

Qualitative research: standards, challenges, and guidelines

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Qualitative research methods could help us to improve our understanding of medicine. Rather than thinking of qualitative and quantitative strategies as incompatible, they should be seen as complementary. Although procedures for textual interpretation differ from those of statistical analysis, because of the different type of data used and questions to be answered, the underlying principles are much the same. In this article I propose relevance, validity, and reflexivity as overall standards for qualitative inquiry. I will discuss the specific challenges in relation to reflexivity, transferability, and shared assumptions of interpretation, which are met by medical researchers who do this type of research, and I will propose guidelines for qualitative inquiry.

A broad base of medical and scientific knowledge is needed if medicine is to maintain its identity as a discipline founded on scientific knowledge. However, interpretive action must also be included in medical knowledge. In my first article,¹ I investigated the nature of clinical knowledge in medicine, exposed some of the shortcomings of quantitative research methods, and briefly introduced qualitative methods as an approach for improved understanding. Here, I shall discuss how scientific quality can be maintained when qualitative research methods are applied. I present some overall standards, describe specific challenges met when the medical researcher uses qualitative research methods, and subsequently propose guidelines for qualitative inquiry in medical research. I do not intend to provide comprehensive guidance for the inexperienced qualitative researcher, who must be prepared to acquire basic skills of qualitative research from the relevant literature. Some of the specific terms that I use are presented in panel 1.

Standards

Qualitative research methods involve the systematic collection, organisation, and interpretation of textual material derived from talk or observation. It is used in the exploration of meanings of social phenomena as experienced by individuals themselves, in their natural context.²⁻⁵ Qualitative research is still regarded with scepticism by the medical community, accused of its subjective nature and the absence of facts. Although the adequacy of guidelines has been vigorously debated within this cross-disciplinary field,^{6,7} scientific standards, criteria, and checklists do exist.^{3,8-11} However, as Chapple and Rogers¹² point out, medical researchers often encounter difficulties when they try to apply guidelines designed by social scientists, which deal with issues important in their own discipline, but which are not necessarily generically valid as scientific standards.

Hamberg and colleagues,¹³ for example, claim that the established criteria for scientific rigour in quantitative research cannot be applied to qualitative studies. Referring to Lincoln and Guba,² they suggest alternative criteria: credibility, dependability, confirmability, and trans-

ferability. They admit that these criteria correspond with traditional ones in some ways, comparing credibility with internal validity, confirmability with objectivity, and transferability with generalisability.

Mays and Pope,⁷ however, maintain that qualitative research can be assessed with reference to the same broad criteria as quantitative research, albeit used in a different way. Referring to Hammersley,¹⁴ they suggest that validity and relevance are essential. Neither of these criteria are straightforward to assess though, and each requires judgments to be made. To improve validity, Mays and Pope⁷ suggest procedures and principles such as triangulation, respondent validation, clear detailing of methods of data collection and analysis, reflexivity, attention to negative cases, and fair dealing. Relevance can be increased by the use of detailed reports and sampling techniques. The importance of clinical relevance has also been emphasised by Giacomini and Cook.¹⁵

I believe that qualitative research methods are founded on an understanding of research as a systematic and reflective process for development of knowledge that can somehow be contested and shared, implying ambitions of transferability beyond the study setting. Drawing on these assumptions, the researcher must be prepared to use strategies for: questioning findings and interpretations, instead of taking them for granted; assessing their internal and external validity, instead of judging them obvious or universal; thinking about the effect of context and bias, without believing that knowledge is untouched by the human mind; and displaying and discussing the processes of analysis, instead of believing that manuals grant trustworthiness. Agreeing with Hammersley,¹⁴ and Giacomini and Cook,¹⁵ I believe relevance and validity are essential standards, but think of reflexivity as an equally important measure, which should be added to the criteria.

Specific challenges

Although there are many similarities between qualitative and quantitative research methods, some procedures are very different, because of the different nature and assumptions of the data and questions to be answered. The effect of an investigator on a study, the principles and consequences of sampling, and the process of organisation and interpretation during analysis, all affect research, and are closely related to different aspects of validity (panel 2).

