SERIOUS HAZARDS OF TRANSFUSION **SHOT**

Summary of ANNUAL REPORT 1996-97

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Key Observations and Recommendations

(see more detailed analysis overleaf)

✧ Of 169 reports received, 81 (47%) were episodes where patients had received a blood component intended for another patient, these resulted in 1 death and 9 cases of morbidity.

✧ Two thirds of such episodes involved a series of errors and incomplete adherence to documented policies.

✧ Collection of blood from its storage site (usually the hospital blood bank) is a major source of primary identification error (30 cases). National standards should be set for a minimal formal identification requirement when a component is collected and for staff training in this area. Novel identification systems are available, but have resource implications. These systems merit evaluation and development.

✧ The bedside check is vital in preventing transfusion error. Every hospital should have a policy for formally checking the blood component at the bedside. There is wide variation in nursing observations during transfusion. A national protocol for administration and monitoring of transfusion is being developed by the British Committee for Standards in Haematology (BCSH).

✧ The one fatal case of ABO incompatibility resulted from bedside transposition of samples taken for cross-matching. This was associated with the use of a pre-labelled sampling tube. This is **not** a recommended 'safe' practice .

✧ Laboratory errors were seen in blood grouping and cross-matching procedures. Blood bank systems and training should be reviewed locally for compliance with national guidelines.

✧ Access to historical blood bank records is essential at all times, since the information may alert staff to errors of requesting, sampling or ABO grouping, and to pre-existing antibody(ies) not detectable at the time of crossmatch.

✧ The investigation of acute and delayed transfusion reactions is highly variable, and would benefit from standardisation.

✧ A newly recognised complication of transfusion has been observed in 4 patients. All experienced hypotension +/- flushing after transfusion of red cells or platelets through a negatively charged bedside leucocyte depleting filter.

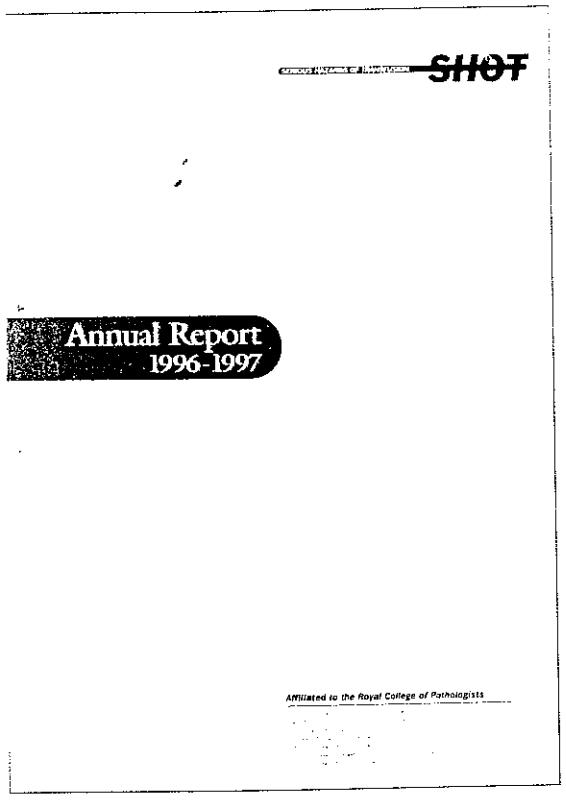
✧ Reported and confirmed transfusion-transmitted infections were rare (8 cases), with bacterial transmission the single commonest infection (3 cases). However, bacterial cases may be under-diagnosed due to incomplete investigation. A standard protocol for investigation of suspected cases is required.

✧ The current BCSH guidelines on prevention of transfusion-associated graft-versus-host disease should be widely available for non-haematology staff who may treat at-risk patients.

✧ Local arrangements for the ordering and administration of blood components should include safeguards to ensure that gamma irradiated components are always given when appropriate.

