MANAGEMENT PROCESS DESCRIPTION MPD637/4

Requirements for Sample Labelling and Request Form Completion

This Management Process Description replaces

MPD637/3.1

Copy Number

Effective **30/06/14**

Summary of Significant Changes

Removal of instructions relating to non-RCI departments.

Removal of borderline/minor discrepancy section.

Document has no shading due to substantial changes. Training is required to the entire document.

Policy

To specify minimum requirements for the labelling of samples and for the completion of request forms for all referrals to RCI laboratories.

Purpose

To ensure sufficient information is received to give confidence in the identity of the patient.

To specify the actions required in circumstances in which information given is discrepant or incomplete.

Responsibilities

Head of Laboratory/Senior Manager

Must ensure compliance with this MPD

NHSBT staff involved in the receipt and testing of samples must ensure samples and forms are labelled to the standards set in this policy.

Senior SpS or Medical staff are required to sign Concession documentation to enable inadequately labelled samples to be tested in exceptional circumstances

Customer Services will communicate the policy to referring organisations (hospitals, antenatal clinics, GP surgeries) and inform them of their responsibilities for ensuring referred samples and request forms are labelled to an acceptable standard

Definitions

A&E - Accident and Emergency

HTR -Haemolytic Transfusion Reaction

FMH - Feto-maternal haemorrhage

ICCBBA - International Council for Commonality in Blood Bank Automation

CHI – (Community Health)The is the unique patient identifier used in Scotland

HCS – (Health and Care)The is the unique patient identifier used in Northern Ireland

PDS - Personal Demographics Service

DTS - Diagnostics and Therapeutic Services

ODT – Organ donation and transplantation

Applicable Documents

British Committee for Standards in Haematology (BCSH)

Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories 2012

British Committee for Standards in Haematology (BCSH)

Guideline on the Administration of Blood Components 2009

ISO15189 Section 5.4.6

SOP1183 Inadequately Labelled Samples - Urgent Investigation and Issue of Blood by RCI Laboratory

MPD13 – SpS Concessions and Planned Deviations for processing inadequately labelled samples

1. Requirements for Acceptable Labelling

1.1 Applications

All samples received by RCI laboratories (other than those collected from blood donors by NHSBT staff). Obtaining consent for the requested tests is the responsibility of the requester, where consent has not been given for material to be used for other purposes e.g. quality control this must be noted in Hematos.

1.2 Sample identification:

Samples and request forms must contain the minimum identification details as required by INF66 – Red Cell Immunohaematology user guide and FRM1597 – RCI Reference Request. These requirements meet and/ or exceed the BCSH guidelines to ensure secure sample/patient identification. All samples for testing by NHSBT Diagnostic and Therapeutic Services Specialist Services laboratories must be labelled with sufficient details to ensure accurate patient/donor identity.

1.2.1 Relevant Guidelines

- Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories. 2012

3.2.2 It is essential that the request form and sample conform to the requirements as described in the guidelines on the administration of blood components (BCSH, 2009).

As a minimum,

The sample tube **must** be completed with the patient core identifiers

(Last name, first name, date of birth, NHS number (if the NHS number is not immediately available, a temporary unique identification number should be used until it is)).

These core identifiers **must** exactly match the request form and patient identification band (or equivalent).

- Date and time of sampling and the identity of the person taking the sample (e.g. initials or signature, according to local policy) should be recorded on every sample tube and request form to provide a full audit trail.
- These minimum labelling requirements apply to both adult and paediatric/neonatal blood samples.
- Sample tubes should never be pre-labelled.
- Pre-printed labels (pre-printed away from the patient or taken from the patient's notes e.g. 'addressograph' labels) should not be used to label pre-transfusion blood sample tubes for compatibility testing. Only labels that are printed 'on demand' and attached to the sample tube next to the patient at the time of phlebotomy are acceptable. All hand-written

sample labels should be completed legibly and accurately (in ball point pen to avoid washing out or smudging).

- Organisations should have a clear policy on the rejection of pre-transfusion blood samples which do not meet minimum labelling requirements. There should be no changes or amendment of patient core identifiers once samples have been sent to the laboratory. It is suggested that organisations should adopt a 'zero tolerance' policy.

