Draft QUALRIS Guidance document--10/4/2016

1. **Background and Purpose** [Suzanne]
   1. Implementation science is a rapidly developing field dedicated to putting evidence based practices to use in real world settings with the ultimate goal of improving health. Theoretical models and frameworks have proliferated (Tabak et al, 2012) while measures and mixed methods figure prominently in the literature. Despite this interest in theory and methods, the use of qualitative methods in implementation science has not been well examined. Little guidance is currently available from the field as to which qualitative approaches might be most productively used in which implementation settings or to answer what sort of research questions.

This document is an initial step to remedy this oversight. In 2015, The National Cancer Institute’s Implementation Science Team convened a group of experts in IS, qualitative research, or both to develop guidance for the use of qualitative methods in IS, with an emphasis on cancer control research. The Qualitative Research in Implementation Science (QUALRIS) group has produced this document.

The document’s purpose is threefold:

* + 1. To describe the role of qualitative research in implementation science.
    2. To offer a set of guidelines for conducting qualitative research in implementation science.
    3. To identify areas of need and opportunities for development of innovative qualitative methods.

1. **Implementation Science**
   1. What is Implementation Science? (Borsika lead)

Implementation Science has been increasingly acknowledged as a critical area of inquiry for public health and health services research due to its great potential to increase the population health impact of health research through sustainable integration and scale up of existing evidence-based interventions into practice and generation of new, actionable, real-world compatible programs (Chambers et al. 2016).

The growing interest of the health research field in Implementation Science led to a number of new mechanisms to develop the science including specialized funding for IS studies (eg: NIH PARs-16-236, 237, 238; QUERI program ), a journal dedicated to Implementation Science topics (Implementation Sciencef), multiple national and international training institutes focusing on Implementation Science (ref), and an Annual Conference for Dissemination and Implementation Science (ref).

Implementation Science can be 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-16-236,237, 238 ( http://cancercontrol.cancer.gov/IS/funding.html) Others define it more broadly to include health research in general (Peters et al. 2013). It is mostly concerned with studying how programs get implemented in various settings and what are the most important factors that are associated with and/or predict adoption, implementation, and sustained use of these programs. Implementation Science is focused on outcomes other than – or as in the case of hybrid implementation/effectiveness studies – in addition to patient/population health. While efficacy studies might assess if an intervention worked with a select population in a specific setting, implementation science studies will focus on more complex research questions of how, why, when, where, under what circumstances did the chosen intervention worked (or did not work). These complex questions also call for more complex methods and rich, multi-level data collected at multiple time points, from diverse stakeholders, using a variety of data collection approaches (including qualitative and mixed methods).

* 1. Rationale for Implementation Science (Jennifer)

Health interventions include programs, practices, guidelines and public and organizational policies that are intended to improve the health of individuals and populations.(cite?) The menu of effective health interventions continues to grow, and yet they are underused in practice (Hannon et al., 2013; Stevens & Staley, 2006). One factor contributing to the underuse of effective interventions is the priority that researchers historically have given to establishing intervention efficacy, often at the expense of establishing external validity.([Glasgow, Lichtenstein, & Marcus, 2003](#_ENREF_2)). A second factor is the limited evidence base to guide the implementation of effective intervention into clinical and community settings.

Although much work remains, intervention research has contributed greatly to our understanding of what interventions are effective at promoting health and at preventing, detecting, and treating a range of health conditions. This research, however, has generated less evidence to guide the design and testing of interventions that will generalize to real world settings (cite?). For an intervention to improve health, it must not only be effective, it also has to be adopted by those with the potential to put it into practice. To achieve maximal impact, an intervention also needs to be implemented with fidelity and maintained over time (Glasgow, Lichtenstein, and Marcus 2003; Rychetnik et al. 2002). Evidence on the perspectives of those who will adopt and implement 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 and Glasziou 2009; Glasgow et al. 2012; Tunis et al. 2003). And yet, researchers often have not attended to how well the interventions they are designing will fit within real world practice settings (Klesges et al. 2005).

