A systematic review and secondary analysis: Content validity of Quality-of-Life patient-reported outcome measures (PROMs) used in women with SUI.

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Introduction

Stress urinary incontinence (SUI)

Prevalent

£117 million per year (1)

Burden will increase as population ages (2)

PROMs Vital for assessing efficacy of treatment

Aims

Evaluate the content validity of the most implemented PROMs assessing QoL in women diagnosed with SUI.

Methods

Search terms based on previous review combined with an adjusted PROM and construct validity filter

Eligibility: adult women with SUI; full-text articles; English language

Step 1 Evaluate the quality of the PROM development, using COSMIN box 1.

Step 2 Evaluate the quality of content validity studies on the PROM (if available), using COSMIN box 2.

Step 3 Evaluate the content validity of the PROM, based on the quality and results of the available studies and the PROM itself, using the scoring system presented in this manual.

Relevance	
1	Are the included items relevant for the construct of interest?
2	Are the included items relevant for the target population of interest?
3	Are the included items relevant for the context of use of interest?
4	Are the response options appropriate?
5	Is the recall period appropriate?
Comprehensiveness	
6	Are no key concepts missing?
Comprehensibility	
7	Are the PROM instructions understood by the population of interest as intended?
8	Are the PROM items and response options understood by the population of interest as intended?
9	Are the PROM items appropriately worded?
10	Do the response options match the question?

Results

PROM	Concept elicitation study – quality	Concept elicitation study – patient involvement	Cognitive study performed	Cognitive study – quality	Overall quality of PROM development study
UDI	Inadequate	Yes	No	n/a	Inadequate
IIQ	Inadequate	Yes	No	n/a	Inadequate
UDI-6	Inadequate	No	No	n/a	Inadequate
IIQ-7	Inadequate	No	No	n/a	Inadequate
PGI-I	Inadequate	No	No	n/a	Inadequate
ICIQ-SF	Doubtful	Yes	Yes	Doubtful	Doubtful
ICIQ- Bladder Diary	Adequate	Yes	Yes	Adequate	Adequate

PROM	Relevance rating; quality	Comprehensiveness rating; quality	Comprehensibility rating; quality
UDI	+/- ; very low	- ; very low	- ; very low
IIQ	+/- ; very low	- ; very low	- ; very low
UDI-6	? ; very low	- ; very low	- ; very low
IIQ-7	? ; very low	- ; very low	- ; very low
PGI-I	- ; very low	- ; very low	- ; very low
ICIQ-SF	+; low	+; low	+; low
ICIQ-Bladder Diary	+ ; moderate	+ ; moderate	+; moderate

Discussion

- PROMs enable clinicians bridge the gap between clinical efficacy and patient QoL.
- Patient involvement in the concept elicitation stage is vital to achieve high content validity of PROMs (3).
- Development should also be undertaken in a population reflective of the population of interest, to ensure relevance and comprehensiveness.
- Only 43% of PROMs used in this study involved patients in the development process.
- 29% of PROMs conducted cognitive interviews: information regarding content modification was possibly inadequate.
- Patient reported problems with relevance or comprehensibility of the measurement tool missing, meaning vital methodological parameters may have been missed.
- Our findings are in agreement with other literature highlighting poor reporting with regards to content validity (4).
- COSMIN methodology was established in 2016. Prior to this no framework, leading to a lack of standardisation of development.

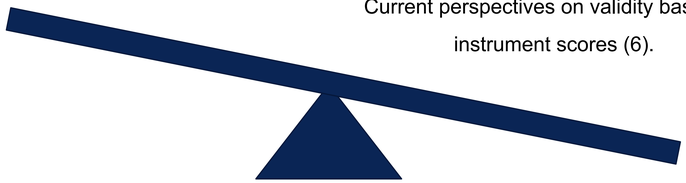
Strengths and Limitations

COSMIN criteria applied

Methods rigorous and reproducible (5)

Assessing measurement properties of PROMs is open to interpretation.

Current perspectives on validity based on instrument scores (6).



Conclusion

This systematic review highlighted poor-quality evidence surrounding content validity for PROMs assessing QoL in women with SUI. This was completed as part of a wider project to develop COS in women with SUI, aiming to reduce the variation of outcome reporting in clinical trials.

References

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