2021 China Primary Health Care and General Practice Research Methodological Quality Assessment Report: Qualitative and Mixed-Methods Research Section Postprint

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Abstract

Background General practice has significant interdisciplinary characteristics, and both qualitative and mixed-methods research are applicable to scientific work in this field. In recent years, the number of relevant academic papers published in China has steadily increased, but the overall quality of the literature has not yet been systematically evaluated.

Objective To investigate the methodological quality of qualitative research and mixed-methods research literature published in the field of general practice and primary healthcare.

Methods From August 2022 to April 2023, four researchers used the qualitative research appraisal tool from the Critical Appraisal Skills Programme (CASP) and the Mixed Methods Appraisal Tool (MMAT) to analyze and evaluate the methodological quality of qualitative research and mixed-methods research published in China's general practice and primary healthcare field in 2021. Researchers were paired into two groups to independently conduct information extraction and quality appraisal.

Results A total of 35 qualitative research articles and 9 mixed-methods research articles were included. The main issues in qualitative research included: 65.71% (23/35) of studies did not adequately consider ethical issues; 94.29% (33/35) of studies did not discuss participant recruitment; 82.86% (29/35) of studies did not adequately consider the relationship between researchers and participants; 42.86% (15/35) of studies had a sample size <20, and 25.71% (9/35) of studies did not discuss data saturation. The main issues in mixed-methods research included: 88.89% (8/9) of studies did not clearly report the type of mixed-methods

research design, and 88.89% (8/9) of studies failed to effectively integrate the different components of the research to jointly answer the research question.

Conclusion The methodological quality of such studies published in recent years in China's general practice and primary healthcare fields still has certain limitations, particularly severely limited in terms of ethics, reliability, and data saturation in qualitative research, and integration in mixed-methods research. It is necessary to further strengthen training in research methodology and strictly adhere to research design and reporting standards to improve the quality of research work and the resulting evidence.

Full Text

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Report on Methodological Quality Assessment of Primary Care and General Practice Research in China in 2021: Qualitative and Mixed Methods Research Section

Quality Assessment Group for Qualitative and Mixed Methods Research in General Practice and Primary Care in China, Chinese General Practice

Abstract

Background General practice has significant interdisciplinary characteristics, and both qualitative research and mixed-methods research are applicable to scientific research in this field. In recent years, there has been a steady increase in the number of relevant academic papers published in China, but the overall quality of the literature has not been systematically assessed.

Objective To explore the methodological quality of qualitative and mixed methods research literature published in the field of general practice and primary care.

Methods From August 2022 to April 2023, four investigators analyzed and assessed the methodological quality of qualitative and mixed methods studies published in the field of general practice and primary care in China in 2021 using the qualitative assessment tools of Critical Appraisal Skills Programme (CASP) and Mixed Methods Appraisal Tool (MMAT), respectively. The researchers were grouped in pairs and independently for information extraction and quality evaluation.

Results A total of 35 qualitative research papers and 9 mixed methods research papers were included. Among the qualitative studies, 23 literature (65.71%) did not sufficiently consider ethical issues; recruitment of participants was not discussed in 94.29% (33/35) of the studies; the relationship between the researcher and the participants was not adequately considered in 82.86% of the studies;

42.86% (15/35) of the studies had a sample size of <20 participants and data saturation was not discussed in 25.71% (9/35) of the studies. Major problems with mixed-methods studies included the fact that: 88.89% of the studies (8/9) did not explicitly report the type of mixed methods research design and 88.89% of the studies (8/9) failed to effectively integrate the different components of the study to answer the research question.

Conclusion The methodological quality of such studies in general practice and primary care published in recent years in China is still partially limited, especially in the ethics, reliability and information saturation among qualitative studies, and the integration among mixed methods researches, which should be further strengthened by training in research methodology and strict adherence to research design and reporting statements in order to improve the quality of research and even evidence for decision making.

Key words Qualitative research; Mixed methods research; Critical Appraisal Skills Programme; Mixed Methods Appraisal Tool; Methodological quality

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General practice is both a unique comprehensive clinical discipline and a core specialty supporting China's basic medical and health services. Research in this field exhibits typical interdisciplinary characteristics, involving clinical medicine, social medicine, medical psychology, and other domains. In practice, general practitioners need the capacity to diagnose and treat multiple diseases while also implementing long-term disease follow-up and management for patients. Therefore, research methods in this discipline include not only clinical epidemiological quantitative approaches but also qualitative methods commonly used in social sciences, as well as mixed methods research that organically integrates quantitative and qualitative studies.

