Center for Phlebotomy Education

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To: CLIAC
From: Dennis J. Ernst MT(ASCP)
Date: 8/9/2013
RE: Public Comment, CLIAC meeting, August 21-22, 2013

My name is Dennis Ernst. I'm the Executive Director of the Center for Phlebotomy Education in Corydon, Indiana. I want to thank the committee for this opportunity to address an issue of great concern to me and of great importance to every patient whose treatment, diagnosis, medication and management depends upon laboratory testing.

I'm here today to talk to you about what I consider to be the elephant in the room. Maybe not this room, but in a lot of laboratories and certainly the "room" that is the laboratory industry. That elephant is the lack of any minimum requirement for those who collect blood samples for clinical testing.

First, for those of you who don't know me well, I want to provide my background and a sense of my qualifications to speak on this important issue.

After 20+ years in the clinical laboratory and 6 years as an instructor in the CLS program at the University of Louisville (Kentucky), I started a company in 1998 that would develop educational resources for all healthcare professionals who perform, teach, or manage blood sample collection procedures and personnel. Since then, I've been doing just that as well as lecturing internationally, writing books and newsletters, and serving CLSI in standards development and the CDC as a member of several Best Practices Evidence Review panels.

Only three states currently require blood collection personnel to be certified or licensed (California, Louisiana and Nevada). Only in California are there minimum training requirements. In every other state, styling someone's hair requires a license, but for something as important and potentially catastrophic as drawing blood, no training requirements or credentials are necessary other than what the employer feels is essential. Some facilities do an outstanding job, but in my interactions in the industry most are woefully inadequate.

To illustrate, let me cite a few statistics:

- The CAP reports 160,000 adverse patient events occur each year as a result of the laboratory misidentifying samples and patients;(1)
- 11% of all transfusion deaths occur because the phlebotomist fails to properly identify the patient or the sample;(2)
- Preanalytical errors constitute up to 93% of all errors committed by the laboratory;(3)
- The average phlebotomist commits 3.5 procedural errors per draw; and that's when they know they are being observed;(4)
- 95% of diagnostic delays are caused by preanalytical errors.(5)
- Blood culture contamination costs facilities up to $8720 per culture in the form of unnecessary antibiotic administration and laboratory costs. That doesn't even take into account the 3.3 days in which the patient remains hospitalized instead of going home.(6)
- It's been estimated that the average preanalytical error costs hospitals $349.(7)
- 26% of preanalytical errors have a significant effect on patient outcomes.(7)

There's no shortage of data that the preanalytic phase of laboratory testing is the most critical and problematic. We all know you can't get an accurate test result from an improperly collected sample, and you can't get a properly collected sample without properly trained and managed preanalytical personnel.

We conducted an informal survey on our web site and found that 25% of responding facilities spend less than 30 hours training new phlebotomists. Forty-five percent of all who train in-house have no didactic component. It's all hands on. Nine percent required no observation whatsoever.

So I would propose to this group that some steps be taken to assure the competency of specimen collection personnel, and I offer to assist in that process. There are several ways to do this, of course, but lobbying federal and state legislators isn't one of them. I've been working that angle since 2003 without any progress.

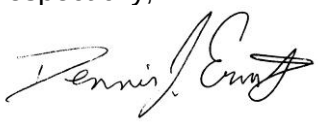
It's my understanding CLIA does not regulate sample collection personnel and that mandating minimum training or certification is beyond the scope of this committee. But CLIA does charge managers with assuring the quality of the samples they test. How do you do that without personnel requirements? Or minimum training? How do you define "quality?" A lab full of analyzers can't produce accurate results if the phlebotomist didn't draw the sample correctly. Where is the quality in that?

Make no mistake, many managers do an outstanding job of it, and they do it by maintaining high standards among their preanalytical personnel. But there doesn't seem to be any guidance or solid requirement to do so like there is for the analytical process. Nor are there consequences for mediocrity other than what the patient suffers.

My question to you is a rhetorical one. CLIA has elevated the quality of the analytical phase of laboratory testing significantly. But the preanalytical phase is still languishing in mediocrity because we're not demanding much of the preanalytic staff. Isn't it time we do?

Thank you for your attention, and please let me know if there's anything I can do work with you toward some solutions.

Respectfully,



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