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CHAPTER

23 Moving From Randomized Controlled Trials to Mixed Methods Intervention Evaluations

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Abstract

This chapter explores why mixed methods intervention evaluations are needed when undertaking randomized controlled trials in order to address a wide range of questions relevant to understanding the effectiveness of an intervention. It ~~provides a description of~~ three ~~different~~ frameworks ~~describing~~ different ways in which mixed methods intervention evaluations may be undertaken within the context of a randomized controlled trial: the temporal framework; the process-outcome framework, which includes process evaluations; and the "aspects of a trial" framework. The chapter considers how the language used to describe qualitative research undertaken with trials can represent different underlying assumptions about the relative value of the qualitative research in relation to the trial. The chapter concludes with a discussion of some of the challenges that arise when undertaking mixed method intervention evaluations and the value of including qualitative research in systematic reviews of trials via evidence synthesis.

Key Words: randomized controlled trials, mixed methods intervention evaluations, process evaluation, evidence synthesis, temporal framework, process-outcome framework, aspects of a trial framework

Introduction

Randomized controlled trials (RCTs) are used in social, education, and health research to test whether interventions are effective (Cnaan & Enosh, 2001; Torgerson & Torgerson, 2001), for example, to test the effectiveness of new approaches to delivering foster care, new curriculum in schools, and new ways of delivering self-management advice to people with chronic health conditions. In this chapter we consider the change in use of RCTs to address the single question of "does an intervention work?" to multimethods (Grissmer, Subotnik, & Orland, 2009) or mixed methods (Creswell, Fetters, Plano Clark, & Morales, 2009) intervention evaluations to address a range of questions related to understanding the effectiveness of an intervention. We call these wider designs "mixed methods intervention evaluations" rather than "mixed methods randomized controlled trials" for reasons we explain later in the chapter. Although multimethod or mixed methods intervention evaluations are undertaken within education and social research—in particular there is a guide to combining multimethods and RCTs produced by the American Psychological Association (Grissmer et al., 2009)—we focus here on health research because RCTs are common within this field and it is our area of expertise.

In the health field a randomized controlled trial is defined as:

> an experiment in which two or more interventions, possibly including a control intervention or no intervention, are compared by being randomly allocated to participants. In most trials one intervention is assigned to each individual but sometimes assignment is to defined groups of individuals (for example, in a household) or

interventions are assigned within individuals. (Cochrane Collaboration, 2013)

The terms *randomized controlled trial* and *randomized clinical trial* are sometimes used interchangeably in the health field because historically they have tested drugs and devices in clinical settings. We prefer the term *randomized controlled trial* (RCT) because this encompasses public health trials that test the effectiveness of interventions that are designed to impact on health behaviors in a range of settings. An example of a public health intervention is peer support delivered in schools to aid smoking cessation among young people (Campbell et al., 2008; Munro & Bloor, 2010).

We have based this chapter on our belief that accepted practice among some communities of researchers has moved from undertaking lone RCTs toward combining qualitative methods and RCTs within mixed methods intervention evaluations. We cannot, however, chart the exact size of this shift and rely on less than ideal methods to suggest its extent. We would ideally compare a random sample of RCTs funded in different decades and measure the proportion using a mixed methods approach within each decade, showing an increase over time. This information is not available, so instead we rely on perceptions that multimethod or mixed methods intervention evaluation is common (Lewin, Glenton, & Oxman, 2009), is increasing (Grissmer et al., 2009), or is a relatively recent phenomenon (Jansen, Foets, & de Bont, 2009). Evidence that mixed methods intervention evaluations are common is available from a range of sources. In a search for pragmatic trials in primary care, Jansen et al. found 33 articles published between 2001 and 2007 reporting the use of qualitative research. Lewin et al. found that between 2001 and 2003, 30% of published trials of changes to organization of health care included qualitative research. In a systematic review of international journal articles reporting qualitative research undertaken with trials in health, we identified 296 articles published between 2008 and September 2010 (O'Cathain, Thomas, Drabble, Rudolph, & Hewison, 2013).

In this chapter we address why the move from lone RCTs to mixed methods intervention evaluations has occurred and the benefits it can deliver. We also describe three existing frameworks for mixed methods intervention evaluations that can help researchers understand the range of ways in which different methods can be used in conjunction with trials, examine the developing language used to describe this approach, and consider the challenges faced by researchers when making the move to mixed methods intervention evaluations. We provide case studies of published evaluations to illustrate some of these points.

Why Are Mixed Methods Intervention Evaluations Necessary?

In the context of health research, RCTs are used to test whether new drugs, services, or technologies improve health. RCTs are considered the "gold standard" in the hierarchy of providing evidence of effectiveness. However, it appears that within health research, the question "is it effective?" is the gold standard question in an implicit research question hierarchy, with the result that methods that best address other questions may be dismissed as inferior and require defending (Giacomini, 2001). We believe that RCTs are an excellent way of addressing the effectiveness question but that this question needs to be expanded to "effective for whom under what circumstances?" (e.g., Pawson & Tilley, 2004). We identify other important questions relevant to evaluations of interventions that RCTs alone cannot address.

If the Intervention Was Effective in the Trial, Will It Be Effective in the Real World?

Policymakers, clinicians, and patients want to implement evidence from RCTs in the real world. If the intervention was shown to be effective under experimental conditions, those wishing to implement these findings want to know which aspects of the intervention are essential to effectiveness (mechanisms of action) and how relevant the context in which the intervention was tested is to their own circumstances (transferability of evidence). For example, the control arm in a trial may be the care that patients usually receive, ~~and~~ the meaning of *usual care* may be different in different countries and over different time periods, with implications for the comparative effectiveness of the intervention under study. The need to address questions related to *how* and *why* interventions work, that is, to understand mechanisms of action and the transferability of the evidence, has led to inclusion of qualitative methods within these evaluative designs.

Why Was the Intervention Not Effective?

RCTs can be expensive and time consuming to undertake. In theory, RCTs producing null results are as valuable as those with positive results. However, in practice, null RCTs, which identify that an intervention was not effective, can feel like a waste of time and money unless researchers can understand why the intervention was not effective and thus steer other researchers away from evaluating similar types of interventions and toward those that have a better chance of effectiveness. Researchers use qualitative and quantitative methods to facilitate understanding of why interventions do not work. For example, these methods can explore whether interventions have been delivered as planned or met barriers to successful implementation.

What Is the Optimal Intervention to Test?

Undertaking a large and expensive RCT of an intervention that is not well understood may waste resources if the results are that an intervention was not effective because it was not feasible for delivery by health professionals or was not acceptable to patients. Questions about feasibility and acceptability of interventions can be addressed in preparation for an RCT to optimize interventions and their implementation before they undergo expensive evaluation. Qualitative methods such as interviews and focus groups with those delivering the intervention can explore feasibility. For example, the intervention being tested in the RCT may be delivered in busy health service clinics that require health professionals to change their work practices. Interviews and focus groups with those receiving the intervention can explore how the intervention fits into the context of patients' lives and their management of their health condition. Nonparticipant observation or structured observation can be used to consider the fidelity of implementation of the intervention, that is, understand whether the intervention in practice was similar to that planned. All of these methods can help to identify how the intervention can be adapted to operate well in the context in which it will be tested and/or delivered in the real world.