Healthcare, public health, and other health-related professionals function as part of interpersonal networks and within complex healthcare and community contexts with numerous components that interact across multiple levels ([Damschroder et al., 2009](#_ENREF_1)). For example, a primary care physician is part of team within a clinic that operates as part of a larger healthcare system, which is governed by a host of reimbursement and regulatory policies. Similarly, a health educator collaborates with colleagues within and outside the health department and in doing so navigates inter-related agency and community systems, resources, and constraints. Evidence on these multi-level factors and how they interact is essential to designing interventions to better fit within those context and to understanding how contexts and interventions interact (Weiner, Amick, Lund, Lee, & Hoff, 2011) (Durlak & DuPre, 2008; Glasgow, 2008). Evidence on the perspectives health professionals and the contexts in which they work is key to designing interventions with implementation in mind, and thereby speeding the their translation to practice.([Klesges, Estabrooks, Dzewaltowski, Bull, & Glasgow, 2005](#_ENREF_3)) Evidence on how interventions interact with contexts also is key to determining when an intervention and/or context may need to be adapted to enhance intervention/context fit (Glasgow 2008).

For interventions to have an effect, they must ultimately be implemented in practice and yet researchers have traditionally collected minimal evidence on implementation (Glenton, Lewin, & Scheel, 2011). Evidence on implementation includes details on the actions or materials required to implement an intervention, barriers and facilitators encountered, and whether or how the intervention can be adapted to fit different contexts (Baker, Brennan Ramirez, Claus, & Land, 2008)(Conn, Cooper, Ruppar, & Russell, 2008). Implementation evidence also includes evidence on the effectiveness of different “implementation strategies”, in other words, “strategies to adopt and integrate evidence-based health interventions into clinical and community settings” (National Institutes of Health [NIH], 2016) ref?.link? Implementation strategies might include reminder systems, audit & feedback, facilitation, and a range of quality improvement methods designed to implement interventions within practice settings (Byron Powell) ref? Evidence on potential barriers and facilitators across different levels is essential to selecting and adapting implementation strategies

* 1. Considerations for qualitative methods in IS (Alison lead)

Implementation research is *action-oriented*, so qualitative methods need to be nimble and flexible in order to support action/practice. A pragmatic need exists to describe: the context(s) in which implementation occurs; the process that occurs during the course of implementation, at multiple levels; the effectiveness of the implementation strategies in supporting implementation; the stakeholders involved in implementation; and the relationship(s) between the theorized and actual change. In each of these instances, key stakeholders are often sought for their knowledge, attitudes, and beliefs (Elsey et al., 2016; Hamilton et al., 2013; Kane et al., 2016; Martinez et al., 2016).

One of the most frequently cited reasons for using qualitative methods in implementation research is to **understand barriers and facilitators to implementation** (Bekelman et al., 2015; Cadogan et al., 2016; Cohen et al., 2016; Elsey et a l., 2016; Lord et al., 2016; Marshall et al., 2008; Marty et al., 2008; Rapp et al., 2009; Sommerbakk et al., 2016; Varsi et al., 2015). A recent search of titles in PubMed revealed 667 published articles that used qualitative methods to identify barriers and facilitators. Research has examined barriers and facilitators often across the life of an implementation study, from pre-implementation (Koenig et al., 2016) to implementation to sustainability (Colon-Emeric et al., 2016).

Another reason for using qualitative method is to **document implementation processes**. 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. Whitley and colleagues (2009) documented the process of implementation of an illness management and recovery program for people with severe mental illness in community mental health settings using qualitative data to assess perceived barriers and facilitators of implementation. Lessard et al. (2016) used semi-structured interviews with implementation facilitators to understand their role and the dynamics of facilitations between facilitators, family medicine groups and other change actors. 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.

Related to an understanding of process is the use of qualitative methods to **evaluate implementation success** by identifying and explaining which aspects of the program are working or not working, for whom, and in what circumstances (McHugh et al., 2016) and to **understand how interventions are sustained** (Cohen et al., 2016; Palinkas et al., 2016; Colon-Emeric et al., 2016) and generate hypotheses about how to sustain complex interventions (Colon-Emeric et al., 2016)

Qualitative methods are also used in implementation research to **develop conceptual models, frameworks and measures** for use in quantitative data collection and analysis. Zazelli and colleagues (2008) connected qualitative data collected from semi-structured interviews with 15 program administrators to the development of a conceptual model of implementation of Functional Family Therapy that could then be tested using quantitative methods. Blasinsky et al, (2006) used qualitative data obtained from semi-structured interviews to develop 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. A study of staff turnover in the implementation of evidence-based practices in mental health care by Woltmann et al (2008) used qualitative data obtained through interviews with staff, clinic directors and consultant trainers to create categories of turnover and designations of positive, negative and mixed influence of turnover on outcomes.

