Summary of ANNUAL REPORT 2001 – 2002

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Writing Group

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Key Observations and Recommendations

Change in reporting year

➢ With effect from 2003 the SHOT reporting year becomes January to December in line with other major confidential enquiries. This report therefore covers a transitional period of 15 months, and data from October 2001 to December 2002 are included. Where comparisons are desirable with statistics from the previous report the figures are either quoted separately or are adjusted for the unequal time periods.

Participation and number of reports

➢ In 2001–2002 378/405 (93%) eligible hospitals participated in the SHOT scheme. However the number of hospitals submitting reports fell slightly (46%, compared with 48% last year). Nevertheless the overall number of reports received in the period from October 2001 to September 2002 was increased by 15.2% compared with the preceding 12 month period, suggesting that reporting mechanisms are improving in the 'active' hospitals. It is of concern that 191/378 (50.5%) of 'participating' hospitals stated that they had seen no incidents, strongly suggesting that incidents are passing unrecognised or unreported.

Incorrect blood component transfused ("wrong blood") incidents (figure 2)

➢ This category again represents the highest proportion (71.7%) of all of reports received. For the 12 month period from October 2001 to September 2002, 258 new initial reports were received, and a total of 343 to the end of the new reporting year, a 21.1% increase over the equivalent 12 month reporting period 2000-2001. This continuing steep rise in IBCT reports suggests a significant degree of underreporting in the past and increasing awareness and confidence in the SHOT scheme. A real increase in numbers of errors cannot however be excluded.

➢ Multiple errors are a consistent feature of 'wrong blood' incidents, with multiple errors in 137 (40%) of cases. Errors continue to occur at all stages of the transfusion process; 26.9% errors in 39% of case reports occurred at the blood sampling, request and prescription stage; 28.4% errors in 35% of cases took place in the hospital transfusion laboratory; 42.7% errors in 45.9% case reports related to collection of blood from hospital storage sites and bedside administration. By far the most common error 103/552; (18.7%), was failure of the bedside checking procedure, which occurred in 30% of all IBCT cases.

➢ Errors originating in the hospital transfusion laboratory may not be detectable further down the transfusion chain, whilst in other cases a correctly performed bedside check would have averted an incident. Of the 157 laboratory errors, 30 (25%) were grouping errors, 24 (20%) were errors in selection/issue of components, 23 (19.1%) were failure to access the patient's laboratory record, hence failing to meet special requirements. The remaining 80 errors included sample transpositions, missed antibodies or incompatibilities, labelling and other clerical errors, failure to provide irradiated components and issue of outdated blood due to failure to clear satellite refrigerators.

➢ The outcomes of errors reported this year were 32 instances of major ABO incompatible transfusion, resulting in 2 possibly transfusion-related deaths and 4 cases of major morbidity. There were 19 cases of RhD incompatibility (13/19 of these errors originated in the laboratory), of which 3 involved females of child-bearing potential, one of whom is known to have developed anti-D. Eighteen cases of other red cell antigen incompatibilities were reported, 1 of which led to major morbidity. Twenty one patients received unnecessary transfusions because of spurious FBC or coagulation screen results, possibly contributing to 2 deaths. Two patients suffered major morbidity due to ABO incompatible fresh frozen plasma (FFP) infusions.

➢ In 83 cases special transfusion requirements were not met; 60 of these were patients at risk of transfusion-associated graft-versus-host disease who did not receive irradiated cellular components. A particular concern was poor communication, contributing to failures in 20 cases.

"Near Miss" events (figure 3)

➢ This year 146/405 hospitals (36%) reported "near-misses", an increase of 7% from last year. There was a 15% increase in numbers of reports received. Again, sample errors were the largest group; (59%), emphasising the risk of patient misidentification at an early stage in the transfusion process as well as at the end. Medical staff were implicated in 59.6% of these errors. There were 42 (6%) request errors, 87 (12%) errors in laboratory handling and/or testing and 91 cases (13%) of error in the selection, handling and storage of components, of which 27/91 related to incorrect storage in clinical areas resulting in wastage. Errors in component issue, transportation, collection from hospital storage sites and administration accounted for 73 (10%) of cases reported. Reporting of "near-miss" events to SHOT is gaining momentum, but is still at a low level.

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Immune complications of transfusion

➢ There was a large increase in the number of reports of transfusion-related acute lung injury (TRALI) this year with a total of 33 completed reports, of which three were brought forward from last year, and four came between October and January i.e. the additional 3 months of reporting. There were thus 26 new cases in the 12-month period 01/10/01 to 30/09/02, compared with 15 in the corresponding period last year. The diagnosis of TRALI was considered to be highly likely or probable in 18/33 cases, whilst 14/33 were considered possibly TRALI and 1 unlikely. The previously noted preponderance of patients with TRALI who were transfused because of haematological malignancy was not a feature this year, the majority of transfusions (14/33) being for surgical indications.

