Research Task Force on Research Standards for Chronic Low Back Pain

- Update to IPRCC

- Partap S. Khalsa, DC, PhD, DABCO
- IPRCC Meeting
- February 4, 2014
Challenge of Back Pain Research

- Chronic Low Back Pain (cLBP) is an enormous health & societal problem
  - Costs & utilizations of all current treatments are increasing,
    - have only modest clinical benefits
    - problem is still increasing
  - NIH-convened expert panels (2009, 2010) and Pain Consortium Steering Committee (2011) deliberations:
    - Comparing data across cLBP studies often not possible
      - Inconsistent assessments, study eligibility criteria, stratification criteria, & outcome measures
    - Key recommendation – NIH lead a process to develop Research Standards for cLBP

- NIH Pain Consortium
  - Sponsored Research Task Force
  - Administratively lead by NIAMS & NCCAM
Research Task Force Goals

- Consider state of existing research relevant to development of standards for research on cLBP
- Conduct comprehensive review of existing case definitions, diagnostic criteria, and outcome measures that are relevant for clinical research on cLBP
- Develop set of research standards for cLBP
- Engage broader research community and representatives from relevant government agencies in developing these standards for research on cLBP
- Chart a general plan for their incorporation into research studies and their future modification
RTF Process

- NIH Pain Consortium -> Steering Committee
  - Invited 16 scientific/clinical experts on cLBP research
    - Task Force chaired by Rick Deyo & Sam Dworkin
    - 3 face-to-face meetings during 2012 - 2013

- Outcome
  - Recommendation for a set of Research Standards for all clinical research on cLBP
    - Definition of chronic LBP
    - Sub-classification of cLBP by impact & prognosis
    - Minimum Dataset
      - Concept framework based on NINDS Common Data Elements (CDE)
Minimal Dataset:

Bio-PsychoSocial Paradigm

1) Demographics, History
   - Substance abuse, compensation/litigation

2) Physical Examination
   - Height & weight only
   - For studies of age > 65, include tests of hip arthritis
   - For studies of certain invasive procedures, should include:
     - Straight leg raise
     - Lower extremity strength & reflexes
     - Imaging results

3) Behavioral, Psychological, and Psychosocial domains
## Behavioral, Psychological, and Psychosocial Items (24)

<table>
<thead>
<tr>
<th># of Items</th>
<th>Item/Variable (Domain)</th>
<th>Source</th>
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<tbody>
<tr>
<td>2</td>
<td>Chronic pain definition (with drawing)</td>
<td>RTF</td>
</tr>
<tr>
<td>1</td>
<td>Pain Intensity</td>
<td>PROMIS</td>
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<tr>
<td>4</td>
<td>Pain Interference</td>
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<td>4</td>
<td>Sleep Disturbance</td>
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<tr>
<td>1</td>
<td>Fear of Movement</td>
<td>STarT Back</td>
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<tr>
<td>3</td>
<td>Catastrophizing</td>
<td>STarT Back</td>
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cLBP Definition

- “Do you have ongoing low-back pain present on at least half the days in the past 6 months?”
  - The precise wording of the question is critical for obtaining sensitivity & specificity

- Accompanied by an illustration or anatomic explanation of the part of the body that is considered the “low back”
Dissemination

- Report submitted to & accepted by NIH Pain Consortium

  - Report is on NIH Pain Consortium website waiting for public issue (coordinated w/ manuscript publication)
  - Report to be issued to IPRCC members

- Manuscript submitted for simultaneous publication in five journals

  - Journal of Pain is acting as lead journal
  - Manuscript accepted (Jan. 2014) with required revisions

- Presentation of Research Standards at scientific & professional societies

- Research Agenda for validation & optimization
Comments & Discussion