The application of human factors to the blood transfusion process

The Application of Human Factors to the Blood Transfusion Process

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by

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Abstract

There are serious safety problems in blood transfusion and a Human Factors (HF) approach has great potential to address these safety issues, but has so far been underutilised. The overall aim of the PhD is to investigate how HF could contribute to improvements for the safety of patients receiving a blood transfusion. The main objectives are to apply and evaluate HF-based methods that could improve transfusion safety and in particular to introduce an enhanced learning process by using HF-based reporting of adverse transfusion incidents and a Safety II-based resilience assessment of the transfusion process in UK hospitals. This thesis attempts to address the following three questions in three studies: (1) What can we learn about human and organisation factors contributing to transfusion incidents and near misses from the existing incident database? (2) Can incident reporting be improved using a newly created human factors investigation tool (HFIT) combined with educational interventions? (3) Can a Safety-II approach improve clinical audit and maximise system resilience throughout the end to end blood transfusion process?

Results have shown existing adverse incident reports contained insufficient information about human and organisation problems for effective HF analysis. Introducing a bespoke HFIT to the blood-transfusion-related adverse incident reporting improved reporting of human and organisation issues, but there was still a tendency to assign most responsibility for errors to individuals rather than investigating underlying system problems; the educational interventions improved that only slightly. A novel approach to clinical audit has shown that in everyday work there is often an inability to resolve the main causes of disturbances to the standard procedure, so adaptations are made to a different part of the process, which may affect overall resilience.

The findings suggest that HF-based learning from incident reporting can encourage healthcare staff, but with some limitations, to report system and organisational factors that contribute to adverse events. The findings from the

last study particularly highlight that Safety II-based resilience assessments can provide in-depth insights into how healthcare professionals in the blood transfusion process adapt their work process. The study has shown that some adaptations are valuable quality improvement ideas that could be shared more widely, and some others are ad hoc alterations or workarounds that attempt to compensate for underlying failures in the system. This implies the Safety II-based resilience assessment questions can improve clinical audit process for blood transfusion (and beyond) by creating an opportunity to improve the potential for resilience in the healthcare organisation.

Overall, this research has contributed to the body of knowledge by introducing and evaluating HF-based methods to improve learning from transfusion incident reports, including embedding a novel human factors investigation tool (HFIT). In addition, a resilience audit method has been developed, which could be applied in healthcare fields beyond blood transfusion, and an innovative method of assessing adaptations has been proposed using an enhanced version of the Concepts for Applying Resilience Engineering (CARE) model in conjunction with categorisations based on the Systems Engineering Initiative for Patient Safety 2.0 model (SEIPS 2.0).

Statement of originality

The author (Alison J. Watt) is solely responsible for the work submitted in this thesis.

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- Loughborough Design School, Loughborough University
- The United Kingdom (UK) forum of Blood Services via their funding of the UK's Haemovigilance Scheme, Serious Hazards of Transfusion (SHOT)
- NHS Blood and Transplant (NHSBT) via their funding of the National Comparative Audit of Blood Transfusion (NCA)

This statement certifies that neither the submission nor the original work contained therein has been submitted for an award of this or any other degree awarding body.

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A special mention to Debbi Poles, SHOT Research Analyst, for remarkable fortitude in the face of my constant requests to extract or check data from the SHOT database.

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Jake, Ross, Beth, this is for you.

Publications

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Author biography

(Alison Watt, MSc, FIBMS)

I am a highly qualified Biomedical Scientist, who has specialised in blood transfusion and related immunology subjects, with over 40 years' experience. So how did I end up doing this PhD as I headed towards retirement? Partly inspired by my last full-time job, but also the simple joy of lifelong learning. I have done all my scientific and professional qualifications on a part-time basis, alongside full-time employment; starting as a school leaver and rising to the top of transfusion science with the masters level professional qualification that led to Fellowship of the Institute of Biomedical Sciences, followed a few years later with a traditional MSc in Immunology. A career detour took me into higher education, so whilst employed as an immunology senior lecturer, I completed a university teaching qualification (PGCHE - Postgraduate Certificate of Higher Education). Later, a short stint as a training manager for a commercial scientific company meant I added a business and marketing qualification. Then after I returned to my biomedical science roots, the Institute of Biomedical Sciences launched a new post-Fellowship Higher Specialist Diploma qualification, so I added that to my list of degrees too. Including the completion of this PhD, I have done 21 years of part-time study throughout my working life.

The idea of a PhD researching errors in blood transfusion first surfaced in the 1990s when I was working from home after having my third child. Day to day problems in blood transfusion laboratories had made me wonder why sometimes, despite apparently following the standard procedure, many hours of laboratory work would go wrong. Staff tended to be blamed, but we could seldom identify where or why things had gone astray and I wondered if people were the only problem in the system. I drafted an outline PhD proposal, but never enrolled to do that research, because I soon realised having three children was not 50% harder than having two; it was more like 150% harder. A mathematician should do a PhD to explain that calculation, but the outcome was that my maternity leave soon disappeared. I returned to a complex transfusion job, so the PhD idea went firmly onto the back burner. That last child was 20 years old before I started the research that became this thesis.

In the meantime, my career steadily progressed, and I rose to the most senior operational management position in the UK Haemovigilance Scheme, known as Serious Hazards of Transfusion (SHOT), which is a confidential enquiry system, receiving anonymised reports of all serious transfusion incidents in the United Kingdom. From the beginning, it was clear to me that SHOT recommendations were largely repeated year on year and often seemed to focus on advising colleagues to get it right next time. My children, who were teenagers at the time, described their mother's new job as Captain Hindsight, the South Park cartoon superhero, who flies in, not to help in an incident, but to use his 20-20 hindsight superpower to tell people what they did wrong and what they should have done better. I decided I did not want to be that kind of superhero. From this fresh perspective grew the idea of using SHOT's wealth of data to research whether Human Factors and Ergonomics (HFE) could be applied to the transfusion process, in order to help my UK-wide transfusion colleagues to find ways to get it right first time, instead of next time.

I discovered that my 20-year-old error problem now had a growing field of human factors scientists and ergonomists looking into similar issues and my enthusiasm for this subject was reborn. It has been a fascinating journey of discovery; learning new concepts to resolve old problems. Now semi-retired, I spend some of my slightly increased spare time volunteering for the Working Expert Group of SHOT, combining my new human factors knowledge with all my old transfusion experience to research and write the human factors chapter in each Annual SHOT Report. As my senior management position in SHOT was followed by immediate appointment to their Working Expert Group; inevitably my lead role with SHOT has been intertwined with the PhD studies throughout. Therefore, I must immodestly point out that when it says in this thesis 'SHOT did…' or 'SHOT recommends…' those initiatives were often either inspired or led by me, in conjunction with the SHOT Medical Director.

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Abbreviations

AABB	American Association of Blood Banks
ABO	The main blood group system of A, B, O and AB, not an acronym
AcciMap	Accident mapping method
ACT	Australian Capital Territory
AFFINITIE	Based on programme title: *A*udit and *F*eedback *IN*terventions to *I*ncrease the uptake of evidence-based *T*ransfusion pract*I*c*E*.
AHCS	Academy for Healthcare Sciences
Anti-D Ig	Anti-D immunoglobulin administration
ADU	Avoidable, delayed or undertransfusion (ADU)
BBT	Better Blood Transfusion
BBTS	British Blood Transfusion Society
CARE	Concepts for Applying Resilience Engineering
CDC	Centers for Disease Control
CQC	Care Quality Commission
CHFG	Clinical Human Factors Group
CIEHF	Chartered Institute of Ergonomics and Human Factors
CMV	Cytomegalovirus
CPSSQ	Centre for Patient Safety and Service Quality
DH	Department of Health (DHSC since 2018)
DHSC	Department of Health and Social Care
FFP	Fresh frozen plasma
FMEA	Failure Mode and Effect Analysis
FRAM	Functional Resonance Analysis Method
GEMS	Generic Error Modelling System
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HEV	Hepatitis E virus
HEE	Health Education England
HF	Human Factors
HFACS	Human Factors Analysis and Classification System
HFE	Human Factors and Ergonomics

HFIT	Human Factors Investigation Tool
HFMEA	Healthcare Failure Mode and Effect Analysis
HIV	Human Immunodeficiency Virus
HRO	High reliability organisation
HSC	Health Service Circular
HSCT	Haemopoietic stem cell transplant
HSE	Handling and storage errors
HSIB	Healthcare Safety Investigation Branch
IBCT	Incorrect blood component transfused
IOM	Institute of Medicine
ISBT	International; Society of Blood Transfusion
IT	Information technology
LIIPS	Leicester Improvement Innovation and Patient Safety
MeSH	Medical Subject Headings
MHP	Major haemorrhage protocol
MHRA	The Medicines and Healthcare products Regulatory Agency
N/A	Not applicable
NBTC	National Blood Transfusion Committee
NCA	National Comparative Audit
NCPS	National Center for Patient Safety
NHS	National Health Service
NHSE	NHS England
NHSI	NHS Improvement
NHSBT	NHS Blood and Transplant
NHSLA	NHS Litigation Authority
NIBTS	Northern Ireland Blood Transfusion Service
NIHR	National Institute for Health Research
NM	Near miss
NMC	Nursing and Midwifery Council
NPSA	National Patient Safety Initiative
PBM	Patient Blood Management
PHE	Public Health England
PSTRC	Patient Safety Translational Research Centre
RAG	Resilience analysis grid

RBC	Red blood cells
RBRP	Right blood right patient
RCA	Root cause analysis
RPN	Risk Priority Number
RRR	Rapid Response Report
RTC	Regional Transfusion Committee
SABRE	Serious Adverse Blood Reactions and Events
SaBTO	Advisory Committee on the Safety of Blood, Tissues & Organs
SEIPS	Systems Engineering Initiative for Patient Safety
SHOT	Serious Hazards of Transfusion
SNBTS	Scottish National Blood Transfusion Service
SOP	Standard operating procedure
SPN	Safer Practice Notice
SRK	Skills Rules Knowledge
STAMP	Systems Theoretic Accident Modelling and Processes
STIR	Serious Transfusion Incident Reporting (Australia)
STPA	System-theoretic Process Analysis
TP	Transfusion Practitioner
TQM	Total Quality Management
UK	United Kingdom
UKAS	UK Accreditation Service (pathology laboratory regulator)
UK Forum	UK Blood Services Forum - committee devolved blood services
UKTLC	UK Transfusion Laboratory Collaborative
URL	Uniform resource locator
USA	United States of America
vCJD	variant Creutzfeldt-Jakob Disease
V2V	Vein to Vein
WAD	Work-as-done
WAI	Work-as-imagined
WBS	Welsh Blood Service
WHO	World Health Organization
WNV	West Nile Virus

Chapter 1 Introduction

1.1 The research problem

Imagine yourself in a hospital bed, feeling quite unwell; tired and weak. Maybe you have had a major operation, or given birth, or been involved in a road traffic accident? A healthcare professional informs you that some blood is being prepared for you to have a transfusion. Would you start to worry? You may have heard there is a risk of getting a virus, such as Human Immunodeficiency Virus (HIV) or Hepatitis B or C (HBV, HCV) or you might be aware that blood can transmit the human prion disease known as variant Creutzfeldt-Jakob Disease (vCJD), which is linked to 'mad cow disease' (bovine spongiform encephalopathy). You probably do not imagine you might be given the wrong blood.

It is not surprising that patients still fear an infection as the most dangerous outcome of exposure to a blood transfusion, because the media have often reported this risk. An inquiry has been established, which is currently examining why people in the United Kingdom (UK) were given infected blood (Infected Blood Inquiry, 2019). The data being submitted to this inquiry relate to thousands of individuals, of which most were haemophiliacs, infected by receiving infusions of blood products, such as Factor VIII (Rosendaal *et al*., 1991), rather than the traditional labile blood components associated with hospital-based blood transfusions. These common liquid blood components are supplied in the UK by National Health Service (NHS) blood transfusion centres from a volunteer blood donor source. Although a small proportion of the historical infections being investigated by the Infected Blood Inquiry were from labile blood components, the biggest risk was as a result of patients receiving regular treatment with blood products. The important distinction is that although blood products are derived from blood, they are classed as medicinal preparations, and therefore, are commonly supplied by commercial pharmaceutical organisations. Blood products are produced in bulk as dried preparations for later reconstitution, and most of the products associated with the infection scandal were sourced from commercial donors in the United

States of America (USA) (Darby *et al*., 1989 & 1997). It is common for plasma products to be made from large pools of 10,000-50,000 donations, which increases the risk of viral transmission, because a single positive donation could infect the whole pool. However, modern methods of plasma fractionation have greatly reduced the risk of transmission of infected agents (Burnouf, 2007), as have improved viral testing (PHE, 2018) and other safety initiatives such as universal leucodepletion (Bianchi *et al*., 2016), improved donor selection strategies and viral inactivation of plasma pools (Barbara, 1998).

Adverse effects of blood transfusion have been recorded via haemovigilance schemes in many countries since the early 1990s (Wood *et al*., 2019) and in the UK since 1996 via the UK haemovigilance scheme, Serious Hazards of Transfusion (SHOT) (Williamson *et al*., 1996). It is now recognised that the major risks from a blood transfusion are related to errors, particularly misidentification issues, as described in the patient safety leaflet (NHSBT, 2016) issued to those who are about to have a blood transfusion by the English Blood Service, National Health Service Blood and Transplant (NHSBT). The outcome of an error in the transfusion process can lead to death or major morbidity, so the current imperative is to find ways to reduce the impact of errors on patient safety and to research whether the transfusion process can be modified to reduce the risk of error and improve the potential for resilience in healthcare organisations that administer blood transfusions.

Before examining human factors in transfusion, it would be beneficial to understand the nature of human error. This is covered in two influential books by human factors experts *The Nature of Error* (Reason, 1990) and *The Field Guide to Understanding Human Error* (Dekker, 2006).

Reason (1990) opens with the view that “Recurrent error forms have their origins in fundamentally useful psychological processes”, then continues with a review of early psychological research, demonstrating that error is an expansion of conventional human performance. This work concludes that the same cognitive processes responsible for normal learning will also give rise to human errors. Reason develops the concept of active (individual human error)

and latent (system error) failures and these are examined in more detail in section 2.4.1. A better understanding of how errors occur can lead to the development of better systems and processes to minimise the chance of errors happening.

Dekker (2006) defines two views of an accident or incident with human error originally seen as the cause of trouble or now understood as the symptom of deeper trouble. He calls the first the old view of human error, while the second is the new view of human error, despite already being over a quarter of a century old (Figure 1.1).

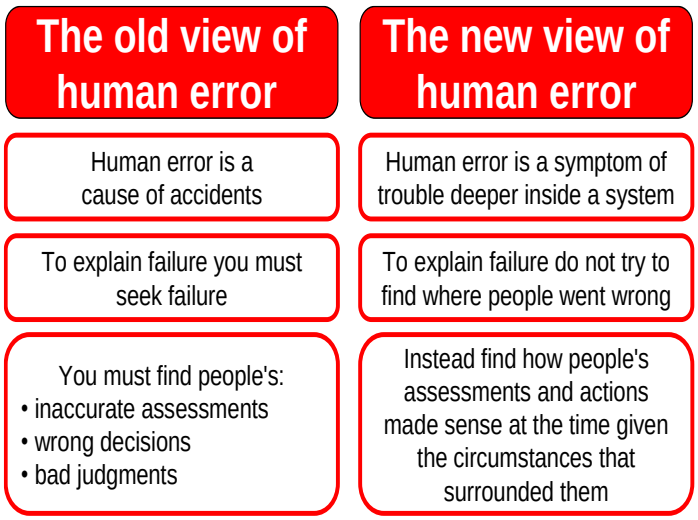


Figure 1.1: Two views on human error

(adapted from Dekker, 2006)

Dekker's Field Guide (2006) compares the old view with the new and demystifies the temptations that encourage those investigating error to fall into traps such as believing the error is a result of a few bad apples, or that a single root cause can be found, or that "large psychological labels may give you the illusion of understanding human error but that they hide more than they explain". The guide also demonstrates how to reverse engineer human error using human factors principles. Both these books set the scene for an enhanced understanding of human error and link the psychological and

cognitive background to ways of assessing the wider aspects and system problems.

A further view on human error posits that it is a misnomer and should not exist as something that can be observable in an incident or accident (Hollnagel, 1983). Although human error cannot be a function, it is often reported as a cause, but that would presuppose that the human was culpable in making the error. Therefore, the activity leading to an incident cannot be classified as human error and is more accurately defined as a failure to achieve the intended outcome. Thus, attributing error to the actions of one person or team is not an objective ascription (Woods *et al*., 1994). As such, the use of the phrase human error is likely to be misleading and might be better not used at all (Hollnagel & Amalberti, 2001).

Any examination of modern attitudes to patient safety begins with two seminal reports published almost simultaneously; in the United States of America (USA) To Err is Human (Kohn *et al*., 2000) and in the United Kingdom (UK) An Organisation with a Memory (Donaldson, 2000). Both highlighted that the cause of errors was not usually individual failure. The USA Institute of Medicine (IOM) (now known as the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine) publication defined error as:

> The failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning).

This definition is based on an original publication (Reason, 1990) which defines error as:

> The failure of a planned sequence of mental or physical activities to achieve its intended outcome when these failures cannot be attributed to chance.

Intention is considered important in defining errors, because it is suggested that these result from two types of failure, either actions do not go as intended or the intended action is not the correct one (Reason, 1990).

Both the USA and UK publications put the problem of patient safety into context with statistical analyses. The IOM estimated that between 44,000 and 98,000 Americans die each year as a result of preventable medical errors (Kohn *et al*., 2000) and these figures were based on studies conducted in Colorado and Utah, which showed adverse events occurred in 2.9% of the hospitalisations and in New York, where adverse events occurred in 3.7% of the hospitalisations. From these studies, the IOM concluded that systems and processes of care needed to be redesigned to prevent and/or mitigate the impact of medical errors. The UK study estimated harm to patients at a rate in excess of 850,000 a year and suggested 60,000 to 255,000 serious disability or deaths (Donaldson, 2000). Those figures were extrapolated for NHS admissions from studies in the USA and Australia, so may not be an accurate assessment for UK healthcare. Major outcomes from the UK publication were the creation of the National Patient Safety Agency (NPSA) in 2001 and the National Reporting and Learning System (NRLS) in 2003, a central database of patient safety incident reports. The NPSA activities, including the NRLS, were taken over by NHS England in 2013 and later merged with NHS Improvement in 2019.

In English NHS hospitals, the incidence of preventable deaths has been shown to be lower than previous estimates (Hogan *et al*., 2012). This review judged 5.2% of deaths as being preventable and extrapolated there would have been 11,859 adult preventable deaths in English hospitals in 2009. As the Hogan *et al*. (2012) study was carried out in NHS hospitals, these figures may be more accurate. More recently, a study in the USA calculated a mean rate of death from medical error of 251,454 per year using studies reported since the IOM report and comparing their estimate to the Centers for Disease Control (CDC) rankings (Makary & Daniel, 2016). While acknowledging the problem with assessing deaths caused by medical error, because these are not coded separately on death certificates, they suggested that medical error is the third

most common cause of death in the USA after heart disease and cancer. This conclusion was disputed in a published response to this paper (Shojania & Dixon-Woods, 2016). Irrespective of the disputed figures, the basic tenet holds, i.e. it is difficult to quantify the estimation of harm by medical error. It was calculated that there is a 1 in 3 million chance of a person dying while travelling by plane and in comparison, the risk of patient death occurring due to a preventable medical accident in healthcare is estimated to be 1 in 300 (Leape, 2007). Estimates also indicate that in high-income countries, about 1 in 10 patients is harmed while receiving hospital care (WHO, 2019). A systematic review pooled international data from January 2000 onwards, comprising 70 studies with over 337,000 patients (Panagioti *et al*., 2019). This meta-analysis found preventable patient harm occurs in 6% of patients and that 12% of preventable patient harm was severe or led to death. Whatever the true scale of patient harm from error, it is important to recognise the dangers, and to study ways of reducing that risk to improve patient safety.

Blood transfusion is considered as an ultra-safe profession, avoiding risk. A paper on safer healthcare (Vincent & Amalberti, 2016) examines three contrasting approaches to safety (Figure 1.2):

- Ultra-adaptive, embracing risk
- High reliability, managing risk
- Ultra-safe, avoiding risk

The authors have demonstrated that each approach differs by a factor of 10 between the best operators and those that are less good within a single area, so the diagram indicates a series of log-scale differences, i.e. 10-2 to 10-3 etc. between embracing risk and avoiding risk.

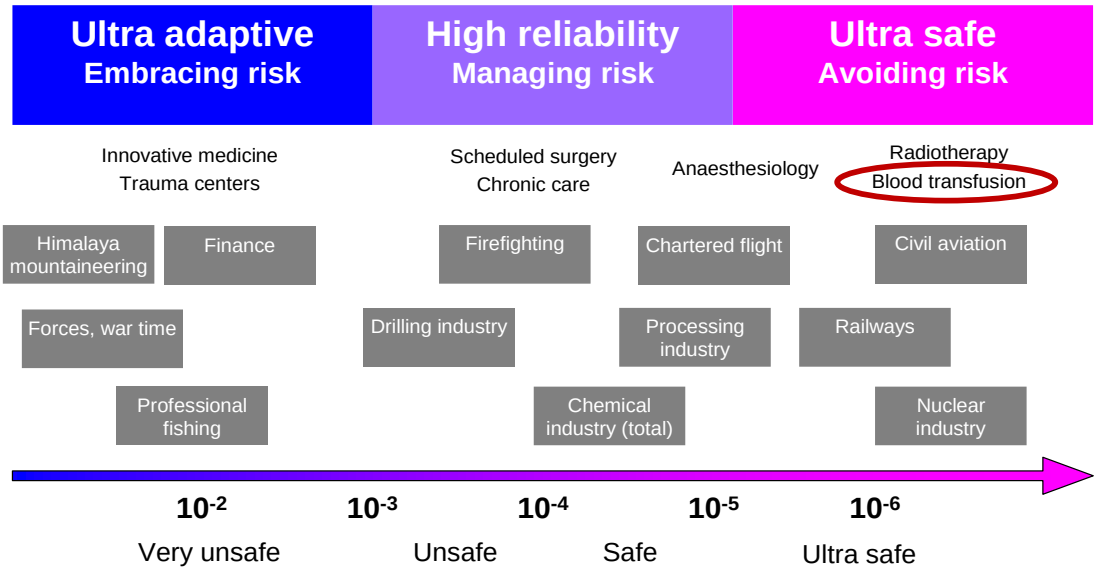


Figure 1.2: Contrasting approaches to safety

(adapted from Vincent & Amalberti, 2016)

This is borne out by the UK haemovigilance analysis that estimates the risk of death as close to 1 in 117,000 components issued, of which the risk of death from avoidable error is approximately 1 in 167,000, the other deaths being unavoidable risks, such as an adverse reaction to the component (Narayan *et al.*, 2019). Errors leading to a mismatch within the ABO system can be particularly dangerous, because ABO is the most crucial of all blood groups for a safe blood transfusion (Schwarz & Dorner, 2003) as humans automatically produce antibodies to the antigens they lack. For example people who are group O lack both A and B antigens, so produce antibodies to both, including a combination antibody (Anti-A,B), whereas group AB people produce no antibodies to A or B antigens. Data from the United Kingdom (UK) haemovigilance scheme, Serious Hazards of Transfusion (SHOT) show that approximately a third of ABO incompatible blood transfusions lead to death or major morbidity (Bolton-Maggs *et al.*, 2014). Therefore, without an understanding of matching for the ABO blood group system, human transfusions would be nothing more than a lottery, akin to Russian roulette with odds that are twice as dangerous.

1.2 How prevalent and serious are transfusion-related incidents?

Errors in transfusion can cause very severe outcomes for patients. The result can be as serious as death and other serious consequences are termed major morbidity, which is defined by the SHOT Steering Group with a list of complications (SHOT Definitions, 2018) that would result in long-term harm or require a prolonged hospital stay, often including admission to intensive care or a high dependency unit. Cumulative figures extracted from Annual SHOT Reports published between 1996 and 2017 (www.shotuk.org) show there have been 262 reported cases of transfusion-associated deaths in that 21 year period, of which 64 were definitely attributed to the transfusion, the others were categorised as probably or possibly associated. A further 1,456 patients have suffered major morbidity. The percentage of deaths and major morbidities has decreased within those 21 years (Figure 1.3) but has recently stabilised at approximately 10% of all haemovigilance cases reported to SHOT each year. Therefore, further measures are now needed to try and reduce the errors that can lead to these harmful outcomes for patients.

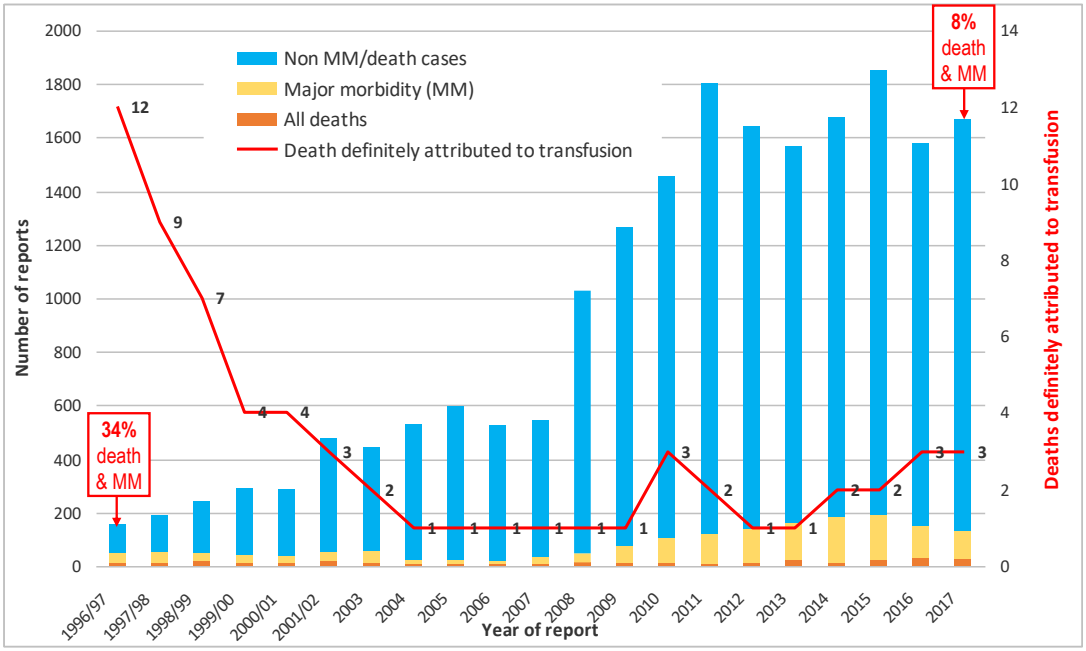


Figure 1.3: Percentages of transfusion deaths and major morbidities within each year's haemovigilance reports

(updated from SHOT Teaching slide set, 2016, with permission)

An illustration of the danger of errors in transfusion is described in Vignette 1.1, which is Case 6.2 as printed in the 2015 Annual SHOT Report (reproduced here with permission) (Bolton Maggs *et al*., 2016). This is the most recent ABO-related death reported to SHOT. The incident occurred in 2014, but as an example of the complexity of such cases, there were complications in completing the inquest, so the report was not finalised for publication until the 2015 Annual SHOT Report (Bolton-Maggs *et al*., 2016). The incident occurred as a result of an error in patient identification at the point of administration of a unit of red cells. Errors such as this, often without such devastating outcomes, are regularly reported to SHOT. It is standard practice to check patient identification at the point of administration of blood components, which prevents many of the errors continuing to transfusion, but similar errors continue to occur.

Vignette 1.1: ABO-incompatible transfusion and death of the patient

An elderly man had urgent coronary artery bypass surgery and required postoperative transfusion. The wrong unit was collected from a remote issue refrigerator, and an error was made when checking the patient identification against the blood. The error was not realised until after the full unit had been transfused. The patient developed suspected cardiac tamponade and died after some hours of active intervention.

Frequently the outcomes of an investigation into an event like this would range from serious punishment or disciplinary measures against the individual staff member(s), including prosecution (NMC, 2017) or dismissal (BBC, 2014), to actions such as retrain the individual(s) involved or reiterate the standard processes to all staff involved in the administration of blood. These interventions are unlikely to reduce the frequency of similar errors, because they are not dealing with the system failures, e.g. in this case, Vignette 1.1, blaming the individual alone would not deal with why or how the incorrect unit was collected and what other aspects may have contributed to the incident, e.g. possible issues related to the remote refrigeration system.

As a result of errors leading to incidents like the case described in Vignette 1.1, SHOT made the following recommendation (Bolton-Maggs *et al*., 2016): "Use a 5-point practice improvement tool (checklist) at the patient's side immediately prior to connection of the transfusion. Never do this away from the patient", and assigned this as an action for Trust/Health Board Chief Executive Officers and Medical Directors responsible for all clinical staff. This recommendation was repeated and strengthened in the 2016 Annual SHOT Report (Bolton-Maggs *et al*., 2017a), which led to NHS alerts in England and Wales (see section 2.2).

Throughout the existence of SHOT, improvement initiatives have succeeded in reducing the risk of transfusion, such as those caused by ABO-related patient-safety incidents, which have reduced from 15 in the first decade to 5 in the second decade. The unintentional transfusion of ABO-incompatible blood components is a Never Event, reportable to the English Department of Health (now known as Department of Health and Social Care) (NHS England, 2018) and similarly reportable in the devolved health services of the UK. However, these safety developments may not be mitigating other patient-risk factors, such as delay, i.e. the patient not receiving a transfusion in a timely enough manner, which was the largest single cause of preventable deaths in both 2016 and 2017, n=16/47 (34.0%) (Bolton-Maggs *et al.*, 2018). SHOT has only recorded incidents leading to unacceptable delays since 2010 and from then until 2017 there have been 31 deaths due to delay, considerably more in eight years than the 2 ABO-related deaths in the same time period (Jan 2010-Dec 2017).

In order to assess the severity of the outcome of error incidents compared to unavoidable adverse transfusion reactions, Figure 1.4 extrapolates data from the Annual SHOT Reports for the last 10 published years (2008-2017) to show deaths due to fully avoidable incidents compared to deaths caused by clinical reactions. By comparing the first five years (2008-2012) and the last five (2013-2017) in Figure 1.4, it can be seen that the number of avoidable deaths has increased from 12/53 (22.6%) to 35/110 (31.8%), despite a number of safety strategy improvements.

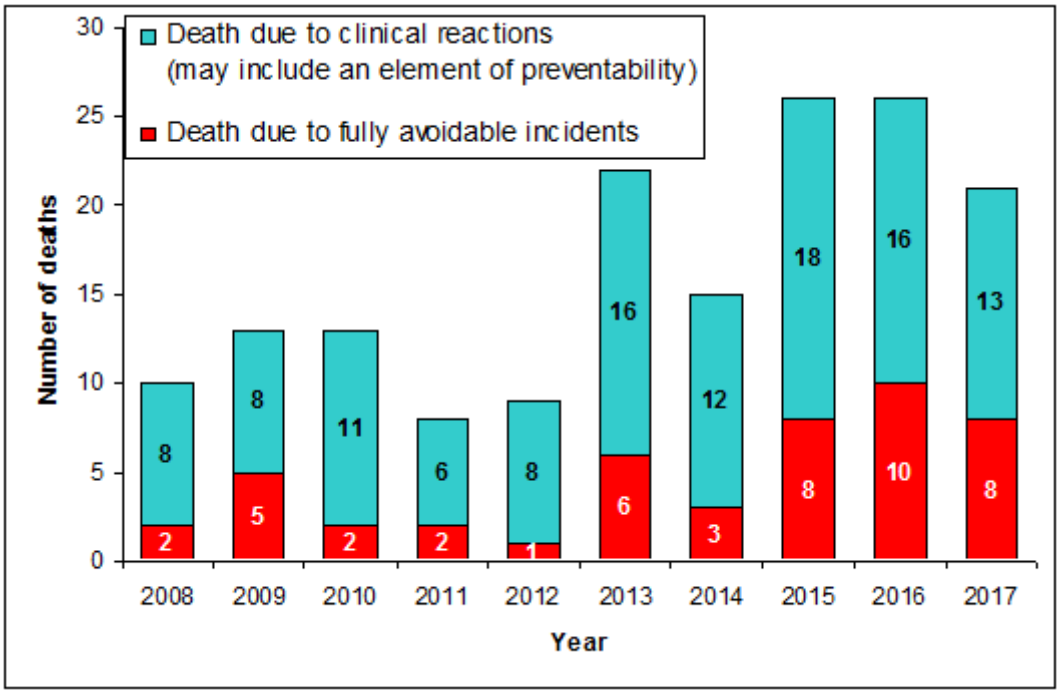


Figure 1.4: Ten years of transfusion deaths 2008 - 2017

(collated from SHOT Reports 2008 - 2017, www.shotuk.org)

There is a grey area between fully avoidable patient-safety incidents and the completely unpredictable, physiological reactions, meaning that some clinical reactions could be classified as preventable incidents, because they have elements of human or organisational factors contributing to situations where these reactions might have been avoided. In 2016 and 2017 SHOT published the total number of avoidable deaths, including defining the clinical reactions that resulted from preventable incidents, such as cases of transfusion-associated circulatory overload (TACO) resulting from an incorrect management of the patient's fluid intake capacity. This showed 30/47 (63.8%) total avoidable deaths in those two years compared to the figures for 2016 and 2017 presented in Figure 1.4, which show 18/47 (38.3%) deaths due to fully avoidable incidents. From that it can be surmised that a sizeable number of the deaths due to clinical reactions in previous years may also have been attributable to human or organisational factors.

1.3 Underexploited human factors approach to transfusion-related patient safety

To complete the move towards an increased focus on patient safety aspects in transfusion, there now needs to be a greater understanding of human factors to enhance error awareness. Healthcare in the UK is embracing human factors as a tool to improve patient safety, for example the formation of the Healthcare Safety Investigation Branch (HSIB), whose investigation model for serious healthcare incidents is based on past research in safety science and human factors (HSIB, 2018, p.2). The General Medical Council (GMC) published a plan in October 2018 to embed human factors into their processes when investigating adverse events and serious failings (GMC, 2018). The independent regulator of health and social care in England, the Care Quality Commission (CQC) has promoted a systems approach to quality improvement in hospitals (CQC, 2018, p34). The NHS patient safety strategy, published in July 2019, supports the development of a network of patient safety specialists in local systems, whose role would include ensuring that systems thinking, human factors and just culture principles are embedded in all patient safety activity (NHSI, 2019b). The strategy also states that research in patient safety demands involvement from patients and staff to be considered valid and to have impact. Therefore, the National Institute for Health Research (NIHR)-funded Patient Safety Translational Research Centres (PSTRCs) encourage collaborative research, which aligns closely with human-centred design and focuses on innovations rooted in reality and human factors. The literature review (Chapter 2) shows there has been very little research into transfusion errors incorporating a human factors approach, so relating human factors principles and research to transfusion will be the next major staging post in transfusion-related patient safety.

There is a need for better learning from transfusion incidents, which might be achieved by applying a human factors approach. There are known problems with incident reporting (Macrae, 2016), such as misguided beliefs that more is better, i.e. report it all, or that rates of reported incidents are a good measure of safety. Macrae (2016) compares healthcare incident reporting to the early days of aviation, when for example British Airways had 47 four-drawer filing

cabinets of reports, but nothing was done with the information. Many healthcare incident reporting systems have little or no feedback process and very rarely any two-way engagement. However, the UK haemovigilance scheme (SHOT) manages to avoid many of these issues, because it is a long-standing confidential enquiry, which has high quality data, provided by every major healthcare organisation in the UK (100% NHS participation). Experts analyse the data annually and make recommendations for changes in practice, so SHOT does not fall into the trap of collecting information and doing nothing with it. In addition, SHOT concentrates only on serious hazards, so does not encourage the traditional healthcare failing of reporting any and all incidents (Macrae, 2016). Conversely, transfusion error reporting does mirror some of the problems identified in other healthcare incident reporting, such as the belief that reporting incidents is a measure of safety performance and the risk of bias when local investigators report incidents to SHOT.

Traditional recommendations have not achieved a sufficient reduction in errors (Figure1.4) and in the 2013 Annual SHOT Report, published 2014, (Bolton-Maggs *et al*., 2014) identified approximately 80% of reports were defined as being related to human error. A key recommendation from that 2013 Report was:

> "Annual SHOT data consistently demonstrate errors to be the largest cause of adverse transfusion incidents. In line with human factors and ergonomics research it may be better to redesign the transfusion process by process mapping and audit at local and national level, to design out the medical errors."

This partially inspired the research being undertaken for this thesis and the problems with error are not decreasing, with recent data showing over 85% of reported incidents are error-related (Narayan *et al*., 2019). As a national incident reporting body, SHOT has a unique position in the UK to improve patient safety in transfusion practice by investigating and addressing system-wide risks (Macrae, 2019).

Another underexploited area where human factors principles could be beneficial is clinical audit of the transfusion process. Regular clinical audits are

undertaken both at a local level within each healthcare organisation and nationally by the National Comparative Audit of Blood Transfusion (NCA). Learning from these audits is compromised in a similar fashion as the learning from incident reporting. Customarily, clinical audits are designed to highlight deviations from standard processes or clinical guidelines, so they only highlight negative aspects and do not encourage learning from resilient properties of the system. In addition, there are problems with feedback and effecting change from audit reports, especially at the national level (Lorencatto *et al*., 2014; Gould *et al*., 2018). As a result there has been an in-depth research programme linked to national transfusion clinical audits, known as AFFINITIE, a name based loosely on the title of the National Institute of Health Research (NIHR) programme: Development and Evaluation of enhanced ***A***udit and ***F***eedback ***IN***terventions to ***I***ncrease the uptake of evidence-based ***T***ransfusion pract***I***c***E***. The AFFINITIE study used implementation science principles in a cluster-randomised trial designed to research options to enhance learning from audits. (Gould *et al.*, 2014; Lorencatto *et al.*, 2016). Early results from the study focus on improving the relevance and specificity of feedback, including behaviour change techniques, and a need to support recipients of the feedback to deliver change locally (Stanworth *et al.*, 2019). However, as this study centres on feedback as the key improvement technique it may have missed the opportunity to consider HF-based developments of the audit process itself.

1.4 Aims and objectives

There are serious safety problems in blood transfusion and a human factors (HF) approach has great potential to address these safety issues, but has so far been underutilised. The overall aim is to apply a human factors approach to blood transfusion safety improvement. The main objectives are to apply and evaluate HF-based methods that could improve transfusion safety and in particular to introduce an enhanced learning process by using HF-based reporting of adverse transfusion incidents and a Safety II-based resilience assessment of the transfusion process in UK hospitals. This thesis aims to address the following three questions in three studies:

(1) What can we learn about human and organisation factors contributing to transfusion incidents and near misses from the existing incident database?
Previously reported transfusion errors will be retrospectively categorised using various human factors (HF) models and methods for accident and incident investigation to investigate what learning could be achieved from historical data.
(2) Can incident reporting be improved using a newly created human factors investigation tool (HFIT) combined with educational interventions?
A bespoke Human Factors Investigation Tool (HFIT) will be incorporated into the national database for reporting transfusion incidents and near misses and a prospective analysis of transfusion errors will be carried out on the data provided.
(3) Can a Safety-II approach improve clinical audit and maximise system resilience throughout the end to end blood transfusion process?
The aim is to audit the transfusion process from end to end in various hospitals using human factors principles to examine the resilience of the process. The study will follow the complete transfusion process, from taking a patient's sample, through to giving components back to the patient. This process involves a multidisciplinary team, usually a different person and often a different profession at each step.

Overall this PhD is intended to fill a knowledge gap, because there is very little evidence of human factors being applied to blood transfusion (Chapter 2). The research, via Studies 1, 2 and 3, will look at the scope of the problem, by categorising incidents using human factors models/methods using past data as well as prospectively examining system and organisation elements of reported incidents and finally analysing the transfusion process for resilience as detailed in Chapters 4, 5 and 6. This will show the effectiveness, or otherwise, of the current Safety-I procedure used in transfusion incident reporting, as examined in Study 1 and Study 2; then Study 3 will analyse examples of how resilience and a Safety-II approach can work in practice (Hollnagel, 2014). Informed by these studies, recommendations can be made to improve the overall design of the process.

1.5 Thesis structure

This thesis contains seven chapters which are briefly summarised below and also depicted in Figure 1.5.

Chapter 1 – outlines the research problem, with particular focus on the prevalence and seriousness of transfusion-related incidents, highlighting that a human factors approach to transfusion has yet to be exploited. The research aims and objectives are given and the structure of the thesis is summarised.

Chapter 2 – reviews the background literature, including a history of blood transfusion safety improvement. Transfusion publications related to human factors are reviewed and there is an examination of literature relevant to human factors for incident reporting and proactive risk/system analysis, including a review of human factors models and methods.

Chapter 3 – describes the research methodology, including the research paradigm and the place of this research within transfusion research as a whole. The research approach is examined and the strategy, design, methods and data collection/analysis. Ethical considerations are reviewed, plus the reliability, validity, generalisability and limitations of methodology.

Chapter 4 – Study 1 is a retrospective review of transfusion incidents. The proof of concept for this section of the research aimed to discover which human factors models/methods would be best to undertake a full review of historical incident records. The results and limitations of this study led to an early termination to allow concentration on the second study. Research from this study was presented at a UK national conference (Watt *et al*., 2017).

Chapter 5 – Study 2 follows logically from Study 1, so this chapter details the creation and use of a human factors investigation tool (HFIT) within the transfusion incident reporting database to improve the quality of consideration of system and organisational factors when reporting incidents. This is a large piece of work, spanning three full calendar years. The chapter presents the HFIT results and amendments, plus the creation and development of self-

learning materials to help with the use of the HFIT. Research from this study was presented at a UK national conference (Watt *et al*., 2018).

Chapter 6 – Study 3 is a prospective analysis of resilience in the full vein to vein transfusion process in the hospital setting. Data collected from hospital visits were analysed using the Resilience Analysis Grid (RAG), Systems Engineering Initiative for Patient Safety 2.0 (SEIPS 2.0) and Concepts for Applying Resilience Engineering (CARE). An enhanced CARE model is proposed and a technique for potentially predicting successful and unsuccessful outcomes of adaptations is described. Research from this study was presented at an international conference (Watt *et al*., 2019a) and has been published in a peer-reviewed journal (Watt *et al*., 2019b).

Chapter 7 – summarises the findings of the research and presents the overall discussions and conclusions. The contribution to the current body of knowledge is examined, including limitations, and the potential for future work is discussed.

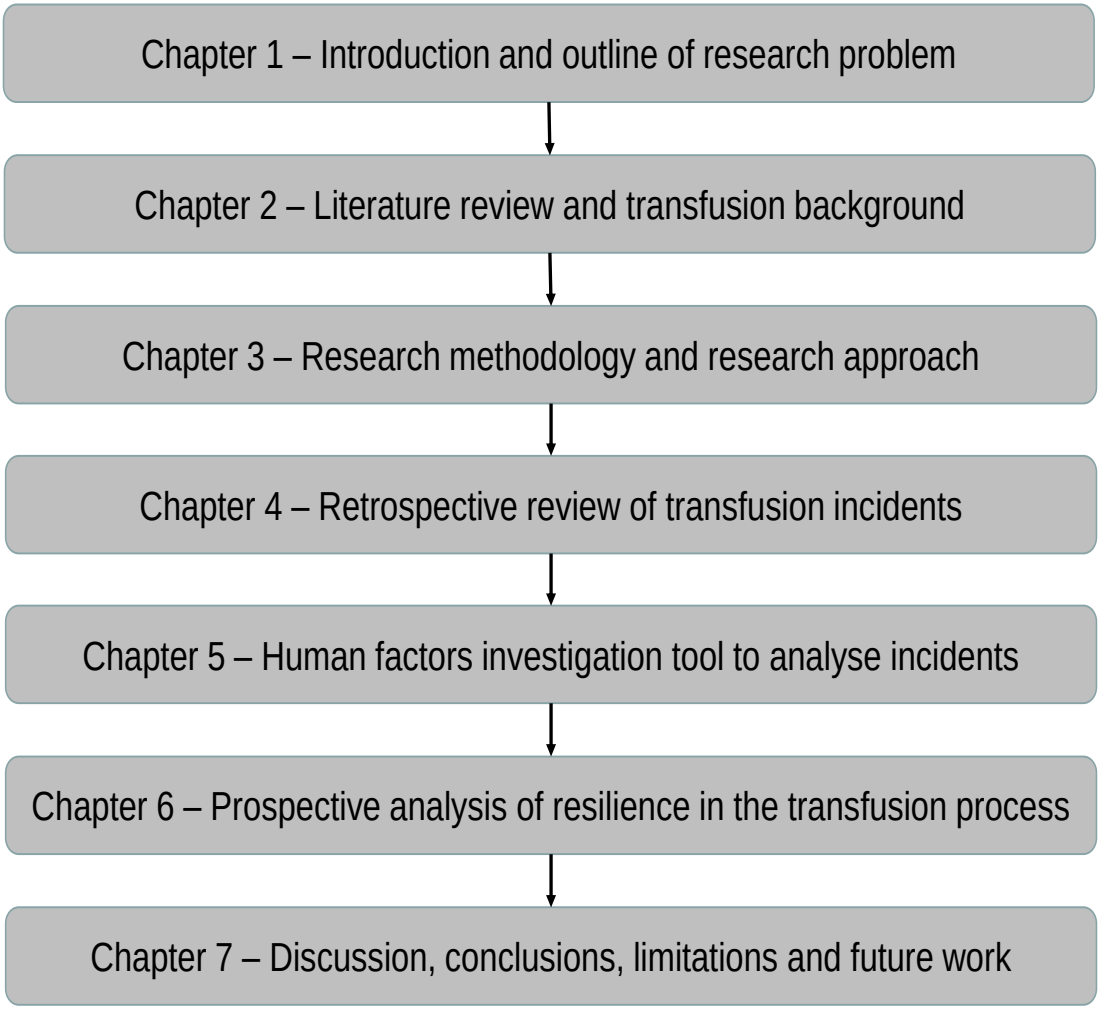


Figure 1.5: Thesis summary

Chapter 2 Background literature

2.1 Introduction

The main purpose of the literature review is to chronicle the current knowledge in the subject and highlight gaps where further original research would have a positive contribution to existing knowledge. To work towards the aims and objectives of this research, a first consideration is what has been done before and the background literature to the research problem. This is not easily achieved for these studies by a traditional systematic review of literature, so this chapter presents a general review that (1) Examines the history of blood transfusion and sets the scene of safety improvement made so far, (2) Considers any existing human factors applications to blood transfusion safety and (3) Investigates relevant human factors applications to incident reporting and resilience assessment. In addition to database searching using multiple search terms, plus recommendations from colleagues and subject experts, reference chasing was also employed whereby references cited in key papers were retrieved and examined for inclusion in the literature review. The literature search was restricted to items in the English language.

The author's in-depth knowledge of blood transfusion was employed to select and review appropriate background literature on transfusion history and safety initiatives. Then, to assess the extent of existing literature about human factors applications to blood transfusion, a wide-ranging database search was conducted. Alongside standard electronic databases and internet search engines, such as PubMed, Science Direct, Scopus, ResearchGate and Google/Google Scholar, it was important to search intensively using specialist health service and transfusion literature resources to ensure that the apparent scarcity of relevant human factors research applied to blood transfusion was genuine (Table 2.1).

Table 2.1: Specialist resources for transfusion literature search

Title	Brief description of resource
National Institute for Health and Care Excellence (NICE) Healthcare databases advanced search (HDAS)	The NICE database also accesses other healthcare databases: - British Nursing Database, - Cumulative Index to Nursing and Allied Health Literature (CINAHL) - Excerpta Medica dataBASE (EMBASE) - Health Management Information Consortium (HMIC) - USA National Library of Medicine (MEDLINE) https://www.nice.org.uk/about/what-we-do/evidence-services/journals-and-databases
Cochrane Library	Includes: - Cochrane Database of Systematic Reviews - Central Register of Controlled Trials - Cochrane Clinical Answers http://www.cochranelibrary.com/
The Transfusion Evidence Library	A database of systematic reviews and randomised controlled trials relevant to transfusion medicine http://www.transfusionevidencelibrary.com/
Centre for Reviews and Dissemination (CRD)	Access to review databases, archived since March 2015 - Database of Abstracts of Reviews of Effects (DARE) - PROSPERO, the international database of prospectively registered systematic reviews in health and social care http://www.crd.york.ac.uk/CRDWeb/
The National Institute for Health Research (NIHR) Journals Library	Accounts of NIHR funded research projects and the final published journal reports http://www.journalslibrary.nihr.ac.uk/
The Knowledge Network of NHS Scotland	The national knowledge management platform for health and social care in Scotland http://www.knowledge.scot.nhs.uk/home.aspx

Conversely, a database search for background literature on human factors applications to incident analysis and health service process resilience would provide an unfeasibly large amount of returns and, as the author has less experience in this field to direct the search, areas for review were based on previous PhD studies and recommendations by domain experts. The intention was to give a broad background without repeating previous evaluations or

assessments of major literature. A subject familiarity with major authors in the field was used as the initial point for identifying research for this part of the review, including Jens Rasmussen, James Reason, Nancy Leveson, Erik Hollnagel and Pascale Carayon.

2.2 Brief history of blood transfusion safety improvement

In order to understand the impact of errors in blood transfusion, it would be useful to review the history of blood transfusion. Successful blood transfusion as a medical treatment only began in the last century (Figure 2.1), but the history of known transfusions can be traced back to Richard Lower in 1666, who experimented with animal transfusions, shortly after William Harvey first described the blood circulation system in 1628 (Boulton & Roberts, 2014). James Blundell is credited with giving the first transfusion to a human in 1818, for post-partum haemorrhage (Blundell, 1818), but the landmark discovery was in 1900, when Karl Landsteiner described agglutination of normal human blood showing patterns that later became defined as the ABO blood group system. Landsteiner's original paper was translated into English and published in the first edition of Transfusion, the journal of the American Association of Blood Banks (AABB) (Landsteiner, 1961).

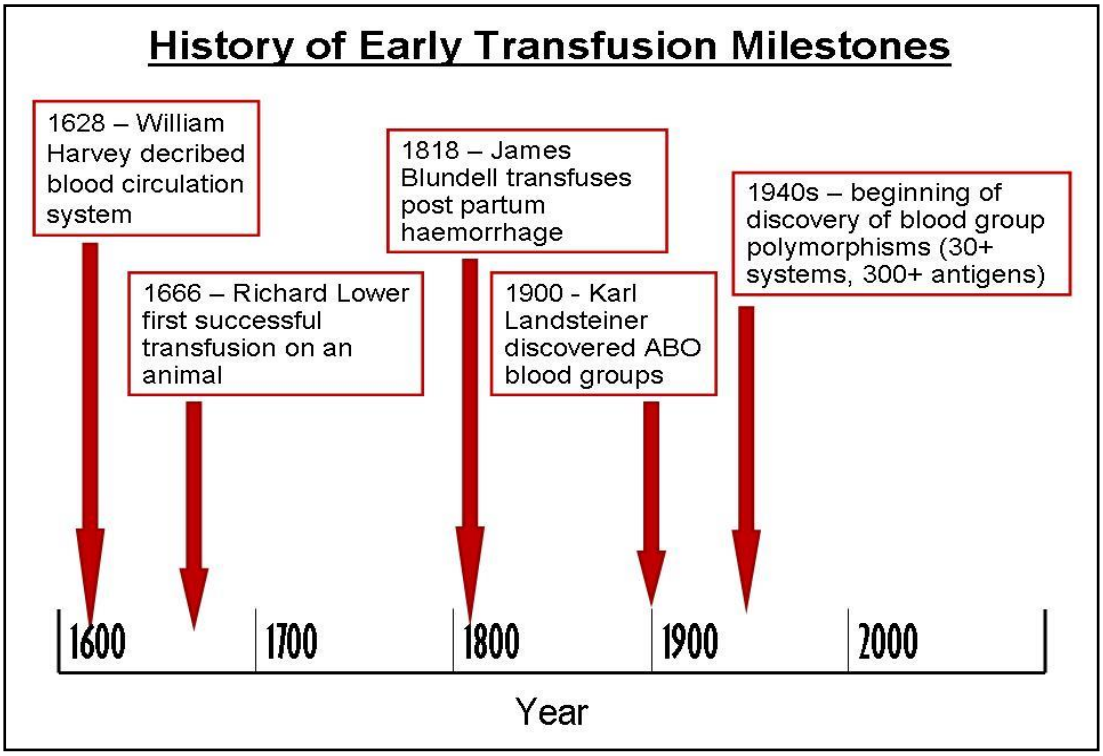


Figure 2.1: Timeline of blood transfusion developments

(sources; Boulton & Roberts, 2014; + personal knowledge)

The early equipment used for blood transfusion, such as that carried out by James Blundell, was very rudimentary and there was very little understanding of microbiological risks and aseptic techniques, so bacterial contamination would have been a common early complication (Figure 2.2). However, as transfusion became safer from an immunological perspective, with the introduction of ABO matching, a deeper understanding of microbiological safety began to emerge, both bacterial and viral (Figure 2.3).

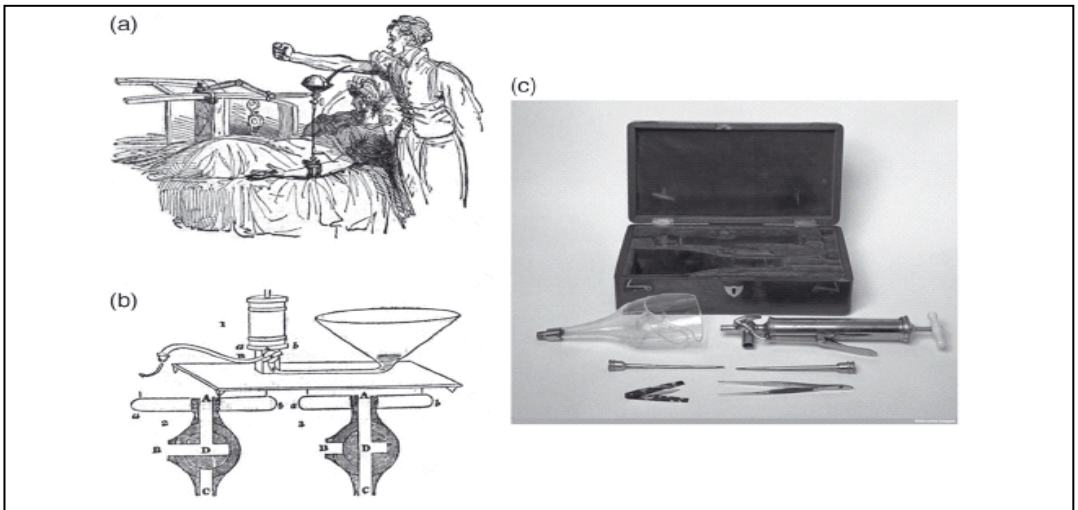


Fig. 1. Blundell's method of blood transfusion. (a) Line drawing of Blundell's early method of transfusion directly from donor to recipient. Republished from Blundell (1828). (b) Schematic diagram of Blundell's improved transfusion equipment showing collection of blood into a reservoir and the operation of a valve to allow infusion of blood from the reservoir into the patient under positive pressure with a syringe. (c) A set of Blundell's improved apparatus for transfusion made by Philip and Wicker of St James, London (previously Savigny & Co.). Images reprinted courtesy of the Wellcome Library, London. These and other pictures of the history of medicine can be seen at www.wellcomeimages.org.