Compared with widely used quantitative research methods such as cross-sectional surveys and randomized controlled trials, qualitative research methods are particularly valuable for evaluating patient and physician perspectives and preferences regarding specific health services, exploring the complexity of general practice, and developing new concepts and theoretical frameworks from practice. Mixed methods research, as a relatively novel approach, can generate more comprehensive, in-depth, and insightful findings through the dual implementation and effective integration of quantitative and qualitative research.

In recent years, the application of qualitative and mixed methods research in China's general practice and primary care fields has been increasing annually, with a growing number of domestic research papers published. However, methodological quality assessment of studies using these approaches in this field remains lacking. As part of the "2021 China Basic Medical and Health Service Research Quality Assessment Project" initiated by *Chinese General Practice*, this study primarily evaluates the methodological quality of qualitative and mixed methods research published in Chinese academic journals in 2021 in the

fields of general practice and primary care, summarizes experiences and identifies main problems in study design and reporting, and aims to provide references for researchers in related fields, thereby enhancing research capacity and generating high-quality evidence.

1.1 Literature Search and Inclusion

This study builds upon a previous scoping review titled "Research Productivity of Basic Medical and Health Care and General Practice in China in 2021." Detailed literature search and classification methods can be found in the original paper. Based on that study, from August 2022 to April 2023, two scientific editors extracted 35 qualitative research papers and 9 mixed methods research papers (including 2 multi-method studies with designs similar to mixed methods) from 3,122 articles, representing literature published by Chinese researchers in 2021 in the fields of general practice and primary care where original articles were accessible.

1.2 Methodological Quality Assessment

For qualitative research papers, we used the "Critical Appraisal Skills Programme" (CASP) qualitative research evaluation tool. This tool has been widely used to assess the reliability and validity of qualitative research in medical fields, covering dimensions such as research purpose, methodology, study design, sampling, data collection, researcher reflexivity, ethics, data analysis, research findings, and research value.

For mixed methods research, we used the Mixed Methods Appraisal Tool (MMAT). This tool is suitable for evaluating the design, implementation, analysis, and reporting of mixed methods research. Its evaluation content involves two screening questions, followed by sequential assessment of the qualitative component, quantitative randomized controlled trials, quantitative non-randomized controlled trials, quantitative descriptive studies, and the mixed methods component.

1.3 Recruitment of Evaluators and Implementation of Assessment

The recruitment of evaluators and group construction methods for this study were similar to those used for the quantitative research assessment component. All four evaluators possessed extensive theoretical and practical experience in research methodology, including three with general practice backgrounds and one clinical research methodology specialist. The evaluators were divided into two groups, each independently assessing half of the randomly assigned studies, after which results were compared. Any disagreements were resolved through group discussion or consultation with a third party. Based on the principle of avoidance, evaluators could not assess the quality of literature published by their own institutions.

1.4 Results Recording and Analysis

Evaluation results were recorded using Microsoft Excel 2019, and data were described using SPSS 27.0. Frequencies and percentages were used to describe different outcomes across methodological quality assessment items. Non-normally distributed measurement data were expressed as median (P25, P75).

2.1 Basic Characteristics of Qualitative Studies

This study included 35 qualitative research papers in the general practice field. Chinese-language literature accounted for 74.29% of the total. Regarding the types of problems addressed using qualitative research, 37.14% involved status, needs, or problems; 25.71% investigated influencing factors; 22.86% evaluated intervention implementation; and 14.29% explored experiences and perspectives. Participants were primarily medical personnel (57.14%). In terms of research methodology, general qualitative research dominated (82.86%). For data collection methods, individual interviews were used in 62.86% of studies, and focus group interviews in 28.57%. Basic characteristics of the included literature are shown in Table 1 .

2.2 Methodological Quality of Qualitative Studies

Overall, all papers demonstrated high methodological quality in three aspects: clearly stating research purposes, appropriately applying qualitative research methods, and suitability of study design for research objectives. Common methodological quality issues involved four aspects: failure to discuss participant recruitment (94.29%), lack of self-reflection on researcher influence during data analysis (85.71%), only 40.00% of studies reporting ethics committee approval, and insufficient discussion of evidence supporting and opposing researcher viewpoints (57.14%). Additionally, 48.57% of papers did not address the reliability of findings, and 48.57% did not discuss whether and how results could be applied to other populations. Detailed quality assessment results are shown in Table 2 .

2.3 Basic Characteristics of Mixed Methods Studies

This study analyzed 9 mixed methods research papers, of which 55.56% were Chinese-language literature. The literature primarily focused on intervention implementation evaluation (66.67%). The vast majority did not explicitly specify the type of mixed methods research design used (88.89%). Data collection mainly employed individual interviews + questionnaire surveys (66.67%). More than half of the studies had a qualitative component sample size of <20 participants (55.56%), and two-thirds had a qualitative component sample size of <40 participants (66.67%). Other basic characteristics are shown in Table 3 .

