Introduction
The 12th SHOT Annual Report is published at the end of June 2009 to coincide with the submission of haemovigilance data to the EU Commission by the competent authority, the Medicines and Healthcare products Regulatory Agency (MHRA).

Over 12 years of reporting, the trends observed by SHOT have borne the hallmarks of an effective vigilance system. The number of events reported has risen, while the frequency of the most serious events, and the mortality directly related to transfusion, has fallen. As the culture of reporting has developed, there has been an increased understanding of how an adverse event system exerts its influence, i.e. by the observation and reporting of trends and patterns, followed by changes of practice to reduce the risks of recurrence, rather than by the creation of a ‘blame culture’.

SHOT demonstrates the utility of an effective haemovigilance system in increasing patient safety through the promotion of a culture of learning and improvement, with an emphasis on safety and quality.

Organisations that require evidence of reporting to SHOT
In the past, reporting to SHOT has been voluntary. However, in recent years a number of quality, inspection and accreditation organisations and government bodies within the United Kingdom have made reporting to SHOT a requirement. SHOT has identified all of these organisations and their specific requirements and they are listed in the full report.

Participation in SHOT
This year SHOT presents participation data for the years 2006, 2007 and 2008. These data represent information accumulated since the implementation of the Blood Safety and Quality Regulations 2005 and reporting via SABRE, and the introduction of quality improvement standards in transfusion in all of the four UK countries. The data presented in the full report should be viewed as providing a baseline against which to measure the success of these standards. It is clear that SHOT is receiving only a fraction of possible reports, and chief executive officers of hospitals and trusts are urged to support and encourage effective systems to capture data on adverse events, and to share the data nationally.

New SHOT database
In a further initiative to facilitate reporting, SHOT has contracted Dendrite Clinical Systems to develop a new web-based data capture system which will be active in the second half of 2009. Details will be regularly posted on the website and distributed via the SHOT Newsletter.

New in this 2008 report
This year, the categories inappropriately unnecessary transfusion and handling and storage errors have been removed from the IBCT chapter, to form separate, stand-alone chapters. For the second year there is a separate chapter on autologous transfusion related adverse incidents and a chapter on transfusion-associated circulatory overload (TACO). In addition, 1 case of transfusion-associated dyspnoea (TAD) has been identified, and is reported in a separate chapter. Reporters are encouraged to send cases in all these new categories. A detailed chapter on paediatric cases is included, and SHOT plans to carry out this analysis annually.
OVERVIEW OF 2008 REPORT
Data analysed for this report were collected between 1st January 2008 and 31st December 2008. The total number of questionnaires reviewed this year is 1040, representing an increase of 85% since 2007, when 561 were reviewed.

Summary of reports reviewed

<table>
<thead>
<tr>
<th>IBCT</th>
<th>I&amp;U</th>
<th>HSE</th>
<th>ANTI-D</th>
<th>ATR</th>
<th>HTR</th>
<th>TRALI</th>
<th>PTP</th>
<th>TA-GvHD</th>
<th>TTI</th>
<th>TACO</th>
<th>TAD</th>
<th>AUTOLOGOUS</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>262</td>
<td>76</td>
<td>139</td>
<td>137</td>
<td>300</td>
<td>55</td>
<td>17</td>
<td>1</td>
<td>0</td>
<td>6</td>
<td>18</td>
<td>1</td>
<td>28</td>
<td>1040</td>
</tr>
</tbody>
</table>

Cases reviewed in 2008  \( n = 1040 \)

