MANAGEMENT PROCESS DESCRIPTION MPD1108/1.2

NHSBT H&I Laboratories Requirements for Sample Labelling and Request Form Completion.

This Management Process Description replaces

MPD1108/1.1

Copy Number

Effective **28/06/17**

Summary of Significant Changes

Amend 1.3.1. to: In the following circumstances no further actions are required as the patient/donor/research participant has been uniquely identified

Add the following to the table in 1.3.1: Research samples received with a sample specific identifier whose identity is confidential and where it is agreed as part of the study that the requester accepts responsibility for the results.

Policy

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

Purpose

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

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

Responsibilities

Head of Laboratory 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 H&I 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, General Practitioners (GP) surgeries, transplant units) and inform them of their responsibilities for ensuring referred samples and request forms are labelled to an acceptable standard

Definitions

ICCBBA - International Council for Commonality in Blood Bank Automation

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

HLA - Human Leucocyte Antigen

HPA – Human Platelet Antigen

NHS CRS - NHS Care Records Service

PDS - Personal Demographics Service

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

NHS Number – **The unique identification number assigned to English and Welsh citizens.**

GUM - Genito-Urinary Medicine

DTS - Diagnostics and Therapeutic Services

ODT – Organ Donation and Transplantation

H&I – Histocompatibility and Immunogenetics

SpS – Specialist Services

LIMS – Laboratory Information Management System

Applicable Documents

European Federation for Immunogenetics (EFI) Accreditation Standards, current version

The Quality and Safety of Organs Intended for Transplantation Regulations, current version

National Patient Safety Agency Safer Practice Notice /2008/SPN001 Issued: 18 September 2008.

British Committee for Standards in Haematology (BCSH), Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, current version

BS/EN/ISO Standards publication "Medical laboratories – Requirements for Quality and Competence" (ISO15189, current version)

NOP 003 - Packaging, Labelling and Transport of Organs in Deceased and Living Donation and Transplantation

MPD13 – SpS Concessions and Planned Deviations for Processing Inadequately Labelled Samples.

DAT260 - H&I Autotext Comments

1. Requirements for Acceptable Labelling

1.1 Applications

All samples received by H&I 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 the SpS LIMS.

1.2 Sample identification

Samples and request forms must contain at least the minimum identification details as required by the guidelines and standards applicable to the type of test(s) requested. All samples for testing by NHSBT H&I laboratories must be labelled with sufficient details to ensure accurate patient / donor identity.

1.2.1 Relevant Guidelines

See appendix 1 - **Summary of requirements of relevant external standards and guidelines**

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 appended standards and guidelines we need to ensure there is sufficient labelling on each sample to minimise the risk of misidentifying a patient or donor.

NHSBT H&I Laboratories Requirements for Sample Labelling and Request Form Completion.

It is important to limit the production of duplicate identities of patients / donors on the SpS LIMS as this can pose an information governance risk, and as such we must endeavour to use unique identifiers such as NHS (or CHI/HCS) numbers with all samples.

Samples should 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. Pretransfusion samples (e.g. for HLA/HPA selected platelets) must have three identifiers, the identity of the person taking the sample (signature or initials) and the sample collection date.

Note samples for pre-transfusion testing must be hand written / demand printed labels.
Addressographs can not be accepted for pretransfusion samples.

	Sample **Note** samples for pre-transfusion testing must be hand written / demand printed labels	**Request Form**
NHS/CHI/HCS number Except for non UK residents or unless patient/donor identity is confidential e.g. GUM or deceased organ donor	**Essential where available** Mandated by NHS England since April 2013	**Essential where available** Mandated by NHS England since April 2013
Name First (given) and last (family) name Unless patient/donor identity is confidential e.g. GUM or deceased organ donor	**Essential**	**Essential**
Date of Birth Unless patient/donor identity is confidential e.g. GUM or deceased organ donor	**Essential**	**Essential**
ODT number for deceased donors only	**Desirable**	**Desirable**
Hospital number	Optional	Optional
Address	Optional	Optional
Sample collection date	**Essential**	**Essential**
Signature of sample collector	**Essential for pre transfusion samples**	Optional
Requesting institution	Not required	**Essential**
Name of requester	Not required	**Essential**
Signature of requester	Not required	**Essential**

