

# How to select outcome measurement instruments for outcomes included in a COS – a practical guideline

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# Background

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

**COMET: Core Outcome Measures in Effectiveness Trials**

**Mutual aim:**

To **improve** the selection of outcome measurement instruments (for outcomes included in a core outcome set)





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## Aim

To develop a guideline for the selection of outcome measurement instruments for outcomes included in a core outcome set (COS)

→ Guidance on 'how' to measure



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# Methods

## Literature review:

To identify existing studies that can provide guidance on instrument selection



## Delphi study:

- ▶ A structured, iterative process to achieve consensus among a group of stakeholders
- ▶ To reach consensus on the methods for selecting outcome measurement instruments for outcomes included in a COS



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# Methods

Example of a question on conceptual considerations:

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

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- Highly recommended
- Desirable
- Not relevant
- Not my expertise

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



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# Methods

## Consensus:

- ▶ Agreement on tasks by  $\geq 70\%$  of the panellists  
(i.e. tasks considered as 'highly recommended' or 'desirable')
- ▶ No opposing arguments
- ▶ Disagreement on tasks by  $\leq 15\%$  of the panellists  
(i.e. 'not relevant')
- ▶ Free text boxes

→ Tasks on which consensus was achieved were included in the guideline





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# Results

	N	%
Participants	120/481	24.9
1 <sup>st</sup> Delphi questionnaire (n=78) completed	95/120	79.2
Countries	14	
Background		
Allied health care professional	30	32
Clinimetrician/psychometrician	29	31
Epidemiologist	40	42
Physician	28	30
Statistician	10	11
Other	15	16
Agreed to participate in subsequent rounds	84/95	88.4
2nd Delphi questionnaire (n=20 + 19 new) completed	65/84	77.4
3rd Delphi questionnaire (n=8 new) completed	72/84	85.7



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# 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
  - c) Other sources
3. Quality assessment of instruments
  - a) Measurement properties
  - b) Feasibility
4. Generic recommendations on the selection of instruments for a COS





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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 (98%)
- ▶ Target population (99%)

## **Guideline:**

*“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.”*



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## 2. Finding all instruments

It is recommended that COS developers aim for finding all existing instruments (72%)

- a. Use existing, good quality and up-to-date systematic reviews of outcome measurement instruments (94%)
- b. MEDLINE (99%) and EMBASE (82%) are the minimum databases that should be consulted, and reference lists should be checked (91%)
- c. Other sources are not recommended but considered optional (89%)



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## 3. Quality assessment

It is recommended that COS developers perform a **quality assessment** of the available instruments:

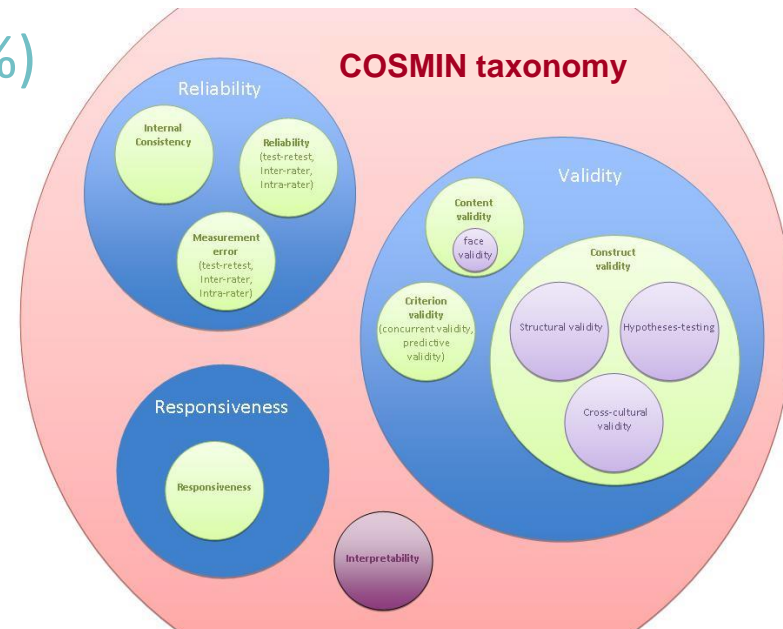
- ▶ Quality of the included studies (e.g. COSMIN checklist)
- ▶ Quality of the instruments (applying quality criteria)

a) All 9 measurement properties (70-93%)

b) Feasibility aspects (77-97%)

For example:

- Length
- Completion time
- Ease of administration
- Costs
- Copy right
- Etc





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## 4. Generic recommendations

### Recommendations on final decision making:

- ▶ select only one ‘best’ instrument for each core outcome (90%)
- ▶ with at least high\* quality evidence for good\*\* content validity and for good\*\* internal consistency (if applicable), which is feasible (81%)
- ▶ to be followed by a consensus procedure among stakeholders, including patients, to agree on the instruments included in the COS (90%)

