SERIOUS HAZARDS OF TRANSFUSION SHOT

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ANNUAL REPORT 2006
SUMMARY

Introduction and summary of current position

The year since the publication of the last SHOT Annual Report has been one of considerable and significant change in the field of haemovigilance in the UK and Europe. This has particularly resulted from the impact of the European Directives on Blood Safety and the Blood Safety and Quality Regulations (BSQR) in the UK.

- SHOT remains an international 'gold standard' in haemovigilance, plays a key role at a national and international level in new developments in the field, and continues to be consulted by other countries as they set up their own haemovigilance systems.
- SHOT continues to collect and analyse adverse incident data extending beyond the statutory requirements of the BSQR (particularly clinical adverse incidents). Additional reporting categories are in development (see page 8), providing a comprehensive, professionally led haemovigilance system to improve practice and patient safety.
- SHOT works closely with the Competent Authority, MHRA (Medicines and Healthcare products Regulatory Agency), co-operating over the SABRE web-based reporting system which collects data both for MHRA and for SHOT, and through the Blood Consultative Committee of MHRA and its Adverse Events subgroup. This collaboration enables a united haemovigilance system encompassing both the legislative and the professional aspects of haemovigilance in the UK.

Key Findings in 2006

- There has been a 13% reduction in the number of reports in existing SHOT categories in 2006 compared with 2005. However, overall there has been an increase in the number of adverse incidents reported to SHOT via SABRE. SHOT reporting categories and definitions have been reiterated in the full SHOT report, with advice on what to report.
- ABO incompatible transfusions are again lower than ever previously recorded, with 8 cases reported in 2006, an improvement which may continue with the introduction of competency assessment in transfusion, as recommended by the NPSA (National Patient Safety Agency) safer practice notice 14.
- Errors involving medical staff are prominent in this report, with 2 fatalities and 123 further cases in which there was a junior doctor error in requesting and/or prescribing blood (including 79 cases where special requirements were not met, and 46 where transfusion was inappropriate).
- In recent years an increasing proportion of IBCT (incorrect blood component transfused) errors have arisen in hospital laboratories, with a disproportionate number occurring outside traditional core hours. The National Transfusion Laboratory Collaborative is addressing this issue.

Overview of 2006 report

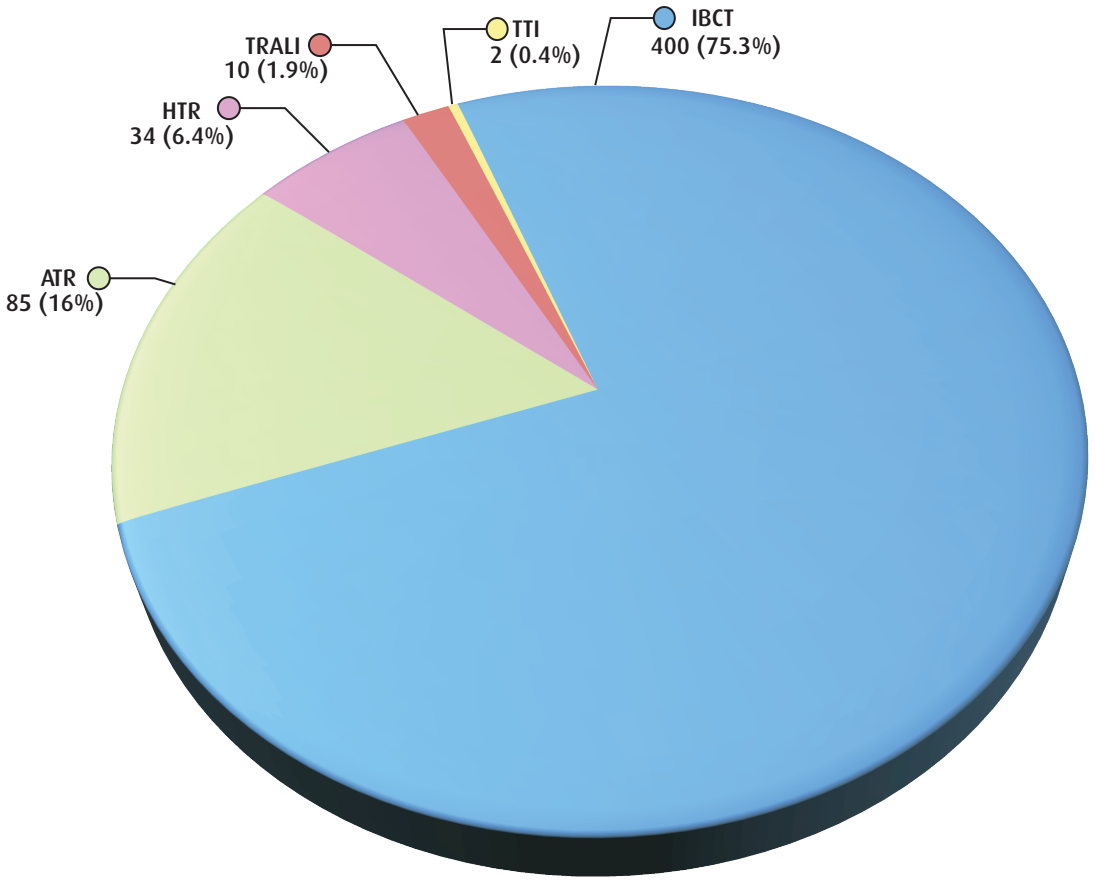
This year's report analyses data collected between 1st January 2006 and 31st December 2006

