

QUALITATIVE METHODS IN IMPLEMENTATION SCIENCE



PREFACE

In recent years, the field of implementation science has significantly grown, both in the theories and frameworks used to explain it and in the available findings used to understand and influence the adoption, implementation and sustainment of evidence-based practices (and the de-implementation of ineffective or harmful practices). Capacity has greatly increased for our investigators to conduct studies that reflect the complexity and dynamism of improving care within clinical, community and public health settings. Improvements have accrued in the range of research designs used, the methods to collect data, and analytical strategies used to make sense of implementation processes and outcomes. From its beginnings, implementation science has recognized the importance of both qualitative and quantitative data and throughout its development, leading scholars have called for mixed methods approaches to ensure maximal return from each investigation.

Despite clear recognition of the value of qualitative research methods within implementation studies, there remains confusion as to which methods to use, how to best use them, and what guidance investigators should follow in their application. The Qualitative Research in Implementation Science (QualRIS) group was formed to reduce this confusion. Our investigators have moved from viewing qualitative research methods as an add-on to the major components of a study (i.e. addition of focus groups to address exploratory work on provider factors affecting implementation outcomes) to a necessary but often underspecified core of a study. In this paper, the QualRIS group explains multiple ways in which qualitative methods can be effectively used to answer a range of high priority implementation science questions, and describes resources that are available to support the community. While the field will continue to progress in its methodologies, this report offers a snapshot of how qualitative methods in implementation science have advanced and where they can go from here. We hope this serves as a helpful resource to investigators and that the report's recommendations are taken on so that the next generation of implementation science studies include the best qualitative research approaches to fit each question.

We are grateful to the QualRIS team for their substantial effort to review progress and offer guidance to the field, and to all those who seek to integrate qualitative research methods to strengthen their implementation science investigations.

Sincerely,

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I. INTRODUCTION

Implementation science is a rapidly developing field dedicated to putting evidence-based practices to use in real-world settings (Brownson et al., 2018; Glasgow et al., 2003; Kessler et al., 2012). Implementation science has been defined as, the scientific study of methods to promote the integration of research findings and evidence-based interventions into healthcare practice and policy. (See NIH PAR-16-237, PAR-18-007, and PAR-18-017 at <u>https://cancercontrol.cancer.gov/funding_apply.html#is</u>.) The field extends beyond healthcare into health behavior and promotion, including public and population health (Leeman et al., 2017), as well as education, policy, and other fields. The evidence-based interventions that are the focus of implementation science in healthcare include programs, practices, guidelines, and public and organizational policies that are intended to improve the health of individuals and populations (Rabin et al., 2008). To meet its overarching aim, implementation science seeks to identify factors and strategies that influence or predict adoption, adaptation, implementation (or de-implementation), sustained use, and scale-up and spread of evidence-based interventions.

Implementation science relies on qualitative and quantitative methods—or mixed methods—to understand the strategies and processes needed to implement an evidence-based change, the outcomes the change produces, the barriers and facilitators to implementing the change, and how all of these may vary across different types of contexts. Qualitative research methods are widely used in implementation science (Palinkas, 2014; Weiner et al., 2011). The power of mixed methods in yielding broader responses to research questions has been demonstrated in numerous areas of inquiry, and its advantages and challenges have been widely discussed (Zhang & Watanabe-Galloway, 2014; Hadi & Closs, 2016; Bishop, 2015). The use of mixed methods in implementation science has gained much recent attention (Tonkin-Crine et al., 2016; Palinkas et al., 2015; Palinkas et al., 2011; Beidas et al., 2014).

The uses of qualitative methods in mixed methods research vary according to the study design and can be quite complex. The discussion of design in mixed methods studies is beyond the scope of this paper. We will not discuss mixed methods specifically, but, rather, refer the reader to some notable resources on the subject (Creswell, 2015; Creswell et al., 2011; Creswell & Plano-Clark, 2011).

While there is a great deal written on standards for qualitative research in general, there are aspects of doing qualitative research in the context of studying implementation that may make the norms and guidance for best practices in this use quite different. For example, demand for timely or rapid turnaround of results, need for multiple stakeholder perspectives, diversity of contexts across implementation sites, and contextual changes over time all pose unique challenges to the agility and rigor of qualitative methods. This paper is an initial step to provide guidance to the field about the use of qualitative methods in implementation science. Our target audiences include implementation researchers with limited to no experience with qualitative research methods, as well as experienced qualitative researchers who are learning about implementation science and potentially partnering with implementation scientists.

II. APPROACH

In 2015, the National Cancer Institute's (NCI's) Implementation Science Team convened a group of experts in implementation science and/or qualitative research, to develop guidance for the use of qualitative methods in implementation science. The Qualitative Research in Implementation Science (QUALRIS) group conducted its work via teleconference, email, and as an NCI online learning community (<u>https://researchtoreality.cancer.gov</u>). The group consulted literature on best practices in qualitative methods and drew upon members' own extensive experience in adapting these methods for implementation science. Following this iterative process, the group determined focal areas to examine, presented preliminary work to scientific audiences (Hamilton et al., 2015), and then drafted this white paper. After several revisions, the draft white paper was reviewed by the group's advisory panel, consisting of five leaders in implementation science and qualitative methods: Ross Brownson, Cam Escoffery, Russell E. Glasgow, Anne Sales, and Bryan J. Weiner.

After briefly describing traditional qualitative research methods, we (1) describe the role of qualitative research in health-related implementation science; (2) offer guidelines for conducting qualitative research in implementation science; (3) identify areas of need and opportunities for the development of innovative qualitative methods; and (4) provide resources for those wishing to employ or learn more about qualitative methods in implementation science.

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III. TRADITIONAL QUALITATIVE RESEARCH METHODS: AN OVERVIEW

Qualitative methods generally emerged from the social sciences, specifically anthropology and sociology, and tend to focus on approaches for studying human behavior and experience. These attributes are particularly salient for implementation science because of its focus on understanding how implementation processes influence and are influenced by dynamic contextual factors, which requires study of human behaviors and experiences, individually and within collectives (e.g., a healthcare organization or setting). Qualitative methods do not depend upon numerical manipulation of data, although basic frequencies and summations may be used to present data, provide contextual information, and transpose data for use in mixed methods analysis.

