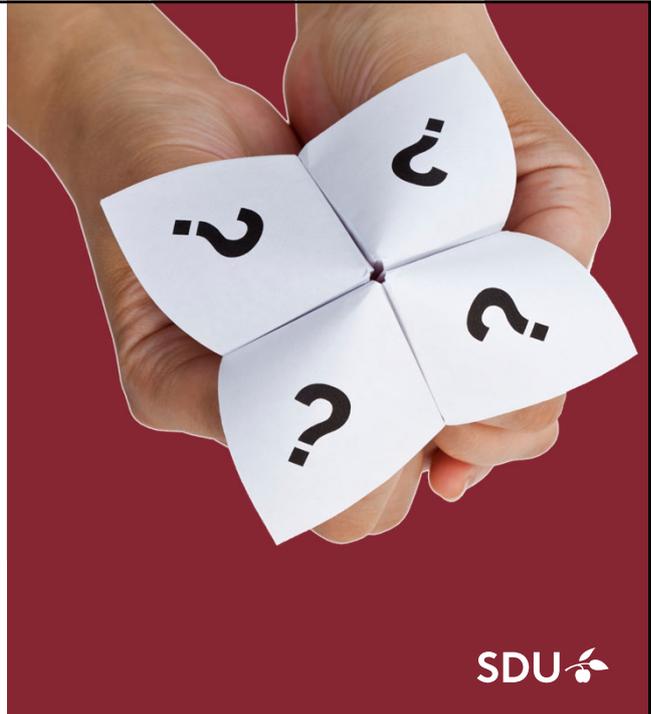


How to select an existing questionnaire?

Henrik Hein Lauridsen
Associate Professor
Research unit for Clinical Biomechanics



SDU 

1

Problems

Choice of questionnaire is often arbitrary

- *Use the same questionnaire as everybody else...*

but...

- Does the questionnaire measure the right domain(s)?
- Is it feasible to use?
- Has it been validated
 - *Population*
 - *Validity*
 - *Reproducibility*
 - *Responsiveness*
 - *Interpretation*

The wrong choice can undermine a clinical study

'Three steps'

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SDU 

2

Overview



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3

STEP 1

What do you want to measure?

(a) Define the outcome you want to measure

E.g.
General health status
Pain intensity
Functional limitations
Activity level
Satisfaction
Psychological aspects
Return to work
Depression
Aso...

Remember, your understanding may be different than someone else's

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STEP 1

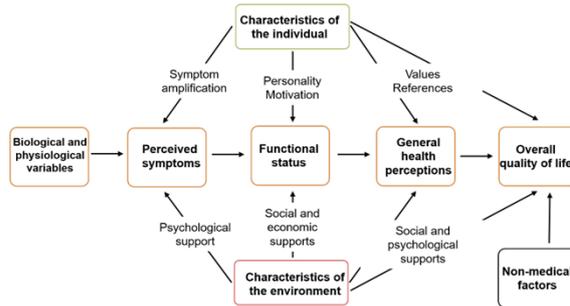
What do you want to measure?

Helps to define what the outcome is, and what it isn't

(b) Use a conceptual framework

- Wilson & Cleary model

A hypothetical causal pathway through which different factors influence HRQOL



Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes. JAMA 1995;273(1):59-65.

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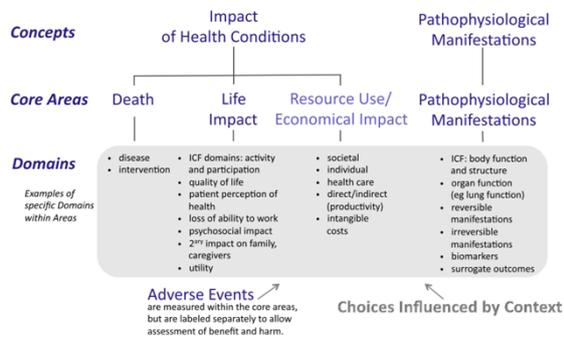
STEP 1

What do you want to measure?

Helps to define what the outcome is, and what it isn't

(b) Use a conceptual framework

- Omeract filter 2.0



Boers M, Kirwan JR, Wells G, et al. Developing core outcome measurement sets for clinical trials: OMERACT filter 2.0. J Clin Epidemiol 2014;67(7):745-53.

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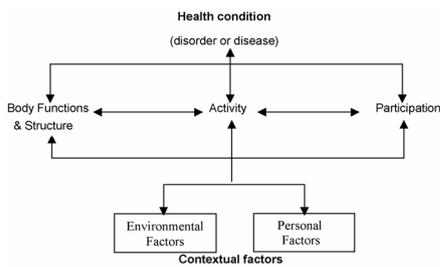
STEP 1

What do you want to measure?

Helps to define what the outcome is, and what it isn't

(b) Use a conceptual framework

- ICF conceptual model



Using linking rules

International Classification of Functioning, Disability and Health 2019

4430 Lifting and carrying objects

Code: 4430

Descriptions: Lifting up an object or taking something from one place to another, such as when lifting a cup or tray or carrying a box, or a child from one room to another.

ICF browser: <https://icd.who.int/browse/2024-01/icf/en>

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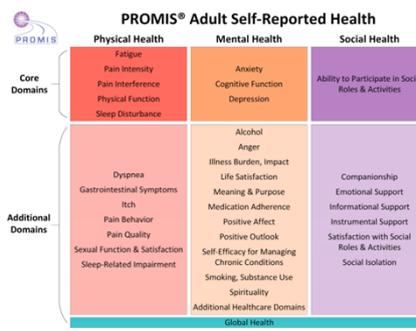
STEP 1

What do you want to measure?