Participation

SHOT reports for 2006 have all been received via the new SABRE web-based reporting system. There are 311 registered reporters to SABRE and there are no known hospitals or Trusts which have not registered. There are a handful of registered (i.e. participating) SABRE reporters who did not send reports to MHRA through SABRE in 2006. 870 reports were submitted to SABRE during 2006, and all relevant reports have been shared with SHOT. In addition there were 567 SHOT only reports. Full reconciliation of participation and reporting rates for SHOT and MHRA reports has not yet been possible, but it is clear that mandatory reporting via SABRE has increased overall participation in haemovigilance in the UK. However, the number of reports submitted in SHOT categories and analysed for the report has decreased from 609 in 2005 to 531 in 2006.

Summary of reports analysed – breakdown of report categories and proportional view

IBCT	ATR	HTR	PTP	TA-GvHD	TRALI	TTI	Totals
400	85	34	0	0	10	2	531



Summary of 2006 report

Transfusion-related mortality

There were 4 deaths definitely attributable to transfusion reported to SHOT in 2006. Two occurred as a result of incorrect prescribing, in both cases by junior hospital doctors, and these are reported in the IBCT chapter in the main report. The first involves lack of precision, and probably knowledge, of component prescriptions for a baby; the second involves a lack of clinical evaluation of a patient with an alleged Hb of 3.9 g/dL. On account of these cases and the large number of reports in which junior hospital doctors contributed to or caused an adverse event, medical education is the theme of the key message and main recommendations this year. There was 1 death from transfusion of platelets contaminated with *Klebsiella pneumoniae* and 1 death from TRALI (with imputability 2).

Incorrect blood component transfused

There were 400 events analysed for 2006 which represents a decrease of 17% since last year. More direct comparison allowing for the decrease in component usage during the reporting period, and excluding anti-D reports, shows 10.6 reports per 100,000 components transfused in 2006, compared with 12.8 in 2005.

The cases were separated into 7 subcategories as shown below in table 5. In each category the proportion of errors occurring in the hospital transfusion laboratory was calculated: 46% of wrong blood events originated in the laboratory, and 35% of all IBCT.

Types of IBCT 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	54 (14%)
Other pre-transfusion testing errors (excluding erroneous Hb)	28 (7%)
Blood of the incorrect group given to recipients of ABO or D mismatched PBSC, bone marrow or solid organ transplant	8 (2%)
Transfusion of blood of inappropriate specification or that did not meet the patient's special requirements	108 (27%)
Inappropriate or unnecessary transfusions	51 (13%)
'Unsafe' transfusion where there were handling or storage errors	74 (19%)
Events relating to administration of anti-D immunoglobulin	77 (19%)
Total	**400**

An infant died after rapid transfusion of an inappropriately large volume of platelets, and an elderly woman died after a high-volume rapid transfusion based on an erroneous Hb. On further analysis a total of 125 cases, including the two deaths, were found to involve errors made by junior hospital doctors.

