

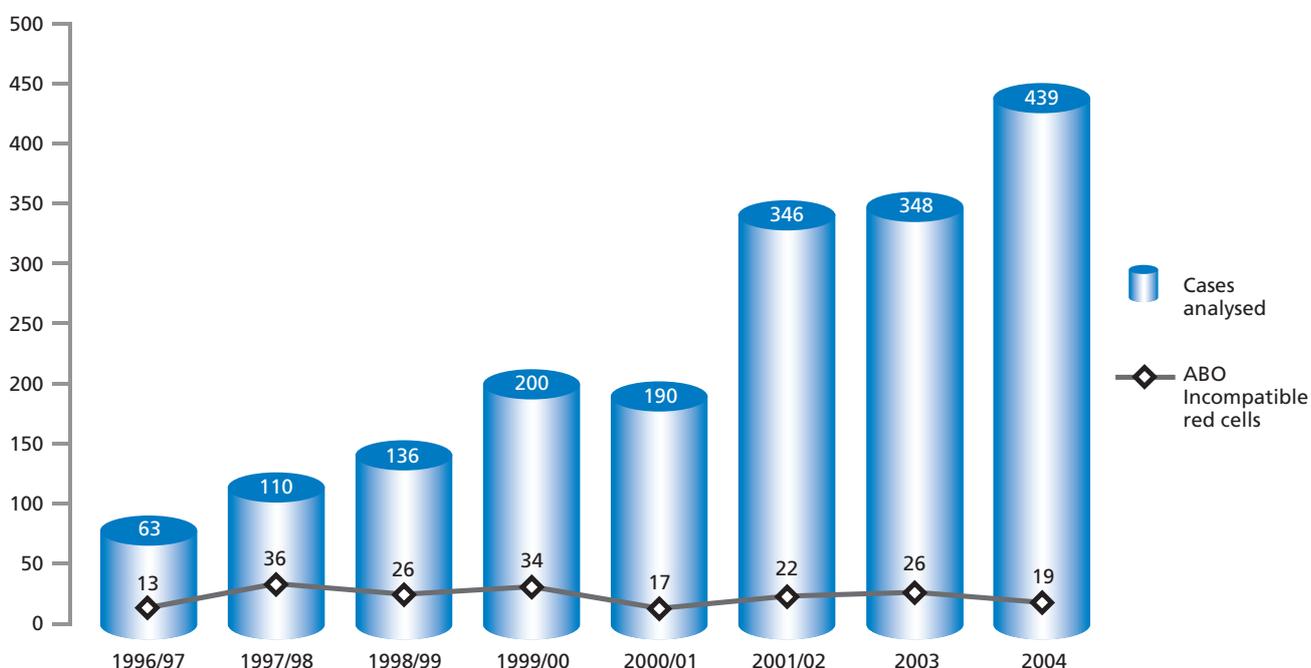
# Summary of ANNUAL REPORT 2004

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## Headline News "Progress in Blood Safety in the UK"



### **Incorrect Blood Components Transfused (IBCT)**

'439 reports were analysed, a further 26% increase from 2003. 428 of these were 'no-harm' events in which the patient suffered minor or no morbidity. In the context of an increase in total reports it is encouraging to note that 2004 saw a further reduction in ABO incompatible transfusions to 23, of which 19 were red cells.'

**Affiliated to the Royal College of Pathologists**

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Health Protection Agency Centre for Infections, Royal College of Anaesthetists, Royal College of Nursing

Royal College of Obstetricians and Gynaecologists, Royal College of Paediatrics and Child Health

Royal College of Physicians, Royal College of Surgeons, The four UK Blood Services

## KEYNOTE MESSAGE: Progress in blood safety in the UK

This year is a momentous one for all involved in the provision of blood transfusion, with the implementation of the European Union (EU) Directive on Blood Safety and Quality. The Directive was incorporated into UK legislation on 8th February 2005 as the Blood Safety and Quality Regulations, and will be implemented on 8th November. It requires that Blood Establishments and Hospital Blood Banks report to the Secretary of State for Health, 'all serious adverse reactions attributable to the safety or quality of blood', and 'all serious adverse events related to the collection, testing, processing, storage and distribution of blood and blood components that may have an influence on their quality and safety'.