Figure 2.2: Early equipment for blood transfusion

(Boulton & Roberts, 2014)

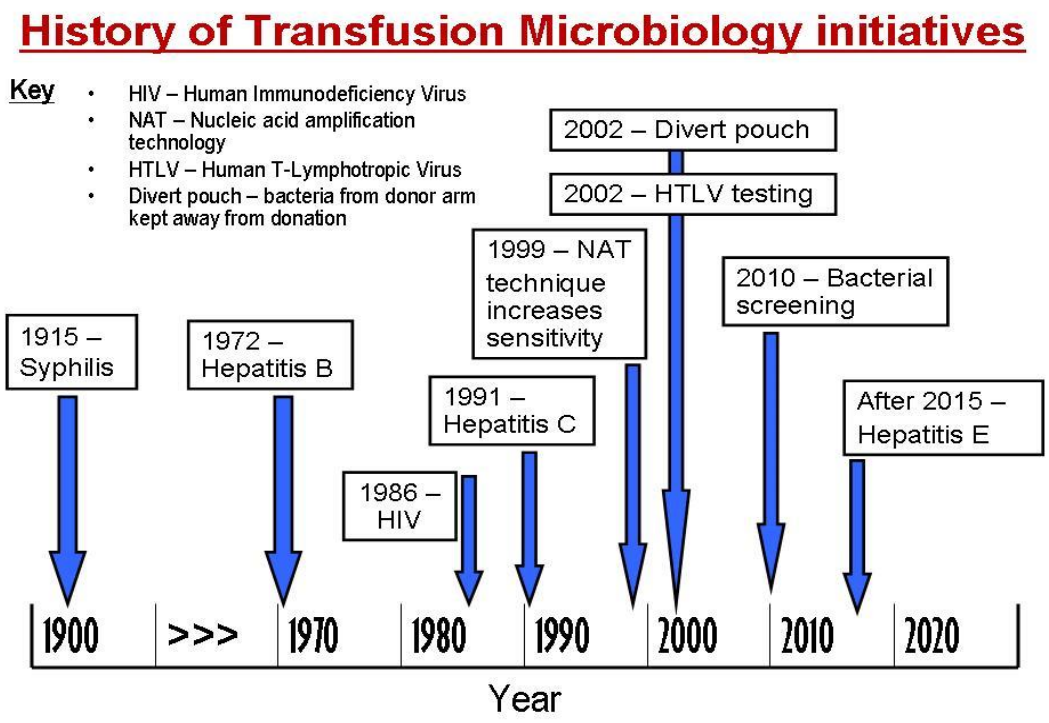


Figure 2.3: Timeline of microbiological testing of blood donations

(sources: Boulton & Roberts, 2014; Penrose, 2015; personal knowledge)

The first milestone in the history of microbiology initiatives was in 1915, when testing began to prevent the transmission of syphilis, caused by the bacterium Treponema pallidum and in time this was followed by testing for other infectious risks (Figure 2.3). Alongside these mandatory microbiological tests that are done on every UK blood donation, there are a variety of non-mandatory tests that are performed on selected units in order to protect the supply. This includes testing for viruses that could adversely affect compromised patients, such as cytomegalovirus (CMV), but also testing for infectious agents that are restricted to geographical areas, such as Malaria, Trypanosoma cruzi (T. cruzi) and West Nile Virus (WNV). Since early 2016 blood components tested for hepatitis E (HEV) have been supplied for transplant patients, following guidance from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) and in 2018 SABTO recommended that all blood donations be tested for hepatitis E, so this has also become a mandatory test (SaBTO, 2018). Most people infected with HEV will be unaware of it, because symptoms are mild or non-existent, therefore may donate while infectious. Most recipients of blood from an HEV positive

donor would not be harmed, but SaBTO has identified there are groups of patients who may become seriously ill if infected and should therefore receive HEV negative blood transfusions. After an initial period of providing a limited supply of HEV tested components, SaBTO has now advised that all donations should be tested, and any positive units should be discarded. Therefore, since 2018 all blood is supplied as HEV negative, after approval by the UK Blood Services Forum (UK Forum) which is the committee established in 1999 to ensure consistency within Blood Services following devolution of governments in the UK. The UK Forum is made up of the medical directors and chief executives of the four national Blood Services in the UK, NHS Blood and Transplant (NHSBT), which provides Blood Services and tissues in England and organs for the whole of the UK, the Scottish National Blood Transfusion Service (SNBTS), the Welsh Blood Service (WBS and the Northern Ireland Blood Transfusion Service (NIBTS).

Transmission of microbial infection remains a risk, but is becoming extremely rare. The Public Health England (PHE) report 'Safe supplies 2017: a year of change' is the annual review from the NHS Blood and Transplant/PHE Epidemiology Unit, 2017, published 2018. From data within that report, Figure 2.4 shows the number of potentially infectious window period donations entering the UK blood supply between 2015 and 2017 (PHE, 2018).

Virus	Risk estimate	Risk of an infectious donation*, one every
Hepatitis B (HBV)	1 in 2.1 million	1 year
Human immuno-deficiency virus (HIV)	1 in 19.6 million	9.3 years
Hepatitis C (HCV)	Not applicable**	Not applicable**

*At 2.3 million donations per year testing will miss a potentially infectious window period donation
**Risk cannot be calculated as there were no seroconversions between 2015 and 2017.
Risk between 2013-2016 was calculated as 1 in 95.8 million (NHSBT/PHE, 2017)

Figure 2.4: Estimated risk that a donation entering the UK blood supply is potentially infectious (2015-2017)

(Source PHE, 2018).

Therefore, in the late 1990s, transfusion medicine began to move the focus from microbiological safety of the blood component to patient safety initiatives related to the transfusion process. Quality management initiatives were introduced to increase safety, such as Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and Total Quality Management (TQM), alongside continuous improvement methods, such as 6-sigma and Lean. However, transfusion safety mainly relies on an understanding of the transfusion cycle, which links the patient, via a blood sample to be tested, from which an appropriate component is selected, which is then given to the patient to complete the cycle. Any break in this cycle, or any error within this process, can compromise patient safety, particularly a failure of patient identification (Figure 2.5).

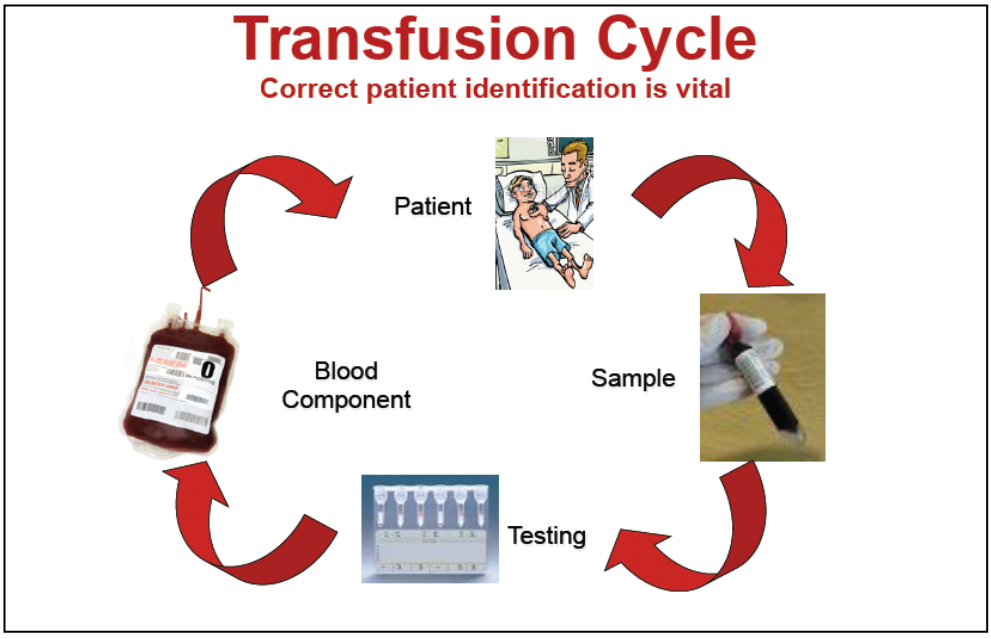


Figure 2.5: Diagrammatic representation of the transfusion cycle from taking a sample to transfusing a component

(reproduced from SHOT Teaching, 2015, with permission)

Two early initiatives were the establishment in 1996 of the UK haemovigilance scheme, Serious Hazards of Transfusion (SHOT), a reporting system for serious transfusion-related incidents (Williamson *et al*., 1996), including the now rare occurrence of infection transmission. Following the first SHOT report, which showed that error was a major cause of transfusion incidents (Williamson *et al*., 1998) the UK chief medical officers organised an evidence-based transfusion symposium which was followed by publication of the first of a series of three Department of Health (DH) Health Service Circulars (HSC) on Better Blood Transfusion (BBT, 1998), which led to the creation of the Transfusion Practitioner (TP) role. The TP role is now established in every major hospital in the UK to improve transfusion safety (Murphy *et al*., 2003). The function of TPs is to improve transfusion safety by training and supporting clinical staff who are responsible for administering transfusions to patients. They are also involved in investigating incidents and errors and ensuring lessons are learned, both locally and also nationally by reporting such incidents in an anonymised format to SHOT. In this respect TPs may play a key part in the integration of a human factors perspective into the transfusion process. At the moment there is no requirement that staff in those roles have any understanding of human factors, although momentum in this respect is gathering pace amongst individuals within the TP profession.

Following the introduction of these two safety programmes, i.e. SHOT and TPs, further transfusion-related patient safety initiatives were established, and these are summarised in Figure 2.6. The National Patient Safety Association (NPSA) was established in 2000, later replaced by NHS Improvement (NHSI) Patient Safety (NHSI 2019a) and NHSI is itself being replaced from April 2019 with a combined body joining with NHS England (NHSE) (NHSE/NHSI 2019). NPSA released three transfusion-related Safer Practice Notices (SPN) (NPSA, 2005, NPSA, 2006 and NPSA, 2007) and also published a Rapid Response Report on transfusion in an emergency (NPSA, 2010). Two more DH Better Blood Transfusion HSCs were published (BBT, 2002 and BBT, 2007) and three professional transfusion working groups were also formed in the early 2000s: The National Blood Transfusion Committee (NBTC), the overarching body for Regional Transfusion Committees (RTC), all of which provide a

framework promote good transfusion practice; The National Comparative Audit (NCA) which carries out regular national audits of transfusion practice and The United Kingdom Transfusion Laboratory Collaborative (UKTLC), which regularly surveys practice in hospital laboratories and publishes standards. All of these initiatives led to the implementation of the Patient Blood Management scheme (PBM) (NBTC, 2012). This is an evidence-based approach to optimising the care of patients who might need a blood transfusion, led by Transfusion Practitioners.

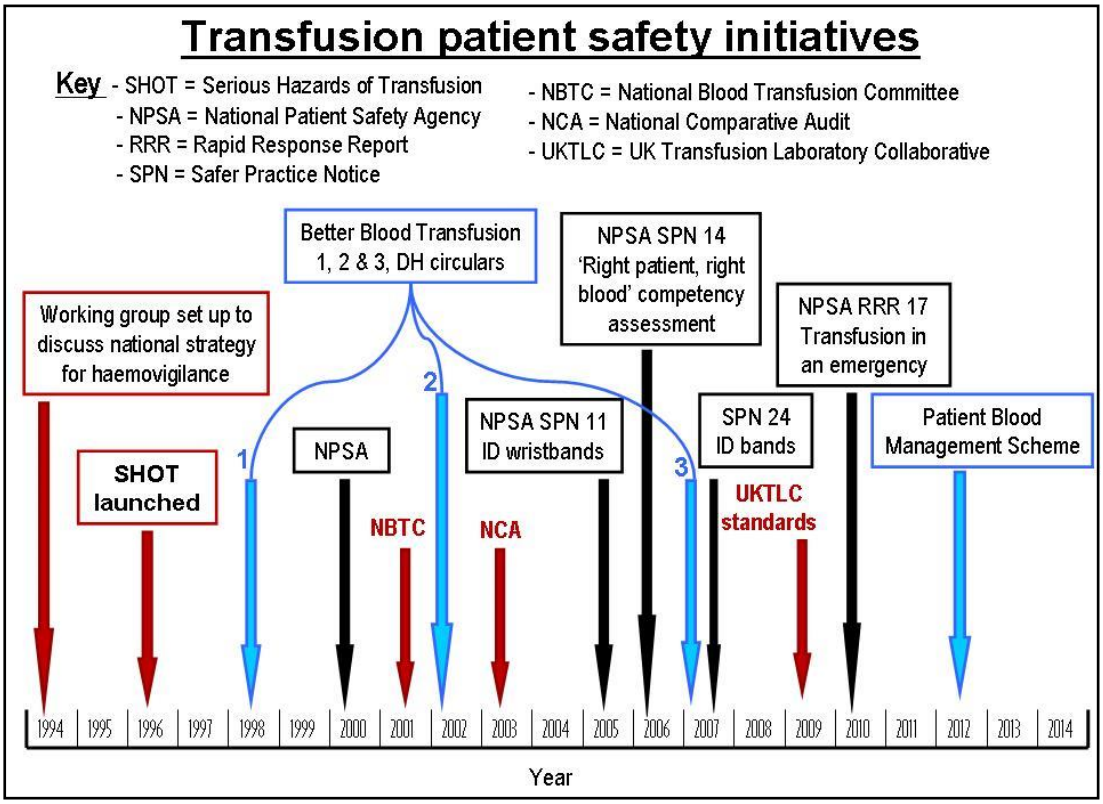


Figure 2.6: Transfusion-related patient safety initiatives introduced in the last 20 years that are not related to microbial safety of the components

(adapted from SHOT Teaching, 2015 with permission)

One of the mechanisms frequently put into place to improve patient safety is the use of a checklist and transfusion is no different. A key transfusion recommendation in both the 2015 and 2016 Annual SHOT Reports was to use a bedside checklist before commencing a transfusion (Bolton-Maggs *et al*.,

2016 and 2017a). This recommendation was reinforced by an NHS England Central Alerting System (CAS) Alert (NHS England, 2017b) and an NHS Wales Patient Safety Notice (PSN) (NHS Wales, 2018). The World Health Organisation (WHO) surgical checklist is a 19-item surgical safety checklist designed to improve team communication and consistency of care, shown to be successful in reducing complications and deaths associated with surgery (Haynes *et al*., 2009). A study of checklists has been made citing the psychological factors relevant to patient safety, including memory, prospective memory, automaticity, and responsibility (Shillito *et al*., 2010). This paper concluded that there is much to learn regarding factors that influence healthcare checking procedures and that examining the gaps from a psychological perspective could improve practice. The problems with checklists in healthcare have also been studied and the research highlighted the difficulties of translating practice from industries such as aviation into the field of healthcare (Catchpole & Russ, 2015). The authors conclude that "A checklist is a complex socio-technical intervention that requires careful attention to design, implementation and basic skills required for the task".

2.3 Review of transfusion publications related to human factors

An investigation was carried out to establish whether there has there been any research so far which applies human factors and ergonomics to blood transfusion. From personal knowledge, human factors techniques and analysis are only just beginning to be incorporated into error management in small areas within blood transfusion and related subjects, such as within the Quality (Murphy, 2016) and Cellular and Molecular Therapies department of NHS Blood and Transplant (NHSBT) (Smythe & Wyre, 2014) and within the UK haemovigilance scheme, Serious Hazards of Transfusion (SHOT). Work being done within NHSBT is related to the testing and processing of blood and tissue donations and is therefore outside the scope of these studies, which are related to patient safety in transfusion. Thus, SHOT is the only one of the major UK transfusion organisations that, to date, has published research correlating human factors and patient-related transfusion errors.

A literature search was done, using the protocol detailed in section 2.1. This produced a total of 46 publications linking transfusion to human factors, but several of these are short abstracts of conference presentations and posters and some of those are duplications of journal papers. This gives a small total of individual studies related to human factors within transfusion and many of these publications are not peer-reviewed papers. This confirms that a PhD on this theme will be very valuable.

The papers in this review were split into three main groups:

- Human factors methods applied to transfusion (n=13) - the most in-depth studies using HF methodology to analyse the transfusion process
- SHOT-related publications (n=16) - the relevance of these publications varies from comprehensive research, including peer-reviewed journal articles, through to fairly minimal mentions of HF
- Non-SHOT publications referencing HF (n=17) - these vary from far-reaching research to very limited allusion to human factors in a more general transfusion or healthcare publication

The literature search returned only 13 publications that specifically describe human factors models and methods applied to transfusion, several of which may not have been rigorously peer-reviewed, including three short abstracts for conference poster presentations, a book chapter and a report from an Australian haemovigilance website (Table 2.2).

Table 2.2.Human factors methods applied to transfusion (n=13)

Title	Author/ date	Aim of study	Type of study	Main findings	Strengths	Limitations
Identification and classification of the causes of events in transfusion medicine	Kaplan *et al.*, 1998	Development of a causal analysis method, the Medical Event Reporting System for Transfusion Medicine (MERS-TM)	Skills Rules & Knowledge (SRK)	A reliable method for identifying and quantifying problems in transfusion medicine	Proposing a common taxonomy that could allow participants to compare experience	Only applied in three hospitals
Seven hundred and fifty-nine (759) chances to learn: a 3-year pilot project to analyse transfusion-related near-miss events in the Republic of Ireland	Lundy *et al.*, 2007	A 3-year pilot using MERS-TM to examine learning from near-miss events	Skills Rules & Knowledge (SRK)	Near-miss reporting 18 times higher than actual events - show low risk errors are signals of underlying defects	Compared near misses with actual events	Variation in reports from similar hospitals may indicate underreporting
Failure mode and effect analysis: an application in reducing risk in blood transfusion	Burgmeier, 2002	Analysis of problems, causes and probable effects to reduce the risk of inherent problems in transfusion process	Failure mode and effect analysis (FMEA)	No outcome errors throughout study or in 8 months following	Study led to a positive outcome - restriction of access without a patient-specific code	FMEA was considered time-consuming, so will only be used for the highest-priority processes

Table 2.2.Human factors methods applied to transfusion (n=13)

Title	Author/ date	Aim of study	Type of study	Main findings	Strengths	Limitations
Failure mode and effect analysis in blood transfusion: a proactive tool to reduce risks	Lu *et al.*, 2013	Evaluation of risks and identification of preventative measures in blood transfusion	Failure mode and effect analysis (FMEA)	Concluded major risk was insufficient pre-operative evaluation of the transfusion needs	Comprehensive analysis of full transfusion process	May be a problem with scoring - came to a different conclusion from most studies (identification failures usually highest risk)
Proactive Risk Assessment of Blood Transfusion Process, in Pediatric Emergency, Using the Health Care Failure Mode and Effects Analysis (HFMEA)	Dehnavieh *et al.*, 2014	Proactive risk assessment of blood transfusion in a Paediatric Emergency setting	Healthcare failure mode and effect analysis (HFMEA)	Used a proactive instead of reactive approach allowed an assessment of possible failures and proposal of improvement strategies	Inclusion of a decision-making tree to decide whether to proceed or stop	Misses the opportunity to analyse specific paediatric problems, such as hard to label small samples
Development of A Double Verification Blood Typing System in Blood Bank Using Healthcare Failure Mode Effectiveness Analysis	Chang *et al.*, 2011	Analysis to determine the critical process in ABO testing	Healthcare failure mode and effect analysis (HFMEA)	Develop a double verification blood typing system to reduce risks	Short poster abstract so contains too little information to assess strengths	Short poster abstract so contains too little information to assess limitations
Application of Risk Management Methodology in Improving the Performance of Blood Transfusion Services	EL-Wakil, 2012	Redesign of the process so the quality of service and delivery of blood remains optimal	Healthcare failure mode and effect analysis (HFMEA)	Corrective action implemented for the highest scoring failure risk with improvements shown after 3 months	Short poster abstract so contains too little information to assess strengths	Short poster abstract so contains too little information to assess limitations

Table 2.2.Human factors methods applied to transfusion (n=13)

Title	Author/ date	Aim of study	Type of study	Main findings	Strengths	Limitations
Simulation Based Risk Assessment to Reduce Blood Transfusion Errors	Elwakil, 2013	Use of simulations to assess the severity of transfusion risks proactively	Healthcare failure mode and effect analysis (HFMEA)	In situ simulation gave a real time observation of failure modes and the effects of failure	Short poster abstract so contains too little information to assess strengths	Short poster abstract so contains too little information to assess limitations
Blood Transfusion with Health Information Technology in Emergency Settings from a Safety-II Perspective	Nakajima, 2015	A book chapter analysing two cases of patients receiving blood components intended for another individual	Functional Resonance Analysis Method (FRAM)	Processes studied from a Safety-II perspective highlighted differences between 'work-as-imagined' and 'work-as-done' sometimes due to inadequate technology	A detailed evaluation of problems with everyday processes in transfusion	The first figure does not explain the FRAM aspects of Case 1
Blood sampling-Two sides to the story	Pickup *et al.*, 2017	To investigate the variability in taking blood samples from transfusion patients	Functional Resonance Analysis Method (FRAM) and Systems Engineering Initiative for Patient Safety (SEIPS 2.0)	Identified that variability was influenced by factors such as working environment, equipment, clinical context, work demands and staff resources	A novel assessment, using both FRAM and SEIPS, of the risks leading to a wrong blood in tube incident, one of the most dangerous aspects of misidentification in transfusion	The use of SEIPS to code observations and identify factors influencing sampling activities could have been described more fully

Table 2.2.Human factors methods applied to transfusion (n=13)

Title	Author/ date	Aim of study	Type of study	Main findings	Strengths	Limitations
Reducing Harm in Blood Transfusion - Investigating the Human Factors Behind 'Wrong Blood in Tube' (WBIT) Events in the Emergency Department	Jeffcott, S., 2010	Study of factors impacting best practice in specimen labelling and patient identification	A multi-method qualitative approach, including FMEA, triangulated to explore HF issues	Identifying opportunities for HF research can allow for the creation of better designed interventions	A thorough investigation of the issues that lead to WBIT incidents	The report is published on the website of the Victoria, (Australia) haemovigilance system, rather than in a peer-reviewed publication
A review on decision support for massive transfusion: understanding human factors to support the implementation of complex interventions in trauma	Enticott *et al.*, 2012	To examine whether massive transfusion cases may benefit from a HF-assisted approach.	Systematic review using multi methods, based on the human factors analysis and classification system (HFACS)	Interventions seeking to improve complex processes; in massive transfusion can be optimised by HF-based approaches	The systematic review format enabled HF principles to be applied to existing research papers on a known risky area of transfusion practice	Massive transfusion is only a small part of transfusion as most blood is used in more routine settings
Improving safety in blood transfusion using failure mode and effect analysis	Mora *et al.*, 2019	To evaluate potential failures to improve transfusion safety in a hospital with a highly complex transfusion service	Failure mode and effect analysis (FMEA)	Identification of factors that reduce safety and the causes of these errors allowing design of corrective measures, and indicators to monitor their application	A comprehensive review of the full transfusion process identifying vulnerabilities throughout the system	The proposed actions to mitigate risks were often limited to training and reminding which are unlikely to be robust

The skills, rules, knowledge (SRK) model has been referenced in two transfusion-related publications (Kaplan *et al*., 1998 & Lundy *et al*., 2007) which both describe the use of a USA system to classify events in transfusion known as Medical Event Reporting System for Transfusion Medicine (MERS-TM). This classification system uses SRK methods and could provide some insight for human factors analysis of transfusion incidents, but is probably being superseded by the incident investigation work being done using SHOT data in the UK, as described in Chapter 5 of this thesis.

The failure mode and effect analysis (FMEA) model has been used in transfusion related areas in three publications (Burgmeier, 2002; Lu *et al*., 2013; Mora *et al*., 2019). These papers demonstrate research using the FMEA technique to examine the patient-level transfusion process. Four publications have been reviewed that used a healthcare modification of the FMEA model (HFMEA). Three of these are short poster abstracts (Chang, 2011; El-Wakil, 2012; Elwakil, 2013) so are of limited breadth. The work of Chang *et al*. (2011) concentrates on an error elimination method within the transfusion laboratory and as such is only related to a small part of the transfusion process. El-Wakil (2012) describes the use of HFMEA for analysis of surgical transfusions and Elwakil (2013) relates HFMEA to simulation of the transfusion process. Both these areas of research might have provided some useful insight into HF in transfusion, but the poster abstracts are too limited to be of much benefit. The fourth HFMEA publication of (Dehnavieh *et al*., 2014) could have been the most useful research, because it deals with a known high-risk area for transfusion, i.e. paediatric patients, who are a particularly vulnerable group of patients with specific transfusion needs. They are known to have a higher risk of associated errors, for reasons that include the complexity of their needs and the reduced opportunities for patient input to their own care (SHOT, 1997 to 2018). However, this paper used HFMEA in a broad sense and not to analyse the specific failure risks associated with paediatric patients.

Two studies used the Functional Resonance Analysis Method (FRAM) method to analyse problems related to misidentification of the patient. A chapter in the

book *Resilient Health Care* (Nakajima, 2015) applied the FRAM model to analyse the transfusion process and compares Safety-I with Safety-II, concluding that 'work-as-done' is not the same as 'work-as-imagined'. The FRAM model was also used in a Scottish study to enable the visualisation of blood sampling functions (Pickup *et al*., 2017) to identify variability that can lead to a wrong blood in tube (WBIT) error, which is when a sample taken for testing pretransfusion is either from the wrong patient and labelled with the intended patient's details or is taken from the intended patient, but wrongly labelled with another patient's details. This research also applied the Systems Engineering Initiative for Patient Safety (SEIPS 2.0) model to the study, but in a limited sphere, which restricted the opportunity for learning. An Australian report published by Serious Transfusion Incident Reporting (STIR), the haemovigilance incident reporting system for Victoria, Tasmania, the Australian Capital Territory (ACT) and Northern Territory (Jeffcott, 2010), used human factors methodology to examine the blood sampling issues that can lead to WBIT incidents. A systematic review used HF principles, particularly the human factors analysis and classification system (HFACS), to examine interventions in massive transfusion (Enticott *et al*., 2012) and concluded interventions could be optimised using an HF approach.

The UK haemovigilance organisation, Serious Hazards of Transfusion (SHOT) is contributing much of the recent literature correlating human factors to patient-related transfusion errors, particularly through publication of the Annual SHOT Report and related articles that highlight SHOT's recommendations and key messages. The earliest publications related to human factors (Bolton-Maggs *et al*., 2013; Bolton-Maggs & Cohen, 2013; Bolton-Maggs, 2013) highlighted the work of the Department of Health Human Factors Reference Group (Keogh, 2012), a group that was set up following the Mid Staffordshire NHS Foundation Trust major patient safety scandal (Francis, 2013). This was followed by a main recommendation in the 2013 Annual SHOT Report (Bolton-Maggs *et al*., 2014), which advised that in line with human factors and ergonomics research the transfusion process should be analysed at local and national level to design out the medical errors. A further publication suggested that errors would be reduced by integrating human factors training into medical

practice and that a workforce aware of human factors would improve patient safety (Bolton-Maggs, 2014).

In the 2014 Annual SHOT Report, the chapter on human factors concentrated on SHOT data and case studies related to failures in patient identification, communication and documentation and concluded that Safety-II principles would complement the existing Safety-I process of reporting adverse events to SHOT (Bolton-Maggs *et al.*, 2015a; Bolton-Maggs, 2015). A paper reviewing the risks of wrong blood in tube incidents concluded that human factors education and training could help to increase awareness of human vulnerability to error (Bolton-Maggs *et al.*, 2015b). The human factors chapter in the 2015 Annual SHOT Report focussed on Just Culture (Dekker, 2012) using data from reported incidents to illustrate this point (Bolton-Maggs *et al.*, 2016) and the launch symposium for the 2015 Report again emphasised the importance of Safety-II in transfusion (Bolton-Maggs, 2016).

From 2017 onwards, SHOT has published data analyses from Study 2 of this PhD in the 2016, 2017 and 2018 Annual SHOT Reports (Bolton-Maggs *et al.*, 2017a, 2018 and Narayan *et al.*, 2019) and all these, along with the 20th anniversary SHOT launch conference report (Bolton-Maggs, 2017) plus a speaker abstract (Bolton-Maggs *et al.*, 2017b) and a poster abstract (Bolton-Maggs & Poles, 2018) summarised the key messages from SHOT's analyses, i.e. the fallacy of blaming individuals for incidents instead of investigating other factors that contribute to adverse events and that the important contributory factors to errors are failures of communication, wrong assumptions, poor handovers and staff overriding alerts in the laboratory information systems. Finally, SHOT's published report of the 2018 International Haemovigilance Seminar and SHOT Annual Symposium (Bolton-Maggs, 2019) introduced the concept of a nationally led, locally delivered audit of transfusion resilience, which is forming Study 3 of this thesis.

Most of these SHOT references are related to the Annual SHOT Reports and the associated Annual SHOT Symposia, at which each year's SHOT Report is launched. Few of the publications are independently peer-reviewed, although

the Annual SHOT Reports are reviewed by the SHOT Steering Group, which is a committee of approximately 40 experts, consisting of nominated representatives of all the UK Medical Royal Colleges and other professional bodies related to the transfusion field. The SHOT-related publications do not often contain specific research linked to human factors, except where the studies that form part of this PhD are included. However, it is the leadership of SHOT that has encouraged those working in the field of transfusion medicine to begin to look at the role of human factors, especially for incident analysis.

The remaining items discovered in the literature search were publications that reference HF to varying degrees, but are not research projects using specific HF models or methods as part of the study and several of the papers only mention human factors in passing (Table 2.3). As with the previous literature reviewed, many of the publications are not peer-reviewed thoroughly, including 10 short poster and speaker abstracts from conferences, each under 500 words and invited reviews, plus one book chapter.

An example of general transfusion publications that have very limited mentions of human factors are two papers that include HF only in their titles, but do not define their meaning of the term human factors and they do not use HF methods or principles in the papers, nor make any HF-based conclusions (Cheng & Lin, 1999; Lau & Cheng, 2001). These two publications describe related research from Hong Kong about computer generated systems to counteract the risks associated with wristbands and other mechanisms of patient identity for transfusion, including a plan to replace the citizens' identity card with an electronic card that could contain the person’s detailed red cell phenotypes in digital code. Their work showed the feasibility of issuing phenotype-matched blood without any pre-transfusion testing, improving both speed of treatment and patient safety. It appears that the use of 'human factors' in the title of these papers indicated the idea of removing humans from the system to reduce error and, although this is a common solution to reduce error, the publications do not discuss this from a human factors stance.

Table 2.3: Non-SHOT publications referencing HF (n=17)

Title	Reference	Notes
Will transfusion errors due to human factors ever be eliminated?	Cheng & Lin, 1999.	Journal letter to editor
To err is human nature. Can transfusion errors due to human factors ever be eliminated?	Lau & Cheng, 2001	Journal conference full paper
Errors in laboratory medicine	Bonini *et al.*, 2002	Journal review paper
The human factors: errors and skills.	St. Pierre *et al.*, 2011	Book chapter
Improving the Management of Major Haemorrhage by Junior Doctors using Simulation Teaching	Green, 2013	Speaker abstract
Clinical Research Focus # 33 - A brief introduction to human factors engineering	Chadwick & Jeffcott, 2013	Journal article
Simulation training improves clinical knowledge of major haemorrhage management in foundation year doctors	Green & Curry, 2014	Journal research paper
Wrong blood in tube – where does the process go wrong?	Alimam *et al.*, 2014	Poster and speaker abstracts, approximately 300-500 words, so contain limited information
Exploratory Research Study into the Effects of Staff Feelings and Perceptions Following a Transfusion Incident Investigation	Creighton & Wright, 2014	
Key factors to better understand the haemovigilance findings can be obtained from surveys	Lopez-Soques *et al.*, 2015	
International Haemovigilance – Opportunities and Challenges	Wood *et al.*, 2015	
How safe is a single practitioner independent checking procedure for blood? Results of a test of change	Cottrell, 2016	
Bridging the gap between theory and clinical practice – addressing human factors in managing major haemorrhage in a major UK trauma centre	Orr *et al.*, 2016	
Transfusion Request Rejection-The Human Factor	Bahadori *et al.*, 2017	
Assessing the impact of human factors on transfusion safety in trauma	Graham *et al.*, 2017	
Modifying human factors to reduce blood transfusion sample rejection rates in NHS Ayrshire and Arran	Tay *et al.*, 2018	
A transfusion prescription template and other human factor interventions to improve balanced transfusion delivery in major haemorrhage due to trauma	Swieton *et al.*, 2018	Journal research paper

It has been a common theme in this review of transfusion publications which mention human factors that the term may be incorrectly used to be synonymous with the phrase human error. Alternatively, some papers interpret human factors as being only related to the human in the system, not the rest of the system issues. There are many similar publications on this subject of error management in transfusion, so these two papers (Cheng & Lin, 1999; Lau & Cheng, 2001) are examples of literature where there is nothing specific about human factors to learn from the research. Such publications that are not directly linked to human factors research will not be of great assistance in the

planned studies, but show that there remains a gap, with more HF research needed in the field of transfusion medicine.

Another paper is similar in that it only mentions human factors in passing (Bonini *et al*., 2002), but this work has a little more relevance, because it is a systematic review of transfusion laboratory errors, which are a major cause of reduced patient safety in transfusion. This review paper makes a major conclusion "...errors are rarely attributable to personal failings, inadequacies, and carelessness and that naming, blaming, shaming, and punishing have not worked in addressing and decreasing errors". This is one of the main reasons for carrying out further human factors research into transfusion errors, because current haemovigilance interventions are not reducing the errors sufficiently.

Two papers examine human factors in a fairly general sense, but also apply the principles to transfusion settings. In the introductory chapter of their book Crisis Management in Acute Care Settings, St. Pierre *et al*. (2011) describe a case study of a transfusion-related death due to a patient being transfused with an incorrect component; a unit intended for another patient. They use that incident to show how it would be inappropriate to assign the total cause of an adverse event to an individual error, because there were many system and organisation failures that also contributed. A clinical research focus article (Chadwick & Jeffcott, 2013) gave a brief introduction to human factors engineering for a readership of transfusion professionals, in which they explained the use of systematic human error reduction and prediction approach (SHERPA) (Embrey, 1986). These may be useful background publications, but are not cutting-edge research applying human factors to blood transfusion.

A speaker abstract and a journal paper with a common author both describe the use of simulation to improve practice in major haemorrhage (Green, 2013; Green & Curry, 2014), including training on human factors, which concluded that targeted simulation sessions resulted in improved understanding and awareness of the major haemorrhage protocol (MHP). This is a constructive HF-based research technique, but the research only covered a small part of

transfusion, because most blood is used in non-haemorrhage situations. However, problems associated with activation of the MHP can lead to delays in transfusion and SHOT data have shown that delay is a major cause of mortality (Bolton-Maggs *et al*., 2017c).

Nine further publications that relate human factors research to blood transfusion are abstracts of poster or speaker presentations at transfusion conferences and each comprises approximately 300-500 words, so they contain limited information, which means it is difficult to assess the strengths and limitations of the research. Alimam *et al*. (2014) looked at human factors in the blood sampling process to identify contributing factors to wrong blood in tube (WBIT) and identified system problems, such as a punitive culture and problems with the labelling protocol. Research into staff feelings and perceptions after an incident suggested that awareness of human factors should be included in training packages (Creighton & Wright, 2014). A study in Catalunya (Spain) compared two haemovigilance surveys 3 years apart to identify system problems affecting transfusion safety (Lopez-Soques *et al*., 2015). An abstract from a keynote conference speech details the opportunities and challenges of international haemovigilance and the focus on understanding human factors in transfusion practice (Wood *et al*., 2015). A test of change study looked at the safety of a single practitioner procedure for administration of blood and "...focused on communication, resources, training, support and the human factors", but the results presented do not define how human factors were examined, so this may be a further example of the phrase being used solely to relate to individuals within the system (Cottrell, 2016), though it should be noted that like all short abstracts there may be insufficient information to make accurate inferences. Similarly, research into transfusion request rejections cites '...the human factor' and makes a conclusion about human error and distraction, which suggests focusing on the individual more than the system (Bahadori *et al*., 2017).

Conversely, an abstract addressing human factors in major haemorrhage management (Orr *et al*., 2016) demonstrated clearly their package of simple human factors interventions and concluded that they may have contributed to

improvement in transfusion ratios and mortality. A speaker abstract detailed their presentation assessing the impact of human factors on transfusion safety in trauma using a mixed-methodology research programme, which identified that multiple human factors contribute to a reduction of patient safety (Graham *et al*., 2017). The last short abstract reviewed was a study aiming to modify human factors to reduce transfusion sample rejection rates, which, like other publications, seems to be using a narrow definition of human factors by concluding that behavioural change is required (Tay *et al*., 2018). The remaining journal paper appraised was a research project that identified human factors techniques transferable from industry and the military (Swieton *et al*., 2018). A package of interventions was developed to improve transfusion delivery in major haemorrhage due to trauma. The outcomes appear positive, but the authors note that the trial did not have enough patients to prove that better transfusion ratios led to improved survival. Also, like the simulation work discussed above, this research only related to major haemorrhage, which is a limited area of the transfusion process.

In summary, the existing literature using HF-based applications in the field of transfusion medicine is sparse and often is not high quality, peer-reviewed research. The transfusion process is a complex socio-technical system and relies on multidisciplinary teams (MDT) of healthcare professionals, hence there are many opportunities for error and consequently many areas that could benefit from the application of human factors research. The emphasis so far has been to try and learn from what goes wrong in transfusion incidents, but applying human factors principles, such as the Safety-II concept, could indicate where the transfusion process might be made more resilient (Wears *et al*., 2015). Authors sometimes apply a limited understanding of human factors, typically those related to individuals, rather than to system and organisational problems. However, it is worthy of note that in recent years more publications are beginning to reference human factors to research of transfusion practice, and it is anticipated the studies in this PhD will contribute to the body of knowledge.

2.4 Examination of literature relevant to HF for incident reporting and proactive risk/system analysis

2.4.1 Review of human factors models and methods for patient safety

This section will review a selection of publications to answer the question of which human factors models/methods would be most appropriate for the planned areas of research. Database searches returned far too many general human factors papers, so from those results the abstracts were reviewed for relevance, as detailed in Section 2.1, before specific publications that detailed the major models/methods were chosen for review. Table 2.4 lists the major publications on human factors models and methods that have been reviewed.

Table 2.4: Publications reviewed on human factors models or methods

HF model or method	Reference
1. Healthcare Failure Mode and Effect Analysis (HFMEA)	DeRosier *et al.*, 2002
2. Systematic human error reduction and prediction approach (SHERPA)	Embrey, 1986
3. Software-Hardware-Environment-Liveware-central Liveware (SHELL)	Hawkins & Orlady 1993
4. Skills Rules Knowledge (SRK)	Rasmussen, 1983
5. Active and latent failures (Swiss cheese model)	Reason, 1990
6. Human Factors Analysis and Classification System (HFACS)	Shappell & Wiegmann, 1997
7. AcciMap	Rasmussen, 1997
8. Systems Theoretic Accident Modelling and Processes (STAMP) and System-Theoretic Process Analysis (STPA)	Leveson, 2004a Leveson, 2004b
9. Functional Resonance Analysis Method (FRAM)	Hollnagel & Goteman, 2004
10. Systems Engineering Initiative for Patient Safety (SEIPS 2.0)	Holden *et al.*, 2013a
11. London Protocol	Taylor-Adams & Vincent, 2004
12. Bowtie Method	De Ruijter & Guldenmund, 2014
13. Human Factors Investigation Tool (HFIT)	Gordon *et al.*, 2005

1. Healthcare Failure Mode and Effect Analysis (HFMEA)

Failure Mode and Effect Analysis (FMEA) is known to have originally been developed by the US Armed Forces and was apparently detailed in the Military Procedures document MIL-P-1629 (USA MIL_P, 1949). An online literature search was unable to locate a copy of that document, but it was discovered that the final version of the USA military document, MIL-STD-1629A, was cancelled on August 4, 1998 (Snee & Rodebaugh, 2008). No further attempts were made to source the original military procedures document, because the updated Healthcare Failure Mode and Effect Analysis (HFMEA) is more relevant to the planned research (DeRosier *et al.*, 2002). DeRosier *et al.* (2002) describe a healthcare application of FMEA, which was developed at the Department of Veterans Affairs (VA) National Center for Patient Safety (NCPS) in the United States of America (NCPS, 2002) and rolled out to 163 centres in the Veterans Affairs health care system. Although the technique is well explained, at the time of writing this original paper there were no results published from use within these 163 centres, so it is difficult to assess the validity or reliability of the technique from this research. The authors reported that "Comments from the field following this training were positive, and additional on-site training is being conducted to reinforce the concepts and process." A database search for HFMEA returned approximately 1000 items, which suggests the technique has had widespread use since its launch in 2002. There are a few transfusion-specific uses of both HFMEA and the original FMEA technique (Table 2.2), but these do not give an in-depth picture of the technique or of its application to transfusion.

HFMEA combines the probability and severity stages in the traditional Failure Mode and Effect Analysis into an algorithm known as a 'Decision Tree'. It is a five-step process:

1 Define the topic
2 Assemble the Team
3 Graphically Describe the Process
4 Conduct a Hazard Analysis
5 Actions and Outcome Measures

Instead of the risk priority number (RPN) used in traditional FMEA there is a hazard score, which can be read directly from a Hazard Matrix Table (Figure 2.7). Any score above 8 requires mitigation to reduce the risk. There are many resources related to HFMEA at the U.S. Department of Veterans Affairs website http://www.patientsafety.va.gov/professionals/onthejob/hfmea.asp

HFMEA Hazard Scoring Matrix™

Probability	Severity of Effect			
	Catastrophic	Major	Moderate	Minor
Frequent	16	12	8	4
Occasional	12	9	6	3
Uncommon	8	6	4	2
Remote	4	3	2	1

How to use this matrix
1. Determine the severity and probability based on the definitions in the matrix
2. Look up the hazard score on the matrix

Figure 2.7: Healthcare Failure Mode and Effect Analysis (HFMEA) Hazard Scoring Matrix

(Source DeRosier *et al.*, 2002)

HFMEA is a prospective risk assessment technique, so would only be relevant for use in Study 3 in the planned research into the application of human factors to the redesign of the blood transfusion process.

2. Systematic Human Error Reduction and Prediction Approach (SHERPA)

The SHERPA technique is a human reliability analysis (HRA) technique (Embrey, 1986), which uses a task activity classification taxonomy to examine: Action failures, Checking failures, Communication failures, Information

retrieval failures and Selection failures. SHERPA has been used in a few healthcare studies, such as anaesthesia errors (Phipps *et al.*, 2008) and in a drug administration system (Chana *et al.*, 2017) and is mentioned in a transfusion review article (Chadwick & Jeffcott, 2013) but was not used for any transfusion research. SHERPA was constructed to extend the basic FMEA model and has been applied to medical device design and risk assessment (Embrey, 2014) The method would only be suited to Study 3 in this research.

3. Software-Hardware-Environment-Liveware + central Liveware (SHELL)

The original Software-Hardware-Environment-Liveware (SHEL) model was initially developed for the aviation industry (Edwards, 1972) and examines the interactions of humans, known as liveware, with other aspects of the working environment: Hardware (H), the physical sources and equipment; Software (S), including rules, regulations, procedures and practices; Environment (E), the physical, economic and social aspects influencing human performance. Later the concept of central Liveware was introduced to distinguish the main actor(s) from the other humans operating in the system and the model was adapted into a building block structure (Hawkins & Orlady,1993).showing how the central L interacts with each other element, i.e. L-S, L-H, L-E and L-L (Figure 2.8).

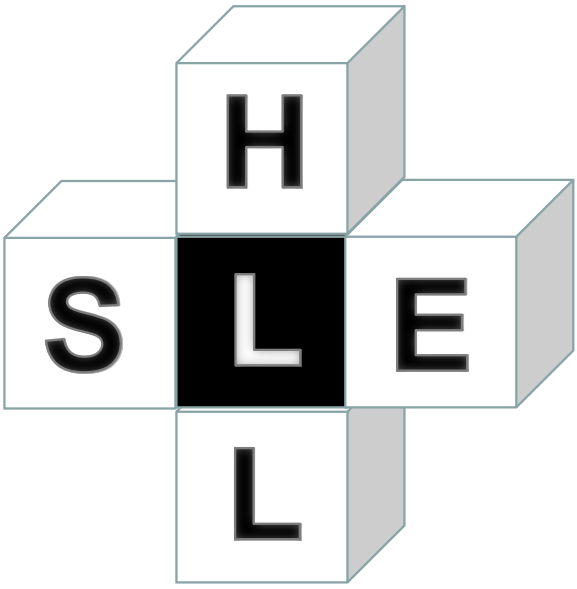


Figure 2.8: The SHELL Model

(Source Hawkins & Orlady,1993)

Although this model has been adopted within healthcare, the uses have been limited (Antunes *et al.*, 2011) and there are no substantial advantages of the SHELL model over other techniques. It would possibly be applicable for Study 3, but would not be suitable for analysing incidents in Study 1.

4. Skills Rules Knowledge (SRK)

The taxonomy of skills, rules, and knowledge (SRK) was defined by Rasmussen in a paper investigating how human performance models can inform the design of computer interface system (Rasmussen, 1983). This paper develops the theme of SRK, as a hierarchical model of human performance:

- Skill-based behaviour requires the least input with operators simply performing their role with very little conscious control.
- Rules-based behaviour requires more input, but operator interaction is limited by regulations or standard operating procedures and as such can be carried out with low levels of underlying knowledge.
- Knowledge-based behaviour requires high levels of operator input and the application of their knowledge and experience to what may be complex tasks or changeable circumstances.

Rasmussen explains how the different aspects of SRK behaviour can be influenced by environmental elements, with skill-based behaviours perceiving signals, rules-based perceiving signs and knowledge-based perceiving symbols.

Rasmussen's descriptions in this paper relate to models of human behaviour and how they can be used to design computer interfaces, so it is not directly applicable to the work proposed for either Study 1 or 3. However, the basic classification of skills, rules, knowledge can be used as a simple reactive categorisation of accidents and incidents and as such will be suitable for use as a model in Study 1 of the planned research.

5. Active and latent failures (Swiss cheese model)

James Reason's Swiss cheese model was developed from the work described in his book, *Human Error* (Reason, 1990). The model is shown to have both active and latent failures. The latent failures may be environmental or organisational aspects that can be hidden over a period of time until they contribute to an accident. Active failures are the direct causes of an accident and can be sub categorised into:

- Slips
- Lapses
- Mistakes
- Violations

Reason postulated that accidents occur when all barriers to prevent failure have been breached. Any defences will potentially have failure points, or holes in the barrier. Reason has likened that to the random holes found in slices of Swiss cheese that could inadvertently line up and allow an accident to occur (Reason, 2000) (Figure 2.9).

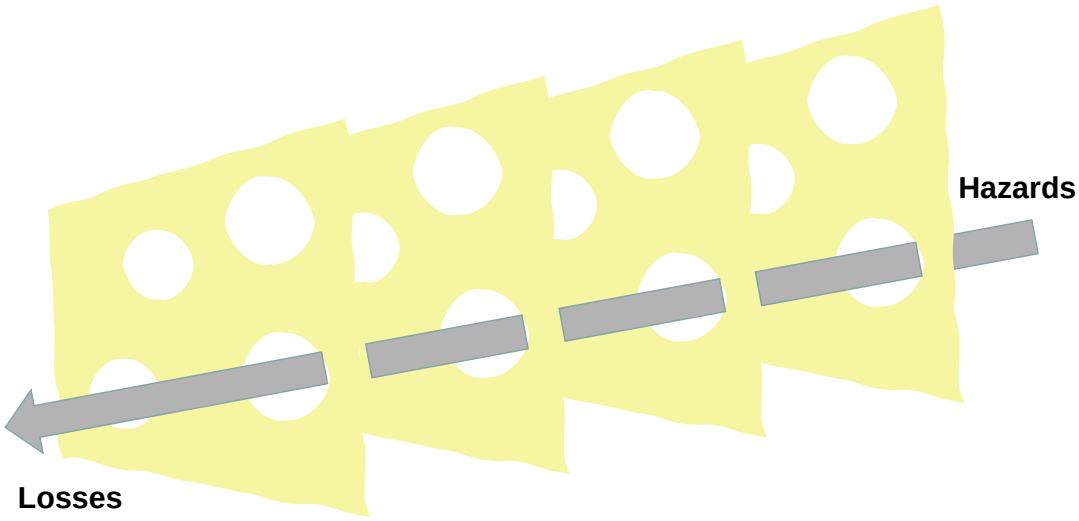


Figure 2.9: Swiss Cheese Model - accidents result from a failure of barriers

(Source Reason, 2000)

These accident categorisations can be linked to Rasmussen's skills, rules, knowledge (SRK) classification, in particular skill-based slips and lapses, plus

mistakes that can be either rule-based or knowledge-based. Reason also presents a generic error modelling system (GEMS), which is a blend of other theories that expands further on Rasmussen's SRK.

Reason's (1990) *Human Error* book is an excellent introduction to human error classifications and management and the basic categorisations of active and latent failures will provide a useful model for Study 1.

6. Human Factors Analysis and Classification System (HFACS)

The development of the Human Factors Analysis and Classification System (Shappell & Wiegmann, 1997) was motivated by Reason's Swiss cheese model (Reason, 1990) and classifies accidents by four levels:

- Level 1: Unsafe Acts
- Level 2: Preconditions for Unsafe Acts
- Level 3: Unsafe Supervision
- Level 4: Organisational Influences

This classification expands the usefulness of Reason's model and allows its application to the causal factors of an incident, rather than the immediate active and latent errors described by Reason. Using this classification Shappell and Wiegmann later analysed nine-years' worth of fatal aviation accidents, which adds strength to the validity of their HFACS method (Shappell & Wiegmann, 2001). HFACS can be used for both an accident analysis and as a proactive risk management tool. It might therefore be suitable for use in both Study 1 and Study 3.

7. AcciMap

The AcciMap system was first described by Jens Rasmussen in his paper *Risk management in a dynamic society: a modelling problem*. (Rasmussen, 1997). It is one of the first attempts at modelling complex socio-technical systems as a whole, rather than by decomposition into elements that are modelled separately. The method allows a view of systemic causes of accidents and therefore shows the high-level reasons that failed to prevent an accident from occurring or contributed to the negative outcome. By looking further than the

immediate causes of an incident this accident analysis can promote a just culture (Dekker, 2012) and move away from blaming an individual.

AcciMap defines accident causes at six levels incorporating government, regulation and societal issues:

- Government
- Regulatory bodies
- Company management
- Operational management
- Staff
- Equipment & surroundings

AcciMap could be used as an incident analysis tool for Study 1 and could be applied to Study 3 as a proactive risk management tool in the transfusion process research.

8. Systems Theoretic Accident Modelling and Processes (STAMP)

Leveson (2004a) introduces an accident model based on systems theory and control theory and discusses how event-based models encourage a linear view of accidents. Important causal factors may not fit into a linear model and, as already shown in multifaceted models, such as AcciMap and HFACS, the underlying causes of an accident might be at higher organisational or regulatory levels, so a broader model for complex socio-technical systems is required. STAMP acts as a bidirectional constraints-based model highlighting interactions between system components and the control mechanisms. Each level in the system hierarchy enforces constraints on the level below and information at the lower levels is communicated upwards to influence controls and constraints at the higher levels.

STAMP can be used for incident analysis by describing control structures and identifying failures that contributed. Control failures are identified with a taxonomy including: inadequate enforcement of constraints (control actions), inadequate execution of control of actions and inadequate or missing feedback.

By undertaking incident analysis with an emphasis on control and feedback, the STAMP model can depict failure across the full system, including the interaction between structures and their control failures that led to the incident.

Leveson (2004b) has developed STAMP into a hazard analysis model System-theoretic Process Analysis (STPA) This extends the use of the STAMP model into a more proactive area of use. STPA can be summarised as:

- Identify accidents and hazards
- Construct the control structure
- Identify unsafe control actions
- Identify causal factors and control flaws

These two models could apply well to each of the studies being planned, with a STAMP analysis being a useful tool within Study 1 and STPA being more applicable to Study 3.

9. Functional Resonance Analysis Method (FRAM)

The Functional Resonance Analysis Method (FRAM) was first described at a similar time to the other systemic models (Hollnagel & Goteman, 2004). It builds on the premise that complex systems need better tools for accident investigation or risk profiling. The paper explains the FRAM technique clearly and demonstrates with examples. The Functional Resonance Analysis Method defines the functional entities in six categories:

- Input
- Output
- Resource
- Controls
- Precondition
- Time

These categories are typically represented graphically in a hexagon (Figure 2.10) and a systemic view of a process can be generated by linking the functional entities of each function or process in the system.

