Topic 3: Designing with Implementation in Mind

Doug Zatzick, MD, University of Washington School of Medicine
Implementation research defined

The scientific study of the use of strategies to adopt & integrate evidence-based health interventions into clinical & community settings in order to improve patient outcomes & benefit population health.

Source: NIH Dissemination and Implementation Research in Health PAR-16-238
Assumption: “If you build it …”

Source: David Chambers’ May 24, 2017, NIH Collaboratory Workshop
Translated to ePCTs: “If you build it pragmatically … they will implement”
NIH Collaboratory ePCT case example: Lumbar Imaging with Reporting of Epidemiology

- LIRE is a large pragmatic, cluster-randomized controlled trial testing the effectiveness of a simple & inexpensive intervention: Inserting epidemiologic benchmarks into lumbar spine imaging reports

- Total patient N ~250,000

- Exemplary PRECIS-2 pragmatic trial

- Stepped-wedge design leaves Intervention “turned on” after study completion
LIRE PRECIS-2 wheel (J. Jarvik, PI)

Source: Johnson et al., 2016. Use of PRECIS ratings in the National Institutes of Health (NIH) Health Care Systems Research Collaboratory
Why give up-front consideration to sustainable implementation?

Challenges in the roll-out of the LIRE ePCT:

• Providers/radiologists adopting the intervention prior to the start of the trial (*substituting*)
• Providers/radiologists accepting the intervention leading to adoption of the intervention prior to the final aggregate study findings (*adoption*)
• Providers/radiologists selectively removing the intervention from reports (*discontinuation*)
• Providers/radiologists temporarily at select clinics discontinuing the intervention during the trial (*discontinuation*, or "mini-revolt")
• HCS discontinuing use of LIRE EHR platform (interrupts naturalistic stepped-wedge continuation of intervention after the trial)
Where to look for cutting-edge information on ePCT sustainable implementation?

The NIH Collaboratory’s Living Textbook of Pragmatic Clinical Trials: www.rethinkingclinicaltrials.org
Designing with implementation & dissemination in mind

Up-front considerations

• What are the needs of the audiences who will use the research findings to make decisions?
• What is the fit with the target patient population & setting?
• Who is able to deliver the intervention?
• Building in tests of training, support & adherence/fidelity
• Methods for observing during the trial roll-out, barriers to high-quality, sustainable intervention delivery

To what extent are the implementation procedures being proposed in an ePCT linked to evidence-based implementation strategies?
Effectiveness-implementation hybrid pragmatic trials

Much has been written about the nature of health care science-to-service gaps both in general and relative specifically to health promotion and numerous medical specialties. Thus far, the literature indicates that gaps between research and practice can result from multiple factors, including educational/knowledge deficiencies and/or disagreements, time constraints for practitioners, lack of decision support tools and feedback mechanisms, poorly aligned incentives, and a host of other organizational climate and cultural factors.

In addition to these provider-level and systems-level barriers to rapid translation, Glasgow et al. and others argue that the time lag between research discovery and routine uptake is also inflated by the dominant developmental approach; that is, one that encourages delimiting, step-wise progressions of research through clinical efficacy research, then clinical effectiveness research, and finally implementation research. In addition, it has been suggested that current conceptions of research designs fail to “maximize clinical utility for practicing clinicians and other decision makers,” for example, through a failure to focus on external validity or implementation-related barriers and facilitators to routine use and sustainability of “effective” practices.

Wells and Glasgow et al. suggested that a blending of the efficacy and effectiveness stages of intervention development could improve the speed of knowledge creation and increase the usefulness and policy relevance of clinical research. We propose that a blending of the design components of clinical effectiveness trials and implementation trials also is feasible and desirable. Such blending can provide benefits over pursuing those lines of research independently; for example:

Source: Curran et al., 2012 Medical Care
The most recent adaptation of these principles, to enhance the relevance of effectiveness designs for translation, are “practical clinical trials,” which have found their newest application in the area of policy-relevant “comparative effectiveness research.” In each of these clinical trial approaches, 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.

Source: Curran et al., 2012 *Medical Care*
Integrating ePCT & implementation science conceptual frameworks

• Early stages of integration
• Pragmatic trials aim to maximize efficiency in trial design & roll-out thereby minimizing costs per subject randomized
• Implementation science emphasizes understanding implementation processes with less attention to efficiency
• Implementation science with dozens of theories & conceptual frameworks
Integrating implementation science & ePCT methods

Methods development can meld pragmatic trial resource constraints & implementation science process evaluations
Where to look for cutting-edge information on dissemination & implementation frameworks?

The NIH Collaboratory’s *Living Textbook of Pragmatic Clinical Trials:*
www.rethinkingclinicaltrials.org
How does your healthcare system learn?

Let it happen  Help it happen  Make it happen

Defining Features

- Unpredictable, unprogrammed, uncertain, emergent, adaptive, self-organizing
- Negotiated, influenced, enabled
- Scientific, orderly, planned, regulated, programmed, systems “properly managed”

Metaphor for Spread

- Emergence, adaptation
- Knowledge construction, making sense
- Diffusion
- Negotiation
- Knowledge transfer
- Dissemination, cascading
- Re-engineering
American College of Surgeons Regulatory Policy
Targeting PTSD & Comorbidity
TSOS effectiveness-implementation hybrid ePCT design

- Effectiveness aim: reduce PTSD symptoms
- Implementation aim: influence US trauma center requirements for sustainable PTSD screening & intervention procedures
NIH Collaboratory methods innovation: “Embedded Implementation Teams Within Embedded PCTs”

Patients & Front-Line Providers

Implementation Team
Front-line MD, RN, PhD, & MSW Clinicians/Researchers, Mixed Methods Expert Consultant

National Policy Change Agents

Clinical Services Research
Novel embedded mixed methods: Rapid Assessment Procedure Informed Clinical Ethnography (RAPICE)

- TSOS research team spends hundreds of hours immersed in trauma care system clinical context
- Front-line clinician-researcher conducts participant observation, not driving up costs of trial
- Field notes & jottings taken, key informant interviews recorded
- Field data regularly reviewed with mixed-method expert consultant
- Themes related to trial roll-out and sustainable implementation iteratively reviewed & documented

Source: Palinkas & Zatzick In Preparation; Zatzick et al 2016; Zatzick et al 2011; Palinkas et al 2004
Important things to know

• Pragmatic trials can simultaneously address effectiveness & implementation aims

• HCS may vary with regard to how practice change derived from clinical trial evidence is rolled out

• Methods that integrate pragmatic trial & implementation science conceptual frameworks are in development
Important things to do

• Consider what aspects of the proposed trial address effectiveness

• Consider what aspects address sustainable implementation

• Consider the question, How does the HCS in which I am conducting the trial learn?

• Consider what key policy or practice change levers I might need to engage up-front in order to enhance sustainable implementation
1. How does the healthcare system I am conducting the trial within learn?
2. What aspects of the proposed trial address effectiveness?
3. What aspects address sustainable implementation?
4. What key policy or practice change levers might I need to engage up-front in order to enhance sustainable implementation?