

SERIOUS HAZARDS OF TRANSFUSION

SHOT

Lessons for Transfusion Laboratory Staff

Update after the SHOT Annual Report 2010

Introduction

The Serious Hazards of Transfusion Scheme (SHOT) is a UK-wide confidential enquiry that collects data on adverse events of transfusion of blood and blood components. These are red cells (including autologous and salvaged red cells), platelets, fresh frozen plasma (FFP, including SD-FFP) and cryoprecipitate, and errors associated with the issue of anti-D immunoglobulin.

SHOT findings are used to:

- Aid the production of national clinical and laboratory guidelines for the use of blood.
- Improve standards of hospital transfusion practice.
- Educate users on the hazards of transfusion and their prevention.
- Inform policy within the four UK transfusion services and via the EU Commission.
- Identify new trends in adverse events and stimulate research.

An annual report and a separate summary have been published each year since the inaugural SHOT Annual Report 1996-97, and several general and specific recommendations made, which aim to improve transfusion safety. Recommendations are aimed at all levels from Chief Medical Officers, through professional bodies, Trust Chief Executive Officers, and to each and every member of hospital staff involved in the transfusion, as everyone has the opportunity to influence safe practice.

What is the most frequent transfusion hazard reported to SHOT?

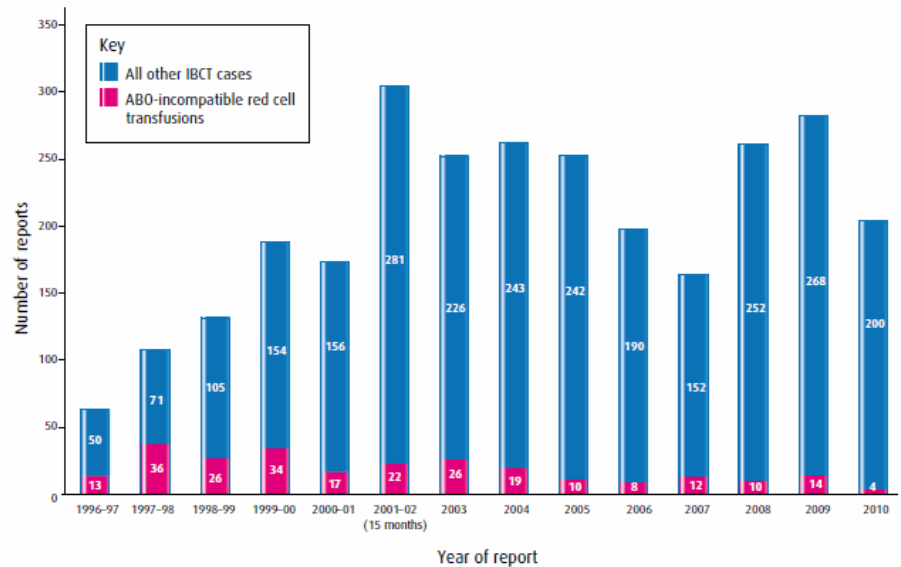
Incorrect Blood Component Transfused (IBCT) has been the most frequent transfusion hazard reported to SHOT since 1996. These incidents make up more than 35% of all incidents reported and are all preventable. However, 2010 has seen a 29% reduction overall in the number of IBCT reports: 57% less in the clinical area and 28% less in the laboratory. In the laboratory, the improvement is likely to be due to a combination of the requirements of meeting the Blood Safety and Quality Regulations (BSQR) 2005 and the recommendations of the UK Transfusion Laboratory Collaborative (UKTLC). However Transfusion-Associated Circulatory Overload (TACO) and Inappropriate & Unnecessary transfusions (I&U) are becoming major issues and have been responsible for the majority of cases of mortality.

Over a 14 year period, from 1996 – 2010, more than 34 million components have been issued from the four UK Blood Services, and there have been 8117 incidents analysed - *excluding those cases of Near Miss and Right Blood Right Patient (RBRP)*. The appointment of Transfusion Practitioners and the establishment of Hospital Transfusion Teams have resulted in an increased awareness of errors and a continuing increase in reporting (8.5 cases per 10,000 components issued in 2009 compared to 9.6 per 10,000 in 2010).

