Procedures for Carrying out a Recall of Blood Components and Other Products

Introduction

It is a requirement of the BSQR (SI 2005 50) Regulation 9 (1)g, Commission Directive 2005/62/EC Annex 9.3 and the EU GMP Chp 8 regulations that all products and components, which are considered to pose a risk to patients, are withdrawn from use. This SOP outlines the set procedures for recall of blood components.

There are 2 different kinds of component recall, *internal recall* and *external recall*. In both cases, a procedure is in place that ensures components are withdrawn rapidly from use ensuring that patients are not placed at risk.

This SOP describes how to: -
(a) Document original recall request
(b) Identify /isolate suspected components.
(c) Quarantine the suspect components.
(d) Return suspected products

Objective

The initiation of a formalised and documented procedure, which allows the department to quickly and efficiently, trace and withdraw a recalled component.

Staffing Requirements

Qualified BMS staff will carry out this procedure

External forms and documentation referred to can be viewed in the related documents attachment for this SOP or accessed via the search function in Q-Pulse using NIBTS.

References

Computer Users manual
CPA Standards D3 &E4
The Blood Safety and Quality Regulations 2005
EC Guide to Good Manufacturing Practice (Orange Guide) Chapter 8

Procedure

The basic principles of acceptable component issue and use is that all elements of the QMS must be in place and implemented. In particular, the transportation of blood components must be in accordance with the laboratory’s local policy for safe transportation of blood components (NPSA (SPN) 14) and must ensure that the cold chain is not broken. There are however, instances where the quality of a component is clearly compromised and a recall must be initiated.
Reasons For Recall

Internal recall

Suspected Transfusion Reaction

When notified of a suspected transfusion reaction, the ward or department must be instructed to return all components whether used or partially used and follow the blood transfusion policy for adverse transfusion reactions.
An incident report must be generated by the laboratory staff in QPulse and categorised as Product Recall within the CAPA module.
A Blood Transfusion Incident Report form should also be completed at ward level indicating the level of reaction and interventions performed. Any unused components (in issue bank / components in fridge) should also be returned immediately.

Failure of Cold Chain

If it is found that issued components have been subjected to unacceptable conditions (breached the 30min rule) during storage or transportation then they should be recalled.
An incident report must be generated by the laboratory staff in QPulse and categorised as Product Recall within the CAPA module.
A Blood Transfusion Incident Report form should also be completed at ward level

Errors due to laboratory testing

Components or products that have been issued based on laboratory results that subsequently prove to be erroneous must be recalled. This may be due to failures in the testing procedure or failure of the reagents in use.
An incident report must be generated by the laboratory staff in QPulse and categorised as Product Recall within the CAPA module.

External Recall

On occasions, the laboratory may be asked by an external source to trace and withdraw components and return to requesting source e.g. NIBTS.
An external component recall may be initiated for many reasons, including the following:
Donation(s) considered to be, a microbiological risk
Donation(s) found to have been collected from donor who did not meet standard acceptance criteria, e.g. following post donation notifications
Problems identified with donation testing
Problems identified with quality of raw materials e.g. blood bag faults
Recall Procedure

All initial internal telephone requests for product recall must be recorded on the blood transfusion telephone request form (1BTTELEPHONE) and should be signed by the person making the telephone call.

The request for a component recall from an external source is usually by phone initially, followed by a written request. All details from the phone request must be recorded on the Blood Transfusion laboratories telephone request form (1BTTELEPHONE) and should be signed by the person receiving the telephone call.

The BMS in charge must be notified of all component recall requests whether written or phoned internal or external.

Product recall may relate to blood component units or a batch plasma product. The Blood Bank menu option (4) sub menu option (7) Enquiry by unit number can be used with the components unique unit number to determine the status of components.

- Free Stock
- Reserved Stock
- Issued to patient/ward/dept/Hospital
- Used/Transfused
- Expired
- Due for return to NIBTS (i.e. pilots used up)

If the recalled components are free in existing stock, the product should be traced and withdrawn immediately. In all cases any returned blood components must be processed through the laboratory computer system (LIMS). This can be accessed as follows

1. Select Blood Transfusion menu.
2. Select (4) Stock Menu
3. Select (8) Miscellaneous options
4. Select (10) Mark unit as QUARANTINED.

