SHOT—A Voluntary System for the Reporting of Serious Hazards of Transfusion in the UK

Background: From 1996-2001 the SHOT scheme has collected a powerful body of data on serious transfusion complications in the UK from which to make firm recommendations for improvements in transfusion safety. The UK Blood Services issue approximately 3.5 million blood components annually.

Results: With 413 eligible hospitals on the scheme, by year five, participation was running at 92%. Of 1,148 fully analyzed reports there were 699 (61%) “wrong blood” incidents. Of these, 161 were ABO incompatible transfusions leading to 11 deaths and 60 cases of major morbidity and 73 were RhD incompatible leading to potential RhD sensitization in 17 young females. Multiple errors occurred in 49% of cases. 55% of errors involved mis-identification at the point of collection from the hospital storage site and/or bedside administration, whilst laboratories and prescription/sampling/request errors contributed 28% and ~13% respectively. Immune complications comprised 35.7% of reports. 70 cases of possible TRALI over 5 years resulted in 49 cases of major morbidity and up to 20 deaths possibly related to transfusion. Transfusion-transmitted infection (TTI) comprised < 3% of reports but of 39 confirmed TTIs 25 were bacterial contamination incidents (21 platelets, 4 red cells) resulting in 6 deaths (5 platelets; one red cells).

Recommendations: “Wrong blood” incidents are avoidable errors. Efforts should be directed at developing computerized bedside identification systems to reduce human error. These can be linked to secure systems to reduce errors at the point of collection from storage and are also applicable in the drugs administration setting. Options to reduce the incidence of TRALI should be explored. Possible strategies to reduce bacterial contamination should be given appropriate priority.

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KEY WORDS

- Hemovigilance
- Blood transfusion
- Transfusion complications
- Blood safety
SHOT is the UK’s approach to the surveillance of complications associated with the transfusion of blood and blood components. It was established as part of the UK’s response to a European Commission (EC) resolution in 1995 on “Blood safety and self-sufficiency in the Community.” This identified that one of the main activities needed to improve public confidence in the safety of the blood supply was the development of a hemovigilance system “based on the existing networks for the collection of data related to the blood transfusion safety chain.”

What Is Hemovigilance?

Hemovigilance is a broad term which comprises detection, data gathering and analysis of untoward effects of blood transfusion in order to correct their cause and prevent recurrence. The overall goal is to make clinical care safer for patients requiring transfusion and to demonstrate to the public, patients and professionals, the safety of existing transfusion systems.

It can be approached in a number of different ways, as illustrated by the variety of systems which have been developed in different countries in recent years. Issues which must be considered when devising a scheme of national hemovigilance or surveillance include the following:

- Its scope: should it be very comprehensive or more restricted with respect to the data it sets out to collect? For example, severe versus all complications; microbial only versus all; patient data only or to include donor data
- Voluntary versus compulsory reporting
- Confidentiality and anonymity
- The different types of information to be collected
- “Ownership” of the scheme: professionals, regulators or Government?
- Sources and level of funding.

The choice for an individual country will be influenced by a number of factors which are governed by the overall organization of blood services within that country. Such factors include the regulatory and legal environment, the modus operandi for other reporting systems covering complications of medical interventions, priorities in health care development and the level of financial resources available.

Two of the earliest national surveillance schemes to be set up, those of the UK and France, clearly demonstrate fundamentally different approaches on which several other countries have based their own schemes. The French hemovigilance system is an example of a very comprehensive national system created by law and comprising a complex network of local and regional personnel entrusted with the responsibility of collecting reports and relaying them to the central blood agency. There is a legal obligation on all health care personnel to report any unexpected or undesirable effect of transfusion. Thus, a large body of data is generated which not only comprises serious adverse outcomes of transfusion but also encompasses minor events and those which eventually turn out to be completely unassociated with transfusion.

This contrasts with the much more restricted confidential and anonymous SHOT scheme in the UK. Both have their advantages and disadvantages and both suffer to a greater or lesser extent from the limitation due to the lack of denominator data concerning recipients and blood usage. Several more countries have either implemented or are in the process of implementing hemovigilance systems based on one of the above models. These include the Republic of Ireland, The Netherlands, Denmark, Greece, Canada and Australia. Other schemes, such as that for New York State, have been in existence for a number of years, and in Germany, surveillance of adverse events of transfusion falls within the remit of pharmacovigilance, which is the responsibility of the Paul Ehrlich Institute, the regulatory authority for Germany.

