NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Designing With Implementation and Dissemination in Mind

Contributors

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Introduction

During the design phase of a PCT, a researcher should consider the causal pathway from trial results to the implementation of a sustainable intervention. Effectiveness research and implementation research may, in fact, produce stronger impacts when they are done together as opposed to separately (Glasgow et al. 2012), although this has not been done as frequently as may be desired (Curran et al. 2012; Brownson et al. 2013), and there is considerable room for improvement when it comes to designing a trial with dissemination in mind (Brownson et al. 2013).

> *In PCTs and comparative effectiveness research "designs rely on controlling/ensuring delivery of the clinical intervention, albeit in a less restrictive setting, with little attention to implementation processes likely to be of relevance to transitioning the intervention to general practice settings." (Curran et al. 2012).*

Expanding on the notion that uptake and implementation in routine care could be studied in conjunction with clinical effectiveness in a PCT, dissemination and implementation could be considered in the early stages of research design—even as part of research topic selection (Curran et al. 2012; Slutsky 2015). Potential issues related to dissemination and implementation could be considered at the design phase as they can be anticipated at many levels: from the patient, the clinicians and organizations delivering the interventions, the financial and political environment, and the broader social context (Glasgow

RESOURCES

Building Partnerships to Ensure a Successful Trial

This Living Textbook chapter describes how to collaborate with healthcare systems leaders and other stakeholders to optimize the utility of evidence generated during an ePCT.

Quick Start Guide for Researcher and Healthcare Systems Leader Partnerships

This Quick Start Guide is designed to help clinical investigators partner with healthcare system leaders to support the successful conduct of an ePCT within their healthcare system. It provides advice from the Collaboratory and serves as an annotated table of contents, pointing readers to essential content in the Living Textbook regarding partnering to conduct an ePCT.

et al. 2012). However, if the intervention is not effective, then there is a need to either pursue the development and testing of an alternative intervention or ensure that the existing intervention does not get taken up in practice; increased attention on "de-implementation" of ineffective practices has occurred as a result of the "Choosing Wisely" campaign and other efforts to reduce use.

Investigators conduct the trial to get information about the effectiveness of an intervention. If no consideration is given to implementation of an intervention at the design stage, then it may be unclear as to whether the intervention can be integrated into various practice settings in its current form. An implementation study, which would seek to understand how to get the practice to be used in healthcare delivery systems, may be necessary if the results are positive. Conversely, in a stepped wedge trial, where the intervention is turned on at all sites over time, if the results are negative, de-implementation may be necessary. One resource that may be useful in gauging the likelihood that the intervention is designed for dissemination and implementation is the PRECIS-2 tool (Loudon et al. 2015; Johnson et al. 2016) This measure assesses, along nine dimensions, the relationship of the intervention, setting and study design with the clinical practice environment where the intervention may be delivered in the future. Researchers may benefit from designing their trials with these criteria in mind.

Researchers could also consider how the intervention will be operationalized within the health care systems. To do this, Proctor et al. suggest defining: (1) the actors: specific actors who will implement the intervention, (2) the action: the required steps, (3) the action target: the specific outcomes the strategy targets, (4) temporality: the order in which the steps are enacted, (5) the dose: the frequency, dose, or intensity of the intervention, (6) the implementation outcome affected: acceptability, adoption, appropriateness, feasibility, fidelity, implementation cost, penetration, and sustainability, and (7) the justification: specific rationale for the strategies used to implement a given intervention (Proctor et al. 2013).

As an example, consider STOP CRC through the lens of Proctor's process: the implementation components were clearly defined and fidelity to the implementation process was measured. The actors were clinic personnel who were trained to use a registry embedded in the EHR. The action was following the specific steps, in a specific order, and at specific time intervals required to use the registry, mail the introduction letter, and mail the FIT tests and reminders. The process measures were the proportion of FIT kits mailed (not the primary outcome of doing the FIT test). Defining and measuring implementation at each site was important because the "job" description of the actor varied at each site, the percent of personnel attending training sessions varied, steps were not always completed as originally planned, and the dose of the intervention varied. The STOP CRC investigators categorized these implementation components at each site and are now conducting a qualitative comparative analysis to determine which of the factors predicted

KEY QUESTIONS

What aspects of the proposed trial address effectiveness?

What aspects address sustainable implementation?

implementation success (high proportion of FITs mailed). This will be important for future implementation of the program.

Key Considerations

Key considerations for the planning stage:

- What impact do you want to have after findings are published in the literature?
- What are the needs of the audiences (including patients) who will use the research findings to make decisions?
- What questions are relevant to those audiences?
- Who can be engaged as a partner from the beginning to help refine the research question, define measurable outcomes, and refine the protocol? (Slutsky 2015)
- What are your plans to assess and monitor potential barriers and contextual changes throughout the PCT?
- What trial design will enable you to best understand the effectiveness and implementation potential?
- Is the intervention designed in a way that it can be delivered in a wide variety of health care settings?
- Who is able to deliver the intervention in usual healthcare settings?
- Are specific resources needed in order to deliver the intervention on an ongoing basis?

Hybrid Designs

Trials that take this dual focus of assessing outcomes and implementation—designed to establish efficacy *and* change practice—are called hybrid trials (Curran et al. 2012). Curran *et al.* propose three types of hybrid trials:

1. Testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation;
2. Dual testing of clinical and implementation interventions/strategies; and
3. Testing of an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes."

KEY QUESTION

How does the healthcare system I am conducting the trial within learn?

Use of the hybrid designs described above could speed the translation of knowledge into practice (Curran et al. 2012).

Stepped-Wedge Designs

With a stepped wedge design, in which, over time, the intervention is turned "on" in all participating sites (Hughes et al. 2015), one might expect that implementation at participating sites would be fairly seamless; if the intervention is working, sites can simply leave it turned on. However, there is a question of timing—does one turn off the intervention while waiting for results or leave it on? And, based on the experiences of the Collaboratory, there is ample variation among sites and individuals regarding the fidelity to an intervention.

In the chapter on Dissemination and Implementation, we describe a case example from the Lumbar Imaging with Reporting of Epidemiology (LIRE) trial.

References

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