

NIH task force proposes standards for research on chronic low back pain

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Standardized research methods are needed to make greater progress toward reducing the high burden and costs of chronic low back pain (cLBP), according to a Task Force report in the June 15 issue of *Spine*.

The article introduces a set of proposed research standards to help in comparing the results of cLBP studies. The recommendations were developed by a Research Task Force convened by the NIH Pain Consortium. The Task Force co-chairs were Drs Richard A. Deyo of Oregon Health and Science University, Portland; and Samuel F. Dworkin of University of Washington, Seattle.

Standards Seek to Promote Consistency in cLBP Research

Chronic [low back pain](#) one of the most important and costly of all public health conditions affecting the U.S. is a major cause of pain and disability, with high costs for health care and the economy at large. Many different treatments for cLBP have been developed and tested—but few have consistently shown substantial, long-term reduction in pain with improvement in functioning. "Researchers use varied inclusion criteria, definitions, baseline assessments, and outcome measures, which impede comparisons and consensus," according to the Task Force report.

To address this issue, the Task Force followed a structured approach to

developing a set of standards for cLBP research. Key issues included defining the problem of cLBP, assessing its impact on patients' lives, identifying the minimum dataset that should be collected in cLBP research, and defining the best outcomes to evaluate treatment effectiveness.

Definition. Research consistency begins with a standard definition of the problem. The Task Force recommends that cLBP be defined as back pain lasting at least three months, and causing pain on at least half of days over the past six months. The definition does not include ratings of pain severity.

Impact. Rather, the Task Force recommends focusing on how back pain is affecting patients' lives. The recommendations suggest a nine-item cLBP "Impact Score," incorporating ratings of pain intensity, interference with normal activities, and functional ability.

Minimum Dataset. A key task was to define a minimum set of data to be gathered in any study of cLBP. The recommended dataset included legal or workers compensation issues, previous treatments, and important contributing factors—especially smoking, obesity, substance abuse, and widespread [pain](#).

The recommendations emphasize the importance of assessing the patient's medical history—even more so than the physical examination. In contrast, the Task Force specified no standard laboratory or imaging tests, citing the lack of association with patient symptoms or functioning. Assessments of physical functioning, depression, sleep disturbance, and catastrophic thinking were rated important for all groups of patients with cLBP.

Outcomes. The Task Force sought to define the most important outcomes to be evaluated in cLBP studies. However, they concluded that there was

no agreed-on definition of what degree of improvement should be considered "clinically important." Neither was there any consensus as to the use of combined outcome measures, time frames for improvement, or adverse effects.

Future Research. Developing and testing new combined outcome measures was identified as an important area for future research. Other included approaches to predicting treatment results and studies to evaluate and improve the minimum dataset.

The Task Force members hope their recommended standards reflect the "complex, intertwined factors" affecting the development and clinical course of cLBP. They write, "As adopted by NIH, these recommendations have the potential to standardize methods for identifying cLBP research cases, describing research subjects, and comparing published reports." But they emphasize that the recommendations should be regarded as a "dynamic document"—in need of further validation and refinement in the years ahead.

More information: journals.na.lww.com/spinejournal/Standards.97160.aspx

Provided by Wolters Kluwer Health

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