Prioritizing Comparative Effectiveness Research Questions for Chronic Low Back Pain: A Stakeholder Workshop

June 9, 2015

10:00am – 4:00pm ET
Washington, DC
Welcome

- Please introduce yourself
- State your name and primary stakeholder affiliation
Housekeeping

**Today’s webinar is open to the public and is being recorded.**
- Members of the public are invited to listen to this webinar.
- Topic briefs and other materials are available on the PCORI site.
- Comments may be submitted via chat. No public comment period is scheduled today.

**Reminders for the group**
- Please signify your intent to speak by standing your name placard on end.
- Where possible, we encourage you to avoid acronyms in your discussion of these topics.

**For those on the phone**
- If you experience any technical difficulties, please alert us via chat or email support@meetingbridge.com.
Purpose of the Workshop

- Identify, refine, and prioritize 2-3 clinical comparative effectiveness research questions on the treatment of chronic lower back pain whose findings could improve patient-centered outcomes.

What are the **comparative benefits and risks** of nursing home, assisted living, and home-based care for older adults with dementia?

**PEOPLE**: the group of people to be studied

**OPTIONS**: the choices or options that should be compared

**OUTCOMES**: what good and bad things a patient can expect from each option to help them make a decision
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Summary of the Topic Brief
Elements of the Topic Brief

- Patient-centeredness
- Burden of illness
- Evidence gaps
- What do guidelines say?
- Ongoing studies
- Likelihood of implementation in practice
- Likely durability of research results
- Proposed research questions
Patient-Centeredness: The outcomes of the study should matter to patients

- The outcomes (pain relief) matter to patients, caregivers, and clinicians, as well as to other key stakeholders, such as employers.
Burden of Illness

• Prevalence: very high
• Mortality: low
• Disability: very high
• Cost to society: very high
Evidence Gaps

• Few studies comparing combinations of proven therapies against the components alone.

• Systematic review authors think that a good, big study could make a difference:

• Little good evidence on disc replacement for degenerative disc disease.
Practice Guidelines

• From: Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society

Practice Guidelines

- **Recommendation 6:** For patients with low back pain, clinicians should consider the use of medications with proven benefits in conjunction with back care information and self-care. Clinicians should assess severity of baseline pain and functional deficits, potential benefits, risks, and relative lack of long-term efficacy and safety data before initiating therapy (strong recommendation, moderate-quality evidence). For most patients, first-line medication options are acetaminophen or nonsteroidal anti-inflammatory drugs (NSAIDs).

- **Recommendation 7:** For patients who do not improve with self-care options, clinicians should consider the addition of nonpharmacologic therapy with proven benefits—for acute low back pain, spinal manipulation; for chronic or subacute low back pain, intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation (weak recommendation, moderate-quality evidence).
### Appendix Table 6. Level of Evidence and Summary Grades for Noninvasive Interventions in Patients with Chronic or Subacute Low Back Pain

