Save a life
Give platelets

NHS
Blood and Transplant

Recall process following a suspected Transfusion reaction with platelets

Platelets

NHSBT implemented 100% bacterial screening for platelet components (apheresis/pooled)

Components will be sampled at a minimum of > 36hrs – 48hrs after collection

Both aerobic and anaerobic culture are performed

Components held for at least 6 hours after sampling (if negative bacteriology)

Components will undergo validation and labelling after 6 hours

Components available for issue with a 7 day shelf life

The culture of the sample will be monitored for the component shelf life

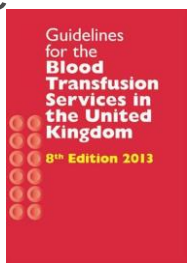
Any positives samples will be recalled

What the standards say….

NHS Blood and Transplant

Recall (JPAC)

A system (usually, but not necessarily, computer software) shall be in place to allow full traceability of products. This will ensure that efficient recall of products can be effected and that look-back studies can be undertaken.



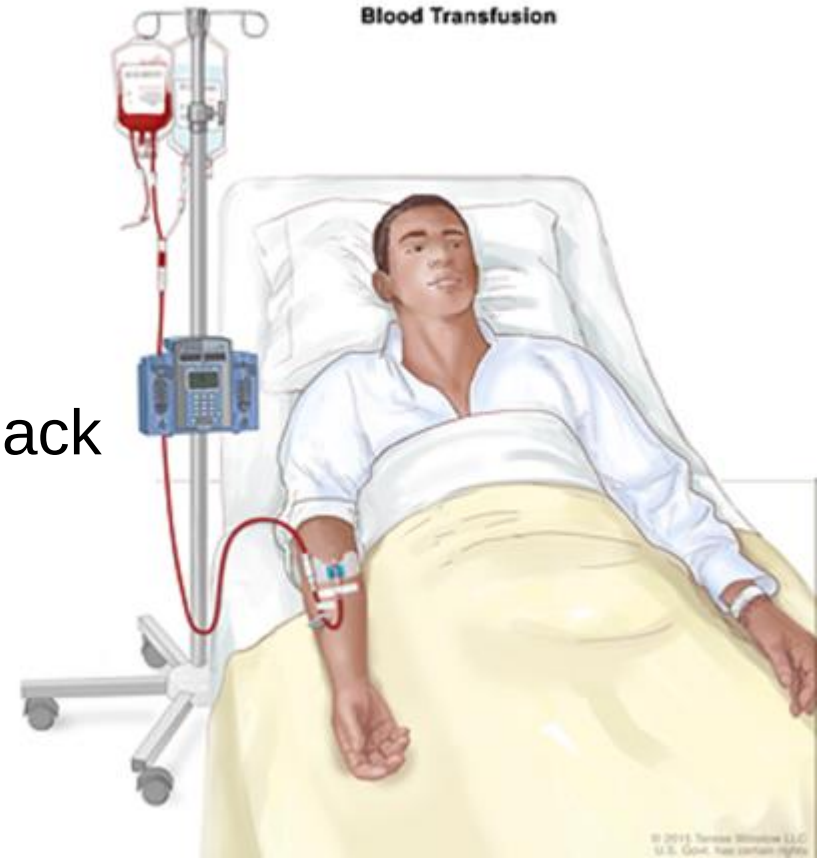
Product Recalls and other potential risk-reducing actions (GMP Guidelines)

There should be established written procedures, regularly reviewed and updated when necessary, in order to undertake any recall activity or implement any other risk-reducing actions

Reasons to Product Recall

There are several different types of product recall that are initiated by NHSBT

1. Bacterial Screening
2. Donor Information
3. Microbiology Reactive
4. Quality Defect
5. Transfusion Microbiology Lookback
6. **Transfusion Reaction**
7. Visual Abnormality



Recall Process – Transfusion Reaction

Initiation of the Recall Process

- If a patient has an acute transfusion reaction, the Hospital will get in touch with the NHSBT on call Patient Consultant (via their local Hospital Services department)

- The NHSBT on call patient consultant discusses the patient reaction with the hospital and decides a recall is required

Recall Process – Transfusion Reaction

Communication with Hospital with the transfusion reaction

- The NHSBT on call patient consultant calls Hospital Services where the unit was issued to initiate a recall process.

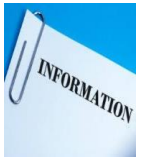
- Hospital Services raise the recall using PCS72 on Pulse, complete **FRM17** and fax to hospital with the transfusion reaction

- The hospital are called with the recall details and are informed to quarantined the unit (if still available in the blood bank)

- A bio bottle is sent to collect the unit / partially transfused unit to return to the NHSBT for investigation (Bacterial Screening). If the unit has been partially transfused

Recall Process – Transfusion Reaction

Communication with Hospitals with associated products



- The hospital raise the recall using PCS72 on Pulse, complete **FRM17** and fax to hospital with associated products

- The hospital are called with the recall details and are informed to quarantined the unit (if still available in the blood bank)

- A bio bottle is sent to collect the unit to return to the NHSBT for investigation (Bacterial Screening).

- If the unit has been transfused the hospital should inform NHSBT during the call/via **FRM17**

Recall – Transfusion Reaction

Communication within NHSBT

- Information sent to QA to log transfusion reaction/recall details into the Quality Management System

Q-Pulse

- All investigatory department are made aware of the recall and appropriate actions required (e.g. NBL, RCI, H&I, IBGRL, CDL)

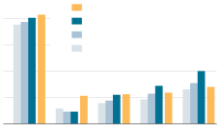
- Bio bottle is sent to the investigatory department for investigation (e.g. NBL - the unit(s) are sent with the Bacterial Screening).

Recall Process – Transfusion Reaction

Review of paperwork and investigation

- Hospital Service Department collate the hospital responses (via FRM17 – Discard /Returned /Transfused)

- NBL and Investigating departments provide results to Hospital Service Department



- NHSBT Patient Consultant writes a letter to hospital that had the reaction, and to any associated hospital that transfused the unit.

  - If suspected bacterial infection, the letter will usually be within 4 weeks.
  - Confirmatory testing will not provide information in a timeframe that is useful for the management of the patient

- All paperwork are sent to QA for review the audit trail for all units and recall letters , once complete the recall can be close

‘Ensure Donors and Patients are at the Heart of Everything we do’