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Blood sampling – Two sides to the story

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ABSTRACT (Words 150)
This study aimed to investigate why there is variability in taking blood.

A multi method Pilot study was completed in four National Health Service Scotland hospitals. Human Factors/Ergonomics principles were applied to analyse data from 50 observations, 15 interviews and 12-months of incident data from all Scottish hospitals. The Functional Resonance Analysis Method (FRAM) was used to understand why variability may influence blood sampling functions.

The analysis of the 61 pre blood transfusion sampling incidents highlighted limitations in the data collected to understand factors influencing performance. FRAM highlighted how variability in the sequence of blood sampling functions and the number of practitioners involved in a single blood sampling activity was influenced by the working environment, equipment, clinical context, work demands and staff resources.

This pilot study proposes a realistic view of why blood sampling activities vary and proposes the need to consider the system's resilience in future safety management strategies.

Key Words: Blood sampling, Wrong Blood In Tube, Resilience

Word count 4153

INTRODUCTION

In acute hospital care, the hazard of testing the wrong patient's blood, due to inaccuracies in sample labelling or patient identification creates a risk of inefficient patient care, patient harm and even death. A wrong blood in tube (WBIT) incident will influence the likelihood that a patient efficiently and safely receives the required intervention e.g. the transfusion of the correct blood component [1]. International evidence cited for WBIT incidents is between 1 in every 1,500 – 3,000 of blood samples taken [2,3]. In the United Kingdom (UK), the Serious Hazards of Transfusion (SHOT) organisation is an independent haemovigilance scheme providing an annual comprehensive analysis and summary of national data associated with transfusion incidents. Currently data suggests few cases of major morbidity or death from WBITs, however, the potential for harm remains as the WBIT rate continues to rise [1]. In 2012 the British Committee for Standards in Haematology [4] requested that unless a secure electronic identification system was in place a second sample of the patient's blood should be requested prior to the transfusion of blood components. This recommendation is intended to mitigate the risk of harm to patients through WBIT incidents, however, it does not address *why* WBITs occur and hence they are likely to continue.

From a safety science perspective the most obvious questions to ask are how and why does blood sampling go wrong? There is, however, an alternative question: how and why does blood sampling usually go right? In 2014 the National Health Service (NHS) in Scotland completed 495,094 samples; for every 1 WBIT, 7583 samples were successfully processed and reported (Scottish National Blood Transfusion Service 2015). Lawton et al (2015) [5] suggests healthcare is being encouraged, like other safety industries [6], to shift safety management strategies away from solely focusing on error detection and incident management (Safety-I approach) [6,7]. Instead a Safety-II strategy is proposed as a more proactive approach to understand safety and increase the focus on safety interventions to ensure more things go right more often, which complements a Safety-I approach [8]. The underlying assumption of Safety-II is

that in complex socio-technical systems adjustments to everyday working environments and human performance are normal, and are relied upon to accommodate uncertainty, fluctuations in demand and organisational constraints. Understanding these adjustments and the trade-offs made by the healthcare workforce provides a realistic view of how an organisation functions and how everyday work is usually done.

Published literature suggests two core issues impact on blood sampling system safety and reliability: patient identification and sample labelling. Formal identification of a patient underpins safety in many healthcare interventions; however, it may not always occur [9, 10, 11]. Mis-labelling of blood samples is a risk which may harm the patient or delay treatment [12, 13, 14]. Evidence reports these events but with the exception of one recent study [15] does not look to understand why. In addition incident reporting systems presents a biased interpretation of data, as reporting does not seek to capture the breadth of system related factors which influence human performance and are not representative of all types of incidents that happen [1, 16, 17, 18, 19].

The aim of this pilot study is to understand why variability in blood sampling performance in acute hospital settings can occur. The methods applied were informed by Human Factors science, to understand *why* performance might vary and *how* a Safety-II approach can inform future safety management programmes.

METHOD

A three-month study at four acute medium – large hospitals in NHS Scotland was completed in 2015 involving three clinical areas which reflect those with the highest proportion of WBIT incidents [1]: Emergency departments, outpatients, and acute wards.

