Summary of **ANNUAL REPORT 2005**

Standing Working Group
Stainsby D*, Jones H*, Cohen H*, Asher D*, Atterbury C*, Boncinelli A*, Brant L*, Chaffe W, Chapman C E*, Davison K, Gerrard R, Gray A, Knowles S*, Milkins C*, Norfolk D R*, Taylor C * Writing Group members

Introduction

There are some encouraging messages to be found in this year's SHOT report. The number of ABO incompatible transfusions has fallen from 19 in 2004 to 10 in 2005, an all-time low and a 54% reduction since 2001/2002. The collaborative project between SHOT, the Chief Medical Officer's National Blood Transfusion Committee (NBTC) and the National Patient Safety Agency (NPSA), aimed at reducing blood administration errors, promises to consolidate this improvement by ensuring the competency of all staff involved in blood transfusion, emphasising the importance of the final patient identification check, and making progress towards a structured national approach to the use of IT in blood transfusion.

This report also documents the reduction in cases of immune-mediated Transfusion-Related Acute Lung Injury (TRALI) following implementation by the UK Blood Services of a policy of using male donors, as far as possible, for fresh frozen plasma (FFP) and the plasma contribution to platelet pools.

The focus of SHOT in recent years has been on improving the safety of blood administration at the bedside. However, errors in hospital transfusion laboratories occurred in 37% of incorrect blood component transfused (IBCT) cases reported in 2005. SHOT is collaborating in a forthcoming initiative, led by the Institute of Biomedical Science (IBMS) and involving other relevant professional bodies, aimed at reducing errors by improving standards in laboratories. This will be launched at a stakeholder workshop in March 2007.

The importance of information from near miss events is well recognised, and SHOT will be reintroducing near miss reporting in 2007, with the intention of improving the quality of information gained from these events.

The UK Blood Safety and Quality Regulations (2005) have had a major impact on hospital transfusion laboratories and also on SHOT, presenting challenges and also opportunities to drive improvements. Discussions are ongoing between SHOT, The Medicines and Healthcare products Regulatory Agency (MHRA), the UK Blood Services, National Blood Transfusion Committees and the Department of Health, to clarify the respective roles and responsibilities of SHOT and MHRA. It is essential that a structure is established that enables UK haemovigilance to flourish and the UK's international recognition in this field to be preserved.

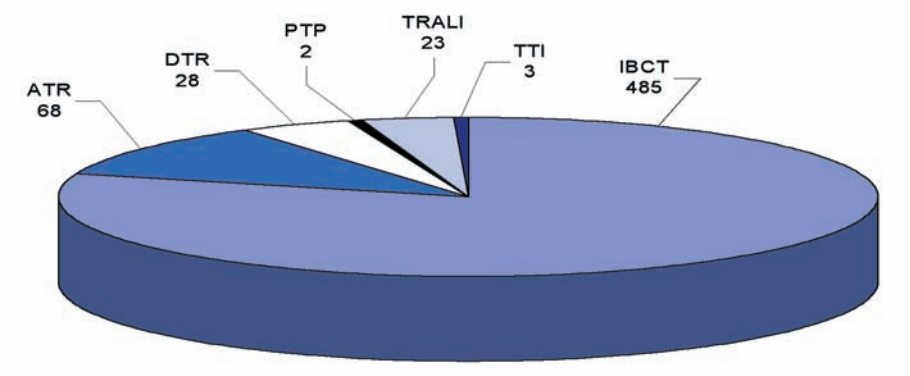
Participation

Two hundred and seventy-nine of 403 eligible hospitals in the UK submitted at least one appropriate report, or near miss, giving an overall participation rate of 69%. Of the 124 non-reporting hospitals, 1 is a high red cell user by the Blood Stocks Management Scheme criteria (i.e. >11,000 units p.a.) and 7 are moderate users (6,000 to 11,000 units) although 2 of these are bordering on the high category. Sixty-seven hospitals are low users (<6,000 units p.a.). No data were available for the remaining 49 non-reporting hospitals most of which receive their stocks via other hospitals. Feedback on participation will be provided to individual hospitals.

Total events reported

The 2005 report includes data from 609 cases, (see figure 1) including 3 transfusion transmitted infection (TTI) reports received from the NBS/Health Protection Agency Centre for Infections Surveillance (NBS/HPA CIS). A further report of probable variant Creutzfeldt Jakob disease (vCJD) transmission has also been included.

