Guidelines for the Blood Transfusion Services

2.7: Reporting of incidents to external bodies

http://transfusionguidelines.org/red-book/chapter-2-quality-in-blood-and-tissue-establishments-and-hospital-blood-banks/2-7-reporting-of-incidents-to-external-bodies

2.7: Reporting of incidents to external bodies

2.7.1: Serious Hazards of Transfusion (www.shotuk.org)

For blood components, serious adverse reactions and events must be reported to the MHRA (see section 2.6.14.4). However, in addition, blood banks and Blood Establishments are encouraged to report to the Serious Hazards of Transfusion (SHOT) scheme. SHOT collects data on serious sequelae of transfusion of blood components. Through the participating bodies, the information obtained contributes to improving the safety of the transfusion process, informing policy within the transfusion services, improving standards of hospital transfusion practice and 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 UK and Ireland. Reports are made via SABRE (see www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Blood/index.htm).

Near misses should also be reported to SHOT. These are incidents where an action has placed a patient at risk. This could include, for example, the placing in stock of incorrectly labelled blood components where the discrepancy in blood group, genotype or test status would have placed a patient at risk of an adverse outcome if the component had been transfused.

It is assumed that if transfusion of products in this ‘near miss’ category occurs resulting in adverse outcome the incident would be reported back to the supplying service, so that they can investigate, identify root cause and prevent further occurrence. In this case it is important that it is understood that in these situations capturing data about events is not about assigning blame or liability but is about improving systems and reducing risk. Such incidents should also be reported to SHOT.

2.7.2: Devices (www.mhra.gov.uk)

The remit of the Medicines and Healthcare products Regulatory Agency (MHRA) is to enhance and safeguard the health of the public by ensuring that medicines work and are acceptably safe.

Blood Services, blood and tissue banks shall have a mechanism to report problems with medicines, medical devices or *in vitro* diagnostic devices to the MHRA. This will provide an opportunity for problems with medicines and devices to be viewed on a UK or European-wide level.

There may be additional local requirements which also must be met. For example, in Northern Ireland there has been a recent Directive that all critical adverse incidents be reported directly to the Northern Ireland Department of Health, Social Services and Public Safety.

Adverse incidents involving medical devices in England and Wales should be reporting using the Yellow Card scheme or via the Yellow Card app. Such incidents should be reported to the Northern Ireland Adverse Incident Centre in Northern Ireland and to Health Facilities Scotland online incident reporting system in Scotland.

2.7.3: Serious untoward incidents

Serious untoward incidents can be defined as ‘something out of the ordinary, or unexpected, with the potential to cause serious harm, and/or likely to attract public and media interest that occurs on NHS premises or in the provision of an NHS or a commissioned service’ (NHS London, 2007).[21] Blood Services may choose to refine this definition further.

Many of these incidents will be captured and investigated using a Blood Service’s quality management system processes. Investigations shall be undertaken promptly, be coordinated by a board director and shall be considered for reporting externally.

Reports may be referred to:

- Department of Health or equivalent
- National Patient Safety Agency (NPSA), although the lead report should be from the Trust or facility where the patient involvement occurred. If this is not a Blood Service then the final report should contain the blood service’s contribution
- National Health Service Litigation Authority (NHSLA) if litigation may result
- NHS Information Authority (NHSIA) for IT-related events
- Police in the case of criminal activity
- Health and Safety Executive (HSE) – RIDDOR
- Department of Health Estates and Facilities for fires
- Local Counter-Fraud Specialist (LCFS) for fraud
- Department of Health Estates and Facilities for defect and failure reporting in plant or facility or associated services
- Other stakeholders identified as relevant during the investigation of the serious untoward incident.