



## AcademyHealth Feedback on Proposed Methodology Standards for Standards for Qualitative Methods (QM) and Mixed Methods (MM) Research

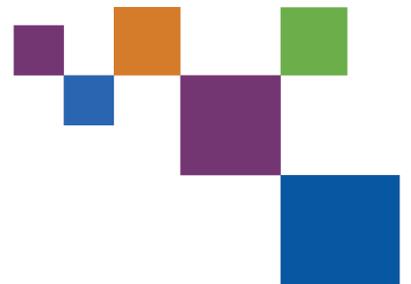
*Below are descriptions for seven new standards under consideration by the PCORI Methodology Committee. In response to an open request for comments on the standards, and on behalf of our members, AcademyHealth submitted the indented, blue comments on September 21, 2018. We wish to thank Dr. Kelly Devers and the members of the AcademyHealth Methods and Data Council for their assistance in compiling this response. Members with questions or comments on this response are invited to contact us at [advocacy@academyhealth.org](mailto:advocacy@academyhealth.org).*

### **QM-1: State the qualitative approach to research inquiry, design, and conduct.**

Identify and describe the evidence gaps that support the need for the qualitative component of the study. Identify which qualitative approach (e.g., ethnography, grounded theory) will be used, including the purpose, why it is an appropriate approach to answer the research question(s), and how it will be operationalized (see PC-2). State the types of data that will be collected, the procedures for data collection (e.g., focus groups, observations, interviews, documents, audio/video recordings), and the timing of data collection (see IR-7). Describe how confidentiality will be maintained through data collection, management, analysis, and reporting. State the computer software programs used to assist with the analysis.

AcademyHealth appreciates PCORI's development of proposed methodology standards for qualitative and mixed methods research and the opportunity to comment on them. Before providing feedback on each proposed standard, a general suggestion is for PCORI to provide citations that support the standards and serve as a resource guide for the field. There is a wide range of methods literature in the basic social sciences and health services and policy research fields, so if PCORI could provide references to those they are feel are most useful for these standards and patient-centered CER, it would very helpful.

Our general comment on QM-1 is that there is a lot bundled into this standard, and some of it seems duplicative of the other standards. For example, some portions of this standard (e.g., operationalizing qualitative methods, types of data to be collected, software used to support data analysis) seem to overlap with parts of QM-3 and QM-4. We suggest PCORI clarify and emphasize the unique aspects of this standard, and cross-reference and align it with other relevant standards, eliminating any duplication. Alternatively, PCORI might consider breaking this single standard up into several separate standards. For example, confidentiality and other human subjects issues, as they specifically relate to qualitative and mixed methods, might be worthy of their own standard.



Additional issues to consider:

- a) Specific qualitative approaches (e.g., ethnography, grounded theory) typically determine or shape the methods used. For example,, ethnography means more observation and informal interviewing in everyday settings, grounded theory means using a more inductive approach to coding. So, the sentence might be modified to read “which qualitative approaches and methods” (adding methods) because methods are how an approach is “operationalized” and the data produced.
- b) The link to PC-2, about operationalization, says that “selection bias” should be minimized. This language does not seem appropriate for qualitative research, where non-probability or purposive sampling strategies are frequently used. PCORI should clarify or alter the language for PC-2 when using it for operationalizing qualitative research.
- c) The link to IR-7 indicates that there should be a plan for sharing data with the broader scientific community. Further clarification and guidance is needed to articulate how this could be accomplished with qualitative data (e.g., de-identified NVivo database, more detailed quotes in papers and reports) while maintaining confidentiality and privacy. It should also link to the recently published PCORI guidance on data sharing.
- d) The last sentence states, “Describe how confidentiality will be maintained...” This portion of the standard may benefit from more explicit reference to the relationship with institutional review boards (IRBs) and human subject protections, including informed consent and privacy. In some cases, participants may be informed but chose to not keep their information confidential or private.

Finally, AcademyHealth suggests that when the final standard is developed, additional effort be made to streamline the language. Below is a potential example of how language and the paragraph might be simplified using the current draft standard.