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Level of Evidence</th>
<th>Net Benefit</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>Fair</td>
<td>Small (no significant harms)</td>
<td>B</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>Fair (some inconsistency vs. sham acupuncture)</td>
<td>Moderate</td>
<td>B</td>
</tr>
<tr>
<td>Psychological therapy</td>
<td>Good for cognitive-behavioral, fair for progressive relaxation</td>
<td>Moderate (cognitive-behavioral) to substantial (progressive relaxation)</td>
<td>B</td>
</tr>
<tr>
<td>Exercise therapy</td>
<td>Good</td>
<td>Moderate</td>
<td>B</td>
</tr>
<tr>
<td>Interdisciplinary rehabilitation</td>
<td>Good</td>
<td>Moderate</td>
<td>B</td>
</tr>
<tr>
<td>Nonsteroidal anti-inflammatory drugs</td>
<td>Good</td>
<td>Moderate</td>
<td>B</td>
</tr>
<tr>
<td>Spinal manipulation</td>
<td>Good</td>
<td>Moderate</td>
<td>B</td>
</tr>
<tr>
<td>Opioids and tramadol</td>
<td>Fair (primarily indirect evidence from trials of patients with other pain conditions)</td>
<td>Moderate</td>
<td>B</td>
</tr>
<tr>
<td>Brief individualized educational interventions</td>
<td>Fair</td>
<td>Moderate</td>
<td>B</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>Fair</td>
<td>Moderate</td>
<td>B</td>
</tr>
<tr>
<td>Massage</td>
<td>Fair</td>
<td>Moderate</td>
<td>B</td>
</tr>
<tr>
<td>Yoga</td>
<td>Fair (for Viniyoga to poor (for Hatha yoga)</td>
<td>Moderate (Viniyoga), unable to estimate (Hatha yoga)</td>
<td>B/Viniyoga</td>
</tr>
<tr>
<td>Tricyclic antidepressants</td>
<td>Good</td>
<td>Small to moderate</td>
<td>B/C</td>
</tr>
<tr>
<td>Antiepileptic drugs</td>
<td>Fair (for gabapentin to poor (for topiramate)</td>
<td>Small (gabapentin in patients with radiculopathy), unable to estimate (topiramate)</td>
<td>C  (gabapentin), I (topiramate)</td>
</tr>
<tr>
<td>Back schools</td>
<td>Fair (some inconsistency)</td>
<td>Small (no benefit or harm)</td>
<td>C</td>
</tr>
<tr>
<td>Firm mattresses</td>
<td>Fair</td>
<td>No benefit or harm</td>
<td>D</td>
</tr>
<tr>
<td>Traction</td>
<td>Fair</td>
<td>No benefit (continuous or intermittent traction), small to moderate (autotraction for sciatica)</td>
<td>D  (continuous or intermittent traction), I (autotraction for sciatica)</td>
</tr>
<tr>
<td>Aspirin</td>
<td>Poor</td>
<td>Unable to estimate</td>
<td>I</td>
</tr>
<tr>
<td>Biofeedback†</td>
<td>Poor</td>
<td>Unable to estimate</td>
<td>I</td>
</tr>
<tr>
<td>Interferential therapy</td>
<td>Poor</td>
<td>Unable to estimate</td>
<td>I</td>
</tr>
<tr>
<td>Low-level laser</td>
<td>Poor</td>
<td>Unable to estimate</td>
<td>I</td>
</tr>
<tr>
<td>Lumbar supports</td>
<td>Poor</td>
<td>Unable to estimate</td>
<td>I</td>
</tr>
<tr>
<td>Shortwave diathermy</td>
<td>Poor</td>
<td>Unable to estimate</td>
<td>I</td>
</tr>
<tr>
<td>Skeletal muscle relaxants</td>
<td>Poor</td>
<td>Unable to estimate</td>
<td>I</td>
</tr>
<tr>
<td>Transcutaneous electrical nerve stimulation</td>
<td>Poor</td>
<td>Unable to estimate</td>
<td>I</td>
</tr>
<tr>
<td>Ultrasoundography</td>
<td>Poor</td>
<td>Unable to estimate</td>
<td>I</td>
</tr>
</tbody>
</table>

* See Appendix Tables 1, 2, and 3 for explanation of grades. Low back pain is considered subacute at 1–3 months’ duration and chronic at >3 months’ duration.
† The use of auditory or visual signals reflecting muscle tension or activity to learn how to inhibit or reduce the muscle activity.
Current Ongoing Research

• 129 RCTs and 35 observational studies are currently in progress

• Target enrollment
  – <100: 102 studies
  – 100-500: 57
  – 500-1000: 5 (all RCTs)
    • Cognitive-behavioral
    • TENS
    • Physiotherapy
    • Osteopathic manipulation
    • Referral models
  – >1000: 2 (both observational)
Clinicians are desperate for better treatments
Health systems likewise
Lots of practice guidelines
High variability in practice: 6x range in spine surgery
Likely Durability of Research Results

- Back pain is a slowly moving field
The Plan for Today

• We could start discussing specific research questions, but we have 29 different interventions and nearly 40 submitted research questions.

• Instead, we are going to discuss different dimensions of a research question and choose the attributes that best complement existing research.

