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"How to select outcome measurement instruments for a 'Core Outcome Set' – a practical guideline"

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COMET IV Meeting, Rome
20-Nov-2014

COSMIN

COMET INITIATIVE

Definition of COS

'Collection Of Style'
Berlin, October 2014

A 'core outcome set' (COS) is a recommendation of ***what*** should be measured and reported in all clinical trials

Once COS are defined, it is then important to achieve consensus on ***how*** these outcomes should be measured

What = outcome
How = outcome measurement instrument

Objective

Overall aim:
To develop a guideline for the selection of outcome measurement instruments for outcomes in a COS (i.e. 'how' to measure)

Collaboration between COSMIN and COMET initiatives

www.cosmin.nl

www.comet-initiative.org

Delphi study

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Definition:
A structured, iterative process to achieve consensus among a group of stakeholders about a given issue

The group of stakeholders does not need to meet which confers **anonymity**; opinions are to be expressed **free from group pressure**; and **possible dominance** of individuals in face-to-face group meetings is being avoided

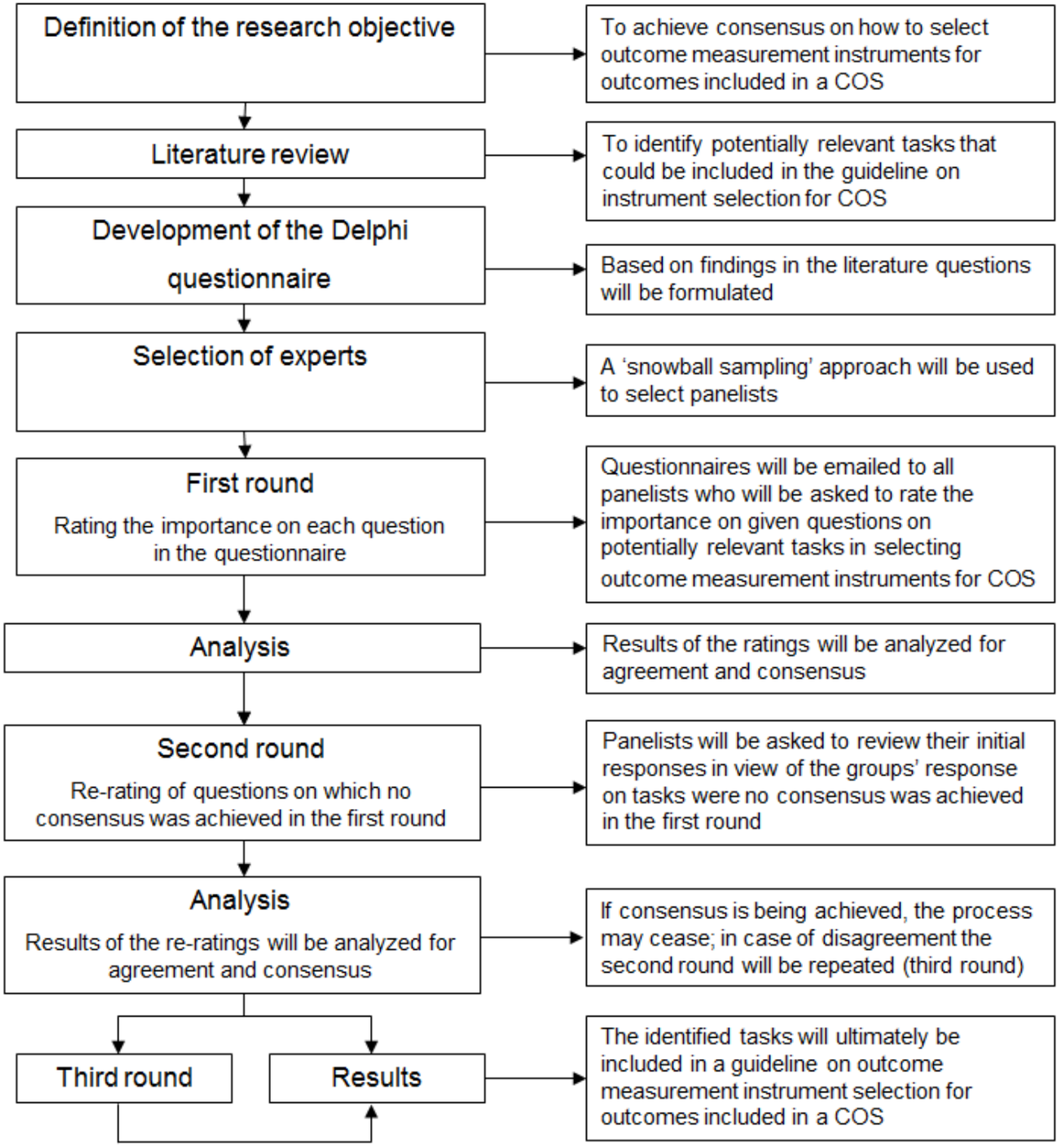
Delphic oracle's skills of interpretation and foresight

