Serious Hazards of Transfusion: A Decade of Hemovigilance in the UK

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The Serious Hazards of Transfusion (SHOT) scheme is a UK-wide, independent, professionally led hemovigilance system focused on learning from adverse events. SHOT was established in 1996 as a confidential reporting system for significant transfusion-related events, building an evidence base to support blood safety policy decisions, clinical guidelines, clinician education, and improvements in transfusion practice. Recommendations are formulated by an independent steering group drawn from medical royal colleges and professional bodies. Ten years after its inception, SHOT has analyzed 2630 transfusion safety events, published 8 annual reports with recommendations, and presented data nationally and internationally. These recommendations have underpinned key initiatives, in particular the UK Department of Health "Better Blood Transfusion" strategy. SHOT has encouraged open reporting of adverse events and "near-misses" in a supportive, learning culture, vigilance in hospital transfusion practice, and evaluation of information technology to support this process. The importance of education and training has been emphasized. Detailed analysis of events has identified weaknesses in the transfusion chain. A collaborative initiative between SHOT, the Chief Medical Officer for England's National Blood Transfusion Committee, and the National Patient Safety Agency aims to reduce ABO-incompatible transfusions by improving bedside practice. Cumulative SHOT data have documented the decline in transfusion-related graft vs host disease after implementation of leucodepletion and have highlighted transfusion-related acute lung injury and bacterial contamination of platelets as important causes of death and morbidity. The UK blood services have developed strategies to reduce these risks. Future SHOT data will evaluate the success of these and other blood safety improvements.

THE SERIOUS HAZARDS OF TRANSFUSION SCHEME

THE SERIOUS HAZARDS of Transfusion (SHOT) scheme was established in 1996 as a national confidential reporting system for significant patient events. It has built an evidence base of transfusion risks that has been used to improve patient safety by informing policy decisions, improving standards of hospital transfusion practice, supporting production of clinical guidelines, and educating clinical users of blood. The scheme encompasses all labile blood components issued by the 4 UK blood transfusion services (the National Blood Service [NBS] in England, the Scottish National Blood Transfusion Service, the Welsh Blood Service, and the Northern Ireland Blood Transfusion Service). Confidentiality of individual patients, donors, and reporters is assured. Participation is voluntary, but SHOT has received strong endorsement from the Department of Health "Better Blood Transfusion" initiative that recognizes the importance of active hemovigilance as part of the UK blood safety strategy.[1] This initiative also encourages all hospitals to establish and support a hospital transfusion team, consisting of a consultant hematologist, a transfusion practitioner, and the blood bank manager. Such teams are vital in promoting good transfusion practice and ensuring that all adverse reactions and events are recognized, investigated, and reported.

The SHOT scheme is professionally led and is affiliated to the Royal College of Pathologists; strategic direction is provided by a steering group, with wide representation from UK royal colleges, the blood services, and professional bodies representing medical, nursing, and laboratory staff, as well as health service managers. A multidisciplinary standing working group, led by the national medical coordinator and accountable to the steering group, undertakes expert review of case reports. Day-to-day running of SHOT is the responsibility of the national medical coordinator and the scheme man-

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ager, supported by a data collection specialist and an administrator based in an NBS blood center. The scheme is funded through the UK blood services.

SCOPE AND METHODOLOGY

Categories and definitions of adverse reactions and events reportable to SHOT are shown in Table 1. The definitions are those currently in use and some have been modified from those originally agreed. The scope of SHOT does not encompass adverse reactions to licensed plasma products (coagulation factors, albumin, immunoglobulin), but, for purposes of comparison and completeness, complications of treatment with solvent detergent fresh frozen plasma (FFP) are invited and errors in administration of anti-D immunoglobulin are also included. In the context of a drive toward reducing exposure to allogeneic blood, it is important to consider the risks of alternatives to homologous blood transfusion. SHOT therefore receives reports of adverse reactions and events associated with autologous transfusion, whether predeposit or blood salvage.

