The Royal College of Pathologists of Australasia
ABN 52 000 173 231

Durham Hall 207 Albion Street Surry Hills NSW 2010 Australia
Telephone 61 2 8356 5858 Facsimile 61 2 8356 5828

RCPA
The Royal College of Pathologists of Australasia

Guideline

Subject: **Specimen Labelling at Point of Collection**
Approval Date: June 2006, August 2008, November 2008, November 2013, February 2016, June 2019
Review Date: June 2023
Review By: BPPQ
Number: 1/2006

SUMMARY.
Many pre-analytical errors originate at the time of specimen collection and occur either due to inadequate patient identification or as clerical errors when labelling samples and completing pathology request forms.

Pathology specimens should meet defined standards of patient identification and specimen labelling to ensure that the chain of information custody from patient to sample to laboratory to report is unbroken.

Pathology laboratories also have an obligation to ensure that samples submitted to them but not collected by them meet these same standards of safe identification.

Inadequate or wrongly labelled specimens have the potential to result in serious harm to patients. For example, Lumadue et al[1] found that specimens failing to meet criteria for specimen acceptance were 40 times more likely to have a blood grouping discrepancy. ABO incompatible blood transfusions can be fatal - and are preventable.

Introduction

Clinical risk management is used in the health care environment to reduce and eliminate errors. Patient identification and specimen labelling has been identified as an activity that is crucial to patient safety and quality outcomes.

Within the context of clinical practice, it is essential that the laboratory provide the treating clinician with the right result, on the right patient in a relevant time frame. This can only occur if positive patient identification and accurate labelling has occurred at the time of and point of specimen collection.

Patient Identification and Specimen Acceptance Policy

To ensure correct patient identification and accurate labelling, a documented procedure should be stringently followed for the collection of pathology samples/specimens.

All accredited Pathology laboratories should have a documented policy for accepting or rejecting specimens that do not meet satisfactory and safe labelling requirements and describing how specimens that are not satisfactorily labelled will be handled. Request forms and corresponding specimen labels should have correct and matching patient information.

Patient Identification

A patient should be positively identified before collection of the sample commences. As a minimum, this should be done by asking the patient (if conscious and rational) to state their full name (surname and first name) and date of birth. In a hospital environment, additional identification should be completed usually by checking the patient's identification (wrist) band, which will normally include a medical record number as a supplementary identification check.

The identity details should match those on the request form.

In a situation where the patient is unable to identify himself or herself, a second mechanism for identification should be used. This may be by way of an accompanying person, family member, interpreter, nurse or a form of photographic identification, such as a driver's licence or passport.

It is good practice for collection of any specimens, and essential in the case of collection of samples for transfusion testing, for the collector to sign a declaration confirming that the identification steps have been performed.

Opportunities to improve the robustness of the patient identification step should be considered. These may include the use of photographic identification of patients, bar-codes for patient identification bands and bar-codes or radio-frequency identification (RFID) tags for samples and blood products.

Specimen collection
Specimens should only be collected into an unlabelled container (tube, swab, slide, etc.), and the sample identification added only after the collection has been completed. Pre-labelling of blank containers with patient identification data before the sample has been collected is an unacceptable practice that leads to an increase in the number of identification errors[2].

Following collection and, before the patient leaves, all samples (tubes, swabs, slides etc.) should be legibly labelled with the following minimum details:

- Two patient identifiers such as the patient's full name and date of birth. (Surname and given name together constitute one identifier, not two). A medical record number (MRN, UN, NHI) is also acceptable as the second identifier.

The following additional detail should be included on the sample or the request form:

- Time and date of collection (This is of particular importance where multiple samples are taken at different times or where results are dependent on dosage times).

The following additional details should be included on the sample and/or the request form, but shall be included on all blood transfusion specimens:

- The collector's initials (or other unique identification)
- Transfusion specimens shall be hand labeled or, where an addressograph or computer generated label is used, this shall be signed by the collector.