The diverse forms of qualitative methods do, for the most part, share common elements and perspectives (Crabtree & Miller, 1999; Padgett, 2008; Pope & Mays, 2006; Southam-Gerow & Dorsey, 2014). Traditionally, such methods seek in-depth understanding, and may be used to generate hypotheses. Qualitative methods are typically inductive and naturalistic; in other words, data are drawn from people, often in their natural settings. Qualitative methods, to varying degrees, seek interpretation of social phenomena, rather than their objective representation. Qualitative methods intend to give a holistic, full representation of complex, dynamic social circumstances reality (Padgett, 2016; Pope, Mays, & Popay, 2006; Damschroder et al., 2009; Kitson et al., 2017). Traditional qualitative research approaches have typically involved deep engagement of researchers in naturalistic settings and with participants over significant periods of time. The immersive and iterative nature of qualitative research allows for the comprehension of the dynamism and complexity of aspects of everyday life.

IV. QUALITATIVE RESEARCH METHODS IN IMPLEMENTATION SCIENCE IN HEALTH AND HEALTH CARE: AN OVERVIEW

Implementation science is *action*- and *change-oriented*, with a focus on understanding what is changing in relation to the intervention and implementation strategies; how, when, where, and why changes happen (or not); and who is involved in the changes. Studies in implementation science usually occur over a relatively short period of time, with a clear before, during, and after. (See Brear et al., 2018; Ivankova, 2015; and Meyer, 2000, for discussions of action research and qualitative methods.) With this backdrop in mind, our team has identified nine key features of the use of qualitative methods within implementation science:

- 1. In contrast to a more constructivist, exploratory, inductive paradigm, qualitative methods in implementation science tend to be more positivist and deductive in nature, with their use increasingly guided by theories and organized by one or more implementation models or frameworks.
- **2.** Qualitative methods in implementation science tend to be practical and targeted, geared more toward explaining specific implementation-related phenomena.
- **3.** Implementation science involving qualitative methods is inherently multidisciplinary rather than discipline-specific.
- **4.** Implementation science typically integrates qualitative and quantitative methods to strengthen findings, often in the context of complex mixed methods designs rather than using qualitative methods alone.
- **5.** Implementation science using qualitative methods typically involve qualitative methods teams rather than solo researchers.
- 6. Qualitative data collection in implementation science is often time-limited, with data collection occurring at single or punctuated time points (e.g., pre-, mid-, and post-implementation), often in rapid fashion rather than continuous data collection over an extended period, a hallmark of traditional qualitative methods.
- 7. Engagement in implementation science tends to be targeted toward multiple stakeholders (e.g., providers, administrators) in multiple, diverse settings (e.g., several health clinics) rather than traditional long-term, indepth engagement within a community.
- 8. Qualitative data analysis in implementation science tends to be targeted to specific *a priori* research questions, is usually more rapid, and is often integrated with quantitative analyses. This contrasts with more traditional qualitative analysis, which tends to be phenomenologically oriented with an emphasis on reflexivity.
- **9.** In addition to contributing to traditional outlets such as the scientific literature, implementation science seeks to disseminate both qualitative and quantitative findings through "grey" literature, including interim reports, policy and operations briefs, workshops and trainings, online resources, site profiles, and implementation metrics that may be more readily accessed by practitioners.

Implementation science is a young, evolving, and complex field of research. Its researchers are confronted with several challenges, including facing and embracing the complexity and dynamic nature of interventions, implementation processes, and intersecting implementation contexts and their interactive effects on outcomes (Abbott et al., 2014; Azar et al., 2015; Brives et al., 2016; Brownson et al., 2012; Damschroder et al., 2009; Glasgow, 2008; Glasgow et al., 2012).

V. VALUE OF QUALITATIVE METHODS IN IMPLEMENTATION SCIENCE

Here we review several ways in which qualitative methods are valuable in implementation research conducted to date.

A. Elicit Stakeholder-Centered Perspectives

Qualitative methods are used to elicit the perspectives of those who have a "stake" in implementation and who are responsible for "healthcare-related decisions that can be informed by research evidence," i.e., stakeholders, such as administrators, providers, staff, patients, clients, families, and community members (Martinez et al., 2016; Concannon et al., 2012). Understanding the perspectives of those involved in and/or affected by implementation of an intervention is essential to ensuring that interventions address problems recognized as high priority and use approaches that are feasible and acceptable within real-world practice contexts (Chalmers & Glasziou, 2009; Glasgow et al., 2012; Tunis et al., 2003). For example, Leeman and colleagues (2014) conducted in-depth interviews with public health practitioners working in obesity prevention to understand factors that influenced the adoption and implementation of evidence-based policy, systems, environmental change interventions at the state and local levels. Kane and colleagues (2014) also conducted interviews with providers to assess perspectives on feasibility and acceptability of new guidelines. Qualitative researchers often bring a participatory perspective, especially when focused on implementing practices to serve marginalized populations, relying on partnerships with a wide range of stakeholders to achieve study goals.

B. Inform Design and Implementation

Qualitative studies have been used to inform the design and implementation of interventions. For example, Proctor and colleagues (2007) conducted a qualitative pilot study to document the perspectives of agency directors on the challenge of implementing evidence-based practices in community mental health agencies prior to the development and testing of a specific implementation intervention. Using a participatory research approach (see Reason & Bradbury, 2008), Elsey and colleagues (2016) conducted qualitative semi-structured interviews and focus groups in Nepal to understand patient and health worker knowledge of tobacco and patients' motivation to quit. Findings were used to inform the design and implementation of a smoking cessation intervention. A Norwegian research team used a series of individual and group interviews with various stakeholders to inform the implementation of tailored interventions to improve the treatment of elderly patients with depression (Aakhus et al., 2015). The stakeholders, including health professionals, researchers, and relatives of elderly patients with depression, were asked to brainstorm interventions to improve adherence to treatment guidelines. These qualitative findings were used to test targeted versus non-targeted interventions to improve adherence in an implementation trial. Semi-structured interviews with mental health practitioners were used to examine the barriers to using a smartphone application to enhance patient compliance to evidence-based psychotherapy for post-traumatic stress disorder (PTSD) (Reger et al., 2017). Based on these interviews, a targeted intervention was developed to increase use of the smartphone application among PTSD therapists.