There were no deaths related to ABO incompatible transfusion, but two patients suffered major morbidity.

Near Miss events

The SABRE web-reporting system was not used in 2006 to collect these data. Near Miss events were collected by the completion of a survey spreadsheet over a 7 month period. A total of 126 participants returned spreadsheets giving data obtained from 136 hospitals (34.3% return). There was a total of 2,702 events of which 1,342 (49.6%) related to sampling.

Transfusion-related acute lung injury

Twelve case reports of suspected TRALI were received in this reporting year, of which 2 were subsequently withdrawn. Of the 10 cases analysed, 2 patients died (imputabilities 2 and 0), 7 suffered short-term major morbidity with full recovery and 1 had long-term morbidity. There were no cases this year related to warfarin reversal. Relevant donor leucocyte antibodies (i.e. donor HLA or granulocyte antibody corresponding with patient antigen) were found in 3 of 7 complete case investigations this year. The reduction in TRALI this year, with the lowest reported mortality since SHOT began reporting in 1996, is likely to be related to the decision made by UK Transfusion Services to change to preferential use of male plasma.

Other immune complications

There were 85 reported cases of acute transfusion reactions (ATR), a 25% increase on 2005, which may be due to the requirement to report all transfusion reactions under the new legislation of the BSQR. These cases consisted of: 20 isolated febrile, 10 minor allergic, 41 anaphylactoid/anaphylactic/severe allergic, 8 febrile with other symptoms, 3 transfusion-associated circulatory overload (TACO) and 3 hypotension. There were no deaths, but 4 cases of major morbidity.

Thirty-four haemolytic transfusion reactions (HTR) were reported, 11 acute and 23 delayed. There was 1 death in the acute group probably unrelated to the transfusion reaction, and 2 cases of haemolysis related to incompatible platelet transfusion. There were no reports of mortality or major morbidity in the delayed group.

In 2006 there were no cases of post-transfusion purpura (PTP), transfusion-associated graft-versus-host disease (TA-GvHD) or events associated with autologous blood transfusion.

Transfusion-Transmitted Infections

During the reporting year, 29 reports of suspected transfusion-transmitted infection were made from throughout the UK to the NBS/HPA Centre for Infection Surveillance. Two reports were deemed to be TTI, both cases due to bacterial contamination of platelets. A report was received in early 2007 of vCJD in a recipient of blood transfusion. This is the fourth case, and involves the same donor as the third case reported in the 2005 SHOT report.