➢ The majority of patients with TRALI (21/33) subsequently made a full recovery. One patient was reported to have recovered but with impaired respiratory function. Eleven patients died, 4/11 from their underlying condition whilst in 7/11 death was considered to be definitely (1), probably (2) or possibly (4) due to the transfusion. Assessment of cases of TRALI, particularly retrospectively, is fraught with uncertainties, nevertheless with 7 deaths and 18 cases of major morbidity this year this is emerging as the most important serious complication of transfusion.

➢ The component most commonly associated with the development of TRALI was FFP (12 cases) with a combination of components in 11 cases, platelets alone in 5 cases and red cells in 5 cases.

➢ Forty-eight cases of acute transfusion reaction (ATR) were analysed; FFP, platelets or a combination of both were implicated in 31/48 and accounted for 27/34 (79%) of allergic or anaphylactic reactions. FFP continues to be used without good clinical indication. Cumulative data showed that ATR to FFP were 4 times more frequent, proportional to the number of units transfused, than those due to red cells (see chapter 6).

➢ A newly recognised adverse reaction, that of transfusion-related neutropenia, was reported this year.

➢ Delayed transfusion reactions (DTR) occurred in 47 patients, and were associated with 3 deaths, 2 definitely and 1 probably due to the transfusion. One further patient suffered severe morbidity. Kidd and/or c antibodies were implicated in 75% of all cases and in all 3 deaths.

➢ There were no new cases of transfusion-associated graft-versus-host disease (TA-GVHD) this year, and only 3 cases of post-transfusion purpura (PTP), lending further support to the likelihood that quality controlled leucodepletion of all blood components, may partially protect against this complication.

Transfusion-transmitted infections (TTI)

➢ Between 01/10/2001 and 31/12/2002, 34 post-transfusion infections (PTIs) were reported by blood centres in the UK, 20.9% fewer than in the previous year despite the extended reporting period. Of these, 5/34 cases were confirmed as transfusion-transmitted infections (TTIs) due to bacterial contaminations; the remainder were considered not to have been caused by transfusion or investigations were inconclusive.

➢ All cases of TTI due to bacterial contamination were caused by platelets, which were 5 days old in 4/5 cases and 3 days old in 1/5. In 3/5 cases the implicated organism was *Staphylococcus epidermidis*. All 5 recipients had major morbidity, and none died.

➢ Since infection surveillance began in 1995, bacterial contamination has accounted for 26/40 (65%) of TTI incidents affecting 26/43 (60.4%) of infected recipients and responsible for 6/7 deaths. Platelets were implicated in 22/26 cases and *Staphylococcus epidermidis* was isolated in 8/22 cases. The platelets were 3 or more days old in 21/22 cases.

➢ The absence of any reports this year of transfusion transmitted HCV (or HIV) infections is consistent with the expected low risk of an HCV infectious donation entering the blood supply in the presence of the current testing of blood donations for both anti-HCV and HCV RNA (and anti-HIV).

MAIN RECOMMENDATIONS BASED ON FINDINGS

GENERAL RECOMMENDATIONS

1. All institutions where blood transfusions are administered must participate in SHOT.

Participation in SHOT, already recommended by the UK health departments, will become a legal requirement when EC Directive 2002/98 on Safety of Human Blood becomes UK law. SHOT, which is the UK Haemovigilance scheme, is a driving force for essential improvements in safety for patients who receive blood transfusions. Participation is an essential component of clinical quality and, as recommended by HSC 2002/009 should form part of assessment by regulatory bodies (the Commission for Health Improvement (CHI) and its successor in England and Wales and NHS Quality Improvement Scotland).

Reporting must be timely and should include notification of "near-misses" as well as serious adverse events related to blood transfusion. It is only by highlighting failures that we can learn from them and change unsafe practices. Whilst many hospitals may be investigating "near-miss" incidents internally, we are losing opportunities to learn from each other if we fail to capture and disseminate this information.

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

Development of a culture in which the emphasis is on learning from errors in blood transfusion is key to participation in SHOT. Fear of criticism or disciplinary action and uncertainty about the consequences of reporting blood transfusion errors leads to underreporting. This results in lost opportunities to learn from errors and help staff to improve practice.