This study introduced the Functional Resonance Analysis Method (FRAM), an approach specifically developed to model complex systems [20]. FRAM offers a systematic approach to describing and examining work as it is done rather than imagined and reflects interactions between functions and their potential variability.

Data collection and Analysis

The methods used to inform FRAM included observations (n=50) and semi structured interviews (n=15), see Table 1. These were supported by two workshops with Transfusion Practitioners to develop and verify the findings and produce the FRAM model. The methods were completed by two researchers (LP & SA). The approach to sampling was pragmatic and convenience sampling was necessary based on staffing levels and availability. A limited number of observations with medical doctors was possible and this informed the sampling process for the interviews completed, which recruited a greater percentage of medical staff. One year of pre blood transfusion sampling incident data (n=61), from 14 regional health boards (authorities) within Scotland (n= 15), were also anonymised and analysed.

Table 1 Data collection details

Observations			
Emergency Department	**Acute Wards**	**Obstetrics**	**Outpatients**
n=12	n=10	n=5	n=23
Doctor	**Healthcare Support Worker**	**Nurse**	**Phlebotomist**
n=2	n=14	n=21	n=13
Interviews			
Doctor	**Healthcare Support Worker**	**Nurse**	**Phlebotomist**
6	1	6	2
Total time = 484 minutes Average time = 40 minutes 30 seconds Range in time = 26 – 58 minutes			

Observation Data

Observations were completed by two of researchers (LP & SA). Fifty observations were completed (Doctors n= 2, Healthcare Support Workers n=14, nurses n= 21, Phlebotomists n= 13) using a standardised observation tool developed specifically for the study (see online supplementary appendix A). Permission was gained from patients. A Human Factors systems model, the Systems Engineering Initiative for Patient Safety (SEIPS) model [21], was used to code observations and identify factors influencing blood sampling activities, a sample of data was double coded by two investigators (LP & SA) to verify and modify the coding strategy.

Semi structured interviews

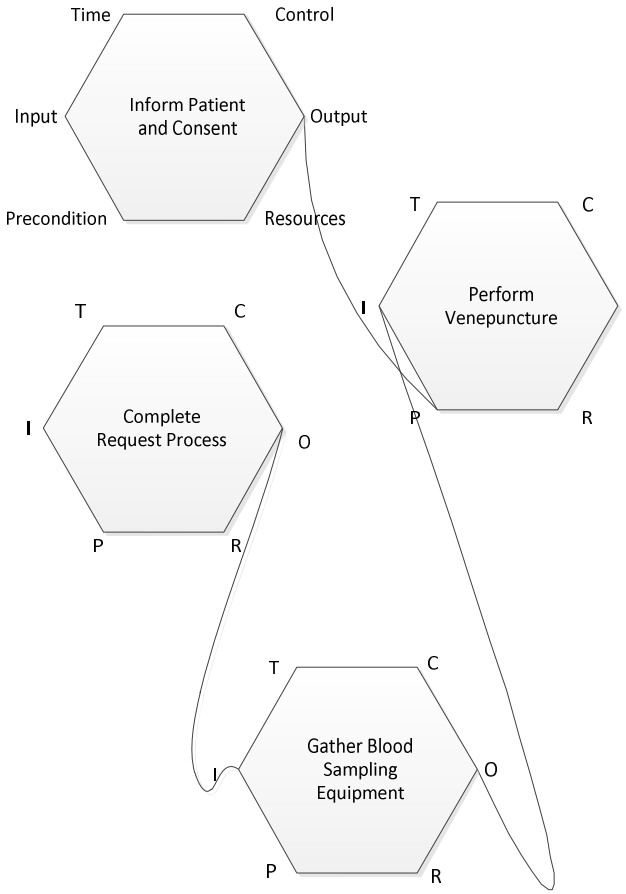
Interview questions (see online supplementary appendix B) were developed following a review of the literature, they were tailored to the time available, and recorded and transcribed with permission. The analysis of the interview data informed FRAM and had two aims [20]: firstly to identify the core functions relevant to describe blood sampling activities. This was completed independently by three of the authors (LP, SA & EH) and compared to obtain a consensus. Secondly the core functions became codes used to thematically analyse the data for sources of variability specific to each function.