C. Understand Contexts Across Diverse Settings

One of the most frequently cited reasons for using qualitative methods in implementation science is to understand contextual factors that influence implementation, such as variations in uptake (Bekelman et al., 2016; Cadogan et al., 2016; Cohen et al., 2016; Elsey et al., 2016; Lord et al., 2016; Marshall et al., 2008; Marty et al., 2008; Rapp et al., 2010; Sommerbakk et al., 2016; Varsi et al., 2015; Damschroder et al., 2017). Since contexts can differ markedly across implementation sites, understanding contexts and their relation to implementation is of critical importance. See <u>Section VI/B</u> below. Qualitative methods are well suited to explore how context, actions, and people contribute to successful (or failed) implementation. Researchers have examined factors that influence implementation of the

life of study or initiative, from pre-implementation (Koenig et al., 2016), to implementation (Moeckli et al., 2013), to sustainability (Colon-Emeric et al., 2016). For example, researchers (Swain et al., 2009) studied implementation of an illness management and recovery program for people with severe mental illness in community mental health settings. Qualitative methods were used to assess perceived barriers and facilitators of implementation such as leadership, organizational culture, training, and staff and supervision. The analysis showed that several cross-site factors worked synergistically to influence implementation (Whitley et al., 2009). Freedman and colleagues (2012) supplemented survey data with in-depth interviews to identify factors critical to a health center's readiness to implement a farmers' market. They found several factors to guide researchers and health center staff in development of a farmer's market to improve access to healthy foods. Damschroder and colleagues (2009) have used qualitative assessments, guided by the Consolidated Framework for Implementation Research (CFIR), to understand variations in implementation success and provide recommendations for scaling up implementation of programs (Damschroder & Lowery, 2013; Damschroder, Reardon, AuYoung et al., 2017; Damschroder, Reardon, Sperber et al., 2017). Internationally, researchers have used qualitative methods to encapsulate findings in conceptual models of system transformations (Bate et al., 2008; Lukas et al. 2007), and have highlighted context as an active agent influencing the implementation and not just a backdrop to it (Dopson & Fitzgerald, 2006).

D. Provide Documentation and Encourage Reflection on Implementation Processes

Another value of qualitative methods is to document and reflect on implementation processes. For example, Aarons and Palinkas (Aarons & Palinkas, 2007; Palinkas & Aarons, 2009) collected qualitative data through annual interviews and focus groups to assess the process of implementation of Safe Care®, an intervention designed to reduce child neglect and out-of-home placements of neglected children into foster care. Hoagwood and colleagues (2007) used a case study of an individual child to describe the process of implementation of an evidence-based, trauma-focused, cognitive-behavioral therapy for treatment of symptoms of PTSD in children living in New York City in the aftermath of the World Trade Center attack on September 11, 2001.

Qualitative methods such as ethnography are well-suited to capture implementation micro-processes, that is, at the level of individual interactions (Nilsson et al., 2018). Furthermore, fidelity to intervention use and implementation strategies and their adaptations can be documented and better understood by qualitative inquiry, as can adoption of improved practices (Bunger et al., 2017; Cohen et al., 2008). Such inquiry can inform development of and contribution to the *adaptome*, an aggregate body of knowledge documenting "adaptations to interventions and their impacts on implementation, service, and health outcomes" as proposed by Chambers and Norton (2016). This also raises considerations of flexibility and fidelity during adaptation (Cohen & Crabtree, 2008).

E. Gain Insight Into Implementation Effectiveness

Qualitative methods are used to study the effectiveness of implementation. Proctor and colleagues (2011) created a taxonomy of implementation outcomes to consider when assessing implementation effectiveness. Many implementation outcomes are well-suited for evaluation via qualitative methods. Furthermore, qualitative methods are often used when valid measures are not available. (See Rabin et al., 2016, for measurement resources in implementation). The effectiveness of implementation strategies, (i.e., approaches employed to integrate an intervention into a new practice setting; Powell et al., 2012; Powell et al., 2017; Powell et al., 2015), also requires evaluation, often best accomplished with qualitative methods. Wozniak and colleagues (2015) evaluated the implementation of an efficacious collaborative care model or patients with diabetes and depression in Canada. Researchers used qualitative interviews among staff and systematic documentation of the implementation to assess effectiveness. The qualitative data analysis identified factors such as lack of training in team operations, physician-nurse relations, and local physician culture as barriers to optimal collaborative care that the model stipulated.

Rapp and co-authors (2008) used a mix of qualitative data collection techniques to identify and evaluate strategies that contributed to successful implementation in six community mental health centers (CMHCs). Data collection techniques included text analysis (e.g., notes, memos, reports), formal and informal interviews, and direct observation. Data was coded according to 26 *a priori* themes and included in comprehensive site reports for each of the six CMHCs. Through an iterative analytic process, investigators and key stakeholders blinded to the original *a priori* categories, created a provisional coding guide. This was used to develop a final coding scheme applied to all six implementation sites. Eight strategies were found that contributed to successful implementation in the six CMHCs.

F. Understand Mechanisms of Change

Qualitative methods can be employed to understand mechanisms of change and the relationship(s) between the theorized and actual mechanisms of change (Kazdin, 2007) by identifying and explaining which aspects of the intervention or its implementation result in change. Now, "mechanism of change" can be defined variously and one study's mechanism may be another study's moderator or intermediate outcome. A discussion of this variation is beyond our scope, but in this section, we will describe some uses of qualitative methods to understand change. (For further perspectives on change, see Lewis et al., 2018; Dalkin et al., 2015; May, 2013; Rycroft-Malone et al., 2012).

Following a continuous quality improvement (CQI) effort for care of Indigenous Australians, Schierhout and colleagues (2013) explored the patterns of change in service delivery in 36 widely-varying health centers that had participated in the CQI project. Using a mixed-methods "realist" approach (see Rycroft-Malone, 2012; Dalkin et al., 2015), implementation researchers conducted key informant interviews to elicit interpretations about cross-site variation's role in producing service-delivery variation. Inductive analysis led to fine grained hypotheses of change and further data were collected though clinical audits, project monitoring reports and workshops with key informants involved in implementation. The team abstracted potential patterns of context, mechanism, and outcomes to develop a working theory of change for program strengthening.

Qualitative methods can help us to understand how interventions (change) can be sustained (Cohen et al., 2016; Palinkas et al., 2016; Colon-Emeric et al., 2016). For example, in a study examining how to sustain complex interventions in long-term care, 15 focus groups were conducted with 83 staff who had participated in the intervention trial (Colon-Emeric et al., 2016). Participants gave perceptions of intervention salience and sustainability. Analysis produced insights about intervention features, organizational context, and external support offering concrete suggestions on how to maintain changes brought about by interventions.

Damschroder, Reardon, AuYoung, and colleagues (2017) mapped qualitatively-identified barriers and facilitators, to specific types of outcomes defined by RE-AIM to identify factors that may moderate the intervention's effects on outcomes. This work highlights the key role qualitative methods can play in explicating multiple potential causal pathways for further testing (Forman et al., 2017).