3. Adequate resources must be made available for improvements in transfusion safety in hospitals.

Commissioners of healthcare (e.g. Primary Care Trusts and Strategic Health Authorities) should ensure that adequate resources are made available to hospitals to allow implementation of the recommendations in this report. They should take an active role in the setting and monitoring of quality standards for blood transfusion.

4. Hospital transfusion teams must be established and supported.

As recommended in HSC 2002/009, hospitals involved in blood transfusion must establish and support a Transfusion Team. As a minimum this comprises a lead consultant in blood transfusion (with dedicated sessions), a hospital transfusion practitioner (nurse, biomedical scientist or medical professional), and the blood bank manager. Chief executives should ensure that the team has full clerical, technical and IT support, and access to audit and training resources.

5. SHOT recommendations must be on the clinical governance agenda.

Hospital clinical governance committees must consider the recommendations contained in SHOT reports and determine an appropriate action plan for improving the safety of administration of blood components within their organisation.

6. Appropriate use of blood components must be strenuously promoted.

Appropriate use of blood is an integral part of any blood safety strategy and should be monitored by regular audit. Concise clinical guidance on the use of blood components is provided by the UK Blood Transfusion Services Joint Professional Advisory Committee and freely available on www.transfusionguidelines.org.uk and as theHandbook of Transfusion Medicine. This guidance is revised in accordance with the current BCSH guidelines. There is a need for continued efforts to ensure that practitioners and patients have ready access to up-to-date, simple, consistent and user-friendly information on best practice.

The finding that 50% of IBCT events occur 'out-of-hours' should be of concern to all hospitals, and transfusions should only take place at night if essential.

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7. Training in blood administration should be implemented and competency testing developed to ensure an effective outcome.
The British Committee for Standards in Haematology (BCSH) guidelines on the administration of blood transfusion provide a basis for training in blood handling.
All hospital staff who contribute to the transfusion chain must receive training in the procedures that they are required to undertake and their competency should be formally assessed and recorded.
Professional organisations should work towards development of a nationally accepted and validated system of competency testing for staff involved in the handling and administration of blood components.

8. Blood transfusion should only be prescribed by authorized clinicians.
Blood transfusion should only be prescribed by clinicians who have been authorized by the Trust following appropriate training.

9. Blood transfusion teaching must be included in all relevant academic curricula.
Teaching on blood transfusion safety must be a formal and required part of nursing and medical undergraduate courses and biomedical scientist training. Blood transfusion medicine, best practice and blood safety should be included in the curriculum for medical professional examinations.

10. Hospital blood bank laboratory staffing must be sufficient for safe transfusion practice.
This year about 35% of blood transfusion errors originated in the laboratory and 31.2% of laboratory errors occurred 'out-of-hours' when laboratory staffing may be sub-optimal. Hospitals should ensure that blood transfusion laboratories have adequate numbers of appropriately trained biomedical scientists to cover the 24-hour working day, including a core of permanent blood transfusion laboratory staff.
Standard-setting bodies need to develop standards for laboratory staffing, both within and outside normal working hours, taking into account pressures such as the requirement for a 4 hour patient turnaround in A & E. Inspection for laboratory accreditation should include the quality of all aspects of the service including 'out-of-hours'.

11. Electronic aids to transfusion safety should be assessed and developed at national level.
Information technology has enormous potential to reduce the risk of transfusion errors. However, a coordinated approach to the development / assessment of new technologies is needed to ensure quality and "connectability" with other key systems used in the hospital such as patient administration systems, electronic records and systems used in Pharmacy and other clinical areas where positive patient ID is critical. This should be organised at national level. The Chief Medical Officer's National Transfusion Committee in England has recently set up an IT Working Group whose first objective is to bring together the disparate agencies and projects developing clinical IT systems in the NHS. New technologies have the potential to overcome inevitable human error but need to be developed and tested in "real life" clinical environments to demonstrate their true value.

