EXECUTIVE SUMMARY

Background: Chronic low-back pain (cLBP) is common and has a major societal impact. Despite rapidly increasing use of medications, injections, and surgery, functional disability has increased in recent decades. Many patients who have procedures to correct putative causes continue to have pain. Further, we often cannot identify mechanisms to explain the major negative impact cLBP has on the lives of many patients. Such cLBP is often termed nonspecific, idiopathic, or mechanical, and may in fact be due to varied and multiple biologic and behavioral etiologies.

In 2009 and 2010, the National Institutes of Health (NIH) Pain Consortium convened two workshops on low-back pain research, noting that researchers use varied inclusion criteria, definitions, baseline assessments, and outcome measures. This impedes comparing studies, replicating findings, pooling data, resolving conflicts, and achieving consensus. It was recommended that NIH establish research standards on cLBP. The NIH Pain Consortium subsequently charged a Research Task Force (RTF) to:

- Consider the state of research relevant to standards for clinical research on cLBP
- Review definitions, diagnostic criteria, and outcome measures for clinical research
- Develop a draft set of standards for research on cLBP
- Engage the research community and government agencies in developing research standards
- Chart a plan for incorporating standards into research studies and making future revisions.

Approach: Co-chairs with complementary expertise were selected, along with 14 additional members who had varied scientific and clinical expertise. The RTF evolved a three-stage work plan, each with a 2-day meeting and intervening literature review. Between meetings, the co-chairs surveyed members by e-mail regarding key elements. These principles emerged:

- The process should be evidence-based and use a biopsychosocial model of chronic pain.
- Data should be useful for patients with degenerative disorders (e.g., herniated disc, lumbar stenosis) as well as those without clear pathoanatomy.
- Patients with underlying systemic or specific diseases were not the target of the Task Force.
- Patients with no clear pathoanatomy should not be assumed to have “psychogenic” pain.
- Classifying cLBP by impact is more feasible and potentially useful than classifying solely by pathophysiology. “Impact” includes pain intensity, interference, and physical function.
- A brief minimal uniform dataset should be reported in all studies of chronic back pain.
- The dataset should be relevant for population, observational, and interventional research.
- An investigator could substitute more detailed and precise measures for a particular domain but should report data for each domain of the minimal dataset.
- Research standards should evolve; we propose a potential research agenda for refinement.

Results: The RTF made six recommendations regarding standards for research on cLBP:

1. Definition of cLBP: The RTF recommended two questions to define chronic pain: (1) How long has back pain has been a problem? (2) What fraction of days in the past 6 months involved back pain? A patient with pain on at least half the days in the past 6 months would have accumulated at least 3 month’s worth of pain days, and this was the recommended definition.

2. Classification of cLBP by Impact: "Impact" was defined by pain intensity, pain interference with normal activities, and functional status. These items have major prognostic and discriminatory importance. Impact is calculated from 9 items of the 29-item Patient Reported Outcomes Measurement Information System (PROMIS) short form.

Using PROMIS data from patients with cLBP, the RTF Impact Classification showed strong correlations with legacy functional measures and was associated with patient satisfaction. Impact scores improved over time, as expected. Effect sizes and standardized response means suggested the Impact Classification was more responsive than the Roland Disability Index.

3. Minimal Dataset: Medical history and examination included demographics, involvement in workers' compensation, work status, education, comorbidity, and previous treatment. For some of these, we adopted the Common Data Elements implemented by the National Institute of Neurological Disorders and Stroke. Physical examination items were reserved for studies of invasive interventions or of older adults. No laboratory or imaging tests were highly ranked by the RTF because of their weak associations with patient symptoms or function. However, magnetic resonance imaging was recommended for studies of surgical interventions. Key self-report domains (in addition to pain and pain-related interference) were physical function, depression, sleep disturbance, and catastrophizing. The short form PROMIS measures were thought to offer the best tradeoff of length with psychometric validity.

4. Outcome Measures: Many parts of the minimal dataset, such as PROMIS measures, are also appropriate as outcome measures. However, primary outcomes of clinical studies will vary, depending on study aims. Thus, the RTF did not recommend a minimal outcome dataset. However, the RTF recommended reporting a "responder" analysis in addition to reporting mean scores of outcome measures. This amounts to determining the "cumulative distribution function" of responders, reported as the percentage of responders at each cutoff value of the outcome score for treatment and control groups.

5. Recommendations for Research on the Proposed Standards: The RTF recommended new research to improve prognostic stratification of patients with cLBP; refine and test composite outcome measures for increasing the clinical importance of study results; undertake patient stakeholder assessment of relevant outcomes; and further evaluate psychometric properties of the minimal dataset.

6. Dissemination: Upon adoption of recommendations by the NIH Pain Consortium, the RTF recommends dissemination to the broad research community. This would include publication of a report in multiple professional journals and presentations at professional meetings.

Conclusion: The RTF believes these recommendations will advance the field, help to resolve controversies, and facilitate future research addressing the genomic, neurologic, and other mechanistic substrates of cLBP. We expect the RTF recommendations will become a dynamic document and undergo continual improvement.