2.4 Methodological Quality Assessment of Mixed Methods Studies Using MMAT

Among the included mixed methods studies, the quality scores for the qualitative component were all >3 points, with 5 papers achieving 5 points (55.56%). The quality of data collection and results interpretation in the qualitative component needed improvement. The quantitative component consisted entirely of descriptive studies with relatively low quality scores; 2 papers scored only 2 points, and only 55.56% had sampling methods appropriate for answering the research question. In the mixed methods component, most papers had poor quality, with only 1 paper effectively integrating qualitative and quantitative components. This indicates insufficient interpretation of qualitative and quantitative results, and difficulty in meeting qualitative or quantitative quality standards in mixed methods research. Detailed quality assessment results are shown in Table 4 .

This study aims to summarize experiences and problems presented in the evaluated studies from a methodological quality perspective, providing references for researchers conducting basic medical and health service research in the future. Based on qualitative and mixed methods research papers published in China's basic medical and health service field in 2021, this study identified five common problems affecting methodological quality, which are discussed below in conjunction with methodological theory.

Problem 1: Insufficient Attention to Ethical Risks in Qualitative Research

The most alarming finding in our analysis is that nearly 60.00% of qualitative studies lacked ethics reporting. Even among qualitative studies published in *Chinese General Practice* in 2021, nearly half did not report ethical statements in the text. This undoubtedly warrants serious attention from research institutions, researchers, and academic journals. Although the application and review procedures for research ethics in China's current primary healthcare institutions are relatively cumbersome, this cannot justify neglecting ethical issues in qualitative research. According to Richards and Schwartz, participants in health services qualitative research may face five types of risks and harm: interviews themselves may trigger emotional and psychological anxiety; power oppression may exist between researchers and participants; participants' autonomy may be constrained by research design and implementation; personal information may be leaked; and participants may suffer time and other losses. Given the interaction time and mutual influence between researchers and participants in qualitative research, the potential for participant harm may be higher than in observational studies and approach that of some interventional studies. Therefore, research institutions, researchers, and academic journals should take action to supervise and prevent ethical risks in qualitative research in this field—this is an urgent task.

Problem 2: Failure to Clearly Report Participant Selection and Ex-

clusion

Our evaluation of 35 qualitative studies revealed that while $ $60.00% of studies detailed their rationale for selecting interviewees, only about 5.00% of papers explained why other potential interviewees were excluded. Considering that most evaluated literature explored primary care and general practice-related policies, services, and clinical practice issues from patient and medical personnel perspectives, failure to report reasons for excluding participants may raise reader and editor concerns about researcher conflicts of interest. For example, one evaluated study examined satisfaction with an APP developed by a district/county CDC. Conducted by CDC staff, with interviewees from community health service centers in the same district/county, results showed high satisfaction among patients and doctors. However, without clear reporting of the participant recruitment process, the conclusions may be subject to "conflict-of-interest suspicion," affecting reliability. Bourdieu's classic case emphasizes the negative impact of inadequate consideration when selecting participants: "Or when examining the knowledge field of judges in the 1950s, you omit Sartre, or when studying American academia, you omit Princeton University. As long as these types of figures and institutional entities still hold significant positions, your field is an incomplete one." Since qualitative research information depends primarily on participants, in-depth consideration must be given when selecting and excluding participants, with sufficient background information provided to readers. The Consolidated Criteria for Reporting Qualitative Research (COREQ) also requires authors to clearly report "how many people refused to participate and why?" to ensure qualitative research arguments are well-founded.

Problem 3: Inadequate Reporting of Researcher Roles and Influence

Another important problem identified is that over 80.00% of qualitative studies did not report how researcher characteristics and relationships with participants might potentially influence study design, processes, and results. Similar to the previous issue, this raises questions about result reliability due to potential status inequality between researchers and participants, as well as researcher-stakeholder relationships with research questions and outcomes. A key difference between qualitative and quantitative research is that researchers in qualitative studies simultaneously play dual roles as researchers and research instruments. As researchers, their personal tendencies influence qualitative research questions and perspectives; as research instruments, their personal characteristics affect social relationships, interactions, interview information authenticity and validity, and information selection, analysis methods, and results with interviewees. Therefore, in qualitative research, reflexivity—the researcher's reflection on their own role and influence in the research process—is considered, like reliability, one of the main quality standards for such research. For example, in one evaluated study, the researcher's institution was a community health service center, study participants were the center's staff, and the issue examined was employee satisfaction, with the main conclusion being high satisfaction. However, the paper did not fully report the researcher's background, specific relationships

with interviewees, or how these relationships might affect information acquisition and analysis. It also did not state whether research results were submitted to participants for review. In such cases, readers inevitably question whether the researcher's personal experiences and characteristics might affect subordinates/colleagues' provision of authentic satisfaction information, and whether the researcher, as a community health service center staff member, might develop cognitive biases when analyzing qualitative information due to personal experiences, potentially affecting research results and their interpretation.