Qualitative methods have also been used to **facilitate the explanation of quantitative findings**. Kramer and Burns (2008) used data from qualitative interviews with providers as part of a summative evaluation to understand the factors contributing to partial or full implementation of a CBT for depressed adolescents in two publically funded mental healthcare settings. Brunette and colleagues (2008) used qualitative data collected from interviews and ethnographic observations to elucidate barriers and facilitators to implementation of integrated dual disorders treatment and explain differences in treatment fidelity across the study sites.

Qualitative methods are used in implementation research to **confirm or validate quantitative analyses** through the technique of triangulation or convergence. Swain and colleagues (2009) used triangulation to identify commonalities and disparities between quantitative data obtained from closed-ended questions and qualitative data obtained from open-ended questions of a survey administered to 49 participants, each participant representing a distinct practice site. Convergence of qualitative and quantitative methods also occurs when qualitative data are quantitized, as in the case of the study conducted by Damschroder and Lowery (2013), where constructs of the Consolidated Framework for Implementation Research (CFIR: Damschroder et al., 2009) embedded in semi-structured interviews are assigned numerical ratings that reflect their valence (positive or negative influence) and their magnitude or strength.

* 1. Qualitative is essential when the focus is on process – Quantitative cannot provide answers for the more contextual (process) questions. The nature of Implementation Science

Implementation science is defined by three specific characteristics. The first characteristic is the generation and application of models and conceptual frameworks that identify potential barriers and facilitators, as well as the process and outcomes, of program, practice, and policy implementation. These include the RE-AIM model (Glasgow, 2009), the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2009), and the Exploration, Preparation, Implementation and Sustainability (EPIS) model (Aarons, Hurlburt, & Horwitz, 2011). These models have been employed in understanding barriers and facilitators to EBP implementation in child welfare and child mental health (Agency for Health Research and Quality, 2014; Bryson, Akin, Blase, McDonald, & Walker, 2014; Garmy, Jakobsson, Carlsson, Berg, & Clausson, 2014). The second characteristic is the development and application of several strategies for facilitating the implementation of EBPs. Examples of such strategies that have been used in child welfare and child mental health include the Availability, Responsiveness and Continuity (ARC) model (Glisson & Schoenwald, 2005), Cascading Dissemination (Chamberlain et al., 2012), and the Institute for Healthcare Improvement Breakthrough Series learning collaboratives (Institute for Healthcare Improvement, 2004). The third characteristic is methodological innovation in the form of new experimental designs and mixed methods. Examples of such innovation in child welfare and child mental health include the use of an adaptive rollout randomized design in evaluating the effectiveness of community development teams (a form of learning collaborative) (Brown et al., 2014).

1. Qualitative Methods in Implementation research

Within implementation science, qualitative methods are used to gain a deep understanding of organizations, communities, or other entities’ experience implementing a new practice. Qualitative methods are well-suited to better understand how context, actions, and people contribute to successful (or failed) implementations. It plays a prominent role in implementation science because of its complexity and because of the relative dearth of reliable and useful quantitative measures. Qualitative methods used in implementation science often reflect a postpositivist perspective grounded in empirical data collection, a tendency toward reducing complexity, a desire to understand cause-and-effect, and embracing multiple perspectives rather than a single reality. Alternatively (or in combination), qualitative researchers may bring a participatory perspective especially when focused on implementing practices to serve marginalized populations, relying on them to help design data collection through framing of findings.

Many approaches are used to establish validity of qualitative findings within implementation science. Consensual coding and analyses methods are often used because of the complexity of the phenomena related to implementation across diverse settings and practices.

Stand-alone qualitative studies

Qualitative methods have been employed in implementation research in two ways, either as a single or “stand-alone” study or within a mixed methods study design where qualitative methods are used in combination with quantitative methods (Cohen et al., 2016; Turner et al., 2016) and findings often rely on mixing quantitative and qualitative data. (Creswell, 2015)

Stand-alone qualitative studies are often conducted with the aim of exploring a particular issue related to implementation. The unit of analysis is typically the entity (a collective of individuals) within which implementation efforts manifested. For instance, Bekelman and colleagues (2016) conducted a qualitative study to understand organizational factors that could influence the adoption and scale-up of outpatient palliative care in chronic advanced illness. Lord and colleagues (2016) used qualitative methods to explore provider and staff perceptions of facilitators and barriers to implementation of a mobile phone substance use recovery support app with clients in 4 service settings.

