Topic 3: Designing with Implementation in Mind

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Collaboratory ePCT Training Workshop

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

Assumption: "If you build it …"

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)
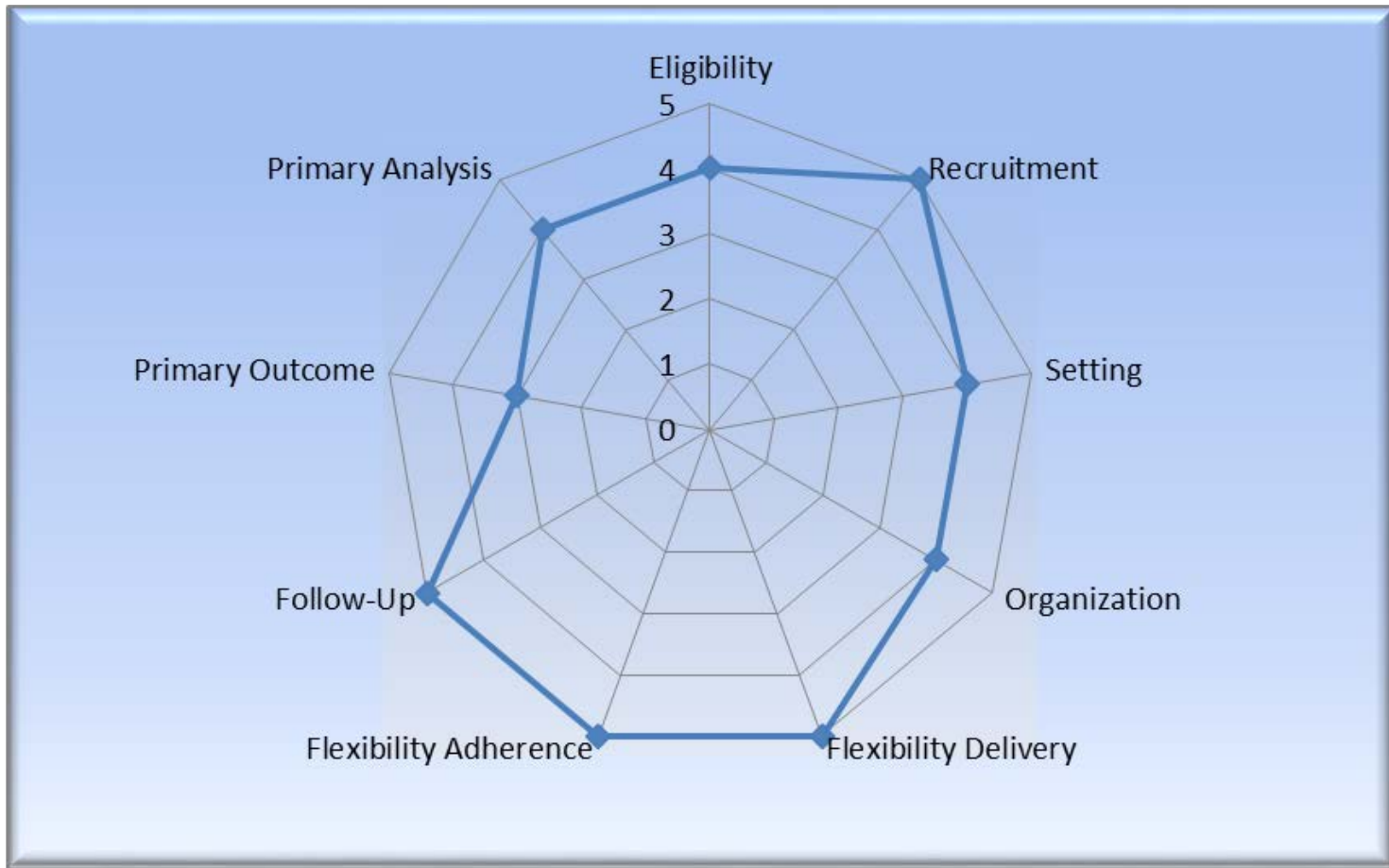
Why give up-front consideration to sustainable implementation?