The EU Directive does not encompass no harm errors in clinical areas, which account for 70% of Incorrect Blood Components Transfused (IBCT) events. It is therefore vital that hospitals continue to report these events to SHOT in order to preserve the safety culture that we have established in the UK and to provide continuity of data for monitoring of the NPSA/NBTC/SHOT initiative outlined below, and other blood safety initiatives.

2004 saw a further 19% increase in total reports to SHOT over 2003. The percentage of hospitals reporting incidents increased from 47% to 54%, and, when "near misses" are included, the figure rises to 67%. SHOT welcomed the recommendation of the Chief Medical Officer (CMO) for England in his 2003 Annual Report that 'participation in the SHOT scheme should be demonstrably active with reports of adverse events and "near misses" made by all hospitals' and looks to Trust Chief Executive Officers (CEOs) to ensure that this happens. The pattern of reports is consistent with that in previous years, with a 26% increase in reports of IBCT and, encouragingly, a further fall in ABO incompatible transfusions.

In December 2004, a stakeholder workshop was held, organised by the National Patient Safety Agency (NPSA), the CMO's National Blood Transfusion Committee (NBTC) and SHOT, to launch a joint initiative aimed at reducing the incidence of ABO incompatible transfusions by 50% over 3 to 5 years. At the workshop, four initiatives already in use in hospitals were selected for further evaluation and possible roll-out. These were; barcode technology, the 'red label' transfusion wristband system, a photo-id system for regularly transfused patients and a sustained approach to training, with the development of a nationally agreed set of competencies for nurses, midwives and porters handling blood.

The main recommendations made by SHOT this year are identical to last year's, as, although progress has been made, problems continue to exist. The National Comparative Audit carried out jointly by the Royal College of Physicians and the National Blood Service (NBS) identified deficiencies in patient identification and in monitoring of transfused patients. SHOT sees the outcome of these system failures. The most important contribution that can be made now by Trust CEOs to improve patient safety in this area is to provide support and resource for training and education of all staff involved in the transfusion process. A framework for education has been developed in Scotland <http://www.learnbloodtransfusion.org.uk> and is the process of being adopted in Wales and by the CMO's NBTC in England.

There has been much international interest this year in SHOT data on transfusion-related acute lung injury (TRALI) and on bacterial contamination of platelets in the light of blood service initiatives, (driven by previous SHOT reports), to improve safety in these areas. Reports of TRALI are reduced in comparison with 2003. However, for the reasons outlined in the section on TRALI, we urge caution in interpreting these data, and advise that a longer period of observation is required to assess the impact of male-only Fresh Frozen Plasma (FFP). Similarly, although there has been no confirmed report of transfusion-transmitted bacterial sepsis in 2004, a longer period of observation is needed before the effect of diversion pouches and improved donor arm cleansing can be proven to have significantly and consistently reduced bacterial transmissions.

SHOT continues to recommend that the UK requires an over-arching body to evaluate and prioritise blood safety initiatives. As this report goes to press, a Department of Health review of the DH advisory committee on Microbiological Safety of Blood, Tissues and Organs (MSBTO) is in progress. SHOT awaits the outcome of this review and hopes that it will encompass the role of haemovigilance in improving transfusion safety in the UK.



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## MAIN FINDINGS AND RECOMMENDATIONS

### SUMMARY OF MAIN FINDINGS

#### Total events reported

539 questionnaires were analysed, plus 1 transfusion transmitted infection (TTI) report received from the NBS/Health Protection Agency Centre for Infections Surveillance (NBS/HPA CIS). A further report of a possible prion transmission has also been included.

#### Transfusion related mortality

There were 4 transfusion related deaths in which there was certain and conclusive evidence that death was related to transfusion (imputability 3) or where the evidence was clearly in favour (imputability 2). Two were related to IBCT, of which one followed an ABO incompatible red cell transfusion and one was caused by an inappropriate transfusion based on a haemoglobin result from the wrong patient. These cases are further discussed in section 4 of the full report. One patient died due to TRALI and one death was reported as acute transfusion reaction (ATR) (see Case 2 page 33 in the full report). For definitions of imputability criteria see Appendix 1 in the full report.