Often, such studies are conducted to inform design and implementation of interventions. For instance, Proctor and colleagues (2007) conducted a qualitative pilot study to capture the perspective 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. Cadogan and colleagues (2016) used qualitative methods to understand general practitioner views on the determinants of ordering immunoglobulin tests to facilitate the development of an intervention to improve immunoglobulin requests in primary care. Using a participatory research approach (Reason & Bradbury, 2008), Elsey and colleagues (2016) conducted qualitative semi-structured interviews and focus groups to understand patient and health worker knowledge of tobacco and patient’s motivation to quit. Findings were used to inform the design and implementation of a smoking cessation intervention.

Mixed methods studies

With respect to their use in mixed method designs, qualitative studies reflect different purposes, structural arrangements of methods and ways of linking qualitative and quantitative data (Palinkas, 2014; Palinkas, Aarons et al., 2011). For instance, some studies are primarily qualitative in nature, but embedded in larger randomized controlled trials (RCTs). Slade and colleagues (2008) nested a qualitative study within a multi-site randomized controlled trial of a standardized assessment of mental health problem severity to determine whether the intervention improved agreement on referrals and to identify professional and organizational barriers to implementation.

Other mixed methods implementation evaluations use a concurrent parallel design, with the goal of integrating qualitative and quantitative findings to answer key research questions. For example, Hamilton and colleagues (2013) drew from semi-structured key stakeholder interviews, field notes, and administrative data to characterize the longitudinal implementation process in a site-level controlled trial, and contextualize the effectiveness findings (i.e., significant improvements in the care target in intervention sites). Turner and colleagues (2016) plan to bring together lessons from qualitative case studies with quantitative data from a national survey and discrete choice experiment to show how interactions between evidence use and factors at the micro and meso levels create a ‘tipping point’ for innovation in different contexts.

Increasingly, mixed methods and qualitative studies are being guided by theoretical frameworks to guide data collection, analysis, and interpretation. For example, Kirk and colleagues (2016) integrated qualitative interview data, quantitative implementation outcomes, and quantified qualitative data to identify contextual factors associated with implementation outcomes, guided by a published framework.

Sampling of participants

Sampling of participants in qualitative studies is generally purposive in nature. Random sampling is occasionally used if participants are to be used 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 (Palinkas et al., 2015). In implementation studies, participants are often sampled based on their level of participation and role in the organization to maximize diversity of perspective (Colon-Emeric et al., 2016), location, length of time qualified, and practice size (single/group) (Cadogan 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.

Data collection

Individual **semi-structured interviews or group focus group** sessions are the primary means of collection of qualitative data in implementation research (Cadogan et al., 2016; Colon-Emeric et al., 2016; Cohen et al., 2016; Lessard et al., 2016; Martinez et al., 2016; McHugh et al., 2016; Palinkas et al., 2016; Saldana, 2014; Turner et al., 2016). 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. Interviews are conducted either face-to-face or by telephone and are usually digitally recorded and transcribed for analysis. The ideal focus group size ranges from 6 to 10 participants (Morgan, 1997).

**Ethnographic methods** are also frequently used in implementation studies and include participant and non-participant observation collection of archival materials and informal interviews with study participants. Site visits are conducted to observe and understand how interventions are implemented (Cohen et al., 2016; Fox et al., 2016; Palinkas et al., 2016), and data include fieldnotes. Padwa and colleagues (2016) participated in administrative meetings with clinic administrators, organizational leaders and behavioral health providers. Detailed notes from these activities were incorporated into the qualitative sample, along with notes of conversations with clinic staff and behavioral health service administrators, emails received from these individuals, and responses to open-ended questions on a survey.

Closely related to ethnographic methods is the **case study** method, another technique commonly used in implementation research. This method is especially appropriate for studies where the unit of implementation is the organization. This method “also addresses a need for ethnographic methods to enable direct observation of ‘live’ decision-making processes (Kyratsis et al., 2014)” (Turner et al., 2016, p .3). Mozaffar and colleagues (2016) conducted a series of longitudinal, qualitative case studies to examine the implementation and adoption of computerized physician order entry and clinical decision support systems for prescribing in hospitals in the UK. Semi-structured interviews were conducted with users, implementers and suppliers of CPOE/CDS systems at six case study sites, followed by two whole day expert roundtable discussions. Kennedy and colleagues (2016) also employed a longitudinal case study design in which ethnographic methods comprising video, non-participant observation of intervention delivery and qualitative interviews at baseline and 6 and 12 months to identify processes and dynamics of delivering asocial network intervention and to capture individual outcomes of the use of a web-based tool that comprises “network mapping, user-centered preference elicitation and needs assessment and facilitated engagement with resources”. Turner and colleagues (2016) plan to conduct in-depth case studies on the use of evidence in “real world” decision-making concerning the introduction or diffusion of three service innovations in acute and primary care “Case studies were chosen because they allow complex phenomena to be studied in-depth, allowing both the case… and the context…to be taken into account, as well as the interactions between the two (Yin, 2013)”.

