Implementation and evaluation of a blood products traceability procedure in a District General Hospital

By

Francis O Ajeneye MSc, FIBMS, CSci, CertHPM

A portfolio of research and development in a professional context

Submitted in partial fulfilment of the

Degree of Professional Doctorate in Biomedical Science

School of Pharmacy and Biomedical Sciences
Faculty of Science
University of Portsmouth
September 2012
Abstract

The main aims of this study were to explore and identify why traceability compliance was poor at the Homerton University Hospital NHS Trust and to implement a suitable model to improve it. This study was a multi-stage exploration of the various practices of staff involved in the blood transfusion chain, both at the Trust and in some other NHS Trusts in the United Kingdom. The study explored the reasons for the Trust’s poor traceability of blood products, which eventually led to poor compliance. It identified the risk factors that led to poor traceability, explored why some wards had better compliance than others and evaluated the direct costs and benefits of wastage.

The principal aim of these activities was to be able to take an informed decision on the development of a new model to improve compliance.

A quantitative approach was adopted as it made it possible to measure the frequency of actions, and this data was used to answer the research questions. Data was collected using questionnaires, observations and an audit of information extracted from the laboratory’s information management systems. A questionnaire was designed, piloted and sent to all ward managers at the Trust, and survey data was analysed using the SPSS statistical package. Some of the issues that were addressed and analysed included: staff training in blood product collection and administration; knowledge of staff members of the concept of traceability compliance; laboratory staff professionalism; ward staff responsibilities for traceability compliance; and ward staff attitudes and opinions about the traceability model.

To add rigour to the study, the survey was followed by structured observations at the blood collection point and the patient’s bedside. This data was also analysed using descriptive statistics and the results showed that traceability compliance was poor in some areas of the Trust. Problems included: the absence of a trainer on the ward, lack of education, few transfusion episodes on the wards, variation in the method of returning labels to the transfusion department, and poor communication between frontline staff and the transfusion laboratory.
The study resulted in the implementation of new approaches to the transfusion chain in order to improve practice. These included: the appointment of a medical laboratory assistant to assist with traceability compliance; the appointment of a clinical transfusion nurse specialist to assist with training and ensure safe practice on wards; the provision of trainers and clinical supervision on particular wards; the development of a competence programme to assess staff involved in blood collection and distribution; the development of clinical guidelines; and the administration of an annual skills checks for staff involved in the transfusion chain.

Most of the recommendations have been implemented and put into practice. A formal audit will be conducted in the future to evaluate their success but to date, 65% of staff members have passed the annual skills' assessment and the traceability compliance of the Trust has remained at 100%.
# Table of Contents

1. **Introduction** ........................................................................................................... 1
   1.1. Globalisation and blood safety ................................................................. 2
   1.2. Epidemiological monitoring of donors ................................................... 5
   1.3. Haemovigilance ............................................................................................. 6
   1.4. Blood transfusion in the UK ........................................................................ 8
   1.5. The regulatory framework ........................................................................... 13
   1.6. Organisational and professional drivers for BSQR ................................. 14
       1.6.1. Serious Hazards of Transfusion (SHOT) ........................................ 14
       1.6.2. Clinical governance .............................................................................. 15
       1.6.3. National Patient Safety Agency (NPSA) ........................................... 16
       1.6.4. The UK Transfusion Laboratory Collaborative ............................... 17
       1.6.5. Better Blood Transfusion (BBT) ....................................................... 17
       1.6.6. European Blood Safety Directives ..................................................... 18
       1.6.7. UK Blood Safety and Quality Regulations ........................................ 19
       1.6.8. Clinical audits and professional standards ......................................... 20
   1.7. Transfusion safety .............................................................................................. 21
       1.7.1. Recipient recall programmes ............................................................. 22
       1.7.2. Methods to identify blood transfusion incidents ............................ 23
       1.7.3. Causes of incidents in blood transfusion ....................................... 27
       1.7.4. Incident reporting .................................................................................. 31
       1.7.5. Traceability compliance ....................................................................... 33
   1.8. Proposed programme of research ............................................................... 40
1.8.1. Research aim and objectives ................................................................. 41

2. Traceability compliance assessment (Method 1) ....................................... 43
   2.1.1. Phase one: Quantitative assessment of traceability compliance ........... 44
   2.1.2. Phase two: Survey of ward managers ............................................ 49
   2.1.3. Phase two: Direct observation ..................................................... 54
   2.1.4. Discussion .................................................................................. 56

3. Blood product tracking models ................................................................. 60
   3.1.1. Introduction .................................................................................. 60
   3.1.2. Method ...................................................................................... 60
   3.1.3. Results ...................................................................................... 61
   3.1.4. Discussion .................................................................................. 64
   3.2. Commercial software products ......................................................... 67
   3.2.1. Barcode tracking systems ............................................................. 67
   3.2.2. Radiofrequency tracking systems .................................................. 69
   3.2.3. Limitations and challenges of barcode and RFID technology .......... 70
   3.3. Survey of blood bank managers ....................................................... 71
   3.3.1. Method ..................................................................................... 72
   3.3.2. Results ...................................................................................... 72
   3.4. Discussion ...................................................................................... 75
   3.4.1. Literature review ......................................................................... 75
   3.4.2. Tracking methods ........................................................................ 76

4. New system implementation (Method 2) ..................................................... 77
   4.1. Quantitative assessment of traceability compliance .............................. 78
   4.1.1. Method ...................................................................................... 78
4.1.2. Results .................................................................................................................. 79

4.2. Further interventions to improve compliance .................................................... 83

4.2.1. Medical Laboratory Assistant ........................................................................ 83

4.2.2. Medical/electronic processing records ............................................................... 84

4.2.3. Transfusion nurse specialist ......................................................................... 84

4.3. Discussion ............................................................................................................. 84

4.4. Change management ............................................................................................ 85

4.4.1. Psychodynamic approaches to change ............................................................ 86

4.4.2. Justification for change .................................................................................... 89

4.4.3. Funding and training ....................................................................................... 90

4.5. Clinical implications .............................................................................................. 90

5. Application to practice ............................................................................................ 91

5.1. Evidence of achievements .................................................................................... 92

5.1.1. Specialist transfusion nurse ....................................................................... 94

5.1.2. Skills assessment .......................................................................................... 94

5.1.3. Redesign of information technology .............................................................. 95

5.1.4. Medical laboratory assistant (MLA) ................................................................ 95

5.1.5. Air tube system .............................................................................................. 96

5.2. Cost-benefit analysis ............................................................................................ 96

5.3. Email questionnaire ............................................................................................. 97

5.3.1. Method ............................................................................................................ 97

5.3.2. Results............................................................................................................ 99

5.4. Summary ............................................................................................................. 99

6. Reflection ................................................................................................................ 101
6.1. Developing the extending role ........................................................................... 106
6.2. Future goals ........................................................................................................ 106
6.3. Dissemination ...................................................................................................... 106

7. References ............................................................................................................ 108
Appendices

Appendix 1  Information form LREC for the study approval
Appendix 2  Approval letter from the Trust Clinical Governance Committee
Appendix 3  Letter to blood bank managers
Appendix 4  Letter to ward managers
Appendix 5  Questionnaire sent to the ward managers
Appendix 6  Questionnaire sent to the NHS Trust blood bank managers
Appendix 7  Structure observation tools developed for blood collection point and bedside checking procedure
Appendix 8  Procedure for collecting EU Directive compliance figures at the Homerton University Hospital NHS Trust
Appendix 9  Developed competency assessment tools for the clinical and non-clinical staff collecting blood products
Appendix 10  Dissemination
# List of tables

Table 1-1 Overview of national haemovigilance systems in the European Union. .. 7

Table 1-2 Blood products issued by UK blood services 1999-2011. ................. 8

Table 1-3 Blood transfusion errors in the UK blood supply 1996-2011 ................ 9

Table 1-4 Total number of reports per 10,000 components 2007-2011 ............... 10

Table 1-5 Number of infected recipients and their outcome from 1996-2011....... 11

Table 1-6 Infrastructure, systems and processes related to clinical governance... 16

Table 1-7 National Comparative Audit on Better Blood Transfusion ............... 18

Table 1-8 Predictive Human Error Analysis (PHEA) technique ...................... 23

Table 1-9 Error identification methods; advantages and limitations .............. 23

Table 1-10 Summary of the types of clinical errors .................................... 26

Table 1-11 Technological causes of blood transfusion errors ....................... 27

Table 1-12 Patient identification tracking systems and errors prevented .......... 28

Table 1-13 Special requirements incidents in the UK .................................. 28

Table 1-14 Literature review of traceability compliance 2001-2012 ............... 36

Table 2-1 Mean ward traceability compliance .......................................... 46

Table 2-2 Compliance as percentage of units issued for all wards 2005-08........ 47

Table 2-3 Traceability compliance for all wards 2005-2008 ........................ 48

Table 2-4 Traceability compliance for usage groups 2005-2008 ................... 48

Table 2-5 Ward demographics .................................................................... 51
Table 2-6 Ward managers’ assessment of traceability compliance ....................... 52
Table 2-7 Observed compliance by ward staff ............................................. 55
Table 3-1 Results of the literature review .................................................. 63
Table 3-2 A sample of commercial products using bar-code technology ........ 68
Table 3-3 Demographics of the 16 NHS Trusts surveyed ......................... 73
Table 4-1 Average ward compliance 2009-2010 ....................................... 80
Table 4-2 Percentage compliance 2009-10 .............................................. 81
Table 5-1 Reduction in red blood cell wastage 2006-2011 ....................... 97
Table 5-2 Demographics of the NHS Trusts surveyed .............................. 98
List of figures

Figure 1.1 Summary of blood transfusion errors 2011 ......................................................... 10
Figure 1.2. The pillars of clinical governance ................................................................. 15
Figure 1.3 Steps in the transfusion chain. ....................................................................... 22
Figure 1.4 Organisational accident model......................................................................... 31
Figure 1.5 Flow diagram identifying elements of the study............................................. 42
Figure 2.1 Correlation between traceability compliance and units transferred............. 47
Figure 2.2 Percentage compliance for usage group......................................................... 48
Figure 4.1 Air-tube system installed at the Trust............................................................... 78
Figure 4.2 Comparison of ward traceability compliance using Methods 1 and 2........... 81
Figure 4.3 shows 2012/13 the average traceability compliance within the Trust.......... 82
Figure 4.4 Usage group traceability compliance under Method 1................................. 83
Figure 4.5 Usage group traceability compliance under Method 2................................. 83
### Abbreviations

| Abbreviation | Description |
|--------------|-------------|
| AIDS         | Acquired Immune Deficiency Syndrome |
| BSQR         | Blood Safety and Quality Regulations |
| EC           | European Commission |
| HBV          | Hepatitis B Virus |
| HCV          | Hepatitis C Virus |
| HPA          | Health Protection Agency |
| HIV          | Human Immunodeficiency Virus |
| IBMS         | Institute of Biomedical Sciences |
| ISBT         | International Society of Blood Transfusion |
| MHRA         | Medicine and Healthcare products Regulatory Agency |
| NHS          | National Health Services |
| NPSA         | National Patient Safety Agency |
| RFID         | Radio Frequency Identification |
| SCBU         | Special Care Baby Unit |
| SHOT         | Serious Hazard of Transfusion |
| UK           | United Kingdom |
| vCJD         | Variant Creutzfeldt Jakob Disease |
Acknowledgements

I would like to thank my Academic Supervisors, Doctors Sally Kilburn and Bernie Higgins and who have taught me and guided me so much. They have unfailingly supported me in higher education and have encouraged me in my professional development.

I am grateful to Professor Graham Mills for his in-depth critique of the study and his support in undertaking the Professional Doctorate alongside my professional practice.

Thanks to Steve O’Kell for the first module of this Doctorate in Biomedical Sciences programme. He stretched me to perform at my best and taught me the art of true reflection. His continued professional support has been crucial to the implementation of the recommendations that have arisen from this research.

I am obliged to those who participated in the questionnaires and who made this thesis purposeful. They gave their time freely and willingly, talked openly and honestly, and trusted me with their experience and knowledge.

I am grateful to work supervisors, Dr R Amos (Haematology Consultant), Ms Yvonne Kelly (Laboratory Manager) and Bala Sirigireddy who painstakingly validated my data at several stages, challenged and debated many issues and assumptions throughout the development of categories, and helped me to value and like my work at a time when I could have put it to one side indefinitely.

I am indebted to Mr Oluwatoyin Olamiji, my friend who embarked with me on the professional doctorate a few years ago when we began to support each other. He offered encouragement and gave me the self-belief that this journey is achievable.

I also thank my family, Oluwaseyi, Tomisin and my wife who have all played their different parts, too numerous to mention individually, in this research journey. I look forward to the return of a sociable family life.
Dissemination

Ajeneye, F. (2012)  Blood storage and the 30-minute rule. The Biomedical Scientist Gazette Vol 56, p.204–205.

Ajeneye, F. (2012)  Blood Safety and Quality Regulations and the hospital laboratory. Biomedical Scientist Gazette Vol 56, p.144–145.

Ajeneye, F. (2008)  Traceability of blood and its products. The pursuit of 100% compliance. Biomedical Scientist Gazette Vol. 52, p.1086–87.

Ajeneye, F. (2007)  Pre-analytical quality assurance: A Biomedical Scientist perspective. Biomedical Scientist Gazette Vol.51, p.86–87.

Ajeneye, F. (2006)  Power and sample size estimation in research. Biomedical Scientist Gazette Vol.50. p.988–990.

Ajeneye, F. (2006)  How to validate a diagnostic research. Biomedical Scientist Gazette Vol.50. p.535–537.

Ajeneye, F. (2005)  Reflective practice: A Biomedical Scientist perspective. Biomedical Scientist Gazette Vol. 49, p.572–573.

Oral presentations

Ajeneye, F. (2011).  The impact of BSQR in the hospital transfusion laboratory: A Biomedical Scientist perspective. IBMS International Congress, U.K.

Ajeneye, F. (2009).  Blood products traceability: Where are we now? IBMS International Congress September, U.K.

Poster presentations

Ajeneye, F. (2012)  The two faces of traceability compliance at the Homerton University Hospital. BBTS Annual Congress 2012.

Ajeneye, F. (2011)  Blood product traceability: The pursuit of 100% compliance. AMT conference, Miami, U.S.
Ajeneye, F. (2009) Common errors in the blood transfusion chain. *BBTS International Congress, U.K.*

Ajeneye, F. (2009) Blood products traceability compliance: How it all happened. *AMT conference*, Minneapolis, U.S.

Ajeneye, F. (2007) Traceability of red cells within Trust: A retrospective audit. *IBMS International Congress* U.K.

Ajeneye, F. (2005) Blood collection audit: compliance with the Trust policy. *IBMS International Congress*, U.K.

Ajeneye, F. (2005) Recent development in blood transfusion. *AMT Conference*, Nevada, U.S.

Ajeneye, F. (2005) Development and audit of rejected transfusion requests within the Trust. *IBMS International Congress*, U.K.

Ajeneye, F. (2005) Common errors in blood transfusion. *AMT Conference*, Kansas City, U.S.
Declaration

I declare that whilst studying for the Doctorate in Biomedical Science at the University of Portsmouth, I have not been registered for any other award at another university. The work undertaken for this degree has not been submitted elsewhere for any other award. The work contained within this submission is my own work and, to the best of my knowledge and belief, it contains no material previously published or written by another person, except where due acknowledgement has been made in the text.

Francis Ajeneye

September, 2012
Dedication

It gives me great pleasure to dedicate this work to all lovers of knowledge, my family and colleagues at work, who dedicated their professional lives to the National Health Service and continue to support it, even in retirement, by the unceasing care and kindness they have bestowed on me.
1. Introduction

Blood is one of the world’s vital substances. The Greeks referred to blood as a component of universal order. The Romans felt blood carried a person’s vital essence; the gladiators drank the blood of their fallen opponents. Doctors, from mediaeval to Victorian times assumed that blood had a fantastical power; draining blood removed evil humour, transfusing blood pacified the deranged (Starr, 2001, pp.119-120).

However, blood is fragile and expensive and has been a heavily traded product across the world. The global trade in blood and its products developed in the early 1970s. Initially, red cells and white cells stayed within national boundaries except for Swiss blood that was exported to Greece and the United States. Eventually, plasma derivatives became international commodities when the United States became the pioneer of plasmapheresis. A darker side of the industry emerged as plasma mills appeared in deprived areas of American cities with donation sessions from drug addicts and prisoners. Although Europe denounced this practice it continued to quietly purchase plasma and its derivatives from America. Other plasma mills, located in South and Central America were destroyed in 1978 (Farrugia, 2006).

The same, effective, system that was responsible for the collection of blood products was equally effective in distributing diseases. Transfusion Transmitted Infection became a significant and daily subject of alarm in western countries. Both clinicians and politicians were blamed for delivering disease to the population rather than preventing it (Feldman & Bayer, 1999, p.268).

Haemophilia patients became reliant on fractionated plasma in the early 1980s. Because they did not need to go to a hospital for a plasma transfusion, some could keep fractionated products at home. Easy access to fraction blood products gave them a normal life (Feldman and Bayer, 1999, p. 269-270). Consequently, the stock of residual plasma products could not meet worldwide demand. However, more pooled plasma was needed worldwide than could be supplied from fresh blood supplies.
Blood and its products (derived from whole human blood or plasma) saves millions of lives every year but the entire process of collecting and distributing blood and its products depends on the trust and the goodwill of the public. Although some adverse events related to blood transfusions may occur immediately, transfusion transmitted diseases may not produce any illness for months, or even years. The ability to trace the path of the blood from the recipient to the original donor and vice versa is an important public health safeguard. In addition, accurate and complete record keeping is an essential part of professional practice.

1.1. Globalisation and blood safety

Globalisation may be defined as the, “transition from national and regional economies to global economies. This includes a nexus of an economic and social process where local market and culture are dominated by global market and cultures” (Fisher, 2004). It is a consequence of the growing interdependence of countries worldwide through an increasing volume of cross-border trading in goods and services.

Data gathered by World Health Organization (World Health Organization, 2006) showed that the blood donation rates and the extent of viral testing are dependent on economic status (Mattar, 2004). In an ideal and globalised environment, one would expect that the challenges faced by the world in terms of the safety and supply of blood and its products would be addressed through the free movement of blood derivatives. However, the developed world’s capacity to deal with established and emerging blood safety threats, many of which are the results of globalisation is lacking (Snyder & Dodd, 2001, p.433). Malaria is the most common transfusion-transmitted infection worldwide and in non-malarious area is introduced into the blood supply via travellers returning from areas where it is endemic. In the United Kingdom deferral measures applied to donors returning from such countries are considered to provide adequate protection (Snyder & Dodd, 2001).

Unfortunately the continuing emergence of infectious agents is a feature of globalisation. It affects the safety of the blood supply and makes the cross-border movement of blood more difficult than in previous times. Nevertheless, the plasma industry, where blood products are traded across national borders is one example of the continuing global nature of the business. The reaction of humans to the
pressures of globalisation is responsible for many of the current challenges posed by trade-related infections (Kimball, Arima & Hodges, 2005, p.2).

Higher levels of traffic in goods and people have affected both blood safety and supply in many ways. The increasing movement of plasma products has eroded some of the historical barriers between countries. Developed countries are strengthening the blood safety infrastructure through the development of new tests and pathogen elimination techniques (World Health Organisation, 2006). Many of these measures are the result of trends initiated by pharmaceutical manufacturers and in the healthcare sector although in general such processes have been restricted to, and focused on, rich countries (Kreil et al., 2003, pp.1023–1026).

Variant Creutzfeldt Jakob Disease (vCJD) is a degenerative disorder that was first recognized in 1996 in the UK. It is caused by bovine spongiform encephalopathy (BSE) contaminated meat. From October 1996 to March 2011, 175 cases of vCJD have been reported in the United Kingdom, 25 in France, five in Spain, four in Ireland, three each in the Netherlands and the United States, two each in Canada, Italy and Portugal and one each in Japan Saudi-Arabia and Taiwan. vCJD is a new disease and the risk of transmission has been a major concern to blood services since its discovery. The precautionary measures taken since 1999 include the removal of white cells believed to contain much of the infectious agent-prions (McClelland et al., 1996).

The first incident of the contamination of blood by Hepatitis B was seen in 1982 in patients with haemophilia who had received blood fractions as therapy for their clotting disorder. These products were produced from the pooled plasma from a large number of donors, which was normal procedure at this time. Until then, the potential contamination of blood products with infectious diseases had not been seen as a risk. Since then, the response to Acquired Immune Deficiency Syndrome (AIDS) that affected government policies and the reputation of the medical profession has been called the blood scandal (Feldman,1999).

Canada, France, Japan, and the United States all contributed to the AIDS scare. All four countries were self-sufficient in whole blood and blood components from voluntary donors although France relied on prisoners as volunteers and Canada and Japan imported blood fractions for haemophiliacs. Haemophiliac patients
organized themselves differently in different countries and this affected the pressure that they were able to exert on the political structure. They gained most recognition in Japan in the 1980s and received substantial compensation. In Canada and France they accepted compensation schemes offered by the government (Baldwin, 2005).

The French blood system was deeply involved in the scandal. Perhaps due to pride in the purity of French blood, the downfall of the system was its involvement in more than half of the blood-transmitted AIDS cases in Europe. In 1991, an internal government document revealed that the early success of heat treatment of factor VIII was ignored. The distribution of older, unheated, contaminated fractions continued from some blood centres in France and was justified by the cost. In 1992, the Director of the National Centre in Paris was sentenced and jailed, an event that is now widely believed to be a miscarriage of justice (Schmidt, 2006).

In Japan, as in France, the driving force behind the AIDS blood scandal was the effect of infected blood fractions on the nation's haemophiliac population. At this time commercial operators took control of plasmapheresis and Japan’s corporations guaranteed plasma collections. It was the product of this unholy alliance that brought HIV to Japan. The problem set the stage for the most prominent health scandal in Japan’s history. Further evidence of failure was found in the continued use of unheated plasma long after the heat treatment of plasma was mandatory in the United States. The principals involved were charged with murder (Schmidt, 2006).

The Canadian blood system combined the problems seen in France of a loosely controlled and overly-trusted source of whole blood, and contaminated plasma from American blood. The government had left the regulation of the blood system to the Canadian Red Cross and the therapy for haemophiliacs was being met by plasma processed in the United States. The public became aware of the disaster as the untreated plasma spread among the haemophiliac population in Canada. The Red Cross’s response was slow and when the government finally decided to fund blood testing, the decision came seven months later than in the United States. The Canadian Red Cross later filed for bankruptcy and removed itself from all activities associated with the blood system. A new National Canadian Blood Service was created to do the work of the Red Cross. Consequently, Canada, France and
Japan’s blood system have been constructed to protect the public from the previous mistakes (Gallo & Montagnier, 2003, pp. 2283–2284).

The United States carried out a major analysis of its blood programme in 1972 following the hepatitis problem. Although the United States was the country in which the new disease (that turned out to be HIV) was first seen in 1990s. The blood scandal resulted in lesser political and social upheaval than in Canada, France and Japan. The peculiarities of United States liability laws required patients to file for compensation in their local jurisdiction (Baldwin, 2005). Blood centres in the United States were protected by blood shield laws passed during the hepatitis era which absolved them of any responsibility if they had carried out the required testing. Although court rulings always found against the patients, many cases never reached the courts. It was not until 1995 that infected haemophiliacs were compensated by the federal government.

Studies by Glynn et al. (2003) and Ling (2010) claimed that blood is safer than ever. However, safety culture was not enforced during the hepatitis era. The Department of Health and Human Services in the United States have implemented a comprehensive safety vigilance system to address the threat from unknown and emerging infectious sources (Busch et al., 1999). Blood is not entirely safe, but neither is it our most dangerous drug. Like many good things, it comes with risks.

1.2. Epidemiological monitoring of donors

The purpose of epidemiology monitoring of donors is to gain a better understanding of the various parameters that lead to donor exclusion either on medical grounds or self-exclusion. In the United Kingdom (UK), data must be recorded in the national blood collection surveillance registry. In 2010, the rate of infection among UK blood donors was low, with approximately 11.7 infected donations per 100,000 tested. In 2010, 2.5 million donations were tested, of which 286 tested positive for a marker of infection. Four out of five infections detected came from new donors (HPA, 2011).