✧ Each hospital should have a hospital transfusion committee or other appropriate forum to ensure local 'ownership' and dissemination of procedures and guidelines throughout the hospital. This forum should also review all cases of procedural error.

✧ Currently, several organisations produce recommendations and guidelines aimed at assuring safety in different parts of the transfusion process. A unified body with overall responsibility for transfusion safety could set priorities and direct resources for maximum patient benefit.



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, the information obtained will contribute to:-

a) improving the safety of the transfusion process

b) informing policy within Transfusion Services

c) improving standards of hospital transfusion practice

d) aiding production of clinical guidelines for the use of blood components.

Participation in the scheme is voluntary, and covers both NHS and private hospitals in the United Kingdom and Ireland.

Cases Included

In its first year, the scheme aimed to capture data on major complications of transfusion:-

Non Infectious

- 'Blood into wrong patient' (whether ABO incompatible or not, and irrespective of whether harm arises)
- Severe haemolysis - acute or delayed
- Anaphylaxis
- Transfusion-related Graft versus Host Disease
- Transfusion-related acute lung injury
- Post transfusion purpura

Infectious

- Suspected or confirmed cases of microbial transmission (bacterial, viral or parasitic).

Adverse events associated with transfusions from volunteer donors, family members and autologous transfusions are included. 'Near-miss' events are not so far included; these should be reviewed locally.

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. **To assure confidentiality and anonymity, once all information has been gathered about a case, all hospital identifiers are removed by the SHOT office before entry to the computerised database.**

Suspected cases of transfusion-transmitted infection are reported through supplying Blood Centres. This is ESSENTIAL to ensure timely withdrawal of other potentially infected components.

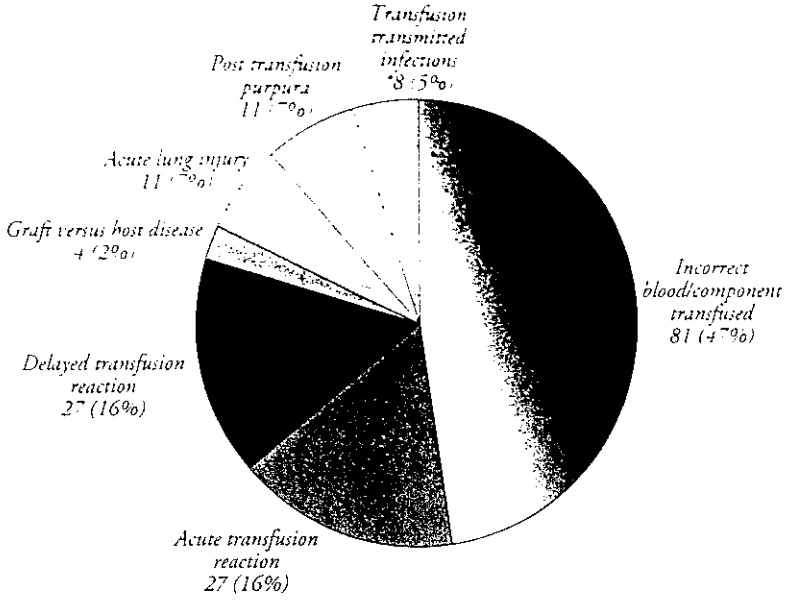
Scope Of This Report

The data in this report are derived solely from analysis of questionnaires concerning non-infectious cases which occurred between 1st October 1996 and 30th September 1997, and also includes 14 incidents which occurred earlier, and which were used to pilot the questionnaires. Twenty-seven incidents are still under investigation and will be included in next year's report. Because post-transfusion infections may be reported months or years after the tranfusion, this report includes data on post-transfusion infection incidents initially reported by blood centres between 1st October 1996 and 30th November 1997, even if the transfusion occurred in previous years.

Overview Of Results

Of the 424 hospitals informed of the SHOT scheme, 94 hospitals reported 169 events.