Helps to define what the outcome is, and what it isn't

(b) Use a conceptual framework

- PROMIS framework



<https://www.healthmeasures.net/explore-measurement-systems/promis/intro-to-promis>

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STEP 1

What do you want to measure?

A COS is an agreed set of outcomes that should be measured in all studies in a specific clinical area

(c) Is a Core Outcome Set (COS) available? • • •



Core Outcome Measures in Effectiveness Trials

"A core outcome set (COS) is an agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of health or health care."

<https://www.comet-initiative.org/>

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STEP 2

Which PROM(s) is/are available?

For each PRO in a COS, a recommendation is made for the most suitable PROM

(a) Is a measurement set for the COS available? • • •

- [COMET database for COS](#)

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STEP 2

Which PROM(s) is/are available?

A review can advise you on the quality of the PROM, and recommend high-quality PROMS

(b) Is a systematic review available?

COSMIN Database of Systematic Reviews

Save time searching for the best available outcome measurement instrument for your construct and population with our database of systematic reviews.

COSMIN systematically collects systematic reviews of outcome measurement instruments. Such systematic reviews are important tools for selecting the instruments for your research or clinical practice and for identifying gaps in knowledge on the quality of outcome measurement instruments, i.e. their measurement properties.

The reviews are available in a searchable database.

The database now contains 1592 reviews. We are continuously working to update the COSMIN database, and we are now working on the update of September 2021 until March 2022.

If you find any imperfections in our database, please notify us at info@cosmin.nl.

[TO THE DATABASE OF SYSTEMATIC REVIEWS](#)

[TO THE MANUAL FOR THE DATABASE OF SYSTEMATIC REVIEWS](#)



<https://www.cosmin.nl/tools/database-systematic-reviews/>

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STEP 2

Which PROM(s) is/are available?

Make sure you get the latest version of a PROM

(c) Where to find a copy of the PROM?

PROQOLID™ is a comprehensive online database designed to assist academic researchers, physicians, students, pharmaceutical companies, health authorities, and international organizations search for and evaluate Clinical Outcome Assessments (COAs).



<https://eprovide.mapi-trust.org/about/about-proqolid>

HealthMeasures consists of **PROMIS**, Neuro-QoL, ASCQ-Me, and NIH Toolbox. These four precise, flexible, and comprehensive measurement systems assess physical, mental, and social health, symptoms, well-being and life satisfaction; along with sensory, motor, and cognitive function.



<https://www.healthmeasures.net/search-view-measures>

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STEP 2

Which PROM(s) is/are available?

Translate and culturally adapt the original version

(d) Is the required language version not available?

- **Review of methods**
 - Acquadro C, Conway K, Hareendran A, et al. Literature review of methods to translate health-related quality of life questionnaires for use in multinational clinical trials. *Value Health* 2008;11(3):509–21.
 - Epstein J, Santo RM, Guillemin F. A review of guidelines for cross-cultural adaptation of questionnaires could not bring out a consensus. *Journal of Clinical Epidemiology* 2015;68(4):435–41.
- **Important guidelines**
 - Beaton DE, Bombardier C, Guillemin F, et al. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine* 2000;25(24):3186–91.
 - Eremenco SL, Cella D, Arnold BJ. A Comprehensive Method for the Translation and Cross-Cultural Validation of Health Status Questionnaires. *Eval Health Prof* 2005;28(2):212–32.
 - Hagell P, Hedin PJ, Meads DM, et al. Effects of method of translation of patient-reported health outcome questionnaires: a randomized study of the translation of the Rheumatoid Arthritis Quality of Life (RAQoL) Instrument for Sweden. *Value Health* 2010;13(4):424–30
- **Manuals**
 - [EORTC translation manual 2017](#)

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STEP 2

Which PROM(s) is/are available?

If no PROM is available that measures your outcome of interest and is validated in your population of interest, here are some options

(e) There is no PROM available – what to do?

- **Is a PROM available that measures your outcome of interest in another population/age-group or the like?**
 - While using it, you can efficiently gather evidence for the measurement properties in your population of interest.
- **Develop your own PROM?**
 - This is a lot of work. It requires a project structure with involvement of the necessary expertise and parties (e.g. clinimetric expertise, patients, health care providers)



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STEP 3

How to report a PRO?

- (a) What information should be included in a *clinical trial protocol* when a patient-reported outcome (PRO) is an outcome?
 - Use **SPIRIT-PRO** guidance¹
- (b) What information should be included in a *clinical trial report* when a patient-reported outcome (PRO) is an outcome?
 - Use **CONSORT-PRO** guidance²

1. Calvert M, Kyte D, Mercieca-Bebber R, et al. Guidelines for Inclusion of Patient-Reported Outcomes in Clinical Trial Protocols: The SPIRIT-PRO Extension. *JAMA* 2018;319(5):483.
2. Calvert M, Blazeby J, Altman DG, et al. Reporting of Patient-Reported Outcomes in Randomized Trials: The CONSORT PRO Extension. *JAMA* 2013;309(8):814.

Additional considerations

- When a PROM has been found, consider →
 - **Clinimetric properties**
 - validity, reliability, internal consistency, measurement error
 - responsiveness & minimal important change
 - **Feasibility**
 - administration, costs, respondent burden
 - **Patient population**
 - has it been tested in Your population?
 - **Type of instrument**
 - Discriminative, evaluative or predictive
 - Generic or disease specific



1. <https://www.ccsmin.nl/tools/pubmed-search-filters/>

Questions?

Please ask in the lecture

