Prioritizing Comparative Effectiveness Research Questions for Treatment Options for Chronic Low Back Pain: A Stakeholder Workshop Meeting Summary

Overview

One of the most prevalent chronic conditions, chronic low back pain is defined as low back pain occurring on at least half of the days in a six-month period. A large majority of chronic low back pain sufferers have nonspecific low back pain, which is defined by the absence of neurological symptoms and signs (e.g., leg pain, numbness or weakness in a nerve root pattern). In 2010, low back pain was the third-largest contributor to disability-adjusted life years in the United States. The total costs of back pain exceed $100 billion per year in the United States. Interventions range from exercise and psychosocial interventions to spine surgery. Hundreds of randomized trials have had uniform results, showing either no effect or small effect sizes. The quality of these studies varies, but there is a core of high-quality studies. Physicians and patients face the challenge of choosing from a relatively small selection of modestly effective treatments, with little or no information to help determine which option is best for an individual patient.

As part of PCORI's efforts to fund high-impact and useful research on critical patient-centered health and healthcare issues, PCORI hosted a multi-stakeholder workgroup to discuss high-priority topics that focus on the comparative effectiveness of treatments for chronic low back pain. On June 9, 2015, 16 participants representing patients, clinicians, researchers, payers, and purchasers were joined by members of PCORI staff and leadership for a one-day workshop on treatment options for chronic low back pain. The meeting was open to the public via teleconference, with slides and meeting materials posted on the PCORI site. Throughout the day, discussions centered on defining the study population, interventions, and outcome measures and on questions submitted by expert stakeholders, as participants focused on identifying the highest-priority research questions.

Key Questions

Thirty-nine questions were submitted to PCORI from members of the multi-stakeholder workgroup for consideration during this one-day meeting. As chronic low back pain is a leading cause of morbidity, lost productivity, and expense, payers and purchasers strongly supported studies of nonspecific low back pain because of its high personal and societal costs. After much deliberation, the multi-stakeholder workgroup chose to focus on combinations of treatments that high-quality studies have demonstrated to be effective. They identified two important research questions to be addressed by randomized trials:

- Question 1: Combined intervention (cognitive and physical) versus cognitive intervention alone versus physical intervention alone. Medication is permitted except for chronic opioids.
- Question 2: Three-way combined intervention (cognitive and physical and lumbar fusion) versus combined two-way nonsurgical intervention (cognitive and physical) alone versus lumbar fusion alone.

The panel felt that the proposed research questions were of great interest because of the dearth of studies on combination therapy and on lumbar fusion surgery. Both questions are designed to compare combination therapy versus its component monotherapies. In addition to identifying questions, the workgroup utilized the PICOT framework in order to better shape the questions of interest in a format that reflects evidence-based practice. The PICOTs outlined for both questions is:

- Population/Patient Problem: Adults with chronic nonspecific low back pain (no neurological symptoms or structural abnormalities other than disc degeneration) on at least 50 percent of days during the past six months despite self-care, physical therapy, muscle relaxants, NSAIDS, etc.
- Exclusion: Daily use of opioids.
- Interventions and Design: As described for Question 1 and 2.
- Outcome: NIH Low Back Pain Task Force outcome measures (function, pain, sleep, mood, medication use, productivity, use of opioids); care utilization (ER visits, surgery, hospital admissions); safety (major medical complications, infections); PROMIS measures required; legacy measures (Oswestry, RMDQ) encouraged
- Time: Follow-up for primary end points for two years
- Setting: Community practice

Moving Forward

PCORI intends to use feedback from the workgroup to conduct further gap analyses and to explore a possible funding announcement in this area.