The residual risk of viral infection can be estimated from data measuring the number and percentage of seropositive donations in previous years, the prevalence of seropositive donors, the length of the pre-seroconversion window period, the sensitivity of the screening test and the probability of blood components being
contaminated. These models have made it possible to identify a number of preventative measures. The evaluation of blood donation safety can also be based on the follow-up of recipient cohorts by assessing residual risks in a given population, such as in multi-transfused patients (Debeir et al., 1999, p.81).

1.3. Haemovigilance

Haemovigilance is defined as, “a system of surveillance and alarm, ranging from the collection of blood products to the follow up of recipients, to gather and assess incidents resulting from the transfusion of the blood products”. The main goal of haemovigilance is to prevent the recurrence of incidents by identifying their causes (McClelland et al., 1998). Haemovigilance contributes to the process of maintaining and improving transfusion safety. It grew out of government-driven reviews of the organization of transfusions following the HIV transmission scare in the early 1980s (Faber, 2002). The mandatory reporting at a national level of any undesirable events related to blood transfusion was introduced in the United States in 1975.

The concept was first implemented in Europe in 1988 by Belgium, Denmark, France, Luxembourg, the Netherlands, Portugal, Spain and Switzerland, with a simple objective of being able to share alerts (Herve, 2002, p.30). In 1995, the member states of the European Union indicated a need for countries to establish a haemovigilance system. This culminated in the European Blood Directive (Faber, 2004). The directive states that, “member states shall ensure that there is a system in place to collect, collate and transmit information about adverse reactions and events related to the collection, testing, processing, storage and distribution of blood and its components to the competent authority”. Consequently, most European countries have had an established system for haemovigilance since 2010. (de Vries et al., 2011).

The European Haemovigilance Network (EHN) was established in 1998 and the International Haemovigilance Network (IHN) was formed from the EHN in 2009.

Table 1-1 gives an overview of the National Haemovigilance Network in Europe in 2010.
Table 1-1 Overview of national haemovigilance systems in the European Union.

| Member States of European Union | Haemovigilance Status | Body responsible        |
|---------------------------------|------------------------|--------------------------|
| Austria                         | Established Mandatory  | OBIG                     |
| Belgium                         | Established Voluntary  | Red Cross                |
| Denmark                         | Established Voluntary  | DART                     |
| Finland                         | Established Voluntary  | Red Cross                |
| France                          | Established Mandatory  | AFSSAPS                  |
| Germany                         | Established Mandatory  | PEI                      |
| Greece                          | Established Voluntary  | SKAE/PEEL                |
| Ireland                         | Established Voluntary  | NHO                      |
| Italy                           | Established Voluntary  | ISS                      |
| Luxembourg                      | Established Voluntary  | Red Cross                |
| Netherlands                     | Established Voluntary  | TRIP                     |
| Portugal                        | Building up Mandatory  | IPS/MoH                  |
| Spain                           | Building up Voluntary  | SSTM/MoH                 |
| Sweden                          | Established Voluntary  | SATM/Hospitals           |
| United Kingdom                  | Established Voluntary  | SHOT/SABRE               |
| Greece                          | Established Voluntary  | SKAE                     |

Source: Updated from de Vries, Faber and Strengers, 2011

Key: AFSSAPS-Agence Francaise de Securite Sanitaire de Produits de Sante; DART-Danish Registry for Adverse Reaction in Transfusion; IPS-Instituto Portugues do Sangue; ISS-instituto Superiore de Sanita; NHO-National Haemovigilance Office; OBIG-Osterreeischiches Bundes-Institut fur Gesundheit; PEI-Paul Ehrlich-Institut; SATM-Swedish Association for Transfusion Medicine; SHOT-Serious Hazard of Transfusion; SABRE - Serious Adverse Blood Reaction and Events; SKAE- Hellinic Coordinating Haemovigilance Centre; SSTM-Spanish Society of Transfusion Medicine; MoH-Ministry of Health.

In Europe, the French and British systems are different. The French haemovigilance system was established in 1994 (Andreu, Morel & Forestier, 2002), it is nationwide and there is a legal obligation to report any untoward effects related to blood transfusion (Andreu, Morel & Forestier, 2002). It must meet three objectives at local and national level: (1) identify risks and related factors and monitor these risks; (2) assess the relevance of medical indicators present in
individuals that wish to donate blood and (3) at the transfusion level, estimate the incidence of transfusion-induced side-effects in recipients (de Vries et al., 2011).

In the UK, the Serious Hazards of Blood Transfusion (SHOT) was launched in 1996. Unlike France, only serious adverse reactions must be reported to SHOT on a voluntary basis (Williamson, 2002). The participation of UK hospitals in haemovigilance has improved since 2009 with an 85% increase in the number of reports submitted in 2010. At the same time, the number of non-reporting hospitals and trusts has fallen.

1.4. Blood transfusion in the UK

Over a 15 year period (1996-2011) more than 36 million blood components were provided by the United Kingdom Blood Services and 4,334 untoward incidents were analysed. Table 1-2 is a summary of all blood products issued 1999–2011 by regional UK transfusion centres. It shows a downward trend in blood products issued due to the postponement of blood donations during the influenza season and measures taken to exclude potential donors to reduce the incidence of vCJD.

Table 1-2 Blood products issued by UK blood services 1999-2011.

| Year     | Blood products issued |
|----------|-----------------------|
| 1999-2000| 3,446,855             |
| 2000-2001| 3,426,782             |
| 2001-2002| 3,404,865             |
| 2002-2003| 3,399,988             |
| 2003-2004| 3,340,221             |
| 2004-2005| 3,103,200             |
| 2005-2006| 3,002,797             |
| 2006-2007| 2,914,228             |
| 2007-2008| 2,845,459             |
| 2008-2009| 2,903,760             |
| 2009-2010| 2,898,425             |
| 2010-2011| 2,956,351             |

Source: Serious Hazards of Transfusion, 2011, p.2
In 2000, blood transfusions were estimated to cost the NHS £898 million, representing a 256% increase since 1994/1995. The introduction of additional technique for the screening of infections such as HIV, HTLV, HepB, HepC and malaria contributed to the rise in cost. The estimated cost for an adult transfusion was £635 for red blood cells, £375 for plasma, £347 for platelets and £834 for cryoprecipitate (Varney, 2003).

The most frequent hazard reported by the Serious Hazards of Blood Transfusion (SHOT) is the transfusion of an incorrect blood component (Serious Hazards of Transfusion, 2011).

Table 1-3 Blood transfusion errors in the UK blood supply 1996-2011.

| Year       | Number of errors |
|------------|------------------|
| 1996-1997  | 63               |
| 1997-1998  | 107              |
| 1998-1999  | 131              |
| 1999-2000  | 188              |
| 2000-2001  | 173              |
| 2001-2002  | 302              |
| 2003       | 324              |
| 2006       | 1279             |
| 2007       | 1341             |
| 2008       | 2177             |
| 2009       | 2475             |
| 2010       | 1464             |
| 2011       | 1815             |

Source: Serious Hazards of Transfusion, 2011, p.16

Figure 1.1 shows the breakdown of errors reported to SHOT in 2011. Incorrect Blood Component Transfused (IBCT) incidents accounted for 13.6% of errors reported, even taking into account under-reporting. IBCT is a preventable error if corrective and preventive actions are put in place.
Figure 1.1 Summary of blood transfusion errors 2011

Key: ATR-Acute transfusion reaction, TACO-Transfusion associated circulatory overload, TRALI-Transfusion related acute lung injury, PTP-post transfusion purpura, HTR-Haemolytic Transfusion reaction, HSE-Handling & Storage Error, IBCT-Incorrect blood component transfused, TAD Transfusion Associated Dyspnoea, IU- intrauterine transfusion.

Source: Serious Hazards of Transfusion, 2011, p.16

The number of incident reports has risen in subsequent year this can be suggestive of open culture in reporting and the activities of the Medicine and Healthcare Products Regulatory Agency – the regulatory body in the UK. However, many UK hospitals still do not submit reports despite legal requirements. Northern Ireland and Wales reported more incidence than Scotland and England which suggest that Northern Ireland and Wales have a high incidence detection level of reporting. This is a major concern from both professional and regulatory viewpoints (Serious Hazards of Transfusion, 2009).

Table 1-4 Total number of reports per 10,000 components 2007-2011

|                | 2007 | 2008 | 2009 | 2010 | 2011 |
|----------------|------|------|------|------|------|
| England        | 4.6  | 7.7  | 8.1  | 8.9  | 10.9 |
| Northern Ireland| 6.6  | 10.0 | 10.5 | 16.0 | 21.1 |
| Scotland       | 3.1  | 5.4  | 6.8  | 10.6 | 14.3 |
| Wales          | 8.4  | 12.3 | 19.6 | 15.2 | 16.4 |
| United Kingdom | 4.8  | 7.8  | 8.5  | 9.5  | 11.6 |
In 1998, there were 33 suspected cases of transfusion-transmitted infection (TTI) reported by blood centres and hospitals in the UK. The investigation of the blood products involved showed that there were four incidents of contaminated units of platelets that were proven to have transmitted bacterial infection to six recipients. By 2008, there were no proven cases of viral or protozoan transmission, although serious complications from bacterial contamination of blood components remained a challenge for the UK Blood Services (Serious Hazards of Transfusion, 2011).

Table 1-5 shows the number of infected recipients identified and their outcome from 1996-2011.

**Table 1-5 Number of infected recipients and their outcome 1996-2011.**

|                | Number of infected recipients identified | Death due to infection | Major morbidity | Minor morbidity |
|----------------|-----------------------------------------|------------------------|-----------------|-----------------|
| Bacteria       | 43                                      | 11                     | 28              | 4               |
| HAV            | 3                                       | 0                      | 2               | 1               |
| HBV            | 11                                      | 0                      | 11              | 0               |
| HCV            | 2                                       | 0                      | 2               | 0               |
| HIV            | 4                                       | 0                      | 4               | 0               |
| HEV            | 1                                       | 0                      | 0               | 1               |
| HTLV           | 2                                       | 1                      | 1               | 0               |
| Malaria        | 2                                       | 1                      | 1               | 0               |
| vCJD           | 4                                       | 4                      | 0               | 0               |
| Prion          | 2                                       | 1                      | 1               | 0               |
| **Total**      | **74**                                  | **18**                 | **50**          | **6**           |

**Source:** Serious Hazards of Transfusion, 2011, p.131

Key: HAV-Hepatitis A virus, HBV-Hepatitis B virus, HCV-Hepatitis C virus, HIV-Human immunodeficiency virus, HEV-Hepatitis E virus, HTLV-Human T cell leukaemia virus, vCJD-Variant Creutzfeldt Jakob disease.
The knowledge of ABO blood group system in the 18th and 19th century was minimal which led to a lot disasters. According to (Starr, 2001). Further blood transfusion procedures led to haemolytic episodes and deaths in the early part of the 18th century and this eventually resulted in a ban for over a century. The discovery of ABO blood group systems in the early part of the 20th century minimised haemolytic episodes but transfusion transmitted infections became a major concern due to global trade of blood products and inadequate screening (Fisher, 2004).

Blood transfusion in the 20th century had informed many of the decisions, initiatives and guidelines in the 21st century and these are discussed fully in the following sections 1.5. Following the increased of transfusion transmitted hepatitis, the term haemovigilance was coined in the United States in the early 1970s to address the threat to patient safety and tighten regulations on the use of blood products. This led to the introduction of a robust quality management system for blood transfusion in order to protect the patient and the public.

This concept was launched in Europe in 1988 and the French established a haemovigilance programme in 1994. An incident in which the use of contaminated blood led to the import and distribution of contaminated plasma products to haemophiliacs in the United Kingdom undermined the government’s ability respond to the threat and led to immeasurable damage to the National Blood Service. Although the European Blood Directive had indicated the need for haemovigilance, the idea did not immediately take off. Consequently, the Serious Hazards of Transfusion (SHOT) scheme was not launched until 1996.

The launch of SHOT was the starting point for haemovigilance in the United Kingdom. Initially not all NHS Trusts fully participated in this scheme; few incidents were reported and the data that was collected was not collated. Nevertheless, improvements in quality assurance of blood and blood product testing became clear as SHOT began to publish annual reports.

The introduction of the European Union Directive in 2002 and Blood Safety and Quality Regulations (BSQR) in 2005 brought a big change in the collection, storage, distribution, and traceability of blood products in the United Kingdom. The
BSQR became law in 2005 and failure to comply was considered to be a criminal act.

The risk of mistransfusion became greater in the 21st century, see Page 34 “The risk of mistransfusion was found to be greater than the risk of transmission of HIV or HCV (Dzik, 2002, p.1190).” SHOT,(2011,p.16) also emphasized of the incidence of incorrect blood component transfused in the U.K. Mistransfusion can also be due to poor control or knowledge of the collection, storage, distribution and traceability of blood products.

My research design was to explore and identify why traceability compliance was poor within the Trust and to implement a suitable model to improve traceability compliance within the Homerton University Hospital NHS Trust and to enhance patient’s safety within the transfusion chain.

1.5. The regulatory framework

European Commission Blood Directives 2002/98/EC (European Union Directive 2002/98/EC) and 2004/33/EC were transposed into the United Kingdom's Blood Safety and Quality Regulations 2005 (Statutory Instruments 2005/50, 2005/1098 and 2006/2013) and became mandatory in the same year. The law imposed new requirements on all hospital transfusion laboratories and clinical transfusion process in the UK. The regulations required “unambiguous traceability” of all blood and blood components from a donor to patient, or the final destination of all blood and its components if not transfused. The final destination of every blood component has to be retained and be made available for 30 years (Blood Safety and Quality Regulations, 2005).

The Council of Europe defined traceability as, “the ability to identify the actual recipient of every component released and, conversely, the ability to identify all blood donors involved in the transfusion given to a patient. The active return of information from the clinical area to the blood transfusion department after the
transfusion act is necessary to provide complete and reliable information about the fate of the given blood component” (Council of Europe, 2003).

European Union Commission Directives 2005/61/EC and 2002/98/EC (2005), also required the full traceability of blood and blood components. Blood establishments and hospitals are required to implement a system that permits the identification of each unit of blood component and its final destination. A system that has proved effective in the UK is the so-called ‘bag & tag’ label system. When a unit of blood is prepared for a patient, a computerised laboratory system prints a tag. This includes information that identifies the patient and two traceability labels bearing the donation number.

It is important to understand the reasons behind the urgency of this current move to the traceability of blood and its products. The emergence of transfusion transmitted diseases has damaged trust in the blood establishment around the world and a survey of various haemovigilance systems indicated that errors in the blood transfusion chain, from the initial recipient identification to final blood administration occur in about 1 in 1000 events (Pagliaro & Rebulla, 2006). Specific tools have been developed to prevent the potentially fatal consequences of such mistakes. These include barcoded patient identification bracelets and mechanical and electronic locks that can allow full audit trail of all transfused blood products. Although a number of studies have demonstrated the effectiveness of these systems, they have not been widely adopted because of financial constraints.

1.6. Organisational and professional drivers of BSQR

A patient is entitled to be cared for by healthcare professionals with relevant and up-to-date skills and expertise (Kennedy, 2001, p.322). For the general public, this means that they can be also involved in the planning, organisation and delivery of healthcare.

1.6.1. Serious Hazards of Transfusion (SHOT)

Serious Hazards of Transfusion is an independent, professionally-led haemovigilance scheme that was launched in 1996 and collects data on serious sequelae caused by the transfusion of blood components. The data collected
contributes to improvements in the safety of the blood transfusion process, informs policy within the transfusion services in the UK and helps in the production of clinical guidelines for the use of blood components.

1.6.2. Clinical governance

Clinical governance consists of the processes healthcare organizations use to monitor and improve the quality of clinical services delivered within the healthcare system. It was introduced in 1998 as part of the UK government’s ten year plan to improve the overall standard of clinical care (Department of Health, 1998).

Figure 1.2. The pillars of clinical governance

Source: National Audit Office, University of Birmingham (2007).

The introduction of clinical governance was aimed at improving the quality of clinical care at all levels of provision. It was seen as a way of addressing concerns about the quality of health care following well-documented variations in standards. It necessitates a more widespread adoption of the principles and methods of continuous quality improvement initially developed in the industrial sector and later applied to the healthcare sector (Berwick, 1989). Table 1-6 summarises the infrastructure, systems and processes related to clinical governance.
Table 1-6 Infrastructure, systems and processes related to clinical governance

| External drivers for clinical governance | Department of Health | Inspection and review mechanism |
|-----------------------------------------|----------------------|---------------------------------|
| Clinical guidelines (NICE, SIGN)        | Trust/Health boards and primary care | Regulatory bodies: CPA, MHRA |
| National Service Framework              | Chief Executive      | Commission for Health Improvement |
| National Patient Safety Agency           | Clinical governance  | Clinical Standards Board for Scotland |
| Blood Safety Quality Regulations        | Clinical governance sub-committee | MHRA |

Source: RCN resource guide, 2003.

Key: NICE - National Institute for Clinical Excellence, SIGN - Scottish Intercollegiate Guidelines Network, CPA - Clinical Pathology Accreditation, MHRA - Medicine and Healthcare products Regulatory Agency

National Health Service research and development programmes have helped to gather the evidence needed to inform clinical decision-making and service planning. The move to evidence-based practices has influenced many healthcare systems in the world. The most obvious contribution is the introduction of technology that enables access to specialist databases and professional knowledge. Evidence-based work in clinical practice has been centred on specific interventions and clinical policies. However, clinical governance is expected to address the question of how good practice in one service can be transferred to others (Oxman et al., 1995).

1.6.3. National Patient Safety Agency

The National Patient Safety Agency (NPSA) set a target of reducing the number of inadvertent incompatible transfusions over 3–5 years and identifying effective local solutions to wrong blood events at the bedside. The Right Patient, Right Blood project was a joint initiative between the NPSA, the Chief Medical Officer’s National Blood Transfusion Committee (NBTC) and SHOT. The purpose of the project was to develop and evaluate the complexities of the transfusion chain to ensure that the right patient received the right blood (Stainsby, 2005, pp.8–12). A labelling system was selected as an initiative for testing and development; it implemented labels
bearing a unique number that provided an additional link between the patient and the blood product to be transfused (National Patient Safety Agency, 2006).

1.6.4. The UK Transfusion Laboratory Collaborative

The UK Transfusion Laboratory Collaborative was established in 2006 in response to a SHOT report. The report identified that 30-40% of wrong blood events originated from hospital blood transfusion laboratories with a disproportionate number of events occurring outside core hours (Serious Hazards of Transfusion, 2001, p.9). The Collaborative was formed between SHOT and the Institute of Biomedical Sciences (IBMS), but extended to other key professional groups involved in laboratory medicine.

The Collaborative has produced recommendations on minimum standards for hospital transfusion laboratories, which address training, staffing, technology and competency (Chaffe et al., 2009). The recommendations were intended to encourage the effective and appropriate use of technology within the framework of legislative requirements, help hospital trusts to achieve minimum standards of proficiency set by the Health Profession Council (HPC) and meet the requirements of Blood Safety and Quality Regulations (Blood Safety and Quality Regulations, 2005). The overall aim was to reduce blood transfusion laboratory errors by 50% in three years. The impact on transfusion laboratories was monitored through existing MHRA inspections and reporting to SHOT.

1.6.5. Better Blood Transfusion

The Better Blood Transfusion circular (Department of Health, 1998a) was sent to all NHS Trusts in the UK that undertook blood transfusions. It asked them to participate in the SHOT scheme and fulfil MHRA requirements for the reporting of Serious Adverse Blood Reaction and Events (SABRE). It also emphasized the need for training for laboratory staff and giving them the power to review requests for blood transfusions in order to reduce the inappropriate use of blood.
Table 1-7 National Comparative Audit on Better Blood Transfusion.

|                            | 2003   | 2004   | 2006   | 2008   | 2010   |
|---------------------------|--------|--------|--------|--------|--------|
| Completion of the questionnaire | 122/259| 160/169| 156/170| 153/166| 153/162|
| HTC met 3 times during last year | 98%    | 99%    | 97%    | 97%    | 94%    |
| HTC includes 2 representatives | 97%    | 91%    | 96%    | 97%    | 94%    |
| Clear report to the Chief Executive | 87%    | 89%    | 94%    | 97%    | 95%    |
| Trusts employing a transfusion nurse | 50%    | 68%    | 92%    | ND     | ND     |
| Trusts employing a consultant for blood transfusion | 74%    | 83%    | 90%    | ND     | ND     |
| Training                  |        |        |        |        |        |
| Medical staff induction   | 66%    | 80%    | 87%    | 89%    | 92%    |
| Medical staff annual update | 25%    | 31%    | 54%    | ND     | ND     |
| Nursing staff induction   | 70%    | 78%    | 83%    | 96%    | 95%    |
| Nursing staff update      | 46%    | 28%    | 88%    | ND     | ND     |
| Phlebotomist induction    | 70%    | 80%    | 74%    | 93%    | 91%    |
| Phlebotomist update       | 33%    | 41%    | 58%    | ND     | ND     |
| Porter induction          | 50%    | 57%    | 69%    | 79%    | 76%    |
| Porter update             | 30%    | 43%    | 58%    | ND     | ND     |
| Policies                  |        |        |        |        |        |
| Transfusion process       | 97%    | 98%    | 98%    | 100%   | 100%   |
| Use of platelets          | 75%    | 68%    | 78%    | 74%    | 78%    |
| Use of red cells in critical care | 44%    | 46%    | 70%    | 67%    | 64%    |
| Use of red cells in surgery | 34%    | 39%    | ND     | 61%    | 54%    |
| Percentage of Trusts indicating that staff involved in administering blood have received competency-based training and assessment (ND = No Data) | | | | | |
| >91%                      | ND     | ND     | ND     | 2%     | 22%    |
| >50%                      | ND     | ND     | ND     | 12%    | 76%    |
| Trusts using barcodes or other electronic systems for blood transfusion | ND     | ND     | ND     | ND     | 16%    |
| Trusts using an electronic blood fridge system for blood tracking. | ND     | ND     | ND     | ND     | 42%    |
| Participation in SHOT     | 99%    | 99%    | 95%    | 97%    | 99%    |

1.6.6. European Blood Safety Directives

The European Council, in its resolution of 2nd June 1995 on Blood Safety and Sufficiency in the European Community invited the European Commission to submit proposals for the development of a blood strategy. The main aim was to set high standards of quality and safety in blood transfusion taking into account the fact that the organization and regulation of blood transfusion is very different in different European countries. The Directive aimed to harmonise these differences in order to improve the level of quality and safety in blood transfusion across the European Community (Faber, 2004).
The European Union Directives (2002/98/EC and 2004/33/EC) set standards for the quality and safety of blood collection and testing of human blood and blood components. Directive 2002/98/EC began as the European Blood Directive regulation. It covers the following areas:

a) Describes the content of the European Blood Directive, 2002/98/EC.

b) Describes the technical requirements addressed in the Directives to be published as European Commission Directives.

c) This article also described the potential impact of the legislation related to blood transfusion activities in the Member States of the European Union and also on its strengths and weakness.

The European Blood Safety Directives became law in the UK on the 8th February, 2005 in the form of the Blood Safety and Quality Regulations 2005. The UK Health Secretary is the designated competent authority for the Directive. The regulation applies to the collection, testing, storage and distribution of blood and blood component when they are intended to be used by humans.

1.6.7. UK Blood Safety and Quality Regulations

The Blood Safety and Quality Regulations 2005 require the full traceability of blood and blood components from the point of receipt of the blood or blood components by the hospital. The confirmed final destination of blood components received by the site must be retained in a readily-available format, recoverable for thirty years.

The Medicine and Health Products Regulatory Agency (MHRA) was designated as the competent authority in the UK under the legislation. The MHRA is a government agency whose role is to enhance and safeguard the public’s health by ensuring that medicine and medical devices meets acceptable standards of safety and they work. The MHRA aims to safeguard public health by:

- Ensuring, through regulation, that medicine and devices have an acceptable balance of risks and benefits.
- Helping people to understand the benefits and risks of medicines and devices.
- Encouraging and helping the development of medicines and devices that will contribute to health.
The regulations required that the competent authority ensure compliance with the relevant regulations. To achieve this, the MHRA developed a compliance report which all hospitals with blood banks must complete annually. Hospital blood banks must provide details of their accreditation status, staffing levels, traceability and quality management system within the department. The report is reviewed and an on-site visit takes place if non-compliances are identified. The MHRA has also established a system of reporting and recording transfusion-related incidents known as Serious Adverse Blood Reactions and Events (SABRE).