Following implementation of the UK Blood Quality and Safety Regulations in November 2005, SHOT receives incident reports electronically via the Serious Adverse Blood Reactions and Events reporting system, developed and hosted by the Medicines and Healthcare Products Regulatory Agency, which have been appointed by the UK Secretary of State as the interim competent authority for the European Directive on Blood Safety and Quality.[2] Reporting to the competent authority of serious adverse reactions and events as defined by the European Directive is mandatory; however, the scope of SHOT is wider than that of the Directive, which does not include no-harm events or "near-misses" occurring in clinical areas.

Suspected cases of transfusion-transmitted infection (TTI) must also be reported urgently to the supplying blood center, to ensure rapid withdrawal of other implicated components and appropriate donor follow-up. Investigation of TTIs is coordinated by the National Blood Authority/Health Protection Agency Centre for Infections posttransfusion infection surveillance system for England, Wales, and Northern Ireland, and by the National Microbiological Reference Unit in Scotland.

After an initial notification of an adverse reaction or event, SHOT issues a detailed follow-up questionnaire specifically designed for each hazard. The questionnaire seeks a full picture of

Table 1. Categories of Adverse Reactions and Events Reportable to SHOT

Category of adverse event	SHOT definition
IBCT	Patient transfused with a blood component or product which did not meet the appropriate requirement or was intended for another patient
ATR	Adverse reactions occurring up to 24 h after transfusion, excluding those due to ICBT
DTR	Clinical adverse reactions (not simple serological reactions) occurring >24 h after transfusion of blood components
TRALI	Acute dyspnea with hypoxia and pulmonary infiltrates within 6 h of transfusion, with no other apparent cause
TA-GVHD	Development of the classical symptoms of fever, rash, liver dysfunction, and pancytopenia occurring 1-6 wk posttransfusion, without other apparent cause. Diagnosis supported by skin/marrow biopsy appearances and/or presence of circulating donor lymphocytes
PTP	Thrombocytopenia 5-12 days posttransfusion associated with antibodies in the patient directed against the human platelet antigen system
TTI	Posttransfusion infection in which • The recipient had no evidence of infection pretransfusion and either • At least one component was donated by a donor with evidence of the same transmissible infection or • At least one component was shown to have been contaminated with the infective agent
Near-miss event	Any error which, if undetected, could result in the determination of a wrong blood group, or issue, collection, or administration of an incorrect, inappropriate, or unsuitable component but which was recognized before transfusion took place
Adverse event or reaction associated with autologous transfusion	Includes PAD and blood salvage

Abbreviations: PTP, posttransfusion purpura; PAD, preoperative autologous donation.

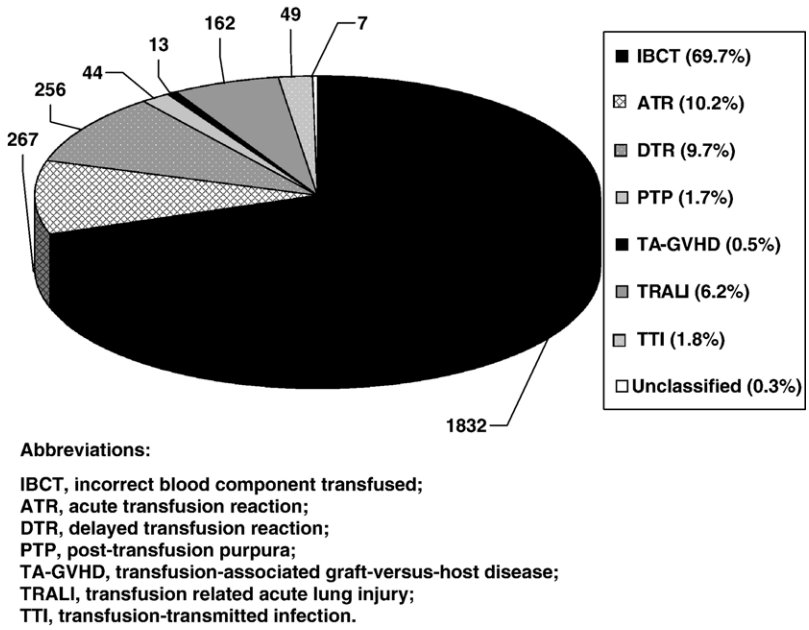


Fig 1. Breakdown of transfusion hazards by category, reported 1996 to 2004 (n = 2630) (excludes 3 TTI cases reported before 1996 but included in Table 4). PTP indicates posttransfusion purpura.

each reaction or event, and there may be confidential discussion of the incident between the SHOT office and the reporter to ensure that the incident has been accurately documented. Each case is then assessed to ensure that it meets the relevant definition, and an expert appraisal is undertaken with respect to diagnosis and imputability, that is, whether an adverse outcome is attributable to the transfusion. No personal identifiable information is retained.

