Shorts on Standards: Estimating measurement uncertainty

The CAP has 30 official liaisons to various organizations who attend scientific meetings or designate others to do so. They report to the Standards Committee, which reports to the Council on Scientific Affairs. We periodically publish bits of what the CAP's outbound liaisons hear and see in their liaison roles.

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March 2020—Quantifying the uncertainty of the laboratory measurements that we report to clinicians is an important quality tool and can assist clinicians in interpreting results. In particular, evaluating patient results over time (longitudinal observation) requires determining whether a result is truly different from a previous result or whether the difference could be attributable to measurement uncertainty. Traditionally, chemistry laboratories have calculated various levels of assay imprecision (within lab, total) to satisfy CLIA validation/verification requirements and to monitor assay quality. These imprecision calculations serve as estimates of measurement uncertainty (MU). Estimation of MU outside the chemistry laboratory (hematology, immunology, microbiology) is not as common.

The CAP administers a voluntary accreditation program (CAP 15189) according to the requirements of the Quality Management Standard from the International Organization for Standardization ISO 15189:2012 Medical Laboratories—Requirements for Quality and Competence that requires that MU information be made available to laboratory users on request. This requires calculation of MU for all reported quantitative results, as well as results that are qualitative but based on quantitative results (drug screens, for example). MU must also be estimated for results that are reported as calculations (for example, urine albumin/creatinine and eGFR). MU estimation for these results requires combining the MU estimates for the individual components of the reported result, a calculation that may be unfamiliar to many technologists and technicians working in the laboratory.

Recently, ISO published ISO/Technical Specification 20914:2019 Medical Laboratories—Practical Guidance for the Estimation of Measurement Uncertainty, which provides background explanation of MU estimation, definitions of relevant terminology, and a structured format for calculating MU with worked examples for chemistry, immunology, coagulation, hematology, molecular, and microbiology analytes. Imprecision calculations that form the basis for the MU estimates will be familiar to clinical chemists but perhaps less familiar to other disciplines. The use of standardized MU vernacular, which is uncommon in U.S. clinical laboratories, will require some getting used to, even for clinical chemists.

ISO/TS 20914:2019 was developed as a "technical specification" and therefore implementation of the document is not required of ISO-15189–accredited laboratories, including those laboratories participating in the CAP program. However, the document should be helpful to laboratories accredited to the ISO 15189 standard in meeting the MU estimation requirement, and it can also be used by any laboratory that wishes to further evaluate its results and the variation that may be seen (and reported) over time.

Dr. Lehman, of ARUP Laboratories, is chair of the CAP Standards Committee. Dr. Castellani, of Penn State Hershey College of Medicine, is a member of the committee, and Dr. Sever, of Presbyterian Hospital in Albuquerque, NM, is vice chair.