Serious post transfusion complications reported by category (n=169)



*3 bacterial, 1 hepatitis A, 1 hepatitis B, 1 hepatitis C, 1 HIV, 1 malaria.

Transfusion related mortality/morbidity at the time of receipt of the completed questionnaire (n=141)

	Incorrect component transfused	Major acute transfusion reaction	Major delayed transfusion reaction	Post transfusion purpura	Graft versus host disease	Transfusion related acute lung injury	Transfusion transmitted infections
Death attributed to transfusion	1	1	2	1	4	2	1
#Major morbidity	9	1	12	3	0	7	7
***Minor/no morbidity**	52+	22	9	7	0	0	0

#Defined as:-

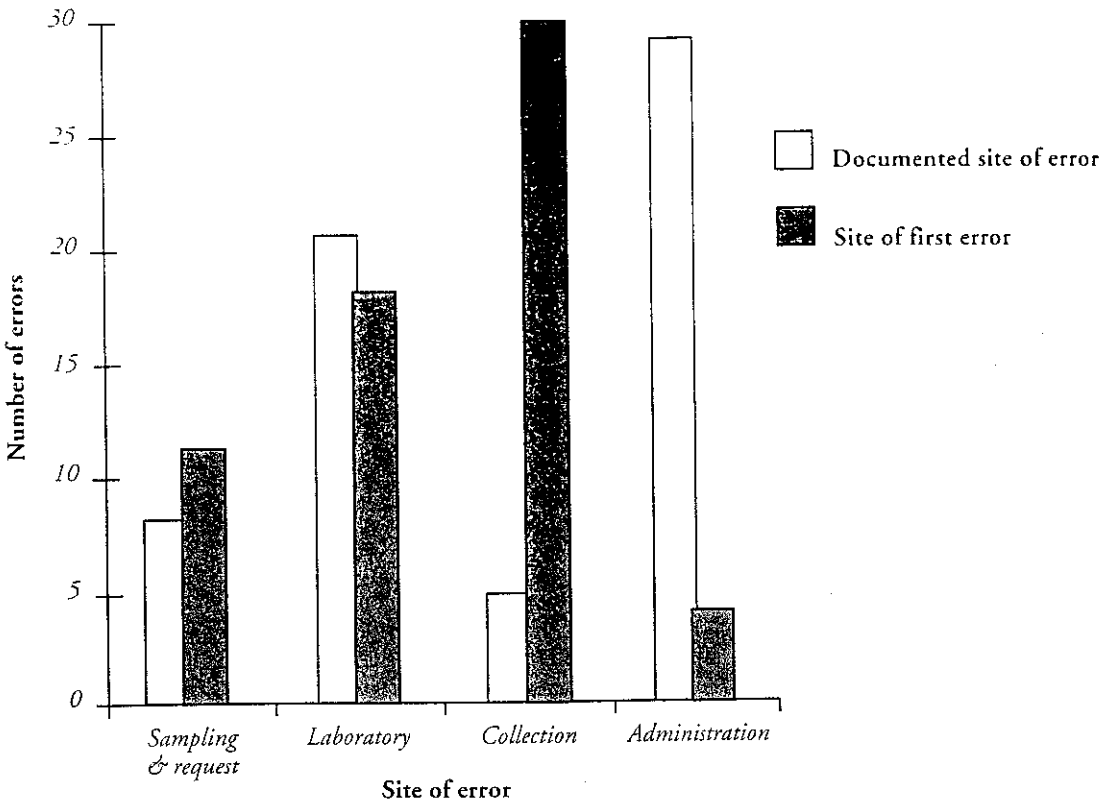
- Intensive care unit admission and/or ventilation
- Dialysis and/or renal dysfunction
- Major haemorrhage
- Jaundice including intravascular haemolysis
- Persistent viral infection
- Acute symptomatic confirmed infection

Eleven patients died of their underlying condition.

+Included 3 cases of potential Rhesus sensitisation in young women/girls.

