Qualitative Methods and Process Evaluation in Clinical Trials Context: Where to Head to?

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Introduction

Until relatively recently, bringing qualitative and quantitative theorists together and incorporating qualitative and quantitative methodologies in clinical trials were impossible tasks. However, due to the growing importance of interpretative research and insights into the patient’s perspective, and the growing recognition of the importance of context and environment on the success of a trial and the intervention being tested (Curry, Nembhard, & Bradley, 2009; Moore et al., 2015), qualitative research is currently playing an increasing role in clinical trials of health-care, behavioral, and public health interventions and particularly in complex intervention settings and trial environments (Lewin, Glenton, & Oxman, 2009; Moore et al., 2015; Morgan-Trimmer & Wood, 2016). Rawlins (2008) argues that the hierarchies of evidence used in existing health research should be replaced by embracing diverse research methods approaches. Today, qualitative research methods are recommended as a way of enabling the development of complex interventions, evaluations and explanations of outcomes, and the transferability of evidence to complex health-care systems and settings (Drabble, O’Cathain, Thomas, Rudolph, & Hewison, 2014; Haynes et al., 2014).

Process evaluation, which is commonly carried out in conjunction with outcome evaluation using qualitative research approaches during or after the implementation of an intervention to evaluate and explain the outcomes (Lewin et al., 2009; Moore et al., 2015), has become a dominant part of clinical trials. Much has been written about the role of qualitative methods alongside or embedded within clinical trials in offering empirically based insights into the fidelity of implementation and the causal mechanism or pathways, interactions, and contexts driving different facets of an intervention and how it is experienced by participants (Curry et al., 2009; Lewin et al., 2009; Moore et al., 2015; Munro & Bloor, 2010). Two previous reviews of randomized controlled trials revealed that qualitative research has been conducted on various aspects of trials: About 71% of qualitative research focused on the content and delivery of interventions tested (254 of 356 aspects in 296 articles reported qualitative research undertaken with trials; O’Cathain, Thomas, Drabble, Rudolph, & Hewison, 2013) and 43% of qualitative studies conducted during or after the trials to explore the implementation/context and participants’ experiences of the interventions (13 of 30 trials included qualitative work; Lewin et al., 2009). Despite the intuitive appeal of qualitative research methods to researchers, practitioners, and policy makers in health services and medical fields, the rigor of qualitative research on process evaluations in the context of clinical trials requires further development.

Quality Qualitative Research, Quality Process Evaluation

High-quality process evaluation starts with high-quality qualitative research. High-quality process evaluation relies on:

- a well-deliberated qualitative component alongside or embedded within a feasibility or full-scale trial;
- a clear description of the phenomenon to be examined in depth;
- a clear linkage of the qualitative research with the trial question/objectives;

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an explicit epistemological basis and methodological rationale for the qualitative inquiry;
• a sound qualitative methods guiding the sampling strategy; the data collection methods, timing, and process; and the organization and interpretation of data;
• a clear plan for the separation or integration of process and outcome data;
• a clear delineation of the expertise and resources needed for the qualitative component; and
• a clear description of ethics approval and strategies to resolve potential ethical dilemmas in qualitative research (Bartlam et al., 2016; Curry et al., 2009; Drabble et al., 2014; Giacomini & Cook, 2000; Moore et al., 2015).

It is vital to ensure the rigor and quality of the conducting and reporting of qualitative components in process evaluations of clinical trials to enable confidence to be placed in the qualitative findings of future systematic reviews of qualitative evidence syntheses, which in turn support robust explanation of the trials findings and help inform decision-making processes (Noyes et al., 2017) and maximize our capacity for care.

Spell Out the Reasons for Qualitative Research

In any trial process evaluation endeavor, the rationale for conducting qualitative research should be aligned with the type of trial and its objectives. Process evaluation is not about the statistical significance or nonsignificance of an intervention attributed to effect size and statistical power. Instead, it relates to how and why the intervention works or does not work in the context of the trial (Lewin et al., 2009; Munro & Bloor, 2010). It is important to ensure the reasons for an intervention working or failing have the best likelihood of being exposed and explained.

The evaluation of the delivery and quality of implementation, the clarification of causal mechanisms or pathways, and the exploration of reasons for or contextual factors associated with variation in outcomes are compelling reasons for conducting qualitative inquiry with trials (Lewin et al., 2009; Moore et al., 2015). However, due to the difficulties associated with the collection of too much data, researchers designing process evaluations should not seek to evaluate all aspects of an intervention in a single study (Munro & Bloor, 2010). An explicit description of the type of trial (efficacy vs. effectiveness) is also needed to set the scene for qualitative process evaluation. An efficacy trial optimizes the observation of an intervention under ideal and controlled circumstances, whereas an effectiveness trial accounts for external patient-, provider-, and system-level factors that may moderate the effects of an intervention under real-world circumstances (Singal, Higgins, & Waljee, 2014). Compared with efficacy trials, effectiveness trials are better suited to the use of qualitative research methods for process evaluation. Moreover, a qualitative inquiry approach is far superior to the conventional quantitative methods of subgroup analysis in helping researchers to understand the variation in outcomes with the breadth and depth in effectiveness trials.

