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Strategies, practices, and challenges in enhancing quality assurance in qualitative biomedical research: A multi-method study protocol

Hamidreza Khankeh [1,2], Mohammad Saatchi [2,3], Mahdieh Motie [4,5], Shima Shirozhan [2,5*], Ulrich Dirnagl [1]

1. QUEST Center for Responsible Research, Berlin Institute of Health at Charité, Berlin, Germany
2. Health in Emergency and Disaster Research Center, Social Health Research Institute, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran
3. Department of Biostatistics and Epidemiology, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran
4. Student Research Committee, Faculty of Nursing, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran
5. Department of Nursing, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran

* Correspondence: Shima Shirozhan. Department of Nursing, University of Social Welfare and Rehabilitation Sciences, Tehran, Iran.
Tel: +989128280286; Email: Shimashirozhan@gmail.com

Abstract

Background: The qualitative research paradigm is crucial for understanding complex human phenomena, making credibility essential for its findings. Challenges in applying quality assessment criteria and promoting responsible practices in biomedical research underscore the need to review strategies, practices, and challenges in evaluating the quality of qualitative research. This protocol aims to support a multi-method study that develops evidence-informed, comprehensive, and practical recommendations to enhance quality assurance in qualitative research within the biomedical field.

Methods: This multi-method study protocol consists of three phases: a systematic scoping review, qualitative content analysis, and a Delphi survey. The scoping review will follow Arksey and O'Malley's five-step approach, using relevant keywords to guide a systematic search across databases such as PubMed, CINAHL, Web of Science, Scopus, and Embase, with no time restrictions. Qualitative content analysis will follow Graneheim and Lundman's (2004) method. Purposeful sampling will be used to select experts in qualitative research. Semi-structured interviews will collect their experiences in evaluating qualitative research quality. Based on the review and interview findings, comprehensive, evidence-informed, and practical recommendations within the biomedical field will be developed and further refined using the Delphi method.

Conclusion: This study aims to critically examine quality achievement and evaluation in the qualitative paradigm and identify challenges, practices, and strategies through a review of existing evidence, focusing on related experiences and perceptions. The study also seeks to address gaps and controversies in the literature using qualitative content analysis. Ultimately, the goal is to develop comprehensive, evidence-informed, and practical recommendations to enhance quality assurance in qualitative research.

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Introduction

Understanding complex social phenomena, especially those not easily quantifiable, requires in-depth qualitative methodologies. This approach encompasses a range of scientific methods, providing a richer comprehension of human experiences and behaviors (1-3). These methods, known as qualitative research or the qualitative paradigm, aim to deeply understand phenomena as experienced and perceived by people (1,2).

Within the qualitative paradigm, diverse methodologies such as grounded theory, phenomenology, action research, and historical research enable researchers to address a wide range of questions (1,2). Exploring individuals' lived experiences, explaining social processes, understanding group cultures, and deepening our understanding of contextual and subjective human phenomena are examples of goals achievable through these methodologies (1-3).

The unique features of qualitative research, which are distinct from quantitative research, facilitate the achievement of these objectives (3). Qualitative methodologies include various data collection methods, such as in-depth individual interviews, observations, and group discussions (1). These approaches accommodate diverse data types, such as participant experiences expressed through words, images, or historical documents (2). Furthermore, in this paradigm, researchers act as instruments for data collection and analysis, and the study design remains flexible, aligning with its philosophical assumptions (1).

Although the characteristics of qualitative research have created advantages over quantitative research, they have always raised concerns about the objectivity of the findings (4,5). The potential impact of the researcher's perspectives, values, and assumptions, which can influence the data collection and analysis process, is one of the criticisms that positivist researchers have made of qualitative research (5,6).

In response to these criticisms, qualitative scholars have proposed various criteria to assess the trustworthiness and quality of qualitative studies (7). The five criteria provided by Lincoln and Guba are the most widely used (8,9). Moreover, other qualitative researchers have introduced criteria to be used in different methodologies, such as qualitative content analysis or grounded theory (7,10).

Although the criteria presented evaluate the quality of a study from different aspects, the multiplicity of criteria has confused researchers in choosing the appropriate criteria (4,5). Additionally, the appropriateness and applicability of these criteria across different qualitative methodologies remain subjects of ongoing debate (4,5,7).

Most of these criteria are derived from the quantitative world, which emphasizes objectivity. However, this is not the primary focus of the qualitative research paradigm. In addition, recent scientific trends and new approaches, such as Responsible Research and Innovation (RRI), have underscored the importance and necessity of more thoroughly examining the challenges and criticisms related to qualitative research evaluation criteria (11-14).

RRI in the field of biomedical science addresses the needs of people in society, achieves high ethical standards, increases the effectiveness of studies, and ensures quality research (11-14). An often-overlooked aspect is the alignment of existing quality evaluation criteria with the objectives of responsible research. Consequently, it is advisable to

incorporate criteria that specifically address the goals of RRI in future studies within both qualitative and quantitative paradigms in this field (11-14).