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?
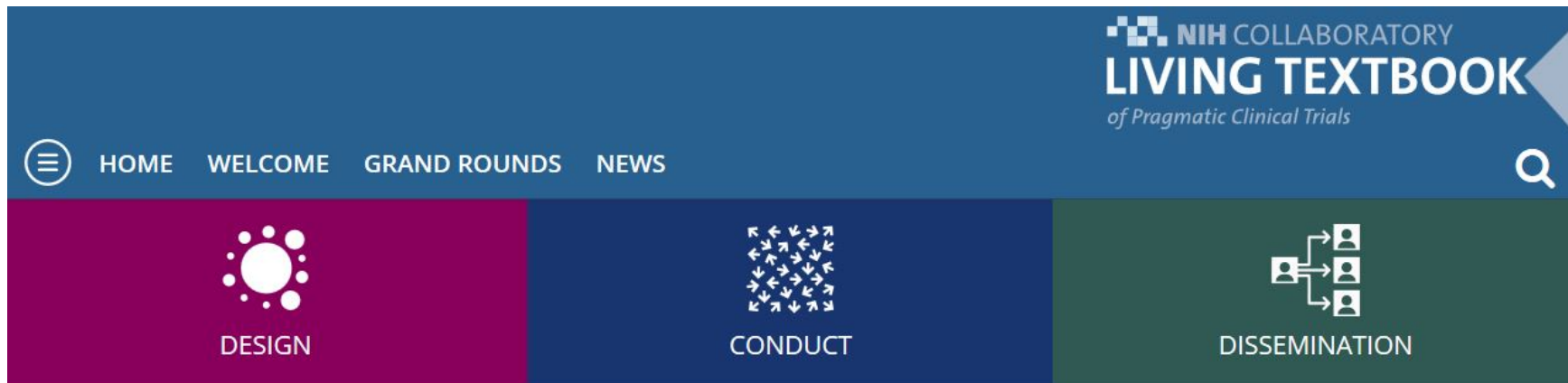
The NIH Collaboratory's *Living Textbook of Pragmatic Clinical Trials*:
www.rethinkingclinicaltrials.org

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

ANNALS OF HSR

Effectiveness-implementation Hybrid Designs
Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact

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Objectives: This study proposes methods for blending design components of clinical effectiveness and implementation research. Such blending can provide benefits over pursuing these lines of research independently; for example, more rapid translational gains, more effective implementation strategies, and more useful information for decision makers. This study proposes a "hybrid effectiveness-implementation" typology, describes a rationale for their use, outlines the design decisions that must be faced, and provides several real-world examples.

Results: An effectiveness-implementation hybrid design is one that takes a dual focus a priori in assessing clinical effectiveness and implementation. We propose 3 hybrid types: (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.

Conclusions: The hybrid typology proposed herein must be considered a construct still in evolution. Although traditional clinical effectiveness and implementation trials are likely to remain the most common approach to moving a clinical intervention through from efficacy research to public health impact, judicious use of the proposed hybrid designs could speed the translation of research findings into routine practice.

Key Words: diffusion of innovation, implementation science, clinical trials, pragmatic designs

Much has been written about the nature of health care science-to-service gaps both in general[1–3] and relative specifically to health promotion[4] and numerous medical specialties.[5–9] Thus far, the literature indicates that gaps between research and practice can result from multiple factors, including educational/knowledge deficiencies and/or disagreements,[10,11] time constraints for practitioners,[12,13] lack of decision support tools and feedback mechanisms,[13] poorly aligned incentives,[14] and a host of other organizational climate and cultural factors.[2,15,16]

In addition to these provider-level and systems-level barriers to rapid translation, Glasgow et al[4] and others[17–20] argue that the time lag between research discovery and routine uptake is also inflated by the dominant developmental approach; that is, one that encourages delimited, 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"[18]; for example, through a failure to focus on external validity or implementation-related barriers and facilitators to routine use and sustainability of "effective" practices.[4,21,22]

Wells[19] and Glasgow et al[4] 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 these lines of research independently; for example,

Source: Curran et al., 2012 *Medical Care*

Curran et al. 2012 (p 18)

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.

