

Summary of ANNUAL REPORT 2003

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This short summary provides an overview of the main findings of the 2003 SHOT report together with headline recommendations. Detail and context can be found in the 87 page report which has been distributed to all hospitals. Additional copies may be obtained from the SHOT office*.

Background data on which the report and recommendations are based can be found on the SHOT website www.shot-uk.org

Participation

- 351/415 (85%) hospitals returned cards stating that they participated in the SHOT scheme.
- 195/415 hospitals stated that they reported incidents; the level of active participation is therefore unchanged at 47%.
- 480 initial reports were received and 449 questionnaires analysed plus 8 transfusion-transmitted infection (TTI) reports not on standard SHOT questionnaires.

Incorrect blood component transfused - IBCT ("wrong blood") incidents

- 358/480 (75%) of all reports were of IBCT; a 25% increase over the previous equivalent 12 months.
- Multiple errors contributed to 52% of "wrong blood" events with 588 errors in 348 analysed cases.
- Approximately 70% of errors occurred in clinical areas (30% prescription, sampling, request and 40% collection and administration) and 30% in laboratories.
- Again the commonest error (156/588) was failure of the pre-transfusion bedside check.

Outcomes of IBCT events

- 33 ABO incompatible transfusions, of which 4 were also RhD incompatible (26 incompatible red cell transfusions and 7 incidents of incompatible fresh frozen plasma (FFP), cryoprecipitate or platelets).
- 22 cases of unintended RhD incompatible transfusions (4 to females of potential child-bearing age).
- 22 cases where other red cell antigen incompatible transfusions were given.
- 1 possible transfusion related death but no definite or probable cases.
- 16 patients suffered major morbidity.

"Near miss" events

- 906 "near miss" reports were received from 163 hospitals.
- 60% of "near misses" were sample errors.
- Anecdotal evidence suggests that "near miss" events are frequent but under-reported.

Immune complications

- Thirty-six case reports of suspected transfusion-related acute lung injury (TRALI) were analysed.
 - 9 patients died; 1 considered to be definitely due to transfusion, 7 possibly and 1 unrelated.
 - 22 suffered short term major morbidity and five minor morbidity.
 - Plasma rich components were implicated in 20 of 21 cases in which there was proven leucocyte incompatibility between donor and patient.
- There were 39 analysable reports of acute transfusion reactions (ATR) accounting for 1 probable transfusion related death and 2 cases of major morbidity.

- Twenty-five delayed haemolytic transfusion reactions (DHTR) were analysed, a marked reduction from last year's 47 reports. It is unlikely that the incidence of these reactions has fallen, and there is a concern DHTRs are under-recognised.
- There were no transfusion-related deaths in the DHTR category and one case of short-term morbidity.
- There were no reports of transfusion-associated graft-versus-host disease (TA-GVHD), and only 1 report meeting the SHOT definition of post-transfusion purpura (PTP).

Transfusion-transmitted infections

38 reports of possible TTIs were received.

Following investigation:

- 8 reports were considered probable TTIs
 - 2 Hepatitis B virus (HBV)
 - 1 Human immunodeficiency virus (HIV)
 - 1 Hepatitis A virus (HAV)
 - 1 malaria
 - 3 cases of bacterial contamination of platelets resulting in one death.
- 24 reports were found not to be related to transfusion.
- 3 had an undetermined source.
- Full investigations on 2 cases are still pending.

The UK's National CJD Surveillance Unit and the NBS reported the first possible case of transfusion transmitted vCJD, identified in 2003 following the death of a transfusion recipient.

SHOT in patients under 18 years of age

- 59 case reports (13%) involved patients less than 18 years of age, 53 of which were reports of IBCT.
- 28/348 (8%) of all analysed IBCT incidents occurred in patients less than 12 months of age.
- 20/28 of these (71%) involved infants in their first month of life.
- There is lack of awareness amongst laboratory, nursing and medical staff of the special needs of paediatric recipients of blood and blood components.
- Nine paediatric patients suffered morbidity or potential morbidity but recovered including 5 who developed intra-vascular haemolysis and 2 RhD negative females who received RhD positive red cells.

Autologous transfusion

- There were no reports of adverse reactions relating to autologous pre-deposit donation.
- 3 reports (2 IBCTs and 1 ATR) were received of adverse events relating to the re-infusion of autologous blood.
- With increasing emphasis on blood conservation techniques it is important that adverse events are reported and documented, so that the relative risks of alternatives to allogeneic blood transfusion can be assessed.