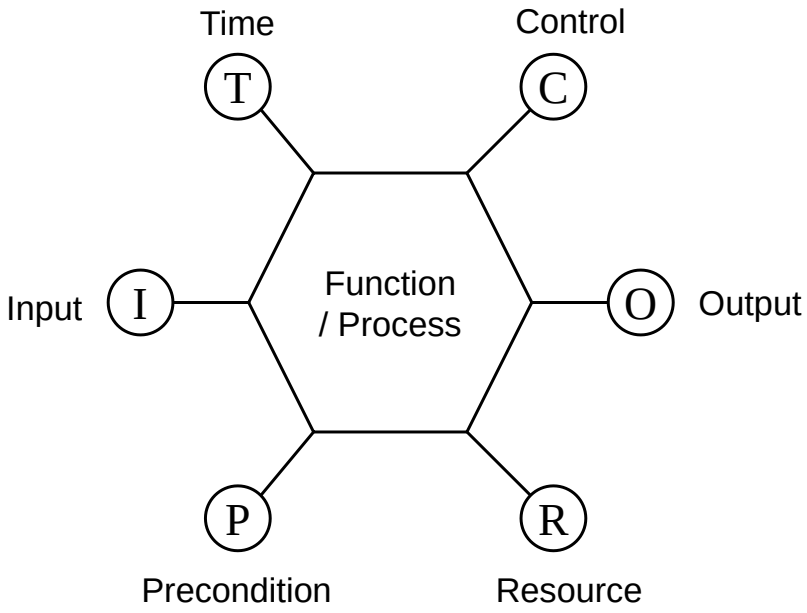


Figure 2.10: Hexagonal representation of a generic functional entity

(Source Hollnagel & Goteman, 2004)

FRAM at its most superficial level may be suited to the error analysis in Study 1 and could also be applicable for Study 3, where it would be applied as an in-depth process analysis. In particular if considered as a method for analysing the transfusion process (Study 3) a FRAM investigation would allow a consistency between analysing the procedures as observed in different institutions.

10. Systems Engineering Initiative for Patient Safety (SEIPS 2.0)

Early uses of Systems Engineering Initiative for Patient Safety (SEIPS) as a model for assessing patient safety systems have been described (Carayon *et al.*, 2006) and it has become one of the most recognised models within healthcare. SEIPS 2.0 (Holden *et al.*, 2013a) refines and extends the model by incorporating extra dimensions. It consists of six interacting components in the socio-technical work system:

- Person(s)
- Tasks
- Tools and technologies
- Organisation
- Internal environment
- External environment

In SEIPS 2.0 the system produces work processes which shape the outcome, and these are complemented by adaptation, which acts as a feedback mechanism, showing the unpredictability and required adaptability of healthcare systems. This is presented diagrammatically (Figure 2.11) which shows the complexity of the model.

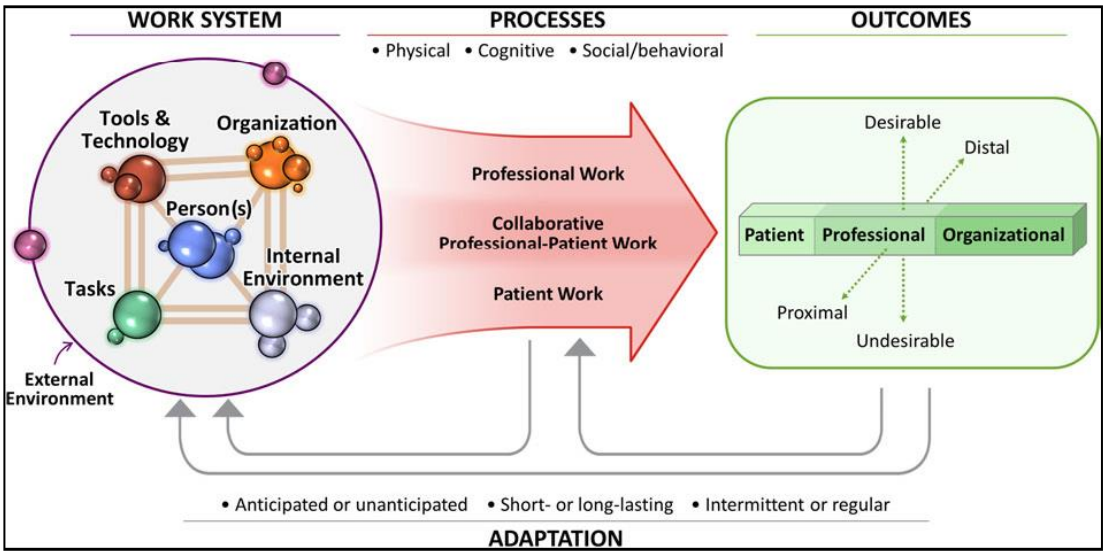


Figure 2.11: The SEIPS 2.0 Model

(Holden *et al.*, 2013a)

This paper validates the SEIPS 2.0 model by demonstrating its use in several situations, showing that it is a practical tool for analysis, as well as a theoretical model. At its simplest the SEIPS model for the work system may be used as an incident analysis process, i.e. for Study 1 and the full model would be suited to the work to be done for Study 3.

11. London Protocol

The London protocol is a method for incident analysis, which was designed for practical use by incident investigators (Taylor-Adams & Vincent, 2004). The protocol covers the entire system of investigation, analysis and recommendations for action, and it emphasises that this approach should be separated from any blame or disciplinary procedures. The full procedure is designed to encourage a more thoughtful and reflective investigation process for incident investigators, but it is unlikely to be of benefit for investigating incidents reported to a third party, as is the intention for Study 1. Also, the London Protocol is intended for incident investigation, not for prospective process analysis, so would have no value in Study 3.

12. Bowtie Method

The precise background of the bowtie method is not well known; hence the technique was examined for this research via a comprehensive review paper (De Ruijter & Guldenmund, 2014). Although knowledge of the bowtie method can be traced to the late seventies, the Royal Dutch/Shell Group was the first main organisation to adopt the bowtie method into its working systems in the early nineties (Zuijderduijn, 2000) and they developed the technique used today. The model resembles a bow tie with prevention and control measures on the left plus recovery measures on the right (Figure 2.12).

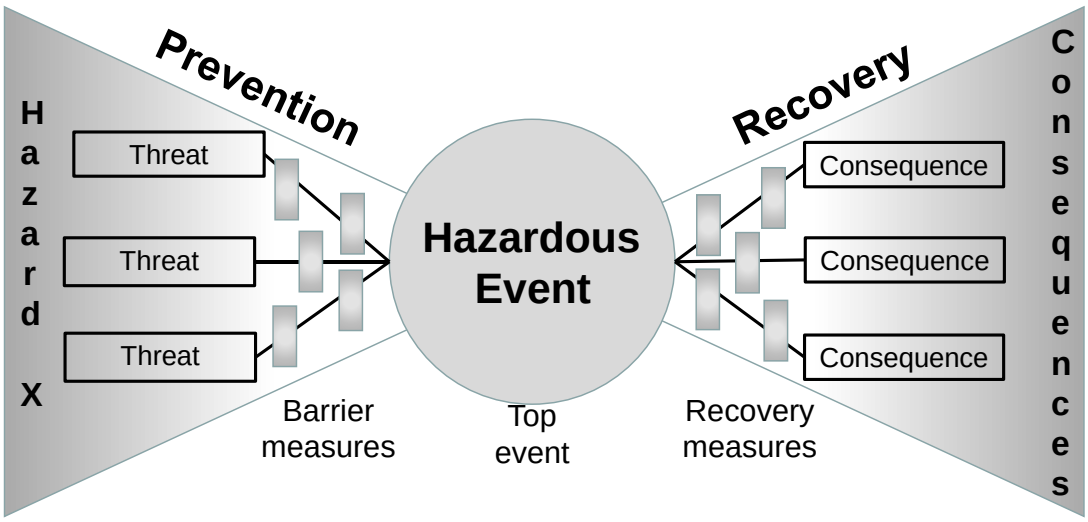


Figure 2.12: The Bowtie Model

(Zuijderduijn, 2000)

The bowtie method is based on Reason's (2000) Swiss Cheese model and is a qualitative risk management system that can be used to analyse the quality as well as quantity of safety barriers that are designed to protect systems and mitigate possible hazards. For this research the bowtie method would be more suited for a prospective analysis, i.e. Study 3.

13. HFIT - Human Factors Investigation Tool

The intended outcome of Study 1 is to inform the requirements of Study 2, i.e. to incorporate an appropriate Human Factors Investigation Tool (HFIT) into the UK haemovigilance process via the Serious Hazards of Transfusion (SHOT) database. SHOT collects reports of errors in blood transfusion and a retrospective review of those cases is planned within Study 1. The intention is to develop a series of questions for Study 2, which would be common to all error reports and would allow an analysis of these incidents from a human factors perspective.

Gordon *et al.* (2005) demonstrate a possible technique for developing such a tool and they describe a linear model that analyses these criteria sequentially: Action errors; Situation awareness; Threats and Error recovery. The HFIT shown in Gordon *et al.* (2005) was developed as a paper-based flow diagram, which could translate very well to the SHOT database, which is an interactive flow-based process, allowing electronic capture rather than on paper. Dependent on the answers given to key questions, SHOT datasets can branch into different subsets, which might allow the development of a flow-based tool. Gordon *et al.* (2005) tested their tool in a series of case studies and analysed the data using Benner's evaluation system (Benner, 1985). This evaluation system could be considered when designing a bespoke HFIT for transfusion errors for Study 2.

2.4.2 Conclusion of literature review for HF models/methods

The literature review of models and methods to be applied to this research returned a large cohort of papers, which were narrowed down to the main models/methods summarised in Table 2.5. The publications were reviewed in

particular to define the proactive and reactive aspects and to decide which are likely to be best suited to Studies 1, 2 and/or 3. A total of seven human factors models/methods were suitable to be applied to Study 1, which is a retrospective analysis of transfusion error reports: SRK, Active & Latent, AcciMap, HFACS, STAMP, FRAM and SEIPS 2.0 and all of these are to be examined in Study 1. Study 2 is planned to be an analysis of transfusion errors reports, using a Human Factors Investigation Tool (HFIT), which will be developed following the initial analysis in Study 1. Nine models/methods could be examined further for applicability to Study 3, which will be a prospective analysis of healthcare institutions' complete transfusion process.

Table 2.5: HF models/methods applicability to Study 1, 2 and/or 3

HF models or methods	Suitable for study 1, 2, 3
HFMEA - Healthcare Failure Mode and Effect Analysis	3
SHERPA - Systematic Human Error Reduction and Prediction Approach	3
SHELL - Software-Hardware-Environment-Liveware + central Liveware	3
SRK - Skills Rules Knowledge	1
Active and latent failures (Swiss cheese model)	1
HFACS - Human Factors Analysis and Classification System	1 & 3
AcciMap	1 & 3
STAMP - Systems Theoretic Accident Modelling & Processes (STPA - System-theoretic Process Analysis)	1 (3)
FRAM - Functional Resonance Analysis Method	1 & 3
SEIPS 2.0 - Systems Engineering Initiative for Patient Safety	1 & 3
London Protocol	None
Bowtie Method	3
HFIT - Human Factors Investigation Tool	2

One conclusion is that there is an element of overlap in some of the models/methods examined. Each newly developed model seems to use aspects of others and whilst they may bring a new twist or an innovative addition the major elements can be quite similar. This proliferation may be most useful where the amendments help to make the model more specific to the industry or study area in which it is primarily to be used, such as the SEIPS 2.0 model, which was specifically developed for application to healthcare. This

is also exemplified by the London Protocol, which is a comprehensive procedure for incident investigation and a similar specific HF model developed by the Health and Safety Executive (HSE) which was developed with the aim of helping the HSE and its key stakeholders to understand human factors in practice (Bellamy & Geyer, 2007). This understanding will be beneficial when creating a bespoke human factors investigation tool (HFIT) for use in Study 2.

2.5 Conclusion of literature review

Overall the literature review has confirmed the need for further research into the application of human factors to transfusion, by showing there is currently a lack of high-quality research in this field (Table 2.2). This is particularly pertinent since transfusion has reached a very high level of microbiological safety (Figure 2.4), which means the components themselves are considered as safe as possible. However, the existing quality and patient-safety initiatives (Figure 2.6) have not shown a major reduction in potentially avoidable deaths (Figure 1.4), so the major risks to patients receiving a blood transfusion can be considered to be error-related.

Chapter 3 Research Methodology

In this chapter the philosophy underpinning the research is set out, i.e. the research paradigm. The ontology and epistemology are considered, and the data collection and analysis methods are outlined, along with measures to assure reliability, validity and generalisability (Leung, 2015). The methodology is examined to assess the appropriateness to achieve the aims of the research and any limitations are considered.

3.1 Introduction to research philosophy

"There are more things in heaven and earth, Horatio,
than are dreamt of in your philosophy" (Hamlet. 1.5.167-8).

As this thesis is to be defended for the award of a doctorate of philosophy (PhD) it is apposite to examine the extensive topic of philosophy, in particular research philosophies. It can be considered that the field of research philosophy began with Immanuel Kant's *Kritik der Reinen Vernunft* or *Critique of Pure Reason* (Kant, 1781; Guyer & Wood, 1998) in which Kant proposed transcendental philosophy to describe the conditions under which knowledge of the existence of things is possible. Before Kant's work, items and objects were regarded separately and considered immutable, but Kant argued there is no innate knowledge, so experience is a combination of the effects of external objects and our own cognitive faculties. This is essentially a definition of how research is executed. The research process has three main elements: ontology, epistemology and methodology, and the research paradigm describes the overall approach of the research encompassing these three aspects.

3.1.1 Ontology

Ontology can be defined as 'what is considered as truth' (Brown *et al.*, 2008) and it relates to philosophical postulations regarding the structure of the world and the nature of reality, i.e. what we can know to exist or be real. Ontology can generally be split into two essential dimensions: objective and subjective. In this respect an objective configuration involves examining the subject from

the stance that reality exists whether we are conscious of it or not, including when it is not being directly experienced or observed. As an example of objectivity, testing a patient's blood group would always result in the same answer, irrespective of who is doing the scientific analysis and the blood remains the same group even when circulating in the patient and not currently being tested. In contrast, a subjective view of reality relies on the connections and insights of living beings. A transfusion-related example could be the preference some healthcare professionals have for handling bags of blood either when they have just been donated and are at body temperature, 37ºC, or when they have been stored and cooled to refrigeration temperature 4ºC. Objectively there would be no difference between those two bags of blood, but different individuals may feel squeamish at having to touch one compared to the other. Subjectivity is related to perceptions of the individual and could be associated with the idiom 'one man's meat is another man's poison'.

3.1.2 Epistemology

Epistemology can be defined as 'ways of getting at the truth' (Brown *et al.*, 2008) and is the is the philosophical theory of how we acquire reliable knowledge. Epistemology concerns the relationship of the researcher to the subject being studied i.e. what it is feasible for us to know and how we can attain a valid understanding. For example, if the weight of an item is guessed, does that constitute reliable knowledge? If not, how can the knowledge be verified? The accuracy of the verification may depend on the circumstances. Comparing a known similar weight object may be sufficient for a food cooking recipe, but a fully verified and accurate weight may be required when preparing a constituent of a planned chemical reaction.

There are four main epistemologies: positivism, critical realism, action research and interpretivism. Positivism is an objective dimension that relies on logic and scientific knowledge and assumes reality can be measured, hence the researcher is independent from the research and depends on accurate tools for valid evaluation. Critical realism is developed from both objective and subjective ontologies and supposes there is an external reality, but the researcher is interdependent with society and culture, so access to this reality

is restrained and biased by human perceptions (Bhaskar, 2013). The critical realist understands that assumptions only establish a temporary reality, so knowledge produced from observations may seem different from another view. In contrast, action research is a phrase designed to encompass a breadth of research processes designed to advance change. Action research advances in a spiral of steps of which each has a cycle of planning, action, and fact-finding about the result of the action (Lewin, 1946), so the researcher specifically intends to change the situation with their research. Interpretivism focuses not on simply measuring, but also on interacting with the research to understand what is happening in a particular situation (Klein & Myers, 1999) and it was developed to counteract the power of positivism at the time. Interpretivism was a rejection of the dominance of scientific theories and research and actively replaced those paradigms to focus on understanding rather than measurement. Therefore, interpretivism controls activities created from within the human mind and confirmation of what actually exists is dependent on the understanding of the researcher.

3.1.3 Methodology

Methodology refers to the study and use of methods and how the researcher practically finds out what needs to be known within their research. Examples of methodology would include both quantitative and qualitative data gathering techniques, with approaches broadly categorised as deductive for quantitative data, and inductive for qualitative data. The methodology may include many techniques, including literature reviews, interviews, surveys and mining existing data including both present and historical information. In this way, the researcher studies the research questions systematically to reach appropriate conclusions. Therefore, methodology is an organised process in which the tools or instruments will be employed most efficiently and suggests the theoretical underpinning for understanding the principles of the research.

3.1.4 Research paradigm

There are three major research paradigms: positivism, pragmatism and constructivism. Positivism starts from the concept that that there is a single reality, and this can be objectively measured and known. Positivism is

therefore more likely to employ quantitative methods, while in comparison constructivism will tend to use qualitative methods, because it is predicated on there being no single reality, so the world needs to be interpreted to understand the multiple realities. As a middle ground, pragmatists consider that reality is constantly reconsidered, deliberated, contemplated and interpreted. Therefore, pragmatism deems that the methods best suited to resolve the questions are the most appropriate to use. In summary, research paradigms can be located on a spectrum ranging from the objectivity of positivist, qualitative research to the subjectivity of constructivist, interpretative qualitative options.

The research paradigm for the studies forming this research will employ a pragmatic approach, mixing a subjective, problem-solving methodology using qualitative research, with elements of quantitative research where suited to the investigations.

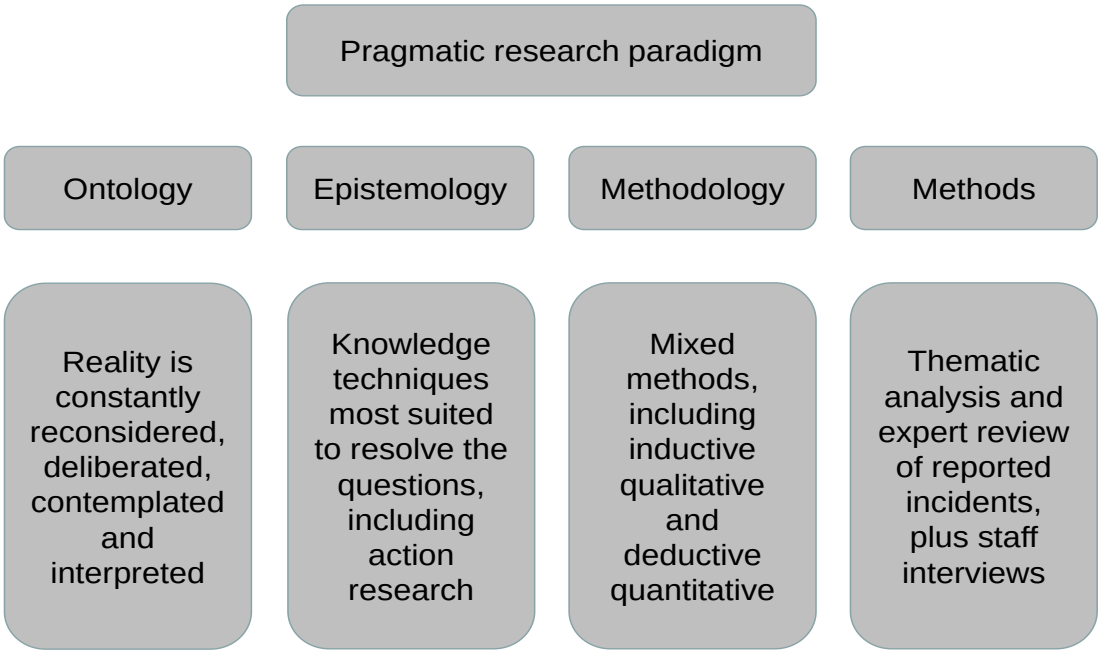


Figure 3.1: Overview of research paradigm for these studies

Pragmatism as a philosophical convention originated in the late 19th century in the USA, led by members of the Harvard ‘Metaphysical Club’, including Charles Sanders Peirce and William James. Their concept of pragmatism was later developed by John Dewey and the three philosophers are referred to as

the ‘classical pragmatists’ (Rylander, 2012). Pragmatism accentuates collaboration and integration, with continuity as the controlling principle, leading to an epistemology that highlights process and experimentation.

Another concept for research paradigms worth considering in relation to this research is the model developed by Burrell & Morgan (1979). They studied the nature of social science and the nature of society to combine aspects of philosophy and social theory, from which they developed four mutually exclusive paradigms (Figure 3.2).

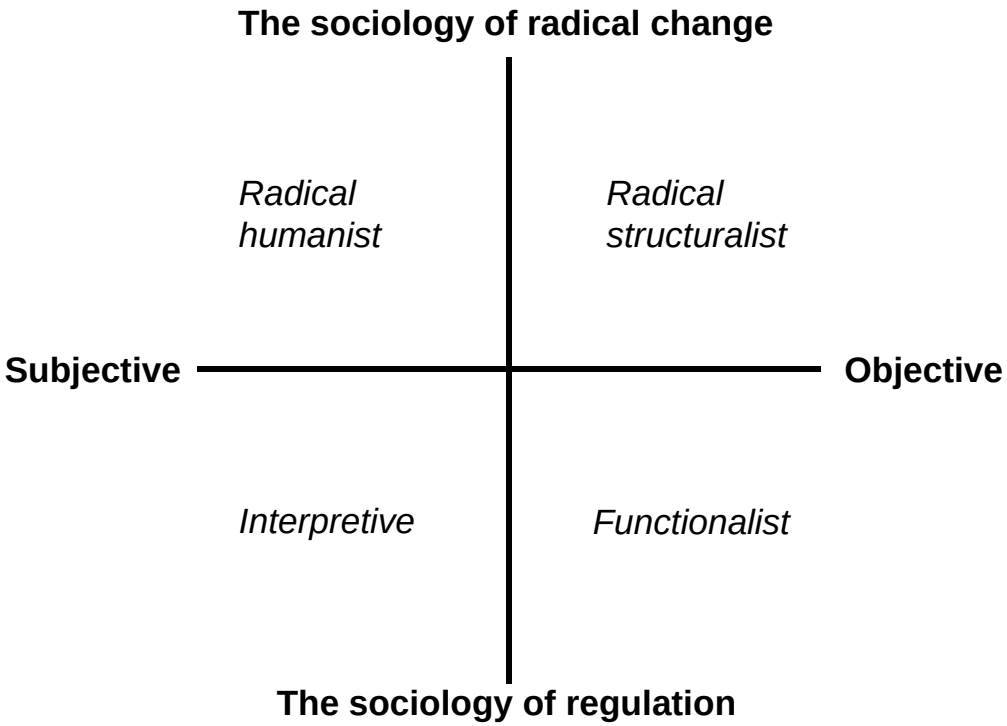


Figure 3.2: Sociological paradigms

(Source Burrell & Morgan, 1979)

In this model, sociological theories are classified between two linear dimensions comprising change (revolution) versus regulation (stability) on one axis and subjectivity (individualistic) versus objectivity (organisational) on the intersecting axis, leading to four quadrants representing:

1. Radical humanist (subjective-radical change) – suggests the world is controlled by major social organisations meaning people are removed from their true selves, thus revolutionary change is justified, and

interventions are aimed at consciousness-raising to effect change in social and economic constructions.

2. Radical structuralist (objective-radical change) – this has been the essential theory of Marx, Engels, and Lenin, asserting that society's struggles cause constant flux through political and economic disasters, so our system is unfair and untenable, meaning a comprehensive revolution is the only means of achieving meaningful change.
3. Interpretive (subjective-regulation) – stability can be viewed from the individual's perspective, so researchers aim to study current processes to understand the individual interpretation. Interventions concentrate on restructuring proceedings and changing the ways individuals regulate their own actions.
4. Functionalist (objective-regulation) – This has been the main paradigm for researching organisations, based on the belief that via hypothesis assessment, organisational behaviour can be understood, because human nature is rational, and organisations are collections of groups who establish social order with shared values. Interventions aim to make adaptations and adjustments to existing configurations where needed.

Burrell and Morgan (1979) contend that from the perspective of each paradigm the world is viewed in an individual way, so each researcher can locate their own frame of reference in one of the four quadrants.

The research forming this thesis is rooted in a functionalist paradigm, because functionalism is a standpoint that is very pragmatic and aims to understand the research questions in such a way that the data produced have a practical use, providing practical solutions. Biological analogies to understand society are preferred in many functionalist theories, which is attractive to this researcher, who comes from a pure biological background. However, there have been attempts to consider perspectives from the least objectivist area of the functionalist paradigm, where it meets the interpretive paradigm, and these introduce the concept of research from the viewpoint of individuals actively

undertaking the activities being studied. Thus, the pragmatic nature of functionalist theory provides an ideal structure for these studies.

3.2 The status of these studies within transfusion research

Blood transfusion practice is a wide-ranging area of healthcare, as described in Chapter 2, so it is inevitable that a human factors (HF) study of this field would require a mixed methods approach. The author is from a transfusion-related biological science background, which is a discipline largely dependent on positivist research and quantitative methods. Scientific transfusion investigations usually result in binary outcomes, leading to single realities, i.e. positive or negative, or measurable quantifications counted in units such as millilitres, grams or percentages etc. As an example, there is seldom any opinion or variation in deciding if a patient's blood type is group A or group B, though for any experienced transfusion scientists reading this statement, there can be rare modulations in ABO grouping that require a more in-depth level of expertise and skill to interpret the outcome.

Therefore, it will be important to construct a valid methodology for these studies in order to produce research studies that will be convincing for traditional scientists, who usually undertake positivist research, preferring quantifiable methods that can be analysed in specific ways with statistical assessments to inform the researchers about the significance of their results. Human factors studies can seldom be undertaken using only quantitative methods. Waterson *et al.* (2015) provided a comprehensive review of methods suitable to analyse complex sociotechnical systems and categorised data collection techniques into five main groups: interviews, observations, surveys, scenarios and task analysis, with similar secondary methods listed, such as focus groups and workshops. Most of these techniques are qualitative and the methodology employed in this research is similarly largely qualitative; although the following chapters include some quantification where appropriate within the analyses, so a mixed methods approach has been used. This could be described as a pragmatic paradigm, using both qualitative and quantitative methods as appropriate to achieve the research aims and objectives. Overall a qualitative approach allows for the ontological requirements of the end to end

transfusion process that can have varying and sometimes competing, realities. This approach will add considerably to the field of knowledge in blood transfusion safety, because as discussed in Chapter 2, there has been very little research of this nature. It is time to add to the body of work in transfusion safety, which to date has largely focused on expanding technological and clinical knowledge using accurate measurement and prediction research methods, i.e. a positivist approach, but has not sufficiently examined the system and organisational factors that may affect patient safety, for which a pragmatic approach will be more appropriate.

3.3 Research approach

Overall, within the pragmatic methodology, an action research approach will be adopted because, as recommended in the 2013 Annual SHOT Report (Bolton-Maggs *et al.*, 2014), these studies concurrently introduce changes to the existing processes, e.g. incident reporting and auditing, alongside developing a greater knowledge and understanding of human factors applications to blood transfusion safety improvement. Action research (Lewin, 1946) is a form of real-world research or evaluation research, which is defined as 'the systematic collection and interpretation of evidence, leading, as part of the process, to a judgment of value with a view to action' (Wolf, 1987).

Action research is an addition to the traditional research purposes of description, understanding and explanation, so it has developed different principles of conduct from standard experimental studies (Winter, 1989) typically requiring a cyclic sequence that is participative, qualitative and importantly reflective, because analytical contemplation of the research outcomes is a vital part of each cycle (Figure 3.3). Thus, this type of study is responsive and emergent, i.e. it is designed to be flexible enough to respond to the emerging needs of the situation.

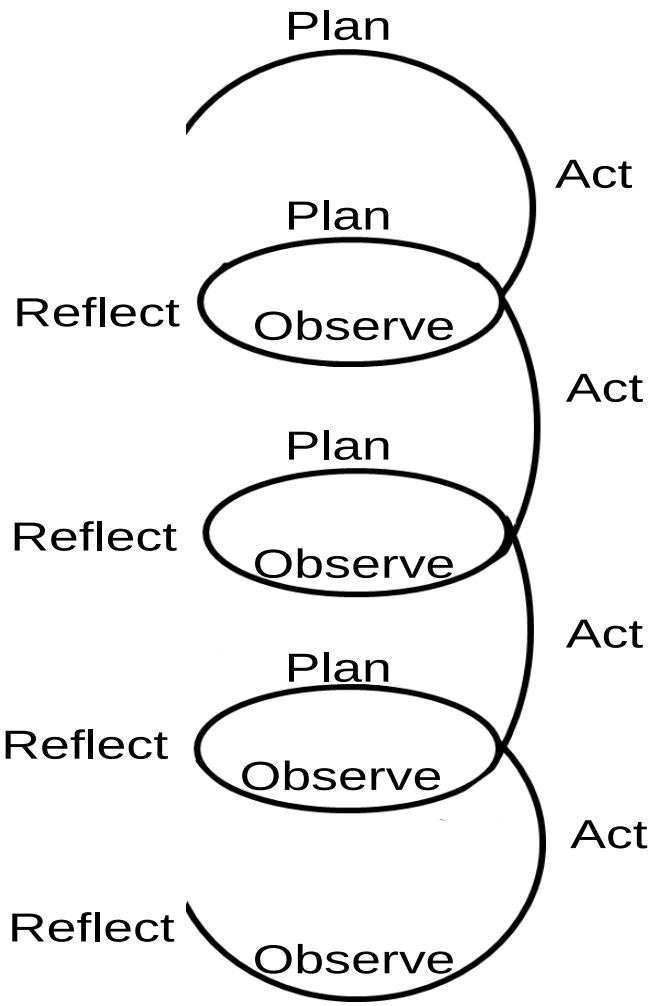


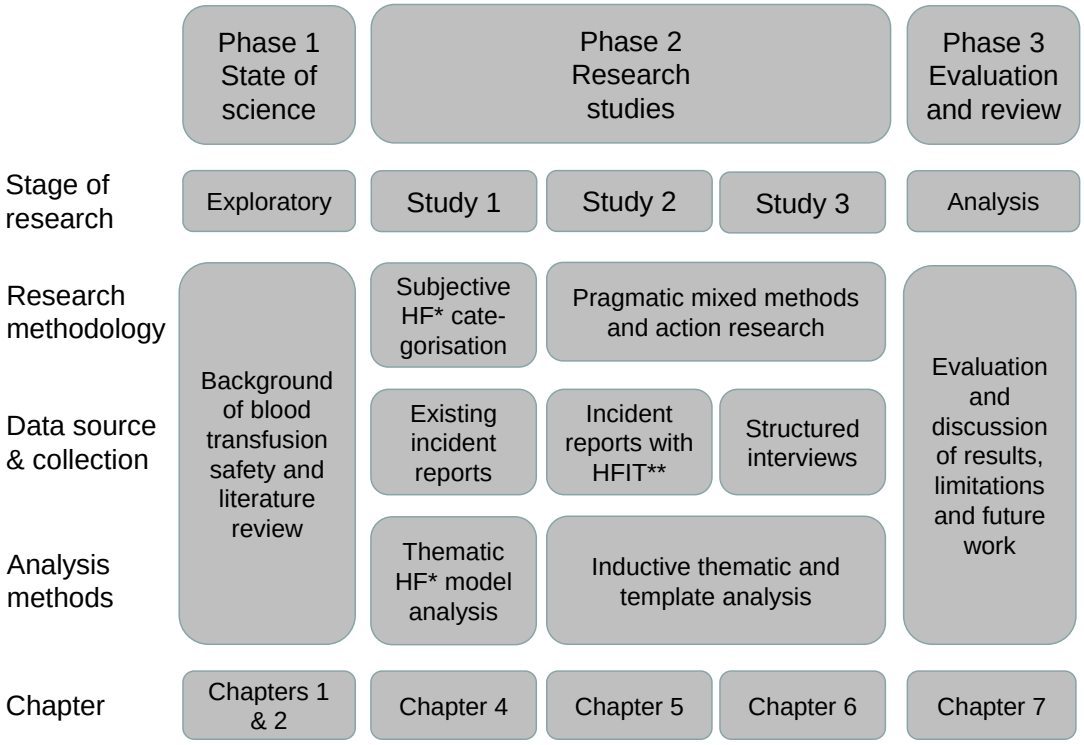
Figure 3.3: Action research approach

An essential part of each cycle is a critical reflection step to augment understanding and inform the design of further stages in the research. Hence the cycle is often known as plan-act-observe-reflect (PAOR) (Kemmis & McTaggart, 1988) with the reflection step cycling back to the next planning step (Figure 3.3). There are similarities with Deming's Wheel, the plan-do-study-act (PDSA) method for quality improvement (Deming, 1986), but there are key differences, such as the PDSA model is used mostly to resolve a specific problem, while action research is designed to have both research and action outcomes (Eather *et al.*, 2013). PDSA's main function presupposes a reductionist approach to investigate individual parts of the clinical process and action research aims for collaborative involvement in a study to determine methods for a sustainable change. Successful action research will result in

process change, so it needs to involve participants who will be directly affected by it, i.e. the research occurs with their commitment, often as equal partners and they are more likely to engage in effective research when included in a collaborative process. In this research, participants have been involved while working in their own sphere, either as reporters of adverse incidents in transfusion (Studies 1 and 2) or recruited to answer specific questions while carrying out their day to day duties (Study 3).

3.4 Strategy and design of methods

There are three studies that form this research. Figure 3.4 shows a summary of the methodology, data collection and analyses used in these studies and how they fit into the overall research approach.



*HF = Human Factors **HFIT = Human Factors Investigation Tool

Figure 3.4: Overview of research approach used in this research

3.4.1 Study 1

The aim of Study 1 was to investigate whether it is possible to elicit information about system and organisational aspects from existing transfusion incident reports. The data source was existing information from the database of

adverse transfusion incident reports made to the UK haemovigilance scheme, Serious Hazards of Transfusion (SHOT) from 1996 onwards. The use of data via SHOT meant that the methodological design was restricted to some extent, although the action research nature of the studies meant that each study could be refined as knowledge developed. On the plus side, using SHOT-related systems enabled committed participant involvement to enhance the action research methodology, because SHOT has strong links with transfusion staff in all UK hospitals who enter haemovigilance information directly into a secure web-based database. These links are bidirectional, because SHOT assumes a leadership role to influence practice within transfusion to improve safety, so there is robust participant involvement in these studies.

The methodology used was to examine historical reports of incidents by means of various human factors models and methods to determine if one or more technique would be suitable for use in a retrospective analysis of system and organisational factors to gain improved learning. The aim of Study 1 was to examine if any techniques might be suitable for a future prospective analysis of transfusion incidents, which would become Study 2. Following a comprehensive literature review of human factors models and methods, seven techniques were chosen for the initial study in which a small selection of historical transfusion incidents were analysed. The chosen incident reports were all taken from what was at the time the latest completed year of reporting (2014). The advantage of using data from 2014 was that those transfusion incident reports had recently been analysed by transfusion experts and the conclusions published in the 2014 Annual SHOT Report (Bolton Maggs *et al.*, 2015), so it was a fully validated set of incident reports. An extra dimension to this study was added by including near miss incidents, which are those where the error was discovered before any blood component was actually transfused. The objective was to understand whether more information about system and organisational factors was available when the incident had been detected before harm came to the patient.

3.4.2 Study 2

As a demonstration of the value of the reflection aspect of an action research cycle, Study 2 built on the knowledge gained in the first study, because that preliminary study showed that existing incident reports often did not include sufficient information to discover system and organisation contributions to adverse incidents. Therefore, additional questions were added to the SHOT incident reporting database to encourage staff reporting incidents to give their own interpretation of the human and system factors involved in each event. This study has the expected limitations of a research methodology dependent on individual perspectives, including subjectivity, bias and possible restrictions on understanding the questions being asked. The format of the questions includes a scoring system asking the reporters to assess the contribution that four human and system factors made to the incident from 0 (no contribution) to 10 (fully responsible). A 10-point scale was chosen to give the incident reporters sufficient granularity to score all four factors within a total of 10 if they chose, although it was unfortunately not possible to define that as part of the research considerations, because of limitations within the database structure. Equally, the use of a scoring system with an even number may be likely to nudge (Thaler & Sunstein, 2008) the respondents to choose between the lower numbers, 1-5 and the higher, 6-10 and hence make an active decision between higher and lower, instead of opting for a median score in an odd range of numbers. Also, each question includes a free text option, allowing further comments that can add to the depth of analyses.

3.4.3 Study 3

Study 3 moves away from incident analysis and aims to analyse the full vein to vein transfusion process in a prospective system. Continuing the theme of action research, the method used is a combination of observation and interview using a single open question, allowing the participants to develop their own narrative in response to the query, along with a 0 to 5 Likert scale question (Likert, 1932). The open question asks for participant responses to problems encountered with the process that they were performing during the observation and aims to identify adaptations being made to standard processes. The objective of the Likert scale question was to assess the

acceptability of adaptations by asking for a score of the support received from managers or colleagues. A five-point Likert scale was used because lessons had been learned from the use of a 10-point scoring system in Study 2. Using a five-point scale is a middle ground between offering enough choice, because two or three options may not provide a clear measure of strength of opinion, and making things easier for respondents, because it became clear from Study 2 that few people would make a valid distinction between minor scale places such as the eighth or ninth point. Another advantage of a five-point scale compared to the 0 to 10 scoring system is that the odd number allows a medium opinion, where the respondent does not feel strongly in either direction, which is beneficial in this study compared to Study 2, where the purpose was to encourage an active decision between positive and negative options. In addition, a five-point scale is quite simple for the interviewer to read out the list of scale descriptors to the staff members being interviewed, e.g. 5 equals very supportive to 1 equals very unsupportive and it has been recommended by researchers, who indicate that it reduces the frustration level of respondents and increases both response rate and quality (Dawes, 2008).

3.5 Data collection and analysis methods

Mixed methods were used for data collection and analysis. In Studies 1 and 2 the starting data came from SHOT's national haemovigilance database and in Study 3 the source data were gathered from observing and interviewing participants. The analysis was iterative, and some aspects involved a subjective assessment by the researcher, but these were checked by inter-rater reliability scoring from collaborators where possible and objective quantitative and statistical examination of the results were carried out when appropriate.

3.5.1 Study 1

The UK haemovigilance database collects anonymised information about transfusion incidents. In order to allow a full examination of the transfusion-related aspects of adverse events, the information includes restricted details about the patient, such as medical diagnosis and investigations performed, plus treatments given and outcomes of the incident. The standard datasets are

interactive, so that in many places specific questions are generated dependent on the answer(s) given to earlier questions. In addition, there are several free text options allowing incident reporters to give further information as necessary. For Study 1, these data were further analysed by the researcher applying seven different human factors models/methods with the objective of defining which parameter of each technique was recorded as the main cause of the error. This assessment was time consuming, because of the use of seven different techniques, and the categorisations were necessarily subjective, relying on the judgment and estimation of a single individual. No attempt was made to improve the analysis, because it became clear that this study was not going to identify a useful technique for further investigation of the wealth of historical incident data, largely because many of the incidents did not include sufficient information about system and organisational factors.

3.5.2 Study 2

In Study 2, the data collection was achieved again via the SHOT database, by incorporating human factors-based questions into each error-related questionnaire. The data collected were qualitative, because the scores were dependent on personal assessments made by staff members reporting the incidents, but the responses could be analysed quantitatively to show which human and system factors were deemed to contribute most to the incidents. Additionally, the comments could be examined using qualitative analysis and in particular an investigation was made using thematic analysis, looking at specific issues that contributed to the highest risk incidents, including staffing problems such as lack of knowledge and/or training, high workload, lack of resources and poor communication.

After the first full year of implementation of these HF-based questions, it became apparent that the scores given were not spread evenly across the four factors being assessed and there appeared to be a disproportionate level of culpability assigned to individual staff members. It was decided that an intervention was needed to try and develop a greater understanding of human factors by the people who are analysing transfusion incidents in UK hospitals. Therefore, a human factors tuition package was developed and linked from the

database. In advance of introducing this self-learning package, a pilot study was carried out with a small focus group of transfusion incident reporters to gauge whether it would be a useable learning tool. This assessment of the educational package used a Delphi method (Trevelyan & Robinson, 2015), because the individuals chosen to comment were experts, being either experienced incident reporters, or members of staff from SHOT, who are the expert analysts of the haemovigilance incident reports. The data from this study were collected via email by asking specific questions about the participants' experience and the analysis carried out by the author led to changes as required in the self-learning package. Before the HF tuition package went live, this was fed back to the expert focus group for final comment, to allow consideration of any further issues that were not covered by previous responses. A similar data-gathering and analysis process was employed after the second year of use of the HF-based questions when an enhanced self-learning package was devised. Alongside this, the expert focus group was asked to decide the most appropriate animated training video out of two suggested. The introduction of the HF-based tuition package, and the later enhanced version with a video link, were both accompanied by extra questions to assess whether the reporters were using these learning opportunities, so the responses to these questions could be analysed quantitatively and compared across the three years of this study. Also, in anticipation of potential problems with video technology in healthcare establishments, a question was asked about access to view the animations, which demonstrated another opportunity for analysis. A simple quantitative assessment could be made of how many individual reports were made by incident investigators who were unable to access the video, but by using underlying data within the database, it was also possible to calculate how many different institutions were identified as having no access to this technology.

3.5.3 Study 3

Study 3 data collection was via a different process and the major part of this study involved observation, by the author, of transfusion staff as they carried out their specific tasks throughout the transfusion process in their own healthcare organisation. The observation was combined with a short,

structured interview consisting of an open question and a 5-likert question, as discussed above and detailed further in Chapter 6. The responses were recorded in writing, but not verbatim, and were later transcribed into a spreadsheet for easier analysis. Each individual staff member was chosen from amongst the staff working in the department during the visit and there was a purposeful aim to recruit a variety of both clinical and laboratory staff covering each stage of the transfusion process. There was an element of stratification in the selection process, because by observing each stage of the transfusion process, we were assured of sampling a variety of both clinical and laboratory staff. There was no attempt to divide staff into specific subgroups before sampling, nor to ensure the strata were mutually exclusive, but as a result of the breadth of the study, the staff members came from a variety of healthcare professions such as doctors, nurses, midwifes and scientists, plus ancillary workers such as phlebotomists, administrative staff, porters and healthcare assistants.

This study produced abundant data, which were able to be analysed thematically to study various aspects about the adaptations made, such as the permanence of the change and whether the adaptation could be described as preferred or forced. In particular, the Systems Engineering Initiative for Patient Safety 2.0 (SEIPS 2.0 model) (Holden *et al.*, 2013a) was used in a template analysis, which is a specific type of thematic analysis technique that categorises data based on theoretical perspectives from prior research (King, 2004). These results have also been expressed in an enhanced version of the Concepts for Applying Resilience Engineering (CARE) model (Anderson *et al.*, 2016). The research carried out in Study 3 was designed to be a forerunner of a much larger data collection process, because the two HF-based questions have been added to a national audit, which is being carried out by the National Comparative Audit for Blood Transfusion (NCA) and covers the entire vein-to-vein transfusion process (NCA, 2018). A few results were available from data collections carried out by local auditors based within the hospitals and the analysis of these showed similarities and key differences from the data collected by the author.

3.6 Ethics

The ethical considerations of this research were straightforward, even though the studies include data ultimately derived from human subjects, both patients and healthcare staff. The investigation was carried out while the researcher was employed in a senior role as the Operations Manager within the UK haemovigilance scheme, Serious Hazards of Transfusion (SHOT). The study was included as part of the researcher's job and some of the research findings were included in the Annual SHOT Reports (SHOT, 2016-2019). UK healthcare organisations that are involved in the process of blood transfusion have a symbiotic clinical improvement relationship with SHOT, in which hospital staff make anonymised reports of transfusion adverse incidents, either under the duty of candour (CQC, 2015) or as a result of European Union (EU) legislative requirements, translated into UK law as the Blood Safety and Quality Regulations (BSQR, 2005). In return SHOT makes recommendations based on these data, which are disseminated widely, alongside provision of education on all facets of transfusion safety. SHOT is managed by a Steering Group, consisting of nominated representatives from the Medical Royal Colleges and other professional bodies, which provides professional ownership and strategic direction, monitors the performance of SHOT and is accountable to the UK Forum (representing the four UK blood services). Thus, the UK healthcare organisations receive leadership via SHOT from experts within transfusion. This relationship fosters a situation where this research using SHOT data, and participation from within the wider transfusion community, is positively encouraged.

Although maintaining professional independence via the Steering Group, SHOT is managed on a day to day basis through the English blood service, NHS Blood and Transplant (NHSBT). Ethical consideration was undertaken by specialist experts from NHSBT's Clinical Research department, who approved the studies and assessed this research as not requiring formal NHS ethical approval via the Research Ethics Committee.

In consideration of the confidentiality and data protection issues concerning use of the SHOT database entries for Studies 1 and 2, the SHOT website

includes both a privacy notice (SHOT Privacy, 2018) and a fair processing statement, which is written to give similar information to patients (SHOT Processing, 2018). These documents identify that the data collected are subject to strict rules of confidentiality as laid down by Acts of Parliament, including the Data Protection Act (DPA, 1998), Health and Social Care Act (HSCA, 2001) and in particular article 6.e and 9.h under the General Data Protection Regulation (GDPR, 2018), which in the UK has been incorporated into a revised Data Protection Act (DPA, 2018). They also note that the only personally identifiable data collected are the patients' sex (male/female) and date of birth, both of which are required to inform the clinical analysis of transfusion events. These data are only available on a need to know basis and in fact only the age, calculated from the supplied date of birth, is shared with SHOT experts for their analysis of cases. In the example of this research, the author would not require access to either sex or age to carry out their studies, so in those circumstances, SHOT would not share such details. The Information Commissioner's Office (ICO) has confirmed that they regard the data collected by SHOT as sufficiently anonymous to maintain patient confidentiality. The privacy and processing documents also reassure individuals that the data are protected by the database hosting and management organisations, which have high levels of security with information governance accredited through compliance with appropriate International Organization for Standardization (ISO) documents and assessment against NHS Information Governance standards.

Study 3 data require a different ethical consideration, because the information was mostly collected directly by the author as a representative of SHOT and under the direction of the National Comparative Audit of Blood Transfusion (NCA), which has a similar clinical improvement relationship with all UK hospitals. The hospital visits were carried out accompanied by local staff, who had obtained appropriate approval in each institution and the additional data collected by audit staff within hospitals, as part of the NCA Vein to Vein audit, was similarly approved by local ethical procedures. The author has agreements to use fully anonymised data from SHOT and NCA for these research studies under the ethical and confidentiality arrangements of those

organisations (Appendices 1 and 2). In addition, the author is state registered, so is subject to the Health and Care Professions Council (HCPC) standards (HCPC, 2019) and is a Fellow of the Institute of Biomedical Sciences (IBMS), which sets professional guidance for registrants including standards for ethics and confidentiality (IBMS, 2019a).

Finally, ethical consideration needs to be given to the special requirements relevant to action research, because these studies have taken place in the real world, involving open communication among the partner participants included in the investigations. Consideration was given to the need for equal access to outcomes produced by the research for all and that participants should be encouraged to influence the work. Ethically the wishes of those who did not want to participate were respected; although, as described earlier, participation in SHOT studies is professionally and to a degree legally mandated, the HF-based questions in the SHOT database were not mandatory, so individual incident reporters could choose not to take part. The use of participant-derived data was undertaken within the ethical and data protection standards already described and the ongoing development of the studies were made visible to participants, particularly through publication in Annual SHOT Reports, which are distributed in hard copy to all SHOT participants, including 100% of NHS healthcare institutions, as well as being available on the SHOT website (SHOT, 1997-2018).

3.7 Reliability, validity, generalisability and limitations of methodology

There are some difficulties with achieving empirical reliability and validity when studies depend on subjective and qualitative methodologies, but every attempt was made to ensure the research would be as replicable as possible. A general method for determining the reliability and validity of qualitative studies is required, but a plethora of published proposals means the topic has become clouded (Dixon-Woods *et al.*, 2004). Using some of the prompts for simplified appraisal of qualitative research published by Dixon-Woods *et al.* (2004) the studies in this research were assessed for reliability and validity (Table 3.1).

Table 3.1: Assessment of reliability and validity of studies comprising this research

Criteria	Assessment
Are the research questions clear?	All studies have clear research questions
Are the research questions suited to qualitative inquiry?	Qualitative research is the most appropriate and quantitative assessments are made when possible
Are the sampling, data collection and analysis clearly described?	Detailed descriptions are given in both the methodology chapter and for each individual study
Are the sampling, data collection and analysis appropriate to the research question?	The sampling, data collection and analyses are specific to blood transfusion safety and are therefore appropriate to the studies undertaken
Are the claims made supported by sufficient evidence?	Evidence collected was enough in both volume and quality to support the conclusions
Are the data, interpretations, and conclusions clearly integrated?	All interpretations and conclusions are well integrated, which gives a comprehensive picture

There was an element of reliability and validity integrated into some of the research, particularly Studies 2 and 3, because the work took place across several years and within different spheres, enabling confirmation of the internal repeatability of results. The outcomes can also be considered generalisable, because of the breadth of these studies. In some circumstances, similar conclusions have been made from the different studies within this research.

A general limitation is the difficulty of how to achieve an objective measure of the quality of qualitative research. There may be a need for additional criteria that recognise the diversity of study designs and theoretical perspectives in qualitative research, and to distinguish between minor errors and fatal flaws (Dixon-Woods *et al.*, 2004). Some limitations emerged as the studies progressed, e.g. the issues with a 0-10 scoring system that were illustrated above. Specific limitations of each study are described in the relevant sections of each study. The most general limitation of the work is the dependence on personal assessments , with potential inherent biases, firstly by the author, but also the many individual healthcare professionals, UK-wide, who contributed. Diversity of input from hospital-based participants could be considered a strength, but a major limitation was that these collaborators often had limited knowledge and understanding of human factors. Hence they did not perceive the data in the same way that experts in analysing complex systems would.

Chapter 4 Study 1 - A retrospective review of transfusion incidents using human factors models/methods

4.1 Chapter summary

This study aimed to investigate a selection of historical transfusion error reports using appropriate human factors models/methods of incident investigation. The objective was to elucidate whether human factors (HF) models/methods could be used to analyse previously reported transfusion errors and expand the lessons that could be learned from these incidents.

Most HF models/methods are not designed for healthcare systems and have traditionally been used for examining incidents in high reliability organisations (HRO) such as aviation and the nuclear industry. However, these industries have different problems from healthcare (Kar, 2019; Macrae & Stewart, 2019; Brennan and Morris, 2019). As a comparison, every aircraft of a certain design will have the same features and complexities, but every patient having the same medical condition or surgical procedure will not be identical in design, so each brings their own unpredictability to an already very complex system. Therefore, various HF models and methods have been reviewed to decide on the best for investigating a selection of historical transfusion error reports.

4.2 Introduction, overview and background

Transfusion errors and reactions that happen in any healthcare organisation in the United Kingdom (UK) have been reportable to the UK haemovigilance scheme, Serious Hazards of Transfusion (SHOT) www.shotuk.org since 1996. Reporting was originally via hard copy questionnaires, but since January 2010 a bespoke, online reporting database has been in use. This means there is a rich source of historical raw data about transfusion incidents and the incident reports since 2010 are particularly useful, because they are in an electronic format.

However, until 2016 the incident reporting questionnaires used for these historical data did not specifically include any examination of the human factors

and systems problems that might contribute to an error. The questionnaires have traditionally focused on obtaining a description of the incident and examining the consequent outcome for the patient. Root cause analysis (RCA) reports can be uploaded to the database to give further information, but that is not a requirement for reporting, so RCA reports are not always supplied. Even when RCA reports are attached to the incident reports the way the analysis was carried out and communicated can be very variable, because they are the product of locally designed processes.

4.3 Study aims and objectives

Study 1 aims to investigate what we can learn about human and organisation factors contributing to transfusion incidents and near misses from the existing incident database. The study was designed to find out 'Can one or more HF model(s)/ method(s) be used to analyse previously reported transfusion errors, and which is/are the most effective to gain the maximum learning from these incidents?'. A retrospective review allows the comparison of HF models/methods with traditional analyses of transfusion incidents. The aim is to examine whether using an HF approach can enhance the analysis of incidents with the objective of improving learning from these historical data.

There are many options for incident investigation using a human factors approach, but the literature review has shown very few publications relating HF to transfusion. Most HF models/methods have been used more extensively for examining incidents in HROs, such as aviation and the nuclear industry rather than healthcare, and may not translate to be applicable to the variability associated with healthcare. Thus, there is no background to show which of the HF incident investigation models or methods would be most useful to be applied to transfusion incidents. This study reviewed various human factors models/methods to select the most appropriate for use in a possible further study, which would be a retrospective review of historically reported transfusion incidents, because a retrospective analysis might be able to highlight the system failings leading to errors and facilitate recommendations for safety improvements within the transfusion process. A secondary objective is to use the information from this study to develop a human factors

investigation tool (HFIT) to be incorporated into the database for reporting transfusion incidents.

4.4 Proof of concept for Study 1

4.4.1 Method

A limited dataset was used of historical transfusion incidents (n=76) reported in calendar year 2014. These had been analysed by transfusion experts in 2015 and categorised as error incidents. The reported cases were sub-divided into two groups and examined using seven different HF models/methods for incident investigation.

Group 1 n=36 errors that led to an incorrect blood component transfusion (IBCT) which is the most dangerous of errors made in the transfusion process and can lead to patient death.

Group 2 n=40 near miss errors similar to IBCT incidents were analysed as a comparison. Near misses are defined by the error being discovered before the transfusion of a blood component actually took place. It was expected that as these errors were detected before any harm came to the patient, there might be better descriptions of how the error happened and what led to the discovery of the incident. It was anticipated that transfusion near miss errors would potentially be a source of information on Safety-II aspects, which could be compared to the current systems of transfusion error reporting that reflect a Safety-I culture (Hollnagel, 2014).