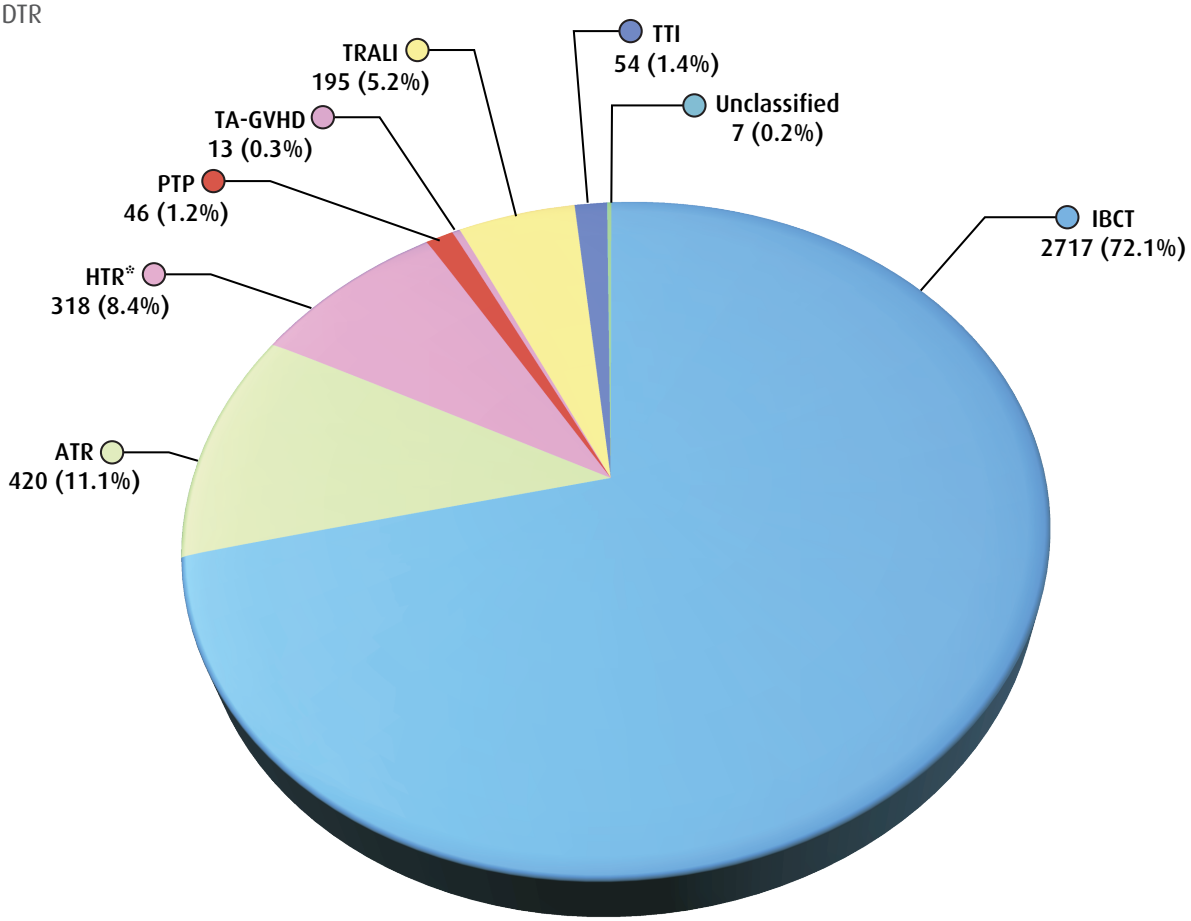
Numbers of components issued

Total issues of blood components from the Transfusion Services of the UK in the financial year 2005/2006

