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Beyond Exploratory: A Tailored Framework for Designing and Assessing Qualitative Health Research

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ABSTRACT

Objective: To develop a framework for assessing the rigor of qualitative approaches that identifies and distinguishes between the diverse objectives of qualitative health research.

Study Design: Narrative review of published literature on qualitative guidelines and standards from peer-reviewed journals and national funding organizations that support health services research, patient-centered outcomes research, and other applied health research fields.

Principal Findings: We identify and distinguish three distinct objectives of qualitative studies in applied health research: exploratory, descriptive, and comparative. For each objective, we propose methodological standards that may be used to assess and improve rigor across all study phases—from design to reporting. Similar to quantitative studies, we argue that standards for qualitative rigor differ, appropriately, for studies with different objectives and should be evaluated as such.

Conclusions: Distinguishing between different objectives of qualitative health research improves the ability to appreciate variation in qualitative studies as well as appropriately evaluate the rigor and success of studies in meeting their own objectives. Researchers, funders, and journal editors should consider how adopting the criteria for assessing qualitative rigor outlined here may advance the rigor and potential impact of qualitative health research.

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1 In recent decades, the role of qualitative research in health services research (HSR) and allied
2 fields has maintained steady, yet unsettled, interest and value. Evidence of steady interest
3 includes publication of qualitative reviews and guidelines by leading journals including *Health*
4 *Services Research*^{1,2}, *Medical Care Research and Review*³⁻⁵, and *BMJ*^{6,7}, and by funders
5 including the Robert Wood Johnson Foundation⁸, National Institutes of Health^{9,10}, and National
6 Science Foundation.^{11,12} In fields such as patient-centered outcomes research (PCOR) and
7 implementation science, qualitative research has been embraced with particular enthusiasm for
8 its ability to capture, advance, and address questions meaningful to patients, clinicians, and other
9 healthcare system stakeholders.^{2,13} The majority (41/50) of pilot projects awarded by the Patient-
10 Centered Outcomes Research Institute (PCORI) incorporated qualitative methods.¹³

11 Yet, despite this sustained interest, the status of qualitative health research remains
12 unsettled, as illustrated by *BMJ's* changing engagement with the method. After championing
13 qualitative methods in 2008^{7,14-17}, *BMJ* editors in 2016 noted that they tended to assign low
14 priority to qualitative studies because such studies are "usually exploratory by their very
15 nature".¹⁸ This statement came in response to an open letter from scholars arguing that *BMJ*
16 should adopt formal policies and training for editorial staff on what distinguishes "good from
17 poor qualitative research" rather than de-emphasizing the method *in toto*.¹⁹ In sum, despite
18 sustained interest from the HSR community, the status of qualitative research remains contested.
19 This status reflects debate over the purpose of qualitative research—*is it a valuable tool to*
20 *advance the field or a low-priority exercise in exploration?*—and an ongoing desire for
21 guidance on how best to distinguish high- from low-quality qualitative research.

22 Assessing rigor and quality in qualitative research is challenging because qualitative
23 methods are epistemologically diverse.²⁰⁻²² This diversity is a strength because it allows for the

1 theoretical and methodological flexibility necessary to engage with a specific topic.¹⁶ However,
2 it also means that investigators do not necessarily approach qualitative research using a unified
3 set of evidentiary rules.²² Thus, scholars may measure the quality of studies using different or
4 even incompatible yardsticks.

5 The challenge of diverse epistemologies has become more acute as qualitative health
6 research has expanded beyond its historical roots in phenomenological or grounded theory
7 studies. Contemporary researchers may use qualitative data and methods to improve the
8 descriptive accuracy of health-related phenomena that have already been characterized by
9 exploratory work or are difficult to capture using other approaches.²³ Researchers also use larger-
10 scale, comparative qualitative studies in ways that resemble quantitative efforts to identify
11 explanatory pathways.²⁴ Therefore, assessing the rigor of a specific qualitative study benefits
12 from first identifying the analytic goals and objectives of the study—i.e. identifying which
13 yardstick investigators themselves have adopted—and then using this yardstick to examine how
14 the study measures up.