These reports had already been fully analysed by SHOT's traditional techniques and published in the 2014 Annual SHOT Report (Bolton-Maggs *et al.*, 2015). Therefore, the dataset was known to be validated and suitable for further research. The HF models and methods that were used are summarised in Table 4.1

Table 4.1: Brief description of the sub-categories of HF models/methods and how each characteristic was interpreted

HF models/methods and application of each characteristic
SRK – Skills, Rules, Knowledge (Rasmussen, 1983)
Skills - Operators performing role with little conscious control.
Rules - Limited by regulations or standard operating procedures (SOP), low levels of knowledge
Knowledge - Application of knowledge and experience to complex tasks or changeable circumstances.
Active & Latent – Swiss Cheese Model (Reason, 1990)
Slips - Skill-based slip - action not carried out as planned
Lapses - Skill-based lapse, such as omission
Mistakes - Rule or knowledge-based error. Faulty plan or intention, i.e. did something believing it to be correct
Violations - Acted against SOP or regulations
Latent - Managerial, organisational and high-level failures
HFACS – HF Analysis and Classification System (Shappell & Wiegmann 1997)
Unsafe acts - Level 1 - errors and violations
Preconditions for unsafe acts - Level 2 - environment, personal (medical, tired, not capable etc) personnel (communication)
Unsafe supervision - Level 3 - training, leadership, known problem, supervisory
Organisational - Level 4 - HR, budget, equipment/facility, climate, operational
AcciMap – Accident Mapping system (Rasmussen, 1997)
Government - Department of Health and Social Care (DHSC) level
Regulatory - Transfusion regulators and guideline publishers
Company – Trust/Health Board management
Operational - Departmental management
Staff – People, including staff and patients
Equipment & surroundings - Local equipment and direct environment
STAMP – Systems Theoretic Accident Modelling and Processes (Leveson, 2004a)
Enforcement constraints - Control actions = unidentified hazard, lack of control of known hazard, process does not enforce control
Execution of control action - Communication, inadequate actuator e.g. IT component that moves/controls system
Missing feedback - Inadequate or missing feedback in system
FRAM – Functional Resonance Analysis Method (Hollnagel & Goteman, 2004)
Input - Start of process
Output - Result of what the function does e.g. by processing the input
Resource - Something needed or consumed while a function is carried out
Controls - e.g. standard operating procedures (SOP), guidelines etc.
Precondition - Function cannot begin before preconditions established.
Time - Temporal relationships, e.g. order of doing things, or if done in parallel
SEIPS 2.0 – Systems Engineering Initiative for Patient Safety 2.0 (Holden *et al.*, 2013a)
Person(s) - Both patients and healthcare professionals
Tasks - Specific actions within larger work processes.
Tools & Technology - Objects that people use to do work or that assist in doing work.
Organisation - External control of time, space, resources, activity etc. - i.e. management
Internal environment - Physical e.g. light, noise, vibration, temperature, physical layout, available space, air quality
External environment - High-level societal, economic, ecological, policy = factors outside an organisation

4.4.2 Results

While attempting to subcategorise the incidents, it became apparent that the details provided were not always sufficient to categorise incidents, n=26/76 (34.2%). Table 4.2 shows a breakdown of which errors were able to be subcategorised and which contained insufficient detail, so they were not assessable for subcategorisation.

Table 4.2: Summary of outcome of sub-categorisation of error incidents

	IBCT	Near miss	Total
Errors subcategorised	27	23	50
Errors not assessable	9	17	26
Overall total	36	40	76

Results for the incidents that could be categorised (n=50) for each HF model/method studied are depicted in Figures 4.1 to 4.7.

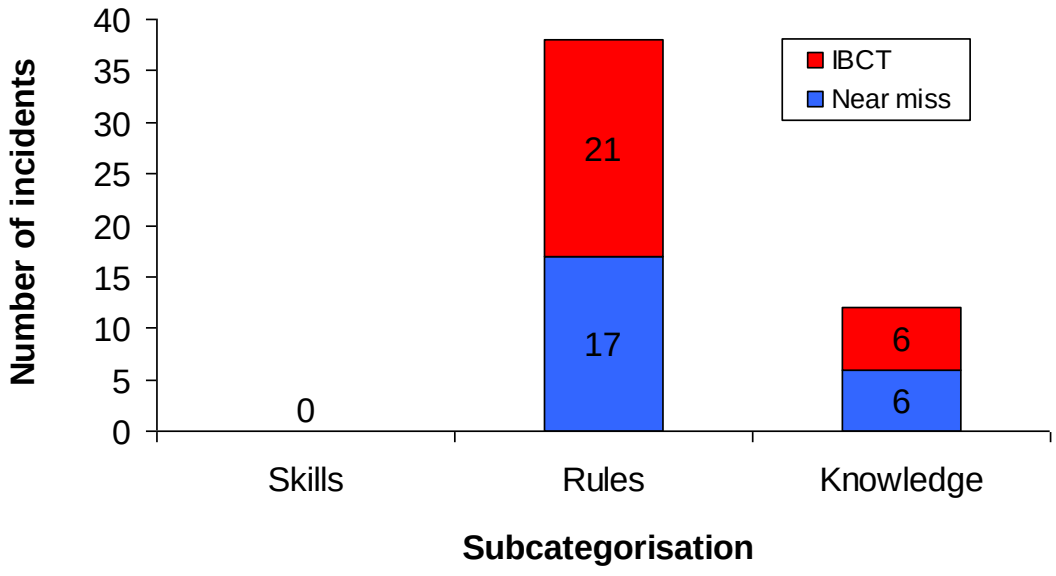


Figure 4.1: Transfusion incidents categorised by SRK

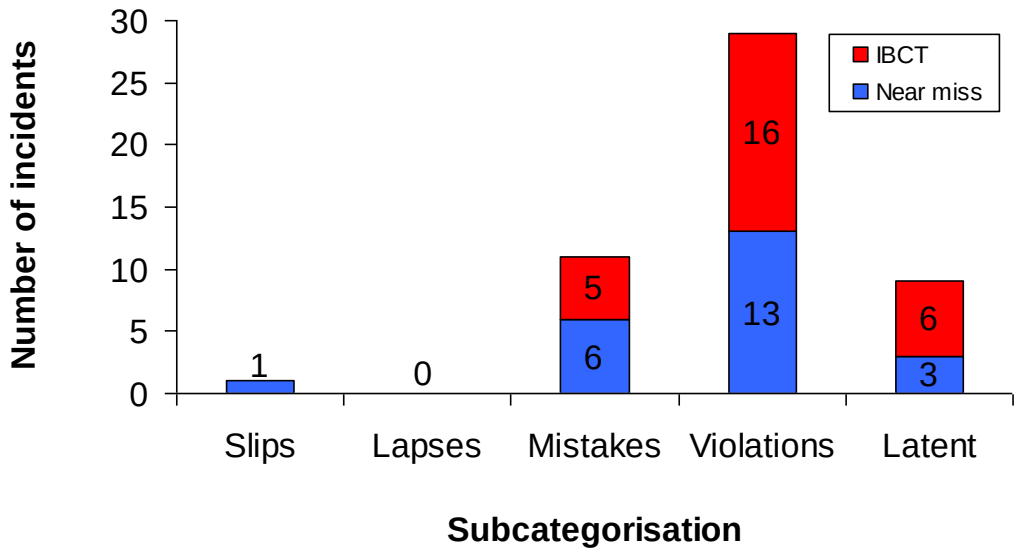


Figure 4.2: Transfusion incidents categorised by Active/Latent (Swiss cheese model)

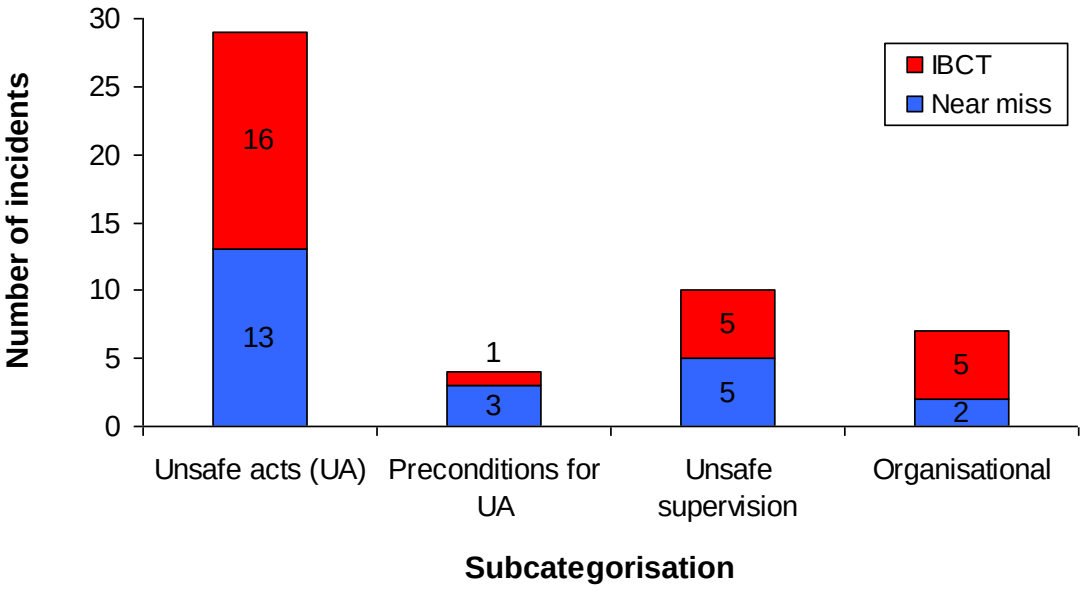


Figure 4.3: Transfusion incidents categorised by HFACS

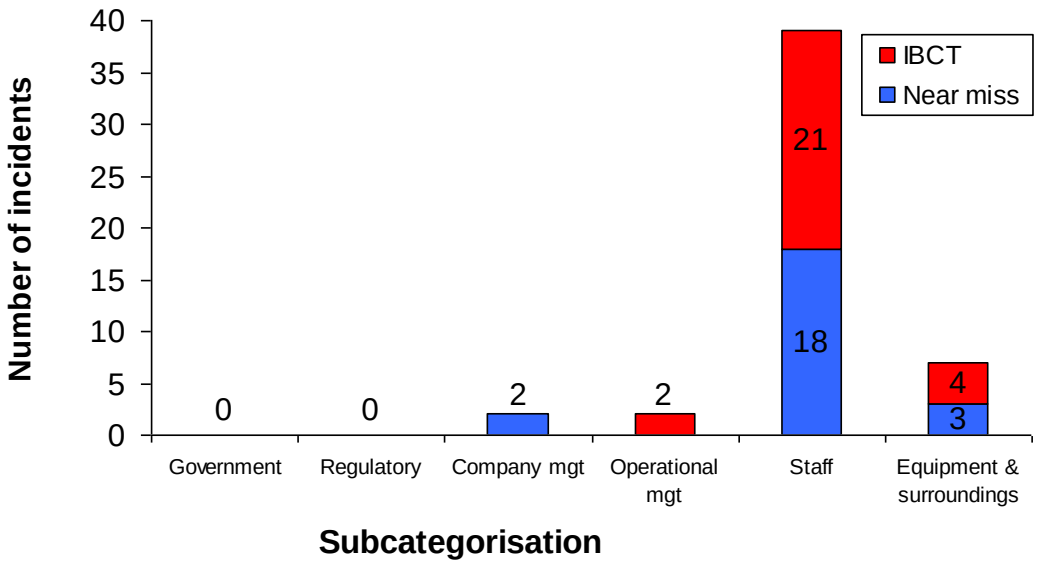


Figure 4.4: Transfusion incidents categorised by AcciMap

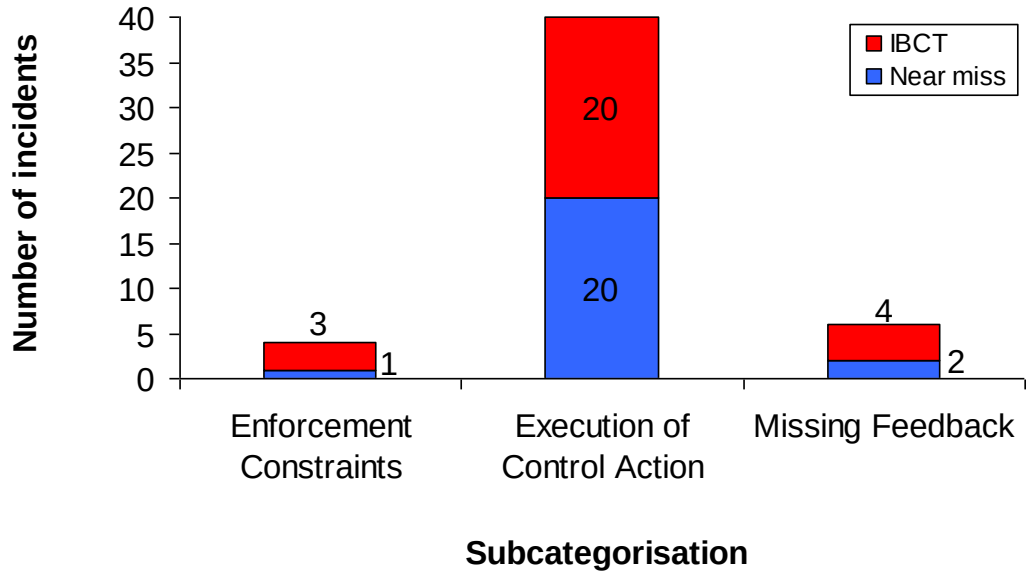


Figure 4.5: Transfusion incidents categorised by STAMP

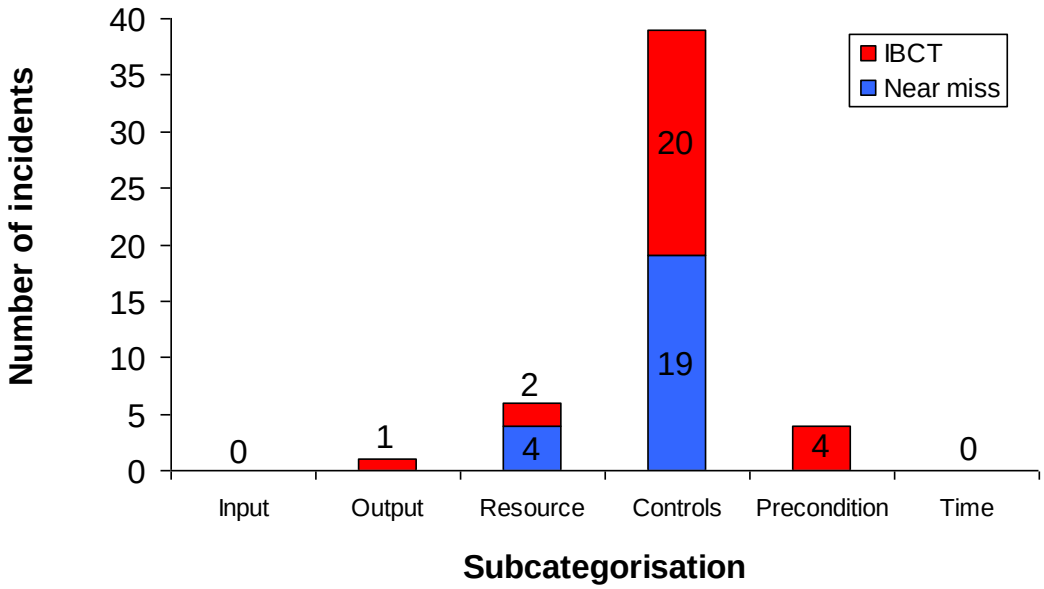


Figure 4.6: Transfusion incidents categorised by FRAM

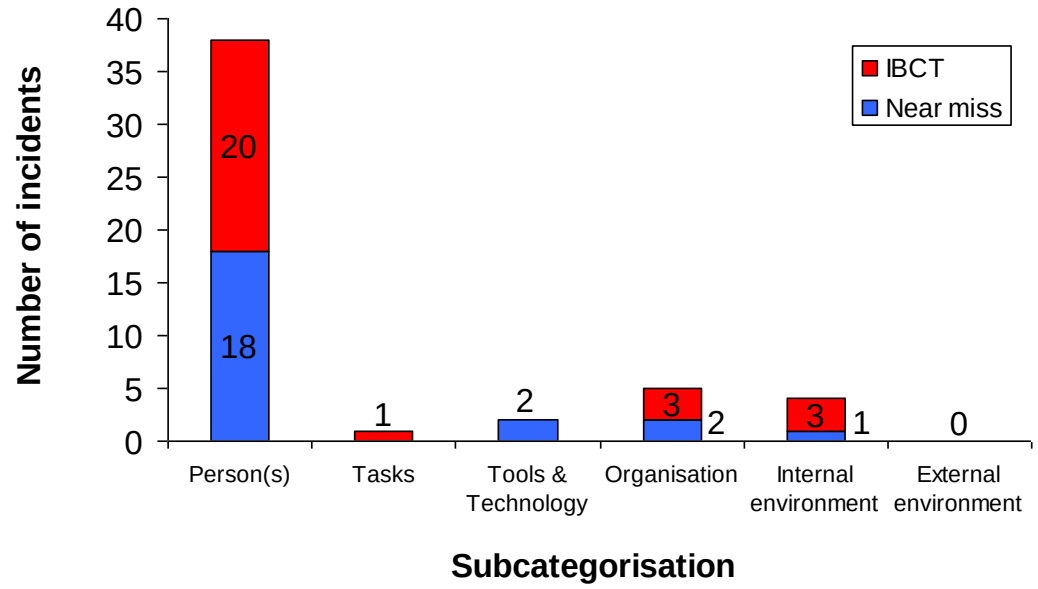


Figure 4.7: Transfusion incidents categorised by SEIPS 2.0

Before starting this sub-categorisation, a set of criteria for ranking the human factors models/methods was developed based on requirements published by Ryan (2015). Each HF model/method, as used in this study, was ranked against the pre-determined criteria shown in Table 4.3 using a scoring system:

0 - does not meet the criteria

1 - barely meets the criteria

2 - partially meets the criteria

3 - fully meets the criteria.

Table 4.3: Ranking of HF models/methods against pre-determined criteria to select the most useful model/method for classification

	Human Factors Models/Methods (abbreviations are expanded in Figures 4.1 to 4.7)						
Criteria to rank HF models/methods	**SRK**	**Active & latent**	**HFACS**	**Acci Map**	**STAMP**	**FRAM**	**SEIPS**
Simple to use with minimum training	2	2	0	0	0	0	0
Has a clear scope for analysis	3	3	3	2	3	0	3
Consistent classification between types of incident	0	0	3	0	2	0	3
Focuses on patient safety	0	0	0	0	0	0	3
Searches for and reveals underlying causes	0	0	3	2	2	3	3
Provides a description of the incident	0	0	2	2	2	0	2
Contributes to corrective and preventative actions (CAPA)	0	0	2	2	0	0	2
Can classify multiple errors occurring in a single incident	0	0	2	2	2	2	2
Helps in generating recommendations	0	0	3	2	2	0	3
Is valid and reliable to provide a clear outcome	insufficient data to rank						
Total	**5**	**5**	**18**	**12**	**13**	**5**	**21**

4.4.3 Discussion

The main aim of this initial study was to define the best HF model/method to use for a large retrospective analysis of historical incidents. However, although this was a small sample of the available historical incident data held by SHOT, the results of this study indicated that further research of this type may not be valuable. The sub-categorisation exercise showed some inconsistencies and in particular some sub-categories have a large number of incidents, whereas others have none. This can often be explained by the nature of the work done in the transfusion process, e.g. in the SRK sub-categorisation there are no cases categorised as skills. This is likely to be because staff undertaking tasks within the transfusion process would be working at higher levels and will not usually be defined as 'operators performing a role with little conscious control'. However, the main reason for the disparity is the paucity of systems and operational information contained within the incident reports.

HF models/methods that consider external factors in depth, e.g. HFACS, AcciMap and SEIPS 2.0, should be useful in helping to get to the underlying causes of an error and from there should contribute to further understanding of corrective and preventative actions (CAPA). To investigate whether a single model might be useful for further investigation, a trial was performed using an AcciMap flowchart process to examine a complex transfusion incident (Appendix 3). This showed a useful method for visualising the factors contributing to an incident, but the assessment was lengthy and complex, requiring an in-depth knowledge of transfusion medicine as well as an excellent knowledge of human factors principles. Hence this would not be a method that could be used to examine a large number of incidents.

There was often insufficient information given in these historical incidents for the analysis to expose the full impact of external factors. Those who report transfusion incidents have a tendency to assign culpability to individual staff members, but do not expand on possible underlying reasons for this, such as lack of training or shortage of suitable staff. As an example, it is common for non-transfusion personnel to be asked to work in transfusion laboratories,

especially in out-of-hours and on-call situations. Largely the reporters do not give specific reasons contributing to the error, such as if the department was understaffed or if the individual was interrupted, tired, overworked etc. The report submitted to SHOT will simply indicate that the individual deviated from the standard operating procedure (SOP), which meant in this HF categorisation exercise there were a number of cases that had to be categorised as individual error, when that may not have been the whole story. Therefore, a disproportionate number of cases were categorised as 'violations' (Active/Latent), 'unsafe acts' (HFACS), 'staff' (AcciMap), or 'persons' (SEIPS 2.0). The finding that quite a high percentage could not be classified raises the issue of whether this approach is ideal. Future analyses were planned, but it was decided that this bias was likely to be considerable in a larger sample, because satisfying the transfusion-related requirements for incident reporting are quite different from the information needed for an accurate human factors analysis.

During the research it was noted that the reports for IBCT incidents generally had more HF-related information than the near miss reports, which was opposite to the expectation prior to analysis. The reasons for this are probably two-fold:

- The questionnaires for IBCT are much longer than those for near misses and they ask a lot of supplementary questions to help get a full picture of the transfusion incident. Although they do not specifically ask for HF information, it seems that the larger amount of general information can help with HF categorisation.

- IBCT incidents are the most serious errors, so the local incident investigators will want to try and understand the incident as fully as possible in order to prevent recurrences. This may lead to more information being available for further investigation.

The questions asked in the SHOT database are very specific to the type of transfusion incident and do not delve into the underlying causes of the error that had been made. As an example, Figure 4.8 is an extract of the current questions asked in the dataset for the SHOT error category, incorrect blood component transfused (IBCT).

Key details of the IBCT event

Question	Answer Options	Data Type
Decision Point – the following question determines which specific pages are generated		
Was there an error	• With the collection of the pre-transfusion sample (Wrong blood in tube) • In the hospital transfusion laboratory • In collecting the component from the hospital storage site • In the bedside administration of the component • At the blood establishment	Multi choice
What was the outcome of the error	• ABO incompatible • D mismatch • ABO non identical • ABO identical • Wrong component type • Other (please specify)	Multi choice
Please specify other		Text
Was this patient the intended recipient	• Yes • No	Single choice
Was a transfusion prescribed for this patient	• Yes • No	Single choice

Figure 4.8: Extract from SHOT dataset of incorrect blood component transfused (IBCT) questions

(reproduced from SHOT dataset with permission)

As can be seen from the text in the yellow box, the transfusion incident database is constructed as a branched system, so answers to questions at a decision point, as shown here, will automatically generate specific questions related to that type of clinical/scientific error. This means that the information requested becomes even more specific as the incident reporter progresses through the questionnaire and the likelihood of any information about system and organisational factors being given, reduces even further.

Therefore, until the beginning of 2016, which marked the introduction of HF-based questions as part of Study 2 in this research, there was no requirement for incident reporters to elaborate on the causes of error-related incidents and particularly no obligation to consider system factors. There was an option to upload additional documents, such as a root cause analysis (RCA) investigation, but those would be reports related to local systems for incident investigation and thus the depth of information about the error would be variable. Furthermore, there is no mandatory requirement to upload any local investigation documents, so many reported transfusion incidents would not contain any supplementary information, even if it were available to the local incident investigator. In fact, very few of the questions in the transfusion incident database are mandatory, so incident reports in general can sometimes contain sparse information.

4.4.4 Limitations of research leading to cessation of future work

There were key limitations of the research, including a discovery that insufficient information was available in many reports meaning that 34.2% of the reported transfusion incidents were not classifiable. It was frustrating that a number of these cases indicated a root cause analysis (RCA) was available, but that document was then not attached to the incident report. A further development has since been made to the incident reporting database to encourage sharing of the RCA if that question is answered positively. Another limitation was the problem that because the analysis was using and comparing several HF models/methods it was only possible to sub-categorise the cases using one subgroup from each model/method. Complex systems can lead to

multifaceted errors, so more than one aspect is likely be needed to describe the error fully.

Several of the more complicated HF models/methods did not lend themselves to being used in this simple overview analysis and some, such as HFACS, AcciMap, FRAM and SEIPS 2.0 may be better suited to a prospective analysis of the end to end transfusion process. The use of a set of criteria and a defined scoring system to select the most appropriate model/method to take forward for the full Study 1 research project was necessarily a fairly subjective, not objective, process. The scoring process could have been refined by adding weighting to some of the different criteria, but in this small sample size being studied, it was difficult to decide which, if any, of the criteria were worthy of a higher weighting.

4.4.5 Conclusion

All the HF models/methods in this study produced constructive sub-categorisations, but none of them proved to be an outstanding option. From the ranking process (Table 4.3) it appears that systems engineering initiative for patient safety 2.0 (SEIPS 2.0) would be the most appropriate for use in further research, although the top score for SEIPS 2.0 was mainly achieved by a disproportionate score for the criterion ‘focuses on patient safety’. Other studies have concluded that additional human factors tools are needed (Thatcher *et al.*, 2019; Salmon *et al.*, 2017) beyond the well-recognised methods and models that were trialled here or that a re-mixing of systems analysis tools may be required, which could include selecting aspects of various tools both within the field of HF and externally (Waterson *et al.*, 2017 and 2015).

The main conclusion from this proof of concept study is that the quality of the data is unlikely to be improved by a further analysis of retrospective cases, because of two major limitations: (1) a lack of HF-related information in the historical incident reports and (2) a tendency for those reporting incidents to place too much culpability onto individuals, rather than examining system and organisational failings that may also have contributed.

The outcome of this study shows that it is difficult for people to learn from errors, because humans have a tendency to construct stories around facts, which serves a purpose in making sense of the world that might otherwise be seen as too complicated. Humans make sense of complicated data by creating patterns, and by doing so the world is seen as a simple place. Hence, a narrative is often constructed to explain the observable facts. Humans are hard-wired to try and turn chaos into order, so they can feel in control of their world. This can be termed ‘narrative fallacy’ (Taleb, 2007) because these rationalisations come after the effect and are not based on empirical data. Scientists are always warned to avoid hindsight bias, but humans have an innate tendency to such bias with the use of narrative fallacy. By creating a story, the individual may feel comforted and safer, but they are not learning from the event. Narrative fallacy means that against all logic, individuals often do not learn from adverse events. Instead of seeing the error as a learning opportunity, the event is rationalised in a more comforting way and the bias of the narrative fallacy means they convince themselves of a less personally threatening story or narrative, including blaming others or over-emphasising the rarity of the danger. Errors are more likely to continue if there is greater belief in the stories instead of a dispassionate examination of the facts and data.

A complex case study in the 2015 Annual SHOT Report (Bolton-Maggs *et al.*, 2016 - p24, Case 6) demonstrates that three narrative fallacies added to the confusion when blood grouping of a patient was difficult after an allogeneic haemopoietic stem cell transplant (HSCT) was expected to change the patient's genetic blood group. The narrative fallacies on this occasion could have led to a patient being mis-grouped as A, instead of their true post-transplant group, which was still group O, while the patient was in the process of engrafting the stem cell transplant to become group A. Fortunately this error was discovered before the patient was transfused with an incompatible group of red cells.

If historical transfusion error reports were to be investigated for learning about the impact of human factors, it would be important to be able to examine the case dispassionately, while making allowance for the narrative fallacy and hindsight bias of the original reporter. Therefore, it was concluded that there was no merit in continuing with further retrospective analysis of existing incident reports, especially as better data would be available from the HFIT incorporated into the SHOT database and these are being analysed in Study 2 (Chapter 5).

Chapter 5 Study 2 – Creation and use of a human factors investigation tool (HFIT) within the transfusion incident reporting database

5.1 Chapter summary

There is a large amount of information in Chapter 5, so the summary begins with a condensed version of the chapter contents to help readers to follow the structure of this study:

The first study has clearly demonstrated that data in the existing transfusion incident reporting system did not contain sufficient information to learn about how human and organisational factors contribute to transfusion incidents. Therefore, there is a need for a new tool to support the gathering of relevant information, so a bespoke human factors investigation tool (HFIT) was created and incorporated within the transfusion incident reporting database. Data were analysed each year, in conjunction with the ongoing annual haemovigilance analysis, to investigate whether increased learning is possible with the use of this HFIT.

Study 2 is multifaceted and covers a period of three full calendar years, so presenting this research is quite complex. The chapter has been structured in a linear fashion, describing each part of the research sequentially and examining the following aspects for each main subsection: methods, findings,

discussion, limitations and conclusions. The chapter begins with a summary, introduction and aims and objectives and ends with sections examining the overall limitations and conclusions of the research. In between, there are five main sections within this study, which are summarised here and within Figure 5.1.

1. Study 2.1 in 2016, designed to test the newly created human factors investigation tool (HFIT)
2. Development and testing of a self-learning package to help transfusion incident reporters to assess the HFIT scores
3. Study 2.2 in 2017, the first full year of the HFIT in conjunction with the self-learning package
4. Further development of the self-learning material including assessing the most suitable training video to be added package
5. Study 2.3 in 2018, the final year of research with the HFIT aided by an enhanced leaning package and video

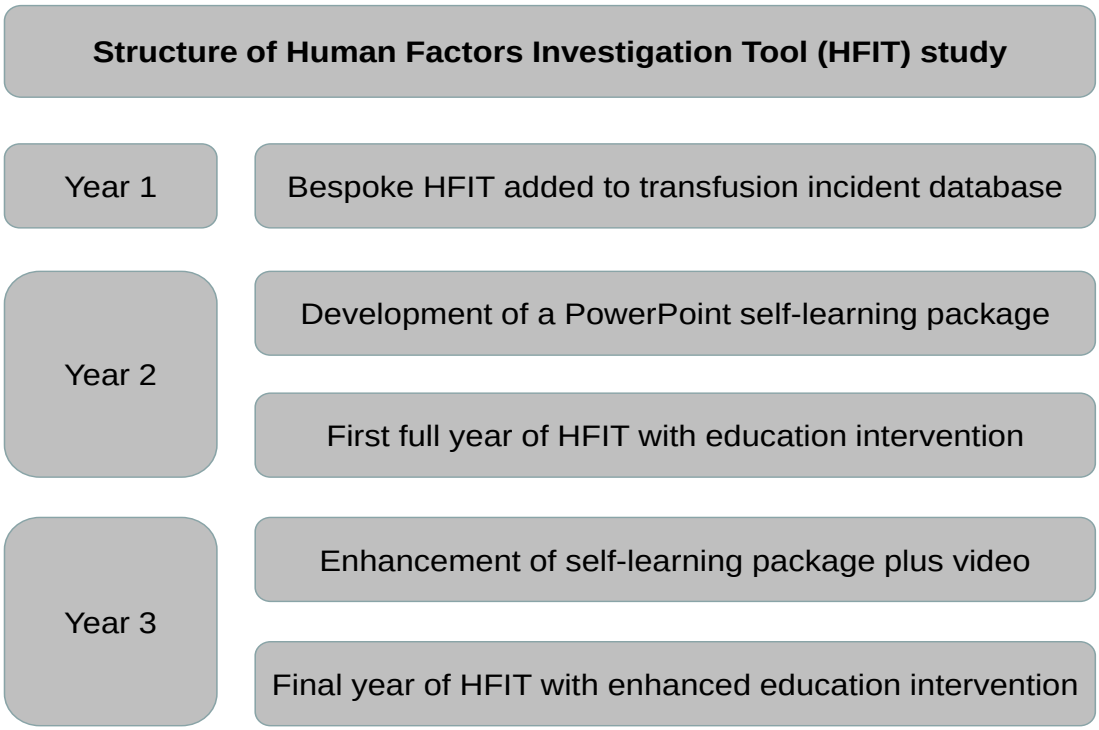
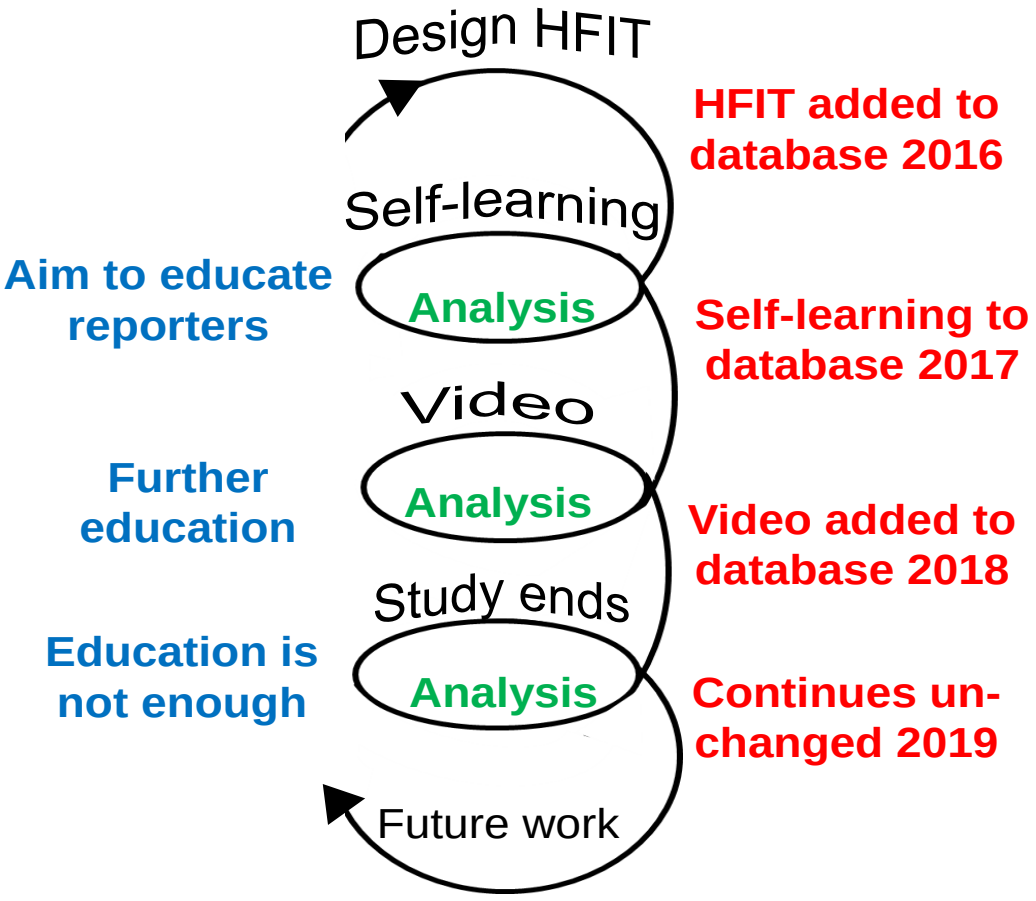


Figure 5.1: Structure of HFIT study

The first year's data (2016) showed there would be difficulties in finalising a useable tool, mainly because the reporters had only a limited understanding of how to answer the HF questions, so two types of self-directed learning material were provided in each of the subsequent two years, a PowerPoint presentation in 2017 and an animated video in 2018. These were designed to assist reporters with using the HFIT to analyse incidents from a human factors perspective. The effects of these interventions were also analysed.

The methodology used for this study was action research, which has been discussed in more detail in Chapter 3. The cyclical nature of the research is summarised in Figure 5.2, which is a variation of Figure 3.3 in Chapter 3. As can be seen in Figure 5.2, the end of this study leaves the way open for continuing research in this area.



HFIT = Human Factors Investigation Tool

Figure 5.2: Action research approach to HFIT study

5.2 Introduction

The importance of considering human factors when investigating transfusion incidents has been highlighted in the first study, which assessed adverse events in transfusion that had previously been reported to the national database created and managed by Serious Hazards of Transfusion (SHOT), the UK haemovigilance scheme. Currently, almost 4,000 adverse reactions and events are reported to SHOT each year and SHOT characterises most incidents as being caused by errors in the transfusion process (SHOT, 1997-2018). SHOT's error categorisations are defined as adverse transfusion incidents that are caused by a failure somewhere in the system, compared to the non-error incidents, which are unanticipated physiological reactions to the transfusion, and for the most part cannot be prevented. Although there can be some crossover with adverse incidents in SHOT reaction categories that may have been preventable by better clinical and scientific assessment of the patient, for the purposes of this research, incidents classified into SHOT's six error categories were studied and these are described in Table 5.1.

Table 5.1: Description of SHOT error categories

SHOT error category	Abbreviation	Level of harm associated
Incorrect blood component transfused	IBCT	Can lead to serious harm, including major morbidity and death
Avoidable, delayed or under/overtransfusion	ADU	
Handling and storage errors	HSE	Can cause serious harm and morbidity, but death is rare
Anti-D immunoglobulin administration	Anti-D Ig	
Right blood right patient	RBRP	Identifies potential for harm, but no actual patient harm occurred
Near miss	NM	

As identified in Table 5.1, there are four categories that can cause patient harm including major morbidity or death (IBCT, ADU, HSE and Anti-D Ig) and two categories not associated with harm to the patient; RBRP, where the patient receives the correct unit for transfusion, despite errors being made in the process and NM, where the errors are discovered before transfusion and the process is amended or aborted. These two non-harm categories can provide useful insight into weak signals, which may be early warnings of potential risks

in the system (Macrae, 2014; Carman *et al.*, 2017). If detected, these weak signals could alert incident investigators to the possibility of a patient harm incident in the future and provide an opportunity for proactive intervention to improve safety.

It was expected that the results from Study 1 would have identified one or more suitable human factors methods to be used to analyse incident reports in greater depth. The conclusion from the first study demonstrated that the information supplied in transfusion incident reporting was not always sufficiently detailed to allow further analysis and none of the established HF models/methods proved ideal for analysing transfusion incidents, especially with the limited information in the datasets being used at that time. Therefore, a human factors investigation tool (HFIT) needed to be developed to allow further HF-related information to be collected at the time of reporting. This was added to the UK haemovigilance reporting system (SHOT database) in January 2016 and the intention was to incorporate the final, validated HFIT as part of the routine error questionnaires in the UK's national transfusion incident reporting database to collect HF data for ongoing analysis. This will be a final outcome of the PhD study, which would then allow further work on this subject.

5.3 Study aims and objectives

The aim was to find a robust method for analysing transfusion incidents from a human factors basis and thus to improve patient safety through learning about the human and organisation factors that contribute to adverse events. The main objective was to develop a workable tool to collect as much HF-related information as possible from the transfusion error reports. This tool was to be based on evaluations of human factors techniques, which would be suitable to assess the contributors to transfusion incidents, as seen in Study 1. It would be necessary to trial an initial draft of the tool to examine if it was easy to use by those staff in all the UK hospitals who are responsible for reporting local incidents to the national haemovigilance database, because these reporters are unlikely to be HF experts, and then from this study to finalise a system suitable to be used routinely going forward.

5.4 *Study 2.1 (2016)*

An initial examination, Study 2.1, was undertaken of the first draft HFIT by incorporating questions into the UK haemovigilance database for one calendar year (2016). The questions listed in Section 5.4.1 below were developed specifically for this examination following the outcome of investigating several HF-related models/methods in Study 1. The results of Study 1 showed that none of the models/methods were suitable to be used unmodified and would particularly not be appropriate for a tool to be used by a wide variety of incident investigators, most of whom were unlikely to have an in-depth knowledge of human factors techniques. Therefore, a simpler tool was developed using questions related to common themes found within the established HF models/methods that had been investigated in the earlier study.

5.4.1 Methods

Human factors questions were added in all major error categories of the transfusion incident reporting database to examine the extent to which human and organisational factors were estimated to be implicated in each incident. The questions asked were:

To what extent is the cause of this incident attributable to:

1. *Unsafe practice by individual staff member(s)*
2. *Unsafe conditions associated with the local environment or workspace*
3. *Unsafe conditions associated with organisational or management issues in your Trust/Health Board (e.g. staffing levels)*
4. *Conditions associated with the government, Department of Health or high-level regulatory issues (i.e. the error was caused by regulatory issues, not reportable as a regulatory failure)*

Each question had a supplementary free text box with the question:

Please give any additional relevant information.

This enabled reporters to add further detail about the human factors related to the incident or to make comments about the questions themselves.

Incident reporters were asked to score each question from 0, no contribution to 10, fully responsible, using radio buttons as the answer options for each

question. The radio buttons provide a graphic rule mechanism that allow the incident reporter only to choose one of the numbers 0 to 10, because each are mutually exclusive options. When a number is selected, the circle appears filled and for those not selected, the circle remains empty or deselected. Only one of the predefined set of numbers can be chosen at any time, but the reporter can amend their selection by re-clicking the circle, which then becomes unfilled allowing another to be selected. This procedure ensured reporters could only indicate one score out of 10 for each of the four factors. Appendix 5 shows a screenshot of the HFIT questions as they appear in the database and Appendix 6 shows an extract from the published datasets of questions within the incident reporting database; incident reporters can download these datasets and use them to focus their investigations. Unfortunately, it was not possible to create a tool where the selections could only add to a total of 10, because the programming required to do that would have been outside the scope of the proprietary structure underlying the UK haemovigilance database. This is an adaptation of a standard database as supplied by Dendrite Clinical Systems™ to a number of medical registries (Dendrite, 2019). It was decided that this limitation was unlikely to make a major difference to the information that could be collected from this research study.

The data collected in this study are qualitative, relying on scores assigned by the transfusion incident reporters based on their personal assessments of the relative contributions of the human and system factors being studied. However, as the results obtained are numerical, they were analysed using quantitative methods to identify total scores given and percentages of those scores given to each factor. In addition, qualitative, thematic analyses were used to elicit information from the comments made in the free text boxes. A further analysis was carried out to assess whether the scoring appeared appropriate, because although that was of necessity a subjective scrutiny, earlier studies had shown the expected results for individual culpability should have been in the region of 10% (Karl & Karl, 2012).

5.4.2 Results

Data from the HFIT questions were analysed for all error incident reports that were completed in the calendar year 2016 (n=2688). These incidents were also analysed from a transfusion perspective for publication in the 2016 Annual SHOT Report (Bolton-Maggs *et al.*, 2017a). Hence, the data had been separately validated by these extensive scientific and medical analyses. In a small number of instances (n=11) HFIT data were not available, because the questions had not been asked for those cases. This occurred where incidents had been transferred from reaction categories (i.e. they were not originally reported as errors) or where incidents involving several patients were duplicated, so individual information was not available on each case. Those incidents were removed from the HFIT dataset being examined, so the final number of error reports analysed for this first year was 2677.

Scores were given for one or more of the four HF questions in 2489/2677 (93%) cases, which indicates that incident reporters were likely to be receptive to the introduction of the HFIT and it is probable that the tool was considered to be straightforward to use with such a high rate of compliance in answering these additional questions.

The results showed that incident reporters scored the contributors to errors as predominantly attributable to unsafe practice by individual staff member(s). At the simplest level, by totalling all the scores attributed to each of the factors, n=26,981, the percentages of scores given to each factor could be calculated (Table 5.2). This showed 62.6% of the cause was attributed to staff members, with the percentages diminishing for the other system and organisation factors.

Table 5.2: Total scores (0-10) for each of the human and system factors

	Staff member	Environment	Organisation	Government / regulatory
Total sum of scores assigned	16,891	5,087	3,862	1,141
Percentage assigned %	62.6	18.9	14.3	4.2

The results demonstrated that lower scores tended to be assigned as the factors got farther away from the individual as illustrated in Figure 5.3.

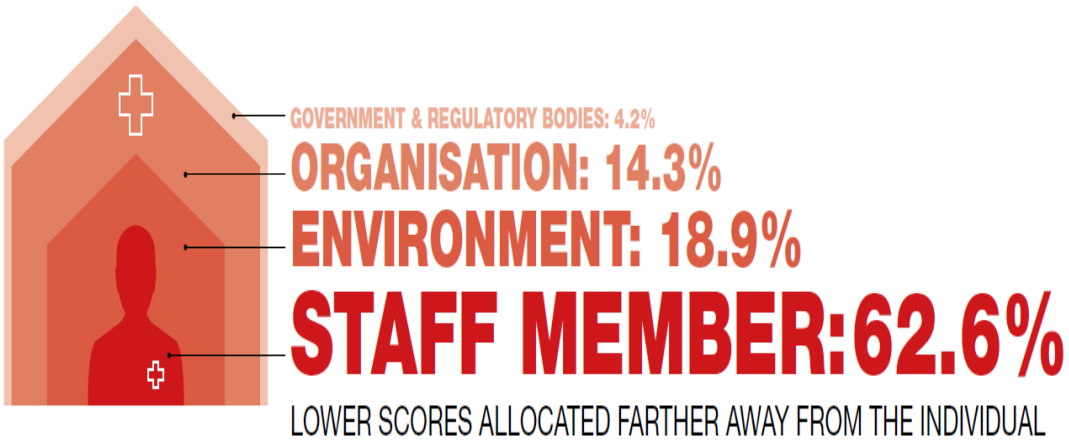


Figure 5.3: Scores for factors other than the staff member decrease the farther away they are from the individual

(reproduced from Bolton-Maggs *et al.*, 2017a with permission)

There was considerable variability in the scores allocated and the disparity is shown in Figure 5.4. This graphic examines each possible score that could be assigned from the maximum 10 to the minimum 0. The chart illustrates each score showing the percentage of that score assigned to each of the four factors, e.g. of all the 10 scores that were assigned, over 90% were allocated to staff members with approximately 4% to each of the environment and organisation factors and <1% to government/regulatory issues. Figure 5.4 shows that the higher scores were most commonly given to the individual staff

member(s), with over 50% of the 10, 9, 8 and 7 scores being assigned that way, whereas lower scores or zero scores were most commonly assigned to system and organisational factors.

Figure 5.4: Estimation of different human factors contribution to errors, score out of 10

(reproduced from Bolton-Maggs *et al.*, 2017 with permission)

Another mechanism for analysing the variability associated with the scores given is to assess whether incident reporters assigned scores to multiple contributing factors, ranging from scores having been given for all four factors in the HFIT, to no score given at all. The results of this analysis are shown in Figure 5.5. Over a third of incidents (993/2677, 37.1%) were scored for a single contributory factor and of these, 953/993 (96%) were given a score only for the individual staff member(s). Conversely, 351/2677 (13.1%) incidents were given a score for all four contributory factors and in these cases the percentage totals scored for the four factors were more evenly spread, as shown in Table

5.3, which can be compared to the totals for all incidents as shown in Table 5.2. As an example, the percentage score for individual staff member(s) was 37.8% when all four factors had been scored, compared to an overall percentage of 62.6% assigned to individual staff member(s) for all cases.

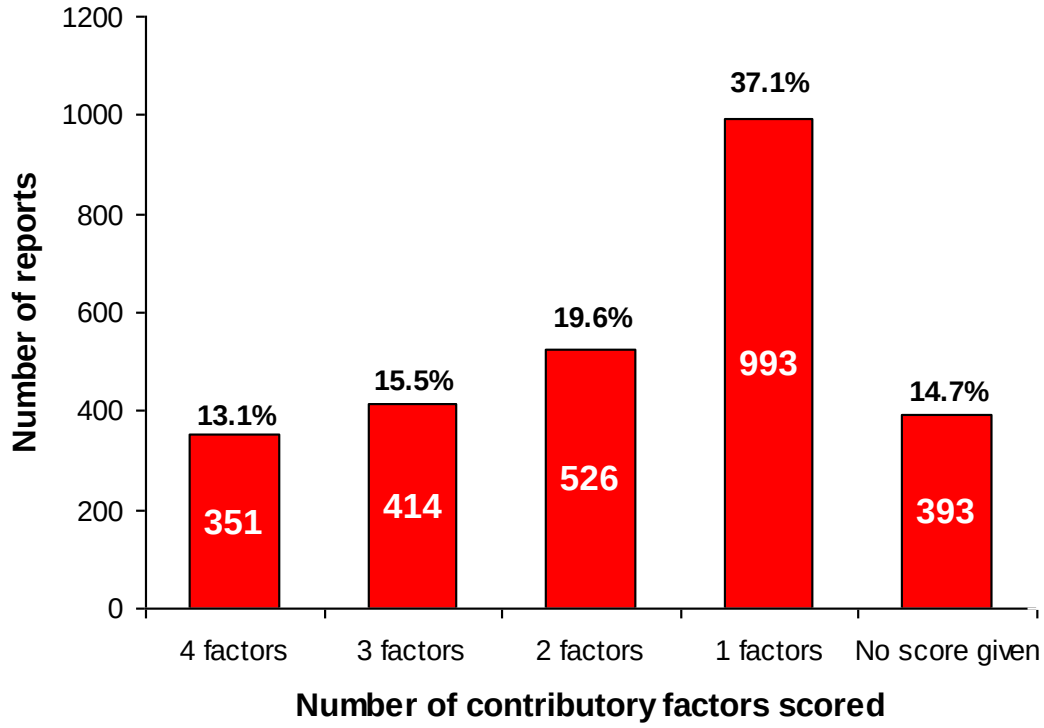


Figure 5.5: Assessment of whether multiple contributory factors were assigned scores

Table 5.3: Totals when the incident was scored for all four of the human and system factors

	Staff member	Environment	Organisation	Government / regulatory
Total sum of scores assigned	2411	1562	1370	1036
Percentage assigned %	37.8%	24.5%	21.5%	16.2%

Data in Table 5.3 relate to 351/2677 (13.1%) cases where scores were given for all four contributory factors

The supplementary comments given in response to the HFIT questionnaire were studied to examine if there were themes emerging, particularly in the two most serious categories of errors, i.e. cases of incorrect blood component transfused (IBCT) and avoidable, delayed or under/over-transfusion (ADU). In 83/96 (86.5%) of the comments analysed, contributory human and organisation factors could be identified and these are summarised in Figure 5.6. These data confirm the anxiety that staff shortages and other staff-related issues, such as lack of knowledge/training might be contributing to errors. Along with staffing issues that were noted in 27/83 (32.5%) cases there were a further 18/83 (21.7%) cases where a high workload or being excessively busy was indicated.

Figure 5.6: Human factors identified from comments in HFIT n=83

(reproduced from Bolton-Maggs *et al.*, 2017 with permission)

An example of a typical staff and workload-related comment is given here:

> *"When the form was labelled with the incorrect patient identification details, the department concerned was short of staff. The staff on duty had worked excess hours, and the forms were prepared at the end of a long shift."*

Concern has been expressed about staff shortages, particularly in transfusion laboratories, with dependence on locum and agency staff. The United Kingdom transfusion laboratory collaborative (UKTLC) survey in 2017 showed that 117/245 (47.8%) transfusion laboratories were carrying vacancies, which is an increase on the figures reported in the 2015 survey, 90/204 (44.1%) (Bolton-Maggs *et al.*, 2019). Also, an increasing number of these laboratories reported that they are using locum or agency staff, rising from 44/166 (26.5%) in 2015 to 73/186 (39.2%) in 2017.

The structure of the UK haemovigilance database did not allow programming to be made to restrict incident reporters to scoring a total of 10 across the four factors being examined. Therefore, they were free to score up to 10 for each factor, so the scoring was examined to reveal how often the scores totalled 10 (Figure 5.7). Just over a quarter of incident reports (25.5%) were given scores for the four factors that totalled to exactly 10 with the rest fairly evenly distributed between being under or over 10. This calculation excludes the 188 cases where no scores were entered for any of the factors. This was a potential limitation of the study, because it is possible some of the 25.5% who gave scores totalling exactly to 10 were artificially restricting their scoring in the belief they were required to allocate only 10 points in total. However, it is not likely that this would adversely affect the overall messages from this research.

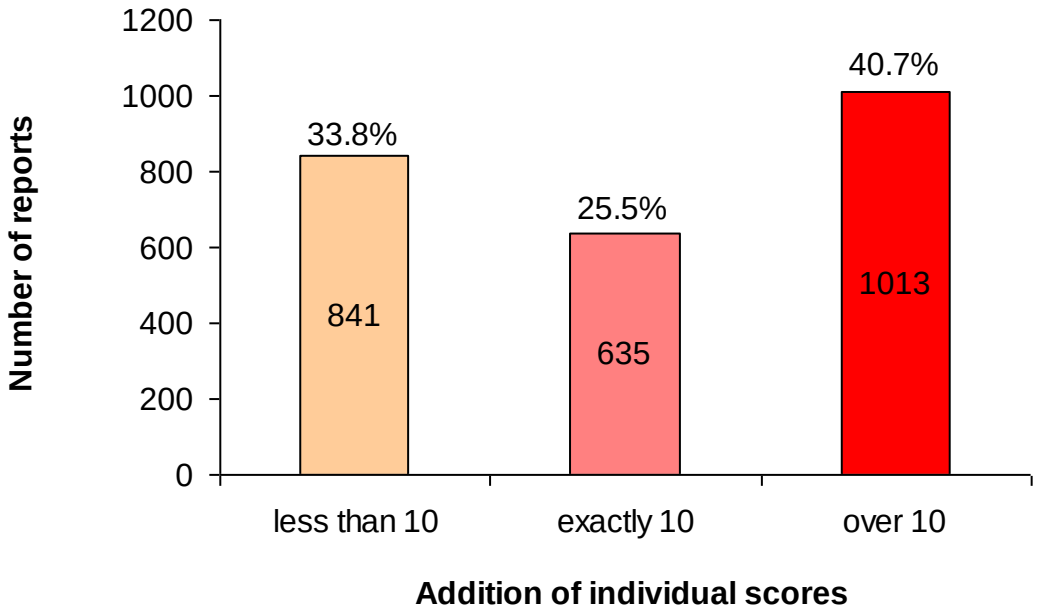


Figure 5.7: Do incident reporters calculate scores as percentage of 10?

The scores given may not always reflect the reality if there is too much focus on individual error. In 860/2677 (32.1%) reports, a score of 10 was given for the contribution of the individual staff member(s) and this percentage of maximum scores given to staff is probably more accurately recorded as 860/2222 (37%), because not all reports gave a score for staff contribution. Therefore, in order to assess whether scoring appeared appropriate, a few selected cases were reviewed to assess whether the details of the incident as reported matched the scores allocated. One example of these is included as Case 6.1 in the 2016 Annual SHOT Report (Bolton-Maggs *et al.*, 2017a) which showed that the scoring of 10 for unsafe practice by the individual, with no scores for any of the other system factors did not seem to be an appropriate score. However, it must be noted that the assessment of Case 6.1 from the 2016 Annual SHOT Report and the incident that is examined in Vignette 5.1 below, have both been performed from the anonymised reports made in the UK haemovigilance database. It is possible that the local incident investigators had other details to inform their scoring decisions which were not made available in the written report to SHOT.

As a further example of disparate scoring, Vignette 5.1 was examined in more depth. This incident report was similar to Case 6.1 in the 2016 Annual SHOT

Report in that it was scored as 10 for culpability by the staff member(s) and 0 for all other system and organisational factors.