The Transfusion Process and the Organization of Transfusion Services in the UK

Ensuring that the right blood is transfused to the right patient at the right time is a complex, multi-step process which crosses many individual and professional boundaries and may involve many individuals. McClelland and colleagues have previously illustrated just how complex this process can be.

In most countries, responsibility for the transfusion process is divided in a number of different organizations or authorities. These tend to fall into three main categories: firstly, the blood agency or service (local, regional or national) with responsibility for selecting donors and processing and testing donations; secondly, the hospital blood bank, responsible for component storage, selection and compatibility testing; thirdly, hospital staff such as nurses, doctors, phlebotomists and porters who are responsible for taking patient samples, prescribing treatment, collecting blood from its storage site, administering the transfusion and monitoring the patient. Mistakes may arise at any point in this process and are often multiple, as SHOT data illustrates later in this paper.

In the UK, regulation and training in these three areas falls under a bewildering number of organizations comprising health services and other agencies which set policies and standards, licensing and accreditation bodies, professional organizations which draw up guidelines and recommendations, and hazard reporting systems such as SHOT. All contribute to various aspects of blood safety, but as yet there is no national organization with overall responsibility for coordinating blood safety, although this is beginning to be addressed.
The SHOT Reporting System: Organization and Practice

The SHOT scheme was launched in November 1996 following two years of intensive development by a small working group comprising hospital and blood service consultant hematologists, a blood bank scientist and a clinical transfusion nurse specialist. In devising the scheme the working group examined the practice of other confidential enquiry systems in the UK and also the French hemovigilance scheme. Following discussions with the Department of Health, the Royal College of Pathologists and the British Society for Haematology, it was concluded and agreed that a voluntary, confidential and anonymous reporting scheme, focusing on serious hazards only, would be a pragmatic solution for the UK. Whilst participation in SHOT has remained voluntary and outside regulatory control, two recent health service circulars, published by the English Department of Health and sent to chief executives of health authorities, have emphasized the necessity to report adverse events to the scheme. 9,10

Ownership of the scheme resides with a multidisciplinary Steering Group comprising representatives from all the medical and nursing Royal Colleges and other professional bodies, including health service management. It is chaired by a hospital-based Consultant Hematologist and provides the SHOT scheme with strategic direction. Affiliation to the Royal College of Pathologists, gained one year after implementation, strengthens the professional standing of the scheme.

A Standing Working Group, accountable to the Steering Group through a National Medical Coordinator, is responsible for the operational working of the scheme. Day-to-day activities are organized in two ways. Non-infectious hazard reports are handled by 3.5 whole-time-equivalent employees lead by the Assistant Coordinator working under the direction of the National Medical Coordinator. The latter is currently a part-time role of a Consultant Hematologist. Reports of infectious complications are collated and analyzed by a second, full-time National Coordinator who has a shared blood service and Public Health Laboratory Service Communicable Diseases Surveillance Centre (PHLS CDSC) appointment. Funding (currently ~£100,000 or ~£160,000 per annum) is provided by the four UK Blood Services (England, Scotland, Wales and Northern Ireland).

SHOT invites reports of major adverse events surrounding the transfusion of single or small pool blood components supplied by blood centers (red cells, platelets, fresh frozen plasma, methylene blue FFP and cryoprecipitate). It does not cover complications of fractionated plasma products (coagulation factors, albumin, immunoglobulin) which are licensed medicinal products and covered by the ‘Yellow Card’ system of the Medicines Control Agency. However, for purposes of comparison, complications of treatment with solvent-detergent-treated FFP should also be reported to SHOT. SHOT also receives and analyzes data concerning inappropriate anti-D immunoglobulin administration under the category of “incorrect blood component transfused” (see below). Hospitals report events under the following categories:

- Incorrect blood component transfused regardless of whether or not harm results (IBCT)
- Acute transfusion reaction (within 24 hours)
- Delayed transfusion reaction (beyond 24 hours)
- Transfusion-associated graft-versus-host-disease (TA-GVHD)
- Transfusion-related acute lung injury (TRALI)
- Post-transfusion purpura (PTP)
- Transfusion-transmitted infection (TTI) comprising:
  - Bacterial contamination
  - Post-transfusion viral infection
  - Other post-transfusion infection, e.g. malaria
- Near-miss events

Initially, from 1997, SHOT conducted only small pilot studies of “near miss” reporting, i.e. incidents where errors were discovered in time to prevent a mistransfusion. This aspect of the scheme has recently been extended to include all hospitals. In addition, collection of data on autologous predonation incidents began in 1998. Since this aspect of the scheme has been poorly subscribed to, resulting in only 7 reports, it will not be discussed further.