The encouraging downward trend in reports of ABO-incompatible transfusions since 1999/2000 shows evidence of a growing safety culture in transfusion in the UK. There are a small number of Trusts' who have not submitted a haemovigilance report, nevertheless we are pleased that 94.7% actually did.

Of the 4 reported ABO-incompatible transfusions in 2010, 1 was due to a laboratory grouping error and the other 3 were due to 1 Wrong Blood in Tube (WBIT) and 2 collection errors not picked up at the bedside.

There were a further 5 cases of RhD-incompatible transfusions, 2 due to laboratory grouping errors and the other 3 were due to 2 WBIT and 1 due to transfusing a patient to whom no blood was prescribed.



All figures unless otherwise stated are from the SHOT 2010 Annual Report.

What are the figures for transfusion related mortality?

There were 3 deaths of imputability 3 (definitely due to transfusion). One case of sudden unexpected death during red cell transfusion. One due to TACO, and the third death occurred in a child with sickle cell disease who suffered from hyperhaemolysis exacerbated by further transfusion.

IBCT Cases Originating in the Laboratory (n = 107)

There were a total of 107 (54%) IBCT cases in the 2010 SHOT report in which the primary error originated in the laboratory, 19% of which accounted for wrong blood incidents. This compares to 14% in 2009.

Morbidity

There were 5 women of childbearing potential transfused with K positive red cells in 2010, and 1 of these had produced anti-K at the time the cases were reported. In view of the unknown K status of the remaining cases the potential for major morbidity is unknown.

In another case an 85 year old patient experienced a delayed haemolytic transfusion reaction as blood was issued as IAT crossmatch compatible without an antibody panel, following a positive antibody screen. An anti-Jka was later identified, the patient recovered.

Wrong Blood (*n* = 21)

The 21 wrong blood incidents fell into the following 5 categories: wrong sample selected, ABO grouping errors, RhD grouping errors, incorrect component selected and incorrect labelling.

- There were 2 cases where the wrong sample was used, one where the incorrect sample was retrieved from a storage rack (out of hours) and another where the BMS took the incorrect sample off the analyser to group manually during an emergency situation.
- Two ABO grouping errors, both involving manual techniques. There was 1 ABO-incompatible red cell transfusion, following an ABO grouping error. Group AB red cells were transfused to a group A patient. *A further 9 grouping errors were reported as Near Miss incidents, all of which occurred while using manual grouping techniques.*



- Four RhD typing errors, 3 due to misreading/transcription errors when performing manual groups. The fourth case involved an inappropriate action by a BMS following an unspecified warning on a blood grouping analyser. Two cases, neither of which involved women of child bearing potential, resulted in RhD positive red cells being given to RhD negative patients, 1 of which resulted in the patient developing anti-D. *Further RhD typing errors were identified in the Anti-D section of the SHOT report, 3 cases of which involved weak RhD types and 4 were transcription errors during manual grouping of mother and cord.*



- Eleven cases of incorrect component selected. Five of these involved platelets, 4 of which resulted in RhD positive platelets being given to RhD negative patients, 3 of whom were paediatric patients. Four involved red blood cells, in which 2 cases involved RhD positive red cells being issued when RhD negative red cells were required. Two cases involved plasma components, 1 case in which a B RhD negative patient was transfused with group O

cryoprecipitate when Group A was available, and the second involved the transfusion of cryoprecipitate when FFP was requested.

- There were 2 cases of incorrect labelling, both involved labels being transposed. One of which resulted in an incompatible unit being labelled compatible and the other resulted in the patient receiving blood that was not crossmatched for them. *A further 34 cases of incorrect labelling were reported as Near Miss incidents and a further 25 cases in RBRP, this is an area of laboratory practice that should be investigated for further improvement.*

It appears that a number of manual groups are being performed on maternal samples in order to issue anti-D Ig, which is hard to understand given that there is a 72 hour window from the time of the sensitising event for the anti-D Ig to be issued and transfused. Routine automated grouping methods would appear to be more appropriate.