15 To address these challenges, we propose a tailored framework for designing different types
16 of qualitative health research common within health services research. The framework
17 recognizes that qualitative investigators have different objectives and yardsticks in mind when
18 undertaking studies and that rigor should be assessed accordingly. We distinguish three central
19 types of qualitative studies common in applied health research: exploratory, descriptive, and
20 comparative. For each type of study, we propose preliminary methodological considerations to
21 help improve rigor across all study phases—from design to reporting. As is the case for
22 quantitative studies, we argue that standards for qualitative rigor differ, appropriately, for
23 different kinds of studies. A tailored framework can help editors, funders, and researchers move

beyond a "one-size-fits-all" approach for conducting and assessing the variety of rigorous approaches comprising qualitative research. The proposed framework offers a nuanced set of tools by which to recognize high-quality qualitative research. The framework also supports efforts to shift debates over the value of qualitative research to discussions on how we can promote rigor across different types of valuable qualitative studies, and underscore how qualitative methods can advance clinical and applied health research.

DESIGNING A TAILORED FRAMEWORK: METHODS AND RESULTS

Our framework is based on a narrative review of published guidelines and standards discussing the scientific conduct of qualitative health research. We drew primarily from peer-reviewed articles and reports published by journals widely read by the HSR community, and by major funders or sponsors of qualitative health research.^{1–8,10–12,21,25–27} In contrast to previous studies²⁸, we did not seek to synthesize these guidelines. Rather we drew upon them to develop a conceptual framework for designing and assessing rigorous qualitative research.

Range of Approaches in Qualitative Research

Qualitative research incorporates a range of methods including in-depth interviews, focus groups, ethnography, and many others.²⁹ Even within a single method, accepted approaches and standards for rigor vary depending upon disciplinary and theoretical orientations. Correspondingly, qualitative research cannot be defined by a single theoretical approach or data collection procedure. Rather many, often debated, approaches exist with distinct implications for appropriate standards for data collection, analysis, and interpretation.

On one end of the spectrum, qualitative researchers guided by the principles of realism

1 subscribe to the assumption that rigorous scientific research can provide an accurate and
2 objective representation of reality, and that objectivity should be a primary goal of all scientific
3 inquiries, including qualitative research.³⁰ These qualitative researchers generally consider
4 standards such as validity, reliability, reproducibility, and generalizability as similarly legitimate
5 yardsticks for qualitative research as they are in quantitative research.³¹ On the other end of the
6 spectrum, relativist approaches to qualitative research typically argue that all research is
7 inherently subjective and/or political³², and some relativists criticize the scientific approach
8 specifically because it claims to be objective.^{33,34} Much of applied qualitative health research
9 falls somewhere between the two ends of the spectrum. For example, Mays & Pope (2000)
10 consider themselves “subtle realists.” They acknowledge that all research involves subjectivity
11 and includes political dimensions, but they also contend that qualitative research should,
12 nevertheless, be assessed by a similar set of quality criteria as quantitative studies. Although we
13 recognize the value strictly relativist approaches provide, the framework we propose is designed
14 primarily for researchers, reviewers, and readers operating under a realist (or subtle realist)
15 framework and to help advance discussions of how best to communicate theoretical and
16 epistemological standpoints of individual investigators across assessments of qualitative rigor.

18 *Tailored Framework for Qualitative Health Research*

19 Given the diversity of approaches, a foundational step to improving the assessment of rigor in
20 qualitative research is to abandon the attempt to develop a single standard for best practices.
21 Instead, standards must begin with an assessment of study objectives, an approach that is similar
22 to standards for quantitative PCOR research³⁵ and mixed-methods research.³³ In this vein, we
23 identified and defined three general types of studies broadly used in applied qualitative health

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1 research (*See* Figure 1). These three types reflect differences in primary study objectives and
2 existing knowledge within a topic area.
3 <INSERT FIGURE 1>
4 In Table 1, we provide preliminary distinctions on how exploratory, descriptive, and comparative
5 studies compare across a range of standards and guidelines that have been proposed for
6 qualitative research (*See* Table 1). Regardless of study type, researchers should report study
7 details in clear, comprehensive ways, using standardized reporting guidelines whenever possible.
8 ^{34,35}
9 <INSERT TABLE 1>
10 Compared to descriptive or comparative studies, exploratory studies approach the topic of
11 study primarily in an inductive fashion to investigate areas of potential research interest that
12 remain mostly or wholly unexamined by the scientific community. Investigators undertaking
13 exploratory studies typically have few expectations for what they might find, and their research
14 design and approach may shift dramatically as they learn more about the phenomena of interest.
15 An example of an exploratory study is a study that uses convenience sampling and unstructured
16 interviews to explore what patients think about a new treatment in a single healthcare setting.
17 At the opposite end of this spectrum, investigators conducting comparative studies aim to
18 use a deductive approach designed to compare and document how well-defined qualitative
19 phenomena are represented in different settings or populations. The qualitative methods
20 employed in a comparative study are typically defined in advance, sampling should be
21 systematic and structured by aims, and investigators enter the field with hypothesized ideas of
22 what findings they may uncover and how to interpret those findings in light of previous research.
23 An example of a comparative study is a multi-site ethnography that seeks to compare how

1 patient-provider communication varies by location, and uses random sampling of patient-
2 provider interactions to collect data.

