Statement of

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American Society for Clinical Pathology (ASCP)

before

The Institute of Medicine
Committee on Diagnostic Error in Medicine

April 28, 2014

My name is Steven Kroft, and I serve as President of the American Society for Clinical Pathology (ASCP), the world’s largest professional organization for pathologists and laboratory professionals. I am also Vice Chair and Senior Associate Medical Director of Clinical Laboratories at the Medical College of Wisconsin. The ASCP mission is to provide excellence in education, certification, and advocacy on behalf of patients, pathologists and laboratory professionals. ASCP appreciates the opportunity to support and appear before this distinguished committee and provide our perspectives, as we consider patient safety and quality practice issues of the highest priority.

Fourteen years have passed since the Institute of Medicine’s report, To Err is Human, revealed the astounding human cost of medical error, yet our health care system continues to struggle with quality. Recent studies suggest the number of preventable patient deaths due to medical error may be substantially higher.

Laboratory testing directly impacts the vast majority of medical diagnoses, emphasizing the crucial role the laboratory plays in patient safety and quality care. Because stringent quality control and quality assurance have been routine in clinical laboratories for decades, analytical error rates have typically been far lower than those seen in other healthcare areas. However, the high volume of laboratory testing relative to other medical procedures means that even a low error rate can carry significant impact. Furthermore, laboratories operate within complex health care systems that present numerous opportunities for pre-analytic and post-analytic error.

An additional factor to consider is that the proliferation of new and complex diagnostics in recent years has led to inappropriate test ordering and failure to fully realize the benefits of test results in patient management. While inappropriate test utilization is often not considered “medical error,” per se, over-utilized or mis-utilized testing may produce misleading results that lead to additional testing or interventions, with associated risks, or even overt misdiagnosis and improper treatment.
It is therefore essential that we improve quality and safety by (1) enhancing the interface between the clinician and the laboratory to reduce testing-related errors that involve pre-analytic and post-analytic issues; (2) ensuring an adequately trained and certified laboratory workforce; (3) educating those that utilize laboratory services, both clinicians and patients, to realize our ultimate objective – to provide the right test to the right patient at the right time with the right result.

In order to achieve quality and safety goals, pathologists and advanced laboratory professionals need to fully engage in multidisciplinary teams to develop structures and systems that reduce error at all points in the testing process; for us in the laboratory, a narrow focus on the analytic phase is no longer sufficient. Our potential contributions include lending expertise in utilization, test interpretation, process management, and knowledge generation and delivery.

In order to assure optimal quality and patient safety, clinical laboratories must be sufficiently staffed with qualified laboratory personnel. ASCP has a major commitment to collecting data related to quantitative and qualitative aspects of the laboratory workforce, and deploying it—through advocacy, education, certification, and communication—to ensure a sustainable, high quality laboratory infrastructure. ASCP is also concerned that existing federal and state personnel standards are insufficient to fully protect patients. ASCP believes that laboratory personnel should be required to demonstrate competency, including through certification and licensure mechanisms.

ASCP is invested in promoting appropriate stewardship of laboratory testing, as evidenced by its participation in the American Board of Internal Medicine Foundation’s Choosing Wisely® Campaign as the only representative from pathology and laboratory medicine. ASCP also advocates the aggressive development of a robust evidence base around clinical utility of various laboratory tests in varied clinical settings, in order to enable local, multi-disciplinary efforts to address laboratory utilization.

In closing, I’d like to recommend that the committee consider whether:

1. Analysis of error be the responsibility of all members of the care team, working together to identify contributing system-related and provider-specific factors;

2. Incentivizing transparency with regard to error might lead to better data, and as a result, solutions that could lower error rates;

3. CMS should be encouraged to include in the CLIA regulations a competency assessment requirement or pathway for testing personnel;

4. Medical education at the undergraduate and graduate levels for all clinical specialties, as well continuing medical education programs, should include training in the appropriate ordering of testing and interpretation results.

5. Vendors of electronic health record systems should be encouraged/required to include resource tools to aid clinicians in test ordering and interpretation.
As in other areas, much work needs to be done in pathology and laboratory medicine to achieve a true culture of safety and quality. We look forward to working with our partners in the house of medicine to fully realize the goal of reducing error to minimal levels.

Thank you.

APPENDIX


