

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



National Center for
Complementary and
Alternative Medicine



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)

# of Items	Item/Variable (Domain)	Source
2	Chronic pain definition (with drawing)	RTF
1	Pain Intensity	PROMIS
4	Pain Interference	PROMIS
1	Comorbidities	RTF
4	Physical Function	PROMIS
4	Depression	PROMIS
4	Sleep Disturbance	PROMIS
1	Fear of Movement	STarT Back
3	Catastrophizing	STarT Back

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

