Annals of Blood

--Manuscript Summary--

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Labeling Tubes Before Collection Threatens Patient Safety

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Conflict of Interest:

Dennis J. Ernst—The Center for Phlebotomy Education is an authorized distributor of CLSI documents.

Blood specimen identification errors continue to threaten patient safety. One study reviewed 4.29 million specimens collected over 24 months and found the frequency of mislabeled specimens, unlabeled specimens, and specimen-requisition mismatches to be 1.0%, 4.6%, and 6.3%, respectively, with undetectable mislabeling presenting the greatest danger (1).[1] Yet there is a small but determined European contingency lobbying national and international organizations to modify when tubes are labeled without any evidence the modification will decrease errors (2).[2] This practice is ill-advised and will increase the frequency of wrong-blood-in-tube errors, negatively impacting patient care.

Blood Specimen Collection Error Prevention Authority

The Clinical and Laboratory Standards Institute (CLSI)'s efforts to prevent mislabeling include (3):[3]

- Requiring patients to state their full name and birth date, and to spell their first name and last name;
- Requiring outpatients to show another form of identification when an ID band is not in use, e.g., a driver's license or insurance card;
- Labeling specimen tubes in the presence of the patient and after the draw;
- Visually comparing the labeled tubes with the ID band, or requiring the patient to confirm samples are properly labeled.

Historical Precedent for Post-collection Labeling

For decades, the standardized protocol for healthcare professionals when drawing diagnostic blood samples in the majority of healthcare facilities around the world has been to label tubes *after* they are filled, not before. Since 1991, six consecutive CLSI standards committees have specified that tubes be labeled after they are filled: NCCLS-1991, NCCLS-1998, NCCLS-2003, CLSI-2007, CLSI-2010, and CLSI-2017 (4–8).[4,5,6,7,8] Also in 2010, the World Health Organization (WHO) joined the international consensus when it published *WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy* (9).[9] Finally, in 2012 the CSA Group (formerly Canadian Standards Association) independently established a post-collection labeling policy for Canadian facilities (10).[10]

That's eight committees, each comprised of a unique assembly of subject matter experts, in three international standards organizations all concluding the same thing: tubes must only be labeled after they are filled.

The Fritsma Factor, Your Interactive Hemostasis Resource surveyed a worldwide sample of convenience December 1–31, 2017 asking, "When is the correct time to label blood specimen tubes?" Of 106 participants, 5% chose "prior to meeting the patient," 29% chose "in the presence of the patient, before collecting the blood," and 66% chose :in the presence of the patient, after collecting the blood." The survey did not distinguish among locations.

Risks Inherent in Pre-collection Labeling

Of great concern to us is the potential for pre-labeled tubes to go unfilled due to a difficult draw, patient illness, syncope, patient refusal, or any of the myriad reasons a draw is delayed or canceled. These common scenarios leave the collector with pre-labeled tubes that, if not discarded, could be mistakenly used on another patient. No patient should have the accuracy of their test results—results that drive 70 percent of his/her physician's medical decisions—depend on someone remembering to discard another patient's pre-labeled, unfilled tubes. Rather than interjecting another opportunity for error into an already error-prone procedure, we strongly advocate post-collection labeling only, especially since there is no evidence pre-collection labeling reduces labelling errors.

Further, pre-labeling can impede visual confirmation that the tube is filling and obscure the manufacturer's optimum fill indicator, leading to underfilled tubes and higher sample rejection rates.

Support for Pre-collection Labeling

Those who support pre-collection labeling often mischaracterize the World Health Organization's position as favoring pre-labeling (11).[11,] In its *Best Practices* guideline, the WHO includes step-by-step illustrations of the adult venipuncture procedure for clinical diagnosis. Step 20, the tube-labeling step, appears after disposing of the needle and supplies, which happens after tubes are filled. Post-collection labeling is also the WHO's protocol for pediatric and neonatal draws and arterial sampling.

Another publication that pre-collection supporters cite also misrepresents the literature. An editorial published in *Clinical Chemistry* characterizes four published articles stating: "the common denominator of all these guidelines and recommendations is that primary blood tubes should be labeled… before venipuncture is performed (12)." [12] However, three of the four articles do not make that recommendation and the fourth shared the same author as the editorial (13). [13] The Swedish National Board of Health and Welfare has established pre-collection labeling to be the standard procedure in Sweden. No other government makes this a national protocol. In Germany and perhaps other European regions, pre-collection labeling is a matter of historical precedent rather than regulation (14).[14] Everywhere else, the CLSI protocol is widely adopted.

No group is pushing for pre-labeling more than the European Federation of Clinical Chemistry and Laboratory Medicine's Working Group on Preanalytic Phase (15).[15] But they and their affiliates are virtually on an island unto themselves. There are no studies that show pre-labeling leads to fewer sample identification errors than the current dominant practice. Without compelling evidence that errors would be prevented, we are not inclined to embrace an accommodation of this magnitude even with the introduction of pre-labeling automation, which, interestingly, seems to have emerged simultaneously.

Summary

Until it can be shown that pre-labeling reduces errors, the practice risks the introduction of a new error point into an already error-prone procedure. Perhaps the overarching question is not so much about when a tube should be labelled, but this: should industry practices dictate the standards or should the standards reflect the practice? We are of the opinion that if a million people believe in a bad idea, it's still a bad idea.

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