

Critical Appraisal Checklist for Qualitative Research Studies

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Abstract. The ability to critically appraise literature is an essential skill for clinicians adopting a population perspective. Conventions exist for reporting and evaluating the quality of quantitative and epidemiological research. The same traditions do not exist in qualitative research for a number of reasons including the number of theories under which this type of research can be conducted and the subsequent incompatibility of indicators of quality. This paper presents a 10-point checklist for assessing the quality of qualitative research in clinical epidemiological studies. We aim to provide a framework for critical appraisal as well as offer direction for qualitative researchers in designing and publishing their work. [Indian Journal of Pediatrics, 2000; 67 (5) : 347-351]

Key words : Critical appraisal; Qualitative methods; Epidemiological research

Clinical epidemiology is an interdisciplinary field, combining concepts and methods from health, statistical and social sciences to generate evidence-based solutions to priority health problems. Recently, qualitative research approaches have been recognised within clinical epidemiology as appropriate for gathering data about the social and behavioural context of health status, care and treatment decisions and outcomes for different population and for generating hypotheses to be tested in subsequent epidemiological studies¹. With the increased use of qualitative methods in health research there is a growing need for investigators to develop skills for both appraising the quality of published qualitative studies and applying qualitative techniques appropriately. This article offers a practical framework for critical appraisal of qualitative research as well as guidelines for designing qualitative investigations.

While the purpose of qualitative research in clinical epidemiology is to provide a different (potentially complementary) type of data to quantitative studies, it nevertheless shares a concern with establishing the trustworthiness of data and of the inferences that can be drawn from findings. The formulation of standard conventions for assessing qualitative research has been hampered by the variety of theoretical approaches (and their preferred methods) which inform empirical studies². We argue that the qualities most appropriate for qualitative

studies within clinical epidemiology (and public health generally) include the ability of the data to be empirically grounded and rigorous (*i.e.*, collected systematically); produce findings which are generalisable to other settings; consider the effects of the researcher and research strategy on the findings (*i.e.*, reflexive); and, generate theoretical understanding of the health issue.³

This article presents a 10-point critical appraisal checklist for qualitative reports (Table 1). The checklist represents a synthesis of the guidelines for best practice offered in the literature. The key issues are presented and discussed with little use of jargon to promote an understanding and use of qualitative methods in clinical epidemiological studies.

1. Is the purpose of the study clearly stated?

The purpose of a qualitative study may be to develop an instrument, illustrate phenomena being addressed in a larger project, provide data on an issue which has not been fully investigated (sensitisation) or build theory (conceptualisation)⁴. A clearly stated purpose is critical to the reader's understanding of an article as it provides a context and generates a set of expectations for evaluation of the report⁴. The purpose of the study may be initially formulated as a broad statement or research question which may be modified or refined through the course of the study. The authors should state whether this alteration is anticipated and in what nature and direction⁵.

2. Is an appropriate rationale provided for using a qualitative approach?

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TABLE 1. Ten Key Issues in Critical Appraisal of Qualitative Research

Key Issues	Factors to consider
1. Is the purpose of the study clearly stated ?	Rationale for study explained Research question clearly presented Context in which results will be interpreted
2. Is an appropriate rationale provided for using a qualitative approach?	Maximise strengths of study design to address study purpose Researcher's expertise demonstrated
3. Do the researchers clearly outline the conceptual framework (if any) within which they are working?	Use of theory described (<i>i.e.</i> , descriptive level only; imposed on or generated from data) Researchers 'alive' to data outside of the theory/framework
4. Do the researchers demonstrate an understanding of the ethical implications of their study?	Appropriate informed consent Opportunity to withdraw Opportunity to retain data Participants given feedback about the study results Appropriate support (<i>i.e.</i> , debriefing and referral) available to participants Results anonymous/confidential Approval of institutional ethics committee and disclosure of funding source
5. Is the sampling strategy appropriate and will the sample represent the target group?	Sampling strategy explained and related to purpose of study Relationship between researchers and subjects explained Sample size explained Sample specifically defined
6. Does the research provide information about data collection procedures and how they were derived?	Relationship of method to research question Description of development of data collection tool (including revisions, changes in structure) Theme/concept list for interviews/group discussions Observation schedule for observations
7. Do the researchers describe the procedures for keeping data organised and retrievable?	Recording of data described (<i>e.g.</i> , audio tape, written notes) Transcriptions checked for accuracy Use of a software program described Field notes and memos kept and included in data analysis
8. What methods of data analysis are used and are they appropriate to address the study purpose?	'Blueprint' for replication Coding systems and interpretation processes clearly described More than one researcher involved
9. Does the researcher address the threats to reliability and validity in data collection, analysis and interpretation?	Prolonged engagement and immersion Peer debriefing and consultation Record of 'progressive subjectivity' Search for negative cases or disconfirming evidence Member checks and iteration Triangulation Audit trail and grounded interpretation Appropriate generalisation
10. Is there a clear progression from research question to conclusions drawn from data?	Clear analytic logic