Reports are compiled annually and are distributed to hospital hematologists and biomedical scientists in charge of hospital blood banks, chairs of professional bodies, and others involved in the practice of blood transfusion. They are also made freely available on SHOT's website, http://www.shotuk.org, to be used for educational purposes by all healthcare professionals involved in the practice of transfusion medicine.

SHOT has now accumulated 8 years of data, during which time 2630 reports have been received and analyzed. A breakdown of transfusion hazards by category is shown in Figure 1; mortality and morbidity in Table 2.

Table 2. Transfusion-Associated Mortality and Morbidity (1996-2004)

		Total	IBCT	ATR	DTR	PTP	TA-GVHD	TRALI	TTI
Deaths	Definitely attributed	45	6	2	6	1	13	8	9
	Probably attributed	12	3	3	1	0	0	5	0
	Possibly attributed	43	11	7	1	1	0	23	0
	Subtotal	100	20	12	8	2	13	36	9
Major morbidity		268	92	6	28	13	0	93	36
Minor or no morbidity		2240	1709	246	219	29	0	33	4
Outcome unknown		15	11	3	1	0	0	0	0
Total		2623*	1832	267	256	44	13	162	49†

*Excludes 7 unclassifiable cases.
†Excludes 3 cases reported before the inception of SHOT.

USE OF DATA TO DETERMINE TRANSFUSION RISKS

Using as a denominator the 27 million blood components issued by the UK blood services from 1996 to the end of 2004, we can calculate the frequency of reported events (Table 3). The accuracy of these calculations is limited by incomplete reporting and lack of denominator data on transfusion episodes, but they nevertheless provide a useful estimate of transfusion hazards relative to activity. SHOT uses as its denominator data figures for blood components issued by the UK blood services. The exact number of components transfused is not known, although hospital wastage of red cells is known to be less than 5% (data from National Health Service [NHS] Blood Stocks Management Scheme courtesy of Ms J Chapman). Moreover, information is not available on the number of transfusion episodes and transfused patients which these components represent. Although epidemiological studies are beginning to cast light on the clinical situations in which blood is used and the age/sex profile and survival patterns of transfused patients,[3,4] further work is needed to identify high-risk patients and environments and to estimate the risk of an adverse reaction or event to an individual patient.

Active reporting in a hospital requires clinical awareness, an open learning culture, and an adequate infrastructure. This should include a specialist transfusion practitioner and a well-resourced and supported hospital transfusion committee empowered to implement change. In a questionnaire survey of implementation of BBT2 in England and Wales in 2004, to which 95% of NHS Trusts and 37% of private hospitals responded, 99% of responding hospitals stated that they participated in SHOT.[5] In 2004, reports of adverse reactions, events, and "near misses" were received from only 67% (271/404) of UK hospitals, suggesting that reporting remains incomplete, although comparison with data on blood components issued from the blood services shows that 84% (114/133) of nonreporting hospitals are low blood users that each receive fewer than 5000 U of red cells annually.