At hospital level, hazards are reported to the local hematologist. Suspected transfusion-transmitted infections must be reported to the supplying blood center to ensure prompt withdrawal of other implicated components and appropriate follow-up of donors and other possible recipients. Blood center personnel are then responsible for onward reporting to PHLS CDSC. Non-infectious hazards may be reported directly to the SHOT office using a simple “initial report” form. This is followed-up using a detailed questionnaire specific to the reported event. Once complete, anonymous data is entered using a unique identification number and the paper records are then shredded to prevent trace-back to individual cases. It should be noted that collection and analysis of data on infectious hazards commenced in 1995, preceding that on non-infectious hazards by one year.

In an anonymous and confidential scheme such as SHOT, denominator data is hard to obtain. However, in order to try to assess the number of hospitals participating annually in the scheme and their workload in terms of units of red cells handled, hospitals are invited each year to submit a “participation” card. Each year an annual report and summary are published and distributed widely to hospitals.

SHOT Key Findings, October 1996 - September 2001

From 1996-2001 the SHOT scheme collected a powerful body of data on serious transfusion complications in the UK from which to make firm recommendations for improvements in...
transfusion safety. The four UK blood services issue approximately 3.5 million blood components each year. Since the inception of the SHOT scheme in 1996 there has been a year-on-year increase in the number of reports. There may be any number of reasons for such a heightened awareness of the importance of reporting; an increase in confidence in the guaranteed anonymity of the scheme, pressure from the Department of Health or perhaps even an increase in the number of incidents occurring, although this last reason is purely speculative and is unlikely, in itself, to account for a total increase of 72% in four years. This information is shown graphically in Figure 1. With 413 eligible hospitals on the scheme, by year five, participation was running at 92%. It can be seen from Figure 2 that the increase in total reports is almost solely the result of an increase in IBCT incidents.

Of 1,148 fully analyzed reports, 699 (61%) were “wrong blood” incidents. Of these 161 were ABO incompatible transfusions leading to 11 deaths and 60 cases of major morbidity, and 73 were RhD incompatible leading to potential RhD sensitization in 17 females of child-bearing potential (Figures 3 and 4).

Multiple errors occurred in 49% of IBCT cases (Figure 5) indicating that problems occur at all stages of the transfusion process and that the final bedside check may fail to detect mistakes made earlier in the transfusion chain.

Approximately 55% of errors involved misidentification at the point of collection from the hospital storage site and/or bedside administration, whilst laboratories and prescription /sampling/request errors contributed 28% and approximately 13%, respectively.

The single most important cause resulting in mistransfusion was failure of some aspect of the bedside checking procedure immediately prior to administering the transfusion. Contributory factors included confusion over patients with the same or similar names, checking remote from the patient’s bedside, interruption
between completion of the checking procedure and administration of the transfusion and failure to note discrepancies between compatibility and donation labels where a preceding laboratory labeling error had occurred. Unusual circumstances contributed to a small proportion of these incidents but in the majority, no clear explanation for the failures was apparent. Missing wristbands or other formal means of patient identification also contributed to bedside errors in some instances. Withdrawal of the wrong component from its storage location in the hospital preceded a bedside administration error in a significant proportion of cases.

Immune complications comprised 35.7% of reports. 70 cases of possible TRALI over 5 years resulted in 49 cases of major morbidity, 8 deaths definitely or probably and a further 12 deaths possibly related to transfusion (Table 1), making TRALI the second largest cause of transfusion-related mortality and morbidity after ABO incompatibility. Whilst “wrong blood” errors should be avoidable, immunological complications in general cannot be predicted and do not reflect poor practice.

Transfusion-transmitted infection (TTI) comprised less than 3% of reports. From 1995-2001, there were 39 confirmed TTIs of which, 25 were cases of bacterial contamination (21 platelets and 4 red cells) resulting in 6 deaths (5 platelets; one red cells). Of the 21 contaminated platelets, 20 were 3 or more days old (where day 0 = day of donation) and in 8/25 cases the donor’s arm was confirmed as the source of contamination, making bacterial contamination the predominant cause of post-transfusion infectious complications. During the same period there were 8 reports of hepatitis B virus transmission, 7 of which were due to donations collected from donors with acute infection in the early infectious incubation period.

Using data from SHOT the risk of transfusion hazards can be roughly calculated as shown in Table 2.