Less frequently used in implementation research are **structured interviewing techniques** that possess a quasi-statistical perspective. Using the technique of concept mapping (Trochim, 1989), Aarons and colleagues (2009), solicited information on factors likely to impact implementation of EBPs in public sector mental health settings from 31 services providers and consumers organized into 6 focus groups. Each participant then sorted a series of 105 statements into piles and rated each statement according to importance and changeability. Data were then entered in a software program that uses multidimensional scaling and hierarchical cluster analysis to generate a visual display of how statements clustered across all participants. Finally, 22 of the original 31 participants assigned meaning to and identified an appropriate name for each of the clusters identified (Aarons et al, 2009). Palinkas and colleagues (2016) are using a free listing exercise to elicit participation’s conceptions of the term sustainment, the elements of their programs they wish to sustain, and the requirements for sustaining these elements. Responses will be weighted based on order of presentation and compared by source of program funding. Other data collection methods include online and hand written implementation **diaries** to document implementation experiences (Cohen et al., 2016; Elsey et al., 2016), collection of **documents**, including meeting minutes, logs, and field notes (Turner et al, 2016; Lessard et al., 2016), use of **photographs** to elicit participant experiences, opinions and knowledge (Elsey et al., 2016), and answers to **open-ended questions** on surveys (McHugh et al., 2016; Swain et al., 2009).

Data analysis

The most commonly used approach to analysis of qualitative data is thematic or content analysis (Hsieh & Shannon, 2009). There are several variations of content analysis, ranging from techniques that are largely inductive to techniques that are largely deductive, with substantial variants in between. Analyses that are predominately inductive in character use approaches such as grounded theory (Charmasz, 2006; Glaser & Strauss, 1967), theory is generated from the data or analytic techniques similar to those used in grounded theory (Willms et al., 1990). Since theoretical frameworks are generally expected to drive implementation research, grounded theory in it’s entirety may not be a good fit. However, principles taken from grounded theory, such as emergent themes from data may be useful. Reflecting more of a deductive approach to data analysis, several studies (Bajunirwe et al., 2016; Elsey et al., 2016) have employed a “framework” approach (Richie, Spencer & O’Connor, 2003) to data analysis. Such approaches are theory or framework driven and involve mapping data onto a priori domains, themes or categories. Cadogan and colleagues (2016) used a framework analysis approach (Gale et al., 2013) in which emergent themes were mapped onto the domains of the theoretical domains framework (TDF: Michie et al., 2014).

One of the better known examples of a framework approach is the use of the Consolidated Framework for Implementation Research (CFIR, Damschroder et al., 2009) to guide the analysis of data collected through semi-structured interviews. For instance, Lord and colleagues (2016) developed a coding scheme “that outlined each of the constructs to represent either a barrier or facilitator to implementation of the mobile recovery support tool. The coders independently coded each transcript using the coding scheme to document presence of given constructs throughout the narrative and whether a barrier or facilitator.” 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. Data are coded using a priori codes based on the conceptual framework. Varsi and colleagues (2015) used the CFIR framework to examine barriers and facilitators for the implementation of an internet-based patient-provider communication service. Transcripts of semi-structured interviews were analyzed using a deductive directed approach. The first step in the analysis, after reading all transcripts, notes, and written responses to obtain an understanding of the whole, was to develop initial coding nodes and subnodes based on the domains and constructs of the CFIR framework. In the second step, units of analysis, such as sentences or longer semantic units, were deductively coded into the nodes and subnodes. Third, the coded text was then subjected to a rating process based on the recommended method described by Damschroder and Lowery (2013), the authors of CFIR. In the rating process, a deliberated consensus process was used to assign a rating to each construct obtained from each hospital unit. The ratings reflected the valence (positive or negative influence) and the magnitude or strength of each construct that emerged in each hospital unit based on the coded text.

Several studies (Elsey et al., 2016; Kennedy et al., 2016; Nordmark et al., 2016) used “normalization process theory (NPT, May & Finch, 2009) to provide “sensitizing concepts” for exploratory data analysis of complex interventions. “NPT seeks to explain what people do when implementing a new intervention. It has four constructs: (i) coherence: making sense of the intervention, its meaning and use, (ii) cognitive participation: the relational aspects between those implementing the intervention, how they initiate involvement and engage with the intervention, (iii) reflective monitoring: how individually and collectively, the process of considering and adapt the intervention is conducted, and (iv) collective action: which is the operational work done to implement the intervention.

