Summary of ANNUAL REPORT 1998-99

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on behalf of the SHOT steering Group

Key Observations and Recommendations

◊ Of the 432 hospitals eligible to participate, 132 (30.6%) submitted reports, representing an increase of 4% over the previous year and an overall increase of 8.5% since the scheme began. A further 204 hospitals sent "Nil to Report" returns. Overall participation is now running at 77.8% (336/432 hospitals), compared with 65% last year. This increase in participation is very gratifying.

◊ A total of 252 reports were received this year, an increase of 27.9% from the 197 new reports last year, and an overall increase of 49.1% since the scheme began. As in the previous years the largest category remains "incorrect blood component transfused" with 144 reports this year, compared with 110 last year, an increase of 30.9%.

◊ **In line with Health Service Circular 1998/999 'Better Blood Transfusion', systems of Clinical Governance within Trusts should ensure a commitment to SHOT reporting and to changes in practice resulting from SHOT observations and recommendations.**

◊ For the third year running the most important single cause contributing to mis-transfusion was failure of some aspect of the bedside checking procedure immediately prior to administering the transfusion. There was some evidence to suggest that interruption during this critical step may have played a significant part in failure of the process.

'WRONG BLOOD' INCIDENTS ARE PREVENTABLE

◊ **An important guideline on how to achieve this has been published by the BCSH (British Committee on Standards in Haematology). This guideline must now be widely promulgated to all staff handling blood. The Hospital Transfusion Committee provides a useful structure through which this can be done.**
Hospitals must ensure that ALL staff handling blood receive correct training and regular retraining.

THE FINAL BEDSIDE CHECK

◊ **The bedside check is the last opportunity to detect an identification error, and it is vital that its importance is recognised. The environment in which the transfusion is conducted must provide adequate space and allow staff responsible for the bedside check to carry this out as an uninterrupted checking procedure.**

◊ **Hospital systems must ensure that there are no exceptions with regard to the provision of patient identity wristbands or their equivalent.** This is particularly important in the outpatient setting where familiarity with the patient may lead to a tendency to cut corners in the formal checking procedure. It is also appreciated that a visible patient identity band may be difficult to achieve in theatre, but since it is the only definitive means of identifying an unconscious patient, all possible steps must be taken to maintain visible patient details.

INFORMATION TECHNOLOGY WILL PREVENT HUMAN ERROR

◊ **COMPUTERISED IDENTIFICATION SYSTEMS ARE AVAILABLE TO ENSURE SAFE TRANSFUSION AT THE BEDSIDE. THESE SYSTEMS MUST NOW BE EVALUATED. THE NHS IT STRATEGY SHOULD TAKE A LEAD IN ASSESSING THIS AREA OF NEW TECHNOLOGY**

◊ The above recommendations relate to the final bedside check. However, this will not necessarily detect errors of sampling or in the blood bank, so importance must be given to the earlier steps in the transfusion chain.

◊ **Individuals responsible for the prescription and request of blood components must be familiar with the special requirements of their patients.**

- **Staff responsible for taking samples for transfusion testing must at all times follow strict procedures to avoid confusion between patients at the time of sampling. Sample tubes must never be pre-labelled and labelling must be completed for one patient before moving on to the next. Special care is required when dealing with "unknown" multiple casualties.**
- **The historical transfusion record must be available in the blood bank, consulted and acted upon at all times.**
- **Blood banks must continue to be vigilant in reviewing procedures, systems, and training to prevent sample handling and technical errors.**
- **Hospitals must develop unambiguous protocols for the management of blood in satellite refrigerators.**
- **Telephoned requests for blood components must be formally recorded and include full patient details plus any special detailed transfusion requirements.**
- **Hospitals must ensure that standards are set for minimum formal identification requirements when blood is collected from the hospital blood bank, and that staff undertaking this procedure are fully trained and aware of the key role which they play.**

IMMUNE COMPLICATIONS OF TRANSFUSION

- There was no clear association between leucodepletion and any specific types of adverse event. There were no cases of TA-GVHD due to failure to prescribe irradiated components appropriately, and none in which irradiated components failed to prevent TA-GVHD.