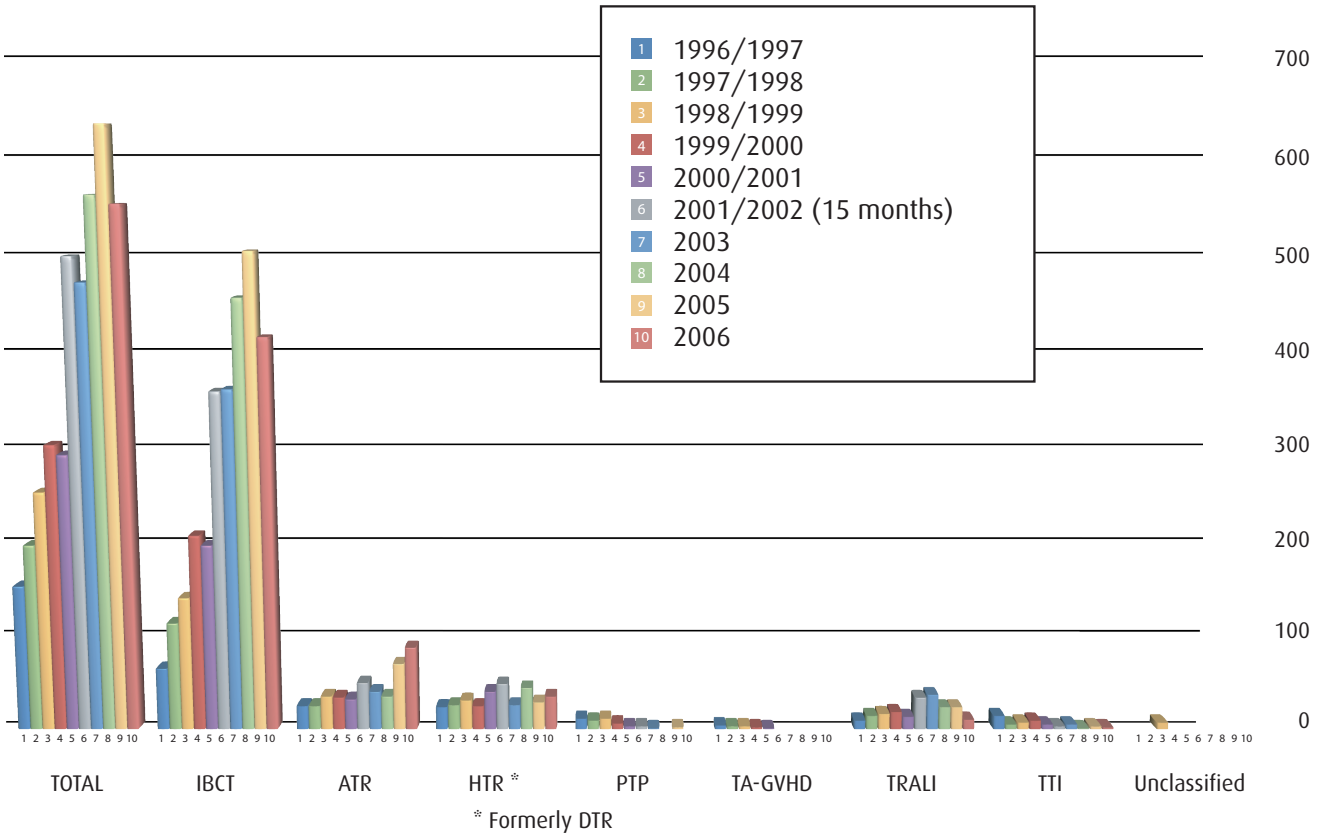
Red cells	2,316,152
Platelets	259,654
Fresh frozen plasma	320,852
Cryoprecipitate	106,139
TOTAL	3,002,797

Cumulative data 1996-2006

Numbers of cases reviewed (n=3770)
* Formerly DTR



Comparison of report types 1996 – 2006



	Total	IBCT	ATR	HTR*	PTP	TA-GVHD	TRALI	TTI
Death definitely attributed to transfusion (imputability 3)	47	7	2	6	1	13	8	10
Death probably attributed to transfusion (imputability 2)	15	4	4	1	0	0	6	0
Death possibly attributed to transfusion (imputability 1)	47	13	7	1	1	0	25	0
Subtotal 1	**109**	**24**	**13**	**8**	**2**	**13**	**39**	**10**
Major morbidity** probably or definitely attributed to transfusion reaction (imputability 2/3)	315	100	17	29	13	0	118	38
Minor or no morbidity as a result of transfusion reaction	3324	2582	387	280	31	0	38	6
Subtotal 2	**3639**	**2682**	**404**	**309**	**44**	**0**	**156**	**44**
Outcome unknown	15	11	3	1	0	0	0	0
TOTAL***	**3763**	**2717**	**420**	**318**	**46**	**13**	**195**	**54**

* Formerly DTR

** Major morbidity is classified as the presence of one or more of the following:

- Intensive care admission and/or ventilation
- Dialysis and/or renal impairment
- Major haemorrhage from transfusion-induced coagulopathy
- Intravascular haemolysis
- Potential risk of D sensitisation in a female of childbearing potential

*** Excludes 7 cases from 1998/99 that were not classified

Recommendations

This year's key recommendations focus on the need for integration of transfusion medicine into the teaching and training curricula for junior hospital doctors, and nursing and scientific staff involved in transfusion. This goes beyond assessment of basic competencies and is recognising the need for solid knowledge and understanding of transfusion therapies so that sound decisions can be made in clinical practice.

As previously, these recommendations have been made after consultation with stakeholders to ensure support for their implementation. The final responsibility for ensuring action in relation to hospital-based recommendations lies with Trust Chief Executive Officers (CEOs), though the day-to-day responsibility may be delegated to members of the Hospital Transfusion Team (HTT).