#### Incorrect blood component transfused (“wrong blood”) incidents

439 reports were analysed, a further 26% increase from 2003. 428 of these were 'no-harm' events in which the patient suffered minor or no morbidity.

In the context of an increase in total reports it is encouraging to note that 2004 saw a further reduction in ABO incompatible transfusions to 23, of which 19 were red cells. See illustration on page 1 of this summary

IBCT reports analysed in 2004 comprised

- 88 (20%) 'wrong blood' events, where a patient received blood intended for someone else or of the wrong ABO group
- 143 (33%) events in which the blood given was not of the appropriate specification, (in 88 of these the component should have been irradiated but was not)
- 29 (7%) pre-transfusion testing errors
- 56 (13%) inappropriate transfusions
- 54 (12%) handling errors.

#### “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. 1076 near miss reports were received this year plus 387 error logs not included in the analysis.

Again this year patient mis-identification at the blood sampling stage resulting in 'wrong blood in tube' was the most frequently reported event accounting for 491 (46%) reports.

#### Immune complications

Twenty-three case reports of suspected TRALI were analysed in 2004, of which 13 were considered highly likely or probable (imputability 2-3). Of these 13 cases, FFP was the implicated component in 6, platelets in 4 (3 buffy coat pools, 1 apheresis), red cells in 2 (1 plasma reduced, 1 Optimal Additive Solution (OAS)), whole blood in 1. All 13 implicated donors were female and all had leucocyte antibodies. There were 34 analysable reports of acute transfusion reactions (ATR) of which 4 were haemolytic, 27 severe allergic or anaphylactic and 3 others.

Forty-three delayed haemolytic transfusion reactions (DHTR) were analysed, a marked increase from last year's 25 reports but consistent with previous years.

There were no reports in 2004 of transfusion-associated graft-versus-host disease (TA-GVHD) or post-transfusion purpura (PTP).

#### Transfusion transmitted infections

In 2004, 34 reports of suspected transfusion transmitted infections (TTI) were referred to the NBS/HPA CIS from blood centres throughout the UK. Only one report (hepatitis E) was confirmed as a TTI. A further report of a possible prion transmission referred to the surveillance scheme is also included in this year's report.

There were no confirmed reports of bacterial infection by transfused components

## SHOT in patients under 18 years of age

67 of all case reports in 2004 (12%) involved patients less than 18 years of age, 57 of which were reports of IBCT. As last year, there was a disproportionately high incidence (7%) of IBCT reports relating to infants under 12 months of age.

## Autologous transfusion

There was one case report of a patient who had pre-deposited autologous blood but received only allogeneic blood. A report of a series of adverse reactions related to re-infusion of salvaged blood following knee replacement was received from a single hospital.

## GENERAL RECOMMENDATIONS

The general recommendations made in last year's report remain pertinent and have been reviewed and updated to take into account additional developments.

1. Active participation in SHOT must continue

**Action: Trust CEOs through Hospital Transfusion Committees (HTCs) and risk management structures, consultant haematologists, hospital staff involved in the blood transfusion process**

2. An open learning and improvement culture must continue to be developed in which SHOT reporting is a key element

**Action: Trust CEOs through risk management structures, staff involved in the blood transfusion process**

3. Resources must be made available in Trusts to ensure that appropriate and effective remedial action is taken following transfusion errors

**Action: Strategic Health Authorities (SHAs), Primary Care Trusts (PCTs), Trust CEOs through HTCs and risk management structures**

4. Hospital transfusion teams (HTTs) must be established and supported

**Action: Trust CEOs through HTCs**

5. Hospital transfusion laboratory staffing must be sufficient for safe transfusion practice

**Action: Trust CEOs, clinical directors of pathology, professional and accrediting bodies**

6. Education and training are of key importance for safe and effective blood transfusion practice. Education in blood transfusion must be included in the curriculum for all clinical staff involved in prescribing and administering blood. Adequate resource is needed in Trusts to ensure that all staff involved in the transfusion chain in hospitals must receive appropriate training, which must be documented. Effectiveness of training should be assessed with assessment based on competency