Reflexivity

A researcher's background and position will affect what they choose to investigate, the angle of investigation, the

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Panel 1: Terms used in qualitative research

Term	Metaphor	Description
Reflexivity	The knower's mirror	An attitude of attending systematically to the context of knowledge construction, especially to the effect of the researcher, at every step of the research process
Preconceptions	The researcher's backpack	Previous personal and professional experiences, prestudy beliefs about how things are and what is to be investigated, motivation and qualifications for exploration of the field, and perspectives and theoretical foundations related to education and interests
Theoretical frame of reference	The analyst's reading glasses	Theories, models, and notions applied for interpretation of the material and for understanding a specific situation
Metapositions	The participating observer's sidetrack	Strategies for creating adequate distance from a study setting that you are personally involved in
Transferability	External validity	The range and limitations for application of the study findings, beyond the context in which the study was done

methods judged most adequate for this purpose, the findings considered most appropriate, and the framing and communication of conclusions. Contemporary theory of knowledge acknowledges the effect of a researcher's position and perspectives, and disputes the belief of a neutral observer.¹⁶ Haraway¹⁷ claims that the perspective of the observer is always limited and determines what can be seen. This notion applies even in laboratory science.¹⁸

Hence, in qualitative (and maybe also in quantitative) inquiry, the question is neither whether the researcher affects the process nor whether such an effect can be prevented. This methodological point has been turned into a commitment to reflexivity. The illusion of denying the human touch is countered by establishing an agenda for assessment of subjectivity. Objectivity, redefined by Haraway,¹⁷ means to recognise that knowledge is partial and situated, and to account adequately for the effects of the positioned researcher. During all steps of the research process, the effect of the researcher should be assessed, and, later on, shared. Adequate accounts of these effects should be presented in the publication, as the frame of discussions of limitations and strengths of the study, and transferability of findings.¹⁹ Bias, in the sense of undesirable or hidden skewness, is thus accounted for, though not eliminated. Subjectivity arises when the effect of the researcher is ignored.

Dependent on positions and perspectives, different researchers might therefore access different, although equally valid, representations of the situation that is studied. In qualitative research, these different ways of approaching the same subject result in an increased understanding of complex phenomena, not in a failure of reliability. Multiple researchers might strengthen the design of a study—not for the purpose of consensus or identical readings, but to supplement and contest each other's statements. The single researcher will have to establish other strategies for broad and critical reading. Validation by consensus or repeatability is seldom adequate in qualitative research.

Panel 2: Factors that affect research

Reflexivity	Share preconceptions Establish metapositions
Transferability	Adequate and sufficiently varied sample Consider whom and what the findings concern
Interpretation and analysis	Describe theoretical frame of reference Transparent, systematic procedure

The investigator always enters a field of research with certain opinions about what it is all about.²⁰ Reflexivity starts by identifying preconceptions brought into the project by the researcher, representing previous personal and professional experiences, prestudy beliefs about how things are and what is to be investigated, motivation and qualifications for exploration of the field, and perspectives and theoretical foundations related to education and interests. Miller,²¹ for instance, writes about the inquisitiveness he felt towards his colleagues' capacity to combine efficiency and a biopsychosocial orientation, whereas Gardner and Chapple²² introduce Gardner's distress as a general practitioner trying to relate to a patient with angina who impeded referral for 6 years.²² In qualitative study, researchers commonly claim that they develop hypotheses, they do not test them. In a scientific culture accustomed to specific procedures for hypothesis testing, such claims are useful for rhetorical purposes, to prevent expectations about identical procedures applied to qualitative material. The researcher should not deny that hypotheses exist. However, the qualitative researcher's task is to explain, and maybe question, the hypotheses as ingredients of the preconceptions and as reflections,²³ rather than applying procedures for testing them.