Objective

Aim:
To reach consensus on the methods for selecting outcome measurement instruments for outcomes included in a COS

We intent to describe the
most optimal methodology
in our guideline

Delphi process



Prinsen et al. *Trials* 2014, 15:247

Literature review

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Three steps were identified:

1. Conceptual considerations in the selection of outcome measurement instruments
2. Finding relevant outcome measurement instruments
3. Evaluation of outcome measurement instruments

Each of these steps include a variety of tasks

Example

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Example of a question on conceptual considerations:

2.1 Should COS developers agree in detail upon the *constructs to be measured* before starting to search for outcome measurement instruments?

( ) Highly recommended
( ) Desirable
( ) Not relevant
( ) Not my expertise

Please provide arguments for your rating in the text box below.

Consensus

Consensus:

≥70% of the panellists considered tasks ‘highly recommended’ or ‘desirable’

and

when no opposing arguments were given

Results

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Participants:

- 120/481 experts agreed to participate (24.9%)
- 95/120 panellists completed the first questionnaire (79.2%)
- 14 countries represented
- Allied healthcare professionals (31.6%), clinimetricians (30.5%), epidemiologists (42.1%), medical doctors (29.5%), statisticians (10.5%), other (15.8%)

- 84/95 agreed to participate in subsequent rounds (88.4%)

- 65/84 panellists completed the 2nd questionnaire (77.4%)

- 72/84 panellists completed the 3rd questionnaire (85.7%) (ongoing)

Results

Consensus on **four main steps** in the selection of outcome measurement instruments for COS:

1. Conceptual considerations
2. Finding all existing instruments
    a) Systematic reviews
    b) Literature search
3. Quality assessment of instruments
    a) Measurement properties
    b) Feasibility
4. Selection of instruments for COS

Results

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1. Conceptual considerations:

Consensus was reached on two aspects *before* starting to search for outcome measurement instruments:

- Construct to be measured (97.8%)
- Target population (98.9%)

"It is recommended for COS developers to agree in detail upon the 'construct to be measured' and the 'target population' before starting to search for outcome measurement instruments."

Results

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2. Finding *all* existing instruments (72.2%):

a) Systematic reviews (SR)

1. Use existing, good quality, and up-to-date SR of outcome measurement instruments
2. If a SR is not up-to-date, perform an additional literature search
3. If a SR is of poor quality, perform a new literature search
4. If no SR exists, perform a literature search

Consensus reached: 93.7%

Results

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2. Finding *all* existing instruments:

b) Literature search

- Medline/PubMed (98.8%) and Embase (82.4%) are the minimum databases that should be consulted
- Reference lists should be checked (91.2%)

Results

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2. Finding *all* existing instruments:

C. Other sources

Other sources, such as relevant database websites, conference proceedings, and book chapters, will not be included as a recommendation but as possible additional sources of information (89.2%)

