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Beyond Exploratory: A Tailored Framework for Assessing Rigor in Qualitative Health Services Research

Abstract

Objective: To propose a framework for assessing the rigor of qualitative research that identifies and distinguishes between the diverse objectives of qualitative studies currently used in patient-centered outcomes and health services research (PCOR and HSR).

Study Design: Narrative review of published literature discussing qualitative guidelines and standards in peer-reviewed journals and national funding organizations that support PCOR and HSR.

Principal Findings: We identify and distinguish three objectives of current qualitative studies in PCOR and HSR: exploratory, descriptive, and comparative. For each objective, we propose methodological standards that can 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 HSR 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 research in patient-centered outcomes and health services research.

Keywords

Qualitative research, health services research, research methodology, patient-centered outcomes

Disciplines

Medicine and Health Sciences

Comments

This article has been submitted for review in a peer-review journal.

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3
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5
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1 ABSTRACT

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3 and distinguishes between the diverse objectives of qualitative studies currently used in patient-
4 centered outcomes and health services research (PCOR and HSR).

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6 standards in peer-reviewed journals and national funding organizations that support PCOR and
7 HSR.

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12 rigor differ, appropriately, for studies with different objectives and should be evaluated as such.

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14 ability to appreciate variation in qualitative studies as well as appropriately evaluate the rigor and
15 success of studies in meeting their own objectives. Researchers, funders, and journal editors
16 should consider how adopting the criteria for assessing qualitative rigor outlined here may
17 advance the rigor and potential impact of qualitative research in patient-centered outcomes and
18 health services research.

19 **Key Words:** Qualitative research; health services research; research methodology; patient-
20 centered outcomes

21

1 INTRODUCTION

2 In recent decades, the role of qualitative research in health services research (HSR) has
3 maintained steady, yet unsettled, interest and value. Evidence of steady interest includes
4 publication of qualitative HSR reviews and guidelines by leading journals including *Health*
5 *Services Research* (1,2), *Medical Care Research and Review* (3–5), and *BMJ* (6,7), and by
6 funders including the Robert Wood Johnson Foundation (RWJF) (8), National Institutes of
7 Health (NIH) (9,10), and National Science Foundation (NSF) (11,12). In fields such as patient-
8 centered outcomes research (PCOR) and implementation science, qualitative research has been
9 embraced with particular enthusiasm for its ability to capture, advance, and address questions
10 meaningful to patients, clinicians, and other healthcare system stakeholders (2,13). For example,
11 more than 4 of 5 PCORI pilot grants (41/50) incorporate qualitative methods (13).

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

1 Distinguishing rigor and quality in qualitative research is challenging because qualitative
2 methods are epistemologically diverse (Barbour 2001; Creswell 2007; Author YEAR.).
3 Qualitative methods appear in an expansive and variegated collection of PCOR and HSR studies
4 ranging from humanistic exploration to randomized trials. This diversity is a strength because it
5 allows for the theoretical and methodological flexibility necessary to engage with a novel topic
6 (16). However, it also means that investigators do not necessarily approach qualitative research
7 using a unified set of evidentiary rules. Thus, scholars may measure the rigor and quality of
8 studies using different or incompatible yardsticks.

9 The challenge of diverse epistemologies has become more acute as qualitative HSR has
10 expanded beyond its historical roots in phenomenological or grounded theory studies.
11 Contemporary researchers have begun to use qualitative data and methods to improve the
12 descriptive accuracy of health-related phenomena that have already been characterized by
13 exploratory work or are difficult to capture using other approaches (23). Researchers have also
14 used larger-scale, comparative qualitative studies in ways that resemble quantitative efforts to
15 identify explanatory pathways (24). Therefore, assessing the rigor of a specific qualitative study
16 cannot be done without first identifying the analytic goals and objectives of the study—i.e.
17 identifying which yardstick investigators themselves have adopted—and then using this yardstick
18 to examine how the study measures up.