Never Mind the Intervention; Will the Randomized Controlled Trial Work?

It can be challenging to run RCTs. For example, RCTs can struggle to recruit sufficient participants, resulting in low statistical power, or they can lack external validity because they recruit a narrow profile of the population that will actually use the intervention in the real world. Questions around how to improve the conduct of the RCT can be important, and qualitative research has been used for this purpose. For example, interviews with health professionals recruiting patients for RCTs, and interviews with the patients approached for participation, can identify misunderstandings that lead to nonparticipation in the trial. Observations of recruitment practices can identify poor communication that has led to these misunderstandings.

Have We Really Understood the Complexities of What We Are Researching?

An industry has grown up around RCTs of drugs. Yet much of what is evaluated in health is more complex than a drug and is known as a *complex intervention*. A complex intervention has been defined in different ways. First, it is defined by what it is not: it is not a drug or surgical procedure (Oakley, Strange, Bonell, Allen, & Stephenson, 2006). When defined by what it is, a complex intervention has many components or active ingredients (Campbell et al., 2007; Munro & Bloor, 2010; Oakley et al., 2006), which combine independently and interdependently (Campbell et al., 2007), making the whole more than the sum of its parts (Hawe, Shiell, & Riley, 2004; Oakley et al., 2006). Complex interventions are also defined as organizationally elaborate and socially mediated (Munro & Bloor, 2010). The complexity of the intervention can take different forms, such as the variation in behaviors of the people delivering or receiving the intervention, the different groups or organizations affected by the intervention, and the variation in outcomes (Medical Research Council [MRC], 2008). Examples of complex interventions include the introduction of lifestyle interventions for people with obesity or the reorganization of the way in which a service is delivered.

Complex interventions are particularly challenging and costly to evaluate because of their multifaceted nature and their dependence on the social context. These create methodological challenges for the RCT (Campbell et al., 2007; Oakley et al., 2006) relating to difficulties in standardizing the design and delivery of the intervention and understanding the characteristics of the local context in which the intervention is delivered (MRC, 2008). While an RCT may be the most rigorous way to evaluate the effectiveness of an intervention, there is growing acknowledgement of the

contribution of qualitative methods to understand the complexity of interventions (Glenton, Lewin, & Scheel, 2011).

Complexity can be related to more than the intervention: drug trials may be undertaken with complex patient groups (e.g., Romo, Poo, & Ballesta, 2009) or within complex environments (e.g., Shagi et al., 2008), benefiting from qualitative methods to engage with this complexity.

Frameworks for Undertaking Mixed Methods Intervention Evaluations

Three frameworks for multimethod and mixed methods intervention evaluations have been described in the literature: the temporal framework, the process-outcome framework, and the "aspects of a trial" framework. These frameworks can help researchers consider the range of questions relevant to their evaluation and the range and timing of methods within their evaluation. We discuss these frameworks in the following sections.

The Temporal Framework

A common approach to describing the use of qualitative research with RCTs is a temporal framework, which considers how qualitative research can be used before, during, or after a trial (Creswell et al., 2009; Jansen et al., 2009; Lewin et al., 2009; Sandelowski, 1996). It is worth reflecting on what these authors mean by *trial* before exploring how qualitative research is used before during and after the trial. By *trial* these authors mean what is variously called the "definitive RCT" (MRC, 2000) or "Phase III" trial, which measures the effectiveness of an intervention in large groups of people (US National Library of Medicine, 2008). When testing drugs, other phases occur before and after this Phase III trial. Before the trial, studies are undertaken to test the safety of drugs in a small group of people (Phase I) and to explore effectiveness in a larger group (Phase II); after the Phase III trial, research is undertaken to test the drug's effect in the longer term (Phase IV). A similar phased approach has been described for complex interventions where early phases are carried out before the definitive RCT to prepare for the Phase III definitive trial, and Phase IV occurs after the definitive trial to study longer term implementation of the intervention in the real world (MRC, 2000). This phased approach to trials of complex interventions has been updated to consider development and feasibility phases prior to the trial of effectiveness, which is then followed by implementation studies (Craig et al., 2008). In Table 23.1 we display the different work authors have suggested qualitative research can do before, during, and after the trial, and then we go on to explore these stages in more detail.

Table 23.1 The Use of Qualitative Research With Trials at Different Stages of the Trial

Timing of Qualitative Research	Suggested Uses of Qualitative Research With Trials	References
Before the trial	To "trial" the trial	Sandelowski, 1996
	To develop an instrument when a suitable instrument is not available to measure an outcome in a trial or select appropriate outcome measures	Creswell et al., 2009; Lewin et al., 2009
	To develop recruitment or consent practices, estimate recruitment or retention, and understand the burden placed on trial participants and caregivers	MRC, 2000, 2008; Creswell et al., 2009
	To understand the context in which the trial or intervention occurs to ensure that the intervention will work in a particular context or to identify any issues that may occur	Creswell et al., 2009; Jansen et al., 2009; Lewin et al., 2009
	To support the need for an intervention by identifying the evidence base and identifying or developing theory and hypotheses	MRC, 2000, 2008; Creswell et al., 2009; Jansen et al., 2009; Lewin et al., 2009

(*continued*)

Table 23.1 Continued

Timing of Qualitative Research	Suggested Uses of Qualitative Research With Trials	References
	To provide baseline information	Creswell et al., 2009
	To obtain information about the feasibility of the intervention	MRC, 2000, 2008; Jansen et al., 2009
	To develop, pilot, and refine the intervention	Jansen et al., 2009; Lewin et al., 2009
During a trial	To validate trial outcomes with participant voices and to identify factors affecting trial outcome measures	Creswell et al., 2009
	To understand how the intervention affects participants (e.g., identifying barriers and facilitators)	Creswell et al., 2009; Jansen et al., 2009; Sandelowski, 1996
	To capture intended and unanticipated experiences of participants during the trial	Creswell et al., 2009; Lewin et al., 2009; Sandelowski, 1996
	To understand processes of change and the context in which the intervention occurs such as its ~~affect~~ on outcomes and alterations to the sociocultural environment.	MRC, 2000, 2008; Creswell et al., 2009; Jansen et al., 2009; Lewin et al., 2009
	To verify fidelity of implementation of the intervention including describing the intervention as delivered, dose delivered, and dose received	Sandelowski, 1996; Creswell et al., 2009; Lewin et al., 2009;
	To identify prospective mediators and moderators of the intervention process	Creswell et al., 2009
	To refine interventions for subsequent trials	Jansen et al., 2009
After a trial	To explore how participants interpret trial results	Sandelowski, 1996; Creswell et al., 2009
	To account for participant feedback in revising a treatment	Creswell et al., 2009
	To understand or explain the trial outcomes (e.g., variation in trial results)	Sandelowski, 1996; Creswell et al., 2009; Lewin et al., 2009
	To establish the long-term effects of the intervention	Creswell et al., 2009
	To understand the trial as an intervention in its own right	Sandelowski, 1996
	To understand in depth how a theoretical model worked	Creswell et al., 2009; Jansen et al., 2009; Lewin et al., 2009
	To verify the fidelity of treatment processes	Creswell et al., 2009
	To consider context when comparing outcomes with baseline data	Creswell et al., 2009
	To generate additional hypotheses	Lewin et al., 2009