3 Descriptive studies occupy a middle position. Such studies build on previously-conducted
4 exploratory work so researchers will be able to proceed with more-focused inquiry. This should
5 include well-defined procedures including sampling protocols and analytic plans, and
6 investigators should articulate expected findings prior to beginning the study. However, as
7 researchers investigate phenomena in new settings or patient populations, it is reasonable to
8 expect descriptive studies to generate surprises. Thus, descriptive studies also feature inductive
9 elements to detect unexpected findings, and must be flexible enough in design to accommodate
10 shifts in research focus and methods based on empirical findings. An example of a descriptive
11 study is a longitudinal study of ovarian cancer patients that employs semi-structured interviews
12 and directed content analysis to examine decision-making across patients in a novel setting.

13 14 **DISCUSSION**

15 Our review identified a number of qualitative standards and guidelines that have been published.
16 The conceptual framework we present here builds on those extant guidelines through the
17 recognition that qualitative health research includes studies of diverse theoretical and
18 epistemological orientations, each of which has distinct understandings of scientific quality and
19 rigor. Given this intellectual diversity, it is inappropriate to use a single yardstick for all
20 qualitative research. Rather, assessments of qualitative quality must begin with an assessment of
21 a study's theoretical orientations and research objectives to ensure that rigor is assessed on a
22 study's own terms. This paper builds on previous discussions of qualitative rigor by describing
23 how dimensions of rigor can be fruitfully expanded to include the assessment of studies that

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1 adopt exploratory, descriptive, or comparative objectives.

2 Existing standards for conducting health research and grading evidence, such as GRADE³⁶,

3 do not capture the diversity of qualitative studies—often designating all qualitative studies as

4 weak. PCORI's own methodological standards have been largely silent regarding qualitative

5 methods until recently³⁵, leaving applicants without clear direction on how to conduct rigorous

6 qualitative research. Incorporation of tailored qualitative standards could help to clarify and

7 improve the rigor of proposal design, review, and completion. Such standards could also guide

8 journal editors in developing transparent standards for deciding priorities for publication. For

9 example, editors may decide against publication of exploratory or descriptive studies, but

10 prioritize well-executed comparative studies that advance the field in ways quantitative studies

11 could not.

12 In addition to these immediate applications, these standards have the potential to address

13 broader challenges facing qualitative health research. These include: a) the need to educate

14 broader audiences about the many goals of qualitative research, including but not limited to

15 exploration; b) the need to create rigorous standards for conducting and reporting various types

16 of qualitative studies to help audiences, editors, and funders evaluate studies on their own merits;

17 and c) the challenges of publishing qualitative research in high-impact journals that will reach a

18 wide range of practitioners, researchers, and lay audiences. We contend that these challenges can

19 be reframed as opportunities to advance not only the science of qualitative research, but also its

20 potential for improving outcomes for patients, providers, and communities.

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AUTHORS' CONTRIBUTIONS

All authors (KR, CA, SG, MG, and DD) helped to design and conceptualize this work including reviewing guidelines and conceptualizing the proposed framework. KR drafted the manuscript, and all authors (CA, SG, MG, and DD) provided substantial review and writing to revisions.

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COMPETING INTEREST STATEMENT

All authors have read and understood the BMJ Group policy on declaration of interests and declare the following interests: none.

Table 1. Considerations when Designing and Assessing Different Types of Qualitative Health Research

