James A. Boiani, M.S., J.D.
1227 25th St., N.W., Suite 700, Washington, D.C. 20036

August 12, 2014

Bill Malone
American Association for Clinical Chemistry
Clinical Laboratory News
1850 K Street, NW
Suite 625
Washington, DC 20006

Re: Letter to the Editor for Publication;
Response to "Managing Risk at the Point-of-Care"

Dear Mr. Malone:

I recently read an *AACC Clinical Laboratory News* article entitled "*Managing Risk at the Point-of-Care*."[1] As an AACC member, I appreciate and applaud the authors' efforts to convey the value of the Individualized Quality Control Plan ("IQCP") at the point-of-care; it's a potentially valuable tool to enhance quality within any lab, regardless of its location. However, I believe the article is unfairly critical of point-of-care testing ("POCT"), referring to it as a "situation ripe for errors;" criticizing the ability of medical professionals to "understand" their role in testing; questioning medical professionals' ability to use tests properly; and suggesting point-of-care tests suffer from technical limitations. Respectfully, these statements do not accurately reflect POCT today, as illustrated by a fair reading of some more recent references cited by the authors.

For example, a 2011 article, *Quality Error Rates in Point-of-Care Testing*,[2] is cited for the proposition that analytical errors are predominant in POCT. In the 2011 article, analytical "errors" include instances where safeguards successfully prevented misuse of POCT – indeed those account for the vast majority of all errors reported in the study (see the Table below summarizing the error rates of the three most frequently used tests in the study). These errors were not test failures, and do not suggest poor quality testing; rather, they suggest that safeguards to limit misuse were effective.

POC Test	Number of Tests	Overall Error Rate	Most Frequent Error (% of total)
Blood Gas	28,676	0.45%	Instrument lockout due to need for minor instrument maintenance **(77.5%)**
Glucose	303,389	0.02%	User did not have personal barcode needed to use meter in the facility **(70.8%)**
Urinalysis	64,370	0.003%	N/A

[1] *Available at* http://www.aacc.org/publications/cln/2014/july/Pages/Preventing-Errors.aspx (last accessed 8/12/14).

[2] M. O'Kane et al., *Quality Error Rates in Point-of-Care Testing*, 57 Clinical Chemistry 1267 (2011), *available at* http://www.clinchem.org/content/57/9/1267 (last accessed 8/12/14).

Some other quality errors mentioned in the 2011 article included failure to stock consumables (5.8% of overall errors), and breaches of healthcare worker good health and safety practice (5.8%). For HB A_{1c} and pregnancy tests (which, in total, represented 2% of the POCT results assessed in the study), problems with external quality assessments or reporting results in a timely manner were listed as the common failures, though the quality error rates remained low – 0.65% and 0.158% respectively. Further, it is notable that the quality errors had no or minimal impact on patient care,[3] and that "[t]here were no instances of erroneous results being generated by POCT or incorrect documentation of results."[4]

So, what are the main messages of *Quality Error Rates in Point-of-Care Testing*? On balance, *Quality Error Rates* conveys that the POCT facilities assessed by the authors were doing a good job and exhibiting a low overall error rate. Errors were not related to test inaccuracy or technical limitations of tests, and most were not even true errors – they were instances where instrument and lab fail-safes to prevent misuse worked as intended. Was there room for improvement? Absolutely – there is always room for improvement. Could an ICQP approach be helpful? Certainly – it's a potentially valuable tool in any laboratory environment, whether at the point-of-care or in an off-site lab. Do the data suggest a lack of medical personnel understanding, or a situation ripe for errors? No, they do not.

A far greater problem facing the POCT community today is the growth of regulatory requirements that unduly limit access to innovative POCTs; tests that can provide substantial value to patients and practitioners due to the rapid diagnostic information they provide. For example, in the United States, problems with current requirements for POCT CLIA waivers for novel diagnostics have been well-documented,[5] and have led to an environment where –

1. Regulators may refuse to grant a CLIA waiver for a test even if the test can be shown, head-to-head, to perform equally well in waived and non-waived testing environments.

2. The CLIA Waiver program is characterized by lengthy review times and high rejection rates where truly novel tests are concerned.

3. The costs of studies to support CLIA waivers have risen exponentially over the last decade as innovators have tried to accommodate unnecessary requirements, discouraging innovation and investment in POCT that would advance the public health.

All of these consequences are keeping valuable diagnostic tests outside the point-of-care. To increase access, and realize the full benefits of POCT, we need to change the regulatory requirements that are being imposed on innovators today to ease the products' path to patients. Doing so would not only expand access to POCT, but would further enhance the quality of POCT. Today's innovative POCTs generally include numerous fail-safes to prevent misuse even in the hands of the most novice user, and go through extensive human factors evaluations; these POCTs help prevent the very kind of misuse the authors of *Managing Risk at the Point-of-Care* are concerned with.

---

[3] It was stated in the article that one-fifth of errors (primarily delays in POCT) could potentially have had a more significant impact, though it was not clear how those assessments were made.

[4] *Quality Error Rates in Point-of-Care Testing* at 1271 (emphasis added).

[5] *E.g.*, J.A. Boiani and S.M. Gerson, *Missing The Point (Of Care): FDA Misreading Of CLIA Waiver Law Undermines Cost-Effective Health Testing*, Washington Legal Foundation Legal Backgrounder (2013), *available at* http://www.wlf.org/upload/legalstudies/legalbackgrounder/10-11-13GersonBoiani_LB.pdf (last accessed 8/12/14).

Quality is everyone's business. The best ways to enhance quality testing at the point-of-care is by (1) continuing to educate healthcare providers about good laboratory practices, and (2) improving the regulatory process for bringing diagnostics to the point-of-care. The authors have done a good job with the former, but we need to spend more time discussing the latter.

Very truly yours,

James A. Boiani, M.S., J.D.
AACC Member, 2014