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Users' Guides to the Medical Literature: XXIII. Qualitative Research in Health Care A. Are the Results of the Study Valid? [The Medical Literature]

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Abstract

Quantitative research is designed to test well-specified hypotheses, determine whether an intervention did more harm than good, and find out how much a risk factor predisposes persons to disease. Equally important, qualitative research offers insight into emotional and experiential phenomena in health care to determine what, how, and why. There are 4 essential aspects of qualitative analysis. First, the participant selection must be well reasoned and their inclusion must be relevant to the research question. Second, the data collection methods must be appropriate for the research objectives and setting. Third, the data collection process, which includes field observation, interviews, and document analysis, must be comprehensive enough to support rich and robust descriptions of the observed events. Fourth, the data must be appropriately analyzed and the findings adequately corroborated by using multiple sources of information, more than 1 investigator to collect and analyze the raw data, member checking to establish whether the participants' viewpoints were adequately interpreted, or by comparison with existing social science

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theories. Qualitative studies offer an alternative when insight into the research is not well established or when conventional theories seem inadequate.

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CLINICAL SCENARIO

At a Monday morning meeting of your hospital's continuous quality improvement committee, the last agenda item is an initiative to enhance patient-clinician communication. The chair proposes that all medical charts include a form to record patient wishes about cardiopulmonary resuscitation and end-of-life care. The committee members agree in principle on the goals of enhanced communication and more accurate documentation of patient preferences. However, you raise potential concerns about how these forms might change the nature of end-of-life decision making and even impair communication. As the meeting draws to a close, you pose a fundamental question to the group for discussion the following week: Could life support preference forms unduly routinize and constrain dialogue between clinicians and patients or family members?

THE SEARCH

Emerging from the meeting, you resolve to learn more about the influence of institutional record keeping on "do not resuscitate" communication during acute illness. Back in your office, you do a quick search of MEDLINE using key words *resuscitation orders* (508 hits) and *patient-physician relations* (5040 hits), and *patient participation* (1680 hits). Of 11 citations, 1 publication is a cultural analysis that you pick up en route to clinic. **1** The objectives of this study were to examine the influence of a Limitations of Medical Care form on discussions about cardiopulmonary resuscitation and the meaning that underlies this communication.



INTRODUCTION

Clinicians are trained to think mechanistically and to draw conclusions using pathophysiologic rationale and deductive reasoning. The biomedical literature reflects this orientation, and clinicians are therefore most familiar with deductive quantitative research. Quantitative studies (such as epidemiologic investigations and clinical trials) aim to test well-specified hypotheses concerning some predetermined variables. These studies suitably answer questions such as whether (eg, whether an intervention did more good than harm), or how much (eg, how strongly a risk factor predisposes patients to a disease). However, medicine is not only a mechanistic and quantitative science but also an interpretive art. **2**

Interpretive research asks questions about social interactions that can be addressed systematically through qualitative methods. **3** Qualitative research offers insight into social, emotional, and experiential phenomena in health care. Examples include inquiry about the meaning of illness to patients, their loved ones, and their families or about the attitudes and behavior of patients and clinicians. Qualitative research questions tend not to ask whether or how much but

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rather to explore what, how, and why. Qualitative studies may pursue a variety of theory-generating aims, including to explore and describe social phenomena faithfully (including surveying diverse perspectives or by giving voice to those not usually heard [4](#)), to identify potentially important variables or concepts, to recognize patterns and relationships, and to generate coherent theories and hypotheses. Qualitative reports do not typically generate answers but rather generate narrative accounts, explanations, typologies of phenomena, conceptual frameworks, and the like. For example, Ventres et al [1](#) explore what patient-physician communication occurred during discussions about resuscitation and how the use of a standard form influences communication between physicians and families about do-not-resuscitate orders. Another qualitative study probes why family members select certain processes for discontinuing life support. [5](#)

Just as clinicians use complementary types of information to draw clinical conclusions, complementary research methods are often useful in examining different aspects of a health problem. [6-9](#) Qualitative studies offer a rigorous alternative to armchair hypothesizing in areas for which insight may not be well established or for which conventional theories seem inadequate. Qualitative and quantitative studies each make useful contributions to knowledge in themselves. They may also be used in tandem—qualitative investigation to generate theories and identify relevant variables and quantitative investigation to test the implied hypotheses about relationships between those variables. Alternatively, qualitative and quantitative approaches can unfold concurrently within a research program, informing each other during the analysis and interpretation phases, yielding findings that are broader in scope and richer in meaning than if only 1 approach were used. Details about how to conduct qualitative research, [10-13](#) as well as the attributes and limitations of qualitative vs quantitative research approaches have been published elsewhere. [14-20](#)

THE GUIDES

In this 2-part Users' Guide, we suggest guides for understanding and critically appraising qualitative research articles using the previously established Users' Guides framework: (1) Are the results of this study *valid* (or *credible*)? (2) What are the results? and (3) How can they help me care for my patients? In the first article of this pair, we focus on assessing the *validity* of qualitative research reports.