19 In this article, we seek to help address these challenges by proposing a tailored framework
20 for advancing and assessing the rigor of different types of qualitative HSR. The framework
21 recognizes that qualitative investigators have different objectives and yardsticks in mind when
22 undertaking studies and rigor should be assessed accordingly. We distinguish three central types
23 of qualitative studies common in patient-centered outcomes and health services research:

1 exploratory, descriptive, and comparative. For each type of study, we propose methodological
2 standards and considerations to help improve rigor across all study phases—from design to
3 reporting. As is the case for quantitative studies, we argue that standards for qualitative rigor
4 differ, appropriately, for different kinds of studies and should be evaluated as such. By providing
5 a tailored framework, our intent is to help editors, funders, and researchers move beyond a "one-
6 size-fits-all" approach for conducting and assessing the variety of rigorous approaches
7 comprising qualitative research. The proposed framework offers a finer set of tools by which to
8 distinguish good from poor qualitative research, supports efforts to shift debates over the value
9 of qualitative research in HSR to discussions on how we can promote rigor across different types
10 of valuable qualitative HSR, and ultimately seeks to facilitate a resolution to the debate over
11 qualitative methods' role in PCOR and HSR studies.

12

13 DESIGNING A TAILORED FRAMEWORK: METHODS AND RESULTS

14 Our framework is based on a narrative review of 14 published guidelines and standards
15 discussing the scientific conduct of qualitative health research (Table 1). We drew primarily
16 from peer-reviewed articles and reports published by journals widely read by the HSR
17 community, and by major funders or sponsors of qualitative health research. In contrast to
18 previous studies (25), we did not seek to synthesize these guidelines but rather drew upon them
19 to develop a broad framework for promoting rigor in qualitative HSR. We also examined a
20 secondary set of guidelines and standards published in specialty qualitative health research
21 journals (*Qualitative Health Research*), in social science journals from disciplines outside of
22 HSR (*Ethnography*, *American Journal of Sociology*, *Anthropological Theory*, *American*
23 *Sociological Review*, *Medical Anthropology Quarterly*, *Sociological Methodology*) and in books

1 that include qualitative methodologies (21,26,27). Information gleaned from the review of this
2 secondary set of sources did not substantially alter the conclusions drawn from the primary
3 sources.

4 <INSERT TABLE 1>

5

6 *Range of Approaches in Qualitative Research*

7 Qualitative research incorporates a range of methods including in-depth interviews, focus
8 groups, participant-observation, ethnography and many others (26). Even within a single method
9 such as ethnography or interviewing, accepted approaches, as well as standards for rigor, vary
10 depending on the disciplinary and theoretical orientations of the researchers and project.

11 Correspondingly, qualitative research cannot be defined by a single theoretical or
12 epistemological approach. Rather many, often debated, approaches exist with distinct
13 implications for appropriate standards for data collection, analysis, and interpretation.

14 On one end of the spectrum, qualitative researchers guided by the principles of realism
15 subscribe to the assumption that rigorous scientific research can provide an accurate and
16 objective representation of reality, and that objectivity should be a primary goal of all scientific
17 inquiries, including qualitative research (28). These qualitative researchers generally consider
18 standards such as validity, reliability, reproducibility, and generalizability as similarly legitimate
19 yardsticks for qualitative research as they are in quantitative research (29). On the other end of
20 the spectrum, anti-realist and "relativist" approaches to qualitative research typically argue that
21 all research, even the most rigorous scientific research, is inherently subjective and/or political
22 (30), and the most dedicated relativists criticize the scientific approach specifically because it
23 claims to be objective (31,32).