Let Philosophical and Epistemological Foundations Guide

Qualitative and quantitative paradigms each have its own distinctive philosophical perspectives and epistemological views (qualitative: constructionism, interpretivism, and postpositivism; quantitative: positivism) and methodological approaches (qualitative: inductive; quantitative: deductive process) within and across disciplines. Yet the epistemological differences between qualitative and quantitative paradigms make them fundamentally incompatible, creating a challenge to methodological congruence (Strudsholm, Meadows, Vollman, Thruston, & Henderson, 2016; Symonds & Gorard, 2008). We need to think afresh about how these two paradigms and methodologies can be reconciled through critical realism and applied to clinical trials. Nevertheless, a shared paradigmatic understanding of methodologies, including their philosophical and epistemological foundations, is crucial to qualitative and quantitative research within trials (Bartlam et al., 2016), especially as trials are growing increasingly more complex, and new variables such as genotype subgrouping might play an important role in the success of an intervention, particular pharmacological agents. Literature indicates that qualitative methods need to retain its paradigmatic nature for the process evaluation of clinical trials but can be intermeshed with quantitative methods to deepen understanding of the phenomenon under study (Moran-Ellis et al., 2006), so that if a trial does not succeed in finding an answer to its question, there are explanations that can inform future interventions and/or trial design. A firm philosophical and epistemological grounding for a range of qualitative methodologies is critical to the effective use of particular qualitative methods (Devers, 1999).

Consistent with the philosophical and epistemological foundations of qualitative research, the qualitative inquiry approaches of grounded theory, ethnography, phenomenology, and interpretative description are well suited to the process evaluation of trials. Grounded theory, characterized by an iterative process of data collection and an interpretive process of constant comparison (Curry et al., 2009), may help to explain the patterns and variation in participants’ experiences of or responses to intervention within trials. The distinguishing feature of ethnography, embeddedness within participants and organizations’ cultures and social worlds through extended periods of fieldwork, may contribute, in particular, to the understanding of contextual factors associated with variation in the outcomes of interventions (Morgan-Trimmer & Wood, 2016). Conventional phenomenological inquiry into patients’ experiences of and reactions to an intervention can yield extensive narrative data (Curry et al., 2009), particularly for evaluating the delivery and quality of implementation. The newly emerging method of applied interpretative description, emphasized interpretation of and reflection on patients’ descriptions of their experiences (Thorne, 2018), may help to explain the participants’ experiences of trialled intervention.
Set Your Qualitative Methods

Sampling for qualitative data collection should be purposive and diverse, with an appropriate array of data sources, to achieve a theoretically comprehensive sample and ensure the transferability of the findings (Pope & Mays, 1995). The sampling process should be iterative, with selection criteria evolved over the course of qualitative data analysis to capture typical cases and new angles on the phenomenon trialled (Giacomini & Cook, 2000). Diverse methods of eliciting and collecting qualitative data are available for use either separately or in combination such as interviews, focus groups, field observations, and document reviews (Curry et al., 2009; Giacomini & Cook, 2000). Details of these methods of qualitative data collection have been published elsewhere. In essence, data collection should be aligned with the chosen approach to qualitative inquiry and comprehensive enough to yield a meaningful description of the phenomenon under trial. Several aspects of qualitative data analysis and interpretation for trials require special consideration and deliberately developed strategies, such as the separation or integration of the qualitative process data and quantitative outcome data; the separation or integration of the qualitative process evaluation and quantitative outcome evaluation teams; whether qualitative analysis should be blind to trial results; and the timing of data analysis (before or after trial results are known). Although integration is not simple, the key findings of qualitative research and associated trial should be integrated to corroborate the findings and thus facilitate interpretation of the trial results (Giacomini & Cook, 2000). Where possible, qualitative analysis should be conducted after data collection of each participant by separate teams unaware of the trial results to avoid the biased interpretation of qualitative findings and provide directions for subsequent qualitative data collection (Curry et al., 2009; Giacomini & Cook, 2000; Moore et al., 2015).

Conclusion

The growing need for and use of qualitative research methods for process evaluations in the context of the clinical trials in health-care and medical research has both created challenges and inspired innovation. Our goal is to ensure high-quality qualitative research and process evaluation. Yet further work is needed to reconcile the qualitative and quantitative paradigms and methodologies in clinical trials context and to develop practical frameworks for qualitative findings syntheses alongside the trials results in process evaluations of future systematic reviews to generate a new momentum toward success in transferability of trials evidence to complex health-care systems and settings.

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