- Electronic positive patient/blood component identification "from vein to vein" using readily available barcode technology and wireless hand-held scanners is already undergoing field trials in the UK. In addition to improving transfusion safety, this technology has many other potential applications in the clinical setting which should increase its affordability. The same electronic ID systems could be used to reduce prescribing and drug administration errors (a considerably greater cause of morbidity and mortality than transfusion errors) and ensure correct attribution of pathology results, dietary regimens and surgical procedures. A coordinated approach is essential to avoid the nightmare scenario of multiple, incompatible, bespoke systems for transfusion, pharmacy, pathology etc in each clinical area.
- Automated laboratory equipment with electronic interfacing reduces the risk of manual transcription and transposition errors but should complement, not replace, skilled and experienced staff.
- Electronic issue of blood from the laboratory without conventional serological "crossmatching" has the potential to improve blood utilization within a hospital and allow laboratories to meet increasing clinical workloads whilst maintaining patient safety. However, secure sample identification and recording of blood group/antibody screen results absolutely essential. Ideally, electronic sample ID and a high level of automated testing, with electronic data transfer, should be used in laboratories using "electronic issue". The standards and specifications of such systems should be clearly defined in authoritative national guidelines which are regularly reviewed to keep up-to-date with technical developments.
- Electronic control of the release of blood components from Blood Banks and satellite refrigerators can improve patient safety and ensure the traceability of blood units. Computer controlled systems with positive patient and product ID, preferably based on barcode reading, can protect patients from one of the most common root causes of mismatch transfusion errors identified in sequential SHOT Reports – collecting the wrong unit from the refrigerator. These systems can also monitor the location and storage status of blood throughout the hospital and improve the traceability of blood as required by the new EU directive. They will be particularly valuable where a central blood bank serves several geographically remote sites or a large number of satellite refrigerators. Once again, these systems should be developed and tested in routine clinical practice to ensure utility and robustness under normal working conditions.

12. There is a need for a national body, with relevant expertise and resource, to advise government on priorities for improvements in transfusion safety.
Each SHOT report contains specific recommendations. However SHOT has no authority over implementation and cannot monitor compliance. Decision-making pathways are needed to enable data from SHOT to influence blood safety policy.
Bodies which support research, development and health technology assessment should consider blood safety and alternatives to transfusion when setting their funding priorities.

13. Poor communication is an important cause of adverse events.
Clear policies must be developed for communicating special transfusion needs of patients to other hospitals or units which may share their care, so as to ensure that all pertinent transfusion history is available. This is particularly relevant to peripheral blood and bone marrow stem cell transplant recipients. Active involvement of patients in this aspect of their care could reduce the frequency of errors and adverse reactions.
Increasing use of fludarabine means that many more patients are susceptible to TA-GVHD. Pharmacy departments should play a role in notifying patients and hospital blood banks when this therapy is commenced. The forthcoming BCSH guidelines on the avoidance of Transfusion Associated GVHD (which extend the current guidelines for irradiation) include advice on communication where there is shared care and include input from the Pharmacists/Pharmacologists community.

SPECIFIC RECOMMENDATIONS

Incorrect component transfused

- **SHOT recommendations should be used locally to support risk management, clinical governance and education.**
  - In order for patients and staff to derive full benefit from the SHOT scheme, local initiatives to disseminate the main messages of the SHOT report are essential. These could form part of induction sessions for all staff groups or be regular sessions at hospital "Grand Rounds" or departmental training programmes.
  - Reporting should be the norm and full investigation of reported incidents should be carried out by individuals who are familiar with good practice guidelines for transfusion. SHOT findings should be part of mandatory training for all staff involved in the transfusion process.
  - All staff should be made aware through the Risk Management Committee of transfusion errors occurring in their department and in other departments within the hospital. This should not reveal the identities of individuals concerned, the emphasis being on avoiding repetition of errors and encouraging staff to analyse their working practices to identify potential "weak links" which can be remedied.
- **Improved training of midwives in relation to anti-D administration is necessary.**
  - There is increasing risk of mis-administration with the rolling out of the routine antenatal prophylaxis programme. More secure and explicit communication of antenatal and postnatal results is required.
- **Human error in relation to patient identification is still the commonest problem leading to wrong-blood-in-patient.**
  - Educational initiatives have been inadequate in resolving this problem. Patients should be empowered to be involved in the bedside checking procedure.
  - Investment in the development and evaluation of technological solutions is essential if errors in the transfusion process are to be significantly reduced.

"Near Miss" events

- Patients should wherever possible be educated about their own special transfusion requirements.
- Hospital protocols must state that there are no exceptions to the requirement for identity wristbands to be worn by all patients.
- As recommended last year, all hospitals must have a training programme in place for phlebotomy which must include medical staff.