Table 3. Frequency of Reported Serious Hazards of Blood Transfusion in the UK (not all incident types are included)

Event	Number of incidents reported	Frequency of reported events per 100 000 components issued
IBCT	1832	7
ABO-incompatible transfusions (all components—included in IBCT)	249	1
Death as a result of IBCT	20	0.07
TRALI	162	0.6
Fatal TRALI	36	0.1
ATR	267	1
TTI (including bacterial)	49	0.2
Total adverse reactions/events	2630	10
Total transfusion-related deaths	100	0.4

ANALYSIS OF DATA 1996 TO 2004

Transfusion-Transmitted Infections

Details of TTI cases with the year of transfusion are shown in Table 4. Criteria for inclusion as a confirmed TTI were evidence of infection in the recipient posttransfusion, with no evidence of infection pretransfusion and no evidence of an alternative source of infection, plus either evidence of the same transmissible infection in the donor or evidence of contamination of the blood component. Reports are not included if the incident involved hepatitis C virus (HCV) or human immunodeficiency virus (HIV) in recipients who had received transfusions in the UK before routine testing (September 1991 for anti–HCV and October 1985 for anti-HIV) or if the incident involved human T-cell lymphoma/leukemia virus (HTLV) in a recipient identified through the HTLV National Lookback. From 1995 to 2004 (including 3 cases reported before the inception of SHOT), 52 cases of TTI have been reported, of which 19 were viral, 2 were malarial, and 29 due to bacterial sepsis. One case of probable transfusion transmission of variant Creutzfeld-Jakob disease (vCJD)[6] and one possible prion transmission found at postmortem[7] are also included. Transfusion transmission of vCJD can never be conclusively confirmed, as a dietary source of infection cannot be excluded.

A reporting system such as SHOT, which relies on recognition of a clinical event and its association with a transfusion episode, is not ideal for identifying TTIs that may have a long incubation period. Assessment of the residual risk of transfusion-transmitted viral infection must include data

Table 4. Confirmed TTI Cases Reported to SHOT via NBS/HPA Infection Surveillance From England, Wales, and Scotland (Scotland from 10/98) (01/10/1997 to 31/12/2004 with year of transfusion)

Year of transfusion	Pre-1997	1997	1998	1999	2000	2001	2002	2003	2004	Total	Deaths
Infection											
HAV	1 (1)	–	–	–	1 (1)	–	–	–	–	2	–
HBV	3 (3)†	1(1)	1(1)	2(3)	1(1)	–	1(1)	1(1)	–	10	–
HCV	1 (1)	1 (1)	–	–	–	–	–	–	–	2	–
HIV‡	1 (3)	–	–	–	–	–	1 (1)	–	–	2	–
HEV								–	1 (1)	1	–
HTLV I	2 (2)	–	–	–	–	–	–	–		2	–
Bacteria	2 (2)	3 (3)	4 (4)§	4 (4)*	7 (7)‖	5 (5)	1 (1)	3 (3)*		29	7
Malaria	–	1 (1)*	–	–	–	–	–	1 (1)	–	2	1
vCJD	1 (1)	–	–	–	–	–	–	–	–	1	1
Possible prion transmission	–	–	–	1 (1)	–	–	–	–	–	1	–
Total	11 (13)†	6 (6)*	5 (5)§	7 (7)*	9 (9)‖	5 (5)	3 (3)	5 (5)*	1 (1)	52	9

Abbreviations: HAV, hepatitis A virus; HBV, hepatitis B virus; HEV, hepatitis E virus.

*Infection was implicated in the death of a recipient.

†One household member who was caring for the recipient has been diagnosed with acute HBV.

‡One additional investigation failed to confirm or refute transfusion transmission of HIV infection during the early 1990s. As the patient had received multiple transfusions, and had no other risk factors for infection, transfusion with HIV infectious blood was concluded to be the probable, although unproven, source of infection.

§Infection was implicated in the deaths of 2 recipients.

‖Infection was implicated in the deaths of 3 recipients.

on the prevalence of virus markers in blood donors and the seroconversion rate. These risks have been calculated as 1:30 million for HCV, 1:8 million for HIV, and 1:260 000 for hepatitis B virus.[8] Updated risk estimates are also included on the Health Protection Agency webpages (http://www.hpa.org.uk/infections/topics_az/BIBD/est_freq_uk.htm).

Successive SHOT reports have highlighted the importance of bacterial contamination of platelets as a reducible cause of mortality and morbidity. Twenty-five of the 29 cases of bacterial sepsis were related to platelets and accounted for 7 deaths. Most were due to skin contaminants, and in 23 of 25 cases the platelets had been stored for 3 or more days. These compelling data have led the UK blood services to implement improved donor arm cleansing and diversion pouches on blood collection bags with ongoing monitoring of positivity in outdated platelets to assess the efficacy of these interventions.

