Published in final edited form as:

J Pediatr Gastroenterol Nutr. 2013 September ; 57(3): 267–268. doi:10.1097/MPG.0b013e3182a025d8.

How Qualitative Studies Can Improve The Quality of Clinical Studies

Chris Feudtner^{1,2,§}

¹The Children's Hospital of Philadelphia; Philadelphia, USA

²Department of Pediatrics, The Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA

Can qualitative studies improve the quality of clinical studies? Let me answer in the affirmative and outline below five ways in which this is possible, drawing on several excellent textbooks regarding how to perform qualitative research^{1–6}, and on the study that appears in the March 2013 issue of the *Journal* from Lipstein and colleagues regarding parents' perceptions of tumor necrosis factor- inhibitor treatment for their children with either Crohn's disease or juvenile idiopathic arthritis.⁷

1. Debugging

Qualitative studies can be done in series or in parallel with quantitative studies. This can occur during the pilot-testing phase of a quantitative study or in the final version of a clinical trial. In either case, the qualitative study can provide insights as to why a quantitative study, such as the evaluation of a medication or treatment regimen, is working or – importantly – not working. Issues that might otherwise go undetected that are undermining the efficacy of an intervention within the framework of a clinical trial can, by this technique, be detected. For instance, if in interviews with subjects enrolled in a clinical trial it becomes apparent that they have fears or anxieties about compliance with the treatment regimen, one might suspect that non-adherence could occur and diminish the potential magnitude of a clinical treatment effect. Similarly, participant observation of a complex intervention in a hospital might reveal that the intervention fidelity has been undermined by competing tasks that the hospital staff has to perform. These insights can help investigators to “debug” an intervention so that in subsequent trials it is more likely to demonstrate its effectiveness. Could the level of stress and anxiety of parents in the Crohn's disease group affect they way that they might agree to or adhere to a course of treatment? Could the way that the clinical team provides information and counsel to parents about treatments inadvertently be augmenting as opposed to diminishing these concerns?

2. Hypothesis Screening

The claim is often made that qualitative studies are “hypothesis generating.” In truth, only investigators who are thinking hard about a topic, ideally with lots of pertinent information at their disposal, can generate hypotheses. A qualitative study, done well, can be part of this vitally important set of pertinent information. As suggested above regarding “debugging”, qualitative studies can give insights as to why interventions may work or may not be

[§]Corresponding author Chris Feudtner, MD, PhD, MPH, CHOP North – Room 1523, The Children's Hospital of Philadelphia, 34th and Civic Center Blvd, Philadelphia, PA 10194, Phone: 267-426-5032, Fax: 267-426-0380, feudtner@email.chop.edu.

Financial Disclosures: The author declares that he has no significant financial relationships to disclose.

Author's contributions: Dr Feudtner conceived of and wrote this manuscript.

working, and these insights can be converted into testable hypotheses for future quantitative evaluation. In fact, investigators who are tackling complex problems often have the difficulty not of needing to generate a hypothesis, but of needing to screen many possible hypotheses and settle on one or at most a few to test. If the clinical problem under study involves human interaction and behavior, either directly or indirectly (in so far as how people behave may affect the way that they adhere to treatment recommendations or otherwise affect outcomes), then preliminary qualitative studies that preceded the design of a quantitative trial can identify a few key issues that then can be converted to hypotheses to be tested. Returning to our example study, both of the questions posed above – about parental stress level and how teams may or may not be affecting these levels – seem to be warranted, and may be worthy of more focused investigation.

3. Concept Building

Underneath any given hypothesis is a theory that both gives rise to the hypothesis and is ultimately being evaluated by testing the hypothesis. These theories may be well-established, and investigators can essentially take them “off-the-shelf” and use them to guide their clinical investigations. But for many important and interesting clinical problems, theories about why the problem arises, or about how a given intervention would prevent, ameliorate, or cure a problem, are either nonexistent or underdeveloped. In these instances, again if the clinical problem has any element of human perspectives, values, or behaviors, qualitative studies can help either to build concepts from scratch, or fill in important details. For example, if we conceive of parents’ decisions to embark on a new level of therapy for their children with a chronic conditions as following the “stages of change” model (also known as the transtheoretical model, which postulates that individual behavior change unfolds in 5 stages of precontemplation, contemplation, preparation, action, and maintenance⁸), how do the findings of Lipstein clarify or refine the model for this group of parents?