Vignette 5.1: Total cause of incident attributed to individual

A patient was admitted through the Emergency Department (ED) with severe bleeding and the massive haemorrhage protocol (MHP) was activated, which is a process by which a standard dose of red blood cells (RBC), thawed fresh frozen plasma (FFP) and platelets are issued as an emergency. Despite this transfusion and a further four units of red cells in the interim, after three days, the patient's haemoglobin (Hb) was found to be very low at 36g/dL. This occurred at 00:43 and ward staff activated the massive haemorrhage protocol again. All components were issued by 01:50, but early the next morning the biomedical scientist (BMS) was contacted about one of the FFP units and realised this was from the batch that had been thawed and issued at the first MHP activation three days previously. FFP must be used within 24hrs of being thawed, but on investigation, the patient had already incorrectly received two units of FFP from the first batch earlier that morning, i.e. three days after thawing and two days after time-expiry of the units.

The following observations can be made from the information provided in this case, which shows that scores probably should have been allocated to system factors as well as to the individual(s):

Local environment or workspace:

This was not ideal, because blood components were issued to a remote refrigerator, so it was difficult for laboratory staff to control that stock. Any remaining fresh frozen plasma (FFP) units, which were unused from the first massive haemorrhage protocol (MHP) activation, should have been removed from the remote refrigerator after 24 hours.

Organisational or management issues in the Trust/Health Board

There were organisation problems, because the refrigerator had not been checked on the day after the initial MHP activation (a Friday) due to low staffing levels. A check would have shown there were thawed units of FFP which would need removing soon. Also, the medical laboratory assistant (MLA) covering weekend mornings was unaware that thawed FFP needs to be removed after 24hrs, so would have missed further opportunities to prevent the forthcoming incident. This could be a training issue of an unqualified staff member, or might be an example of downskilling, i.e. employing an unregistered member of staff for this task, rather than a qualified state-registered Biomedical Scientist (BMS). It is also possible there were training issues with the ward staff, who should be expected to know not to transfuse units of FFP past their expiry. Communication issues, which would also be classified as organisational, were evident too, such as failure to inform the laboratory staff that all units had not been transfused at the first emergency. As well as the erroneously transfused FFP, it was also discovered the original unit of platelets had not been transfused.

Government, Department of Health or regulatory issues:

It can be argued that there are government issues related to funding of the NHS that lead to understaffing, such as that given here as the reason for not checking the remote refrigerator routinely. The 2017 Care Quality Commission (CQC) report (CQC, 2017) stated ‘The scale of the challenge that hospitals are now facing is unprecedented’, so it is well known that healthcare organisations are under huge pressure.

Therefore, in this case it might be more accurate to have a spread of scores across all four of the human and organisation factors being examined in this study.

5.4.3 Discussion

The analysis in Study 2.1 showed that the HFIT is an appropriate and adequate method of elucidating which human and organisation factors are considered

most likely to be contributory to blood transfusion errors. The vast majority of reports (93%) included answers to the HFIT questions, which ensured there were sufficient data for analysis. Also, the tool must have been widely acceptable for use with such a high level of participation.

The main finding was that incident reporters gave higher scores to staff members as a cause of error than the scores given to the other potentially contributory factors. Studies have been done using James Reason's decision tree for determining the culpability of unsafe acts (Reason, 1997) that show 90% of quality lapses are defined as blameless (Karl & Karl, 2012). Therefore, the answers given to the HFIT questions may have considerably overestimated of the contribution of staff members at 62.6% if culpability by the individual is expected to be about 10%.

5.4.4 Limitations

The reporters scored the contribution to errors as predominantly attributable to unsafe practice by individual staff member(s), so there would be a resultant underestimation of the impact of environmental, organisational or government/ regulatory factors. It may be that this overemphasis on individual culpability was due to the probability that most reporters would have a limited understanding of the science of human factors, so it was decided to introduce some self-learning options with future studies in this area.

A further limitation was that some incident reporters restricted themselves to scoring out of a total of 10, but others scored each factor independently out of 10, allowing a total score of up to 40. As discussed earlier, it was not possible to programme the database to remove this variability, but it was decided that the issue would not considerably affect the data, because the option to score up to 10 for each factor was open to all reporters and there were no instructions to limit the scores to add to 10 in total. The fact that 25.5% of cases were scored as a total of 10 suggests many reporters may have limited themselves, but the overall conclusions from this research are unlikely to have been affected by this issue. With hindsight it may have been better to acknowledge this limitation and format the scoring system with a smaller range, such as a

five-point scale, so that it was more apparent that participants could score each factor independently.

A minor limitation was the small cohort of cases (n=11) where HFIT data were not available, because the questions had not been asked when the incident reports had been transferred or duplicated. Further efforts were made during Studies 2.2. and 2.3 to ensure these data were made available wherever possible, so this limitation only applied in the first year of study.

5.4.5 Conclusions

Study 2.1 demonstrated that the HFIT can illustrate which factors contribute to the cause of blood transfusion errors, but the major limitation is that the scores may not always reflect reality if there is too much focus on individual error. The incorporation of an HFIT into the database for transfusion incident reporting has increased the details given of the contributory reasons for errors being made and this would make it more viable for HF-related analyses to be made of the reports in future, using one or more of the models that were trialled in Study 1. That work is not planned within this research, but it is intended that future analyses will include an investigation into whether the scoring accuracy could be improved by introducing a self-learning package as described below.

5.5 Development of a self-learning package

Following the conclusions from the initial HFIT analysis, Study 2.1, a self-learning package was developed consisting of a PowerPoint presentation (Appendix 9). This package includes real case studies and examines how best to categorise and score the human factors aspects of these cases. The self-learning package was published on the SHOT website (SHOT Tuition, 2018) and reporters are requested to read this when completing a transfusion incident report in the SHOT error categories. The self-learning package was made available from January 2017 to help reporters better understand the human factors aspects of adverse incidents.

5.5.1 Methods

A first draft PowerPoint presentation was created to be used as a self-learning package to help reporters understand how to analyse errors from a human factors viewpoint. The presentation contains information about the HFIT and examines case studies from the first year of reporting.

In order to refine this draft, it was shared with a selection of people who report incidents (n=6) and members of the haemovigilance team who analyse these incidents for greater learning (n=5). This small focus group was asked the questions listed in Table 5.4.

Table 5.4: Focus group questions on first draft self-learning package

	Question	Answer Options
1.	How easy/hard was this package to understand	Very Easy / Easy / OK / Hard / Very Hard
2	What did you like most about it?	Free text
3	What did you dislike most about it?	Free text
4	Would incident reporters find this useful when discussing incidents with the staff who were involved?	Yes / No / Undecided
5	Has your understanding of human factors improved after reading this package?	Yes / No
6	Any other comments?	Free text

5.5.2 Findings

Of the 11 people who were asked for feedback on the draft learning package, seven responded. Their answers and any resultant amendments are summarised in Table 5.5.

Table 5.5: Focus group responses on first draft self-learning package and amendments made

Q1. How easy/hard was this package to understand?	Very Hard (0) Hard (0) OK (0)	Easy (4) Very Easy (3)
Q2. What did you like most about it?	Case studies (3) Examples of how to complete HF sections (2) Comparison between original score and adjusted score (2)	
Q3. What did you dislike most about it? (4 responses)	Comment	Amendment made
	Final thank-you page was too extravagant (2)	Not changed as unlikely to affect the data
	More general information on Human Factors	Information and weblinks added
	Needs formatting	Formatting improved
Q4. Would reporters find this useful when discussing incidents with the staff who were involved?	Yes (7)	No (0)
Q5. Has your understanding of human factors improved after reading this package?	Yes (6)	No (1) (already knew a lot)
Q6 Other comments? Five individuals gave eight responses	Comment	Amendment made
	Specify 78% errors is from 2016 reported data	Not changed - package to be updated annually
	Add a screenshot of the HFIT page	Screenshot added
	Produce a video for self-learning	Video could be problematic as NHS IT often unable to support (N.B. added in 2018)
	The Swiss Cheese model is beneficial	Swiss Cheese model not relevant
	Produce a crib sheet for users to print out and keep	HFIT questions can be downloaded from database
	Government section is a bit political, so may not get accurate answers	No change, but will monitor responses
	We are quick to blame the individual whereas often “set up to fail”	No change needed
	Package is good especially the advice for organisational and government issues as I always ponder over these	No change needed

Following the findings from the focus group, amendments were made as described in Table 5.5. The final version was made available on the SHOT website and was put into use from January 2017. The questions on the database include an option to comment on the self-learning package, so that ongoing improvements can be considered. After the first half of 2017 these comments were evaluated as an interim assessment of the acceptability of the

package. There were 27 positive comments and 2 negative, which suggested the learning package was being perceived as helpful. Only one comment was made to suggest an enhancement to this process:

> *"Would recommend that it [the self-learning package] is sent out perhaps twice a year as a reminder, but also so that new staff can become familiar with it."*

Therefore, the link to the self-learning package was distributed to all registered reporters at that point and sent out on a regular basis in following years.

5.5.3 Discussion

The focus group findings confirmed that the PowerPoint presentation was straightforward, because all respondents described it as easy or very easy to use. It was also judged by all as useful to reporters when discussing incidents with the staff who were involved, and most felt it improved their understanding of human factors.

5.5.4 Limitations

There are limitations as to how incident reporters can be educated and trained to complete the HFIT more accurately, because they are employed independently within each healthcare establishment in the UK. Therefore, a teaching strategy had to be used that every individual could access to teach themselves, hence the use of a PowerPoint-based training package.

A general limitation of the SHOT Database is that any changes have to be made at the beginning of each calendar year. This is because the data are collected for a full year before being analysed, so changes are only made annually to ensure the dataset remains consistent and is not compromised by any changes made throughout the year. The self-learning package went live on 1st January 2017 and remained unchanged until 1st January 2018, at which point amendments were made consistent with the analysis of results from the first full year of the study.

5.5.5 Conclusions

After an interim evaluation following 6 months of use, the HFIT self-learning package appeared to be suitable for use and was expected to improve the accuracy of scores assigned, but this would only be verifiable at the end of the first full year's use, which is shown in Study 2.2.

5.6 Study 2.2 (2017)

The next stages of analysis took place across two calendar years, 2017 and 2018, with an interim analysis after the first year, hence Study 2.2 data (2017) are presented here in Section 5.6, and the Study 2.3 data (2018) are presented in Section 5.8. The research aimed to confirm whether the incorporation of an HFIT into the database for transfusion incident reporting would increase understanding of the factors contributing to errors being made and thus improve the potential learning from transfusion incidents. Also, whether the incident reporters would use the self-learning package provided and if they did, would it improve their accuracy of reporting HF aspects of transfusion incidents.

5.6.1 Methods

The overall method is as described in 5.4.1, i.e. four questions asked to elicit the extent of the contribution to each transfusion error incident of four human factors defined as unsafe practice or conditions associated with: Individual staff member(s); Local environment or workspace; Organisational or management issues and Government, Department of Health or regulatory issues.

In addition, a self-learning package was added as described in Section 5.5 and the following text was added to the HFIT in order to encourage reporters to use the PowerPoint presentation to enhance their understanding:

SHOT has recognised how difficult it can be for reporters to score the human factors aspects of an incident. Therefore, a short self-learning package has been prepared and published on the SHOT website. Please copy and paste this link <www.shotuk.org/human-factors-tuition-package/> into your internet browser to access the tuition package.

Two further questions were added to obtain more information about the efficacy of the self-learning package:

1. *Please indicate if you read the human factors self-learning tuition package this time.*
   Answer options: Yes / No, but have read it previously / No
2. *Please add any comments about the self-learning package if you wish.*
   Answer option - free text

Knowing whether the reporter has read the self-learning package and how recently that was done should inform an analysis of whether a greater understanding of human factors leads to a more accurate assessment.

5.6.2 Findings

Data from the HFIT questions were analysed for all error incident reports that were completed in the calendar year 2017 (n=2760). The total of errors reported was slightly higher than in 2016, by a difference of 72 cases, which is a reflection that reports to the UK haemovigilance scheme tend to increase year on year. As with the data for 2016, these incidents had been separately analysed from a transfusion perspective by scientific and medical experts and thus had been validated for publication in the 2017 Annual SHOT Report (Bolton-Maggs *et al.*, 2018). Also, as noted with Study 2.1, the vast majority of incident reports included scores for one or more of the four HF questions 2559/2760 (92.7%). This indicates that the incident reporters continued to find it acceptable to answer the HFIT questions.

In the same way as Study 2.1, the results showed that scores were predominantly attributable to unsafe practice by individual staff member(s). The percentages of scores given to each factor were calculated, which showed 56.6% of the cause was attributed to staff members, which was slightly lower than the total percentage assigned to individuals in 2016 (62.6%). The percentage scores for the other factors showed a correspondingly slight increase (Table 5.6).

Table 5.6: Total scores (0-10) for each of the human and system factors

	Staff member	Environment	Organisation	Government / regulatory
Total sum of scores assigned	17357	6519	4755	2039
Percentage assigned %	56.6	21.3	15.5	6.6

Figure 5.4 in Section 5.4.2 shows the percentage estimation of different human factors contribution to errors, scored out of 10 from the HFIT Study 2.1 in 2016. Figure 5.8 below shows a similar summary of the reporters' estimation of different human factors contribution to errors, comparing data from both 2016 and 2017. This shows that the higher scores were slightly less commonly given to the individual staff member(s) in 2017 than in 2018, but the difference was not marked and no statistical significance was attempted on these results, because there was a further year of the study to run. However, additional information was available from the 2017 study, because of the inclusion of a self-learning package, so a slightly clearer picture can be seen by comparing the total scores given by those who had read the self-learning package and those who had not (Figure 5.9).

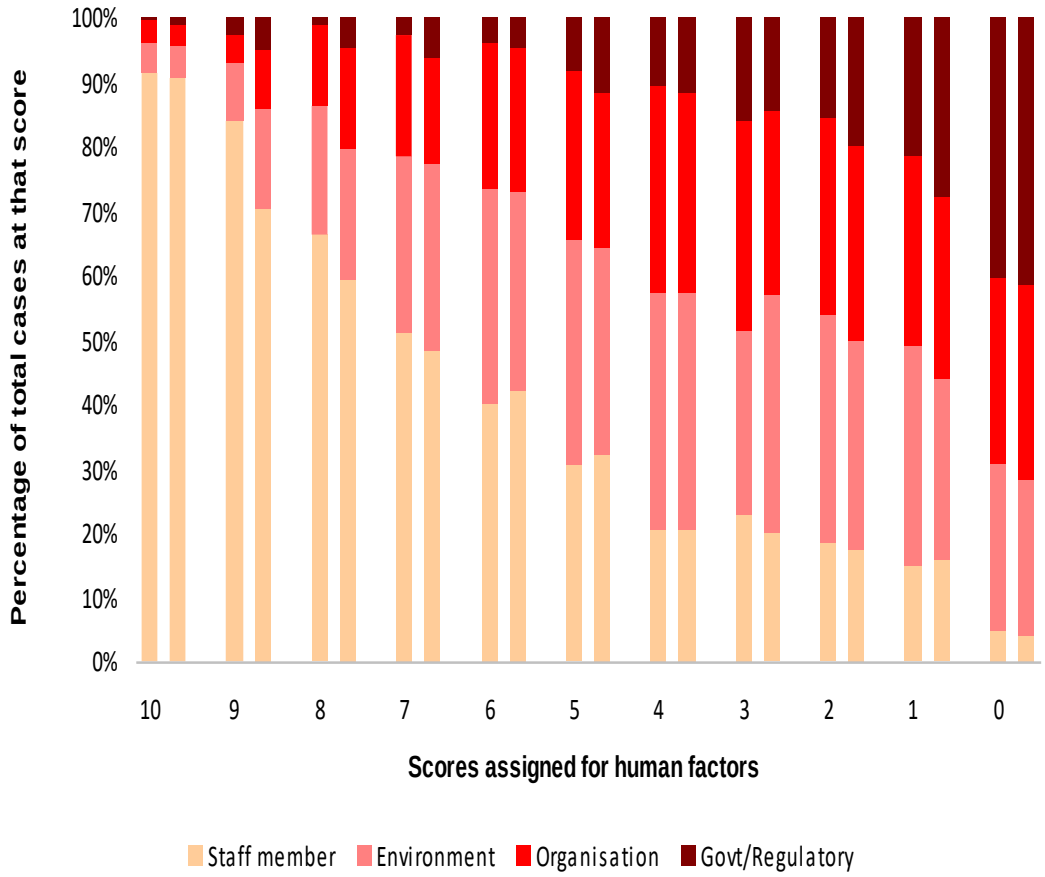


Figure 5.8: Comparison of percentage of scores out of 10 given to four human factors in 2016 (left column) and 2017 (right column)

Figure 5.9 shows that those who had not read the self - learning package (24.2%) gave a higher percentage of their scores to the individual than those who had read the educational material (75.8%) and consequently gave lower scores to system and organisational factors.

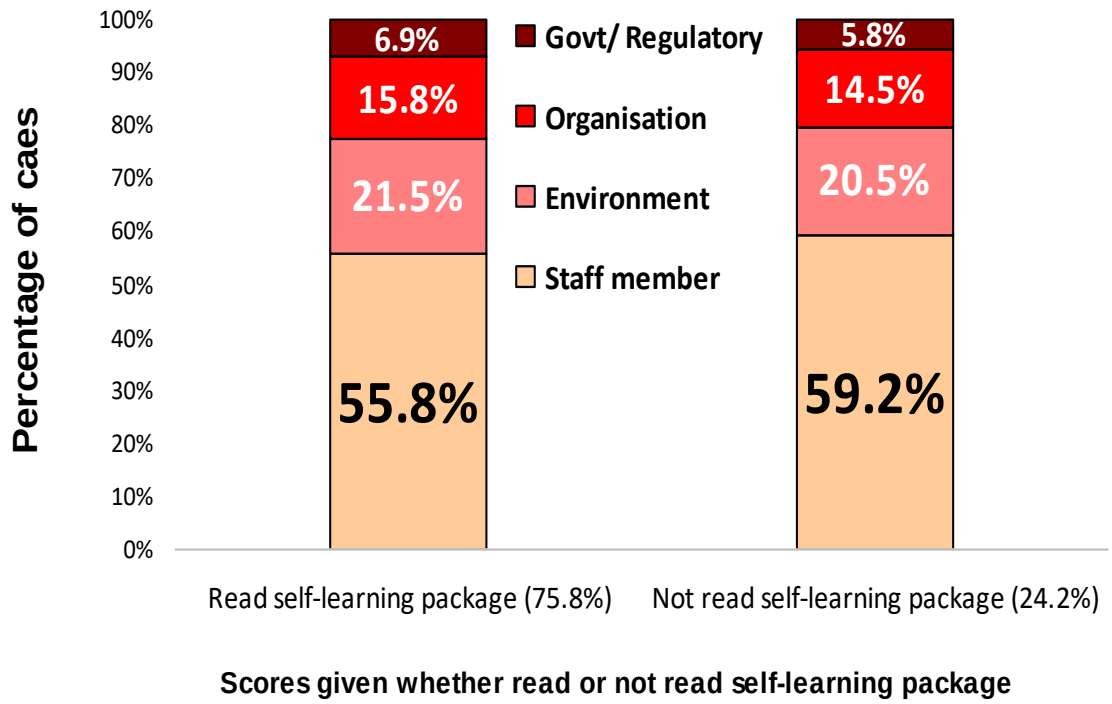


Figure 5.9: Scores given by those who had read or not read the self-learning package

Individuals who report transfusion errors to SHOT will usually report on numerous occasions, so it would be unrealistic to expect them to read the self-learning material on each occasion. By examining the answers to the questions of if and when they have read the self-learning package an indication is given of whether they have studied how to assess the implicated human factors before inputting the scores and if so, how recently did they read it. This allows an analysis to be made of whether studying the self-learning material influences the likelihood of assigning any scores to the HFIT questions (Figure 5.10).

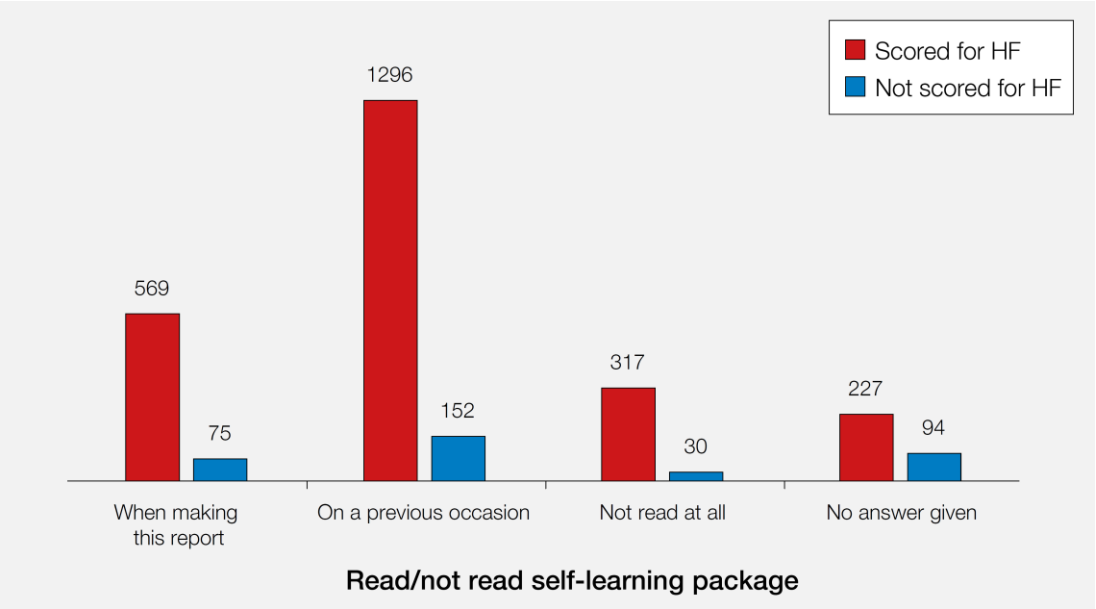


Figure 5.10: Evaluation of uptake of self-learning opportunity

(reproduced from Bolton-Maggs *et al.*, 2018 with permission)

Overall 2092/2760 (75.8%) cases were reported by colleagues who answered that they had read the self-learning package, either when making that report (n=644) or when reporting a previous error (n=1448). In comparison 668/2760 (24.2%) indicated that the reporter had not read the self-learning package, either by a direct 'no' response to the question, or by not giving an answer to that question. Of the total reports made by individuals who had read the package 1865/2092 (89.1%) included a score for the four human and system factors, but in comparison 544/668 (81.4%) of those who had not read the package included a score for the factors. Therefore, it was a little more likely that those who have read the self-learning package will then go on and complete the questions about contributory factors.

Comments were invited about the introduction of the self-learning package and 49 incident reports included an appropriate response to the question; 11 comments were excluded from this assessment, because they were not about the self-learning package, but instead were comments related to the incident itself or about other aspects of the database. Positive observations were made in 45/49 (91.8%) of the incident reports that recorded a comment about the

package. Although a total of 49 comments from 2760 incident reports seems a low figure, it is probable that these were mostly from different individuals, because 41/49 (83.7%) had answered that they read the self-learning package on this occasion rather on a previous occasion. Typically, there are just under 200 healthcare organisations in the UK that report to SHOT (that number varies due to mergers and reorganisations each year) so if those 49 comments were from different institutions they would represent about a quarter of all reporters.

5.6.3 Discussion

A high compliance rate was maintained with 92.7% of incidents reported including scores for one or more of the four HFIT questions. The results continued to reflect a tendency to place most responsibility for incidents on individual staff members, despite the attempt to encourage a greater spread of scores via the self-learning package. Also, the scores did not demonstrate a clear difference whether or not the self-learning package was read. It was decided not to attempt a statistical analysis of the scores until the full study was completed, because the self-learning package was to be extended before the final year's assessment was made.

Comments made about the self-learning package were largely supportive and of the four negative comments, one indicated they could not access the package, which may have been a local internet issue and one requested more examples, so was not particularly critical. The remaining two negative comments demonstrated the incident reporters thought the scoring was subjective (which of necessity it is) and found the self-learning package unhelpful and difficult to understand. While it is always disappointing to receive negative comments, the overwhelmingly positive response indicates that mostly the self-learning package was received well.

5.6.4 Limitations

A major limitation was that access to the self-learning package had to be included with instructions to copy and paste the link into the user's internet browser. The SHOT database is configured in an off the shelf IT programme

created by Dendrite Clinical Systems™ and the construction of this system meant it was not possible to include a direct hyperlink to the package within the SHOT database. The need to copy and paste is likely to have discouraged reporters from reading the self-learning package, compared to a hyperlink accessed by a simple click and unfortunately this restriction could not be overcome.

A general limitation of this study is the inherent requirement for confidentiality associated with SHOT data. As an example, it is not possible, nor ethical, to identify the specific reporters of incidents, so all results are examined at the level of individual cases, although it might be enlightening to consider whether there are patterns associated with different individuals who are making the reports or their specific reporting organisations. This is a limitation that has to be tolerated within this study, as it would not be appropriate to circumvent the inbuilt confidentiality.

5.6.5 Conclusions

There is no clear evidence that the accuracy of reporting HF aspects of transfusion incidents has been improved by the inclusion of a self-learning package, but neither is there any evidence that it has had a negative impact. It is problematic to use self-learning at a distance to try and educate a large cohort of professionals from a different field to have sufficient understanding of the principles of human factors to be able to make valid assessments, but the make-up of this workforce means there is no reasonable alternative. Therefore, it was decided that further amendments would be made to the self-learning material, particularly the addition of a video, as described below.

5.7 Further development of the self-learning package including a video

Following the analysis of the effects of the self-learning package, as used in 2017, a decision was made to revise the package for 2018. The PowerPoint presentation was extended to include new examples of HF-based scoring using cases that were reported during 2017, in an effort to explain further how system and organisational factors could be scored in reports of adverse incidents. Consideration was also given to adding a simple human factors

video to the self-learning materials, because that might be helpful for incident reporters for whom a PowerPoint presentation was not a suitable method of distance learning.

5.7.1 Methods

Two simple animated videos were found that could be made available for use in this study:

A. *Human Factors: A Quick Guide* (HEE, 2017). Approximate length of video is 6 minutes.

B. *Systems Thinking - A New Direction in Healthcare Incident Investigation* (Systems Thinking, 2017). Approximate length of video is 4 minutes.

Links to these videos were shared with the same small focus group of people who trialled the draft self-learning PowerPoint package (Section 5.5.1) and they were asked a standard set of questions (Table 5.7).

Table 5.7: Focus group questions for extending the self-learning package with a video

	Question	Answer Options
1.	Can you watch videos, such as these, via your work IT system?	Yes / No / Only one video would play (please indicate which)
2	Which video did you like most?	Free text
3	Please indicate any reason(s) affecting your choice	a. Liked it being shorter/longer b. Found it easier to understand c. More relevant to my work d. Better graphics e. Trusted video creators more f. Any other reasons
4	While accessing these videos, did you watch any other videos linked from this page?	Yes / No
5	Any other comments?	Free text

5.7.2 Findings

Nine of the people asked for feedback on the draft videos responded and their answers are summarised in Table 5.8.

Table 5.8: Focus group responses for extending the self-learning package with a video

Q1. Can you watch videos, such as these, via your work IT system?	Yes (8)	Yes, but my browser would not support full screen (1)
Q2. Which video did you like most?	A (6)	B (3)
Q3. Please indicate any reason(s) affecting your choice	a. Liked it being shorter/longer	2 agreed
	b. Found it easier to understand	5 agreed
	c. More relevant to my work	6 agreed
	d. Better graphics	4 agreed
	e. Trusted video creators more	0 agreed
	f. Any other reasons	6 responded, but all were repeating reasons a to d
Q4. While accessing these videos, did you watch any other videos linked from this page?	No (6)	
	I did view some other videos on this site, I think that these two are the most suitable (1)	
	No response (2)	
Q5. Other comments? Three individuals gave responses	It would be good to have more depth, the "how does that work practically" side – How it ties in with root cause analysis (RCA) models etc, or even specific human factors RCA models	
	Chose B but actually I like the graphics in A better	
	I think that the use of a training video needs to be centred around the target audience rather than as a general training video on 'human factors'	

5.7.3 Discussion

In the comments made by the focus group for the original self-learning package (Section 5.5.2), one respondent suggested a video should be produced, but it was thought that this could be problematic as NHS organisations have been known to restrict access to video platforms. Therefore, following the decision to suggest inclusion of a video for self-learning, question 1 was asked to give an assessment of any problems with access. It was pleasing that all members of the focus group could access the videos, with only one reporting a slight problem of being unable to view them in full screen mode. However, it was

decided that it would be prudent to ask that question in the live database too, in order to get a sense of how many organisations restrict access.

The results of question 2 showed the clear favourite to be video A, *Human Factors: A Quick Guide* (HEE, 2017) and the responses to question 3 showed the reasons supporting the respondents' choices. It was a deliberate decision to offer reason choices in this survey, because free text can be difficult to analyse and it was noteworthy that all responses to the free text option 3f were essentially repeating reasons already covered by options 3a to 3e. Question 4 was asked to assess whether incident reporters might be tempted to watch related videos once they had accessed the chosen version and thus gain a little more insight into the subject of Human Factors. Only one of the focus group accessed any further videos, but it was valuable that they indicated they thought the chosen two were the most suitable.

5.7.4 Limitations

The main limitation of this work was that videos had to be sourced from existing online content, because there were neither the funds, nor the time to produce a bespoke video for this specific purpose. However, this was not a major problem, because there were two suitable animations already in existence and for which permission could be obtained easily.

5.7.5 Conclusions

Positive responses from the focus group suggested that adding a video to the self-learning materials would be likely to be beneficial to incident reporters and as a result of their responses, video A, *Human Factors: A Quick Guide* (HEE, 2017) was chosen. The uniform resource locator (URL) for this video was added to the HFIT questions from January 2018 and remains in place to date.

5.8 Study 2.3 (2018)

The HFIT study was scheduled to take place over a period of three years and to end with a finalised process for collecting information on human and system problems that contribute to adverse events in blood transfusion, which would become part of the routine haemovigilance process in the UK. Therefore, Study 2.3 (2018) is the analysis of the final year of the research.

5.8.1 Methods

As before, the overall method is described in Section 5.4.1 and the self-learning package was detailed in Section 5.5. For the final year a video was added after the assessment as shown in Section 5.7 and the self-learning package was updated with added information, including details of the video, plus new case studies (SHOT Tuition, 2018). The following text was added to the HFIT in order to encourage reporters to view the video as well as the self-learning PowerPoint presentation:

> *In 2017 a tuition package of slides was published on the SHOT website. An updated version for 2018, including new case studies, can be accessed if you copy and paste this link www.shotuk.org/human-factors-tuition-package/ into your internet browser.*
>
> *New for 2018, we suggest watching a short video for more information about human factors. Please copy and paste this link <https://t.co/qTeUoPiUlq> into your internet browser to access the video, which is approximately 6 mins long.*

A further question was added to obtain more information about the efficacy of the video as well as the similar question about the self-learning package:

Please indicate if you watched the human factors video this time.

Answer options: Yes / No, but have read it previously / No / I cannot access a video from my organisation's IT system

In addition, a new question was added to ask*:*

If you could change one thing to make this incident less likely to happen again, what would it be?

Answer option: Free text

5.8.2 Results

The results from the final year of the study continued to show that the highest scores were attributed to unsafe practice by individual staff member(s). As previously, the percentages of scores given to each factor were calculated and showed 55.5% of the cause was attributed to staff members, which was again slightly lower than the total percentages assigned to individuals in 2017 (56.6%) and 2016 (62.6%) (Table 5.9).

Table 5.9: Total scores (0-10) for each of the human and system factors

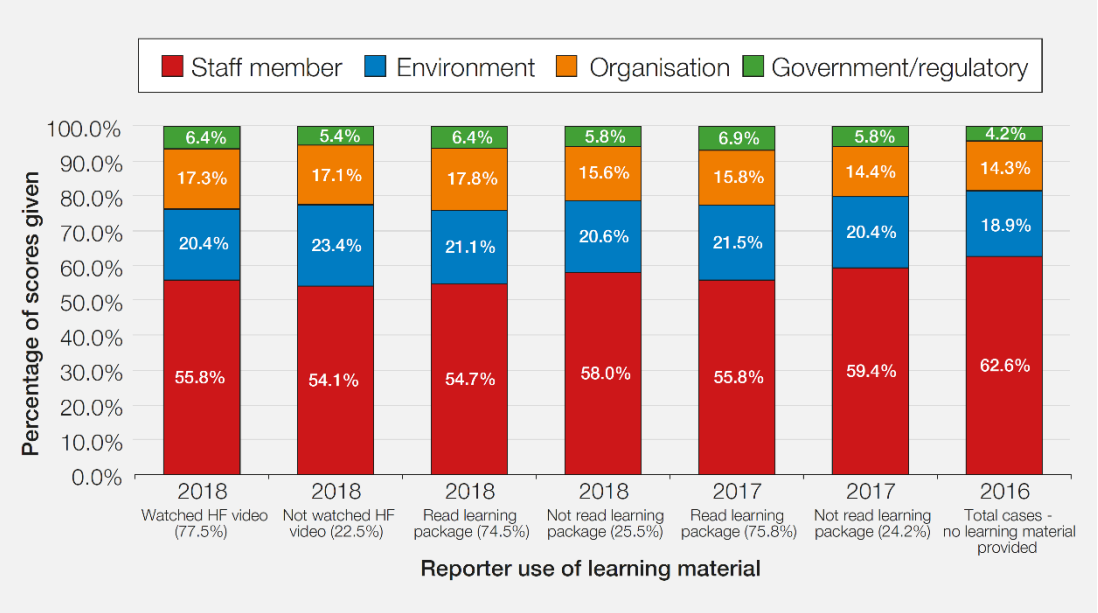
	Staff member	Environment	Organisation	Government / regulatory
Total sum of scores assigned	18214	6902	5677	2052
Percentage assigned %	55.5%	21.0%	17.3%	6.2%

As a further example of the tendency to concentrate only on individual error, scores of 10/10 for 'attributable to unsafe practice by individual staff member(s)' were given in 427/2905 (14.7%) of the incident reports where no scores were given for any of the other three system and organisational factors. Of these reports, 83/427 (19.4%) gave a response to the new question that asked which one thing they would change to make this incident less likely to reoccur and many of the answers pointed to a necessary change in the system. This indicates it is unlikely the total cause of these incidents could have been the responsibility of individual employees.

In over a third of all cases reported, 1022/2905 (35.2%), there was an answer to the new question of one thing to change, which means the additional question may be helping hospital staff to identify safety improvements in the blood transfusion process. A small proportion of these, 29/1022 (0.3%), gave an answer despite scoring zero or blank for all four factors, so the addition of the HFIT with the associated questions, may be encouraging healthcare staff

to consider system improvements irrespective of their proficiency at scoring the incident for aspects of culpability.

Figure 5.11 shows the comparison of whether the self-learning material was used and the percentage scores given by incident reporters for the four human and system factors. In the labels of each column for 2017 and 2018 there are percentages that correspond to the cases in each category. It can be seen that in the region of three-quarters of incident reports were made by colleagues who had used each type of learning material, while in approximately a quarter of incident reports, the reporter did not indicate that they used the self-learning opportunities.



Percentages in column labels=proportion of cases where the reporters used/did not use learning material

Figure 5.11: Scores given by those who had used or not used the self-learning material

(reproduced from Narayan *et al.*, 2019 with permission)

A statistical analysis was carried out on all the data from the full three years of the study (Appendix 4). This proved difficult for several reasons, because the dataset was not consistent. This included issues caused because each reporter can report more than one incident, so the data are not independent. In addition, the scoring system is not consistent, because some reporters have assumed that the total contribution made by all four human factors towards the

incident cannot exceed a total score of 10, whereas others have scored the four factors completely independently. The statistical analysis concluded that there is some limited evidence that the use of the self-learning material led to a reduction in the extent to which reporters attributed staff as a cause of the incident, p=0.10. There was also strong evidence that the use of self-learning increased the extent to which reporters attributed environment, organisation, and regulation as contributing to the incident, p<0.0001 for all three of these factors.

In 102/2905 (3.5%) incident reports it was stated that the reporter was unable to access a video via their organisation's information technology (IT) system and therefore could not watch the human factors animation. Further analysis showed that this comment had been made in reports from 36/191 (18.8%) of the different reporting institutions that submitted reports to SHOT in 2018, including NHS Trusts and Health Boards, plus independent healthcare providers, so it appears a sizeable proportion of healthcare organisations do not always support access to educational videos.

5.8.3 Discussion

Over the three years of this study there has not been a major change in the distribution of scores given to the four human factors, although the trend across the three years is to assign slightly less responsibility to the staff members, especially if the self-learning package has been read. The statistical analysis showed that when the incident reporter has used some form of self-learning, the attribution of culpability to staff is reduced and is increased for each of the other factors, environment, organisation, and government/regulatory.

It is disappointing that there are constrained or outmoded IT systems in almost 1 in 5 healthcare institutions (18.8%), which result in incident reporters being unable to access media such as videos. We live in an age where many people can view videos from their mobile phone, so it is a retrograde step that they may have reduced opportunities for learning via their employers' IT systems. This would inevitably affect not only learning about human factors, but also many other video-based training options or online resources that could help to

keep the workforce generally well educated and professionally developed. Lack of knowledge and training have been shown to contribute to incidents (Figure 5.6).

The opportunity to resolve underlying system problems may be lost If the investigation of incidents places too much emphasis on individual error, as shown by the comments on some incidents that were attributed solely to staff member (s) that indicated a change in the system would be the 'one thing' they would change to make the incident less likely to happen again. Key messages in the Annual SHOT Reports strongly encourage incident investigators to use human factors and ergonomics principles to assess all causes of an incident.

5.9 Overall limitations of HFIT research *and possible future work*

Limitations have been discussed in previous sections and were resolved throughout the study where possible. The remaining limitations have mostly not affected the data in any substantial manner, but the most useful amendment in future would be to find a way of supporting the incident reporters to assess the relative contributions of all four human and system factors to each adverse incident. This is likely to remain a difficult problem to resolve, because the staff involved in this process are all independently employed by local healthcare institutions and their job role does not specifically require any knowledge or understanding of human factors.

If it becomes possible to configure the SHOT database in a more user-friendly way, it would be beneficial to include hyperlinks to the self-learning material from the database instead of requiring incident reporters to copy and paste a URL. Similarly, if it were possible to require the scores for the four factors being studied to total 10, instead of each being out of 10, this would be worth studying, because it might positively affect the distribution of the scores and discourage the overemphasis on individual culpability.

5.10 Overall conclusions from HFIT Study

If incident reporters can develop a fully accurate attribution of the contributory factors to adverse events, it is probable that more could be learnt about the

system and organisational factors that may contribute to the cause of adverse events and this would give healthcare organisations the opportunity to resolve some of the underlying problems that are leading to errors. Although it might have cost implications for the UK National Health Service (NHS), there are also costs associated with serious, but preventable, adverse events, not least the human cost for patients, such as mortality or morbidity. In addition, there would be costs related to adverse effects on staff, especially those who are being assigned sole blame for an error. Damaging outcomes for staff such as losing their job, or suffering legal challenges are likely to have a negative effect on healthcare workload, with no improvement in patient safety.

It is anticipated that reporting of human and system problems involved in transfusion incidents will improve over time as the messages about accurate examination of these aspects are disseminated, partially by the inclusion of the self-learning material, but also by the higher profile that the science of human factors is achieving. This in turn should lead to improved systems and a resultant higher level of patient safety.

Chapter 6 Study 3 – Prospective analysis of resilience in the transfusion process in the hospital setting

6.1 Chapter summary

This study is a prospective analysis of resilience as a Safety-II process in the hospital-based transfusion procedure, which would enable the development of a tool for use by each institution to analyse their own transfusion process and discover the risks at each stage of the system. Resilience data were collected from healthcare professionals using questions to assess the transfusion system in their own institutions. These data allowed research to be carried out comparing the use of the HF-based tool in assessing resilience at various stages of the transfusion process. Data were analysed using the Resilience Analysis Grid (RAG) (Hollnagel, 2010), Systems Engineering Initiative for Patient Safety 2.0 (SEIPS 2.0) (Holden *et al.*, 2013a) and the Concepts for Applying Resilience Engineering (CARE) model (Anderson *et al.*, 2016). The research identified that adaptations in the transfusion process are mostly made in a different aspect, commonly tasks and processes, from the trigger requiring an amendment to be made, so the adaptations show the gulf between work-as-imagined and work-as-done. Most adaptations were identified as forced workarounds, while a few are proactive improvements. There is often a failure to learn, because managers are frequently unaware of adaptations.

6.2 Introduction

The research question for this study is ‘Can a Safety-II approach improve clinical audit and maximise system resilience throughout the end to end blood transfusion process?’. The objective is to audit the entire transfusion process from end to end in various hospitals using human factors principles to examine the potential for resilient performance in their systems. The study will follow the complete transfusion pathway, from taking a patient’s sample through to giving components back to the patient, which can be described as the vein to vein process, i.e. a sample taken from a patient's vein leading to a transfusion back into the same patient's vein (Figure 6.1). The process is a complex multidisciplinary procedure, often involving a variety of healthcare professions

and usually a different person at each step. Nine major steps have been identified in the process, from requesting a transfusion and taking a sample from the patient for crossmatching, through all the procedures necessary before transfusing a component to the patient (Figure 6.1). Errors at any step can result in patient death or major morbidity.

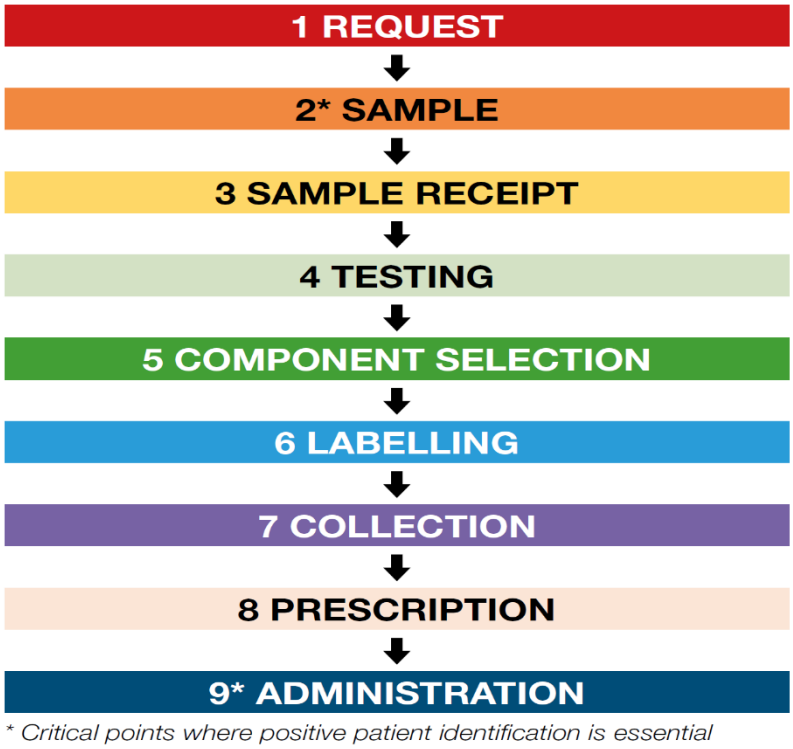


Figure 6.2: The nine steps in the vein to vein transfusion process

(Reproduced from Bolton-Maggs *et al.*, 2014 with permission)

6.3 Study aims and objectives

This research aims to take a prospective approach to learning from work-as-done (WAD) compared to work-as-imagined (WAI) (Hollnagel, 2015a, Braithwaite *et al.*, 2016) by exploring a new way of discovering how the processes involved in transfusion are being adapted. Until recently, improvements in the transfusion process have relied on recommendations resulting from incident investigation, which is a safety-I system (Hollnagel, 2014). It is known that patient-safety incident reporting has general flaws, such as a failure to analyse incident reports fully and a level of bias in many initial reports, which are typically written from one person's viewpoint. Thus, there can be limitations to learning from incident reporting (Macrae, 2016) and this

has been confirmed by Studies 1 and 2 in this PhD. Similar problems exist with standard clinical audits of processes, such as those involved in blood transfusion. These audits, plus the recurrent regulatory audits carried out by the Care Quality Commission (CQC, 2019), the United Kingdom Accreditation Service (UKAS, 2019) and the Medicines and Healthcare products Regulatory Agency (MHRA, 2019) amongst others, promote a situation where staff are expected to work in a regimented fashion and are observed for their adherence to standard operating procedures (SOP) and evidence-based guidelines. Healthcare processes are complex multidisciplinary procedures, so traditional audit procedures may not be meaningful. Audits might not reflect the truth, because they are not designed to discover or understand the many adaptations staff make to deal with the dynamic healthcare environment. Examining adaptations made in the complex, dynamic environment of transfusion can be a safety-II model for learning from positive adjustments, i.e. from what goes right (Hollnagel, 2014).

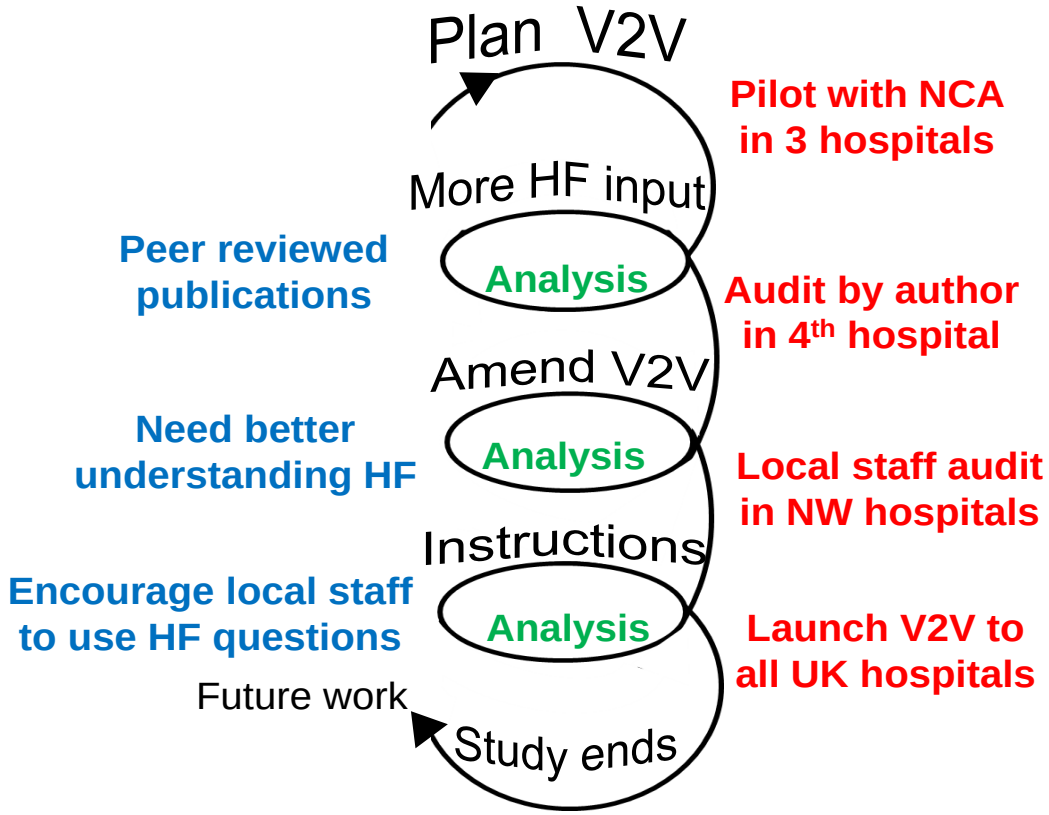
The research in this study has been initiated to examine the normal transfusion process and analyse what staff members do when things do not go as planned, i.e. how do they adapt and do those adaptations improve the opportunities for resilience within the system? The exploration was linked to a pre-planned audit by the National Comparative Audit (NCA) team, known as the Vein to Vein (V2V) audit. The NCA V2V audit is designed to produce tools for use in local audits by hospital staff, mostly Transfusion Practitioners, who will be experienced in collecting transfusion data, but will not necessarily have an understanding of human factors (HF), so the research questions will need to be uncomplicated. Each section of the transfusion process will be audited separately, so there is not a requirement to audit the whole process at one time. Therefore, the design for the HF study needed to fit with that protocol and allow data to be collected, when possible, alongside the audit data.

6.4 Methods

Several methods were used, which are described individually below. In summary a data collection process was developed and studied as a proof of concept for implementation as part of an ongoing national audit process.

Investigations incorporated both thematic and quantitative analyses and examinations using human factors models including the Resilience Analysis Grid (RAG), Systems Engineering Initiative for Patient Safety 2.0 (SEIPS 2.0) and the Concepts for Applying Resilience Engineering (CARE) model.

As outlined in Chapter 3, action research is the main methodology used for Study 3. Figure 6.2 is an adaptation of Figure 3.3 from Chapter 3 to show a summary of this research, which is predicated on questions to analyse system resilience being incorporated into a much larger national audit process, the Vein to Vein audit (V2V). The cycles completed so far have been a proof of concept to develop the questions, then test them firstly by the author as part of the wider V2V pilot, then, after peer review, a further study was carried out by the author alone. Each cycle allowed improvements to be made, before the final full audit was released to be tested by local audit staff in selected hospitals. This allowed additional development of the audit tool before release to all hospitals UK-wide.



Abbreviations: V2V=Vein to Vein audit, NCA=National Comparative Audit, HF=Human Factors, NW=North-West

Figure 6.3: Action research summary of Study 3

6.4.1 Outline of data gathering process

The research procedure was to request a narrative from participants, while they were undertaking aspects of the transfusion process, detailing any problems faced and how they were overcome. All those approached agreed voluntarily to be interviewed and no one declined the request. There was an element of stratification in the selection process by interviewing a mixture of both laboratory and clinical staff covering each of the nine stages of the transfusion process as shown in Figure 6.1. By this technique the staff members recruited included an extensive range of healthcare professions including doctors, nurses, midwifes and scientists, plus ancillary workers such as phlebotomists, administrative staff, porters and healthcare assistants. The ethical considerations of these studies are discussed in Section 3.6; NHS ethical approval via the Research Ethics Committee was not required for this research.

An open question was asked with the expectation that the answers would give some indication of adaptability in the transfusion processes being studied within that organisation. This was followed by a closed question using a Likert scale to assess local support for the adaptation made. It was anticipated that the results may indicate if it was an appropriate adaptation, because lack of management support could be due to concern at the safety implications of the amendment made to the standard process. This method is based on research done by Mark Sujan and colleagues analysing the various hassles that practitioners experience in their everyday clinical work (Sujan *et al.*, 2011a;b and Sujan & Furniss, 2015). The full proposal for asking these adaptation questions as part of the V2V audit is at Appendix 7, and their inclusion in the pilot V2V audit diary can be seen in Appendix 8.

In summary the questions asked are:

Q1. “Please give a short outline of the biggest or most recent difficulty that you have faced when carrying out this procedure and what did you do about the issue?”
Answer = Box for free text of around 100-150 words.

Q2. “How supportive was your manager/department for how you solved the issue?”
Answer = Five Likert scale from 5 = very supportive to 1 = very unsupportive, plus 0 if the question was not applicable.
Comment box - Please add comments if you wish:

The responses to question 1 were analysed thematically using various categorisations and models described below, while the responses to question 2 allowed a quantitative analysis of the Likert-scale points given. The aim was to discover if management and front-line staff had become disconnected such that managers might not be aware of local adaptations. This separation of management from work-as-done, might result in managers either being unsupportive of certain adaptations, even though they are increasing resilience for the workers, or tacitly approving adaptations known to violate standard procedures.

6.4.2 Methods for proof of concept studies

An initial proof of concept study was undertaken by the author, in conjunction with the National Comparative Audit (NCA), in three volunteer UK NHS hospitals, one in the Midlands and two in Greater London. A further investigation was done by the author alone in a North-Western hospital, so there was a geographical spread of organisations, albeit restricted to England. All four organisations are large teaching hospitals that provide major acute care services, and thus the full nine steps (Figure 6.1) of the transfusion process are carried out in each of these institutions. Some smaller healthcare organisations might not cover the entire vein to vein process or may contract out parts of the procedure to other institutions. The visits were carried out in

line with each hospital's internal audit process. The trial of the questionnaires gave an opportunity to gather some data on adaptations, which would allow the opportunity to refine the questions for future data collection if necessary. This would mitigate the potential danger of the wrong questions being asked when the full V2V audit was launched and/or that the answers would be disappointing, such as insufficient detail being given or staff not responding fully. The staff responses to the questions outlined in Section 6.4.1 were logged and thematically analysed considering queries such as: did the adaptations described cover all nine steps of the transfusion process, why and how they adapted and what was the efficacy of their adaptations?

6.4.3 Resilience Analysis Grid (RAG)

The potential for resilience within a routine procedure carried out in an organisation can be measured by considering the four abilities of a resilient organisation (Hollnagel, 2010), which are described as the ability to:

- *Respond* to regular and irregular variability, disturbances, and opportunities. This is the ability to address the *actual*.
- *Monitor* that which happens and recognise if something changes so much that it may affect the organisation's ability to carry out current or intended operations. This is the ability to address the *critical*.
- *Learn* from experience; understand what has happened and learn the right lessons from the right experience. This is the ability to address the *factual.*
- *Anticipate* developments that lie further into the future. This is the ability to address the *potential*.

A method was developed to analyse the qualitative data received in these narratives using the resilience analysis grid (RAG) (Hollnagel, 2011). Every narrative and associated adaptation was scored for these four cornerstones of resilience using Hollnagel's suggested five-Likert scale ranging from 5 = excellent to 1 = deficient or 0 = missing (Hollnagel, 2011).

6.4.4 Systems Engineering Initiative for Patient Safety 2.0 (SEIPS 2.0)

The answers given to question 1 were evaluated via a template analysis, a specific type of thematic analysis, using the Systems Engineering Initiative for

Patient Safety 2.0 model (SEIPS 2.0) (Holden *et al.*, 2013a) to identify the triggers that led to the need for an adaption and the types of adaptations that were made in response to these triggers.

The categories used were:

- Person(s) - Staff-related factors such as knowledge, education, needs and motivation of people in the system
- Tasks - Specific actions within the process
- Processes - procedures within the larger system
- Tools/Technology (IT) - Information Technology (IT) is a major tool used in healthcare
- Tools/Technology (Non-IT) - Objects used to do work or that assist in doing work, that do not relate to Information Technology (IT)
- Organisation/management - Management control of time, space, resources, activity etc.; organisational culture
- Internal environment - Physical e.g. light, noise, vibration, temperature, physical layout, available space, air quality
- External environment - Factors outside an organisation, e.g. high-level societal, economic, ecological, policy etc.