Are the Results of the Study Valid?

Clinical readers traditionally think of research validity as the truthful correspondence of results with an objective reality. Qualitative research offers empirically based insights about social or personal experiences, which necessarily have a strongly subjective—but no less real—nature than biomedical phenomena. To avoid confusion, qualitative researchers typically avoid the term *valid* in favor of alternatives such as *credible*. [9, 12](#)(pp289-331) Even so, qualitative insights must emerge from systematic observations and competent interpretation, correspond well to the social reality experienced by the participants and also have meaning for those who will read and learn from the report. Clinical readers in particular need to judge the relevance of qualitative research reports to their own practice, interests, or patient care questions.

To judge the methodologic rigor of qualitative research reports, readers need to appraise critically the study design and analysis. This appraisal should examine whether the study was designed to address its research question and objectives appropriately and whether it was

conducted rigorously enough to achieve its empirical aims. Ventres et al [1](#)(p134) clearly describe their objective: "to examine the use of the Limitations of Medical Care form in the context of actual hospital practice,... to evaluate interactive elements of the resuscitation decision,... [and] to explore what is said when discussing code status, how information is communicated among parties involved, and the meaning that underlies this communication." Consistent with typical aims of qualitative inquiry, the study focuses on social interactions and their meaning. The objectives describe the social phenomena to be explored and described, rather than specific hypotheses to be tested.

The Methods section of a qualitative study should describe several aspects of the research design, including (1) how study participants were selected, (2) the methods used to generate data, (3) the comprehensiveness of data collection, and, (4) procedures for analyzing the data and corroborating the findings. As with any research, qualitative research involving human subjects must undergo ethics review and approval and this approval should be noted in the report. Special ethical dilemmas in qualitative research [21](#) should be addressed in the ethics and peer review of the study protocol, but usually cannot be appraised from the published report alone. Following are some general guidelines to help readers determine whether qualitative research design and execution is appropriate for the research objectives.

Were Participants Relevant to the Research Question and Was Their Selection Well Reasoned?

Qualitative studies discover and describe important variables, particularly in terms of the social dynamics and the subjective realities of those involved a given situation. [3](#), [12](#)(pp70-91) The units of analysis in a given qualitative study therefore may include myriad social phenomena, such as individuals, groups, documents, artifacts, interactions, dialogues, incidents, or settings.

The exploratory nature of qualitative research typically requires investigators not to prespecify a study population in strict terms, lest an important person, variable, or unit of analysis be overlooked. In some studies (eg, content analyses of documents), the scope of data collection can be prespecified, but if so, the rationale should be sensible to the reader. The consecutive or random selection of participants that is common in quantitative research is replaced by purposive sampling in qualitative research. Sampling aims to cover a range of potentially relevant social phenomena and perspectives from an appropriate array of data sources. Selection criteria often evolve over the course of analysis, and investigators return repeatedly to the data to explore new cases or new angles. Purposive sampling might aim to represent any of the following: typical cases, unusual cases, critical cases, politically important cases, or cases with connections to other cases (ie, *snowball sampling*). [12](#)(pp187-220) [13](#)(pp145-198) Least compelling is the pursuit of merely convenient cases that are most easily accessed. Nevertheless, many qualitative studies do rely on convenience sampling to some extent (eg, for pragmatic reasons, study participants may only be those who speak the same language as the investigators, or only individuals who are willing to be interviewed). Readers of qualitative studies should look for sound reasoning for describing and justifying the participant selection strategies.

In the report by Ventres et al, [1](#) the unit of analysis was not the patient but rather the social interaction among several parties: the patient, family members, nurses, social workers, clergy, and residents involved in resuscitation discussions about a particular patient. From a potential sample of 8 patients, 3 cases were selected for in-depth study. The criteria for selecting these particular 3

cases were not specified, leaving readers unable to judge their appropriateness and how comprehensively they illustrate communication issues involving resuscitation directives in the hospital.

Were the Data Collection Methods Appropriate for the Research Objectives and Setting?

The most common qualitative data collection methods involve field observations, interviews, or document analysis, separately or in combination. The collected data allow the researchers to observe, as clearly as possible, the social interactions or behavior that they seek to describe.