The quarantined unit must then be placed in the dedicated Quarantine area.

All quarantined components must have a ‘QUARANTINE’ adhesive label attached to prevent inadvertent use.

A quarantined unit can be removed from quarantine by following steps 1-3 above but selecting (11) un-quarantine a unit at step 4.

The withdrawn components after all investigations have been completed should then be fated accordingly e.g. returned to requesting source as instructed along with the
completed product recall form / as wasted or returned to stock (i.e if no transfusion reaction was confirmed ). A copy of the documentation should be kept. If necessary, replacement stock should be ordered.

If the recalled component is blood, FFP, Cryoprecipitate or platelets and these have been issued for a patient but unused, the recalled component must be traced and withdrawn from issue.

The ward/dept should be notified of any delay to issue a component to the patient arising from the ‘product recall’.

Replacement stock should then be reserved for the patient and processed accordingly (i.e. if unit of blood, then compatibility testing should be done etc).

Where multiple components are recalled, reconciliation should be carried out to confirm the fate of each individual component. If necessary, replacement stock should be ordered.

If a batch product (eg. Anti-D, albumin etc.) has been issued, each ward the product has been issued to must be notified immediately and the status of the product determined i.e. used or unused.

All unused products must be retrieved immediately. Reconciliation should be carried out to ensure that all received product can be reconciled against the patient records.

Replacement stock should then be either reserved for patients as required (if issued on a named patient basis) or issued as stock to the relevant Dept (if issued as a batch).

The recalled product should be returned to requesting source as per instructed along with the completed documentation. A copy of the documentation should be kept.

The return of the recalled component must be recorded in the laboratory’s computer system.

If necessary, replacement stock should be ordered.

If the recalled component / product has been used/transfused then this should be recorded on the component recall documentation and returned to the requesting source. A copy of the documentation should be kept.
Withdrawal of Component and Return to NIBTS

When NIBTS require a product to be returned to them for whatever reason, a phone call is received from NIBTS followed up by their product recall form.(DD:046:07:NIBT)

Section 1 has details of the component required to be returned.

All details in section 2 are completed by the BMS in CAH/DHH blood bank and if the product is retrievable it is returned with the completed form to NIBTS Quality Assurance Department.

These may be returned using the Belfast Driver who leaves the laboratory at 1PM every weekday.

A copy of the completed form is made and filed in the “Product Recall” black file found on the shelf above the printer.

The component/product for return is placed in the Blood Bank refrigerator in the area clearly marked ‘quarantine’, the component/product must be clearly marked ‘NOT FOR USE’ and returned according to hospital policy for transfer of blood and blood components to NIBTS for investigation.

The fate of the component/product must be recorded on the LIS computer as above.

Defected Products returned to NIBTS

Any product received from NIBTS, which is not satisfactory for infusion, for whatever reason, must NOT be used but returned to NIBTS using their defect form.

Defect form

Section 1 completed, by the BMS returning the product and the product itself must be sent back to NIBTS Quality Assurance Department as soon as possible.

This is be done using the Belfast Driver who leaves CAH at 14.00 hours each weekday.

A phone call to the Quality Assurance department of NIBTS before sending the offending product is desirable.

Section 2 of this form is completed by the NIBTS Quality Assurance Staff after their investigations are complete and a report is sent back to Craigavon Area Hospital with their findings.

The offending unit is quarantined in the Blood Bank refrigerator in the area clearly marked ‘quarantine’, the component/product must be clearly marked ‘NOT FOR
USE’ and returned according to hospital policy for transfer of blood and blood components to NIBTS for investigation.

A copy of all documents must be filed in the ‘Product Defect’ file located above the printer.

**Limitations/Pitfalls**

Wrong details entered into the computer system.
Not recording the return of recalled components to requesting source on the laboratory computer system.
Not copying the documentation, which is returned to the requesting source.
Failure to fix ‘QUARANTINE’ label.