BEFORE-TRIAL

According to Creswell et al. (2009), a before-trial design entails the collection and analysis of qualitative data before the trial with the purpose of improving the subsequent trial; Sandelowski (1996) refers to this as "to 'trial' the trial" (p. 361). The qualitative research occurs at the development or feasibility/piloting phases of an evaluation (Craig et al., 2008) and can ensure that the definitive or Phase III trial evaluates the optimum intervention, recruits participants efficiently, and measures the right outcomes in a valid way. The focus of the qualitative research can be on the intervention, the trial conduct, or both. In their study of trials of complex interventions designed to change the organization of care, Lewin et al. (2009) found that half of the studies combining qualitative research and RCTs (14/30) collected qualitative data before the trial. O'Cathain et al. (2013) found that a quarter of journal articles reporting qualitative research undertaken with RCTs were based on data collection carried out before the definitive trial. The definitive trial can benefit from the before-trial qualitative research findings if the learning is acted upon whereby researchers adapt the intervention, improve recruitment practices, or select outcomes informed by the benefits the patients believe they have gained from the intervention. Although researchers have described the use of qualitative research before the definitive trial, quantitative and qualitative methods can be used at this stage within a mixed methods intervention evaluation. Case study 1 describes how researchers used a mixed methods study prior to a trial to consider adapting an effective intervention for use within a different group before it was then tested in the definitive trial.

Case Study 1: Adherence to Treatment of Cystic Fibrosis in Adolescents

This study (Marciel, Saiman, Quittell, Dawkins, & Quittner, 2010) was conducted in the United States using mixed methods (focus groups, interviews, survey) before an RCT to adapt a peer support group intervention for adolescents, which had previously been tested on preschool and school-age children. The aim of the intervention was to improve adherence to treatment for cystic fibrosis. Focus groups were undertaken with 17 health care professionals and interviews with 18 adolescent patients, 6 adult patients, and 12 parents. The qualitative research identified that adherence in this age group was particularly difficult due to feelings of invincibility and lack of knowledge about the consequences of nonadherence. It also identified that the mobile phone technology used in the intervention offered other benefits and allowed adolescents to have direct contact with their healthcare team. In the interviews, facilitating adherence was found to be difficult for parents, who identified time constraints, lack of motivation, and forgetting treatments as barriers to adherence. Interviews with adolescents identified the acceptability of the proposed intervention to them. The research facilitated confidence in the proposed intervention prior to testing in an RCT.

DURING-TRIAL

A during-trial design involves the collection of qualitative data during the definitive trial to understand how the intervention is implemented in practice. Lewin et al. (2009) found that 9 of 30 studies collected qualitative data solely during the trial, and 2 studies collected data both before and during the trial. Process-outcome evaluations are a during-trial design, and these are described in detail in the next framework. The purpose of understanding how the intervention was implemented in practice is usually to explain the trial results. Yet, interestingly, authors who use this temporal framework include the use of qualitative research to explain the trial results in the after-design, where qualitative research is used after the trial. There is no doubt that the trial must be complete and the results known before qualitative research can be used to help interpret those results. However, the data collection and analysis of qualitative research can be carried out during the trial. Indeed, explaining the trial results is often the key aim of process evaluations undertaken alongside RCTs.

AFTER-TRIAL

An after-trial design involves collecting qualitative data after the trial has ended to explore the longer term implementation of an intervention (MRC, 2000, 2008). Lewin et al. (2009) found that very few of their studies (4/30) included qualitative research conducted after the trial. Some studies collect qualitative data after a trial that could have been collected during a trial. In Case Study 2, qualitative research was conducted after a trial to help to explain why an intervention was not as effective as expected.

Case Study 2: An Exploration of the Structural and Personal Factors That Might Have Reduced the Acceptability or Feasibility of the Intervention

A cluster RCT (Pope et al., 2010) was carried out in 20 primary-care clinics in the Eastern Cape Province of South Africa. The RCT, which tested an intervention of provider-initiated HIV counseling for newly diagnosed tuberculosis, had a positive result, but the magnitude of the effect was smaller than expected. Once these results were known, a qualitative study of interviews and focus groups was undertaken with the tuberculosis nurses who conducted the education, counseling, and testing sessions to identify barriers to implementation. Three potential barriers to delivery of the intervention were identified: inadequate staffing levels due to the use of nonqualified nurses to provide counseling who then needed to find a qualified nurse to provide HIV testing; a lack of space and privacy in a primary-care environment to conduct counseling sessions; and nurses' beliefs that despite the importance of counseling and testing, the skills required to deliver counseling are innate and therefore cannot be taught, which may have led to inadequate training. In this case, the qualitative research conducted at the end of the RCT enabled the team to understand structural and individual level factors that influenced the success of HIV counseling and testing for newly diagnosed tuberculosis patients. This explained the small effect size in the RCT and highlighted the need for future research to consider innovative and coordinated approaches to service provision in a primary-care environment.

We have used the temporal framework to show how qualitative research can be usefully conducted at different phases of an RCT. In the next section we discuss an alternative framework, the process-outcome evaluation framework, which considers how both quantitative and qualitative research may be used to explore processes within an evaluation where the outcomes are measured using an RCT.

The Process-Outcome Framework

Process evaluations are usually undertaken alongside definitive or Phase III trials and complement the trial's focus on outcomes. They started in health research in the mid- to late 1980s in the context of evaluating applied public health interventions but have a longer history of use within program evaluation (Linnan & Steckler, 2002). Process evaluations were seen as a necessary addition to trials of complex interventions because trials cannot provide insights about the mechanisms behind interventions or how interventions are actually delivered in practice (Glenton et al., 2011; Oakley et al., 2006). Researchers have argued that process evaluations should be an integral part of trials of complex interventions, researching why and how interventions work or do not work (e.g., Linnan & Steckler, 2002; Munro & Bloor, 2010; Oakley et al., 2006; Siu, Shek, & Poon, 2009). Their strength is the ability to distinguish between what is planned in a particular setting and what is actually done in practice, which may depend on factors such as the resources available, the organizational structure in which the intervention is delivered, and the stakeholders involved in delivering the intervention (Aro, Smith, & Decker, 2008). In particular, process evaluations can distinguish between "interventions that are inherently faulty (failure of intervention concept or theory) and those that are badly delivered (implementation failure)" (Oakley et al., 2006, p. 413). This can help to avoid what has been termed "type III errors" (Audrey, Holliday, Parry-Langdon, & Campbell, 2006), that is, where a trial has a null result because the intervention was inadequately implemented rather than a failure in the intervention design itself. It has been argued that process evaluations are particularly useful in cluster or multisite trials to understand the context when the same intervention is delivered at different sites (Oakley et al., 2006) and when an intervention is trying to change the organization of healthcare delivery (Glenton et al., 2011). A process evaluation can help to explain the results of trials with positive results by identifying which aspects of the intervention contributed to its success and trials with null results in terms of why the intervention was not effective (Linnan & Steckler, 2002). Whilst many process evaluations are conducted during the definitive trial, the importance of process evaluations used alongside feasibility and pilot studies prior to the definitive trial has also been highlighted; for example, when used alongside a pilot trial, process evaluations can aid the decision about whether to progress to the definitive trial, and they may inform changes to the intervention to be tested in that definitive trial (Munro & Bloor, 2010).

