

Selecting outcome measurement instruments for COS

C.A.C. (Sanna) Prinsen, PhD
Caroline B. Terwee, PhD

VU University Medical Center
Amsterdam Public Health research institute
Department of Epidemiology and Biostatistics

‘What to measure’ ‘How to measure’

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Trials

REVIEW

Open Access

The COMET Handbook: version 1.0



Paula R. Williamson^{1*}, Douglas G. Altman², Heather Bagley¹, Karen L. Barnes¹, Jane M. Blazeby³, Sara T. Brookes³, Mike Clarke^{4,5}, Elizabeth Gargon¹, Sarah Prinsen *et al. Trials* (2016) 17:449
DOI 10.1186/s13063-016-1555-2
Cecilia A. C. Prinsen⁶, Jochen Schmitt⁷, C

Trials

RESEARCH

Open Access

How to select outcome measurement instruments for outcomes included in a “Core Outcome Set” – a practical guideline



Cecilia A. C. Prinsen^{1*}, Sunita Vohra^{2,3,4}, Michael R. Rose⁵, Maarten Boers^{1,6}, Peter Tugwell⁷, Mike Clarke⁸, Paula R. Williamson⁹ and Caroline B. Terwee¹

COSMIN-COMET collaboration

COSMIN: COnsensus-based **S**tandards for the selection of health **M**easurement **IN**struments initiative

COSMIN aims to improve the selection of outcome measurement instruments in research and clinical practice

COSMIN tools:

- Taxonomy of measurement properties
- Methodology for systematic reviews of outcome measurement instruments
- Database of systematic reviews of outcome measurement instruments



Content

Four steps in the selection of OMI for COS

1. Conceptual considerations
2. Finding all available OMI
3. Quality assessment of the OMI
 - a) Measurement properties
 - b) Feasibility
4. Selection of OMI for COS

1. Conceptual considerations

Aspects to consider **before** starting to search for outcome measurement instruments:

- a) Construct of interest
- b) Target population

Aspects to consider:

Are the **constructs to be measured** (i.e. core outcomes) and the **population of interest** clearly (enough) described in the scope of the COS or is more detail required for the selection of instruments?

1. Conceptual considerations

a) Construct of interest

COS developers should agree in detail upon the construct to be measured before starting to search for outcome measurement instruments

For example:

Construct: pain → What exactly do you want to measure?

Pain intensity, pain interference, pain behaviour?

Average pain last week, current pain, achievement of an acceptable pain state, area under the curve of pain scores during a given period of time, ... ?

1. Conceptual considerations

b) Target population

Explore relevant subgroups and determine if there will be separate recommendations needed for outcome measurement instruments most applicable to each of the potential subgroups

For example: age, gender, disease characteristics, etc

Also consider the context of use

For example: inpatient or outpatient setting, administration mode, country/language version, etc

2. Finding all existing instruments

It is recommended that COS developers aim for finding all existing instruments

Three sources of information:

- a. Use existing, good quality and up-to-date **systematic reviews** of outcome measurement instruments
- b. Perform a comprehensive **literature search or systematic review** if a good systematic review is not available (MEDLINE, EMBASE)
- c. Use other sources (optional)



COSMIN database

www.cosmin.nl or <http://database.cosmin.nl/>

Search !

Keywords

Author

Drop down menu

www.cosmin.nl

perform a new search

Your search:

- Construct
- Population
- Disease
- PRO / non-PRO
- Health-related/non-health related
- Type of measurement instrument
- Purpose of measurement
- Measurement properties
- Feasibility aspects
- Interpretability aspects
- Reviews using COSMIN

Keywords: (title, abstract)
Fatigue, COSMIN

Author:
Choose author

Search articles

Result:
A total of 3 articles have been found on your search query.

You have searched the following tags:
Fatigue, COSMIN

1. **Assessing severity of illness and outcomes of treatment in children with Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME): a systematic review of patient-reported outcome measures (PROMs)**
Haywood
Child Care Health Dev. 2014,40:806-24.