“Identify and describe evidence gaps supporting the need for a qualitative component(s) of the study. Identify the qualitative approach and/or methods to be used. For example, approaches can include: ethnography, narrative, phenomenological, grounded theory or case study. Qualitative methods can include observation, individual interviews, group interviews or focus groups, audio or video recordings, and document analysis. Include the purpose, rationale and appropriateness of the proposed approach and method(s) to answer the research question(s) and how the approach will be operationalized (see PC-2). Describe the types of data to be collected, procedures for data collection (e.g., focus groups, observations, interviews, documents, audio or video recordings) and when the data will be collected (see IR-7). Clearly describe how data confidentiality and privacy will be protected through data collection, management, analysis, and reporting processes. “

**QM-2: Select and justify an appropriate qualitative methods sampling strategy.**

Describe and provide the rationale for the sampling strategy (see RQ-3, RQ-4, and PC-2), including how the strategy flows logically from the qualitative approach and how it fits the research question(s). State the expected sample size and justification. Describe how the methods will ensure that the data capture the depth of experiences of the participants or phenomenon of interest (see PC-2 and PC-3). State the criteria for deciding when no further sampling is necessary (e.g., thematic saturation), if appropriate.

The terms 'describe' and 'provide' in the opening sentence seems duplicative. There also seems to be a variance in how research components are described. Qualitative work will ultimately have a sample size, for example the total number of people ultimately interviewed, but sample size may not be as firmly specified in advance. For example, the number of interviews and types of people interviewed may be informed by what is being learned during the interviews, specifically when information saturation (i.e., no new concepts or themes are emerging) has been reached. There also appears to be some dis-junctures in the language at the link to RQ-4, which refers to sufficient power, adequate precision, and other concepts appropriate for quantitative but not qualitative research.

We suggest PCORI specifically reference purposive (non-probability) sampling strategies including: rationales for using them; similarities and differences between them and probability samples; types of purposive sampling strategies; and, their strengths and limits.

Finally, AcademyHealth suggests that when the final standard is developed, some additional effort be made to streamline the language. Below is a possible example of how language and the paragraph might be simplified using the current draft standard.

“Provide rationale for sampling strategy/strategies (see RQ-3, RQ-4, and PC-2) including the logical flow and relationship of the strategies to the research question(s). Describe methodologies related to sample size or saturation to ensure capture of experiential depth of the participant(s) or phenomenon (see PC-2 and PC-3).”

**QM-3: Link the qualitative data analysis, interpretations, and conclusions to the study question.**

State who will be involved in the data analysis and interpretation. Describe how qualifications, training, and expertise equip them to understand and address the complexities and challenges unique to qualitative methods. Describe data analysis procedures (e.g., coding of themes) and/or cross-case analyses and the link to the study's research questions. Describe the process by which inferences and themes are to be identified and developed. State how this process is congruent with the chosen qualitative approach and its methodology. Describe how explanations and conclusions will be derived and how they relate to interpretations and content of the original data.

AcademyHealth notes that the first two sentence focuses on staff and their qualifications. Evaluating staff and their qualifications is part of evaluating the merits of a research proposal but we are not sure if it should be included in the standard for how to carry out the research. Using staff with appropriate training and qualifications is not unique to qualitative methods, rather it is appropriate for and important to the conduct of all research methods (quantitative as well as qualitative and mixed methods). Additionally, is PCORI confident that they can assess what qualifications, training, and expertise would equip a researcher to understand and address the complexities of qualitative research? For example, there are many economists, epidemiologists, and physicians with little or no formal qualifications or training on qualitative methods who propose using them.

There are at least two possible approaches to addressing this problem: 1) Remove it from the qualitative methods standards and include guidance on this matter elsewhere; or 2) Add language about staff qualifications to standards for quantitative research, making standards for quantitative and qualitative research consistent.

