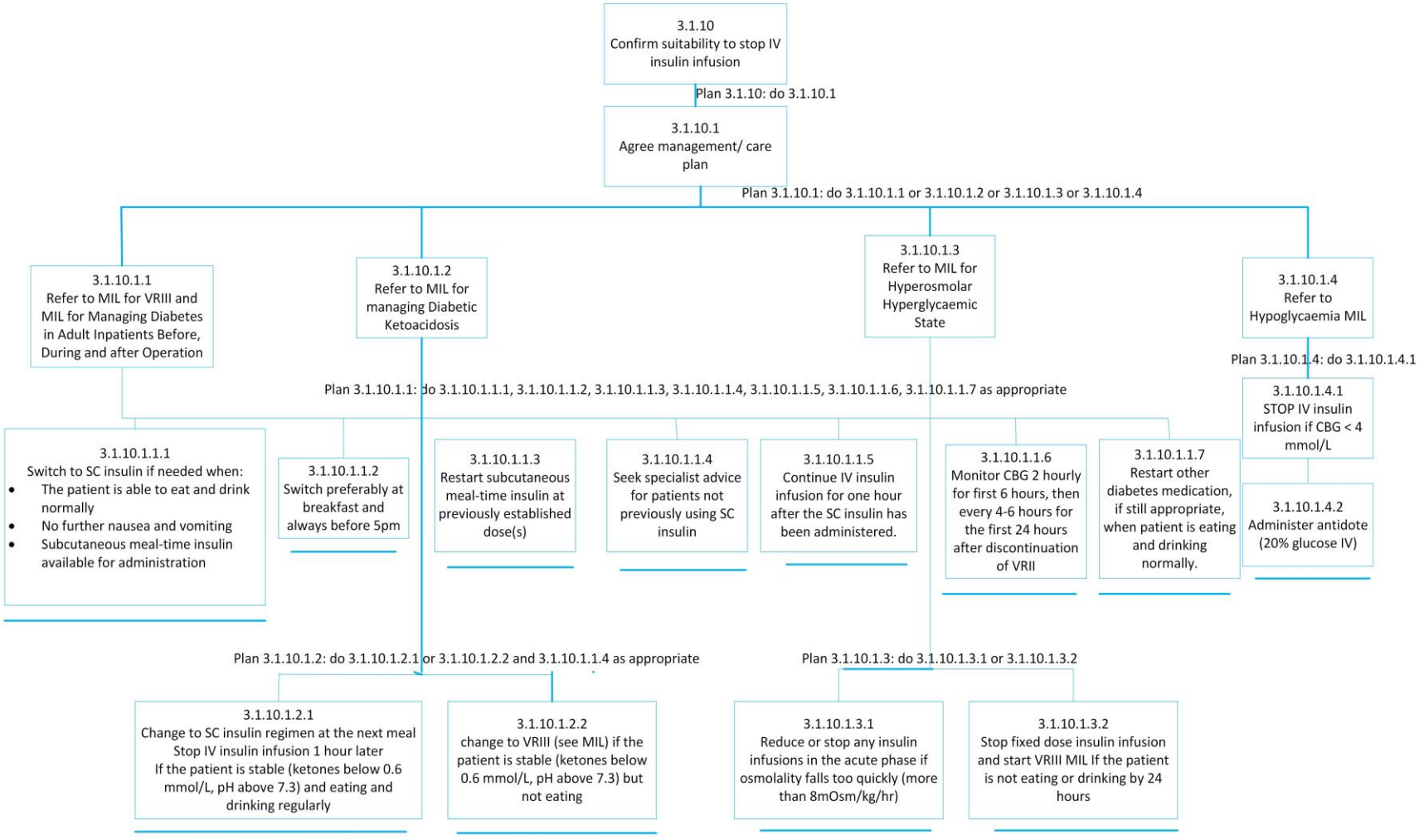
APP, As per policy; CBG, Capillary blood glucose; EPR, Electronic patient record; IV, Intravenous; VRIII, Variable rate IV insulin infusion.

Figure 4: Hierarchical task analysis diagram for 'Administer' sub-goal.



EPR, Electronic patient record; IV, Intravenous; MIL, Medicines information leaflet; VIP, Visual infusion phlebitis.

Figure 5: Hierarchical task analysis diagram for 'Monitor' sub-goal.



CBG, Capillary blood glucose; IV, Intravenous; MIL, Medicines information leaflet; SC, Subcutaneous; VRIII, Variable rate intravenous insulin infusion.

Figure 6: Hierarchical task analysis diagram for 'Confirm suitability to stop IV insulin infusions' sub-goal.

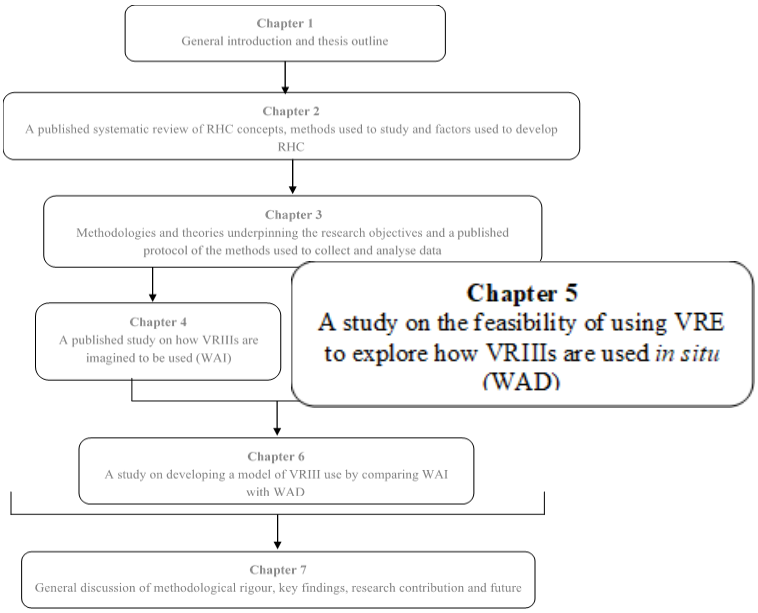
Chapter 5

Video reflexive ethnography methodology to explore the use of variable rate intravenous insulin infusions

Chapter summary: Following on from Chapter 4 in which WAI was explored, this chapter evaluates the feasibility of using VRE in this context, including recruitment and data collection, and their acceptability by healthcare practitioners. The chapter also discusses how VRIII was used *in situ* (WAD) using a mixed-methods approach.

Bibliographic details: Iflaifel MH, Lim R, Crowley C, Greco F, Iedema R. *Video reflexive ethnography methodology to explore the use of variable rate intravenous insulin infusions.* BMC Health Serv Res. 2021. Submitted.

Author contributions: MI, RL, CC and RI made a substantial contribution to the design of the work. MI collected the data, transcribed the video footage and analysed the video and the reflexive meeting transcripts. MI, RL, CC, RI and FG extensively discussed how to analyse and interpret the data. RL assisted in analysing the reflexive meeting transcripts and all authors participated in discussing the themes. MI drafted the initial manuscript. All authors revised the manuscript critically for intellectual content, agreed and approved the final version to be published.



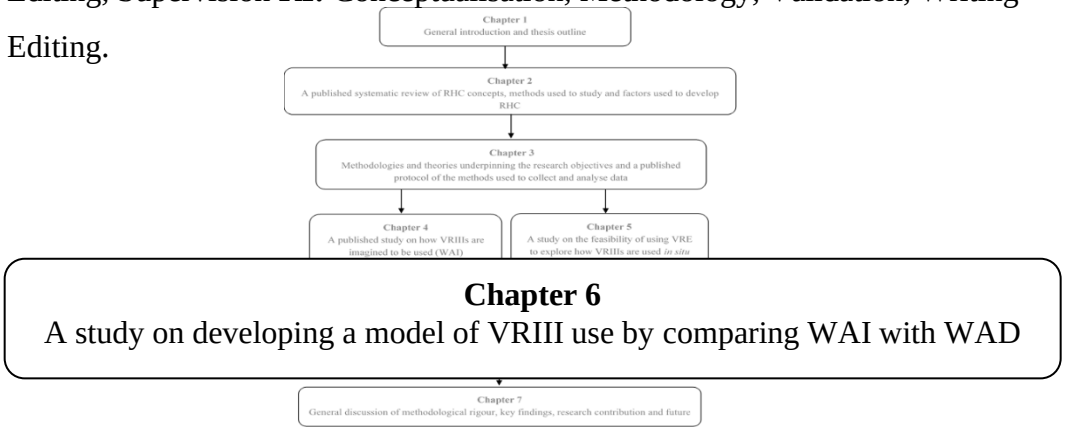
Chapter 6

Modelling the use of variable rate intravenous insulin infusions in hospitals by comparing Work as Done with Work as Imagined

Chapter summary: Combining the findings presented in Chapters 4 and 5, this chapter presents the development of separate HTAs for WAI and WAD in order to understand alignments and misalignments between them in the use of VRIII. The chapter also provides a detailed description of the process of developing a model of VRIII use.

Bibliographic details: Iflaifel M, Lim R, Crowley C, Greco F, Ryan K, Iedema R. *Modelling the use of variable rate intravenous insulin infusions in hospitals by comparing Work as Done with Work as Imagined*. Res Social Adm Pharm. 2021; 11:S1551-7411(21)00210-2.

Author contributions: MI: Conceptualisation, Methodology, Software, Validation, Formal analysis, Investigation, Resources, Data curation, Writing- Original Draft, Visualization, Project administration, Funding acquisition **RL:** Conceptualisation, Methodology, Validation, Formal analysis, Writing- Review & Editing, Supervision, Project administration, Funding acquisition **CC:** Conceptualisation, Methodology, Validation, Writing- Review & Editing, Supervision, Project administration **FG**: Methodology, Investigation, Writing- Review & Editing, Supervision, Project administration **KR:** Conceptualisation, Methodology, Writing- Review & Editing, Supervision **RI:** Conceptualisation, Methodology, Validation, Writing- Review & Editing.



ABSTRACT

Background: Variable rate intravenous insulin infusions (VRIII) are widely used to treat elevated blood glucose (BG) in adult inpatients who are severely ill and/or will miss more than one meal. VRIII can cause serious harm to the patient if used incorrectly. Recent safety initiatives have embraced the Resilient Health Care (RHC) approach to safety by understanding how VRIIIs are expected to be used (Work as Imagined, 'WAI') and how it is actually used in everyday clinical care (Work as Done, 'WAD').

Objectives: To systematically compare WAI and WAD and analyse adaptations used *in situ* to develop a model explaining VRIII use.

Methods: A qualitative observational study was conducted in a Vascular Surgery Unit by video-recording healthcare practitioners using VRIII. The video data were transcribed and inductively coded to develop a hierarchical task analysis (HTA) to represent WAD. This HTA was compared with a HTA previously developed to represent WAI. The comparison output was used to develop a model of VRIII use.

Results: While many of the tasks in the WAD HTA were aligned with the tasks presented in the WAI HTA, some important ones did not. When misalignment was observed, permanent adaptations (e.g. signing as a witness for a changed VRIII's rate without independently verifying whether the new rate was appropriate) and temporary workarounds (e.g. not administering intermediate-acting insulin analogues although the intermediate-acting insulin prescription was not suspended) were the most frequently observed adaptations used. The comparison between WAI and WAD assisted in developing a model of VRIII use. The model was designed to shed light on strategies used to imagine everyday work (e.g. audits, incident reports and VRIII guidelines), how everyday work was accomplished (e.g. context-dependent adaptations such as seeking verbal orders in emergencies) and how this contributed to both successful and unsuccessful outcomes.

Conclusions: This study provided in-depth understanding of the tasks required while using VRIII, and of responses and adaptations needed in clinical work to achieve safer care in a complex environment.

Key words: Resilient Health Care; variable rate intravenous insulin infusion; hierarchical task analysis; Work as Done; Work as Imagined.

Abbreviations:

ANTT - Aseptic Non-Touch Technique, BG - Blood glucose, CARE - Concepts for Applying Resilience Engineering, CAS - Complex adaptive system, CBG - Capillary Blood Glucose, DISN - Diabetes inpatient specialist nurse, ePMA - Electronic Prescribing and Medicines Administration, EPR - Electronic Patient Record, FRAM - Functional Resonance Analysis Method, FY1/2 - Foundation Year One/Two Doctor, HTA - Hierarchical Task Analysis, IV - Intravenous, NA - Nurse assistant, NaDIA - The National Diabetes Inpatient Audit, RAG - Resilience Analysis Grid, RHC - Resilient Health Care, SpR - Specialist Registrar, SRQR - Standards for Reporting Qualitative Research, VRE - Video reflexive ethnography, VRIII - Variable rate intravenous insulin infusions, WAD - Work as Done, WAI - Work as Imagined

INTRODUCTION

Variable rate intravenous insulin infusions (VRIII) are the main treatment modality for acutely unwell hospitalised patients with elevated blood glucose (BG) who are unable to eat/drink by mouth, are vomiting, miss more than one meal, or are severely ill (e.g. sepsis) [1]. Despite the efficacy of VRIII to quickly control elevated BG, this treatment can cause serious problems such as hypoglycaemia or ketoacidosis if used in error [2]. The seventh National Diabetes Inpatient Audit (NaDIA) 2017 reported 40% of patients receiving insulin had experienced at least one medication error. The report stated that almost 6% of the errors were related to inappropriate use of VRIII, resulting in increased risk of developing hypoglycaemia or experiencing a medication error [3]. The use of VRIII is considered clinically complex where multiple interacting factors increase the risk of complications and error. Such factors include limited evidence for a threshold for starting VRIII [1, 4], need for frequent BG monitoring [2], insufficient staff to patient ratio [5], co-administration of other medications and suboptimal knowledge about VRIII's use and its potential complications [6].

Patient safety is a priority for every healthcare institution and in the last two decades there has been an increasing focus on improving safety and quality [7]. Various initiatives have been introduced to enhance patient safety in the use of VRIII, among them daily review of the need for the VRIII and of the patient's clinical status, the use of VRIII-specific guidelines and the use of prefilled ready-to-administer insulin infusion syringes [2]. Although these initiatives have reduced errors and enhanced patient safety – e.g. in 2019 18% of inpatient drug charts had one or more insulin errors, compared to 26% in 2010 [8, 9] − the frequency of error is still a cause for concern. The current initiatives are predominantly based on traditional safety approaches and follow the 'centralised control' mode of safety improvement, or what is called Safety-I. Safety-I focuses on identifying errors and implementing solutions to eliminate or prevent their recurrence through standardisation of roles and procedures, analysing hazards and monitoring conformance [10, 11].

Healthcare systems are complex adaptive systems (CASs), the term defining a collection of individual agents with freedom to act in ways that are not always totally predictable and whose actions are interconnected so that one agent's actions change the context for other

agents [12]. Evidence suggests that new approaches are needed if further improvements are to be made [11, 13, 14]. These approaches focus on the 'decentralised mode' of safety, known as Safety-II, which in turn focuses on increasing the adaptive capacity of systems and individuals through understanding the complexity of everyday work. Safety-II advocates how practices and behaviours emerge because of continuous interactions across the system's components, and supports the idea that clinical work usually succeeds, but sometimes fails [7, 11]. Resilient Health Care (RHC) is a relatively new approach that takes a comprehensive view based on exploring and enhancing the system's adaptive capacity by learning from how clinical work usually succeeds and how it might fail [10, 11]. Understanding how clinical work is actually done (WAD) and comparing it with how work is expected to be done (WAI) provides a rich framework to explore complexity and inform the development of safety interventions by re-aligning WAI with WAD [15]. Therefore, the aims of this study were to systematically analyse and compare WAI and WAD in the use of VRIIIs, analyse adaptations used in the clinical environment to identify areas of weakness and strength, and develop a model of VRIII use based on RHC principles.

METHODS

Study design

This study drew on the constructivism paradigm [16]. The researcher focused on the context and interpreted the findings from her position as a clinical pharmacist with experience in diabetes management to construct and accumulate knowledge of what had been observed and translated it into tasks and plans to compare WAD with WAI. This study was conducted in four stages: 1) video-observations of everyday work to explore WAD while using VRIII; 2) video-observations analysis; 3) comparison between WAD and WAI; 4) developing a model of VRIII use. This study adheres to the Standards for Reporting Qualitative Research (SRQR) [17].

Study setting

This study was conducted in a Vascular Surgery Unit in a large tertiary, acute National Health Service (NHS) teaching hospital in England, UK.

In the Unit, the VRIII process was not automated. The electronic prescribing, monitoring and administration (ePMA) system within the electronic patient record (EPR) provided a prescribing proforma with clinical decision support to assist healthcare practitioners in patient assessment and in their decision-making. This decision support was based on the hospital guidance. Insulin infusions were supplied to the clinical area as a 50 unit in 50ml syringe as a ready-to-administer presentation. Bar-coded medicines administration was not used. The Unit used a syringe pump for insulin infusion and a volumetric pump for IV glucose-containing fluids with the rate programmed in ml/hr; dose error reduction software was not used. Point of care monitoring of the capillary blood glucose (CBG) and blood ketones via networked wireless meters provided a direct upload of the patient test results in the EPR. The delivery of patient care while using VRIIIs depended on various elements, e.g. manual bedside monitoring of CBG and blood ketones, and choosing the appropriate VRIII rate and IV fluids to be administered along with VRIIIs. Decision-making was used by healthcare practitioners to understand the linking and interactions between these elements to ensure the delivery of patient care. Two nurses conducted independent verification of prescriptions, patients, infusion pump programming, CBG, VRIII initial rate and of each rate change. There was generally one nurse per six patients and foundation year one/two (FY1/2) doctors were regularly present.

The use of VRIIIs was well placed to provide an example to assess the limits of RHC principles. Specifically, the use of VRIIIs is complex and multidimensional. It encompasses various factors, e.g. BG monitoring frequency and lack of clinical knowledge regarding the use of VRIIIs, interacting in ways that result in clinical work practices and adaptations that are often unpredictable. We believe that analysing the nature and the permanence status of these adaptations is complex enough to explain RHC constructs, clarify the concept of RHC, and propose recommendations for enhancing patient safety innovated from understanding the misalignments between WAI and WAD observed in situ.

Stage 1: Video-observation to explore WAD

Sample and Data Collection

This study is part of a wider project [18] which in part assessed the feasibility of using video reflexive ethnography (VRE) methodology to understand WAD. A purposive sampling approach is considered appropriate for feasibility studies if a wide range of the intended measures are likely to be faced by the participants to which the method or interventions are directed [19]. A purposive sample of two inpatients treated with VRIII and healthcare practitioners caring for these patients and involved in the use of VRIII, were recruited. The eligibility criteria for participants are presented in Box 1.

Box 1: Eligibility criteria for the recruitment of participants. Adapted from Iflaifel *et al.* (2019) [18]

Inclusion criteria

Healthcare practitioners who are:

1- Willing to be observed by video recording.
2- Working in the Vascular Surgery Unit.
3- Managing/caring for patients on VRIII.

Patients who are:

1- Aged ≥ 18 years old.
2- Receiving VRIII for at least 24 hours to treat elevated BG.
3- Under the care of a healthcare practitioners who have consented to participate in this study.
4- Able to provide informed consent.

Exclusion criteria

Healthcare practitioners who are:

1- Not willing to be observed by video recording.
2- Not working in the Vascular Surgery Unit.
3- Not involved in the use of VRIII.