Chronic Fatigue Syndrome or Myalgic Encephalomyelitis (CFS/ME) in children is characterized by persistent or recurrent debilitating fatigue which results in a substantial reduction in activity. There is a growing interest in the use of questionnaires, or patient-reported outcome measures (PROMs), to assess how patients function and feel in relation to their health and associated healthcare. However, guidance for PROM selection for children with CFS/ME does not exist. We reviewed the quality and acceptability of PROMs used with children with CFS/ME to inform recommendations for practice. We conducted a systematic review of PROMs completed by children with CFS/ME. The quality of the evaluative studies and the reviewed measures were assessed against recommended criteria using an appraisal framework and the COSensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist. We sought evidence of measurement (reliability, validity, responsiveness, interpretability, data quality) and practical properties (acceptability, relevance, feasibility). Sixteen articles were included in the review, providing evidence of reliability and/or validity for 13 PROMs. Of these, five were child-specific (one health-related quality-of-life, four emotional well-being) and eight were not (four emotional well-being, three fatigue-specific; and one generic). All measures had limited evidence of measurement properties and no evidence of practical properties. Recommendations for patient-reported assessment are difficult to make because of limited evidence of the quality and acceptability of PROMs for children with CFS/ME. The appraisal method highlighted significant methodological and quality issues which must be addressed in future research. There is a lack of qualitative evidence describing the outcomes of healthcare that are important to children with CFS/ME, and the relevance or appropriateness of available measures. Future PROM development and evaluation in this group must seek to involve children collaboratively to ensure that the outcomes that children care about are assessed in an acceptable way.

Pubmed: www.ncbi.nlm.nih.gov/pubmed/24661148

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2. **Self-report fatigue questionnaires in multiple sclerosis, Parkinson's disease and stroke: a systematic review of measurement properties**
Elbers
Qual Life Res. 2012;21:925-44.

PURPOSE:
To critically appraise, compare and summarize the measurement properties of self-report fatigue questionnaires validated in

Publications

Prinsen CAC, Mokkink LB, Bouter LM, Alonso J, Patrick DL, de Vet HCW, Terwee CB. COSMIN guideline for systematic reviews of Patient-Reported Outcome Measures. Qual Life Res in press.

Terwee CB, Prinsen CAC, Chiarotto A, Westerman MJ, Patrick DL, Alonso J, Bouter LM, de Vet HCW, Mokkink LB. COSMIN standards and criteria for evaluating the content validity of Patient-Reported Outcome Measures: a Delphi study. Qual Life Res in press.

Mokkink LB, de Vet HCW, Prinsen CAC, Patrick DL, Alonso J, Bouter LM, Terwee CB. COSMIN Risk of Bias checklist for systematic reviews of Patient-Reported Outcome Measures. Qual Life Res 2017, Dec 19 [Epub].