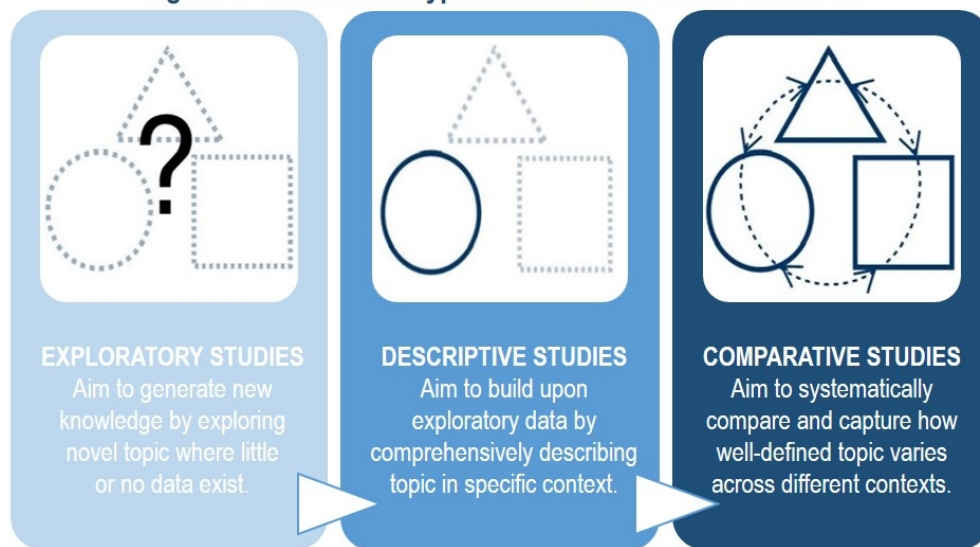
	EXPLORATORY STUDIES	DESCRIPTIVE STUDIES	COMPARATIVE STUDIES
EPISTEMOLOGICAL FRAMEWORK	All studies should identify the epistemological framework under which they and/or the study is guided. The framework presented here is primarily designed for those guided by a subtle relativist or relativist framework.		
STATE OF EVIDENCE	Little to no data exist on the specific topic.	Exploratory data on the topic exist.	Exploratory and descriptive data on the topic exist.
RESEARCH AIMS	Define aims in broad, exploratory questions guided by theoretical framework. <i>A priori</i> hypotheses are unnecessary and inappropriate.	Define aims based on existing knowledge and/or theoretical framework. <i>A priori</i> hypotheses may be useful, but not needed.	Define aims based on existing knowledge and/or theoretical framework. <i>A priori</i> hypotheses are recommended.
SAMPLING STRATEGY	Appropriate to use a single, homogenous sample. Convenience, purposeful, or theoretical sampling is appropriate.	It may be appropriate to use a single, homogenous sample if little is known about a specific subgroup or site. Purposeful or theoretical sampling is appropriate.	Include a diverse sample that supports comparison between groups. May consider integrating probability-based sampling stratified by groups of interest. Convenience sampling is inappropriate.
DATA COLLECTION	Document interview or focus group data using audio-recording and transcribe data verbatim, whenever possible. Any qualitative or ethnographic data that cannot be audio-recorded should be collected using a systematic field note process.		
INSTRUMENT	Develop an unstructured or semi-structured guide based on aims. Adapt as new themes emerge.	Develop semi-structured guide based on aims and existing knowledge. Avoid changing key domains of interest; however, adding new themes is likely appropriate.	
DATA ANALYSIS	Develop clear analytic steps, guided by a theoretical or conceptual framework.		
CODING	Inductive, iterative coding is appropriate. Consider developing a coding dictionary and using independent coders to code data.	A mix of deductive coding based on aims, and inductive, iterative coding to explore new themes is appropriate. Develop and systematically apply a coding dictionary. Use independent coders to code data, if possible.	A primarily deductive coding approach based on aims is appropriate. Develop and systematically apply a coding dictionary. Use independent coders to code data and assess inter-coder reliability. Consider using data triangulation and negative case review to improve reliability.
RESEARCHER REFLEXIVITY	Consider and declare potential biases of researchers.	Consider and declare potential biases of researchers. Consider ways to mitigate biases in study design.	Consider and declare potential biases of researchers. Identify ways to address and/or avoid strong biases.
REPORTING RESULTS	Include clear details on study aims, sampling, data collection and analysis. Consider using standardized reporting guidelines such as COREQ or SRQR.		
LEVEL OF EVIDENCE PRODUCED	Evidence of phenomena within a specific sample. Findings do not establish wider significance or prevalence of phenomena.	Evidence of previously known phenomena in different setting or group. Findings support the wider significance of phenomena.	Evidence of the wider significance and prevalence of defined phenomena within the bounds of the study populations or settings.

FIGURES INCLUDED

Figure 1. Three Broad Types of Qualitative Health Research

For peer review only

Figure 1. Three Broad Types of Qualitative Health Research



159x95mm (150 x 150 DPI)

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ABSTRACT

Objective: To develop a framework for assessing the rigor of qualitative approaches that identifies and distinguishes between the diverse objectives of qualitative health research.