Some specific issues to consider include:

- a) Per above, we recommend potentially removing information on staff and staff qualification from the standards and including it elsewhere. However, if PCORI choses to retain this as part of the methods standards, it is important to acknowledge that often times there are multiple researchers involved in the data collection, analysis, and interpretation. So, each staff and their relevant qualifications, training, and role on the project should be described if staff and their qualifications remains part of the standard. And, the language of the standard should be clarified. For example, “who is involved” might be rephrased to “which researcher or researchers are leading or contributing to the qualitative data analysis and interpretation.”
- b) “Describe data analysis procedures (e.g., coding of themes) and/or cross-case analyses and the link to the study’s research questions.” Coding is done to IDENTIFY themes in the data, so some clarification of language is needed. Additionally, because cross-case analysis is often part of the general data analysis procedure, the rationale for separating it out is unclear. We suggest that a more relevant question to pose is, “what is the ‘case,’ how does it relate to development of codes, analyses performed, and ability to answer the main research questions?”
- c) Further guidance on coding, specifically, how the code list is developed, how discrepancies between coders will be resolved, and what inter-rater reliability has been or should be achieved would be helpful. Alternatively, some cross-reference should be added to QM-4.
- d) We suggest trying to combine and clarify guidance about data analysis, using articles and text about use of appropriate qualitative data analysis techniques that increase credibility and trustworthiness of the results as in the next standard. For example, with respect to the sentence “Describe the process by which inferences and themes are to be identified and developed,” development of taxonomies and themes come before inferences, and related to understanding of how explanations and conclusions are derived, which is described below in another sentence (i.e., “Describe how explanations and conclusions will be derived and how they relate to interpretations and content of the original data.”)

Again, AcademyHealth suggests that when the final standard is developed, some additional effort be made to streamline the language. Below is a potential example of how language and the paragraph might be simplified using the current draft standard.

“Describe the qualifications, training and expertise of the data analyst(s), particularly their ability to understand and address the complexities posed in carrying out qualitative methods. Provide qualitative data analysis procedures, such as theme coding, and/or cross-case analyses and their link to study research questions. Describe the theoretical approach and methods to be used based on the qualitative methodological approach and how the analyses will be used to interpret the association of the results to the qualitative approach.”

#### **QM-4: Establish trustworthiness and credibility of qualitative research.**

Describe a detailed audit trail, and maintain fairness, balance, and neutrality. State how documentation regarding all phases of the analysis will be captured, as well as the processes used for inter-coder agreement (if applicable). Multiple data collection methods (e.g., interviews, focus groups, observations) and/or experts with diverse backgrounds (also known as triangulation) can be used. To enhance credibility, discuss three distinct elements: rigorous techniques and methods, the role of the researchers (e.g., values, preferences, and beliefs that could bias the research), and the value of participants’ perspectives and experiences. Credibility must be explained (see RQ-1, RQ-2, and IR-7) and demonstrated in the analysis in at least one of the following three ways: reflexivity, negative case analysis, and/or member checking.

Definitions of the terms ‘trustworthiness’ and ‘credibility’ would be helpful, along with a brief description of their similarities or differences to reliability and validity used on quantitative research. Additionally, references would be helpful here, as some researchers applying to PCORI may not be familiar with the terms trustworthiness and credibility and how to achieve them. For example, one of our Methods and Data Council members stated:

“This section seems to be more related to the quantitative approach. Are you asking for methodological details on how the focus groups are conducted? How the audio or video tapes will be reviewed and coded? How the natural process of saturation is accomplished? Qualitative work is often done with an emergent design and is less structured than quantitative work. Each qualitative method has a unique method of acquiring information to understand the social process of interest.”

Additional specific comments include:

- a) “Multiple data collection methods (e.g., interviews, focus groups, and/or observations) and/or experts with diverse backgrounds (also known as triangulation) can be used.” We believe “triangulation” refers only to using different types of methods and data to increase credibility and trustworthiness. Using experts with diverse backgrounds is not triangulation of methods and data, but simply the use of multidisciplinary research teams, expert panels and/or input. PCORI should clarify and/or provide a citation.
- b) “...the processes used for inter-coder agreement (if applicable).” This issue/language should be part of the standard QM-3 or cross-referenced there and perhaps further information added. See comment “c” above.