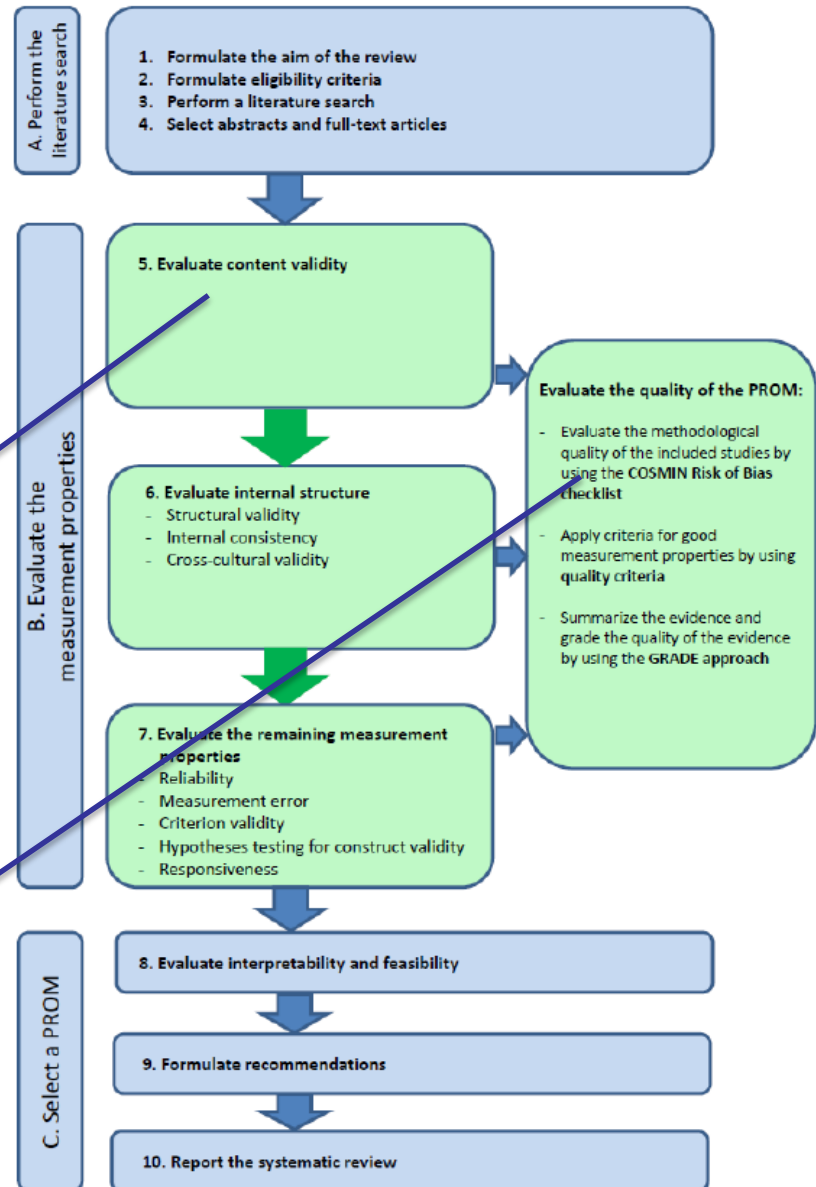


Figure 2. Ten steps for conducting a systematic review of PROMs [4]

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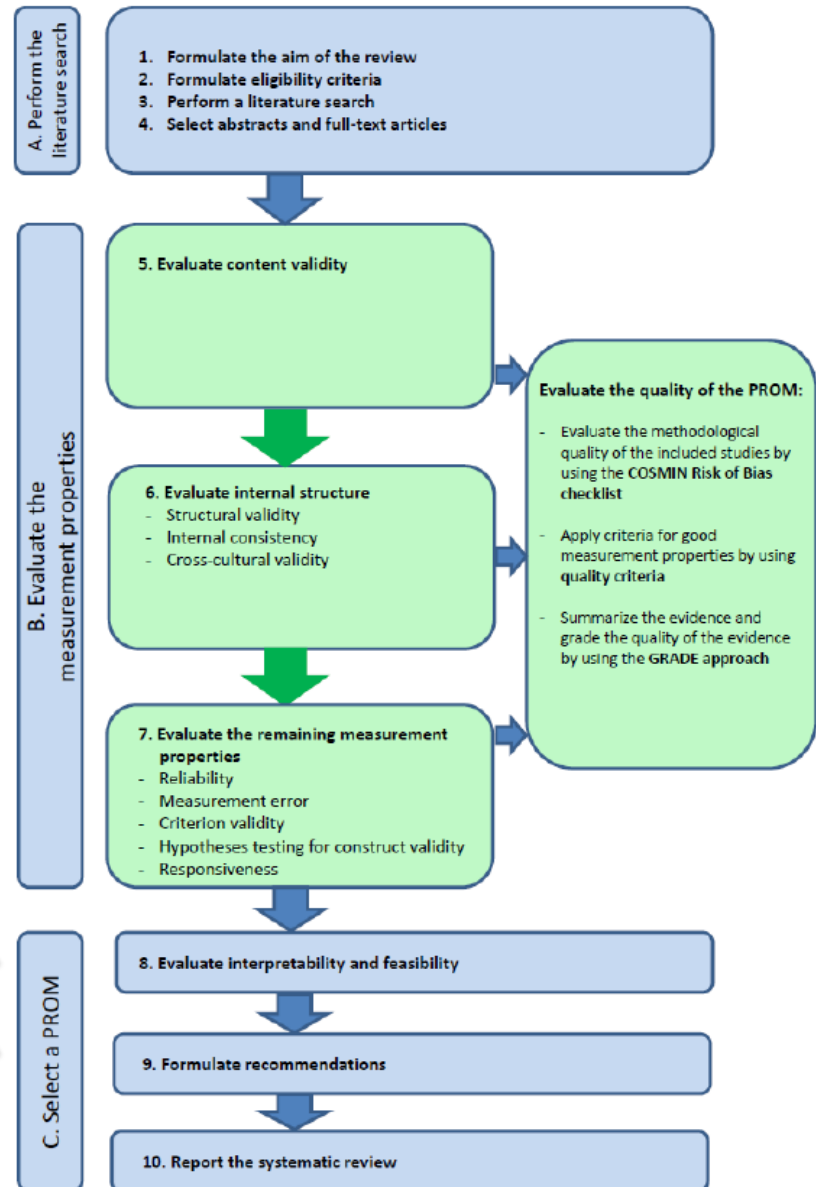


