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Patient-Reported Outcomes

Informing *a priori* Sample Size Estimation in Qualitative Concept Elicitation Interview Studies for Clinical Outcome Assessment Instrument Development

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ABSTRACT

Objective: Evidence-based recommendations for the *a priori* estimation of sample size are needed for qualitative concept elicitation (CE) interview studies in clinical outcome assessment (COA) instrument development. Saturation is described as the point at which no new data is expected to emerge from the conduct of additional qualitative interviews. **Study Design:** A retrospective evaluation of 26 CE interview studies conducted with patients between 2006 and 2013 was completed to assess the point at which saturation of concept was achieved in each study. **Methods:** For each of the 26 interview studies, saturation of symptom concepts was assessed by dividing the sample into quartiles and then comparing the number of responses elicited from the first 25% of participants to the next 25% of participants, from the first 50% of participants to the next 25% of participants, and then from the first 75% of participants to the last 25% of participants. The number of interviews required to achieve

saturation was documented for each study and then summarized across studies. **Results:** Findings indicate that 84% of symptom concepts emerged by the 10th interview, 92% emerged by the 15th interview, 97% emerged by the 20th interview, and 99% by the 25th interview. **Conclusions:** Results provide practical guidance for estimating the number of interviews that may be needed to achieve saturation in a qualitative CE interview study for COA instrument development; address an important gap in qualitative research for the development of COAs in the context of medical product development; and offer useful information for study design and implementation. **Keywords:** clinical outcome assessment, concept elicitation interview, sample size, saturation of concept.

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Introduction

In measurement science, qualitative research is useful for establishing the content validity of clinical outcome assessment (COA) questionnaires [1]. More specifically, best practice guidelines for COA questionnaire development encourage qualitative concept elicitation (CE) research as a means to identify, describe, and substantiate measurement concepts that are important and relevant to the target population and to inform the content of these questionnaires [2,3]. The US Food and Drug Administration's regulatory guidance on the use of COA (specifically, patient-reported outcome [PRO]) data in medical product development also recognizes the importance of qualitative CE data when developing questionnaires that will be used to support product approval and labeling goals [4]. For this reason, clinical researchers in the medical product development industry are increasingly

relying on qualitative research methods broadly and CE studies more specifically [5–7].

An important consideration when conducting qualitative research is the estimation of sample size. Unlike quantitative research studies that use statistical techniques to estimate sample size requirements, qualitative research sample size estimation is based on the number of participants needed to achieve saturation of concept [8]. In the context of COA development, saturation of concept has been defined as the point in the qualitative data collection process when little or no new relevant or important information emerges, and collecting additional data will not add to an understanding of the participant experience of a concept [2,4,9]. The notion of saturation first emerged in the context of grounded theory, where the sampling of patients is purposive and data analysis and collection is iterative based on the information provided by the patient sample [8]. Although

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Table 1 – Example concept elicitation saturation grid.

Concept	Total study sample (N = 20)			
	Group 1 (n = 5 transcripts)	Group 2 (n = 5 transcripts)	Group 3 (n = 5 transcripts)	Group 4 (n = 5 transcripts)
Pain	×			
Weight loss	×			
Fever		×		
Fatigue	×			
Night sweats		×		
Neuropathy	×			
Fractures			×	

The “x” marks represent the first time that a concept was mentioned during the course of interviews.

saturation of concept provides an indicator of whether an adequate sample size has been achieved, it does not offer guidance for the *a priori* estimation of sample size in qualitative interview studies. Minimum sample size recommendations have been published for various types of qualitative research; however, as summarized elsewhere [10–12], most provide little to no empirical evidence in support of these recommendations. In a recent article, Cleary et al. [13] called upon qualitative researchers to “justify their sample size on the grounds of quality data” (p. 473), and noted that information relating to sample size estimation and saturation be reflected in the study documentation.

Some recent research has attempted to estimate qualitative sample size requirements using sophisticated quantitative approaches; however, these methods may not be applicable or practical for estimating minimal sample size requirements for qualitative CE studies. For example, Tran et al. [14] proposed a data-driven methodology for predicting saturation in qualitative research using mathematical models from ecological research; however, this approach was specifically designed for use in surveys with open-ended questions. Van Rijnsoever [15] used data simulations to predict minimum sample size for qualitative research, taking into account purposive sampling methods and different sampling scenarios. However, as noted by the author, applications of results from this study are limited in that the scenarios may not represent real-world sampling procedures.

A few studies offer evidence-based guidelines for the determination of saturation (including tests of adequacy for sample size required to achieve saturation) in interview research involving purposive sampling methods. Guest et al. [11] documented a systematic approach toward achieving saturation during a thematic analysis of data that involved the iterative assessment of new coding required after numerous rounds of interviews, and concluded that a sample size of 12 may be sufficient for interview studies designed to explore common experiences in a relatively homogeneous sample. However, they emphasized the need for future research in that approaches to saturation analysis are highly dependent on the research question, study design, sample (homogeneity/heterogeneity, subgroups of interest), and context of the research. Francis et al. [16] proposed a standardized methodology for the assessment of saturation for theory-based qualitative interview studies, demonstrating the approach using data from two studies, and found that a minimum purposive sample of 13 study participants (10 interviews and 3 additional interviews to demonstrate the emergence of no new themes in the data) were required to evaluate and report data saturation in a reliable manner for this research context. Acknowledging that other types of interview research (e.g., those that focus on the elicitation of ideas “to be pursued further with carefully sampled participants,” or those that focus on contrasts and contradictions within and between participants) may require different sample sizes, Francis et al. highlight the value of a

standardized and transparent approach to the evaluation of data saturation, and describe the importance of accumulating evidence to establish conventions for decision-making regarding sample sizes in different types of interview studies.

The discussion on concept saturation continues in the literature [12,13], and to our knowledge, no research has been conducted that informs the *a priori* estimation of sample size specifically for qualitative CE interview studies used to establish the content validity of COAs. The goal of the current study was to evaluate data from multiple qualitative CE interview studies designed to explore patient experiences of the burden of disease. Results from each of these studies informed the development of COA questionnaires and, in this context, provide information that supports sample size estimation for future similar studies. Specifically, a retrospective evaluation of 26 CE interview studies conducted with patients between 2006 and 2013 was completed to assess the point at which saturation of concept was achieved in each study, with the goal of informing *a priori* decisions for the sample size in qualitative CE COA development research.

Methods

Data Source

Adelphi Values reviewed an internal database of qualitative research studies conducted between 2006 and 2013 to find CE patient interview studies conducted for the purpose of identifying and documenting the important and relevant concepts that depict the patient symptom experience of their disease or condition. Studies were considered for inclusion in this evaluation if they involved individual, one-on-one interviews with participants who were found to have an acute or chronic health condition, and if those interviews elicited symptom concepts related to the participant's experience of his or her health condition. Interview studies conducted for a purpose other than for COA instrument development, did not involve one-on-one interviews with participants, or did not elicit disease symptom-focused concepts were excluded from this evaluation. Twenty-six studies were identified for the evaluation.

Materials and Procedure

Materials included saturation tables from each of the 26 interview studies and group-level summary descriptive information for each study's sample. A saturation table organized by concept code was developed to systematically document concepts emerging from successive interviews in each of the 26 interview studies. The saturation table, commonly used for analyses in this type of research, tracks the appearance of new concepts

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