Learning Points

- UKTLC recommends the use of 24/7 automation for ABO/D typing.
- Variations in RhD typing of patients with a weak D antigen may be unavoidable as technologies differ in their sensitivity but it is important that the RhD type is determined by the most robust method available.
- Manual processes are more prone to error. During process validation ensure that manual procedures and interventions are kept to a minimum and that appropriate checks are in place at weak and manual points of a process.
- Training and competency based assessment must include basic, manual checking procedures.
- Competency-based training for laboratory staff must include staff who work out of hours,, both those staff who do not work regularly in transfusion and those who do, and must apply to locum members of staff.

Pre-transfusion testing and procedural errors ($n = 34$)



Eight errors occurred during pre-transfusion testing, which mirror those of previous years; incomplete testing, inappropriate actions following alerts and misinterpretation during antibody identification.

The 26 procedural errors included failure to find patients-historical records, the use of unsuitable samples for crossmatch, and incomplete testing.

All laboratories should have implemented the requirements of the Medicines and Healthcare products Regulatory Agency (MHRA) Guidance on Electronic Issue (May 2010) by March 2011. Properly implemented use of this guidance would have prevented 4 of the cases in this chapter.

Learning Points

- RhD grouping errors resulting in the erroneous administration of anti-D Ig should be reported as a grouping error under Anti-D errors. Reporters are reminded that if the primary error was in the determination of the RhD group that involved the transfusion of a blood component or product which resulted in transfusion of a component of an incorrect RhD group then the case should be reported as a grouping error under IBCT.
- Laboratories must ensure that robust systems are in place for highlighting outstanding work on a patient, for example positive antibody screen awaiting identification or group and screen not complete.
- To echo the advice given by the UK NEQAS BTLP, when interpreting antibody identification results all available information should be reviewed including patient phenotype, differential reaction by technique and result of all cells tested including screening cells.

Events in which the Special Requirements were Not Met ($n = 37$)

There has been a significant reduction in the number of cases reported, 37 compared to 67 cases in 2009. There could be a number of factors involved in this improvement, for example the effects of the BSQR 2005 and the ethos of GMP with improvements in root cause analysis and CAPA following errors and audits. The majority of these cases involved failure to provide irradiated blood components for patients treated with purine analogues/undergone a stem cell transplant. Many of the cases were as a result of warning flags being ignored/overridden/misinterpreted or the flags not being in place/updated which could have alerted BMS staff to a special requirement.

Learning Points

- Laboratories should critically assess the use of alerts/warning/algorithms on the LIMS and ensure they are being used as effectively as possible. The ability to override warnings/alerts should be discouraged.
- Training and competency-based assessment must include appropriate actions on receipt of alerts/warnings.
- Risk assess the process in place for alerting the laboratory to the need for special requirements and ascertain if that method is as robust as possible.

Additional errors originating in the Laboratory

Handling & Storage (lab-related) Errors (n = 53)

Errors continue to occur in the handling and storage of blood. Some of the cases reported were due to problems with satellite blood fridges and in many cases it was difficult to ascertain responsibility for the error.

Communication is equally important between clinical and laboratory staff. It is important to document the storage and transportation of all blood components as it acts as a communication link between clinical and laboratory staff when determining the fate of a unit.



Learning Points

- Hospitals should have a robust policy in place for removing expired blood components and components past their suitability date from the satellite fridges.

Inappropriate & Unnecessary (lab-related) Errors

The number of I&U transfusions continues to rise with similar findings to previous years with respect to the causes of misleading laboratory results. There were 56 cases in which transfusions took place that were based on wrong Hb, platelet or coagulation results.

Learning Points

- Unnecessary transfusions could be avoided if:
 - a) laboratories did not transmit results they know or suspect to be inaccurate, but instead requested a second sample
 - b) laboratories required confirmation of correct transmission of telephoned results.
- In accordance with HSC 2007/001 (Better Blood Transfusion) protocols should be in existence which empower lab staff to question the appropriateness of requests for transfusion.

Haemolytic Transfusion Reactions

In 3 cases (1 acute and 2 delayed) an antibody was only detectable in an eluate made from the patient's red cells. This is a recurring theme, but despite this an eluate was not tested in a majority of the 40 HTR cases reported in 2010.