Patients who are:

1- Not willing to be observed by video recording.
2- Not prescribed VRIII.
3- On IV insulin and glucose infusion for hyperkalaemia (potassium levels > 5.5mmol/L).
4- Unable to provide informed consent.
5- Non-English speakers.

Data were obtained by video-recording healthcare practitioners while using VRIII (e.g. prescribing, administering and monitoring). Data collection was performed between November 2019 and March 2020.

Stage 2: Video-observations analysis

The video data, including both verbal utterances and observed activities, were interpreted and transcribed by the researcher (XX). The video transcripts were inductively coded by XX to explore and understand what tasks and sub-tasks were required to achieve the main goal (see Supplementary file 1 for the coding of the video transcripts). A hierarchical task analysis (HTA), one of the most widely used types of task analysis [20] was used to represent the tasks required *in situ* while using VRIII. HTA describes a task as an overall goal with a hierarchy of subordinate steps. At each sub-task level, the plan directs the sequence of task steps and explains how the sub-tasks are to be undertaken [20]. The HTAs were developed by the research team and the process was iterative.

Member checking technique was used to enhance trustworthiness and research credibility [21]. The final draft of the developed HTAs was validated by one of the healthcare practitioners who had been video-observed. The healthcare practitioner validated the WAD HTAs by checking the tasks and the plans presented in the HTAs and confirming the accuracy of the data interpretation. No changes were suggested during this process.

Stage 3: Comparison between WAD and WAI

A separate study that produced a HTA of WAI (see Supplementary file 2) was used to conduct a comparison of WAI and WAD. The WAI HTA was developed using a triangulation of two sources of data: VRIII guidelines and related documents and focus groups with guideline developers, managers and healthcare practitioners [22]. The observed tasks, sub-tasks and plans presented in the WAD HTA were compared with the related tasks and plans in the WAI HTA to identify alignments and misalignments. One member of the research team (XX) reviewed the HTAs' comparison outputs and a discussion with the wider research team (XX, XX, XX and XX) was conducted to consider various aspects and perspectives of the video interpretations and the results of comparing WAI with WAD. Where misalignments were identified, further analysis was undertaken to understand the adaptations used and to classify the status of these adaptations and the resulting outcomes. Drawing on Watt *et al.* (2019)'s work, observed adaptations were classified either as permanent (regularly performed in the course of everyday work) or temporary (arranged ad hoc to respond to immediate challenges

only) [23]. The classification was made based on discussions between the researcher and healthcare practitioners during the reflexive meetings.

Stage 4: Developing a model of VRIII use

The model was developed based on findings from stages 2 and 3, and relevant literature. Although the model retained the RHC principles, its development was data-driven, a process including clarifications and additions based on empirical data resulting from comparing WAI with WAD in the use of VRIII in the study hospital. The model development also drew on the relevant literature's differentiation between three types of tasks (simple, complicated and complex) accomplished within the healthcare environment as a requirement to identify what resources, assessment tools and solutions are required to improve delivery of patient care [24-26]. The model development was highly iterative and involved the whole research team. The first draft was developed by organising and analysing the findings from stages 2 and 3. A series of meetings to inform the development of the model were planned and held with the research team and the study site collaborator. Much discussion centred on clarification of terms used in the model. For example, the first draft of the model used "acceptable" and "unacceptable" to represent the outcomes. These words were viewed to be insufficient to comprehensively classify all potential outcomes resulting from everyday work. "Proximal" and "distal" were used instead to represent the immediate, short-term impact of everyday work, and the long-term impact that might emerge over time, respectively. Issues raised and all resulting modifications to the model were discussed and validated in the research team meetings and the final draft was developed to illustrate the use of VRIII *in situ*.

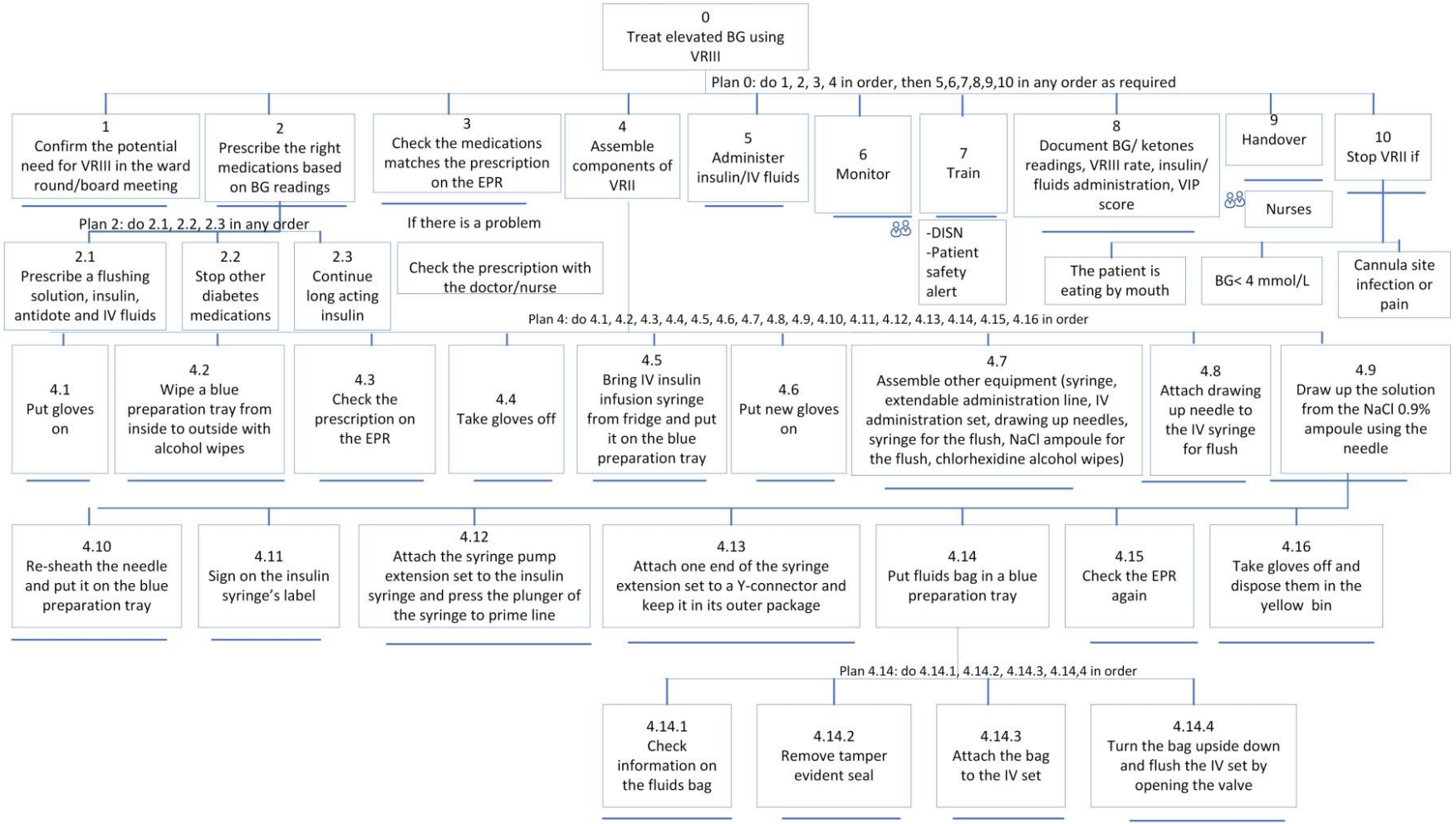
Ethics

Ethical approval was obtained by the XX Ethics Committee (UREC) (ref: 18/03), NHS Research Ethics Committee (REC) and Health Research Authority (HRA) (ref: 18/SC/0456).

RESULTS

Exploring WAD

Thirteen hours of video recordings of 10 healthcare practitioners who were caring for two patients were used to develop the final HTA (see Fig. 1). Although it was planned to video both patients' cases over 24 hours (day and night) [18], the researcher was unable to stay in the hospital overnight and healthcare practitioners were too busy to help with the video recordings when the researcher was not available. As a result, the 13 hours of video recording was all captured during the day. Treating elevated BG was identified as a key goal while using VRIII. The HTA highlighted more than 100 practical tasks needed to achieve the goal. The sub-goals necessary to achieving the main goal were predominantly related to confirming the potential need for VRIII, prescribing the right medications based on BG readings, checking that the prescribed medications matched the prescription and adjusting the medication administered to aim for BG readings within the normal range, to prevent complications such as hypo/hyperglycaemia.



BG, Blood glucose; DISN, Diabetes inpatient specialist nurse, EPR, Electronic patient record; IV, Intravenous; NaCl, Sodium chloride; VIP, Visual infusion phlebitis; VRIII Variable rate intravenous insulin infusion; People; End of the goal or sub-goal

Fig. 1. A HTA of using VRIII based on WAD.

The sub-goal, *prescribe the right medications based on BG readings,* was decomposed into several tasks. This sub-goal requires the doctors to prescribe VRIII, IV fluids and IV glucose, to stop all diabetes medicines other than long-acting insulin analogues which should continue.

To accomplish the *assembling of the components of the VRIII,* the nurses first checked that the medication matched the prescription on the Electronic Patient Record (EPR) and assembled equipment as expected.

To *administer insulin/IV fluids* (see Supplementary file 3), the nurses recorded the medications to be administered on the EPR (VRIII and IV fluids). Before preparing the VRIII and IV fluid pumps, an independent verification of the VRIII/IV fluids before administration was observed. A separate nurse checked the label of the prefilled ready-to-administer insulin infusion syringe against the prescription information on the EPR screen and then signed her initials and added the time and date. The nurse then checked the label on the IV fluid infusion bag and signed as a witness in the 'Recording details' window on the EPR. Ideally, two registered professionals must set up and independently check the initial insulin infusion rate and each rate change. In one case, the nurse signed as a witness without checking the changed rate and its appropriateness to the CBG readings. During the observations, it was clear that the nurses always sought a witness before administering the VRIII and IV fluids, but if they were unable to find one free then they might proceed to start administration without this happening. Seeking a witness was not always feasible as other nurses might sometimes be busy. One way this was managed was by administering the medication before performing the independent verification in order to prevent a delay in administering the VRIII and thus prevent complications.

The sub-goal *monitor* (see Supplementary file 3) is used to describe a broad range of monitoring including CBG, blood ketones, cannula and patient complaints. It was observed that the nurses tried to follow the hospital guidelines by monitoring CBG every hour while the patient was on the VRIII. However, it was observed that during busy shifts, nurses were unable to monitor CBG every hour and the monitoring was delayed by between five and seven hours.

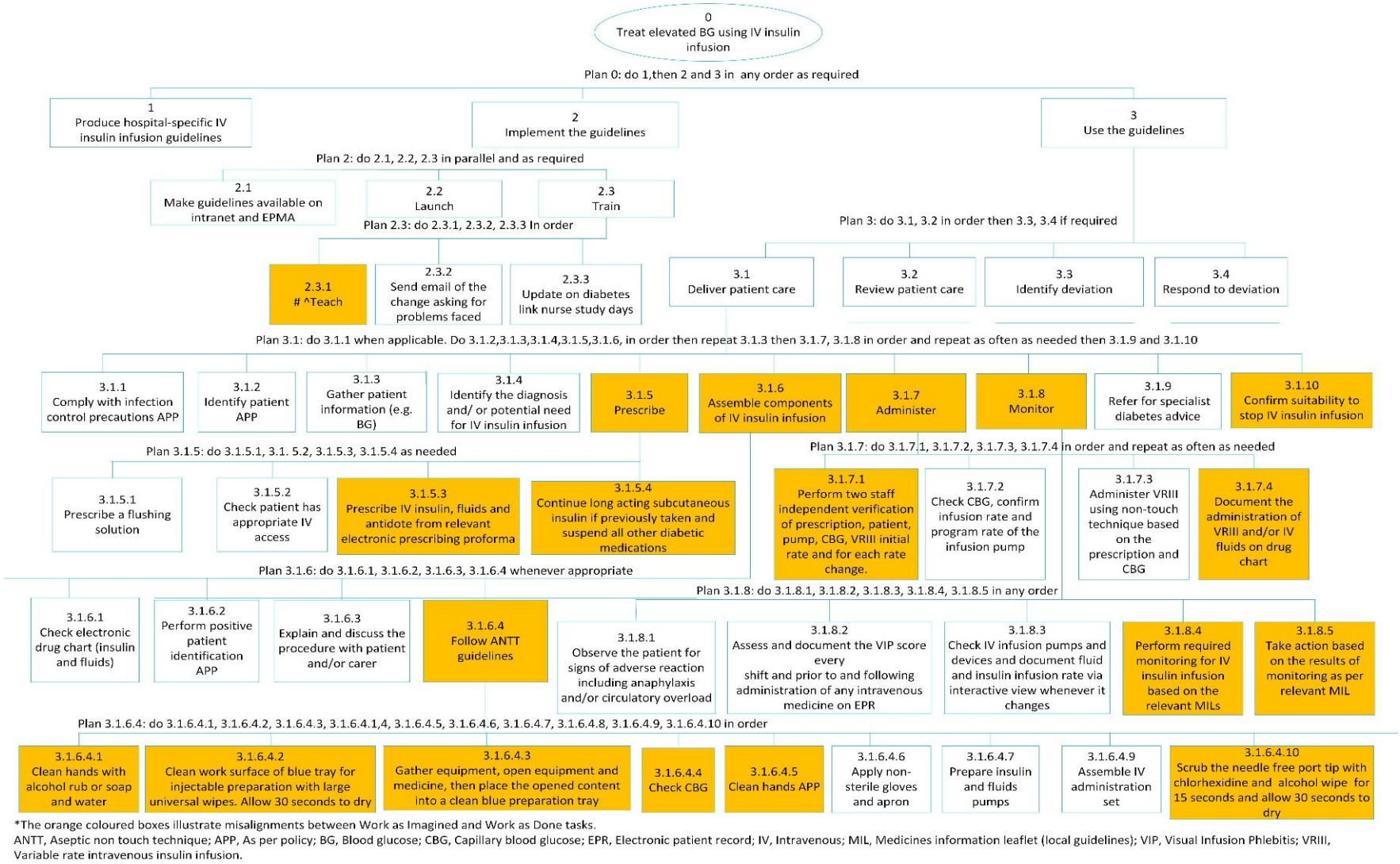
There were multiple tasks observed as part of accomplishing the *training* sub-goal. A diabetes inpatient specialist nurse (DISN) came to deliver a 10-minute teaching session about hypoglycaemia treatment to the staff on the ward. Interestingly, the DISN nurse delivered the teaching session as expected but there was only one student nurse who attended the session.

From the HTA, it was clear that the electronic *documentation of CBG/ketones readings, VRIII rate, insulin/fluids administration and VIP score* is a required step in almost every task needed to accomplish the key goal. However, it was observed in one case that the VRIII rate was changed on the infusion pump but the change was not documented in the EPR.

Treat hypoglycaemia if BG<4 mmol/L (see Supplementary file 3) was another major sub-goal in the successful treatment of elevated CBG using a VRIII. This required the doctors to prescribe IV glucose 20% as an antidote and for the nurse to assemble the equipment, administer the IV glucose 20% and check the patient's CBG level after 15 minutes.

WAI and WAD: To what extent do they differ?

The misalignment between tasks in the WAD HTA and WAI HTA are highlighted in orange in Fig. 2. The observed tasks that matched that of the WAI HTA included prescribing a flushing solution, insulin, antidote and IV fluids, assembling and administering the VRIII and IV fluids via an infusion pump and treating hypoglycaemia.



*The orange coloured boxes illustrate misalignments between Work as Imagined and Work as Done tasks.
ANTT, Aseptic non touch technique; APP, As per policy; BG, Blood glucose; CBG, Capillary blood glucose; EPR, Electronic patient record; IV, Intravenous; MIL, Medicines information leaflet (local guidelines); VIP, Visual Infusion Phlebitis; VRIII, Variable rate intravenous insulin infusion.

Fig. 2. A mapped HTA illustrates similarities and differences between WAI and WAD.

Misalignments were primarily related to the 'Teach', 'Prescribe', 'Assemble components of the VRIII', 'Administer', 'Monitor' and 'Confirm suitability to stop the VRIII' sub-goals, all of which are crucial tasks to ensure patient safety while using VRIII. The misalignment between WAI and WAD tasks is shown in Table 1.

Table 1. WAI tasks and their execution *in situ*.

Tasks in the WAI-HTA	**Status**	**Evidence from WAD**	**Observable outcome**	**Adaptations' permanence status**
2.3.1 Teach				
Ten-minute espresso teaching	PD	A Diabetes Inpatient Specialist nurse conducted a 10-minute teaching session about hypoglycaemia.	One student nurse attended the session and no other nurses attended.	NA
3.1.5 Prescribe				
3.1.5.3 Prescribe IV insulin, fluids and antidote (20% glucose IV) using the relevant electronic prescribing proforma	PD	The VRIII and the antidote were prescribed but the IV fluids were not prescribed.	The nurse found out that the IV fluids were not prescribed and went to the SpR and asked him to prescribe it.	Temporary
3.1.5.3.4 Select appropriate IV fluid to avoid hypoglycaemia and electrolyte imbalance	ND	The SpR prescribed the IV fluids and electrolytes.	Based on the hospital guidelines, the potassium content of the prescribed fluid was not appropriate for the patients' serum potassium level.	Temporary
3.1.5.4 Continue long-acting subcutaneous insulin if previously prescribed and suspend all other	PD	The SpR did not suspend the regular prescription for subcutaneous intermediate-acting insulin when initiating the VRIII.	The nurse did not administer the intermediate-acting insulin to the patient.	Temporary

medications for diabetes.				
3.1.6 Assemble components of IV insulin infusion				
3.1.6.4 Follow Aseptic Non-Touch Technique guidelines	ND	The ANTT guidelines were not followed.	NO	NA
3.1.6.4.1 Clean hands with alcohol rub or soap and water	ND	The nurse did not clean hands with alcohol rub or soap and water but applied non-sterile gloves before checking the EPR.	NO	NA
3.1.6.4.2 Clean work surface of blue preparation tray for injectable preparation with large universal wipes. Allow to dry for 30 seconds	D	The nurse cleaned the blue injectable preparation tray whilst putting on gloves.	NO	NA
3.1.6.4.3 Gather equipment, open equipment and medicine, then place the opened content into a clean blue preparation tray	PD	The nurse gathered equipment and put it inside the blue preparation tray before opening the outer package.	NO	NA
3.1.6.4.4 Check CBG	ND	CBG was not checked before opening and priming the IV line.	The nurse spent time assembling and priming the IV line, then found that the patient was hypoglycaemic.	NA
3.1.6.4.5 Clean hands as per protocol	ND	Hands were not cleaned before applying gloves. The nurse applied gloves directly, without washing hands.	NO	NA
3.1.6.4.10 Scrub the needle free	ND	The nurse attached the insulin and fluids to	NO	NA

port tip with chlorhexidine and alcohol wipe for 15 seconds and allow 30 seconds to dry.		the patient cannula without wiping the needle free port tip.		
3.1.7 Administer				
3.1.7.1 Perform two-staff independent verification of prescription, patient, pump, blood glucose, VRIII initial rate and for each rate change.	PD	Patient case 1: a senior nurse changed the infusion rate of VRIII, then told a second nurse that the rate had been changed, asking for the nurse to sign as a witness on the EPR. Patient case 2: The independent verification before administering VRIII was not done as the second nurse was busy with another patient and the nurse chose to proceed with the task.	The VRIII rate was changed and the second nurse signed on the Electronic Patient Record without checking the changed rate. The nurse administered the VRIII and IV fluids to the patient without delay. Following this, the second nurse checked and signed on the EPR.	Permanent Temporary
3.1.7.4 Document the administration of VRIII and/or IV fluids on drug chart	D	This task was performed before the nurse administered VRIII to the patient.	NO	NA
3.1.8 Monitor				
3.1.8.4 Perform required monitoring for IV insulin infusion based on the relevant MILs	PD	Based on the Medicines Information Leaflet, CBG monitoring for patients on VRIII should be performed hourly.	BG monitoring was performed every 1-7 hours.	Permanent

3.1.8.5 Take action based on the results of monitoring as per relevant the Medicines Information Leaflet	PD	In the hospital guidelines there is no clear description on how to clean the planned skin puncture site before checking blood glucose. However, instructions are provided in the CBG monitoring training to wipe the planned skin puncture site with damp cotton wool.	Two different practices were observed to clean the planned skin puncture site: Patient case 1: one nurse used wet cotton wool dampened with tap water. Patient case 2: a second nurse used dry cotton wool.	Permanent
3.1.10.1.4.1 Stop VRIII if blood glucose < 4 mmol/L				
3.1.10.1.4.2 Administer antidote (20% glucose IV infusion)	D	Sometimes the nurses proceeded with administering the antidote and checked in retrospect that it was prescribed. In other cases, the nurse asked for a verbal order before administering the antidote.	Hypoglycaemia was treated without delay.	Permanent

Key: (D) Done; (PD) Partially Done; (ND) Not Done; (NA) Not Applicable; (NO) Not Observed.
ANTT Aseptic Non-Touch Technique; *CBG* Capillary Blood Glucose; *ePMA* Electronic Prescribing and Medicines Administration; *EPR* Electronic Patient Record; *FY1/2* Foundation Year One/Two Doctor; *IV* Intravenous; *MIL* Medicines Information Leaflet; *SpR* Specialist Registrar; *VRIII* Variable Rate Intravenous Insulin Infusions.