**Action: General Medical Council, Deans of Schools of Nursing and Medical Schools, Postgraduate Medical Education and Training Board, Nursing and Midwifery Council, Medical Royal Colleges. Local, regional and national transfusion committee network, NPSA/SHOT/NBTC initiative. Trust CEOs**

7. Mechanisms must be put in place for appropriate and timely communication of information regarding special transfusion requirements

**Action: CMO's NBTC in England and its counterparts in devolved administrations to make recommendations on suitable mechanisms for implementation by Trust CEOs through HTCs, HTTs**

8. Appropriate use of blood components must be strenuously promoted and evaluated. This must include monitoring for serious adverse effects of alternatives to transfusion

**Action: CMO's NBTC and counterparts to develop action plans, Trust CEOs through HTCs, clinicians administering blood transfusion, hospital transfusion teams**

9. Information technology as an aid to transfusion safety should be assessed and developed at national level. A co-ordinated approach is essential

**Action: NPSA/SHOT/NBTC initiative, CMO's NBTC IT Working Group, Connecting for Health**

10. Further national initiatives are needed to drive forward blood safety issues in hospital transfusion laboratories

**Action: CMO's NBTC in England and its counterparts in Scotland, Wales and Northern Ireland to develop action plans in collaboration with relevant professional bodies**

11. There is a need for a national body, with relevant expertise and resource, to advise government on priorities for improvements in transfusion safety

**Action: DH**

## SPECIFIC RECOMMENDATIONS

### INCORRECT BLOOD COMPONENT TRANSFUSED

- Training and competency testing of all staff involved in the transfusion process must emphasise the importance of positive patient identification, with particular attention paid to critical care situations.

**Action: HTC's**

- All newly qualified doctors must receive education in blood transfusion as recommended by the CMO for England. A web-based education package ([www.learnbloodtransfusion.org](http://www.learnbloodtransfusion.org)) is included in the FY1 curriculum in Scotland and should be implemented throughout the UK.

**Action: CMO's NBTC, Postgraduate Medical Education and Training Board (PMETB)**

- Pending the availability of an effective IT solution, hospitals should take steps to implement robust methods to ensure that the patient's transfusion history including special requirements is kept up to date and accessible to the transfusion laboratory at all times. A patient held booklet is one possible solution.

**Action: CMO's NBTC, RTC/HTC network**

- The EU Directive requires that hospital transfusion laboratories implement a quality system. Elements of this include ensuring adequate staffing levels, systematic and documented training, validation of methods and change control. This presents an opportunity to drive improvements in practice and must be fully supported, resourced and monitored.

**Action: Trust CEOs**

### NEAR MISS

- All hospitals are encouraged to report "near miss" events as required by HSC 2002/009 (BBT2) in order to further identify local weaknesses in the transfusion process. All instances of 'wrong blood in tube' must be fully investigated.

**Action: HTTs**

- Training and education in blood sampling, including the practical aspects of venepuncture and positive patient ID, should be included in the curriculum for medical and nursing students.

**Action: CMO's NBTC, Undergraduate Deans of Schools of Nursing and Medicine**

- All staff involved in the pre-transfusion sampling, testing and issue of blood must be deemed competent having undergone appropriate training, which must be documented.

**Action: Trust CEOs through risk management structures**

- Robust systems for noting patients' special requirements should be developed together with a policy of empowering patients to be more aware of their own special needs.

**Action: Clinicians, HTCs, HTTs**

- Hospital transfusion laboratories must develop and adhere to policies for the timely clearing of satellite refrigerators, required by the Blood Safety and Quality Regulations 2005.

**Action: Hospital transfusion laboratories**

- Ward staff at all levels must be trained in appropriate storage of blood components once they have been collected from the blood bank.

**Action: Ward managers, HTTs**

### ACUTE TRANSFUSION REACTIONS

- In the continued absence of a published national guideline for investigation of ATR, SHOT is developing, in collaboration with the BCSH Transfusion Taskforce, a minimum standard for investigation. This will be included in the Toolkit on the SHOT website.

