



Better health through
laboratory medicine.

August 19, 2014

John R. Ball, MD, JD
Chair, Study on “Diagnostic Error in Health Care”
Institute of Medicine
Keck Center, 764 500 Fifth St. NW
Washington, DC 20001

Dear Dr. Ball:

The American Association for Clinical Chemistry strongly supports the efforts of the Institutes of Medicine (IOM) to identify sources of “*Diagnostic Error in Health Care*” and make recommendations for improving patient care. As you move forward with this study, we urge you to consider the lack of harmonized clinical test results (i.e., when a patient’s sample, measured by different laboratory methods, gives a different result) as a potential source of clinical errors and an area for improving patient care.

In today’s evidenced-based environment, clinical practice guidelines are used to help physicians make informed patient care decisions. These guidelines frequently rely upon laboratory test results to establish a cutoff point for determining if and when clinical intervention is necessary (e.g, above the cutoff take action, below don’t). We are concerned that clinicians may not understand that different laboratory methods give different numeric values for the same test. Applying clinical practice guidance in the absence of harmonized test results could contribute to clinician error and harm to the patient.

AACC believes that test results should be comparable irrespective of the laboratory, method or time when measurements are made. Comparable (harmonized) test results would permit clinicians to better monitor and interpret a patient’s condition over time, improve the quality of clinical practice guidelines, enhance the clinical research data used in developing guidelines, and make test results a more meaningful component of electronic health records. A lack of recognition that results may be neither standardized nor harmonized may hinder efforts to improve the quality of health care.

Dr. Ball
August 19, 2014
Page Two

The ideal practice for ensuring that laboratory results are in agreement is to calibrate each device or method to a known standard reference method or to a certified reference material. Currently, these standard reference methods and certified reference materials are only available for a small portion of the more commonly ordered laboratory tests. The best alternative is to ‘harmonize’ the test outcomes by way of correlation studies, thereby generating a common numeric value for the health care professional and patient. AACC is working with other laboratory medicine professional societies around the world to advance this approach and improve overall patient care.

AACC, with the help of medical device manufacturers, physicians, professional laboratory scientists and standards development organizations, among others, recently created an International Consortium for Harmonization of Clinical Laboratory Results to develop a global approach for prioritizing, organizing and managing the harmonization of clinical laboratory test results. This is a long-term initiative to develop comparable test results to improve the quality of patient care, while also reducing unnecessary costs. AACC would like your help in raising awareness of this issue among policymakers, health care providers, and the public as well as assist us in reducing diagnostic errors.

I am pleased to report that the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies Appropriations recently recognized the importance of harmonizing clinical laboratory test results in the report accompanying its draft 2015 fiscal year budget proposal. In the report, the subcommittee states:

“Developing a process to ‘harmonize’ these differing laboratory numbers into a common value is critical to reducing medical errors, improving the quality of care and empowering patients to participate in decisions affecting their care.”

AACC strongly supports this language. We urge IOM to join congressional health leaders in recognizing this issue and educating physicians and the public about the need to harmonize test results and reduce the possibility of misdiagnosis or treatment errors.

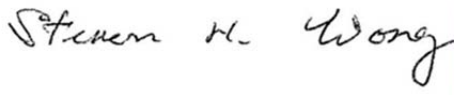

AACC has developed a position statement that more fully examines harmonization and its importance to improving health care. I am attaching a copy of this statement. In addition, AACC plans to publish a white paper on this topic within the next few months. We will forward you a copy once it is completed. AACC looks forward to working with IOM on this important issue. Also, we would be willing to provide public testimony on this topic at one of your future meetings if you would find it helpful.

By way of background, AACC is the principal scientific association of professional laboratorians--including MDs, PhDs and medical technologists. AACC’s members develop and use chemical concepts, procedures, techniques and instrumentation in health-related

Dr. Ball
August 19, 2014
Page Three

investigations and practice in hospitals, independent laboratories and the diagnostics industry worldwide. The AACC provides international leadership in advancing the practice and profession of clinical laboratory science and medicine and its applications to health care. If you have any questions, please call me at (336) 716-2639, or Vince Stine, PhD, Director, Government Affairs, at (202) 835-8721.

Sincerely,

Steven H. Wong, Ph.D., DABCC (TC), FACB
President, AACC

CC: Erin Balogh, MPH, Program Officer