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<th>Table 2</th>
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<tr>
<td><strong>Risk of Transfusion Hazards 1996-2001</strong></td>
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<td><strong>per Component Issued (17 Million Components Issued)</strong></td>
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<tr>
<td>Risk of IBCT (all categories)</td>
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<td>Risk of ABO incompatible</td>
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<td>Risk of major complication</td>
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<td>Risk of death (all categories)</td>
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<td>* 1 in 280,000 if deaths possibly related to transfusion are included.</td>
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“Near miss” data collection commenced in 1997 and was initially limited to small pilot studies. Reporting was extended to include all hospitals in 2000. So far, participation in this aspect of the scheme is running in 29% of hospitals, which is disappointing. However, a total of 812 reports were received from 121 hospitals under five error categories: sample, request, laboratory sampling/handling, laboratory component selection, handling/storage and component issue, transport and patient identification. Analysis of these revealed that sample errors comprised almost 32.1% of the total, indicating that phlebotomy errors are the major cause of “near miss” events and as for “wrong blood” transfusions analysis highlighted problems with patient identification.

<table>
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<th>Table 1</th>
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<tr>
<td><strong>Cumulative Mortality/Morbidity for Immunological Complications 1996-2001</strong></td>
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<td><strong>(n = 410)</strong></td>
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<td>Deaths imputability Definitely related</td>
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<td>Probably related</td>
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<td>Possibly related</td>
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<td>Unrelated</td>
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<tr>
<td>Major Morbidity</td>
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<td>Minor or No Morbidity</td>
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<td>Outcome unknown</td>
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<td>TOTALS</td>
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How Does SHOT Compare With Other European Hemovigilance Systems?

A number of other European countries have recently implemented or are considering implementing national hemovigilance schemes. Precise comparisons are difficult owing to the lack of common definitions and variations in the range and type of data collected. In some countries participation in hemovigilance is a legal requirement, as in France and Germany, whilst in others it is currently voluntary, as in the UK. The longest established, since 1994, is the French system of mandatory reporting. This comprises a comprehensive network of local, regional and national hemovigilance officers. Many of the events reported to this scheme are minor and many turn out to have little or no association with transfusion. Of the more serious events associated with transfusion, ABO incompatible transfusions and bacterial contamination of platelets are the most prominent categories which have been identified for remedial action. This is in keeping with the findings of the Danish system (DART) which has been modeled on the SHOT scheme. In 3 years, 72 reports have been received, 49% of which involved transfusion of an incorrect blood component (risk: 1 in 40,000). This scheme has identified a death rate, from an adverse outcome of transfusion, of 1 in 450,000 and rate of severe reaction of 1 in 65,000 (Jan Jørgensen, 2002, personal communication). The more recently established voluntary hemovigilance scheme in Ireland (www.ibts.ie) has also highlighted incorrect blood component transfusion as the largest single category of incidents, comprising 48% of 144 reports in 2001, with ABO incompatibility occurring at a rate of 1 per 27,000 components transfused. Thus, despite the differences highlighted above, the key findings of each of these schemes are similar, pointing to common problems and priorities for action.

How Can Hemovigilance Data Be Used to Aid Decision-Making?

Originally conceived in the wake of highly publicized and damaging outbreaks of transfusion-transmitted infections, such as human immunodeficiency virus and hepatitis C, the development of surveillance systems for adverse outcomes of the transfusion process have raised the profile of other complications less prominent in the public perception. As SHOT data demonstrates, the risk of contracting a transfusion-transmitted viral infection is now very small in comparison to other adverse events such as “wrong blood to patient,” transfusion-related acute lung injury and bacterial contamination incidents.

Whilst transfusion in the developed world is now probably safer than at any other time, there is continuing pressure to further reduce the already very low risk of infection transmission by genomic detection assays, viral inactivation processes and the extension of mandatory testing (for example, tests for hepatitis B core, HIV and HBV genome, and bacterial contamination of platelets are not mandatory in the UK). In addition, the UK in particular is facing the as yet unknown risk that vCJD may be transmissible in the blood supply, leading to expensive precautionary measures such as universal leukodepletion and outsourcing of plasma from non-UK suppliers. In the context of increasing pressures on health services, in terms of funding and human resources, data which helps to establish the relative risks of complications of the transfusion process can be used to set priorities for future spending in the field of transfusion medicine.