Fig 1 – Breakdown of reports received in 2005 (n=609)



Transfusion related mortality

There were 5 transfusion related deaths. In 1 case involving an ABO incompatible red cell transfusion (case 1, chapter 5 of the full report) there was certain and conclusive evidence that death was related to transfusion (imputability 3). In another, caused by an anaphylactic reaction to FFP (case 10, chapter 7), the evidence was clearly in favour (imputability 2). In 2 patients, death was possibly due to TRALI (cases 7 and 13 in the TRALI tables available on the SHOT website www.shot-uk.org) and 1 patient (case 17, chapter 5) died possibly related to overtransfusion (all 3, imputability 1).

Incorrect blood component transfused ('wrong blood') incidents

Four hundred and eighty-five reports were analysed, of which 481 (99%) were 'no-harm' events in which the patient suffered minor or no morbidity. These reports were analysed in 7 sub-groups, summarised in Table 1.

Table 1 – Types of events

Type of event	Number (%)
'Wrong blood' events where a patient received a blood component intended for a different patient or of an incorrect group.	87 (18%)
Other pre-transfusion testing errors – including incorrect D groups, missed allo-antibodies and missed serological incompatibility	22 (4.5%)
Blood of the incorrect group given to recipients of ABO mismatched PBSC or bone marrow transplant.	2 (0.5%)
Failure to provide blood of appropriate specification or that did not meet the patient's special requirements	141 (29%)
Inappropriate or unnecessary transfusions	67 (14%)
'Unsafe' transfusion where there were handling or storage errors	79 (16%)
Events relating to administration of anti-D immunoglobulin	87 (18%)
Total	**485**

In each sub-group, the contribution of errors in clinical areas and in laboratories was assessed. In 50/87 (57%) 'wrong blood' cases, in which 115 separate errors were identified, the pre-transfusion checking procedure was carried out incorrectly or omitted altogether.

Hospital transfusion laboratory errors occurred in 180/485 (37%) of all cases.

There were 169 IBCT reports in which an incorrect blood component was transfused due to a bedside administration error and the time of transfusion was known. Thirty-seven percent of these took place between 2000 hours and 0800 hours. These data were compared with an observational study on the time and location of blood transfusion carried out in 28 hospitals in the Northern and Yorkshire regions in September 2005. (H Tinegate, C Thompson, unpublished data), which found that 28.5% of red cell units were transfused between 2000 hours and 0800 hours, indicating that blood transfusions outside of core hours are inherently less safe.

Near miss events

SHOT defines 'near miss' as 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 recognised before transfusion took place. 1358 near miss incidents were reported during 2005, an increase of 26% compared to 2004. A further 204 reports were reported as error logs from 3 hospitals. As in previous years, patient mis-identification at the blood sampling stage resulting in 'wrong blood in tube' was the most frequently reported event, accounting for 574/1358 (42.2%) of reports.

Transfusion related acute lung injury

Twenty-three case reports of suspected TRALI were analysed in 2005, of which 6 were considered highly likely or probable (imputability 2-3) and the diagnosis was supported by the finding of a relevant antibody in the donor. In none of these 6 cases was FFP the implicated component. Three were related to platelets (1 pool and 2 apheresis), 2 to red cells and 1 to cryoprecipitate. In all 6 cases the donor of the implicated component was female.

Other immune reactions

There were 69 analysable reports of acute transfusion reactions of which 5 were haemolytic, 24 anaphylactic, 28 severe allergic, 7 hypotensive or unclassifiable and 3 febrile. Twenty-three reactions were due to red cells, 24 to FFP and 19 to platelets. It is of particular concern that, in 8/24 (33%) of the adverse reactions to FFP, including one fatality and 2 cases of serious morbidity, there did not appear to be a clear clinical indication for FFP use.

Twenty-eight delayed haemolytic transfusion reactions were analysed. Six patients were asymptomatic and 22 had evidence of increased red cell destruction but without renal impairment.

There were 2 reports of post-transfusion purpura and no reported case of transfusion-associated graft-versus-host disease.

Transfusion transmitted infections

Forty-six reports of suspected transfusion transmitted infections were made from blood centres throughout the UK (41 in England and Wales and 5 in Scotland) to the NBS/HPA CIS during 2005. Three reports, 1 of hepatitis B (HBV) transmission and 2 cases of bacterial contamination of platelets, were confirmed as TTIs. In addition there were 2 reports of predicted hepatitis A (HAV) transmission. A further report was received from the Health Protection Agency of a clinical diagnosis of vCJD in a blood transfusion recipient.