1.6.8. Clinical audits and professional standards

The power of audits in the quality improvement process is well recognised, which is reflected in the standards of a number of professional health organisations. The Health Professions Council’s Standards of Proficiency for Biomedical Scientists (Health Professions Council, 2004) state that the skills required for application of practice are:

“To be able to audit, reflect on and review practice you must understand the principles of quality control and quality assurance, be aware of the role of audit and review in quality management, including quality control, quality assurance and the use of appropriate outcome measures, be able to maintain an effective audit trail and work towards continual improvement, participate in quality assurance programmes, where appropriate, understand the value of reflection on practice and the need to record the outcome of such reflection and recognise the value of case conferences and other methods of review.”

The General Medical Council’s Good Medical Practice states:

“You must work with colleagues and patients to maintain and improve the quality of your work and promote patient safety. In particular, you must take part in regular and systemic audit. take part in systems of quality assurance and quality improvement and respond constructively to the outcome of audit, appraisals and performance reviews, undertaking further training where necessary” (GMC, 2011).

The Nursing and Midwifery Council’s standards of conduct, performance and ethics (Nursing and Midwifery Council, 2009) requires registrants to provide a high standard of practice and care at all times, and states,
“You must work with colleagues to monitor the quality of your work and maintain the safety of those in your charge and also take part in appropriate learning and practice activities that maintain and develop your competence and performance. Traceability and identification management techniques increase interest in healthcare is well emphasized.”

Some other performance management and improvement processes are:

- The Healthcare Quality Improvement Partnership (HQIP)
- NHS Litigation Authority Risk Management Standards
- The Healthcare Commission

1.7. Transfusion safety

Although the potential untoward effects of blood transfusion have been recognized almost since the practice began, no systematic data was collected for decades despite the publication of several reports (Herve et al., 2000). The major steps in the clinical transfusion process involve obtaining a patient sample, labelling it and submitting it to the transfusion laboratory for cross-matching (Figure 1.3). The intention is, “getting the right blood, to the right person, at the right place, at the right time” (McClelland et al., 1996). Eliminating errors in matching patients with their care is one of the key ways of improving safety. Although there are no accurate figures on the frequency or cost of mismatching errors, research has indicated that they form a significant proportion of healthcare errors (National Patient Safety Agency, 2005).
Figure 1.3 Steps in the transfusion chain.

Hospitals must be able to show that their blood transfusion practices are safe, clinically effective and efficient. This requires a paradigm shift in favour of a strongly founded belief that quality, safety and effectiveness must be built into the blood transfusion process, total process control and procedures that prevent errors.

1.7.1. Recipient recall programmes

Recipient recall programmes refer to the practice of notifying a large group of recipients who have been exposed to an infectious agent at the time of the transfusion (Busch, 1991, p.655) and who have been identified as infected with a specific disease. It requires hospital blood transfusion services to trace transfusion records in order to identify the individuals that received the specific component. The recipient is usually notified of their potential risk by their clinician. Further tests are carried out after counselling. Current regulations require the recall of donors who have been identified as infected with a blood-borne infection. The requirements specifying which recipients must be informed are complex because of the evolution of Hepatitis C screening and confirmatory tests (Goldman et al., 1996).
1.7.2. Methods to identify blood transfusion incidents

Human error is routinely blamed for accidents in healthcare. Humans tend to rush to judgement following an incident and, all too often, blame the person most associated with the accident. This prevents the discovery of the whole story (Cook, Wood & Miller, 1998).

Table 1-8 shows the results of a study that examined a series of events and departures from safe practice which were influenced by the working environment and the wider organisational content (Vincent, Stanhope, & Crowley-Murphy, 1999).

**Table 1-8 Predictive Human Error Analysis (PHEA) technique**

| Planning error                      | Checking error                   | Communication error                           |
|-------------------------------------|----------------------------------|-----------------------------------------------|
| Incorrect plan executed            | Check omitted                    | Information not communicated                   |
| Correct but inappropriate plan      | Check incomplete                 |                                               |
| Correct plan but too soon or late   | Right check, wrong blood         |                                               |
| Operating error                     | Selection error                  | Retrieval                                      |
| Operation too long or short         | Selection omitted                | Information not obtained                       |
| Operation inappropriate             | Wrong selection made             | Wrong information obtained                    |
|                                     |                                  | Information retrieved incomplete               |

**Source: Embrey, 1992; Hollnagel, 1998**

A number of methods have been identified to reduce the contribution of human errors to the risk of blood transfusion.

Table 1-9 shows some common methods used for error identification and these are reviewed in the following paragraphs.

**Table 1-9 Error identification methods; advantages and limitations**

| Method                | Advantages                              | Limitations                                      |
|-----------------------|-----------------------------------------|--------------------------------------------------|
| Observation/Audit     | Accurate method to identify performance of individual | Labour intensive and limited lasting value       |
| Accident analysis     | This is used to determine error rate and understand misadventures | Limited by hindsight and delay in investigation. Often lack information. |
Simulation | An accurate way to assess team and individual performance and decision making | Difficulty to create and can only simulate some aspects of the transfusion.
---|---|---
Record review | Standard method of documenting outcome and many processes | Only as good when the information is recorded.
Event reporting | Captures near misses events and deviations as perceived by individuals. Gives perspective of individual involved. | Subject to underreporting because individual do not feel comfortable.

**Source: Kaplan et al., 1998**

One approach is direct observation by skilled observers in the actual operating environment. Schulman (2004, p.652) developed a multidisciplinary approach to quality assurance and improvement directed at reducing patient identification error. The authors found in-service education to be effective in increasing compliance and reducing the risk of error. However, the observation itself may have altered the circumstances studied.

A second approach is accident analysis. This approach has been extensively used in aviation by the National Transportation Safety Board (Nagel, 1988). However, hindsight bias and incomplete data can lead to distortion of the facts. Despite this limitation, accident analysis has also been an important source of information in blood transfusion incidents. For example, Mummert and Tourault (1993) reviewed 150 transfusion-associated fatalities from 1990–1992. They concluded that nearly a third of fatalities could have been prevented by full adherence to standard operating procedures. Interestingly, a failure to follow procedures is also responsible for a third of major air carrier accidents Nagel (1988) who also stressed the need for models of human error to be used in conjunction with error data collection and classification. The management of error to limit adverse outcomes or unplanned effects is now recognised to be of fundamental importance in system design and training (Reason, 1990). Although the importance of this has been recognised in transfusion medicine it has not been fully implemented in all critical areas of operation.

A third approach is the study of error through laboratory simulation. This approach is useful as it enables the simplification and control of variables; although
simplification may itself be an important shortcoming in understanding inherently complex situations (Nagel, 1988). Taswell et al. (1974, p. 491) modified the conditions of work by introducing known errors and provided positive feedback when they were found. The blood transfusion department involved in the study not only improved the detection rate of introduced errors, but also increased the detection of real, previously undetected errors, from four in the first three months of the study to 73 in the final three months.

A fourth approach to error identification is the review of records. This has been a traditional way to perform quality assurance checks and document patient outcomes. Patient records document actions performed and can highlight missing information. The audit of records against predetermined criteria can be a valuable way to identify errors or near misses. Classen et al. (1991, p.301) successfully used a sophisticated automated hospital information and record system to identify adverse drug events that would otherwise not have been reported.

A fifth approach is the event report, including self-reporting. In aviation, despite excellent record keeping, human error is identified as a casual factor in more than half of all airline accidents. More than 250,000 reports have been archived, analysed and made available for research and study by interested professionals and regulatory bodies (Nagel, 1988). This no-fault, confidential, voluntary, self-reporting system enables pilots and controllers to report all non-calamitous mistakes, including caught errors. Confidentiality and immunity from prosecution for non-criminal acts are other important features of this or any system intended to capture operational errors. The no-fault, confidential nature of the system has led to an increased frankness in reporting and the provision of invaluable data (Classen et al., 1991).

1.7.2.1 Haemovigilance

Haemovigilance provides information that is useful in the analysis of the various causes of the untoward effects of blood transfusion. It provides reminders of known protective measures and helps to identify new ones. Haemovigilance has also helped to identify major technical, organizational and human errors. Table 1-10 Summary of the types of clinical errorsTable 1-10 is a summary of the various types of clinical errors.
Table 1-10 Summary of the types of clinical errors

| Type of Error                                                                 | Number of cases in 2010 | Number of cases in 2011 |
|------------------------------------------------------------------------------|-------------------------|-------------------------|
| Wrong blood in tube (WBIT)                                                   | 3                       | 5                       |
| Collection and administration                                               | 7                       | 21                      |
| Administration alone                                                        | 8                       | 8                       |
| No information provided to the laboratory concerning the required group change | 1                       | 1                       |
| Total                                                                        | 19                      | 35                      |

Source: Serious Hazards of Transfusion, 2011, p.27

In the first 18 months following the implementation of haemovigilance in France, seven fatalities related to the bacterial contamination of blood components were reported, while three fatalities related to ABO incompatibility were reported over the same period, leading to increased awareness of bacterial contamination as a major complication of blood transfusion (Engelfriet & Reesink, 2000, pp.59–62).

1.7.2.2 Benign and caught errors

The study of benign or caught errors in transfusion medicine could provide a rich database for improving the safety of the blood supply (Gambino & Mallon, 1991, p.14). The relationship between near misses and accidents has been compared to a pyramid or iceberg. Zapt and Reason (1994, p.427) indicated that error detection is the first step of error management. If an error is not detected, it cannot be managed. Errors that are not detected for a long time can have disastrous consequences.

The goal of error management should be to increase error detection and the error response rate. High reporting rates indicate a high detection sensitivity level (DSL). Few reported events indicate a low DSL. A low DSL can be seen as an indicator of inadequate error detection and reporting. When the DSL is high, the severity level of the incidents should decrease over time as corrective actions are implemented (Kaplan, 2005, pp.1071–1081). In order to achieve a high DSL, an organisation must remove any impediments to reporting events. Confidential no-fault reporting is one of the best ways to encourage event reporting (Kaplan et al., 1998).
1.7.3. Causes of incidents in blood transfusion

1.7.3.1 Technology

The incorrect use or deficiencies in the technology used in blood transfusions continues to cause incidents (Tables 1.11 and 1.12).

Table 1-11 Technological causes of blood transfusion errors.

| Error                                      | Wrong Blood component | Non-Irradiated component | Antigen positive unit | Non-CMV unit | Wrong blood group | Others | Total |
|--------------------------------------------|-----------------------|--------------------------|-----------------------|--------------|-------------------|--------|-------|
| Failure to consult historical record       | 2                     | 0                        | 3                     | 0            | 1                 | 0      | 6     |
| Historical record not linked, merged or identified | 1                     | 2                        | 3                     | 0            | 0                 | 0      | 6     |
| Ignored warning or missed flag             | 3                     | 3                        | 2                     | 3            | 0                 | 1      | 12    |
| Failure to use flag or logic rule          | 8                     | 2                        | 2                     | 0            | 1                 | 1      | 14    |
| Failure to update flag                    | 1                     | 0                        | 1                     | 0            | 3                 | 0      | 5     |
| Computer or related IT failure            | 5                     | 0                        | 2                     | 0            | 0                 | 2      | 9     |
| Errors related to computer system         | 2                     | 2                        | 0                     | 0            | 0                 | 0      | 4     |
| Error related to electronic blood management system | 4                     | 0                        | 0                     | 0            | 0                 | 7      | 11    |
| Incorrect results entered or accessed manually | 3                     | 0                        | 2                     | 0            | 0                 | 2      | 7     |

Despite barriers created to prevent mistransfusion, few technological errors have been reported by SHOT. Common errors were due to software failure and hardware failure during blood product issuing. This reiterates the importance of human in the transfusion process.
Table 1-12 Patient identification tracking systems and errors prevented.

| Year | Author                        | System   | Number of units | Errors prevented |
|------|-------------------------------|----------|-----------------|------------------|
| 1991 | Wenz                          | BloodLoc | 672             | 3                |
| 2006 | AuBuchon                      | BloodLoc | 86000           | 3                |
| 1996 | Mercuriali et al.             | BloodLoc | 10995           | 4                |
| 2000 | Marconi et al.                | I-Trac   | 621             | 0                |
| 2003 | Turner, Casbard and Murphy    | I-Trac   | 51              | 0                |
| 2006 | Pagliaro and Rebulla          | I-Trac   | 18890           | 5                |
| 2009 | Davis et al.                  | RFID     | -               | -                |

Source: Serious Hazards of Transfusion, 2011, p.54

Table 1-12 documented the errors prevented from blood tracking system, the figure might be low but this can been documented as good return of investment, litigation of accidents within health sectors can be very high.

1.7.3.2 Compatibility testing

Table 1-13 Special requirements incidents in the UK

| Type of special requirement | Clinical cause of omission | Laboratory omission | Total |
|-----------------------------|----------------------------|---------------------|-------|
| Irradiation                 | 69                         | 22                  | 91    |
| CMV negative                | 5                          | 11                  | 16    |
| CMV & Irradiation           | 5                          | 6                   | 11    |
| HLA matched                 | 4                          | 3                   | 7     |
| HBS negative                | 1                          | 5                   | 6     |
| Pediatric methylene blue    | 0                          | 1                   | 1     |
| Phentyped component         | 3                          | 16                  | 19    |
| Antigen negative component  | 1                          | 0                   | 1     |
| Pediatric platelets         | 0                          | 0                   | 0     |
| TOTAL                       | 88                         | 64                  | 152   |
1.7.3.3 Active and latent failures

Reason (1990) identified two major categories of failures or error that occur in a complex system: active and latent. The distinction hinges on who initiated the failure. Latent failures are the delayed-action consequences of technical designs or organisational issues and decisions. They are often initiated at the upper levels of the organisation. Active failures are committed by people in direct contact with human/system interface. They are linked to human cognitive processes and associated behaviours. Error researchers have stressed the importance of examining both active and the underlying latent causes of system failures.

Rasmussen (1987, p.23) distinguishes the following types of human behaviour underlying human error.

- Skill-based behaviour: This refers to routine tasks requiring little or no conscious attention during execution.
- Rule-based behaviour: This refers to familiar procedures applied to frequent decision-making situations.
- Knowledge-based behaviour: This refers to problem-solving activities that happen when confronted with a new situation for which no readily available standard solution exists.

Most health professionals operate in a skill-based behavioural mode for routine tasks, from blood collection to the transfusion process (Kaplan et al., 1998). These highly skilled activities become routine and can be executed without any thought. Slips are unintended errors caused by either not doing part of the routine or being distracted by someone. Slips can be prevented by the redesign of equipment and procedures in ways that make it harder to make a slip. For example, feedback mechanisms can be designed into the process that alerts individuals.

Rule-based behaviour involves recognising a situation and selecting the proper routine or protocol. Mistakes happen under two conditions, either by selecting the wrong rule for a given situation, or selecting the correct rule but carrying it out incorrectly. Such failures can occur when someone carries out a procedure that they are not trained or qualified to perform. Another example is inadequately
assessing the situation, for example failing to check the patient’s identity before a transfusion (Kaplan et al., 1998). Routine violations often occur when procedures are changed and individuals continue to apply the old procedures. In some cases, rule-based failures can be prevented by redesigning the task to force a procedure to occur. An example would be a blood lock that prevents a transfusion starting until the patient’s identity has been matched to the blood product.

Knowledge-based behaviour involves solving unique problems or selecting a plan of action in a new or unfamiliar setting. It often occurs with new employees who do not have the knowledge to operate in a highly skilled mode and cannot draw upon experience to select the appropriate rule or protocol to carry out the appropriate task or solve a problem.

This suggests that the expert and the novice are likely to make different types of errors. The expert is more likely to make a slip or an occasional rule-based error, while the novice is more susceptible to knowledge-based failures. This is a strong argument for assessing the performance of an individual when they move to a new job or assume new responsibilities.

We can never eliminate human or active errors, but we can eliminate latent technical or organisational aspects that may set people up for an active failure (Reason, 1990). Reason refers to these as latent errors as organisational pathogens, which wait to combine with the right active human failure to have an adverse consequence. It is difficult to recognise a latent error or identify how it might manifest in the future as there are so many possible outcomes of technical and management decisions. However, since an event represents a fixed outcome, one is often able to identify the causes of latent errors by reasoning backward from the event. Once latent failures have been recognised, they can be diagnosed and corrected before they combine with an active error to produce an unwanted outcome.

Technical aspects associated with latent failures include such things as equipment design, software and mobile and material facilities. Organisational aspects stem from normal management responsibilities, which include the structure of the organisation, planning and scheduling, forecasting, budgeting and allocating resources.
1.7.4 Incident reporting

Although health care professionals share a common focus, which is taking personal responsibility for applying their skills to solve the patient’s health problem (Curtain, 1997), Perper (1994) noted that there is substantial underreporting of medical misadventures.

This can be attributed to the tendency in the healthcare field to blame the individual or individuals associated with an active failure. This produces a climate where individuals are reluctant to report events in case there are adverse consequences. In addition, in a litigious environment it is easiest to blame the person involved. Reason (1990) pointed out that blaming individuals leads to ineffective countermeasures: disciplinary action, exhortations to be more careful, retraining and writing new procedures. Instead, error management efforts should be directed at learning how the system actually operates, as opposed to how to management thinks it is operating. Additionally, it is important to separate event reporting from employee assessment. Figure 1.4 highlights some factors that contribute to errors in healthcare delivery.

![Organisational accident model](image)

Figure 1.4 Organisational accident model (adapted from Reason, 2001).
Blood transfusion safety can be improved if errors (that are an indication of a weak system) can be identified before they result in an adverse outcome for a donor or patient. It is also important to avoid assigning blame when an error is identified, and to instead find the root causes of the error.

1.7.4.1 Barriers and limitations to incident reporting

Under-reporting of incidents is a widespread problem in the healthcare sector (Murff et al., 2003). The key factor highlighted by many authors is that the fear of reporting prevents the organisation from learning from the events and improving practices. Research in the healthcare and other industries has indicated that unjustified negative consequence have discouraged members of staff from reporting incidents. The non-punitive approach taken by the aviation industry has been a significant contributory factor to their impressive safety record in recent years (Vincent, Stanhope, & Crowley-Murphy, 1999). In 2004, the National Patient Safety Agency highlighted that the creation of strong safety culture in the healthcare system was necessary. They indicated that timely feedback and recommendations were essential to improved practice (National Patient Safety Agency, 2004).

1.7.4.2 Overcoming the barriers to incident reporting

High levels of reporting are a mark of high-reliability organisation. Research shows that Trusts in the UK with a high level of incident reporting are more likely to demonstrate a safety culture (National Patient Safety Agency, 2006). The involvement of all members of staff in the organisation can overcome under-reporting. Staff members need to be provided with opportunities to reflect on practices in a multidisciplinary environment in order to become less fearful and give management an insight into the origins of incidents. More importantly, event analysis should be carried out with the members of staff who were involved in the incident, supported by a facilitator (Murff et al., 2003). Regulatory bodies and the health service have developed various reporting systems, although it is doubtful whether these reporting systems have in fact been utilised for organisational learning or to improve practice.
1.7.5 Hazards of poor traceability compliance

There is a lack of appreciation of the complexity of the traceability pathway. Traceability is poorly understood and inadequately controlled in many cases. The level of safety, efficacy and quality of blood products must be maintained and optimised on an on-going basis. The only real test of effectiveness tends to be in live situations when an adverse event has occurred and needs to be handled urgently. In such situations traceability has often found to be wanting with long delays in tracing products and identifying recipients (Ashford, 2006).

Traceability is defined by three distinct elements. These are: the initial prescription of blood components, the distribution sheet stating the name of the recipient and the return of this sheet to the transfusion centre when the procedure is completed. The prescription, distribution and transfusion of blood components is a complex process within the transfusion chain, traceability compliance explores the quality management system of the process.

1.7.5.1 The problems

In 2007 the National Health Service issued the Health Service Circular ‘Better Blood Transfusion 2007’, which outlined detailed actions to be taken by Trusts, NHS Blood and Transplant (NHSBT) and clinicians to improve transfusion practice (Department of Health, 1998a). In 2008 a national audit was carried out using an online survey. The survey showed that 60% of Trusts in the UK had implemented blood usage policies, 12% of Trusts had only assessed half of their staff and 13 Trusts administered less than 10% of transfusions using technology.

In 2001, an audit tool was developed for blood transfusion practice in a joint collaboration between the Royal Colleges and specialist blood transfusion societies. Fifty hospitals participated in the audit. The audit showed that 21% did not provide training to staff members in blood administration procedures and there was no wristband policy for patient identification at 11% of hospitals. While 80% of hospitals had compatibility reports attached to the patient’s prescription chart only 59% recorded the patient’s pulse. The audit demonstrated considerable variations in standard procedures in relation to blood transfusion administration. However, it was difficult to draw valid conclusions as over half of hospitals failed to participate and patient selection was different at different hospitals.
In 2003, the National Patient Safety Agency commissioned a study of manual checking processes and the use of technologies in matching patients with blood (National Patient Safety Agency, 2004). The evidence revealed failures in the use of wristbands. An audit conducted at Guy's and St. Thomas Hospital identified that 34% of patients were not wearing a wristband.

Murphy and Kay (2004) looked at the extent of errors in many aspects of healthcare, including blood transfusion. Their review addressed issues of procedural errors and patient identification. The transfusion of blood to the wrong patient has been identified as the most important hazard. The risk of mistransfusion was found to be greater than the risk of transmission of HIV or HCV (Dzik, 2002, p.1190). The mistransfusion of blood products typically results from errors made during bedside checks prior to the transfusion (Sazama, 1990, p.583); this study estimated mistransfusion to occur at a rate of 1 in 12,000 units. Similar results were reported by Robillard, Chan and Kleimann (2004, p. 95) in Quebec. Moreover, they estimated that the incidence of mistransfusion was probably even higher due to the failure to recognise many errors. Another review by Pagliaro and Rebulla (2006, p.98), noted that errors in the blood transfusion chain seem to occur at a rate of 1 in 1,000 events and the data probably underestimated the magnitude of failures, not least because only one-third of errors have clinically significant consequences (Steinbrook, 2002, p.1758).

Finally, a Belgian study (Baele et al., 1994, p.117) uncovered numerous instances of mistransfusion that went unrecognised. When active tracking was introduced, they estimated that 1 in 400 units were mistransfused and the true frequency of some form of error in bedside blood administration was 30 times higher than rates reported using passive systems.

1.7.5.2 Potential solutions

Such studies have prompted the development of simple and effective methodologies to ensure correct patient identification in transfusion processes (Goodnough & Spence, 2003, p.161). The first positive donor-recipient identification study was described by Chambers et al. (1973, p.34). Since then, the main strategies that have been developed include the appointment of a transfusion safety officer, regular training, skills assessments, system re-engineering and the
introduction of standard operating procedures (Shulman, Saxena & Ramer, 1999, p.595).