Incident data analysis

Descriptive statistics were completed of the incident data and a content analysis using thematic coding [22], was completed by one investigator (LP). Level one codes represented the outcome of the incident. Level two codes were based on the SEIPS model [21]. As a pilot study the opportunity was taken to explore if this form of incident data analysis was practical and contributed to informing FRAM. This form of analysis is not essential to FRAM and project resources only allowed for one researcher to be allocated to this task.

Functional Resonance Analysis Method (FRAM)

FRAM applied the findings from analysis of interview and observational data to describe the functions relevant to the entire blood sampling process. Each function was described using up to six aspects (Box 1); the 'output' from one function was linked as a necessary 'input' or 'precondition' for a subsequent function. A FRAM model was created within a workshop with Transfusion Practitioners using a software tool (http://functionalresonance.com/tools-visualisation/index.html). This explored how the functions interact and which key interactions and sources of variability will potentially influence a functions 'output' –either with regard to its timing or quality.



Time	Time influencing or constraining how the function is completed
Control	Artefacts or other functions which determines or regulates how the function is completed e.g. procedures, guidelines
Output	The result of the function and links to functions downstream
Resources	That consumed or required to complete a function e.g. manpower, competence, software
Precondition	System conditions that **must** be fulfilled before a function can be commenced
Input	That which activates the function or is used or transformed to produce the output. This is the link to upstream functions.

Box 1 FRAM descriptors and a sample of functions which represent the blood sampling process

Analysis of the FRAM model focused on understanding which core functions contribute to the success of multiple subsequent functions, and combinations of closely dependent functions. The FRAM model provided a visual representation that challenged how the clinical teams believed the blood sampling procedures were applied to the reality. This verified that the final FRAM model represented what does, or potentially could, happen when blood sampling is completed rather than perceived to happen as reflected in protocols and guidance.

FINDINGS

Incident Data Analysis

Job roles associated with WBIT incidents

Descriptive statistics of the incident data supported evidence [1] on the prevalence of WBIT incidents being greater for Doctors (42%) than Nurses (23%), Midwifes (23%) and Phlebotomists (3%). However, without the frequency with which each job role takes the relative risk for each professional group can't be calculated.

The data suggests the majority of incidents occurred during normal working hours with peaks at around 12.00, and 15.00-16.00 hours, Figure 1. This may well reflect when the majority of samples are taken or be linked to other factors which may contribute to fatigue [23].

WBIT outcomes and influencing factors

Table 2 summarises the percentage split of the codes attributed to the outcome and factors influencing the incident based on the SEIPS model.