Learning Points

- Testing an eluate is an important part of investigating a HTR, and may be the only way of identifying any or all of the antibodies present.
- Systematic exclusion of all antibodies of likely clinical significance is an essential part of the antibody identification process and may necessitate the use of further red cells or techniques.

Paediatric Laboratory Errors ($n = 15$)

There were an increased numbers of paediatric laboratory error reports in 2010. Eight were from infants <1 year of age, with 3 relating to the laboratory not taking into account maternal antibodies when issuing blood for young infants, and 2 in infants >4 months old issued paedipaks without serological testing. Two involved RhD errors, 1 in RhD grouping and 1 where an RhD negative neonate was given RhD positive red cells. In the final infant report, paedipaks (CMV negative, irradiated) were issued for neonatal exchange transfusion instead of neonatal exchange red cells.



Learning Points

- Laboratories should critically assess:
 - the way in which mother and baby records are linked on the LIMS
 - the way in which alerts/warnings/algorithms are used on the LIMS
 - the process in place for alerting the laboratory to patient specific special requirements.
- Training and competency based assessment must include:
 - actions to take on receipt of alerts/warnings on both the LIMS and on analysers
 - and highlight the less common transfusion scenarios

Key Recommendations for Transfusion Laboratory Staff

Improving Laboratory Standards

SHOT supports the recommendations of the UK-Transfusion Laboratory Collaborative with regard to hospital transfusion laboratory staffing, technology, training and competencies.

Trusts should implement the recommendations of the UKTLC. Work should continue with suppliers of LIMS to improve the capability of IT systems to generate warning flags and implement component selection algorithms based on data incorporated in the component label. These improvements should be in line with the recommendations of the BCSH guidelines on laboratory IT systems currently in preparation.

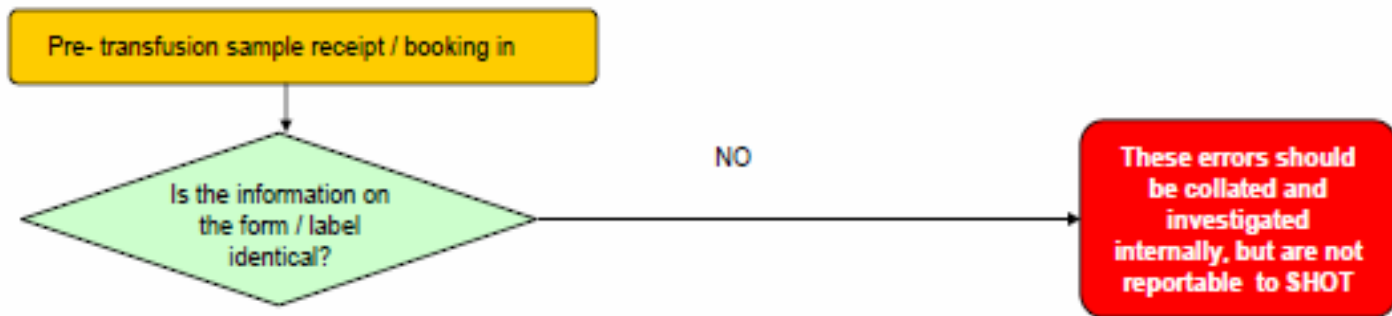
Laboratory and Clinical IT Systems

IT solutions to patient ID and for documentation of the audit trail for blood components have become more common in recent years. Undoubtedly the occurrence of certain errors can be reduced by appropriate implementation of IT-based checking systems, but new possibilities of error may also be introduced. Over-reliance on IT and believing it circumvents human error can result in a decrease in understanding of and engagement with the transfusion process among the staff involved.

Adequate knowledge and skills are no less essential in the presence of vein-to-vein electronic tracking system, and education and training must be comprehensive and appropriate to the staff groups involved at each stage. All staff must be familiar with the process, able to carry it out safely (with or without electronic aid) and able to detect deviations from normal situations, and make safe and appropriate decisions as each circumstance arises.