Study Design: Narrative review of published literature on qualitative guidelines and standards from peer-reviewed journals and national funding organizations that support health services research, patient-centered outcomes research, and other applied health research fields.

Principal Findings: We identify and distinguish three objectives of qualitative studies in applied health research: exploratory, descriptive, and comparative. For each objective, we propose methodological standards that may be used to assess and improve rigor across all study phases—from design to reporting. Similar to hierarchies of quality of evidence within quantitative studies, we argue that standards for qualitative rigor differ, appropriately, for studies with different objectives and should be evaluated as such.

Conclusions: Distinguishing between different objectives of qualitative health research improves the ability to appreciate variation in qualitative studies and to develop appropriate evaluations of the rigor and success of qualitative studies in meeting their stated objectives. Researchers, funders, and journal editors should consider how developing and adopting the framework for assessing qualitative rigor outlined here may advance the rigor and potential impact of this important mode of inquiry.

1 In recent decades, the role of qualitative research in health services research (HSR) and allied
2 fields has maintained steady, yet unsettled, interest and value. Evidence of steady interest
3 includes publication of qualitative reviews and guidelines by leading journals including *Health*
4 *Services Research*^{1,2}, *Medical Care Research and Review*³⁻⁵, and *BMJ*^{6,7}, and by funders
5 including the Robert Wood Johnson Foundation⁸, National Institutes of Health^{9,10}, and National
6 Science Foundation^{11,12}. In fields such as patient-centered outcomes research (PCOR) and
7 implementation science, qualitative research has been embraced with particular enthusiasm for
8 its ability to capture, advance, and address questions meaningful to patients, clinicians, and other
9 healthcare system stakeholders^{2,13}. The majority (82%) of inaugural projects awarded by the
10 Patient-Centered Outcomes Research Institute (PCORI) incorporated qualitative research
11 methods¹³. More recently, reflective of continued prevalence of these approaches in the field,
12 PCORI incorporated qualitative methods into their methodological standards.

13 Yet, despite this sustained interest, the status of qualitative health research remains
14 unsettled, as illustrated by *BMJ's* changing engagement with the method. After championing
15 qualitative methods in 2008^{7,14-17}, *BMJ* editors in 2016 noted that they tended to assign low
16 priority to qualitative studies because such studies are "usually exploratory by their very nature"
17¹⁸. This statement came in response to an open letter from scholars arguing that *BMJ* should
18 adopt formal policies and training for editorial staff on what distinguishes "good from poor
19 qualitative research" rather than de-emphasizing the method *in toto*¹⁹. In sum, despite sustained
20 interest from the HSR community, the status of qualitative research remains contested. This
21 status reflects debate over the purpose of qualitative research—*is it a valuable tool to advance*
22 *the field or a low-priority exercise in exploration?*—and an ongoing desire for guidance on how
23 best to distinguish high- from low-quality qualitative research.

Assessing rigor and quality in qualitative research is challenging because qualitative methods are epistemologically diverse²⁰⁻²². This diversity is a strength because it allows for the theoretical and methodological flexibility necessary to fully understand a specific topic from multiple perspectives¹⁶. However, it also means that investigators do not necessarily approach qualitative research using a unified set of evidentiary rules²². Thus, scholars may measure the quality of studies using different or even incompatible yardsticks.

The challenge of diverse epistemologies has become more acute as qualitative health research has expanded beyond its historical roots in phenomenological or grounded theory studies. Contemporary researchers may use qualitative data and methods to improve the descriptive accuracy of health-related phenomena that have already been characterized by exploratory work or are difficult to capture using other approaches²³. Researchers also use larger-scale, comparative qualitative studies in ways that resemble quantitative efforts to identify explanatory pathways²⁴. Therefore, assessing the rigor of a specific qualitative study benefits from first identifying the analytic goals and objectives of the study—i.e. identifying which yardstick investigators themselves have adopted—and then using this yardstick to examine how the study measures up.