Results

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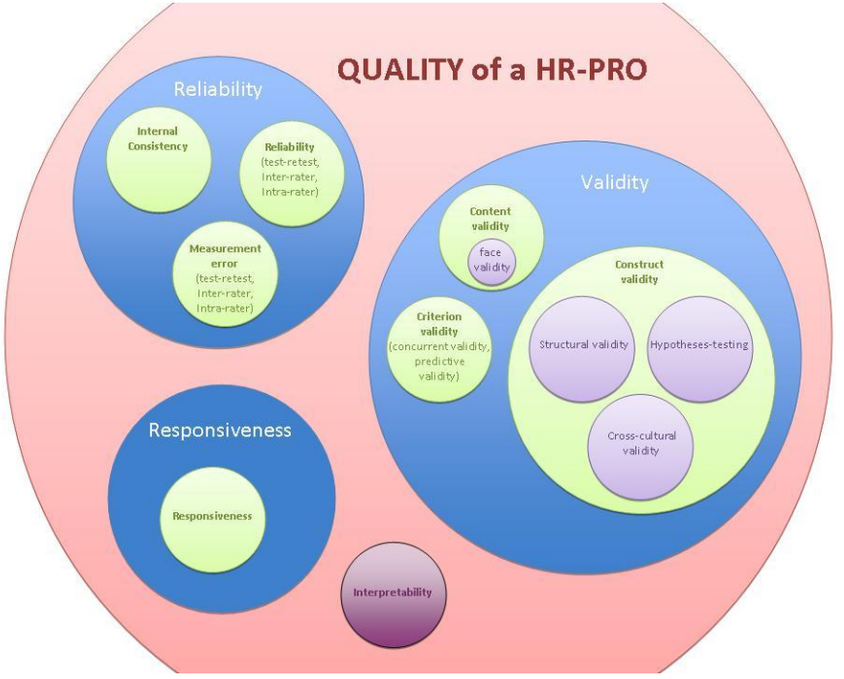
3. Quality assessment of instruments:

a) Measurement properties

Evidence on the following measurement properties should be available in the target population:

Content validity	(93.2%)
Reliability	(90.9%)
Responsiveness	(90.9%)
Face validity	(89,9%)
Internal consistency	(89.5%)
Structural validity	(83.3%)
Measurement error	(82.8%)
Construct validity	(82.1%)
Criterion validity	(76.1%)
Cross cultural validity	(70.1%)



Results

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3. Quality assessment of instruments:

b) Feasibility

The following aspects (n=16) should be considered in the selection of outcome measurement instruments for a COS:

- Type of instrument
- Type and ease of administration
- Patient's and clinician's comprehensibility
- Patient's mental and physical ability level
- Costs and copyright of an instrument
- Interpretability
- Length and completion time
- …

Consensus reached: 83.9% to 96.6%

Results

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4. Selection of instruments for COS:

"We recommend, in principle, to select only one outcome measurement instrument for each outcome in a COS to avoid difficulties in pooling the results in meta analyses of future clinical trials."

"In case of a complex outcome (e.g., pain) that consists of multiple aspects (e.g., pain intensity, pain during activity), we recommend to consider these different aspects as different outcomes. For each of these outcomes, we recommend to select one outcome measurement instrument."

Consensus reached: 89.6%

Results

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4. Selection of instruments for COS:

"In case more than one instrument has good measurement properties, we recommend that COS developers decide what is 'the best' instrument, taking all aspects of feasibility and measurement properties into consideration and the specific situation for which the instrument is intended (as defined in the scope of the COS)."

Consensus reached: 85.3%

Results

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4. Selection of instruments for COS:

"We recommend that in case no outcome measurement instrument exists that meets the requirements of adequate measurement properties and feasibility, an outcome measurement instrument can be included preliminary in a COS if there is at least evidence for feasibility, face validity, content validity, and internal structure (if applicable)."

"If there is no evidence for feasibility, face validity, and content validity in the literature, COS developers may assess these aspects themselves."

Consensus reached: 83.3%

Results

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4. Selection of instruments for COS:

"We recommend that COS developers involve patients in assessing the face validity of outcome measurement instruments"

Consensus reached: 85.9%

"In case there are multiple instruments that measure the same construct and are of equal quality, we recommend that COS developers involve patients in the selection of outcome measurement instruments"

Consensus reached: 82.3%

Summary

The selection of outcome measurement instruments for a COS includes **four main steps**:

1. Conceptual considerations
2. Finding all existing instruments
    a) Systematic reviews
    b) Literature search
3. Quality assessment of instruments
    a) Measurement properties
    b) Feasibility
4. Selection of instruments for COS

Conclusions

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This study results in a consensus agreed published **guideline** on the methods for selecting outcome measurement instruments to be included in a COS

Final draft version expected for December 2014

COSMIN

www.cosmin.nl

COMET INITIATIVE

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