Permanence status of the adaptations: permanent or temporary

The analysis of the permanence status of the adaptations resulted in categorising adaptations as either permanent or temporary. Permanent adaptations were divided into planned adaptations that aimed to proactively improve the care or forced adaptations that were routinely done because the ideal solution for the problem faced was not available at that time. An example of a permanent, planned adaptation was when healthcare practitioners predicted the urgency and acuity of developing hypoglycaemia and responded proactively by administering the antidote without checking the prescription or by only seeking verbal orders.

The other type of permanent adaptation consisted of forced adaptations, in which the nurses made sure that the signature of a witness appeared on the system; however, this was not executed as required. The witness did not independently verify the changed rate of VRIII but signed to confirm they had on the electronic system.

Most of the observed adaptations were temporary workarounds that did not resolve the underlying system problem and relied on how each healthcare practitioner responded at that point in time. For example, the SpR did not suspend the intermediate-acting insulin but the nurse did not administer it due to her previous knowledge of the importance of discontinuing all diabetes medicines, except long-acting ones, when VRIIIs are prescribed. Such adaptations were temporary workarounds that had a localised effect; they brought no permanent improvement to the system as they were not reported, which might have led to such improvement. Another example of temporary adaptation was when some nurses adapted by assigning nurse assistants (NAs) to monitor CBG levels. When a nurse delegated monitoring CBG to NAs, some NAs were not familiar with the frequency of monitoring CBG for patients on VRIII and this led to variability in monitoring frequency with consequent negative effect on the patients' CBG levels.

The observed outcomes

Table 1 shows the observed successful and unsuccessful outcomes resulting from healthcare practitioners' adaptations when performing specific tasks. Whenever misalignments were identified, various adaptations were made to ensure that VRIII, antidote and IV fluids were prescribed on the EPR so that they could be administered. On one hand, adaptations in this case resulted in accelerating the process of prescribing IV fluids; however, an inappropriate fluid type for the patient was prescribed instead. On the other hand, the nurse's response by not following the prescription resulted in ensuring that the patient's safety remained the priority. The nurse did not administer the intermediate acting insulin despite the fact that it had not been suspended by the doctor. For the independent verification of a rate change for VRIII, although the main aim was to ensure that the signature of a witness appeared on the EPR when administering VRIII or after changing its rate, one nurse adapted by deciding not to wait for the other nurse to countersign the EPR, which resulted in the VRIII being administered to the patient without delay.

Monitoring was one of the overarching tasks to focus on when the goal was to make sure that BG monitoring was performed hourly and the VRIII rate changed based on CBG readings. Healthcare practitioners' adaptations by assigning the monitoring task to other staff, e.g. an NA, or by performing the monitoring themselves when they were free, resulted in the patient being hyperglycaemic throughout the day (24 hours) and in monitoring being delayed by two to seven hours. Treating hypoglycaemia is a crucial task and it was observed that some healthcare practitioners would not wait to check the electronic prescription and would adapt by administering the antidote before checking the prescription or by seeking verbal orders in order to prevent complications and to ensure patient safety.

Modelling VRIII use

A model representing the use of VRIII was developed (see Fig. 3). The general structure of the model is that WAI (left) represents strategies used to inform and enhance WAD (middle) to produce outcomes (right). A feedback loop represents continuous adjustments based on reviewing patient care delivery and everyday work. The arrows pointing to the right, between WAI and WAD and between WAD and outcomes, indicate that the directionality is left to right. The dashed arrows in the opposite direction indicate the potential of feedback mechanisms. The dashed lines rectangles represent that the WAI, WAD and outcomes are dynamic and can change in response to results from continuous monitoring of everyday work and patient care delivery outcomes.

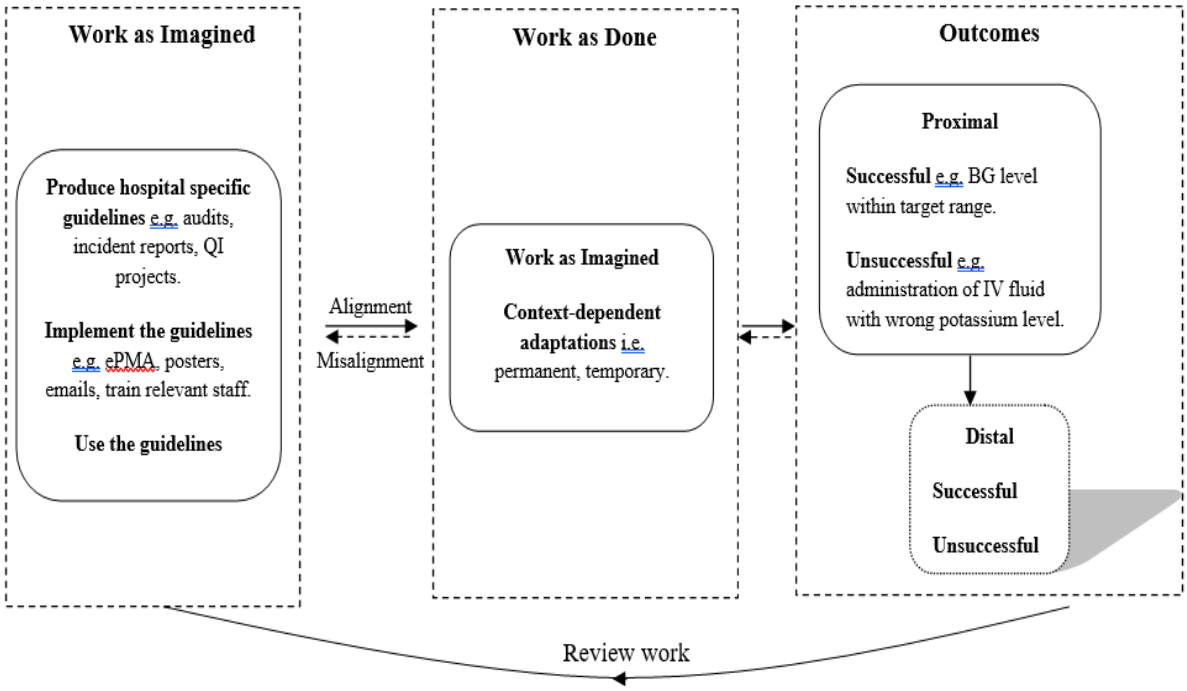


Fig. 3. Model of VRIII use in a hospital.

Work as Imagined

The left side of the model illustrates WAI that is planned to achieve alignment with WAD. This alignment cannot be completely achieved because of the complex nature of healthcare systems, in which unexpected situations that need adaptations and adjustments are always likely to arise [27]. However, systems use various strategies to imagine how everyday clinical work is accomplished, in order to strengthen work and narrow the gap between WAI and WAD. WAI has been previously addressed in the context of using VRIII in the hospital unit [22]. The hospital used various resources to produce its own hospital-specific guidelines, such as the relevant Joint British Diabetes Societies for Inpatient Care guidelines, the National Diabetes Inpatient Audit, local incident reports, feedback, clinical audits and quality improvement projects. Various strategies were used to implement the guidelines, such as ensuring the availability of the guidelines on the hospital's intranet and ePMA, training staff and preparing group-specific material, e.g. posters, handbooks, meetings and memos, to explain to staff the rationale of the new guidelines. The hospital guaranteed the delivery of patient care by ensuring the use of the hospital-specific guidelines. Any identified deviation was approached by having conversations and asking questions designed to identify the reasons

behind the deviation, giving feedback, finding a compromise, providing immediate informal education, and finally changing the wording of guidelines or modifying the content of mandatory training materials if required [22].

Work as Done

It is apparent from the model in Fig. 3 that WAD (middle) is accomplished by using standardised practices developed by the study site (WAI), e.g. VRIII guidelines and/or context-dependent adaptations.

Outcomes

Outcome (on the right side of the model) is a broad concept that has consequences for patients, professionals and organisations. Outcomes are defined as a state resulting from everyday work [28]. The model also highlighted that outcomes could be proximal or distal. Proximal outcomes are defined as the direct result of everyday work, while distal outcomes are results that emerge over time [28]. Proximal outcomes included preventing errors by not administering the intermediate-acting insulin to the patient; achieving target BG within 15 minutes of administering IV glucose to treat hypoglycaemia in one patient; and not achieving a target BG with persistent hyperglycaemia in another patient because of infrequent BG monitoring. These proximal outcomes could have affected distal outcomes, but this was not observed in this study because of the short observation time. In the above model, the distal outcomes were illustrated by a perspective shadow that shows the need for longitudinal future research to explore distal outcomes such as patient survival versus mortality; staff burnout; system brittleness because of frequent local workarounds; or lessons learned from planned, permanent adaptations.

Outcomes were also divided into successful and unsuccessful. Successful and unsuccessful outcomes are subject to various interpretations, acceptance of which based on goals of different stakeholders and the contextual factors that affect the outcome. For example, it was not possible to perform independent verification before administering VRIII because of the lack of healthcare practitioners' availability. The nurse prioritised conflicting goals to achieve a better outcome by administering VRIII before performing the independent verification in

order to prevent a delay in controlling the patient's elevated BG and thus prevent complications.

Feedback loop

The model depicts a feedback loop, illustrating review work. The hospital Trust employed various means to continuously review the delivery of patient care, such as quality improvement projects; audits; comments and feedback from healthcare practitioners; and incident reports using the local incident reporting system [22]. In CASs, reviewing clinical work should include monitoring and investigating everyday work and the resultant outcomes by engaging different stakeholders to discuss practical solutions in an attempt to counter the misalignment between WAI and WAD and to enhance patient safety [28]. Understanding the task type affects the way work is reviewed and how strengthening strategies could be applied. Simple − what Johnson *et al.* call 'reliable' – tasks, such as hand hygiene procedures, are best investigated by cause-and-effect methods to identify the cause of errors. Standardisation is considered a useful tool in monitoring these tasks, entailing the use of protocols, checklists and policies that make the procedures easier to carry out correctly [29]. Complicated or 'robust' tasks, such as routine CBG monitoring, need tools such as clinical audits in which clinical work is monitored against agreed standards and guidelines to ensure the required clinical work is delivered with minimal variation [29]. It is widely accepted that there is no point using the above tools in highly complex or unpredictable processes. Dealing with a deteriorating patient needs flexible and goal-oriented tools rather than rigid and task-oriented ones. Here, tools used to review and monitor care tend to contemplate and explore the complexity of everyday tasks and make sense of context in order to support healthcare practitioners in dealing with challenges and making decisions in unexpected situations. Such tools include VRE [30], Resilience Analysis Grid (RAG) [31] and the Functional Resonance Analysis Method (FRAM) [32].

DISCUSSION

To our knowledge, this is the first study to operationalise RHC principles in analysing the use of VRIIIs by comparing WAI and WAD, identifying misalignments and adaptations used to

deliver patient care, and developing an explanatory model to explain the complexity of work associated with using VRIIIs in a clinical environment.

The comparison between WAI and WAD HTAs gave a clear illustration of the complexity of using VRIII to treat elevated BG. Several studies have focused on the gap between WAI and WAD and shown there to be a remarkable difference between the two [13, 33, 34]. Some of the tasks performed by healthcare practitioners *in situ* and illustrated in the WAD HTA, were aligned with the tasks presented in the WAI HTA. This could be due to VRIII guideline developers in the study hospital using a variety of resources in addition to the national guidelines and audits, for example by consulting the Think Glucose Group (a multidisciplinary group of healthcare professionals at the study hospital concerned with inpatient diabetes), an inpatient specialist nursing team who have extensive hands-on experience, and junior doctors [22]. They also followed up the implementation of the guidelines through the ward managers and link nurses, who informed the guidelines developer team about the problems and queries faced in frontline care, which were then addressed by the team and shared in question and answer form with all healthcare practitioners.

The RHC concept has often been misinterpreted as maintaining the focus on adaptations and giving the impression that adaptations are always opposite to control strategies imposed by WAI, and that the two things cannot coexist. However, in this study, the developed model showed that the use of VRIII was accomplished by using both standardised practices (WAI) and adaptations to ensure delivery of patient care. A recent perspective paper argued that standards play a crucial part in ensuring safer and generally better patient care and that standards need to be continually adjusted and refined based on how everyday work is actually done and by engaging healthcare practitioners who actually provide clinical care and services [35].

In this study, where misalignments between WAI and WAD were identified, the analyses of the permanence status of the observed adaptations revealed that very few were intentional adaptations that aimed to proactively improve overall patient care and safety. Most of the observed adaptations were either permanent, forced adaptations or temporary workarounds which healthcare practitioners adopted because no solution was available, the system was deficient and the practitioner was in no position to wait for better solutions that might be

implemented in the future. These adaptations cannot be expected to have a long-term effect on the success of the system and might indeed increase the brittleness of the system. Our results are in accord with those of a recent study conducted to explore resilience in the blood transfusion process [23]. The study found that forced adaptations and local workarounds can be dangerous and result in unsafe work [23]. However, there would be an opportunity to learn from them for future local improvement [23]. Healthcare systems are CASs in which repeated adaptations and adjustments are routinely made in order to accomplish clinical work [36]. Understanding the reality of everyday work is crucial to co-designing the system for better patient care [29]. For example, in complex and emergent situations, adaptations are inevitable and they demonstrate the difficulties and problems faced by healthcare practitioners and the system [23]. It is important to note that understanding the permanence status of adaptations is crucial to differentiating between work that has long-term or short-term success. Improvement could be achieved, on one hand, by cultivating new skills learned from adaptations that have had long-term success and incorporating them into standards and guidelines. On the other hand, short-term adaptations could take the form of valuable measures used to identify where the system is liable to fail and to proactively prevent failures from happening.

The model developed in this study highlighted that a starting point to assist in reviewing work and implementing effective interventions, is to apply monitoring tools correlated to the type of tasks and situations being reviewed. In the present study, it was found that the misalignments did not always result from emergent unexpected situations. Some misalignments were identified in simple, routine tasks such as following the ANTT technique guidelines, others in the performance of more complicated ones such as prescribing medications using the ePMA system. Therefore, it is important to understand the type of the tasks undertaken in order to identify the most appropriate tools to investigate delivery of better patient care [29].

Previous studies that focused on studying resilience in healthcare used various methods appropriate to reviewing patient care and exploring the complexity of healthcare settings, among them FRAM [32, 34], RAG [37] and VRE [38].VRE has evolved into a powerful methodology for exploring ordinary everyday work by engaging healthcare practitioners themselves to review their work, discuss the factors affecting their performance and suggest solutions from their perspective to improve their performance and to enhance patient care delivery. Engaging healthcare practitioners to analyse their own work makes observations less

biased and more comprehensive. Clinical audits [22, 39] and local incident reports [40] are examples of strategies that are usually used to review care and optimise work. Such strategies tend to observe the extent to which healthcare practitioners adhere to pre-specified standards and evidence-based guidelines. For example, traditional clinical audits tend to identify situations where deviation from standards occurs without an intention to promote learning from everyday work [23]. A recent study was conducted to explore how VRIIIs were used in work using VRE [38]. Unlike traditional audits and investigation tools, the study focused on the perspective of healthcare practitioners in the use of VRIII, the challenges faced while using VRIII and the factors affecting the adaptations used to counter variability in work [38].The use of such tools could encourage healthcare practitioners to more consciously assess their everyday work and modify guidelines and protocols accordingly.

The study site employed various strategies to improve the use of VRIII, e.g. VRIII guidelines; policy for prescribing, preparing and administering injectable medicines; clinical audits; and feedback [22]. Understanding the type of task will not only influence the tools used to review work but can also influence the type of improvement strategies that will be used to improve work. Checklists or protocols are used to improve performance of simple/reliable tasks [29]. Complicated/robust tasks could be improved by implementing evidence-based guidelines and more goal-oriented clinical audits and benchmarking [29]. Goal-oriented audits could influence work only if the stakeholders involved agree with benchmarking, agree that the work under review is feasible for improvement and agree that the change in work is essential for the quality and safety of their patients and work [41]. For complex tasks, a number of safety improvement strategies were used, among them simulations [42], the TenC model and negotiations [43].

Limitations of the study

The present study was limited by its short observational time and small number of participants, and was based on data from a single site, which could be viewed as limiting its generalisability. However, the use of method triangulation to study WAI, and of mixed methods to study WAD, using both VRE and quantitative data, strengthens the credibility of the findings. Although the comparison between WAI and WAD and the interpretation of the data were conducted by one researcher, the analysis of the data was reviewed by the wider

research team, the developed HTAs were confirmed for accuracy by the study participants. The raw video data were also reviewed to provide confidence that all findings extracted from the comparison were consistent with what was actually observed.

Research and clinical implications

This study's findings make several contributions to the current literature. First, it highlighted the alignments and misalignments between WAD and WAI and found a large number of detailed sub-tasks and plans presented in the WAD HTA that were not captured by the WAI HTA. For example, it was not mentioned in the hospital's documents how to assemble and prepare equipment before monitoring patients' BG and blood ketones at bedside. However, the WAD HTA clearly illustrated how this task was accomplished in everyday work. To improve system's performance, there is a need to understand the context before intervening, because without understanding how work is actually done, interventions and protocols may mystify rather that demystify the work. The findings of this study's comparison could help the study site to explore what strategies were used to achieve this alignment, in order to learn from them and to more thoroughly understand where, how and why misalignments occurred in everyday work, by engaging various stockholders in a genuine learning process, based on a deep understanding of WAD, that would result in the identification of practical solutions to enhance patient safety.

Second, the findings explained the importance of understanding the type of task, where a gap has been identified in order for healthcare practitioners, guideline developers and safety professionals to determine, within a given context, what tools could be used to best monitor work and improve clinical performance.