Transfusion-Related Acute Lung Injury

Transfusion-related acute lung injury (TRALI) is one of the most controversial and complex complications of transfusion, characterized by respiratory distress and hypoxemia associated with transfusion of plasma-containing blood components and in the absence of fluid overload or cardiac failure.[9] The diagnosis of TRALI depends on clinical awareness and is confounded by the nonspecific clinical picture, the lack of a universally accepted definition, and absence of a conclusive diagnostic test. In institutions with a high index of suspicion of TRALI, its incidence has been estimated at 1:2000 to 1:8000 plasma-containing components.[10,11] Reports of TRALI to SHOT were constant at an average of 14 (range, 11-19) per year for the first 5 years up to 2001, but rose to 26 in 2001/2002, and 36 in 2003, with increasing awareness of the condition. While taking into account uncertainties regarding diagnosis and imputability, the accumulation of 162 reports of TRALI to SHOT over 8 years and its implication in 36 deaths and 93 cases of major morbidity has led to its recognition as the most important cause of transfusion-associated mortality and morbidity.

Classical immune-mediated TRALI appears usually to be triggered by passive transfer from the donor of HLA or granulocyte antibodies arising as a result of pregnancy or transfusion. SHOT data indicate that it is 5 to 7 times more likely to occur in association with “plasma-rich” components such as FFP, platelets, and whole blood than with components containing only a small volume of plasma. Hence, its occurrence should be reducible by sourcing plasma from male donors, as far as is

operationally feasible, for FFP and for resuspension of buffy coat–derived platelets. This strategy was implemented in the UK during 2003/20044. The number of TRALI cases reported to SHOT in 2004 fell to 23,[12] which is encouraging, although a longer monitoring period is necessary to fully evaluate this initiative. The use of pooled solvent-detergent–treated plasma appears also to protect against this complication. Options for reducing further the risk of TRALI from platelets include screening female platelet pheresis donors for leukocyte antibodies, and the use of platelet additive solutions to replace 70% of the plasma in apheresis platelets.

Allergic and Anaphylactic Reactions

SHOT does not accept reports of minor febrile or allergic reactions. SHOT has defined anaphylaxis as hypotension with one or more of the following: rash, dyspnea, angioedema, and allergy as rash with dyspnea or angioedema but without hypotension. These definitions are currently under revision. One hundred and fifty-nine such cases have been reported in the acute transfusion reaction (ATR) category over 8 years, and, like TRALI, these are notably more commonly observed in association with plasma-containing components (2 per 100 000 FFP units issued and 3 per 100 000 platelet doses) than with red cells (0.5 per 100 000). These findings highlight the importance of appropriate use of blood components, in particular FFP, which is not infrequently prescribed without good clinical indication and not in accordance with guidelines.[13] One unusual allergic reaction, manifest as a polyarthropathy, occurred 2 days after a transfusion of red cells and was reported as a delayed transfusion reaction (DTR). The patient was found to be immunoglobulin A deficient with immunoglobulin A antibodies.

Other ATRs

A further 64 ATRs consisted of febrile reactions reported in the first few years of SHOT but not subsequently accepted, metabolic disturbances, and reports in which there was insufficient clinical detail to enable the case to be categorized.

Hemolytic Reactions

Hemolytic reactions where a transfusion error is identified are reported in the incorrect blood component transfused (IBCT) category. A further 44 acute hemolytic reactions (recognized within 24 hours of completion of the transfusion) have been reported of which 35 were due to red cells and 9 to group O platelets given to group A (8 cases) or B (1 case) recipients. Two patients have died as a result of acute hemolytic reactions and 5 have suffered major morbidity.

Two hundred and fifty-five delayed hemolytic reactions (recognized 24 hours or more after completion of the transfusion) have been reported, accounting for 8 deaths and 28 cases of major morbidity. The most frequently implicated antibodies in delayed hemolytic transfusion reactions are Kidd, accounting for 53% of cases, with or without other specificities, followed by Rh in 38% of cases, again either with or without other specificities. In 1 fatal case, there was delay in recognition of the reaction; the fall in hemoglobin was thought to be due to bleeding, and the patient was subjected to further surgery from which he did not recover. In another, a 51-year-old female patient had catastrophic hemolysis and died while awaiting compatible blood.

