



Methodologies for assessing and demonstrating data saturation in Qualitative inquiry supporting patient-reported outcomes research

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Objective

- To provide an evidence-based foundation for the evaluation of data saturation by operationalizing the concept of data saturation with a specific focus on qualitative inquiry for the purpose of PRO research.

Introduction

- Qualitative research provides the foundation for PRO questionnaire item and response option development, development and validation of the PRO conceptual framework and evaluation of existing PROs for their suitability in a new target population etc.
- Inadequate sample sizes can undermine the credibility of research findings but power analyses can never be used to determine sample sizes in qualitative research.
- Glaser and Strauss (1967) first defined data saturation as the point at which "no additional data are being found whereby the [researcher] can develop properties of the category."
- In recent years, data saturation has become the gold standard by which purposive sample sizes are determined in qualitative health science research (Guest et al, 2006).
- In the literature there currently exists no description of how saturation might be determined and there are no practical guidelines for estimating sample sizes for purposively sampled interviews for PRO research to a sufficient standard for regulatory review.

Process for evaluating data saturation

There is a three-step process that should be employed in order to evaluate data saturation to a standard sufficient for regulatory review:

Step 1: Development of a Codebook.

- Involve at least two experienced qualitative researchers
- Form one component of a more extensive qualitative analysis plan.
- Each code definition has five parts:
 - Brief definition to jog the analyst's memory;
 - Full definition that more fully explains the code;
 - 'When to use' section that gives specific instances, usually based on the data, in which the code should be applied;
 - 'When not to use' section that gives instances in which the code might be considered but should not be applied;
 - Example selection of quotes pulled from the data that are good examples of the code.

Figure 1: Sample Codebook: Impact of Nocturia on Patients Health-Related Quality of Life

Code	Brief Definition	Full Definition	When to Use	When not to Use	Example
Disrupted sleep	Most troublesome impact: disrupted sleep	Disrupted sleep because of nocturia is felt to be the most troublesome to the participant.	When the participant explicitly states that disrupted sleep is the most troublesome impact of nocturia.	If the participant discusses the impact of disrupted sleep e.g. daytime tiredness, daytime irritability etc.	"Well the sleep disruption is the main thing but the causes are so varied, like what they're saying, like what she said, when you get up I feel so comfortable, dreaming or not, when you wake up and you're just like oh, you just feel great and then you got to get up and go pee, now your body's all stimulated basically because you walked and you can't get back to sleep and you think, well now I'm hungry. It's disruptive, it's just really disruptive."
Drinking habits	Impact of daily drinking habits	Participant makes a conscious decision to alter the volume, type or time of drinking fluids in order to influence their nocturia experience.	When the participant discusses changed drinking habits that can include soft drinks, hot drinks and alcoholic drinks.	If the change in drinking habits is not a conscious decision of the participant, but a physical consequence of having nocturia.	"I try to limit the amount of fluid that I drink, like after a certain time in the night."
Others' sleep	Impact on others' sleep	Impact on relationships with others is specified as having an effect on the sleep patterns of others in the household.	When the participant describes their nocturia experience as affecting the quality, quantity or pattern of others' sleep.	If the sleep patterns of others are affected by issues other than the participant's nocturia e.g. those in the household may have their own urinary issues such as OAB, nocturia, BPH.	"Yes, it affects like family reunions or when I go visit my family, my sisters in Georgia and we're all, you know, then I'm getting up, so you know, we always when we get together, we always stay up late watching movies and talking; fall asleep 1:00 and then 2 or 3:00 I'm up, I might wake up the baby, or wake up one of my grand nieces, so it affects your relationship with other people, with me, because I'm single."

Step 2: Document Progression of Theme Identification.

- The codebook is a working document that is updated through the process of the analysis, and a careful record is kept of all updates and changes by the researchers involved in the analyses.
- Codebook structure is monitored for:
 - Any newly created codes;
 - Changes to existing code definitions after each interview or set of interviews were analysed in order to evaluate for data saturation.

Step 3: Evaluation of Data Saturation.