Thirdly, the researchers were able to identify the outcomes and the permanence status of the adaptations required to help to co-create a new description of how clinical work is performed using VRIII. This might be achieved not by asking healthcare practitioners to write protocols or guidelines, but by engaging different users to understand everyone's job and to analyse the status of the adaptations and the resultant outcomes to determine whether they acted as long-term successes or short-term workarounds. This engagement can help management as well as healthcare practitioners to share learnings from long-term successes and identify indicators for

short-term workarounds, in order to proactively prevent their occurrence by providing realistic, practical and more sustainable interventions.

Conclusion

A model of VRIII use was developed based on the practical findings resulted from comparing WAI and WAD. The systematic comparison provided a detailed approach to finding where misalignment occurred and the effect of observable adaptations on the subsequent tasks and sub-tasks in the process of using VRIII. This study emphasises that everyday work performed by healthcare practitioners can sometimes lead to brittleness in some parts of the system while strengthening other parts. To enhance the safety of patient care and strengthen the system, review work needs to be informed by everyday work and aligned in a way that facilitates safe variations. Further research can use the findings of this study as a base to further explore the distal outcomes emerging from everyday work and the long-term impact on patients, healthcare practitioners and systems. Future studies can build on insights from the current developed model to determine what tools could appropriately be used to monitor and improve everyday work and patient safety.

Conflicts of interest

None

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Supplementary information

Modelling the use of variable rate intravenous insulin infusions in hospitals by comparing Work as Done with Work as Imagined

Supplementary File 1: Hierarchical task analysis diagrams for Work as Imagined in the use of variable rate intravenous insulin

Please see Supplementary File 4 in Chapter 4 pages 106-111.

Supplementary File 2: Coding video transcripts

The table below illustrates an excerpt of the main tasks and codes extracted for each task.
Different colours were used to represent codes related to specific sub-tasks in the developed HTA.
Red: 'Prescribe', Green: 'Check VRIII/fluids prescription on the EPR', Blue: 'Assemble components of VRIII', Purple: 'Administer insulin/IV fluids', Orange: 'Monitor BG, blood ketones, cannula', Dark red: 'Train', Dark blue: 'Stop VRIII if BG < 4 mmol/L'.

Video number	Task time and photo	Task	Transcription	Codes
Video 1M	0.00.19-0.03.32	Double check the prescription with the doctor	Nurse S was struggling to find the fluid prescription, so decided to speak to the doctor. S: I need to speak to the doctor … to prescribe it. The nurse went out of the treatment room; the doctor was working on his computer in the corridor outside the patient's bay. S: D: Yah, I am doing it. He clicks on the screen. D: Is it that one? 40 sodium, 40 ml. 40 ml of sodium. S: Yah, it has glucose in it as well. S:[Pause] This one. D: Glucose? S: Yes, it comes all three together. D: What is it? S: The fluids. Glucose, sodium and potassium. D: Right. S: Mmm, is it NIL? Wasn't he yesterday … it comes like a package when you put variable rate in the prescription, and then you put a variable rate and then the fluids come underneath it.	Double check if there is a problem Prescribe IV fluids

			The doctor was doing as the nurse told him. Both were looking at the screen and the nurse was showing him what to click on. S: So, that is the standard one [VRIII regimen]. D: This is the saline, glucose. S: Yah, and then you choose your fluids according to the level of potassium. She was pointing at the screen, showing the doctor which fluid to choose. S: So when he checked, he checked results of potassium and it was 4. something. D: No … no … no, it's fine. Looking at the screen, the doctor asked: D: Which fluid is it? S: 40 mmol of potassium, 20. D: Glucose 4%, NaCl. Is that the one we have? S: We have both, yes. S: OK, thank you. The nurse went back to the treatment room; while she was on her way the doctor asked her: D: How much you want? 1000? S: Yah, 1000 please, 100 mls/hour.	Prescribe IV fluids based on K level
	0.08.40-0.10.16	Gathering equipment	S removed her gloves and picked out a new pair, opened the fridge and took an insulin syringe, closed the fridge and locked it. She read what was written on the syringe to check it. She then put the syringe in the blue preparation tray and put the gloves on before collecting the other equipment (extendable administration line, IV administration set for fluids, drawing up needles, syringe for the flush, NaCl ampoule for the flush) from	Steps to assemble equipment

			the treatment room drawers. She opened five drawers before finding what she was looking for. She put all the collected equipment in the blue preparation tray and brought some chlorhexidine alcohol wipes.	
	0.10.17-0.14.19	Assemble equipment	S removed a syringe from its outer packaging and attached it to a needle. She opened an ampoule and drew up fluid using the needle, then re-sheathed the needle and put it in the blue preparation tray. She put the outer packaging in the bin then opened the outer packaging of the insulin syringe, throwing it in the black bin before writing some information on the insulin syringe label. She opened the outer packaging of a syringe pump extension set with integral anti-syphon valve, attaching it to the insulin syringe and pressing the plunger of the syringe until a small amount of insulin went through to the syringe pump extension set. She then attached one end of the syringe pump extension set to a Y-connector with dual anti-reflux valves, keeping it in its outer packaging. She then took off the packaging and placed that too in the black bin. Her gloves still on, S returned to her computer and checked the EPR for the prescription. S: The computer is not working. I can't really start anything. Need to wait. She took the gloves off.	Steps to assemble equipment
	0.05.22-0.09.31	Preparing the pump	S entered the patient's bay; the patient was lying on his back. She fixed the insulin driver pump under the fluids driver on the same stand then moved the stand to the patient's bedside. The patient talked with other patients while the nurse fitted the infusion's plugs into the	Preparing insulin/fluids pumps

			sockets behind the patient's bed, taking a minute and a half to do so. The patient was coughing. S: Coughing, you? Patient (P): Yah, yesterday.	
Video 3M	0.00.00-0.00.33	Confirming the hypoglycaemia treatment plan	S: Everyone is looking for you. K: Oh, I'm busy. S: …ME he is … is 3.8 K: Well, you need to treat that with some IV glucose … because you can't start sliding scale until this should corrected. S: Is it like a…? K: Check his prescribe, it will be the drip mmm 20%. While walking to the treatment room, S turned and asked: S: Over 15 minutes? K: Yes.	Treatment of hypoglycaemia
	0.00.34-0.03.47	Assembling equipment and drugs to treat hypoglycaemia	S entered the treatment room and went to check the prescription on the EPR, hovering over the glucose to see the instructions. The information showed Glucose 20% short infusion over 15 minutes via a large vein. S took a pair gloves and took out the Glucose 20% from the cupboard. She went back to her computer, opened the outer packaging of the Glucose, took a blue preparation tray then took the glucose meter out of the blue preparation tray and put it on the computer trolley. Putting the Glucose infusion in the blue preparation tray, she put the gloves, then brought an IV administration set and opened the outer package. She next removed the cap from the cannula end of the IV administration set, removed the seal from the glucose	Steps to treat hypoglycaemia Assemble equipment to treat hypoglycaemia

			infusion and connected the giving set to the glucose infusion by inserting the spike, then squeezed the drip of the giving set until some fluids went in, adjusting the flow control on the administration set as the fluid was running through the drip. She went back to the EPR and checked the patient's medications before going to the cupboard and putting all the tablets in a cup and the cup in the blue preparation tray. She ticked the Glucose 20% on the 'Medication administration' window, then took the blue preparation tray and left the treatment room.	Administer other medications Documentation the antidote administration on the EPR
Video 5M	0.00.00-.0.02.20	Disposing waste and witnessing the order	S went to the treatment room, disposed of all waste in the yellow bin, wiped the blue preparation tray with an alcohol wipe, disposed of the gloves in the bin, then washed her hands with soap and water. She opened the administration window on the EPR and ticked both the fluids and insulin. She hovered over the fluids and a yellow box appeared. Clicking on the yellow box she chose 'Record details' and recorded the site of injection as 'left hand'. She then hovered over the insulin and when the yellow box appeared again chose 'Record details'. The site of injection had been already chosen but the 'Witnessed by' field needed to be filled out. She went out to ask a nurse to witness but the nurse was busy with another patient. S: K:	Documentation of insulin/ fluids administration and witness signing
	0.02.22-0.05.39	VRIII, and IV fluids administration	S then entered the patient's bay. S: 2mls per hour. P: Oh, wow, I thought you meant by mouth.	Inform the patient with treatment regimen

			S: No… P: Yah. S set the insulin rate, which was 2mls/hour on the insulin pump and the screen showed 'On hold'. She put gloves on and attached the insulin and fluids to the patient cannula, setting the fluid rate on the infusion device to 100 ml/hr. She adjusted the insulin pump and the screen showed 'Infusing'. She next took a tape from her pocket and fixed the Y-connector to the patient's hand. She took her gloves, went out of the patient's bay and washed her hands with soap and water.	Setting insulin rate Steps to start VRIII and IV fluids
	0.05.41-0.08.02	Documentation	S opened the EPR and chose 'PowerNote'. She documented the below information at 13:58. **Patient Information:** I care taken at 07:30. **General Clinical Assessment:** Patient alert and oriented**.** Patient NBM from midnight. VRII started at 14:00 at 2ml/hr. BM 10.1. Previous BM 3.8, Glucose 20% given as prescribed. S signed and then clicked on 'Lines-Tubes-Devices'>Peripheral Venous Access. She documented that the peripheral IV site on the left hand condition was healthy, the VIP score 0, and the peripheral line dressing dry, intact and transparent. She clicked on 'Titratable infusions and Pumps' > Titratable Infusions, did not enter anything then finished.	Documentation on the PowerPlan after administration
Video 6M	0.03.45-0.07.09	Flushing cannula	After the nurse had applied a dressing to the patient's right foot, he complained of pain at the cannula site. S held the insulin and IV fluids infusions, washed her hands with soap and water, and brought a flushing fluid and some chlorhexidine alcohol wipes from the blue preparation tray.	Dealing with patient's complain about cannula site (Flushing cannula site)

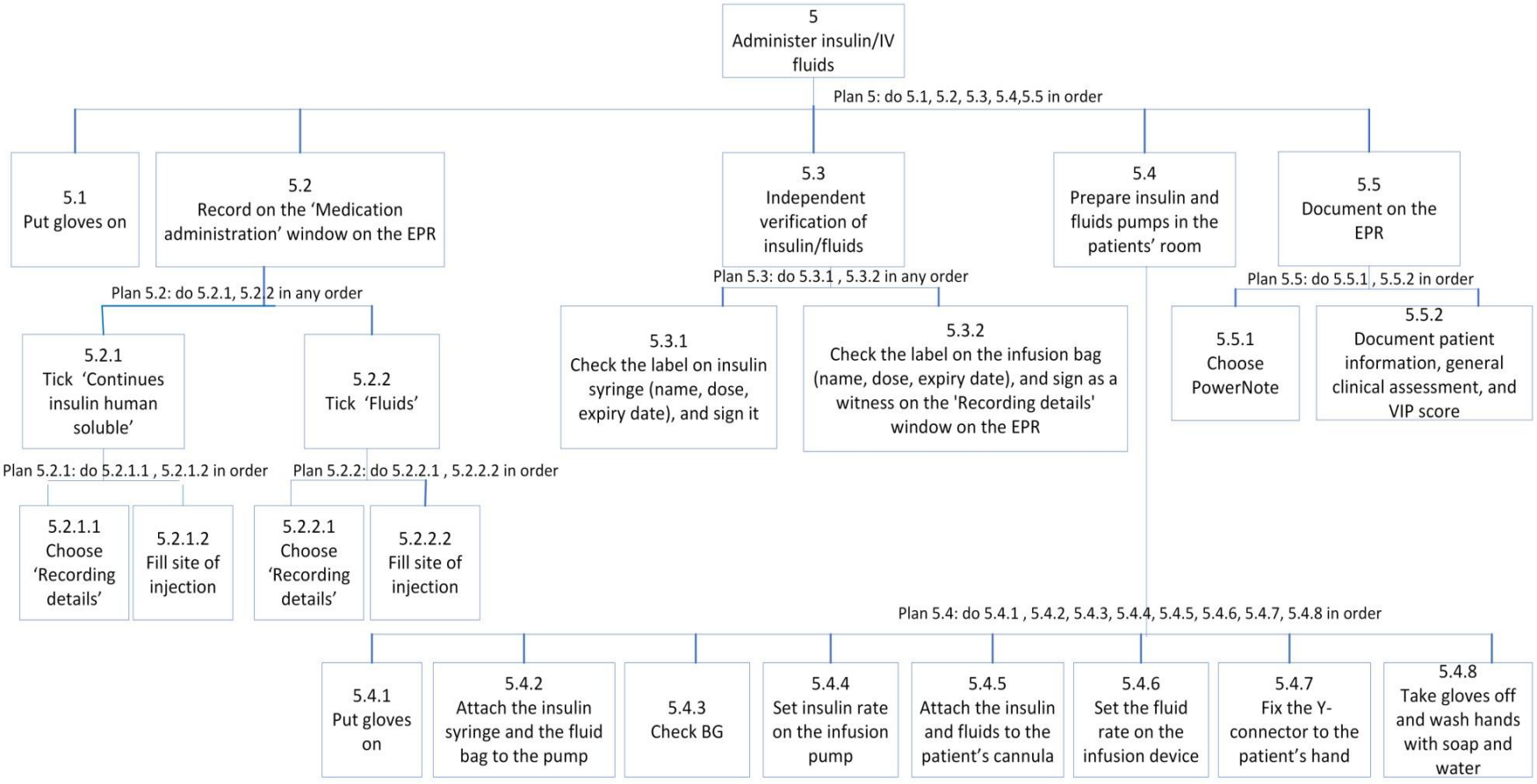
			P: That's come off a bit now. S: I have just stopped it, that's why. S: P: S: Let me try to put a flush through it and tell me if it still hurting. P: Because it … normally hurt … good. S detached the IV administration set from the cannula, closed the port and put the set on the patient's bed. While flushing the cannula on his left hand, she asked: S: How is that? Is it burning? P: No, I can feel it. S: Does it hurt? P: No S: Sting, stinging sensation? P: No, no, just cold. S: OK, let's try again, and tell me if it still hurts. P: S reattached the IV set to the cannula of the left hand after finishing the flush. S: S ran the IV and insulin pumps again. S: Let me know if anything changes. S returned the chlorhexidine alcohol wipes that had not been opened to the blue preparation tray, took the waste with her and left the blue preparation tray in the patient's bay. S: Let me know … you can put on your call button. P: Yah.	

Video number	**Task time and photo**	**Task**	**Transcription**	**Coding**
Video 1A	0.00.00-0.02.42	BG checking	Two nursing assistants were in the patient's bay. The patient was sleeping. He was on VRIII 2 units/hr and IV fluids infusion (KCL 0.15%, NaCL 0.18%, Glucose 4%) at a rate of 100ml/hr. There was a trolley that had a glucose meter, yellow box, and a white box that had cotton wool balls, BG reagent strips and lancets. Both nurses had their gloves on. N1 dampened a cotton wool ball, opened the white box and took a BG reagent strip. N1: I'm just going to check your BS, is that OK? The patient raised his hand in a way that showed he was ready to have his BS checked. N1 scanned her ID using the glucose meter and did patient identification by scanning the wristband. She then scanned the BG reagent strip and inserted it into the glucose meter. She opened a blood lancet, threw the cap in the yellow box and with the wet cotton wool ball wiped the puncture site on a finger of the patient's right hand. Another nurse come into the bay but left immediately when she realised the camera was on. N1 pressed the release button of the lancet and squeezed the patient's finger until a drop of blood appeared, then brought the meter with the strip and checked the patient's BG. N1: 17.1. She threw the strip in the yellow box and said: N1: I'll do another one.	Equipment prepared for BG monitoring Asking for permission from the patient Patient identification Steps to check BG Checking ketone level

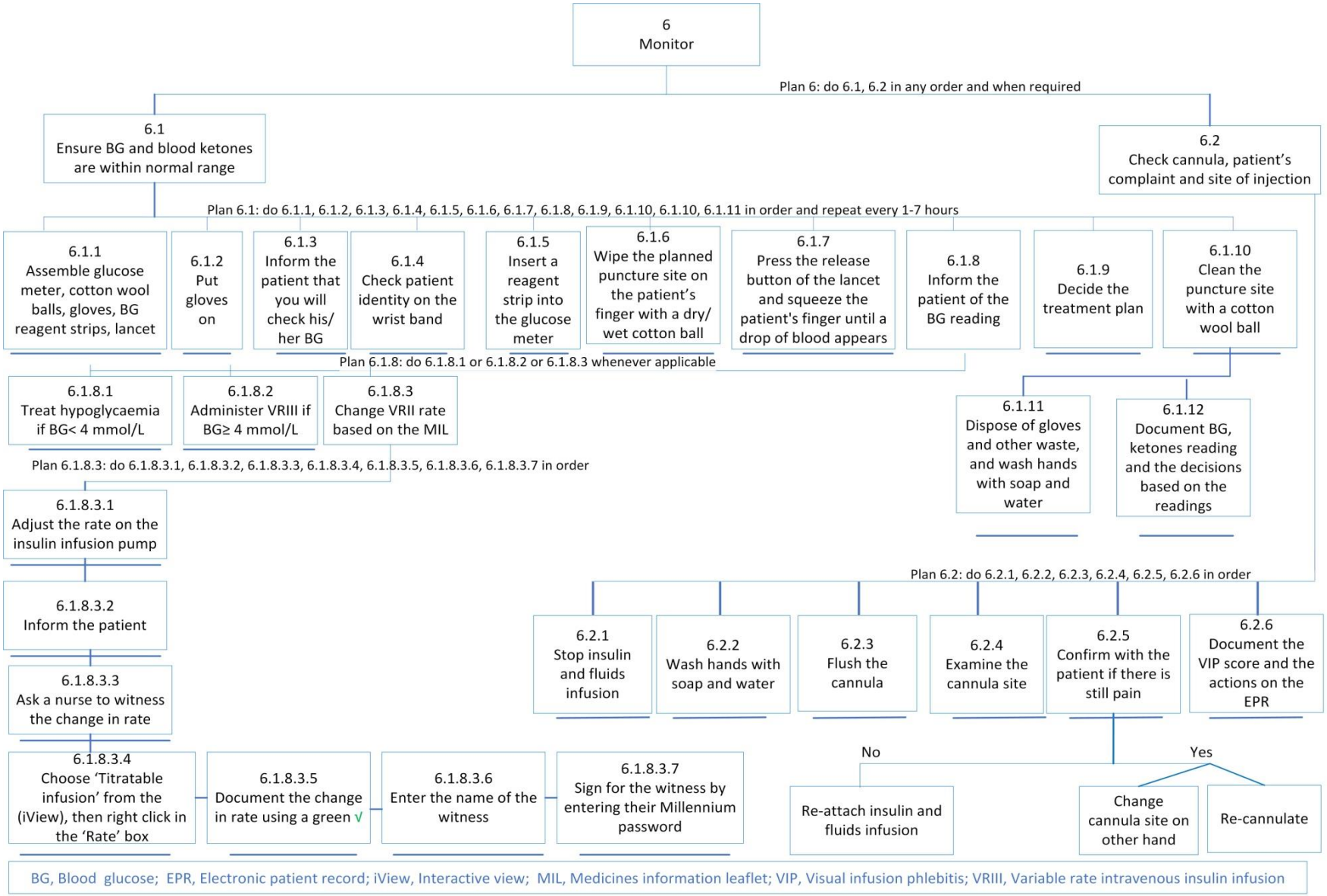
			She checked the patient wristband again while keeping pressure on the patient's finger. N1: Can I have a…? The other nurse (N2) handed a strip to N1, who scanned the outer packaging of the strip. N1 inserted the strip into the meter and again checked the patient's BS. N2 handed some tissues to N1, who used one to clean the patient's finger. N1 looked at the meter but did not read out the number [I think the reading was the same as in the first trial]. Both nurses took off their gloves and throw them in the bin. N2 was talking to a deputy sister (N3), who was sitting on her computer at the entrance of the patient's bay, about the glucose readings: N2: 17.1 and 0.3. N2 then signed a yellow paper.	Informing a deputy nurse about BG and ketone levels
	0.02.43- 0.05.29	Changing the rate of VRIII	The VRIII rate was 2 ml/hr. N3: I am gonna to change it, the rate. Adjusting the insulin infusion pump, she said: N3: Hello Arthur. Your BS is up again. That is after the lunch. What did you have for lunch? The patient was looking at N3 but didn't talk. N3: So I get to change it again, OK? N3: It is fine, nothing to worry about. N3 changed the infusion rate to 3 ml/hr. N3 then went to her computer and said: N3: I am going to change it here (on the EPR). She was trying to find where she could change the rate from. N3: No, this is not the one.	Informing patient about VRIII rate change Documentation of rate change on EPR

