

# To Infinity and Beyond: How Do We Know When We're Done?

## PROs and CONs of Sample Size Estimation Methods in Qualitative Research

Katy Benjamin, Director, Clinical Outcomes Assessment

May 23, 2018



### The Question: How can we estimate sample size in qualitative research to ensure confidence in results?

---

- Trade off between data quantity and data quality
- Quantitative studies
  - Large sample to understand characteristics of high-level phenomena (examples: survival, change in clinical biomarker, improvement in functional status)
  - Hypothesis-driven based upon probability of detecting known parameters ("effect size")
  - Not designed to detect new or different concepts but to test existing theories about concepts
- Qualitative studies
  - Smaller sample to understand in-depth information about how people's perceptions and experiences shape their thoughts and actions around specific phenomena
  - Not hypothesis-driven
  - Designed to discover new concepts, or the universe of specific concepts in order to generate new theories

....BUT!

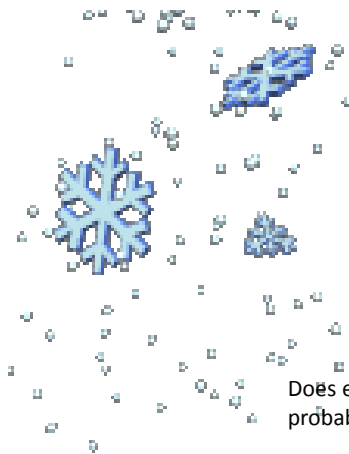
---

*“You note that there was no difference in the experience of the key symptoms between groups. But given the limited sample size, how much “power” would you have had to detect a difference?”*

Reviewer, recent submission to a well-known medical journal

AND NO TWO PATIENTS ARE ALIKE

---



SO HOW DO WE KNOW  
WHEN WE'RE DONE?

Does each new subject = an independent  
probability?

## METHODS OF SAMPLING IN QUALITATIVE RESEARCH

- Purposive
  - Selective sampling based upon specific factors
    - Time/resource constraints
    - Expected complexity of questions to be addressed
    - Ability to manage data quantity
    - Specific population characteristics
    - Sample eligibility criteria remain fixed
- Theoretical
  - Based in Grounded Theory (Glaser and Strauss 1967)
  - Sample continuously until saturation is reached on all identified themes; sample eligibility criteria may change
  - Probability sampling “inappropriate” given structure of data collection
  - Cannot estimate sample size in advance

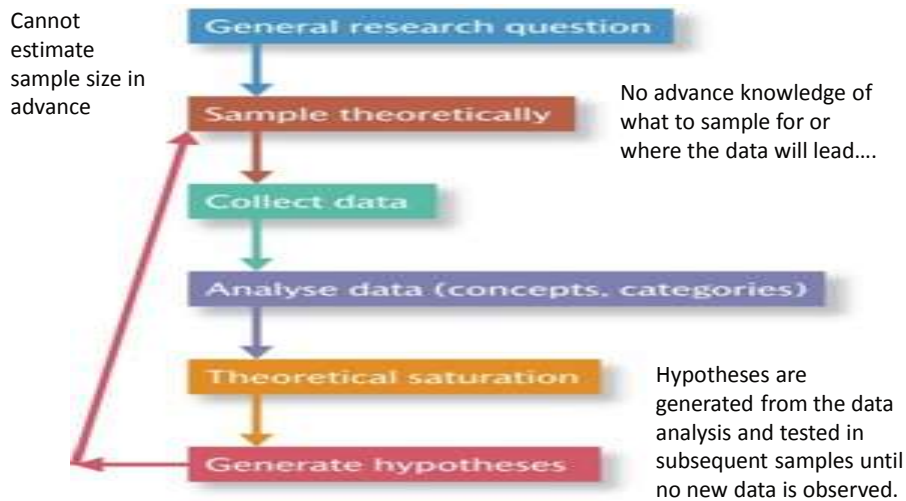
### Many methods, no numbers

Table 1 Various examples of qualitative sampling

Strauss & Corbin (1990)	Theoretical sampling — three stages <ul style="list-style-type: none"> <li>• open sampling</li> <li>• relational and variational sampling</li> <li>• discriminate sampling</li> </ul>
Patton (1990)	All sampling is purposeful — 15 strategies <ul style="list-style-type: none"> <li>• extreme or deviant case sampling</li> <li>• intensity sampling</li> <li>• maximum variation sampling</li> <li>• homogeneous samples</li> <li>• typical case sampling</li> <li>• stratified purposeful sampling</li> <li>• critical case sampling</li> <li>• snowball or chain sampling</li> <li>• criterion sampling</li> <li>• theory-based or operational construct sampling</li> <li>• confirming and disconfirming cases</li> <li>• opportunistic sampling</li> <li>• purposeful random sampling;</li> <li>• sampling politically important cases</li> <li>• convenience sampling</li> </ul>
Morse (1991)	Four types: <ul style="list-style-type: none"> <li>• purposeful sample</li> <li>• nominated sample</li> <li>• volunteer sample</li> <li>• total population sample</li> </ul>
Sandelowski <i>et al.</i> (1992)	selective sampling
Sandelowski (1995)	theoretical sampling
	All sampling is purposeful — three kinds <ul style="list-style-type: none"> <li>• maximum variation</li> <li>• phenomenal variation</li> <li>• theoretical variation</li> </ul>