Where computer-generated or "addressograph"-type labels are used to identify samples, the laboratory should (where the laboratory controls the process) have procedures that ensure only the current patient's labels are accessible at time of sample collection. This is because there is a higher rate of patient identification error when a pre-printed label is used to identify specimens rather than hand-writing the label. Removing a single patient label from a strip of labels from multiple patients, all of which are accessible at time of collection, is an unsafe and unacceptable practice. In situations where the laboratory does not have control of the collection procedure, the laboratory Director should communicate the importance of information accuracy to the relevant healthcare institution's Management so that Management is aware of the requirements for specimen collection.

Blood transfusion requests Request forms shall include the signature of the collector to confirm the correct labelling of the sample at the time of collection. The collector must sign a declaration on the request form as follows[3]:

"I certify that I collected the accompanying specimen from the above patient, whose identity was confirmed by inquiry and/or examination of their name band, and that I labelled the specimen immediately following collection and before leaving the patient".

Note that, while this statement is *required* for all transfusion collections, it is good practice for *all* collections.

Genetics requests
Genetic testing may have lifelong implications for both the patient and for members of the patient's family. For this reason, samples and request forms for genetic testing may involve additional identification safeguards. (Refer to the College Position Statement "Sample requirements for medical genetic testing").

Specimens collected by patients or persons other than health care workers:
Every effort should be made to have specimens collected in the presence of a health care worker, to ensure proper labelling procedures. Where this is not possible (for example, where a patient collects their own specimen and forwards it to their doctor or directly to the pathology laboratory):

1. The specimen should be collected into a container bearing suitable identification, and the person collecting the specimen should be instructed to complete identification details.
2. The specimen should be delivered personally by the collector/patient, or through a known chain of custody, so that he/she can confirm the patient identification and nature of the specimen.
3. The person accepting delivery should immediately transcribe the identification details onto the specimen container if this has not already been done.
4. Whenever an unlabelled specimen collected by a patient or a person other than a health care worker is received, the laboratory should ensure that the request form accompanies the specimen in a way which guarantees that the specimen and request form belong to each other. The laboratory report should also document the fact that the specimen was received unlabelled, or with only qualified identification.

Audit and Compliance
Accredited pathology laboratories must provide training in these procedures to all their specimen collection staff, and training records must be maintained demonstrating staff competence. Hospitals also have accreditation requirements for governance, patient identification and staff training.

Where the specimen collection is not performed by staff of the pathology laboratory, it is an obligation of an accredited pathology laboratory to provide appropriate copies of procedures and competence-based training to these collectors or referring medical practitioners.

Accredited pathology laboratories should maintain records of all instances of patient or specimen mis-identification, and should ensure that these incidents are investigated to determine their root causes.

ISO15189 indicates that external quality assessment (EQA) programs should check the entire examination process including pre-examination procedure and the NPAAC guideline for EQA states that all aspects of management, specimen processing, testing and reporting of results should be considered where external proficiency testing programs exist for these non-analytical aspects. As EQA for pre-analytical errors exist in the RCPAQAP KIMMS program, the RCPA recommends all laboratories should enrol in KIMMS otherwise they must develop their own system for inter-laboratory benchmarking of these errors.

Best Practice Note:

Clinical Information
Accurate laboratory result interpretation can only be optimal where there is the provision of adequate clinical information. Information needed may include fed state (fasting/ non-fasting), time, route and dosage of drugs, expected date of confinement ("EDC") and clinical information. Other relevant information may also be required, including the site and type of specimen, whether tissue is fresh or fixed, and patient posture.

Accredited Pathology laboratories should have a documented policy for ensuring that sufficient clinical information is provided to allow proper analytical performance and clinical interpretation of the results. Where this information is not provided at time of request, the laboratory should have procedures to obtain it subsequently, or to provide relevant educational advice and result qualification on the report.

[1]Lumadue JA, Boyd JS, Ness PM. Adherence to a strict specimen-labelling policy decreases the incidence of erroneous blood grouping of blood bank specimens. Transfusion. 1997 Nov-Dec;37(11-12):1169-72.

[2]Dzik WH, Murphy MF, Andreu G, et al. An international study of the performance of sample collection from patients. Vox Sang. 2003;85:40-7.

[3]
National Pathology Accreditation Advisory Council 2017, *Requirements for Transfusion Laboratory Practice*, 3rd Edition, Canberra