GENERAL RECOMMENDATIONS

1. Participation in SHOT must be active.

Action: Trust Chief Executive Officers (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 structure

4. Hospital transfusion teams must be established and supported.

Action: Trust CEOs through HTCs

5. Hospital blood bank laboratory staffing must be sufficient for safe transfusion practice.
Action: Trust CEOs, clinical directors of pathology, professional and accrediting bodies
6. Education and training is of key importance for safe and effective blood transfusion practice.
 - i) Blood transfusion must be included in the curriculum for:
student nurses, and medical undergraduates.
Action: Deans of Schools of Nursing and Medicine
specialist trainees, particularly anaesthetists and critical care nurses.
Action: Medical Royal Colleges, Universities
 - ii) The BCSH guideline on blood transfusion in neonates and older children should be implemented.
Action: Staff in paediatric units and transfusion laboratories
 - iii) An ongoing programme of education and training in blood transfusion is essential for all hospital staff involved in the transfusion process.
Action: Local, regional and national transfusion committee network
 - iv) An important role of the Regional Transfusion Committee (RTC) is to support translation of guidelines into local practice.
Action: RTCs and user groups
7. Mechanisms must be put in place for appropriate and timely communication of information regarding special transfusion requirements.
Action: Trust CEOs through HTC, HTTs
8. Appropriate use of blood components must be strenuously promoted and alternatives to transfusion evaluated. The latter must include monitoring for serious adverse effects.
Action: Department of Health (DOH), CMO's National Blood Transfusion Committee (NBTC), Trust CEOs through HTCs, clinicians administering blood transfusion, HTTs
9. Electronic aids to transfusion safety should be assessed and developed at national level.
 - i) Blood transfusion must be included on the agenda of the Design Authority and other bodies responsible for setting standards and priorities in the NHS IT strategy.
 - ii) National standards and specifications should be developed for blood bank laboratory computer systems.
 - iii) Bar-code technology for positive patient identification, and to control and monitor access to hospital blood refrigerators, should undergo continued development and evaluation co-ordinated at national level.
Action: CMO's NBTC, Design Authority, British Blood Transfusion Society (BBTS), British Committee for Standards in Haematology (BCSH), National Patient Safety Agency (NPSA), enthusiasts in the field
10. The CMO's NBTC in England and its counterparts in Scotland, Wales and Northern Ireland should take a proactive lead in driving forward blood safety issues in hospitals.
Action: CMO's NBTC in England and its counterparts in Scotland, Wales and Northern Ireland
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: DOH

SPECIFIC RECOMMENDATIONS – based on reports in each SHOT category

Incorrect Blood Component Transfused

- Hospital risk management committees must ensure that all staff undertaking venepuncture for blood sampling have received the necessary training and have their practical competency formally assessed and recorded.
Action: Hospital risk management committees
- Hospital risk management procedures should include 'drills' for high risk situations such as massive transfusion, involving all relevant staff.
Action: Hospital risk management committees

- All patients at risk of TA-GVHD should receive an information card and leaflet. Haematologists must ensure that there is an effective system of flagging special transfusion requirements in the laboratory. Referrals for shared care must include timely communication of all relevant information.

Action: Clinicians prescribing purine analogues and administering blood transfusion, HTTs, pharmacists, pharmaceutical industry, suppliers of laboratory IT systems

- Hospital blood bank laboratory staffing must be sufficient for safe transfusion practice. Standards should be established for manpower appropriate to the level of workload and this should be subject to inspection.

Action: Clinical directors of pathology, professional and accrediting bodies

- Paediatric units undertaking transfusion must ensure that staff are educated in the special transfusion requirements of children.

Action: Paediatricians and laboratory staff responsible for transfusion of paediatric patients, HTCs

- The most important contribution which could now be made to the safety of blood transfusion would be an initiative to improve the safety of the bedside pretransfusion checking procedure. This will require investment in education and audit, and also in evaluation and implementation of suitable information technology. The CMO's NBTC has the necessary remit to take this forward.

Action: CMOs NBTC through regional and hospital transfusion committees, HTTs

Transfusion-related acute lung injury

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

Action: Clinicians administering blood transfusion

- FFP should only be used when clinically indicated in accordance with BCSH guidelines.

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 encouraged.

Action: HTTs, clinicians administering blood transfusion

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

Action: Clinicians administering blood transfusion, 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: Reference laboratories

- The NBS TRALI risk reduction project has led to the implementation of procedural changes such as using plasma from male donors only for FFP. UK Transfusion Services should continue with implementation of such initiatives.

Action: UK Transfusion Services

Acute transfusion reactions

- The BCSH guideline on the investigation and management of ATRs is awaited and emphasis should be placed upon the need for identifying underlying causes that will impact upon the choice of future component therapy.

Action: BCSH

- There is continued evidence of inappropriate clinical use of FFP. Further local audits and educational programmes should be encouraged through the Transfusion Committee network.

Action: Regional and hospital transfusion committees

- The Transfusion Services should be encouraged to ensure that sufficient group A platelets are always available for group A neonates and older children.

Action: UK Transfusion Services

Delayed transfusion reactions (DTR)

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

Action: Hospital 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 transfusion laboratories

- Consideration should be given to issuing antibody cards to all patients with clinically significant red cell antibodies.

Action: Hospital transfusion laboratories supported by UK Transfusion Services

- There is a need for a review, co-ordinated by a professional national body, of how long specimens should be kept post-transfusion.