Field Observation

The purpose of field observation is to record social phenomena directly and prospectively. There are 2 basic approaches: direct observation by investigators themselves and indirect observation through audiotape or videotape recording. In direct observation, investigators spend time in the social milieu that they are studying and record observations in the form of detailed field notes or journals. Observational techniques are categorized according to the role of the investigator in the setting (ie, nonparticipant or participant) observation. Field analysis techniques require investigators to consider explicitly how their presence might influence their findings.

In nonparticipant observation, the researcher stays relatively uninvolved in the social interactions he/she observes. The crucial question for critical appraisal is whether a "fly on the wall" observer of a particular social setting will effectively be ignored by study participants or might instead inadvertently influence participants' behavior. For example, a researcher in crowded waiting room may go unnoticed and hence observe the natural unfolding of events. In contrast, in a clinic examining room, he/she may be conspicuous, and significantly change the social interactions he/she is there to observe. Audiotape or videotape recordings are sometimes used as less intrusive methods of capturing data. However, they also have drawbacks. First, recorders can occupy a social role and be experienced by participants as partaking in surveillance, thus influencing participants' behavior. Second, recorders' observational powers are limited by their range of operation: if the action is moving around or if visual cues are missing, important information may be lost.

In participant-observation investigations, the researcher is acknowledged as a part of the social setting, either as a researcher per se or as a more directly involved actor (eg, social worker, ethicist, committee member, etc). Again, the question for critical appraisal is whether the dual observer-participant role allows access to natural candid social interactions among other participants in the setting.

In both participant and nonparticipant field observation, the effect of the researcher on the social setting can never be controlled for (a common goal of experimental study designs). Interactions between researchers and those they study are somewhat paradoxically but necessarily regarded as both a useful source of data and a potential source of bias. [12](#)(pp92-109) More than 1 observational technique (eg, personal observations and audiotape recording dialogue) can sometimes be used to capture more detailed data and to help analyze observer effects.

Interviews

Qualitative studies may use several types of interviews. The most popular are semistructured, in-depth, individual interviews and focus groups. Structured approaches, such as standardized

questionnaires, are usually inappropriate for qualitative research, because they presuppose too much of what respondents might say and do not allow respondents to express themselves in their own terms. These problems limit the opportunity to gain insight into personal and social phenomena and can impose the investigators' preconceived notions onto the data.

The appropriate interview method depends on the topic. Individual interviews tend to be more useful for evoking personal experiences and perspectives, particularly on sensitive topics. Group interviews tend to be more useful for capturing interpersonal dynamics, language, and culture. Focus groups can be appropriate for discussing emotionally sensitive topics if participants feel empowered to speak in the presence of peers; however, the public forum of a focus group can also inhibit candid disclosure. [22-23](#) Critical readers should look for the rationale for choosing a particular approach and its appropriateness for the topics addressed. Using more than 1 interview method may be helpful for capturing a wider range of information.

Document Analysis

Finally, documents such as charts, journals, correspondence, and other material artifacts can provide qualitative data. [24](#) These are especially useful in policy, historical, or organizational studies of health care. There are different approaches to the analysis of documents. One involves counting specific content elements (eg, frequencies of particular words being used) while the other involves interpreting text as one would interpret any other form of communication (eg, seeking nuances of meaning and considering context). The former approach, especially if used alone, rarely provides adequate information for a qualitative, interpretive analysis.

Ventres et al [1](#) used 3 types of data collection: participant observation, audiotapes of discussions, and semistructured interviews. Details of the interview strategy appear in an appendix and provide additional information about the content of the interviews and techniques used to elicit responses. Three types of questions were asked: open-ended, semistructured, and contrast questions, to elicit opinions on contrasting hypothetical patient situations. The use of multiple data collection methods and sources adds rigor to this study, because it allows investigators to examine discussions of the Limitations of Medical Care from several angles and to capture information with one method that may be overlooked for another.

Was the Data Collection Comprehensive Enough to Support Rich and Robust Descriptions of the Observed Events?

Another critical appraisal question is whether the social setting or experience was observed thoroughly enough to support rich and robust descriptions of the observed events. The analytic issue here is not one of sample size in the statistical sense. Rather than aim for a specific number of participants (or other units of analysis), researchers should strive for adequately in-depth observations. A qualitative study involving many participants but only cursory interactions with each 1 may be less rigorous than a study involving few participants but extensive observation of each. Data collection needs to be comprehensive enough in both breadth (types of observations) and depth (extent of observation of each type) to generate and support the interpretations. This criterion has a circular quality, that is, whether data are adequate depends to some extent on the nature of the findings and vice versa. For this reason, qualitative data collection and analysis steps usually iterate: data collection is followed by analysis, which in turn gives direction for new data

collection, and so forth.