1 Much of qualitative HSR falls somewhere between the two ends of the spectrum. For
2 example, Mays & Pope (2000) consider themselves “subtle realists.” They acknowledge that all
3 research involves subjectivity and includes political dimensions, but they also contend that
4 qualitative research should, nevertheless, be assessed by a similar set of quality criteria as
5 quantitative studies. At a different position on the spectrum, grounded theorists emphasize
6 inductivism in research, and their assessments of quality and rigor thus underscore whether
7 investigators use inductive tools and techniques while avoiding unwarranted deductivism. As
8 these examples illustrate, assessing the rigor of qualitative health research requires a sensitivity
9 to the theoretical and epistemological standpoints of individual investigators, and an ability to
10 assess the sometimes subtle and diverse ways these shape the approaches of specific studies
11 (20,33).

12

13 *Tailored Framework for Assessing Rigor in Qualitative HSR*

14 Given the diversity of qualitative approaches in HSR, a foundational step to improving the
15 assessment of rigor in qualitative research is to abandon the attempt to develop a single standard
16 for best practices. Instead, standards must begin with an assessment of study objectives, an
17 approach that is similar to standards for quantitative PCOR research (34) and mixed-methods
18 research (27). In this vein, we identified and categorized three general types of qualitative studies
19 used in current qualitative HSR. These three types reflect differences in primary study objectives
20 as well as the state-of-knowledge within a topic area. All three study types can employ the same
21 research method, for example in-depth interviews, but they will use these methods to achieve
22 different ends depending on the study's objectives and researchers' epistemological orientations.
23 The three general types are:

- 1 • **Exploratory studies**, which aim to generate new knowledge by exploring areas where
2 little or no data exist regarding a patient population, clinical condition, intervention, or
3 healthcare setting.
- 4 • **Descriptive studies**, which aim to expand upon existing knowledge by describing how
5 previously identified phenomena occur or vary in novel or underexplored patient
6 populations, clinical conditions, interventions, or healthcare settings.
- 7 • **Comparative studies**, which aim to collect representative qualitative data by comparing
8 how well-defined phenomena occur or vary across different patient populations, clinical
9 conditions, interventions, or healthcare settings.

10

11 In Table 2, we distinguish how exploratory, descriptive, and comparative studies compare across
12 a range of standards and guidelines that have been proposed for qualitative research (*See* Table
13 1). These include approaches for each component of study design and execution including a)
14 research aims and hypotheses; b) sampling strategy; c) data collection; d) data analysis; e)
15 researcher reflexivity; f) researcher training; g) reporting of results; h) stakeholder engagement;
16 and, i) study interpretation. We recommend that regardless of study type researchers report study
17 details in clear, comprehensive ways, using standardized reporting guidelines whenever possible
18 (35,36). We have also compiled an accompanying list of checklist questions that can be used by
19 researchers, funders, editors, or others to design, conduct, report, and evaluate qualitative HSR
20 (Supplementary Digital Content 1).

21 <INSERT TABLE 2>

22 Compared to descriptive or comparative studies, exploratory studies approach the topic of
23 study primarily in an inductive fashion in order to investigate areas of potential research interest

1 that remain mostly or wholly unexamined by the scientific community. Investigators undertaking
2 exploratory studies typically have few expectations for what they might find, and their research
3 design and approach may shift dramatically as they learn more about the phenomena of interest.

4 At the opposite end of this spectrum, investigators conducting comparative studies aim to
5 use a deductive approach designed to compare and document how well-defined qualitative
6 phenomena are represented in different settings or populations. The qualitative methods
7 employed in a comparative study will typically be defined in advance, sampling should be
8 expansive and structured by groups, and investigators will enter the field with hypothesized ideas
9 of what findings they may uncover and how to interpret those findings in light of previous
10 research.

11 Descriptive studies occupy a middle position. Such studies build on previously-conducted
12 exploratory work so researchers will be able to proceed with more focused inquiry. This should
13 include well-defined procedures including sampling protocols and analytic plans, and
14 investigators should articulate expected findings prior to beginning the study. However, as
15 researchers investigate phenomena in new settings or patient populations, it is reasonable to
16 expect descriptive studies to generate surprises. Thus, descriptive studies also feature inductive
17 elements to detect unexpected findings, and must be flexible enough in design to accommodate
18 shifts in research focus and methods.

