

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

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

Short title: Modelling the use of variable rate intravenous insulin infusions

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Declaration of interest:

None

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ABSTRACT

Background: Variable rate intravenous insulin infusions (VRIIs) are widely used to treat elevated blood glucose (BG) in adult inpatients who are severely ill and/or will miss more than one meal. VRIIs 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 VRIIs 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 VRII use.

Methods: A qualitative observational study video-recording healthcare practitioners using VRII. 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 VRII 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 VRII's rate without independently verifying whether the new rate was appropriate) and temporary workarounds (e.g. not administering long-acting insulin analogues although the long-acting insulin prescription was not suspended) were the most frequently observed adaptations. The comparison between WAI and WAD assisted in developing a model of VRII use. The model shed light on strategies used to imagine everyday work (e.g. incident reports, VRII guidelines), how everyday work was accomplished (e.g. context-dependent adaptations) and how these contributed to both successful and unsuccessful outcomes.

Conclusions: This study provided in-depth understanding of the tasks required while using VRIIs, and responses and adaptations needed 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 infusion, WAD - Work as Done, WAI - Work as Imagined

INTRODUCTION

Variable rate intravenous insulin infusions (VRIIs) 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 VRII 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 VRII, resulting in increased risk of developing hypoglycaemia or experiencing a medication error (3). The use of VRII 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 VRII (1, 4), need for frequent BG monitoring (2), insufficient staff to patient ratio (5), co-administration of other medications and suboptimal knowledge about VRII'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 VRII, among them daily review of the need for the VRII and of the patient's clinical status, the use of VRII-specific guidelines and the use of prefilled 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 VRHIs, analyse adaptations used in the clinical environment to identify areas of weakness and strength, and develop a model of VRHI 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 VRHIs; 2) video-observations analysis; 3) comparison between WAD and WAI; 4) developing a model of VRHI use. This study adheres to the Standards for Reporting Qualitative Research (SRQR) (17).

Study context

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 VRHI 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 VRIIs depended on various elements, e.g. manual bedside monitoring of CBG and blood ketones, and choosing the appropriate VRII rate and IV fluids to be administered along with VRIIs. 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, VRII 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 VRIIs was well placed to provide an example to assess the limits of RHC principles. Specifically, the use of VRIIs is complex and multidimensional. It encompasses various factors, e.g. BG monitoring frequency and lack of clinical knowledge regarding the use of VRIIs, 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 VRII 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 $> 5.5\text{mmol/L}$).
- 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 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).

Stage 4: Developing a model of VRIII use

The model was developed based on findings from stages 3 and 4, 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 3 and 4. 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*.