In addition to these organisational strategies, technology derived from industry and commerce has been incorporated into the blood transfusion chain. The ultimate purpose of these systems is to make the right and wrong actions easy and difficult respectively (Kohn, Corrigan & Donaldson, 1999).
The aim of the study by Ballard et al. (2002, p.127) was to establish whether a patient had received a particular unit recorded on the blood transfusion computer system. They reported that 486 blood products were issued over a two-month period. Of these, 409 units (84%) could be verified against patient notes, but 77 units could not. These results are slightly lower than a national audit which found 92% compatibility (Murphy, Lowe & Pearson, 2001). The study was not large; a random sample of 5% of patients transfused February–March 2001. It also

| Author                  | Method                  | Blood components evaluated (red cells) | Traceability compliance | Not measured                                                                 |
|-------------------------|-------------------------|----------------------------------------|-------------------------|------------------------------------------------------------------------------|
| Ballard et al., 2002    | Evaluation              | 486 units                              | 84%                     | Number of beds, training, specialties                                        |
| Turner, Casbard & Murphy, 2003 | Evaluation              | 51 units                               | 100                     | Specialty, number of beds.                                                   |
| Whitehead et al., 2003  | Evaluation              | 1212 units                             | 96%                     |                                                                               |
| Kent & Sussex NHS, 2005 | Evaluation              | 250 units                              | 10%                     | Number of beds, training, specialties, fractionated products                 |
| Dalton, Poncet and Rossini, 2005 | Evaluation              | 1500 units                             | 100%                    | Number of beds, training, specialties, fractionated products                 |
| Dzik, 2006              | Review                  | 2000 units                             | 75%                     | Number of beds, training, specialties. Fractionated products not traced.     |
| Davies et al., 2006     | Observation evaluation  | 80 units                               | 60%                     | Number of beds, training, specialties. Fractionated products not traced.     |
| Pasqualoepaolo, 2008    | Evaluation              | 235 units                              | 100%                    | Number of beds, training, specialties. Fractionated products not traced.     |
| Murphy, 2008            | Audit                   | 153 units                              | 92%                     | Number of beds, training, specialties, fractionated products                 |
| Bennardello et al., 2009| Evaluation              | 7282 units                             | 100%                    | Number of beds, training, specialties                                        |
| Davis et al., 2009      | Evaluation              |                                        |                         | Blood product                                                                |
| Mathur, 2006            | Evaluation              | 311 units                              | 64%                     | Specialties, training, number of beds                                        |
highlighted inconsistencies in documentation. Although the blood bank kept records of the issue of blood components, they did not know the ultimate destination of the blood, unless it was returned to them. The only proof that a specific unit had been transfused to a patient lay in the patient’s notes. This study did not identify or describe the problem across different medical specialities.

Turner, Casbard and Murphy (2003) carried out a retrospective study. A total of 51 blood units were audited before and after the introduction of barcode patient identification. The baseline data showed that only 14% of patients were asked to verbally identify themselves before the administration of blood. Twelve per cent of patients were not wearing their identification wristband when identification checks were carried out. Non-compliance was shown to be particularly related to poor checking of special blood requirements; proper procedures were followed in only 41% of cases. Furthermore, the study highlighted that there was no audible communication between staff members and the patient in relation to special blood requirements. After the introduction of barcode technology patients were asked to state their surname and forename and 96% of patients with special requirements had these matched to information on the blood bag. However, the barcode technology did not guarantee that all the necessary steps had been carried out as individuals could indicate that they had carried out checks when in fact they had not. This study also did not identify the particular medical area.

Whitehead et al. (2003) conducted a survey of 500 sets of patient notes. A total of 1,212 blood components were issued and 47 labels were found to be missing. Nursing staff in the clinical area were asked to assess a new system that used peel-off labels to be stuck in patient notes. Almost all respondents preferred the new system and found the labels easy to use. Other initiatives to improve the safety of the blood transfusion process included an improved blood collection protocol and staff training by a transfusion nurse.

Davies et al. (2006) carried out an extended evaluation of an electronic blood collection system based on barcode technology. Practices were evaluated before and after its introduction in cardiac surgery. The baseline audit showed that patient documentation was brought to the refrigerator in 84%, 40% and 10% of collections from the main blood bank, theatre and the cardiac rehabilitation unit refrigerators respectively. Following the introduction of the electronic process, this increased to
The study estimated that there were 23 steps in the collection of blood before the implementation of the electronic process; this was reduced to nine.

The baseline audit demonstrated that there was very poor documentation of the date and time of transfusion and the number of units transfused. Observation of practices before implementation of the new procedures revealed that almost all the key steps in the transfusion process were not carried out correctly. The design of the electronic process highlighted the complexity of the transfusion process, which was identified as a problem. Another problem was improved training to avoid over-reliance on the technology for the patient identification. A further weakness was that nursing staff were not required to enter any observations during and after the transfusion.

The study highlighted that the main reason for introducing electronic checking was that checking procedures were not being carried out correctly. However, the authors pointed out that total reliance the electronic system was also undesirable as the system was likely to fail from time to time. The study concluded that technology should not be used to take over thinking and that it was vital not to underestimate the role of education, training, and continued support.

A study by Davies et al. (2006, p.361) observed that traceability compliance was poor in some clinical areas because of the complexity of the transfusion chain and procedures. There were many steps in the requesting, matching, delivering and transfusing of blood products that involved a number of different departments and staff of different grades.

A pilot study at San Raffaele Hospital in Milan by Dalton, Poncet and Rossini (2005) used radiofrequency identification (RFID). Blood donors were given a RFID wristband and a label was placed on their donor unit at the time of donation. Later, at the time of transfusion, the data on the wristband and the blood unit were compared at the bedside using a handheld RFID reader. The reader communicated with the hospital computer via a hospital-wide wireless network. Users of this device reported that they were 27% more productive and no errors were observed during the pilot. Although it was difficult to measure the impact of the technology as
only data estimates were collected prior to the study, 70% of staff commented that the system had dramatically reduced their fear of making errors.

Another pilot study at Maidstone Hospital in Kent used a questionnaire to evaluate a new labelling system. Seventy-nine per cent of respondents agreed that the labels were easy to use, although the poor response rate made it impossible to draw robust statistical conclusions from the analysis (NPSA, 2006).

Salmi, Azanowsky and Perez (1997, pp. 964–974) highlighted that data gathered from alert systems must be carefully interpreted to minimise bias. While Battle et al. (1998) emphasized that the characteristics of a good vigilance system should include no-fault reporting. They recommended that the donation number for blood and blood components and batch products for pooled blood products should be specifically recorded on the transfusion record. They also recommended the establishment of national documentation standards.

Other solutions have been proposed to the problem of ensuring that the correct blood unit is given to the patient. They include paper-based systems (Lau et al., 2000), mechanical systems (AuBuchon & Littenberg, 1996) and electronic systems (Norfolk, 2000). Dzik (2003) discussed technological approaches. The study highlighted that reductions in transfusion-related, knowledge-based errors depended on increased knowledge, more informed decision making and enhanced feedback. It also noted that reductions in slip errors was a problem ideally suited to machine-readable identification systems. Consolidated methodologies include biometric technologies, such as fingerprint identification, facial and vocal recognition (Ashbourn, 2004). Some of these technologies are not readily applicable to the field of medicine and surgery.

1.7.5.3 Conclusions

Although considerable effort has been devoted to improving traceability compliance following the introduction of national regulations, guidelines and mechanical barriers to prevent mistransfusion Davies et al. (2006), the literature review did not reveal any clear procedure for achieving it. The studies described in the previous sections suggest that the traceability of blood products is a problem in all hospital transfusion laboratories. Dzik (2006) and Murphy, Stearn and Dzik (2004) suggest
that training and education might improve matters. Bennardello et al. (2009) and Pagliaro and Turdo (2008) also agreed that mechanical intervention may help.

However, none of these approaches attempted to assess the impact of ward size, speciality, training, traceability methods or volume of transfusion. There were considerable variations in the population and sampling criteria used in the various studies, and weaknesses in the audit tools. The articles reviewed also varied in quality and relevance. Most studies did not describe how fractionated products were traced from the donor to the recipient and none of them evaluated the variables that may affect traceability compliance, such as blood product usage by different specialities.

The design of some the studies was not explained which may have affected the results obtained. Other studies highlighted the problem before the introduction of the new model or simply explained improvements in traceability compliance. (Murphy and colleagues 2003), However, identified in their study tha the barcode technology did not guarantee that all the necessary steps had been carried out and the system can be overridden.

These findings justified the need of further investigation into why traceability compliance was poor within the Trust and why some wards were more compliant than others and the associated risk factors. While patients may be the victims of human errors, members of staff can be the targets and casualties of systems that are highly error-prone this will mostly contradict the research conducted by (NPSA,2006) that demonstrated that Trusts in the UK with a high level of incident reporting are more likely to demonstrate a safety culture (National Patient Safety Agency, 2006).

1.8 Proposed programme of research

The literature review had revealed weakness in traceability procedures in the healthcare sector and looked at some reasons why compliance is poor is some areas. In some Trusts, considerable effort has been devoted to improving training, redesigning electronic systems and proper patient identification before and after
transfusion. However, none of these approaches have fully addressed the complexity of the transfusion chain which involves different specialities and staff.

Mandatory requirements introduced by European legislation, clinical governance and patient safety concerns made this project necessary. There is a need for further exploration and better understanding of the issues surrounding traceability. I have some identified some that are realistic within the scope of this study. The findings from this study will provide new knowledge and understanding of these challenging problems.

1.8.1 Research aim and objectives

The overall aims of the project were to establish why traceability compliance was poor in the Homerton University NHS Trust, to implement changes to improve traceability compliance and to ensure that hospital wards complied with traceability procedures. Compliance was also expected to identify blood distribution and administration within the Trust.

1.8.1.1 Objectives

The study's objectives were as follows:

i. To undertake a six year cohort study to identify the risk factors of traceability compliance for blood products within all wards of the Homerton University Hospital NHS Trust and identify the processes that lead to poor compliance.

ii. To select an appropriate traceability model and labelling procedure for blood products within the Homerton University Hospital NHS Trust.

iii. To evaluate the subsequent intervention.

iv. To evaluate impact and direct cost and saving blood products.

v. To examine the transferability of this evaluation and reflect on the impact on practice.
Cross sectional study
detailed audit of ward compliance
Questionnaires sent to ward managers
– training, knowledge, responsibilities, opinion, training, blood collection and administration

Risk factors for poor compliance within the Trust

Select an appropriate traceability model

To implement the new traceability model

The impact of traceability mechanism within the Trust

Fig. 1.5 Flow diagram identifying elements of the study.
2 Traceability compliance assessment (Method 1)

This chapter describes the situation in Homerton University Hospital NHS Trust with respect to compliance with traceability requirements for blood products at the beginning of the study. It also identifies the processes associated with poor levels of compliance. The information gathered and the analyses carried out in this phase of the project provided the basis for the development of the modified traceability system described in Chapter 4.

This stage of the project took place from 2005-08. At this time the Trust had implemented a paper-based traceability method and paperwork was transported by porters (referred to as Method 1).

Compliance was evaluated in two phases. In phase 1, traceability compliance was calculated as the number of blood units successfully traced as a percentage of all units issued from the blood stock fridge. The second phase looked at the potential causes of poor compliance. Data was collected on the communication of the traceability procedure to ward managers, access to training and the communication of audit results to the wards. A statistical analysis of the data made it possible to estimate the risk factors that influenced ward compliance rates within the Trust See Table 2-1. Furthermore, a structured observation tool evaluated the compliance of a sample of ward staff with the following procedures:

i. Blood collection at the blood stock fridge.
ii. Ward bedside checking procedures.

The Trust is a 500 beds hospital, medium size teaching hospital and offers many services that require high amounts of blood transfusion in the Accident and Emergency (A/E), Special Care Baby Unit (SCBU), Medical Day Unit (MDU), Delivery Suite (DEL) and Acute Care Unit (ACU). Biomedical scientists routinely carry out pre-transfusion testing prior to the issue of blood products and transfusions are subsequently carried out on the wards or theatre by nursing staff. Since 2005, an average of 6,000 red blood cells have been transfused annually.
Transfusion compatibility labels had been modified by the Hospital Transfusion Team prior to the implementation of the European Union Directive (Blood Safety and Quality Regulation, 2005) to include the date, time of transfusion and signatures of nurses. Following each transfusion the ward nurse was responsible for removing the empty blood bag and completing the information on the label. Finally, the completed labels were placed in a Perspex box marked “returned transfused tags”.

Hospital porters visited the wards on a daily basis to collect and return labels to the laboratory. Data from the ward (date and time of transfusion) was entered into the blood transfusion computer system by the medical laboratory assistant. Data was compiled on a monthly basis and sent to the respective wards.

2.1.1 Phase one: Quantitative assessment of traceability compliance

2.1.1.1 Ethics

The hospital’s local Research and Ethics division confirmed that the project did not require ethical approval by a NHS Research Ethics Committee or the Trust’s research and development department; however approval was needed from the Trust’s clinical governance committee. Appendix 2 is a copy of the approval document.

2.1.1.2 Method

Data about patient blood transfusions was gathered and reviewed after every transfusion and the subsequent discharge of the patient. The data was extracted from the blood transfusion information system and consisted of the final destination of all transfused blood that could be traced and all the blood units assumed to have been transfused (where tags were missing or labels had been destroyed). The final traceability compliance was calculated as the number of units successfully traced as a percentage of the total units issued.

All wards with more than two transfusion episodes per week were eligible for inclusion in the study. Others, with less than two transfusion episodes per week were excluded because their patients would eventually be transferred to other
wards. Participation in the study was voluntary. I extracted data for each ward from the blood transfusion laboratory information system on a monthly basis.

Compliance was calculated as the total number of units where the final destination could be traced (T) divided by the total of number of blood units issued (I) expressed as percentage.

I implemented a database to record all the units transfused and calculated the percentage compliance using the Statistical Package for Social Sciences (SPSS, 2010) software.

Descriptive statistics were used to determined the mean and standard deviation of the annual compliance rate for each ward. Variance analysis determined whether the frequency of transfusion was a predictor of compliance at a ward level. Wards were categorized into three groups according to blood usage. Those that consumed less than 500 units were grouped as low users, medium users transfused 500-1200 blood units and those that transfused over 1201 blood units were grouped as high users.

2.1.1.3 Results

The compliance data was normally distributed from 2005-08, the average traceability compliance ranged from 50 – 90% (see Table 2-1 below). The overall mean compliance for the entire period for all wards was 72% with a standard deviation of 10.4.
An analysis by year showed that although there was a steady increase (50-80%) in overall percentage compliance from 2005-2007, in 2008 it fell to 65%. The overall average traceability compliance for all wards for 2005-2008 was 69% with a standard deviation of 13.5. The transfusion department approach after the visitation of MHRA in 2006 was to target non-compliant ward and personnel through incident reporting, this led to a revolt by some clinicians who definitely opted out and labels

Table 2-1 Mean ward traceability compliance.

| Ward     | Number of blood units transfused 2005-08 | Mean compliance 2005–2008 (%) |
|----------|------------------------------------------|------------------------------|
| CCU      | 244                                      | 50                           |
| TEMP     | 284                                      | 60                           |
| TUR      | 307                                      | 60                           |
| OT1      | 585                                      | 60                           |
| HAL      | 1156                                     | 60                           |
| COX      | 276                                      | 61                           |
| DEL      | 1200                                     | 64                           |
| DEFOE    | 262                                      | 69                           |
| MAU      | 284                                      | 70                           |
| ST JOE   | 376                                      | 70                           |
| TAUD     | 310                                      | 71                           |
| PRI      | 985                                      | 72                           |
| ACU      | 2268                                     | 72                           |
| ASKE     | 563                                      | 74                           |
| LAMB     | 447                                      | 75                           |
| EC       | 1414                                     | 75                           |
| ITU      | 1728                                     | 75                           |
| AE       | 3051                                     | 76                           |
| LLOYD    | 697                                      | 79                           |
| ANC      | 2501                                     | 83                           |
| DSU      | 262                                      | 84                           |
| HAE      | 420                                      | 87                           |
| SCBU     | 4962                                     | 90                           |
| MDU      | 3597                                     | 90                           |
were incomplete labels were discarded in wards bins but retrieved for audit, this might have suggest a poor compliance in 2008 as shown in (see Table 2-2).

Table 2-2 Compliance as percentage of units issued for all wards 2005-08.

| Year | Compliance as a % of all units issued | Standard deviation |
|------|--------------------------------------|--------------------|
| 2005 | 49.6                                 | (17.7)             |
| 2006 | 65.9                                 | (15.4)             |
| 2007 | 82.3                                 | (9.9)              |
| 2008 | 64.8                                 | (14.4)             |

An interesting finding was that as the number of units transfused increased there was a corresponding increase in traceability compliance (Figure 2.1).

Figure 2.1 Correlation between traceability compliance and units transfused

This relationship was analysed in more detail and wards were divided into low, medium and high usage groups. Variance analysis showed that there was a significant difference in the compliance of the three groups ($F = 14.52; p < 0.001$) (Figure 2.2) and this relationship was maintained even when each year was evaluated individually (Table 2-3).
In the period 2005-2008, low usage groups had an average compliance of 68.5%. Medium usage groups had an average compliance of 73.8 and high usage groups had an average compliance of 80.2% (see Table 2-4). Moreover, the low usage group had a significant lower compliance rate than the medium and high usage groups ($p < 0.001$) using the independent T test.

**Table 2-4 Traceability compliance for usage groups 2005-2008**

| Usage group | Compliance | Confidence interval |
|-------------|------------|---------------------|
| Low         | 68.5%      | 95% CI = 65.1 to 68.6 |
| Medium      | 73.8%      | 95% CI = 72.4 to 75.2 |
| High        | 80.2%      | 95% CI = 79.7 to 80.7 |
2.1.2 Phase two: Survey of ward managers

The study was approved by the clinical governance committee of the Homerton University Hospital NHS Trust. Emphasis was placed on voluntary informed consent. The questionnaire was anonymous and any personal information that could identify the respondent was kept to a minimum.

2.1.2.1 Method

A quantitative method was used because the frequency of occurrence was used to answer my research questions and this approach ensured that I was able to collect data and interpret comparatively. A major strength of using this method is that it minimise bias in gathering, communicating information and makes it possible to obtain precise information. Numbers are less vague than words. Qualitative findings often are the basis for formulating hypothesis. Qualitative studies help shape perceptions of a problem or situation and were not used.

The questionnaire was initially piloted to ensure that respondents could understand the questions and the response format was suitable. It was divided into sections that covered various aspects of the transfusion chain, including user satisfaction and performance related to traceability compliance. The objective of the survey was to gather more information related to the following research areas:

- Training related to blood product collection and administration.
- Knowledge of traceability procedures.
- How traceability compliance can be improved within the Trust.
- Laboratory staff professionalism.
- Ward staff responsibilities related to compliance.
- Ward staff opinion on traceability.
- General considerations.

A postal questionnaire was used as this mitigates the effect of social acquiescence particularly as some questions could have been considered sensitive (e.g. ward staff compliance with Trust policy). A self-addressed envelope was enclosed for return of the questionnaire. A reminder letter was sent approximately a month later to encourage replies from non-responders. The initial response was not satisfactory with a total of 10 out of 36 (28%) returns. Further telephone calls were made to
ward managers and a further 20 questionnaires were returned with a final response rate of 30 out of 36 (83%). During the data analysis, the outstanding non-responders returned their questionnaires, which were included in the final analysis shown in Table 2-5.

A Likert-style rating scale was used, which asked the respondent to rate how strongly they agreed or disagreed with a statement or series of statements. The data collected was verified by a departmental biomedical scientist to ensure accurate data entry, eliminate errors and identify missing values.

The data collected from the questionnaire was entered into a spreadsheet and analysed using the SPSS statistical package (SPSS, 2010). All data was screened to ensure that it did not violate the assumptions of non-parametric testing. Descriptive statistics for each item were calculated.

The Kruskal-Wallis test is a non-parametric test used to compare more than two independent groups. This test was used to compare the compliance rate between different groups (e.g. specialities). Spearman’s rank correlation coefficient was used to analyse the strength of the relationship between continuous variables and traceability compliance and the Mann-Whitney U test was used to compare differences between two independent groups when the dependent variable was either (a) ordinal or (b) interval but not normally distributed.

2.1.2.2 Results

The results of the questionnaire sent to ward managers are shown in table 2-5 and 2.6 below.
Table 2-5 Ward demographics

| Specialty    | n = 36 | Frequency (%) |
|--------------|--------|---------------|
| AE           | 1      | (3)           |
| Medical      | 19     | (53)          |
| Surgical     | 5      | (14)          |
| SCBU         | 1      | (3)           |
| Obstetrics   | 7      | (19)          |
| Geriatric    | 3      | (8)           |
| Total        | 36     | (100)         |

Number of beds on the ward

| Range  | Number | Percentage |
|--------|--------|------------|
| 1-10   | 12     | (32)       |
| 11-20  | 15     | (43)       |
| 21-30  | 5      | (14)       |
| 31-40  | 4      | (11)       |
| Total  | 36     | (100)      |

Schedule of transfusion

| Day and night | Number | Percentage |
|---------------|--------|------------|
| Day           | 4      | (11)       |
| Not applicable| 11     | (30)       |
| Total         | 36     | (100)      |

Trainer on the wards

| Trainer | Number | Percentage |
|---------|--------|------------|
| No trainer | 32  | (89)       |
| Trainer  | 4      | (11)       |
| Total    | 36     | (100)      |

Method of sending of transfused labels

| Sending procedure     | Number | Percentage |
|-----------------------|--------|------------|
| Single sending procure | 24     | (67)       |
| Multiple sending procedure | 12  | (33)       |
| Total                 | 36     | (100)      |

Staff training within the Trust %

| Scores       | Number | Percentage |
|--------------|--------|------------|
| 0-25         | 1      | (3)        |
| 26-50        | 7      | (19)       |
| 51-75        | 6      | (17)       |
| 76-100       | 22     | (61)       |
| Total        | 36     | (100)      |
Table 2-6 Ward managers’ assessment of traceability compliance.

| Traceability compliance training (n = 36) | Agree | Disagree | No response |
|-----------------------------------------|-------|----------|-------------|
| All my staff have been trained          | 27 (75%) | 1 (3%) | 8 (22%)     |
| I have enough training materials        | 27 (75%) | 1 (3%) | 8 (22%)     |
| I need more resources for training      | 27 (75%) | 2 (6%) | 7 (19%)     |
| Some staff were trained on the job      | 28 (78%) | 1 (3%) | 7 (19%)     |
| E-learning will help me do my job       | 5 (14%) | 27 (78%) | 3 (8%) |
| Locum staff can collect blood products  | 3 (8%) | 31 (86%) | 2 (6%)     |
| **Knowledge**                           |       |          |             |
| I understand the importance of traceability compliance | 30 (83%) | 2 (6%) | 4 (11%)     |
| I understand the importance of returning labels | 31 (86%) | 2 (6%) | 3 (8%)     |
| Labels are returned immediately after transfusion | 30 (83%) | 3 (8%) | 3 (8%)     |
| We are given monthly feedback about ward compliance | 17 (48%) | 16 (44%) | 3 (8%) |
| **Improving traceability compliance**  |       |          |             |
| Competency assessment can improve traceability compliance | 26 (76%) | 6 (16%) | 3 (8%)     |
| Methods of returning labels can be improved | 20 (56%) | 13 (36%) | 3 (8%)    |
| Too busy to send labels back to the laboratory | 21 (59%) | 12 (33%) | 3 (8%)     |
| **Attitude and perceptions to lab staff** |       |          |             |
| I get prompt responses from the laboratory | 32 (89%) | 3 (8%) | 1 (3%)      |
| We are informed about missing labels    | 28 (78%) | 5 (14%) | 3 (8%)     |
| We are given feedback about traceability compliance | 20 (56%) | 13 (36%) | 3 (8%)     |
| Staff courtesy and professionalism is good at all times | 28 (78%) | 5 (14%) | 3 (8%)     |
| Response time in answering telephone calls is acceptable | 32 (89%) | 3 (8%) | 1 (3%)      |
| **Ward staff responsibilities**         |       |          |             |
| The ward staff are responsible for returning compatibility labels | 32 (89%) | 2 (5%) | 2 (6%)      |
| The porters return compatibility labels | 12 (33%) | 20 (56%) | 4 (11%)    |
| There are clear procedures for returning labels | 26 (72%) | 7 (19%) | 3 (8%)     |
| Labels are left on the transfusion bag and sent to the lab | 11 (31%) | 22 (61%) | 3 (8%)   |
| **Transfused patients**                 |       |          |             |
| Patients are constantly transferred to a different ward | 18 (50%) | 15 (42%) | 3 (8%)     |
| Transfusion rarely takes place on the ward | 19 (53%) | 13 (36%) | 4 (11%)    |
| Wrong ward details on the labels and forms are common | 14 (39%) | 17 (48%) | 5 (13%)      |
| **Ward staff attitude**                 |       |          |             |
Ward staff know what to do if compatibility labels are misplaced

|                | 26 (72%) | 7 (20%) | 3 (8%) |
|----------------|----------|---------|--------|

Ward staff are regularly informed about traceability compliance

|                | 13 (36%) | 20 (56%) | 3 (8%) |
|----------------|----------|---------|--------|

Ward staff are encouraged to report lost or damaged labels

|                | 19 (53%) | 14 (39%) | 3 (8%) |
|----------------|----------|---------|--------|

The data was not normally distributed; a Kruskal-Wallis test was used to compare the relationship between average compliance and the various specialties. The results showed that there were no significant differences in compliance rates between specialties (p > 0.05; median 0.21). These outcomes suggested that traceability compliance was not associated with speciality. However, as there were only six specialty groups the study may not have been in a position to detect a significant difference.

