

International Standards: Research Guidelines and Harmonized Terminology

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As the global economy continues to expand rapidly, international standards are increasingly important. The national community for clinical laboratory standards (currently known only by the initialism NCCLS) is the leading producer of global consensus standards and guidelines for the world's health-care community. Gary L Myers explained how diagnostic testing has evolved from national and regional sales into a global marketplace. Because the same test results are expected wherever tests are performed, harmonized laboratory standards are critical to global health care. The lack of standardized terms is an impediment to harmonized health care.

Three harmonization programs are under way at NCCLS. The first is the harmonization database publicly available at www.nccls.org. It is a relational database of terms and definitions that are based on the work of the National Reference System for Clinical Laboratories (NRSCL), the International Organization for Standardization (ISO), the European

Committee for Standardization, and NCCLS. Just type in a term, and the internationally preferred definition will be provided with examples.

The second program is the operational plan to ensure that new standards are developed and existing ones revised. Within NCCLS, a harmonization team that includes representatives of industry, regulatory and professional bodies, professional societies, and individuals has been formed. This group provides guidance to subcommittees on harmonization procedures during document development.

The third NCCLS harmonization program involves communication outreach to editors and writers of medical journals, textbooks, and other material. The goal of the program is to promote the use of harmonized terms, specifically by including information on the NCCLS harmonized-terminology database in journals' instructions for authors.

Myers emphasized that the task of achieving harmonization of terminology is extremely challenging and that journal editors are vital to the program's success. He implored CSE members to support NCCLS efforts in harmonization by encouraging authors and reviewers to use the harmonized-terminology database and by monitoring publications for accepted international terminology.

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) also encourages higher standards in research. David Hutchins is a member of the ISPOR Task Force on Retrospective Databases, which includes representatives of industry and academe. Retrospective databases have a number of advantages over clinical trials. They allow researchers to examine real-world medical care; they often include large study populations and long observation periods, which allow for subpopulation analysis; and stud-

ies that use them are relatively inexpensive and quick.

The ISPOR task force developed guidelines to help decision-makers (such as CEOs and CFOs of health plans) and others, such as editors, evaluate the quality of published studies that use health-related retrospective databases. The guidelines were developed in a long form (27 questions) for researchers and statisticians and a short form (10 questions) for editors and decision-makers.

Both forms are divided into three major sections: data sources, methods, and discussion and conclusions. When one is considering data sources, the relevance and context of the database must be established. In the methods section, high-quality studies will include the rationale for the research design and acknowledge potential limitations. Study elements—including selection criteria, metrics, and other variables—should be clearly described and should refer to literature supporting the rationale behind their use. Sensitivity analyses should be performed for any uncertain criteria, and appropriate statistical techniques should be used. Finally, in the discussion, the practical significance of the findings should be explained by comparing the statistical with the clinical or economic results of the models. A theory and alternative explanations should also be provided to explain the results.

Hutchins cautioned that the guideline is just that—a guide—and it may be necessary to follow up with authors with specific queries regarding database evaluations. The task force's checklist and final report are available at www.ispor.org/workpaper/healthscience/FinalReportRetroR.pdf and www.ispor.org/workpaper/healthscienc/ret_dbTFR0203.asp. 