  Any possible impact of universal leucocyte depletion of the blood supply (achieved in November 1999) on TA-GVHD incidence will take several years of further monitoring to emerge, so it is critical that details of all cases are reported to SHOT. A standard protocol for the investigation of suspected TA-GVHD cases should be developed.

  Patients at risk of TA-GVHD who are receiving shared care between a transplant/oncology centre and their referring hospital should carry a card to indicate their need for irradiated components.
- PTP is almost certainly underreported, but cases were investigated and managed appropriately. This is the first year in which platelet alloantibodies combined with heparin-associated antibodies have been reported. As many as 50% of patients receiving heparin develop antibodies detectable by ELISA techniques.

  In patients diagnosed as having heparin-induced thrombocytopenia in whom there is no thrombosis, platelet-specific alloantibody investigations should be considered if the patient has ever been pregnant or transfused.
- **UK Transfusion Services should consider possible strategies for prevention of TRALI. This recommendation needs to be considered in its broadest aspects, including an option appraisal of different approaches to donor selection/screening, logistics, effect on the blood supply and cost-effectiveness.**

TRANSFUSION TRANSMITTED INFECTION

Of 34 suspected cases of transfusion-transmitted infections only 7 were confirmed to be related to transfusion. Thesecomprised 1 hepatitis B, 1 hepatitis C and 5 bacterial transmissions of which 2 were fatal. Of the 5 bacterial cases, 1 was a fatal Yersinia enterocolitica transmission from a 33-day old non-leucocyte depleted unit of red cells, 2 were from apheresis platelets (1 Staph epidermidis and 1 E coli), and 2 were from pooled platelets (1 Staph epidermis and 1 Bacillus cereus, cultured from the donor arm). All 4 platelet donations were at least 3 days old.

- The full report contains many recommendations which require action at local level. However some proposals require policy decisions taken centrally, either by the UK Transfusion Services or by the Department of Health e.g. allocation of new resources into patient identification systems, strategies for TRALI prevention. The UK still lacks a single strategic framework for blood safety which incorporates all relevant expertise, including that from the specialties of Public Health and Health Economics.
- **There remains a need for an overarching approach to decision making in relation to blood safety. A national unified body is needed, with appropriate relevant expertise and representation from professional bodies which can prioritise new initiatives in blood safety. This should be complemented by a parallel initiative on appropriate prescription of blood.**

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.

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
- Transmission-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 Public Health Laboratory 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 (E M Love and K Soldan) together with an assistant (H Jones) are responsible for receiving and collating reports.

Standing Working Group

Dr L M Williamson (Chair), Dr E M Love (Secretary), H Jones, D Asher, Dr D Norfolk, Dr A Todd, C Atterbury, Dr D Gozzard, J Revill, Dr H Cohen

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 Committee for Standards in Haematology	*Dr P Kelsey*
◊ British Society for Haematology	*Dr H Cohen (Chair)*
◊ Institute of Biomedical Science	*Mr JA Revill (Secretary)*
	Mr B McArdle
◊ Institute of Health Service Managers	*Mr IR Cumming*
◊ Public Health Laboratory Service/ Communicable Disease Surveillance Centre	*Dr M Ramsay*
◊ Royal College of Anaesthetists	*Dr AJ Mortimer*
◊ Royal College of Nursing	*Mrs S Scott*
	Ms C Atterbury
	Mrs P Hooper
◊ Royal College of Obstetricians and Gynaecologists	*Mr DL Economides*
◊ 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*

Overview Of Results For This Report

◊ Of the 432 hospitals eligible to participate, 132 (30.6%) submitted initial reports during the reporting year. 103 of these hospitals confirmed that they had previously submitted a report when they returned the "Nil to Report" card. The 132 reporting hospitals represents an increase of 4% over the previous year and an overall increase of 8.5% since the scheme began. A further 204 hospitals sent "Nil to Report" returns. Combining these 204 with the 132 hospitals which sent reports, participation is now running at 77.8% (336/432 Hospitals), compared with 65% last year.