Several aspects of a qualitative report indicate how extensively the investigators collected data: the number of observations, interviews, or documents; the duration of the observations; the duration of the study period; the diversity of units of analysis and data collection techniques; the number of investigators involved in collecting and analyzing data; and, the degree of investigators' involvement in data collection and analysis.

Interpretive research is characterized by voluminous data, consisting of paper files (eg, field notes, transcripts, journals, analytic memos, photocopied documents, etc) and electronic media (eg, word-processed transcripts, audiotapes, videotapes, etc). How these data are recorded and accessed affects the depth and quality of the findings. The goal of data collection is to produce detailed data as representative of the experience as possible and to leave a trail of data and analysis that another investigator could potentially follow. While qualitative research cannot be replicated, it can be audited. Of course, outsiders to a study cannot observe exactly what the investigators observed, and because auditors bring their own unique perspectives, they can legitimately develop somewhat different interpretations of the same data. Such alternative interpretations would not necessarily reveal an analysis as faulty, since there are multiple truthful ways to depict social behavior. Nevertheless, in principle, qualitative researchers should organize and interpret their data in such a way that another investigator could follow what was done and could see a clear correspondence between the empirical data and the interpreted findings.

There are several conventions for taking field observations and interview notes. [12](#)(pp250-288) [13](#)(pp199-276) [25-26](#) Most emphasize thoroughness, the classification of observations, and self-consciousness of personal experiences and biases. Taping and transcribing interviews (or other dialogue) is desirable. Qualitative research transcription is different from that used for medical dictation. For typical medical records, breathing, pauses, and changes in volume are ignored by the transcriptionist. For a qualitative research transcript, these behaviors can provide valuable data that help elaborate the meaning of the spoken words; in fact, transcripts are seldom corrected for grammar or word choices. Qualitative investigators also often keep records of their personal thoughts and experiences to distinguish them carefully from other observations. This helps to isolate personal biases, as well as to use personal experiences as analytically useful information. [12](#)(pp250-288) [13](#)(pp199-276, 371-459) [25-26](#)

Ventres et al [1](#) conducted their study over 4 months, during which family practice residents identified 8 hospitalized patients about whom they had discussions regarding resuscitation. Of these, investigators observed 3 discussions among patients, their families, and their physicians; 2 of these 3 cases are reported in detail. Both before and after the discussions, interviews were conducted with the patients, family members, nurses, social workers, clergy, and physicians regarding the decision-making process. Ventres et al audiotaped and transcribed interviews as well as discussions among physicians, patients, and families. The transcription process is detailed in an appendix to the article. An observer also made written records of nonverbal communications, which are not well captured by audiotape. Finally, the investigators also recorded secondary interpretive data (ie, their personal interpretations of the discussions they observed). By collecting data using several methods, these investigators enhanced their ability to capture important nuances in communication and to develop robust accounts of the discussions.

The inclusion of patients, family members, and several members of the health care team as participants in this study increases the number of perspectives from which the issue of resuscitation was considered. No key participant's perspectives seem to have been overlooked in the data collection. However, whether data collection was comprehensive for each participant is difficult to assess, given the different roles that each have in such decisions and the complexities of end-of-life dialogue. Examining only 3 cases in which resuscitation is discussed is unlikely to capture the diversity of perspectives, content, and styles found in such conversations and could produce a limited description. The authors themselves note that this small number of cases is a potential study limitation and that more variability may have yielded further insight into other possible structures of resuscitation discussions.

Were the Data Appropriately Analyzed and the Findings Adequately Corroborated?

Qualitative researchers begin with a general exploratory question and preliminary concepts. They then collect relevant data, observe patterns in the data, organize these into a conceptual framework, and resume data collection to explore and challenge this conceptual framework. This cycle may be repeated several times. The iteration between data collection, analysis, and theory development continues until a conceptual framework is well-developed and further observations yield minimal or no new information to further challenge or elaborate the framework (a point variously referred to as *theoretical saturation* 27 or *informational redundancy* 12(pp221-249)). This analysis-stopping criterion is so basic to qualitative analysis that authors seldom declare that they reached this point and assume this to be understood by the reader.