**Action: SHOT, BCSH TTF, HTTs investigating ATRs**

- In the event of a patient death during or immediately following blood transfusion, the possibility of an ATR must be considered and investigated.

**Action: HTCs for inclusion in transfusion policies**

### ADVERSE REACTIONS TO POST-OPERATIVE CELL SALVAGE

- Users of post-operative salvage should continue to monitor patients for adverse reactions. Those of sufficient severity to require discontinuation of transfusion should be reported to SHOT together with information on total numbers of procedures.

**Action: HTTs**

### DELAYED TRANSFUSION REACTIONS

- Investigation of a suspected DHTR should include retesting of the pre-transfusion sample (where still available) by different or more sensitive techniques. This may involve referral to a reference centre.

**Action: Hospital blood transfusion laboratories**

- Automated systems or changes to indirect antiglobulin test (IAT) technology should be validated using a range of weak antibodies to ensure appropriate sensitivity.

**Action: Hospital blood transfusion laboratories**

- Consideration should be given to issuing antibody cards or similar information to all patients with clinically significant red cell antibodies. These should be accompanied by patient information leaflets, explaining the significance of the antibody and impressing that the card should be shown in the event of a hospital admission or being crossmatched for surgery. Laboratories should be informed when patients carrying antibody cards are admitted.

**Action: The CMO's NBTC and its counterparts in Scotland, Wales, and Northern Ireland**

- There is a need for a review, co-ordinated by a professional national body, of how long specimens should be kept post transfusion. The review needs to consider the relative risks and benefits of storing specimens beyond the time that they are suitable for use in further crossmatching tests.

**Action: British Blood Transfusion Society (BBTS) and BCSH**

## TRALI

- Every effort must be made to avoid unnecessary transfusion of plasma rich blood components including FFP and platelets.

**Action: Clinicians administering blood transfusion**

- FFP continues to be associated with risks of reactions including TRALI and should only be used when clinically indicated in accordance with BCSH guidelines. Guidelines for the management of high international normalised ratio (INR)s due to warfarin therapy should also be followed.

**Action: Clinicians administering blood transfusion**

- Transfusion of whole blood should be discouraged.

**Action: HTTs**

- Hospital staff should continue to be aware of TRALI and report possible cases to the local Blood Centre to facilitate investigation. Continued education of all relevant staff about this condition is needed.

**Action: HTTs, clinicians administering blood transfusion**

- Cases should be evaluated early by the consultant(s) involved. A team approach including the haematologist and chest physician and/or intensive care unit (ICU) consultant is recommended. There should be early liaison with the local Blood Centre.

**Action: Clinicians administering blood transfusion plus haematologists, chest physicians and ICU consultants**

- Serological investigation of suspected TRALI cases must include tests for antibodies to human leucocyte antigen (HLA) Class II, HLA Class I and granulocyte specific antigens.

**Action: UK Blood Services**

- UK Blood Services should continue to consider strategies to minimise the risk of TRALI from apheresis platelets.

**Action: UK Blood Services**

## TRANSFUSION TRANSMITTED INFECTION

- Efforts to prevent bacterial contamination of blood components should continue. These include
  - Continuation of diversion of the first 20-30 mL of the donation (likely to contain any organisms entering the collection needle from the venepuncture site).
  - Careful attention to adequate cleansing of donors' arms.
  - Adherence to BCSH guidelines (1999) with regard to the visual inspection of blood components for any irregular appearance immediately prior to transfusion.

**Action: UK Blood services, hospital transfusion laboratories, staff undertaking pre-transfusion bedside checking**

- Hospitals should consult guidelines and the blood service about the investigation of transfusion reactions suspected to be due to bacteria. Attention should be paid to the sampling and storage of implicated units or their residues.

**Action: HTTs**

- Hospitals should continue to report and investigate all possible incidents of post-transfusion infection appropriately and adequately.

**Action: HTTs**

- UK Blood Service collection teams should ensure donor selection guidelines are adhered to at all times in order to prevent transmission of blood borne infections.

**Action: UK Blood services**

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.

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