Wrong Blood To Patient

Of 63 fully investigated cases, 16 were ABO incompatible, resulting in 1 death and 9 cases of major morbidity, including frank intravascular haemolysis in 4.



✧ The 63 cases fully analysed revealed 142 procedural failures. Two-thirds of cases involved more than 1 error at different stages of the process.

✧ The one fatal case of ABO incompatibility resulted from bedside transposition of samples taken for cross-matching. This was associated with the use of a pre-labelled sampling tube. This is not a recommended 'safe' practice .

✧ Five errors involved failure to order irradiated or CMV negative components for at risk patients. All were associated with the patient or supply point being remote from the specialist unit. Two further errors involved telephone requests. Clear procedures for telephone/off site ordering are needed, which define the respective responsibilities of medical and blood bank staff, with regard to provision of special requirements.

✧ There were 21 cases of laboratory error, including incorrect grouping/crossmatching (13), mislabelling (3) or selection of the wrong component (5). In 2 cases an incompatible transfusion could have been prevented by reference to historical records. Access to previous transfusion records in the laboratory containing grouping information should be available at all times.

✧ Blood banks should review procedures and systems including enforcement of the current BCSH guidelines, in addition to training to prevent technical or sample handling errors.

✧ Collection of blood from its storage site (usually the hospital blood bank) is a major source of primary error (30 cases). Hospitals should review their current system to ensure that errors in this area can be prevented. National standards should be set for a minimal formal identification requirement when a component is collected. Novel identification systems are available, but have resource implications. These systems merit evaluation and development.

✧ Misidentification of the patient at the time of transfusion can be the first site of error (4), but was more commonly associated with failure to recognise earlier errors (29). Hospital procedures should ensure that patients can be formally identified at the time of both sampling and transfusion. Out-patient transfusions require particular care in identifying the patient.

✧ The bedside check is vital in preventing transfusion error. Staff should be vigilant in checking identification details of the component against those of the patient. Every hospital should have a policy for formally checking the blood component at the bedside. This area is currently being addressed by BCSH.

✧ In 1 case, a blood component was given to a patient for whom transfusion had not been prescribed. Blood components should always be administered against a written prescription.

Specific

Acute and Delayed Transfusion Reactions

- In general, these do not result from poor practice and cannot usually be predicted.

- Patients repeatedly reacting to transfusions often receive multiple doses of hydrocortisone. The use of a simple anti-pyretic such as paracetamol should be considered.

- There is wide variation in the frequency and nature of nursing observations. National standards are required and are being developed by BCSH.

- There is also wide variation in the way such episodes are investigated, sometimes resulting in incomplete data. A national review of the requirements for samples and investigations following both acute and delayed transfusion reactions is recommended.

- In 4 cases, the cross-match sample was taken > 4 days prior to the transfusion. This is not recommended in current BCSH guidelines for pre-transfusion compatibility testing.

- A recently recognised type of reaction is hypotension following the use of bedside leucocyte depleting filters with negative surface charge (4 cases; 1 red cell, 3 platelets). This has previously been reported after platelet transfusion in patients receiving treatment with angiotensin converting enzyme inhibitor drugs (1case here), and is now also evident in the absence of such treatment in 1 recipient of a red cell transfusion.

- The importance of taking full transfusion and obstetric histories should be stressed.

- Access to off-site computer records may alert to pre-existing antibody(ies) not detectable at the time of crossmatch.

Transfusion-Transmitted Infections

- Reported and confirmed transfusion-transmitted infections are now rare. Data will require to be analysed over several years to allow a complete picture to emerge. Full reporting of such cases to local transfusion centres is essential.

- Four confirmed cases were transfused in 1996 - 1 hepatitis A, 1 hepatitis B, 1 hepatitis C, 1 HIV. Four confirmed cases were transfused in 1997 - 3 bacterial, 1 malaria (fatal).