• We will then have one or more clusters of attributes that describe a study that has a good chance of making a contribution to a very crowded body of evidence.
The Plan for Today

• The dimensions of a cluster/study are:
  – Study population
  – Intervention
  – Comparator
  – Outcomes
  – Time of observation
  – Clinical setting

• Using these templates/clusters, we can:
  – Create studies on our own
  – Identify nominated studies from those submitted by work group members
  – Describe a template for applicants to use to design a study that meets our needs.
A cluster with some pre-specified options:

- **Condition**: non-specific low back pain
- **Type of intervention**: between-intervention combination of therapies vs. single intervention
- **Type of intervention**:
- **Type of study design**: randomized trial
- **Number of comparisons**:
- **Outcomes**: improvement in physical function
- **Ascertainment period**:
- **Population characteristics**: Examples
Another cluster with some pre-specified options:

- **Condition**: degenerative disc disease
- **Type of intervention**: single-interventions
- **Type of intervention**: randomized trial
- **Number of comparisons**: 
- **Outcomes**: improvement in physical function; safety outcomes
- **Ascertainment period**: 
- **Population characteristics**: 

Examples
Example of a cluster and a fully specified study:

- **Condition**: non-specific low back pain
- **Type of intervention**: between-intervention combination of therapies vs. single intervention
- **Type of intervention**: chiropractic + biobehavioral vs. NSAIDS
- **Type of study design**: randomized trial
- **Number of comparisons**: two
- **Outcomes**: improvement in physical function
- **Ascertainment period**: 10-12 months
- **Population characteristics**: adult, any gender, any occupation, any education, no previous back surgery.
Conditions

- Non-specific chronic low back pain (the commonest form), characterized by absence of neurological symptoms such as leg pain, numbness or weakness in a nerve root pattern. Non-specific includes degenerative disc disease or “discogenic back pain” (an entity with a distinctive MRI signature but little research).

- Specific pathoanatomy of degenerative conditions associated with neurological symptoms: herniated disc with radiculopathy, spinal stenosis, spondylolisthesis or scoliosis associated with neurogenic claudication.
Types of Comparison

- Single-interventions vs. single intervention
- Combinations of interventions vs. single interventions
- A combination of interventions vs. another combination of interventions

- Within-intervention category comparisons
- Between-intervention category comparisons

- Within-category combinations
- Between-category combinations
Outcomes

• Validated patient-reported outcome measurements for the following domains:
  – Improvement in pain intensity and interference
  – Improvement in physical function
  – Free from opioid use
  – Improvement in mental health (depression, catastrophizing)

• Consistently defined and ascertained safety outcomes for invasive treatments and surgical devices:
  – Infection
  – ER visits
  – Readmission
  – Reoperation
  – Life-threatening complication or Death
Ascertainingment Periods

- 10-12 months for primary end points
- 1 month to assess early recovery, pain relief and return to function
- ≥ 2 years for assessment of sustained benefits
For All Questions:

- **Population/Patient Problem:** Chronic Non-Specific Low Back Pain, without neurological symptoms or structural abnormalities (other than disc degeneration) after unsatisfactory response to > 6 months of self-care, physical therapy, muscle relaxants, NSAIDS, etc.
- **Intervention:** A, B, C
- **Comparison:** Combinations of A, B, C
- **Outcome:** NIH Task Force (function, pain, sleep, mood, medication use, productivity, reduction in opioid use, and safety [ER visits, surgery, hospital admissions, major medical complications, and infections])
- **Time:** 1, 2, and 3 years
- **Setting:** community practice
Question 1:

\[A + B] \text{ vs } A \text{ vs } B, \text{ where:}

- \(A = \) Psychosocial Rehabilitation (includes behavioral health [e.g. CBT, MBSR, ACT, MI, etc.] + Physical Rehabilitation [manipulation and/or supervised exercises])*

- \(B = \) Medication (evidence-supported prescription medication, such as duloxetine)

*OTC allowed
Question 2:

[A + B] vs A vs B, where:

• A = Behavioral Therapy (e.g. CBT, MBSR, ACT, MI, etc.) + Active Physical therapy

• B = Lumbar Fusion
Closing remarks

- Meeting summary will be distributed in a few weeks
- Prioritized questions and deliberations from workshop will be shared with PCORI leadership
- PCORI governance will determine next steps
Thank You

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