Figure 2. Ten steps for conducting a systematic review of PROMs [4]



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4. Selection of OMIs for COS

*“We recommend that an outcome measurement instrument can be provisionally included in a COS if there is **at least strong evidence for good content validity and for good internal consistency** (if applicable), and if the instrument seems feasible.”*

“Conversely there should be an absence of strong evidence that one or more other measurement properties are poor.”

“When no instrument with good content validity is available, we recommend developing a new instrument, followed by a quality assessment of the instrument.”

COSMIN criteria for determining the evidence for measurement properties

The total body of evidence for a measurement property is rated as sufficient (good) or insufficient based on criteria for good measurement properties

example

Reliability	+	ICC or weighted Kappa ≥ 0.70
	?	ICC or weighted Kappa not reported
	-	ICC or weighted Kappa < 0.70

COSMIN (GRADE) grading of the quality of the evidence

Each rating is accompanied by a grading for the quality of the evidence (based on GRADE)

Table 5. Definitions of quality levels

Quality level	Definition
High	We are very confident that the true measurement property lies close to that of the estimate* of the measurement property
Moderate	We are moderately confident in the measurement property estimate: the true measurement property is likely to be close to the estimate of the measurement property, but there is a possibility that it is substantially different
Low	Our confidence in the measurement property estimate is limited: the true measurement property may be substantially different from the estimate of the measurement property
Very low	We have very little confidence in the measurement property estimate: the true measurement property is likely to be substantially different from the estimate of the measurement property



COSMIN (GRADE) grading of the quality of the evidence

The quality of the evidence is high unless there is risk of bias, inconsistency, imprecision, or indirectness of results.

Quality of evidence	Lower if
High	Risk of bias
Moderate	-1 Serious
Low	-2 Very serious
Very low	-3 Extremely serious
	Inconsistency -1 Serious -2 Very serious
	Imprecision -1 total n=50-100 -2 total n<50
	Indirectness -1 Serious -2 Very serious

Risk of bias	Downgrading for Risk of Bias
No	There are multiple studies of at least adequate quality, or there is one study of very good quality available
Serious	There are multiple studies of doubtful quality available, or there is only one study of adequate quality
Very serious	There are multiple studies of inadequate quality, or there is only one study of doubtful quality available
Extremely serious	There is only one study of inadequate quality available



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Example conclusions

“There is low quality evidence for insufficient internal consistency of instrument X”


“There is moderate quality evidence for sufficient test-retest reliability of instrument X”

“There is no evidence on the responsiveness of instrument X”

COSMIN recommendations for selecting instruments

PROMs are categorized into three categories

- (A) PROMs with evidence for sufficient content validity (any level) AND at least low quality evidence for internal consistency;
- (B) PROMs categorized not in A or C.
- (C) PROMs with high quality evidence for an insufficient measurement property