An examination was also made of how permanent each adaptation was, in order to assess if the changes were temporary alterations to the system and therefore reveal whether they were likely to be proactive planned improvements or local workarounds.

6.4.5 Concepts for Applying Resilience Engineering (CARE)

It can be difficult to assess whether or not adaptations are resilient changes, so the Concepts for Applying Resilience Engineering (CARE) model has been developed to provide a framework for studying organisational resilience (Anderson *et al.*, 2016). The CARE model (Figure 6.3) shows that there is a potential for the same adaptive processes to have either acceptable or unacceptable outcomes.

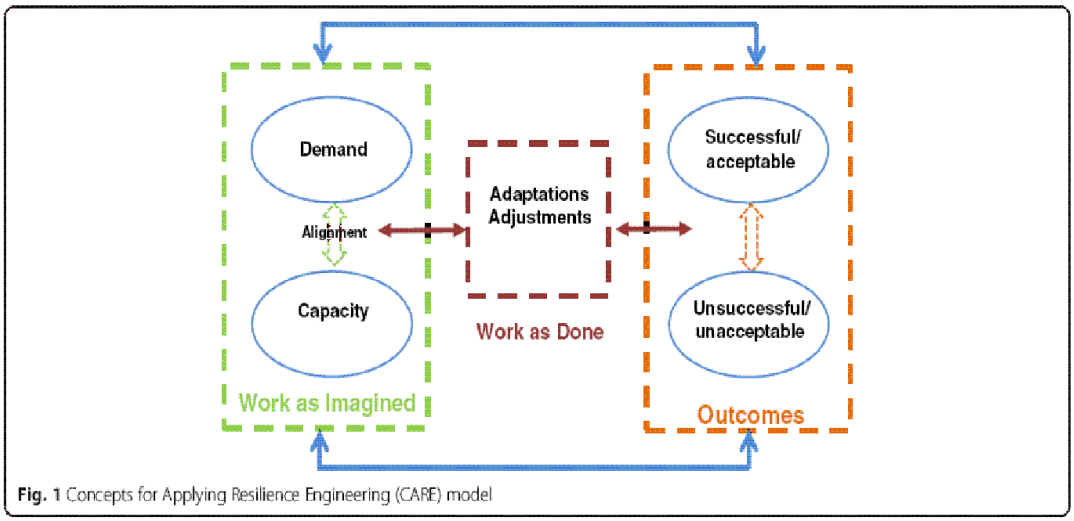


Figure 6.4: Concepts for applying resilience engineering (CARE) model (Anderson *et al.*, 2016)

Work-as-imagined is planned with an assumption that there is an alignment between demand and the capacity within the system to meet that demand. In the CARE model, work-as-done incorporates the adjustments needed to accommodate misalignments between demand and capacity.

The staff narratives were categorised into three groups according to how the adjustment was intended to manage the misalignment between demand and capacity (Back *et al.*, 2017):

- Reduce demand - Measures taken to try and reduce the level of demand that would otherwise be placed on the service.
- Increase capacity - Attempts to manage the capacity, such as bringing in extra resources or deploying current resources, including staff differently.
- Increase efficiency - Methods to improve the efficiency aiming to balance demand and capacity.

In addition, an evaluation was made combining the data gathered from the analysis using SEIPS 2.0 and incorporating that into an enhanced CARE model to demonstrate the disparity between the trigger for an adaptation and the aspect in which the adaptation was made.

6.4.6 Data collection from full V2V audit

The final data collection opportunity was the launch of the full V2V audit in the north-west of England. This involved a trial of the audit tools by Transfusion Practitioners employed in hospitals from this region, which was the first opportunity to examine whether the research could be scaled up to receive data from the questions outlined in Section 6.4.1 as part of the larger V2V audit in all UK hospitals. A brief evaluation of these data was carried out just before time ran out on the PhD study.

6.5 Results

The results from the four hospital visits have been analysed according to the sub-sections detailed in the methods section above (Section 6.4):

- Thematic analysis of responses to adaptation query (question 1)
- Quantitative analysis of supportiveness (question 2)
- Resilience Analysis Grid (RAG)
- Systems Engineering Initiative for Patient Safety 2.0 model (SEIPS 2.0)
- Concepts for Applying Resilience Engineering (CARE)

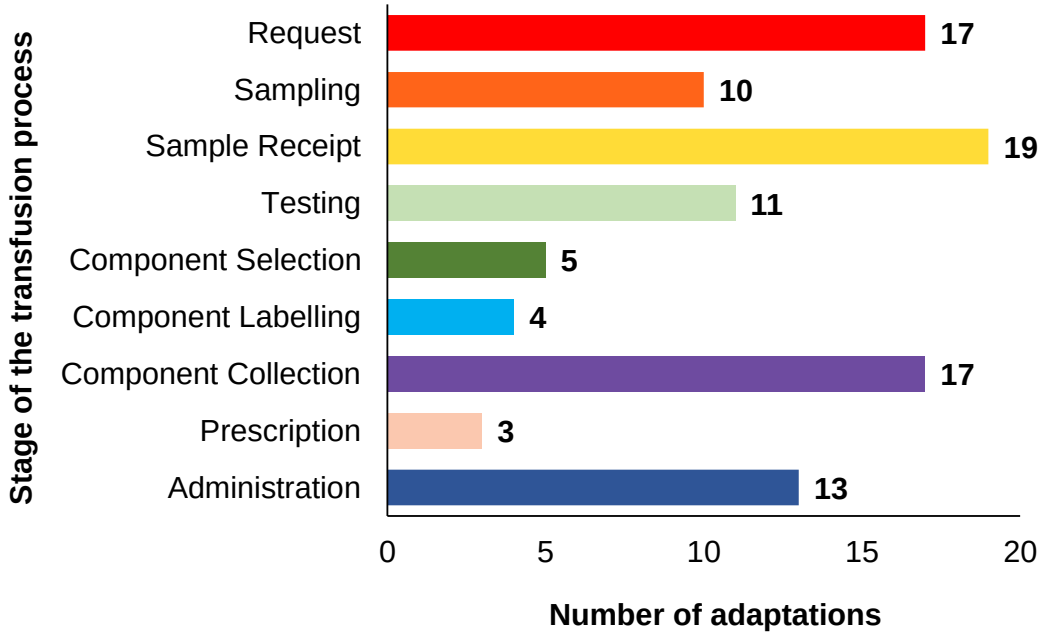
Plus an overview was performed of the early data collected via full V2V audit.

The adaptations narratives were documented by the author during interviews and later transcribed to an Excel spreadsheet for further assessment. The data analyses arising from these accounts were necessarily subjective, so the initial examination required an in-depth knowledge of blood transfusion, plus an understanding of human factors models and methods such as Resilience Analysis Grid (RAG); Systems Engineering Initiative for Patient Safety 2.0 model (SEIPS 2.0) and Concepts for Applying Resilience Engineering (CARE). The analysis was first undertaken by the author who is a blood transfusion subject matter expert and an experienced student of human factors, particularly via the studies for this thesis. Following the primary data analysis, categorisation of the adaptations was independently assessed by two PhD supervisors, who are subject matter experts in human factors and complex

systems. Classifications were discussed and adjusted as required following suggestions for change.

6.5.1 Findings from thematic analysis of question 1 responses

A total of 59 individuals were questioned in the four hospitals studied and all gave at least one example of a problem/adaptation. Several staff members described more than one adaptation giving a total of 99 and adaptations were seen at every stage of the nine-step transfusion process (Figure 6.4).



Colours coded to match those used in Figure 6.1 that have become synonymous with each transfusion step

Figure 6.5: Adaptations at each stage of the transfusion process

(Stages reproduced from Bolton-Maggs *et al.*, 2014 with permission)

In order to analyse the narratives, each story was transcribed into a spreadsheet. A count was made of the words in each narrative cell to assess whether the planned text box of 100-150 words would be a sufficient size. The results were:

Word count range	13 to 133
Word count mean	44
Word count median	37
Total narratives	99

Therefore, it was concluded that a text box size up to 150 words would be suitable when the audit tools were launched to all UK hospitals.

A thematic analysis of the narratives to examine why and how staff had adapted showed that amendments were sometimes made to attempt to improve the system if a potential failure were detected, while other changes were to overcome actual issues with processes and/or to cope with deficiencies in staffing, resources or training (Figure 6.5). These can be summarised as:

- Preferred adaptations to improve the system where the process has actively been amended due to noticing or anticipating potential problems or failures. These are likely to be more resilient adaptations, but are not always the most effective, because there may be constraints that staff cannot circumvent. An example would be adding a checking step as an adaptation due to anticipating failure, but if the check is needed because inexperienced staff have been employed elsewhere, then the ‘preferred’ adaptation is not the most robust solution.

care

- Forced adaptations when ideal solutions are outside of their control, so workarounds and coping strategies are required. Forced adaptations can be caused by many factors and have been categorised in Figure 6.5 to show general workarounds, but also the two largest subcategories i.e. the inability to affect IT design and the requirement to cope with staffing deficiencies, such as understaffing or insufficient training.

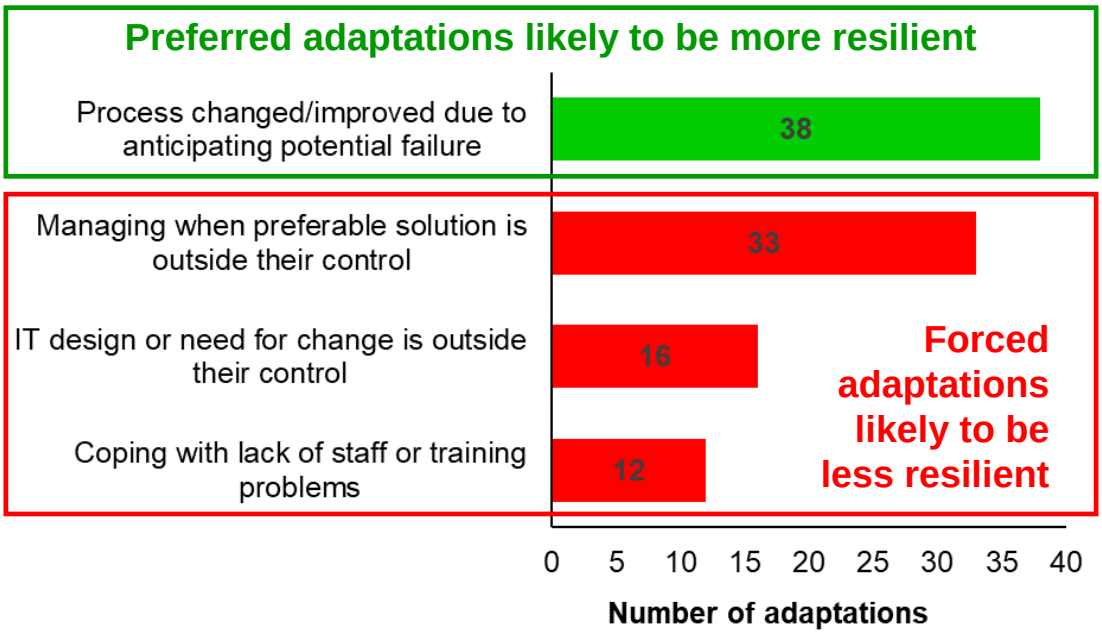


Figure 6.6: Type of adaptation made

A further analysis was undertaken to examine the efficacy of adaptations, by assessing the permanence status of the changes made. It was identified that adaptations could be permanent or temporary changes and an assessment was made as to whether the permanent adaptations were proactive planned quality improvements (Figure 6.6) or if the permanent changes were made because no other option was available.

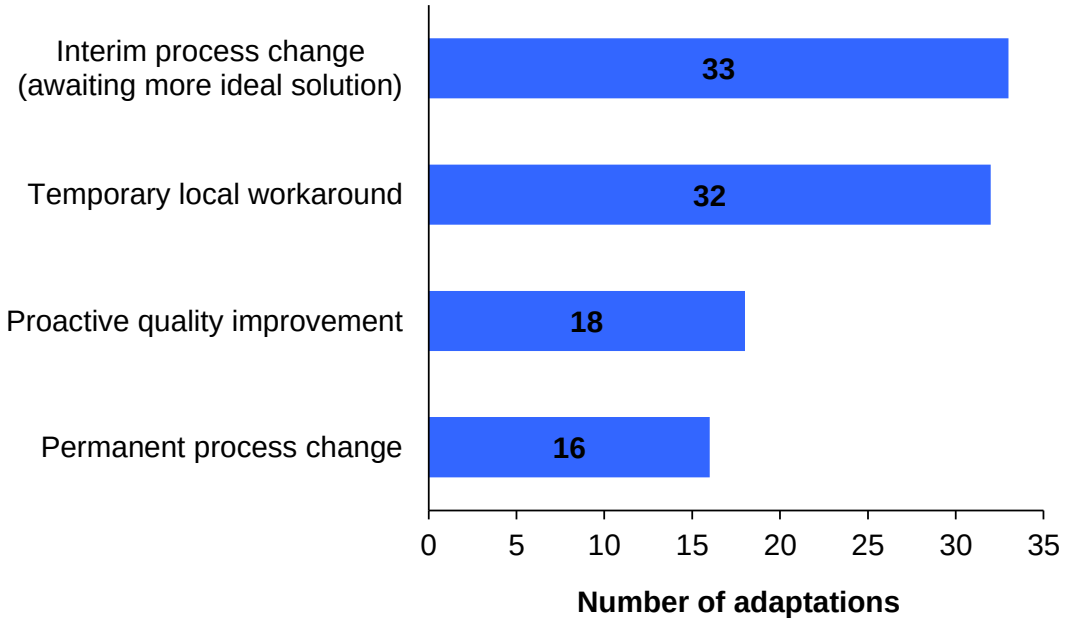


Figure 6.7: Permanence status of adaptations

There were 34/99 (34.3%) permanent adaptations of which 18 were deliberate amendments aimed at developing the system. These can be interpreted as quality improvements designed to enhance the process in comparison to the other 16 permanent process changes that were not system quality changes. In these situations, ideal solutions were not going to be available in the foreseeable future, so less than perfect permanent adaptations were made. Most changes made were provisional adaptations, approximately evenly spread between semi-permanent, interim adaptations (n=33), made while awaiting a more ideal solution or ad hoc, temporary local workarounds (n=32) that may have become normal custom and practice for a department or an individual.

6.5.2 Findings from assessment of question 2 about supportiveness

This investigation was designed to assess whether the adaptations met with managerial or departmental approval. The response most often given for question 2, "How supportive was your manager/department for how you solved the issue?" was not applicable (N/A), (73/99, 73.7%) (Figure 6.7), which indicates the adaptations were commonly made without the involvement of management or departmental colleagues. Good support, e.g. those scoring 5 (n=16) may point to the adaptation being suitable and, hence increasing resilient abilities. Poor support e.g. score 1 (n=4) could signify managers or colleagues have concerns about the safety consequences of the adjustment made to the standard process.

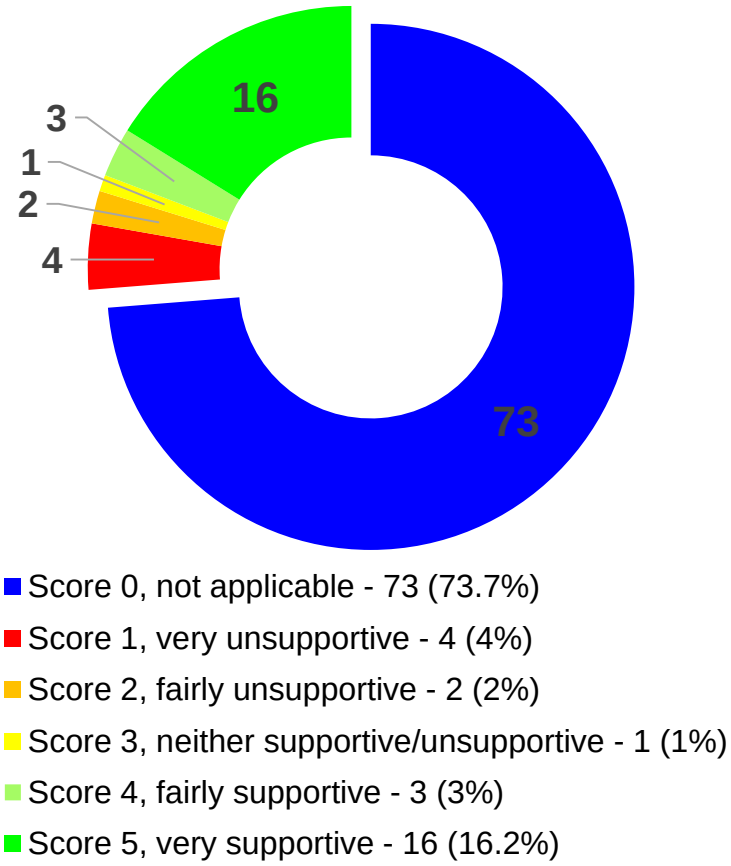


Figure 6.8: Supportiveness of manager/department for the adaptations

6.5.3 Findings from assessment using Resilience Analysis Grid (RAG)

The assessment of the four abilities of a resilient organisation, respond, monitor, learn and anticipate, could only demonstrate a limited insight into whether the system is performing in a manner that is resilient. Hollnagel (2011) has published a set of detailed issues related to each of the four abilities, but every adaptation is only a small snapshot of a larger process, so there was usually insufficient information for an in-depth assessment. Therefore, the adaptations were scored for the four abilities and a mean average was calculated for each of the four hospitals visited in this study. These averages were used to assess the overall level of the four abilities within the transfusion process of each organisation and displayed in a radar chart as established by the work of Hollnagel (2011) (Figure 6.8). These results showed the four hospitals scored averages from just under 2 to just over 3 within a 1 to 5 scale for each of the cornerstones. Therefore, it appears all the hospitals visited have room for further improvement.

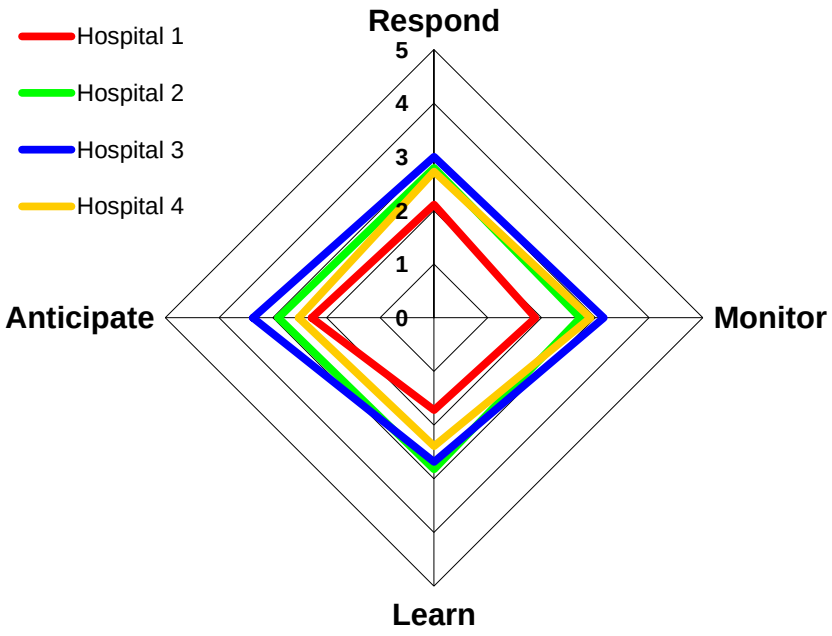


Figure 6.9: Resilience analysis grid (RAG) comparing the vein to vein transfusion process in four hospitals

6.5.4 Findings from assessment using Systems Engineering Initiative for Patient Safety 2.0 model (SEIPS 2.0)

The findings from the analysis carried out as described in Section 6.4.4 are summarised in Table 6.1, which shows that the mechanisms for change did not usually occur in the same part of the system as the trigger. Less than a third of adaptations were made in the same part of the system, 28/99 (28.3%); these cells are shaded to highlight where triggers and adaptations match.

Most commonly it was the process that was adapted (n=27) or changes were made to a specific task (n=18), which shows that adaptations are generally made within the sphere of influence of staff members. They have the authority to amend task or process aspects, but it may be outside their control to change other parts of the system, such as organisation and management issues or technology and tools, particularly information technology systems.

Table 6.1: Comparison of the initial trigger requiring a change with the system adaptation made

	Adaptation made through							
Adaptation triggered by	Person(s)	Tools/technology		Task/process		Internal environment	Organisation/ management	**Totals**
		IT	Non-IT	Small task	Large process			
Person(s)	2	5	0	8	14	0	1	**30**
Tools/technology (IT)	1	4	1	7	8	0	0	**21**
Tools/technology (Non-IT)	0	1	4	5	6	0	0	**16**
Task (small task)	0	0	0	4	0	0	0	**4**
Process (large process)	1	2	0	0	11	0	0	**14**
Internal environment	1	1	2	2	1	3	0	**10**
Organisation/ management	0	0	0	2	2	0	0	**4**
Totals	**5**	**13**	**7**	**28**	**42**	**3**	**1**	**99**

6.5.5 Findings from assessment using Concepts for Applying Resilience Engineering (CARE)

This study aimed to research how staff managed difficulties, so it is expected that the adaptations made would demonstrate some level of misalignment between demand and capacity. Figure 6.9 depicts the adaptations categorised into groups according to how the adjustment was intended to manage the divergence between demand and capacity by increasing efficiency or capacity or by reducing demand. In addition, Figure 6.9 includes colour coding to show the author's assessment of the likely outcome of the adaptation ranked from excellent to very poor. It is important to note that the assessment of potential outcome was a subjective evaluation done by the author. The judgement was based on extensive expertise in the field of transfusion, but was inevitably dependent on the quality of information provided and could therefore be imperfect.

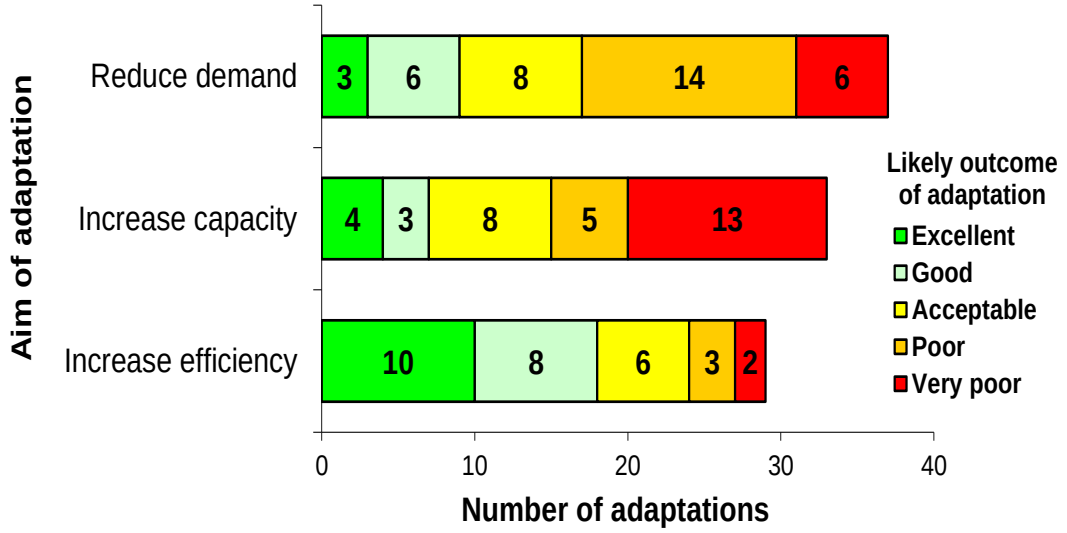
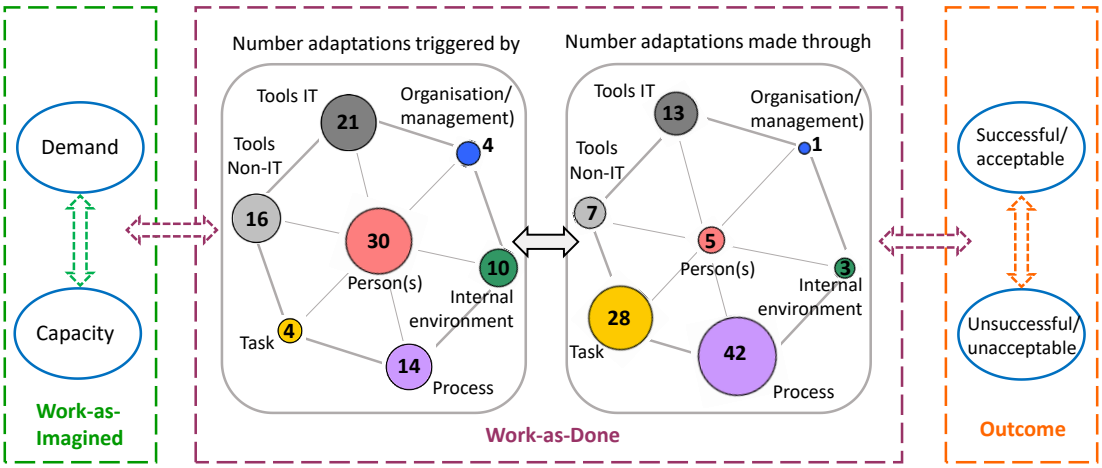


Figure 6.10: How adaptations aim to manage demand/capacity and the consequent likely outcomes of the adaptations made

6.5.6 Findings from using an enhanced CARE model

As a result of the findings of triggers and types of adaptations, an enhanced CARE model was developed as shown in Figure 6.10. The original CARE model shows that the same adaptive processes can potentially have either successful/acceptable or unsuccessful/unacceptable outcomes. The analyses performed in this research examined in more depth the ways adaptations were triggered and then enacted. The SEIPS 2.0 model helped categorise both the triggers of adaptations and the various system components adapted and these are illustrated by Figure 6.10, which uses scaled circles to demonstrate the disparity visually between the system components in blood transfusion where triggers for adaptation are most common, i.e. staff-related issues (persons) and IT problems, and where adaptations actually occur, i.e. task and process aspects of the system.



Size of circles in the Work-as-Done box are scaled to correspond to the data in Table 6.1

Figure 6.11: An enhanced CARE model embracing the SEIPS 2.0 adaptation mechanism

An alternative combined SEIPS 2.0 and CARE model is proposed as depicted in Figure 6.11, which could be used as a mechanism for assessing likely outcomes of adaptations. This model identifies that the trigger in the system is the disturbance between demand and capacity as suggested by the CARE model, then the triggers can be categorised using SEIPS 2.0, as shown by the findings reported in Section 6.5.4. A subject matter expert would probably be

required to assess the adaptations, but the Transfusion Practitioners who are most likely to carry out these resilience audits are experts in the field. Their assessment could be augmented by using the techniques described in this research, i.e. analysing if the trigger and adaptation are in the same or different aspects of the SEIPS 2.0 model, evaluating the supportiveness score and considering the permanence status of the adaptation to identify proactive quality improvements or temporary local workarounds.

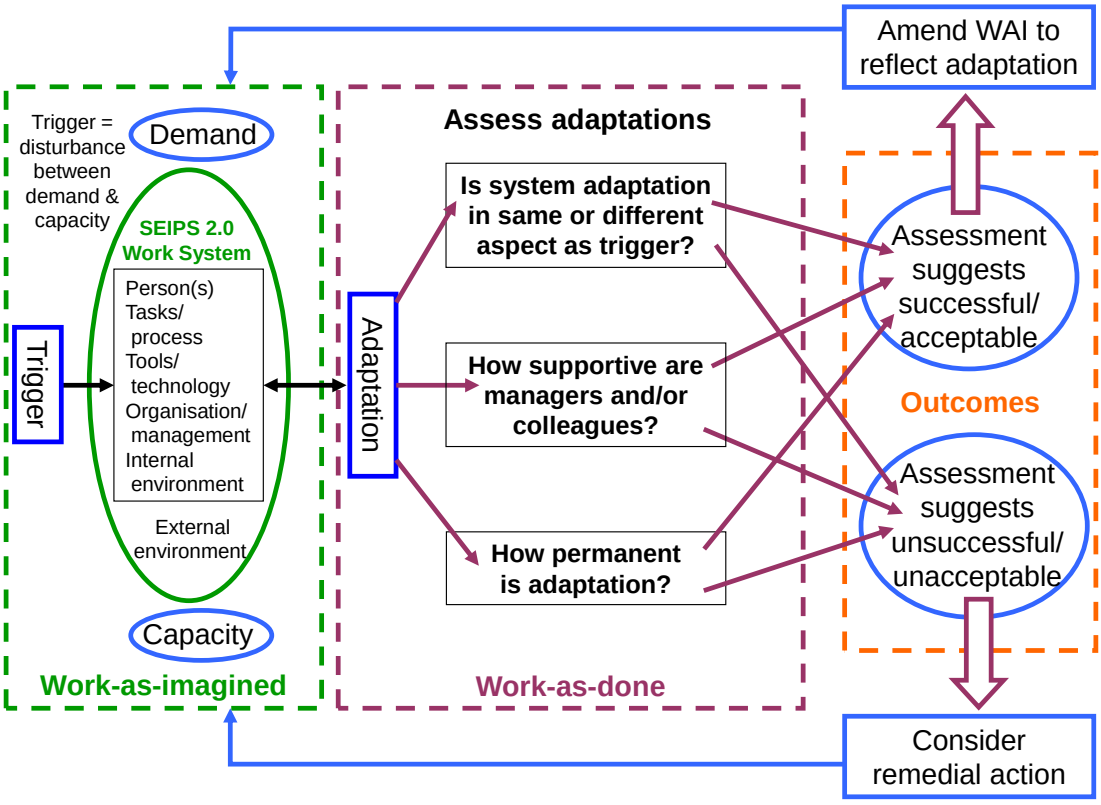


Figure 6.12: Combined SEIPS 2.0 and CARE model, which could be used to assess likely outcomes of adaptations

A worked example using the model proposed in Figure 6.11 is shown in Figure 6.12, which tracks two real-life adaptations (Examples 1 and 2) from the hospital visits through the model. The examples are colour coded pink (Example 1) and light blue (Example 2) to facilitate ease of tracking and they are assessed respectively as likely to be successful/acceptable or unsuccessful/ unacceptable, using the analyses already performed on those two adaptations. Example 1 was categorised as an adaptation in the same

aspect of the system as the trigger, scored 5/5 for supportiveness and is a permanent amendment to the process. Conversely, Example 2 was categorised as an adaptation in a different aspect of the system from the trigger, scored N/A for supportiveness and is a temporary local workaround.

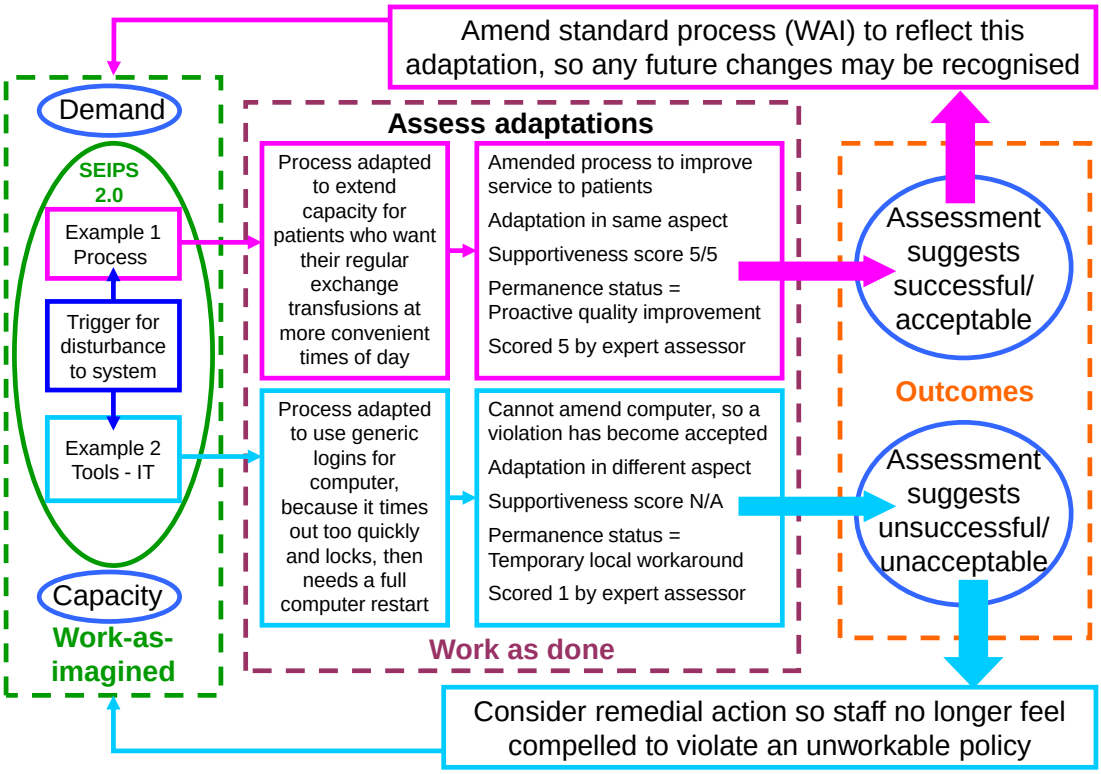


Figure 6.13: Worked example of combined SEIPS 2.0 and CARE model, used to assess likely outcomes of adaptations

6.5.7 Findings from data collected via full V2V audit

Shortly before the end of the PhD study, the full vein to vein (V2V) audit was launched to selected hospitals in the UK and the questions forming this research were included, as detailed in Section 6.4.1. The V2V pilot audit diary is at Appendix 8. Two hospitals, designated A and B, submitted data in time for evaluation and their results are summarised in Table 6.2. Coincidentally, Hospital A was the same as one of the hospitals visited during the author's research, which allows a unique opportunity to compare results obtained by the author with those conveyed by the local auditors.

Table 6.2: Summary of results from two hospitals piloting V2V audit

	Hospital A	Hospital B
Audits completed	9 1 audit at all nine steps	26 13 audits at each of 2 steps: - Component collection(G) - Prescription(H)
Adaptation narratives (Q1)	7*/9 (77.8%)	7/26 (26.9%)
Supportiveness scores (Q2)	All 7 scored 5	All 7 scored N/A
Trigger/Adaptation same	0	1
Trigger/Adaptation different	7	6
Interim process change	3	0
Temporary local workaround	4	5
Permanent process change	0	2
Proactive quality improvement	0	0

Notes: *1 adaptation was extracted from responses to other audit questions
Hosp A was visited by author, so is also included in original study

The number of results is small, so absolute conclusions cannot be made, but there are some noteworthy findings. Both hospitals often did not complete the HF questions, particularly hospital B, which only gave a response in 7 of 26 (26.9%) audits. All the scores from hospital A were 5/5 for the supportiveness of their manager/colleagues, but comparing these local results to the data obtained in the author's visit there is a disparity. The previous supportiveness scores were N/A in 21/33 (63.6%) and where scores were given, they ranged from 1 to 5. Hospital B gave the more common N/A for supportiveness in every response.

6.6 Discussion

Based on previous research into hassles in a hospital dispensary (Sujan *et al.*, 2011a;b and Sujan & Furniss, 2015) it was anticipated that comments about the causes of problems and the outcomes of any adaptations would flow naturally from the request for a brief overview of any difficulties faced. The results from the four hospital visits proved this to be valid with all 59 individuals interviewed giving narratives that detailed 99 problems and solutions. The adaptations described covered all nine steps of the transfusion process (Figure 6.1), which gave a comprehensive dataset for further analyses.

Adaptations may be more likely to happen in healthcare where staff are affected by changeable work system elements and therefore react and adapt to the work system (Carayon *et al.*, 2014). A thematic analysis of the 99 adaptations described showed they are generally made within the sphere of influence of staff members. They usually adapted to overcome actual or potential difficulties with the system and to cope with deficiencies in staffing, including training issues, or resource issues, particularly poor IT systems. The types of adaptations were classified into preferred, which show the surrounding system is adequate, but a development of the process may improve performance and well-being; or forced, which indicate the surrounding system is inadequate, so people may need to adapt to get work done (Figure 6.5). Some preferred adaptations may be good practices with lessons to be shared and these should be implemented as part of normal work procedures. In contrast, adaptations that are forced may not be desirable, so are unlikely to be suitable for shared learning, but they may be valuable indicators at a local level of a system that is liable to fail, i.e. a potential future accident/incident could be prevented. Regrettably, this binary distinction of preferred or forced does not always correlate to good or bad practices. Preferred adaptations may have been forced by circumstances when a different solution would have been safer and forced adaptations may be examples of good practice dependent on the circumstances. Then, even more confusingly, the same adaptation can be good practice in many situations until different conditions turn it into poor practice.

The probable efficacy of adaptations was assessed by considering the permanence status of the changes made. If the permanent adaptations were proactive planned improvements (Figure 6.6) these could be considered quality improvements or system developments and were likely to be more resilient changes than adaptations that had been permanently implemented when more appropriate options were possible, but were not available to the staff making adaptations. Interim adaptations while awaiting a more ideal solution or ad hoc, temporary local workarounds were the least likely to be effective adaptations. In considering the permanence status of adaptations, a

spectrum of changes was revealed that gave an indication of whether the adaptation would be a long-term success or was a short-term workaround.

The aim of the Likert-scale second question was to assess the level of managerial or departmental support for the adjustments being made, but the high number of N/A scores (Figure 6.7) may demonstrate there was insufficient endorsement, often because managers and colleagues were not made aware of changes implemented, which may reduce the opportunities for resilience. Characteristically the reason for this shortcoming was because the staff making adaptations either had no confidence that raising the problem with others, especially management, would result in any improvement, or they were aware that they were deliberately not following standard processes, hence were breaking the rules.

The results from the investigation using the Resilience Analysis Grid (RAG) were of limited use, because most adaptations related to a small phase of the procedure. RAG may be a useful method for determining the resilient abilities within a defined process in healthcare organisations, as demonstrated by this evaluation of the complete transfusion process in four hospitals, but the in-depth use of RAG is more suited to defining the potential for resilience in an entire system or organisation (Hollnagel, 2015b). There was not enough information within a single adaptation to assess the detailed issues relating to each resilience ability (respond, monitor, learn, anticipate). Instead, a simple assessment was made of the average scores for each ability within each organisation, which allowed a comparison of the resilience potential of all four hospitals in each resilience ability.

Using the Systems Engineering Initiative for Patient Safety 2.0 model (SEIPS 2.0) it was found that adaptations were often forced upon the employees by unforeseen issues. The difficulties that were addressed by adapting the same part of the system as the trigger were less than a third 28/99 (28.3%). In contrast, over two-thirds of adaptations (71/99, 71.7%) amended a different part of the system (Table 6.1) and changing a different aspect may be a less desirable adaptation, though not necessarily less resilient. Equally, even

adaptations that are made in the same aspect as the trigger are not always the most ideal solution, because of wider limitations, such as resource constraints. An example of this is an adaptation made in recognition that if a patient collapsed while being transfused sitting in a chair, they would need to be laid flat for resuscitation. A resilient adaptation has been made to purchase transfusion chairs that can easily be made into a flat bed, but these are expensive and there is no budget to replace them all. Therefore, some patients are still transfused sitting in rigid chairs and would have to be laid on the floor if resuscitation were needed.

The two largest triggers requiring staff to adapt were staff-related issues (persons) and poorly designed health Information Technology (IT) systems that could not be amended or redesigned in a timely manner, if at all (Table 6.1). Although those triggers accounted for over a half of all adaptations (51/99, 51.5%) the most common adaptations made were changes to the individual task, or larger process (70/99, 70.7%). Therefore, it seems staff are often unable to resolve the cause of the disturbance to the system, i.e. they do not have the power to improve staffing or amend IT, so they adapt elsewhere in order to make the system workable. These results may also relate to a tendency to ‘find and fix’, i.e. staff adapt in order to resolve a difficulty, then may forget about it when other priorities take over. Research has defined three types of find and fix (Jeffs *et al.*, 2012): (1) 'doing a quick fix’ with no further action; (2) ‘going into a black hole’ where problems are reported, but no feedback is received and (3) ‘closing off the Swiss-cheese holes’, in which the reported problem is corrected at an organisational level, which would be the most resilient amendment. It has been shown that healthcare staff may not prioritise reporting if a safety problem is fixed (Hewitt *et al.*, 2015), thus removing the opportunity to learn lessons and possibly resolve the difficulty at management level. The responses to question 2 bear this out with 73/99 (73.7%) adaptations remaining unreported to managers or colleagues. Of those not reported to managers or colleagues, 54/73 (74%) showed the adaptations were made in a different part of the process to the underlying difficulty. Of these, 36/54 (66.7%) had a trigger related to either IT or person issues. These two difficulties are often problematic to resolve at organisational

level, so employees accurately assess that their pleas for more resources are unlikely to succeed. Therefore, staff adapt elsewhere and do not report the actual problem, particularly if they know it is management policy to cut finances for IT and staff. Under-resourcing of the UK NHS means adaptations can result from an acceptance that requesting improved staffing, training or equipment is not realistic.

The Concepts for Applying Resilience Engineering (CARE) model identifies that divergence between demand and capacity would be the cause of problems leading to a mismatch between work-as-imagined and work-as-done. Applying the CARE model to the data, showed that the attempt to manage the misalignment was not always achieved by the adaptation made to increase efficiency or capacity, or to reduce demand (Figure 6.9). Hence, the adjustment could be assessed as unlikely to be resilient and the potential outcome could be poor. Other examples of adaptations were judged as likely to be more resilient and therefore acceptable. However, success and failure are not fixed categories and will be subject to interpretation and judgement based on the context (Anderson *et al.*, 2016). This shows there is a drawback if healthcare organisations blame individuals for an incident that occurs after amending a standard process, because the same adaptation might have previously been required on numerous occasions and have proved successful. An organisation employing a just culture would have a more equitable method of assessing such incidents (Dekker, 2012).

The development of an enhanced CARE model (Figure 6.10) enabled the inclusion of additional details about the adaptation triggers and mechanisms from the SEIPS 2.0 model and therefore provided further support for studying organisational resilience. This may provide examples of good practice to be widely shared. The enhanced CARE model can help to develop an in-depth understanding of organisational resilience and could show whether different parts of healthcare organisations have a different prominence of various system components in adaptation triggering and resultant mechanisms of change (different size of the circle, as in Figure 6.10). The newly proposed framework may also have the potential to build on the work already undertaken

for Study 2 in the area of learning from incident analysis and this could be an area for further study.

An alternative combined SEIPS 2.0 and CARE model is depicted in Figure 6.11 and was used to work through two examples from the adaptation narratives (Figure 6.12). Example 1 demonstrated a permanent adaptation that is in the same aspect of the system as the trigger and was scored 5/5 for supportiveness of the manager/colleagues. This amendment can be classified as a quality improvement, because the system has been changed to make it more convenient for patients who require a specific type of regular transfusion known as an exchange transfusion, commonly used to treat conditions like sickle cell disease, where patients simultaneously have their own blood removed and replaced with donated blood. This treatment can take many hours and may need repeating monthly, so it can be inconvenient in the lives of otherwise fairly healthy individuals. Amending the system to accommodate more convenient timing is a service improvement and enhances safety, as patients are more likely to keep their regular appointments. Using expert knowledge of the transfusion process, this can be assessed as likely to be a successful adaptation, so following through the CARE model the outcome should be to amend the standard process, i.e. the work-as-imagined, so any future drift from the revised normal process can be monitored. In contrast, Example 2 showed a temporary local workaround of using a generic login that is in a different aspect of the system from the trigger and was scored N/A for supportiveness of the manager/colleagues. This amendment is a violation of the standard process, but it has become accepted local practice with staff knowingly contravening the IT regulations in order to solve a problem with the way the computer has been configured. At the local level, staff are unable to amend the IT system and the not applicable (N/A) score for supportiveness indicates they have probably not raised the problem with senior managers, possibly because they have no confidence the issue would be resolved.

Analysing the limited results from two further hospitals undertaking the full V2V audit indicated the data achieved in the hospital visits by the author may not be scalable when the studies are being undertaken by local audit staff. Results

from hospital A were useful, because that institution was also visited by the author, so earlier results are available for comparison. As an example, the supportiveness scores were very different from the previous visit. This may have been because the local audit was carried out by a senior manager, so staff may have been less likely to admit to adaptations of which that manager was not aware or supportive. This shows a potential major flaw when this audit is launched nationwide, because staff may be less candid when discussing problems and adaptations in interviews or audits undertaken by their colleagues. Conversely, it may have been that in this case a senior manager who was committed enough to participate in a trial of a national audit is generally a very supportive and involved manager, so the 5/5 scores were merited in those circumstances.

The problem with obtaining different results from local auditors appears to be a similar issue to that encountered in Study 2, where it was shown that local incident investigators may not have sufficient knowledge of human factors and complex systems to give fully reliable scores when assessing incidents for the human factors investigation tool (HFIT). The local auditors who will be participating in the V2V audit will often be the same individuals as the investigators of transfusion incidents, particularly each healthcare institution's Transfusion Practitioner(s). Identifying a lack of HF understanding amongst local transfusion auditors and incident investigators is not meant as a criticism of the individual staff members, because human factors is a completely separate academic profession and for the duration of these studies there was no requirement for transfusion staff to have any knowledge or experience of the subject.

In order to give the local auditor some assistance with completing the HF questions in the V2V audit, some prompt questions have been developed, which should lead respondents towards giving more information. Details are in Appendix 7. Another problem with the two local audits was that sometimes a problem was listed, but no solution given, which meant it was not possible to assess the adaptation. When the V2V audit is fully launched it will need to include some advice to encourage local auditors to probe further when

participants identify a problem and to allow interviewees time to consider issues they may have had previously with each task. The hospitals visited by the author did not show a single instance of failure to give a narrative of a difficulty and the solution, but that has been shown to be a considerable problem in the two local audits.

6.7 Limitations

There were a few limitations of the research for Study 3 of which the most crucial were the time constraints. The original intention was that the proof of concept for the HF questions studied here would be the forerunner of further data collection following a full launch of the nationwide V2V audit. However, there have been considerable delays to the launch which were outside the control of the researcher. Some conclusions can be drawn from results supplied by two hospitals piloting the full V2V audit, but a larger dataset for comparison would have been very advantageous to this research.

There was a small issue that the geographical spread of the hospitals visited by the author was limited to institutions in England only, although the audit will be available throughout the UK, including the countries with devolved healthcare. Similarly, only NHS hospitals were visited, although non-NHS and private healthcare organisations will be included in the audit process. However, it would not have been a sensible use of time to visit hospitals where only parts of the transfusion process were carried out and many non-NHS establishments, along with smaller NHS hospitals, may contract out parts of the process, particularly the laboratory stages.

There were some drawbacks with the methods and analyses used, which are discussed in the relevant sections above. A particular difficulty was the use of the Resilience Analysis Grid (RAG) where issues were encountered, because it was not ideally suited to examining individual adaptations, so the four abilities of a resilient organisation adaptations could not be analysed in more detail as suggested by Hollnagel (2015b). However, the grid was developed to allow a comparison of resilience between several healthcare institutions and this could become a useful enhancement in real practice.

An overall limitation was the dependence on questioning individual staff members, because that relies on the employees giving open and honest responses. There is no reason to suspect interviewees were not sincere or truthful with their replies, but if their employers do not have a no blame or just culture (Dekker, 2012) that could influence their level of trust that their responses would remain off the record and not held against them. This is less likely to have been an issue with the studies carried out by the author, but these concerns might have affected replies when the questions were asked by local auditors.

A final limitation is related to the qualitative and interpretivist approach to the analyses in the results section. These depended on subjective classifications made initially by the author. The potential for bias or prejudice was mitigated with checks on the categorisation carried out by experienced HF professionals.

6.8 Conclusions

The aim of this study was to increase the recognition and appreciation of the major role played by adaptations within the transfusion process. Through this understanding, the intention was to use a Safety-II approach to enhance the clinical audit process, which has so far been limited to considering where processes deviate from expected guidelines, standards and policies. A publication from the National Institute for Clinical Excellence (NICE), now known as National Institute for Health and Care Excellence, (NICE, 2002) includes the definition 'Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria…'. The final two words of that extract are highlighted by the thesis author to underline that standard clinical audits are usually constructed to show if staff are following policies and guidelines. An updated guidance for best practice has been published by the NHS England Healthcare Quality Improvement Partnership (HQIP) which gives a similar definition 'Clinical audit is a quality improvement cycle that involves measurement of the effectiveness of healthcare against agreed and proven standards for high quality…' (NHS HQIP, 2016a) and again the highlighted section shows the

focus on auditing against pre-defined standards. In addition, the NHS is very highly regulated and a study to map the landscape of regulation in the English NHS, i.e. excluding the devolved healthcare systems in the UK, identified that at least 126 organisations have some safety regulatory effect (Oikonomou, 2019). This convolution of monitoring places a substantial burden on the NHS and overlapping or contradictory regulatory interventions may adversely affect local plans to expand quality and safety. Hence, audits are often seen as a penalising activity, by which staff may be disciplined if deviations are seen. Audits may therefore not be meaningful or truthful, as they are not designed to uncover or understand the many adaptations made by staff to cope with dynamic healthcare problems. Therefore, traditional clinical audits do not encourage potential learning from adaptations.

Healthcare staff are affected by erratic work system components, so they may be more inclined to react to such changeability by making adaptations, because the general lack of resources in healthcare can lead to inadequate systems (Carayon *et al.*, 2014). There is a problem for healthcare workers in balancing the system between total rule compliance, and autonomy or liberty to discharge their duties according to knowledge, experience and the prevailing circumstances. This is made more challenging when the conditions are not ideal, but that is beyond the control of those working in the system.

Adaptations show the difficulties involved in healthcare delivery and each task needs to be evaluated to select what is best for that part of the work system (Hale & Swuste, 1998; Hale & Borys, 2013 a,b). Healthcare has been depicted as a complex adaptive system (Braithwaite *et al.*, 2013) in which continual adjustment is unavoidable. Therefore, adaptations are often regular modifications that healthcare professionals make in their day to day work, rather than uncommon rarities. The adaptability of individuals in work systems has been acknowledged for decades (Rasmussen & Jensen, 1974), as has the relationship between error and adaptation (Rasmussen, 1990). Human behaviour is inclined to drift towards the boundary of acceptable performance (Rasmussen, 1997). As a result, the design of work systems needs to understand that conditions cannot always be predicted and adaptation should

be nurtured, rather than plan to use common tools and methods alone, such as task analysis (Rasmussen, 2000; Hopkins, 2019).

Adaptations can be a demonstration of the Efficiency-Thoroughness Trade-Off (ETTO) theory (Hollnagel, 2009), which emphasises the conflict involved in balancing risk and safety. ETTO is a mechanism to portray the adjustments that form part of everyday operations in complex socio-technical systems, such as healthcare. Healthcare IT is a good example of the ETTO principle, whereby the efficiency of introducing computerised systems quickly, and often piecemeal, in healthcare can be perceived as a trade-off against the thoroughness that would be required to construct interconnecting, fully configurable IT systems. The research in Study 3 has exposed IT difficulties as a key reason for making system changes and IT adaptations have previously been well recognised (Holden *et al.* 2013b; Novak *et al.*, 2013). IT workarounds are ubiquitous, and badly designed IT is an enduring issue concerning patient safety. IT security may be sacrificed, because staff feel compelled to adapt to be able to complete their tasks. Wears and Hettinger (2014) identify the adaptability of people within a system as a tragedy, because it presents a false impression of equilibrium within a dysfunctional system. Adaptation involves the capability to adjust through reorganisation of available resources, so failures have been described as an inability of the system to adapt to disturbances given finite resources and therefore trade-offs can be made as a result of unrelenting pressure on resources. Organisational resource constrictions can amplify exposure to risk (Madni & Jackson, 2009).

In addition, accumulating resources from a common pool has been revealed as a practice that produces an extra margin locally, but is often to the detriment of other areas that may need the resources that are being hoarded (Stephens *et al.*, 2011). The research of Stephens and colleagues showed three ways that resources could be treated: defensively to restrict actions of others, autonomously by reorganising to create new margin, or cooperatively by working with others to maximise common pool resources. It has been suggested by studies of common pool resource management that polycentric

controls can balance extremes in order to establish resilient systems (Ostrom, 1999).

Transfusion is a highly regulated area of healthcare, for example there are in excess of 250 international guidelines related to transfusion practices (ISBT, 2019a), so there does not seem to be much freedom for staff inventiveness, especially when this is contrasted with a total of 128 international safety standards in the nuclear industry (IAEA, 2019), which is often identified as a high reliability organisation (HRO). Healthcare institutions often aim to emulate HROs such as the nuclear industry (Health Foundation, 2011), but limited resources mean it is unlikely that healthcare could attain the features found in HROs, such as extensive training and redundancy (Jeffcott *et al.*, 2009).

In summary, Study 3 showed that staff tended to make adaptations within their sphere of influences, so managers or senior staff were more likely to have the power to make potentially resilient changes, because they had the necessary authority. By asking two simple queries concerning issues faced, the resilience audit method introduced in this research used Safety-II principles to improve the clinical audit process. The methods used in this study could be tailored for use as a proactive part of regular local clinical audits to highlight where adaptations are being made. There are similarities to the observational work done in air traffic management (ATM), i.e. Normal Operations Safety Survey (NOSS) (Skybrary, 2016) and the aviation audit procedure that uses trained observers in normal flights, Line Operations Safety Audit (LOSA) (Skybrary, 2017). In the United States of America, the Vanderbilt Center for Patient and Professional Advocacy, based at Vanderbilt University Medical Center, has developed a proprietary observation system known as CORS^{sm} (Co-worker Observation Reporting System) which is used to produce timely feedback designed to encourage self-reflection and promote accountability in healthcare staff (Webb *et al.*, 2016). The resilience audit technique could be introduced to inspire staff to assess their own adaptations in an ongoing fashion, so that standard processes could be adjusted dynamically allowing any drift into failure (Dekker, 2016) to be monitored actively.

Future work could include developing the RAG assessment, which was used in this research to assess the overall potential for resilience in the transfusion process. If a RAG tool could be produced for use by each hospital, that process could in turn be used as a comparison device for regional transfusion committees (RTC) and the equivalent bodies in the devolved countries of the UK. RTCs and similar bodies already monitor transfusion practice in matters such as incident reporting, so it would be an additional benefit for comparisons to be examined routinely in the area of resilience.

Chapter 7 Overall discussions and conclusions

7.1 Chapter summary

This chapter amalgamates and integrates the lessons learned from the research throughout the PhD studies. The aim is to demonstrate how the research carried out in these studies has answered the primary research question of whether human factors (HF) could contribute to improvements for the safety of patients receiving a blood transfusion. Where the research has raised further questions and highlighted other areas in which improvements could be made, these are assessed and ideas for future research are incorporated into the overall discussion and conclusion.