In the course of analysis, key findings are also triangulated, meaning that they are corroborated using multiple sources of information (the term *triangulation* is a metaphor and does not mean literally that 3 or more sources are required). The appropriate number of sources will depend on the importance of the findings, their implications for theory and the investigators' confidence in their validity. Because no 2 qualitative data sources will generate exactly the same interpretation, much of the art of qualitative interpretation involves exploring why and how different information sources yield slightly different results. 9, 28

Readers may encounter several useful triangulation techniques for validating qualitative data and their interpretation in analysis. 9, 12(289-331) 28 Investigator triangulation requires more than 1 investigator to collect and analyze the raw data, such that the findings emerge through consensus between investigators. This is best accomplished by an investigative team. Use of external investigators is controversial because their involvement in the case could be too superficial to yield deep understanding. 12(pp289-331) 28 Team members representing different disciplines helps to prevent the personal or disciplinary biases of a single researcher from excessively influencing the findings. Member checking involves sharing draft study findings with the participants to inquire whether their viewpoints were faithfully interpreted, whether there are gross errors of fact, and whether the account makes sense to participants with different perspectives. Theory triangulation, 29 is a process whereby emergent findings are corroborated with existing social science theories. 21 It is conventional for authors to report how their qualitative findings relate to prevailing social theory, though it is controversial whether such theories should be used to guide the research design or analysis.

Some qualitative research reports describe the use of qualitative analysis software packages.

Readers should not equate the use of computers with analytic rigor. Such software is a data management tool offering efficient methods for storing, organizing, and retrieving qualitative data. These programs do not perform analysis. Investigators themselves conduct the analysis as they create the keywords, categories, and logical relationships used to organize and interpret electronic data. The credibility of qualitative study findings depend on these investigator judgments that cannot be programmed into software packages. More generally, credible qualitative interpretation requires well-trained and well-prepared investigators who approach their work with both discipline and creativity. ⁹

We indicated earlier that qualitative data collection must be comprehensive—adequate in its breadth and depth to yield a meaningful description. The closely related criterion for judging whether the data were analyzed appropriately is whether this comprehensiveness was determined in part by research results themselves, with the aims of challenging, elaborating, and corroborating the findings. This is most apparent when researchers state that they alternated between data collection and analysis, collected data with the purpose of elucidating the analysis-in-progress, collected data until analytic saturation or redundancy was reached, or triangulated findings using any of the methods mentioned.

Ventres et al ¹(p141) approached data coding using 3 broad preliminary concepts in patient-clinician communication: (1) control, (2) giving or withholding information, and (3) attentiveness. Researchers commonly use sensible, broad conceptual categories such as these to begin making sense of their data, but the categories also are commonly revised in the course of analysis. These investigators noted that data collection and analysis proceeded iteratively, by reporting that, "data collected and analyzed on the first members of the sample influenced the collection of information on subsequent members." Several triangulation techniques were used, including methodologic triangulation (using several data collection methods of participant observation, audiotaping, and semistructured interviews), investigator triangulation (duplicate interpretation of audiotapes), disciplinary triangulation (clinical, anthropological, psychiatric, and sociologic perspectives), and member checking (by professional and lay participants in the study).

The authors report that the principal author and a sociolinguist reviewed the audiotapes blinded to "all but necessary case information," however it is unclear which data were and were not available to these investigators prior to analysis. Readers should not assume that blinding necessarily improved the rigor of the analysis, since limiting access to data also limits investigators' ability to make well-informed interpretations of possibly complex social interactions.

We note that Ventres et al's final findings quite appropriately do not strictly follow their 3 provisional analytic categories (control, information giving, attentiveness), but instead reveal more specific and concrete dynamics focusing on (1) the Limitations of Medical Care form's tendency to frame discussions to exclude patient values and beliefs, (2) family-physician differences in reasoning style, and (3) consequential confusion between instrumental treatment decisions and more general goals of care. This progression suggests that the conceptual findings did develop as a result of the empirical observations. The authors relate their findings back to general social health policy and ethical concerns about who is and who should be in control of limitations-of-care decision processes.

Having determined that the validity of the study by Ventres et al ¹ is sufficient to gain some understanding of the impact of a Limitations of Medical Care form on patient-clinician

communication, we turn to the second part of this Users' Guide. In it, we will address, What are the results, and How do they help me care for my patients?

The original list of members (with affiliations) appears in the first article of the series (JAMA. 1993;270:2093-2095). A list of new members appears in the 10th article of the series (JAMA. 1996;275:1435-1439). The following members of the Evidence-Based Working Group contributed to this article: Gordon H. Guyatt, MD, MSc, Daren Heyland, MD, Anne Holbrook, MD, MSc, Virginia Moyer, MD, MPH, Andrew D. Oxman, MD, MSc, and W. Scott Richardson, MD. Dr Cook is a Career Scientist of the Ontario Ministry of Health. Dr Giacomini is a National Health Research Scholar of Health Canada.

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