Preconceptions are not the same as bias, unless the researcher fails to mention them. If reflexivity is thoroughly maintained, personal issues can be valuable sources for relevant and specific research. However, the investigator should take care not to confuse knowledge intuitively present in advance, embedded in preconceptions, with knowledge emerging from inquiry of systematically obtained material. This situation can be avoided by declaration of beliefs before the start of the study. Reflexivity can also be maintained by looking at the data, or its interpretation, for competing conclusions. In a study, in which we asked patients to keep a diary, Stensland and myself²⁴ suggest strategies for obtaining metapositions as a way of improving reflexivity, whereas Miller²¹ recommends that data be taped and transcribed, therefore allowing others not involved in the study to audit them. Based on a review of 29 publications in which qualitative methods were applied, Hoddinott and Pill²⁵ concluded that important contextual details were often missing, implying that critical appraisal of the reports was hampered.

Transferability

The importance of sampling is closely related to validity. Internal validity asks whether the study investigates what it is meant to, whereas external validity asks in what contexts the findings can be applied. The nature and extent of the

data will ascertain which conclusions can be drawn about what. The aim of research is to produce information that can be shared and applied beyond the study setting. No study, irrespective of the method used, can provide findings that are universally transferable. The study design should show a thorough consideration of what an adequate degree of transferability would be, in view of the assumptions of the research question, and present a relevant sampling strategy. Sampling strategies might seem fundamentally different for qualitative and quantitative inquiry. The key to understanding how these different approaches still accommodate scientific quality is to move beyond procedures and to keep the principles of the research in mind.

Purposeful or theoretical sampling are commonly done to obtain qualitative material.²⁶ Previous experience and theoretical frameworks will indicate where to go for resources—ie, Skelton and colleagues²⁷ designed a study to investigate the heterogeneity of practices and of a wide

range of practitioners, and Stensland and I²⁴ adapted our design to investigate patients with longstanding symptoms without clinical findings, representing varying duration of illness and symptom presentation.²⁴ Sampling is usually done in a stepwise way, including more data from one group or another dependent on what extra material is needed to answer the research question effectively. A discussion about who and what the findings actually relate to is a key component of external validation in a qualitative study.^{23,28}

The procedures described are fundamentally different from those used to deal with prevalences, distributions, or numerical differences, in which large representative or random samples, allowing for calculations of probability with subsequent inference to a defined population, are required. In qualitative inquiry, the aim with respect to external validity is to ascertain whether or not the study hypothesis or results can be applied in other settings. Presentation of contextual background material, such as

Panel 3: Guidelines for authors and reviewers of qualitative studies

Aim

Is the research question a relevant issue?
Is the aim sufficiently focused, and stated clearly?
Does the title of the article give a clear account of the aim?

Reflexivity

Are the researcher's motives, background, perspectives, and preliminary hypotheses presented, and is the effect of these issues sufficiently dealt with?

Method and design

Are qualitative research methods suitable for exploration of the research question?
Has the best method been chosen with respect to the research question?

Data collection and sampling

Is the strategy for data collection clearly stated (usually purposive or theoretical, usually not random or representative)?
Are the reasons for this choice stated?
Has the best approach been chosen, in view of the research question?
Are the consequences of the chosen strategy discussed and compared with other options?
Are the characteristics of the sample presented in enough depth to understand the study site and context?

Theoretical framework

Are the perspectives and ideas used for data interpretation presented?
Is the framework adequate, in view of the aim of the study?
Does the author account for the role given to the theoretical framework during analysis?

Analysis

Are the principles and procedures for data organisation and analysis fully described, allowing the reader to understand what happened to the raw material to arrive at the results?
Were the various categories identified from theory or preconceptions in advance, or were they developed from the data?
Which principles were followed to organise the presentation of the findings?
Are strategies used to validate results presented, such as cross-checks for rival explanations, member checks, or triangulation.
If such strategies are not described in this section, they should appear as validity discussions later in the report.

Findings

Are the findings relevant with respect to the aim of the study?
Do they provide new insight?
Is the presentation of the findings well organised and best suited to ensure that findings are drawn from systematic analysis of material, rather than from preconceptions?
Are quotes used adequately to support and enrich the researcher's synopsis of the patterns identified by systematic analysis?