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Qualitative methods are best applied in areas involving unexplored, sensitive or intense personal experiences, issues within small and difficult to access groups, culturally defined experiences or perspectives which the researcher does not share⁶. The rationale for using a qualitative approach should move beyond these considerations of the topic and population characteristics to detail why and how well the method(s) can address the study purpose, why the chosen approach is better than others and how the approach relates to the existing knowledge concerning the study purpose⁷. The researcher should also demonstrate expertise with the method through his/her awareness of the historical origin of the method selected, its past uses, controversies surrounding its use, and critical appraisal of past research which has employed the method⁵.

3. Do the researchers clearly outline a conceptual framework (if any) within which they are working?

In clinical epidemiological studies, most qualitative research is concerned with describing the issues of interest. At this level, no conceptual framework is used. Some authors will seek to explore the data from a theoretical perspective whereas others will generate theory from the data in a grounded manner⁸. Qualitative reports should clearly state whether the interpretation emerged from the data (*i.e.*, in the grounded theory tradition) or from a planned conceptual investigation.

Grounded theory approaches are favoured for hypothesis generation, exploring new and/or ill defined topics and action-based research⁹. Researchers should state if a literature review has been delayed (or excluded) and how this may have shaped the investigation⁵. Evidence of iteration (a systematic procedure for cycling between data, interpretation and theory building) should be presented if a grounded approach is employed¹⁰.

If the research adopts a conceptual framework, evidence from the data is sought to support the proposed theory or hypothesis. In such a case, a thorough literature review should be demonstrated as well as how the imposition of the framework will influence the interpretation of data⁵. Researchers using this approach must also be aware of data which may disconfirm or fall outside the theoretical framework¹¹.

4. Do the researchers demonstrate an understanding of the ethical implications of their study?

The in-depth, open-ended nature of qualitative methods makes ethical considerations of particular importance⁷.

Any research study should be guided by an institutional ethics committee and general ethical principles in recruitment of participants, data collection, analysis and dissemination of findings.

Anonymity and confidentiality are especially important because of the smaller number of participants often involved in qualitative research. Care should be taken to remove any identifying information from stored data and written reports⁹. Because of the potentially personal nature of information collected and the level of disclosure, the researcher should demonstrate care in defining the boundaries of their role, in allowing appropriate debriefing and in offering referral to professionals where necessary. Participants should have been offered the opportunity to retain a copy of the data they have provided and have access to feedback on research findings.

5. Is the sampling strategy appropriate and will the sample represent the target group?

Qualitative sampling techniques differ from the rigorous randomised strategies used in epidemiological research. Qualitative studies generally employ purposive sampling strategies where subjects are selected based on the richness of their experience with the area of study¹². The researcher should demonstrate how the sampling strategy aligns with the purpose of the study.

Bias as a result of sampling is an issue for qualitative research. Systematic bias in sampling can be minimised by including random selection where possible, such as selecting subjects at random from a list of possible subjects or, if seeking subjects through referral, approaching health care professionals at random. Bias may also be introduced through the relationship between the researcher and subjects, so this should be clearly described (*e.g.*, personal acquaintances, professional/client relationship)⁷.

While qualitative studies employ small sample sizes, the size of the sample should be determined by the point of redundancy, when no new information is gleaned from additional subjects and the key themes are consistently reiterated (sometimes called category saturation)¹¹. The qualitative researcher should specifically define and describe the target group or issue so that the reader can judge whether generalisations to other groups or issues are logical¹³.