*New categories for this year

Yearly summary of issues by the 4 UK Blood Services 1999–2008

<table>
<thead>
<tr>
<th>Year</th>
<th>Red Blood Cells</th>
<th>Platelets</th>
<th>FFP</th>
<th>Cryoprecipitate</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999–2000</td>
<td>2,737,572</td>
<td>249,622</td>
<td>365,547</td>
<td>94,114</td>
<td>3,446,855</td>
</tr>
<tr>
<td>2001–2002</td>
<td>2,679,925</td>
<td>251,451</td>
<td>385,236</td>
<td>88,253</td>
<td>3,404,865</td>
</tr>
<tr>
<td>2002–2003</td>
<td>2,678,098</td>
<td>251,741</td>
<td>377,381</td>
<td>92,768</td>
<td>3,399,988</td>
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<tr>
<td>2004–2005</td>
<td>2,428,934</td>
<td>258,528</td>
<td>313,019</td>
<td>102,719</td>
<td>3,103,201</td>
</tr>
<tr>
<td>2005–2006</td>
<td>2,316,152</td>
<td>259,654</td>
<td>320,852</td>
<td>106,139</td>
<td>3,002,797</td>
</tr>
<tr>
<td>2006–2007</td>
<td>2,235,638</td>
<td>255,474</td>
<td>306,444</td>
<td>116,672</td>
<td>2,914,228</td>
</tr>
</tbody>
</table>
Total issues of blood components from the Transfusion Services of the UK in the financial year 2007–2008

<table>
<thead>
<tr>
<th>Year</th>
<th>Red Blood Cells</th>
<th>Platelets</th>
<th>FFP</th>
<th>Cryoprecipitate</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Blood Service</td>
<td>1,816,872</td>
<td>218,459</td>
<td>250,644</td>
<td>99,928</td>
<td>2,385,903</td>
</tr>
<tr>
<td>Welsh Blood Service</td>
<td>95,207</td>
<td>8,526</td>
<td>12,121</td>
<td>2,418</td>
<td>118,272</td>
</tr>
<tr>
<td>Scottish National Blood Transfusion Service</td>
<td>208,909</td>
<td>24,065</td>
<td>25,554</td>
<td>14,703</td>
<td>273,231</td>
</tr>
<tr>
<td>Northern Ireland Blood Transfusion Service</td>
<td>53,268</td>
<td>7,369</td>
<td>6,766</td>
<td>650</td>
<td>68,053</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>2,174,256</strong></td>
<td><strong>258,419</strong></td>
<td><strong>295,085</strong></td>
<td><strong>117,699</strong></td>
<td><strong>2,845,459</strong></td>
</tr>
</tbody>
</table>

Cumulative numbers of cases reviewed 1996–2008  \( n = 5374 \)

* New categories for this year

Comparison of report types 1996–2008

* NB 2001–02 was a 15 month period
Summary of 2008 report

Transfusion-related mortality

There was 1 death reported in 2008 that was a direct consequence of the blood component transfused. This was a case of transfusion-transmitted bacterial infection, in which a pancytopenic patient with AML received a routine prophylactic platelet transfusion and died from *Klebsiella pneumoniae* infection proven to have been transmitted from the donor via the platelets.

There were a further 9 deaths where a patient who was already very unwell died following a transfusion reaction, in which the reaction was considered to have contributed to the death. This included 2 cases of inappropriate and unnecessary transfusion, 4 acute transfusion reactions, 1 haemolytic transfusion reaction, 1 transfusion-associated circulatory overload, and 1 further transfusion-transmitted bacterial infection via the same apheresis platelet donor as in the case in the paragraph above, from the second half of the same donation.

Incorrect blood component transfused (IBCT)

A total of 477 cases were reported on IBCT questionnaires in 2008. This represents an increased reporting rate, now 16.8 per 100,000 components issued, compared with 11.4 in 2007. Handling and storage errors (139 cases) and inappropriate and unnecessary transfusion (76 cases) are described in separate chapters, as the incorrect blood is not transfused in these events. This leaves 262 true IBCT events.

There were 11 ABO-incompatible transfusions given in 2008, which included 10 ABO-incompatible red cell transfusions. Four of these cases arose from bedside administration errors, 3 from ‘wrong blood in tube’ phlebotomy errors and 3 from laboratory errors. This figure remains very low, despite the great increase in the number of true IBCT reports from 164 in 2007 to 262 in 2008. There were no cases of incompatible platelet or FFP transfusion resulting from clinical errors, but 1 transfusion of ABO-incompatible FFP resulting from a laboratory error.