The Kruskal-Wallis test also was used to compare the relationship between number of beds and average traceability compliance. The number of beds on the wards did not influence compliance rates (p = 0.70; median 0.49).

The Mann-Whitney U test was used to compare the relationship between average compliance and the presence or absence of a trainer on the ward. A statistically significant difference was found; average traceability compliance was better with a trainer on the ward (p = 0.03; median 0.16). Sixty-one per cent of respondents reported that 76-100% of their staff had been trained within the past year. It was evident that as the number of trained staff increased, compliance improved across all wards. Spearman’s rank correlation coefficient showed a strong correlation between the proportion of trained staff and traceability compliance (r = 0.59; p = 0.002).

Another statistically significant difference was found between timing of transfusions and average traceability compliance (p = 0.04; median 0.59). Traceability compliance was better during the day than at night. However, the compliance rate was not associated with the method of sending labels (p = 0.14; median 0.40).
Table 2-6 shows that not all respondents had a clear understanding of the procedures for sending **transfused blood labels** back to the laboratory. Nineteen per cent of respondent did not agree that there were clear procedures for returning labels, although 56% of respondents agreed that they were informed about monthly traceability compliance. It was also evident that some respondents did not think that they should report damaged or destroyed labels.

The **transfer of patients** between wards could be considered another **risk factor** for traceability compliance. Fifty per cent of respondents agreed.

2.1.3 Phase two: Direct observation

Direct observation was used to supplement the information obtained through the questionnaire.

2.1.3.1 Method

A structured observation checklist was designed to evaluate blood collection and bedside checking procedures at the Trust. The checklist highlighted relevant information about how blood products should be collected and checked at the issue fridge and patient’s bedside respectively. The checklist covered the procedures and standards issued by National Patient Safety Agency and SHOT, and British Committee for Standard in Hematology guidelines for blood collection. It also included the procedures displayed at the blood collection point and the bedside checking procedure on the ward.

The drawback of observational data activities is that they are time-consuming and the volume of data generated is immense. Therefore the sample size was kept small. One of the threats to the validity and reliability of data collected through observation is that of the observation effect. Another is time error. It is essential that the time at which the observation is conducted does not provide data that is atypical of the total period of the study.

I gave careful consideration to the composition of the sample. Because of variations in blood collection, shift patterns, time availability and other practical difficulties, I was the only researcher involved in data collection. Random sampling would have been preferable but this was impossible because of the transfusion
patterns in the Trust. An average of six transfusions takes place on a normal day and fewer than two during the night.

Due to a lack of access to the target population, a sample of 58 different transfusion episodes was observed. This represented 10% of the average monthly transfusions on the wards. The study was entirely voluntary and personal information that could be used to identify participants was kept to a minimum. All wards involved in the collection and administration of blood products with more than two transfusion episodes per week were included. Participants included staff members who collected and administered blood products on the ward. The anonymity of the staff members observed was protected.

2.1.3.2 Results

Data from the checklist was entered on into a spreadsheet and analysed using SPSS software (SPSS, 2010). The data generated by the observation was coded to enable a numerical analysis. Coding took the form of: 1 = compliant, 2 = non-compliant and 3 = non-applicable.

**Table 2-7 Observed compliance by ward staff**

| Question                                                   | Compliant | Non-compliant |
|------------------------------------------------------------|-----------|---------------|
| **Blood collection procedure**                             |           |               |
| Patient's prescription chart brought to the collection point | 56 (97%)  | 2 (3%)        |
| Blood pack ID checked against report and labels            | 57 (97%)  | 1 (3.0%)      |
| Procedure for blood collection followed as stated by the standard operating procedures | 54 (83%)  | 4 (17%)       |
| Transport box used to collect unit                         | 48 (82%)  | 10 (18%)      |
| **Bedside checking procedure**                             |           |               |
| Patient's notes brought to the bedside                     | 50 (86%)  | 8 (14%)       |
| Patient's ID checked against the form                      | 48 (83%)  | 10 (17%)      |
| Blood pack ID checked against the patient's ID wristband   | 50 (86%)  | 8 (14%)       |
| Checking procedures carried out by two qualified nurses    | 56 (97%)  | 2 (3%)        |
| Patient confirms all details                               | 56 (97%)  | 2 (3%)        |
| All identification correct                                 | 56 (97%)  | 2 (3%)        |
| Starting time of transaction recorded                      | 54 (93%)  | 4 (7%)        |
Overall, the results obtained from the blood collection point and bedside check suggested that most of the time ward staff did comply with checking procedures at the blood collection point and the patient’s bedside. However, full compliance was not achieved at the blood collection point. Seven per cent of observed participants did not bring the prescription sheet for checking at the blood collection point, leading to the possibility of collecting the wrong blood. The transport box was not used by 18% of participants for blood collection, which increases the incidence of storage and wastage error. There was also non-compliance with the bedside checking procedure by ward staff. Seventeen per cent of observed staff did not check the patient’s identification against the blood transfusion request form. The patient’s notes were not used in the bedside checking procedure by 14% of observed staff and the blood pack was not checked against the form by another 14%.

My results was comparable to the National Comparative Audit of blood collection conducted in 2009, which identified that 3.9% of staff did not bring documented patient identification during blood collection and 5.3% did not check documentation against the blood bag collected.

2.1.4 Discussion

The peak percentage traceability compliance of 82% was obtained in 2007. This was followed by a drop to 65% in 2008. This led to the conclusion that the existing approach to resolving poor compliance (reporting non-compliance using the Trust’s incident reporting mechanism and targeting staff) did not resolve the issue. Moreover, reviewing the volume of incidents from wards was not sustainable. The lowest traceability compliance was 50%, in 2005. The overall average traceability compliance from 2005-2008 was 69%. This shows that there was some improvement but it was not good enough. The results justified the need for establishing an enhanced system of transfusion practice and a well-structured change management programme which was not given a full attention during the study. The presence and absence of a trainer on the ward had a positive impact on traceability compliance within the Trust, there was a significant difference.

It was encouraging to note that most of the procedures in the observation checklists were being adhered to. It was also encouraging to note that there was a
high awareness of error reporting in the Trust. Safety in blood transfusion is enhanced if errors can be identified before they result into an adverse outcome for a donor or patient (AuBuchon & Littemberg, 1996). Sellu et al., (2012) also highlighted in their study that simulation training is one way in which staff within the blood transfusion chain can be assessed effectively. This form of training has been used in the aviation industry to decrease system failures and individual errors and to introduce this method in the transfusion process is not easy as thought.

2.1.4.1 Blood usage levels and compliance

The study demonstrated a positive, significant correlation between the number of units transfused and user compliance. Medium and high usage groups had higher average traceability compliance than low usage groups throughout the years that were investigated (2005-2008). High and medium usage groups did not have significantly different means.

2.1.4.2 Staff training

Eighty-nine per cent of respondents reported that they did not have a trained transfusion trainer or nurse on their ward, while 11% said they had such a specialist in-house. When there was no in-house trainer, the results showed that training was still given importance, even if a trainer was not available. This outcome suggested that training is a key element in the Trust.

The majority of the wards were aware of the importance of staff training, and this was highlighted by Murphy et al. (2004) who found that training and education may improve traceability compliance. The employment of a ward trainer is not as critical as the provision of other modes or means of training. However, the provision of training is significantly and positively correlated with traceability compliance.

2.1.4.3 Blood labelling

The results of the survey suggested that staff members agreed on the importance of blood labels. Moreover, survey participants strongly agreed that labels should be returned immediately after transfusion and they understood the importance of traceability compliance. It was encouraging to note that all the statements in the survey related to this area were evaluated positively by respondents.
2.1.4.4 Blood and patient identification

Out of all the behaviours that were observed using the bedside point observation checklist, the ones which were least observed were the patient's identity being checked against forms and labels and the blood pack identification being checked against reports and labels. Of the blood collection point checklist behaviours that were observed, the ones that were least respected were using the right transport box, patient identification being brought to the collection point and patient identification being checked against reports and labels. While staff members take their responsibilities in the transfusion process seriously, acknowledge the importance of training and skills assessment and generally follow working procedures there may be a need for a more permanent, technological intervention to increase traceability compliance.

This is consistent with the results from Novis et al. (2003) who assessed the frequency with which the basic elements of bedside checking procedures were performed, including patient identification, blood compatibility identification and expiry date information. Their study revealed a failure to match wristband identification with the compatibility label in 25% of blood transfusions. The outcomes of the current study showed persistent difficulties in observing these patient identification protocols.

Errors in the blood transfusion process frequently relate to patient identification, blood units and its components. These erroneous slips can be reduced with the help of different techniques (Linden et al., 2000). In the case of the current study, it was found that majority of the wards still employed a paper-based tracking system. There are many alternative technological approaches that may help to improve traceability compliance, such as mechanical barriers, barcodes, computerisation, automatic interface systems, portable computers and radiofrequency devices, and automated blood stores.

2.1.4.5 Feedback mechanisms

Slips are unintended errors caused by either not doing part of the routine or being distracted by someone. Slips can be avoided by the redesign of equipment and procedures in ways that make it more difficult to make a slip. For instance, a feedback mechanism can be designed into the IT system that alerts the individual
when a slip is made i.e. alert from system to request label sent back and time and question operator if odd decisions were made. This is one approach that could be taken by the Trust to enhance traceability compliance.

2.1.4.6 Technology

Tracking blood samples using RFID technology has been cited in a number of studies looking at blood products and may be considered by the Trust. However, carrier and reader consistency and reliability are problems. A detailed evaluation is necessary to establish the limits of such advanced technology.

2.1.4.7 Patient transfer periods

The results indicated that the patient transfer period was significantly and positively correlated with ward compliance. The patient transfer period was measured by the number of patients transferred to other wards. Transfers happen regularly on wards and it is common to find the wrong ward indicated on the compatibility form and label.

The transfer period may be classified as an active failure since it is the health professional who decides it. A significant and positive correlation with traceability compliance indicates that as transfers to different wards become more frequent and the identification of the wrong ward on compatibility forms and labels increases, the likelihood of compliance increases correspondingly. Possibly, the identification of such errors causes more stringent enforcement of procedures, leading to higher traceability compliance within the ward.

2.1.4.8 Latent factors

It may also be worth noting some latent errors behind non-compliant behaviours. Technical aspects associated with latent failures include such things as equipment design, computer software and mobile and material facilities, the barcode on the transfusion labels were not water proof, this need to be transcribed onto the computer system manually when damaged by an medical laboratory assistant. One aspect of organisational failures stems from normal management issues. This includes the structure of the organisation, planning and scheduling, forecasting, budgeting and allocating resources.
3 Blood product tracking models

This chapter first reviews the literature on the effectiveness of commercial traceability products. It then describes a survey of blood transfusion managers in NHS Trusts in North East England that gathered information about the actual process of traceability from professionals in the healthcare sector. The data gathered was used to inform the choice of traceability processes implemented by the Trust and described in Chapter 4. The purpose was to evaluate the error detection level, robustness, sampling techniques and the secondary outcomes of the blood tracking systems available.

3.1.1 Introduction

The aim of the literature review was to determine the range of blood tracking systems available and to summarise the evidence on the effectiveness of these systems. The specific objectives were:

- To compare traceability procedures with the previous system or no system.
- To assess performance in terms of percentage compliance, error detection levels and mistransfusion events.
- To assess secondary measures such as cost-effectiveness, robustness and acceptance by staff members.

The review included any studies that evaluated the outcome of a traceability process. Traceability processes could include electronic tracking systems or paper-based methods. I included both randomized controlled trials and non-random trials, but as it was unlikely there would be many studies of this type, I also reviewed post-use evaluation reports and uncontrolled before-and-after studies.

3.1.2 Method

The review sought to identify all papers related to tracking systems for blood transfusion. I used search engines such as Medline (1966-2012), EMBASE (1980-2012) and CINAHL® (1982-2012), the Cochrane Library and the transfusion evidence library, which contains the National Health Service Blood and Transplant systematic reviews and Health Business Elite texts.
The search terms used were traceability (including tracking*, traceable*, tracking system or vigilance), blood (including haem*, transfusion, red cell, blood* or blood products*), haemovigilance (or vigilance*) and blood products (including red cells, blood* or blood products*). In addition, the search included the websites of medical companies that produce well-known tracking systems and a manual search of conference proceedings up to 2012. The references of full papers were identified electronically and also included in the review.

The data collected related to the number of beds, number of blood units transfused, the need to trace blood products leaving the hospital (for external or home use), the quality of the study, the date of implementation and description of the new system, the system being replaced and outcome data. Studies were graded according to quality i.e. designed and outcome. Controlled studies were considered to be better quality than uncontrolled. Before-and-after and post-evaluation were both considered as uncontrolled studies.

3.1.3 Results

The initial review identified 378 references. Of these, 106 were found to not be relevant to the research question and were removed. The remaining 272 references were screened for eligibility against predefined criteria. Twelve references were identified to be of particular interest. These are described in detail in Table 3-1.
Twelve studies identified included in quantitative synthesis
### Table 3-1 Results of the literature review

| Author                              | Method                      | Type of traceability                          | Sampling                                      | Outcome                                                                                     |
|-------------------------------------|-----------------------------|-----------------------------------------------|-----------------------------------------------|----------------------------------------------------------------------------------------------|
| Royal Bournemouth and Christchurch Hospitals, 2010 | Before and after evaluation | Olympus electronic tracking                   | 42 wards across two hospital sites            | Improved traceability compliance from 70% to 100%                                            |
| Davis et al., 2009                  | Radiofrequency technology   | Tag and labels readability                    | Blood centre                                  | Radiofrequency improves tracking                                                              |
| Uriz et al., 2011                   | Evaluation                  | Tracking system                              | 520 beds hospitals                           | Improved traceability compliance from 48% to 99%                                              |
| Doughty & Hitchinson, 2010          | Before and after evaluation | Transfusion practitioner & MLA( blood handler) | 600 units of blood                           | Attained from 89% to 100% traceability compliance.                                            |
| Bachs et al., 2009                  | Pre and post evaluation     | Grifols – bar code reader                     | 400 beds                                      | Improved compliance from 61% to 94%.                                                           |
| Askeland et al., 2008               | Pilot                       | Barcode tracking system                       | Not specified                                 | Incident reporting reduced by 60% per month                                                    |
| Ingrand et al., 1998                | Evaluation                  | Paper based                                   | 390 units of blood                           | Attained 81.9% compliance                                                                     |
| Hammadi, 2009                       | Retrospective evaluation    | Patient records checked for traceability compliance | 2200 units of blood                          | Compliance increased from 32% to 80%                                                          |
| Al Abdulrazzak et al., 2009         | Evaluation                  | Data management system                        | 1500 blood bags                               | Data capture was improved from 40% to 98%                                                     |
| Murphy, Stanworth & Yanzer, 2011    | Before and after evaluation | Handheld barcode                             | Not specified                                 | 11.8% to 100% improvement in patient identification                                            |
| Chan et al., 2004                   | Evaluation                  | Barcode tracking system                       | Not specified                                 | 90% compliance                                                                               |
| Verret et al., 1998                 | Evaluation                  | Tracking system                              | 2 hospitals                                   | 97% of products were traced                                                                   |
3.1.4 Discussion

The study at the Royal Bournemouth and Christchurch Hospitals showed that traceability compliance had improved significantly by employing the Olympus blood tracking system. Prior to the implementation, only 70% of transfused blood could be traced. The blood tracking system enabled positive patient identification and consisted of modular software, 2-dimensional barcoding and a wireless personal digital assistance. The system was introduced on 42 wards in the Trust and improved traceability compliance to 100%. The team also anticipated that future financial savings would be made by the elimination of blood wastage and ultimately free up staff time in the transfusion chain.

Davis et al. (2009) highlighted the benefits of Radiofrequency Identification (RFID) technology, which included the reduction of discarded product and enhanced visibility of large quantities of incoming stock. They claimed that more timely, detailed and accurate information would support ‘Lean operations’. High frequency passive RFID technology was found to perform satisfactorily in blood centres and assessed as safe when used with red blood cells and whole blood derivatives platelets. However, they highlighted that additional research was needed to confirm the performance and safety of RFID at very low temperatures with plasma products.

Uriz et al. (2011) carried out a retrospective study of blood transfusion services at their hospital. The Gricode® electronic identification system (EIS) had been implemented in order to improve services. The EIS comprised a portable reader with software tailored to the hospital's existing systems, sufficient storage space and the ability to transfer data to the transfusion service. It recorded the beginning and the end of the transfusion at the bedside and any adverse reactions. It enabled patient, document and sample identification, together with the blood products transfused and time tracking. Following the implementation of the new system in 2005 high levels of traceability were obtained, ranging from 99.5% in 2005 to 99.7% in 2008. Monthly analyses indicated that traceability was consistent. The failure of ward staff to perform controls was also assessed in a subsequent analysis. The emergency room failure rate was above 20% due to the malfunction of the reader and the loss of data. The neuroscience unit failure rate was 25%, although only a few transfusions were performed by the unit.
The transfer of data between hospitals and National Blood Service is emerging in the U.K blood services but in its early stages. This will provide a complete traceability of blood products in the future, lately we could assess patient’s serology reports from the NBS and check blood products issued to hospitals across the country, and this is a beginning of total traceability within the health sector.

Doughty and Hitchinson (2010) described blood handling practices across several sites serving one Trust and eight smaller sites. A medical laboratory assistant was employed to handle the product, collect daily information from the ward and reconcile it with the blood issue forms. A transfusion practitioner was also appointed to deliver training to key groups of staff. They suggested that factors contributing to good compliance included the appointment of a hospital transfusion practitioner, electronic prescribing, a medical laboratory assistant in clinical units, timely feedback and reinforcing success. The cost effectiveness of the full tracking system requires further exploration.

Bachs et al. (2009) evaluated the safety transfusion system and traceability compliance following the implementing of improvement measures. A tracking system (Gricode®) was employed in the transfusion department. The software could be accessed from the nurses’ station and barcode readers were provided in 28 areas of the Trust in order to scan the transfusion process. The data collected included the blood sample, the patient’s identification bracelet, and the start and end times of transfusion. All data was downloaded on a daily basis to the main blood transfusion system where the whole process was supervised. The study showed that wards with low levels of compliance were those that carried out the fewest transfusions.

Askeland et al. (2008) evaluated incident reporting associated with the introduction of wireless devices and barcoded labels to the transfusion process. Data was collected from before and after the implementation. Incident reports decreased from a mean of 41.5 reports per month in the six months before implementation to a mean of 7.2 reports per month after the implementation. Errors detected by the system included mis-scanning, skipped steps, wrong steps and identification errors. The authors estimated that the new system had caused the mistransfusion rate to drop to about once every 100 months. The bar-code based computerized tracking
system was shown to have reduced the proportion of errors in the transfusion chain and enhanced patient safety.

Ingrand et al. (1998) conducted a pilot survey using information gathered from the medical record department in a French university hospital. The availability of transfusion information varied according to patient records and the type of ward. The study showed 81.9% traceability. The study also showed that traceability compliance differed according to the clinical area and was worst in surgical units. They recommended that robust, efficient change in the organization and information systems was needed.

Hammadi (2009) described the tools used for evaluating traceability compliance in the medical sector. The patient's case notes, transfusion card and the transfusion register were used to evaluate the final destination of transfused blood. The study found that with the introduction of an electronic tracking system, the rate of traceability compliance improved from 39% in 2001/2002 to 83.3% in 2006.

Al Abdulrazzak et al. (2009) conducted an evaluation of 1,500 red cells issued by the Kuwait Central Blood Bank. Prior to the introduction of the Data Management System (DMS), one hospital discarded all traceability records, while a second did keep some but a lot were missing. The rates of missing data were 87% and 40% respectively. After the DMS installation both hospitals were provided with a list of products supplied/received and were requested to check individual traceability records. Traceability compliance was found to have increased to 98%. The DMS implementation had resulted in a significant decrease in the number of missing records in both hospitals. The study recommended that manual records should not be discarded, but should be archived for easy access and retrieval.

All methods of traceability system from this systematic review had improved traceability compliance to a varied degree. The introduction of interactive training and prompt built into this tracking system will be a useful innovation to improve compliance and also a barrier to minimise poor compliance in areas of low usage of blood product as identified by Bachs and colleagues. It is also important to identify failure rate of electronic tracking system, an incident was identified in the emergency room highlighted by Uriz et al., 2011. The use of electronic tracking had improved traceability compliance in most of studies, but the occasional failure rate
requires a risk assessment and further exploration of the limitation of this systems. Askeland et.al, (2008), also identified incidents such as mis-scanning of blood products, skipped steps and wrong steps. This shows the vulnerability of this system.

### 3.2 Commercial software products

As early as the 1970s, Sherer et al. (1977) described studies that implemented prototype handheld bedside donor-recipient identification systems, but none of the systems proved acceptable under the clinical conditions. Since then, only small-scale experiments have been reported, which makes it difficult to compare the effectiveness of different technical approaches.

Murphy et al. (2004) highlighted that the current safeguards to prevent mistransfusion are inadequate. Minimising transfusion errors requires a coordinated effort from all stakeholders to enhance patient safety throughout the transfusion chain. Automated identification and data capture systems such as barcoding and radiofrequency identification (RFID) can be a key enabler in reducing errors in blood transfusion, although the limitations of the technology have proved to be a barrier to widespread adoption (Hopkins, 2005).

#### 3.2.1 Barcode tracking systems

Gradual progress has been made in the last decade to apply barcode technology to patient identification and transfusion medication safety. Barcode systems consist of a handheld terminal, a barcode reader, a biometric sensor for reading fingerprints and a keypad. The biometric sensor records the fingerprints of hospital staff and the patient. The system makes it possible to identify and check which blood units to assign to patients. Patients can be easily identified whether they are conscious or unconscious. The technology is a widely used, stable and inexpensive means of machine readable identification. Several commercially available products have been deployed by hospitals and others are in development (Aller, 2005). Progress in forward-looking hospitals is being stimulated by products that have been specifically developed for the healthcare sector (Table 3-2).

**Table 3-2 A sample of commercial products using bar-code technology.**
Barcode tracking systems such as I-TRAC (and its modified versions Safe Track and I-TRAC Plus) consist of a barcoded wristband for patient identification and a handheld portable data terminal. The patient and the blood pack are identified using a scanner and the information is downloaded via a portable printer.

Such a system was installed at the Georgetown University Hospital in the United States (Sandler, Langeberg & Dohnalek, 2005), while Chan et al. (2004) described a simplified bar-coded method that reduced error rates in a Hong Kong hospital. They reported that although compliance averaged 90%, problems were encountered with battery failures of the handheld device. In the United States, the University of Iowa evaluated a similar system and found that it was ten times better at capturing errors than the manual process. Despite the advantages of barcode systems, some studies found that traceability compliance did not improve (Nichols et al., 2004) as the barcodes on wristbands can be blurred and difficult to read. Barcode-based systems require that the wrist and blood unit be scanned each and every time; in urgent situations this can make the process very clumsy.

The Tracesoft blood tracking system was designed to scan blood packs to be delivered to wards. It was designed to search for blood packs and identify their location. A central server provides a web-based view of activity, controls access to blood fridges and bedside software. All tracking base and bedsides devices are linked to the central server in a real-time thereby providing an overview of all product movements. Each process has a full audit trail and the system can send both visual and audible alerts to a nominated workstation. Full access control is incorporated into the system. Every user has a login and password. It also provides fine-grained control over access rights.
In 1991 the Albert Einstein College of Medicine in the United States evaluated the BloodLoc system. In this system, an alphabetic code taken from the patient identification bracelet must be used to access the assigned blood unit. The same system was implemented at the Dartmouth-Hitchcock Medical Centre in New Hampshire (United States) and the Gaetano Pini Orthopaedic Institute in Milan, Italy (Mercurialli et al., 1996).