19

20 DISCUSSION

21 Our review identified a number of qualitative standards and guidelines that have been issued by
22 HSR stakeholders. The framework we present here builds on those extant guidelines through the
23 recognition that qualitative HSR includes studies of diverse theoretical and epistemological

1 orientations, each of which has distinct understandings of scientific quality and rigor. Given this
2 intellectual diversity, it is inappropriate to use a single yardstick for all qualitative HSR. Rather,
3 assessments of qualitative rigor or quality must begin with an assessment of a study's theoretical
4 orientations and research objectives to ensure that rigor is assessed on a study's own terms. This
5 paper builds on previous discussions of qualitative rigor by describing how their dimensions of
6 rigor can be fruitfully expanded to include the assessment of studies that adopt exploratory,
7 descriptive, or comparative objectives.

8 Existing standards for conducting PCOR and other principles for grading evidence, such as
9 GRADE (37), do not capture the diversity of qualitative studies—often designating all
10 qualitative studies as weak—further highlighting the need for developing and incorporating
11 tailored qualitative standards. PCORI's own methodological standards are largely silent
12 regarding qualitative methods (34), leaving applicants without clear direction on how to conduct
13 rigorous qualitative research. Incorporation of tailored qualitative standards into PCORI's
14 standards could help to clarify and improve the rigor of proposal design, review, and contracting.
15 Such standards could also guide journal editors, such as those at *BMJ*, in developing transparent
16 standards for deciding on priority for publication.

17 In addition to these immediate applications, these standards have the potential to address
18 broader challenges facing qualitative health research. These include: a) the need to educate
19 broader audiences of the many goals of qualitative research, including but not limited to
20 exploration; b) the need to create rigorous standards for conducting and reporting various types
21 of qualitative studies to help audiences, editors, and grant reviewers evaluate studies on their
22 own merits, rather than misconceived notions of what qualitative research is or is not; and c) the
23 challenges of publishing qualitative research in high-impact journals that will reach a wide range

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

4
5 In this article, we presented a tailored framework for conducting qualitative health research
6 that takes into account the objectives of the study—whether it be exploratory, descriptive, or
7 comparative—and argued that studies should be evaluated based on their self-declared intent
8 rather on the global basis of being “qualitative”. This framework mirrors the structure of other
9 standards proposed by PCORI, NIH, and others for evaluating rigor in quantitative research. We
10 have also proposed a checklist of key questions that can help researchers to decide *a priori* the
11 most appropriate methods for a specific qualitative study. Although there is still work that needs
12 to be done to translate these guidelines into specific publication or review criteria, this
13 framework may be useful to editors, funders, and other audiences that seek to advance the state
14 of qualitative health research. Instead of reifying disciplinary differences, frameworks—such as
15 the one presented here—can help advance the rigor, acceptance, and value of qualitative health
16 research in HSR, PCOR, and across diverse audiences.

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SUPPLEMENTAL DIGITAL CONTENT

Supplemental Digital Content 1.docx

Table 1. Primary Sources Reviewed
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TABLE 2. TAILORED FRAMEWORK FOR ASSESSING RIGOR IN QUALITATIVE HSR