Clinical information/test required	Not required	**Highly desirable /** **Essential in some cases**
Sample source e.g. blood, spleen	**Essential if not peripheral blood**	**Essential if not peripheral blood**

1.3 Exceptions

1.3.1 Exception where no further action is required

In the following circumstances no further actions are required as the patient/donor/research participant has been uniquely identified.

Bone marrow registry donors with a unique registry identifier.
Patients or donors whose identity is confidential [e.g. GUM, R&D, Bone Marrow Registry donors with a unique registry identifier or pre-transplant samples].
Samples with only two identifiers (i.e. name and date of birth) taken from potential stem cell donors who are not covered by anonymity are acceptable for testing if they are accompanied by a form that ▪ contains at least three person identifiers **and** ▪ clearly identifies the respective, potential recipient ▪ Identifiers on sample and form must match
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.
Research samples received with a sample specific identifier whose identity is confidential and where it is agreed as part of the study that the requester accepts responsibility for the results

1.3.2 Exceptions where a comment must be made in the report

Samples from the following groups may be accepted; however a comment must be recorded in the SpS LIMS and on the report to state that NHSBT may not fully accept responsibility for these results see DAT260. A concession need not be raised if **labelling is sufficient to ensure the patient/donor is uniquely identified**.

Minor differences in spelling between form and sample or previous LIMS records when the patient details can be confirmed by an enquiry to the requester or to the NHS Personal Demographic Service. N.B. The enquiry and the outcome must be recorded in the patient record.
Samples with only two identifiers (i.e. name and date of birth) are acceptable for testing if they are accompanied by a form that contains at least three person identifiers. Providing the request for testing is not for transfusion purposes.
Samples with three identifiers but with a test request form with only two of the same identifiers can be accepted if the testing is not for transfusion purposes.

1.3.3 Authorised Concessions

In **exceptional** circumstances samples with inadequate and/or discrepant labelling may be accepted for testing but only with a documented authorised concession [see MPD13]. A comment must be recorded in the SpS LIMS and on the report stating NHSBT does not accept responsibility for these results [See DAT260].

Investigations where the sample cannot be replaced or a fresh sample obtained. Examples include but are not limited to: ▪ Samples taken pre transfusion or transplant ▪ Samples taken at specific time periods o [e.g. monitoring acute transplant rejection, monitoring antibody removal] ▪ 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 blood components is urgent and repeat samples cannot be supplied in time. 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 senior member of H&I staff for discussion with the patient's clinician. It may be agreed with the requester that the investigation will begin, but a report will not be issued until the work has been repeated on a new fully labelled sample. If the investigation is too urgent to wait for a repeat sample the original sample may be tested only as an authorised concession and with all necessary documentation. Blood components cannot be labelled as 'compatible' or 'suitable for', but should be issued for transfusion at the discretion of the patient's clinician.

1.4 Deviations

It should be noted that BSCH guidelines restrict the use of pre-printed labels for samples used for pre transfusion 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. 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.

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 NHSBT cannot be fully responsible for errors made as a result of unacceptable labelling in the referring organisation.
Hospitals and GPs with systems that have been checked and accepted by NHSBT are listed at: **G:\001 National Share\001 Everyone\Sample labelling**

1.5 Unacceptable for Testing

Samples that are completely unlabelled or with significant discrepancy between sample and request form, are unsuitable for testing in any circumstances.

2. 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:-

- A separated sample may be accepted if it is the only sample available for referral and the sample cannot be repeated e.g. pre- transplant
    - These samples must be subject to a documented authorised concession (MPD13)
- 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.

3. Reporting of samples with labelling discrepancies or issues

Where appropriate, standard comments from the SpS LIMS 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. Requests for repeat sample(s) should be sent as soon as possible, if appropriate.