G. Contribute to Theoretical Development

There is ample description, cataloguing, and discussion of conceptualization, that is, theory, frameworks, and models in implementation science (Nilsen, 2015; Chambers, 2014; Tabak et al., 2012; Davies et al., 2010; May et al., 2009; Eccles et al., 2005) but less agreement on terminology. According to Tabak and colleagues (2018), theory and frameworks can both be considered to belong to the category of models. Davidoff and colleagues (2015) recognize multiple levels of theory, grand, mid-level, and lower. They propose that lower or "program" level theories are perhaps the most useful in improvement work. Similarly, Chambers (2014) points out that rather than "classical" theory, these more immediate-level models or frameworks are useful in formulating specific research questions and explaining dissemination and implementation processes across diverse stakeholders and settings.

Researchers have explicitly challenged the implementation science community to contribute to advancing existing theoretical frameworks to stimulate new theoretical developments (Damschroder et al., 2009; Kitson et al., 2008). Theory provides an efficient way to build the knowledge base through shared language and concepts that are foundational for guiding data collection, measurement, analyses, and interpretation, and creates a natural bridge of comparison to other studies using the same theories (Colquhoun et al., 2014; Foy et al., 2011). Qualitative approaches can advance conceptual development in multiple ways.

Qualitative methods can inform the development of conceptual models or frameworks through grounded methods (Corbin & Strauss, 2008; Glaser & Strauss, 1967). For example, Zazzali and colleagues (2008) developed a conceptual model of implementation of Functional Family Therapy using qualitative data elicited through semi-structured interviews with 15 program administrators. Their model could then be tested using quantitative methods. Blasinsky et al. (2006) developed a rating scale to construct predictors of program outcomes and sustainability of a collaborative care intervention to assist older adults suffering from major depression or dysthymia based on qualitative data obtained from semi-structured interviews. Woltmann et al. (2008) created categories of turnover and designations of positive, negative, and mixed influence of turnover on outcomes using qualitative data obtained through interviews with staff, clinic directors, and consultant trainers in their study of staff turnover during implementation of evidence-based practices in mental healthcare.

Testable theories of implementation within organizations have been evaluated using qualitative methods. For example, Klein and colleagues' model of implementation (Klein & Sorra, 1996; Klein et al., 2001) was first tested in a manufacturing setting. This model was then adapted for clinical settings and assessed for applicability and usefulness in two different studies using qualitative data (Helfrich et al., 2007; Damschroder et al., 2011) collected through semi-structured interviews of key stakeholders. Both studies recommended refinements to the model based on their respective qualitative findings. The adapted model can be further tested in more settings and verified using a full range of methods including qualitative, quantitative, and/or mixed methods.

Highly cited implementation frameworks have been developed based on foundational, empirical qualitative data including the Promoting Action on Research Implementation in Health Services (PARIHS) (Kitson, 2008) and Normalization Process Theory (NPT) (May, 2006; May et al., 2009). PARIHS developers further developed their framework into i-PARIHS, based on a growing knowledge base (Harvey & Kitson, 2015), and May (2013) further extended NPT to create a generalized, mid-range theory of implementation based, in part, on accumulating qualitative findings from several researchers using NPT. Because of the complex and dynamic interplay between implementation processes, places, and people, qualitative methods are often used in conjunction with frameworks to guide evaluation or execution of implementation. For example, a systematic review of published studies using the CFIR, revealed that 23 of 26 eligible studies used qualitative methods (Kirk et al. 2016).

VI. METHODOLOGICAL CONSIDERATIONS FOR THE USE OF QUALITATIVE METHODS IN IMPLEMENTATION SCIENCE

When using qualitative methods in implementation science, several considerations should be kept in mind, including *sampling procedures*, the *timing* of data collection, the *role of the qualitative researcher*, procedures for *collection and analysis* of qualitative data, and *presentation of findings*. Each of these considerations is examined briefly below.

A. Sampling

Sampling of participants in qualitative studies is generally purposive in nature (Palinkas et al., 2015). Random sampling is occasionally used if participants are involved in quantitative studies as well or if there is a need to generalize study results in a manner that cannot be accomplished with maximum variation or other forms of purposive sampling. In implementation science, participants are often sampled based on their level of participation in the implementation process and role in the organization to maximize diversity of perspectives (Colon-Emeric et al., 2016). Bekelman and colleagues (2016) conducted stratified purposeful sampling to capture the range of perspectives from providers of different disciplines who provide or have patients enrolled in outpatient palliative care. They also recruited leaders who were likely to decide whether and how to adopt and sustain outpatient palliative care in their settings.

Implementation scientists may also select the entire population of those implementing or receiving the intervention, particularly when the population is small, such as in a feasibility pilot study of an implementation strategy. Sample size may also be limited by geographic setting, such as population defined by a census tract. To be sure, size is not the most important sampling issue, depth or data saturation is the goal. The state of saturation is reached by sampling to the point of redundancy or repetition, when data collection in a particular sample yields no new information (Crabtree & Miller, 1999; Francis et al., 2010).

Samples may be selected from any population of interest, not only individual persons but of care delivery sites, political or economic institutions, geographic entities, and so on. Focusing on case study analyses, Sax et al. (2013) purposefully sampled six hospitals from a larger study of 15 hospitals involved in an infection control implementation project across Europe. The investigators used criteria sampling to choose three "high potential for change" hospitals and three "low potential for change" hospitals to examine the process of uptake of the intervention designed to reduce hospital infections in intensive care units. This sampling strategy was based upon preliminary qualitative results. Researchers then used key informant interviews, ethnographic observation, written protocol collection, guideline collection, and photography to collect data relevant to infection control. Preliminary analysis of data found 15 themes relevant to successful implementation of infection control practices (Casillas et al., 2013) across the hospitals and factors influencing leadership dynamics in infection control (Clack et al., 2013).

B. Timing of Data Collection

Due to implementation science's orientation toward change, qualitative researchers must pay particular attention to the dynamic nature of the contexts in which they are working (Chambers et al., 2013). See <u>Section V/C</u> above. Time is a central factor to consider when conducting qualitative research in implementation science. Early in implementation studies, qualitative researchers are often called upon to assess the organizational or community context in which the intervention will be implemented. This may require semi-structured interviews with the key stakeholders who will be involved or impacted by the intervention to examine the "baseline" context of a setting, asking questions such as, what is the stakeholders' current practice in relation to the target outcome? (Stewart et al., 2010; Nutting et al.,

2010). Observations of the community or clinical setting are frequently conducted to assess the interactions of the stakeholders and whether their behavioral practices are consistent with the perceptions they articulated in interviews. Observations can be especially helpful in documenting current processes (Nilsson et al., 2018).