Immune complications of transfusion

- **Patients receiving transfusion must be monitored.**
  - Patients receiving any blood component must be monitored to detect an acute reaction. Patients must be checked prior to the transfusion of each component and 15 minutes after its commencement.
- **Reduction of the risk of TRALI demands a high priority.**
  - Hospitals should continue to be aware of TRALI and to investigate and report possible cases. Continued education of all staff about this condition is encouraged so that cases may be investigated appropriately and implicated donors withdrawn.
  - Following evaluation of available options (e.g. sourcing of FFP from untransfused male donors, suspension of platelets in plasma-free medium), UK Transfusion Services should take all steps possible to reduce the risk of TRALI from blood components.
- **All adverse reactions should be fully investigated and reviewed.**
  - Analysis of cases of acute transfusion reaction and TRALI was unsatisfactory as many cases were not fully investigated and clinical details were sketchy. It is recommended that there is early evaluation of cases by the consultant(s) involved. A team approach including the haematologist and chest physician and/or ITU consultant may be helpful. The blood services are refining the algorithm for investigation of TRALI so the laboratory investigation of cases should in future be more consistent and complete.
  - Patients who have had a severe allergic reaction (anaphylactic/anaphylactoid) should be investigated for IgA deficiency.
  - There is a need for a guideline dealing with the investigation of all acute transfusion reactions.
  - A system of open, non-anonymised reporting to SHOT and specialist review of cases would improve evaluation of the risk of TRALI and should be developed.
- **FFP continues to be associated with significant risks of reactions including TRALI.**
  - FFP should only be used when clinically indicated in accordance with BCSH guidelines. It is particularly important that guidelines for the management of high International Normalised Ratios (INRs) due to warfarin therapy are also followed.
  - There is continued evidence of inappropriate use of clinical FFP and further local audits and educational programmes should be encouraged. A revised BCSH guideline is expected during 2003; in the meantime, existing BCSH guidelines should be followed.
- **Particular care should be taken when providing blood for patients with a positive direct antiglobulin test (DAT), who are known to have an autoimmune haemolytic anaemia or have been recently transfused.**
  - Referral to a reference centre, if time allows, should be considered.
  - Where plasma samples are routinely used for pre-transfusion testing, it is recommended that serum samples are also used in the investigation of suspected transfusion reactions.
- **Suspected delayed haemolytic transfusion reaction should be carefully investigated.**
  - Investigation should include retesting of the pre-transfusion sample by different or more sensitive techniques. This may involve referral to a reference centre.
  - Serum (+ plasma if used routinely) should preferentially be used, to give maximum potential for identifying all antibody specificities present, including weak complement binding antibodies.
- **Patients with sickle cell disease (SCD) should be phenotyped prior to transfusion and blood selected for Rh and K.**
- **Automated systems or changes to indirect antiglobulin test (IAT) technology should be validated using a range of weak antibodies to ensure appropriate sensitivity.**
- **Information on previous transfusion history must be available to all who need it.**
  - Consideration should be given to issuing antibody cards to all patients with clinically significant red cell antibodies. These

should be accompanied by 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 cross-matched for surgery.
  - When the care of patients with haematological disorders requiring transfusion support is shared, there is a risk that not all pertinent transfusion history will be available to both sites. In the absence of networked pathology information systems, it is essential that local procedures are devised for adequate communication.

- **Withholding transfusion may be a greater risk than DTR.**
  - When the laboratory cannot supply compatible red cells within the time-frame requested, there should be communication between the haematologist and the responsible clinician to determine whether the risk of delaying the transfusion outweighs the risk of a transfusion reaction and whether potentially incompatible red cells should be given.

- **No cases of TA-GVHD this year, but risk remains of this fatal consequence of transfusion.**
  - Despite the lack of cases this year, hospitals should remain aware of TA-GVHD and should be rigorous in putting systems in place to ensure that all patients at risk receive gamma irradiated products.
  - Products where partial haplotype sharing is likely should be irradiated. If donor lymphocytes are homozygous for one of the patient's haplotypes the donor lymphocytes can survive. Because they do not share the other haplotype of the patient, however, they can recognise the patient as foreign and set up a GVHD reaction. This is particularly likely to happen if HLA matched products or products from family members are used and for this reason these products should always be irradiated.
  - New chemo- or immuno- therapeutic regimes should be assessed for their potential to cause TA-GVHD and guidelines modified accordingly.

- **PTP is a rare but treatable consequence of transfusion.**
  - Clinicians should remain aware of this rare but treatable consequence of transfusion. The mainstay of treatment is high dose intravenous gammaglobulins +/- steroids, with random (i.e. unmatched) blood components given only if there is significant bleeding.
  - If PTP is suspected, there should be urgent liaison with a reference laboratory for appropriate specialist investigation.
  - PTP is induced by a re-exposure to HPA antigen in individuals with a history of previous immunising events. PTP can therefore occur following transfusion with any platelet-containing product. Now that leucodepletion removes most platelets from red cell components it may be that the classic picture of PTP occurring after red cell transfusion will change and we will see proportionately more cases following platelet transfusion. Non-classical cases should be reported to SHOT.
  - Patients with HPA antibodies should have appropriate antigen-negative cellular products if they require transfusion in the future. Screening should be offered to female relatives of child-bearing potential to see if they are at risk of forming antibodies capable of causing fetal/neonatal alloimmune thrombocytopenia. For HPA-1a this would include HLA typing for HLA DR 101 to identify those who are likely to form antibodies.