Discussion

Are questions about internal validity (what the study is actually about), external validity (to what other settings the findings or notions can be applied), and reflexivity (the effects of the researcher on processes, interpretations, findings, and conclusions) addressed?
Has the design been scrutinised?
Are the shortcomings accounted for and discussed, without denying the responsibility of choices taken?
Have the findings been compared with appropriate theoretical and empirical references?
Are a few clear consequences of the study proposed?

Presentation

Is the report easy to understand and clearly contextualised?
Is it possible to distinguish between the voices of the informants and those of the researcher?

References

Are important and specific sources in the field covered, and have they been appropriately presented and applied in the text?

demographics and study setting, is necessary if the reader is to be able to ascertain for which situations the findings might provide valid information. The pursuit of diversity and contradictions in interpretive analysis of textual material is not logically compatible with the standardisation assumptions underlying probability statistics. Additionally, the findings are not supposed to be valid for population groups at large. Random sampling is therefore rarely a relevant tool for validity in these studies

Good qualitative research does not exaggerate the extent of the material. During analysis the researchers should have a thorough knowledge of the study material, so that they are aware of the content of the data and what they mean, and so that they are able to ascertain what in the material is relevant when trying to answer the research question. Computer programs are useful for storing, ordering, and retrieving information, but they cannot do the analysis itself. Additionally, a large amount of material does not actually guarantee transferability, and might result in a superficial analysis, since the researchers are not able to test reflexivity and look at counterhypotheses. The transcripts from 15 patients and their four doctors, therefore, might be more than sufficient.²² The nature of the research question and the material, combined with the intention of external validity, will determine the correct number of participants for a study. One individual, as in a case study,²⁹ might be sufficient dependent on the topic and scope of the investigation.^{21,23,30} The findings from a qualitative study are not thought of as facts that are applicable to the population at large, but rather as descriptions, notions, or theories applicable within a specified setting.

Interpretation and analysis

A thorough, well prepared, and well documented analysis is what distinguishes scientific approach from superficial conjecture (panel 3). The researcher's task is to organise, compare, and validate alternative interpretations. Only when the researcher can identify the systematic procedure that has been followed in this process, can it be shared with others.³¹ Declaring that qualitative analysis was done, or stating that categories emerged when the material had been read by one or more persons, is not sufficient to explain how and why patterns were noticed.

Qualitative data represent large amounts of information, and analysis implies abstraction and some degree of generalisation. Components from the individual informant's history and expressions are used to gain knowledge applicable to others. Analysis of qualitative data involves decontextualisation and recontextualisation.³² Decontextualisation allows parts of the subject matter to be lifted out and investigated more closely, together with other elements across the material that tells about similar issues. Recontextualisation will make sure that the patterns still agree with the context from which they were collected, and is important to prevent reductionism and to maintain the connections between the field and the informants' accounts of reality.

The processes of systematic analysis of qualitative data vary from project to project, dependent on the research question, material, and choice of analytical style.³ Miller and Crabtree³³ present three styles of analysis, according to the degree of predetermined or theoretically founded categories for interpretation. With the immersion/crystallisation (intuitive) analysis style, the researcher organises data by examining the text thoroughly and then crystallising out the most important aspects.²¹ With the editing (data-based) analysis style, the researcher identifies units in the text, forming the basis for data-developed categories, which are used to reorganise the text

so that its meaning can be clearly seen.²⁸ With the template (theory-based) analysis style (not very frequently applied in medical research), the text is organised according to pre-existing theoretical or logical categories, to provide new descriptions of previously known phenomena. A researcher should always reveal the style of analysis used.

Interpretation is an integral part of qualitative inquiry. The qualitative researcher might aim for induction, in the sense of development of theory from data. However, knowledge never emerges from data alone, but from the relation between empirical substance and theoretical models and notions.³³ The theoretical framework can be equated with the reading glasses worn by the researcher when she or he asks questions about the material. Sharing the type and role of framework is essential to maintain communicative validity.⁵ A frequent shortcoming in report writing is to omit information about whether the presented categories represent empirical findings or if they were identified in advance.