To address these challenges, we propose a tailored framework for designing and informing assessments of different types of qualitative health research common within health services research. The framework recognizes that qualitative investigators have different objectives and yardsticks in mind when undertaking studies and that rigor should be assessed accordingly. We distinguish three central types of qualitative study objectives common in applied health research: exploratory, descriptive, and comparative. For each type of study, we propose preliminary methodological considerations to help improve rigor across all study phases—from design to

1 reporting. As is the case for quantitative studies, we argue that standards for qualitative rigor
2 differ, appropriately, for different kinds of studies. The objective of this commentary is not to resolve
3 all potential conflicts between philosophical assumptions of different qualitative approaches, but rather
4 help to advance broader and richer understanding of qualitative rigor in relationship to other evidence
5 hierarchies. The proposed framework offers a nuanced set of categories by which to conduct and
6 recognize high-quality qualitative research. The framework also supports efforts to shift debates
7 over the value of qualitative research to discussions on how we can promote rigor across
8 different types of valuable qualitative studies, and underscore how qualitative methods can
9 advance clinical and applied health research.

10
11 **DESIGNING A TAILORED FRAMEWORK: METHODS AND RESULTS**

12 Our framework is based on a team-based review of published guidelines and standards discussing
13 the scientific conduct of qualitative health research. Guided by expert consensus and targeted
14 literature scan, we identified and reviewed 17 peer-reviewed articles and expert reports published
15 by journals widely read by the HSR community, and by major funders or sponsors of qualitative
16 health research (1-12, 21, 33-36). In contrast to previous reviews ²⁵, we did not seek to
17 synthesize these guidelines. Rather we drew upon them to develop a conceptual framework for
18 designing and informing formal assessments of rigorous qualitative research.

19
20 ***Range of Approaches in Qualitative Research***

21 Qualitative research incorporates a range of methods including in-depth interviews, focus
22 groups, ethnography, and many others ²⁶. Even within a single method, accepted approaches and
23 standards for rigor vary depending upon disciplinary and theoretical orientations.
24 Correspondingly, qualitative research cannot be defined by a single theoretical approach or data

collection procedure. Rather many, often debated, approaches exist with distinct implications for appropriate standards for data collection, analysis, and interpretation.

On one end of the spectrum, qualitative researchers guided by realism subscribe to the assumption that rigorous scientific research can provide an accurate and objective representation of reality, and that objectivity should be a primary goal of all scientific inquiries, including qualitative research²⁷. These qualitative researchers generally consider standards such as validity, reliability, reproducibility, and generalizability as similarly legitimate yardsticks for qualitative research as they are in quantitative research²⁸. On the other end of the spectrum, relativist philosophical approaches to qualitative research typically argue that all research is inherently subjective and/or political²⁹, and some relativists criticize the scientific approach specifically because it claims to be objective^{30,31}. Much of applied qualitative health research falls somewhere between the two ends of the spectrum. For example, Mays & Pope (2000) consider themselves “subtle realists”⁶. They acknowledge that all research involves subjectivity and includes political dimensions, but they also contend that qualitative research should, nevertheless, be assessed by a similar set of quality criteria as quantitative studies. Although we recognize the value strictly relativist approaches provide, the framework and design considerations we propose are largely guided by a realist (or subtle realist) orientation. However, in addition to resonating with those who operate under similar orientations, we hope this framework will serve to advance discussions of how best to communicate and assess qualitative research using different theoretical and epistemological standpoints.

Tailored Framework for Qualitative Health Research

Given the diversity of approaches, a foundational step to improving the assessment of rigor in

1 qualitative research is to abandon the attempt to develop a single standard for best practices
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1 qualitative research is to abandon the attempt to develop a single standard for best practices
2 regardless of study orientation and objective. Instead, standards must begin with an assessment of
3 epistemological assumptions and corresponding study objectives, an approach that is similar to
4 standards for quantitative PCOR research ³² and mixed-methods research ³³. In this vein, we
5 identified and defined three general types of study objectives broadly used in applied qualitative
6 health research (See Figure 1). These three types reflect differences in primary study objectives
7 and existing knowledge within a topic area.

8 <INSERT FIGURE 1>

9 In Table 1, we provide preliminary distinctions on how exploratory, descriptive, and comparative
10 studies compare across a range of standards and guidelines that have been proposed for
11 qualitative research (See Table 1). Regardless of study type, researchers should report study
12 details in clear, comprehensive ways, using standardized reporting guidelines whenever possible
13 ^{34,35}.

14 <INSERT TABLE 1>

15 Compared to descriptive or comparative studies, exploratory studies approach the topic of
16 study primarily in an inductive fashion to investigate areas of potential research interest that
17 remain mostly or wholly unexamined by the scientific community. Investigators undertaking
18 exploratory studies typically have few expectations for what they might find, and their research
19 design and approach may shift dramatically as they learn more about the phenomena of interest.
20 An example of an exploratory study is a study that uses convenience sampling and unstructured
21 interviews to explore what patients think about a new treatment in a single healthcare setting.