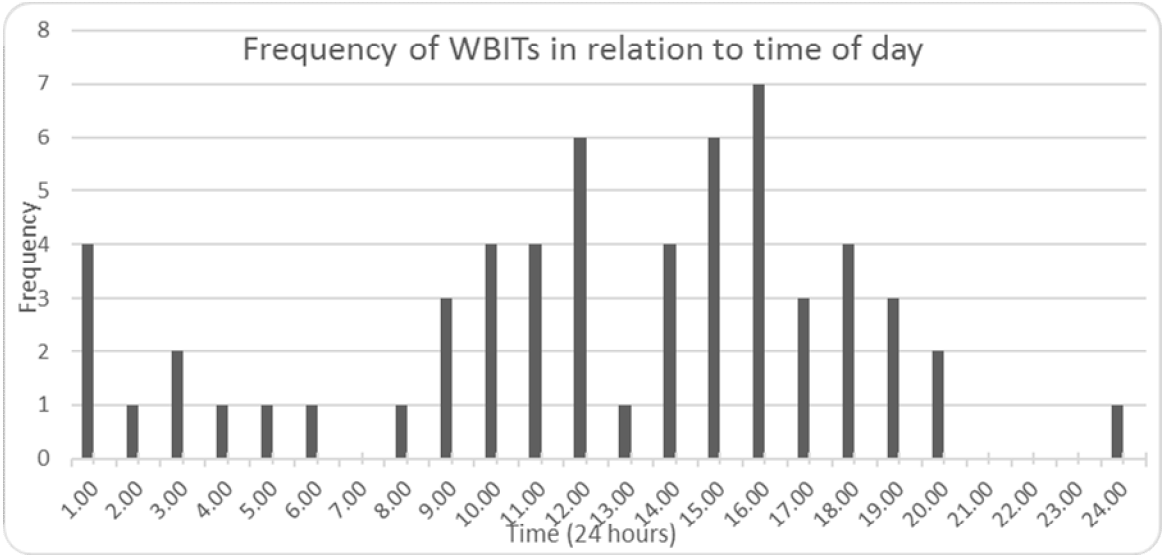


Figure 1 Time of day of WBIT incidents.

Table 2 Systems Engineering Initiative for Patient Safety (SEIPS) Model and Incident Data Codes

SEIPS Components	Selection of Element Examples	Wrong Label	Wrong Patient	Wrong Patient Information
Person	Education, skills and knowledge, motivation, needs, physical characteristics,	**9%**	**32%**	**25%**
		Fatigue, compassion for patient	Alertness, fatigue	Fatigue, fake patient identity
Organisation	Team work, communication, organisational culture and patient safety culture, work schedules, social relationships, supervisory and management style	**13%**	**5%**	**25%**
		Procedure practicality, training, team communication, staff rotation, staff resources	Procedures – practicality, team work	Work schedule
Technologies and tools	Various information technologies: electronic health record, medical devices. Other technologies and tools, human factors characteristics e.g. usability	**16%**	**5%**	**13%**
		Unavailability, usability	Usability	Usability
Tasks	Variety of tasks, job content, challenge and utilisation of skills, autonomy, job control and participation, job demands (e.g. workload, time pressure, cognitive load, need for attention)	**51%**	**53%**	**25%**
		Job demands, time pressure, distractions, interruptions, multi-tasking, similar information, information presentation, task sequence and timing	Job demands, distractions, workload, similar information, need for attention, multi-tasking	Need for attention

Environment	Layout, noise, lighting, temperature, humidity and air quality, workstation design.	**9%**	**5%**	**13%**
		Noise - distractions	Noise - distractions	Noise - distractions
Care processes and other processes	Care processes, other processes: information flow, purchasing, maintenance, cleaning, process improvement activities	**2%**	**0%**	**0%**
		Equipment maintenance and repair		

The data revealed that the greatest number of incidents were associated with an outcome of the 'wrong label', these were more frequently associated with the 'task' code. This highlighted the challenge posed in the labelling of samples created from checking similar information, multi-tasking and time pressure.

Additional contributory factors were: usability of interfaces to select the correct patient from a drop down list, the presence of different patient labels in the same proximity, unavailability of technical systems, practicality of procedures and staffing levels.

FRAM analysis

A FRAM model was produced including 31 functions representative of blood sampling activity. The number of interactions between functions, upstream or downstream dependencies, are presented in Table 3 columns 2 and 3. The model was used to present two instantiations for blood sampling as observed in outpatients and reported on in an emergency situation. Variability typical to completing the core functions within these two instantiations were elicited from the data, Table 3. Interactions and dependencies between functions highlight potential differences in the sequence of functions (Table 3) and how different practitioners complete clusters of functions (see online supplementary appendix C, each colour illustrates a different practitioner). One blood sample in the Outpatients clinic setting typically involved four practitioners and in an acute emergency situation potentially three or more.

Table 3 Summary of function outputs and variability in blood sampling functions

Function	Up-stream Influence	Down-stream Influence	Function Output	Variability of Output In Outpatients*	Outpatients sequence**	Emergency sequence**	Variability of Output In Emergency*
Maintenance support	**0**	**4**	IT systems available				
Collect relevant information	**3**	**5**	Clinical information Priority of sample Patient identity	On time – completed prior clinic Acceptable – consultation with patient provides information	**2**		Omitted – patient identity unknown
Produce and attach patient wristband	**0**	**3**	Wristband				
Decide to take a blood sample	**0**	**6**	Decision to take blood Required samples	On time – completed prior to clinic. Acceptable – accepted as appropriate from referring Doctor	**1**	**2**	On time – often one of the first interventions. Acceptable – immediate activity required to determine interventions
Assign appropriate staff	**0**	**4**	Competent staff				
Schedule work (sampling)	**4**	**3**	Sample collection time Sampling sequence				

*These columns illustrate how the timing or accuracy of relevant resources and information may impede, and/or require staff to adjust the sequence or performance of the blood sampling functions. The reliability and sequence of the request and labelling of blood sample functions is determined by the clinical context and availability of technical resources.

