

Recall process for Hospitals

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Introduction

- Recalls can be required for many reasons by NHSBT
- Hospital transfusion laboratories need to be able to respond to recalls 24/7
- MHRA have defined timescales for recalls
- Communication is between NHSBT Hospital Services dept. and the Hospital Lab
- Patient safety is the priority

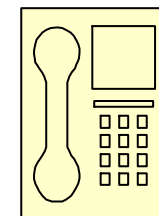


Reasons for recall from NHSBT

- Donor information
- Patient adverse event
- Repeat Reactive virology test
- Visual abnormality
- Quality Defect
- Lookback
- Bacterial Screening
- Non-UK plasma
- Large scale recall (pack defect etc)



NHSBT process



- Hospital Services receive recall information
- Recall paperwork is sent to the transfusion laboratory (usually by fax but can be an e-mail if agreed and there is a dedicated e-mail address)
- Hospital services phone the transfusion laboratory to confirm receipt of paperwork (within 1 hour)
- The Hospital services department contacting the hospital could be from any of 6 NHSBT sites (Filton, Colindale, Tooting, Sheffield, Manchester or Birmingham)
- If there is any action required for the recipient of a transfused unit NHSBT consultant will provide advice

Example paperwork

Notification of NHSBT Recall or Discard to Hospital or Customer

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Section A To be completed by NHSBT Hospital Services

Prepared On: 08/10/2017 16:51

SIM Reference :- W006737

Name of hospital or customer : UCH London

This letter confirms the details of the telephone call to :

Contact Name :

Time :

Date :

If component (s) untransfused please : Discard at hospital

NHSBT Hospital Services to return completed form and components, if requested, to :

NHSBT Centre : NHSBT-Colindale

FAX number 0208 957 2971

Signature :

NHSBT Hospital Services Dept.

Section B Instructions to hospitals or customers

- 1) Please would you trace the component (s) listed on the attached Recall report
- 2) Enter the fate of the component (s) using the outcome codes below on the Recall report.
DIS = Discarded at hospital
RET = Returned to NHSBT
TRA = Transfused
UKN = Unknown
QAH = Quarantine at hospital
- 3) Sign and date the form.
- 4) If you have been requested in Section A to return components to the NHSBT :-
Please attach a label to the component (s) and write the SIM (Stock Incident Management) Reference Number, given above, on the label before returning it to the NHSBT Hospital Services Department indicated on this form.
- 5) Return a copy of the completed form to Hospital Services Centre indicated above.

Hospital Actions on receiving recall

- Trace the fate of the component on the recall notice and let NHSBT HS know if the component has been transfused.
- A guidance document on managing bacterial testing recalls and clinical follow-up is available on the Hospital and Science website.
- <http://hospital.blood.co.uk/diagnostic-services/reporting-adverse-events/component-recall/>
- Discard or return the pack if requested (NHSBT will arrange return of the pack in a Bio bottle)
- Packs must be removed from stock or from a ward or operating theatre to prevent transfusion as soon as possible but no more than 3 hours, from notification. (MHRA Guidance)
- Complete the required recall paperwork.
- Return the completed paperwork by Fax (or e-mail to HS if agreed) as soon as possible.



Datasheet 2939

DATASHEET DAT2939Z

Effective: 07/06/15

Recall Reason information for Hospitals

Copy No:

Recall Reason	Information	Action if recalled unit transfused	Follow up from NHSBT if transfused
Statistical Screening	A sample from labelled units are notified to the laboratory for screening. If there is an alert after the plasma (or associated components) have been issued, confirmatory tests are performed (may take up to 2 weeks). If the sample is found to be positive or clinically 'high' local bacteria	Monitor patient for up to 24 hours. If no reaction occurred, no further action is required. If suspected transfusion reaction, discuss with local pathologists who can contact NHSBT for further advice. Local Hospital Services Department.	Letter sent to Transfusion Laboratory within 4 weeks. Local blood can be closed once letter has been received. NB: Confirmatory testing will not provide the reassurance that is useful for the management of the patient.
Transfusion Reaction	If a patient had an acute transfusion reaction, the patient is notified. If from components from the same donation, immediately so that associated units can be recalled.	Monitor patient for up to 24 hours. If no reaction occurred, no further action is required. If suspected transfusion reaction, discuss with local pathologists who can contact NHSBT for further advice. Local Hospital Services Department.	Letter sent to Transfusion Laboratory within 4 weeks. Local blood can be closed once letter has been received. NB: Confirmatory testing will not provide the reassurance that is useful for the management of the patient. NB: Rarely, NHSBT Clinical Support Team will contact when further action is required.
Donor Information	Additional information provided by donors post donation e.g. flu, sickness, infection, low risk to the patient.	None.	None, recall event can be closed. NB: Rarely, NHSBT Clinical Support Team will contact when further action is required.
Microbiology Reactive	If a donation tests positive for mandatory testing, MHQA requires a recall of in-date components from the previous donation. The majority of these investigations do not confirm an infected donation.	None.	None, recall event can be closed. NB: Rarely, NHSBT Clinical Transfusion Microbiology Team will contact when further action is required.

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Cross Referenced in Primary Document: MHQ17

Recalls initiated from hospital

- **Visually abnormal component** (unusual colour, cloudy, lipaemic) Inform Hospital Services. Could be bacterial contamination.
- **Leaking or damaged pack** Inform Hospital Services and complete pack defect form (on Website)
- **Patient adverse reaction** (Inform NHSBT Consultant)
- NHSBT will sometimes request packs to be returned for investigation
- NHSBT will advise of any further action required and a letter will be sent to confirm outcome of investigations (e.g. Bacterial testing results)



Closure of recall

- The recall datasheet DAT2939 details if a recall letter will be sent from NHSBT.
- If a specific closure letter is not required the recall can be closed once recall actions have been completed by the hospital.
- If a letter is required from NHSBT then close the recall once letter is received.
- NHSBT will send letter within one month if specified. This is to allow time for further investigations to be completed by NHSBT (usually bacterial culture results)



Any Questions?