The baseline assessment of context is then used to make key decisions in the next stage of the study. Qualitative findings are often used to choose the most appropriate implementation strategies or, at the very least, to tailor strategies to settings and actors. The timing of when the intervention must be implemented, therefore, impacts how the baseline data will be analyzed. With a typically shorter turnaround time, qualitative researchers in implementation science have turned toward rapid analysis techniques, including template analysis, in which key concepts are identified in advance to structure and focus the inquiry (Reger et al., 2017; Hamilton, 2013; Fox et al., 2016).

Qualitative researchers are often asked to conduct formative evaluations of implementation processes, which may entail documentation of implementation strategies as they are used in real time. Qualitative researchers may also be asked to provide feedback as the implementation process is occurring to aid in the change process, asking questions such as, what are the major facilitators and barriers to implementation, and what could be changed to improve implementation and sustainability?

Finally, qualitative research may be conducted at the end of an implementation study to understand and explain both implementation and effectiveness outcomes. It may also be used to assess and consider the reactions of adopters of the intervention as well as stakeholders who resisted adoption.

An issue related to timing is the iterative nature of qualitative and mixed methods research in implementation science. Understanding and facilitating implementation and sustainment of innovative and evidence-based practices is a continuous learning process. With multiple time points of data collection and attention towards change, this can make harnessing the iterative nature of qualitative research more difficult. This also raises the issue of when qualitative methods "cross over" and become part of the implementation strategies, e.g., when key stakeholder interviews become mechanisms of education about and engagement in an intervention (Hamilton et al., 2017).

C. Roles of Qualitative Research Teams in Implementation Science

Implementation science is a truly interdisciplinary field. The health-related implementation science team generally includes clinical experts, social-behavioral scientists, biostatisticians, economists, intervention developers, and organizational scientists (Fernald & Duclos, 2005; Guest & MacQueen, 2008). Qualitative researchers need to consider this team as they develop interview and observational guides as well as when they decide who will conduct the interviews, and who will participate in the analysis process (Damschroder & Lowery, 2013). The qualitative expert will need to lead these activities while managing the interdisciplinary team's involvement. Leading a multidisciplinary team can be a challenging undertaking (see Vogel et al., 2014; and Hesse-Biber, 2016; Crabtree et al., 1994, on team science). The challenge can be amplified when the qualitative expert is not the principal investigator. See <u>Section VIII</u>.

D. Data Collection

Several different data collection techniques have been used in implementation science, such as one-on-one interviews, focus groups, observation, and archival or document analysis

Interviews can be conducted either in-person, by telephone, or electronic media (e.g., Skype) and are ideally digitally recorded and transcribed verbatim for analysis. (Mealer & Jones, 2014; Kothari et al., 2012; DiCiccio-Bloom & Crabtree, 2006), Also used in implementation science are semi-structured interviews or elicitation methods techniques that utilize a quasi-statistical perspective. For example, Palinkas and colleagues (2016) reported using a free list exercise to elicit

participants' conceptions of the term sustainment, the elements of their programs they wished to sustain, and the requirements for sustaining these elements. Responses were weighted based on order of presentation and compared by source of program funding.

Focus groups, also called group interviews, are widely used in health research and in implementation science (Reichstadt et al. 2007; Tausch & Menold, 2016; Kitzinger, 2006; Krueger & Casey, 2000; Thomas et al., 1992). The advantage of the group interview approach is that it capitalizes on within group interaction to stimulate thought resulting in rich detailed accounts of the focal topic (Asbury 1995). Focus groups are usually held on-site, gathering participants in a common locality (Howard et al., 2017) but they can also be held online. DuBois and colleagues (2015) conducted online focus groups about decision-making among gay and bisexual adolescent males. Focus groups tend to be popular with researchers not only because of the results they generate, but also because they frequently offer a more economic use of financial and spatial resources as well as time. However, there are drawbacks and limitations to focus groups and the decision to use focus group technique is the potential impact of censoring and conforming behavior in group interaction. Participants can be strongly influenced by each other, potentially narrowing the range of ideas obtained. Also, participants may feel uncomfortable to express a sincerely held idea or opinion, which calls into question the accuracy of results (Smithson, 2000).

Observation often occurs during site visits, which are conducted for a variety of reasons, including assessing local contexts and observing the nature and intensity of how interventions are being implemented (Cohen et al., 2016; Fox et al., 2016; Palinkas et al., 2016). Data gleaned from observation is typically in the form of field notes, which may be more structured in implementation science than in traditional ethnographic research, in order to facilitate more rapid or targeted analysis. When conducted over a period of time, such observations capture the interactions and behaviors of participants in their natural settings (e.g., a hospital or community-based organization). For example, Escoffery and colleagues (2009) made annual observations of 40 swimming pools during the five-year, mixed-methods implementation study of an evidence based skin cancer prevention program along with qualitative interviews and quantitative surveys.

Archival analysis entails the collection of documents, including meeting minutes, logs, policies, guidelines, and health records (Turner et al., 2016; Lessard et al., 2016). Pelcastre-Villafuerte and colleagues (2014) evaluated the processes and performance of Project "Casas" to deliver culturally and linguistically appropriate services to indigenous women in four Mexican states. Data were collected through extraction from archived regulatory and program documents as well as semi-structured interviews. The study not only evaluated the past performance of the project, it also provided information for the improvement of the existing program sites, as well as more cost-effective implementation of the model in new sites. Other archival data include diaries and videotapes used to document implementation experiences (Cohen et al., 2016; Elsey et al., 2016), videotaping, and photography (e.g., photo voice) (Kowitt et al., 2015).

Implementation science typically includes multiple data sources to aid in triangulation. For example, Kennedy and colleagues (2016) employed a longitudinal case study design in which ethnographic methods comprising video, non-participant observation of intervention delivery, and qualitative interviews at baseline, six and 12 months were used to identify processes and dynamics of delivering a social network intervention and to capture individual outcomes of the use of a web-based tool. Shea et al. (2014) studied the feasibility of implementing a virtual tumor board program that connected community-based clinicians to academic tumor boards. Methods included observation of virtual tumor board cases using a structured observation checklist and semi-structured interviews with participants. In an implementation study of behavioral health counseling in primary care practices, Cohen and colleagues (2011) used visit notes, documents, interviews, and online implementation diaries in a comparative analysis of nine different interventions in nine practice-based research networks. They found practice health risk assessment and brief counseling, coupled with referral and outreach to a valued and known counseling resource, to be the best way to consistently coordinate and encourage follow-through for health behavior counseling.

