SERIOUS HAZARDS OF TRANSFUSION SCHEME

TERMS OF REFERENCE
(Updated November, 2001)

1. AIMS

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 and on autologous pre-deposit donation. These will include post-transfusion infections, collected via Transfusion Service/PHLS-CDSC surveillance, and major non-infectious events such as blood being given to the wrong patient. The Scheme will not include fractionated plasma products, which are already covered by MCA procedures for licensed drugs. Reports will be widely distributed. 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
e) collaboration with other NHS patient safety initiatives

Participation in the Scheme is required by the Department of Health[1], is confidential, voluntary, and covers NHS and private hospitals in the United Kingdom and Ireland and the Transfusion Services that supply them.

2. ORGANISATION

The Scheme's strategic direction comes from a Steering Group with wide representation from Royal Colleges and professional bodies. The operational aspects of the Scheme are the responsibility of a Standing Working Group, which is accountable to the Steering Group. National Co-ordinators are responsible for receiving and collating reports.

Ownership of the Scheme and data generated from it resides with the Steering Group.

Minutes of Steering Group Meetings are sent to the Department of Health for information.

For the first three years of the Scheme, funding has come from the Transfusion Services within the UK and Ireland. Generous grants have been received from the British Society for Haematology and the British Blood Transfusion Society. Funding sources will again be reviewed following the establishment of NICE.

3. BLOOD COMPONENTS INCLUDED

The Scheme covers transfusion of red cells, platelets, fresh frozen plasma and cryoprecipitate, including any virus inactivated equivalents. Although solvent/detergent treated fresh frozen plasma is a licensed plasma product, it would be helpful for comparative purposes if complications due to this component were also sent to SHOT.

Adverse events associated with transfusion of blood components from volunteer donors, family members and autologous blood should all be included.

The Scheme also covers major complications associated with pre-deposit autologous donation, haemodilution and cell salvage procedures.

4. COMPLICATIONS INCLUDED

The Scheme aims to capture data on **serious** complications of transfusion under the following headings.

Non infectious

Blood intended for another patient or not suitable for patient to whom it was given (whether ABO incompatible or not, and irrespective of whether harm arises).

Acute reaction (<24 hours after transfusion) } of any type
Delayed reaction (>24 hours after transfusion) }
Transfusion associated graft-versus-host disease
Transfusion-related acute lung injury
Post transfusion purpura
Near Miss incidents

Infectious

Suspected or confirmed cases of microbial transmission – bacterial, viral or parasitic, other agents.

Autologous donation or re-infusion

Serious adverse events of any kind.

6. SYSTEM FOR REPORTING NON-INFECTIOUS CASES

Cases under the non-infectious headings above should be reported in the first instance to the hospital haematologist responsible for transfusion, who should then report cases confidentially to the National Co-ordinator on a designated report form. Staff are encouraged to report via haematologists with transfusion responsibilities, but in exceptional circumstances reports from other members of staff will be accepted. However, SHOT is not intended to replace or compromise existing local arrangements for forward communication of transfusion problems to supplying transfusion centres.

IT IS **ESSENTIAL** TO INFORM THE SUPPLYING BLOOD CENTRE URGENTLY OF SUSPECTED CASES OF INFECTIOUS COMPLICATIONS FOLLOWING TRANSFUSION, SO THAT OTHER POTENTIALLY INFECTED COMPONENTS CAN BE WITHDRAWN. THE BLOOD CENTRE WILL THEN COMPLETE THE DETAILED REPORT OF THE INCIDENT.

'Nil to Report' cards will be issued periodically, and at least annually, to allow hospitals with no reportable events to participate in SHOT.

7. QUESTIONNAIRES

On receipt of a report of a non-infectious hazard, the National Co-ordinator will follow up the report with a detailed questionnaire. These have been developed to gain relevant information about serious consequences of transfusion.

THIS INFORMATION IS IMPORTANT, AND SHOULD BE COMPLETE AND ACCURATE.

Staff may write in confidence to the SHOT office under separate cover if they wish.