Linnan and Steckler (2002) present seven key components of a process evaluation that are similar to how qualitative research can be used at the during-trial stage (see Table 23.1), even though process evaluations make use of both qualitative and quantitative methods. Each component is described in the following: context, reach, dose delivered, dose received, fidelity, implementation, and recruitment.

Context includes the broader social, political, and economic setting in which the intervention is delivered (Glenton et al., 2011). For example, a process evaluation undertaken alongside a trial of a treatment for diabetes may use interviews with stakeholders or analysis of policy documents to allow the researcher to consider what is already available for participants in the community, how the intervention fits in with this, and how the intervention is delivered within the existing context of a general practice.

Reach is the proportion of the target population that participates in the intervention. For example, in a trial of medication for blood pressure, it is important to access as many participants who can benefit from the medication as possible, including hard-to-reach subgroups of the population. Interviews with service providers may reveal information about particular groups of patients that have been excluded, even if this was not the intention of the trialist. For example, family practitioners screening patients for inclusion in a trial of medication for reducing high blood pressure may exclude those with diabetes even though they are eligible for the study. This has implications for the generalizability of the RCT results.

Dose delivered is how much of the intervention is intended to be delivered to participants and is often determined by the behavior of the people delivering the intervention; for example, in a trial of cognitive behavioral therapy provided through the Internet, it may be how many sessions were actually delivered to participants. Quantitative methods can be used to record numbers of sessions delivered. Closely related to dose delivered is *dose received*, which in the previous example of cognitive behavior therapy would be the proportion of Internet sessions participants actually accessed and completed.

Fidelity is identified by Linnan and Steckler (2002) as the most difficult component to assess and relates to the quality of the implementation of the intervention, that is, the extent to which the intervention was delivered as planned. Assessment may include quantitative methods such as checklists of how aspects of the intervention were delivered and qualitative methods to make a subjective assessment of whether it was delivered in the "manner and the spirit in which it was intended" (p. 13). This could involve observations of therapy sessions or consultations or questionnaires for staff delivering the intervention.

Program implementation is a combination of reach, dose, and fidelity and is conceptualized by Linnan and Steckler as a composite score indicating the extent to which the intervention has been implemented and received by the intended population. There is debate about how to calculate implementation and what an acceptable implementation score would be.

Recruitment concerns how trialists attract and approach prospective participants and how they interact with participants once the trial starts. It is important for trialists to recognize sampling bias in the study, identify how this bias might affect the results, and determine how the intervention should be implemented in clinical practice. Researchers should be aware of problems concerning generalizing the findings of the trial to subgroups that were not included in the participant sample or consider whether the trial findings apply to all participants in the trial sample.

While it is possible to see how aspects of process evaluations such as reach, dose delivered and received, and certain features of recruitment or program implementation can be assessed through quantitative methods such as checklists and surveys, others such as context and barriers or facilitators to successful implementation are more readily assessed by qualitative methods such as interviews, focus groups, diaries, and observations. Process evaluations usually include a combination of qualitative and quantitative methods, thereby constituting mixed methods studies (Oakley et al., 2006). Case Study 3 describes how process evaluations for two RCTs for the same intervention addressed different aspects of a process evaluation from the previous list. The process evaluation for the first trial focused on reach, implementation, and participant satisfaction, whereas the one for the second trial focused on dose delivered and received, implementation, and context. This shows how even trials of a similar intervention can utilize different components of process evaluation according to the needs of the evaluation. Indeed, in order to gain the most benefit from process evaluations, Linnan and Steckler (2002) suggest that researchers focus on the most salient processes to reduce the volume of data collected, particularly

if cost is an issue. Case Study 3 also highlights the mixed methods approach to these process evaluations, with methods such as questionnaires, interviews, and observations used in both evaluations. Additionally, it is interesting to see process evaluations undertaken at the during-trial phase, where an RCT is used to test the effectiveness of an intervention, and then at the after-trial phase, where an RCT is used to test different strategies for implementing the effective intervention. Finally, it highlights that Linnan and Steckler's components of a process evaluation are not comprehensive and could also include acceptability of an intervention.

Case Study 3: Process Evaluations for the Pool Cool Efficacy and Diffusion Trials

Pool Cool was a skin cancer prevention intervention in the United States initially tested in a RCT in 1999 at 28 swimming pools in Hawaii and Massachusetts (Glanz, Geller, Shigaki, Maddock, & Isnec, 2002; see also Escoffery, Glanz, & Elliott, 2008; Escoffery, Glanz, Hall, & Elliott, 2009). The intervention program was aimed at children age 5 to 10 years, their parents, lifeguards, and swimming instructors. The intervention included staff training, sun safety lessons, onsite interactive activities, provision of sunscreen, shade and signage, and promotion of safe sun environments in order to improve sun protection. The control groups received an intervention program aimed at bike safety, traffic safety, fire safety, or poisoning and choking prevention. The process evaluation focused on three aspects of the intervention—reach, implementation, and participant satisfaction—assessed using monitoring forms, questionnaires, and posttest observations. The trial showed that the Pool Cool skin cancer prevention program improved sun protection behaviors and environments at swimming pools. The process evaluation showed that the Pool Cool program was successfully implemented at swimming pools and that it was well received by both parents and children. The Pool Cool trial was followed by a diffusion trial, which ran over four years, evaluating the effects of two strategies for carrying out the Pool Cool program (Escoffery et al., 2008, 2009). The basic strategy was to send a tool kit to sites that included a leaders' guide about how to implement the program, laminated lesson cards and interactive cartoon cards, materials for poolside sun protection activities, a large dispenser of sun cream, and signage targeting poolside tips for sun protection. In the enhanced strategy, pools received the basic strategy materials and additional sun safety items, environmental supports, supplementary guidance, and incentives to promote the Pool Cool program. The process evaluation focused on dose delivered and received, implementation, and context utilizing a mixture of surveys, interviews, observations, and records to assess the maintenance and sustainability of the different implementation strategies employed. In the trial, no difference was found between the effectiveness of the basic and enhanced strategies. The process evaluation identified that the basic strategy, which had higher levels of teaching sun safety lessons and sunscreen use in the first year, was appealing to children and easy to implement whereas the enhanced strategy was not much more intensive in terms of the additional materials offered. The authors suggested that further incentives, training, and monitoring could improve results in the enhanced strategy.

The Aspects of a Trial Framework

We have considered two frameworks for thinking about mixed methods intervention evaluations. A third and final framework is offered by ourselves and detailed in O'Cathain et al. (2013), where we considered how qualitative research was actually used in practice with RCTs rather than how it *might* be used. That is, this framework was empirically rather than theoretically based. We identified 296 articles published between January 2008 and September 2010 that reported qualitative research undertaken with RCTs and mapped the focus of the qualitative research in relation to the RCT. We found that 28% of these publications had been carried out before the trial. However, it was difficult to distinguish between qualitative research undertaken during or after a trial because data collection might occur during the trial, but analysis and interpretation might occur after the trial results were known. The timing of data collection, analysis, and interpretation of the qualitative research in relation to the RCT was rarely clearly reported in these articles. Thus the temporal framework described earlier was not a helpful way of categorizing these articles in practice, and instead a new framework was developed inductively from reading the 296

publications identified. We found five aspects of a trial that qualitative research could inform (O'Cathain et al., 2013): the intervention, the trial design and conduct, the outcomes, the process and outcome measures used, and understanding of the health condition at which the intervention was aimed (Table 23.2).