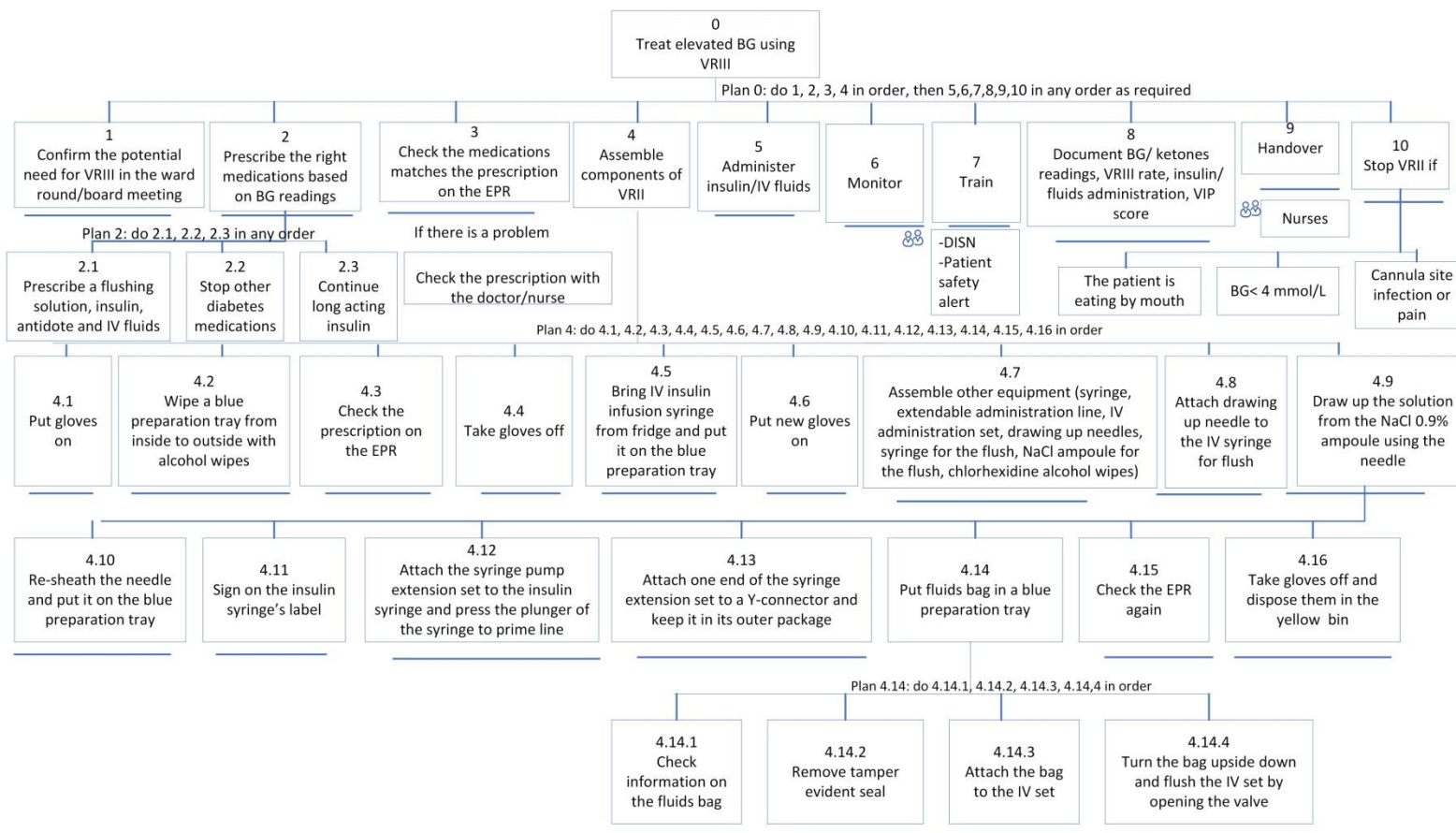
Ethics

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). Treating elevated BG was identified as a key goal while using VRIIs. 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 VRII, 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 pre-filled 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 were keen to monitor CBG every hour or two while the patient was on the VRIII. However, it was observed that during busy shifts, the nurses were unable to monitor as frequently 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