3.2 Samples which have not been tested:

Non-tested samples must be recorded in the SpS LIMS and should be reported using standard comments from the SpS LIMS in preference to free text [See DAT260]. Include a request for repeat sample(s) as soon as possible, if appropriate.

Appendix 1 – Summary of requirements of relevant external standards and guidelines

BS/EN/ISO Standards publication "Medical laboratories – Requirements for quality and competence" ISO15189

The following criteria must be met.

- Samples must be unequivocally traceable, by request and labelling, to an identified patient/donor and site.
- Laboratory must have documented criteria for acceptance or rejection of samples which must be followed.
- When problems present with patient / donor or sample identification, sample instability due to delay in transport or inappropriate container(s), insufficient sample volume, or when the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample, the final report shall indicate the nature of the problem and, where applicable, that caution is required when interpreting the result.
- All received samples must be recorded. The date and time of receipt and/or registration of samples shall be recorded. Whenever possible, the identity of the person receiving the sample shall also be recorded.
- Samples received into the laboratory must be evaluated to ensure that they meet the acceptance criteria relevant for the requested examination(s).
- SOPs must provide instruction for the receipt, labelling, processing and reporting of urgent referrals, including any special labelling, handling, testing and reporting requirements.

<u>Request form information</u>

The completed request form or electronic equivalent must include provision for the following information;

- Patient/Donor identification, gender, date of birth, location / contact details of the patient and unique identifier.
- Identification of requesting clinician, healthcare provider or other legally authorised requestor and the destination and contact details for the report recipient.
- Sample type and where relevant anatomical site of origin.
- Examinations requested.
- Relevant clinical details.
- Date and where relevant time of primary sample collection.
- There must be an unequivocal link between the patient/donor identification details on the sample and request form.

European Federation for Immunogenetics (EFI) "Standards for Histocompatibility Testing"

Specimen submission and requisition

- The laboratory must have available and follow written policies and procedures regarding specimen collection
- The laboratory must perform tests only at the written or electronic request of an authorised person
- The laboratory must ensure that the requisition includes:
    - The patient's or donor's name or other method of specimen identification to assure accurate reporting of results
    - The name and address of the authorised person or of the service who ordered the test
    - Date of specimen collection
    - Time of specimen collection, when pertinent to testing
    - Source of specimen (e.g. bone marrow, spleen cells) if pertinent
- Blood or tissue samples must be individually labelled with:
    - The name, and/or other unique identification marker of the individual
    - Date of collection
- When multiple blood containers are collected, each container must be individually labelled
- The laboratory must:
    - Maintain a system to ensure reliable specimen identification
    - Document each step in the processing and testing of patient specimens to assure that accurate test results are recorded.
    - Have criteria for specimen rejection
    - Have mechanism to assure that specimens are not tested when they do not meet the laboratory's criteria for acceptability

Packaging, Labelling and Transport of Organs in Deceased and Living Donation and Transplantation

The requirements for labelling a live donor sample are Donor name, DOB and hospital number **/**CHI number
The requirements for labelling a deceased donor sample are Donor ODT number, DOB and hospital number/CHI number.

National Patient Safety Agency Safer Practice Notice /2008/SPN001 Issued: 18 September 2008

By 18 September 2009, all NHS organisations in England and Wales that provide primary, secondary and all other types of care such as community pharmacy, should take the following action:
1 Use the NHS Number as the national patient identifier; OR the NHS Number as the national patient identifier in conjunction with a local hospital numbering system (NB where local hospital numbers are used they must be used alongside and not instead of the NHS Number).
2 Use the NHS Number (and its bar-coded equivalent) in/on all correspondence, notes, patient wristbands and patient care systems to support accuracy in identifying patients and linking records.

3 Put processes in place to ensure that patients can know their own NHS Number and are encouraged to make a note of it (for example through patient literature that explains the NHS Number, its uses and advantages, and how patients can use it to increase safety).

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

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).

As a minimum, the request should:

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.