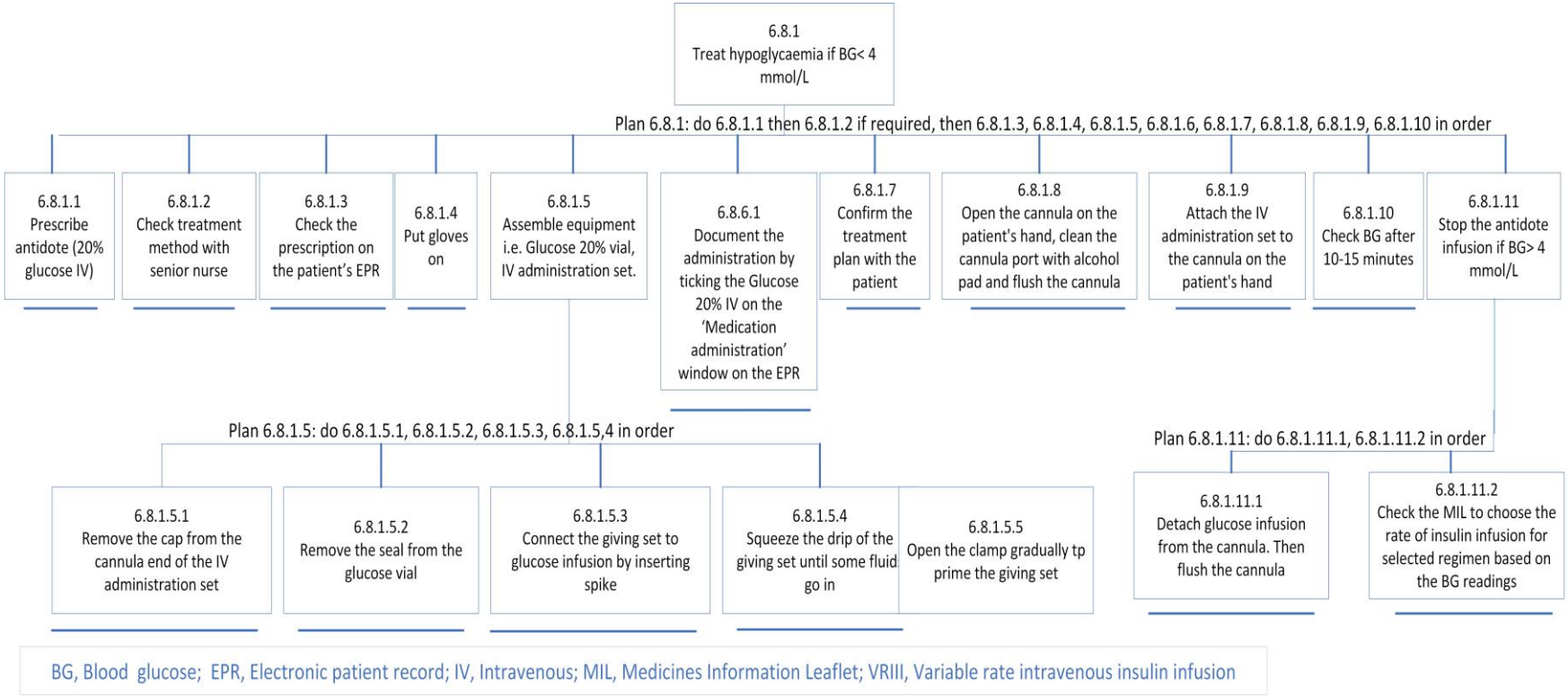
			She asked another nurse who was standing behind her. N3: Would you mind to signing? I changed the rate. She was trying to find the proper page. N3: Interactive view. The other nurse showed her where to click on the screen. SN3 right-clicked on the 'Rate' box and entered '3ml/hr at 13:35 pm'. N4: Then press enter. Then click on the green one. A box for entering the name of the witness appeared. N3: [the witness name]? N4: Yes. N3 entered the witness name then N4 put in her Millennium password.	Witness for changing VRIII rate

Supplementary File 3: Hierarchical task analysis diagrams for Work as Done in the use of variable rate intravenous insulin infusions



BG, Blood glucose; EPR, Electronic patient record; VIP, Visual infusion phlebitis


6
Monitor
Plan 6: do 6.1, 6.2 in any order and when required
6.1
Ensure BG and blood ketones are within normal range
6.2
Check cannula, patient's complaint and site of injection
Plan 6.1: do 6.1.1, 6.1.2, 6.1.3, 6.1.4, 6.1.5, 6.1.6, 6.1.7, 6.1.8, 6.1.9, 6.1.10, 6.1.10, 6.1.11 in order and repeat every 1-7 hours
6.1.1 Assemble glucose meter, cotton wool balls, gloves, BG reagent strips, lancet
6.1.2 Put gloves on
6.1.3 Inform the patient that you will check his/ her BG
6.1.4 Check patient identity on the wrist band
6.1.5 Insert a reagent strip into the glucose meter
6.1.6 Wipe the planned puncture site on the patient's finger with a dry/ wet cotton ball
6.1.7 Press the release button of the lancet and squeeze the patient's finger until a drop of blood appears
6.1.8 Inform the patient of the BG reading
6.1.9 Decide the treatment plan
6.1.10 Clean the puncture site with a cotton wool ball
Plan 6.1.8: do 6.1.8.1 or 6.1.8.2 or 6.1.8.3 whenever applicable
6.1.8.1 Treat hypoglycaemia if BG< 4 mmol/L
6.1.8.2 Administer VRIII if BG≥ 4 mmol/L
6.1.8.3 Change VRII rate based on the MIL
6.1.11 Dispose of gloves and other waste, and wash hands with soap and water
6.1.12 Document BG, ketones reading and the decisions based on the readings
Plan 6.1.8.3: do 6.1.8.3.1, 6.1.8.3.2, 6.1.8.3.3, 6.1.8.3.4, 6.1.8.3.5, 6.1.8.3.6, 6.1.8.3.7 in order
6.1.8.3.1 Adjust the rate on the insulin infusion pump
6.1.8.3.2 Inform the patient
6.1.8.3.3 Ask a nurse to witness the change in rate
6.1.8.3.4 Choose 'Titratable infusion' from the (iView), then right click in the 'Rate' box
6.1.8.3.5 Document the change in rate using a green √
6.1.8.3.6 Enter the name of the witness
6.1.8.3.7 Sign for the witness by entering their Millennium password
Plan 6.2: do 6.2.1, 6.2.2, 6.2.3, 6.2.4, 6.2.5, 6.2.6 in order
6.2.1 Stop insulin and fluids infusion
6.2.2 Wash hands with soap and water
6.2.3 Flush the cannula
6.2.4 Examine the cannula site
6.2.5 Confirm with the patient if there is still pain
6.2.6 Document the VIP score and the actions on the EPR
No
Yes
Re-attach insulin and fluids infusion
Change cannula site on other hand
Re-cannulate
BG, Blood glucose; EPR, Electronic patient record; iView, Interactive view; MIL, Medicines information leaflet; VIP, Visual infusion phlebitis; VRIII, Variable rate intravenous insulin infusion

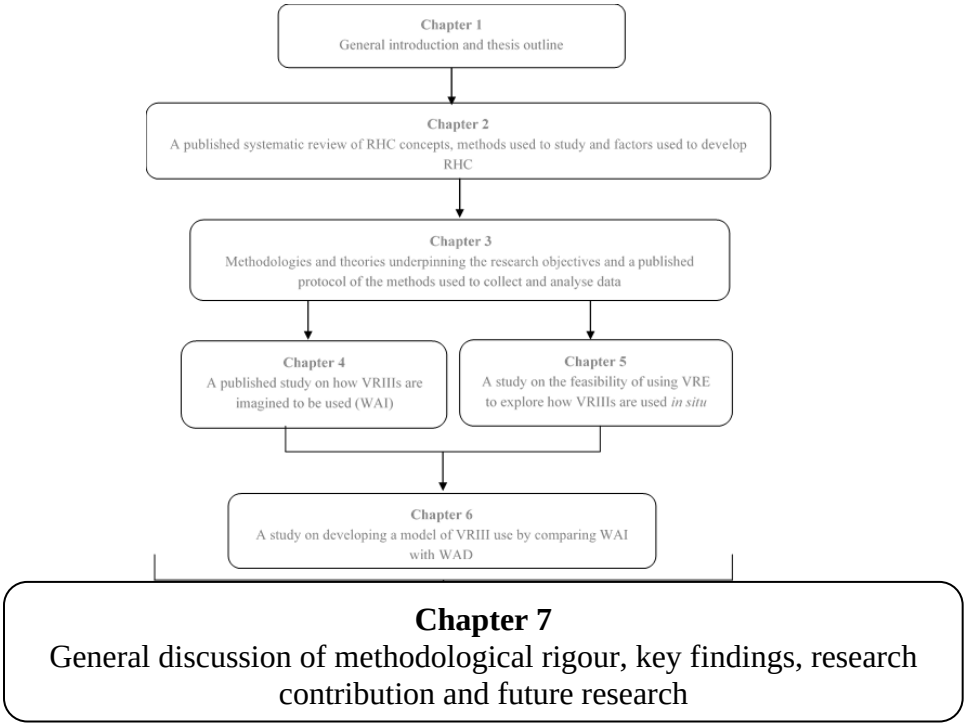


BG, Blood glucose; EPR, Electronic patient record; IV, Intravenous; MIL, Medicines Information Leaflet; VRIII, Variable rate intravenous insulin infusion

Chapter 7

General discussion

Chapter summary: In this chapter the strategies used to ensure methodological rigour are presented. The main thesis findings and their contribution to research and clinical practice are discussed. Finally, future research to improve VRIII safety is proposed.



7.1 Introduction

The use of VRIII is clinically complex, multifaceted and multidimensional. It encompasses numerous factors, e.g. comorbidities, co-administration of other medications, BG monitoring frequency and lack of clinical knowledge regarding the use of VRIII – all of which constantly interact in ways that are often unpredictable [1]. Errors during the prescription, preparation and administration of VRIIIs are common and are associated with significant risk and could be lethal [2].

The importance of improving the quality and safety of diabetes care and insulin use in hospitals has been placed as a national priority [3]. This research is particularly timely in light of the findings of the NaDIA national report (2020) which found that 30% of inpatients with diabetes across England experienced insulin-related medication error during their hospital stay [4]. The importance of this research is further illuminated by the national patient safety syllabus 1.0 which recognises the importance of thinking differently about patient safety by incorporating proactive system approaches to identify and prevent harm before occurrence [5]. This thesis explored the complexity in the use of VRIII by incorporating a key RHC construct which focuses on proactively identifying the gap between WAI and WAD, and incorporates recommendations for how they may be realigned.

In this chapter, I will present how methodological rigour was maintained throughout the research process (section 7.2). The key findings and unique contributions of the thesis are discussed in section 7.3. Finally, section 7.4 presents suggestions for future research in areas of RHC and VRIII safety.

7.2 Methodological rigour

Quantitative research uses specific criteria to assess rigour, such as reliability, objectivity and internal and external validity [6]. These criteria are not appropriate for assessing the quality of qualitative research. To assess the quality and trustworthiness of qualitative research, Lincoln and Guba (1985) suggested criteria such as credibility, dependability, confirmability and transferability [7]. The following sections discuss how quality and trustworthiness were

maintained throughout the present research by using the Lincoln and Guba (1985) criteria along with an additional criterion: reflexivity.

7.2.1 Credibility

Credibility is concerned with establishing confidence that the research results are true, believable, extracted from the participants' original data and truly representative of the participants' perspectives [8]. Various strategies are suggested to ensure credibility in qualitative research, including triangulation, persistent observation, prolonged engagement and member checking [8, 9].

Triangulation

Triangulation is the process of using multiple approaches to understand a given phenomenon, an example being methodological, theoretical and data-source triangulation [10, 11]. Methodological triangulation was addressed in this study by taking a mixed-methods approach to understanding WAD, as described in detail in Chapters 5 and 6. Theoretical triangulation was represented in this research by combining RHC theoretical constructs with VRE theoretical principles to understand WAD in the use of VRIII (Chapter 5). Lastly, numerous data sources were used, among them focus groups, hospital documents, video observations, field notes and patient medical records (Chapters 4, 5 and 6). Data source triangulation was also obtained by including participants' accounts presented in the reflexive meetings (Chapter 5) to inform the researcher's understanding of the use of VRIII.

Prolonged engagement and persistent observation

The purpose of investing sufficient time with participants in the field is to become acquainted with the context, to build trust with the participants, to identify relevant elements on which to focus while conducting the research and to generate an authentic picture of the study setting [10, 12]. The researcher had a continuing engagement with the Unit's clinical and managerial leads as well as the healthcare practitioners, over a period of two years. She joined several meetings in order to meet as many healthcare practitioners as possible. The researcher also familiarised herself with the healthcare environment by using data from focus groups

conducted with participants working in the unit, which provided insights and helped identify areas of work using VRIII on which to focus during the video observation stage. Chapters 4, 5 and 6 illustrated how this prolonged engagement and persistent observation were applied.

Member checking

According to Schein (1987), member checking relates to the researcher's aim of gathering feedback from participants on the researcher's interpretation of the data obtained from them [13]. In this study, member checking was conducted by asking three healthcare practitioners from the study hospital to establish the fit between the participants' views and the researchers' interpretation of the final HTA diagrams that represent both WAI and WAD. The developed model for the use of VRIII was also discussed with one of the Medicines Safety team in the study hospital to evaluate its applicability.

7.2.2 Transferability

Transferability describes the degree to which research findings are applicable in other contexts and settings [7]. To ensure transferability, a detailed description of the participants, the study setting, and the research process need to be provided, in order to enable the reader to assess if the research could be transferable to their own work [10]. Transferability was made possible in this research by developing a comprehensive research protocol (Chapter 3) which provided a detailed description of the study's setting (itself described in Chapter 1), sampling strategy, recruitment, eligibility criteria, focus groups and reflexive meeting discussion guides, and ethical considerations. Further details on the participants' invitation letters, participants' information sheets and consent forms used during the research, are presented in Appendices A, B and C at the end of this thesis. Detailed descriptions of the data analysis, the codes and themes developed for interpreting focus groups, the reflexive meetings, and the vignettes from video transcripts, were used to illustrate key findings for this study and also served as support for the results of the study (see Appendices and Additional Files to Chapters 4, 5 and 6).

7.2.3 Dependability and confirmability

Dependability includes ensuring that results are repeatable and the analysis process is based on accepted standards [7] and focuses mainly on consistency [10]. Confirmability focuses on neutrality and implies that the findings should be based on the study data rather than on researchers' own views or preferences [10]. One strategy to ensure dependability and confirmability is known as audit trail [7, 9]. Audit trail focuses on transparently presenting all research steps from the start of the research design development until the interpretation of data and results [14]. This strategy allows other researchers to assess replicability by following the trail and comparing it with their own interpretation, in order to ensure that the findings are clearly derived from the data and not from the researcher's preconceived ideas [9, 10]. In this research, steps were taken to keep a record of the data-collection process, which was continually discussed with the research team in order to ensure it adhered to the study protocol. The research team (MI, RL and KR) independently reviewed and coded the focus group transcripts, and (MI and RL) also independently coded a sample of the video reflexive meetings. The developed codes and themes were discussed with the wider research team (MI, RL, CC, FG, RI) and the detailed coding and analysis of the transcripts were submitted with the published studies and were reviewed by external reviewers from the publishing journals.

7.2.4 Reflexivity

Reflexivity is the process of critically and sensitively acknowledging the researcher's prior assumptions and experience in shaping the data collection, analysis and interpretation [9, 15]. Reflexivity is a key factor in developing knowledge in qualitative research in general and in ethnography and VRE in particular [9, 16]. Iedema *et al.* suggested that researcher reflexivity is critical to underpinning attempts to enhance safety using VRE, as the researcher's position will inevitably have a fundamental contribution to the outcomes achieved [16]. The researcher embraced reflexivity by acknowledging her background in diabetes management and qualitative research (Chapters 4, 5 and 6), her previous experience, and personal views that emerged during the research period while compiling reflexive notes for focus group and reflexive meeting discussions and video observations (Chapter 5).

7.3 Main findings and thesis contribution

7.3.1 Main research findings

The chief findings of this thesis are summarised under four main themes: 1. the use of VRIII is far more complex than providing national guidance (Chapter 4); 2. the use of VRIII: standardised practices and context-dependent adaptations (Chapter 5); 3. lack of clinical knowledge as the main challenge, and continuous training as a main strategy for overcoming this challenge (Chapters 4 and 5); and 4. model development of VRIII use (Chapter 6). Table 7.1 gives an overview of the main findings under each theme.

Table 7.1: Summary of the main research findings.

1. The use of VRIII is far more complex than providing national guidance	Producing hospital-specific guidelines was an iterative process in which different stakeholders/users were engaged to ensure guidelines were relevant to their local hospital. The guidelines were written in a technical way that not every healthcare practitioner could understand unless they were very experienced in hospital work generally and insulin use specifically. The study site used a multi-pronged approach to ensure the implementation of the VRIII guidelines using various strategies, e.g. ensuring the availability and accessibility of the guidelines on the hospital intranet, using clinical audits, feedback and continuous training.
2. The use of VRIII: standardised practices and context-dependent adaptations	Context-dependent adaptations (administering 20% IV glucose and then checking if it was prescribed to prevent a delay in treating hypoglycaemia) and standardised improvements developed by the hospital (e.g. availability of VRIII guidelines) were the most described and observed strategies employed while using VRIII.
3. Lack of clinical knowledge as the main challenge, and continuous training as a main strategy for overcoming this challenge	The use of VRE methodology was a useful approach that helped healthcare practitioners discuss their work and its challenges and reach solutions tailored to their work. The most common challenges were mainly related to lack of clinical knowledge in relation to prescribing the appropriate IV fluid, discontinuing other diabetes medicines and treating hypoglycaemia.