*“We recommend that an outcome measurement instrument can be provisionally included in a COS if there is **at least strong evidence for good content validity and for good internal consistency** (if applicable), and if the instrument seems feasible.”*



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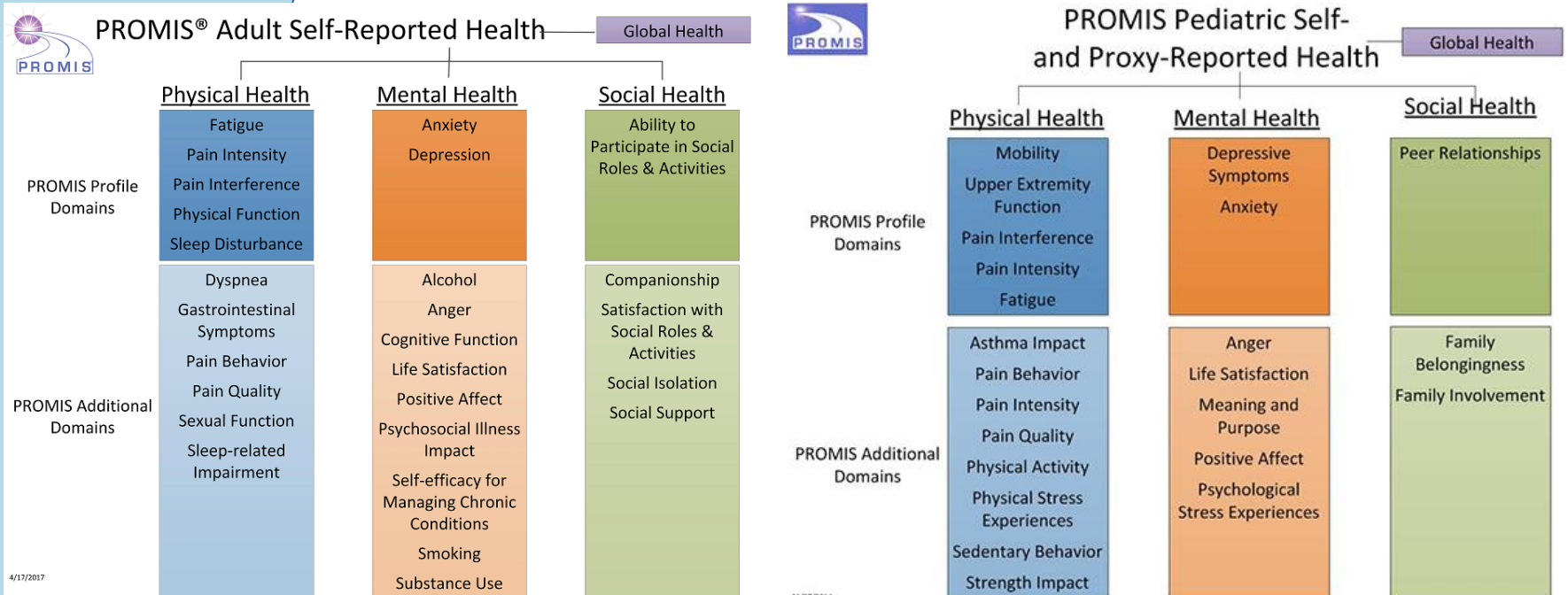
Consider new outcome measurement instruments

Newly developed instruments are often based on more patient input → Better content validity

Newly developed instruments are increasingly based on Item Response Theory (IRT) → better internal structure, better reliability, better interpretability

Patient-Reported Outcomes Measurement Information System (PROMIS)

PROMIS contains generic IRT-based instruments than can be used across patient populations (www.healthmeasures.net/promis)