Transfusion-transmitted infections

- **Transfusion-transmitted bacterial infection remains an avoidable cause of death and major morbidity and merits increased efforts to prevent bacterial contamination of blood components.**
  - These include implementation of diversion of the first few mL of the donation (likely to contain any organisms entering the collection needle from the venepuncture site) and improvements in cleansing of donors' arms. Methods for testing platelets for bacterial contamination should be evaluated.
  - The risk of transfusion of a contaminated component can be reduced by adherence to BCSH guidelines with regard to the visual inspection of units for any irregular appearance immediately prior to transfusion (particularly platelets).
  - Hospitals should consult the blood service about the investigation of transfusion reactions suspected to be due to bacteria. National guidance on the investigation of these cases are available from all NBS centres. Cases that are inconclusive due to discard of the implicated pack before sampling continue to be reported, therefore particular attention should be paid to the sampling and storage of implicated units.

Neonates and children are a vulnerable group with special transfusion requirements.

- Laboratory, nursing and medical staff should all be aware of the special consideration of component selection and/or manipulation for neonatal transfusion.
- The wearing and checking of patient identification is essential in the paediatric age group, who may not be able to identify themselves verbally.
- Children receiving blood components should be closely monitored.
- BCSH guidelines are as applicable to children as to adults and should be followed.
- Paediatricians should be encouraged to report suspected transfusion-related adverse events and to disseminate lessons learned.

What is SHOT?

The Serious Hazards of Transfusion (SHOT) Scheme was launched in November 1996, and aims to collect data on serious sequelae of transfusion of blood components, as listed below. Through the participating bodies, SHOT findings can be used to:

a) inform policy within transfusion services
b) improve standards of hospital transfusion practice
c) aid production of clinical guidelines for the use of blood components
d) educate users on transfusion hazards and their prevention

Cases included - The scheme aims to capture data on major complications of transfusion:

Non-infectious

- Incorrect blood component transfused (*even if no harm arises*)
- Acute or delayed transfusion reactions
- Transfusion-associated graft-versus-host-disease
- Transfusion-related acute lung injury
- Post-transfusion purpura
- Autologous pre-deposit incidents

Infectious

- Bacterial contamination
- Post transfusion viral infection
- Other post-transfusion infection e.g. malaria

System for Reporting

Cases are reported in the first instance to the hospital haematologist responsible for transfusion. Non-infectious hazards are then reported confidentially to the National Co-ordinator on a simple report form. This is followed up with a detailed questionnaire. Meaningful data depend on questionnaires being fully completed. Staff may write to the SHOT office under separate cover.

Suspected cases of transfusion-transmitted infection are reported by haematologists through supplying Blood Centres to the National Blood Authority/Health Protection Agency Communicable Disease Surveillance Centre. Local Blood Centre involvement is **ESSENTIAL** to ensure rapid withdrawal of other potentially infected components.

Confidentiality

Data are stored in a password-protected database in a secure location. Once all the information has been gathered about an event and entered onto the database without patient, staff or hospital identifiers, all reporting forms and other paper records which contain any identifiers are shredded. The questionnaires (which have any possible identifiers removed) are kept in a secure container until data analysis for the report is complete after which they are shredded.

SHOT does not provide details of individual cases, or any form of summarised data to any outside person or organisation, other than that provided in the report.

Limitations of the SHOT system

Reporting to the SHOT scheme is voluntary. We acknowledge that many incidents may go unrecognised or unreported, and that the reports analysed cannot provide a full picture of transfusion hazards.

Organisation

SHOT is affiliated to the Royal College of Pathologists. The operational aspects of the scheme are the responsibility of a Standing Working Group, which is accountable to the Steering Group. Two National Co-ordinators (D Stainsby and K Davison) together with an assistant (H Jones) are responsible for receiving and collating reports.