This framework, which is based on articles researchers published from the qualitative research they carried out with RCTs, has some notable differences compared with the two frameworks presented earlier. One of the five aspects of the trial within this framework was the intervention. We identified eight aspects of the intervention addressed in the articles, some of which appeared in the two frameworks presented earlier: intervention development, mechanisms of action, the feasibility and acceptability of an intervention, fidelity,

Table 23.2 Framework of the Focus of Qualitative Research Used With Trials

Category	Subcategory	Description
Intervention content and delivery	Intervention development	Pretrial development work relating to intervention content and delivery
	Intervention components	Exploring individual components of a complex intervention as delivered in a specific trial
	Models, mechanisms, and underlying theory development	Developing models, mechanisms of action, and underlying theories or concepts relating to an intervention in the context of a specific trial
	Perceived value and benefits of intervention	Exploring accounts of perceived value and benefits of intervention given by recipients and providers of the intervention
	Acceptability of intervention in principle	Exploring stakeholder perceptions of the "in principle" acceptability of an intervention
	Feasibility and acceptability of intervention in practice	Exploring stakeholder perceptions of the feasibility and acceptability of an intervention in practice
	Fidelity, reach, and dose of intervention	Describing the fidelity, reach, and dose of an intervention as delivered in a specific trial
	Implementation of the intervention in the real world	Identifying lessons for "real-world" implementation based on delivery of the intervention in the trial
Trial design, conduct, and processes	Recruitment and retention	Identifying ways of increasing recruitment and retention
	Diversity of participants	Identifying ways of broadening participation in a trial to improve diversity of population
	Trial participation	Improving understanding of how participants join trials and experience of participation
	Acceptability of the trial in principle	Exploring stakeholders' views of acceptability of a trial design
	Acceptability of the trial in practice	Exploring stakeholders' views of acceptability of a trial design in practice
	Ethical conduct	Strengthening the ethical conduct of a trial (e.g., informed consent procedures)

(*continued*)

Table 23.2 Continued

Category	Subcategory	Description
	Adaptation of trial conduct to local context	Addressing local issues that may impact the feasibility of a trial
	Impact of trial on staff, researchers, or participants	Understanding how the trial affects different stakeholders (e.g., workload)
Outcomes	Breadth of outcomes	Identifies the range of outcomes important to participants in the trial
	Variation in outcomes	Explains differences in outcomes between clusters or participants in a trial
Measures of process and outcome	Accuracy of measures	Assesses validity of process and outcome measures in the trial
	Completion of outcome measures	Explores why participants complete measures or not
	Development of outcome measures	Contributes to development of new process and secondary outcome measures
Target condition	Experience of the disease, behavior, or beliefs	Explores the experience of having or treating a condition that the intervention is aimed at, or a related behavior or belief

Source. Adapted from O'Cathain et al., 2013.

reach and dose, and implementation of the intervention in the real world. However, we also found articles of qualitative research used to describe the intervention in practice, including identifying hidden or unexpected components of the intervention. We also distinguished between qualitative research to identify the acceptability of the intervention in principle for future trials and in practice for current trials because the possibility of fixing problems identified with an intervention is different for each of these. Understanding these aspects of an intervention could help researchers to explain the trial results.

The second aspect of a trial addressed by qualitative research in our framework was design and conduct. Very little of this aspect was addressed by the earlier frameworks presented. There was overlap in terms of understanding ways of improving recruitment and retention within the specific trial or future trials. Indeed, Creswell et al. (2009) give an example of the innovative work by Donovan et al. (2002) who use interviews and observation before the trial to improve recruitment practices iteratively to ensure the successful implementation of the future trial. We found many other uses of qualitative research to explore the acceptability of the trial in principle and in practice and identify ways of improving the ethical conduct of future trials.

We also found articles focusing on the breadth and variation in outcomes and the development and accuracy of outcome and process measures; these are largely included in the temporal framework. One aspect of the trial that was not identified either by the temporal framework or the process-outcome evaluation framework was the use of qualitative research to explore patient experiences of the disease or behavior at which the RCT intervention was aimed, for example, exploring the lived experience of having a particular illness or condition. Researchers may have set out to explore this, or it may have been a by-product of exploring the intervention itself. We would suggest that it may be problematic to set out with an aim of exploring patient experiences of a health condition using participants in an RCT because trials are rarely representative of the population with that condition. However, it may be an additional bonus for the mixed methods intervention evaluation to understand something more about the health condition, especially if this has implications for the intervention under study.

While presenting these three frameworks we have drawn on language used by scholars discussing this methodology. The temporal framework privileges the RCT by describing other methods undertaken in relation to the RCT. Similarly the aspects of a trial framework considers qualitative research in relation to the trial. The process-outcome evaluation framework offers a more balanced relationship between the mixed methods components and the RCT. The language used to describe the combination of qualitative methods and trials may indicate the value given to different aspects of a mixed methods intervention evaluation, and therefore we discuss it next.

Developing Language for a Developing Methodology

Researchers use a variety of terms to describe the relationship between qualitative research and the trial that is carried out within mixed methods intervention evaluations. Creswell et al. (2009) use the term *embedded* for a qualitative study carried out during a trial. Similar terms used by other researchers include *incorporating, nested, sample from*, and *sub-study*. One could argue that these terms relegate the qualitative research to secondary status, with the trial as the primary method. Indeed Hesse-Biber (2012) identifies how terms such as *embedded* suggest a positivistic lens applied to the qualitative research, where it is given a secondary role as an "add-on" to the more important and valued trial. She argues that this limits the ability of the qualitative research to inform the trial other than in terms of validating or confirming the dominant quantitative results. However, Plano Clark et al. (2013) discuss variations in and disagreements about the definition of the term *embedded* and how it can be used to mean a more integrated approach between methods. They then go on to describe how interpretive qualitative research was embedded in an RCT.

Embedding can occur in other ways. Some researchers describe mixed methods intervention evaluations as trials embedded in qualitative research (Donovan et al., 2002; Hoddinott, Britten, & Pill, 2010), signifying the way in which qualitative research has shaped the trial. Case Study 4 is an example of an innovative study design that does just that by embedding a trial within a broader qualitative study. The case study is interesting because it shows how adopting this different perspective allowed the researchers to step outside the bounds of the single question of effectiveness to consider contextual differences between clusters in a cluster RCT.