Some implementation studies have employed a realist evaluation, a theory-driven approach that “tells us where to look” and “what to look for… directs us to vital explanatory components…their interrelationships and things that bring about those interrelationships” (Pawson, 2013, p. 62), to guide data collection and analysis. McHugh and colleagues (2016) conducted a realist evaluation 1) to elicit and formulate the programme theory underlying the National Diabetes Programme and its work streams (national retinopathy screening programme, national foot care model and national model of integrated care), 2) collect data to test these initial theories, 3) analyze data to interrogate the theories, and interpret analysis to refine the initial programme theories” (p 4). They used a “framework approach” (Ritchie & Lewis, 2003) to systematically identify contexts (C), mechanisms (M), and outcomes (O) in interview transcripts and documents, and chart hypothetical relationships between them (C\_M\_O) configurations) to formulate programme theories for each programme component”.

Other conceptual frameworks used in the analysis of qualitative data include the Conceptual Model of Evidence-Based Practice Implementation in Public Service Sectors (Aarons et al., 2011), used by Padwa and colleagues conducted a directed content analysis of qualitative data.

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 (BoA) perspective to move beyond a single timeframe and evaluate the situation from initiation to use, to move beyond a “localist” perspective and to examine both technical and nontechnical aspects of the system. 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 multilevel model of barriers and facilitators [year?]. Turner and colleagues (2016) will use a combination of inductive and deductive approaches drawing on ideas emerging from the empirical data as well as existing literature (Bradley, Curry & Devers, 2007). Turner and colleagues (2016), for instance, propose to conduct a thematic analysis of literature and documents, supported by stakeholder feedback on the conceptual framework using focus groups to identify any gaps of themes that require further exploration. “The focus groups will also be used to determine how stakeholders define ‘acceptability’, ‘credibility’, and ‘strength’ in relation to different types of evidence and in relation to different decision-making contexts” (Turner et al, 2016). Kane and colleagues (2016), propose a comparison of themes across clinic sites and provider type.

Whether inductive, deductive, or a combination of the two approaches, thematic analysis usually involves the process of constant comparison 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 (Fox et al., 2016). Summaries are analyzed using matrix analysis and key actionable findings are shared with the implementation team to guide implementation (e.g., the variable use of implementation strategies) in real time, particularly during the course of phased implementation research such as in a hybrid type II study(Curran et al. 2012). When warranted, this rapid approach typically feeds into more in-depth hybrid analytic approaches described above.

Meeting as a group to reach consensus appears to be the most common strategy for assessing reliability in coding and construction of themes (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 reference to the use of a consensus-based directed content analysis approach (Hill et al., 2009) (ref ?) to strengthen the trustworthiness of the analysis. 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 the process to help maximize validity of findings (Damschroder & Lowery, 2013).

1. Guidelines for use of qualitative methods in implementation research

The QUALRIS group has conducted its work via teleconference, email and as an NCI online learning community (https://researchtoreality.cancer.gov). The group consulted literature on best practices in qualitative methods, and employed members’ own extensive experience. Folllowing this iterative process, the group determined focal areas to examine and then drafted pertinent guidelines.

* 1. Selecting the right tool for the job
     1. *There appears to be an overemphasis on grounded theory approaches to collection and analysis of qualitative data when the aim of the study is not to generate a theory.*
     2. *“Positivistic” content analytic approaches have come to dominate the field because they are somewhat mechanistic and (more) easily understood by quantitatively trained researchers unfamiliar with qualitative methods.*
     3. *Phenomenological approaches to understanding “lived experience” may better capture elements of implementation process and experience, but are infrequently used.*
     4. *Use of QCA approaches when deductively applying existing models and frameworks like CFIR.*
        1. *LJD: we use the CFIR and relatively deductive approach (while remaining open to other themes); consensual process (see refs and methods in: Damschroder, Laura J., and Julie C. Lowery. "Evaluation of a large-scale weight management program using the consolidated framework for implementation research (CFIR)." Implementation Science 8.1 (2013): 1.)*
           1. *Emphasis on using common language (terms, definitions) though with a qual lens 🡪 to build knowledge across diverse studies and settings*
  2. Collecting and analyzing data with rigor

Qualitative methods encompass diverse approaches yet they share a need to foster standards of quality and methodological rigor (Guba & Lincoln, 1985; Tracy, 2010). Given differences in paradigmatic or epistemological orientations, qualitative researchers may adhere to a non-prescriptive interpretivist 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 research 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. Evaluative standards are a pedagogical imperative as instruction in qualitative methods depends on agreed-upon procedures in order to introduce students to the basic techniques. 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).