- Three cases (1 HBV, 1 HCV, 1 HIV) were due to donors in the marker negative 'window period' of infection. All 3 cases were from 'repeat' donors. Two of the cases (1 HAV, 1 HCV) were identified after 'lookback' testing of recipients of previous donations from donors who had either sero-converted (in the case of HCV), or reported a hepatitic illness soon after donation (in the case of HAV).

- Two incidents of bacterial infection were associated with platelet transfusion, and the other with red cells (Serratia liquifaciens of unknown origin). One platelet-associated transmission arose from bacteria on the donor's arm (Bacillus cereus); the source of the other (Escherichia coli) was not identified. Confirmation of such cases depends on collection of appropriate samples following the transfusion. A national protocol for the investigation of such cases is being developed.

- The malaria transmission related to a donor who had been resident as a child in a malarious area. Donor selection criteria have now been amended to permanently exclude such individuals as cell donors, unless they are shown to be negative for malarial antibodies.

Transfusion-related Acute Lung Injury

- There were 9 cases, including 2 fatalities. Three other cases required ventilation.

- Unexpectedly, the implicated component was red cells in 3 cases (platelets in 3 and fresh frozen plasma in 2).

- In 7 cases, positive serology was obtained on the donor (HLA and/or granulocyte antibodies). All suspected cases of TRALI should be reported to Blood Centres for appropriate investigation.

- Donors implicated in cases of TRALI may be unsuitable even for collection of red cell components containing little plasma. Such donors should be withdrawn from donor panels.

Post-Transfusion Purpura

- All 11 cases (1 fatality) resulted in a dangerously low platelet count. PTP should be considered in any parous woman who develops thrombocytopenia with or without haemorrhagic features after red cell transfusion.

- As the time of onset is generally > 5 days after transfusion, patients may present after discharge from hospital.

- Early involvement of a haematologist in cases of significant unexplained post-operative thrombocytopenia will ensure appropriate investigation. All cases were associated with platelet alloantibodies in the patient (HPA-1a in 8).

- In 10 cases, treatment with intravenous immunoglobulin +/- steroids was associated with normalisation of the platelet count in <7 days.

Transfusion-Associated Graft-Versus-Host Disease

- There were 4 cases, all fatal.

- One case was an infant with a highly unusual form of immunodeficiency, 2 were in adults with B cell non-Hodgkin's lymphoma, and 1 was in an apparently immunocompetent adult.

- In view of the small number of cases reported, no firm conclusions can be drawn as to whether current recommendations for TA-GVHD prevention require review. Hospitals are urged to report any further cases so that a complete picture can emerge.

- The current BCSH guidelines on prevention of transfusion-associated graft-versus-host disease should be widely available for non-haematology staff who may treat at-risk patients.

- Local arrangements for the ordering and administration of blood components should include safeguards to ensure that gamma irradiated components are always given when appropriate. Where patients are being treated on a 'shared care' basis between eg a bone marrow transplant centre and their local hospital, a warning card carried by the patient may be helpful.

Organisation

Ownership of the scheme and data generated from it resides with the Steering Group, with wide representation from Royal Colleges and professional bodies. Post-transfusion infection reporting is jointly run by the Public Health Laboratory Service Communicable Disease Surveillance Centre and the National Blood Service. The operational aspects of the scheme are the responsibility of a Standard Working Group, which is accountable to the Steering Group. Two National Co-ordinators are responsible for receiving and collating reports. For the first 2 years, funding will come from the Transfusion Services within the UK and Ireland. A generous grant from the British Society for Haematology is gratefully acknowledged.

Steering Group

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** Also member of Standing Working Group*

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This summary has been sent to hospital haematologists with responsibilities for transfusion (as identified through serology NEQAS), blood bank managers, and NHS Trust Chief Executives. Copies of the full Annual Report 1996-1997 (£15) are available from the SHOT office - please send a cheque made payable to National Blood Service, Northern Zone-SHOT.

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