7.2 Summary of findings

The main objective of these PhD studies was to apply and evaluate HF-based methods that could improve transfusion safety. The three individual studies carried out in this research have demonstrated some novel and thought-provoking outcomes. The main findings can be examined from the perspective of each research question asked.

7.2.1 What can we learn about human and organisation factors contributing to transfusion incidents and near misses from the existing incident database?

The short answer to this question was that very little could be learnt from the existing incidents reported to the UK haemovigilance scheme, Serious Hazards of Transfusion (SHOT). The main objective for Study 1 was to investigate whether it is possible to elicit information about system and organisational aspects from existing transfusion incident reports. A secondary objective was a comparative review of human factors models and methods to decide which would be most suitable for extending Study 1 to analyse the system and organisational factors in the thousands of existing error-related reports in the transfusion incident database. However, it was difficult to achieve either objective fully, because it became clear that there was insufficient information in many reports to perform a meaningful HF-based analysis.

Three major findings emerged from the research in Study 1. The first and most vital, was that the historical reports often did not contain sufficient information to analyse the incident for system and organisational factors related to the error. The lack of information is mainly because the original questions asked in the database were designed to elicit information about the type of incident being reported, deviations from standard practice, the clinical and scientific details related to the case and the outcome for the patient. Where questions are asked about the error they tend to concentrate on the transfusion-related elements of the incident. Secondly it became apparent that those making reports to the transfusion incident database tended to concentrate on the culpability of individuals, so they seldom gave any useful information about other contributory factors. The final outcome was the knowledge gained from the review of strengths and limitations of different HF methods/models to investigate what could be used for both this retrospective study and a potential prospective study (Study 2). A very simple HF framework for incident database analysis was tried, because the quality of data available was not known. It transpired that the quality of data is biased too much towards human error and thus does not include sufficient detail about underlying factors, so lessons that could be drawn from this HF analysis of historically reported incidents were limited. However, the information gained from the investigation of different HF models/methods inspired the use of the SEIPS 2.0 model for Study 3, because it represents various system structure components and adaptation aspects of the process.

7.2.2 Can incident reporting be improved using a newly created human factors investigation tool?

Necessity is the mother of invention and it could be argued that the major outcome from Study 1 was the requirement to invent a human factors investigation tool (HFIT) to gather the data needed in order to be able to assess the human factors related to transfusion incidents. A simple to use scheme was required to encourage incident reporters to consider human and organisational factors when reporting errors to the transfusion incident database, so a bespoke tool was created to estimate the relative involvement

in the adverse incident of individual staff member(s); the local environment or workspace; organisational or management issues and conditions associated with government or regulatory issues.

The HFIT was instigated at the beginning of 2016, then data were analysed each calendar year across a period of three years. The rationale behind carrying out the analysis on a full year's data was to mirror the routine analyses done by SHOT experts on the data collected each year. That meant the data being analysed for Study 2 related to incidents that were also fully substantiated as valid transfusion-related errors. Within the three-year study, two educational interventions were introduced for the second and third years and the relative success of these interventions was also assessed.

In summary, the main findings from Study 2 included the confirmation that incident reporters tend to attribute most accountability for incidents to the staff member(s) involved, with total scores at about 60% culpability for individuals, which is unlikely to be a legitimate assessment of the contribution of human failings to transfusion incidents, as studies have shown 10% would be a more accurate estimation (Reason, 1997; Karl & Karl, 2012). Disappointingly, this was not ameliorated by the provision of two sets of self-learning material that were aimed at facilitating more reliable scores for the factors contributing to an incident. There was a limited effectiveness of this intervention in improving the quality of blood transfusion incident reporting about system level factors. It may be that incident reporting is not an appropriate mechanism for learning about underlying contributing factors. SHOT has used incident reporting for identifying and monitoring previously unrecognised trends and risks in transfusion practice, rather than investigating causal mechanisms of errors. The NHS National Reporting and Learning System (NRLS, 2019) similarly monitors trends and new risks, rather than examining error causes. Hence, this study demonstrates these limitations of incident reporting systems and confirms the purpose of incident reporting should be to identify new risk patterns. Separate work by experts on further investigating underlying mechanisms is needed, rather than attempting to make the incident investigators into systems experts.

7.2.3 Can a Safety-II approach improve clinical audit and maximise system resilience throughout the end to end blood transfusion process?

Studies 1 and 2 were based on existing Safety-I principles for incident investigation, so it was important to investigate whether a Safety-II approach could also be introduced to improve the overall safety of blood transfusion. Therefore, the research moved on to examine the clinical audit process in order to investigate methods for a proactive analysis of the end to end transfusion process. A straightforward data collection method was devised based on an open question asking staff to detail the biggest or most recent difficulty that they have faced when carrying out their role in the transfusion process and what they did about the issue. This elicited a valuable array of data on adaptations that staff make to get their day to day work done, which was enhanced by a follow up question about the support these adaptations received from managers and colleagues. Several HF-based models were used to analyse the data and as result an enhanced Concepts for Applying Resilience Engineering (CARE) model was developed, which incorporates aspects of the Systems Engineering Initiative for Patient Safety 2.0 model (SEIPS 2.0).

The key finding from the third study was that in approximately two-thirds of the adaptations made by staff in work-as-done, the adaptation was made in a different aspect of the system from the aspect that was defined as the trigger necessitating the modification. This shows that the way risk is prospectively managed by clinical audit may need to be modified to reveal work-as-done more effectively than current methods allow.

7.3 Discussion of findings from research studies

There are three main outcomes from the research:

1. Traditional transfusion incident reports were incomplete to the extent that they often did not include enough information on system and organisational problems for a suitable human factors analysis.

2. When asked to attribute causes of incidents, the investigators largely attribute most culpability to individuals for errors and therefore opportunities to learn about other system failings are missed
3. A proactive analysis of risk in the transfusion process showed that the triggers requiring adaptations in working practice are often not in the same aspect as the change made, typically because resolution of the actual trigger is not within the power of the staff affected by the problem, so they adapt elsewhere.

From the conclusions of the literature review (Chapter 2) it was demonstrated that very little human factors research had been applied to blood transfusion, so this PhD is the first major study to investigate the use of human factors in understanding transfusion errors and it has demonstrated some very useful learning points from the main findings listed above.

7.3.1 Considering bias in transfusion incident reports

Study 1 showed that the correct and complete story is not always given in reports of transfusion errors and Study 2 demonstrated that blame is disproportionately attributed to people, rather than to system failings. These disparities may be caused by various forms of cognitive bias (Tversky & Kahneman, 1974) where something appears to be obvious after the event. Transfusion incident reports to the UK haemovigilance scheme, Serious Hazards of Transfusion (SHOT) are usually, though not always, made by the same individual who has investigated the incident, because of the unique nature of the Transfusion Practitioner role in the UK (Murphy *et al.*, 2003). In cases where a single individual has responsibility for both the investigation and reporting, the level of bias will relate to those emanating from that one person. Where a local investigation is passed to a third party, such as a quality assurance officer, for onward reporting, the cognitive bias may be compounded by having two people's views affecting the outcome.

It has been reported that incident investigations are often flawed, because there is a risk of investigator or reporter bias (Macrae, 2016) and in Chapter 4 the role of narrative fallacy (Taleb, 2007) when constructing incident reports

was discussed. This is a demonstration of hindsight bias, which happens when individuals feel that they "knew it all along" (Roese & Vohs, 2012). Three levels of hindsight bias are described by Roese and Vohs (2012): memory distortion, 'I said it would happen'; inevitability, 'It had to happen' and foreseeability, 'I knew it would happen'. Believing that an incident was more predictable after the event than it was before it became known, can encourage overemphasis of a single cause for the incident while neglecting, and therefore not learning from, all other possible explanations. This can lead to misplaced certainty by incident investigators about their opinion as to the cause of an incident, especially after they discover something in the investigation that confirms their hindsight bias; hence this aspect is known as confirmation bias (Nickerson, 1998).

Another common bias seen in transfusion incident reports is counterfactual thinking, which literally means thinking contrary to the facts (Roese, 1997) although it is usually restricted to representing alternative versions of the past. Counterfactual thinking can affect incident investigations, by concentrating on what individuals could or should have done to prevent a specific outcome and thus not explaining why they did what they did (Vignette 7.1). This can be exacerbated by time delays before incident investigation, so those involved have constructed a different view of the past events by the time they are asked to contribute to the incident report. It has also been shown that linear reporting, based only on facts deemed as relevant by the incident investigator, may increase the likelihood of actions to be blame-focussed (Heraghty *et al.*, 2018). Therefore, the organisation fails to consider potentially serious issues that have been determined as unimportant by the individual reporter. Experimental research has shown little difference in causal attribution between counterfactual and factual thinking (Mandel, 2003), so it may be beneficial for incident reporting templates to encourage neutral investigations. However, a system to support incident investigators to review alternative causes for an event may reduce hindsight bias (Roese & Vohs, 2012).

Vignette 7.1: Counterfactual thinking restricts an incident investigation

A time-expired unit of red blood cells was taken to the ward area, but not transfused, because the expired date was noticed by the ward staff. The incident investigation only concluded that all units matched for this patient had short expiry dates and should have been kept in the laboratory cold room to ensure they were used or returned before expiry and the action proposed was 'Laboratory staff reminded to check expiry dates and store appropriately'.

The scoring in the human factors investigation tool (HFIT) was 5/10 for the staff member and zero scores for the three system and organisational factors. There was no further information about other factors contributing to the incident, nor details of any other actions. Hence the counterfactual thinking related to what the staff member 'should have' done means the investigator did not appear to have looked for any explanation of why they did what they did.

In Study 2 the enduring inclination of reporters to score individual error higher than other contributory factors is an example of fundamental attribution error, which is a term coined by Lee Ross (Ross, 1977). Fundamental attribution error can be defined as a tendency to overestimate the importance of personal or disposition factors relative to environmental influences and therefore to underestimate the influence of situational factors when explaining the behaviour of others. The theory postulates that we tend to explain someone's behaviour by attributing a cause (Vignette 7.2). However, the tendency is to place undue emphasis on the internal characteristics of other people (e.g. their character or intention), while overemphasising external factors (e.g. system and organisational problems) in relation to one's own behaviour. This particularly happens when the behaviour is negative.

Vignette 7.2: Attribution error adversely affects incident investigation

Pre-operative testing of a patient's blood sample showed atypical antibodies. This was not followed up before the patient went to theatre, at which point historical records confirmed that the patient had a complex phenotype, with four different atypical antibodies, requiring a specific combination of antigen negative blood types for transfusion. Only two units of red blood cells on site met the patient's needs, so extra units had to be ordered from the Blood Centre, requiring a blue-light emergency delivery. The patient was held under general anaesthetic for several hours whilst waiting for blood cover to be organised before the operation began.

The incident investigation concluded 'the laboratory staff member is well aware of the requirements … but failed to apply this'. The scoring in the human factors investigation tool (HFIT) was 6/10 for the staff member and zero scores for the three system and organisational factors. Root cause given as 'Failure to apply transfusion knowledge to clinical scenario' and the action plan included 'Staff involved to write reflective practice statements to demonstrate learning from the incident'.

Some system failures were identified, resulting in minor changes to procedures, but the overemphasis on the individual's failure to apply their knowledge may have restricted the opportunities to learn about the wider impact of system and organisational factors. As an example, there was a recognition that the incident occurred during a night shift, where the staff member was maintaining a service for three actively bleeding patients, but it was concluded that 'this does not mitigate the failure'.

A classic experiment to illustrate the phenomenon of attribution error involved reading essays for and against Fidel Castro and showed that subjects were unable to see the influence of the situational constraints placed upon the writers; even when told the writers were assigned to their pro or anti stance randomly by coin toss. (Jones & Harris, 1967). The experimental group could not refrain from attributing sincere belief to the writers and therefore provided more internal attributions towards the individuals. This effect is also known as

correspondence bias, although it has been argued that the fundamental attribution error and correspondence bias are related but independent phenomena, with the former being a common explanation for the latter (Gilbert, 1998). The effect of fundamental attribution error can be to make it difficult to get a clear picture of an adverse event, because the person approach is often preferred when reporting the incident. It seems that “blaming individuals is emotionally more satisfying than targeting institutions” (Reason, 2000). Generally, leaders/managers seek to understand the cause of an event, assess responsibility for the outcomes and appraise the personal attributes of the involved parties at the same time. Fundamental attribution error explains how these thinking processes are related to conclusions about the development and causation of an event (Palmieri *et al.*, 2008). By concentrating on the person approach, the healthcare practitioners involved in errors are deemed to be at fault for neglecting to protect the patient. Attribution bias explains how incident investigators typically do not wait until they have all the evidence before generating an inference, but instead they roughly estimate a solution to a problem, then smooth out the rough estimate as they proceed with the investigation (Tversky & Kahneman, 1974).

To show the complexity when considering the role of bias, further examples of attribution biases have been described including the principles of similarity and salience (Wallace and Ross, 2016). Similarity suggests that big events are more commonly explained with big reasons (McCauley & Jaques, 1979) so if a transfusion incident has a large impact, there may be a tendency to look for a large cause of the event.

This can lead to a blame culture, because seeing incidents as failures by individuals, rather than by the system in totality, means that people will probably be subjected to individual corrective actions. Even if the recommendations are not overly punitive, it is likely that staff will feel they are being blamed; no one wants to be made to do retraining or asked to reflect on their poor performance. It is apparent from transfusion incident reports that the model of a just culture (Dekker, 2012) may not have been applied objectively, when it can be seen that after three years of encouraging a systems and

organisational analysis of incidents in Study 2, over 55% of the culpability is still assigned to individual staff members (Table 5.8) although some research has shown that 10% individual culpability is more likely (Karl & Karl, 2012). Anecdotally, healthcare staff have expressed their belief that standard protocols are designed mainly to protect the organisation when errors happen, because any deviation from expected practice, including those forced by other system problems, leaves the staff member open to blame if an incident occurs. A common position taken by employers/managers seems to be to reinforce that the organisation has a just culture stance, but unfortunately on this occasion you, the individual, are to blame. This was demonstrated by a member of the focus group who contributed to the trial of the draft self-learning package to assist incident reporters to use the human factors investigation tool (HFIT) as described in Section 5.5. The questions for the focus group members concentrated mostly on the ease of use and value of the self-learning package, but a verbal comment was made about the examples used in the package, suggesting they should be scored higher for individual culpability, because if staff did what they should, then incidents would not happen.

The outcomes from studies 1 and 2 indicate a persistence of a blame culture and it seems it will be a difficult task to persuade transfusion staff to consider system and organisational failures when investigating incidents. The pervasiveness of apportioning blame to individual staff members could affect the way organisations deal with the second victim (Wu, 2000), i.e. the healthcare professional(s) involved in adverse incidents. Wu (2000) reports that unconditional sympathy and support are rarely forthcoming for the second victim, although this understanding for medical staff is really needed. A later publication identified that healthcare was doing better at investigating incidents and creating a safer healthcare environment and had improved the handling of patients (Wu & Steckelberg, 2012) but they reported that very little attention had been devoted to healthcare workers involved in adverse events to help them cope. A small study related to second victims following a transfusion incident concluded that the reactions and feelings of staff can be overwhelming and support for staff is a crucial aspect of the lessons learned in the wake of an error (Creighton & Wright, 2014). It is possible that the ineffective

application of a just culture and the failure of empathy for healthcare staff as second victims could reduce patient safety, because of the negative effect on the individual staff members involved in transfusion incidents. If the investigation of transfusion incidents is increasing the pressure on second victims, as evidenced by scoring the staff more highly for culpability than the surrounding system and organisation, this may lead to staff resigning or being on long term sickness due to stress, further stretching an over-burdened system.

7.3.2 Problems with root cause analysis in transfusion incident reports

Incident reporting has limitations in investigating underlying mechanisms so incident investigation is important for certain patterns of risk. However, system-based incident investigation is not easy, as evidenced by the previous research, and it requires expertise. Usually, transfusion incident investigations use root cause analysis (RCA) tools as a structured process to identify the cause(s) of an incident. RCA has roots in the 1980-90's growth of total quality management (TQM) as a business tool (Wilson *et al.*, 1993). RCA use in healthcare is now ubiquitous and is recommended by NHS quality organisations (NHSI, 2018; NHS HQIP, 2016b). In blood transfusion RCA is encouraged by leading professional organisations (JPAC, 2015; SHOT Bite, 2018; IBMS, 2019b). However, evaluations have indicated that RCAs are being used extensively in healthcare without consideration of the work settings or backgrounds (Peerally *et al.*, 2017). The process of RCA is generally too linear and concentrates on finding a single cause, when one single cause is unlikely to be the root of an adverse event. A linear approach is encouraged by tools such as '5 whys' (NHSI, 2018) and the value of this approach has been questioned (Card, 2017). The simplistic view of cause and error is not sufficient and Hollnagel (2008) discusses a 'What-You-Look-For-Is-What-You-Find (WYLFIWYF)' principle, meaning that any lesson learned is limited by the assumptions on which the investigation is based.

Ineffective RCAs can lead to poor corrective actions being proposed that are at the lower end of the hierarchy of effectiveness (Trbovich & Shojania, 2017).

An assessment of the strength of recommendations arising from RCAs (Hibbert *et al.*, 2018), using the USA Department of Veteran Affairs' criteria (Bagian *et al.*, 2011), showed that action outcomes from incident investigations are often not effective or sustainable. Hibbert *et al.* (2018) categorised only 8% of recommendations as strong and found the most common types of action were reviewing or enhancing a policy, guideline or documentation, plus training and education. The imperative to propose SMART actions (Specific Measurable Achievable Realistic Timely) can encourage incident investigators to opt for simple corrective actions, such as reminding and retraining staff, because they are more achievable than dealing with major issues, such as equipment problems or lack of sufficient staffing. This is compounded by the observation that investigation teams are not obliged to use evidence to justify their recommendations (Hibbert, 2018).

7.3.3 Safety-I and Safety-II in the transfusion process

Traditionally organisations like the UK haemovigilance scheme are examples of a Safety-I system and this research, particularly Study 3, has shown the benefit of adding a Safety-II perspective to the transfusion process. The idea of Safety-I and Safety-II was developed by Erik Hollnagel (2014) to explain the difference between standard safety processes that rely on counting failures in the system (Safety-I) compared to a novel concept where safety is monitored by learning from situations where everything goes as planned (Safety-II). Current transfusion monitoring schemes, including incident reporting processes and clinical audits are examples of Safety-I, relying as they do on analysing when safety is compromised either by incidents or by audits highlighting inappropriate practices that do not conform to standard protocols or guidelines.

There are no major problems with these Safety-I systems in blood transfusion, which achieve their aims of identifying where processes are failing. Also, there is no suggestion that Safety-I monitoring should be ceased or replaced entirely by Safety-II. However, viewing safety as a situation where nothing fails, i.e. Safety-I, means essentially monitoring a non-event. If nothing is found to be

going wrong there is no measure of the safety of the system. This is known as the regulator paradox (Hollnagel, 2014), because when incidents are reduced to zero, safety investigators cannot know if the processes are completely safe or are in fact very close to the edge and at risk of a safety failure. Also, if the perception is that safety is very high, it can be tempting for the organisational management to direct resources elsewhere, so active monitoring of safety issues is reduced, and the risk increases again.

Therefore, it becomes necessary to find a method to measure the effects of safety management beyond simply investigating incidents or detecting violations (Reason, 1990) via clinical audits. Incorporation of the techniques described in Study 3 could move the blood transfusion system towards a Safety-II process for monitoring patient safety. A key tenet of Safety-II is the understanding of the difference between work-as-imagined (WAI) and work-as-done (WAD) and this has been supplemented by two other varieties of human work, ‘work-as-prescribed’ and ‘work-as-disclosed’ (Shorrock, 2016) (Figure 7.1). Work-as-imagined is the way those that are remote from the frontline believe that work is carried out, so work-as-prescribed becomes the manner in which those that are not directly involved prescribe, via policies guidelines and regulations, what they think is the safest way to work. Work-as-done represents the actuality of day to day tasks, but when asked, e.g. during a clinical audit or an incident investigation, staff may not feel able to reveal the full truth, hence it becomes work-as-disclosed. As described by Shorrock (2016) there are many nuances within these descriptions of the different perceptions of work and it is only by recognising the variations that the totality of work can be understood, with the myriad problems that can arise.

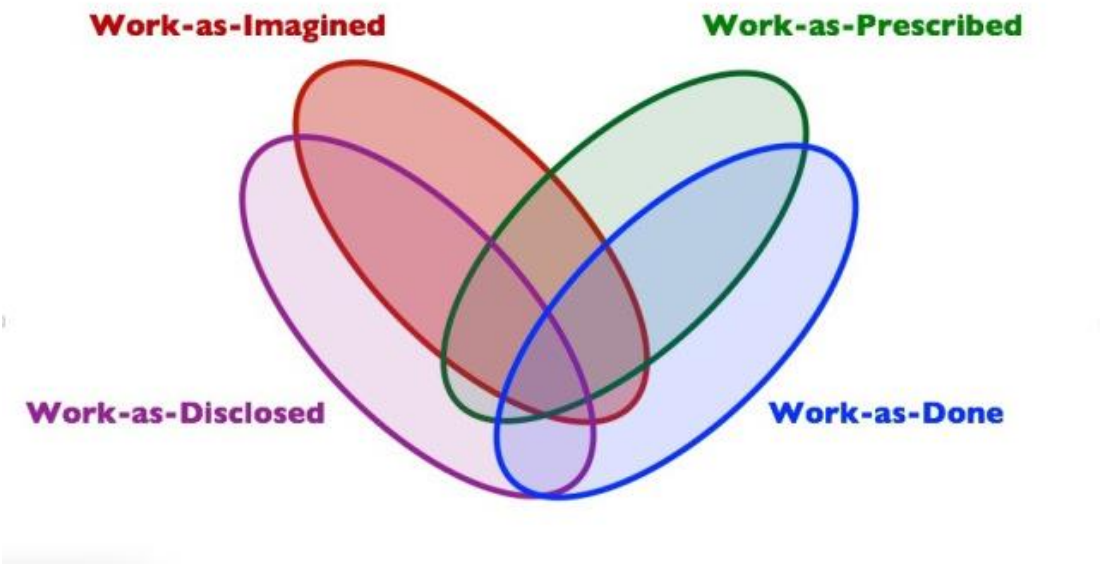


Figure 7.1: The varieties of human work

(Shorrock, 2016)

Study 3 has identified mechanisms for studying and analysing work, particularly work-as-done. The research methods encouraged an open description of adaptations and resilience in daily work, i.e. there was less likelihood of the reality being obscured by responses in the work-as-disclosed mode. The work within Study 3 also introduced a method for using an adapted Concepts for Applying Resilience Engineering (CARE) model (Anderson, 2016) to assess the safety of adaptations made when prescribed work is modified to allow the task to be achieved, i.e. work-as-done. When there is a full appreciation of work-as-done, there is an improved chance of knowing how well a system is functioning or if there has become a normalisation of deviance (Vaughan, 1996), when small changes from normal practice gradually become the norm and from there, systems can be drifting into failure (Dekker, 2016).

7.4 Limitations

Each chapter has incorporated a discussion of limitations, including any effect of these on the research undertaken and suggestions for mitigation where possible. An overall limitation was the challenge of doing human factors

investigations in the NHS, because it is not yet a well-recognised science in healthcare, which is why part of the research in Study 2 included making educational material available for distance learning. In addition, there are ethical and confidential difficulties when carrying out healthcare research, although that was not a major obstacle in these studies, as they were done in partnership with major healthcare organisations.

The main limitations of the three studies are summarised here:

Study 1

The initial comparison of human factors (HF) models/methods was deliberately limited to subcategorisation of the apparent main cause transfusion incident reports, as a brief study to decide on the most useful method for more in-depth use. This proved to be an advantageous limitation, because the early work identified that the existing incident reports did not contain sufficient information to allow a detailed HF analysis, so a different approach was developed for Study 2 involving the use of a bespoke human factors investigation tool (HFIT) to collect data on systems and organisational factors. Another limitation identified a problem that could be resolved for future reporting, because many of the incident reports indicated that there was further incident-related documentation available, such as a root cause analysis (RCA), but these had not been uploaded. This finding led to a development within the UK haemovigilance transfusion incident database, so that such documents were automatically linked from the primary reporting system, the Medicines and Healthcare Products Regulatory Agency (MHRA) reporting system known as Serious Adverse Blood Reactions and Events (SABRE) (MHRA, 2019).

Study 2

The major limitation related to the incorporation of a human factors investigation tool (HFIT) was the requirement to rely on hospital-based colleagues to score the four factors in the HFIT. These partners would not necessarily have any understanding of human factors and therefore may not score the incidents as an expert might. Attempts were made to mitigate this by developing a self-learning package, including a PowerPoint presentation and a video, but the problem remained apparent throughout the three years of

study. There were inbuilt limitations with the self-learning package, not least the requirement for it to be a remote study system, but also difficulties with how to present the learning material and the restrictions on choice of a training video. One frustrating limitation of the self-learning material was the discovery that an educational video could not be watched in 18.8% of the UK institutions reporting transfusion incidents due to the restriction in their IT system (Section 5.8.2).

Study 3

There have been substantial delays resulting in a failure, to date, to launch the national audit programme which was scheduled to be used as a vehicle to obtain UK-wide data from the research in Study 3. However, the data gathered directly by the author during hospital visits have been a comprehensive source of information for analysis. A potential limitation is the reliance on staff to give candid answers to the questions asked, although there was no suggestion that the answers given during Study 3 were not open and honest. Healthcare professionals are bound by a statutory duty of candour (CQC, 2015) and have become comfortable with discussing areas of healthcare that are problematic, although that may be dependent on the culture prevailing in their place of employment.

There were also limitations associated with the methodology used within these studies, particularly the possible fundamental biases associated with research that relies on judgements by individuals with a variety of backgrounds and differing experience and knowledge. Similarly the analyses by the author often depended on a qualitative and interpretivist approach with subjective classifications made initially by the author, before checks made by colleagues. The use of action research can be sensitive in some circumstances, because it may reveal problems in the system being studied, but this was not a specific risk with this research, partly because the aim was to reveal problems in both incident reporting and audit processes, with the intention that these can be remedied as a result of uncovering the difficulties. Also, within the action research process used in Study 3, the methodology allowed healthcare professionals to reveal problems and explain how they resolved them,

sometimes with commendable adaptations that deserved to be shared widely for improved learning. This compares to traditional clinical audits, which are designed specifically to identify when staff are not following standard procedures, sometimes in a censorious manner. Another potential limitation of action research is if the researcher loses control over the investigation, because of the effects of collaboration, but this was not an issue with these studies and an equal balance was created between the investigator and participants that was advantageous to both parties.

A general limitation of the research was the need to maintain confidentiality. This meant that for Studies 1 and 2 it was not possible to identify trends of reporting from particular healthcare organisations or specific reporters of incidents. It would not have been acceptable to sidestep the intrinsic confidentiality of the transfusion incident reporting database for these studies, but consideration could be given to obtaining ethical approval to carry out some less constrained research in the future.

A constraint across the entire PhD research was the limitation of time and all the studies could have been extended and possibly modified or improved if time had allowed. As the research had to be completed in a restricted timeframe, there will inevitably be further work for future researchers to add to this body of knowledge.

7.5 Future work

Any research of the size of this thesis will leave opportunities for the work to be developed into new studies with additional or different facets. As a result of the studies within this PhD, human factors research and assessment has become established in transfusion routines, particularly incident reporting and clinical audit. Therefore, it is important that HF research continues in blood transfusion and the opportunities for future work include developing areas of identified weakness, such as the limitations of the scoring system used in Study 2, which is the human factors investigation tool (HFIT) that has been incorporated permanently into the transfusion incident database

questionnaires. An area of work that could be explored would be to expand the research that was done in Study 1 and examine if any of the human factors models/methods, such as SEIPS 2.0 or AcciMap (Appendix 3), could be used to analyse transfusion incidents in detail, because there is now more information available about human and system factors as a result of the HFIT questions. Similarly, a study could be carried out to investigate if the scoring associated with the HFIT could be performed more effectively by experts within the UK haemovigilance organisation, Serious Hazards of Transfusion (SHOT) instead of relying on scores assigned by local hospital-based incident investigators. Currently, SHOT employs Incident Specialists who analyse and categorise the reported incidents from a clinical and scientific perspective. These experts use the information provided in incident reports to make expert assessments about the clinical and scientific aspects of each case, so a similar process could be researched for categorisation and analysis of the human factors related to each incident, with the potential that providing an analysis by a human factors Incident Specialist could become part of the expert service provided by SHOT.

One area of interest that was not explored as far as expected in this research, is whether near miss incident reports may elicit different lessons about organisational systems than reports from incidents that were not prevented from causing patient harm. The planned comparison of near miss data with information from full incidents was halted, because of a lack of information in the reports being studied, but all reports now include the questions for the human factors investigation tool (HFIT), so there may be better prospects of research in this area in the future. In particular, it may be valuable to use the enhanced Concepts for Applying Resilience Engineering (CARE) model (Section 6.5.6) to analyse lessons from near miss incident reports. More generally, the enhanced CARE model may be suitable for use to analyse transfusion incidents using the data now available from the HFIT questions.

The AFFINITIE study, which is a cluster-randomised trial to research enhanced learning from audits. (Gould *et al.*, 2014; Lorencatto *et al.*, 2016) is a related area of research that may prompt a linked opening for further

investigation. The AFFINITIE programme focuses on feedback as the main enhancement method to improve clinical audits in blood transfusion, but there may be opportunities to combine the AFFINITIE work with the techniques researched in Study 3 developing human factors-based changes to clinical audit practice. Also linked to AFFINITIE is the theme of behaviour change techniques (Abraham & Michie, 2008) that has been further developed by one of the contributors to the AFFINITIE project (Lorencatto *et al.*, 2013). Following a presentation of this topic at the Annual SHOT Symposium 2019 (Lorencatto, 2019) it was suggested by a delegate that behavioural change interventions could be incorporated into areas of transfusion practice, and this should be led by SHOT. Hence, this would be a natural direction in which to extend the research from this PhD.

Similarly, the Yorkshire Contributory Factors Framework is a tool which is an empirically based framework of the factors contributing to patient safety incidents (Lawton *et al.*, 2012) and it has been identified as the first evidence-based framework of accident causation in hospitals. It could be an interesting development to apply this framework to transfusion incidents and compare it with the research in this PhD.

Other suggestions for future work include the potential to apply the work in this thesis to other areas of healthcare, because incident reporting or clinical audit in any medical discipline might benefit from the methods and analyses examined in this work. Another topic to examine could be methods to involve patients in a more active way in their care, potentially investigating approaches to give patients an understanding of human factors and safety risks related to transfusion. Conversely, human factors research could be applied at the other end of the transfusion process, i.e. from where it begins with blood donation and the work done in blood transfusion centres to test and process the donated blood.

The work from this thesis could have many applications in the future and perhaps our only limitation is imagination (quote adapted from Charles F. Kettering, American inventor, 1876 – 1958).

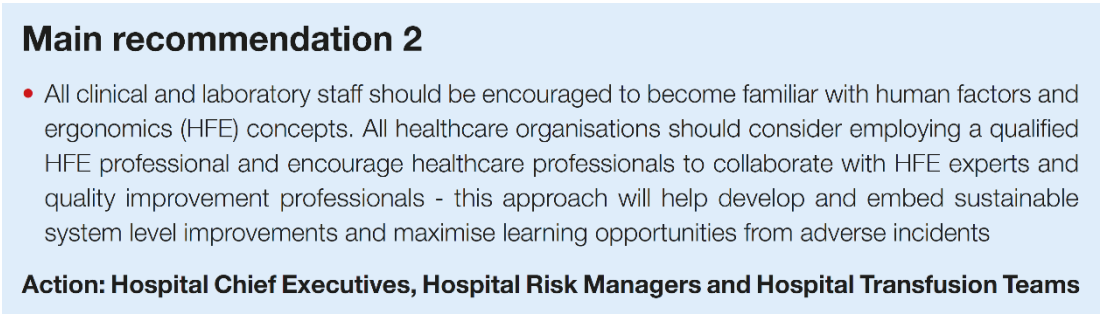
7.6 Final conclusions

This research has made substantial contributions to the to the body of knowledge in both blood transfusion and human factors. To date most transfusion research has concentrated on the scientific and medical aspects of the subject, as evidenced by the publications in Transfusion Medicine, the journal of the British Blood Transfusion Society (BBTS), which is one of the most respected transfusion-related journals (BBTS, 2019). Similarly, it is rare for any research other than the scientific and medical aspects of transfusion to be published in Transfusion, the journal of the American Association of Blood Banks (AABB, 2019) or Vox Sanguinis the journal of the International Society of Blood Transfusion (ISBT, 2019b). It was shown in the literature review for this thesis that it is uncommon for studies to be published that have used human factors and ergonomics principles to undertake research in blood transfusion. Therefore, this thesis will add considerably to the existing body of knowledge in blood transfusion, partly by showing that major research in transfusion can be achieved outside the traditional clinical and technical fields, but mainly by demonstrating the value of applying human factors principles to improve safety within blood transfusion. HF-based methods have been introduced and evaluated to improve learning from transfusion incident reports, including embedding a novel human factors investigation tool (HFIT), which will now become part of the routine annual analysis of transfusion incidents.

In addition, a resilience audit method has been developed, which is not only an important advancement to improve clinical audit in transfusion, but could also be applied in many healthcare fields beyond blood transfusion. An innovative method of assessing adaptations was proposed in Study 3, using an enhanced version of the Concepts for Applying Resilience Engineering (CARE) model in conjunction with categorisations based on the Systems Engineering Initiative for Patient Safety 2.0 model (SEIPS 2.0). This research has presented a mechanism for examining adaptations to predict the likelihood that they will be successful or unsuccessful and, whilst this cannot be a failsafe evaluation, it demonstrates the possibility of foreseeing risks developing in a process.

The overall conclusion of this thesis is that human factors principles can most definitely be applied to the blood transfusion procedure and, from this first major piece of research into the application of these concepts, there appears to be a huge opportunity to improve patient safety by understanding human factors. The leadership role of the UK haemovigilance organisation, Serious Hazards of Transfusion (SHOT) will be a key driving force in delivering on their recommendation 'to redesign the transfusion process in line with human factors and ergonomics research' (Bolton-Maggs *et al.*, 2014) which ultimately led to the research carried out here.

One of the main outcomes from this research has been the finding that it is difficult for human factors analyses to be performed by healthcare professionals who are employed in other fields, especially if they have no training or education in the science of human factors. SHOT has now made familiarity with HF a main recommendation and more importantly suggests healthcare organisations consider employing a qualified human factors and ergonomics professional (Narayan *et al.*, 2019) (Figure 7.2).


Main recommendation 2

- All clinical and laboratory staff should be encouraged to become familiar with human factors and ergonomics (HFE) concepts. All healthcare organisations should consider employing a qualified HFE professional and encourage healthcare professionals to collaborate with HFE experts and quality improvement professionals - this approach will help develop and embed sustainable system level improvements and maximise learning opportunities from adverse incidents

Action: Hospital Chief Executives, Hospital Risk Managers and Hospital Transfusion Teams

Figure 7.2: SHOT recommendation from 2018 Annual SHOT Report
(Narayan *et al.*, 2019)

It is surely time that healthcare, one of the most complex systems in existence, should employ HF professionals to advise on safety initiatives and ergonomic design. A study in 2018 identified only one suitably qualified Chartered Ergonomist and Human Factors Specialist' (CErgHF) employed in the entire NHS workforce of 1.5 million (Shorrock, 2018). In comparison, following a UK chief medical officers' evidence-based symposium on transfusion and the

publication of the first of a series of three Department of Health (DH) Health Service Circulars (HSC) on Better Blood Transfusion (BBT, 1998) a new job known as a Transfusion Practitioner (TP) was created and this role was soon established in every major hospital in the UK (Murphy *et al.*, 2003). The function of TPs includes investigating blood transfusion incidents to make sure lessons are learned for improved patient safety. Therefore, in a short space of time a new professional role was created, and large numbers of staff were employed in a very small section of healthcare to help avoid adverse incidents in blood transfusion. Human factors professionals could justifiably be employed in droves now to perform a similar role across all departments of a hospital and in many other areas of healthcare.

As this thesis ends, the independent public statutory inquiry into the use of infected blood continues to gather evidence of the historical harm done to patients, and their families and friends, by viral infections transmitted by blood transfusion in the 1970s and 1980s (Infected Blood Inquiry, 2019). The risk of viral transmission via blood transfusion is now vanishingly small (PHE, 2018), but every effort should be taken to ensure there is never any need for a future independent inquiry into continued harm caused by blood transfusion. It is now time to act on the knowledge gained from this research and from human factors and ergonomics in general, because minimising the risk of harm from error is the next logical step in making blood transfusions safer for all. The work described here provides a roadmap for beginning that journey and transfusion medicine professionals need to learn from the past and use this new knowledge to change the future and improve transfusion safety for all.

"Those who cannot remember the past are condemned to repeat it."

(Santayana, 1905).

Epilogue

What I have learnt from 5 years spent researching a PhD in human factors.

The whole world needs an understanding of human factors. Time and again over the five years of these studies I have spotted design flaws in objects or systems or personal behaviour and smiled to myself as I mutter something like ‘blasted human factors’ under my breath. My main aspiration for the results of this research is improved patient safety in blood transfusion, but I hope the lessons will spread far beyond. Certainly, any area of healthcare would benefit from looking at their own incident and audit procedures to see if improvements can be made by using human factors principles. However, I could also see the techniques described in this research being applied elsewhere. That simple question, ‘What is the biggest or most recent difficulty that you have faced when carrying out this procedure and what did you do about the issue?’ could be asked to any staff anywhere to uncover the adaptations they make, often without telling anyone else. I might try that out next time I go to the supermarket.

So, what else have I learnt of human factors in day to day life? Doors are a good example. Most HF professionals can expound on the pointlessness of handles on doors that are supposed to be pushed while watching a stream of people pulling the push only door. Signs saying ‘PUSH’ help a little, but mostly just make the individual who has pulled in error feel even more daft as they read the sign too late. A friend tells me the door in the gents at our local pub has both a handle and a sign saying ‘PULL’, but it is now a push only door – that is just cruel. The most recent door issue I encountered is at the entrance to the community centre that I frequented as a space to encourage me to write up this thesis. There was a correctly placed handle on the outside of the pull only door to encourage pulling and a panel on the inside, so people could only push. However, on the inside of the door, a sign had also been placed onto the transparent windowpane adding the unnecessary instruction to push. Human brains are too quick, and I watched as some of those entering the

building seemed to notice the sign for push and tried to comply with it, even though it was inside and backwards, and the door has a handle.

Moving away from door annoyances, did I learn anything more useful? Of course, I acquired a lot of insight into other healthcare dangers. I heard about anaesthetic machines that seem the same, but on one the big red button gives more oxygen and on the other the big red button is the off switch. Note to self, remember to check if the anaesthetist is aware of that danger if I ever need an operation. Highlighting system dangers, I read a tale (that might be apocryphal) of an orthopaedic surgeon who worked in two hospitals where one used a cross to identify the limb for operation and the other used a cross on the limb not for operation. I became aware of the horrible dangers of lookalike drugs and I was also stunned to discover that despite well-known incidents of deaths, it was still possible to give intravenous drugs intrathecally, i.e. into the spine, because despite recommendations almost two decades ago to make this impossible (Toft, 2001), the interconnecting ports (Luer tapers) were still inappropriately compatible, although that should be improving now, as there was a December 2017 deadline for starting the transition to intrathecal connectors (NHS England, 2017a). I thought back to my early days in blood transfusion when different ABO blood groups had different colour labels, Yellow for A, pink for B, blue for O and white for AB. They also had black for Rh D positive and red for Rh D negative. Why was this ever changed? Relying on memory for the reason, I recalled it was to encourage people to read the label more carefully and not rely on colours, but about thirty years on and with the benefit of HF knowledge, that sounded counterproductive. After a bit of checking with my go-to guru for transfusion history (Needs, 2019), I discovered that the change was part of an international plan to harmonise blood pack labelling, because although most countries used colours, they were often different. This caused major problems in the first Gulf War in 1990-91 when blood from different countries was being used and there were dangerous confusions due to the differences in colours used. All labels internationally are now white, so would it have been better to harmonise the colours? Probably not, as there would have been at least an interim period of chaos as staff familiar with one colour coding system had to become familiar with another.

The fact that I can still correctly remember the UK colours from nearly 30 years ago shows how entrenched that kind of memory-retention can be.

I also discovered how my own apparent stupidities were more often system related than fuzzy-brain related. There was the day my car was towed away from my favourite, slightly secret, city centre parking spot. The parking ticket machine had been removed during building works, so there were up to 5 free spaces right by my flat. I had been a little surprised that all five were empty when I arrived to park one evening, but humans like to put together stories from available evidence, so I reasoned it was late-ish on a Monday evening and the nightclub next door was closed, so not surprising no one else was parked there. I failed to notice the sign high up on one lamppost warning the road was to be closed at 8am. Early in the morning, long before I was out of bed, the council workers said they had put traffic cones in the road to stop commuters parking there, but that bit of the system failed for me as I live in the city and commute out. They also told me they would always put an advance warning on the ticket machine, but that system failed, because there was no ticket machine. In the end I had to pay a huge sum to get my car back, and a half day off work, because I had failed to notice one sign, above my height on one a lamppost. I was an idiot in their eyes, but now I understand their system failures.

I have noticed how the design of items is sometimes improved these days to offset some identified ‘mistake-waiting-to-happen’ problems. Cars are a great example and, as an example, the car I had when I stated these studies would sound an alarm if I opened the door without remembering to turn off the lights. However, I managed to fool that piece of technology one day when I had to park my car very near a wall, so crawled over to the passenger side to exit and that door was not alarmed. A neighbour saved me from a flat battery, but car manufacturers keep developing, so my current car has an automated setting on the switch, so the lights come on or turn off as needed and go off when the engine is stopped. You can spot the modern cars at every motorway tunnel now, as a stream of lights go on and switch off like a Christmas tree.

I also learnt that general personal wellbeing is a human factor too, so we should not expect staff to work ridiculous hours or to give up breaks to keep a failing system going. When I worked in transfusion laboratories, we used to work a 32-hour shift, from 9am one day until 5pm the next. Officially we were 'on-call' and we had the luxury of a tiny on-call bed to sleep overnight, if we could, which was rare. When I used that term on-call to friends they would imagine a plumber who gets called out once in a blue moon. They would not understand that it often meant 24 hours of a Sunday working alone barely being able to take a break to eat, drink or get to the toilet, My frequent greeting to the first day staff arrival after the lone-working part of a 32-hour shift was 'Thank goodness you're here, I need a wee'. As a laboratory professional, you cannot eat on the job, because of the risk of infection. The patients' blood I would be handling (and to a lesser extent the donor blood) could potentially contain things like HIV, hepatitis or prion disease. To eat, drink or go to the toilet you have to take off your protective laboratory coat and gloves, wash carefully and leave the area. It is only Quincy who drinks coffee and eats a sandwich in a laboratory, though I will admit, occasionally it was also me, when I realised that lack of food, and more importantly water, was putting the patients at risk as well as myself.

I also now understand the importance of a no blame, or just culture, in life as well as in healthcare. I would have been a better parent if I had understood that concept when I was yelling at my kids for their latest indiscretions and had instead asked them to explain the problems with the system that had led them to put toast in the video recorder. This leads into the issues caused in all work situations if the culture is one of bullying and harassment. Humans cannot work well under that kind of pressure any more than they can work with the inhuman conditions of a 32-hour shift, or worse; my medical colleagues were regularly working 80 hours straight in those days.

Last but not least, I learnt the term 'second victim' to describe the damage caused to staff involved in a patient-harm incident. Some have suggested staff should be third or fourth victims, but I prefer to think of family and friends and anyone else who feels the pain of harm to a patient as all being equal second

victims along with the staff member. My own experience of this is as fresh as yesterday, although it was over 30 years ago. I had done the first 24 hours of my regular 32-hour shift and early into the 8 hours of a routine working day as the laboratory manager, I was called to the Consultant Haematologist's office. The opening words were: "You killed a patient last night." The circumstances of the patient case are not relevant, but the 'crime' for which I was being blamed had originated from a direct verbal instruction by that same consultant, who was clearly now backpedalling. I quickly realised that (a) I had no proof of their verbal instruction and (b) I was devastated by the news that I had been involved in any way in a patient's death. In different circumstances I could have been prosecuted for gross negligence manslaughter and I would have had a very difficult time proving I was not to blame. The reality is no one was to blame, neither me nor the consultant. System faults included budgetary restrictions that definitely affected the original clinical decision, primarily made to save money; lack of experience, because both the consultant and I were first-time senior managers; healthcare hierarchy, because the ward staff would not question our earlier decision even though they had more up to date information on a deteriorating patient and finally overwork, because not only was I working alone through the night, but it had been a very busy shift. Inevitably, that meant I never contacted the ward staff for an update on the patient's situation and, although that level of overwork means I would probably have contributed to saving many lives that night, it also means I will never forget the horrible heart-sink moment of hearing about the one that died.

There is no terrible ongoing story to this tale. Nothing came of the blame and related accusations, apart from an abiding distrust of that individual consultant and presumably they equally distrusted me. I soon moved on to a new and better job and had a long and successful career. However, the incident taught me some very good lessons early in my managerial life. In particular, I always made an effort to get written confirmation of verbal instructions and I ensured I never treated my staff and colleagues like I had been treated that morning. It took me 30 years to learn the phrase second victim, then realise I had been one. It could so easily have been 30 years of consequences of being a second victim instead.

In conclusion, my abiding lesson from everything over the last five years can probably be depicted by the final illustration:

Figure 7.3: Photo of a sign that sums up 5 years' research

The End

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Appendices

Appendix 1 - Agreement with Serious Hazards of Transfusion (SHOT) for use of their data

Agreement for access to SHOT data

Background
Alison Watt is a part-time PhD student at Loughborough University Design School, researching "The Application of Human Factors to the Redesign of the Blood Transfusion Process". This student is currently two years into the research project.

A risk has been identified that this study is dependent on access to Serious Hazards of Transfusion (SHOT) data, which is outside the control of the student and the university. Therefore, a request is being made to the SHOT Steering Group to approve permission for the student to have access to the required data throughout the period of study. University regulations allow up to seven years for completion of a PhD, so the request is made for access to data until 30 September 2021.

Advantages to SHOT
Expected outcomes of this student's research are:

- A full PhD thesis publically available
- Other publications including chapters within the Annual SHOT Report, abstracts for presentations or posters at conferences and academic publications in peer-reviewed journals.
- A literature review of human factors in blood transfusion
- Execution of the recommendation from the 2013 Annual SHOT Report at a national level. (Recommendation was "In line with human factors and ergonomics research it may be better to redesign the transfusion process by process mapping and audit at local and national level, to design out the medical errors.")
- Access throughout the PhD to experts from Loughborough University Design School who can give free advice on complex health systems/services design. This compares to a fee quoted in 2014 from a commercial organisation of £1162 per day for assistance with this project.
- SHOT will obtain the relevant expertise and a member of the SHOT Working Expert Group (WEG) will gain the understanding to apply human factors to future SHOT recommendations.

Approval for access to SHOT data

On behalf of the SHOT Steering Group, the undersigned agree to facilitate access to the following SHOT data for use in a PhD up to 30 September 2021:

- A download of all error reports from calendar years 2014 to 2020 inclusive
- Attachments as requested from all error reports from calendar years 2014 to 2020 inclusive
- A separate download of responses to the Human Factors questions in all error reports from calendar years 2016 to 2020 inclusive

No data from SHOT will be published without further approval from the SHOT Medical Director or SHOT Steering Group Chair and full acknowledgement will be given when any data are used.
This approval for access will be terminated automatically at the submission of the PhD thesis or at any time before that by mutual agreement. Termination of access can also be initiated at any time by either party where there is good reason.

Dr Paula Bolton-Maggs DM FRCP FRCPath
Medical Director , SHOT

Dr Dafydd Thomas MBChB, FRCA
Chair, SHOT Steering Group

Appendix 2 - Agreement with National Comparative Audit for Blood Transfusion (NCA) for use of their data

Agreement for access to NCA data

Background
Alison Watt is a part-time PhD student at Loughborough University Design School, researching "The Application of Human Factors to the Redesign of the Blood Transfusion Process". This student is currently two years into the research project.

A risk has been identified that this study is dependent on access to National Comparative Audit (NCA) data, which is outside the control of the student and the university. Therefore, a request is being made to the NCA Steering Group to approve permission for the student to have access to the required data throughout the period of study. University regulations allow up to seven years for completion of a PhD, so the request is made for access to data until 30 September 2021.

Advantages to NCA
Expected outcomes of this student's research are:

- A full PhD thesis publically available
- Other publications including chapters within the Annual SHOT Report, abstracts for presentations or posters at conferences and academic publications in peer-reviewed journals.
- A literature review of human factors in blood transfusion
- Tools to enable execution of the recommendation from the 2013 Annual SHOT Report at a national and local level, which was an action for the NCA (Recommendation was "In line with human factors and ergonomics research it may be better to redesign the transfusion process by process mapping and audit at local and national level, to design out the medical errors. Action: …the National Comparative Audit Programme")
- Access throughout the PhD to experts from Loughborough University Design School who can give free advice on complex health systems/services design. This compares to a fee quoted in 2014 from a commercial organisation of £1162 per day for assistance with this project.

Approval for access to NCA data

On behalf of the NCA Steering Group, the undersigned agree to facilitate access to the following NCA data for use in a PhD up to 30 September 2021.

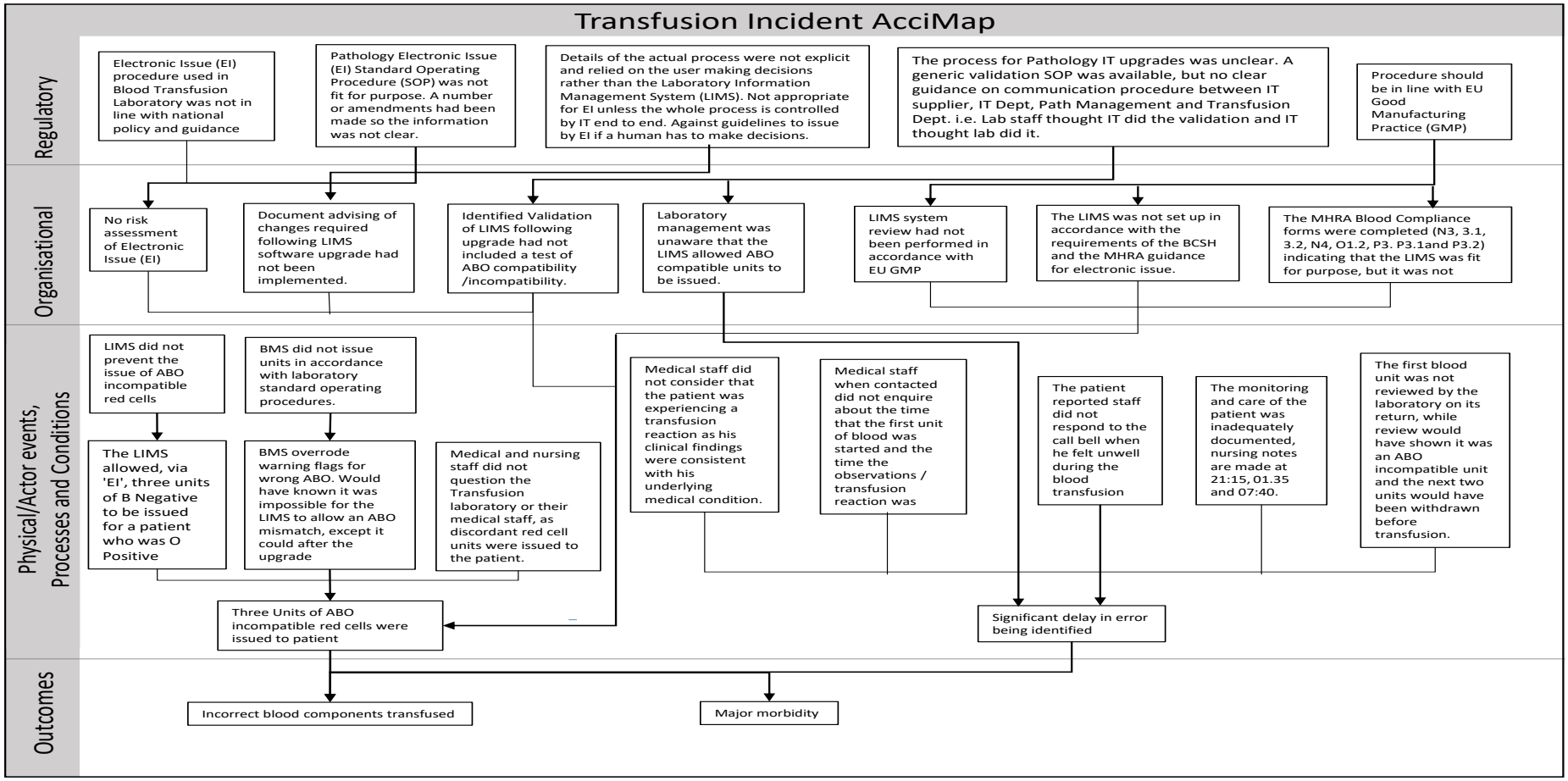
- Raw data from the Vein to Vein Audit, in particular data related to Human Factors

No data from NCA will be published without further approval from the NCA Programme Manager or the NCA Steering Group Chair and full acknowledgement will be given when any data are used.
This approval for access will be terminated automatically at the submission of the PhD thesis or at any time before that by mutual agreement. Termination of access can also be initiated at any time by either party where there is good reason.

John Grant-Casey
NCA Programme Manager

Lise Estcourt
Chair, NCA Steering Group

Appendix 3 – AcciMap of Blood Transfusion Incident



Appendix 4 - Human factors in incidents - statistical analysis

Incident reporters were asked to score the four human factors (Staff, Environment, Organisation, Regulation) to indicate the extent to which they thought the factor contributed to the incident. The lower the score for a factor, the less that factor was thought to have contributed to the incident.

A self-learning package was introduced in the second year and in the third year this package was supplemented by a self-learning video. The aim is to determine if the use of self-learning impacted on the scores reporters assigned to the human factors.

ISSUES WITH THE DATA

Over a three-year period, 2016 to 2918, 7764 incidents were reported. Scores between 0 to 10 inclusive were provided by each reporter.