Standing Working Group

Dr D Stainsby (Chair), Mrs H Jones, Mrs D Asher, Ms C Atterbury, Dr H Cohen, Dr D Norfolk, Mr J Revill, Ms K Davison, Dr A Todd, Dr C Beatty, Dr S Knowles, Dr C Taylor, Ms C Milkins

Steering Group

Ownership of the scheme and data generated from it resides with the Steering Group, which has representation from the following Royal Colleges and professional bodies:

British Blood Transfusion Society	*Dr JAJ Barbara*
British Society for Haematology	*Dr H Cohen (Chair)*
Institute of Biomedical Science	*Mr W Chaffe*
	Mr JA Revill
Institute of Health Care Management and NHS Confederation	*Mr I R Cumming*
Health Protection Agency/Communicable Disease Surveillance Centre	*Dr M Ramsay*
Royal College of Anaesthetists	*Dr AJ Mortimer*
Royal College of Nursing	*Ms C Atterbury*
	Ms B Cottam
Royal College of Nursing Midwifery Society	*Ms. P. Edkins*
Royal College of Obstetricians and Gynaecologists	*Dr T Johnston*
Royal College of Pathologists	*Prof M Contreras*
Royal College of Paediatrics and Child Health	*Dr B Gibson*
Royal College of Physicians	*Dr CG Taylor*
Royal College of Surgeons	*Prof JSP Lumley*
UK Transfusion Services	*Dr DBL McClelland*
Blood and Tissue Safety Assurance	*Dr E M Love*
Founding Member	*Dr L Williamson*

Overview of results for this report

The numbers of reports in each category received since the first SHOT annual report are shown below.

Table 1: Adverse events reported during the five reporting years 1996/97 to 2001/02

	1996/1997	1997/1998	1998/1999	1999/2000	2000/2001	2001/2002*
IBCT	81	110	144	201	213	258(343)
ATR	27	28	34	34	37	38(49)
DTR	27	24	31	28	40	33(46)
PTP	11	11	10	5	3	3(3)
TA-GVHD	4	4	4	0	1	0(0)
TRALI	11	16	16	19	15	26(32)
TTI	8	3	9	6	6	5(5)
Unclassified	0	0	7	0	0	0
TOTAL	**169**	**196**	**255**	**293**	**315**	**363(478)**

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

* The figures in brackets are the total numbers of reports received during the full 15 month period 1st October, 2001 to 31st December, 2002.

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Figure 1: Overview of 482 cases for which fully completed questionnaires were received

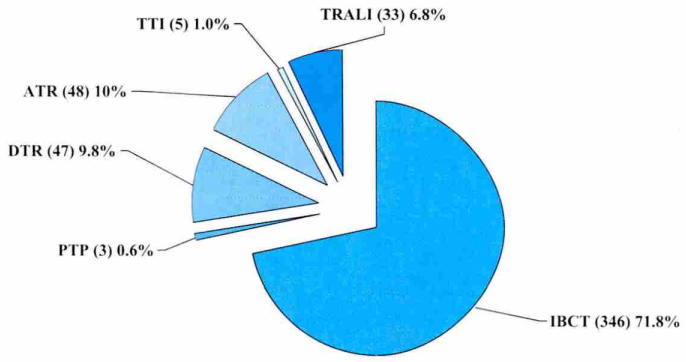


Table 2: Transfusion related mortality/morbidity according to the type of hazard reported in 482 completed questionnaires

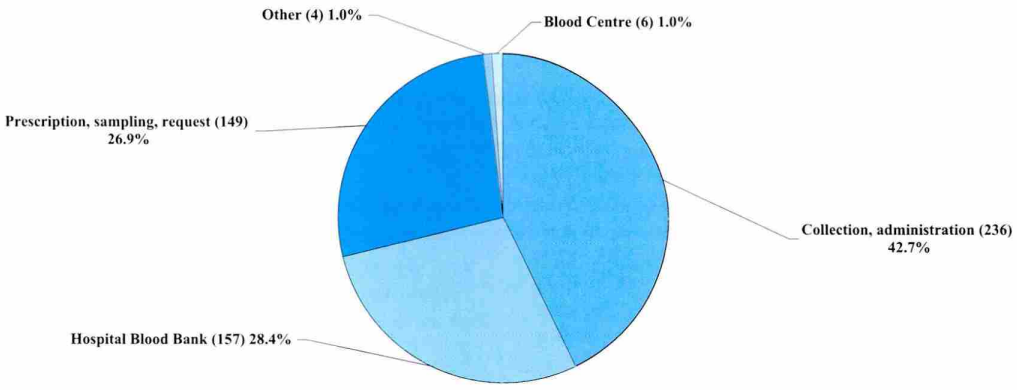
	Total	IBCT	ATR	DTR	PTP	TRALI	TTI
Death definitely attributed to transfusion	**3**	0	0	2	0	1	0
Death probably attributed to transfusion	**5**	1	1	1	0	2	0
Death possibly attributed to transfusion	**8**	3	1	0	0	4	0
Death due to underlying condition	**33**	18	5	6	0	4	0
Major morbidity	**35**	9	0	2	1	18	5
Minor or no morbidity	**393**	310	41	36	2	4	0
Outcome unstated	**5**	5	0	0	0	0	0
Totals	**482**	**346**	**48**	**47**	**3**	**33**	**5**