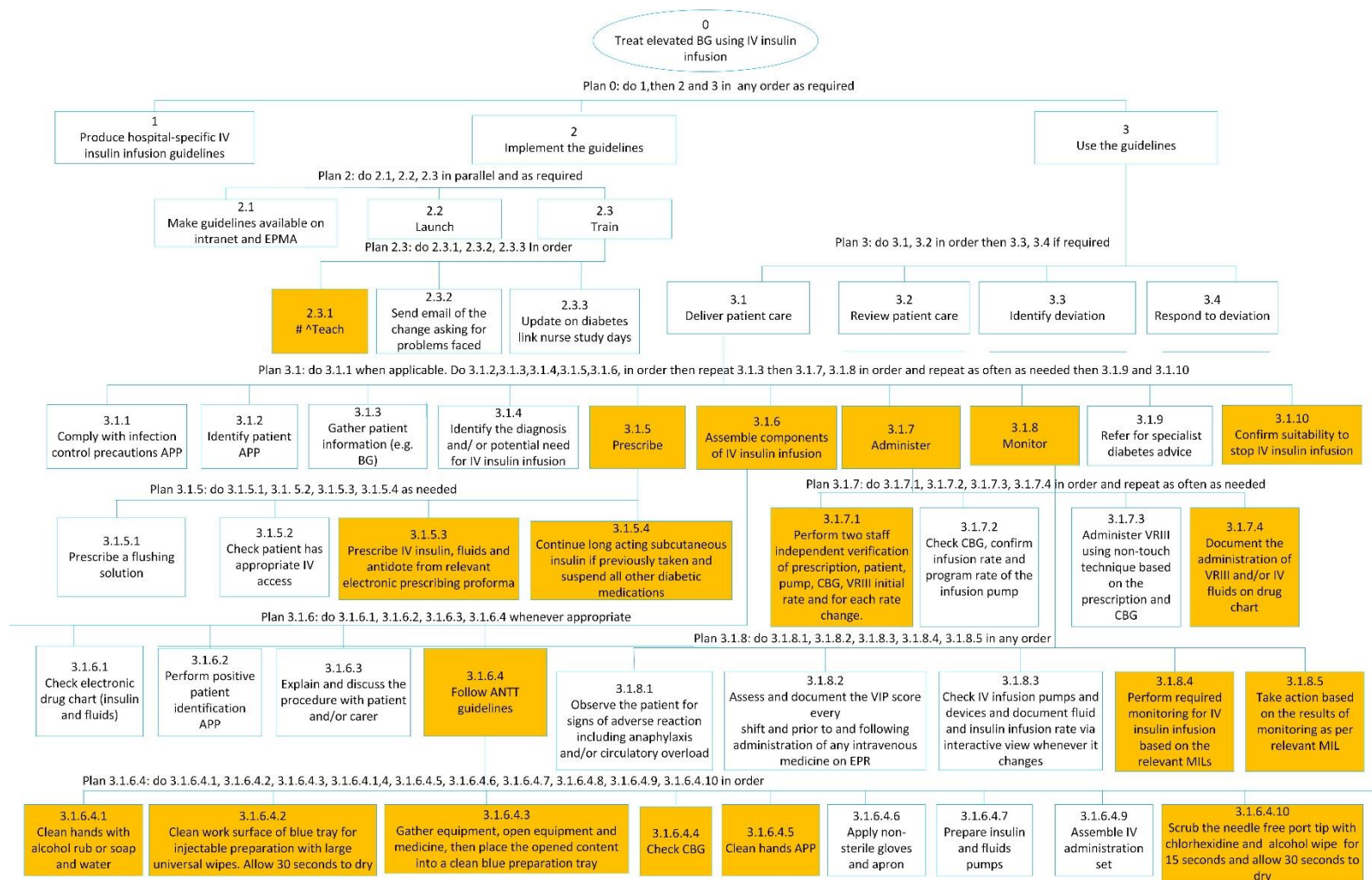
hypoglycaemia treatment to the staff on the ward. Interestingly, the DISN nurse delivered the teaching session as expected but there was only one student nurse who attended the session.

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 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 VRIIIs. 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				
<i>Ten-minute espresso teaching</i>	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				
<i>3.1.5.3 Prescribe IV insulin, fluids and antidote using the relevant electronic prescribing proforma</i>	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 specialist registrar (SpR) and asked him to prescribe it.	Temporary
<i>3.1.5.3.4 Select appropriate IV fluid to avoid hypoglycaemia and electrolyte imbalance</i>	ND	The SpR prescribed the IV fluids and electrolytes.	The potassium content of the prescribed fluid was not appropriate for the patients' serum potassium level.	Temporary
<i>3.1.5.4 Continue long-acting subcutaneous insulin if previously prescribed and</i>	PD	The SpR did not suspend the regular prescription for subcutaneous intermediate-acting	The nurse did not administer the intermediate-acting insulin to the patient.	Temporary

<i>suspend all other medications for diabetes.</i>		insulin when initiating the VRIII.		
3.1.6 Assemble components of IV insulin infusion				
<i>3.1.6.4 Follow Aseptic Non-Touch Technique guidelines</i>	ND	The Aseptic Non-Touch Technique guidelines were not followed.	NO	NA
<i>3.1.6.4.1 Clean hands with alcohol rub or soap and water</i>	ND	The nurse did not clean hands with alcohol rub or soap and water but applied non-sterile gloves before checking the Electronic Patient Record.	NO	NA
<i>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</i>	D	The nurse cleaned the blue injectable preparation tray whilst putting on gloves.	NO	NA
<i>3.1.6.4.3 Gather equipment, open equipment and medicine, then place the opened content into a clean blue preparation tray</i>	PD	The nurse gathered equipment and put it inside the blue preparation tray before opening the outer package.	NO	NA
<i>3.1.6.4.4 Check CBG</i>	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
<i>3.1.6.4.5 Clean hands as per protocol</i>	ND	Hands were not cleaned before applying gloves. The nurse applied	NO	NA