**MM-1: Specify how mixed methods are integrated across design, data sources, and/or data collection phases.**

State the mixed methods approach to inquiry, describing how it will inform the procedures of the study, and explain how integration will be achieved. Describe whether the quantitative and qualitative methods are to be sequential, concurrent, or a mixture of both, over time. Describe how the mixed methods design will integrate qualitative and quantitative approaches at one or more stages of the research process and achieve the intent of the design (e.g., by aligning the aims to data collection instruments, procedures and analyses of data, and the interpretation of the findings). State the strategies used to ensure that the credibility/validity of the individual and integrated qualitative and quantitative components remains intact over the course of the study (see IR-5 and QM-4). Describe the research team's capacity and expertise to support mixed methods inquiry (see QM-1).

As noted with QM-1, there is a lot bundled into this one standard, and some of it seems duplicative of MM-3. For example, language around integration seems to overlap considerably with MM-3. Our suggestion is to consider clarifying and emphasizing the unique aspects of this standard and cross-referencing and aligning it with other relevant standards, eliminating any duplication. Alternatively, PCORI might consider breaking this single standard up into several separate standards.

We also suggest that this section include descriptions of the timing of the qualitative and quantitative (e.g., concurrent, sequential, multiphase) approaches. It should also describe the specific mixed methods design approach (convergent parallel, explanatory, exploratory, embedded, transformative or multiphase designs). Finally, it should be noted that qualitative and mixed methods research is iterative and some flexibility is often needed: there may be a plan of how the MM study will be approached but the flexibility to modify that plan is essential.

With respect to the phrase "credibility/validity of the individual and integrated qualitative and quantitative components remains intact over the course of the study," this section should cross-reference or refer back to the appropriate QM standard defining credibility and trustworthiness and how they are similar or different from validity and reliability. Additionally, it would be helpful for PCORI to provide references or resources for how best to integrate various qualitative and quantitative approaches, methods, and data to achieve the aims of the proposed project.

Finally, similar to our comment above, we do not think language about staff capacity or qualifications belongs in the language describing the methodology standard as having the appropriate capacity and qualifications is applicable to all research methods; it is not unique to mixed methods. We suggest that PCORI remove the language about staff capacity and qualifications or add it to methods standards for quantitative methods.

**MM-2: Select and justify an appropriate mixed methods sampling strategy.**

Provide a clear description of the relationship between the sampling techniques and the generation of different types of data (i.e., numeric or closed-ended versus narrative or open-ended) (see RQ-3, RQ-4, and QM-2). Describe the sampling strategies and outline the temporality with which these will take place, as they relate to selected qualitative and quantitative methodologies (see IR-1, IR-2, PC-2, PC-3, and QM-1), including a justification of the emergence of other samples that may arise during the study, as applicable.

AcademyHealth notes that qualitative data is not easily reduced to numeric data and there is some controversy about if, when, and how to do so. We suggest PCORI remove the word numeric or describe further what they mean.

**MM-3: Integrate data analysis, data interpretation, and conclusions.**

Describe the analytic approaches to integration and demonstrate how the analysis plan is congruent with the study design and aims, and that it has been developed based on the methodological approach (i.e., either a priori or emergently) (see IR-1, IR-2, PC-2, PC-3, QM-1, and QM-3). Identify the order of study components and the points of integration. State who will conduct the integration; describe how their qualifications, training, and expertise equip them to understand and address the complexities and challenges unique to mixed methods analysis; and explain how integrated analyses will proceed in terms of the qualitative and quantitative components. Describe the approach used to interpret integrated data and how conclusions are supported by the context of original qualitative and quantitative findings. Address divergent findings from both qualitative and quantitative components, as well as method-specific biases across the methods (see QM-4).

Similar to our previous comment on MM-1, some of this language is duplicative with the first standard. Additionally, the language regarding staff and qualifications may not belong in the language of the standard itself. It may better be located in guidance outside the standard.

Perhaps reference to the quantitative methods standards should be made, as those standards would be relevant to the component parts of a mixed methods approach.