**These columns illustrate the order in which the functions were typically observed during the study. This illustrates variability exists in the sequence of blood sampling functions between clinical contexts to obtain a sample.

Function	Up-stream Influence	Down-stream Influence	Function Output	Variability of Output In Outpatients	Outpatients sequence	Emergency sequence	Variability of Output In Emergency
Maintain adequate stock levels of equipment	**0**	**4**	Request forms Equipment available Labels, In date tubes				
Complete request process	**3**	**5**	Written request form IT system request Documentation of required samples	On time – completed prior to clinic. Acceptable – as patient presents on clinic list requiring bloods	**3**	**6**	Imprecise – inaccuracy of completion or selection of details. Too late – delayed request for temporary identifier
Print labels and collect	**4**	**4**	Labels Printed labels Printed IT system form	On time –printed local to clinic prior to patient arrival. Precise – paper clipped to patient case notes used to check identity	**4**	**7**	Too late – labels may be printed after blood sampling Imprecise – wrong labels printed or collected
Check the form / requests	**2**	**4**	Documentation of required samples Patient identity	On time – without check unaware of patient identity requiring sample	**5**	**8**	Too late – unavailable prior to sample taken
Gather blood sampling equipment	**3**	**2**	Blood sampling equipment	On time – prepared prior to clinic starting	**7**	**3**	Too late – interrupts or delays the sampling process if equipment is unavailable
Label tube	**2**	**1**	Labelled tube				
Prepare oneself for taking a sample	**4**	**2**	Preparations completed Clean hands, gloves	On time – sink and equipment available and accepted norm within team	**10**		Omitted –may not be completed - time pressure, patient or clinician characteristics
Perform venepuncture	**5**	**1**	Access to vein	On time – as the resource of blood sampling knowledge is likely to be high in this context	**11**	**4**	On time – as the resource of blood sampling knowledge is likely to be high in this context

Function	Up-stream Influence	Down-stream Influence	Function Output	Variability of Output In Outpatients	Outpatients sequence	Emergency sequence	Variability of Output In Emergency
Locate intended patient	**4**	**1**	Location of patient	Acceptable – called from waiting room	**6**	**1**	Acceptable
Check identity of patient	**4**	**3**	Correctly identified patient	Imprecise – unreliable checking wrong patient Not at all – familiarity inhibits checking. Distraction/interruption	**8**		
Communicate to establish identity	**0**	**3**	Patient conformance Relative conformance				
Inform patient and consent	**2**	**1**	Permission to take blood sample	Not at all – assumed consent, familiarity with patient	**9**		
Label blood sample	**7**	**4**	Labelled sample	Imprecise – incorrect minimal ID data set attached to sample	**13**	**9**	Imprecise – incorrect minimal ID data set attached to sample
Take blood samples	**4**	**1**	Blood sample taken	On time - as the resource of blood sampling knowledge is likely to be high in this context	**12**	**5**	On time - as the resource of blood sampling knowledge is likely to be high in this context
Cross check patient ID to request	**4**	**3**	Correctly identified patient Samples required	Not at all – check of patient ID omitted unintended patient Imprecise - unreliable checking unintended patient			
Bag samples	**2**	**1**	Bagged samples		**15**	**11**	

Function	Up-stream Influence	Down-stream Influence	Function Output	Variability of Output In Outpatients	Outpatients sequence	Emergency sequence	Variability of Output In Emergency
Cross check intended patient ID on blood sample	**3**	**1**	Cross check completed				
Record samples completed	**3**	**0**	Documentation	Acceptable – record of samples completed	**14**	**10**	
Send samples to lab	**5**	**1**	Sample received	Not at all – pod system malfunctions and may prevent samples reaching correct destination	**16**	**12**	Omitted – pod system malfunctions and may prevent samples reaching correct destination

Practitioner Resources

The function 'Assign appropriate staff' will influence the ratio between the demand for blood samples and the ability for a healthcare system to respond. Practitioners suggested this function may compromise later checking functions.