In response to current challenges and emerging approaches, this study aims to review existing criteria for assessing the quality of qualitative research in biomedical science, address related criticisms and gaps, and develop comprehensive, evidence-informed, and practical recommendations to enhance quality assurance in qualitative research within the biomedical field.

Methods

This protocol will guide researchers in conducting a multi-method study across three phases: a systematic scoping review, qualitative content analysis, and the Delphi method. The phases of this study will complement each other. The scoping review will identify research gaps and existing evidence. In the next phase, qualitative research will be used to explore challenges through participant input. The identified gaps will be addressed by collecting qualitative experiences from experts, such as faculty members or researchers. After completing the first two phases, their results will be integrated, and the combined findings will proceed to the Delphi stage for finalization by specialists.

First phase (Systematic scoping review)

This systematic scoping review study will follow the 5-step method suggested by Arksey and O'Malley. According to this approach, the following steps will be implemented to achieve the study's aim: [1] identifying the research question; [2] identifying relevant studies; [3] study selection, establishing inclusion and exclusion criteria; [4] charting the data and sorting information; and [5] collating, summarizing, and reporting the results. Step 6, the "consultation exercise," which is optional, will not be considered in this study (15). In developing this protocol, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for protocols will be followed (16). In addition, the PRISMA extension for the scoping reviews checklist will be used to report the findings of the scoping review (17).

Identifying research questions

Three main questions are raised to achieve the aim of this study, which involves identifying the strategies, practices, and challenges in the quality assessment of qualitative research in the field of biomedical science.

I. What are the quality evaluation criteria for qualitative research in the field of biomedical science?

II. What strategies or practices do qualitative researchers use to assess the quality of qualitative studies in this field?

III. What challenges do researchers face in evaluating the quality of qualitative studies in the field of biomedical science?

Identifying relevant studies

Selecting keywords for searching electronic databases involves reviewing relevant literature and considering medical subject headings (MeSH) or subject heading search terms related to key concepts. Once the keywords are chosen, an advanced search expert will create a tailored search strategy for each database. An example of the search strategy is provided in Table 1. A systematic search will be conducted across several databases, including PubMed, CINAHL, Web of Science, Scopus, and Embase, with no time restrictions, allowing for a comprehensive exploration of relevant literature. Hand searching via the Google Scholar search engine, a review of key journals, and an examination of the reference lists of highly relevant articles will complete the search. The retrieved articles will be imported into EndNote data management software for subsequent review.

Table 1. PubMed search strategy

(("biomedical science"[Title/Abstract]) OR ("Biomedical Research"[Mesh])) AND (("strategies"[Title/Abstract] OR "approaches"[Title/Abstract] OR "challenges"[Title/Abstract] OR "barrier"[Title/Abstract] OR "obstacle"[Title/Abstract]) AND (("Qualitative Research"[MeSH Terms] OR "qualitative method*"[Title/Abstract]) AND ("Reproducibility of Results"[MeSH Terms] OR ("trustworthiness"[Title/Abstract] OR "research integrity"[Title/Abstract] OR "responsible research"[Title/Abstract] OR "rigor"[Title/Abstract]))))

Study selection

Study selection will occur in two stages of screening. Initially, two researchers will independently review article titles and abstracts to identify relevant studies. In the secondary screening, studies that meet the inclusion criteria will be selected for the final report. The inclusion criteria will include all relevant English-language studies with accessible full texts. Any disagreements between the researchers during the review process will be addressed within the research team. Cohen's kappa coefficient (κ) will be used to assess inter-rater agreement after full-text screening. The PRISMA flow diagram will present the screening results.

Charting the data

Data charting will align with the study's purpose and address the key research questions. The data extraction table will be developed with input from the research team and calibrated by reviewing several articles before the actual extraction begins. This table will include essential study information such as [1] authors, [2] subject of study, [3] methodology, [4] publication year, [5] quality evaluation criteria, [6] strategy/practice for applying criteria, and [7] any challenges encountered. Two researchers will independently perform data extraction, and their results will be compared and integrated.

Collating, summarizing, and reporting the results

The study's findings will be presented in various formats, including graphs, tables, and diagrams. Researchers will aim to present the collected data coherently and meaningfully, enabling readers to address the research questions. Furthermore, discussions and comparisons with existing evidence will enhance reader comprehension. Ultimately, the study results will be published as an article in a peer-reviewed journal relevant to the research topic.

Second phase (Qualitative content analysis)

In this phase, the researchers' experiences in the field of quality assessment of studies will be explored through a conventional content analysis study using the approach of Graneheim and Lundman (2004) (1,10). Furthermore, the existing practices and challenges in the field of quality assessment across different methodologies in qualitative research will be discussed. Additionally, the recommendations and solutions proposed by the researchers to address these challenges will be extracted.

The study population

The study population includes researchers with experience in conducting qualitative research using various methodologies.

Selection of participants

The method of selecting participants for qualitative content analysis will be purposeful, based on the study's inclusion criteria: having experience in conducting qualitative research and guiding or mentoring doctoral students in their qualitative research endeavors, being willing to participate in the study, and being able to express their experiences (1). To achieve maximum diversity, participant selection will be based on a review of their background in conducting qualitative research, with final decisions made in consultation with the research team members.