There are several issues with the data:

1) A reporter can report more than one incident and within this dataset it is thought that most reporters would have reported multiple incidents. This means the data are not independent which violates a key assumption of many statistical tests. To overcome this, the analysis should include a random 'reporter' effect that would account for the fact that multiple incidents can be reported by one person. However, for this study it is not known which incidents were logged by the same reporter, so it is not possible to cater for the fact that some reporters may tend to score high whereas others may tend to score low.
2) The scoring system used by reporters is not consistent. Some reporters have assumed that the total contribution made by all four human factors towards the incident cannot exceed 100%. In these cases, the total score across the four factors is at most 10. Others have scored the four factors completely independently, so the total score can be anything up to 40.
3) Scores for some human factors were not provided but it cannot be assumed that a missing score is zero as some incidents had a set of scores that included both zero and missing.

In the second year a self-learning package was introduced to help guide reporters. Use of this reading material was voluntary. In the third year the self-learning was updated and made available in video form. Consequently, the use of self-learning is confounded with year.

METHODS

Scores were not provided for a number of incidents and these incidents were excluded from the analysis. A total of 7107 incidents across the three years were analysed.

To overcome the issues with the data, within each incident the scores were ranked from 1 to 4 inclusive with the lowest score assigned a rank of 1 and the highest score a rank of 4. Human factors with the same score were assigned the same rank and a missing score was assigned the lowest rank of 1. Using ranks loses information about the extent to which a reporter considered the human factor contributed to the incident but retains the relative importance the reporter attached to each human factor.

Ordinal logistic regression was used to model the effect of self-learning on the human factors. Each human factor was analysed separately. For each human factor the model response was the set of ranks, 1 to 4 inclusive, and the explanatory variable was the combined self-learning factor with three levels: No self-learning used at all; Some form of self-learning used; No information provided about the use, or not, of self-learning. Further details of how the combined self-learning factor was created are given in the **Appendix**.

RESULTS

Some form of self-learning was used by the reporter for 4058 (39%) of the 7107 incidents reported. Self-learning was either not used by the reporter, or unavailable to the reporter, for 2802 (57%) of incidents. For 247 (4%) of the incidents, there was no information provided on whether the reporter used self-learning or not.

The table below shows the distribution of ranks assigned to each human factor.

Number of incidents in each rank, by self-learning used or not

Self-learning	Rank 1 N (%)	Rank 2 N (%)	Rank3 N (%)	Rank 4 N (%)	**Total** **N (%)**
Staff					
No self-learning	367 (5.2)	128 (1.8)	267 (3.8)	2040 (28.7)	**2802 (39.4)**
Self-learning used	437 (6.2)	225 (3.2)	563 (7.9)	2833 (39.9)	**4058 (57.1)**
Not reported	23 (0.3)	14 (0.2)	24 (0.3)	186 (2.6)	**247 (3.5)**
Environment					
No self-learning	1656 (23.3)	328 (4.6)	717 (10.1)	101 (1.4)	**2802 (39.4)**
Self-learning used	2034 (28.6)	653 (9.2)	1180 (16.6)	191 (2.7)	**4058 (57.1)**
Not reported	108 (1.5)	27 (0.4)	102 (1.4)	10 (0.1)	**247 (3.5)**
Organisation					
No self-learning	1944 (27.4)	490 (6.9)	283 (4.0)	85 (1.2)	**2802 (39.4)**
Self-learning used	2523 (35.5)	837 (11.8)	417 (5.9)	281 (4.0)	**4058 (57.1)**
Not reported	158 (2.2)	51 (0.7)	26 (0.4)	12 (0.2)	**247 (3.5)**
Regulation					
No self-learning	2725 (38.3)	51 (0.7)	17 (0.2)	9 (0.1)	**2802 (39.4)**
Self-learning used	3814 (53.7)	147 (2.1)	60 (0.8)	37 (0.5)	**4058 (57.1)**
Not reported	232 (3.3)	11 (0.2)	4 (0.1)	0 (0)	**247 (3.5)**

The models are summarised in the **Annex**. There is some limited evidence that the use of self-learning led to a reduction in the extent to which reporters attributed Staff as a cause of the incident, p=0.10. There is strong evidence that the use of self-learning increased the extent to which reporters attributed Environment, Organisation, and Regulation as contributing to the incident, p<0.0001 for all three human factors.

CONCLUSION

The extent to which an incident is attributed to Staff is reduced when the incident reporter has used some form of self-learning. The extent to which an incident is attributed to each of Environment, Organisation, and Regulation is increased when the reporters has used some form of self-learning. The use of self-learning had more of an impact on the Environment, Organisation, and Regulation factors than on the Staff factor.

Frances Seeney, Mark Jones

Statistics and Clinical Studies **April 2019**

ANNEX EFFECT OF SELF-LEARNING ON EACH OF THE FOUR HUMAN FACTORS

A combined Self-Learning indicator variable was created for the three years to indicate if some form of self-learning (either the package, the video, or both) was used or not. The indicator levels are:

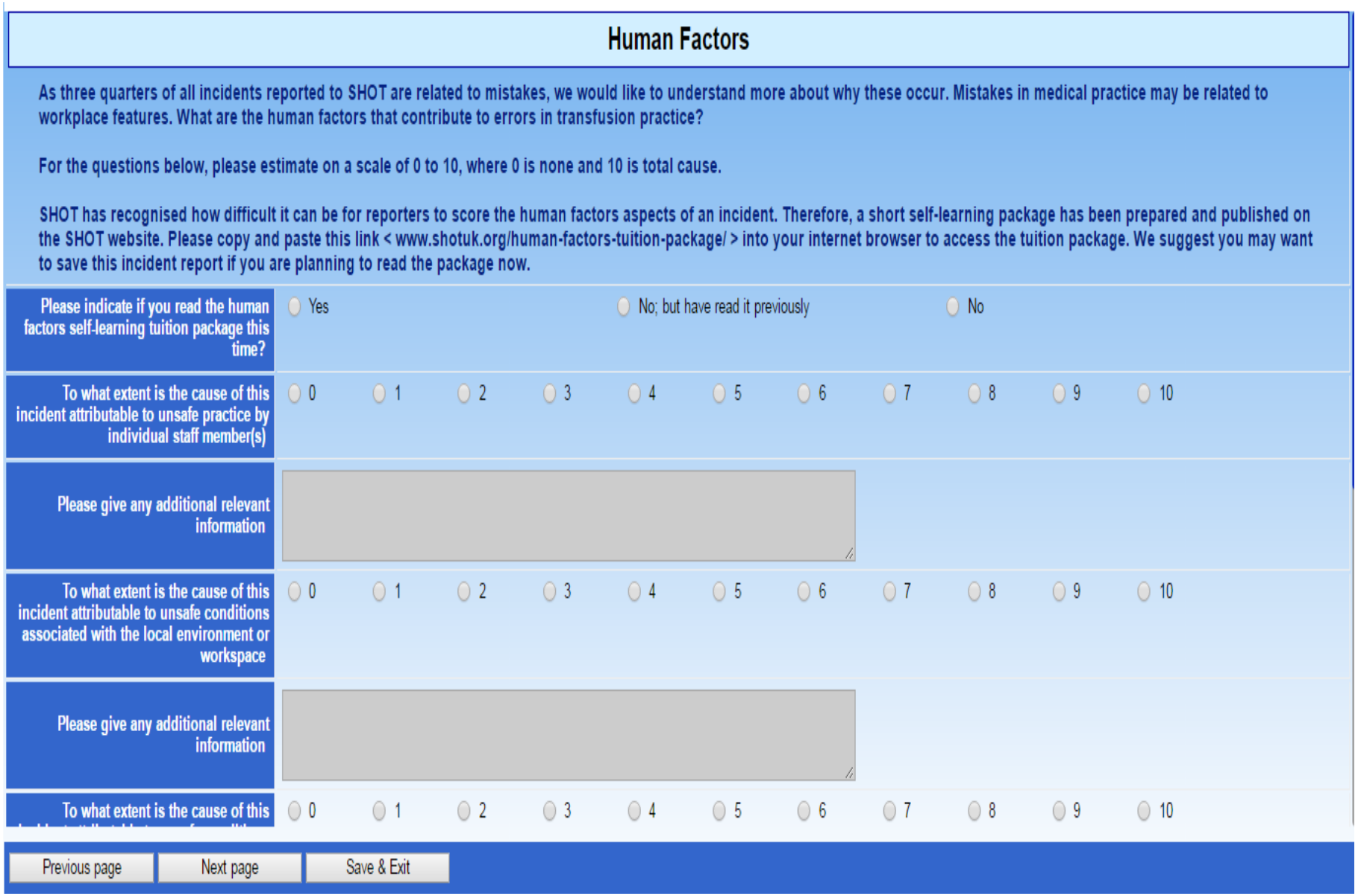
No – where the reporter indicated that they did not use either form of self-learning over the three years, or where self-learning was unavailable (e.g. in 2016 when self-learning was not provided, or in 2018 when some reporters did not have access to the video)

Yes – where the reporter indicated that they used either the self-learning package or the self-learning video when reporting the incident, or where they had used one or the other form of self-learning previously

Not reported – where the reporter did not provide any information on whether they used the video and/or package or not.

Human factor	Self-Learning used	Estimate	Standard error	P-value	Comments
Staff	No	-	-	-	
	Yes	-0.09	0.05	0.10	There is some evidence of a reduction in the contribution attributed to Staff where some form of self-learning was used compared to where self-learning was not used.
	Not reported	0.16	0.15	0.30	There is no evidence of a difference in the contribution attributed to Staff for those incidents where the use of self-learning was not reported and where it was not used.
Environment	No	-	-	-	
	Yes	0.31	0.05	<0.0001	There is very strong evidence that where some form of self-learning was used there is an increase in the contribution attributed to Environment, compared to where self-learning was not used.
	Not reported	0.63	0.12	<0.0001	There is strong evidence of an increase in the contribution attributed to Environment where some form of self-learning was used compared with where it was not reported.
Organisation	No	-	-	-	
	Yes	0.34	0.05	<0.0001	There is strong evidence of an increase in the contribution attributed to Organisation where some form of self-learning was used compared with where self-learning was not used.
	Not reported	0.24	0.13	0.08	There is some evidence of an increase in the contribution attributed to Organisation where some form of self-learning was used compared to where the use of self-learning was not reported.
Regulation	No	-	-	-	
	Yes	0.82	0.13	<0.0001	There is strong evidence of an increase in the contribution attributed to Regulation where some form of self-learning was used compared with where self-learning was not used.
	Not reported	0.82	0.29	0.005	There is strong evidence of an increase in the contribution attributed to Regulation where some form of self-learning was used compared with where the use of self-learning was not reported.

Appendix 5 - Screenshot of human factors investigation tool (HFIT) from UK haemovigilance reporting database



Human Factors

As three quarters of all incidents reported to SHOT are related to mistakes, we would like to understand more about why these occur. Mistakes in medical practice may be related to workplace features. What are the human factors that contribute to errors in transfusion practice?

For the questions below, please estimate on a scale of 0 to 10, where 0 is none and 10 is total cause.

SHOT has recognised how difficult it can be for reporters to score the human factors aspects of an incident. Therefore, a short self-learning package has been prepared and published on the SHOT website. Please copy and paste this link < www.shotuk.org/human-factors-tuition-package/ > into your internet browser to access the tuition package. We suggest you may want to save this incident report if you are planning to read the package now.

Please indicate if you read the human factors self-learning tuition package this time?	Yes ○ No; but have read it previously ○ No ○
To what extent is the cause of this incident attributable to unsafe practice by individual staff member(s)	0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○
Please give any additional relevant information	
To what extent is the cause of this incident attributable to unsafe conditions associated with the local environment or workspace	0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○
Please give any additional relevant information	
To what extent is the cause of this	0 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○

Previous page | Next page | Save & Exit

Appendix 6 – Extract from published SHOT datasets detailing the HFIT questions

To what extent is the cause of this incident attributable to unsafe practice by individual staff member(s)	Rating scale 0-10	Single choice
Please give any additional relevant information		Free Text
To what extent is the cause of this incident attributable to unsafe conditions associated with the local environment or workspace	Rating scale 0-10	Single choice
Please give any additional relevant information		Free Text
To what extent is the cause of this incident attributable to unsafe conditions associated with organisational or management issues in your Trust/Health Board? (E.g. staffing levels)	Rating scale 0-10	Single choice
Please give any additional relevant information		Free Text
To what extent is the cause of this incident attributable to unsafe conditions associated with the Government, Department of Health or high level regulatory issues (i.e. the error was caused by regulatory issues, not reportable as a regulatory failure)	Rating scale 0-10	Single choice
Please give any additional relevant information		Free Text

Appendix 7 – Human factors questions for incorporation into the Vein to Vein audit

Background

As part of a PhD study, two specific questions about human factors (HF) are to be incorporated into the Vein to Vein (V2V) audit. The overall aim will be to examine resilience within the transfusion process. In summary, the research will look at how staff in the transfusion process make adaptations to their standard procedures in order to overcome problems that arise and whether these adaptations are successful/acceptable or unsuccessful/unacceptable. Adaptations like this are part of an organisation's resilience (Hollnagel, 2010).

In addition, it is anticipated that some HF learning will become available from answers to the general audit questions and these can be examined alongside the specific PhD study.

HF questions to be added

These two questions are to be added to **each** audit tool, i.e. covering all the steps of the transfusion process:

Q1. "Please give a short outline of the biggest or most recent difficulty that you have faced when carrying out this procedure and what did you do about the issue?"
Answer = Box for free text of up to 150 words.

Q2. "How supportive was your manager/department for how you solved the issue?"
Answer = Five Likert scale (Likert, 1932)

Very supportive	Supportive	Neither supportive nor unsupportive	Unsupportive	Very unsupportive
5	4	3	2	1

Comment box - Please add comments if you wish:

Low text limit on this box to encourage brevity in comments

Prompts

Question 1 is deliberately a very open question, because the aim is to let the local operator tell their own story to see what comes out of that narrative. However, the local site auditors may need guidance notes to prompt answers to this section and in order to encourage relevant information, the suggested prompts are:

“As appropriate, please ask for more information to be added to the free text using the following questions:

- How did you respond to the issue you faced?
- What monitoring is done for issues like this?
- What is being done to anticipate such issues?
- What were you able to learn from dealing with the issue?”

These prompts will encourage collection of data on the four abilities of a resilient organisation (Hollnagel, 2010).

Conclusion

Adding HF questions to each of the V2V audit tools should give a rich source of data for analysis of the resilience of the transfusion process. Potentially, this may lead to an ongoing HF assessment tool that could be provided jointly via SHOT and the National Comparative Audit (NCA).

Hollnagel, E., 2010. How Resilient Is Your Organisation?. *An Introduction to the Resilience Analysis Grid (RAG). Sustainable Transformation: Building a Resilient Organization, Toronto, Canada*.

Appendix 8 – Vein to Vein pilot audit diary

National Comparative Audit of Blood Transfusion

NHS Blood and Transplant

Vein to Vein Audit of the Blood Transfusion Process

PILOT AUDIT DIARY

Introduction to the Vein to Vein audit

In the past we have audited various, discrete parts of the whole process that leads to a blood transfusion, and this audit brings those parts together and adds new parts so that the whole process from requesting the component to administering the blood can be audited. But this audit goes further than previous audits. We know from previous audits that some things are not done correctly, but we often do not know why, so it's difficult to change practice. This audit asks you to identify if something has not been done as we would expect and then immediately investigate why, to understand the root cause and therefore any potentially corrective intervention.

This audit, then, differs from other audits in that it is an *observational* audit. Data is collected real-time and questions are asked at the time of the event. If we used casenotes, found a problem and then went to ask why, few people would be able to recollect the reason, which in any case might be related to special circumstances that day.

The purpose of this diary is to record all issues involved in the data collection for this audit, for questions that have not previously been piloted. But for all 9 sections we are interested in your experience of asking the "why did this happen" type of question.

In this diary, the following questions form the foundation of the issues we are interested in:

- Were the data available?
- Did you experience any problems obtaining these data?
- What advice / information would you give to people who will audit this in future?

The following vignettes provide an example of how the Vein to Vein audit might operate and the action taken:

Sample collection

Jo is an FY2 doctor working on a Medical Assessment Unit and is taking a sample from an elderly woman so that a group and save can be done, because the woman is suspected of having a GI bleed following recent bouts of haematemesis. The sample was taken at 11:10 and when you audited it after the sample had been taken you found that the sample label was incomplete and that there was a mismatch between the sample and the request form. You speak to Jo to explain that you would like to find out why Jo was unable to follow the standard process in labelling a sample and completing a request form. Jo explained that she was told by an SpR to pre-label the sample bottles "because it's chaotic after the ward round and they panic if you don't take samples quickly. So always label the bottle using what's in the notes – there will always be enough to keep the lab happy. They want too much information anyway!". You code Jo's response on the audit form at Q10 and then summarise what she told you about the SpR's advice in Q11. Further inquiry reveals that Jo did not challenge the advice because she knows it's done differently in different areas so she just thought 'that's how we do things round here'. You do not enter anything in Q11 or Q12 because Jo did not try to resolve the problem. You now have to decide what you might do next to address the issue of the SpR's misleading advice

Administration

Indira is a Band 5 nurse working on a late shift on surgical ward G4. She is in charge of the shift because the Band 7 called in sick, and is working with another qualified nurse and 2 health care assistants. It has been decided to give a blood transfusion at 22:00 to an elderly man who is due to go to theatre in the morning. Indira's shift finishes at 23:00, and she has to handover to the night staff. The patient is not wearing a wristband, but nonetheless Indira proceeds with the transfusion because the patient needs the blood and she feels she has to get as much done as possible before the night shift starts. You have decided to make yourself unpopular by prowling round the wards at night, because you know that is when a lot of errors occur. You ask Indira why the patient is not wearing a wristband. Indira tells you that the wristband printer has been broken for a few days now and although IT have been asked to fix it, nothing has happened. She also explains that "in the old days" she would have put details on a wristband label and attached that to the patient, but the 'manual' wristbands were all thrown away 'because they don't have barcodes on them and all patients have to have a barcoded wristband'. Indira even thought of going to the ward next door to ask them to print one out, but felt she was running out of time. You complete Section I of the Vein to Vein audit form. Indira didn't know why the patient was not already wearing a wristband, so you tick the 'Don't know' option at Q4. You record Indira's narrative at Q20 and Q21, and explore with Indira what the most appropriate answer to Q22 is. You then decide what actions you might take to address the issues faced by Indira

Audit Tool Evaluation Form

There is a section in this diary for each of the 9 domains, but where we have already piloted the data collection questions, the section only focusses on the "why did this happen" type questions. For the other sections, the data collection questions are new, so they are included as well as the "why did this happen" questions. Here's how it works:

Suppose you are going to audit Section A: Requesting the group and save sample/blood component. Use data collection form A and gather the information for question 1. These data are the things which guidance suggests should be on each request. Once you have completed Q1, look at the data and decide if there is anything missing or wrong. If not, then you could feedback how well the requester has done. If there are things wrong or missing, then you go to Q2. You speak to the person completing the request and use Q2 to

explore with them what problems or issues they face which means things were not done as they should be. This is an open type of question, since there are no right answers. The job of Q2 is to find out why things are not being done the way they should be and what, if anything, the requester did about overcoming any difficulties the faced. Sometimes things are not done correctly because the requestor chooses to do it differently, or does not know what the correct procedure is, but sometimes they are not done correctly because there are things the requestor cannot correct or control. This is where Q3 comes in, as does your assessment of the situation. If the requestor encountered an operational problem, we want to know if they escalated it to their manager/department for resolution, and if they did, how supportive they were. The previous vignettes illustrate this point.

Each diary section lists the data collection and Human Factors questions, and we ask you to evaluate each question in turn. Tell us if you think the data asked for in the question is relevant to what we are auditing, whether the wording is clear or is capable of more than one interpretation and if the data was easy to find. Then tell us the source of that data (casenotes, charts, electronic record) so that we can develop guidance notes for future auditors. Rate each question as follows: **score each question 1 – 3 with: 1 = Agree 2 = Neither agree nor disagree; 3 = Disagree. Circle the score under each section question if completing on paper, OR delete the score numbers not needed.**

Finally you can add in specific comments or suggestions as appropriate for each question, and at the end of the diary you can tell us if there is anything you would add or exclude to the questions or the audit steps themselves.

The sections and questions now follow . . .

SECTION A: Requesting the group and save sample /blood component – We need to evaluate all questions

	Validity	*Feasibility*	*Feasibility*	*Feasibility*	
	Data relevant	**Wording clear**	**Data easy to find**	**Source of data**	**Comments/Suggestions**
A1	**Does the request for group and save/component issue confirm:**				
	1 2 3	**1 2 3**	**1 2 3**		
A2	**Please ask the person who tested the sample if there were any additional circumstances that need to be taken into account and record below**				
	1 2 3	**1 2 3**	**1 2 3**		
A3	**What was the biggest or most recent difficulty you have faced when carrying out this procedure and what did you do about this issue?**				
	1 2 3	**1 2 3**	**1 2 3**		
A4	**How supportive was your manager/department in eventually resolving the issue?**				
	1 2 3	**1 2 3**	**1 2 3**		

SECTION B: Sample collection – We only need to evaluate the use of “Human Factors” questions

	Validity	*Feasibility*	*Feasibility*	*Feasibility*	
	Data relevant	**Wording clear**	**Data easy to find**	**Source of data**	**Comments/Suggestions**
B11	**Please ask the person who has taken the blood if there were any additional circumstances that need to be taken into account and record below**				
	1 2 3	**1 2 3**	**1 2 3**		
B12	**What was the biggest or most recent difficulty you have faced when carrying out this procedure and what did you do about this issue?**				
	1 2 3	**1 2 3**	**1 2 3**		
B13	**How supportive was your manager/department in trying to resolving the issue?**				
	1 2 3	**1 2 3**	**1 2 3**		

SECTION C: Sample receipt in the laboratory - We need to evaluate all questions

	Validity	*Feasibility*	*Feasibility*	*Feasibility*	
	Data relevant	**Wording clear**	**Data easy to find**	**Source of data**	**Comments/Suggestions**
C1	**Was the sample labelled using a secure electronic patient ID system?**				
	1 2 3	**1 2 3**	**1 2 3**		
C2	**If "No", does the patient have a previous record of a blood group?**				
	1 2 3	**1 2 3**	**1 2 3**		
C3	**If "No", what would be the next course of action?**				
	1 2 3	**1 2 3**	**1 2 3**		
C4	**Did the information on the sample tube(s) match the request?**				
	1 2 3	**1 2 3**	**1 2 3**		
C5	**Did the information on the sample tube(s) and request contain the minimum required amount of information?**				
	1 2 3	**1 2 3**	**1 2 3**		

	Validity	*Feasibility*	*Feasibility*	*Feasibility*	
	Data relevant	**Wording clear**	**Data easy to find**	**Source of data**	**Comments/Suggestions**
C6	**If "No", what information was missing from the *sample*?**				
and	**1 2 3**	**1 2 3**	**1 2 3**		
C6	**If "No", what information was missing from the *request*?**				
and	**1 2 3**	**1 2 3**	**1 2 3**		
C6	**Was any other information missing (please describe)?**				
	1 2 3	**1 2 3**	**1 2 3**		
C7	**Was the sample rejected?**				
	1 2 3	**1 2 3**	**1 2 3**		
C8	**If "Yes" to C7, why was the sample rejected?**				
	1 2 3	**1 2 3**	**1 2 3**		

	Validity	*Feasibility*	*Feasibility*	*Feasibility*	
	Data relevant	**Wording clear**	**Data easy to find**	**Source of data**	**Comments/Suggestions**
C9	**If the answer was "No" to Questions 4, 5 or 6, please ask the person assessing the sample & request why the sample *was not* rejected?**				
	1 2 3	**1 2 3**	**1 2 3**		
C10	**Please ask the person who assessed the sample if there were any additional circumstances that need to be taken into account and record below**				
	1 2 3	**1 2 3**	**1 2 3**		
C11	**What was the biggest or most recent difficulty you have faced when carrying out this procedure and what did you do about this issue?**				
	1 2 3	**1 2 3**	**1 2 3**		
C12	**How supportive was your manager/department in eventually resolving the issue?**				
	1 2 3	**1 2 3**	**1 2 3**		

SECTION D: Testing in the laboratory- We need to evaluate all questions

	Validity	*Feasibility*	*Feasibility*	*Feasibility*	
	Data relevant	**Wording clear**	**Data easy to find**	**Source of data**	**Comments/Suggestions**
D1	**Was the sample processed?**				
	1 2 3	**1 2 3**	**1 2 3**		
D2	**Did the blood grouping result require any manual checking?**				
	1 2 3	**1 2 3**	**1 2 3**		
D3	**If "Yes", is the manual edit recorded on the laboratory information system?**				
	1 2 3	**1 2 3**	**1 2 3**		
D4	**What was the antibody screen result?**				
	1 2 3	**1 2 3**	**1 2 3**		
D5	**If the antibody screen was positive, was antibody identification performed?**				
	1 2 3	**1 2 3**	**1 2 3**		

	Validity	*Feasibility*	*Feasibility*	*Feasibility*	
	Data relevant	**Wording clear**	**Data easy to find**	**Source of data**	**Comments/Suggestions**
D6	**How was compatibility testing performed?**				
	1 2 3	**1 2 3**	**1 2 3**		
D7	**Please ask the person who tested the sample if there were any additional circumstances that need to be taken into account and record below**				
	1 2 3	**1 2 3**	**1 2 3**		
D8	**What was the biggest or most recent difficulty you have faced when carrying out this procedure and what did you do about this issue?**				
	1 2 3	**1 2 3**	**1 2 3**		
D9	**How supportive was your manager/department in eventually resolving the issue?**				
	1 2 3	**1 2 3**	**1 2 3**		

SECTION E: Selection of the component - We need to evaluate all questions

	Validity	*Feasibility*	*Feasibility*	*Feasibility*	
	Data relevant	**Wording clear**	**Data easy to find**	**Source of data**	**Comments/Suggestions**
E1	**Were more than 1 patient's unit(s) issued at the same time?**				
	1 2 3	**1 2 3**	**1 2 3**		
E2	**How many individuals were involved in the compatibility testing?**				
	1 2 3	**1 2 3**	**1 2 3**		
E3	**If 2 or more, is there an audit trail on which BMS did which part of the procedure?**				
	1 2 3	**1 2 3**	**1 2 3**		
E4	**How was compatibility testing performed?**				
	1 2 3	**1 2 3**	**1 2 3**		
E5	**Please ask the person who selected the component if there were any additional circumstances that need to be taken into account and record below**				
	1 2 3	**1 2 3**	**1 2 3**		

	Validity	*Feasibility*	*Feasibility*	*Feasibility*	
	Data relevant	**Wording clear**	**Data easy to find**	**Source of data**	**Comments/Suggestions**
E6	**What was the biggest or most recent difficulty you have faced when carrying out this procedure and what did you do about this issue?**				
	1 2 3	**1 2 3**	**1 2 3**		
E7	**How supportive was your manager/department in eventually resolving the issue?**				
	1 2 3	**1 2 3**	**1 2 3**		

SECTION F: Labelling, issuing and storage of the component - We need to evaluate all questions

	Validity	*Feasibility*	*Feasibility*	*Feasibility*	
	Data relevant	**Wording clear**	**Data easy to find**	**Source of data**	**Comments/Suggestions**
F1	**Were more than 1 patient's unit(s) labelled at the same time?**				
	1 2 3	**1 2 3**	**1 2 3**		
F2	**What checks were performed to ensure the correct label was attached to a component?**				
	1 2 3	**1 2 3**	**1 2 3**		
F3	**What happened to the unit after issue?**				
	1 2 3	**1 2 3**	**1 2 3**		
F4	**If the unit was sent to a fridge remote from the laboratory, how was it transported?**				
	1 2 3	**1 2 3**	**1 2 3**		
F5	**Please ask the person who labelled/issued the component if there were any additional circumstances that need to be taken into account and record below**				
	1 2 3	**1 2 3**	**1 2 3**		

	Validity	*Feasibility*	*Feasibility*	*Feasibility*	
	Data relevant	**Wording clear**	**Data easy to find**	**Source of data**	**Comments/Suggestions**
F6	**What was the biggest or most recent difficulty you have faced when carrying out this procedure and what did you do about this issue?**				
	1 2 3	**1 2 3**	**1 2 3**		
F7	**How supportive was your manager/department in eventually resolving the issue?**				
	1 2 3	**1 2 3**	**1 2 3**		

SECTION G: Component collection prior to transfusion – We only need to evaluate the use of “Human Factors” questions

	Validity	*Feasibility*	*Feasibility*	*Feasibility*	
	Data relevant	**Wording clear**	**Data easy to find**	**Source of data**	**Comments/Suggestions**
G9	**Please ask the person who collected the component if there were any additional circumstances that need to be taken into account and record below**				
	1 2 3	**1 2 3**	**1 2 3**		
G10	**What was the biggest or most recent difficulty you have faced when carrying out this procedure and what did you do about this issue?**				
	1 2 3	**1 2 3**	**1 2 3**		
G11	**How supportive was your manager/department in eventually resolving the issue?**				
	1 2 3	**1 2 3**	**1 2 3**		

SECTION H: Authorisation/prescription of the blood component – We only need to evaluate the use of “Human Factors” questions

	Validity	*Feasibility*	*Feasibility*	*Feasibility*	
	Data relevant	**Wording clear**	**Data easy to find**	**Source of data**	**Comments/Suggestions**
H8	**Please ask the person who authorised the component if there were any additional circumstances that need to be taken into account and record below**				
	1 2 3	**1 2 3**	**1 2 3**		
H9	**What was the biggest or most recent difficulty you have faced when carrying out this procedure and what did you do about this issue?**				
	1 2 3	**1 2 3**	**1 2 3**		
H10	**How supportive was your manager/department in eventually resolving the issue?**				
	1 2 3	**1 2 3**	**1 2 3**		

SECTION i: Administration – We only need to evaluate the use of “Human Factors” questions

	Validity	*Feasibility*	*Feasibility*	*Feasibility*	
	Data relevant	**Wording clear**	**Data easy to find**	**Source of data**	**Comments/Suggestions**
i10	**If the answer to i9 was “No”, why was it difficult to comply with the procedure?**				
	1 2 3	**1 2 3**	**1 2 3**		
i18	**If the answer to any items in i17 was “No”, why was it difficult to comply with the procedure?**				
	1 2 3	**1 2 3**	**1 2 3**		
i20	**Please ask the person who administered the component if there were any additional circumstances that need to be taken into account and record below**				
	1 2 3	**1 2 3**	**1 2 3**		
i21	**What was the biggest or most recent difficulty you have faced when carrying out this procedure and what did you do about this issue?**				
	1 2 3	**1 2 3**	**1 2 3**		
i22	**How supportive was your manager/department in eventually resolving the issue?**				
	1 2 3	**1 2 3**	**1 2 3**		

What would you have included in the audit tool, and why?

What would you have excluded from the audit tool, and why?

Appendix 9 – SHOT self-learning package 2018

(including case studies from 2017 package)

SERIOUS HAZARDS OF TRANSFUSION SHOT

Useful tips for the SHOT Human Factors Investigation Tool (HFIT)

Background information to help categorise the Human Factors elements of transfusion incidents reported to the SHOT database

Compiled by Alison Watt, SHOT Operations Manager
For queries contact 0161 423 4208 or shot@nhsbt.nhs.uk

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SHOT advises watching a short video with more information about Human Factors

https://t.co/qTeUoPiUIq

This link is to a simple video giving more information about human factors

It will take approximately 6 minutes to view this video

SHOT did not produce this video and we would like to acknowledge the creators:

- Health Education England (HEE)
- The Chartered Institute of Ergonomics & Human Factors (CIEHF)
- Medisense

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2

What is Human Factors (HF)?

- The term 'Human Factors' relates to how a human interacts with processes, systems, equipment and the environment
- It is equivalent to the term ergonomics
- It should not be mistaken for being only about factors relating to the human themselves
- A badly designed system or piece of equipment could be categorised as human factors because it could lead to errors and incidents
- The following slide has links to further information if you want to know more about human factors

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Further information and reading about human factors

- SHOT human factors resources (N.B. current resource listings may later be archived)
  - Current resources https://www.shotuk.org/resources/current-resources/
  - Figures from 2016 Report – Fig 6.1 onwards
    - Cases from 2016 Report – Cases slide 8 onwards
    - Teaching slide set from 2016 Report - Slides 20 and 31
  - Archived resources https://www.shotuk.org/resources/archived-resources/
    - Figures from 2015 Report - Fig 6.9 Double and confusing nomenclature for K and k
    - Cases from 2015 Report – HF cases slide 3 onwards
    - Teaching slide sets - From 2014 Report slides 43-60, From 2015 Report slides 59-69
  - http://www.shotuk.org/wp-content/uploads/LunchtimeTalkBBTSUpdate-2016_11_03-Final.pdf Slides 3-23
- Clinical Human Factors Group http://chfg.org/
- NHS England Human Factors Concordat https://www.england.nhs.uk/wp-content/uploads/2013/11/nqb-hum-fact-concord.pdf
- Chartered Institute of Ergonomics & Human Factors healthcare page https://www.ergonomics.org.uk/Public/Resources/Sector%20Information/Healthcare/Public/Resources/Sectors/Healthcare.aspx
- Free book - *Safer Healthcare, Strategies for the Real World* by Vincent & Amalberti http://www.springer.com/gb/book/9783319255576

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4

SHOT Human Factors Investigation Tool (HFIT)

- Almost 9 out of every 10 incidents reported to SHOT are related to errors (87% in 2016)
- Errors in healthcare may be related to the workplace environment and these can be the human factors that contribute to mistakes in transfusion
- In January 2016, SHOT introduced human factors questions, i.e. a human factors investigation tool (HFIT). Reporters were asked to estimate the factors related to the incident on a scale of 0 to 10, where 0 is none and 10 is the total cause
- In January 2017, SHOT produced and published this learning package
- In January 2018, SHOT updated this learning package with lessons that had been learnt after a further year of studying human factors
- The case studies have been renewed, but the cases from the original learning package are included at the end of this presentation

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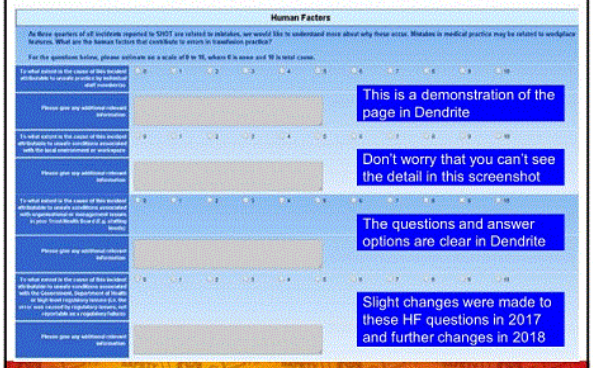
5

HF page in SHOT Database (Dendrite)



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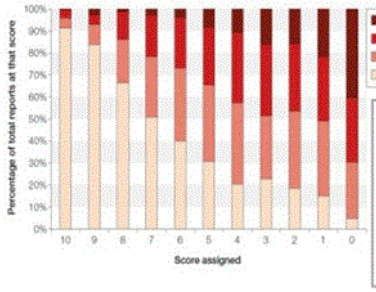
6

2016 Estimation of different human factors contribution to errors, score out of 10



From the first year of data, it appears that reporters assign the highest scores for cause of the incident to the individual staff member and often score little or nothing against other factors

7

Organisational and Government factors are hard to score

Reporters may struggle to assign scores the farther away it gets from the individual and the actual incident, because these can be difficult to assess.

Discussion points in the following case studies may give ideas for factors to consider that are outside the control of the individual or their local managers.
In particular it may be worth considering if outside factors could result in staff failing to follow policies.

8

How can we assess cases to get an accurate human factors score?

This tuition package on Human Factors is designed to help reporters to score the SHOT human factors questions.

In particular it may help reporters to consider the non-staff related factors that can contribute to the cause of an incident, such as:
- The work environment
- Organisational factors
- Government or high level factors

Please note: All scores are subjective and there are no right or wrong answers. Suggested scores given in cases below are not necessarily any more correct than the original scores. Reporters investigating the case locally may have more information that would lead them to score differently.

9

All the case studies are real cases

- All case studies and the initial scores given are from real cases reported to SHOT in the first year of incidents reported using the human factors investigation tool (HFIT)
- SHOT is very grateful to reporters for sharing their cases and completing the HFIT questions
- Reporters are not expected in any way to be human factors experts, so there is no criticism implied by the discussion of scores originally given or now suggested in these case studies
- Cases are fully anonymised

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Case study 1 (2017) - Total cause of incident initially attributed to individual

- Patient was transfused 2 units of red cells with a Hb of 79g/L, despite known risk factors for transfusion-associated circulatory overload (TACO)
- According to the protocol only 1 unit should have been administered initially and then the patient clinically reassessed, but the patient was not monitored between units and the consultant haematologist for transfusion believes the second unit was inappropriate
- The nurse administering the transfusion had not recognised the risk and only carried out routine blood transfusion observations
- A junior doctor (F1) reviewed the patient after the 2nd unit for complaints of shortness of breath. The F1 documented unlikely to be TACO as the patient calmed down during the examination with reassurance and was not in consistent respiratory distress. The case was reviewed by the Transfusion consultant and SHOT experts who concluded this was an inappropriate transfusion that resulted in TACO
- Patient had a cardiac event, but survived

11

Case study 1 (2017) Human factors scores initially given

Cause attributable to unsafe practice/conditions associated with:	Score out of 10
Individual staff member(s)	10
The local environment or workspace	0
Organisational or management issues in the Trust/Health Board	0
Government, Department of Health or high level regulatory issues	0

12

Case study 1 (2017) - discussion

- This case was originally scored with 10 for the individual staff member and nothing for any other human factors
- However, the local environment or workspace was not ideal, because no pump was available so the transfusion was given by free flow. The second unit was given too quickly at 1 hour 45 mins instead of 3 hours
- There were also organisational issues with shared care and co-morbidities:
  - The patient was on regular transfusions at a different hospital for myelodysplastic syndrome (MDS) but treated here for infected leg ulcers
  - The patient was taken off regular diuretic medication prior to having computerised tomography (CT) angiography, but was on fluids for acute kidney injury (AKI)
  - Appears to have been given the blood, because her regular 3-weekly transfusion was due, without taking into account her inpatient status
- A patient with complex transfusion issues was being monitored by a nurse who didn't recognise the TACO risk and was referred to a junior doctor to assess the shortness of breath. If apparently inexperienced staff were involved due to poor staffing levels that could be seen as a Department of Health level issue, because of possible underfunding of the health service

13

Case study 1 (2017) - HF scores when further info considered

*** The suggested scores assume all discussion points are valid, but the local investigator may know more detail and might score differently**

Additional information case study 1	Initial score	Suggested score *
Individual staff member(s): • TACO risk patient was not monitored between units	10	4
The local environment or workspace: • no pump was available so the transfusion was given by free flow leading to rapid infusion	0	7
Organisational issues: • shared care patient with co-morbidities • taken off regular diuretic medication • maybe was given regular 3-weekly transfusion without taking into account other issues	0	7
Government, DH or high level issues: • poor staffing levels resulting in inexperienced carers	0	4

14

Case study 2 (2017) Causes attributed evenly to all factors

- Anti-D immunoglobulin (Ig) was not administered following a potentially sensitising event (PSE) in pregnancy
- Following the PSE the community midwife referred the woman to the emergency department (ED) for appropriate Anti-D Ig administration
- However, due to incorrect information about the woman's blood type, no Anti-D Ig was given
- It was confirmed that the woman was D-negative and should have received appropriate prophylaxis treatment following the PSE
- The event came to light at a routine Anti-D clinic appointment, outside the period where Anti-D Ig could have been administered
- Routine antenatal Anti-D Ig prophylaxis (RAADP) was given at 28-30 weeks

15

Case study 2 (2017) Human factors scores initially given

Cause attributable to unsafe practice/conditions associated with:	Score out of 10
Individual staff member(s)	7
The local environment or workspace	7
Organisational or management issues in the Trust/Health Board	6
Government, Department of Health or high level regulatory issues	4

16

Case study 2 (2017) - discussion

- This case had scores attributed evenly in the original incident report
- Explanatory comments were given about each score, so their accuracy could be determined
- No suggested changes to the original scores were needed when the further information was analysed

17

Case study 2 (2017) - HF scores stay the same when further info considered

Additional information case study 2	Initial score	Suggested score
Individual staff member(s): • Clinician should have questioned the discrepancy and the possibility of error between what the midwife had written and the incorrect information about the woman's D-type	7	7
The local environment or workspace: • Problems between IT data entry systems due to use of different identifiers, i.e. NHS or Hospital numbers • When systems sharing fails, staff manually transcribe data, thus increasing the risk of incorrect data entry	7	7
Organisational issues: • This IT issue is common to other members of this Trust • Has been escalated accordingly, but no suggestions for resolution or to prevent this issue recurring	6	6
Government, DH or high level issues: • Lack of resources • Lack of national uniformity, i.e. using a unique patient identifier such as the NHS numbers throughout	4	4

18

Case study 3 (2017)
Causes attributed evenly to all factors

- A group A D-positive patient received a haemopoietic stem cell transplant (HSCT) from a group A D-negative donor
- The transplant protocol was received in the laboratory, but the specific transfusion instructions were not recorded in the laboratory information management system (LIMS)
- Post transplant, two units of A D-positive platelets were transfused instead of A D-negative platelets. The lack of transplant information in the LIMS means a new sample may not have been tested before issuing platelets
- A later group and save request highlighted the error that the patient's transplant had not been recorded in the LIMS
- There was no harm to the patient and it can be shown that at the time of the platelet transfusion the recipient was still grouping as A D-positive, i.e. had not yet converted to the donor's A D-negative group.

19

Case study 3 (2017)
Human factors scores initially given

Cause attributable to unsafe practice/conditions associated with:	Score out of 10
Individual staff member(s)	5
The local environment or workspace	6
Organisational or management issues in the Trust/Health Board	5
Government, Department of Health or high level regulatory issues	6

20

Case study 3 (2017) - discussion

- This case had scores attributed evenly in the original incident report
- Explanatory comments were given about each score, so their accuracy could be determined
- No suggested changes to the original scores were needed when the further information was analysed

21

Case study 3 (2017) - HF scores stay the same when further info considered

Additional information case study 2	Initial score	Suggested score
Individual staff member(s): • BMS followed procedure but omitted one step	5	5
The local environment or workspace: • Interruptions by colleagues and other healthcare professionals whilst inputting data into the LIMS • Doing different tasks at the same time, i.e. multitasking	6	6
Organisational issues: • Staff shortages • Implementation of a shift pattern has resulted in fewer qualified staff available during routine hours	5	5
Government, DH or high level issues: • Insufficient NHS funding leading to inability to increase staff levels to cope with increased work loads and changes in work patterns	6	6

22

Case study 4 (2017) - Total cause of incident accurately attributed to individual

- Two samples were received in the laboratory for a patient that were bled by the same person, but labelled as taken one hour apart
- Both samples grouped as A D-positive
- Historically this patient is O D-positive
- This showed a contravention of the group check policy, also known as the two-sample rule
- These samples were wrong blood in tube (WBIT) and could have resulted in an ABO-incompatible red cell transfusion
- As there was a historical group on record, a second sample would not have been needed anyway

23

Case study 4 (2017) - Human factors scores initially given

Cause attributable to unsafe practice/conditions associated with:	Score out of 10
Individual staff member(s)	10
The local environment or workspace	0
Organisational or management issues in the Trust/Health Board	0
Government, Department of Health or high level regulatory issues	0

24

Case study 4 (2017) - discussion

- It is rare for total responsibility to be individual staff member(s), but in this case the person taking the sample deviated from the group-check policy which is designed to prevent wrong blood in tube errors
- Taking two samples at the same time is never appropriate:
  - If a second person cannot take an independent sample, the original sampler should return after a period of time for a new venepuncture repeating all checks
  - If a group-check sample cannot be obtained, the safe option is to proceed as recommended for an emergency under the British Society for Haematology (BSH) guidelines, e.g. depending on local policies, the patient may be given group O red cells until a group-check sample can be taken
  - This error was detected due to a discrepancy with a previously known historical group, so there was no requirement for a group-check sample
- No mitigating factors were reported, such as high workload, low staffing, insufficient training or resources etc.

25

Case study 4 (2017) - HF scores stay the same when further info considered

Additional information case study 4	Initial score	Suggested score
Individual staff member(s): • did not follow the correct procedure for taking a group-check sample • did not revert to the failsafe options available in the guidelines if a second sample cannot be obtained	10	10
The local environment or workspace: • no evidence of workload issues	0	0
Organisational issues: • no evidence of organisational issues	0	0
Government, DH or high level issues: • no evidence of high level issues	0	0

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Summary

- Human factors is all about how humans interact with processes and systems
- It is common to think the individual is totally responsible for an error, but consider whether they may be working in a poor system
- Our top tip is to review all contributing factors before scoring the human factors section in the SHOT Database questionnaires
- If in doubt, please ask the SHOT Office, SHOT@nhsbt.nhs.uk, 0161 423 4208

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Thank you

- SHOT owes a huge debt of gratitude to all reporters for sharing their cases with us
- Many thanks for reading these tips about Human Factors and we hope you have found them useful

Kind regards,

The SHOT Team

28

The following slides contain case studies originally used in the self-learning package created in 2017

These cases are taken from SHOT incidents reported in 2016

29

Case study 1 (2016) - Total cause of incident initially attributed to individual

- Patient A had a pre-transfusion sample taken by a nurse in a side room of the ward
- The nurse was also co-ordinating the ward beds and labelled the sample away from the bedside, while dealing with a query from another member of staff about patient B
- The nurse labelled the sample and request form with patient B's details instead of patient A
- Patient B had a historical blood group result, so the ABO mismatch was detected by the laboratory testing
- The nurse then realised her error and repeated the sampling of patient A
- There was a slight delay in ordering blood for patient A, but no major harm was caused

30

Case study 1 (2016)
Human factors scores initially given

Cause attributable to unsafe practice/conditions associated with:	Score out of 10
Individual staff member(s)	10
The local environment or workspace	0
Organisational or management issues in the Trust/Health Board	0
Government, Department of Health or high level regulatory issues	0

31

Case study 1 (2016) - discussion

- This case was originally scored with 10 for the individual staff member and nothing for any other human factors
- However, the local environment or workspace was not ideal, because the nurse was working in a side room, whilst also being responsible for coordination of all ward beds
- If there were not appropriate systems and policies in place, that would be an organisational issue, e.g.
  - A member of staff involved in the critical task of taking pre-transfusion samples should not be disturbed by another staff member
  - A patient's request form should be available in advance of taking a sample, so the details can be cross-checked during the sampling process, but on this occasion that was not done
  - Does that mean there were no systems or policies in place to cover these items? Or if staff did not comply with policies because of an excessive workload that would be another organisational factor
- If the excessive workload was caused by poor staffing levels, that could be attributed as a Department of Health level issue, because of possible underfunding of the health service

32

Case study 1 (2016) - HF scores when further info considered

*** The suggested scores assume all discussion points are valid, but the local investigator may know more detail and might score differently**

Additional information case study 1	Initial score	Suggested score *
Individual staff member(s): • request form should be available, but ?no policy • sample must be labelled at the bedside	10	5
The local environment or workspace: • working in a side room, possibly away from resources • while also being responsible for all ward beds • interrupted by colleague when doing a critical task	0	7
Organisational issues: • ? no policies about request form, interruption etc. • ? poor compliance, due to excessive workload	0	6
Government, DH or high level issues: • ? excessive workload caused by poor staffing levels as a result of government underfunding	0	4

33

Case study 2 (2016) - Causes attributed evenly to all factors

- Red cells were prescribed to be administered via a blood warmer, because the patient has cold haemagglutinin disease (CHAD).
- The blood transfusion was commenced without a blood warmer

34

Case study 2 (2016)
Human factors scores initially given

Cause attributable to unsafe practice/conditions associated with:	Score out of 10
Individual staff member(s)	10
The local environment or workspace	9
Organisational or management issues in the Trust/Health Board	9
Government, Department of Health or high level regulatory issues	9

35

Case study 2 (2016) - discussion

- This case had scores attributed evenly in the original incident report
- Explanatory comments were given about each score, so their accuracy could be determined
- No suggested changes to the original scores were needed when the further information was analysed

36

Case study 2 (2016) - HF scores stay the same when further info considered

Additional information case study 2	Initial score	Suggested score
Individual staff member(s): • Agency nurse, so unable to verify transfusion training and competency - it is against hospital policy to administer transfusion without training/competency	10	10
The local environment or workspace: • No blood warmer kept on Acute Admissions Unit • Nursing staff were unable to locate one anywhere else in the hospital	9	9
Organisational issues: • Use of agency nurses due to staffing levels • Agency staff administering transfusions	9	9
Government, DH or high level issues: • Funding issues - staffing and equipment	9	9

37

Case study 3 (2016) - Cause initially seems accurately attributed to individual

- Wrong blood in tube discovered when unexpected prophylactic anti-D was detected during a routine blood test
- On investigation the staff member who took the sample recognised the error and knew who the patients were, so realised the sample had been labelled with the wrong patient's details
- The incident investigation concluded:
  - the member of staff must have had more than one patient's documentation on her workspace
  - the sample was labelled away from the patient
  - there was a failure to follow policy

38

Case study 3 (2016) Human factors scores initially given

Cause attributable to unsafe practice/conditions associated with:	Score out of 10
Individual staff member(s)	10
The local environment or workspace	0
Organisational or management issues in the Trust/Health Board	0
Government, Department of Health or high level regulatory issues	0

39

Case study 3 (2016) - discussion

Does this extra information change the conclusion that the cause was totally attributable to the staff member?

- On a Thursday the staff member involved worked 8:30 to 22.30 dealing with a very difficult and distressing situation in the delivery suite and a patient subsequently sectioned under the mental health act
- By Friday at 12:00 the staff member was at work again in a clinic for pregnant women without a local GP. Saw four women, three of whom were 28 weeks pregnant and required routine blood tests and one who was 25 weeks pregnant and did not require blood samples, but did need a urine sample to be referred
- There were a number of interruptions with telephone calls about the distressing case from the night before
- So one of the blood samples from a 28-week pregnant woman was erroneously labelled with the 25-week pregnant woman's details
- The staff member concluded they probably were not fit to have attended the clinic on that day as there was too much going on from the unpleasant incident the day before – did they feel pressured to work?

40

Case study 3 (2016) - Human factors scores when further information considered

Additional information case study 3	Initial score	Suggested score
Individual staff member(s): • Did not follow procedure	10	5
The local environment or workspace: • Interruptions • Doing different tasks at the same time (multitasking)	0	6
Organisational issues: • Worked long hours in distressing circumstances • Was required to concentrate on several different complex situations	0	9
Government, DH or high level issues: • Did a lack of resources mean the staff member felt pressured to work when not really fit to do so?	0	5

41

Case study 4 (2016) - Total cause of incident accurately attributed to individual

- Sample booked in for patient 1 at 07:35 for referral to a reference laboratory and allocated lab number XXX05
- Sample booked in for patient 2 at 07:39 for routine testing and allocated lab number XXX07
- At 11:40 it was noted that the barcode for XXX05 (= patient 1) was placed on the sample from patient 2
- Barcode XXX07 was not present on patient 1's sample or form, nor was it on any of the other samples booked in around the same time
- Outstanding tests were cancelled and all other samples received for each patient that day were checked and the labels were correct

42

Case study 4 (2016)
Human factors scores initially given

Cause attributable to unsafe practice/conditions associated with:	Score out of 10
Individual staff member(s)	10
The local environment or workspace	0
Organisational or management issues in the Trust/Health Board	0
Government, Department of Health or high level regulatory issues	0

43

Case study 4 (2016) - discussion

- The member of staff had not followed line clearance instructions, i.e. duplicate barcode labels were not cleared from the line
- This deviation from procedure had been previously observed and discussed with the member of staff
- The member of staff verified the sample alone, but the procedure is this must be carried out by a second person
- The verification was done without retrieving the actual specimen, but the procedure is that details on the sample must be checked against the LIMS record
- The member of staff indicated workload was high, but a review showed no suggestion of a heavy workload for the time of the incident e.g. no bleeps recorded between 07:08 and 07:43 and there was a normal level of laboratory tasks

44

Case study 4 (2016) - HF scores stay the same when further info considered

Additional information case study 4	Initial score	Suggested score
Individual staff member(s): • did not follow procedures for barcoding samples • did not follow procedure for verifying patient ID on sample tube	10	10
The local environment or workspace: • workload was reviewed for time of incident and found not to be excessively busy (laboratory internal review of phone calls, bleeps, component issue and fridge collection)	0	0
Organisational issues: • no organisational issues	0	0
Government, DH or high level issues: • no high level issues	0	0

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Appendix 10 - Agreement with Serious Hazards of Transfusion (SHOT) for reproduction of copyright material

Copyright Permission Request to Serious Hazards of Transfusion (SHOT)

Date:16 September 2019

Re: Permission to Use Copyrighted Material in a Doctoral Thesis

Dear Dr Narayan,

As well as being a volunteer on the Serious Hazards of Transfusion (SHOT) Working Expert Group (WEG), I am a Loughborough University graduate student completing my Doctoral thesis entitled "The Application of Human Factors to the Blood Transfusion Process". My thesis will be available in full-text on the internet for reference, study and/or copy. Except in situations where a thesis is under embargo or restriction, the electronic version will be accessible through the Loughborough University Research Repository.

I would like permission to allow inclusion of the following material in my thesis:

> *Data and text from Annual SHOT Reports published 1997 to 2019 inclusive - any derivative data and figures have been checked with the SHOT Research Analyst.*
>
> *In particular, permission is requested for reproduction of data, text and figures from the Human Factors Chapters in Annual SHOT Reports, which were written by me and published in 2015, 2016, 2017, 2018 and 2019.*

The SHOT material will be attributed through citations.

I appreciate your consideration of this permissions request.

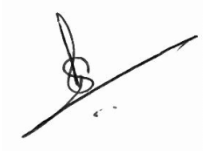
Please confirm that these arrangements meet with your approval by signing and dating this request below. Please return by email.

Yours sincerely,

Alison Watt

Permission is hereby granted for specified use of Serious Hazards of Transfusion (SHOT) material with the agreement that all data/text and figures included will be cited and referenced appropriately.

Name: Shruthi Narayan, SHOT Medical Director

Signature: 

Date: 25th September 2019