22 At the opposite end of this spectrum, investigators conducting comparative studies aim to
23 use a deductive approach designed to compare and document how well-defined qualitative

phenomena are represented in different settings or populations. The qualitative methods employed in a comparative study are typically defined in advance, sampling should be systematic and structured by aims, and investigators enter the field with hypothesized ideas of what findings they may uncover and how to interpret those findings in light of previous research. An example of a comparative study is a multi-site ethnography that seeks to compare how patient-provider communication varies by location, and uses random sampling of patient-provider interactions to collect data.

Descriptive studies occupy a middle position, building on previously-conducted exploratory work so researchers will be able to proceed with more-focused inquiry. This should include well-defined procedures including sampling protocols and analytic plans, and investigators should usually articulate expected findings prior to beginning the study. However, as researchers investigate phenomena in new settings or patient populations, it is reasonable to expect descriptive studies to generate surprises. Thus, descriptive studies also feature inductive elements to detect unexpected findings, and must be flexible enough in design to accommodate shifts in research focus and methods based on empirical findings. An example of a descriptive study is a longitudinal study of ovarian cancer patients that employs semi-structured interviews and directed content analysis to examine decision-making across patients in a novel setting.

DISCUSSION

Our review identified a number of qualitative standards and guidelines that have been published. The conceptual framework we present here draws upon those extant guidelines through the recognition that qualitative health research includes studies of diverse theoretical and epistemological orientations, each of which has distinct understandings of scientific quality and

1 rigor. Given this intellectual diversity, it is inappropriate to use a single yardstick for all
2 qualitative research. Rather, assessments of qualitative quality must begin with an assessment of
3 a study's theoretical orientations and research objectives to ensure that rigor is assessed on a
4 study's own terms. This framework and suggested approaches may help to advance evaluations
5 of qualitative rigor that acknowledge and differentiate between studies that report exploratory,
6 descriptive, or comparative study objectives.

7 Existing standards for conducting health research and grading evidence, such as GRADE
8 ³⁶, do not capture the diversity of qualitative studies—often designating all qualitative studies as
9 providing weak levels of evidence. PCORI's own methodological standards have been largely
10 silent regarding qualitative methods until recently ³², leaving applicants without clear direction
11 on how to conduct rigorous qualitative research. Incorporation of tailored qualitative standards
12 could help to clarify and improve the rigor of proposal design, review, and completion. The
13 establishment and integration of such standards could also guide journal editors in developing
14 transparent standards for deciding priorities for publication. For example, editors may decide
15 against publication of exploratory or descriptive studies, but prioritize well-executed
16 comparative studies that advance the field in ways quantitative studies could not.

17 In addition to these immediate applications, implementing standards that incorporate the
18 diversity of objectives within applied qualitative research has the potential to address broader
19 challenges facing qualitative health research. These include: a) the need to educate broader
20 audiences about the many goals of qualitative research, including but not limited to exploration;
21 b) the need to create rigorous standards for conducting and reporting various types of qualitative
22 studies to help audiences, editors, and funders evaluate studies on their own merits; and c) the
23 challenges of publishing qualitative research in prestigious and high-impact journals that will

1 reach a wide range of practitioners, researchers, and lay audiences. We contend that these
2 challenges can be reframed as opportunities to advance not only the science of qualitative
3 research, but also its potential for improving outcomes for patients, providers, and communities.

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AUTHORS' CONTRIBUTIONS

All authors (KR, CA, SG, MH, and DD) helped to design and conceptualize this work including reviewing guidelines and conceptualizing the proposed framework. KR drafted the manuscript, and all authors (CA, SG, MH, and DD) provided substantial review and writing to revisions.

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COMPETING INTEREST STATEMENT

All authors have read and understood the BMJ Group policy on declaration of interests and declare the following interests: none.