3.2.2 Radiofrequency tracking systems

Another method is radiofrequency identification (RFID) to link barcodes or microchips to palm computers. In the mid-1990s, little attention was paid to RFID but since then it has gained momentum as the cost of implementation has decreased. Most studies show that the technology is suitable for transfusion medicine but its implementation may present challenges. All blood bag trials have used a frequency of 13.56 MHz, because of the ability to take readings through fluids. Trials have tested the durability of tags under real conditions, such as centrifugation, temperature changes and irradiation. There appear to be no trials that investigated the entire blood chain, from blood bag manufacturers to donation, production, storage, distribution and transfusion. Consequently, no studies have been identified that determine the return on investment from RFID.

Radiofrequency tracking systems have several advantages over barcoding in terms of patient safety. RFID chips can hold more data than a barcode and can include more information such as patient allergies, blood needs and any special requirements. Secondly, unlike a barcode, RFID does not require the use of light beams and RFID chips are interrogated through simple proximity to an electric reader. Dzik (2005) and Sandler, Langeberg and Dohnalek (2005) described the radiofrequency (RFID) identification method using a frequency of 13.56 MHz. Blood bag tags were integrated into the blood bank computer system. Tags and patient wristbands were read by a built-in radiofrequency reader.

There are two kinds of RFID technology. In Active RFID the chip is powered by a battery and emits energy that can read over a distance, this is commonly used to track assets within an establishment. Passive RFID technology is more suited for blood bags and patient identification as it emits no energy. Tags are read only when in close proximity to the reader. At Massachusetts General Hospital (United
States) a pilot study was conducted using passive RFID. A bedside reader was used to identify the blood bag and to provide feedback on the match between the identity of the patient and the blood bag (Dalton, 2005).

RFID was used at Saarbrucken Hospital in Germany to track blood bags, record transfusions and ensure that patients received the right blood, this was a small study and the effect of durability of the tags, centrifugation, temperature changes, irradiation was not investigated (Wessel, 2006). Hospital staff attached self-adhesive labels to all blood bags arriving at the hospital. The labels contained passive RFID chips with two kilobytes memory for storing unique identification numbers. The Return of investment is a big issue with the use of RFID in transfusion medicine and this require full further evaluation.

3.2.3 Limitations and challenges of barcode and RFID technology

Although traceability should enable tracking of all phases of the transfusion process, it can also breach privacy. Patient’s data are stored on chips and transmitted at different frequency depending on the reader and carrier. The full security of this data have not been fully evaluated, even though firewalls can be created to prevent access.

Carriers and readers are an important aspect of tracking. Carriers come in many forms, such as barcodes, data matrices, RFID and smartcards and each carrier has its own standards. RFID, for example, uses three frequency ranges (125 kHz, 13.56 GHz. and 900 MHz), each with advantages and disadvantages. Carriers and readers must be standardised if the codes they carry are to be easily read and stored. Moreover, there are still reliability problems with carriers. As yet, there is no ideal carrier; the choice depends on physical and environmental constraints as well as robustness and cost. Despite a lack of reliable studies, RFID is a very promising technology and may have a significant impact in healthcare (Fanberg, 2004, p.43).

In the United States, the American Food and Drug Administration requested the national RFID consortium to subject blood products to radiofrequency energy in worst-case conditions to determine whether there was any in vitro adverse impact. The aim of the study was to ensure that any impact of exposure to the radiofrequency reader on blood safety could be assumed to be acceptable. Testing
included an evaluation of product heating and any key biochemical changes from exposure to an intense radiofrequency magnetic field for longer than 23-25 hours (Davis et al., 2009).

The use of handheld devices to capture barcoded information from the patient wristband improves patient safety and minimises mistransfusion. The handheld device of a typical commercially available system receives and transmits information about patients and blood units. This requires an interface between the handheld device and the hospital network or a dedicated wireless network. Privacy and security are concerns with the use of both RFID and wireless technology. Other technological limitations include the implementation of firewalls to protect the RFID database, tag disposal and recycling and shielding RFID tag or tag reading areas with metal screens to prevent unauthorized access (Davis et al., 2009). The use of RFID on blood products is in its early stages, because of its return on investment cannot be ascertain, most studies have been carried out on red cells, the effect of radiation on plasma products requires further exploration and effect of electromagnetic radiation on blood products is currently under investigation. The cost of installing a tracking system is becoming affordable and cost-effective since the inception of this study compared to RFID.

3.3 Survey of blood bank managers

This phase of the study aimed to provide information about the actual process of traceability and opinions from healthcare professionals. The data gathered was used to inform the choice of traceability processes implemented by the Trust and described in Chapter 4.

Data was gathered through a self-administered questionnaire sent to blood bank managers working in NHS Trusts in North East of London. It aimed to answer the question, “What variables are associated with traceability compliance in NHS Trust hospitals in North East of London” (Appendix 6). Most of the NHS Trusts that participated in this study came from Brentwood user group.
The Homerton University Hospital NHS Trust clinical governance committee approved the study. Participants were informed in writing that their participation was voluntary and anonymous. Non-respondents were not followed up as it was felt that they should not have to justify their decision not to participate.

3.3.1 Method

Hospitals with no blood bank services were excluded from the study. Twenty-five questionnaires were sent to blood bank managers who were invited to participate on a voluntary basis. A covering letter was attached to the questionnaire explaining that all data collected would be treated anonymously and destroyed following analysis. The questions related to individual Trust traceability compliance and addressed issues such as bed capacity, the availability of a satellite fridge, whether there was a tracking system in place, its cost and training.

Questionnaires were posted to participants together with a self-addressed envelope for the return of the questionnaire. Reminders were sent a month later to maximize the response.

Completed questionnaires were numerically coded to facilitate the analysis and organise the results. Descriptive statistics were used to evaluate the sample. The data was not normally distributed; the Kruskal-Wallis test, Spearman’s rank correlation coefficient and the Mann-Whitney U test were used in the analysis.

3.3.2 Results

The response rate was 64% (16 out of 25 trusts) and table 3-3 shows the demographics of the Trusts surveyed.
Table 3-3 Demographics of the 16 NHS Trusts surveyed.

|                                | Frequency (n=16) | %      |
|--------------------------------|------------------|--------|
| **Bed capacity**               |                  |        |
| 1-100                          | 1                | (6.3)  |
| 101-200                        | 2                | (12.5) |
| 401-500                        | 7                | (43.8) |
| >500                           | 6                | (37.5) |
| **Trusts with satellite fridges** |                  |        |
| Yes                            | 13               | (81.3) |
| No                             | 3                | (18.7) |
| **Transferring blood to other sites** |              |        |
| Yes                            | 16               | (100)  |
| **Tracking system in place**   |                  |        |
| Paper tracking                 | 12               | (75.0) |
| Electronic tracking            | 4                | (25.0) |
| **Cost of tracking system in place** |              |        |
| Medical Laboratory Assistant   | 9                | (56.3) |
| Not known                      | 7                | (43.7) |
| **Hospital staff trained in the collection of blood** | | |
| 51-75%                         | 8                | (50.0) |
| 76-100%                        | 8                | (50.0) |
| **Red cell units transfused in the last 12months** | | |
| >5000                          | 13               | (81.3) |
| <5000                          | 2                | (12.4) |
| Unknown                        | 1                | (6.3)  |
| **Average traceability compliance** |              |        |
| <75%                           | 1                | (6.3)  |
| >75%                           | 15               | (93.7) |
| **Feedback mechanism to users** |                  |        |
| Yes                            | 13               | (81.3) |
| No                             | 3                | (18.7) |
| **Audit of the transfusion process** |              |        |
| Yes                            | 13               | (81.3) |
| No                             | 3                | (18.7) |
Table 3-3 shows that 44% of the Trusts had a bed capacity of 401-500, similar to the Homerton University Hospital NHS Trust.

Demographic data was not normally distributed; hence the Kruskal-Wallis test was used to compare the relationship between bed capacity and average traceability compliance. The number of beds on the wards did not influence compliance ($p = 0.64$; median 0.62).

All respondents confirmed that they transferred blood products to other sites or hospitals, however the transfer of blood products to satellite hospitals did not influence traceability compliance ($p = 0.44$).

Seventy-five per cent of respondents said they had a paper-based tracking system, while 25% said they were using electronic tracking. The analysis showed that there was no relationship between electronic tracking and traceability compliance ($p = 0.52$; median = 0.25). It was evident that although electronic tracking and paper-based methods improved traceability compliance, the cost of the two systems required further exploration.

Regarding the percentage of staff trained in the collection of blood products, 50% said the percentage was 51-75%, while the other half assessed it to be 76-100%. The Trusts with most trained staff had better traceability compliance as Spearman’s correlation showed there was a positive correlation between training and traceability compliance but not clinically significant ($r = 0.48$; $p = 0.06$).

Eighty-one per cent of respondents said that their hospital had transfused less than 5,000 red cell units in the past year. Twelve per cent reported transfusing more than 5,000 red cell units and 6% did not know the number. There was positive correlation between transfused units and traceability compliance ($r = 0.54$; $p = 0.03$).

Ninety-four per cent of respondents said that average traceability compliance was greater than 75%. At the same time, few Trusts were working towards improving their compliance which suggested that both tracking methods (paper and electronic) improved traceability compliance.
3.4 Discussion

The objective of this review of current practice was to identify and explore the effectiveness of different blood product tracking models to inform the choice of traceability processes implemented by the Trust and described in Chapter 4. It was evident that staff training within the transfusion chain remained a big issue in some of the Trusts surveyed, and not all staff had been adequately trained.

Overall, the results showed that audits, regular feedback, traceability methods and the percentage of trained staff positively influenced traceability compliance. Nevertheless, there are limitations related to data collection and the transferability of the study. The sample size was small and the selection of participating Trusts was not representative, which might have skewed the data. Participant’s were assured that all respondents will not be identified, there is tendency that compliance might have been overstated if they felt that they might be identified or data might be used outside the purpose of this study. The NHS Trusts with good compliance will likely give more information how compliance was achieved. Error detection level within NHS Trusts remains a concern, hospital laboratories with high error reportable level tends to come under scrutiny by regulatory bodies, consequently this has led to underreporting of incidents as identified by SHOT, 2011. Further studies will be required on a larger scale to assess the transferability and problems with traceability compliance.

3.4.1 Literature review

Of the 12 studies identified in the literature review, nine included data about post-implementation traceability compliance. However, the quality of the evidence varied and was subject to limitations. First, some studies did not specify the medical speciality concerned. In other studies a before-and-after comparison was made, but the lack of concurrent controls meant that there could be alternative explanations for the change in the compliance rate. Moreover, before-and-after studies and non-blind studies are prone to a reporting bias. One study simply reported post-implementation compliance rates. There were inconsistencies in the descriptions of how the studies were conducted and outcomes were reported. In addition to the limitations of individual studies, there were several potential biases in the review process itself. Relevant data may not have been captured either
because it was not provided or because it was not published. It was evident that
both the tracking system and the paper-based method shown in Table 3-1
improved traceability compliance; therefore the cost-effectiveness of both systems
needs further exploration. The tracking system also freed up staff time by sorting
blood products, reducing wastage and increasing the use of old stock.

3.4.2 Tracking methods

Documentation and tracking methods are important as they many improve
compliance. The review of records or audits has conventionally been a way of
performing quality assurance checks and documenting patient outcomes. The audit
of records against predetermined criteria can be an important method in identifying
errors or near miss events. In the survey of blood bank managers, 75% said they
had a paper-based tracking method, while 25% said they were using electronic
tracking. While this may be an area for improvement in compliance, technology is
not a panacea. Moreover, electronic tracking may be an expensive option, reflected
in the fact that 44% of respondents said they did not know the cost of the current
system.

RFID technology may be a valuable tool, if it is affordable. It captures the
movement of all blood products using a reader and carrier. It keeps patient
information safe and secure, reduces the turnaround time for blood products
tracing and helps to track and sort blood products in time and date order, hence
reducing wastage and improving stock management.

Self-assessment may be another way to improve practices that are likely to lead to
increased compliance. Self-assessment must be carried out regularly and
monitored so that incidents can be reported immediately. To achieve secure and
traceable procedures concepts regarding quality, security and efficiency must be
incorporated into the process itself. On the other hand, the members of staff that
are involved in the transfusion process must initiate action. Practices and methods
must be established to prevent errors. Furthermore, it is essential to have a robust
policy, implement systems that support the policy, assess the skills of staff
members against national standards and audit the process.

The cost benefit of RFID in light of its capability is enormous but requires NHS
funding.
4 New system implementation (Method 2)

The Trust had initially attempted to meet the requirements of MHRA guidelines using a paper-based method, which failed to achieve 100% compliance. As the guidelines required all Trusts to achieve 100% compliance this had become a concern and the hospital management and transfusion teams were made aware of the situation.

The Trust was not able to explore the electronic tracking systems described in Chapter 3 because of lack of funding for this project. There were doubts about whether it would be able to resolve the non-compliance issues. Consequently, the Trust management asked the transfusion team to provide a business case for alternative methods in order to achieve full compliance. This chapter describes and evaluates the changes that were made to quality control processes to improve traceability compliance at the Trust.

The new system consisted of an air-tube that was primarily designed for sending samples from wards to the pathology department. In 2009 it was extended to various other wards in the Trust who were asked to use it to return the labels from transfused blood units. Every ward within the Trust was equipped with an air-tube station and canisters. Samples and transfused labels sent directly to the blood transfusion reception arrived within 60 seconds (Figure 4.1). An evaluation showed that this brought about a huge improvement in traceability compliance.
The system enables the fast delivery of labels from transfused blood units to the transfusion laboratory and labels from the wards to the pathology department. This means that wards can send labels without the need for a porter or a laboratory assistant. The layout of the system is flexible and transfers can be made at any time of day. The canister is bar-coded to allow redirection to the right ward and the system can be easily altered or extended according to the needs of the Trust.

4.1 Quantitative assessment of traceability compliance

4.1.1 Method

A two-year follow-up study was undertaken from 2009-2010 to evaluate the impact of Method 2 on traceability procedures. Information regarding blood transfusions was gathered and reviewed after every transfusion episode and the subsequent
discharge of the patient. Data was extracted from the blood transfusion information system and included the destination of all blood sent to the wards and all the blood units assumed to have been transfused (included missing tags and destroyed labels). Traceability compliance was calculated as the number of units successfully traced as a percentage of all units issued from the blood fridge.

All wards using blood products in 2009-2010 were included in this study. Participation was voluntary. All wards that carried out more than two transfusion episodes per week were included in the study, other wards were excluded. The data for each ward was extracted from the blood transfusion laboratory information system on a monthly basis.

The data extracted consisted of the total number of units where the final destination could be traced (T), minus those assumed to have been used (U), divided by the total of number of blood units issued (I). I implemented a database to record all the units transfused and calculated the percentage compliance using SPSS (SPSS, 2010) software.

Descriptive statistics was used to answer the research question to determine the mean and standard deviation of the annual compliance rate for each ward and visually illustrating data using graphs. The variance analysis was used to investigate the predictors of compliance at user group level (i.e. low, medium and high usage groups) and the one-sample t-test compares the mean score of method 1 and method 2 average compliance.

4.1.2 Results

Over all wards and both years the mean compliance rose to 91% (standard deviation 8.7%); although in 2010 there was a sharp increase in compliance (from 82–100%).
Table 4-1 Average ward compliance 2009–2010.

| Ward       | Blood units transfused 2009-2010 | Average compliance 2009-2010 (%) |
|------------|----------------------------------|----------------------------------|
| Adult R    | 138                              | 55                               |
| St Jose    | 224                              | 82                               |
| Cox        | 188                              | 86                               |
| Halley     | 712                              | 86                               |
| Turpin     | 163                              | 88                               |
| Theatre    | 505                              | 90                               |
| Templar    | 295                              | 90                               |
| Deliver    | 870                              | 91                               |
| Mau        | 196                              | 91                               |
| CCU        | 137                              | 92                               |
| Lloyd      | 646                              | 92                               |
| Acute C    | 1358                             | 93                               |
| Day Sta    | 197                              | 93                               |
| Defoe      | 148                              | 94                               |
| Priestly   | 503                              | 94                               |
| AE         | 1409                             | 95                               |
| Edith      | 666                              | 95                               |
| Thomas     | 321                              | 95                               |
| Intensive  | 963                              | 96                               |
| Lamb       | 264                              | 96                               |
| Aske       | 282                              | 97                               |
| Medical    | 2650                             | 97                               |
| SCBU       | 2273                             | 98                               |
| Haematology| 292                              | 100                              |
Table 4-2 Percentage compliance 2009–10.

| Year | Percentage compliance n = 24 | Standard deviation |
|------|-----------------------------|--------------------|
| 2009 | 82.0                        | (17.2)             |
| 2010 | 100.0                       | (0.0)              |

A one sample t-test was carried out to compare the two methods. These results showed that overall compliance rates improved with the introduction of the new traceability method (see The mean compliance for Method 1 was 65% with a 95% confidence interval (54.1–70.7; standard deviation 11.7%) while for Method 2 it was 91% also with a 95% confidence interval (86.9–93.3; standard deviation 8.7%).

![Figure 4.2 Comparison of ward traceability compliance using Methods 1 and 2](image)
Figure 4.3 shows 2012/13 the average traceability compliance within the Trust
Variance analysis showed that there was no significant difference in the compliance means of the low, medium and high usage groups during the period (F = 0.70; p = 0.51) and this relationship was maintained each year.

4.2 Further interventions to improve compliance

Two further interventions were made to improve traceability compliance. These were the appointment of a Medical Laboratory Assistant (MLA) and the implementation of medical records follow-up procedures.

4.2.1 Medical Laboratory Assistant

A business case was approved by the hospital management early in January 2009 to employ a member of staff to follow up missing labels, track patients and collect information on every blood unit transfused in the Trust on a daily basis. The
employment of the MLA also had a positive impact; traceability compliance improved to 91%.

4.2.2 Medical/electronic processing records

A small audit was conducted in 2010 to identify what had happened to labels that went missing following transfusions, which could not be accounted for by ward staff. The audit involved a sample of 20 missing labels.

I requested the patient’s medical notes to confirm the final destination of the transfused product. This required a day's notice to receive the notes from the medical records department and took an average of 45 minutes per note to find the information required. Transfusion information for all 20 missing labels was identified in the patient’s notes and this finding formed the basis for a discussion with the Trust’s management about the appointment of additional staff. The Trust approved the appointment of an additional MLA in 2010 in support of the aim to achieve full compliance. The role of this MLA was to monitor all instances of unreturned blood labels. Subsequently, unreturned labels or missing blood labels were followed up by requesting the patient notes from the Trust’s medical records department, and checking the wards and operating theatres for disposed labels.

4.2.3 Transfusion nurse specialist

The training of staff involved in the transfusion chain was the responsibility of a part-time specialist transfusion nurse. The Trust management also agreed to convert this post to a full-time post.

4.3 Discussion

Although between 2005-08 traceability compliance improved in some areas of the Trust, it remained only fair in other wards. I had hoped that the clinical units where compliance was poor would be visited daily but this was not achievable due to staff shortages. In 2009-10, major changes were introduced following discussion with the Trust’s Chief Executive at a monthly Hospital Transfusion meeting. The air tube system designed for sending samples from Accident and Emergency and operating theatres was extended to all wards within the Trust; this was followed by approval for a full-time Medical Laboratory Assistant and a full-time Transfusion Practitioner.
Shulman, Saxena and Ramer (1999, p.595) highlighted that the main elements of a quality approach for preventing identification errors include having a transfusion safety officer, regular training, competent staff, system re-engineering and standard operating procedures. Similarly, Doughty and Hitchinson (2010) identified the factors associated with good levels of compliance as the appointment of a hospital transfusion practitioner, electronic prescribing, having a medical laboratory assistant in clinical units, timely feedback and reinforcing success. In the light of these studies there are ongoing initiatives in the Trust to develop better testing and assessment of competency for both clinical and laboratory staff. The major changes made within the traceability procedure had improved our compliance to 100% as shown in fig. 4.3.

SHOT report (2011) pointed out that continued errors in the basic transfusion process were disappointing given the various national initiatives and standards introduced in the past ten years. They highlighted communication failures between clinical and laboratory staff, and sharing care between hospitals or between hospitals and the community as ongoing problems. In the project, good communication helped to demonstrate that the new system had helped to solve the issue of non-compliance.

Simple, innovative methods were developed to alert staff in the transfusion chain. A barcode label was created to simplify data input into the hospital’s information system and minimise errors. This was attached to every blood product issued.

4.4 Change management

This project attempted to ensure the rapid adoption of traceability compliance by wards in the Trust and improve the attitude of stakeholders to patient safety. A major challenge of the project was to instigate a change in staff behaviour, encourage them to move away from ritualistic practice and demonstrate that change can be a good thing. It was difficult to introduce change in such a complex setting and I encountered difficulties in breaking old habits.

Change management has been an integral part of organisational theory and practice for a long time. Indeed, some suggest that the future survival of all organisations will depend on their ability to successfully manage change (Burnes,
1996; Peters, 1989; Toeffler, 1983). Organisational change is usually required when there are changes in the environment in which an organisation operates. However, it can be also be brought about by environmental factors such as political, economic, sociological and technological variables (Jury, 1997, p.27). It was anticipated during the design of this study that managing change will not be a problem. Consequently, there was resistance from senior clinicians within the Trust and complaints from the wards. In my role as a BMS I had to change the approach of frontline staff and explain our intentions in plain language. The study also assisted getting through to core staff within the Trust to explain the changes that need to be met.

Orlikowski and Hoffman (1997, pp.11–21) proposed an improvisational model for managing technological change. The model is based on the assumption that technological changes constitute an ongoing process and that changes associated with an ongoing process cannot be anticipated in advance.

Evans (2000) highlighted that in the twenty-first century change leadership is not simple. He sees modern leadership as a balance between a track record of success and the ability to admit mistakes and handle failure well. He argues that leaders need to balance their efforts across three dimensions of organisational change, namely:

- **Outcomes**: Developing and delivering outcomes.
- **Interests**: Mobilizing influences, authority and power.
- **Emotions**: Enabling people and organizational culture to adapt.

### 4.4.1 Psychodynamic approaches to change

#### 4.4.1.1 The Kubler-Ross model

The idea that human go through a psychological process during change was first introduced by Kubler-Ross (1969). The word 'psychodynamic' is used to express the idea that when facing change in the external world an individual can experience a variety of internal psychological states. Kubler-Ross noted that patients would typically go through five stages as they came to terms with their prognosis.
People faced with a potential change do not actually take it in, but become emotionally numb and have a sense of disbelief. In a sense they shut down and avoid thinking about the news. In the Trust, the clinical staff felt that additional tasks had been added to their workload and became resistant to further information. When people allow themselves to acknowledge what has happened, they enter a stage of anger and begin to ask themselves, why me? They focussed their anger and frustration externally. Anger is a way of displacing real feelings to a situation. Within the Trust labels were misplaced and discarded.

When they have exhausted themselves by attacking others or themselves, people still try to wrest back some control of the situation or their fate. Kubler-Ross identified bargaining as the next stage. The person desperately looks for something to remedy the situation. In the Trust, it was made mandatory to account for all transfused labels; a clinical incident was raised whenever a label was not returned.

Staff become depressed when it becomes clear that no amount of bargaining is going to provide an escape route from the situation, Kubler-Ross observed that many people move out of depression into a fifth stage of acceptance. Within the Trust, clinical incidents raised were investigated and corrective action was initiated.
4.4.1.2 The Satir model

Satir et al. (1991) observed individuals and families experiencing a wide range of changes. The model not only has a number of stages but also highlights two key events that disturb or move an individual. These are the ‘foreign element’ and the ‘transforming idea’. The study describes the initial stage as the status quo. This changes when something new enters the system. Satir calls this a ‘foreign element’ in the sense that a factor previously not present is introduced. A period of chaos ensues. While the external world continues to function the individual’s internal world is turned upside down. During the period of chaos, we see elements of anger and disorganisation permeating the individual world. Feeling of dread, panic and despair are followed by periods of apathy and a sense of pointlessness.

However, the integration of new air tube system within the Trust brought in a bit of ease to the staff on the wards and visits by the MLA to the wards was another assurance that we are introducing innovation to ease the workload in the clinical areas of the Trust. Satir et al. (1991) concluded that once the transforming idea has taken root, the individual can begin the journey of integration. This period of integration requires the new world order to be assimilated into the individual’s own world. As time goes on, the new structure is bedded into the organisation, roles and responsibilities are clarified, new objectives and ways of working are specified and results are achieved. A new status quo is born.