Problem 4: Potentially Inadequate Sample Sizes in Some Qualitative Studies

In our evaluated studies, about 1/4 did not report data saturation, and about half had fewer than 20 participants. This may also raise reader questions about the adequacy of sample size and information volume in qualitative research. The minimum sample size required for qualitative research has long been a hotly debated issue. Unlike quantitative research, which calculates minimum sample size through mathematical formulas, qualitative research sample size calculations are typically derived theoretically from data or thematic saturation, mostly based on rules of thumb and varying by research question. Therefore, researchers' own reports of data saturation are often considered one of the judgment criteria. However, there are at least two commonly used evaluation methods in academia: assessment based on past empirical data (typically using 9-17 in-depth interviews or 4-8 focus groups as reference sample sizes for small qualitative studies) and calculating minimum sample size for data saturation through quantitative formulas. Given that China's general practice and basic medical and health service system are in a rapid development phase, many qualitative studies focus on common universal issues such as basic public health service projects, family doctor contract systems, chronic diseases and common diseases in the elderly, and personnel training. Moreover, the patient and doctor populations involved in China's basic health services are both large and complex. While this study cannot assert that small-sample qualitative studies cannot explore important issues, some studies with overly small sample sizes may indeed have serious quality limitations. For example, one qualitative study examining the scientific research management system in community health centers only interviewed 5 primary care research managers from a district/county and did not report consideration of information saturation. This design means the maximum applicability of research results may be limited to that district/county's community health service centers, potentially limiting both result reliability and transferability—the applicability of research results to similar institutions and personnel in other regions.

Problem 5: Inadequate Understanding of Mixed Methods Integration Design

When evaluating mixed methods studies, we identified two frequently occurring problems: lack of reporting on mixed methods research types (nearly 90.00%) and inadequate integration of mixed methods research components

(over 50.00%). Both issues involve the core design concept of mixed methods research—generating the most valuable "1+1=3" component based on quantitative and qualitative research. This highlights that as a relatively advanced and complex research method, its methodology and design theory still require further dissemination and training in China's general practice and primary care fields. Regarding the three basic designs of mixed methods research for different contexts—convergent design, explanatory sequential design, and exploratory sequential design—their concepts, steps, application scenarios, and corresponding integration methods have been detailed in a methodological paper published by our research team at the end of 2022. Using a JAMA Network Open study on factors associated with the use of low-sodium salt substitutes among rural hypertension and coronary heart disease patients (a topic closely related to behavioral interventions in chronic disease management in China's primary care) as an example, the paper comprehensively demonstrated how to conduct joint display and meta-inference in mixed methods research. The meta-inference section illustrated three common scenarios in mixed methods research integration: Confirmation, Expansion, and Discordance. Therefore, this study will not elaborate excessively on basic methodological theory but only recommends that researchers in China's general practice and primary care fields pay more attention to the unique design content of mixed methods research beyond basic quantitative and qualitative studies. In particular, they need to emphasize the mutual empowerment, verification, and complementary design of qualitative and quantitative components in four stages—research questions, research methods, research results, and research reports—and the further insights generated thereby.

Based on these five problems and consensus opinions from all evaluators, this study proposes four recommendations for relevant research managers, researchers, and academic journal editors: (1) To maintain the research reputation and improve research quality in general practice and primary care, high attention should be paid to ethics application and review in qualitative research. (2) Emphasis should be placed on checking the reliability of qualitative research, focusing on the validity of design, process, and results and corresponding verification methods. In particular, the two easily overlooked aspects—participant checking and reflexivity checking—should limit potential negative researcher impacts through transparent reporting and effective review. (3) Qualitative research should ensure adequate sample size and information volume. Although academic debate continues, to ensure necessary information saturation and transferability of research results, research projects addressing universal research questions should avoid implementing and publishing qualitative studies recruiting only a few participants when research conditions permit. (4) When research conditions allow, emphasis on the design and integration components of mixed methods research should be strengthened. This will stimulate the value and research potential of mixed methods research, making it an important approach for generating high-quality evidence in general practice and primary care, and prevent it from becoming a "gimmick" that

simply combines poorly conducted quantitative and qualitative studies to hype methodological concepts.

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Note: Figure translations are in progress. See original paper for figures.