

Saturation Reporting in COA Development and Validation Studies: A Scoping Overview

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Background

- In qualitative research, the adequacy of sample size depends on the research objective and the completeness of the information collected (e.g. diversity, depth of information) (Francis et al., 2010; Hennink et al., 2022). Saturation, defined as the point when no new relevant or important information emerges, is often used to confirm the representativeness of the sample size. In clinical outcome assessment (COA), this is the point at which “collecting additional data will not likely add to the understanding of how patients perceive the concept of interest and the items in the questionnaire” (FDA, 2009).
- Saturation is not a unitary concept: different models are described in the literature (e.g., theoretical, inductive or a priori thematic, and concept saturation), which differ in terms of their focus, such as data collection, analysis, and theorizing (Saunders et al. 2018).
- The analysis and reporting of saturation, is not always consistent with the evidence. For example, a recent review (Carmichael et al., 2023) found that thematic analysis is one of the most common qualitative methods used in COA studies. However, saturation is not recommended when conducting this analysis (Braun & Clarke, 2021).
- To ensure the implementation of rigorous methods, a better understanding of the use of saturation in COA studies is needed. The aim of this overview is to understand the use and reporting of saturation in COA development and inform future research and reporting standards.

Method

- The focus of this preliminary overview was limited to the ISPOR presentation database as the leading scientific and educational organization for health economics and outcomes research.
- Abstracts reporting saturation in COA assessment and development studies were searched.
- No time limits were applied.
- Studies which implemented concept elicitation during qualitative interviews were included.
- Posters (or manuscript when posters were not available) were inspected to extract details regarding data analysis and saturation procedures, including the type of saturation used and reporting of saturation results.

Results

- The search retrieved 54 abstracts. Thirteen COA development/validation studies were identified. Overall, of the ten studies that reported saturation to confirm the adequacy (77%), 80% referred to concept saturation, whereas 20% referred to data saturation.
- Among the identified studies, 54% (n = 7/13) provided details on the qualitative analysis performed, with the majority (6/7; 86%) implemented thematic analysis, and one study implemented grounded theory analysis.
- Of these, four studies (4/7; 57%) referred to conceptual saturation, two to data saturation, (2/7; 29%), and one (1/7; 14%) did not indicate the type of saturation used to confirm the adequacy of the sample size.
- Saturation analysis process was reported in four studies (n = 4/7; 57%) as based on inspection of individual interviews or groups, whereas the remaining (n = 3/7; 43%) only indicated that saturation was reached with no further details. Among the studies that did not describe the data analysis in detail, three reported saturation results (Table 1).

Conclusion

- Against recent recommendation (Braun & Clarke, 2021) the findings confirm that saturation, described as either conceptual or data saturation, is often used in conjunction with thematic analysis. Furthermore, operational details of how saturation was reached are not always reported. The rationale for the type of saturation used and the analysis process associated to it need to be made explicit in each COA report to enhance data robustness and support sample representativeness. Due to the limited scope of this overview, further research is needed to confirm these preliminary findings and inform the development of standardized reporting practice for saturation analysis.

Table 1: Description of analysis and saturation of the studies identified on ISPOR database

Authors (Year)	Title	Data Analysis	Type of saturation	Saturation analysis described
Williams et al. (2020)	Symptoms and Impacts of Nonsense Mutation Duchenne Muscular Dystrophy: A Qualitative Study and the Development of a Patient-Centred Conceptual MODEL	Thematic analysis	Data saturation	Individual interviews
Shields et al. (2023)	Fibrodysplasia Ossificans Progressiva (FOP): The Patient Experience	-	-	-
Brod et al. (2023)	Understanding and Assessing the Patient Experience of Symptoms for Polycystic Liver Disease (PLD): Development of a New Disease-Specific Symptom Patient-Reported Outcome Measure (PROM)	Grounded theory	Concept saturation	Individual interviews
Al-Zubeidi et al. (2023)	Concept Elicitation Interviews to Refine a Conceptual Model of the Patient Experience of Amyotrophic Lateral Sclerosis (ALS)	-	Concept saturation	-
Roberts et al. (2023)	Qualitative Exploration of the Patient Experience of Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP) Via Concept Elicitation Interviews with Patients and Neurologists	Thematic analysis	Concept saturation	-
Belizan et al. (2023)	Validating an Herpes Zoster Health Related Quality of Life Conceptual Model in Argentina: Literature Review and Qualitative Study	-	-	-
Yeh et al. (2022)	Development and Content Evaluation of a Novel Osteoporotic Vertebral Fracture Patient-Reported Outcome Questionnaire	-	Concept saturation	Groups
Altman et al. (2022)	Development of a Conceptual Model of the Patient Experience in Small Cell Lung Cancer (SCLC): A Qualitative Interview Study	Conceptual and Thematic analysis	Conceptual saturation	Groups
Johnston et al. (2022)	Concept Elicitation Interviews to Understand the Patient Experience of Limb Girdle Muscular Dystrophy	Thematic analysis	Concept saturation	-
Chladek et al. (2022)	Development of a Novel Patient-Reported Outcome (PRO) Measure to Assess Hormonal-Based Treatment Symptoms and Their Impacts in Patients with Prostate Cancer	Thematic analysis	-	-
Turner-Bowker et al. (2019)	Development of the side effects of peanut oral immunotherapy diary (sepod)	-	Concept saturation	-
Thaliffdeen et al. (2019)	A conceptual model for adult ulcerative colitis patients	-	Concept saturation	-
Williams et al. (2021)	Symptoms and impact of aromatic L-amino acid decarboxylase deficiency (AADCD): A qualitative study	Thematic analysis	Data saturation	Individual interviews

Reference

- Braun & Clarke (2021). Qualitative research in sport, exercise and health, 13(2), pp.201-216.
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