6. Do the researchers provide information about data collection procedures and how they were derived?

Qualitative research methods collect rich information using a flexible approach. Methods commonly used include interviewing (with groups or individuals)^{14,15},

observation¹⁶ and document analysis¹⁷. The researcher should justify that the methods chosen were the most appropriate for the research purpose¹¹.

Researchers should describe the process of developing their data collection tools (*e.g.*, information derived from literature review, pilot studies, key informants, popular opinion). A key concern for researchers is the degree of structure built into data collection tools. It is appropriate that tools change over time, being refined or becoming more structured as research efforts are progressively focussed. Where the data collection tool is modified during data collection, the rationale behind these refinements should be explained in relation to the research question.

For interviews and focus group discussions, a theme or concept list should be provided showing the areas covered by the interviewer. Similarly, for observation studies, an observation schedule for recording the target observations and the overall context in which they occur should be provided. For analysis of documents or written material, a protocol for identifying appropriate material and method for extracting information from the material should be provided.

7. Do the researchers describe the procedure for keeping data organised and retrievable?

The voluminous amount of data produced by the interactive nature of qualitative research can leave researchers with data overload¹⁸ and threaten the reliability of the study. Researchers should demonstrate that data are managed in a systematic way. They should describe how the data were recorded (*i.e.*, audio tape, video tape, researcher notes), the transcribing process and the method of verifying transcript accuracy⁷. Computer programmes used to store data and assist with analysis should also be described. Researchers often make field notes and memos which record reflections, impressions and ideas for analysis and interpretation. The means of including these field notes and memos in the data analysis process should be explained.

8. What methods of data analysis are used and whether they are appropriate to address the research question?

Regarding data analysis, there are no absolute rules except the use of one's full intellect to fairly represent the data and communicate what the data reveal, given the purpose of the study. In the absence of formal guidelines, reports of data analysis procedures should give enough details to form a 'blue print' for other researchers to follow^{7,19}. Information about coding systems used and refinements made to them as well as processes of interpretation should

be included. More than one person should be involved in the data analysis process to include perspectives of another researcher^{11,18}.

9. Do the researchers address the threats to reliability and validity in data collection, analysis and interpretation?

Some qualitative research traditions downplay the relevance of reliability and validity because of their long association with positivist and quantitative work. Further, some authors warn that a report does not represent an unchallengeable reality, but is knowledge constructed as part of the research process⁷. Alternate concepts to reliability and validity, such as trustworthiness, credibility, transferability and dependability have been proposed as more relevant to qualitative investigations²⁰. The key concept of qualitative application of all these terms is the move to minimise the effects of bias on data collection, analysis and interpretation or make apparent where uncontrolled bias may have had an effect.

Each of the previous sections in this critical appraisal checklist have addressed issues to minimise biases and hence minimise threats to reliability and validity (or promote the trustworthiness) of the conclusions drawn from the qualitative data. Further techniques to minimise bias can be employed in all aspects of the research process.

An investigator's prolonged contact can facilitate familiarity with the context and subject of inquiry. The opportunity to consult other researchers and debrief with peers opens the data and its interpretation to critics and deeper understanding. The researcher should maintain a record of his or her progressive subjectivity as a record of the researcher's internal processes²⁰.

The researcher should search for negative cases or disconfirming evidence to extend the interpretation of the data. The researcher can undertake 'member checks' and interactive cycling of the data with participants at a number of points in the research projects (*e.g.*, confirm that the data were recorded, summarised and interpreted accurately)¹⁸.

Triangulation is a menu of techniques aimed at ensuring that the findings are not an artefact of a single method, a single source or a single investigator's biases²¹. This menu includes using multiple data sources, multiple methods of examining the data, multiple researchers and multiple theoretical perspectives.

The researcher should undertake to provide an audit trail which can be used to show that all conclusions drawn can be traced to the data and its source²⁰. Interpretations of the data should be grounded in the data itself¹⁰ using *in*

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vivo codes (taken from the language used by the informant) and quotes from the data to aid interpretation¹⁹. Generalisations from the data should be appropriate and related to the study purpose as well as bounded by the scope of the sample from which the data were drawn.

10. *Is there a clear progression from research question to conclusions drawn from data?*

A report of qualitative research should contain a strong and clear analytic story throughout the text²². Each decision and activity in the project should relate to this analytic logic and be apparent in the description of the process.