E. Data Analysis

A commonly used analytic approach to qualitative data in implementation science is thematic analysis (Hsieh & Shannon, 2009). There are several variations of thematic analysis, ranging from techniques that are largely deductive to techniques that are largely inductive, with substantial variation in between. Reflecting more of a deductive approach to qualitative data analysis, several studies (Bajunirwe et al., 2016; Elsey et al., 2016) have employed a framework or template approach (Gale et al., 2013; Parkinson et al., 2016; Srivristava & Thomson, 2009) to data analysis. See <u>Section VIII</u>. Such approaches are theory- or framework-driven and involve mapping data or emergent themes onto *a priori* domains, themes, or categories. Cadogan and colleagues (2016) used a framework analysis approach to map emergent themes onto the Theoretical Domains Framework (Michie et al., 2014). Several studies (Elsey et al., 2016; Kennedy et al., 2016; Nordmark et al., 2016) have used NPT (May & Finch, 2009) to provide conceptual orientation for exploratory data analysis of complex interventions.

One of the better known examples of a framework approach is the use of the CFIR (Damschroder et al., 2009) to guide the analysis of data collected through semi-structured interviews. For example, Bekelman and colleagues (2016) conducted semi-structured interviews, using the CFIR domains to assess barriers and facilitators to the adoption and scale-up of outpatient palliative care. Varsi and colleagues (2015) used the CFIR to examine barriers and facilitators for the implementation of an internet-based patient-provider communication service (Forman et al., 2017). Hamilton and colleagues (2018) used CFIR post-hoc to examine the impact of external context on implementation of an evidence-based prevention intervention (Hamilton et al., 2018).

Content analysis typically involves identifying pre-selected incidents or references in the data (Padgett, 2016). Frequently used with archival materials, content analysis does not entail a search for deeper meanings and interpretations. Padwa and colleagues (2016) conducted a directed content analysis of qualitative data using the Conceptual Model of Evidence-Based Practice Implementation in Public Service Sectors (Aarons et al., 2011) to understand the implementation of integrated behavioral health protocols in primary care settings.

Since theoretical frameworks are generally expected to drive implementation science (Tabak et al., 2012), highly inductive approaches such as grounded theory (Charmaz, 2006) may not always be a good fit for analyzing qualitative data gathered in implementation science (Davidoff et al., 2015). In grounded theory, preconceived conceptual categories must "earn their way" into the findings, rather than drive the data collection effort (as in implementation science). However, principles of grounded theory can still be useful in informing implementation-related qualitative analysis (e.g., being data-driven).

Perhaps the most common strategy for data analysis is to combine inductive and deductive approaches. For instance, Mozaffar et al. (2016) conducted a thematic inductive and deductive analysis, using a biography of artifact perspective to move beyond a single timeframe and a "localist" perspective and to examine both technical and nontechnical aspects of computerized hospital physician order entry and clinical decision-support systems. Colon-Emeric et al. (2016) analyzed interview transcripts using framework analysis of *a priori* concepts, combined with inductive analyses. Sommerbakk and colleagues (2016) used a combination of thematic analysis using an inductive approach and theoretical thematic approach, applying codes to Grol & Wensing's (2004) multilevel model of barriers and facilitators. Using a combination of inductive approaches, analysts can draw on ideas emerging from the empirical data as well as frameworks and existing literature (Bradley, Curry, & Devers, 2007).

Whether inductive, deductive, or a combination of the two approaches, thematic analysis usually involves the process of constant comparison (Strauss & Corbin, 1998) to construct themes based on a taxonomy of codes. Themes may be compared across organizations and stakeholder groups (Kane et al., 2016). In the rapid analytic approach used by Hamilton (2013), main topics (domains) are drawn from interview and focus group guides, and a summary template is

developed and used to summarize transcripts (e.g., Fox et al., 2016). Summaries are analyzed using matrix analysis and key actionable findings (e.g., the variable use of implementation strategies) are shared with the implementation team to guide further implementation in real time, particularly during the course of phased designs such as in a Hybrid Type II Study (Curran et al., 2012). This rapid approach can inform more in-depth hybrid analytic approaches, described above.

In terms of assessing interrater reliability during data analyses, coding independently then meeting as a group to reach consensus appears to be the most common strategy (Bekelman et al., 2016; Cadogan et al., 2016; Lessard et al., 2016; Lord et al., 2016; Martinez et al., 2016). During these meetings, investigators compare how the same texts are coded by different coders and resolve discrepancies in terminology and assignment of codes (Fox et al., 2016). Some qualitative studies (Damschroder & Lowery, 2013; Lord et al., 2016) make explicit use of a consensus-based directed content analysis approach (Hill, 2012). In a few instances, this comparison is quantified by calculating percent agreement or kappa statistics in assignment of codes (Palinkas et al., 2013; Saldana, 2014). Occasionally, a qualitative expert not integrally involved in the study is employed to review or "audit" the process as an effort to maximize validity of findings (Damschroder & Lowery, 2013). (For a thorough discussion of team-based qualitative analysis see Guest & McQueen, 2008, and consult section VI/c, above.)

F. Presentation of Qualitative Findings

It is a challenge to present depth of qualitative analysis in the limited space allowed for journal articles. Most implementation science presents qualitative results organized by themes illustrated with direct quotations from study participants, an approach that is accessible to readers (Sandelowski & Leeman, 2012). Results should not merely be comprised of a list of themes, but should specify which themes were emergent and which were *a priori*, and when relevant, how themes are related to one another. Although verbatim quotations are commonly used to document the existence or character of a theme, they should also provide a level of eloquence and insight not possible with a summary of the theme. Usually, one quote is sufficient to make a specific point, unless the point itself contains important nuances or contrasts that require more than one quotation to illustrate.

When using quotes, it is advisable to link them to a participant identification number so that readers can be assured that different participants are being quoted. When multiple stakeholders are involved, identifying their role (e.g., hospital administrator, nurse, physician), if permissible, helps to contextualize what is being said and by whom. In addition, for multi-site studies, it is useful to use identifiers to distinguish between sites and demonstrate contextual patterns within and across sites and/or experimental conditions, if relevant.

