

Challenge to Coordinate Harmonization Activities on an International Level

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In this issue of *Clinical Chemistry*, Dr. Little and coauthors describe the situation where several research efforts to harmonize C-peptide were started independently of each other and the challenges subsequently encountered with implementing a reference measurement system for calibration traceability of C-peptide (1). In the US, a National Institutes of Health-sponsored standardization program developed a reference measurement procedure that was listed by the Joint Committee for Traceability in Laboratory Medicine (JCTLM), and qualified a panel of pooled serum reference materials for use as secondary reference materials for calibration traceability of medical laboratory measurement procedures. The Japanese Committee for Clinical Laboratory Standards and the National Metrology Institute of Japan developed both a pure substance C-peptide certified reference material and a reference measurement procedure that were listed by the JCTLM. Japan also organized a national program to standardize results of medical laboratory measurement procedures using pooled serum supplemented with C-peptide as reference materials. The International Bureau of Weights and Measures and the National Metrology Institute of China organized a key comparison among 10 national metrology institutes that used a purified C-peptide preparation for the purpose of determining performance for mass balance of a peptide reference material. The Metrology Institute of China subsequently provided this material as a pure substance C-peptide certified reference material. Finally, the stocks of the World Health Organization (WHO) reference reagent intended for use to calibrate immunoassays were exhausted and replaced with a new international standard of pure substance C-peptide intended for use by immunoassays.

These noncoordinated activities were all intended to improve standardization of C-peptide measurements. However, manufacturers of measurement procedures had no clear direction regarding how to implement calibration traceability that would be acceptable on a global

basis. A coherent approach for calibration traceability is now being developed as described in the Little et al. report.

Lack of coordination of harmonization activities is a major barrier that can cost hundreds of man-hours and cause hundreds of thousands of research dollars to be inappropriately expended to achieve harmonization for a single measurand. Collaboration among researchers and organizations is important to remove potential bottlenecks and better stimulate development of a coherent solution to analytical problems faced in developing reference measurement systems for calibration traceability of medical laboratory measurement procedures. The need to better coordinate harmonization activities on an international level was recognized as a challenge requiring action in a 2010 leadership conference convened to address how to improve harmonization of laboratory test results (2).

There are resources currently available to provide important information on reference measurement system components. For example, the JCTLM maintains a database of reference measurement procedures, reference materials, and reference measurement laboratories certified against appropriate ISO standards. This database provides information to researchers on what has already been developed by various international organizations for specific measurands. However, the JCTLM database does not provide any information on what is currently under development or what is a priority need.

To fill this void, the International Consortium for Harmonization of Clinical Laboratory Results (ICHCLR) was formed to provide a resource center for information on global activities to harmonize clinical laboratory measurement procedures. The ICHCLR has two main functions: one is to prioritize measurands on the basis of medical impact for which harmonization is needed or for which implementation is incomplete; the second is to provide information on activities by international organizations that are actively addressing harmonization of particular measurands. By making available information on harmonization activities that are either in progress or are being planned, coordination of work will improve, thereby resulting in minimized duplication of effort and better use of limited resources.

The ICHCLR has launched a newly updated website at www.harmonization.net, which is designed to serve as an information portal on global harmonization

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activities. The website's "Measurands" tab lists measurands with a harmonization status, including priority for harmonization, justification for that priority, and links to organizations actively addressing harmonization. To accomplish its task, the ICHCLR needs organizations actively addressing harmonization of specific measurands to provide pertinent information on their work that can be listed on the ICHCLR website. With the appropriate information provided by international organizations, the ICHCLR can serve as a clearinghouse for harmonization activities worldwide and support better cooperation in developing reference measurement systems. We encourage organizations to contact the ICHCLR through its website and provide information on their activities to develop reference system components for harmonization.

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