Action: BBTS and BCSH

Transfusion-associated graft-versus-host disease

- Gamma irradiation of blood components for those at risk of GVHD remains essential.
- Awareness of the potential for this condition must be maintained by all involved in the transfusion process.
- Good communication is required in all cases especially when patient care is shared. Hospitals must have clear protocols to ensure that information is communicated in a timely manner. Provision of the BCSH/NBS patient card and leaflet are also recommended.
- New chemo or immuno-therapeutic regimens must be evaluated for their potential to predispose individuals to TA-GVHD. Regular update of guidelines is required.

Action: Clinicians prescribing purine analogues and administering blood transfusion, HTTs, pharmacists, pharmaceutical industry, suppliers of laboratory IT systems

Post-transfusion purpura

- Clinicians need to maintain awareness of this rare but treatable complication of transfusion.
- When PTP is suspected there should be urgent referral to a platelet reference laboratory for relevant investigation.

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.
- Hospitals should consult guidelines and the blood service about the investigation of transfusion reactions suspected to be due to bacteria.
- Hospitals should continue to report and investigate all possible incidents of post-transfusion infection appropriately and adequately.

Patients less than 18 years of age

- Specific education in paediatric transfusion practice is crucial.

Action: HTTs

- The wearing and checking of wrist or ankle namebands is essential in the paediatric age group.

Action: Staff of paediatric units

Autologous transfusion

- All adverse events associated with autologous donation and re-infusion should be reported to SHOT so that the relative risks of alternatives to allogeneic transfusion can be assessed.

Action: HTTs

OVERVIEW OF RESULTS

Table 1: Adverse events reported during the seven reporting years 1996/97 to 2003 (initial report forms)

	1996/1997	1997/1998	1998/1999	1999/2000	2000/2001	2001/2002 [^]	2003
IBCT	81	110	144	201	213	258(343)	358
ATR	27	28	34	34	37	38(49)	44
DTR	27	24	31	28	40	33(46)	32
PTP	11	11	10	5	3	3(3)	1
TA-GVHD	4	4	4	0	1	0(0)	0
TRALI	11	16	16	19	15	26(32)	37
TTI	8	3	9	6	6	5(5)	8
Unclassified	0	0	7	0	0	0	0
TOTAL	169	196	255	293	315	363(478)	480

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.

Figure 1: Questionnaires by incident 1996/97 – 2003 (n = 2087)

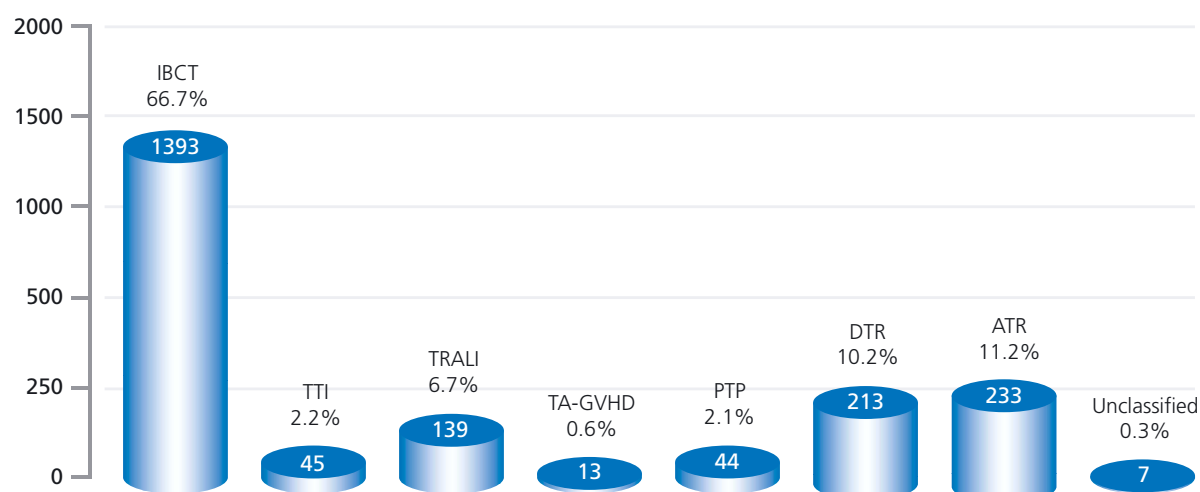


Table 2: Transfusion related mortality/morbidity according to the type of hazard reported in 457 completed questionnaires received in 2003

	Total	IBCT	ATR	DTR	PTP	TRALI	TTI
Death definitely attributed to transfusion	2	0	0	0	0	1	1
Death probably attributed to transfusion	1	0	1	0	0	0	0
Death possibly attributed to transfusion	9	1	1	0	0	7	0
Death due to underlying condition	23	16	3	3	0	1	0
Major morbidity	49	16	2	3	1	22	5
Minor or no morbidity	373	315	32	19	0	5	2
Totals	457	348	39	25	1	36	8

An electronic copy of the report is available on the SHOT website together with selected presentations from the Progress meeting on 6th July 2004

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