Although themes and associated quotes typically form the narrative structure of the findings, tables have also been used to organize the presentation of themes with illustrative quotes. Tables have the advantage of presenting the results in a condensed form, enabling authors to publish in journals that have more stringent word limitations. Elsey and colleagues (2016) used qualitative data to construct a table of barriers and facilitators to implementation using NPT (May et al., 2009). Also, Guetterman, Fetters, and Creswell (2015) investigated mixed methods displays and discussed what each display type communicated and represented.

A third form of presentation of study results is the use of figures and diagrams that illustrate relationships among themes identified from analyses of qualitative data. Palinkas and colleagues (2008) used a figure to illustrate relationships among themes and subthemes representing predictors and outcomes of short-term implementation of three evidence-based treatments for depression, anxiety, and behavioral problems in 8- to 13-year-old youths. Lessard and colleagues (2016) used figures to depict a conceptual framework of facilitation categories and themes, the relationship between implementation-oriented facilitation roles and support-oriented facilitation roles, and the dynamic interrelations between groups of actors and/or between actors in the same group of facilitators. Elsey and colleagues (2016) used qualitative data to construct a figure outlining patient flow in a proposed smoking cessation intervention.

VII. COLLECTING AND ANALYZING QUALITATIVE DATA WITH RIGOR

Qualitative methods encompass diverse approaches, yet they share a need to foster standards of quality and methodological rigor (Lincoln & Guba, 1985; Tracy, 2010). Given differences in paradigmatic or epistemological orientations, qualitative researchers may adhere to a non-prescriptive interpretive approach or they may prefer a somewhat more structured or formalized approach (post-positivist) to determining quality. Most qualitative researchers in health services and implementation science opt for explicit standards without sacrificing the flexibility that is the hallmark of qualitative inquiry.

It is helpful to distinguish between criteria applied to completed qualitative studies (evaluative standards) and specific strategies or actions undertaken as part of the study's design and procedures. This distinction, beginning with a discussion of evaluative standards and moving on to recommending specific strategies for rigor, will comprise this section. Evaluation standards are an imperative from the beginning to insure all members of the team agree upon the procedures and basic techniques that will be used to determine assess outcomes (Frankel, 1999; Cohen & Crabtree, 2008). Such standards have become especially salient with the rise of qualitative systematic reviews where the diversity of methods and approaches makes consensus a challenging but necessary goal (Tracy, 2010).

The provision of evaluative standards specific to qualitative inquiry began with Lincoln and Guba (1985) and later gave rise to standards in various disciplines, including medicine and healthcare (Mays & Pope, 1995). In 2008, the Robert Wood Johnson Foundation's Qualitative Research Guidelines Project reviewed the extant literature and promulgated guidelines (<u>www.qualres.org/index.html</u>) for qualitative researchers. These guidelines begin with an overall indication of quality, known as trustworthiness, meaning the qualitative study inspires confidence in the ways it was conducted and the data were interpreted.

The Cochrane Collaboration has assembled a list of checklists and software tools that might be applied to assess the quality of qualitative studies, and advocates a focus on four core principles: credibility, transferability, dependability, and confirmability. Qualitative findings are "transferable" by yielding new concepts or frames of reference that can apply to different settings. Examples of the type of criteria that might be applied include, assessing (1) the qualitative methods employed, which often differ from the terms authors use to name their methods; (2) the relevance of sources (informants, documents, etc.) to research questions; (3) efforts employed to ensure reliability in data analysis; (4) consideration of how findings relate to context; and (5) extent to which sample size and composition are adequately described and sufficient to support the findings (Hannes, 2011). Qualitative research methods value "thick and rich" description (see Robert Wood Johnson Foundation at <u>www.qualres.org/HomeThic-3697.html</u>).

Qualitative researchers do not try to fully eliminate subjective researcher bias from a study. In other words, they accept that scientific inquiry cannot be value-free. This contrasts with much quantitative research, which seeks to remove subjective bias and control for or eliminate other sources of bias. However, diligent qualitative researchers seek to minimize bias, where possible, by identifying their biases early on and reckoning with them throughout a study. This is accomplished through "reflexivity," or maintaining vigilance and mindfulness during the study, acknowledging one's biases and reflecting on them in a way that lends credence to the findings.

Some qualitative researchers believe that they need not (and should not) adhere to quantitative standards of internal and external validity as these would compromise the very nature and value of qualitative methods. However, qualitative researchers do not share complete consensus on evaluative standards nor the optimal means of meeting these standards. We suggest that the best approach for methodological integrity is for implementation researchers to articulate the standards they use for trustworthiness and be transparent in describing the methods used and rationale for their use. Once the study is complete, the researchers are accountable for demonstrating that their chosen standards were met in the design, conduct, and analysis.

Enhancing trustworthiness implies use of strategies for rigor throughout the study (Padgett, 2016). Unlike evaluative standards that inform the study and establish criteria for evaluating its overall quality, strategies for rigor are specific techniques or actions taken before and during the course of the study. When it comes to rigor strategies, there are no rigid formulaic expectations but there is a menu of options from which the researcher can choose, as befits the study design. Below is a list of the most commonly used strategies and what they entail.

- **Triangulation of data**—using more than one source of data (e.g., interview transcripts, field notes, archival material, survey results).
- **Prolonged engagement**—with study participants and in study settings, via multiple interviews, extended periods of observations, etc.
- *Member checking*—returning to participants to verify or validate portions of the data or interpretations. This can be especially important in community-based research as well as patient-centered research.
- **Audit trail**—the use of analytic memos, journals, and other means of documenting the study's procedures to enhance transparency of methods.
- **Peer debriefing and support**—meeting regularly with the study team to share study findings and processes to identify biases as well as support one another.
- **Negative or deviant case analysis**—seeking alternative explanations in the data to avoid foreclosing analyses and conclusions prematurely.

For implementation science that incorporates qualitative methods, some, but not necessarily all, of these strategies would be appropriate. For example, prolonged engagement, the *sine qua non* of ethnography, is more challenging in implementation science, but not impossible. In the European hospital study by Sax and colleagues (2013), prolonged engagement entailed devoting two days to ethnographic site visits to hospitals. Their rationale stated, "Staying for two days rather than just one allows us to take advantage of the exposure re-exposure effect. This helps to counter the Hawthorne effect," (Sax et al., 2013) wherein individuals modify their behavior in response to their awareness of being observed (McCambridge et al., 2014).