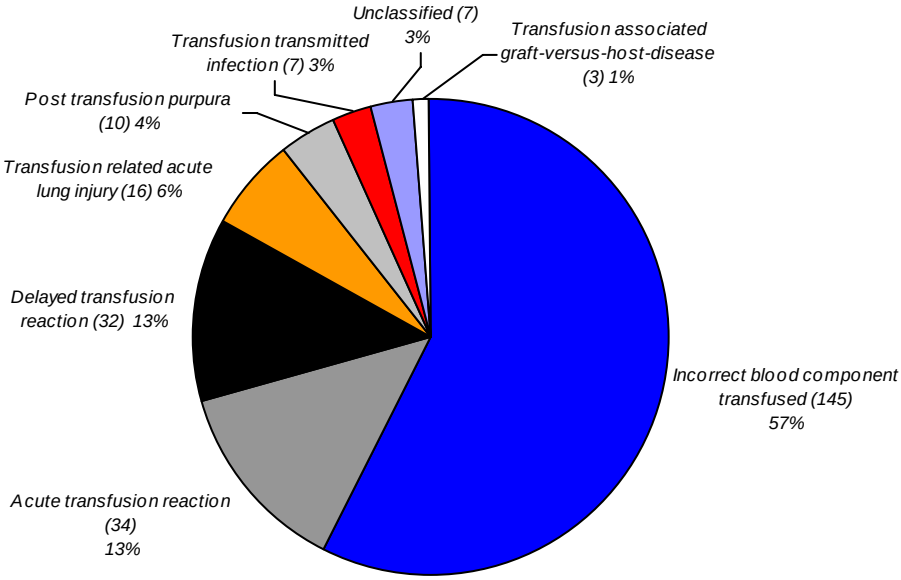
◊ This reporting year showed an increase in reporting of 27.9% (252 initial reports compared with 197 in the previous year). The numbers of reports in each category received since the first SHOT annual report are shown below.

		1997/1998		
	1996/1997	New Cases	Total	1998/1999
IBCT	81	110	121	144
ATR	27	28	30	34
DTR	27	24	27	31
PTP	11	11	13	10
TA-GVHD	4	4	4	3
TRALI	11	16	16	16
TTI	8	4	4	7
Unclassified				7
TOTAL	**169**	**197**	**215**	**252**

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

* Unclassified 7 reports which we were unable to categorise

Overview of 252 cases for which initial report forms were received



Transfusion related mortality/morbidity according to the type of hazard reported in completed questionnaires (244)

	Total	IBCT	ATR	DTR	PTP	TA-GVHD	TRALI	TTI	Unclass-ified
Death definitely attributed to transfusion	**7**	1	0	1	0	3	0	2	0
Death possibly attributed to transfusion	**9**	2	2	0	1	0	4	0	0
Death due to underlying condition	**14**	10	1	2	0	0	0	1	0
Major morbidity	**29**	12	1	0	0	0	12	4	0
Minor or no morbidity	**176**	108	27	27	9	0	0	0	5
Patient outcome - unknown	**9**	3	3	0	1	0	0	0	2
Totals	**244**	**136**	**34**	**30**	**11**	**3**	**16**	**7**	**7**

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
- ◊ Jaundice including intravascular haemolysis
- ◊ Potential RhD sensitisation in a female of child-bearing potential
- ◊ Persistent viral infection
- ◊ Acute symptomatic confirmed infection

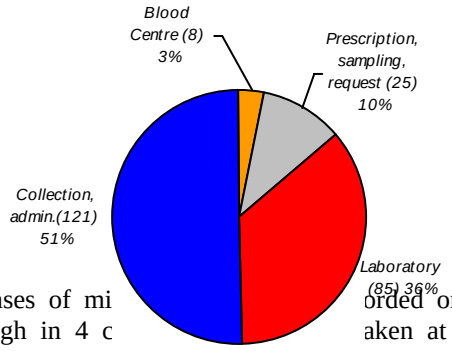
Incorrect Blood Component Transfused

As in previous years this category represents the highest number of reports (144 or 57.1% of 252 new cases). 132 questionnaires plus 4 explanatory letters were analysed (136 cases) including 5 which were outstanding from the previous year. Patient outcome of these 136 cases is presented in the table below.

