Labeling tubes before collection threatens patient safety

Dennis J. Ernst¹, George A. Fritsma², David L. McGlasson^{3*}

¹Center for Phlebotomy Education, Corydon, IN, USA; ²The Fritsma Factor, Your Interactive Hemostasis Resource, Trussville, AL, USA; ³59th Clinical Research Division, JBSA Lackland, San Antonio, TX, USA

*The author has retired from the unit.

Correspondence to: George A. Fritsma, MS, MLS. The Fritsma Factor, Your Interactive Hemostasis Resource, 153 Redwood Drive, Trussville, AL 35173, USA. Email: gfritsma@gmail.com.

Received: 26 December 2017; Accepted: 29 January 2018; Published: 26 February 2018. doi: 10.21037/aob.2018.02.06 **View this article at:** http://dx.doi.org/10.21037/aob.2018.02.06

Introduction

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 mislabeling presenting the greatest danger (1). Yet efforts are underway to influence national and international standards organizations to modify the sequence in which tubes are labeled (2). This modification, which advocates for labeling prior to collection, is ill advised and risks the possibility of raising the frequency of mislabeled tubes, negatively impacting patient care.

Blood specimen collection error prevention authority

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

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

Historical precedent for post-collection labeling

For decades, the worldwide-standardized protocol for drawing diagnostic blood specimens has been to label tubes after they are filled, as specified by six consecutive CLSI standards: NCCLS-1991, NCCLS-1998, NCCLS-2003, CLSI-2007, CLSI-2010, and CLSI-2017 (4-8). In 2010, the World Health Organization (WHO) confirmed the international consensus when it published *WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy* (9). In 2012 the CSA Group (formerly Canadian Standards Association) established a post-collection labeling policy for Canadian facilities (10). Altogether eight committees, each comprised of a unique assemblage of subject matter experts, representing three international standards organizations, concluded that tubes must be labeled after they are filled.

The Fritsma Factor, Your Interactive Hemostasis Resource (https://fritsmafactor.com/post/when-labeltubes-0) surveyed a worldwide sample of convenience December 1–31, 2017 asking, "When is the correct time to label blood specimen tubes?" Of 124 participants, 6 (5%) chose "prior to meeting the patient," 36 (29%) chose "in the presence of the patient, before collecting the blood," and 82 (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 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 additional reasons a draw

Page 2 of 3

is delayed or canceled. These common situations leave the collector with pre-labeled tubes that, if not discarded, could be mistakenly used on a subsequent patient. Experts assert that laboratory results drive 70% of physician medical decisions. No patient should risk having the accuracy of their test results compromised when the collector fails to discard pre-labeled, unfilled tubes. Further, pre-labeling impedes visual confirmation that the tube is filling and often obscures the manufacturer's optimum fill indicator, leading to underfilled tubes and higher sample rejection rates. There is no evidence pre-collection labeling reduces labelling errors. Rather than adding a new opportunity for error into an already error-prone procedure, we strongly advocate for postcollection labeling.

Support for pre-collection labeling

Although their position has been misinterpreted as favoring pre-labeling, in its Best Practices guideline, WHO provides stepwise illustrations of adult venipuncture (11). Step 20, the tube-labeling step, appears after disposal of the needle and supplies, therefore, after tubes are filled. Post-collection labeling is also the WHO's protocol for pediatric and neonatal draws and arterial sampling.

A 2011 editorial (2) misrepresents four earlier publications, stating, "*The common denominator of all these guidelines and recommendations is that primary blood tubes should be labeled...before venipuncture is performed.*" However, 3 of the 4 citations do not make that recommendation and the fourth is a self-reference (12).

The Swedish National Board of Health and Welfare alone has established pre-collection labeling to be their standard procedure. No other government makes this a national protocol. In Germany and other European regions, pre-collection labeling is a matter of historical precedent rather than regulation (13). CLSI, WHO, and CSA protocols prevail everywhere else.

The European Federation of Clinical Chemistry's Laboratory Medicine Working Group on Preanalytical Phase and its supporters advocate for pre-labeling (14-17). However, there are no studies that show pre-labeling leads to fewer sample identification errors. Without compelling evidence those errors would be prevented, we are not inclined to embrace an accommodation of this magnitude even with the introduction of pre-labeling automation.