A further benefit of a transparent system of adverse event reporting such as SHOT, is that it can increase public confidence by demonstrating the safety of existing systems whilst also showing that, where problems exist, these are recognized and effectively tackled in a culture of “no blame.” This is in keeping with a recent National Health Service initiative for a system of reporting and analyzing all adverse health care events.

Hemovigilance schemes may have their limitations. Whilst SHOT and other data can be used to calculate risk of death and major complication per unit transfused, accurate calculation of risk per transfusion episode or per patient transfused, may not be possible due to lack of relevant denominator data. Nor is there comprehensive information on the clinical situations in which blood is used, the timing of transfusions and the timing and workload in clinical areas and laboratories, all of which may have a bearing on the outcome of a transfusion. Schemes such as SHOT are well suited to providing data on immediate hazards but transfusion-transmitted infections, with long preclinical incubation periods, may be less likely to be picked up. Voluntary schemes may suffer from underreporting but full reporting cannot be guaranteed for mandatory schemes.

Despite these limitations, hemovigilance schemes have quite clearly demonstrated priority areas for actions to improve transfusion safety. The establishment of clear decision-making pathways are key to the success of influencing blood safety policies using data provided by hemovigilance schemes. SHOT produces reports annually but has no authority to insist on the implementation of the recommendations they contain. Instead, it relies on its professional standing to influence other UK Health Service organizations to consider what actions to take. It does this by means of annual reports, educational symposia and presentations, representation on the Chief Medical Officer’s National Blood Transfusion Committee and by stimulating production of professional guidelines through the UK Blood Services and the British Committee for Standards in Haematology (BCSH).
What Has SHOT Achieved?

It would be wrong to suggest that the increasing profile of transfusion practice over recent years has been solely as a result of SHOT activities. The impact of vCJD as a possible transfusion-associated risk has been enormous, focusing attention on blood safety issues and appropriate blood usage. However, since the SHOT scheme was launched in November 1996, its recommendations have played their part in a variety of new initiatives aimed at improvements in transfusion safety. These were highlighted in the 5th annual (SHOT) report published in April 2002.11

Measures to address the need for an overarching framework in which to consider blood safety requirements include the establishment of a National Blood Transfusion Committee for England, reporting to the Chief Medical Officer, and formation of a National Blood Service (NBS), England, Blood and Tissues Safety Assurance Group which works closely with the Department of Health’s Economics and Operational Research division. However, as yet there is no single body for the UK which has the responsibility for assessing transfusion safety hazards and prioritizing blood safety initiatives.

Transfusion errors have been highlighted as the single largest category of transfusion hazard. Reports and developments to prevent these, in line with SHOT recommendations, include the publication of a guideline from the BCSH on blood handling and administration,13 projects to evaluate information technology solutions for bedside identification and implementation of computer-controlled blood refrigerator access in one of England’s largest Hospital Trusts.

SHOT findings have also influenced the development of new guidelines to assist with the investigation and management of a number of immunological complications including acute transfusion reactions, TRALI and TA-GVHD. In addition, the NBS is currently considering what action could be taken to minimize the risk of TRALI.

Transfusion-transmitted infections form only a very small percentage of reports to SHOT but the majority of these have been cases of bacterial contamination, particularly of platelets. Initiatives to reduce this risk include the implementation of improved arm cleansing techniques and the use of diversion pouches for the first 20 mL of each blood donation. The implementation of bacterial testing of platelets is currently being considered and studies of pathogen inactivation of platelets are planned for the future. To further minimize the residual risk of transfusion-transmitted hepatitis B virus (HBV), it is planned to assess the impact of the extension of donation testing to include HBV DNA and/or anti hepatitis B core.

Conclusion

In the five years since its inception, the SHOT scheme has collected a powerful body of data on serious transfusion complications in the UK from which to make firm recommendations for improving transfusion safety. These recommendations have influenced the development of a number of new initiatives that seek the accomplishment of these improvements.

In common with reports from several other hemovigilance schemes, SHOT has continued to draw attention to three key issues: transfusion errors (especially ABO incompatibility), bacterial contamination and TRALI. Efforts should be directed at developing computerized bedside identification systems to reduce human error. These can be linked to secure systems to reduce errors at the point of collection from storage and are also applicable in the drugs administration setting. Options to reduce the incidence of TRALI should be explored. Possible strategies to reduce bacterial contamination should be given appropriate priority.

There remains a need for an overarching organizational and intellectual framework for assessing transfusion hazards and prioritizing blood safety initiatives, including the appropriate use of blood and alternatives to blood transfusion.

REFERENCES