Expert review of these hemolytic reactions suggests that, although there was no identifiable error, 14% might have been avoided by improved practice, such as transfusion of ABO identical platelets, full investigation of patients with autoimmune hemolytic anemia to exclude masked allo-antibodies, use of appropriate, sensitive pretransfusion testing, and a systematic approach to antibody identification, and better use of reference facilities to elucidate complex mixtures of antibodies. In at least 6 cases of delayed hemolytic reaction, the implicated antibody, undetectable in pretransfusion testing, had previously been identified by another laboratory, but this information was unavailable at the time of transfusion.[14]

Transfusion-Associated Graft-vs-Host Disease

In the first 3 years of SHOT, from 1996 to 1999, 12 cases of transfusion-associated graft-vs-host disease (TA-GVHD) were reported, all with a fatal outcome. None was due to failure to comply with indications for irradiation of blood components; 5 cases occurred in patients with B-cell malignancies (3 B-cell NHL, 1 Waldenstrom's macroglobulinemia, 1 myeloma); 2 in patients not known to be immunocompromised at the time of transfusion and 5 in apparently immunocompetent patients, in

whom there may have been partial haplotype sharing between the recipient and a homozygous donor, although this was only proven in 1 case. Since the introduction of universal leucodepletion by the blood services in 1999, only 1 further case has been observed, in 2000, occurring in a patient with B-cell acute lymphoblastic leukemia.[15] These findings suggest that quality-controlled leucodepletion offers some protection against TA-GVHD (manuscript in preparation). Of concern is that, every year, increasing numbers of cases are reported of patients at risk of TA-GVHD who receive unirradiated cellular components; this despite the introduction of a patient-information card and leaflet. While no patient has developed this complication as a result of error, there is a need for improved communication systems and increased vigilance.

Posttransfusion Purpura

This is a rare complication of transfusion, only 46 cases having been reported in 8 years, of whom 2 died and 13 had major morbidity. Most cases are attributable to antihuman platelet antigen-1a, with all except one seen in previously pregnant women. Most patients responded to intravenous immunoglobulin G. Again, there has been a reduction in incidence since implementation of leucodepletion (manuscript in preparation).