Summary

Until provided with data that prove pre-labeling reduces errors, we assert the practice introduces an unnecessary error point that is a threat to patient safety. We further recommend that blood collection standards should not be influenced so much by historical protocol as for the need to provide reliable laboratory results.

Acknowledgments

Funding: None.

Footnote

Provenance and Peer Review: This article was commissioned by the editorial office, *Annals of Blood*. The article did not undergo external peer review.

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi. org/10.21037/aob.2018.02.06). DJ Ernst: The Center for Phlebotomy Education is an authorized distributor of CLSI documents; GA Fritsma: The Fritsma Factor, Your Interactive Hemostasis Resource, sponsored by Precision BioLogic Inc., Halifax, Nova Scotia. The other author has no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the manuscript and ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Open Access Statement: This is an Open Access article distributed in accordance with the Creative Commons Attribution-NonCommercial-NoDerivs 4.0 International License (CC BY-NC-ND 4.0), which permits the non-commercial replication and distribution of the article with the strict proviso that no changes or edits are made and the original work is properly cited (including links to both the formal publication through the relevant DOI and the license). See: https://creativecommons.org/licenses/by-nc-nd/4.0/.

References

1. Wagar EA, Tamashiro L, Yasin B, et al. Patient safety in the clinical laboratory: a longitudinal analysis of

Annals of Blood, 2018

specimen identification errors. Arch Pathol Lab Med 2006;130:1662-8.

- 2. Lippi G, Sonntag O, Plebani M. Appropriate labelling of blood collection tubes: a step ahead towards patient's safety. Clin Chem Lab Med 2011;49:1921-3.
- CLSI. Collection of Diagnostic Venous Blood Specimens---Approved Standard (GP41-A7). Wayne: Clinical and Laboratory Standards Institute, 2017.
- National Committee for Clinical Laboratory Standards. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture—Third Edition; Approved Standard, (H3-A3). Villanova: NCCLS, 1991.
- National Committee for Clinical Laboratory Standards. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture —Fourth Edition; Approved Standard, (H3-A4). Villanova: NCCLS, 1998.
- National Committee for Clinical Laboratory Standards. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture —Fifth Edition; Approved Standard, H3-A5. Wayne: NCCLS, 2003.
- CLSI. Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard— Sixth Edition. H3-A6. Wayne: Clinical and Laboratory Standards Institute, 2007.
- CLSI. Accuracy in Patient and Sample Identification---Approved Guideline (GP33A). Wayne: Clinical and Laboratory Standards Institute, 2010.
- World Health Organization. WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy. Geneva:

doi: 10.21037/aob.2018.02.06

Cite this article as: Ernst DJ, Fritsma GA, McGlasson DL. Labeling tubes before collection threatens patient safety. Ann Blood 2018;3:16. WHO Press, 2010.

- CSA Group. Primary sample collection facilities and medical laboratories—patient safety and quality of care requirements for collecting, transporting, and storing samples. Z316.7-12. Mississauga: CSA Group, 2012.
- van Dongen-Lases EC, Cornes MP, Grankvist K, et al. Patient identification and tube labelling—a call for harmonisation. Clin Chem Lab Med 2016;54:1141-5.
- 12. Sciacovelli L, O'Kane M, Skaik YA, et al. Quality Indicators in Laboratory Medicine: from theory to practice. Preliminary data from the IFCC Working Group Project "Laboratory Errors and Patient Safety". Clin Chem Lab Med 2011;49:835-44.
- Guder WG, da Fonseca-Wollheim F, Heil W, et al. The Quality of Diagnostic Samples. Recommendations of the working group on preanalytical variables of the German Society for Clinical Chemistry and the German Society for Laboratory Medicine. Darmstadt: GIT, 2000.
- Lippi G, Caputo M, Banfi G, et al. Recommendations for collection of venous blood. Biochim Clin 2008;32:569-77.
- 15. Lippi G, Plebani M. Blood tubes should be labeled before drawing blood. Ann Blood 2017;2:18.
- Lippi G, Mattiuzzi C, Bovo C, et al. Managing the patient identification crisis in healthcare and laboratory medicine. Clin Biochem 2017;50:562-7.
- 17. Lippi G, Chiozza L, Mattiuzzi C, et al. Patient and sample identification. Out of the maze? J Med Biochem 2017;36:107-12.