The BCSH guideline for the pre transfusion compatibility procedures in blood transfusion laboratories, refer to the BCSH guideline on the administration of blood components for sample labelling requirements.
Section 12.3 states:-

12.3 Sample labelling

- The sample tube must be completed with the patient core identifiers (see section 8.1). These core identifiers must exactly match the request form and patient identification band (or equivalent).
- Date and time of sampling and the identity of the person taking the sample (e.g. initials or signature, according to local policy) should be recorded on every sample tube and request form to provide a full audit trail.

Section 8.1 states

- In 2007 the NPSA produced a Safer Practice Notice 'Standardising Wristbands Improves Patient Safety'. This notice states that only the following core identifiers should be used on patients identification bands:
  - last name
  - first name
  - date of birth
  - NHS number (if the NHS number is not immediately available, a temporary unique identification number should be used until it is).

1.2.2 Minimum Sample Labelling

As a national organisation, the NHSBT receives samples from many sources, so there is an increased chance of shared identifiers such as name, date of birth and hospital number. In order to comply fully with the above guidelines and standards we need to ensure there is sufficient labelling on each sample to minimise the risk of misidentifying a patient or donor.

Samples must be labelled with 3 identifiers, one of which is the NHS/CHI/HCS number if available; the identifiers supplied on the sample and request form must match.

	Sample **Note** samples for pre-transfusion testing must be hand written /demand printed labels	**Request Form**
NHS/CHI/HCS number	**Essential (if available)**	**Essential (if available)**
Name First and last name spelt correctly * Unless patient/donor identity is confidential	**Essential**	**Essential**
Date of Birth	**Essential**	**Essential**
Hospital Number or temporary unique identification number.	Optional * must be used if NHS number is not available	Desirable* must be used if NHS number is not available
Address	Optional	Optional
Date	**Essential**	**Essential**
Signature	**Essential**	**Essential**
Requesting institution	Not required	**Essential**
Requesting Clinician	Not required	**Essential**
Signature of requester	Not required	**Essential**
Clinical information/test required	Not required	**Essential**
Sample source e.g. blood, spleen	**Essential if not peripheral blood**	**Essential if not peripheral blood**

1.3 Exceptions

Samples from the following groups may be accepted; however a comment must be recorded in Hematos and on the report to state that NHSBT may not fully accept responsibility for these results, a concession need not be raised if labelling is sufficient to ensure patient identity.

Trauma or unconscious A&E patients where identity is not yet established that have a least one **unique** identifier e.g. A&E or trauma number, Bone marrow registry donors with a unique registry identifier Ideally the sex and approximate age of the patient should also be given.
Patients or donors whose identity is confidential [e.g. Bone Marrow Registry donors with a unique registry identifier or pre-transplant samples]
Donation samples where the donor details are recorded in a secure system and the samples are identified by ICCBBA (International Council for Commonality in Blood Bank Automation) registered ISBT128 barcode donation numbers
Labelling must be sufficient to ensure patient identity.
Pre/post transplant monitoring which are time critical
Samples from the partners of pregnant women with red cell antibodies may be accepted if both sample and request form have 3 identifiers, not necessarily including NHS/CHI/HCS number/ hospital number, e.g. name, DOB and address

1.4 Authorised Concessions:

In exceptional circumstances samples with inadequate labelling may be accepted for testing but only with a documented authorised concession [see MPD13]. A comment must be recorded in Hematos and on the report stating NHSBT may not accept full responsibility for these results

Investigations when the delay in acquiring a new sample might **seriously** prejudice a successful clinical outcome for a patient – for urgent RCI investigations see SOP1183
Investigations where the sample cannot be replaced. Examples include: ▪ Samples taken pre transfusion or transplant ▪ Samples taken at specific time periods [e.g. investigation of FMH or monitoring acute transplant rejection] ▪ Samples for specialist referral from abroad ▪ Stored samples [e.g. cryovials] ▪ Samples from a foetus
Samples from neonates or small children that may be difficult to replace, a decision should be made on an individual basis and not on the grounds of age alone
If the investigation, or supply of products is urgent and repeat samples cannot be supplied in time

1.5 Deviations:

In exceptional circumstances, referring organisations may be unable to comply with all sample labelling regulations. Customer Services will organise a documented authorised deviation [see MPD13] to allow samples to be tested with the understanding that the NHSBT cannot be fully responsible for errors made as a result of unacceptable labelling in the referring organisation.