	EXPLORATORY STUDIES	DESCRIPTIVE STUDIES	COMPARATIVE STUDIES
PRIMARY STUDY OBJECTIVE	Provide new knowledge about a novel patient population, clinical condition, intervention, or healthcare setting.	Expand upon existing knowledge by describing how previously-identified phenomena occur or vary in novel or underexplored patient populations, clinical conditions, interventions, or healthcare settings.	Collect representative qualitative data by comparing how well-defined phenomena occur or vary across different patient populations, clinical conditions, interventions, or healthcare settings.
STATE OF EVIDENCE	Little to no data exist on the specific study topic.	Exploratory data on the study topic exist.	Exploratory and descriptive data on the study topic exist.
RESEARCH AIMS	Define research aims in broad, exploratory terms or questions.	Define research aims based on existing knowledge.	Define research aims based on existing knowledge and link to measurable outcomes.
<i>Hypotheses</i>	A priori hypotheses are unnecessary and typically not appropriate.	A priori hypotheses may be useful, but are not necessary.	Formulating a priori hypotheses are likely necessary and appropriate.
SAMPLING STRATEGY	Appropriate to include a single, homogenous sample.	It may be appropriate to include a single, homogenous sample if little is known about a specific subgroup or site.	Include a diverse sample that supports comparison between groups. Single homogenous sample is likely inappropriate in most cases.
<i>Subgroups</i>	Sample from relevant subgroups of interest whenever possible.	Sample from relevant subgroups of interest whenever possible.	Sample from all relevant subgroups to increase representativeness of data.
<i>Approach</i>	Convenience or purposeful sampling is appropriate.	Purposeful sampling is appropriate.	Consider rigorous sampling approaches (e.g. randomized sample from groups). Convenience sampling is not appropriate.
<i>Reporting</i>	Clearly document and report sampling approach, including any changes to the approach during the study.		
DATA COLLECTION	Identify how the planned method(s) of data collection and research site/population will yield the data needed to answer the research aims. Ensure that data are collected thoroughly and systematically from all study participants. Data	Identify how the planned method(s) of data collection and research site/population will yield the data needed to answer the research aims. Ensure that data are collected thoroughly and systematically from all study participants. Data	Identify how the planned method(s) of data collection and research site/population will yield the data needed to answer the research aims. Ensure that data are collected thoroughly and systematically from all study participants.

	collection should continue until saturation is achieved.	collection should continue until saturation is achieved.	Consider defining <i>a priori</i> stopping rules for data collection for primary outcomes. For novel themes, data collection should continue until saturation is achieved across all groups.
<i>Focus areas & approach</i>	Select areas of focus and specific methods based on research questions. Areas of focus might be broad or change over the course of the study.	Select areas of focus and specific methods based on research aims and previous study subject knowledge. Areas of focus should be matched to previous knowledge, but new topics can also be explored.	Select areas of focus and specific methods based on research aims and previous study subject knowledge. Areas of focus should be matched to comparators of interest, but new topics can also be explored.
<i>Instrument development</i>	Develop an unstructured or semi-structured interview (or focus group) guide based on research aims. Consider adapting as new themes emerge during the study.	Develop semi-structured interview (or focus group) guide based on research aims and existing knowledge. Avoid changing key domains of interest during the study; however, adding new themes is appropriate.	Develop semi-structured interview (or focus group) guide based on research aims and existing knowledge. Avoid changing key domains of interest during the study; however, adding new themes is appropriate.
<i>Data capture</i>	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.		
<i>Missing data</i>	Exploratory studies are likely to have some missing data as topical investigation might be fluid across the study. However, whenever possible, ensure all key themes are explored across participants and any participant or site characteristics are collected systematically.	Ensure that all <i>a priori</i> domains of interest are collected and explored systematically to reduce missing data. Identify ways to reduce missing data for key themes and any participant or site characteristics collected.	Ensure that all comparators of interest are collected and explored systematically to reduce missing data. Identify ways to reduce missing data in the data collection phase. Report any missing data and analytic steps to mitigate effect of missing data.
DATA ANALYSIS	Develop clear analytic steps, guided by a theoretical or conceptual framework.		
<i>Coding scheme</i>	Inductive, iterative coding is appropriate.	A mix deductive coding based on research aims, and inductive, iterative coding to explore new themes is appropriate.	A primarily deductive coding approach based on research aims is appropriate.
<i>Codebook</i>	Consider developing a coding dictionary to	Develop and systematically apply a	Develop and systematically apply a