Coyne LT. (1997) Sampling in Qualitative Research: Purposive and Theoretical Sampling: Merging or Clear Boundaries? J Adv Nursing; 26:623-30

## The Process of Grounded Theory Research



Bryman, A. Social Research Methods, 2011.

abbvie

Patient-Centered Outcomes | Date 02.19.18 | Company Confidential © 2018

## GUIDANCE FOR SAMPLE SIZE IN QUALITATIVE RESEARCH

### Little guidance based upon clear and specific justifications

- COSMIN: "Consensus was not reached on sample size requirements. It was argued that saturation is more important than sample size."  
-- Terwee et al. (2018) COSMIN methodology for evaluating the content validity of patient-reported outcomes measures: a Delphi study. *Quality of Life Research*
- EMPRO: No specific quality measure based on sample size or determination  
-- Valderas et al. (2008) Development of EMPRO: A tool for the standardized assessment of Patient-Reported Outcomes Measures. *Value in Health*
- FDA Draft Guidance on PFDD: "For qualitative studies, sample size determination is often less formal and based on the concept of saturation, which roughly means little new information (i.e., new concepts of importance and relevance to subjects and research question) is gained by recruiting additional patients..."  
-- FDA (2017) Collecting Comprehensive and representative input. Workshop on PFDD Guidance 1.

abbvie

Patient-Centered Outcomes | Date 02.19.18 | Company Confidential © 2018

## QUANTITATIVE APPROACHES

---

A lot of assumptions! Can we always make these?

- Fofana: “Number of concepts elicited = number of concepts relevant to the research question.”
  - Do we always know *a priori* how many concepts are relevant to the research question?
- Rijnsoever: Estimates sample size based upon probabilities of observing a minimal or maximum number of codes.
  - Requires making these estimates of potential number of codes *a priori* based upon knowledge of the information sources
  - Allows for additional sampling where there are “new developments,” or “an information source does not yield any new codes”

## QUANTITATIVE APPROACHES

---

- Fugard and Potts: Yay! A sample size table! However....
  - Assumes a priori knowledge of the prevalence of “themes” in population of interest.
  - No clear guidance on how researchers should estimate value of “least prevalent theme” or how large the size of the “most prevalent theme” should be for specific study purposes (e.g., COA measure development)

## Can we answer all these questions *a priori*?

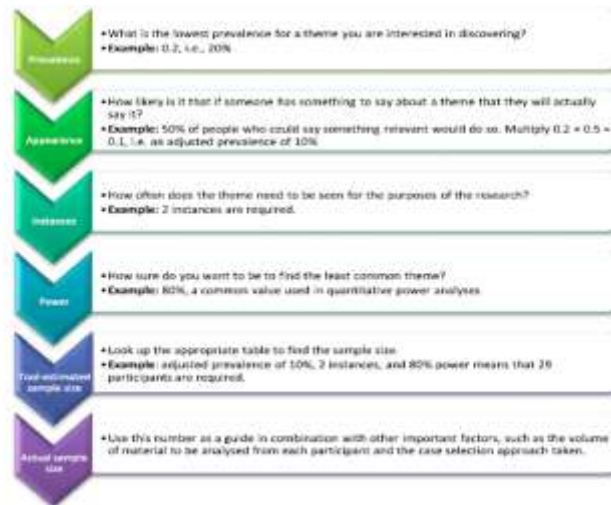


Figure 3. Summary of approach taken.

Fugard AJB and Potts HWW. Supporting thinking on sample sizes for thematic analyses: a quantitative tool. *Int J Soc Res Methodol* 2015; 18(6):669-684.

## THE BOTTOM LINE

- There may be a practical difference between researchers conducting qualitative research for applied purposes (e.g., to elicit concepts for development of a COA instrument) and those conducting research for purposes of adding to the knowledge base of a specific population
- Much of the literature on sample size estimation does not focus on applied research situations
- Most applied research uses a purposive sampling strategy designed to elicit information from the population of interest; this is not true Grounded Theory methodology
- Mixed methods qualitative studies may provide additional evidence of concept relevance and completeness in a more representative sample of the population
- Researchers should strive to obtain at least a sample that is representative of the population characteristics important to answer the research questions
- More thought needs to be given to other types of qualitative research, e.g., cognitive interviews, PPI, patient experience studies, exit interviews

THANK YOU!

---

To infinity  
and  
beyond



BACK UP SLIDES

---

## Grounded Theory sampling

---

- Theory comes directly from the data
- “Ongoing process” of data collection determined by the emerging theory and therefore cannot be predetermined.
- Glaser and Strauss (1973):

“The general procedure of theoretical sampling is to elicit codes from the raw data from the start of data collection through constant comparative analysis as the data pour in. Then one uses the codes to direct further data collection, from which the codes are further developed theoretically with properties and theoretically coded connections with other categories until each category is saturated. Theoretical sampling on any category ceases when it is saturated, elaborated, and integrated into the emerging theory.” Deciding where to sample next is theoretical sampling. (Glaser, 1992)

- Probability sampling “inappropriate”
- Sample size cannot be estimated in advance