Case Study 4: The Breastfeeding in Groups Study

Hoddinott, Britten, and Pill (2010) used the term "prospective mixed method embedded case studies" approach (p. 777) to describe how they assessed the effectiveness of an intervention to improve breastfeeding rates. The breastfeeding in groups trial was a cluster trial of 14 localities in Scotland in which 7 intervention localities were asked to increase group activities related to breastfeeding. The seven control localities did not change their existing group activities. Hoddinott's research team adopted an ethnographic, realist evaluative approach (Pawson & Tilley, 2004) to their trial design and conduct, keeping reflective diaries about meetings, telephone conversations, e-mails, and their thoughts and views about their experiences during the trial. They explored their backgrounds as a general practitioner and a former breastfeeding volunteer and how this interacted with their research roles. They hypothesized that there would be differences between the clusters receiving the intervention related to the local environment in which the intervention was conducted. They carried out focus groups, interviews, and breastfeeding group observations throughout the study. Before conducting analysis of the outcomes of the trial, they used the qualitative research to formulate an explanatory model of factors contributing to the success or failure of the localities in terms of delivering the intervention. The trial itself had a null outcome, with breastfeeding rates declining in three of the seven intervention localities. The model built from the qualitative data helped the researchers to explain differences in outcomes between clusters, identifying problems with the leadership, rooms where the group sessions were held, and a lack of resources in clusters with declining breastfeeding rates.

Another set of terms is also used to describe the relationship between methods in mixed methods intervention evaluations: *alongside, concurrent, in combination with, linked,* and *parallel*. These could suggest a more equal relationship between the RCT and other methods, or alternatively they could suggest separation between the trial and other methods

when integration is needed in terms of the qualitative research shaping and impacting the RCT. Concerns about the language used may diminish over time as a variety of relationships between the trial and other methods emerges, and researchers select the language that best describes the relationship between the methods they have used. This may be facilitated by a move to view these types of studies as complex evaluations rather than as trials with extra parts (Song, Sandelowski, & Happ, 2010). We have chosen to use the term *mixed methods intervention evaluation* in this chapter to describe these types of studies, deliberately using the term *evaluation* rather than *RCT* so that no method is privileged. This consideration of the challenge of the language being used to describe studies that combine qualitative research and RCTs highlights that, although there are considerable benefits to this endeavor that we have described earlier in the chapter, there are also challenges involved in moving from RCTs to mixed methods intervention evaluations. We discuss some of these challenges in the next section.

Challenges of Making the Move from Randomized Controlled Trials to Mixed Methods Intervention Evaluations

We now explore some challenges for researchers in moving from an evaluation consisting of a single RCT to a mixed methods intervention evaluation. When more than one method is involved, consideration needs to be given to integration of those methods, since different methods may be associated with different research traditions and paradigms and the increase in funding may be required to deliver them. Additionally, there is a tradition of synthesizing evidence from RCTs, thus if studies are undertaken as mixed methods intervention evaluations, then the challenge of synthesizing this multicomponent evidence arises.

Integration Between Methods

A key value of mixed methods research is that the whole is more than the sum of its parts (Barbour, 1999). For this to happen, one method must influence in some way the objectives, sampling, data collection, analysis, or interpretation of the other method within the study (O'Cathain, Murphy, & Nicholl, 2007). Within mixed methods intervention evaluations, the expectation is that the qualitative research should help to optimize the intervention to be trialed, improve the efficiency and ethics of the trial conducted, increase the internal validity of the trial by ensuring the right outcomes are measured in the right way, help interpret trial results, or facilitate the transferability of the trial findings to contexts outside the trial (O'Cathain et al., 2013). Thus the expected integration is one directional, with the qualitative research working to enhance the trial (Popay & Williams, 1998; Song et al., 2010). Examples of this integration are qualitative research showing how differences in staff attitudes and resources between clusters in a cluster RCT could explain differences in the primary outcome of breastfeeding rates between those clusters (see previous Case Study 4; Hoddinott et al. 2010), with qualitative research identifying problems with recruitment practices and the solutions to these problems resulting in increasing recruitment rates so that the trial was viable (Donovan et al., 2002) and qualitative research identifying a problem with an outcome measure in a feasibility study, which resulted in the use of a different outcome measure in the main trial (Farquhar, Ewing, Higginson, & Booth, 2010). However, Lewin et al. (2009) identified that publications from mixed methods intervention evaluations often had no evidence of integration of the findings from the qualitative research and the trial. That is, the promise of qualitative research helping to explain the trial findings was simply not delivered in practice, or at least not in a way that was visible outside the original research team. We drew a similar conclusion from our review of the use of qualitative research with trials (O'Cathain et al., 2013), as well as identifying examples of visible integration. This lack of visible integration is not surprising given the paucity of visible integration of data or findings within mixed methods studies generally in health research (O'Cathain et al., 2007), but it is disappointing given the potential value of the qualitative research to the endeavor of generating evidence of effectiveness. A challenge to all researchers engaged in mixed methods intervention evaluations is to explicitly report in journal articles the "yield" or insights gained from undertaking qualitative research and RCTs within the same study.

When integration occurs, careful consideration may need to be given to processes of integration. Some researchers have argued that the analysis of process evaluation data needs to be separate from

the analysis of the trial outcomes so that researchers can anticipate factors likely to affect outcomes uninfluenced by prior knowledge of the outcome of the trial (Ellard & Parsons, 2010; Munro & Bloor, 2010). This may be difficult where roles within the trial team overlap (Audrey et al., 2006), for example, if the trial manager is also the qualitative researcher. Whether researcher bias is a real issue or not, it is important that data collection processes and integration are addressed up front by the evaluation team, with a clear data collection and analysis plan and reflective and critical engagement about any potential challenges around integration. Otherwise the qualitative research or process evaluation risks being no more than "post-hoc allocation of success or failure," only useful for the development of future interventions (Jansen et al., 2009, p. 224).

Integration may be difficult because some evaluation team members may not feel able to act on findings generated from the qualitative research. The findings may not be available at the time they are needed, the findings may not have credibility among some team members such as the lead researcher, the trialists may be wedded to a particular path for their intervention and trial and be unwilling to deviate from it, or the qualitative research may challenge established ways of thinking and practice. For example, Jansen et al. (2009) raise a concern that researchers do not consider how an intervention can be adapted to fit the context in which it will be delivered but actually focus on adapting the context to fit the intervention. With such a mindset, qualitative research suggesting a need to adapt the intervention to fit the context may be unpalatable to the wider team. To facilitate integration, the whole evaluation team may need to adopt a reflexive approach associated with qualitative research (Hesse-Biber, 2012) and described earlier in Case Study 4. This occurs best at an early stage of study implementation when teams can discuss values and beliefs that shape their actions and reflect on their openness to different possibilities. This is likely to be essential when the qualitative research challenges aspects of the trial in terms of questioning the integrity of the processes utilized during the trial, the ability of the trial to generalize to a population, and the underlying theory on which the intervention is based. Case Study 5 explores this last point, describing how qualitative research can challenge the accepted theoretical basis for an intervention.