> *"I like to double check and make sure I have got the right person…. in this situation that you are totally busy that kind of double checking process can sometimes go out the window"*

Time pressure contributes to workload, and is a stressor which can negatively impact individual performance in tasks that rely upon attention to ensure accuracy [24]. Unpredictability in workload and availability of a venepuncturist can create real and perceived time pressures.

Context of Blood Sampling

The number of practitioners involved to complete a single blood sample varied. Instantiations (scenarios) using the FRAM model illustrated two clinical contexts. In an emergency, several practitioners may attempt to take blood, the sample might be passed to another practitioner to initiate the request process and label the bloods. Further complications or delays occur for an unidentified patient. Without the minimum patient core identifiers, practitioners are unable to access technical systems and request investigations. To enable the sample to be processed a temporary identification number is created. However, once the identity of the patient is established unique identifiers e.g. CHI or NHS numbers will be used and at some stage the patient may have two numbers.

In the first instantiation the urgency of the context justifies distributing functions within the team to allow those with clinical expertise to remain with the patient. In outpatients the demand for blood samples, time constraints and physical work environment influenced why practitioners distributed the functions.

Both strategies aimed to positively influence the system's efficiency where time was limited for different reasons. In outpatients the working practices also aimed to reduce the risks associated with checking a patient's information in a challenging working environment; where multiple practitioners work with several patients in the same workspace with distractions and interruptions. The absence of wristbands in this setting combined with time pressures and familiarity with patients, highlighted why variability in identify checks may occur.

"I think sometimes you see so many patients you just forget (to check). Not intentionally, sometimes you think I know this patient. "

Information

Three functions: 'Decide to take blood sample', 'Collect relevant information' and 'Complete request process' influenced the greatest number of other functions within the model. The expertise of the practitioner is instrumental to the decision and demand for blood samples. Increased demands were predicted as expertise fluctuates e.g. during the rotation of foundation year medical staff.

Accessibility of information was also influential to the reliability and variability associated with decision making. The usability of information sources was suggested as influential to the efficiency and accuracy with which patient details are recorded and the patient is correctly identified.

Collecting information to complete requests may be pulled from several sources. The lack of accessibility, usability and standardisation between clinical settings, were reported as influential to the accuracy and efficiency in which information can be collected.

> *"I have just come back from working in hospital X and each of the group and save forms is different and I think that can sometimes causes bits of it not to be filled out well"*

This potential for variability in collecting patient information introduces a greater dependency upon later checking to ensure a success. However, observations suggested familiarity with patients may impede this check.

Labelling Blood Samples

'Labelling the blood sample' is influenced by seven functions with the potential for variability in timing or accuracy. The dependency upon a high number of functions creates vulnerability. The quality of labelling determines efficiency and safety in management of blood samples. Hand written labels are required for samples completed prior to a blood transfusion. Incorrectly labelled samples risks a patient receiving incompatible blood components or delaying transfusions. Writing neatly on a sample bottle with a non matt, curved surface, whilst ensuring all text remains inside boxes approximately 2mm high was considered a challenge. This combined with contextual factors such as time

pressure, competing work requests and distractions were all cited as influential to variability in performance.

Printing blood sample labels is acceptable for the majority of blood tests. This requires access to technical systems, without which practitioners need to adjust the sequence of blood sampling functions. Unavailability of these systems were reported due to: system maintenance, insufficient numbers in proportion to staff working within an area, equipment failure and delayed repairs. Practitioners implied the unavailability of technology should not delay obtaining a blood sample; delays may consequently impede the transition of a patient, access to treatment or discharge from hospital. Subsequently, requests and labels may be gathered after a sample is obtained. This suggests the details on the requests and labels may not be used to inform the remaining functions associated with 'checking identity of patient'.