8. CONFIDENTIALITY AND LITIGATION

Once all information has been gathered about a case, all hospital and patient identifiers will be removed by the SHOT office before entry to the computerised database. The hospital may wish to destroy copies of completed SHOT questionnaires.

9. FEEDBACK

Reports will be provided at appropriate intervals which will analyse the findings and make recommendations, but without identification of individual cases.

10. NATIONAL CO-ORDINATORS

1. Non infectious hazards

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2. Infectious

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from whom further information may be obtained.

Reference

1. Health Service Circular, Better Blood Transfusion, HSC 19981224, 11 December 1998

SHOT Steering Group - Terms of Reference

1. To be the strategic and policymaking body for the SHOT Scheme, and to ensure that ownership of SHOT, its activities and data remain confidential and firmly within the professional bodies to whom it belongs.
2. Its members bring to the Steering Group the views of the professional body which they represent, and in turn seek endorsement from their professional body for major changes to the Scheme.
3. Its members communicate to their professional body information about new SHOT initiatives, and promote SHOT activities through their professional network.
4. To review and oversee the activities of the Standing Working Group from whom regular reports will be provided.
5. To provide financial oversight of SHOT activities.
6. To produce periodic reports to an agreed format.
7. To ensure that recommendations resulting from these reports are disseminated via professional bodies in an open fashion whilst maintaining strict anonymity/confidentiality.
8. The Steering Group may convene one or more Working Parties for specific functions as required.
9. All reports, publications and written media communications must be approved by the Steering Group. In urgent situations the Chair and Secretary of the Steering Group may approve written media statements without reference to the whole group.
10. Any proposed changes to questionnaires must be submitted to the Steering Group for approval.

Membership and Organisation of Meetings

1. The Steering Group will meet twice every year.
2. Membership will consist of nominated representatives of Royal Colleges and professional bodies as listed below. The Steering Group should always include the National Co-ordinators the Assistant National Co-ordinator, the Chair of the Standing Working Group, a representative from PHLS/CDSC, and a representative from the BCSH Transfusion Task Force. The duration of membership of an individual member will normally be three years, renewable for further three-year terms subject to agreement of the body which he or she represents.
3. There will be a Chair and Secretary elected from among the members. Each should hold the appointment for three years, renewable for further three-year terms but with flexibility to allow some overlap with the incoming Chair and Secretary.
4. The budget will be managed by the National Co-ordinator, who will provide regular financial reports to the Chair.
5. Steering Group minutes will be provided to members of the Standing Working Group, and to the Department of Health for information.

SHOT Standing Working Group - Terms of Reference

1. The primary responsibility of the Standing Working Group is to implement the policy set by the Steering Group, through the work of the National Co-ordinators.
2. To monitor the functionality of the Scheme, taking into account feedback from participants on the reporting form and questionnaires.
3. To maintain close liaison with the Steering Group, and to be accountable to it for its activities.
4. To draft detailed proposals for changes and new initiatives for presentation to the Steering Group.
5. To draft reports for presentation to the Steering Group.
6. To draft an annual business plan.
7. To maintain links with haemovigilance systems internationally.

Membership and Organisation of Meetings

1. The Standing Working Group will meet as necessary, but not less than four times per year.
2. The membership will be no more than eight, and must always include at least two hospital based haematologists responsible for transfusion, at least one hospital based transfusion technologist, a transfusion nurse, at least two transfusion service consultants and a representative from Serology NEQAS. Duration of membership will normally be three years, renewable for three years.
3. The Chair and Secretary of the Steering Group, the two National Co-ordinators and Assistant National Co-ordinator are also members in their own right.
4. A Chair and Secretary will be elected from among the members. Term of office will normally be three years, renewable for three years.
5. Appointment of new members and renewal of terms of office must be approved by the Steering Group.
6. The Standing Working Group may co-opt members if required, with Steering Group approval.
7. Minutes of meetings will be sent to all members of the Steering Group.

Steering Group Members - Serious Hazards of Transfusion

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National Co-ordinator: **Dr E M Love**

Assistant Co-ordinator: **Mrs H Jones**

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