4.4.1.3 Force field analysis

Kurt Lewin (1951) developed the idea of organisational change. Lewin introduced the idea of force field analysis, which examines the driving and resisting forces in any change situation (Figure 4.6). The underlying principle is that driving forces must exceed resisting forces if change is to happen.
Figure 4.6 Lewin's force field analysis applied to the Trust

Lewin suggested that the organisational change occurs in three stages; the first stage is ‘unfreezing’ the current state of affairs. This involves defining the current stage, highlighting the driving forces and the resisting forces and identifying the desired outcome. The second stage is the move to a new state through participation and involvement. The third stage is refreezing and stabilizing the new state of affairs by setting policy, rewarding success and establishing new standards. Driving forces formed the focus of the implementation phase, and I did not foresee any additional resisting forces. However, resistance did come from clinical areas of the Trust, and it had a negative impact on the Trust's average compliance in 2008. Figure 4.6 highlights resisting forces such as staffing issues, lack of funding and poor compliance. Frontline clinical staff members were not comfortable with the approach. Some senior staff opted out of blood transfusion activities due to their inability to comply with basic instructions, while most staff members asked for improvements to the methodology.

4.4.2 Justification for change

Despite dramatic improvements in blood safety and the low risk of viral transmission, infection and mistransfusion are still major concerns. The Blood Safety and Quality Regulations (2005) were the key driving force for implementing change. These regulations require full traceability of blood and blood components from the point of receipt by the hospital. Additionally, the final destination of all
components should be retained in a readily available and recoverable format for thirty years.

4.4.3 Funding and training

It is important to note that funding was a concern. Hiring additional staff to help to achieve compliance with the new regulations was a challenge for the Trust. The potential benefits of electronic tracking systems will be explored when funding becomes available and a cost-benefit analysis will have to be carried out.

An in-house training session was developed for all staff involved in the transfusion process and it is now a mandatory requirement that only trained staff members can collect and administer blood products.

4.5 Clinical implications

This study has shown that several aspects of blood product traceability require more rigorous research. For example, there are few studies that have looked at traceability procedures after a blood product leaves the blood fridge. The impact of temperature and electromagnetic radiation on blood products has not been fully investigated and bacteria contamination has only been investigated. Few studies have examined how blood products were traced offsite or when patients are in transit or at home.
5 Application to practice

To reiterate briefly, the aims of the project were to explore reasons why traceability compliance was poor within the Trust and identify why compliance varied between wards. The key objectives were:

- To assess traceability compliance for blood products in all wards of the Trust and identify the processes that led to poor compliance.
- To select an appropriate traceability model and labelling procedure for blood products.

The results of the study showed that blood transfusion is a complex chain that involves many stages. Some key variables were identified that had immediate financial and business benefits i.e. there was a drop in wastage of blood within the Trust, staff communication with transfusion department improved, more staff phoned the department and were willing to get involved in the training and assessment programme.

It also showed that training varied between wards and few wards were equipped with a trainer. In fact, the majority of ward staff only had a formal introduction to blood transfusion during their induction when they were first employed by the Trust. Consequently, ward staff were not sure how to return transfusion labels to the laboratory. Wards that carried out a large number of transfusions were more compliant that wards that only did them occasionally.

The study also showed that traceability processes vary from Trust to Trust and the most Trusts anticipated that they would request tenders for an electronic tracker system in the future.

The study’s objectives were as follows:

To examine the transferability of this evaluation and reflect on the impact on practice.
5.1 Evidence of achievements

As a result of the project, the following objectives were met.

Objective 1.

To undertake a six year cohort study to identify the risk factors of traceability compliance for blood products within all wards of the Homerton University Hospital NHS Trust and identify the processes that lead to poor compliance.

- **Specialist transfusion nurse**: It was evident from my report that, the wards with a trainer had better traceability compliance. The report of my findings was sent to the Hospital Transfusion Committee, which agreed that we could submit a business case for a specialist transfusion nurse because the frontline staff lacked the skills in blood transfusion. It took a further three years to get funding but eventually the Trust approved full funding for the position.

- **Development of competency**: Following the appointment of the specialist transfusion nurse, a skills assessment was developed to be taken by all staff involved in the collection and administration of blood products. Although the proposal was not welcomed by clinicians it eventually became mandatory. Training has begun, but only 20% of staff members have been assessed.

- **Provision of clinical supervision**: There is now a system in place to support all staff involved in blood transfusion, day and night. Academic training has been provided to improve practice. The training is cascaded by the specialist transfusion nurse and credits are awarded to participants to promote professional development.

Objective 2

To select an appropriate traceability model and labelling procedure for blood products within the Homerton University Hospital NHS Trust.

The Trust Chief Executive approved funding for the extension of the air-tube system to the various wards within the Trust. The evidence gathered from the auditing of patient’s note resulted to the submission of a business case which
eventually led to the appointment of an MLA. This had impact on practice by improving the return rate of labels from 90% to 100% and also investigating what had happened to blood units with missing labels.

- **Air tube system**: This was ordered by the pathology manager to improve the turnaround time of samples sent from the various wards. Ward managers were asked to use this traceability system to return labels to the transfusion laboratory as soon as the transfusion was completed.

- **Redesign of information technology**: Transfusion labels and forms were redesigned to include the date, time and signature of the staff member that checked the product at the bedside before the transfusion began. Currently there are two different systems in place which do not comply with the requirement for full traceability of blood products.

**Objective 3**

To assess the impact on traceability compliance at the Trust.

- **Annual skills check**: it has become mandatory for all staff to be re-assessed annually to prove that they are fit to practice. In the event of non-compliance they are re-trained and assessed before being allowed to collect or administer blood products.

- **Development of clinical guidelines**: The Trust intranet has been updated to cover aspects of Blood Safety and Quality Regulations and provide links to examples of good practice, quality improvement and information about clinical audits on blood transfusion topics, monthly feedback of traceability compliance.

**Objective 4**

To evaluate the cost effectiveness of the traceability model.

The cost effectiveness of the traceability model was not fully met in this study but the direct cost savings in wastage was evaluated in this study. I make total of £67,790 saving over a 6 year period see Table 5-1.
The following sections provide an overview of the implementation of these recommendations, although it is not possible to provide complete details of the planning, development and implementation of each initiative.

5.1.1 Specialist transfusion nurse

The study demonstrated that the role of a specialist transfusion nurse is crucial in the delivery of an effective service. Results showed that wards with a trainer had better traceability compliance than wards with no trainers. It was also clear that supervision and training from a practitioner with skills in transfusion was an essential requirement. The final outcome of the research was initiatives designed to meet the need identified by the study. In particular:

- Teach and support frontline staff throughout their induction and while working on the wards.
- Offer information and support to frontline staff on a daily basis.
- Promote a range of continuous professional development options for staff responsible for the collection and administration of blood and its products.
- Assist staff in their training and become more proactive in identifying their learning needs.
- Promote and offer clinical supervision for the collection and transfusion of blood products.
- Liaise with transfusion laboratory scientific staff on clinical staff learning.
- Plan, teach and support practice nurses throughout their induction training programme.

This finding enabled the development of a tool for all frontline staff to encourage them to maintain a personal development plan. This initiative was in keeping with the requirement of the General Medical Services contract (Department of Health, 2003). It also provided supporting evidence for progression through the knowledge and skills framework along within the Agenda for Change implementation (Department of Health, 2004).

5.1.2 Skills assessment

In response to concerns from the National Patient Safety Agency, the clinical governance committee suggested a training programme and competency
assessment designed to meet personal and professional accountability requirements. This initiative prompted the development of an in-house weekly training programme followed by a competency assessment. This new initiative enabled frontline staff involved in the collection and administration of blood to understand the issues, share their concerns and challenge evidence, which led to improvements in the services provided by the Trust. In addition, a forum was organised to improve awareness of blood transfusion services within the Trust.

5.1.3 Redesign of information technology

It was apparent that frontline staff involved in the transfusion chain lacked the skills to handle evidence-based information. The hospital intranet was updated with more information on transfusion services and hand-outs were made available. Nurses were encouraged to enter all records of transfusion procedures into the information system for accurate traceability.

5.1.4 Medical laboratory assistant (MLA)

The data obtained from this research revealed that there were various methods for returning transfusion labels to the department. It was evident that although some labels were left on the wards and others were found in the disposal bin the majority were sent through the air-tube system. The appointment of an MLA had impact on practice by improving the return rate of labels and also investigating what had happened to blood units with missing labels. The appointment of an MLA met the need highlighted in the study by:

- Improving traceability of labels after the completion of the transfusion.
- Encouraging frontline staff to call the laboratory when labels were misplaced or destroyed.
- Identifying areas of poor traceability compliance within the Trust as a stimulus for more training.
- Minimising potential problems in the surgical setting where there was previously low compliance.
5.1.5 Air tube system

The air tube system installed at the Trust alleviated the pressure of returning the labels from transfused products to the laboratory promptly. The system has also changed and improved the rate of return to the pathology laboratory. The return of the labels enables the transfusion department to track the destination of the unit and update the system within 4-8 hours following the transfusion. Annual skills check

Clinical governance introduced systems for continuing professional development (Department of Health, 1997). These systems are monitored and linked to registration, peer assessment, evidence-based standards of care and individual appraisal (Barr, 2000, p.81). Clinical governance is concerned with the ways in which the National Health Service can improve and maintain the quality of care and services provided for patients (Scally & Donaldson, 1998, p.61). National Occupation Standards were developed to raise the standard of practice in a given sector and providing a benchmark against which the performance of both the individual and the organization could be assessed and measured. These standards provide a systematic approach to the establishment of good practice, supported by a clear framework of underpinning knowledge, standards and expected outcomes (National Institute for Mental Health in England, 2003, p.3, 5).

5.2 Cost-benefit analysis

There has been a drop in annual blood wastage within the Trust from 290 units in 2006 to 100 units in 2011. The benefit of these savings amounted to £67,790 over the five year period within the Trust. The cost of for the full implementation was not evaluated in this study. The average cost of a full tracking system in a medium size hospital was valued at £350,000 excluding training and staffing during our lunch time presentation by vendors. The main area of cost impact were the appointment of a transfusion practitioner, a medical laboratory assistant and installation of the air-tube system within Trust. Porters were not needed to carry out deliveries, the
reduction in manpower was also a big savings to the Trust and there was an improved of turnaround times in labels deliveries.

Table 5-1 Reduction in red blood cell wastage 2006-2011

| Month     | 2011 | 2010 | 2009 | 2008 | 2007 | 2006 |
|-----------|------|------|------|------|------|------|
| January   | 5    | 9    | 24   | 12   | 10   | 28   |
| February  | 4    | 5    | 9    | 15   | 31   | 7    |
| March     | 4    | 4    | 10   | 18   | 5    | 39   |
| April     | 8    | 11   | 30   | 11   | 7    | 6    |
| May       | 6    | 6    | 9    | 5    | 4    | 11   |
| June      | 8    | 10   | 18   | 7    | 25   | 10   |
| July      | 12   | 8    | 32   | 10   | 15   | 9    |
| August    | 6    | 15   | 15   | 30   | 15   | 55   |
| September | 10   | 18   | 14   | 10   | 13   | 8    |
| October   | 20   | 39   | 22   | 40   | 5    | 20   |
| November  | 13   | 17   | 12   | 22   | 25   | 10   |
| December  | 4    | 5    | 24   | 20   | 110  | 6    |
| **Total** | 100  | 147  | 215  | 200  | 265  | 290  |
| **Cost**  | £13,000 | £19,110 | £27,950 | £26,000 | £34,450 | £37,700 |

5.3 Email questionnaire

The duration of the project prompted a follow-up questionnaire to identify any gaps and capture the current trends in traceability compliance. An email-based survey was chosen to reduce the time and resources involved in individual interviews and to eliminate travel requirements.

5.3.1 Method

Participants were purposively selected from NHS Trust hospitals in the North East of London. The twenty respondents were blood bank managers. Participants were asked closed questions on individual Trust traceability compliance. The responses to the various questions were coded. As before, data was entered into a spreadsheet and analysed using SPSS software (SPSS, 2010). The data generated was coded to enable a numerical analysis. The data was not normally distributed,
Table 5-2 Demographics of the NHS Trusts surveyed.

|                                | Frequency (n=20) | %   |
|--------------------------------|------------------|-----|
| **Bed capacity**               |                  |     |
| 1–500                          | 6                | (30) |
| 501–1,000                      | 13               | (65) |
| > 1,000                        | 1                | (5)  |
| **Trusts with satellite fridges** |                  |     |
| Yes                            | 16               | (80) |
| No                             | 4                | (20) |
| **Transferring blood to other sites** |            |     |
| Yes                            | 16               | (80) |
| No                             | 4                | (20) |
| **Tracking system in place**   |                  |     |
| Paper tracking                 | 14               | (80) |
| Electronic tracking            | 6                | (20) |
| **Cost of tracking system in place** |            |     |
| Medical laboratory assistant   | 13               | (65) |
| Not known                      | 7                | (35) |
| **Hospital staff trained in the collection of blood** | | |
| 0–25%                          | 1                | (5)  |
| 26–50%                         | 6                | (30) |
| 51–75%                         | 2                | (10) |
| 76–100%                        | 11               | (55) |
| **Red cell units transfused in the last 12 months** | | |
| > 5,000                        | 16               | (80) |
| < 5,000                        | 3                | (15) |
| Unknown                        | 1                | (5)  |
| **Average traceability compliance** |                |     |
| < 75%                          | 1                | (5)  |
| > 75%                          | 19               | (95) |
| **User feedback mechanism**    |                  |     |
| Yes                            | 15               | (75) |
| No                             | 5                | (25) |
| **Audit of the transfusion process** |                |     |
| Yes                            | 16               | (80) |
| No                             | 4                | (20) |
5.3.2 Results

Table 5-2 showed that out of 30 emails sent to blood bank managers, 20 responses (66%) were acknowledged. The results obtained were similar to my previous study on page 71. There was a positive correlation between transfusion and traceability compliance ($r = 0.59; p = 0.01$) and training but with no significant difference ($r = 0.30; p = 0.38$).

5.4 Summary

The findings from the study reiterated that the importance of continuous professional development and skills assessments cannot be overemphasized, effective training at ward level improved traceability compliance.

The findings from this study also reiterated the importance of a trained specialist transfusion nurse who can provide support and training to frontline personnel involved in the collection and transfusion of blood products. Their role is also to ensure that training and the delivery of healthcare meet acceptable standards. The research highlighted the importance of training and continuing professional development. Wards where there are trainers provide a higher standard of care than wards without a trainer.

I also found out that wards that carried out many transfusions performed better than those that only carried out a few. This information enabled enhanced training to be provided in the poorly performing units.

The project provided an insight into the variety of services delivered to the end-users of transfusion services. It highlighted a lack of training tools; poor procedures for the return of labels and the unreliability of porters. Poor communication between the laboratory and end-users was identified as another issue. The response to these problems led to the innovative use of the air tube system and greater incident reporting at every stage of the transfusion process.

The initial survey provided a baseline from the problems that can be encountered at the blood collection point and in the bedside checking procedure. The issues that were identified included incomplete documentation brought to the blood collection point and untrained personnel collecting blood products at the blood collection
The problem of blood product collection was addressed by providing security locks on the blood fridges to deter untrained staff collecting blood products. In greater number of cases this had been effective. It has become mandatory that two nurses must check blood products administered on the wards.

It became evident that traceability compliance varied from one Trust to the other and various strategies were being deployed to attain full compliance. Technology has been introduced by many Trusts, but in this case there was neither the time nor the money to investigate it fully. This may not be so much of a problem; the study by Murphy et al. (2004) observed that most tracking systems could be overridden and concluded that such systems could only assist in reducing errors. Arinsburg et al. (2011) also concluded from their study that additional training in transfusion medicine would be beneficial by physicians in all specialities. This was based on their findings from the survey conducted which demonstrated lack of knowledge of transfusion medicine across all specialities and all training levels.

It was also evident that previous studies had only focused on blood product traceability and not on the direct or indirect variables that affected traceability e.g. ward size, transfusion times, training, traceability methods, transfusion volume, emergency situations, training and errors in the transfusion chain. The full impact of traceability will only become clear when more rigorous, large-scale studies are conducted that take into consideration all possible variables.
6 Reflection

My enrolment onto the professional doctorate has been an attempt to advance the scope of my practice and become a competent professional. I have found the professional doctorate to be both challenging and rewarding. The course has improved how I think about different situations and how I function as an advanced practitioner.

According to Honey and Munford (1992) I was exposed to new experiences compared to my prior learning. The professional doctorate influenced me to adopt a new learning style as an activist and a reflective thinker. Active learning engages students in class activities was encouraged and cooperative learning (working in small group teams under conditions that hold all team members accountable for the learning objective associated with the assignment (Felder and Brent, 2003, pp.282-283).

The curriculum was well-structured and related to my employment. There were opportunities to ask questions and read extensively in order to confirm any unclear evidence which I have missed during my previous learning.

Berhold et al. (2000, p.191) described two groups of students, one taught in a circle and the other taught with tradition methods. The course grade of the two groups were compared and indicated that the traditionally taught students were more likely to get lower grades than the students taught in a circle. They concluded that holistic instruction may help a more diverse group to succeed. According to Kolb (1993, pp.3-4), learning begins with a concrete experience; the effect is reflective observation, documenting what happened and making sense, then investigating or theorizing. This allows conclusions to be drawn and plans to be made in order to take further action based on the experience.

Felder and Brent (2004, p.269) proposed five instructional conditions that provide a balance of challenge and need to promote intellectual growth:

- Variety and choice of learning tasks.
- Explicit communication and explanation of expectation.
- Modelling, practice and constructive feedback.
A centred instructional environment.
- Aware of current levels of development.

![Kolb's Learning Cycle](image)

**Figure 6-1 Kolb’s learning cycle, adapted from Kolb and Fry, 1975**

Kolb and Fry (1975, pp.35-36) argued that the learning cycle can begin at any of the four points and should be approached as a continuous spiral. In this context, I was able to reflect on my previous employment about wastage of resources within the transfusion department.

Bloom (1956, p.6) ranked learning into categories of knowledge e.g. ability to recall from memory to the most sophisticated and complex evaluations of making critical judgement. It is clear to me that the learning methods employed within the professional doctorate were designed to guide me to an advance stage of acquiring and understanding. The theoretical application in the real world encouraged me to decide on an issue and make critical judgments when planning to undertake any research for the department. This process also reinforces the importance of Kolb learning cycle.

The professional doctorate at the University of Portsmouth comprises two parts. Part one was the taught element that covered professional review and development, advance research techniques and publication and dissemination. Part two consisted of the project proposal and the research thesis.
I was motivated throughout the course to learn new skills in research methodology, which I have overlooked in the past. The qualitative analysis was a challenge that was completely new to me, which I later found useful. It became obvious that I needed to focus more to understand this aspect. Aspects were the publication and dissemination module, and research and development that I found more relevant in. I have put this process into practice in decision-making as well as the modification of the training programme for Biomedical Scientist undertaking professional portfolio examination in Biomedical Sciences.

Part two of the course entailed completing an innovative research project that can also help in providing data in support of evidence-based information in blood transfusion.

I was excited to start this thesis that aimed to implement and evaluate blood product traceability procedures at the Homerton University Hospital NHS Trust. In the initial stages, it was clear that coordination was a problem because of a lack of funding to implement a tracking system and the lack of support from management. Most of the activities aimed at achieving good traceability compliance were carried out behind closed doors and a lot of phone calls were made in order to follow up on poor compliance within the Trust. This meant that there was a heavy workload for myself and junior staff in the department and a steep learning curve. The project entailed big changes within the Trust which I overlooked in the early stages. While not stopping to think before taking action can produce spectacular results, I can recall that on many occasions I made things worse by blaming frontline staff and raising incident reports. Although this is normal procedure it did not resolve the problem of poor compliance. This happened because I failed to stop and think before trying to changes things. Later, I realised that I had to take a broader, educational approach to deal with the situation and frontline staff.

The visit by the Medicines and Healthcare products Regulatory Agency (MHRA) at an early stage of my project resulted in a change in direction concerning how traceability was perceived by frontline staff. The visit reinforced the importance of achieving full compliance, particularly as the Trust’s management including the Chief Executive were present to hear the MHRA’s summary of the inspection. This showed that traceability compliance was poor and that there were no structures in
place or indications that the Trust was addressing the situation. This gave my work fresh impetus and management then took a lot of interest in my area of study.

I realised that I must take time to review the situation and consider theoretical aspects prior to commencing any work. I was aware of the risk that I might lose focus when working on such a large project, but I have a good record of bringing tasks to completion. I believe that I have achieved success when I have unconsciously taken the approach of breaking the task down into smaller bits, and approaching the problem logically. I now appreciate that this approach includes reflection as it creates natural breaks where I have been able to reflect upon what has been done and plan what remains to be done; this has contributed to my success.

The Trust’s Chief Executive became involved when a message was sent to all staff members saying that the collection, handling and usage of blood products was an area of great concern. I realised at this stage that a few senior clinicians had opted out, but the majority of frontline staff members were happy to be trained and assessed.

In 2008, I was nominated by my professional body, the IBMS, and became an assessor for Specialist Portfolios in Haematology and Blood Transfusion. This means that I must provide reports against pre-defined standards, and made me pay further attention to quality issues in blood transfusion; I compared information from visits and developed a framework for my thesis as the study progressed.

Although my project has finally ended, the importance of clinical and non-clinical personnel in the transfusion chain cannot be overemphasized. It was difficult to coordinate and pass instructions to frontline staff at every stage of the study. These issues were eventually overcome by asking the transfusion practitioner to feedback any problems as soon as they occurred. During the project, it was necessary for me to encourage open thinking.

I do feel that I have benefited from the course, even though it took me a while to prepare the research proposal. The principles underpinning the whole study were learnt throughout the course. I feel now that I can conduct and develop a research method using the advanced research skills and the professional knowledge that I
have in my specialist area. I also fully understand the skills necessary to publish rigorous clinical research.

I spent the early part of the course to learning critical reflection practices and putting these into practice by reflecting on my own needs and learning styles. This also helped in all the modules of the professional doctorate and find ways to better understand what I was learning. The idea for my professional doctorate was initially conceived through my reflective practices and I decided to write few publications on these areas in my professional journal, the IBMS gazette.

I have taken the technique of reflection back to my clinical practice in order to evaluate all the procedures we follow. My colleagues knew there would have to be changes within the section. We set aside time for to investigate and reflect upon incidents. We developed a habit of responding as fast as possible to incidents and enquiries and since I started the professional doctorate the service within the Trust has changed.

The research has been daunting. It has required me to rally a multidisciplinary task force within the Trust for data collection and analysis. I had to get the complete support of staff and the Trust for the study to succeed.

I found the data analysis very difficult, but interesting. It required coding and rechecking for missing figures. The module I took on data analysis using SPSS was useful and this was followed by months of writing up. I would like to commend the patience of staff members; although many had little time, they listened and participated in the study.

The literature review during the study, highlighted incidents in the early days of blood and the advancement in blood, problems with blood safety, innovation achieved in the collection, testing, distribution and traceability of blood products. The human error in the handling and the use of blood and its products remains a challenge in the 21st century. My thesis, identified that there was lack of knowledge and training of personnel in the handling and the use of blood within the Trust which led to.
6.1 Developing the extending role

Achieving traceability compliance within the Trust had been a painful and complex process. I had to engage with all staff in the Trust in order to highlight the importance of full traceability. The Trust management were very helpful in providing their time and expertise. That the project has succeeded clearly demonstrates that biomedical scientists can interact with other Trust professionals and extend their role beyond the laboratory using their knowledge to provide diverse health service models.

6.2 Future goals

The professional doctorate considerably contributed to my self-development and management skills. I am confident in discussing research with my colleagues. My role as the transfusion lead has led to increased exposure at a more senior level allowing further development of my career.

My goal is to use my rich experience in clinical research to teach, and develop protocols and guidelines within the profession. Specifically, to influence practice through meetings, special interest group and disseminating information. I am also keenly looking forward to helping others to develop and maximize their skills in laboratory medicine. The achievement of the doctorate will help me to progress towards the post of consultant biomedical scientist.

6.3 Dissemination

A requirement of the doctorate is to ensure dissemination of the data and the outcome of the project; this has been achieved through various means both locally and nationally.