	Training junior doctors in how to prescribe using the PowerPlan, ward-based training (10-minute espresso teaching) and e-learning courses, were approaches used by the hospital to facilitate the use of VRIII. However, more VRIII- focused and face-to-face training was suggested to overcome the challenges healthcare practitioners face.
4. Model development for VRIII use	The comparison between WAI HTA and WAD HTA resulted in the development of a model of VRIII use. The model showed that standardisation (WAI) and flexibility (context-dependent adaptations) must complement each other to ensure the delivery of better patient care while using VRIII. The model highlighted two key points: 1) The permanence status of adaptations is crucial to differentiating between work that has long-term or short-term success. 2) A starting point to assist in reviewing work and effectively implement interventions is to apply monitoring tools correlated to the type of tasks and situations being reviewed.

7.3.2 Contribution of knowledge and recommendations

Despite increased efforts and technological improvements to increase patient safety when treating elevated BG using VRIII, evidence indicates that widespread improvements have not occurred. A possible explanation is that this may be due to a mismatch between the approaches and interventions employed, and the real nature of the system to which they are applied. The challenge is therefore how to successfully shift the focus from process-oriented, technical solutions towards greater understanding of the system, its complex adaptive nature, and the crucial role of healthcare practitioners in ensuring the successful delivery of patient care under a wide range of circumstances. The contribution of this thesis to research and clinical work, as well as some general recommendations for improving the use of VRIII in a clinical environment, are presented in the following sections.

7.3.2.1 Contribution to research

The findings presented in Chapters 4, 5 and 6 make several contributions to the current literature, of which three are of particular significance and are therefore described here.

The novel use of HTA to systematically represent WAI and WAD

The complexity in medicine is context-dependent [17] and needs to be functionally decomposed into tasks in a way that is comprehensible to researchers and all stakeholders in a system [18]. The first contribution is the use of HTA, for the first time, to provide a comprehensive view of treating elevated BG using VRIII by providing a detailed description of how work should be done (Chapter 4) and how work was in fact done *in situ* (Chapter 6). The task decomposition resulting from the WAI and WAD HTAs, supported by the video reflexive meeting results presented in Chapter 5, was also used as a cornerstone to model the use of VRIII.

HTA has a solid tradition in healthcare research studies. Yu *et al.* (2014) used HTA to describe surgical procedures in detail and to identify variations among techniques used by surgeons [19]. Razak *et al.* (2019) conducted a study in a UK-based hospital that used HTA to compare WAI and WAD in the Emergency Department in response to Chemical, Biological, Radiological, and Nuclear events [20]. Ashour *et al.* (2021) used HTA as a framework for exploring the gap between how dispensing medication in community pharmacy settings was imagined to be accomplished and how it was actually done in practice [21]. Although, the use of HTA in these earlier studies decomposed tasks at more detailed structural levels, it did not show the interactions within and across different levels [22, 23]. In contrast, Patriarca *et al.* (2018) used HTA to support modelling of WAI activities, which supported the subsequent FRAM modelling used to analyse complexity in the neurosurgery peri-operative patient's pathway [23].

In this thesis, the developed HTAs facilitated the comparison of WAI with WAD in a systematic, unified and more practical way which enhanced the identification of alignments and misalignments in task performance. The developed HTAs facilitated task visualisation for both WAI and WAD which could act as artefacts to facilitate understanding how several plans were used to achieve the overall goal. This visualisation may also be useful for enhancing system (re-)design and usability of electronic systems. This could be achieved by explicitly representing how the system is functioning while using VRIII in relation to the users, specifying the tasks required, their sequence and their allocation [24].

The innovative use of VRE to explore the use of VRIII

A second contribution is Chapter 5's innovative use of VRE to explore WAD in the use of VRIII. Although there is clear understanding of the key principles that guide VRE [16], there is a need for understanding the feasibility of VRE's successful delivery in a clinical context specific to VRIII. In Chapter 5, the findings indicated that it was feasible in terms of recruitment strategy, data-collection procedure, and participants acceptability, to use the VRE to explore the use of VRIII in the Vascular Surgery Unit. VRE has been more commonly used in research, and has a track record of delivering practical changes and improvements in healthcare [25]. Challenges faced during the recruitment and data-collection stages echoed previously reported challenges using VRE, such as awareness of the camera's presence potentially affecting healthcare practitioners' performance, concerns about patient privacy and confidentiality, and the difficulty of arranging for all the healthcare practitioners who appeared in the video recording to participate in the same reflexive meeting [25-27].

The successful use of VRE methodology to understand WAD was contingent on adapting the delivery of this method to the local context. In keeping with the RHC complementary perspective of learning from incidents as well as understanding how everyday clinical work is performed successfully [25], the use of VRE methodology did not ignore the negative organisational aspects. Rather, it represented an alteration of the researcher's emphasis, from taking what went wrong as the starting point to learning lessons from ordinary work that was, most of the time, accomplished well [31].

Several studies used RHC principles to identify quality improvement interventions in emergency departments [28], to examine the nature of adaptations throughout the blood transfusion process [29], and to explore sources of performance variability for intravenous infusion administration [30]. The methods used in these studies to explore WAD were mainly based on field observations and interviews [28-30]. These methods do not give a complete and visual picture of work and do not allow for data validation from the perspective of the participants [31]. In contrast, the novelty of using VRE resides in the 'nothing about us without us' element [32], meaning the examination of WAD was not based solely on the researchers' analysis of the video data but included a fundamental contribution to the analysis

of their work by the healthcare practitioners who were recorded. The approach employed in this thesis to explore the use of VRIII in everyday work might well be one of the first attempts to thoroughly examine WAD in other clinical areas.

A model of VRIII use

Turning to the third main contribution of this thesis to the literature, the comparison between WAI and WAD assisted in developing a model of VRIII use (see Figure 3, Chapter 6). The model provided in-depth understanding of the RHC concept through context-based clarifications and additions relating to the use of VRIII and elaborated insights relating to improvements and interventions. Based on the results illustrated in the developed model, the researcher used the term 'tempering-fortification' to describe and discuss the model.

'Tempering' is a term used in various fields, e.g. iron-based alloys and chocolate manufacture, to describe processes that are used to enhance resilience through hardship [33]. In this clinical context of using VRIII, the term is intended to represent the strategies used by healthcare practitioners and systems to deal with expected and unexpected situations. This can be seen in most of the observed context-dependent adaptations, e.g. when one nurse did not administer the intermediate acting insulin to the patient even though it had not been suspended by the SpR on the electronic prescribing system. Tempering strategies tend to produce immediate strength by realigning skills and abilities and get work done. However, some tempering could produce unsafe work that simultaneously makes the system brittle and more liable to failure. In accordance with these results, previous studies have shown that when adaptations are used there is a possibility of having positive consequences, e.g. solving problems and preventing harm [29, 34, 35], as well as negative ones, e.g. practitioners asking colleagues to access health information exchange systems, resulting in many clinical decisions being based on incomplete information [36, 37].

'Fortification' is also a term used in other fields, e.g. the military [38], neurobiology and psychology [33], and is employed in this study because it explains the other type of strategies that were observed to enhance the delivery of patient care. Fortification strategies are those used to make work stronger, protect against potential or actual risks and in this case counter the brittleness that may be produced by tempering [33]. Such strategies included proactive,

planned adaptations, i.e. administering the antidote before checking the prescription to prevent delay in treating hypoglycaemia and the use of ready-to-administer insulin syringes, which improved the work of using VRIII and enhanced patient safety by decreasing both the error rate and the time needed for accomplishing tasks. This suggests that fortifications can be mobile and dynamic rather than following the traditional idea of a defensive wall that is static.

Compared to previously developed resilient models in healthcare systems [29, 39], the one described in this thesis represents a reconceptualisation of the RHC concept, which had mainly focused on the ability of the system to adapt to and sustain required operations under both expected and unexpected conditions. The RHC concept has often been misconstrued, as adaptations have been regarded as being opposite to control, the implication being that the two cannot coexist [40]. The reconceptualisation of RHC based on the results of this thesis, focuses on using 'tempering-fortification', a term combining what are in my opinion the two principal strategies used to strengthen systems and enhance their resilience and safety.

7.3.2.2 Recommendations to clinical work

In this section, three specific areas were identified and recommendations made that could contribute to better patient care while using VRIII. The three identified areas are top-down and bottom-up approach to embrace complexity; RHC and adaptive capacity; and combining process-oriented with goal-oriented strategies. These recommendations were shared with the guideline developers' team at the hospital Trust in their annual meeting to update the guidelines.

Top-down and bottom-up approach to embrace complexity

The hospital Trust used various resources and approaches to produce and implement VRIII guidelines and ensure their proper use. However, the use of VRIII is not only about implementing guidelines but also about how work is accomplished *in situ* and whether healthcare practitioners actually use the guidelines. Key issues therefore needed to be considered when developing the guidelines in the study hospital, such as who they are intended for, whether they would actually be used, and how they should be designed and

delivered to ensure their information would make sense to users in relation to the work they have to do.

A recent study compared the effectiveness of the current NHS Injectable Medicines Guide (IMG) with that of an IMG version revised in light of user-testing [41]. A single-blind, randomised parallel group *in situ* simulation experiment with nurses and midwives who prepare and administer intravenous infusions was conducted. The study found that, although there was no significant difference in moderate-severe IMG-related errors between the user-tested guidelines compared with current guidelines (risk ratio: 0.82; 95% CI 0.66 to 1.02), there were significantly more simulations completed without any IMG-related errors with the user-tested guidelines compared with current guidelines (risk ratio: 2.46; 95% CI 1.68 to3.60). The use of user-tested guidelines resulted in more confidence in preparing and administering IV infusions among nurses [41]. Although the study site engaged a range of users (consultants, junior doctors, pharmacists and inpatient adult specialist nursing team) and used emails to get users' feedback on the new guidelines and to share them, and answer any queries arising from them, with other users, this process could be enhanced. Based on findings in Chapters 5 and 6 of this thesis, the actual healthcare practitioners present while VRIIIs were being used were registrars, junior doctors, registered nurses and NAs. These healthcare practitioners were busy most of the time and sending emails to get their feedback or questions about the new guidelines might not prove efficient, given that healthcare practitioners may be unable to respond promptly because of their workload. I would suggest that the guideline developer team conduct group discussions with healthcare practitioners (especially registrars, junior doctors, registered nurses and NAs), in different units, to help revise the VRIII guidelines and to carefully consider their feedback about retrieving and understanding the relevant information in order to ensure the guidelines produced are both locally derived and practical.

Implementation strategies used at the hospital Trust must be adapted to the clinical context and be more contemplative and reflective if their success and sustainability are to be guaranteed. This could be achievable by having a double-loop learning and feedback process [42, 43] rather than only single-loop learning. Engaging different users to understand everyone's job would help in co-creating new descriptions of how work is performed using VRIII rather than focusing on specific cases (errors, incidents), which would in turn help to bring learning to a

higher level. Multidisciplinary participation with 'the whole system in the room' (a concept from 'appreciative inquiry' [44]), is important to understanding how work is actually done, gathering information and experiences from various perspectives, and creating agreement on the feasibility of change.

In the hospital studied in this thesis, training was one of the strategies used to implement the guidelines. Most of the training, for example e-learning, 10-minute espresso sessions, posters and handbooks, focused on diabetes treatment in general, not VRIII and the basic needs of healthcare practitioners. Therefore, it is imperative that healthcare practitioners themselves define the scope of their work with the clarity needed for harmonised, tailored training and development plans [45]. Understanding WAD and the needs of healthcare practitioners may ease the demand on system resources as well as satisfying healthcare practitioners' needs.

Lastly, reflecting on my perspective as a clinical pharmacist with experience in diabetes management in hospitals, a recommendation about the VRIII guidelines' wording and presentation was also suggested. I suggest providing a concise definition of Tailored Regimen, and highlighting that the Tailored Regimen could be used if the patient is on Standard or Increased Regimen and failing to achieve the target CBG range. I further suggest adding a definition to the table, showing the rate of VRIII based on BG readings, to flag that Tailored Regimen should be used if BG is persistently low on Reduced Regimen or persistently high on Increased Regimen.

RHC and adaptive capacity

Evidence strongly suggests the necessity of understanding and increasing the adaptive capacity to respond, anticipate, monitor and learn to develop a bank of knowledge about the use and effectiveness of adaptations [28, 36, 46]. In this research, knowledge about how adaptation was developed, and its effectiveness in the context of using VRIII, was explored. The comparison between WAI and WAD directed my attention to two key findings that warrant consideration: the permanence status of the adaptations and the resultant outcomes. Planned, permanent adaptations were used by healthcare practitioners to ensure patient safety and improve the delivery of patient care. The hospital Trust can assimilate this type of adaptation and, without considering it a deviation from standard practice, use it to redesign the

guidelines. Forced, permanent and temporary adaptations were used by healthcare practitioners because no solution was available. The hospital Trust needs to investigate both proximal and distal outcomes emerging from these types of adaptations, which cannot be expected to have a long-term (distal) effect on the success of the system, and indeed might increase its brittleness. Monitoring CBG every hour proved hard to achieve given the increased workload and shortage of nurses. One suggestion could be around providing clearer guidance on an acceptable window for BG monitoring frequency based on the patient's case and the stability of their BG readings. For example, monitor BG every hour; if four consecutive readings are within the target range, then reduce the frequency of monitoring to two-hourly and return to hourly monitoring if BG moves outside the target range [47].

Combining process-oriented with goal-oriented strategies

A starting point to assist in reviewing work and effectively implement interventions, is to apply monitoring tools correlated to the types of tasks and situations being reviewed [48]. The hospital Trust used various methods to review clinical work, e.g. quality improvement (QI) projects, clinical audits, feedback and incident reports. These methods are useful for simple e.g. performing hand hygiene and complicated tasks e.g. prescribing IV fluids with VRIII in which the goal is more process-oriented. Given the complexity that was found in the use of VRIII and how unpredictable situations emerged, it is imperative to think about adding goal-oriented methods focusing on functions and variability, e.g. FRAM [49], and engaging healthcare practitioners to explore the taken-for-granted work, e.g. VRE [50], in order to understand and investigate complexity in everyday work. Translating these methods into healthcare is difficult to achieve with the resources currently available. The NHS needs a clear shift in its safety strategy towards embedding safety professionals who are aware of the depth and breadth of these methods and are able to act as part of a healthcare system in which they are able to learn from adaptations and adjustments, suggest more context-related solutions and interventions, and engage in system design which will in turn help in realigning WAI and WAD and decreasing the gap between the two [51, 52].

7.4 Future work

The work described in this thesis is the first to use RHC principles as a basis for developing a model of VRIII use in adult hospitalised patients. However, further research should be carried out to provide better understanding of the human aspects in relation to the use of VRIII. This would include the role of patients and their families in the delivery of patient care, the communication between different stakeholders and the importance of people's perspectives involved in, and empowered to maintain, safe delivery of patient care using VRIII. Further research also needs to focus on representing a wider picture of how VRIII is used *in situ* and what strategies are needed to enhance the safe delivery of patient care. Finally, VRE has an interpretive as well as transformative nature in which it can simultaneously act as methodology and intervention [32, 53]. While it was not within the scope of this thesis to investigate the effect of using VRE as an intervention to change work, it is foundational for future research to go beyond simply using VRE and progress to understanding complexity, in order to explore how VRE could collaboratively empower healthcare practitioners to improve their work. Below I will discuss further some specific suggestions for future research. In this thesis various ways of ensuring the rigour and diversity of data sources have been used. However, ensuring diversity of perspective may also benefit from patient and family involvement [54, 55]. A previous study highlighted the importance of engaging cardiology patients with their discharge medications process in order to identify system vulnerabilities and develop self-management strategies for reducing the risk of medication errors [56]. Another study that engaged patients and family members found that this engagement served as an active agent in decision-making and knowledge-sharing activities in the discharge process [57]. Thus, further research is vital to investigate how the active involvement of patients and families in the study of everyday work may affect our understanding of RHC while using VRIII.

Patient and Public Involvement (PPI) is considered best practice and is required when changes to everyday work are proposed [58]. Healthcare practitioners were engaged in deciding how best to video-record themselves and the patients, but patients and/or their carer were not included in the early stages of the design or the research conduct because the focus was on understanding how the tasks related to VRIII use were delivered by healthcare practitioners.

INVOLVE is an NHS National Institute for Health Research advisory group that distinguishes between the roles that public and patients can have in health and social care research [59]. Previous studies highlighted the value of involving patients at various stages of research design and conduct [60, 61]. For example, Furniss et al. (2016) showed that PPI had a great impact by providing feedback on the patient information sheets, thereby improving the clarity of these, and by enabling PPI to share experiences about their medications which helped extend the focus of the study to include other factors that might affect the quality and safety of intravenous medication safety research [60]. Another study highlighted the value of extending the PPI involvement beyond agenda setting and protocol development into greater involvement in data collection by helping researchers in conducting observations which added new perspectives to the data collected and the consequent findings [61]. Future work can focus on encouraging patients, carers or patients' representatives with experience of using VRIIIs in hospitals to share their experiences about their treatment, a step that could extend the research focus to include other factors relating to the safety of using VRIIIs. PPI could be introduced into future work by the participation of patients and public in the early stages of designing and shaping the research, e.g. soliciting their advice on how VRE methodology should be conducted, reviewing patient information sheets, gathering data and views about WAI and WAD from the patient perspective, and informing the analysis of video reflexive meetings by allowing these stakeholders to engage with healthcare practitioners in analysing everyday work.

In this thesis, the research was conducted in one unit in the hospital (the Vascular Surgery Unit) where VRIII was used on a daily basis; however, there were other units in the hospital that used VRIII. Furthermore, this thesis explored one snapshot in time with respect to the use of VRIII in everyday clinical work which was limited to 13 hours of video recordings made during the daytime, which meant not all tasks performed were captured. It also limited the focus on capturing work during the daytime, which might be different from work at night with different healthcare practitioners and workload. However, it is important to note that the researcher spent 15 hours of informal observations familiarising herself with the study setting, time she used in a reflexive way to decide how the data would be interpreted.

Thus, there is room for further progress by: 1) Replicating the methods used to explore WAD across many units in the study site and across different hospitals, thus providing a more comprehensive insight into how work is accomplished while using VRIII to better inform policy makers and clinical work. 2) Validating the model of VRIII use as a framework to help healthcare practitioners cope with everyday complex work while using VRIII across different units and hospitals. 3) Conducting multiple or repeated VRE 'cycles' with participants to track changes in practice over time [62, 63]. This would help in investigating how VRIII is used in as many situations as possible − pre-operation, post-operation, conscious/unconscious patient, and complicated cases (e.g., diabetic ketoacidosis), − and to understand the types of adaptations and outcomes resulting from them. 4) Conducting longitudinal research to provide insights into how healthcare practitioners adapt and respond to challenges over time and to understand the long-term outcomes (distal) of their adaptive work. Moreover, longitudinal work would allow additional exploration of how macro-, meso- and micro-systems interrelate with different tasks required while using VRIII.

Finally, given the early stage of development of RHC, recent evidence suggests combining detailed empirical research in diverse healthcare settings in one country with cross-country comparison of resilient capacities elsewhere, as a basis for improving safety and quality in healthcare [64, 65]. Additional comparative studies across the UK and other countries are warranted to develop a full picture of resilience in the use of VRIII by exploring teamwork, organisational factors and each country's healthcare policy and regulatory system, including how these factors might affect adaptive capacity at different systems' levels [65]. This comprehensive understanding at different system's level is important to capture and support resilience and adaptations across entire healthcare systems and subsequently, inform the development of interventions to improve the safety and quality of patient care while using VRIII.