ABO incompatible transfusion did not cause any fatalities in 2008, but there were 4 cases of major morbidity.

The increased reporting has been especially marked among the laboratory error category, possibly due to increased awareness as a result of the emphasis placed on the laboratory by the Blood Safety and Quality Regulations 2005.
### Inappropriate and unnecessary transfusion (I&U)

There were 76 cases reported, with the largest group involving patients transfused on the basis of an erroneous laboratory value resulting from sampling, transcription or communication errors. A further significant category includes cases in which transfusion was given as a result of poor knowledge and decision making. There were 2 fatalities in this group, 1 from massive overtransfusion, and 1 from undertransfusion, and one case of major morbidity.

Attainment of appropriate knowledge and experience in transfusion medicine for clinical staff remains a major issue for medical educators.

### Handling and storage errors (HSE)

A total of 139 cases were reported in this category, none of which caused mortality or major morbidity.

It is essential that clinical and portering staff involved in the transfusion process have sufficient knowledge to appreciate the critical points in the task and that they work to clear protocols.

### Anti-D events

There were 137 anti-D events reviewed this year. There were 58 cases in which administration of anti-D Ig following potentially sensitising events was delayed or omitted, placing the patient at risk of developing immune anti-D. This constitutes major morbidity according to SHOT criteria. In 63 cases anti-D was inappropriately administered, resulting in unnecessary exposure to a human blood product.

Robust education, training and protocols are required to ensure that anti-D is issued appropriately, for named patients.

### Acute transfusion reaction (ATR)

A total of 300 acute transfusion reactions were reviewed this year. There were no deaths directly attributable to ATR, but 4 cases in which the transfusion reaction might have contributed to the patient’s deterioration and death. These 4 cases include 2 hypotensive reactions, 1 classified as a febrile reaction with other symptoms or signs and one angioedema or venous obstruction. This year there were 9 cases of major morbidity either because patients suffered cardio-respiratory arrest, or because they needed admission to intensive care because of the new symptoms.

Reporting of ATR and its management is very variable across the UK and between different hospitals and trusts. All adverse transfusion reactions that are of sufficient severity to warrant stopping the transfusion should be investigated appropriately and reported.

### Haemolytic transfusion reaction (HTR)

There were 55 cases of haemolytic transfusion reaction reviewed this year, 9 acute and 46 delayed. This is an increase of 139% compared to last year’s 23 cases. There were no deaths caused, or contributed to, by acute reactions but there were 2 cases of major morbidity. There was 1 death in the delayed reaction group in which the reaction (imputability 2) possibly contributed to death, and there were 4 cases of major morbidity.

Group O platelets, even when labelled as negative for high-titre haemolysins, are still implicated in AHTR, and great care must be taken to weigh up all risks when selecting platelets, especially where children are concerned.
Transfusion-related acute lung injury (TRALI)
Seventeen cases were reviewed: 8 were assessed as being unlikely to be TRALI (imputability 0), 3 were possible TRALI (imputability 1), 2 were probable TRALI (imputability 2) and 4 were highly likely to be TRALI (imputability 2/3). Six of the 17 cases were late reports of incidents which occurred in 2007. No deaths occurred as a result of TRALI this year.

Observed rates of TRALI remain lower than in 2003–2004, when TRALI risk-reduction strategies were first initiated. It should be noted that 3 cases of proven TRALI from FFP occurred due to FFP from female donors in the English NBS.

Post-transfusion purpura (PTP)
There was 1 proven case involving a female whose HPA genotype was HPA-1b1b, and she had HPA-1a alloantibodies. She was treated with intravenous immunoglobulin (IVig) and made a full clinical recovery. The decrease in the frequency of this complication has again been sustained since universal leucodepletion commenced in 1999.

Transfusion-associated graft-versus-host disease (TA-GvHD)
No new case of TA-GvHD was reported in 2008. There has been a negligible incidence of this complication since universal leucodepletion was introduced in 1999.