2. Unsuitable Labelling

2.1 Unacceptable

Some samples, e.g. those that are completely unlabelled or totally discrepant, are unsuitable for testing In any circumstances.

2.1.1 If urgent and/or if blood products are required

The requester must be contacted to discuss the provision of a replacement sample. If there are serious difficulties in replacing the sample or it is stated that the patient's clinical outcome may be seriously prejudiced, the case should be referred to a SpS clinician or senior member of SpS staff for discussion with the patient's clinician.

2.2 Discrepancies between request form and sample

Samples where the patient details can be confirmed by an enquiry to the requester or to the NHS Personal Demographic Service. e.g. minor differences in spelling between form and sample. may be tested,

- if a corrected request form is supplied by requestor.
- the sample is not to be used for transfusion or transplantation purposes, and
- The enquiry and the outcome is recorded in the patient record, either hard copy or electronic. The discrepancy must be included in the report of the investigation.

2.3 Printed Labels

Extract from Guidelines on the administration of blood components (BCSH, 2009).
Pre-printed labels (pre-printed away from the patient or taken from the patient's notes e.g. '*addressograph'* labels) should not be used to label pre-transfusion blood sample tubes for compatibility testing. Only labels that are printed 'on demand' and attached to the sample tube next to the patient at the time of phlebotomy are acceptable
Addressograph labels are acceptable on request forms providing they don't obscure other vital details.
Labels which have been generated and attached at the bedside from scanning bar-coded wristbands at the time of phlebotomy from an automated system are acceptable for samples.

Since it is not possible to distinguish reliably between these and *addressograph* labels they can be accepted only from referring organisations which have informed the NHSBT, in writing, that their sample labels are generated in an audited system and are demand printed at the time of phlebotomy. Bedside generated labels need to have positive, traceable identification of the sample taker, but do not require a signature.

Hospitals and GPs with systems that have been checked and accepted by NHSBT are listed at: G:\001 National Share\001 Everyone\Sample labelling

2.4 Separated samples and serum or plasma only samples

Samples from which the serum/plasma or DNA has been separated by the referring organisation will not be accepted routinely.

Exceptions:-

- Particular tests where separation at the time of sampling may be advantageous. The NHSBT SpS laboratory will be responsible for discussing the need for separated samples in such circumstances and must explain the exceptional conditions to the referring organisation. Samples must be clearly labelled and signed by the person separating the samples. Accompanying documents should clearly state the nature of the samples, details of the person separating the samples and the time and date of sample separation. The original sample container should be included if available and the details transposed onto the secondary container must be complete and identical to those on the original sample.
- A separated sample may be accepted if it is the only sample available for referral and the sample cannot be repeated e.g. HTR investigation, pre- transplant
- Separated samples may be transferred between laboratories within the NHSBT. These would be acceptable as the separation and labelling procedures would be covered by internal operational procedures, including this MPD.

Separated samples are not acceptable for crossmatching red cells unless there are exceptional circumstances

In those circumstances, every effort must be made to confirm the ABO group of the plasma/serum sample(s) and ensure they match previous records, including those held by the referring hospital. The sample is only to be accepted for crossmatch if all these agree and there is a documented authorised concession

3. Reporting:

Where appropriate, standard comments from the SpS IT system should be used in preference to free text.

3.1 Samples tested under a concession/exception

If a concession has been approved, only those tests for which the concession was raised should be reported. Any further investigation should be carried out on a fully labelled sample. Reference to the concession documentation should be included in the report Details of the labelling deficiency/ discrepancy should be included. Include request for repeat sample(s) as soon as possible, if appropriate

3.2 Samples which have not been tested:

Non-tested samples should be reported using standard comments from the SpS IT system in preference to free text.
Include request for repeat sample(s) as soon as possible, if appropriate.