Incorrect Blood Component Transfused

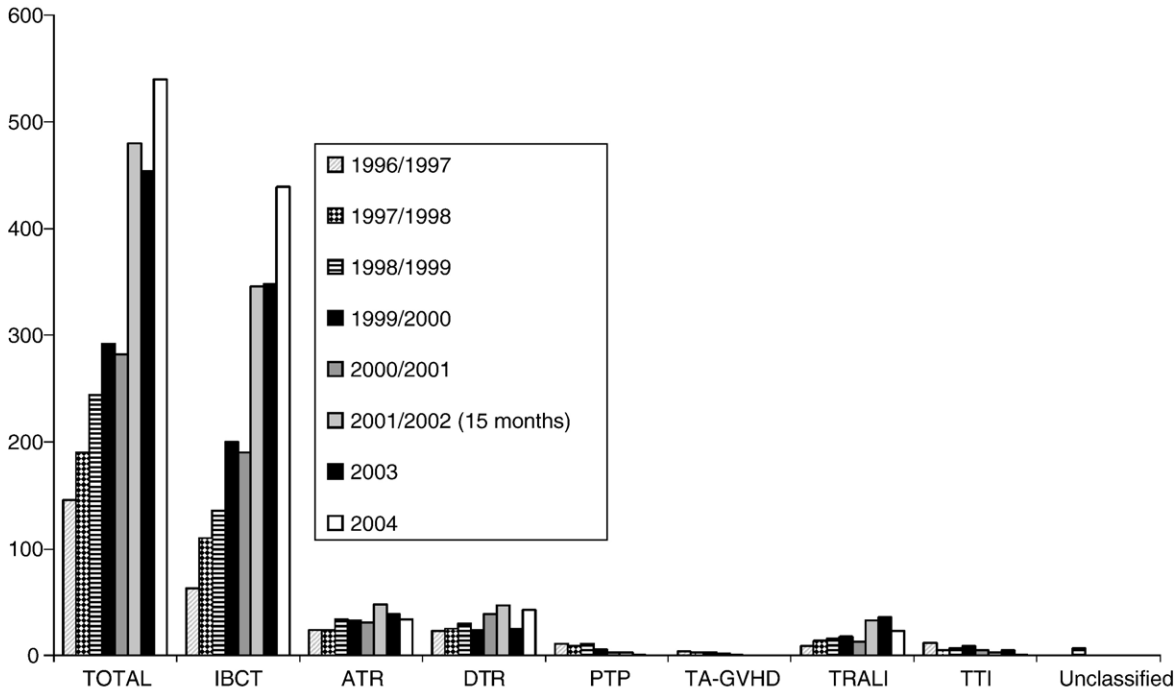
Seventy percent of incidents reported (1832/2630) relate to episodes of IBCT, due to potentially avoidable system failures throughout the transfusion chain. The predominance of errors over other adverse incidents has become progressively more marked as hospitals have gained confidence in the confidentiality of reporting (Fig 2), and the year-on-year increase in reports shows no sign of reaching a plateau. Process mapping of the task of prescribing, requesting, providing, and administering blood components reveals that it is a complex chain, with opportunities for error at several critical points.[16] Acute intravascular hemolysis due to major ABO incompatibility is the most feared outcome, with the highest risk of death or morbidity. However, transfusion errors can cause patient harm in other ways, such as failure to provide blood of an appropriate specification for the patient (eg, suitable for neonates), RhD sensitization of women of child-bearing potential, and inappropriate transfusion, based on erroneous laboratory results, leading to volume overload or unnecessary exposure to blood components. Fortunately, 1709 (93%) of 1832 patients receiving incorrect blood components survived with no short- or long-term ill effects; nevertheless, over the course of 8 years, 20 deaths have been attributed wholly or in part to transfusion errors and 92 patients suffered major morbidity.

Analysis of IBCT events has revealed that, in approximately half of cases, more than 1 error contributes to an adverse outcome, and that approximately 70% of errors take place in clinical areas, the most frequent error being failure of the final patient identification check at the bedside.

The transfusion chain in hospital begins with the decision to transfuse. SHOT does not encompass inappropriate transfusion due to wrong clinical decision making, but erroneous, misdocumented, or misinterpreted laboratory results are an important cause of IBCT events. Caution must be exercised if a laboratory report does not match the clinical picture, as an incorrect result may be due to an unsuitable sample or an analytical error. A telephoned report may be wrongly transcribed or assigned to the wrong patient.

An adverse event may also result from failure by the requesting clinician to provide the transfusion laboratory with crucial information regarding the patient's transfusion history or special blood requirements, such as a previously detected alloantibody or an indication for irradiated or cytomegalovirus-negative blood components. The blood prescription also provides instruction regarding the rate and volume of transfusion. Particular care must be exercised when prescribing for infants, children, and small adults, in whom overtransfusion may result in serious morbidity.

The next critical stage of the process is that of blood sampling for pretransfusion testing. Fortunately, most sampling errors are detectable by the laboratory if there is a previous record of the patient, but if no previous record is available there is no means of detecting such errors. Only 10 of the 348 IBCT cases analyzed by SHOT in 2003[17] involved samples taken from the wrong patient, but 5 of those patients received ABO-incompatible blood as a result, of whom 1 died and 4 had major morbidity. Analysis of near-misses, in which an error occurs that could have led to an IBCT event but was detected and prevented, reveals the true



Abbreviations

IBCT, incorrect blood component transfused;
ATR, acute transfusion reaction;
DTR, delayed transfusion reaction;
PTP, post-transfusion purpura;
TA-GVHD, transfusion-associated graft-versus-host disease;
TRALI, transfusion related acute lung injury;
TTI, transfusion-transmitted infection.

Fig 2. Predominance of errors over other adverse events.

extent of problems in sample collection and labeling. Since near-miss reporting began in 2000/2001, 3503 events have been reported of which 1976 (56%) relate to errors at this stage.