Data collection

Data collection will be conducted through in-depth, semi-structured interviews. To leverage the experiences of diverse individuals, participants will be selected from various universities across Iran. Researchers will strive to conduct interviews in person; however, if this is not feasible, the interviews will take place virtually through a platform that is convenient for the interviewees. To facilitate these interviews, the research team will develop an interview guide, which will be calibrated through several preliminary interviews. This guide will include opening questions and main questions, followed by probe and follow-up questions based on each participant's responses (1). The sample questions designed for this study are as follows:

- In the qualitative research you have conducted to date, what practices have you implemented to evaluate and enhance the rigor and trustworthiness of your studies?
- What challenges have you encountered when applying different evaluation criteria?
- Which existing frameworks (e.g., Lincoln and Guba; Corbin) do you utilize to assess the quality of qualitative research?
- If you were to propose novel strategies or methods for assessing the quality of qualitative research, what would they entail?

To conduct the interviews, they will be scheduled after obtaining the necessary permits and coordinating with participants on timing and location. Before starting each interview, the researcher will introduce herself to the interviewee and explain the purpose of the research. The researcher will also explain the possibility of recording the participant's voice, the principle of information confidentiality, and the participant's right to withdraw from the study. Informed consent will be obtained in written or oral form (Along with the recording of the participant's voice) (1).

The researcher will be obligated to obtain informed consent throughout the research process, from the beginning of the interview, during and after the interview, and until the end of the research, if needed, to ensure the participant's willingness to continue. Data collection and interviews will continue until data saturation occurs, meaning the categories are sufficiently enriched, and no new concepts are emerging (1).

Data analysis

The data will be analyzed using the approach of Graneheim and Lundman (2004). Simultaneously, data analysis will begin with the process of data collection through interviews. The researcher will listen to each of the recorded interviews and transcribe them word by word, paying close attention to the participant's tone during transcription. After conducting the interview, the researcher will first read the transcript several times to gain a general understanding of the study atmosphere (1,10).

In the next step, the analysis begins with a line-by-line examination of the text, dividing it into meaning units. The meaning units related to the purpose of the study will be selected. Following this, condensation will be performed, and coding will be done. After coding, the codes will be sorted into sub-categories based on the differences and similarities among the codes. Sub-categories will describe these similarities and differences and will be named based on their content. The formed sub-categories will be grouped into categories. As the analysis progresses, the researcher can move towards latent content analysis and identify the underlying themes (1).

Third three (Delphi)

In the third phase of the study, the Delphi method will be employed to gather expert opinions with the objective of improving the quality of qualitative research studies. This structured approach facilitates consensus-building among experts through a series of iterative feedback rounds. Initial recommendations for quality assurance, derived from the integrated findings of a scoping review and qualitative research conducted by the research team, will be shared with a panel of experts specializing in qualitative research methodologies.

These experts will be invited to review and provide constructive feedback on the proposed recommendations in two distinct rounds. During the first round, the experts will evaluate the preliminary recommendations, offering their insights and suggestions for improvement. Based on their input, the research team will refine and revise the recommendations to reflect the collective expertise and address any identified gaps or concerns.

In the second round, the revised recommendations will be presented to the same group of experts for a final review. This phase aims to achieve a high level of agreement and consensus on the proposed strategies. By the conclusion of the two Delphi rounds, the recommendations will be finalized, resulting in a comprehensive and rigorously developed framework for enhancing quality assurance in biomedical qualitative research. This method ensures the incorporation of diverse expert perspectives and promotes the development of robust, practical, and widely applicable quality assurance strategies.

Conclusion

Considering the substantial impact of qualitative research on knowledge development, scientists have consistently debated and expressed concerns about the rigor and quality of qualitative findings in the field of biomedical science. Applying quality assessment criteria has posed challenges for researchers in qualitative studies. Meanwhile, the emphasis on RRI practices highlights the significance of the trustworthiness of qualitative research and the need to reevaluate the criteria for assessing study quality. The researchers anticipate that the results of this research will assist those intending to conduct qualitative research in improving the quality of their studies. Additionally, it aims to guide reviewers and readers in evaluating the quality of published qualitative studies. The findings of this study can also help students and new career researchers by providing strategies to enhance the quality of qualitative methodology.

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Ethical statement

This study will be conducted with the approval of the Ethics Committee of the University of Social Welfare and Rehabilitation Sciences. Participants will be fully informed about the research process and will provide informed consent. Interviews will be recorded with the participant's knowledge and consent, ensuring the confidentiality of all personal information. The researchers are committed to publishing the study's findings in a manner that benefits stakeholders. This study will also undergo evaluation by the IR.USWR.REC.1403.193 Ethics Committee.

Conflicts of interest

The authors declare that they have no conflicts of interest.

Author contributions

HKh: Conceptualization, Methodology, Project administration, Writing - original draft, Writing - review and editing. MS: Drafting of the Protocol, Methodology. MM: Drafting of the Protocol. ShSh: Drafting of the Protocol, Methodology. UD: Conceptualization, Funding acquisition, Methodology, Writing - review and editing, and Supervision. All authors gave final approval for publication and agreed to be held accountable for the work performed therein.

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