SHOT Reporting Laboratory Flow Chart

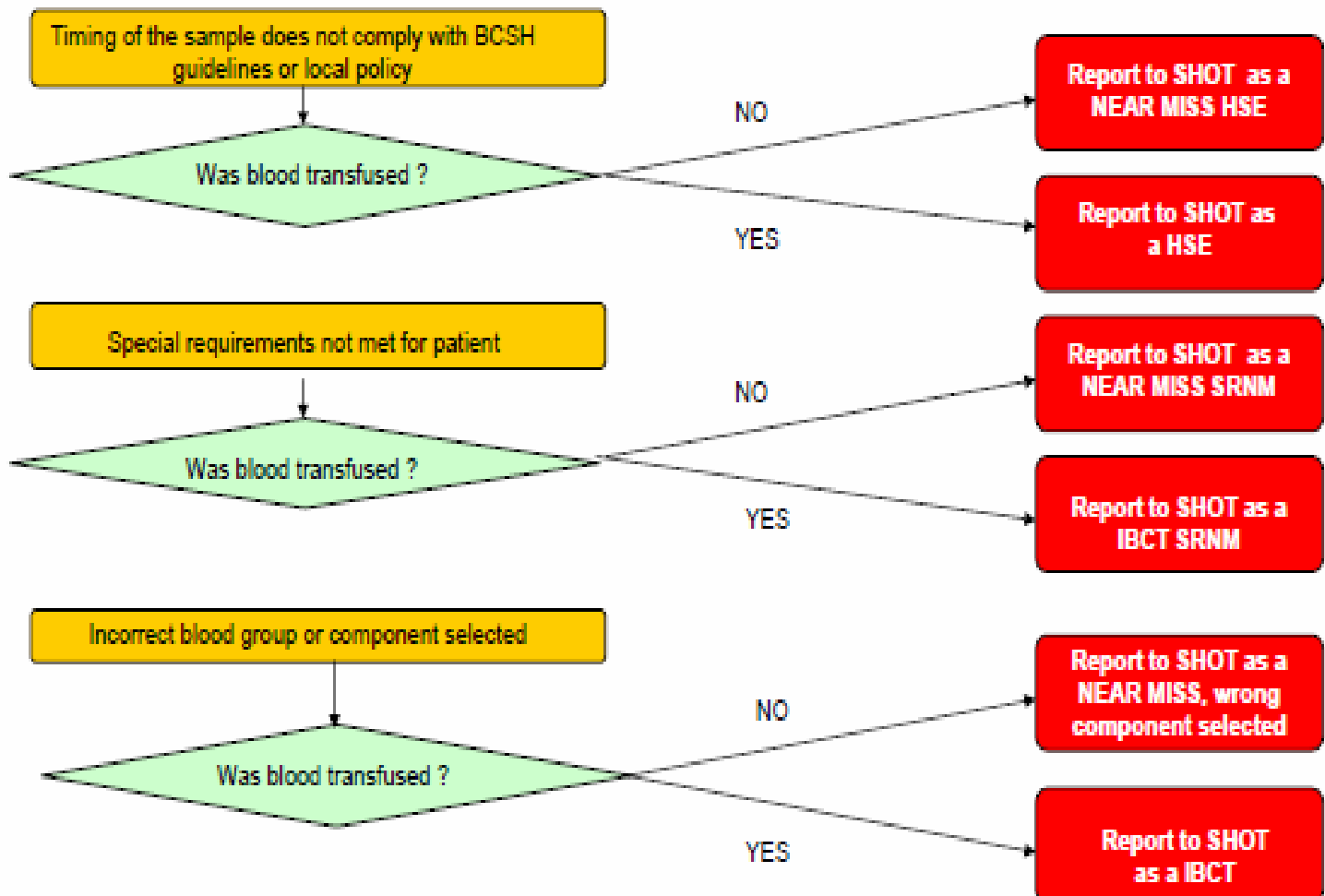
Sample receipt



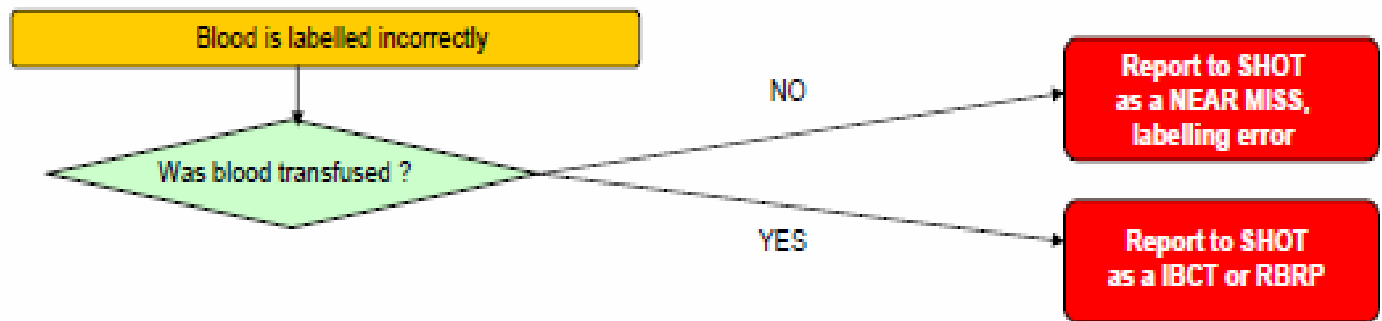
Grouping



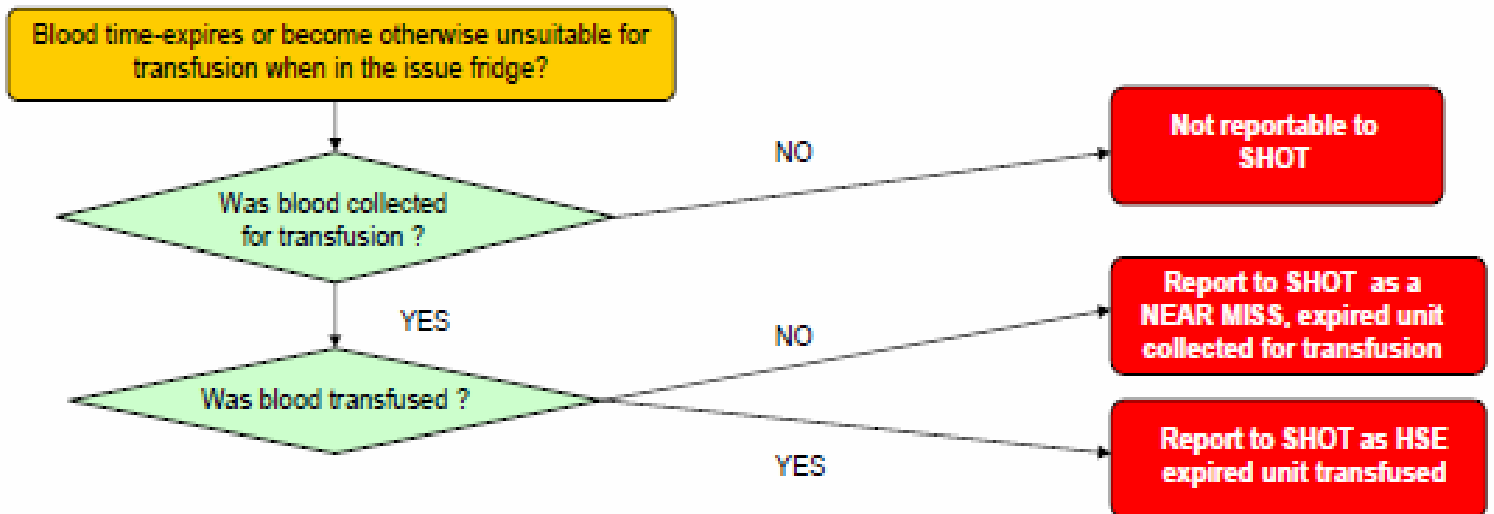
Crossmatching



Labelling



Issue/Collection



If you would like more information on SHOT please contact:

The SHOT Office, Manchester Blood Centre, Plymouth Grove, Manchester M13 9LL

Telephone: 0161 423 4208

Email: shot@nhsbt.nhs.uk

Website: www.shotuk.org

For laboratory related queries you can contact the Laboratory Incident Specialist directly on:

Telephone: 0161 423 4235

Email: hema.mistry@nhsbt.nhs.uk