Approximately 30% of errors in IBCT occur in the hospital transfusion laboratory and may involve selection of the wrong sample for testing, transposition of labels, technical or transcription errors in manual pretransfusion serology, or knowledge-based errors such as selection of components that were not of the appropriate specification. A disproportionately high number of laboratory errors take place outside of "core hours." Results of a 2003 laboratory activity survey, distributed by SHOT, showed that the ratio of workload done in "core" vs "noncore" hours is 80:20, whereas the ratio of lab errors made in core vs noncore hours is 60:40. Staff working outside of core hours are fewer in number and may be relatively inexperienced and working under pressure (D Asher, personal communication).

The stage of greatest risk of error in the transfusion chain is the collection of the wrong component from the blood bank or satellite refrigerator followed by failure to recognize the error at the bedside. Errors at this stage constituted 40% of those reported to SHOT in 2003 and resulted in 12 ABO-incompatible transfusions. Anecdotal case reports provide insights into the system failures contributing to collection errors, such as inaccurate verbal instructions and the common pitfall of similar patient names. In 2003, 10 of 45 patients for whom the wrong blood was collected from the blood bank and subsequently

administered at the bedside without further checking were undergoing urgent or massive transfusions in critical care environments such as operating theaters, recovery suites, emergency departments, intensive care units, or delivery suites. Lack of denominator data makes interpretation of such figures speculative, but it is tempting to conclude that there is a greater risk of error in situations of extreme clinical urgency.

Failure to carry out the final patient identification check adequately at the bedside has consistently been the commonest single error in successive SHOT reports, accounting for 27% of errors in 348 case reports in 2003.[17] In the majority (87%) of these, a previous failure could have been detected at this stage but was not, whereas in the remainder, the first and only error resulting in blood being given to the wrong patient was made at this final and most critical stage in the process. Analysis of individual cases reveals contributory factors such as checking the component away from the bedside, nursing staff distracted or interrupted during the checking process, patient identification wristbands missing, illegible, or hidden.

SHOT RECOMMENDATIONS AND THEIR IMPACT ON BLOOD SAFETY

The effectiveness of adverse event reporting is measured not only by accurate collection and analysis of data but also by its use to make recommendations that improve patient safety.[18]

In addition to specific recommendations aimed at blood services, successive SHOT reports have encouraged open reporting of adverse events and near-misses in a supportive, learning culture, vigilance in hospital transfusion practice, and evaluation of information technology to support the transfusion process. The importance of education and training has been emphasized. SHOT, in common with other hemovigilance systems, has no power to implement change, but exerts its influence through the professional bodies represented on the steering group and by feedback, education, and lobbying. Effective partnerships have been developed with other organizations, and, with the agreement of reporters, work is ongoing to build a comprehensive picture of transfusion safety, drawing on data from the UK National External Quality Assurance Scheme for blood group serology and the NHS/NBS Blood Stocks Management Scheme,[19] together with denominator data from epidemiological studies.[3] The development of supporting infrastructures, such as the NBS hospital liaison function in England, the Effective Use of Blood program in Scotland, and the establishment of national, regional, and hospital blood transfusion committees have provided networks for development and dissemination of good practice, and a part-time nursing secondment to SHOT has greatly enhanced communication with hospital transfusion practitioners.[20] Collaboration between SHOT, the chief medical officer for England's National Blood Transfusion Committee, and the National Patient Safety Agency has resulted in an initiative aimed at reducing ABO-incompatible transfusions by improving bedside practice.[21]

A constant theme of SHOT recommendations has been the need for a single overarching body with a remit to evaluate transfusion risks and prioritize safety initiatives-this is still awaited and, in the context of ever increasing precautions to reduce the risk of transfusion transmission of vCJD, is perhaps more urgent than ever. The cost-effectiveness of blood safety initiatives compared to other health interventions has been quite rightly questioned. However there are no agreed national or international benchmarks for acceptable expenditure on blood safety. Comprehensive hemovigilance will continue to play an important role by providing data on comparative risks and the effect of blood safety initiatives.

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