Locally, I made audits presentations at lunchtime meetings to health personnel in the Trust. Information was disseminated to wards with poor compliance levels in writing during the implementation stages. Furthermore, I developed feedback on the clinical effectiveness of the model, this was needed in order to assess its success and determine any modifications required to improve full traceability compliance.
Nationally, the findings of the project and the implementation of new compliance measures have been disseminated through poster presentations and lectures at meetings, including the Biomedical Sciences Congress (2011) in Birmingham and the British Blood Transfusion Conference (2012) in Harrogate. A poster presentation was also given at the American Medical Technology International Conference (2011) in the United States.

The major learning outcome from the dissemination of my work was the ability to communicate information in a clear and precise manner, particularly the ability to communicate with the audience during poster presentations and hear their feedback.
References

Abdulrazzak, R., Al-Muharib, S., Dashty, R. et al. (2009). Traceability of red cells components. A two stage audit on the accuracy of traceability records in Kuwait Central Blood Bank and two small hospitals blood banks. Vox Sanguinis, 96, 208.

Aller, R. (2005). Positive patient identification: more than a double check. CAP today, 26–34.

Andreu, G., Morel, P. and Forestier, F. (2002). Haemovigilance Network in France. Transfusion, 42: 1356-1364.

Arinsburgh, S., Skerrett, D., Friedman, M., Cushing, M. (2012). A survey to assess transfusion medicine education needs for clinicians, Transfusion Medicine, 22:44-51.

Asamoah, A. (2006). Not as easy as it appears: Using radiofrequency identification technology. Food Drug Law Journal, 2, 385–418.

Ashbourn, J. (2004). Where we really are with biometrics. Biometric Technology Today, 12(4), 7–9.

Ashford, P. (2006). ISBT 128 – improving security by international standardization. ISBT Science Series, 1(1), 242–245.

Askeland, R. W., McGrane, S., Levitt, J. S., Dane, S. K., Greene, D. L., Vandeberg, J. A., Walker, K., ...Kemp, J. D. (2008). Improving transfusion safety: implementation of a comprehensive computerized bar code-based tracking system for detecting and preventing errors. Transfusion, 48 (7), 1308–17.

AuBuchon, J. (2006). How I minimise mistransfusion risk in my hospital. Transfusion, 46, 1085–1089.

AuBuchon, J. and Litternberg, B. (1996). A cost effectiveness analysis of the use of a mechanical barrier system to reduce the risk of mistransfusion. Transfusion, 36, 222–226.
Bachs, A., Aliu, G., Gmez, I., Orfila, R. and Mingo, T. (2009). Balance after implementing a new transfusion safety system: A 2 year experience. *Transfusion Medicine, 20*, 1295.

Baele, P., De Bruyere, M., Deney, V. and Dupont, E. (1994). Bedside transfusion errors. A prospective study by Belgium Sanguins group. *Vox Sanguinis, 66*, 119–121.

Baldwin, P. (2005). *Disease and Democracy. The Industrialised World Faces AIDS*. Berkeley.

Ballard, S. J., Liewelyn, C., Murphy, M. and Williamson, L. (2002). Tracing blood units to their recipients: results of a two-centre study. *Transfusion Medicine, 13*, 127–130.

Battle, J., Kaplan, H., Van der schaaf, T. and Shea, C. (1998). The attributes of medical events-reporting system for transfusion medicine. *Archives of Pathology & Laboratory Medicine, 122*, 231–238.

Barr, H. (2000) NHS new collaboration, New agenda for Education. *Journal of Interprofessional Care, 14* (1), 81–6.

Berhold, L., Bingham, W., McDonald, P. and Atta, M. (2000). Impact of Holistic and Learning-Oriented Teaching on Academic Success. *Journal of Engineering Education, 89*(2), 191–99.

Bennardello, F., Fidone, C., Cabibbo, S., Calabrese, S., ... Bonomo, P. (2009). Use of an identification system based on biometric data for patients requiring transfusion guarantees transfusion safety and traceability. *Blood Transfusion, 7*, 193–203.

Berwick, D. (1989). Continuous improvement as an ideal in health care. *New England Journal of Medicine, 32*, 53–56.

Blood Safety and Quality Regulations (2005). The Stationery Office Ltd, London.

Bloom, B. (1956). *Taxonomy of Education objectives*. New York: David Mckay and Co.
Burnes, B. (1996). *Managing Change: A Strategic Approach to Organisational Dynamics.*

Busch, M. (1991). Let's look at human immunodeficiency virus look-back before leaping into hepatitis C virus look-back. *Transfusion, 31,* 655.

Busch, M., Chamberland, M., Epstein, J., Kleinman, S., Khabbaz, R. and Nemo, G. (1999). Oversight and monitoring of blood safety in the United States. *Vox Sanguinis,* 77, 67–76.

Chaffe, B., Jones, J., Milkins, C., Taylor, C., Asher, D., Glencross, H., Murphy, M. and Cohen, H (2009). UK Transfusion Laboratory Collaborative Recommended minimum standard of hospital transfusion laboratories. *Transfusion Medicine,* 19, 156–158.

Chambers, R., Rubin, M., Rath, C., Sandler, S. and Ball, J. (1973). A positive donor recipient identification system for a regional blood transfusion service. *Transfusion,* 13, 34–6.

Chan, J., Chu, R., Young, B., Chan, F., Chow, C., Pang, W., Chan, C., Yeung S., Leung, P. (2004). Use of an electronic barcode system for patient identification during blood transfusion: 3 year experience in a regional hospital. *Hong Kong Medical Journal,* 10,166-71.

Classen, D., Stanley, M.D., Pestonik, S., Evans, R. and Burke, J. (1991). Computerized surveillance of adverse drug events in hospital patients. *JAMA,* 266, 2847–2851.

Cook, R., Wood, D. and Miller, C. (1998). A tale of two stories: contrasting views of patient safety. *US National Patient Safety Foundation, MA.* Retrieved from http://www.npsf.org/exec/front.html.

Council of Europe (2003). *Guide to the preparation use and quality assurance of blood component.* Recommendation No. R(95)15. Ninth Edition. Strasbourg.

Currie, L. (2003). Clinical Governance: An RCN resource guide. Retrieved from www.ntac.nhs.uk/web/files.
Curtain, L. (1997). When negligence becomes homicide. *Nursing Management*, 2, 7-8.

Dalton, J., Poncet, I., Rossini, S. (2005). "Using RFID technologies to reduce transfusion errors. Retrieved from http://www.cisco.com/global/IT/local_office/case_History/rfid_in_blood_transfusion_final.pdf

Davies, J., Kay, J., Casbard, A. and Murphy, M. (2006). End to end electronic control of the hospital transfusion process to increase the safety of blood transfusion: Strengths and weaknesses. *Transfusion*, 46, 352-364.

Davis, R., Geiger, B., Gutierrez, A., Heaser, J. and Veeramani, D. (2009). Tracking blood products in blood centres using radio frequency identification: a comprehensive assessment. *Vox Sanguinis*, 97, 50–60.

de Vries, P., Faber, C. and Strengers, W. (2011). Haemovigilance: an effective tool for improving transfusion. *Vox Sanguinis*, 100, 60–67.

Debeir, J., Noel, L., Aulien, J., Frette, C., Sar, F., Mai, M.P. and Cosson, A. (1999). The French Haemovigilance System. *Vox Sanguinis*, 2, 77–81.

Department of Health. (1997). The New NHS: modern, dependable. London: HMSO.

Department of Health (1998). *A first class service. Quality in the new NHS*. London: HMSO.

Department of Health (1998a). Better Blood Transfusion. Health Service Circular 1998/224.

Department of Health. (2003) Developing NHS Direct: a strategy document for the next three years. London: HMSO

Department of Health. (2004). Pathology Modernisation., London: HMSO

Dodd, R. (2006). Other emerging viral pathogens. *ISBT Science Series*, 1(1), 257–262.
Doughty, H. and Hitchinson, M. (2010). A tale of traceability. *Transfusion Medicine, 20*, 53.

Dzik, W. (2002). Transfusion safety in hospital. *Transfusion, 43*, 1190–1198.

Dzik, W. (2003) Emily Cooley Lecture 2002: transfusion safety in the hospital, *Transfusion, 43*, 1190–1199.

Dzik, W. (2005) *Technology for enhanced transfusion safety*. *American Society of Hematology, Education Program*, 476-82.

Dzik, W. (2006). New technology for transfusion safety. *British Journal of Hematology, 136*, 181-190.

Embrey, D. (1992). Quantitative and qualitative prediction of human error in safety assessment. *Institute of chemical Engineering*. Rugby.

Engelfriet, C. and Reesink, H. (2000). Bacterial contamination of blood components. *Vox Sanguinis, 78*, 59-67.

European Union Directive 2002/98/EC. Retrieved from http://www.europa.e.int.

Evans, P. (2000) Management 21st Century: Someday we will all manage this way. *Chowdbury Financial Times*. Prentice Hall, London.

Faber, J. (2002). Haemovigilance around the world. *Vox Sanguinis, 1*, 71-76.

Faber, J. (2004). The European Blood Directive: a new era of blood regulation has begun. *Transfusion Medicine, 14*, 257-273.

Fanberg, H. (2004). The RFID revolution. *Marketing Health Services*. Fall 24, 22-4.

Farrugia, A. (2006). Globalization and blood safety. *ISBT Science Series, 1*(1), 25-32.

Feldman, E. and Bayer, R. (1999). *Blood Feud: AIDS, Blood and the politics of Medical Disaster*. New York: Oxford University Press.
Felder, M. and Brent, R. (2003) Learning by doing. *Chemical Engineering Education, 37*(4) 282-3.

Felder, M. and Brent, R. (2004). The intellectual development of Sciences and Engineering Student. Models and Challenges. *Journal of Engineering Education, 93*(4), 279-91.

Fisher W.(2004) The role of WIPO in addressing the health crisis in developing countries. Retrieved from www.tacd.org/events/wipo/w_fisher.ppt.

Fisher W. (2004). *The role of WIPO in addressing the health crisis in developing countries*. Retrieved from http://www.tacd.org/events/wipo/w_fisher.ppt.

Gallo, R. and Montagnier, L. (2003). *The discovery of HIV as a case of AIDS, New England Journal of Medicine*, 349, 2283-2285.

Gambino, R. and Mallon, P. (1991). Near Misses: an untapped database to find root causes. *Lab report* 13, 41-44.

General Medical Council (2011). Good Medical Practise Framework for appraisal and revalidation, London. Retrieved from www.gmc-uk.org/doctors/revalidation/asp.

Glynn, S., Busch, M., Schreiber, G. and Murphy, E. (2003). Effect of a national disaster on blood supply and safety. *JAMA, 17*, 2246-2253.

Goodnough, L. and Spence, R. (2003). Bloodless medicine: clinical care without allogeneic blood transfusion. *Transfusion, 43*, 668-676.

Goldman, M., Long, A., Roy, G., Decary, F. and Delage, G. (1996). Incidence of bacterial cultures after donor call back. *Transfusion, 36* (11-12), 1035.

Hammadi, A. (2009). The haemovigilance in Saida hospital - A prospective study. *ISBT Science series*, 217.

Hay, S., Scanga, L. and Brecher, M.E. (2006). Life, death, and the risk of transfusion: A University hospital experience. *Transfusion, 46* (9), 1491-1493.

Health Professions Council (2004). HPC Standards of proficiency – Biomedical Scientist. Retrieved from: http://www.hpc-uk.org/publications/index.asp?id=40.
Health Protection Agency Report (2011). Surveillance of viral infection in donated blood (England and Wales). Annual report 2011.

Herve, P. (2002). Haemovigilance network in France: organisation and analysis of immediate transfusion incident report from 1994 to 1998. *Transfusion, 42*, 1356-1364.

Herve, P., Rebibo, M., More, P. and Andreu, G. (2000). Haemovigilance in France. *Rev Bras Hematol.Hemoter, 22*(3), 368-373.

Hollnagel, E. (1998). *Cognitive reliability and error analysis method*. Elsevier, Oxford.

Honey, P. and Munford, A. (1992). *The Manual of Learning Styles*. Ardingly House, Maidenhead: Peter Honey.

Hopkins, S. (2005). Advance in patient and specimen ID. *Advance New Magazine*, 2:13.

Ingrand, P., Salmi, R., Benz-Lemoine, E. and Dupuis, M. (1998). Evaluation of the actual traceability of labile blood products using medical records. *Transactions of Clinical Biology, 6*, 397-407.

Jury, G. (1997). Managing Technology. *Engineering Management Journal*, 7, 27-32.

Kaplan, H., Battles, J. and Van der Schaaf, T, Shea, C.E. and Mercer, S.Q. (1998). Identification and classification of the causes of events in blood transfusion medicine. *Transfusion, 38*, 1071-1081.

Kaplan, H. (2005). Getting the right blood to the right patient: The contribution of near miss events reporting and barrier analysis. *Transfusion Clinique et Biologique, 12*, 380-384.

Kennedy, I. (2001). *The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995*. 

114
Kimball, A., Arima, Y. and Hodges, J. (2005). Trade related infection: farther, faster, quieter. *Globalisation and Health, 1*, 1–6.

Kleinman, S. (1991). Donor screening procedures and their role in enhancing transfusion safety. *American Society of Clinical Pathologists*, p.207.

Kolb, D. and Fry, R. (1975). Toward an applied theory of experiential learning. In C.L. Cooper (ed.), *Theories of group processes* (33-57). Chichester: Wiley & Sons.

Kohn, L., Corrigan, J. and Donaldson, M. (1999). *To err is human: building a safer health system*. National Academy Press, Washington, DC.

Kolb, D. (1993). *The process of experiential learning. Culture and processes of adult learning*. London: Routledge.

Kreil, T., Berting, A., Kisnter, O. and Kindermann, J. (2003). West Nile virus and safety of plasma derivatives. *Transfusion, 438*, 1023–1028.

Kubler-Ross, E. (1969). *On Death and Dying*. Macmillan, New York.

Lau, F., Wong, R., Chui, C., Ng, E. and Cheng, G. (2000). Improvement in transfusion safety using a special design transfusion wristband. *Transfusion Medicine, 1*, 121-124.

Lewin, K. (1951). *Field Theory in Social Sciences*, Harper and Row, New York.

Linden, J., Wagner, K., Voytovich, A.E. and Sheehan, J. (2000). Transfusion errors in New York State: an analysis of 10 years' experience. *Transfusion, 40* (10), 1207–1213.

Ling, A. (2010). Failure of routine HIV test in a case involving transfusion of seroconversion blood components during the infection window period. *Journal of American Medical Association, 284*, 210-14.

Lovis, C. (2008). Traceability in Healthcare: Crossing Boundaries. *Yearbook of Medical Informatics 1998*, 105–113.
Marconi, M. and Sirchia, G. (2000). Increasing transfusion safety by reducing human error. Current Opinion in Haematology, 7, 382-386.

Mathur et al., (2006) Compliance of West of Scotland Bolld Centre Audit of Hospital Compliance with Traceability. Transfusion Medicine, 16:22

Mattar, M. (2004). Blood and you. Health and Science Alternative Medicine.

McClelland, B., McMenamin, J., Moore, M. and Barbara, J. (1996). Reducing risks in blood transfusion. Transfusion Medicine, 6(1), 1-10.

McClelland, B., Love, E., Scott, S., & Williamson, M.(1998). Haemovigilance: concept, Europe and UK initiative. Vox Sanguinis 74,431-439.

Mercuriali, E., Inghilleri, G., Colotti, M., Fare, M., Vinci, A., Podico, M. & Scalamogna, R. (1996). Bedside transfusion errors: Analysis of two years use of a system to monitor and prevent transfusion errors. Vox Sanguinis, 70, 16-20.

Mummert, E. and Tourault, M. (1993). Review of transfusion related fatalities: many preventable. Hospital Technology Scanner, 4, 1-3.

Murff, H., Patel, V., Hripcsak, G., Bates, D. (2003) Detecting adverse events for patient safety research: a review of current methodologies. Journal of Biomedical Informatics, 36, 131-143.

Murphy,M. and Kay, J. (2004) Barcode identification for transfusion safety. Current Opinion in Haematology, 5, 334-38.

Murphy, M., Stanworth, J. and Yazer, M. (2011). Transfusion practice and safety: current status. Vox Sanguinis, 100, 46–59.

Murphy, M., Lowe, D. and Pearson, M (2001). National audit of the blood transfusion process in the U.K. Transfusion Medicine, 11, 363-370.

Nagel, C. (1988). Human error in aviation operation. Academic Press, San Diego.

National Patient Safety Agency (2004) Incident Decision tree. Online retrieved from http://www.npsa.nhs.uk.
National Patient Safety Agency (2005). *Improving patient safety through better manual and technology based system for identification and matching of patients with care*. Retrieved from http://www.npsa.nhs.uk.

National Patient Safety Agency (2006). *Safer practice notice: Right Patient, Right Blood*. London NPSA.

Nevalainen D., Berte, L. and Callery, M. (1998). *Quality system in blood bank environment*. Second edition. Bethesda,MD: American Association of Blood Banks.

Nevalainen D. and Lloyd, H. (1995). ISO 9000 quality standards: a model for blood banking?. *Transfusion, 35*, 521-24.

Norfolk, D. (2000). *Experience with electronic system control in clinical transfusion process*. SHOT Annual report.

Nichols, J., Bartholomew, C., Brunton, M., Clintron, C. Elliott, S., McGirr, J., Morsi, D., Sinha, D. (2004). Reducing medical errors through barcoding at the point of care. *Clinical Leadership Management Review, 18*, 328-34.

National Audit Office (2006). Progress in implementing Clinical Governance in Primary Care Trust. Stationary Office.

National Institute for Mental Health in England (2003). *National Occupational Standard Implementation Guide*. UK.

Novis, D., Miller, K., Howanitz, P., Renner, S. and Walsh, M. (2003). Audit of transfusion procedures in 660 hospitals. *Transfusion Medical Review, 17*, 169-180.

Nursing and Midwifery Council. (2009) *Code of professional conduct*. London: NMC.

Orlikowski, W.J. and Hoffman, J.D. (1997). An improvisational model for Change Management: The Case of Groupware Technologies. *Sloan Management Review, 11–21.*

Oxman, A., Thomas, M., Davis, D. and Hayes, R. (1995). No magic bullets: a systematic review of 102 trials of interventions to help health professionals deliver
services more effectively and efficiently. *Canadian Medical Association Journal*, 153,1423-31.

Pagliaro, P. and Rebulla, P. (2006). Transfusion recipient identification. *Vox Sanguinis*, 91, 97-101.

Pagliaro, P. and Turdo, R. (2008). Transfusion management using a remote-controlled automated blood storage. *Blood Transfusion*, 6, 101-106.

Perper, J. (1994). Life-threatening and fatal therapeutic misadventures. In Bogner, M.S., Ed., *Human Error in Medicine*. Hillsdale, NJ.

Peters, T. (1989). *Thriving on Chaos*. Macmillan Ltd, London.

Rasmussen, J. (1987). The definition of human error and a taxonomy of technical system design. London: John Wiley & Sons LTD.

Reason, J. (1990). *Human Error*. Cambridge University Press, New-York.

Reason, J. (2001). Understanding adverse events: the human factor. In: Vincent C (ed).

Robillard, P., Chan, P. and Kleimann, S. (2004). Haemovigilance for improvement of blood safety. *Transfusion Apheresis*, 31, 95-98.

Salmi, L., Azanowsky, J. and Perez, P. (1997). Haemovigilance in France: Where we stand in 1985. *Proceedings of the ISBT-Ed*, 964-974.

Sandler, S., Langeberg, A. and Dohnalek, I. (2005). Bar code technology improves positive identification and transfusion safety. *Developments in Biologicals*, 120, 19-24.

Satir, V., Banmen, J., Gerber, J. and Gomori, M. (1991). *The Satir Model: Family therapy and beyond*.

Sazama, K. (1990). Reports of 355 transfusion associated deaths 1976-1985. *Transfusion*, 7, 583-590.
Scally, G. and Donaldson, L. (1998). Clinical governance and the drive for quality improvement in the new NHS in England. *British Medical Journal, 317*, 61-65.

Schreiber, G., Busch, M., Kleinman, S. and Korelitz, J.J. (1996). The risk of transfusion transmitted viral infection: The Retrovirus epidemiology donor study. *The New England Journal of Medicine, 334*, 1685-1690.

Schulman, P. (2004). General Attributes of safe Organisation. *Quality and Safety In Healthcare, 13*, 39-44.

Sellu, D., Davis, R., Vincent, A. (2012). Assessment of blood administration competencies using objective structured clinical examination. *Transfusion Medicine, 22*: 409-417.

Serious Hazards of Transfusion (2001-2011) *SHOT Reports and summaries*. Retrieved from http://www.shot-uk.org.

Serious Hazards of Transfusion (2011). *Serious Hazards of Transfusion Annual Report 2011*. SHOT Office, Manchester, UK

Serious Hazards of Transfusion (2009). *Serious Hazards of Transfusion Annual Report 2009*. SHOT Office, Manchester, UK

Sherer, P., Chambers, H., Taswell, C., Althshuler, R., Aster, K., Covino, S., Gordon, M., Gajewski, A., Smith, S., Horrigan, K., & Pfatt, K. (1977). Automated Donor-Recipient Identification Systems as a mean of reducing human error in blood transfusion. *Transfusion, 17*, 586-597.

Shulman, I., Saxena, S. and Ramer, L. (1999). Assessing blood administering practices. *Archives of Pathology & Laboratory Medicine, 123*, 595-598.

Snyder, E. and Dodd, R. (2001). Reducing the risk of blood transfusion. *Haematology, 433*-442.

SPSS Inc (2010) SPSS Version 19.0 for Windows user guide. SPSS Inc, Chicago, IL.
Stainsby, D. (2005). ABO incompatible transfusion experience from the UK Serious Hazard of Transfusion scheme. *Transfusion, 12*, 380-384.

Starr, D. (2001). Medicine, money, and myth: an epic history of blood. *Transfusion Medicine, 11*(2), 119-121.

Steinbrook, R. (2002). Nursing in the crossfire. *New England Journal of Medicine, 346*, 1757-1766.

Taswell, H., Smith, A., Sweatt, M. and Pfaff, K. (1974). Quality control in blood bank: a new approach. *American Journal of Clinical Pathology, 62*, 491-495.

Toeffler, A. (1983). *Future shock*. Bodley Head.

Turner, C., Casbard, A.C. and Murphy, M.F. (2003). Barcode technology: its role in increasing the safety of blood transfusion. *Transfusion, 43*, 1200-1209.

Tversky, A., Kahneman, D. (1974). Judgement under certainty: Heuristics and biases. *Science, 185*, 1124-1131.

Uriz, J., Antelo, M., Zalba, S., Ugalde., N. and Corcoz, P. (2011). Improved traceability and transfusion safety with a new portable computerized system in a hospital with intermediate transfusion activity. *Blood Transfusion, 9*, 172–81.

Varney, S. (2003). The annual cost of blood transfusion in the UK. *Transfusion Medicine, 13*, 205-218.

Verret, C. (1998). Evaluation of aa tracking system for labile blood products in the Midi-Pyrenes region. *Transfusion Clinique et Biologique, 5*, 275-282.

Vincent, C., Stanhope, N., and Crowley-Murphy, M. (1999). Reasons for not reporting adverse incidents: An Empirical study. *Journal of Evaluation in Clinical Practice, 1*, 13-21.

Wenz, B., (1991). Improvement in transfusion safety using a new blood unit and patient identification systems as part of safe transfusion practice. *Transfusion, 31*, 401–403.
Wessel, R. (2006) German clinic uses RFID to track blood. *RFID Journal*, retrieved from http://www.rfidjournal.com/article/view/2169.

Whitehead, S., Kenny-Siddique, S., Scott Y, Parker, P.l., Hardy, J. and Wallis, J.P. (2003). ‘Tag and label’ system for checking and recording of blood transfusions. *Transfusion Medicine, 13*(4), 197-204.

Williamson, L. (2002). Transfusion hazard reporting: powerful data, but do we know how best to use it. *Transfusion, 42*, 1249-1252.

World Health Organisation (2006). The clinical use of blood: Handbook. *World Health Organization*.

Zapt D. and Reason J. (1994). Introduction to error handling. *Applied Psychology, 43*, 427-432.