4. Disruptive

Qualitative studies also offer the prospect of novel insights and subsequent innovation (that prized but elusive quality of the best research). Indeed, qualitative studies may be judged in part on whether they spark new ideas: if at the end of a qualitative study, one is still thinking precisely the same thoughts that one had when starting, then the study may well have failed. This failure can happen, sadly, by the attempt in certain qualitative methodologies to reach consensus prematurely amongst the investigators regarding how to interpret elements of the qualitative data. Specifically, teams of investigators that review interview transcripts or other qualitative “raw data” and seek to come up with a common codebook without engaging in vigorous debate first, are likely to use “common sense” notions that when assembled into broader ideas of “themes” may be simply reiterations of the “common sense” view of what is going on. The end result of this process is simply analysis from the perspective of the most common but lowest denominator. Qualitative research needs to fight the temptation to view easy consensus as indicative of analytic rigor. Instead, investigative teams doing qualitative research need to foster openness to new ways of viewing what is going on, if they ever hope to see things afresh, to notice what others have not, and provide insights that are worth having. Admittedly, this is potentially risky business: one doesn’t want qualitative studies that are speculating wildly and coming up with novel descriptions just for the sake of novelty. But with a focused and disciplined attempt to analyze qualitative data in a manner liberated from preconceived notions, combined with investigators’ intelligence and integrity, the results can be eye-opening and path-blazing. In this regard, the finding that more information did not alter decisionmaking, and instead only confirmed choices for some while augmenting anxiety for others could challenge the overly simple

equation that, in matters of informed consent, more information is uniformly better, and instead provoke us to think of other ways to help improve the decisionmaking process in an ethically appropriate manner that facilitates the best outcomes for patients and their parents.

5. Learning

To summarize all of the above: qualitative studies can help us to learn. The learning curve that qualitative studies put us on is quite different – I am tempted to joke both qualitatively and quantitatively, but the point is apt – from the learning curve of quantitative, hypothesis-driven investigations. The successful design and conduct of a qualitative study requires an openness to learning about people, as individuals and as collections of individuals that exhibit group behavior, in a way that is quite different from the equipoise that a clinical investigator may want to foster about the potential effectiveness of an intervention. Qualitative studies also take a deceptively long amount of time and effort to complete (not that quantitative studies are by any means short and simple, but rather to emphasize that qualitative studies are far harder to execute and people often think).

Qualitative research may never be everyone's cup of tea, but in an era of medical research that wants to see more innovation and efficiency, this mode of inquiry clearly complements other quantitative approaches, adding value to the clinical research itself and ultimately to its application in everyday life to the betterment of patients.

Acknowledgments

Funding/Support: This work was supported in part by R01-NR-01206-03 from the National Institute of Nursing Research.

Role of the Sponsor: The funding organization had no role in the design of the study beyond the critique offered by the peer-review process; and had no role in the conduct of the study, including the collection, analysis, and preparation of the data or the drafting, editing, review, or approval of the manuscript. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH National Institute of Nursing Research.

References

1. Morse, JM.; Field, PA. Qualitative Research Methods for Health Professionals. 2. Newbury Park: SAGE Publications, Inc; 1995.
2. Patton, MQ. Practical Evaluation. Newbury Park: SAGE Publications, Inc; 1982.
3. Patton, MQ. How to Use Qualitative Methods in Evaluation. Newbury Park: SAGE Publications; 1987.
4. Pope, C.; Mays, N. Qualitative Research in Health Care. 2. London: BMJ Publishing Group; 1996.
5. Rosenbaum, PR. Observational Studies: Chapter 11: Planning an Observational Study. 2. New York: Springer-Verlag New York, Inc; 1995.
6. Strauss, A.; Corbin, J. Basics of Qualitative Research. 2. Thousand Oaks: SAGE Publications, Inc; 1998.
7. Lipstein EA, Lovell DJ, Denson LA, et al. Parents' information needs in tumor necrosis factor-alpha inhibitor treatment decisions. *J Pediatr Gastroenterol Nutr.* Mar; 2013 56(3):244–250. [PubMed: 23059648]
8. Prochaska, JO.; Redding, CA.; Evers, KE. The Transtheoretical Model and Stages of Change. In: Glanz, K.; Rimer, BK.; Viswanath, K., editors. Health Behavior and Health Education. 4. San Francisco: Jossey-Bass; 2008.