Qualitative research, in particular, addresses research questions that are different from those considered by clinical epidemiology. Qualitative research can investigate practitioners' and patients' attitudes, beliefs, and preferences, and the whole question of how evidence is turned into practice. The value of qualitative methods lies in their ability to pursue systematically the kinds of research questions that are not easily answerable by experimental methods.1

Although qualitative research is not a new paradigm for many disciplines (ie, anthropology's use of in-depth interviews or the use of focus groups in market research), it is a relatively new approach in medical research in the last 10 to 15 years.

In recent years, several authors, as well as journal editors, have set forth criteria to evaluate the scientific rigor of qualitative studies.2–8 This chapter summarizes their observations and recommendations. Further, we provide examples of studies that combine both qualitative and quantitative methodologies demonstrating how complementary both research paradigms are, therefore providing a richer and more holistic perspective of the research topic.

However, one must be cautious in applying rigid checklists to qualitative research.5 As Barbour notes,

Although checklists have undoubtedly contributed to the wider acceptance of such methods [qualitative], these can be counterproductive if used prescriptively. The uncritical adoption of a range of "technical fixes"… does not, in itself, confer rigour.9

This is reinforced by the fact that qualitative inquiry “also comprises a particular way of seeing and a framework for a certain kind of research ethics in which subjective experience is acknowledged and harnessed.”10 Thus, in evaluating the rigor of qualitative research, the reader needs to critique the research from a holistic perspective and not just tick off specific techniques from a checklist. Nonetheless, some basic and fundamental principles can assist the reader in determining the rigor of a qualitative study.

LEARNING OBJECTIVES
On completion of this chapter, the reader should be able to

1. Understand the connection between qualitative research and evidence-based medicine
2. Determine what constitutes a scientifically rigorous qualitative research study both in design and in execution

THE RESEARCH QUESTION
Payne asserts that “at the heart of all research lies a well formulated and potentially answerable research question.”11 Furthermore, Frankel argues that “the research question should always determine the method and not the other way around.”4 Thus, a problem arises when the research question is posed in a manner that does not resonate with the qualitative paradigm. For example, the question “How often do breast cancer patients use complementary/alternative medicine (CAM) to treat their disease?” would be best answered by a cross-sectional, quantitative survey. In contrast, if the study question was “What is the experience of breast cancer patients in the use of CAM in the management of their disease?” then using qualitative methods would be more appropriate. Thus, the research question and the method of study must fit hand in glove.

SAMPLING STRATEGIES
Recruiting participants for study requires selecting a purposive sample; this is not equivalent to a convenience sample, nor is the use of a random sample appropriate. Rather, it means identifying participants through a variety of sampling techniques (ie, maximum variation, homogeneous, theoretic, snowball or chain,
and confirming/disconfirming sampling) that best address the study question. For example, maximum variation sampling reflects diversity and depth. Diversity implies that the participants reflect a wide range of characteristics and experiences, such as ethnicity, sex, age, socioeconomic status, geographic location, length of diagnosis, duration, and chronicity of disease. The greater the variation of the participants’ experience, the more depth the data collection will reach and ultimately answer the study question. Seeking both confirming and disconfirming cases helps researchers be convinced that they have a full understanding of all possible perspectives on the phenomenon under inquiry.  

DATA COLLECTION  
There are numerous forms of data collection in qualitative research, each designed to most adequately answer the research question, such as in-depth interviews, focus groups, key informant interviews, or participant observation. To reiterate, the means for collecting the data must suit the study question.

Data collection is also inextricably linked to sample size and recruitment. There are some basic principles guiding data collection, which have evolved out of the cumulative experience of the current generation of qualitative researchers, such as a minimum of four focus groups or 8 to 10 in-depth interviews. But the fundamental question is, When have the researchers reached saturation? In other words, at what stage in the data collection have they come to the point that they are no longer hearing new themes or key concepts? Has the data collection been sufficiently iterative that diversity and depth have been achieved?

The data collection process needs to be described, such as audio- or videotaping, verbatim transcription of the data, and the use of field notes or memos. Payne recommends two sets of field notes, one a descriptive account of what happens and another much more personal account which deals with the emotional aspects of observational work. It is essential to be meticulous and methodical in writing field notes up after each episode of data collection because memory fades quickly.

It is also important to document the context of the study, including who conducted the data collection and their role in the research study.