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Appendix A

Participant invitation letters

Phase I: Participant invitation letter for focus group 1 (guidelines developers)

Primary Supervisor
Dr Rosemary Lim

PhD Researcher
Mais Iflaifel

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Date:

Dear _____

Project Title: Developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients.

A team of researchers consisting of Mais Iflaifel (PhD researcher), Dr Rosemary Lim (Primary Supervisor) and Professor Kath Ryan (Second Supervisor) from Reading School of Pharmacy, University of Reading and Dr Clare Crowley (external co-supervisor) from Oxford University Hospitals NHS Foundation Trust (OUH), are conducting a research study to explore and understand how intravenous (IV) insulin infusions are used in adult inpatients in your hospital. We are interested in how IV insulin infusions are used safely in everyday clinical work.

We are writing to you because you are involved in developing one or more guidelines in the use of IV insulin infusion in OUH. We are interested to learn from your experiences in developing the guidelines in a focus group with others that have developed guidelines for IV insulin infusions. The findings will be compared with actual practices using IV insulin infusions to help us understanding of pressures, problems facing healthcare practitioners while using IV insulin infusions to enable the development of a set of recommendations and solutions for making the use ofIV insulin infusions easier and safer.

Before you decide whether or not you would like to participate, it is important for you to understand why we are doing this research and what it would involve for you if you decide to participate. Please take time to read the enclosed information sheet carefully and take time to think about whether or not you would like to take part.

If you are interested to participate or have any questions about the research then please do contact the PhD researcher directly on and she will be happy to discuss any questions you may have.

Yours sincerely,
The Research Team on behalf of
Dr Rosemary Lim, Primary Supervisor
Tel:
Email:

The Queen's Anniversary Prize 2011

Phase I: Participant invitation letter for focus group 2 (managers)

Primary Supervisor
Dr Rosemary Lim

PhD Researcher
Mais Iflaifel

Second Supervisor
Professor Kath Ryan

University of Reading

Reading School of Pharmacy
Room 1.05c, Harry Nursten
Whiteknights, PO Box 226
Reading RG6 6AP

Date:

Dear _____

Project Title: Developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients.

A team of researchers consisting of Mais Iflaifel (PhD researcher), Dr Rosemary Lim (Primary Supervisor) and Professor Kath Ryan (Second Supervisor) from Reading School of Pharmacy, University of Reading and Dr Clare Crowley (external co-supervisor) from Oxford University Hospitals NHS Foundation Trust (OUH), are conducting a research study to explore and understand how intravenous (IV) insulin infusions are used in adult inpatients in your hospital. We are interested in how IV insulin infusions are used safely in everyday clinical work.

We are writing to you because you are involved in overseeing the implementation of IV insulin infusion guidelines. We are interested to learn from your experiences in a focus group with other manager with the use of IV insulin infusion guidelines. The findings will be compared with actual practices using IV insulin infusions to help us understanding of pressures, problems facing healthcare practitioners while using IV insulin infusions to enable the development of a set of recommendations and solutions for making the use ofIV insulin infusions easier and safer.

Before you decide whether or not you would like to participate, it is important for you to understand why we are doing this research and what it would involve for you if you decide to participate. Please take time to read the enclosed information sheet carefully and take time to think about whether or not you would like to take part.

If you are interested to participate or have any questions about the research then please do contact the PhD researcher directly on and she will be happy to discuss any questions you may have.

Yours sincerely,
The Research Team on behalf of
Dr Rosemary Lim, Primary Supervisor
Tel:
Email:

The Queen's Anniversary Prize 2011

Phase I: Participant invitation letter for focus group 3 (healthcare practitioners)

Primary Supervisor
Dr Rosemary Lim

PhD Researcher
Mais Iflaifel

Second Supervisor
Professor Kath Ryan

University of Reading

Reading School of Pharmacy
Room 1.05c, Harry Nursten
Whiteknights, PO Box 226
Reading RG6 6AP

Date:

Dear _____

Project Title: Developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients.

A team of researchers consisting of Mais Iflaifel (PhD researcher), Dr Rosemary Lim (Primary Supervisor) and Professor Kath Ryan (Second Supervisor) from Reading School of Pharmacy, University of Reading and Dr Clare Crowley (external co-supervisor) from Oxford University Hospitals NHS Foundation Trust (OUH), are conducting a research study to explore and understand how intravenous (IV) insulin infusions are used in adult inpatients in your hospital. We are interested in how IV insulin infusions are used safely in everyday clinical work.

We are writing to you because you are involved in treating hyperglycaemia using IV insulin infusion. We are interested to learn from your experiences of using IV insulin infusions in different situations in a focus group with other healthcare practitioners who are using IV insulin infusions in treating hyperglycemia. The findings will be compared with actual practices using IV insulin infusions to help us understanding of pressures, problems facing healthcare practitioners while using IV insulin infusions to enable the development of a set of recommendations and solutions for making the use ofIV insulin infusions easier and safer.

Before you decide whether or not you would like to participate, it is important for you to understand why we are doing this research and what it would involve for you if you decide to participate. Please take time to read the enclosed information sheet carefully and take time to think about whether or not you would like to take part.

If you are interested to participate or have any questions about the research then please do contact the PhD researcher directly on and she will be happy to discuss any questions you may have.

Yours sincerely,
The Research Team on behalf of
Dr Rosemary Lim, Primary supervisor
Tel:
Email:

The Queen's Anniversary Prizes 2011

Phase II: Participant invitation letter (healthcare practitioners)

Primary Supervisor
Dr Rosemary Lim

PhD Researcher
Mais Iflaifel

Second Supervisor
Professor Kath Ryan

University of Reading

Reading School of Pharmacy
Room 1.05c, Harry Nursten
Whiteknights, PO Box 226
Reading RG6 6AP

Date:

Dear _____

Project Title: Developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients.

We are a team of researchers consisting of Mais Iflaifel (PhD researcher), Dr Rosemary Lim (Primary Supervisor) and Professor Kath Ryan (Second Supervisor) from Reading School of Pharmacy, University of Reading and Dr Clare Crowley (external co-supervisor) from Oxford University Hospitals NHS Foundation Trust (OUH), are conducting a research study to explore and understand how intravenous (IV) insulin infusions are used in adult inpatients in your hospital. We are interested in how IV insulin infusions are used safely in everyday clinical work.

We are writing to you because you are involved in treating patients with hyperglycaemia using IV insulin infusion. The enclosed information sheet provides full details about the study and one of our researchers will speak to you about the study in more detail.

If you decide to take part, we will observe your work through videoing. We will video how you use IV insulin infusions. Then, you will attend a meeting to discuss clips of the video footage to help us understanding pressures, problems facing youwhile using IV insulin infusions and in turn the identification of realistic solutions and recommendations for making your job of using IV insulin infusions easier and safer.

You may want some time to think about our invitation or to discuss it with a colleague. **No-one will mind if you say "No".**

Yours sincerely,

The Research Team on behalf of
Dr Rosemary Lim, Primary Supervisor
Tel:
Email:

The Queen's Anniversary Prize 2011

Phase II: Participant invitation letter (patients)

Primary Supervisor
Dr Rosemary Lim

PhD Researcher
Mais Iflaifel

Second Supervisor
Professor Kath Ryan

University of Reading

Reading School of Pharmacy
Room 1.05c, Harry Nursten
Whiteknights, PO Box 226
Reading RG6 6AP

Date:
Dear _____

Project Title: Developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients.

We are a team of researchers consisting of Mais Iflaifel (PhD researcher), Dr Rosemary Lim (Primary Supervisor) and Professor Kath Ryan (Second Supervisor) from Reading School of Pharmacy, University of Reading and Dr Clare Crowley (external co-supervisor) from Oxford University Hospitals NHS Foundation Trust (OUH). We are conducting a research study to look at how healthcare workers useinsulin infusionsto treat patietns with high blood glucose levels. Insulin is a medication used to help maintain blood glucose levels within a range where the body best functions. It is hoped that this study will help us understand how insulin infusions are used in hospitals and what minimies risks to patients and makes healthcare environment safer.

We are writing to you because your treatment includes insulin infusions. The enclosed information sheet provides full details about the study and one of our researchers will speak to you about the study in more detail.

If you decide to take part, the researcher will use your electronic records to collect information such as (age, weight, gender, blood glucose level, insulin infusion regimen selected, how often the insulin infusion is monitored, and other medicines or illnesses that may affect the insulin dose). The healthcare practitionner who is taking care will be also observed by video. The aim of this study is not to video you but to video the work of healthcare practitioners providing care to you using an insulin infusion and while video recording is on, you or parts of your body for example your hand may appear in the video records.

One of our researchers will be speaking to you and ask if you want to take part in our study. **Please read the enclosed leaflet before you decide. No-one will mind if you say "No".**

You may want some time to think about our invitation or to discuss it with family or friend.

Yours sincerely,

The Research Team on behalf of
Dr Rosemary Lim, Primary Supervisor
Tel:
Email:

The Queen's Anniversary Prize 2011

Appendix B

Participant information sheets

Phase I: Participant information sheet

Primary Supervisor
Dr Rosemary Lim
Room 1.05c, Harry Nursten
PO Box 226, Whiteknights, Reading,
Berkshire RG6 6AP

PhD Researcher
Mais Iflaifel

Second Supervisor
Professor Kath Ryan

PARTICIPANT INFORMATION SHEET

Study title: Developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients.
Can you help us with a study?

Please read the information below before you decide.

What is the purpose of this study?
Controlling blood glucose in hospitalised patients is very important for optimal health outcomes. Intravenous (IV) insulin infusions are considered the treatment of choice to achieve a blood glucose target range in critically ill patients and patients unable to eat and drink for at least two meals with elevated blood glucose. However, problems have been reported with the use of IV insulin infusions worldwide.

Traditional approaches for improving safety have focused on unwanted events and their causes in order to develop strategies to eliminate them. Arguably, such approaches do not take into account the dynamic and complex nature of healthcare systems, which cannot be controlled solely by following standards and procedures. Although it is important to understand what goes wrong, there is also value and lessons to be learnt from what goes right. An emerging approach called Resilient Healthcare proposes that it is necessary to learn from the full range of outcomes including normal outcomes (when things go right), negative outcomes and everything in between despite the risks and complexity in healthcare.

The primary aim of this study is to understand Resilient Healthcare surrounding the use of IV insulin infusions in adult inpatients. This research involves three phases:

1- Phase I will focus on understanding how work is expected to be done (imagined) in the use of IV insulin infusion by conducting focus group discussions and analysing documents such as guidelines and policies for the use of IV insulin infusion.
2- Phase II will focus on understanding how work is actually done
3- Phase III will compare findings from phase I and II in order to construct a model of using IV insulin infusion safely.

You will be part of phase I which will explore how work is expected to be done in the use of IV insulin infusion in different situations.

Who will be invited to participate in this study?
Different groups of participants are invited to this study. Each group will participate in separate focus groups.

- Group 1: Guidelines developers for IV insulin infusions (Adult Inpatient Diabetes Specialist Team).
- Group 2: Managers such as Clinical Leads, Ward Manager, Sister/Charge Nurses, Deputy Sister, and Matrons.
- Group 3: Healthcare practitioners: Foundation year one or two doctor (FY1/2s), Anaesthetic Registrar/Consultant (without Clinical or Divisional Lead role) and Nurses.

If you wish to participate in this study, please contact Mais Iflaifel, PhD researcher via email

What does this study involve?
If you agree to participate, you will be asked to attend a focus group. A focus group is an organised discussion with a group of people to gain their views and experience in a specific topic, which in our study will be the use of IV insulin infusions.

The main aim of the focus group is to explore your understanding of the use of IV insulin infusions. You will join a focus group with other participants with similar roles. For example, if you are a healthcare practitioner, you will join a focus group with other healthcare practitioners. You will not join a focus group with other managers. The PhD researcher will contact you to arrange a suitable time for a focus group. The focus group will be conducted by the PhD researcher (Mais Iflaifel) and a final year Masters of Pharmacy research student and will be held in a private room away from clinical areas at the Oxford University Hospitals Foundation Trust. The focus group will be digitally audio-recorded and will last around 60 minutes.

Before the focus group discussion
A week before the focus group, the PhD researcher will also email you a case scenario where IV insulin infusions may be used. This is because we would like to discuss how you would usually manage a given case in practice. Reading case scenario will take around 5 minutes if you get a chance to do any pre-reading. If not, no worries.

On the day of the focus group, prior to the discussions, the PhD researcher will check that you are clear about the study and ask you to sign a consent form. You will be given a copy of the consent form to keep with this leaflet. This normally takes around 5 minutes.

During the focus group discussion
The PhD researcher will lead the focus group assisted by the research student. The PhD researcher will start with a brief introduction of the study aim and objectives and will distribute printed copies of IV insulin infusion guidelines that were sent via email prior to the focus group. This will be followed by open discussion on how IV insulin infusions are used in different situations based on your understanding and experience of using hyperglycaemia guidelines in your hospital, along with a brief discussion of a case scenario (which was also sent to you prior to the focus group) focusing on how you would manage glycaemic control using IV insulin infusion.

Are there risks and benefits to me in taking part in this study?

- This study is designed with minimal potential risks to all participants. Taking part will mean giving some of your time which is likely to be around 60 minutes for most people. The PhD researcher and the research student will avoid asking any sensitive questions. You have the right not to answer every question. Please be advised that although the research team will take every precaution to maintain the confidentiality of the data, the nature of focus groups prevents the research team from guaranteeing confidentiality. The research team would like to remind participants to respect the privacy of their colleagues and not repeat what is said in the focus group to others. You will be asked to indicate in the consent form, that you will not reveal any information that is shared in confidence in the focus group. The researchers are interested in learning about how IV insulin infusions are used and not in assessing individuals' performance or expectation.
- Please be assured that your participation in the study will not be made known to your manager by the research team.
- There might be no direct benefits to you for taking part, but what you tell our researchers might help us find ways to make using IV insulin infusions easier and safer, and thus to help improving how IV insulin infusions are used for patients and other practitioners.

What if I don't want to take part in this study?

Your participation in this research is entirely your choice. You have the right to accept or not respond to the study invitation. You may also withdraw from the project at any time without giving a reason and have the right to decide whether your data can still be used in the study.

How will my confidentiality be protected?

Confidentiality will be ensured by not revealing information to other personnel, except for those directly involved in the study, such as the PhD researcher (Mais Iflaifel), Masters of Pharmacy research student and University of Reading project supervisors (Dr Rosemary Lim and Professor Kath Ryan). The data will be anonymised by using codes on the focus groups transcripts. Any quotes used in the research (such as in the PhD thesis, Masters dissertation, publications, presentations at conferences or seminars will use non-identifiable codes rather than the participant's name. Electronic data will be password-protected and saved on the University of Reading's server. Any paper copies of focus group transcripts and analyses will be protected by storage in a secured locked cabinet used only by the PhD researcher, research student and University of Reading project supervisors.

University of Reading is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. University of Reading will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information athttp://www.reading.ac.uk/internal/imps/DataProtection/imps-d-p-dataprotectionandresearch.aspx

The PhD researcher/ research student will use your name, email, and telephone number to contact you about the research study. Individuals from the University of Reading and regulatory organisations may look at your research records to check the accuracy of the research study. The only people in the University of Reading who will have access to information that identifies you will be the PhD researcher, research student and University of Reading supervisors who need to contact you to arrange for focus group meetings. The External co-supervisor/site collaborator and the study advisors will not be able to identify you and will not be able to find out your name, or contact details.

What will happen to the information that I give you?
It will be used in a thesis to be submitted for Mais's PhD degree and the research student's masters dissertation and the results will be used in publications, presentations at conferences, or seminars and research and teaching purposes. A report of the overall findings of this study, containing only anonymised data, will be also shared with the Adult Inpatient Diabetes Team at the OUH to aid continuous quality improvement, and with different parties interested in safety and resilience of IV insulin infusion such as Patient Safety Team at NHS Improvement, The Getting It Right First Time (GIRFT) Programme and The Joint British Diabetes Societies (JBDS) for Inpatient Care Group.

Who should I contact if I have concerns about the conduct of this study?
If you have any concerns you can contact Dr Rosemary Lim, Primary Supervisor, on or or the University of Reading's Quality Assurance in Research at

Is there a payment for participating in this study?
No, it is an accepted and usual practice not to pay NHS staff involved in research studies.

Who is organising and funding the research?
The study is being led by researchers from the School of Pharmacy, University of Reading and supported by the Adult Inpatient Diabetes Team and the Neurosciences, Orthopaedics, Trauma, Specialist Surgery (NOTSS) Division, Oxford University Hospitals NHS Foundation Trust.

Who has reviewed the study?
The study has been reviewed and approved by the University of Reading Research Ethics Committee (UREC) (ref: 18/03), NHS Research Ethics Committee (REC) and Health Research Authority (HRA) (ref: 18/SC/0456) and OUHs through the Research and Development Approval Processes (ref: 13827).

Where can I get more information?
If you would like to take part in the study or if you have any questions, please contact:

- Mais Iflaifel, PhD researcher. Email:

If you have further enquiries, please contact:

- Dr Rosemary Lim, Primary Supervisor to Mais at 0118 378 8010, Email:

- Prof Kath Ryan, Second Supervisor at Email:
- Dr Clare Crowley, External co-supervisor/site collaborator at , Email:

Thank you for considering this invitation.
This information sheet is for you to keep.

Phase II: Participant information sheet (healthcare practitioners)

Primary Supervisor
Dr Rosemary Lim
Room 1.05c, Harry Nursten
PO Box 226, Whiteknights, Reading,
Berkshire RG6 6AP

PhD Researcher
Mais Iflaifel

University of Reading

Second Supervisor
Professor Kath Ryan

PARTICIPANT INFORMATION SHEET

Study title: Developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients.

Can you help us with a study?

Please read the information below before you decide.

What is the purpose of this study?
Controlling blood glucose in hospitalised patients is very important for optimal health outcomes. Intravenous (IV) insulin infusions are considered the treatment of choice to achieve a blood glucose target range in critically ill patients and patients with elevated blood glucose. However, problems have been reported with the use of IV insulin infusions worldwide.

Traditional approaches for improving safety have focused on unwanted events and their causes in order to develop strategies to eliminate them. Arguably, such approaches do not take into account the dynamic and complex nature of healthcare systems, which cannot be controlled solely by solid guidelines. Although it is important to understand what goes wrong, there is also value and lessons to be learnt from what goes right. An emerging approach called Resilient Healthcare proposes that it is necessary to learn from the full range of outcomes including normal outcomes (when things go right), negative outcomes and everything in between despite the investable risks and complexity.

The primary aim of this study is to understand Resilient Healthcare surrounding the use of IV insulin infusions in adult inpatients. This research involves three phases: 1- Phase I will be focusing on understanding how work is expected to be done (imagined) in the use of IV insulin infusion by conducting focus group discussions and analysing documents such as guidelines and policies for the use of IV insulin infusion. 2- Phase II will be focusing on understanding how work is actually performed, and 3- Phase III will be a comparison between phase I and II in order to construct a model of using IV insulin infusion safely. You will be part of phase II which will explore the use of IV insulin infusion in practice. This will involve observations of work using video followed by a discussion of recorded video footage. The aim is to understand how you work through different scenarios and to identify in collaboration with you solutions and recommendation to improve patient safety. Such knowledge can potentially then be used to help make using IV insulin infusions easier and safer.

Why are you invited to participate in this study?

