Labeling Before Collection Threatens Patient Safety

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Blood specimen identification errors threaten patient safety. A 2006 report reviews 4.29 million specimens collected over 24 months and documents three critical identification errors: mislabeled specimens, unlabeled specimens, and specimen-requisition mismatch. Prevalences were 1.0%, 4.6%, and 6.3%, respectively (1).[[1]](#endnote-1) Of these, mislabeled specimens represent the greatest threat as they may go undetected.

# Error Prevention

Boxes 1 and 2 list the Clinical and Laboratory Standards Institute (CLSI)’s efforts to prevent mislabeling. Portable digital means, increasingly available, enhance these efforts as blood collectors scan the patient’s armband, electronically match armband identification to requisition entries, and print specimen labels on site to be affixed to blood specimen collection tubes.

**Box 1: Efforts to prevent blood specimen mislabeling when no armband is available**

* Require the patient to spell their first name and last name, and to state their birth date, if able.
* Require the patient to show written identification such as driver’s license or insurance card, if able.
* Label specimen tubes in the presence of the patient.
* Require the patient to review and confirm completed specimen labels, if able.

**Box 2: Efforts to prevent blood specimen mislabeling when an armband is available**

* Using a portable digital system, scan armband to print on-site specimen labels.
* In absence of portable digital system, label tubes while referencing armband identification.
* Affix labels to specimen tubes or write labels in the presence of the patient.
* Require the patient to review and confirm completed specimen labels, if able.
* If patient is unable to communicate, compare labeled tubes with armband.
* Employ the portable digital system or visual confirmation to match armband, labels, and requisition.

Box 3 lists potential blood collector errors that may disrupt efforts to prevent mislabeling. These errors may be attributed to well-meaning collectors’ attempts at efficiency or simple negligence.

**Box 3: Blood collector errors that may lead to mislabeling**

* Preparing labels in the absence of the patient, for instance, preparing labels in advance or after the patient is dismissed.
* Failure to require patients’ verbal identification or failure to refer to armband identification.
* Failure to match tube labels to patient identification and requisition.
* Failure to require patient confirmation, if able.
* Failure to label tubes.

In addition to electronic aids, laboratory scientists select, educate, manage, and check the proficiency of blood specimen collectors. Electronic interventions and continuing education efforts address and attempt to prevent blood collection errors. However, one question remains—must the blood collector label specimen tubes before (pre-collection) or after collection (filled tubes, post-collection)?

# Labeling Blood Tubes: Pre- or Post?

In the absence of outcomes data, laboratory scientists rely on the logic of specimen collection experts, most of whom require post-collection labeling. Since 1991, six consecutive Clinical Laboratory and Standards Institute (CLSI) standards have specified that tubes be labeled after they are filled (2).[[2]](#endnote-2) This principle is documented in the 2017 CLSI Standard GP41-A7 (3).[[3]](#endnote-3) The World Health Organization and the CSA Group (formerly Canadian Standards Association) independently confirm post-collection labeling (4, 5).[[4]](#endnote-4),[[5]](#endnote-5)

CLSI, WHO, and CSA conclude that pre-labeling generates an unanswered error point—pre-labeled tubes may go unused during a difficult draw, patient illness or syncope, patient refusal, or patient departure against medical advice. There may also arise an emergent need for alternative tubes, thus unlabeled, during collection. The blood collector is left with functional, pre-labeled tubes that must be discarded, but could misguidedly find their way to another patient. The first instance produces waste, and in the second instance, the subsequently filled, mislabeled tubes are likely to go undetected. Further, pre-labeling obscures blood collector vision during collection and covers the manufacturer’s optimum fill indicator, leading to underfilled tubes.

The experts who insist on pre-labeling offer the opinion that post-labeling encourages inattentive failure to label (6, 7, 8).[[6]](#endnote-6),[[7]](#endnote-7),[[8]](#endnote-8) They assert, as do post-labeling advocates, that specimens must be labeled in the presence of the patient and that labeling must be confirmed subsequent to collection. However, those who advocate for post-labeling point out that failure to label occurs in either instance, and further, that while an unlabeled specimen generates inconvenience, anxiety, delay and expense; mislabeling is an authentic patient safety threat as it leads to publication of erroneous results. They ask, under what circumstances might a post-collection comparison not occur that would be prevented by pre-labeling?

# Pre-collection Labeling Advocates

The *European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Preanalytical Phase* is one of the few groups that support pre-labeling, as it mischaracterizes the 2010 WHO position (9).[[9]](#endnote-9) In the WHO stepwise blood collection protocol, the tube-labeling step appears immediately after needle and supply disposal, a logical sequence that is further reflected in the WHO protocol for pediatric and neonatal venous and arterial sampling. A 2011 editorial distortion (7) characterizes four publications by the statement, “*the common denominator of all these guidelines and recommendations is that primary blood tubes should be labeled…before venipuncture is performed*.” However, of the four citations, three did not make the claimed recommendation, and the fourth is a self-reference (10, 11).[[10]](#endnote-10),[[11]](#endnote-11)

In Germany, pre-labeling is a historical custom. Norway holds conflicting guidelines, pre-labeling for transfusion services, post-labeling elsewhere, but their policies are under revision. Sweden’s National Board of Health and Welfare has established pre-labeling as their standard. Post-labeling is the standard in all other industrialized societies.

The Fritsma Factor, Your Interactive Hemostasis Resource, a contemporary hemostasis blog, conducted an international sample of convenience “Quick Question” survey, November 28 to December 22, 2017. The survey asked, “*When is the correct time to label blood specimen tubes*?” Of the 108 who replied, 6 (5%) selected “*Prior to meeting the patient*;” 31 (29%) selected “*In the presence of the patient, before collecting the blood*;” and 71 (66%) selected “*In the presence of the patient, after collecting the blood*.” None selected the fourth answer, “*Just after dismissing the patient*.” Responses were not sorted by location, but the majority supports post-labeling in practice.

# Conclusion

Worldwide, agencies with specimen management responsibilities such as CLSI agree on the necessity for eliminating blood collection identification errors, which include failing to label, failing to match specimen label to laboratory requisition, and mislabeling. Failure to label or mismatch may occur at equal prevalence whether the collector labels the specimen pre-collection or post-collection. Both result in a compromise that is readily identified and requires the specimen be quarantined or discarded. Specimen loss is wasteful, inconvenient, inefficient, and may cause patient anxiety, but does not represent a threat to patient safety. Pre-labeling adds an error point, the possibility that a labeled tube may be used for the wrong patient. The mislabeled specimen is likely to go undetected, resulting in an erroneous laboratory report, which is a clear threat to the patient. This point seems self-evident to specimen management experts, but a clinical trial comparing error rates in pre-labeling versus post-labeling may ultimately put the issue to rest.

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