DATA ANALYSIS  
Although participant recruitment goes hand in hand with data collection, perhaps the most essential aspect of the qualitative process is the data analysis strategy, which exemplifies the iterative nature of qualitative research. A variety of strategies may provide a framework for the analysis (ie, grounded theory, phenomenology). The key point is that the analysis process begins the moment that the researcher begins to interview the first participant. The researcher is guided by the participant’s response(s) and is thus led toward the answer to the study question. Participants are actively engaged in the research process. In qualitative research, the “voice” of the participants defines the data and must always take prominence. Researchers must never make assumptions or project their own views on the participants’ stories because each story is unique and is a valuable source of information. Researchers are also looking for deviant or negative cases that challenge or refute the emerging themes or concepts. The analysis process also involves both independent and team analysis, which enhances the trustworthiness of the findings. The analysis is ongoing and continues throughout the report writing process as the researchers seek further synthesis, clarification, and understanding of the data collected. The final stage reflects an illumination of the study findings that address the research question.

CREDIBILITY AND TRUSTWORTHINESS  
Throughout the process of qualitative inquiry, a sense of transparency must exist that promotes the credibility and trustworthiness of the data collection and analysis. This is akin to validity in quantitative research. There are a variety of means to achieve credibility and trustworthiness, such as member-checking and triangulation of data sources. Member-checking involves providing a summary or synopsis of the findings to participants for clarification or confirmation. The process of triangulation brings together various data sources (ie, interviews, field notes, direct observation) as a means of ensuring the comprehensiveness of the data collection and interpretation.

As noted previously, there is a subjective aspect to quality research that requires researchers to attend to their own personal and professional biases and interpretations. Several authors have referred to this as reflexivity: how the researchers must be sensitive and attuned to how their own personal and professional perspectives, as well as the research process, shape and influence the data collection and interpretation. The use of interdisciplinary teams brings not only diverse perspectives and expertise to the research process but also helps confront and clarify discipline-specific biases.

Qualitative analysis software packages are being used more and more. Although they are an excellent means of organizing and retrieving data, they cannot analyze the data. This remains the responsibility of the researchers, who must employ their own creative and interpretative skills to make sense of the data.

Finally, the reader must be able to assess the degree to which the findings resonate or are applicable to their own experience. This may include their own clinical
practice, personal experience of illness, or interaction with the health care system. In qualitative research, the goal is not the generalizability of the results to a broader population but rather the transferability of the findings to the readers’ personal/professional experience. As Green and Britten note, it is “a transfer of conceptual versus numerical information.”

**REPORT WRITING**

One of the greatest pitfalls is to falsely translate qualitative data into quantitative terms. This often happens when researchers are trying to reduce volumes of data into a clear and concise research report. Describing the findings is not merely a listing of key themes or concepts but requires an interpretation of their meaning and relevance. As Mays and Pope observe, “the written account should include sufficient data to allow the reader to judge whether the interpretation proffered is adequately supported by the data.” The words of Clark reinforce the necessity of well-written qualitative research:

> Poorly written qualitative research can be indigestible fare. Let us therefore look to qualitative researchers for a sense of poetry and a felicity of language which, in building on the insights of the method, create for us a brighter and more perceptive understanding of the world.

**EXAMPLES**

A study by Boon and colleagues serves as an example of how combining qualitative and quantitative methods enhanced the examination of a challenging study question: “Why do breast cancer survivors use CAM to ‘treat’ their cancer?” This study was conducted by an interdisciplinary team of researchers with expertise in pharmacy, epidemiology, social work, oncology, and family medicine. The diversity of the investigators was essential to the study question and analysis.

The first phase of the study was qualitative. Using the technique of focus groups, the investigators’ goal was to explore how the participants, breast cancer survivors, defined CAM and then why and how they decided to use or not use CAM in the treatment of their breast cancer. The findings of this portion of the research then informed the second phase of the research, a prevalence study associating patient factors with CAM use. This involved a survey questionnaire, which was mailed to a random sample of breast cancer patients. Together both phases of the study helped illuminate the challenges and struggles of women living with breast cancer and how CAM was one aspect of their experience of care.

Another study by McWilliam and colleagues also combined quantitative and qualitative methods to explore ways of gaining health after hospitalization for chronically ill elders. The quantitative portion of the study was a randomized controlled trial evaluating home-based health promotion for elderly persons just discharged from hospital. For the qualitative component of this project, in-depth interviews were conducted with a purposive sample of information-rich participants. They were identified from the larger quantitative sample in the intervention group to illuminate the older persons’ experiences of the process of health promotion.

As Malterud states, “Rather than thinking of qualitative and quantitative strategies as incompatible, they should be seen as complementary.”

**QUESTIONS TO ASK WHEN EVALUATING QUALITATIVE RESEARCH**

1. Are the study question and the qualitative method chosen to examine the question congruent?
2. Has the appropriate purposive sample technique been used? Was saturation achieved?
3. Do the researchers provide an account of the data collection and analysis that includes documentation of saturation and the iterative process?
4. Is there evidence of techniques to ensure the credibility and trustworthiness of the data collection and analysis?
5. Are the findings described in such a manner that the key themes or concepts are readily apparent and illustrated by appropriate and relevant quotations?

**REFERENCES**