	identify emergent themes.	coding dictionary.	coding dictionary. Consider using data triangulation and negative case review to improve reliability.
<i>Coding techniques</i>	Consider using independent coders to code data. Consider using qualitative data analysis software to organize coding.	Use independent coders to code data, if possible. Strongly consider using qualitative data analysis software to support coding and data retrieval.	Use independent coders to code data and assess inter-coder reliability. Use qualitative data analysis software to support coding and data retrieval.
RESEARCHER REFLEXIVITY	Consider and declare potential biases of researchers.	Consider and declare potential biases of researchers. Consider ways to mitigate biases depending on study aim.	Consider and declare potential biases of researchers. Identify ways to address and/or avoid strong biases.
RESEARCHER TRAINING	Ensure that all research members are adequately trained to conduct qualitative research, preferably supervised by researcher with extensive qualitative training and experience.		
REPORTING RESULTS	Include clear details on study aims, sampling, data collection and analysis. Consider using standardized reporting guidelines such as COREQ or SRQR.		
STAKEHOLDER ENGAGEMENT (PCOR STUDIES)	Incorporate feedback from stakeholders at all stages of the research process, from study design to dissemination. Identify (through data collection or previous PCOR studies) outcomes of interest to stakeholders, and include in study. Incorporate stakeholders directly in the dissemination and communication of results		
STUDY INTERPRETATION & IMPACT	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 (but not prevalence) of phenomena.	Evidence of the wider significance and prevalence of defined phenomena within the bounds of the study populations or settings.

APPENDIX A. DESIGNING, REPORTING AND EVALUATING QUALITATIVE HSR: A GUIDING CHECKLIST	
1.	What is the primary area of study (including specific population, clinical condition, intervention, or healthcare setting), and what patient-centered or other outcomes are to be explored or measured?
2.	What is the current state of the clinical, social, and epidemiological evidence in the primary area of study?
3.	What qualitative data are available with regard to the primary area of study?
4.	What specific gap (with regard to the area of study) will the study fill and why are qualitative methods most appropriate for filling this gap?
5.	Which of the following types of study best matches the primary study purpose and state of evidence? <ul style="list-style-type: none"> • Exploratory studies aim to generate new knowledge by exploring areas where little or no data exist regarding a patient population, clinical condition, intervention, or healthcare setting. • Descriptive studies aim to expand upon existing knowledge by describing how previously identified phenomena present or vary in novel or underexplored patient populations, clinical conditions, interventions, or healthcare settings. • Comparative studies aim to collect representative qualitative data by comparing how well-defined phenomena present or vary across different patient populations, clinical conditions, interventions, or healthcare settings. What are the explicit or implicit theoretical assumptions guiding the research design and analysis?
6.	How will the data be collected and how does this method align with the research aim? <ul style="list-style-type: none"> • How will the study identify and recruit participants? Include sampling strategy used and attrition procedures. • Are members of the research team appropriately trained to collect data? • What potential personal biases exist in the research team with regard to the study topic, including financial or personal interests, or the patient population(s)? • Will a semi-structured or structured interview guide be developed a priori? • Is prolonged engagement with the study population required to conduct the research? • Will observation or participant observation be a component of the study? • Where will data collection occur? Including detailed description of setting and steps for achieving entree. • What are the characteristics of the participants, and what are the inclusion/exclusion criteria? • How will data be recorded? Describe use of audio-recording, observational notes, or other methods. • How long will the data collection phase last? • How will ethical issues regarding confidentiality, consent, and human subjects be addressed?
7.	How will the data be analyzed and how does it align with research aims? <ul style="list-style-type: none"> • Are members of the research team appropriately trained to analyze the data? • Will any triangulation, negative cases, or other methods be used to improve trustworthiness of study findings? • How will the data be coded? Include type of software used, number of coders, development of coding scheme, and consensus reaching methods across coders. • How will the research team determine if/when data saturation is reached? • How will data themes be identified and presented? • What empirical data (e.g. quotes, field notes) will be presented to support findings?
8.	What are the plans for sharing findings with relevant scientific and community stakeholders including patients, providers, and others?
9.	What standardized reporting approach (e.g. SPQR or COREQ) will the team use to ensure all relevant details of the study are reported?