University of Reading

You are invited to participate in this study because you are one of the healthcare practitioners (Consultants, Registrars, Foundation Year One and Two Doctors (FY1, FY2), Pharmacists, Matrons and Nurses) working at the Neuroscience Critical Care Unit or Vascular Surgery Unit.
If you wish to participate in this study, please contact Mais Iflaifel, PhD researcher via email

What does this study involve?

If you agree to participate, you will be video- recorded using a digital camera while you are starting, monitoring, switching to other dosage forms and stopping the IV insulin infusions through one day and night shift. You will then be invited to attend a reflexive meeting discussion together with other colleagues who are also on the video footage to watch and analyse your practices. Using your experiences to identify both good and poor practice, realistic and workable solutions to improve both your work and patient safety can be identified. The reflexive meeting will be audio- recorded using a digital audio-recorder and will last around 60 minutes. The video- recording and the reflexive meeting discussions will be conducted by the PhD researcher (Mais Iflaifel). The reflexive meetings will be held in a private room away from clinical areas at the Oxford University Hospitals Foundation Trust.

Are there risks and benefits to me in taking part in this study?

- Possible risks include psychological risks; there may be some issues that, as a result of being observed and filmed, cause personal concern. If the participants experience distress they would be supported in the first instance by the ward sister/shift coordinator, the participant could then be referred or self-refer to Occupational Health and Wellbeing at OUH. Previous studies of this kind have had a positive impact on participants as they have had the chance to review their own ways of working and reflect on their practices in a trustful environment.
- Taking part in the reflexive meeting discussion will mean giving some of your time which is likely to be around 60 minutes for most people. The aim of the discussion is to analyse your work in an interactive way with your colleagues to identify poor and good practices and to identify a realistic solutions to improve your work and patient safety in the use of IV insulin infusions and the PhD researcher will avoid asking any sensitive questions. Please be advised that although the research team will take every precaution to maintain confidentiality of data, the nature of reflexive meeting prevents the research team from guaranteeing confidentiality. The research team would like to remind participants to respect the privacy of their colleagues and not repeat what is shown and said in the reflexive meetings to others. You will be asked to indicate in the consent form, that you will not reveal any information that is shared in confidence in the reflexive meeting discussion. The researcher is interested in learning about IV insulin infusion systems and not in assessing individuals' performance or expectation.
- Please be assured that your participation in the study will not be made known to your manager.
- There might be no direct benefits to you for taking part, but what you tell our researcher might help us find ways to make using IV insulin infusions easier and safer, and thus to help improving systems for patients and other workers.

What if I don't want to take part in this study?
Your participation in this research is entirely your choice. You have the right to accept or not respond to the study invitation. You may also withdraw from the project at any time before starting data analysis without giving a reason.

Your decision whether to take part or not to take part, or to take part and then withdraw; will not affect your employment at the Oxford University Hospitals NHS Trust Foundation.

If you decide to withdraw from this study, please formally notify Dr Rosemary Lim, the Primary Supervisor by email

How will my confidentiality be protected?
Confidentiality will be ensured by not revealing information to other personnel, except for those directly involved in the study, such as the PhD researcher (Mais Iflaifel) and University of Reading project supervisors (Dr Rosemary Lim and Professor Kath Ryan). No information that identifies you will be made public. All records containing identifiers will remain confidential.

Information will be provided in such a way that you cannot be identified. Field notes, audio and visual records will be de- identified before any publication, PhD thesis submission, presentations, conferences and seminars. Original material of video and audio records will be password-protected and saved on the University of Reading's server. Any paper copies of field notes, reflexive meeting discussions and analyses will be protected by storage in a secured locked cabinet used only by the PhD researcher and University of Reading project supervisors.

University of Reading is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. University of Reading will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at
http://www.reading.ac.uk/internal/imps/DataProtection/imps-d-p-dataprotectionandresearch.aspx

The PhD researcher will use your name, email, and telephone number to contact you about the research study. Individuals from the University of Reading and regulatory organisations may look at your research records to check the accuracy of the research study. The only people in the University of Reading who will have access to information that identifies you will be the PhD researcher, and University of Reading supervisors who need to contact you to arrange for focus group meetings. The External co-supervisor/site collaborator and the study advisors will not be able to identify you and will not be able to find out your name, or contact details.

What will happen to the information that I give you?
It will be used in a thesis to be submitted for Mais's PhD degree and the results will be used in publications, presentations at conferences, or seminars and research and teaching purposes. A report of the overall findings of this study, containing only anonymised data, will be also shared with the inpatient diabetes team at the OUH to aid continuous quality improvement, and with different parties interested in safety and resilience of IV insulin infusion such as Patient Safety Team NHS improvement, The Getting It Right First Time (GIRFT) Programme and The Joint British Diabetes Societies (JBDS) for Inpatient Care Group.

Who should I contact if I have concerns about the conduct of this study?
If you have any concerns you can contact Dr Rosemary Lim, Primary Supervisor, on
or or the University of Reading's Quality Assurance in Research at

Is there a payment for participating in this study?
No, it is an accepted and usual practice not to pay NHS staff involved in research studies.

Who is organising and funding the research?
The study is being led by researchers from the School of Pharmacy, University of Reading and supported by the Adult Inpatient Diabetes Team and the Neurosciences, Orthopaedics, Trauma, Specialist Surgery (NOTSS) Division, Oxford University Hospitals NHS Foundation Trust.

Who has reviewed the study?
The study has been reviewed and approved by the the University of Reading Research Ethics Committee (UREC) (ref: 18/03), NHS Research Ethics Committee (REC) and Health Research Authority (HRA) (ref: 18/SC/0456) and OUHs through the Research and Development Approval Processes (ref: 13827).

Where can I get more information?
If you would like to take part in the study or if you have any questions, please contact:

- Mais Iflaifel, PhD researcher Email:

If you have further enquiries, please contact:

- Dr Rosemary Lim, Primary Supervisor to Mais at Email:

- Prof Kath Ryan, Second Supervisor at , Email:
- Dr Clare Crowley, External co-supervisor/site collaborator at , Email:

Thank you for considering this invitation.
This information sheet is for you to keep.

Phase II: Participant information sheet (patients)

Primary Supervisor
Dr Rosemary Lim
Room 1.05c, Harry Nursten
PO Box 226, Whiteknights, Reading,
Berkshire RG6 6AP

PhD Researcher
Mais Iflaifel

Second Supervisor
Professor Kath Ryan

PARTICIPANT INFORMATION SHEET

Study title: Developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients.
Can you help us with a study?

Please read the information below before you decide.

What is the purpose of this study?
The treatment of choice in hospitals for patients who have hyperglycaemia (too much glucose in blood) and unable to eat or drink by mouth are injecting insulin via the veins. However, there are some problems with injecting insulin such as injecting at the wrong part of the vein, how much and when insulin is injected. The traditional approach to solving medication problems in hospitals have been to identify what has gone wrong, why these problems have occurred and then find a solution to fix them. Although there has been considerable amount of work done to understand why things go wrong and implement solutions to address these problems, progress to reducing errors have been slow and errors are still happening. 'Resilient healthcare' is a different way of thinking about safety that focuses to improve patient safety by learning lessons from how work can be performed successfully as well as how work has failed. In this project, this approach will be uniquely used to understand how work is performed by videoing the practices of staff using injected insulin. Staff will then be able to see themselves and their colleagues at work by watching the videos which gives them opportunity to analyse, and suggest realistic solutions to improve their work and patient safety.

Why are you invited to participate in this study?
You are invited to participate in this study because you are one of the patients who are currently treated for their elevated blood glucose using an insulin infusion. You will be under the supervision of one of the healthcare workers who will be videoed while treating your elevated blood glucose using insulin infusions.
If you wish to participate in this study, please contact Mais Iflaifel, PhD researcher via email

What does this study involve?
The researcher(s) will video-record healthcare workers responsible for you who are treating your elevated blood glucose level using insulin infusions. If you agree to participate, the healthcare workers' work practices whilst using insulin infusions will be video-recorded using a digital camera. As you will be under the supervision of the healthcare workers who will be video-recorded, you or

some of your body parts may appear in the video records (arm, leg, face). Clinical decisions regarding you will be also recorded.

The researcher will review your electronic records to collect information such as (age, weight, gender, blood glucose level, injectable insulin regimen, how often the insulin infusion be monitored, and other mediciness or illnesses that may affect the insulin infusion dose).

Before you make your decision, the PhD researcher will be available to answer any questions you have.

If you decide to take part, the unit consultant responsible for your care will be informed that you are taking part of the study.

Are there risks and benefits to me in taking part in this study?

- At any stage of videoing, if it adversely impacts your care, the researcher(s) will immediately stop recording as your care is the priority.
- There might be no direct benefits to you for taking part, but videoing the actual practices of healthcare workers while they are treating your elevated blood glucose using an insulin infusion might help us find ways to make using insulin infusions easier and safer, and thus to help improving systems for patients like you and other healthcare workers.

What if I don't want to take part in this study?

Your participation in this research is entirely your choice. You may also withdraw from the project at any time before starting data analysis without giving a reason.

Your decision whether to take part or not to take part, or to take part and then withdraw; will not affect your care at the Oxford University Hospitals NHS Trust Foundation.

If you decide to withdraw from this study, please formally notify Dr Rosemary Lim, the Primary Supervisor by email

How will my confidentiality be protected?

Confidentiality will be ensured by not revealing information to other personnel, except for those directly involved in the study, such as the PhD researcher (Mais Iflaifel) and University of Reading project supervisors (Dr Rosemary Lim and Professor Kath Ryan). No information that identifies you will be made public. All records containing identifiers will remain confidential.

To protect privacy, the researcher(s) will switch off the camera and leave the area when asked by you or the healthcare practitioner. The researcher(s) will only stay if you are comfortable with that, and you have the right to ask the researcher(s) to leave the room during any activity that requires privacy.

Information will be provided in such a way that you cannot be identified. Visual records will be de-identified before any publications, PhD thesis submission, presentations, conferences and seminars. Original material of video records will be password-protected and saved on the University of Reading's server. Any information from your medical records and analyses will be protected by

storage in a secured locked cabinet used only by the PhD researcher and University of Reading project supervisors.

University of Reading is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. University of Reading will keep identifiable information about you for 10 years after the study has finished.
Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at
http://www.reading.ac.uk/internal/imps/DataProtection/imps-d-p-dataprotectionandresearch.aspx

The PhD researcher will collect information about you for this research study from your electronic records. This information will include your name, NHS number, age, weight, gender, blood glucose level, injectable insulin regimen, how often the insulin infusion be monitored, and other medicines or illnesses that may affect the insulin infusion dose, which is regarded as a special category of information. We will use this information to identify the number of times you have very high or very low blood glucose level, the time that the insulin infusion will be stopped for low blood glucose level, and the number of times that you might require glucose to treat low blood glucose level.

What will happen to the information that I give you?
It will be used in a thesis to be submitted for Mais's PhD degree and the results will be used in publications, presentations at conferences, or seminars and research and teaching purposes. A report of the overall findings of this study, containing only anonymised data, will be also shared with the inpatient diabetes team at the OUH to aid continuous quality improvement, and with different parties interested in safety and resilience of IV insulin infusion such as Patient Safety Team NHS improvement, The Getting It Right First Time (GIRFT) Programme and The Joint British Diabetes Societies (JBDS) for Inpatient Care Group.

Who should I contact if I have concerns about the conduct of this study?
If you have any concerns you can contact Dr Rosemary Lim, Primary Supervisor, on
or or the University of Reading's Quality Assurance in Research at

Is there a payment for participating in this study?
No, you will not be paid for your participation in this study.

Who is organising and funding the research?
The study is being led by researchers from the School of Pharmacy, University of Reading and supported by the Adult Inpatient Diabetes Team and the Neurosciences, Orthopaedics, Trauma, Specialist Surgery (NOTSS) Division, Oxford University Hospitals NHS Foundation Trust.

Who has reviewed the study?
The study has been reviewed and approved by the University of Reading Research Ethics Committee (UREC) (ref: 18/03), NHS Research Ethics Committee (REC) and Health Research Authority (HRA) (ref: 18/SC/0456) and OUHs through the Research and Development Approval Processes (ref: 13827).

Where can I get more information?
If you would like to take part in the study or if you have any questions, please contact:

- Mais Iflaifel, PhD Researcher Email:

If you have further enquiries, please contact:

- Dr Rosemary Lim, Primary Supervisor to Mais at Email:

- Prof Kath Ryan, Second Supervisor at , Email:
- Dr Clare Crowley, External co-supervisor/site collaborator at , Email:

Thank you for considering this invitation.
This information sheet is for you to keep.

Appendix C

Consent forms

Phase I: Consent form

Primary Supervisor
Dr Rosemary Lim

PhD Researcher
Mais Iflaifel

Second Supervisor
Professor Kath Ryan

University of Reading

School of Chemistry, Food & Nutritional Sciences and Pharmacy
Whiteknights
PO Box 266,
Reading RG6 6AP, UK
phone
fax

CONSENT FORM

Study title: Developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients.

Please initial boxes

1. I confirm that I have read and understand the Participant Information Sheet dated _____for the above study, which was explained by the PhD researcher, Mais Iflaifel. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without your relationship with your managers being affected in any way. ☐
3. I have received a copy of this Consent Form and the accompanying Participant Information Sheet. ☐
4. I understand that the information I provide will remain anonymous throughout data reported. ☐
5. I understand that I have the right to withdraw from the focus group at any point. ☐
6. I understand that data collected will be stored securely, safely and in accordance with the General Data Protection Regulation 2016 (GDPR) and the Data Protection Act 2018 which controls how your personal information is used by any organisation. ☐
7. I understand that I am not obliged to answer any question in the focus group. ☐
8. I understand that my participation in this study involves audio-recording of the focus group that I will attend. I give my permission to the researcher to audio-record the focus group using a digital audio-recorder. ☐
9. I understand that I will not reveal any information that is shared in confidence in the focus group. ☐

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10. I wish to receive a summary of the overall results once the study is complete and analysed ☐ Yes ☐ No

11. I understand that the data collected from me in this study will be preserved and made available in anonymised form, so that they can be consulted and re-used by others, and I have the ability to review the data before being available for public release. ☐

12. I agree to take part in the above study, which has been subject to ethical reviews according to the procedures specified by the University of Reading Research Ethics Committee (UREC) (ref: 18/03), NHS Research Ethics Committee (REC) and Health Research Authority (HRA) (ref: 18/SC/0456) and OUHs through the Research and Development Approval Processes (ref: 13827) and has been allowed to proceed. ☐

Participant details

Name of Participant: _____

Signature: _____ Date: _____

Witnessed by

Name of researcher taking consent: _____

Signature: _____ Date: _____

Phase II: Consent form (healthcare practitioners)

Primary Supervisor
Dr Rosemary Lim

PhD Researcher
Mais Iflaifel

Second Supervisor
Professor Kath Ryan

University of Reading

School of Chemistry, Food & Nutritional Sciences and Pharmacy
Whiteknights
PO Box 266,
Reading RG6 6AP, UK
phone
fax

CONSENT FORM

Study title: Developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients.

Please initial boxes

1. I confirm that I have read and understand the Participant Information Sheet dated _____for the above study, which was explained by the PhD researcher, Mais Iflaifel. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation in this study involves:

   a) Video-recording of my practices of using IV insulin infusions. I give my permission to the researcher to video-record me while using IV insulin infusion using a digital camera. ☐
   b) Audio- recording of the reflexive meeting discussions. I give my permission to the researcher to audio-record the reflexive meeting discussions using a digital audio- recorder. ☐

3. I understand that my participation is voluntary and that I am free to withdraw at any time before starting data analysis without giving any reason and without my relationship with my managers and employer being affected in any way. ☐

4. I have received a copy of this Consent Form and the accompanying Participant Information Sheet. ☐

5. I understand that research data gathered from the study will be used for scientific purposes, for example, the PhD student's thesis, presentation of research at conferences, seminars and publications, and that I will not be identified. ☐

6. I understand that the information I provide in the reflexive meeting discussions will remain anonymous throughout data reported. ☐

7. I understand that data collected will be stored securely, safely and in accordance with the General Data Protection Regulation 2016 (GDPR) and the Data Protection Act 2018 which controls how personal information is used by any organisation. ☐

PLEASE TURN OVER

University of Reading

8. I understand that I am not obliged to answer any question or discuss any point in the reflexive meeting discussion. ☐

9. I understand that I will not share any information shown or discussed in confidence in the reflexive meeting. ☐

10. I wish to receive a summary of the overall results once the study is complete and analysed. ☐ Yes ☐ No

11. I understand that the data collected from me in this study will be preserved and made available in anonymised form; so that they can be consulted and re-used by others and I have the ability to review the data before being available for public release. ☐

12. I agree to take part in the above study, which has been subject to ethical reviews according to the procedures specified by the University of Reading Research Ethics Committee (UREC) (ref: 18/03), NHS Research Ethics Committee (REC) and Health Research Authority (HRA) (ref: 18/SC/0456) and OUHs through the Research and Development Approval Processes (ref: 13827) and has been allowed to proceed. ☐

13.

a. I understand that the anonymised videos may be shared with and used by academics, broadcasters, developers of training courses, website developers, information providers and others for research and teaching purposes. It will not be used for advertising or purely commercial purposes. ☐

b. To enable the use of my anonymised videos, I assign my copyright in my contribution in this research to the University of Reading. In return for my assignment my videos will only be used in the manner set out above.

Signature:

Participant details

Name of Participant: _____

Signature: _____ Date: _____

Witnessed by

Name of researcher taking consent: _____

Signature: _____ Date: _____

Phase II: Consent form (patients)

Primary Supervisor
Dr Rosemary Lim

PhD Researcher
Mais Iflaifel

Second Supervisor
Professor Kath Ryan

University of Reading

School of Chemistry, Food & Nutritional Sciences and Pharmacy
Whiteknights
PO Box 266,
Reading RG6 6AP, UK
phone
fax

CONSENT FORM

Study title: Developing a model of resilience in the use of intravenous insulin infusions in hospital in-patients.

Please initial boxes

1. I confirm that I have read and understand the Participant Information Sheet dated _____for the above study, which was explained by the PhD researcher, Mais Iflaifel. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that this study involves video-recording of healthcare workers' practices of using IV insulin infusions and my body or parts of my body may appear. I give my permission to the researcher to video-record me when healthcare providers attend to me, using a digital camera. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time before research data is analysed without giving any reason and without my care being affected in any way. ☐
4. I have received a copy of this Consent Form and of the accompanying Participant Information Sheet. ☐
5. I understand that research data gathered from the study will be used for scientific purposes, for example, the PhD student's thesis, presentation of research at conferences, seminars and publications, and that I won't be identified. ☐
6. I understand that data collected will be stored securely, safely and in accordance with the General Data Protection Regulation 2016 (GDPR) and the Data Protection Act 2018 which controls how personal information is used by any organisation. ☐
7. I wish to receive a summary of the overall results once the study is complete and analysed ☐ Yes ☐ No

PLEASE TURN OVER

8. I understand that the data collected from me in this study will be preserved and made available in anonymised form, so that they can be consulted and re-used by others. ☐

9. I agree to take part in the above study, which has been subject to ethical reviews according to the procedures specified by the University of Reading Research Ethics Committee (UREC) (ref: 18/03), NHS Research Ethics Committee (REC) and Health Research Authority (HRA) (ref: 18/SC/0456) and OUHs through the Research and Development Approval Processes (ref: 13827) and has been allowed to proceed. ☐

Patient details

Name of Patient: _____

Signature: _____ Date: _____

Witnessed by

Name of researcher taking consent: _____

Signature: _____ Date: _____