- Data saturation is determined as the point in data collection and analysis when new information produces little or no change to the codebook.
- Thematic prevalence is determined as the relative importance of codes, with code importance defined as the proportion of individual interviews/focus groups to which a code is applied.
- There are also quantitative approaches to determine data saturation e.g. Cronbach's alpha.

Methods

- Data from five recent PRO studies have been drawn on to demonstrate the operationalisation of data saturation in PRO research.
- Data were collected through the process of a qualitative individual and focus group interviews, conducted by experienced qualitative researchers based on a semi-structured interview guide specifically designed for each study, all individual/focus group interviews were recorded and transcribed in the original language, and later translated to English in the case of the international study. Thematic analysis was performed on the transcripts.
- Each of these studies were systematically documented to evaluate the degree of data saturation and variability of the course of the analysis.

Results

Table 1: Evidence of Data Saturation in PRO Research

Type of Study	Development of Conceptual Model for PRO Evaluation	PRO Development	PRO Development	PRO Measure Content Validity Evaluation	Health State Development
Disease Area	Respiratory	Rheumatology	Urology	Urology	Oncology
Qualitative Approach	Thematic Analysis	Thematic Analysis	Thematic Analysis	Thematic Analysis	Thematic Analysis
Study Location	USA (English)	USA (English)	International: 6 countries	USA (English)	USA (English)
Number of Focus Groups/Interviews	8 focus groups	33 individual interviews	14 focus groups	2 focus groups	12 individual interviews
Focus Group/ Interview Number	% Cumulative Thematic Codes Generated				
1	78	19	63	92	56
2	87	31	74	100	72
3	90	39	80	-	84
4	95	47	86	-	85
5	97	61	91	-	87
6	97	68	92	-	91
7	100	73	92	-	97
8	100	76	95	-	97
9	-	82	95	-	100
10	-	82	95	-	100
11-15	-	85	100	-	100
16-20	-	95	-	-	-
21-25	-	95	-	-	-
26-30	-	99	-	-	-
31-35	-	100	-	-	-
Total Number of Thematic Codes	59	110	65	59	76

- Analysis of the cumulative percentage of thematic codes generated revealed that 90% of the thematic codes had been generated by the 3rd focus group for the respiratory study, the 5th focus group for one of the urology studies, the 6th interview for the oncology study and by the 20th interview for the rheumatology study.
- Data saturation was not achieved for one of the urology studies.
- Internal consistency analysis through an evaluation of Cronbach's alpha revealed that Cronbach's alpha ≥ 0.70 was demonstrated for all studies within the first 1-10 interviews/focus groups for all studies except one of the urology studies that comprised just two focus groups.

Table 2: Overall Relative Importance of Codes: Qualitative Oncology Study

Interview Proportion	% of Codes Applied (n=76 codes)	Examples
$\geq 90\%$ interviews	15.79	• Side effect appearance – duration • Side effect precaution – coping strategies – awareness
70-89% interviews	2.63	• Side effect sensation – nausea
50-69% interviews	17.11	• Side effect impact – anxiety • Side effect sensation – chest pain
30-49% interviews	25.00	• Side effect psychosocial impact – none • Disease physical impact – urinary frequency
10-29% interviews	17.11	• Disease physical impact – urinary incontinence • Concerns prior to treatment – dying
<10% interviews	22.37	• Disease psychosocial impact – masculinity • Side effect psychosocial impact – frustrated

- 15.9% of the thematic codes from further analysis of the oncology study data were applied to $\geq 90\%$ of the 12 individual interviews that were conducted.
- Examples of these highly important codes were information on the duration of the treatment side effect under discussion and the use of awareness as an approach for coping with the side effect under discussion.

Conclusions

- Data saturation is an essential component of assessing qualitative data.
- Failure to achieve data saturation severely impedes the quality of the research, affecting the content validity of the PRO measure resulting in poor PRO measurement tools.
- This analysis demonstrated that because PRO qualitative research is generally focused on a homogenous patient population data saturation is regularly achieved within 10 individual interviews, with some evidence that this can be achieved with fewer focus groups.