Table 1. Framework for Designing Different Types of Applied Qualitative Health Research and Developing Evaluative Instruments to Assess Their Rigor

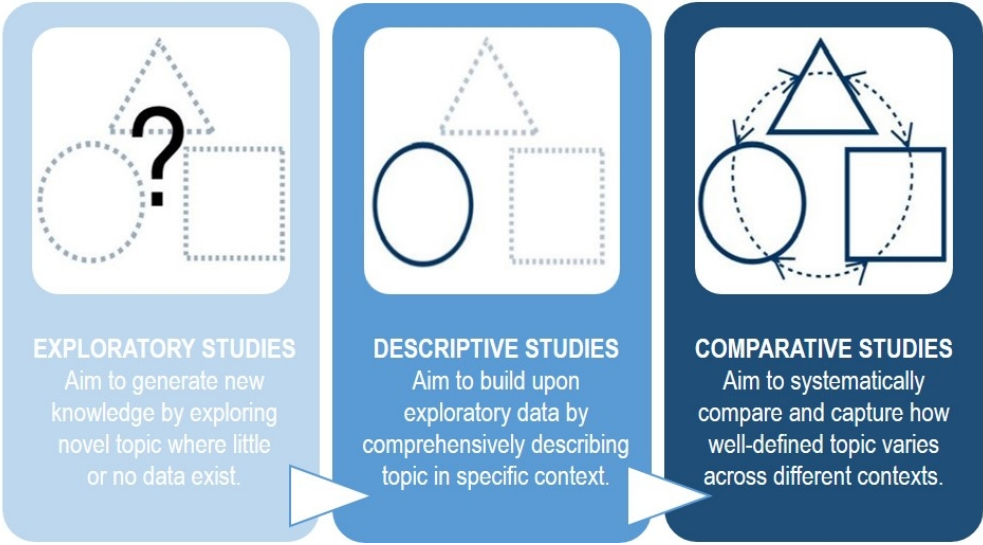
	EXPLORATORY STUDIES	DESCRIPTIVE STUDIES	COMPARATIVE STUDIES
EPISTEMOLOGICAL FRAMEWORK	All studies should identify the epistemological framework under which they and/or the study is guided.		
STATE OF EVIDENCE	Little to no data exist on the specific topic.	Exploratory data on the topic exist.	Exploratory and descriptive data on the topic exist.
RESEARCH AIMS	Define aims in broad, exploratory questions guided by theoretical framework. <i>A priori</i> hypotheses are unnecessary and inappropriate.	Define aims based on existing knowledge and/or theoretical framework. <i>A priori</i> hypotheses may be useful, but not needed.	Define aims based on existing knowledge and/or theoretical framework. <i>A priori</i> hypotheses are recommended.
SAMPLING STRATEGY	Appropriate to use a single, homogenous sample. Convenience, purposeful, or theoretical sampling is appropriate.	It may be appropriate to use a single, homogenous sample if little is known about a specific subgroup or site. Purposeful or theoretical sampling is appropriate.	Include a diverse sample that supports comparison between groups. May consider integrating probability-based sampling stratified by groups of interest. Convenience sampling is inappropriate.
DATA COLLECTION	Document interview or focus group data using audio-recording and transcribe data verbatim, whenever possible. Any qualitative or ethnographic data that cannot be audio-recorded should be collected using a systematic field note process.		
INSTRUMENT	Develop an unstructured or semi-structured guide based on aims. Adapt as new themes emerge.	Develop semi-structured guide based on aims and existing knowledge. Avoid changing key domains of interest; however, adding new themes is likely appropriate.	
DATA ANALYSIS	Develop clear analytic steps, guided by a theoretical or conceptual framework.		
CODING	Inductive, iterative coding is appropriate. Consider developing a coding dictionary and using independent coders to code data.	A mix of deductive coding based on aims, and inductive, iterative coding to explore new themes is appropriate. Develop and systematically apply a coding dictionary. Use independent coders to code data, if possible.	A primarily deductive coding approach based on aims is appropriate. Develop and systematically apply a coding dictionary. Use independent coders to code data and assess inter-coder reliability. Consider using data triangulation and negative case review to improve reliability.
RESEARCHER REFLEXIVITY	Consider and declare potential biases of researchers.	Consider and declare potential biases of researchers. Consider ways to mitigate biases in study design.	Consider and declare potential biases of researchers. Identify ways to address and/or avoid strong biases.
REPORTING RESULTS	Include clear details on study aims, sampling, data collection and analysis. Consider using standardized reporting guidelines such as COREQ or SRQR.		
LEVEL OF EVIDENCE PRODUCED	Evidence of phenomena within a specific sample. Findings do not establish wider significance or prevalence of phenomena.	Evidence of previously known phenomena in different setting or group. Findings support the wider significance of phenomena.	Evidence of the wider significance and prevalence of defined phenomena within the bounds of the study populations or settings.

FIGURES INCLUDED

Figure 1. Three Broad Types of Qualitative Health Research

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Figure 1. Three Broad Types of Qualitative Health Research



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