Outcome	Number of incidents
Death definitely related to transfusion	1
Death possibly related to transfusion	2
Death unrelated to transfusion	10
Recovered from complications of intra-vascular haemolysis	5
Major morbidity	7
Survived with no ill effects	108
*Unknown	3

* 3 cases had outcomes unknown at the time of reporting. 1 patient had been referred to another hospital and 1 was still receiving dialysis. In a third case the reporter stated that it had been difficult to obtain co-operation from the relevant consultant.

- As has been pointed out in our first two reports, ensuring that the right patient receives the right transfusion at the right time is a complex multi-step process which crosses several professional and managerial boundaries and may involve many individuals.
- The 136 cases analysed yielded a total of 239 errors. In 14 cases 3 errors were made, in 4 cases there were 4 errors each and in 1 case a total of 7 errors was identified. The distribution of errors is shown below.



- No cases of mi orded on this occasion although in 4 c aken at the bedside to transfuse inappropriate components.
- The most common request error was failure to request irradiated components for patients at risk, notably 3 patients being treated with Fludarabine, 2 neonates with a history of previous intra-uterine transfusion and 2 patients with Hodgkin's Disease.
- There were 2 cases involving the taking of samples from the wrong patient.
- Errors in the labelling of request forms and/or samples were noted on 8 occasions.
- As in previous years hospital blood bank errors were not restricted to either inexperienced staff or to "out of hours" situations. 2 errors were made by a driver / health care assistant who had been authorised to collect blood products without reference to an MLSO.
- 5 errors fell into the category of transposition of samples. 4 of these resulted in the transfusion of ABO incompatible red cells. 3 patients survived with no ill effects but one died, possibly related to the adverse effects of the transfusion.
- There were 22 errors related to a failure to consult / act on the historical blood bank record.
- 25 errors occurred in grouping, screening and cross-matching resulting in 13 cases of RhD positive red cells being transfused to RhD negative patients, 3 transfusions of ABO incompatible red cells, 2 cases of administration of anti D immunoglobulin to RhD positive patients and 2 cases of transfusion of incompatible FFP.
- Incorrect labelling of component and/or issue voucher was reported in 9 cases and resulted in 3 ABO and 2 RhD incompatible transfusions.
- Failure to clear stocks of components from satellite storage sites resulted in the transfusion of out-dated or incompatible red cells. These incidents serve to highlight the confusion which surrounds the management of satellite blood component storage areas in some hospitals.
- As in previous years the withdrawal of an incorrect component from its storage site continues to be a significant source of error. 30 errors were reported in this category.
- Collection errors were always followed by failure of some aspect of the bedside checking procedure illustrating how mistakes at this important intermediate stage in the transfusion process set the scene for subsequent errors resulting in "wrong blood" incidents. The 60 incidents which fell into the category of failure of bedside checking procedures comprised 25% of all procedural errors. "Wrong blood" incidents resulted in 19 cases of major ABO incompatibility.
- Causes of mid-identification included remote checking of the component at the nurses' station rather than at the patient's bedside, confusion of patients with the same or similar names and failure to check the component label details against the patient. In one case, confusion over two patients with same surname resulted in the mis-transfusion of a group O patient who, although anaemic, had only been requested for a "group and screen". A subsequent transfusion reaction was noted but not acted upon. This patient became very ill and died within six hours of the transfusion.
- **"Wrong blood" incidents are without exception avoidable errors and it cannot be over-emphasised that the bedside check is the final, vital step in preventing mis-transfusion.**
- **Every hospital must have a formal policy for the bedside check which must be rigidly enforced on all occasions.**

Immune complications of transfusion

- There was a slight increase in reports of acute and delayed reactions (65), with new reports of TA-GVHD (3), PTP (10) and TRALI (16) remaining at a constant level.