Major morbidity was defined as the presence of one or more of the following:

- Intensive care admission and/or ventilation
- Dialysis and/or renal dysfunction
- Major haemorrhage from transfusion-induced coagulopathy
- Intravascular haemolysis
- Potential RhD sensitisation in a female of child-bearing potential
- Persistent viral infection
- Acute symptomatic confirmed infection (viral, bacterial or protozoal)

Incorrect Blood Component Transfused

Figure 2: Distribution of total errors according to the main reporting categories (n=552)



Cumulative data from 6 years of SHOT reporting 1996/97 to 2001/02

Figure 4: Questionnaires by incident 1996/97 – 2001/02 (n=1630)

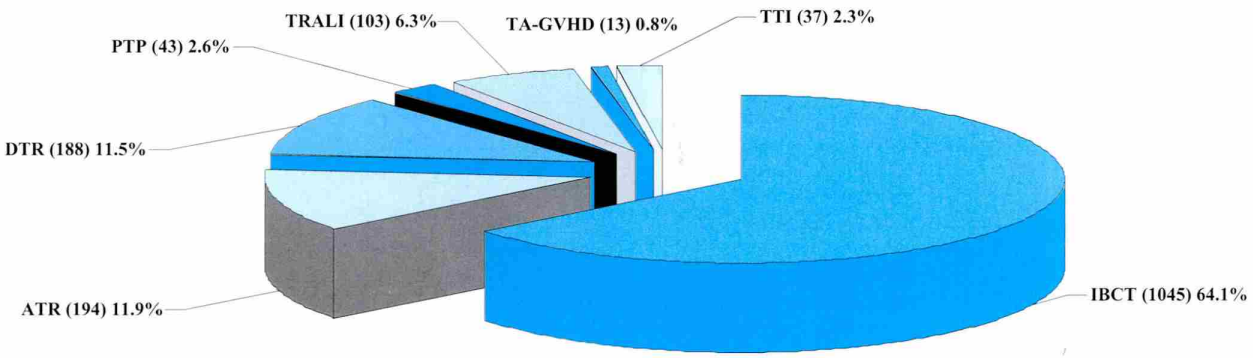
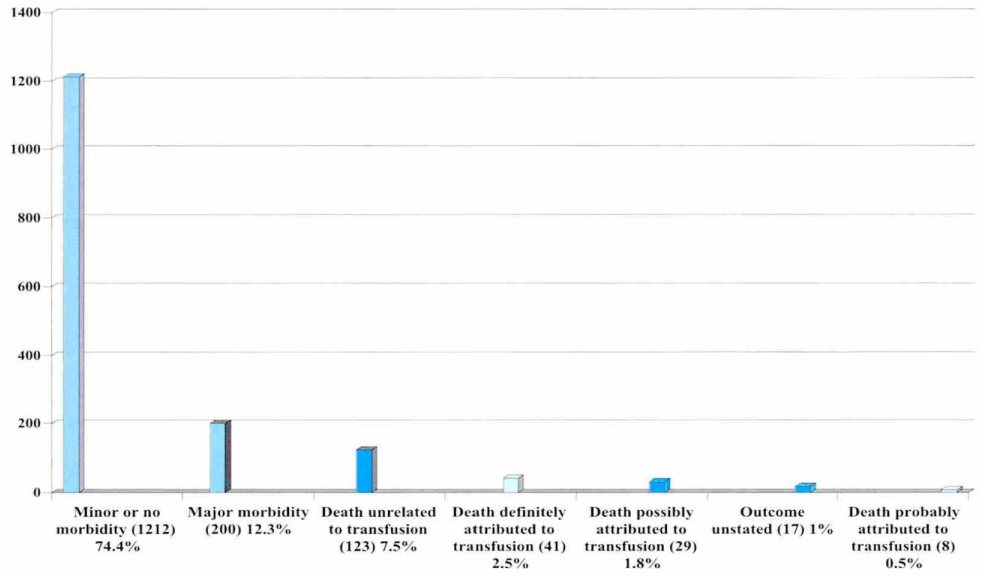


Figure 5: Overall mortality/morbidity figures 1996/97 – 2001/02 (n=1630)



This summary has been sent to hospital haematologists, blood bank managers, and NHS Trust Chief Executives. Copies of the full report (price £25) are available from the SHOT office. Please make cheques payable to National Blood Authority and write 'SHOT' on back of cheque. National Health Service employees are invited to apply to the SHOT office for a free copy of the report.

An electronic copy of the report is available on the SHOT website together with selected presentations from the Symposium on 26th September 2003

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