

Methods for the Development of a Core Outcome Set for Non-Specific Low Back Pain



Musculoskeletal Health

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Core set for LBP

- 1997: LBP Forum, consensus-based core set
- 1998: Publication on the core set
 - Five domains and corresponding instruments were recommended
 - Positive uptake over the years
- 2012: LBP Forum, an update is timely



Why an update?

- Are there missing core domains?
- Lack of the patients' perspective
- Large body of new evidence on measurement properties of recommended instruments
- Recent developments in the field of core outcome set (COS) development (i.e. COMET, OMERACT)
- Recent developments in the field of clinimetrics (i.e. COSMIN)



People involved

Project Team VU/VUmc Amsterdam

Alessandro Chiarotto

Maarten Boers

Caroline Terwee

Raymond Ostelo

International Steering Committee

Richard Deyo (USA)

Terry Corbin (USA)

Nadine Foster (UK)

Bart Koes (The Netherlands)

Christine Lin (Australia)

Adam Pearson (USA)

Mark Schoene (USA)

Maurits van Tulder (The Netherlands)

Rachelle Buchbinder (Australia)

Leonardo Costa (Brazil)

Margreth Grotle (Norway)

Francisco Kovacs (Spain)

Chris Maher (Australia)

Wilco Peul (The Netherlands)

Dennis Turk (USA)

Scope of this COS

“Measurement of efficacy or effectiveness of health interventions in clinical trials conducted in patients with non-specific low back pain”

Stepwise approach:

→ “What” to measure (i.e. domains)

→ “How” to measure (i.e. measurement instruments)



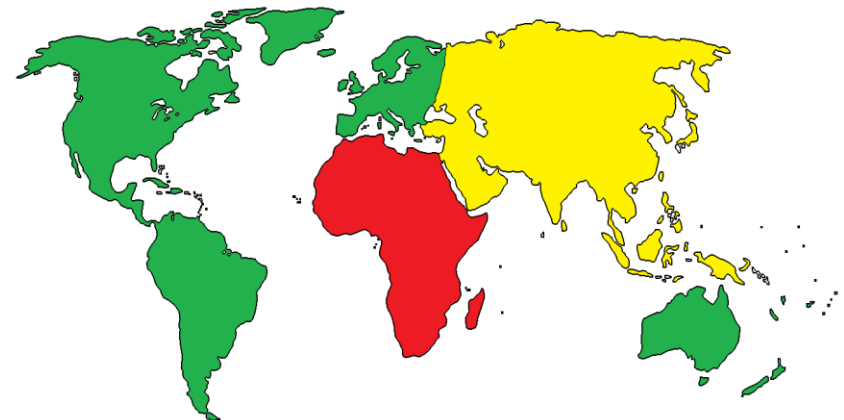
Stakeholders

Different stakeholders from various disciplines were involved:

- 1) Health Care Researchers
- 2) Health Care Providers
- 3) Professionals working both as Researchers and Providers
- 4) Patients with Non-Specific Low Back Pain

Continents represented:

- 4 in the Steering Committee
- 5 in the Delphi panel

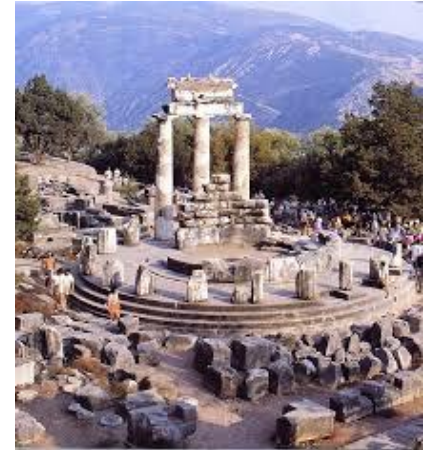


Consensus Methods

A modified Delphi Survey was used to reach consensus on core domains

- ↑ Participation of experts
- ↑ Anonymity of responses
- ↑ Possibility to reconsider responses based on views of others
- ↑ Possibility to combine different stakeholders

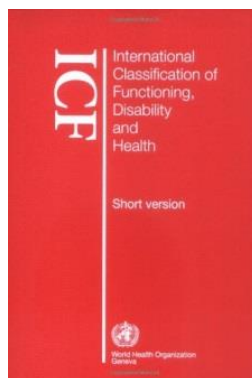
- ↓ Bigger group of stakeholders can influence overall results
- ↓ Difficult to combine patients with other stakeholders



Potential Core Domains

Domains were searched in:

- 1) Clinical Trials included in 5 Cochrane Reviews
- 2) Comprehensive ICF Core Set for LBP
- 3) Conceptual Framework developed to characterize the burden of LBP



The OMERACT Framework 2.0 was used to frame and structure the domains within Core Areas

Selection of Panelists

1) Health care researchers

- Systematic literature search in Web of Science & PubMed
- Convenience sampling

2) Health care providers

- Convenience sampling

3) Patients

- Convenience sampling
- Consent to participate
- Informative booklet

4) Members of the Steering Committee



Delphi Round 1

Combination of close and open-ended questions on domains:

- 1) IMPORTANCE for inclusion in the COS
- 2) CONCEPTUAL OVERLAP
- 3) ADDITION of missing domains
- 4) MODIFICATIONS of terminology

EXAMPLES:

- 1) Is the domain 'Health-Related Quality of Life' important enough to be included in a core domain set for LBP clinical trials?
'Health-Related Quality of Life' is defined here as: '[...]'
Possible answers: 'Yes', 'No', 'Unsure/Not my expertise'.
Please provide arguments for your choice.
- 2) In your opinion, are there any domains in this core area that have too large conceptual overlap?
If yes, please mention them.