Conclusions

This article outlined ten issues for critical appraisal of qualitative research which are related to a number of underlying themes. All activity within a research project should be related to the research question or underlying logic. Bias is an inherent threat to any research endeavour and steps should be taken within each activity to minimise its effects. In research reports the activities and procedures should be clearly described so that the reader can come to his or her own conclusions about the trustworthiness of the methods, analytical procedures and interpretation of the data. A further challenge for qualitative researchers is to present the degree of detail needed to address these issues in journal papers where space is limited.

We believe that the use of qualitative methods is a valuable and suitable tool for research in clinical contexts. This checklist presents a guide for qualitative research undertaken within clinical epidemiological studies.

REFERENCES

1. Creswell J.W. *Qualitative Inquiry and Research Design: Choosing Among Five Traditions*. London; Sage, 1998.
2. Connor L, Treloar C, Higginbotham N. How to perform transdisciplinary research: Qualitative methods and approaches. In: Higginbotham N, Albrecht G, Connor L eds. *Health Social Science: A Transdisciplinary Perspective*. Oxford University Press (in press).
3. Denzin NK, Lincoln YS. *Handbook of Qualitative Research*. Thousand Oaks; Sage Publications, 1994.
4. Knafl KA, Howard MJ. Interpreting and reporting qualitative research. *Research in Nursing and Health* 1984; 7 : 17-24.
5. Cobb AK, Hagemaster JN. Ten criteria for evaluating qualitative research proposals. *J Nurs Educ* 1987; 26 : 138-143.
6. Krahn G, Hohn MF, Kime C. Incorporating qualitative approaches into clinical child psychology research. *J Clin Child Psychol* 1995; 24: 204-213.
7. Banister P, Burman E, Parker I, Taylor M, Tindall C. *Qualitative Methods in Psychology: A Research Guide*. Buckingham; Open University Press, 1994.
8. Glaser B, Strauss A. *Discovery of Grounded Theory: Strategies for Qualitative Research*. Chicago; Aldine de Gruyter, 1967.
9. Britten N, Jones R, Murphy E, Stacy R. Qualitative research methods in general practice and primary care. *Family Practice* 1995; 12 : 104-114.
10. Stiles WB. Quality control in qualitative research. *Clin Psychol Rev* 1993; 13 : 593-618.
11. Patton MQ. *Qualitative Evaluation and Research Methods*. Newbury Park; Sage Publications, 1990.
12. Kuzel AJ. Sampling in qualitative enquiry. In: Crabtree BJ, Miller WL eds. *Doing Qualitative Research*. Newbury Park; Sage Publications, 1992; 31-44.
13. Borman KM, LeCompte MD, Goetz JP. Ethnographic and qualitative research design and why it doesn't work. *American Behavioral Scientist* 1986; 30 : 42-57.
14. Bernard HR. Unstructured and semistructured interviewing. In: *Research Methods in Cultural Anthropology*. Newbury Park; Sage Publications, 1988; 203-229.
15. Morgan DL. When to use focus groups and why. In: *Successful Focus Groups: Advancing the State of the Art*. Newbury Park; Sage Publications, 1993; 3-25.
16. Adler PA, Adler P. Observational techniques. In: Denzin NK, Lincoln YS eds. *Handbook of Qualitative Research*. Thousand Oaks; Sage Publications, 1994; 377-392.
17. Hodder I. The interpretation of documents and material culture. In: Denzin NK, Lincoln YS eds. *Handbook of Qualitative Research*. Thousand Oaks; Sage Publications, 1994; 393-402.
18. Miles M, Huberman A. *Qualitative Data Analysis: A Source Book of New Methods*. London; Sage Publications, 1994.
19. Strauss AL. *Qualitative Analysis for Social Scientists*. Cambridge; Cambridge University Press, 1987.
20. Guba EG, Lincoln YS. *Fourth Generation Evaluation*. Newbury Park; Sage Publications, 1989.
21. Willms D, Johnson N. *Essentials in Qualitative Research: A Notebook for the Field*. 1993.
22. Engel JD, Kuzel AJ. On the idea of what constitutes good qualitative inquiry. *Qualitative Health Research* 1992; 2 : 504-510.