\*Consistent findings in multiple studies of at least good quality OR in one study of excellent quality AND a total sample size of  $\geq 100$  patients

\*\*A “+” rating according to the criteria for good measurement properties





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## 4. Generic recommendations

*“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.” (90%)*





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## 4. Generic recommendations

*“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).”*

(85%)

## 4. Generic recommendations

*“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.”*

*“If there is no evidence for feasibility, face validity, and content validity in the literature, COS developers may assess these aspects themselves.”*  
(83%)



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## 4. Generic recommendations

*“We recommend that COS developers **involve patients** in assessing the face validity of outcome measurement instruments” (86%)*

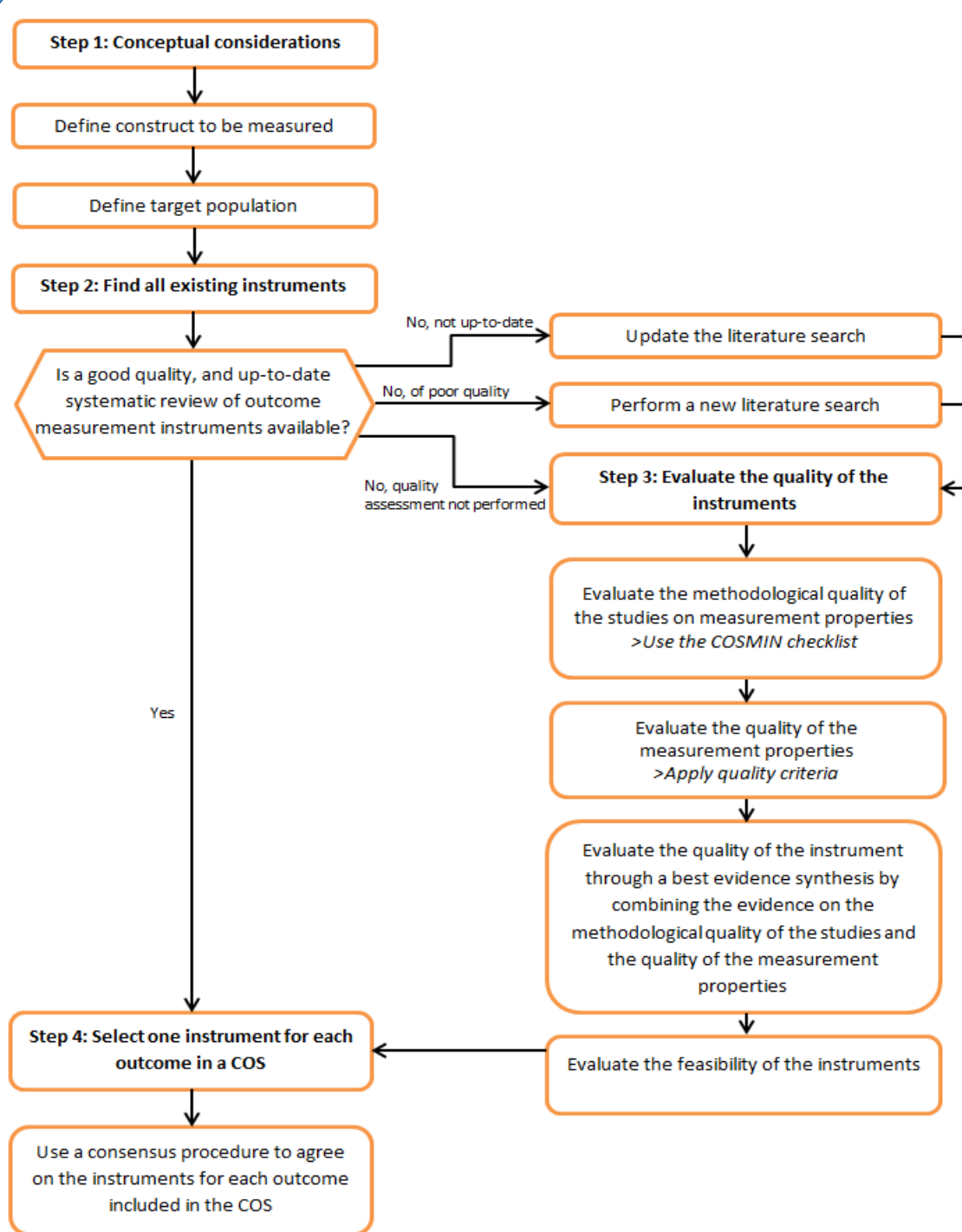
*“In case there are multiple instruments that measure the same construct and are of equal quality, we recommend that COS developers **involve patients** in the selection of outcome measurement instruments” (82%)*





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# Workshop 3

**How to measure?  
Selecting measurement instruments for  
core outcome sets**

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# Questions?

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Trials

RESEARCH

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

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