Transfusion-transmitted infections (TTI)
During 2008, 33 suspected TTI incidents were reported by blood centres and hospitals throughout the UK. Four incidents were confirmed as bacterial TTIs, involving transfusion to 6 recipients. All incidents related to platelet transfusion, and these resulted in one fatality directly caused by the transfusion, one fatality in which the transfusion was implicated, and one case of major morbidity. One further bacterial report remained undetermined (i.e. it was not possible to confirm or refute that the infection was acquired via blood transfusion). In an additional 2 incidents it was not possible to confirm or refute TTI because the blood unit was not investigated.

Serious complications from bacterial contamination of blood components remains a challenge for the UK blood services.

Transfusion-associated circulatory overload (TACO)
This is a new category for 2008. Eighteen cases were reviewed of which 6 were assessed to be highly likely (imputability 3), 8 probable (imputability 2), and 4 possible (imputability 1). TACO appears to be a significant cause of transfusion-related major morbidity and mortality, which is potentially preventable in many cases. In this relatively small series (n = 18) there was 1 death where TACO was probably contributory (imputability 2); 6/18 patients (approximately 33%) required ITU admission / ventilation / CPAP; and in 4/18 cases (approximately 22%) the reporter assessed the reaction as life threatening.

TACO is a serious complication of transfusion and is commonly reported to haemovigilance systems in Europe and Canada. As TACO is a new reporting category for SHOT, it is anticipated that the number of reports will increase.

Transfusion-associated dyspnoea (TAD)
A single case originally reported as transfusion-associated circulatory overload (TACO) was, on review, thought to be more accurately described as TAD. It involved a female patient whose reaction following transfusion necessitated admission to ITU for CPAP. She remained in ITU for 1 week and was discharged from hospital 2 weeks later. The case met the criteria for neither TACO nor TRALI, nor did it have classical features of an allergic reaction; it was therefore categorised as a probable case of TAD.

Autologous transfusion
The intraoperative and postoperative Cell Salvage Adverse Events Pilot was a joint initiative between the UK Cell Salvage Action Group and SHOT. While cell salvage techniques are very safe when used by trained and competent staff, to date there has been no systematic collection of adverse incidents data. In all, 28 questionnaires were received and reviewed. There were 5 cases of hypotensive reaction related to intraoperative cell salvage. There was no mortality or major morbidity.

Monitoring of patients receiving autologous transfusion is as important as it is for those receiving allogeneic transfusion. SHOT will continue data collection for adverse events related to cell salvage and all other forms of autologous transfusion.
Paediatric cases
In 2008, 92 of the total 1040 reports (8.8%) involved patients who were less than 18 years old. Furthermore, 74/1040 (7.1%) involved children less than 16 years old, 31/1040 (3.0%) involved infants less than a year old, and 20/1040 (1.9%) involved neonates who were 4 weeks old or less. The overall number of reports has increased compared to previous years, particularly in the older age groups, but when compared with the summary data from the first 9 years of SHOT and the paediatric chapters in 2003 and 2007, the percentage of paediatric cases in 2008 is lower. However, there are not sufficient data from consecutive years to draw clear conclusions from these trends.

Paediatric transfusion is an area with many specific considerations relating to the age, size and disease spectrum of this group of patients, and input from specialists in paediatric transfusion medicine is required.

Near Miss reporting
SHOT has been running a Near Miss pilot exercise in 2008–09 looking at errors associated with transfusion samples, with the aim of obtaining up-to-date denominator data against which to benchmark other transfusion errors. The proportion of all sample errors attributable to medical staff appears disproportionately high.

The development of the new SHOT database later this year should facilitate the reporting and analysis of the whole range of Near Miss events, including WBIT errors, component selection and handling errors, and collection and pre-administration errors.

RECOMMENDATIONS
This year’s SHOT Report has highlighted the differences between different hospitals, trusts, regions and countries in the way that certain parts of the transfusion process are carried out, in particular regarding the use of local or regional protocols and SOPs and the standards used and expected within these. Of SHOT’s six recommendations this year, the first three major recommendations relate to the standardisation of practice across the UK in haemovigilance participation, laboratory IT systems and competency assessment.