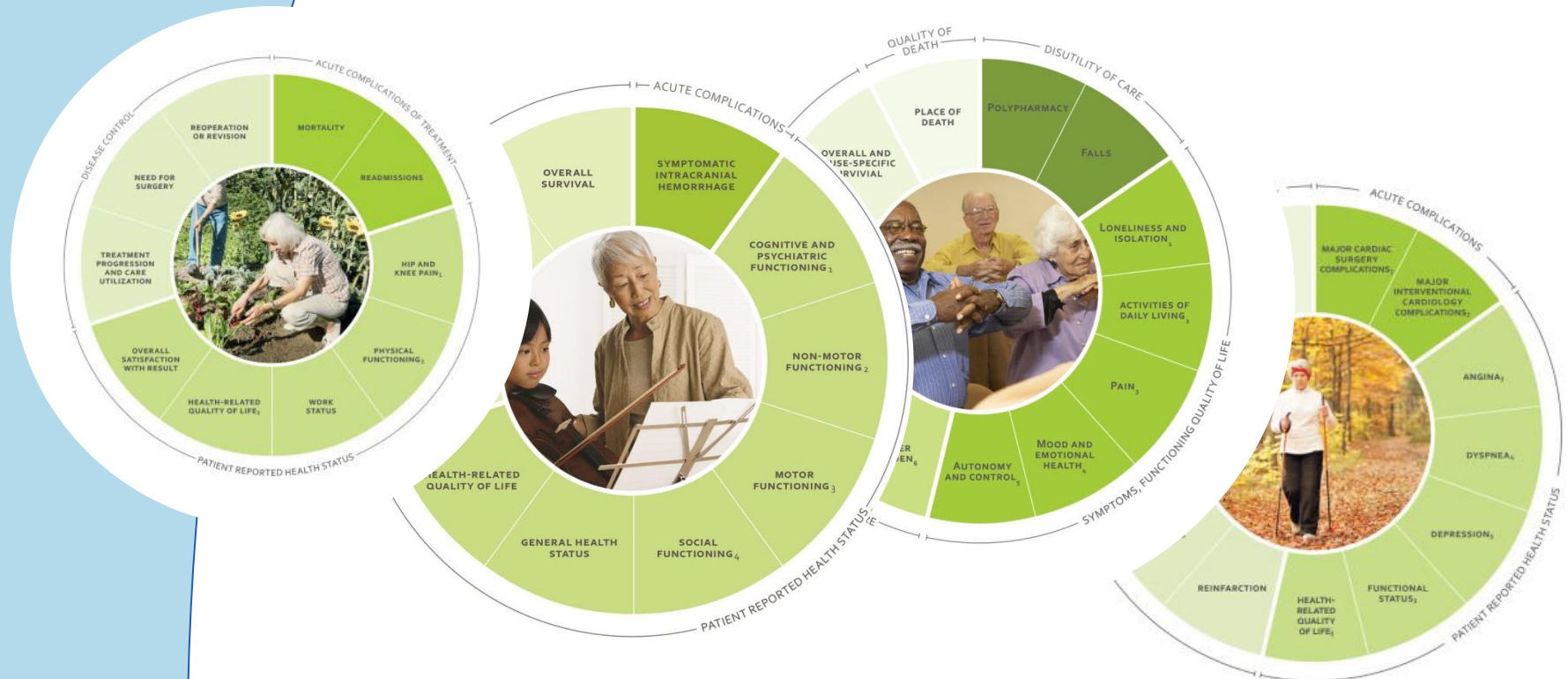




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Consider ICHOM sets

The International Consortium for Health Outcomes Measurement (ICHOM) develops Standard Sets for clinical practice → content overlaps with COS



4. Selection of OMI for COS

*“We recommend, in principle, to **select only one outcome measurement instrument** for each outcome in a COS. This will enhance the comparability of future clinical trials.”*

*“If the outcome of interest is a **complex outcome** (e.g., pain) that consists of multiple aspects that are being measured by different outcome measurement instruments (e.g., pain intensity, pain interference), we recommend that these different aspects be considered as different outcomes.”*

Summary

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1. Conceptual considerations
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Consider new, preferably IRT-based instruments



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Questions?



c.prinsen@vumc.nl