Neglect of the theoretical considerations does not enhance the scientific quality of any study. Yet, the medical researcher is not supposed to become a social scientist, even when doing qualitative inquiry. Different degrees of theoretical thoroughness are relevant for different purposes. The medical researcher is advised to draw on theory from other disciplines, yet to maintain the ambition of constructing medical knowledge. Investigators should be encouraged to declare that their readings or interpretations have been supported, for instance, by models about self efficacy,²⁶ health belief,²² or proinflammatory cytokines,²⁸ without being expected to permeate these thoroughly. However, the task of transforming theory from other disciplines so that it is applicable to medicine will require some in depth research, as exemplified by Nessa,³⁰ who has developed a method for transcription of consultations from pragmatics and textlinguistics.

Researchers who claim that they approach their material inductively, without applying any theory for analysis, fail to realise that their stance is unavoidably affected by theory. This notion is particularly true for those working in medicine, where the role of the theoretical framework is seldom explicitly spelled out. Failure to acknowledge the effect of theory might be a major threat to objectivity, since notions and models used in interpretation of data are always derived from a theory of some sort. Clarification and declaration of the standpoints by a researcher, instead of denial or hiding of the frame of reference, will enhance intersubjectivity, in quantitative as well as qualitative inquiry.

A medical researcher might find the task of condensing their research to fit the limits of a journal article, without compromising quality, difficult. To overcome this dilemma, investigators, referees, and editors need to work together. Because a range of procedures can be applied in qualitative analysis, a transparent description of the path from data to findings is necessary to convey what was done to the reader. Clarification of the role of different data sources is an important part of this description.^{21,24,28} To indicate that a computer program was used for analysis is just as insufficient as saying that SPSS was applied, without stating the type of statistics involved. Furthermore, a researcher cannot simply say that the material was coded for typical patterns, resulting in some categories; the reader needs to know the principles and choices underlying pattern recognition and category foundation. The balance between flexibility and rigidity is a demanding challenge in creative qualitative analysis. Yet, reference to a previous, well described procedure can satisfy the reader and save precious words in a journal article. Unfortunately, word

limits in medical journals might restrain development and dissemination of innovative or complex qualitative research methods.

Two basic methods of data analysis are commonly referred to in the literature. Grounded theory, based on the theory of social interactionism, is used to develop social issues and theories grounded in qualitative data. Strauss and Corbin³⁵ provide specific procedures for analysis, including open coding, axial coding, and selective coding. Their constant comparative method can be applied to approach a core category and a storyline as the main outcomes of analysis. Giorgi's analysis,³⁶ based on phenomenological philosophy, and modified by myself,³¹ is suited for development of descriptions and notions related to human experience.^{24,28} Giorgi recommends a four-step analysis procedure: getting a total impression, identifying meaning units, abstracting the contents of individual meaning units, and summarising their importance.

Analysis might also be presented as a narrative.^{21,30,37} An investigator often considers many factors before answering the research question, and the reader should be aware of them all. However, the more intuitively the analysis procedure is accomplished, the harder it is to account for what has been done. The beginner is therefore advised to follow a path that has been trodden by others, even though the more artistic potentials of analysis might then be traded off for a more mechanical, but transparent, approach. The experienced researcher, however, might move more freely in the material without losing hold of the process that is to be accounted for.²³

Qualitative and quantitative methods

When qualitative and quantitative approaches are combined, the methods are often applied in sequential order. Semistructured interviews or observational data might, for example, be used to explore hypotheses or variables when planning a large epidemiological study, resulting in enhanced sensitivity and accuracy of survey questions and statistical strategy. In such instances, qualitative studies might be thought of as precursors of "real" science. However, qualitative studies can also be added to quantitative ones, to gain a better understanding of the meaning and implications of the findings. More creative combinations are seen in triangulation.³ The idea of triangulation originated from a craft used by land surveyors, who increase the validity of a map by incorporating measures from different angles. Multiple and diverse observations can enrich the description of a phenomenon—ie, an elephant looks very different when seen from above or below. Someone reading a report might gain a better understanding of what goes on in a medical consultation if data from various sources, such as doctors and patients,²² have been combined. The aim of triangulation is to increase the understanding of complex phenomena, not criteria-based validation, in which agreement among different sources confirms validity.