DISCUSSION

This pilot study sought to understand why variability in blood sampling performance in acute hospital settings can occur. The findings provide insights into why practitioners modify their work practices to manage the context and environments where blood sampling is required.

Healthcare seeks to identify a 'cause' for an accident or incident [5], with the practitioner often suggested as the more unpredictable component of the system.

This pilot study has highlighted why variability in practice is likely and is in fact the norm, with the potential for both positive and negative outcomes for patient safety and accommodating organisational demands.

An organisation or complex system is a dynamic entity which operates within a safety envelope. Gradually everyday work practices or adjustments are made to accommodate organisational priorities which will impact the decisions made daily by practitioners. The emergence of strategies can introduce 'drift' in the way work is done [25]. The term 'Resilience' or 'Resilience engineering' 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 functions. 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 [26].

The concept of system resilience is a developing approach which informs a Safety-II approach for healthcare to consider as an alternative to improve the quality and safety of their systems by ensuring more things can go right [8,27]. This assumes variability in human performance is normal but aims to promote positive performance variability whilst dampening the negative.

FRAM has provided a realistic model of blood sampling to understand why variability occurs and how the system succeeds through adaptability of practitioners and where system resilience can be improved. Four key themes are proposed for further consideration to enhance the quality, safety and efficiency of blood sampling activities: design, reliability, resources and reporting.

Design

Equipment and technology relied upon within environments such as healthcare should be informed by the principles of good design [28]. These require consideration to the context, task and users to inform on a design which can promote usability, safety and efficiency [29]. The FRAM analysis highlighted how the function of 'collect relevant information' is influential to the accuracy of several other core functions. The checking of the identity of the patient is a function intended to defend against errors associated with these functions and the majority of safety interventions focus upon practitioner behaviour when labelling and checking. Evidence relating to improvement strategies for blood sampling activities highlights that several interventions in combination can have an impact upon reducing WBIT incidents, however, these are rarely maintained and a fresh look at the problem has been called for [1, 2].

There appeared little evidence relevant to the physical design, presentation and quality of the equipment and interface design influencing collecting the correct information. Hand writing blood sample labels on a curved and small writing surface requires physical dexterity. Combined with wearing gloves and high levels of distractions highlights how well practitioners do to succeed.

Job design should also be explored further to understand why a difference between job roles and WBIT prevalence exists. The characteristics of work

activities and control of the timing of these activities may differ between job roles predisposing some job roles to performance influencing factors more likely to influence blood sampling activities.

Designing to make it easier to do the right thing as often as possible is at the heart of Human Factors. This would seem relevant to the design of software interfaces, request forms and blood sample bottles, which need to consider when and where blood sampling occurs and associated system hazards (e.g. time pressure, conflicting work demands), to evaluate the usability of any design and ensure risks are As Low as Reasonably Practicable (ALARP)[30].

Standardising through design can influence variability in performance. Practitioners are regularly required to rotate around hospitals or move between departments. Standardisation of the design of the artefacts that support patient safety relevant activities common to any healthcare setting could reduce variability in the format that information is presented.

Reliability

Healthcare's reliance upon technology to complete core activities will continue to increase. The instantiations captured within the FRAM model highlighted the significance of the reliability and availability of technical systems to the sequence order and adjustments necessary to complete blood sampling within a required time frame. Practitioners will delay, adjust the order or distribute functions within a team to ensure blood sampling did not delay patient care. This flexibility to adapt to technical failures was highlighted as frequent and necessary to manage patient care and work demands within care settings studies.

The resilience in systems, with increased dependency upon technology, needs to consider how to learn, monitor and respond to expected and unexpected failures or maintenance. Proactive systems to understand the risks associated with failure in technology, effective failure and maintenance reporting systems and procurement of user tested systems could benefit healthcare as it has done in high reliability industries [31]. This pilot study suggests organisational effectiveness and practitioner behaviour will both be influenced by the reliability of technology necessary to obtain relevant patient information, complete a request and label a blood sample. The ability to anticipate and respond to any

fragility in these systems would seem to be essential but as such does not appear to be a priority.

Resources

The ratio of blood samples obtained compared to competent and confident practitioners available to complete them influenced several outputs of the functions.