1. **Awareness of criteria for reporting adverse events and reactions**
   Reporting organisations should ensure that all members of the hospital transfusion team and the broader staff involved in the transfusion process are fully aware of the criteria for reporting adverse events and reactions to SHOT (and MHRA) including the reporting of cell salvage and Near Miss events. Details of what to report and how to report it are readily available on the SHOT and MHRA/SABRE websites as well as in the Annual SHOT Report. This process would be aided by a position statement on the requirements for haemovigilance in the UK. SHOT and MHRA will provide information and support for hospitals and trusts to achieve this.

   **Action:** HTTs

2. **A national specification for transfusion laboratory IT systems**
   A national specification for transfusion laboratory IT systems should be developed defining minimum standards, which should be met by all hospital transfusion laboratories participating in any way in pre-transfusion testing or issuing of blood components for transfusion. The national transfusion committees should lead this initiative in collaboration with the UK Transfusion Laboratory Collaborative, BCSH and BBTS. Liaison with software developers is essential to enable safety initiatives to be effectively incorporated into existing systems.

   **Action:** NBTC and equivalents in Scotland, Wales and Northern Ireland
   Developers of software for laboratory IT systems

3. **Competency assessment and standardised, transferable competency certification of all staff involved in transfusion**
   Hospitals and Trusts are in the process of rolling out competency assessments for all staff involved in the transfusion process as a result of the NPSA recommendation (SPN 14) and the MHRA requirements for laboratory competencies. Comprehensive competency frameworks have been developed by NPSA which are used within trusts as a basis for local training and competency assessments. However a standard, nationally transferable, checklist of minimum requirements for certification of competency for staff involved in transfusion needs to be developed, agreed and disseminated. The NPSA should initiate this project in collaboration with relevant stakeholders.

   **Action:** NPSA
Three further recommendations relate to the process of the administration of blood to patients. The first of these involves the inappropriate use of the compatibility form for the bedside checking of blood component and patient identification, which resulted in 18 cases of wrong blood administration in 2008. The second relates to the timing of routine monitoring observations of patients undergoing transfusion: throughout this report it is clear that many transfusion reactions occur later than 15 minutes after the start of a blood component transfusion, and sometimes many hours later. A third recommendation is more generic, relating to the need for a more supportive culture of teamwork in the clinical practice of medicine, including transfusion medicine. The NPSA initiative (Seven Steps to Patient Safety) is a helpful guide for trusts in their development of a supportive culture of safe working aimed at NHS staff in all health care settings (www.npsa.nhs.uk/sevensteps).

4. **Discontinue use of the compatibility form for checking patient identification**
   The compatibility form issued from the transfusion laboratory computer system (at the time of printing the blood component labels) should be discontinued except in hospitals where it is an integral part of the traceability record for the component in question.

   **Action:** HTTs

5. **Ensure adequate observation of patients receiving transfusion**
   Guidelines for blood administration must include a requirement that observations are done at baseline, throughout the transfusion of blood components and regularly during the subsequent 24 hour period, in order that serious transfusion reactions are identified immediately and not missed. Patients having day case transfusions should be advised to contact the clinical team if late reactions occur, and they should be given a ‘contact card’ with access to 24 hour clinical advice.

   **Action:** BCSH

6. **Develop a supportive culture for hospital staff involved in transfusion**
   Doctors, nurses, midwives, biomedical scientists and other staff should be encouraged to ask for help and clarification when they recognise that their own knowledge and skills are inadequate for the situation in which they find themselves. Failure to do so could be deemed negligent if an incident occurred. A culture of supportive, friendly surveillance and teamwork needs to be encouraged and nurtured in all clinical and laboratory areas, and any lessons learned must be shared with the relevant governance and risk management groups and users.

   **Action:** Trust directors of clinical governance and risk management

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