		gloves directly, without washing hands.		
<i>3.1.6.4.10 Scrub the needle free port tip with chlorhexidine and alcohol wipe for 15 seconds and allow 30 seconds to dry.</i>	ND	The nurse attached the insulin and fluids to the patient cannula without wiping the needle free port tip.	NO	NA
3.1.7 Administer				
<i>3.1.7.1 Perform two-staff independent verification of prescription, patient, pump, blood glucose, VRIII_initial rate and for each rate change.</i>	PD	<p>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.</p> <p>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.</p>	<p>The VRIII rate was changed and the second nurse signed on the Electronic Patient Record without checking the changed rate.</p> <p>The nurse administered the VRIII and IV fluids to the patient without delay. Following this, the second nurse checked and signed on the EPR.</p>	<p>Permanent</p> <p>Temporary</p>
<i>3.1.7.4 Document the administration of VRIII and/or IV fluids on drug chart</i>	D	This task was performed before the nurse administered VRIII to the patient.	NO	NA
3.1.8 Monitor				
<i>3.1.8.4 Perform required monitoring for IV insulin infusion based on the relevant MILs</i>	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 VR/III 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; *SpR* Specialist Registrar; *VR/III* Variable Rate Intravenous Insulin Infusion.

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 which 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 VRIII is 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.

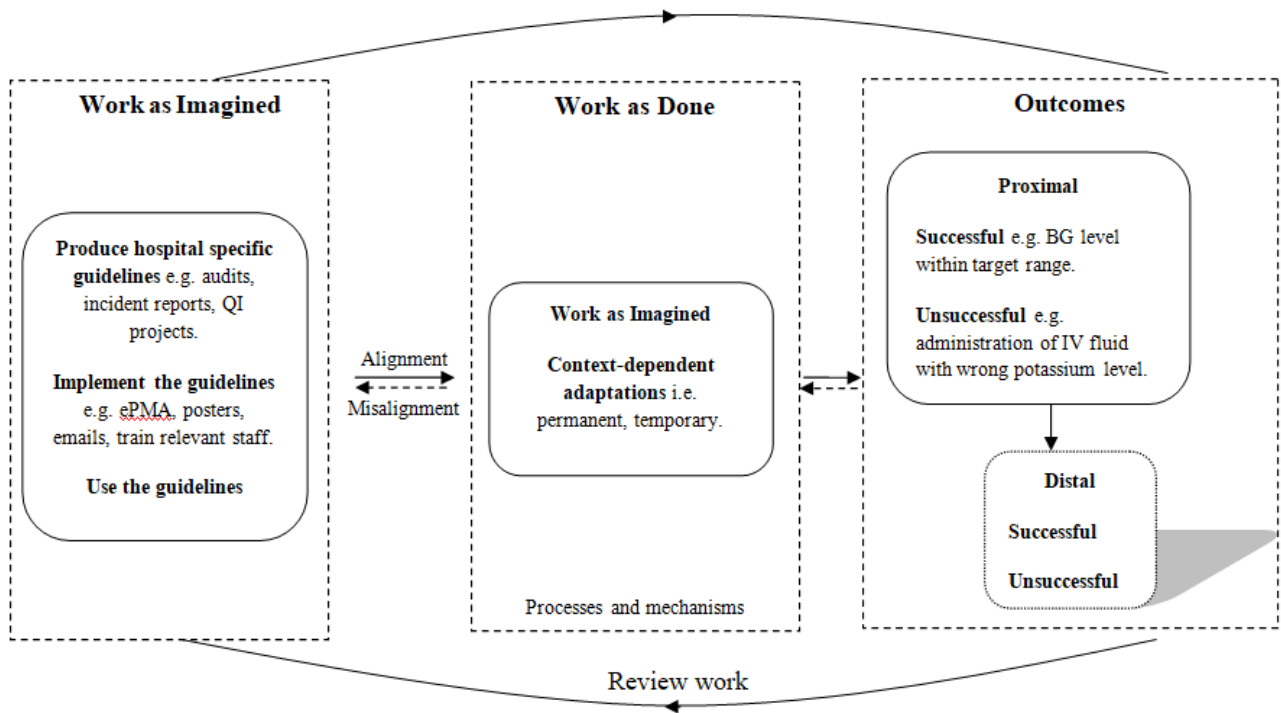


Fig. 3. Model of VRIII use in a hospital.

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, (4) (4) (4) (4) 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 proximal 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 site 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 VRIIs 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 VRIIs, the challenges faced while using VRIIs 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 VRII, e.g. VRII 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 than 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 VRIIs. 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 VRIIIs. 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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