Quantification of phenomena or categories can be done to gain an overview of qualitative material, but the application of such numbers should be done with caution. Quasistatistical analysis of textual material, also termed content analysis, has gained some popularity, and computer programs are available to count the occurrence of specific words or utterings in a text. However, the scientific logic of statistics and transferability is far from accomplished in a non-representative sample in which questions were not asked in a standardised way to all participants. We do not know to whom the findings can be transferred, and we do not know the potential answers from informants who just did not mention the issue. Prevalences, distributions, and

differences cannot be inferred from this kind of material. Correspondingly, the search for meaning and experience in responses constructed by the researcher in advance, is a risky business.

Accordingly, the principles of meta-analysis should be thoroughly reconsidered when qualitative and quantitative studies are analysed together. Complete integration is not a realistic objective. In the context of medical research, integration of methods invariably denotes treating the qualitative study as if it were a quantitative one, recording the material as variables, which are counted and aggregated. Healthy and innovative meta-analysis should develop methods for reasonable combination of findings from qualitative and quantitative studies, acknowledging and using the potential of the different nature of these approaches. Interpretation of textual materials and purposeful samples is different to the calculation of numerical materials and random samples. Findings from qualitative and quantitative studies can certainly be aggregated and complemented by secondary analysis, contributing to an extended approach to the phenomenon in question, as well as a mutual validation. However, such meta-analysis should be done on the results, and not by accumulating and mixing quantitative and qualitative data, which require fundamentally different procedures for scientific analysis. When combining qualitative and quantitative studies, the meta-analyst should be prepared to handle contradictory findings, without having to discard one and appoint the other as the gold standard.

Conclusions

Medical research needs diversity. We need to prevent methodological separatism and supremacy if the field of medical knowledge is to be expanded, not just strengthened or divided. Responsible application of qualitative research methods is a promising approach to broader understanding of clinical realities. No research method will ever be able to describe peoples lives, minds, and realities completely though, and medical doctors should be reminded that scientific knowledge is not always the most important or relevant type of information when dealing with people.

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Uses of error: Surprises in diagnosis

Working through the night back in the mid-1960s, I was trying to break what we thought was a lupus flare in a Hispanic woman who had entered the hospital 2 weeks before with fever of unknown origin. She had been worked up for various bacterial and viral diseases with the usual chest radiograph, blood, urine, and cerebrospinal fluid microscopy and cultures. No infectious agent was found. The leading diagnosis was a flare-up from her lupus erythematosus. High doses of steroid were given and although her fever subsided she still had weakness and signs of her autoimmune disease during her course at the hospital. That night she was especially compromised with difficulty in breathing and high fever. Despite high steroid doses and close attention by the staff, she died.

As a group, the house staff was not satisfied with the diagnosis of lupus erythematosus on the death certificate. We thought some other process must have taken place, but that we had ruled out all the obvious possible causes. She had a slightly enlarged liver and spleen, again believed secondary to her autoimmune disease. We were able to do a liver biopsy in an attempt to uncover some unexpected disease.

As often happens, she died on a Friday and we had the weekend to wait in anticipation. Finally, the pathology report came back: *Mycobacterium tuberculosis* throughout the liver. The surprise of this obvious diagnosis was a lesson to us all. Of course, with high-dose steroids, tuberculosis should have been high on our list, but she had not given us any indication of tuberculosis. Her lungs had been clear on admission, and the tuberculin test was negative, probably secondary to her steroid dose.

As a lesson in medicine, she was presented at our weekly clinical pathological conference in which surprises in diagnosis were routinely considered. We had all learned in medical school about the reactivation of mycobacterial infection during immunosuppression, but engrossed in treating one disease, we failed to consider what we knew. This patient was entitled to more than one diagnosis and miliary tuberculosis, to which she most probably succumbed, could have been approached with appropriate therapy.

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