VIII. NEED AND OPPORTUNITIES FOR INNOVATION IN USE OF QUALITATIVE METHODS IN IMPLEMENTATION SCIENCE

Use of qualitative methods in implementation science reflects practices consistent with their use in the broader fields of health services and the social and behavioral sciences. However, the demand for such methods in implementation science represent both needs and opportunities for using *existing methods in innovative ways or developing entirely new methods. First, though team-based* qualitative methods are commonly used in implementation science (e.g., Reger et al., 2017; Damschroder & Lowery, 2013; Moeckli et al., 2013), there is a need *to bring greater transparency to and documentation of team-based analysis* (Guest & MacQueen, 2007). See <u>Section VI</u>. Most qualitative studies of implementation describe holding meetings that are designed to reach consensus in coding of data or construction of themes. However, it is unclear what constitutes consensus (e.g., is it 100 percent agreement on all decisions, greater than 50 percent agreement), and whether reaching consensus represents a uniform process with a uniform outcome such that it can be replicated within the same study or compared from one study to the next.

Second, we need to continue to strengthen tools and techniques for conducting rapid qualitative assessment and analysis. Rapid assessment procedures (RAP) are frequently used in program planning and evaluation (Cifuentes et al., 2006; Scrimshaw & Hurtado, 1987; Scrimshaw et al., 1991). RAP is generally characterized by a small research team and compressed time frame, in which specifically described and quite limited research questions are addressed using multiple sources of qualitative data such as observation and interviews (Beebe, 2001; Utarini et al., 2001). RAP is especially appropriate for implementation research because it (1) reduces the time required to conduct the study, thereby reducing the gap between research and practice, and (2) is more likely to involve a partnership between researchers and practitioners, enabling both groups to contribute to study results and to learn from one another in the process. Innovations in the use of RAP might include developing standardized procedures for training research assistants, use of social media and other forms of technology for data collection and analysis, and developing quality control procedures for insuring consistency and rigor in activities conducted by teams of researchers and practitioners. (See also Ash et al., 2008, for a variation on RAP.)

The template or framework approach mentioned earlier is well-suited to RAP as it provides a ready-made structure for the inquiry based upon key constructs identified in advance (Padgett, 2016). Pioneered by Crabtree and Miller (1999) and Miles and Huberman (1994), the template approach was used by Hamilton (2013) to quickly abstract urgently needed data from a broader, deeper data pool following a predetermined template. More specification of the template approach and its utility is needed in future implementation science. See <u>Section VI</u>.

Third, it is important that qualitative methodologists explore methods of qualitative data collection and analysis not commonly used in implementation science (Jennings, Sandelowski, & Higgins, 2013). These include phenomenological methods to understand the lived experience (van Manen, 2015) of implementation. As well, elicitation techniques such as pile sorts, photo elicitation interviews, semantic frames, and rank order tasks represent more structured, quasi-statistical ways to assess stakeholder perceptions of implementation goals, requirements, barriers, facilitators, and outcomes.

Fourth, there is a need to contribute to the development of a common language when conducting qualitative research in implementation science. Semantic consistency is needed for clear communication and meaningful comparisons, especially in a multidisciplinary field such as implementation science. Work on pragmatic, consistent, intelligible terminology to describe qualitative methods in implementation science is much needed (Colquhohn et al., 2014; Rabin et al., 2008). For example, qualitative reports in implementation science should be transparent and explicit in describing the methods used, e.g., clarifying how grounded theory informed one's analytic approach. They should also describe what and when strategies for rigor were used to enhance trustworthiness (Padgett, 2016).

Fifth, a field that is as context-dependent as implementation science needs to develop meaningful approaches for cross-context comparison and synthesis of qualitative data. Too much emphasis on standardization can be counter to the intent and value of qualitative inquiry. Still, a theoretically sound and demonstrably useful approach to contextual comparisons of qualitative data for the specific purpose of informing implementation science is much needed.

There are currently several methods that synthesize and compare qualitative research findings such as meta-synthesis, meta-ethnography, qualitative synthesis, and others. Leeman et al. (2010) used realist synthesis methods to identify and summarize context and process related evidence that might advance understanding of factors that influence the implementation of antiretroviral therapy adherence interventions. All contend with the challenge that qualitative data is inherently contextual and that qualitative methodologists do not always agree on the uniform standards of quality that such syntheses necessitate (Padgett, 2016). This tension between maintaining contextualization and diversity of approach while trying to synthesize findings across very different implementation sites and qualitative studies represents an ongoing challenge in implementation science (see Benzer et al., 2013, on between and within site variation). The emphasis by some researchers on technology of synthesis or meta-analysis at the expense of attention to epistemology and conceptualization has been cautioned against by several authors (Sandelowski et al., 2006; Bondas & Hall, 2007; Finfgeld-Connett, 2016; Ludvigsen et al., 2016; Thorne, 2017). The use of these approaches in implementation science are important to increase the utility of qualitative studies, yet as the authors cited above have noted, this must be based on theoretically sound and solid methodological research. Certainly, there is much methodological work to be done.

IX. CONCLUSION

Rigorous qualitative methods are essential to the field of implementation science. Many implementation researchers have limited or no experience in qualitative methods, despite the wide use of these methods in the field. Furthermore, many qualitative experts have little to no knowledge of the sphere and unique challenges of implementation science, despite the centrality of qualitative research in implementation science. Hence, the QUALRIS group has offered its collective knowledge and experience to describe the value of qualitative methods, methodological considerations, typical approaches to the use of qualitative methods, and needs and opportunities for innovation.

This manuscript has notable limitations. The authors have tried to communicate at a level accessible to researchers new to qualitative approaches, avoiding jargon and advanced methodological concepts. The paper is not intended to be a comprehensive rendering of the difficulties and dilemmas encountered in the conduct of qualitative inquiry in implementation science. It does not systematically review the multitude of studies that have encountered and attempted to address the challenges posed. Another important limitation is the paper's tendency to focus on implementation science conducted within the United States. This likely reflects the research emphases of the authors and limits to the group's time and resources, which prohibited a broader international scope. The authors urge other researchers to expand this focus to a global exploration of how qualitative methods are used in implementation science, the difficulties encountered, and solutions that have been generated.

There is a pressing need for methodological innovations to meet the challenges for the rigorous use of qualitative methods in implementation science. There is also great opportunity to advance both qualitative methodology and implementation science in pursuing such innovations. This can be facilitated by an implementation science-wide conversation about these topics. We have offered here some perspectives on the value and use of qualitative methods in implementation science. We invite the larger research community to contribute to the dialogue.

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