- One report of an acute transfusion reaction was received in which a child had two attacks of facial oedema following administration of leucodepleted components. **Clinicians should continue to report all serious adverse events as this may act as an early alert to adverse effects of novel techniques.**
- There is little evidence of poor laboratory practice in cases of delayed transfusion reactions. The majority of DHTRs occurred as the result of the development of new antibodies which could not have been detected or predicted pre-transfusion. However there is evidence that in some cases antibodies may have been present but "masked" by other antibodies in the sample. **Laboratories should ensure that any antibodies which may be masked have been excluded by the use of additional panels and techniques (e.g. enzyme treated cells).**
- Over the 3 year period SHOT has been running, there have been a total of 43 reported cases of TRALI. Of these, 6 have been fatal, and a further 23 have required ITU care. If all such cases truly had TRALI as a sole or contributory factor to their outcome, this total of 29 cases makes TRALI the second most common cause of death/ITU care following transfusion after ABO incompatibility.
- All cases of PTP were treated appropriately and promptly with intravenous immunoglobulin. There is no evidence that steroids offer any additional advantage.
- TA-GVHD remains a rare complication of transfusion, with 3-4 reports annually for the last 3 years. It is disappointing that questionnaires giving a full description of the case have been received for only 2 of the 4 new cases.

Transfusion-transmitted infections

- 34 initial reports of post-transfusion infections were made by blood centres during the reporting year. Of these, 7 (21%) were classified, after appropriate investigation, as transfusion-transmitted infections.

Year of transfusion	1997	1998	1999 (to end Sep)	Total
Infection				
HBV	-	1(1)	-	1(1)
HCV	1(1)	-	-	1(1)
Bacteria	-	2(2)[a]	3(3)[a]	5(5)[ax2]
Total[b]	**1(1)**	**3(3)**[a]	**3(3)**[a]	**7(7)**[ax2]

Notes: [a] Infection was implicated in the death of a recipient
[b] Additionally, one probable transfusion transmitted bacteraemia (not fatal), transfused during 1998, was reported in Scotland.

- **Clinicians should report all post-transfusion infections to the blood service for appropriate investigation.**
- **Donors' clinicians (and donors themselves) can aid the detection of TTIs by communicating with the blood service about any relevant history of blood donation on diagnoses with blood borne infections.**

Near Miss Scheme

- Last year a small pilot study was carried out which, this year, has been expanded to include approximately 25 hospitals. In total 145 reports were received during the study period (1st March 1999 to 30th September 1999). Reports fell into the following categories:

Sample errors	84 (57.9%)
Laboratory components selection, handling and storage errors	25 (17.3%)
Laboratory sample handling and testing errors	14 (9.7%)
Request errors	8 (5.5%)
Component issue, transportation and patient identification errors	8 (5.5%)
Miscellaneous problems	6 (4.1%)

- Poor phlebotomy procedures were the major problem in all reported events.
- 6 reports involved lack of notification to the laboratory of the need to irradiate components for patients on Fludarabine
- This larger study identified a significantly lower incidence of laboratory sample handling/testing errors than the pilot study (9.7% compared with 25%).

Blood Safety in the UK

- SHOT data can now provide a powerful body of evidence concerning current residual transfusion risks in the UK which can be used to inform decisions taken around transfusion safety.
- Responsibility for the safety of blood components is spread across a large number of bodies and a number of initiatives have already been taken by some of these. However considerable investment in novel information technology systems would be required to reduce drastically the numbers of 'wrong blood' episodes.
- Decisions regarding the implementation of new initiatives could, in theory, be taken by different responsible bodies without reference to the others.
- One possible solution would be to create a unified body with overall responsibility for blood safety. However ongoing dialogue would be needed to ensure that transfusion risks did not increase because of slow centralised decision-making.

This summary has been sent to hospital haematologists, blood bank managers, and NHS Trust Chief Executives. Copies of the full report (£25) are available from the SHOT office. Please make cheques payable to National Blood Service, Northern Zone - SHOT

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