Case Study 5: The Use of a Narrative Approach to Understand Smoking Cessation and Challenge Current Thinking

A process evaluation was undertaken alongside a pilot trial of smoking cessation groups in Scotland (Ritchie, Schulz, & Bryce, 2007). The intervention tested in this pilot trial included narrative therapy that encouraged participants to tell stories about their smoking and offered flexibility in group membership, allowing participants to choose whether to attend group sessions or not depending on their needs at a particular time. Ritchie, Schulz, and Bryce (2007) conducted observations of 12 existing smoking cessation groups over a six-week period, debriefing sessions with the group facilitator, and interviews with people who had attended sessions at least three times over six months to assess perceptions and impact of the intervention on smoking behavior. They used narrative analysis to make explicit practitioners' assumptions underlying their work in the cessation groups and participants' views about the groups. The use of narrative therapy was valued and accepted by participants. Facilitators felt that using stories helped the participants to understand information and engage with the group better than simply giving them facts and figures. Many participants perceived that their intention to stop smoking was unstable and that they required long-term support. This long-term support was offered by the intervention in terms of helping with the decision to stop and in continuing not to smoke. Furthermore, participants valued flexibility in making the decision to stop smoking and how and when to attend group sessions. Researchers also found that the inclusion of smokers, those still trying to quit and those who had lapsed, to be beneficial by providing motivation and valuable insights to others at different/earlier stages of the quitting process. The research challenged many previous smoking cessation interventions that were often based on an uncritical adoption of the "one size fits all" "stages of change" model (Prochaska & DiClemente, 1983), which leads to assessment of motivation and readiness to quit as a stable concept.

There may also be tension around expectations for the qualitative research and what can be delivered in practice. Although the qualitative research

may enrich understanding of the trial findings, this understanding "will always be nuanced and qualified and rarely determinate" (Munro & Bloor, 2010, p. 710), and the researcher must always remain open to the possibility of other interpretations of the data. Munro and Bloor (2010) discuss a process evaluation carried out alongside a feasibility study for a definitive RCT, highlighting a challenge they faced in practice whereby after completing their data collection for the process evaluation, they were asked to explain unexpected findings from the feasibility study. The feasibility study concerned an intervention to train influential school pupils as "peer supporters" to be able to discuss smoking cigarettes and/or cannabis with their peers in order to educate them about the dangers of smoking. The trial had three arms: two schools had peer supporter training in cigarette smoking, two schools had peer supporter training in cigarette and cannabis smoking, and two schools were controls. One of the outcome measures was the intention to smoke cannabis in three months and at age 16. The researchers found that there was no evidence of an effect of the intervention on intention to smoke cannabis in the intervention schools, but unexpectedly they found an increase in expectations among peer supporters that they would be smoking cannabis by the time they were 16. By the time this unexpected finding emerged, the process evaluation data collection was complete and there was no resource for further data collection. Therefore the researchers had to analyze the data they had already collected in the hopes of finding some reasons for this outcome. Although they suspected that the fatalism of the teenagers in being subjected to drugs through their training as peer supporters underpinned this unexpected outcome, they were unable to provide evidence of this because it had not been explored specifically in their focus groups. Although they did find limited evidence that it was more difficult to talk about smoking cannabis than smoking cigarettes, Munro and Bloor (2010) argued that there is a danger in process evaluations of trying to generalize findings from single cases.

We have presented a number of challenges around integration of the qualitative research and RCT that we consider to be surmountable. We recommend that, in order to gain the benefits of mixed methods intervention evaluations explored earlier, researchers should

- Be explicit in publications about the insights for the trial gained from the qualitative research so that this learning is visible to other researchers, intervention developers, and research users.
- Plan how and when integration will occur, and who will be involved in it, so that issues such as researcher bias can be explicitly considered and addressed if appropriate.
- Adopt a reflexive approach to the whole evaluation at the beginning, where team members discuss their underlying beliefs and values about the intervention, the methods, and how integration can occur. This can help to prepare team members to be open to any challenging findings from the qualitative research and hopefully help them to take appropriate actions based on those findings.
- Manage expectations of what the qualitative research or process evaluation can deliver within the constraints of the evaluation so that the strengths and limitations are recognized when interpreting the findings.

Paradigmatic Differences

Paradigmatic differences between quantitative and qualitative research tend be ignored in mixed methods intervention evaluations in health (Oakley et al., 2006) but can be a challenge to researchers working on these studies. There can be a tension between the RCT with its assumptions of generalizability, its predetermined protocols, and its determination to control the context in which the research takes place and the more inductive, flexible nature of qualitative research that focuses on context and subjectivity. The ontological position of researchers conducting RCTs is realism: that an objective truth is out there. This ontological position can be shared by the researchers undertaking the qualitative research, and indeed one could argue that qualitative researchers believing in idealism would not be interested in working in the context of an RCT. However, the epistemological positions of trialists and qualitative researchers may be diverse and in tension. Trialists emphasize the objectivity of researchers who must desist from allowing their values to contaminate the research environment (Hesse-Biber, 2012). This can shape the way in which the research is conducted from the formulation of research questions through to how the data is collected and analyzed, who is qualified to do that, and the credibility of the knowledge that is produced (Hesse-Biber, 2012). This may result in the qualitative research being limited in the questions it addresses and having values imposed on it that are more important to quantitative research, for example, large sample sizes. The epistemological stance of the trialists can be dominant because the qualitative research takes an

enhancing role within the mixed methods intervention evaluation rather than being viewed as integral to the evaluation (Song et al., 2010). If studies are viewed as evaluations rather than trials with added qualitative components, then teams can pay attention to a variety of epistemological stances and consider the best approach to take within their evaluation.

It is standard practice to publish a protocol for an RCT so that researchers can be held to account, for example in their choice of primary outcome. Oakley et al. (2006) argue that process evaluations should prospectively specify a set of research questions and identify the processes to be studied, the methods to be used, and the procedures for integrating the findings of the process evaluation with the results of the trial. We concord with this view because it encourages planning of the qualitative research and sharing of this plan with the whole team, something that we believe can facilitate integration between relevant components of the study. This approach has been taken up by some research communities where researchers include a process evaluation within published trial protocols (e.g., Murphy et al., 2010) or publish standalone process evaluation protocols (e.g., Ellard, Taylor, Parsons, & Thorogood, 2011; Grant, Dreischulte, Treweek, & Guthrie, 2012).

High-quality RCTs are governed by external trial steering committees, and data monitoring committees are conducted according to standardized operating procedures and are reported uniformly in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement (Schulz, Altman, & Moher, 2010). This raises the question of whether other methods used with trials should be included in these trial practices and procedures. This requires careful thought of the pros and cons so that qualitative research is not blindly subsumed within all these procedures with an accompanying loss of its key strengths, nor blindly excluded from core aspects of the evaluation. Discussion about the whole study at trial steering committees, rather than only the trial, can ensure more opportunities for integration and that the study is seen as a whole rather than a trial with add-ons. It is also the case that process evaluations can uncover worrying issues about adherence to a planned intervention and the potential for bias within the study, which steering committees may need to be aware of and take action on (Riley, Hawe, & Shiell, 2005). Having a standard operating procedure for the qualitative research undertaken with a trial may ensure that thought is given to any possible damage qualitative research can do to the experiment (Rapport et al., 2013).

For all the potential benefits there might be to including qualitative research in the usual processes and procedures of a trial, we recommend a cautious approach be taken so that a key strength of qualitative research—its flexibility—is not damaged. In particular, a CONSORT statement for reporting qualitative research carried out with trials may be more prohibitive than helpful because of the range of approaches to data collection and analysis, the wide range of possible insights to be gained, and the wide range of ways of reporting these insights. There is also an alternative approach to consider—that the approach to trials is shaped by issues associated with qualitative research. In Case Study 6, Hawe et al. (2004) discuss how using qualitative research in community-based complex interventions may provide an alternative way of conceptualizing the relationship between the variability of the community context and the standardized RCT.