Qualitative researchers do not try to fully eliminate bias from a study. In other words, they accept that scientific inquiry cannot be value-free. But diligent researchers do seek to identify their biases early on and reckon with them throughout the study so that the findings are trustworthy. This is done 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 as grounded in the data rather than in the researcher’s conscious or unconscious prejudices.

When viewed in comparison to quantitative methods, qualitative studies offer ‘ecological validity,’ or the benefits of immersion in naturalistic settings. Qualitative researchers need not (and should not) adhere to quantitative standards of internal and external validity. Similarly, they value thick and rich description as the foundation of data collection rather than the broad but thin data characteristic of quantitative studies. While not intended to be replicable or generalizable, qualitative studies are judged by their ‘transferability’ or applicability to other contexts. Rather than seek to generalize from a sample to a larger population through inferential statistics, qualitative findings are ‘transferable’ by yielding new concepts or frames of reference that can apply to different settings. Erving Goffman’s writing on stigma is a classic example of such transferability (1963).

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 health care (Mays & Pope, 1995). In 2008, the Robert Wood Johnson Foundation’s “Qualitative Research Guidelines Project” reviewed the extant literature and promulgated guidelines (<http://www.qualres.org/index.html>) 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. Enhancing trustworthiness implies use of strategies for rigor during the course of the study (Padgett, 2016).

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 particular approach being used. Below is a listing of the most commonly used strategies and what they entail:

1. *Triangulation of data*--the use of more than one source of data (interviews, observation, documents)
2. *Prolonged engagement* with study participants and in study settings— via multiple interviews, extended periods of observations, etc.
3. *Member checking*—returning to participants to verify or validate portions of the data or interpretations
4. *Audit trail*—the use of analytic memos, journals and other means of documenting the study’s procedures to enhance transparency of methods
5. *Peer debriefing and support*—meeting regularly with others on the study team (or other qualitative researchers) to share study findings and processes to identify biases as well as support one another
6. *Negative or deviant case analysis*—seeking alternative explanations in the data to avoid foreclosing analyses and conclusions prematurely

For any given qualitative study, some but not necessarily all of these strategies would be appropriate. Negative case analysis, for example, is a better fit for grounded theory studies in which analytic hypotheses or ‘small t’ theories are the goal (Glaser & Strauss, 1967). Similarly, prolonged engagement is the *sine qua non* of ethnography and less likely to be used in a time-limited study. Triangulation and prolonged engagement help to promote ‘evidentiary adequacy’ i.e., the depth and breadth of data needed to answer the study questions (Morrow, 2005). Inadequate evidence may arise from ‘thin’ interviews, abbreviated timelines and reliance on a single source of data.

With reference to qualitative methods in implementation research, the likelihood that qualitative methods are part of mixed methods designs and complex study procedures points to the need for greater attention to strategies for rigor and to maintaining the viability of the methods so that ‘rich’ data are collected to support both vivid description and insightful interpretation. MORE HERE?

* 1. Detailed description of methods

The qualitative methods traditionally used in implementation science research are similar to those used in other areas of qualitative health research, namely individual and group semi-structured interviews and observations of implementation settings. Many sources exist describing how to conduct these methods in a rigorous and systematic way. (ADD CITATIONS; What are the group's favorites?) The methods are conducted in the same way in IS; however, due to IS's orientation toward change, qualitative researchers must pay particular attention to the dynamic nature of the context in which they are working.

First, time is a central factor to consider when conducting qualitative research in IS. Qualitative researchers are often called upon to assess the organizational or community context in which the intervention will be implemented. This often requires semi-structured interviews with the keys stakeholders who will be involved or impacted by the intervention to examine the "baseline" context of a setting. What is the stakeholders' current practice in relation to the target outcome? Observations of the community or clinical setting also are often conducted to assess the interactions of the stakeholders and whether their behavioral practices are consistent with the perceptions they articulated in interviews. Observations can also be helpful in mapping current processes.