The variability and potential mismatch between demand and resources was reported as influencing the time pressure and work demands for practitioners. Practitioners highlighted the need to balance patient safety when completing functions with an efficiency to ensure optimal patient care and satisfy organisational goals. An organisation may not be able to sustain an ideal ratio, however, understanding how to predict and respond to sudden or sustained mismatches may enhance resilience. Seasonal fluctuations associated with increases in patient caseload and the rotation of junior practitioners were two such examples reported as increasing the number of blood samples. A mismatch in resources and demand may influence the individual's cognitive performance and compromise the ability to remain engaged with a task, alertness, short term memory, attention and motivation levels [24,32,33,34]. The concept of leading indicators, where key performance indicators are identified and monitored, are used by other industries [31] to proactively identify factors predicted as likely to influence performance. Leading indicators aim to build resilience into the system with an ability to anticipate, monitor and respond in a planned way rather than rely upon frontline staff to absorb variability in the system.

Monitoring, Reporting and feedback

Incident reports and near miss data cannot be interrogated to consider how internal factors may influence variability in performance e.g. stress, fatigue, nutritional levels. There was no evidence to suggest time on duty, time since last break and factors associated with fatigue are recorded as standard practice in the healthcare settings collecting incidence data [1]. The incident analysis process will heavily influence the lessons gained by organisations to inform future interventions or strategies to manage safety concerns identified [5].

Healthcare incident data is limited by seeking a single 'cause' or deviation from expected practice with little consideration to underlying influences that contribute to the outcome recorded [19]. The SEIPs model has informed the

analysis of incident data in this pilot study. This has provided a broader systems approach to factors recognised as influencing human performance and potentially contributing to the outcome recorded. This avoids the assumption that a single cause can always be identified and instead seeks to identify factors within a healthcare system that did/could contribute to undesirable variability in performance. The practicality of procedures for all work contexts may imply that 'noncompliance' or adjustments to the procedure is normal to everyday work practices. Furthermore, there is no process to capture positive reporting on why and how the system succeeds or indicate the success rate of different job roles in relation to the frequency of completing an activity. Proactive monitoring of performance indicators and observations or reports on everyday work can focus an organisation's attention to how safety is really achieved and where safety concerns may emerge. Timing of feedback to practitioners and how practically actions can be achieved and evaluated by an organisation to ensure an effective response addresses the contributory factors identified is instrumental to a positive reporting culture and system resilience [13].

STRENGTHS AND LIMITATIONS

A number of study strengths were apparent. We adopted a holistic Human Factors methodological perspective in trying to understand the full range of system factors which may influence variability and performance. Similarly we also applied the FRAM approach which is particularly suited to understanding why things go well in complex socio-technical systems and to address the type of safety problem at hand. The multi-professional make-up of the research team also provided a broad range of Human Factors, safety science, clinical and managerial experience and expertise.

A number of limitations were apparent. This was a pilot study and as such data collection was limited by the time and number of participants recruited for interviews and observations. The observations were focused on clinical environments reflected by NHS Scotland and within the SHOT 2013 Annual report as suggesting greater risk of WBIT [1]. Limitations in the verification of the coding of incident data have already been highlighted and require further investigation. SEIPs appears to offer codes relevant to the incident data analysed here, however, future studies are required to consider its usability for the

analysis of all healthcare incident data and the inter and intra reliability of this approach.

It is questionable if any methodological approach can fully specify a work process in a complex socio-technical system, so it is likely that system factors of interest have yet to be captured. Given the small study scope and the focus on NHS Scotland hospitals then we should treat the findings with caution in terms of any wider generalisability, however they will still be of interest to the international practitioner, policy and research communities.

CONCLUSION

This pilot study has proposed a realistic model of blood sampling activities and why variability in performance exists. Practitioners may adjust their practice to balance patient safety in the context of fluctuating demands and challenging work environments and equipment.

Adopting a Human Factors approach and using the FRAM model has enabled the team to better understand how work is really done and why variability exists in a complex healthcare environment. The results of the study will be used to consider where resilience within the system can be enhanced.

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