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To: CLIAC
From: Dennis J. Ernst MT(ASCP)
Date: 4/3/2018
RE: Public Comment, CLIAC meeting, April 10-11, 2018

My name is Dennis Ernst. I have written five books on the preanalytic aspect of laboratory testing, given over 500 lectures nationally and internationally, participated in numerous CDC/LMBP Evidence Review Panels, chaired multiple committees as a volunteer for the Clinical and Laboratory Standards Institute drafting industry standards and guidelines, and serve as a member of CLSI's Board of Directors (ad hoc). But I'm submitting my comments to you today as the Director of the Center for Phlebotomy Education in Corydon, Indiana.

CLIA has done an outstanding job credentialing those who test laboratory samples for clinical diagnosis. I think it's time to turn our attention toward those who collect the samples, i.e., phlebotomists and other preanalytic personnel.

We all know the laboratory cannot report an accurate result on a sample that has been compromised during collection, handling and transport. Yet only four states currently require blood collection personnel to be certified or licensed (California, Louisiana, Washington and Nevada). Among those, California is the only state that has minimum training requirements (the other three require certification, which may or may not include formal training). In the remaining 46 states, a license is required to style hair, but not for drawing blood. That means 86% of Americans have their blood drawn by healthcare professionals for whom no training. It's no wonder I'm regularly asked by attorneys to review cases involving phlebotomy-related injuries. One of our industry's dirty little secrets is that phlebotomists and other preanalytic personnel are inflicting permanently disabling nerve injuries, responsible for fractures and paralysis from falls during or after venipuncture procedures, and making mistakes in patient and sample identification that lead to patient death. The cases I've seen would make you cringe at how little some people who wield a venipuncture needle know about what they're doing. It's time to act.

To illustrate the magnitude of the problem we are perpetuating by not credentialing preanalytic personnel, let me cite a few statistics:

- 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)
- On average, each preanalytical error costs hospitals \$349.(7)
- 26% of preanalytical errors have a significant effect on patient outcomes.(7)

As you can see, 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.

My company 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 those who do train provide no didactic component. 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 preparing phlebotomists, and they do it by maintaining high standards among all preanalytic personnel. But there doesn't seem to be any guidance or solid requirement to do so, as there is for the analytical process. Nor are there consequences for mediocrity, other than that which the patient suffers.

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?

For the record, neither I nor my company stand to benefit from my efforts in this regard. We do not run a school, nor are we a certification agency. Quite frankly, I'm just sick and tired of seeing patients suffer life-changing injuries at the hands of the unskilled who are allowed to draw blood in ignorance.

Thank you for your attention, and please allow me to assist in this important next step toward assuring a fully credentialed laboratory workforce.

Respectfully,



Dennis J. Ernst MT(ASCP)
Director
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References

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