Case Study 6: Community Trial Design

Hawe et al. (2004) argue that RCT design for complex interventions can learn from complexity theory, which allows for real-world contexts by considering the interaction between the context and the intervention. The RCT would measure the effect of an intervention that has integrity, but the integrity is not defined compositionally through standardized processes in the laboratory (form) but rather functionally as being adapted to the local community context (function). For example, in an intervention to educate patients with depression, an intervention that was standardized based on form would distribute the same written patient information to all sites, whereas an intervention based on standardized function would tailor the information at each site based on the local culture, including factors such as the learning styles of the population and their language and literacy needs. Rather than assuming that the "best" evidence comes from a laboratory setting, which becomes gradually compromised in real-world applications, trials should start by conceptualizing communities as complex systems focusing on the standardization of the complex intervention by function rather than form. The study would then be about how the community system recurrently produces the health problem in order to understand how it can be changed in different contexts to achieve the desired outcome.

We have presented a number of challenges related to paradigmatic differences and recommend that researchers:

- Recognize that there are a variety of philosophical and methodological approaches to mixed methods intervention evaluations that they may wish to consider. Undertaking an embedded qualitative study within a trial is not the only option.
- Continue to publish protocols for process evaluations and reflect on the strengths and weaknesses of doing so.
- Proceed with caution in terms of including qualitative research within the formal procedures of trials, thinking about the evaluation as a whole rather than attempting only to squeeze qualitative research into the RCT paradigm.

An Additional Expense?

It costs money to undertake research in preparation for an RCT, process evaluations alongside RCTs, and studies of implementation after RCTs. It has been argued that the additional costs of conducting process evaluations are outweighed by greater explanatory power and an understanding of how well the intervention can be generalized (Oakley et al., 2006). It may also be argued that investment in preparation for a trial is beneficial because optimizing the intervention and having confidence in the feasibility of the full trial can save money by reducing the probability of expensive trials of flawed interventions or failed trials due to inability to recruit.

Even so, mixed methods intervention evaluations occur in the context of limited resources, time, and researchers to collect and analyze data (Linnan & Steckler, 2002). Therefore decisions need to be made about how much qualitative research is necessary for a particular trial, as well as how much can be resourced. Even in the context of ample resources, the volume of data generated by qualitative research can be challenging to analyze, and it may be necessary to focus on salient components in order to gain the most benefit.

There is also the challenge of false economy. Setting up qualitative research that is underresourced by employing unskilled researchers and placing unreasonable limits on time required to complete an in-depth analysis may lead to poor-quality research that lacks credibility.

We believe that qualitative research undertaken with trials is valuable and is worth paying for. We recommend that it is

- Properly resourced for focusing on important aspects of a particular RCT.
- Proves its value by explicitly communicating in publications the impact it has had on the endeavor of evaluating the effectiveness of an intervention.

Moving Beyond Primary Research Toward Evidence Synthesis

Systematic reviews of RCTs are carried out to summarize the evidence of effectiveness of specific interventions. We have shown in this chapter that qualitative research undertaken with trials can help to explain the findings of a specific trial. Qualitative research is also relevant to systematic reviews of trials, potentially adding to their value by helping to explain heterogeneity of trial findings (Noyes, Popay, Pearson, Hannes, & Booth, 2011). An excellent example of this is described in Case Study 7, where an evidence synthesis of qualitative research focusing on different approaches to promoting healthy eating in children helped to explain the different effect sizes found in trials of healthy eating interventions (Thomas et al., 2004).

Case Study 7: Integration of Qualitative Research and Trials in Systematic Reviews of Healthy Eating Promotion Interventions in Children

Thomas and colleagues (2004) conducted a systematic review of trials of interventions to increase healthy eating in children ages 4 to 10 years. First, they conducted a meta-analysis of data from trials showing that interventions increased children's consumption of fruit and vegetables by an average of half a portion per day. However, effect sizes varied between trials; while most trials increased it only by less than one portion, one trial achieved a two portion a day increase. Interested in these differences in effect sizes, Thomas and colleagues next synthesized results from qualitative studies about healthy eating in children, analyzing the authors' findings thematically for barriers and facilitators of healthy eating and ideas for possible interventions from the children's point of view. They found that children see health as the responsibility of their parents and that children prioritize taste over health, so interventions should not actively promote health over taste. They also found that children distinguish between fruit

and vegetables rather than perceiving them as both belonging to a healthy food group. Finally, Thomas and colleagues synthesized the results of both reviews in a matrix to explore the relationship between the interventions used in the effectiveness trials and the children's views. They concluded that studies in their sample that had little or no emphasis on health messages were more likely to promote increases in fruit and vegetable consumption. This use of evidence synthesis of both qualitative research and trials can be further mined by synthesizing evidence from mixed methods intervention evaluations so that the qualitative research undertaken with a specific trial is used to understand the context in which those trial results were achieved. Combining learning from each mixed methods intervention evaluation can then lead to an understanding of the important components of interventions and the subpopulations and the health environments in which they may be effective.

Conclusions and Future Directions

In this chapter we have discussed the move from the lone RCT addressing the single question of intervention effectiveness to a mixed methods intervention evaluation addressing a wide range of questions relevant to understanding effectiveness of interventions. We present this as a positive move driven by researchers understanding the complexity of the interventions they evaluate, the trials they conduct, and the environments in which they research. While it can be argued that this move has become part of routine practice in some research communities, we have identified a number of challenges with this approach in health research. These challenges relate to a current and ongoing shift in how researchers evaluate interventions. None of the challenges presented are insurmountable, and indeed reflecting on these challenges is likely to help research communities to understand how to gain the potential benefits of mixed methods intervention evaluations. Our main hope is that, as time goes by, we see a further move from qualitative research taking an enhancement role within trials toward researchers viewing their evaluations as whole studies—mixed methods intervention evaluations—with value placed on all components of these complex evaluations.

Discussion Questions

1. What are the benefits of using mixed methods intervention evaluations rather than standalone RCTs?

2. Why do you think we need to consider the language used to describe the relationship between the qualitative research and the trial?

3. What are some of the challenges in moving from RCTs to mixed method intervention evaluations?

Suggested Websites

http://www.mrc.ac.uk/documents/pdf/complex-interventions-guidance/

The Medical Research Council provides guidance for the development and evaluation of complex interventions, including RCTs and multimethods.

http://www.methodologyhubs.mrc.ac.uk/default.aspx

MRC Hubs for Trials Methodology Research is a focus for the development of trials methodology in the UK.

http://www.bristol.ac.uk/social-community-medicine/centres/conduct2/

ConDuCT-II, the collaboration and innovation in difficult or complex RCTs in invasive procedures, is one of the MRC hubs with a theme of qualitative research with pragmatic RCTs.

http://www.shef.ac.uk/scharr/sections/hsr/mcru/quart/conf

The MRC Hubs for Trials Methodology organization funded a conference on the use of qualitative research with trials, and some of the talks are available here.

http://www.apa.org/ed/schools/cpse/randomized-control-guide.pdf

A guide to multimethod trials in social science and education produced by the American Psychological Association.

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