The next step is one decision point that can vary tremendously from other qualitative health research. In IS, the baseline assessment of context is 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 the strategy to the particular setting. The timing of when the intervention must be implemented, therefore, impacts how the baseline data will be analyzed. With ample time, the qualitative analysis is conducted in a similar way to any other qualitative analysis, including audio recording and transcribing interviews, reviewing content for thematic content, and developing coding dictionaries.(ADD CITATIONS; What are the group's favorites?) However, with a shorter turnaround time, qualitative researchers in IS have turned toward more rapid analysis techniques, including templates analysis. Whether researchers have a short or extended period of time, the analysis process must match the theoretical and study aims and can include a more ground theory approach focusing on emergent themes (CITATION) or a mix of inductive and deductive thematic codes.

Finally, qualitative researchers are often asked to continue to conduct qualitative research during the implementation process. This gives researchers a chance to document and examine the implementation strategy as it evolves. Qualitative researchers may also be asked to provide feedback as the implementation process is occurring to aid in the the change process. What are the major facilitators and barriers to the implementation strategy and what could be changed to improve implementation?

Besides timing, other factors impact qualitative research in IS. These factors have been discussed in relation to qualitative research outside of IS, but are worth noting in the area of IS specifically. One is the constant challenge of the iterative nature of qualitative research; it is a continuous learning process. With multiple time points of data collection and particular attention towards change, this can make haraness the iterative nature of qualitative research more difficult. Another factor is that IS is a truly interdisciplinary field. The health-related IS the team generally includes clinical experts, intervention developers, organizational scientists, and those who focus on the change process. Qualitative researchers need to consider this team as they develop interview and observational guides, who will conduct the interview, and who will participate in the analysis process. The qualitative expert will need to lead the processes, while managing the interdisciplinary team and the lessons he or she learns from qualitative research.

* 1. Presentation of qualitative findings

Most qualitative studies of implementation present results organized by themes and illustrated with quotations obtained from study participants. Results should not merely be comprised of a list of themes, but should specify which themes were emergent and which were a priori, and how themes are related to one another. Although quotations are commonly used not 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.

In several instances, tables have been used to organize the presentation of results. Tables generally provide a taxonomy of themes with illustrative quotes. Tables have the advantage of presenting the results in condensed form, enabling authors to publish in journals that have word limitations. Elsey and colleagues (2016) used qualitative data to construct a table of barriers and facilitators to implementation using NPT.

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 8-13 year old youth. Lessard and colleagues (2016) used figures to provide a conceptual framework of facilitation categories and themes as well as the relationship between implementation-oriented facilitation roles and support-oriented facilitation roles, and to illustrate 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.

1. What innovations are needed in qualitative methods especially focusing on IS?

[Palinkas>] The first innovation needed is to bring greater precision in the description and operationalization of the process of reaching consensus. 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% agreement on all decisions, greater than 50% 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.

The second innovation needed is to develop new tools and techniques for conducting rapid assessment procedures (RAP) for collecting and analyzing qualitative data. RAP is a distinctive form of qualitative methods that 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) involves a partnership between researchers and practitioners, enabling both stakeholders 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 assigning data collection and analysis responsibilities, use of social media and other forms of technology for data collection and analysis, and procedures for insuring reliability and validity in activities conducted by teams of researchers and practitioners.

Finally, it is important that qualitative methodologists explore methods of data collection and analysis used in health services research but not commonly used in implementation research. These include phenomenological methods to understand the “lived experience” of implementation and quasi-statistical methods such as pile sorts, semantic frames, and rank order tasks to assess stakeholder perceptions of implementation goals, requirements, barriers, facilitators, and outcomes. [<Palinkas]

* 1. Adoption of common language while remaining “true” to qual approach; consistency and yet avoid “cookbook” approach
  2. But also still need to embrace inductive approaches, theory-building … more about this?
  3. Ways to compare data across sites/contexts

1. How can qualitative methods catalyze implementation science and lead to different ways of thinking?
   1. The 3 most widely used frameworks that I know of in IS (I’m sure there are others) – CFIR, TDF, NPT – all rely on qualitative methods. TDF and NPT(?) have developed survey measures but none that have been validated widely
   2. Continue to provide a way forward in articulating aspects of the complexities of implementations: generating new or building on existing theories, and the usual roles for qualitative
   3. Hypothesis generating
   4. Measure development
2. I believe qual will always be necessary in IS because I believe quant models will only ever have success in explaining a proportion of variation and we will continue to need qualitative methods to understand sufficiently deep dynamics that have not (or cannot) be reliably measured quantitatively. This may be a bold statement…but I’m throwing it out to trigger discussion
3. Recommendations and next steps

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