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.

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Summary of the Topic Brief

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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:
  - acupuncture, TENS, behavioral interventions, low-level laser light, botulinum toxin injections.
- Little good evidence on disc replacement for degenerative disc disease.

Practice Guidelines

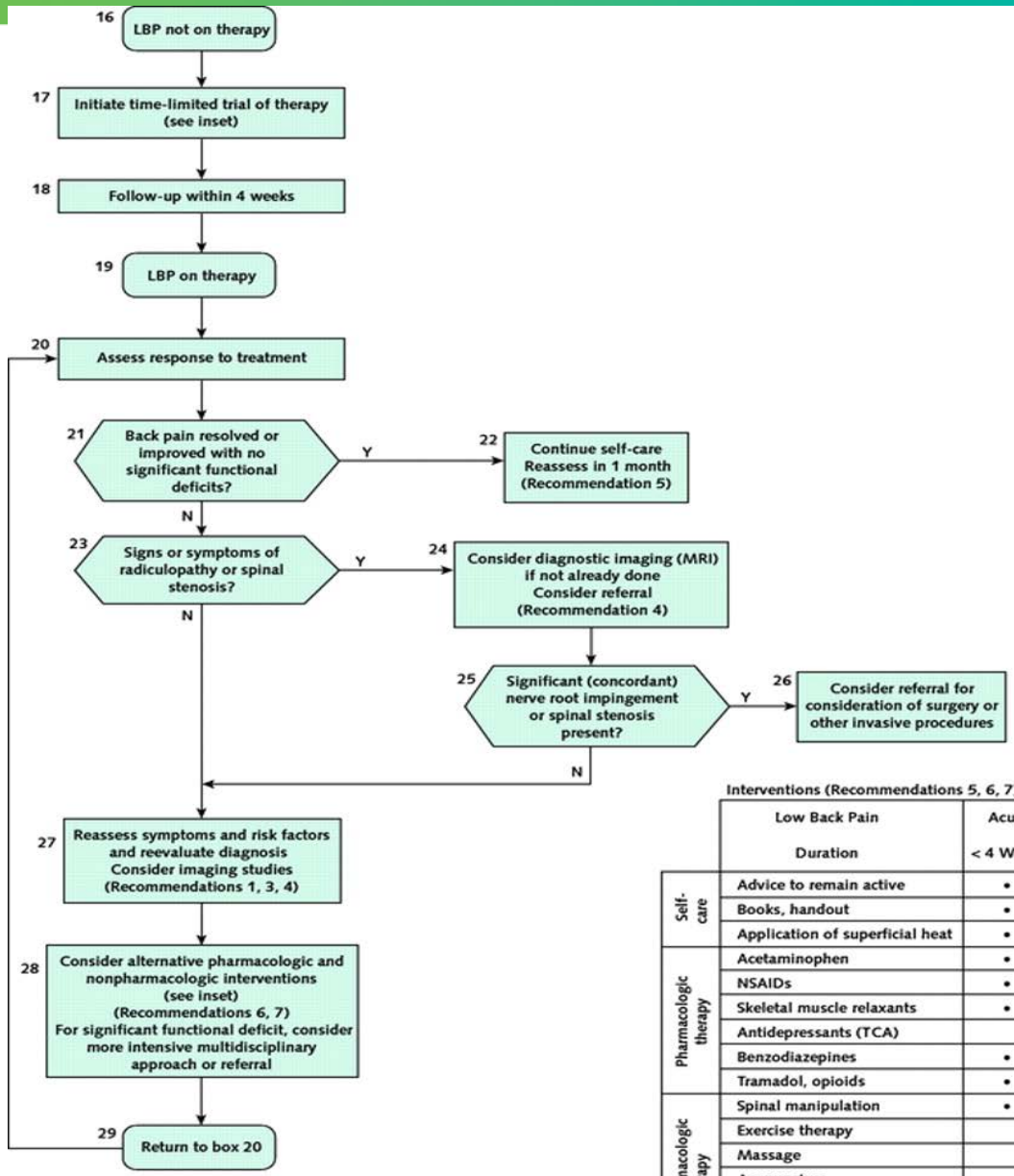
- From: Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society

- Ann Intern Med. 2007;147(7):478-491. doi:10.7326/0003-4819-147-7-200710020-00006

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).*



Interventions (Recommendations 5, 6, 7)

	Low Back Pain Duration	Acute < 4 Weeks	Subacute or Chronic > 4 Weeks
Self-care	Advice to remain active	•	•
	Books, handout	•	•
	Application of superficial heat	•	
Pharmacologic therapy	Acetaminophen	•	•
	NSAIDs	•	•
	Skeletal muscle relaxants	•	
	Antidepressants (TCA)		•
	Benzodiazepines	•	•
	Tramadol, opioids	•	•
Nonpharmacologic therapy	Spinal manipulation	•	•
	Exercise therapy		•
	Massage		•
	Acupuncture		•
	Yoga		•
	Cognitive-behavioral therapy		•
	Progressive relaxation		•
	Intensive interdisciplinary rehabilitation		•

• Interventions supported by grade B evidence (at least fair-quality evidence of moderate benefit, or small benefit but no significant harms, costs, or burdens). No intervention was supported by grade A evidence (good-quality evidence of substantial benefit).

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Appendix Table 6. **Level of Evidence and Summary Grades for Noninvasive Interventions in Patients with Chronic or Subacute Low Back Pain***

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

* 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.

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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)

Likelihood of Implementation in Practice

- 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.

Examples

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:
- Type of study design: 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

Ascertainment 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

DISCUSSION

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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] vs A vs B, 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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