Delphi Round 2

Results Round 1 were addressed with questions on domains:

- 1) EXCLUSION
- 2) AGGREGATION
- 3) RETENTION
- 4) IMPORTANCE for inclusion of new domains

EXAMPLE:

- 1) Do you agree with our proposal of excluding the domain 'Health-Related Quality of Life' from the list of potential core domains?

Definition, quantitative and qualitative answers of Round 1 for this domain can be seen on pages (...) of the feedback report.

Possible answers: 'Yes', 'No', 'Unsure/Not my expertise'.

Please provide arguments for your choice.

Delphi Round 3

Close and open-ended questions on domains:

1) IMPORTANCE for inclusion in the COS

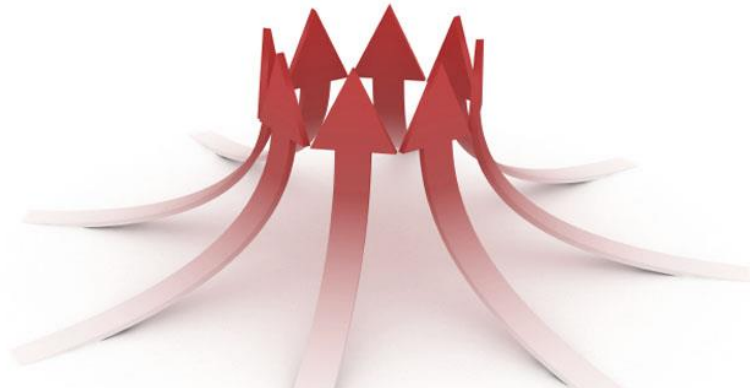
EXAMPLE:

1) Is the domain 'Health-Related Quality of Life' indeed a core domain to be included in all LBP clinical trials?

'Health-Related Quality of Life' is defined here as: '[...]'

Possible answers: 'Yes', 'No', 'Unsure/Not my expertise'.

Please provide arguments for your choice.



Analyses

- Frequencies for close-ended questions
 - A-priori criteria for consensus on inclusion or exclusion of domains
- Subjective assessment of comments provided
 - Consistency across respondents
 - Potential strength of arguments
 - Consistency with frequencies
- In every round, patients responses and comments were isolated in order to “hear their voice”
- In Round 3, frequencies were calculated for each stakeholder group

Results



Development of a Core Domain Set for Non-Specific Low Back Pain: Results from an International Delphi Study

Alessandro Chiarotto¹, Caroline B. Terwee², Maarten Boers², Raymond W. Ostelo^{1,2}; on behalf of the International Steering Committee for the Core Outcome Set for Low Back Pain

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Background & Aim

- Heterogeneous reporting of outcomes can occur in clinical trials for non-specific low back pain (NSLBP)
- Inconsistency of outcomes measurement hinders comparison of findings and statistical pooling
- In 1998 Deyo et al. proposed a standardized set of outcomes for LBP clinical research
- This study purposed to update the existing standardized set by developing a core outcome set for NSLBP

Methods

- * 200 among researchers, clinicians and patients from 5 continents were selected and invited to participate in a modified Delphi study
- * Generation of a list of potential core domains was done using CONFRACT 2.0 framework
- * Round 1: rating of importance of each domain
- * Round 2: rating of Round 1 suggestions on overlap, aggregation or addition of domains
- * Round 3: rating if each domain is indeed core
- * In each round: a priori criteria for consensus
- * In each round: patients' responses were assessed separately to 'hear their voice'

Results

- * Response rates of the three rounds were 82%, 80% and 45%
- * Among 41 potential core domains: 6 were excluded in Round 1, 22 in Round 2 and the other 13 presented for rating in Round 3
- * Patients' responses did not substantially differ from total panel in the first two rounds
- * Overall consensus was reached on 3 core domains: 'Physical Functioning', 'Pain Intensity' and 'Health-Related Quality of Life'
- * Ratings across stakeholder groups were not consistent for 'Work Ability', 'Psychological Functioning' and 'Self-rated Health'

Figure 1. Results Delphi Round 1

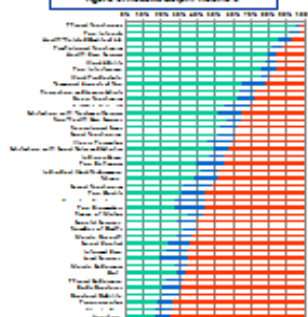


Figure 2. Results Delphi Round 2

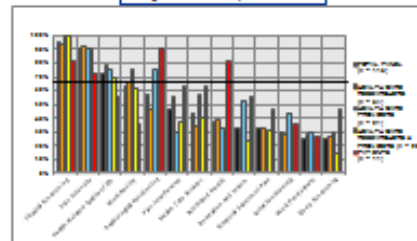


Table 1. Definitions of the three domains rated as core by the Delphi Panel

Physical Functioning	Patient's ability to carry out daily physical activities required to meet basic needs ranging from walking to more complex activities that require a combination of skills
Pain Intensity	How much patient hurts, reflecting the overall magnitude of the pain experience
Health-Related Quality of Life	Physical, psychological and social domains of health, seen as defined and influenced by a person's experiences, beliefs, expectations and perceptions

Conclusions

- Consensus was reached on 3 core domains: 'Physical Functioning', 'Pain Intensity' and 'Health-Related Quality of Life'
- This core domain set is applicable to NSLBP clinical trials and represents the update of the set proposed in 1998
- Next step will be to determine which measurement instruments best measure the core domains

A close-up photograph of a hand in a dark suit jacket giving a thumbs up gesture. The hand is the central focus, with the thumb pointing upwards. The background is dark and out of focus.

THANK YOU FOR YOUR ATTENTION

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