SHOT RECOMMENDATIONS 2005

Formulation of these recommendations has included consultation with stakeholders, in response to feedback last year from the National Blood Transfusion Committee. This consultation process will be further developed in the future and it is hoped that it will strengthen support for the recommendations and ensure implementation. Specific recommendations relevant to individual chapters and learning points from IBCT events can be found in the main report and on the website, and will also be included in educational material aimed at specific professional groups, which will be developed and distributed during the year.

Recommendations made in previous reports remain active, and progress against these is summarised in Chapter 3 of the full report. In particular, SHOT continues to support a nationally co-ordinated initiative to evaluate information technology, and the establishment of an over-arching body to prioritise transfusion safety initiatives.

The ultimate responsibility for implementation of SHOT recommendations in hospitals lies with their respective Chief Executive Officers (CEOs). However, the day-to-day responsibility is likely to be delegated to the consultant haematologist with responsibility for transfusion, together with the Hospital Transfusion Committee (HTC) and Hospital Transfusion Team (HTT). The introduction of transfusion practitioners and multidisciplinary HTTs with adequate staffing and support underpins hospital transfusion safety. It is essential that transfusion safety is maintained as hospitals reprofile clinical services in response to financial and other organisational pressures.

1 **'Right patient – right blood':** This joint initiative between the NPSA, SHOT and the NBTC aims to reduce the risk of ABO incompatible transfusions by improving the safety of blood administration. Hospitals must act on the Safer Practice Notice 'Right patient – right blood' within the required timescale. A crucial element of this initiative, also required by the Blood Safety and Quality Regulations 2005, is competency-based training, which must be implemented for all staff involved in the blood transfusion process. It is essential that hospital CEOs recognise that this is a necessary and ongoing process and will add to the workload of the HTT.

Action: Hospital CEOs

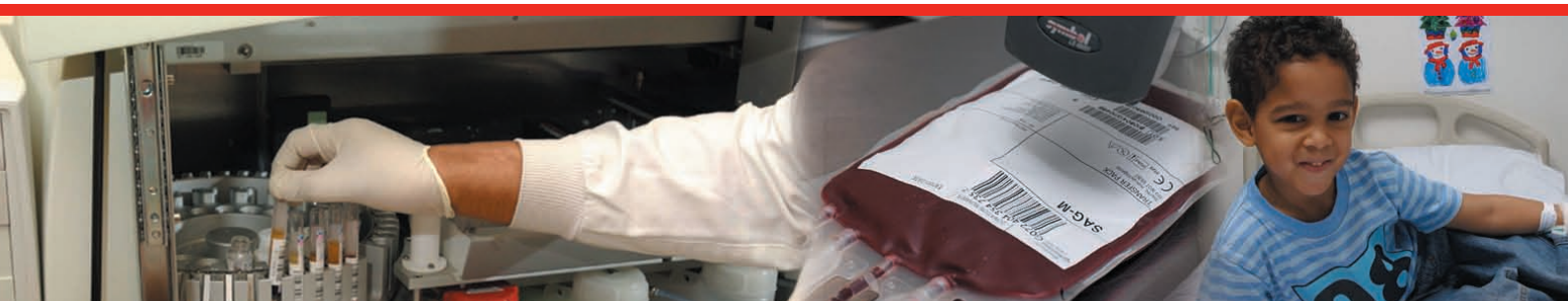
2 **Appropriate use of blood components:** Considerable progress has been made in limiting unnecessary transfusion of red cells, but the use of FFP and platelets continues to rise. Acute transfusion reactions are more frequent following transfusion of plasma-rich components than red cells and this year in 8/24 (33%) of severe allergic or anaphylactic reactions to FFP, including one fatality and 2 cases of serious morbidity, there did not appear to be a clear clinical indication for FFP use.

Current national British Committee for Standards in Haematology (BCSH) guidelines on the appropriate use of FFP and platelets should be incorporated into local protocols that are readily available in relevant clinical and laboratory areas, included in induction and update training and subject to clinical audit.

Action: Consultant haematologists with responsibility for transfusion together with the HTC and HTT.

3 **Better laboratory practice:** Hospital laboratory errors occurred in 37% of all IBCT reports. An initiative aimed at improving practice in hospital transfusion laboratories is under way, led by the IBMS. In the meantime, local quality improvements must be supported and resources provided to underpin the development of quality systems. It is essential that the quality and responsiveness of hospital transfusion laboratories is maintained as Pathology Services in England face major reorganisation following the Carter Report, with the possible development of independent Pathology Trusts and diversification of providers of pathology services.