The recommendations this year appear in three sections of the full SHOT report:

- SHOT Recommendations of the Year
- Active recommendations from previous years: update
- Specific recommendations relevant to each reporting category

SHOT Recommendations of the Year

1. **Inclusion of transfusion medicine in core curriculum for junior doctors:** In this SHOT report there are two fatalities arising from incorrect decision making when prescribing components. In addition there are numerous cases of inappropriate transfusion and incorrect specifications of blood components given. As recommended in the 2002 report, it is imperative that the curricula of junior doctors in training in all hospital-based specialties include transfusion medicine. This must go beyond safe practice in patient ID and blood administration, and include core knowledge, clinical assessment and decision making when considering transfusion therapy. This cannot be delivered by competency testing alone, but requires that transfusion medicine is integrated into training in relevant specialties. A sufficient number of subspecialty trained transfusion consultants must be maintained to lead on education and training.

   Action: NBTC, JRCPTB (Joint Royal Colleges of Physicians Training Board), Royal Colleges of Physicians, Paediatrics, Pathologists, Anaesthetists, Surgeons, Obstetricians and Gynaecologists, the Academy Postgraduate Education Committee

2. **Specialty accredited laboratory and clinical staff in all hospitals**: In the 2001 report SHOT recommended an ongoing programme of education and training of all staff involved in transfusion and this is reiterated this year. The NPSA safer practice notice 14 requires documented training of all relevant personnel, and competency assessments based around blood sampling, collection and administration practice. This is underway in many hospitals. However, all transfusion practitioners and a quorum of hospital transfusion laboratory staff must be trained to a higher level, and should be encouraged to achieve BBTS certification for laboratory practice or as transfusion practitioners. Hospital transfusion laboratories should ensure that an accredited transfusion specialist is available at all times.

   Action: Hospital CEOs, National Transfusion Laboratory Collaborative, BBT network, RCN, BBTS

3. **Comprehensive reporting to SHOT by all hospitals**: Whilst the number of SHOT reports has increased year-on-year, this year has seen a slight downturn in numbers of reports. This is likely to be the effect of the implementation of the new system for reporting adverse incidents under the Blood Safety and Quality Regulations. However, SHOT reporting, although 'voluntary' in statutory terms, is not voluntary in professional terms, and is a requirement for Clinical Pathology Accreditation (CPA) and the NHS clinical governance framework. Reporting to MHRA does not include the breadth of incident categories or detail of data reportable to SHOT and does not provide analysis and feed back to hospitals on adverse events. The joint SABRE web-based reporting system facilitates reporting to both MHRA and SHOT to fulfil both legislative and professional requirements.

   Action: Hospital CEOs, SHOT, consultants with responsibility for transfusion together with HTC and HTT

New developments in SHOT reporting

TACO

From 2008, reports of Transfusion-Associated Circulatory Overload (TACO) will be collected separately and not as a subset of ATR, where TACO was previously a subcategory. A questionnaire will be specifically designed for this and will be launched in the new reporting year.

Cell salvage

A new sub group has recently started to work with SHOT to develop a reporting questionnaire for adverse incidents relating to cell salvage. There will be further updates on progress with this in the SHOT newsletters.

Inappropriate transfusion

There has been an increased number of reports of inappropriate transfusion this year and these are currently included in the IBCT category. This includes transfusion based on erroneous laboratory results, or to patients without adequate clinical or laboratory indications for transfusion. However, in the future (2008 reporting year) SHOT plans to separate out the inappropriate transfusion adverse events and analyse these separately. Although a small group at present, these incidents are probably under-reported as SHOT has not previously specifically requested this kind of report. Those that have been reported include the two fatalities from the 2006 reporting year, making this a highly significant category for SHOT to develop and analyse to improve patient safety in the future.

Near Miss

In 2008 SHOT plans to pilot Near Miss reporting which will be focused in the first instance entirely on sample errors which do not reach the testing phase in the laboratory. A new questionnaire will be designed and circulated to a cohort of hospitals in time for a reporting pilot in early 2008.

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