Action: Hospital CEOs



4 **Avoid blood transfusions outside of core hours:** Available data indicate that blood administration and pre-transfusion testing outside of core hours are less safe and should be avoided unless clinically essential. Hospitals planning to move to '24/7' working must employ adequate numbers of appropriately skilled clinical and laboratory staff to ensure transfusion safety. It may be useful to audit the occurrence of patient safety incidents in hospitals during different time periods.

Action: Hospital CEOs, consultant haematologists with responsibility for transfusion together with HTCs and HTTs.

5 **Investigation of serious transfusion reactions:** All serious transfusion reactions must be fully investigated. An update of BCSH guidelines is in progress.

Action: Consultant haematologists with responsibility for transfusion should implement current best practice

6 **Communication of complex transfusion requirements:** Failure to communicate special transfusion requirements is an important contributory factor in many cases of IBCT. Effective mechanisms must be developed for communication of information on complex transfusion requirements (e.g. for patients requiring irradiated components, those with allo-antibodies, stem-cell transplant recipients). The involvement of pharmacists in flagging prescription of purine analogues is helpful in ensuring provision of irradiated components. Patient awareness and empowerment should be encouraged. Organisations should work together to implement and, where necessary, develop appropriate tools (e.g. documentation for patients transferred between hospitals, patient held booklets, standard antibody cards with accompanying advice).

Action: UK National and Regional Blood Transfusion Committees to facilitate and co-ordinate, Hospital CEOs to implement.

7 **Increase safety of routine antenatal anti-D prophylaxis:** Reports of errors relating to anti-D immunoglobulin (Ig) administration are increasing, and 2 cases were reported in 2005 in which misinterpretation of the antenatal antibody investigation resulted in severe haemolytic disease of the fetus. Implementation of routine antenatal anti-D prophylaxis must be supported by education of primary care clinicians and hospital laboratory staff. Current legislation surrounding the issue and prescription of anti-D Ig requires clarification and is a potential source of system error. National guidelines on antenatal testing must be incorporated into agreed local policies and subject to clinical audit.

Action: Royal Colleges of Midwives, General Practitioners, Obstetricians and Gynaecologists. Consultant haematologists, HTCs and HTTs.

8 **Further measures by the blood services to reduce TRALI and bacterial contamination:** Measures implemented thus far appear to have reduced the risks of TRALI and bacterial contamination of platelets. Further measures require evaluation including the implications for availability and efficacy of blood components as well as cost-effectiveness.

Action: UK Blood Services, Department of Health (DH) advisory mechanisms

Recommendations for future developments

1 **Blood transfusion outside the hospital setting:** Against the background of a trend towards provision of care closer to the patient, there is a need for a standard of practice to be developed for transfusion in the community setting, including provision for appropriate management and reporting of adverse events

Action: UK National Blood Transfusion Committees to facilitate and co-ordinate.

2 **Need for clinical studies:** There is a paucity of good quality randomised studies from which to develop evidence-based transfusion practice. Well designed clinical studies should be undertaken to answer some of the questions that arise in clinical practice, including the optimal methods of patient identification, systems organisation and appropriate blood product support in different clinical settings. This will require action from clinical researchers, statistical & analytical support and assistance from funding bodies.

Action: UK National Blood Transfusion Committees, UK Blood Services, Funding bodies e.g. Health Technology Assessment and National Institute for Healthcare Research

3 **Future development of haemovigilance:** The implementation of the Blood Safety and Quality Regulations provides a unique opportunity to develop and re-enforce haemovigilance in the UK. It is essential that a structure is established that enables UK haemovigilance to flourish and to maintain its international recognition.

Action: DH, UK Blood Services, UK National Blood Transfusion Committees.

An electronic copy of the full report is available on the SHOT website (see below) or can be obtained in hard copy from the SHOT office.

SHOT office:
Manchester Blood Centre
Plymouth Grove,
Manchester,
M13 9LL

Tel: +44 (0) 161 251 4208
Fax: +44 (0) 161 251 4395

Email: shot@nbs.nhs.uk

Website: http://www.shot-uk.org

Steering Group Chair:
Dr. H. Cohen
Email: hannah.cohen@uclh.nhs.uk

National Co-ordinators:
Dr. D. Stainsby
Email: dorothy.stainsby@nbs.nhs.uk
Ms. K. Davison
Email: Katy.Davison@HPA.org.uk

Scheme Manager:
Mrs. H. Jones
Email: hilary.jones@nbs.nhs.uk

Printed on 55% recycled paper