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?

| DESIGN | CONDUCT | DISSEMINATION |

DISSEMINATION AND IMPLEMENTATION

SECTION 2

Dissemination and Implementation Frameworks

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There are multiple models and conceptual frameworks for the targeted and widespread dissemination and implementation of health care interventions. A major challenge for research

SECTIONS

1 Conceptualizing the Challenge

2 Dissemination and Implementation Frameworks

3 Let It, Help It, Make It Happen

4 Changes to Policy and Guidelines

5 Legislative Changes

6 Creation of Targeted Tools

7 Stepped Wedge Designs

8 Intervention Staffing and Training Flexibility

9 Partnering With Quality Improvement and Population

The NIH Collaboratory's *Living Textbook of Pragmatic Clinical Trials*:
www.rethinkingclinicaltrials.org

How does your healthcare system learn?

Help it happen

Let 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

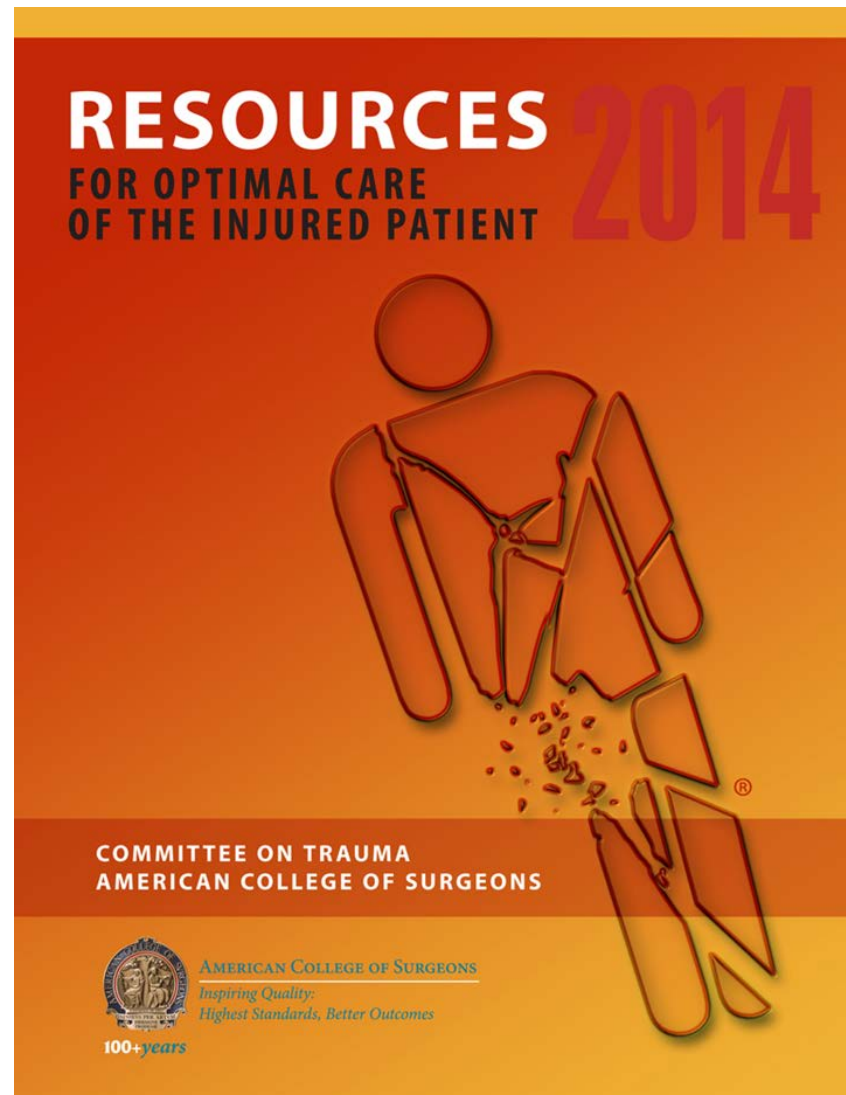|						
Emergence, adaptation	**Knowledge construction, making sense**	**Diffusion**	**Negotiation**	**Knowledge transfer**	**Dissemination, cascading**	**Re-engineering**

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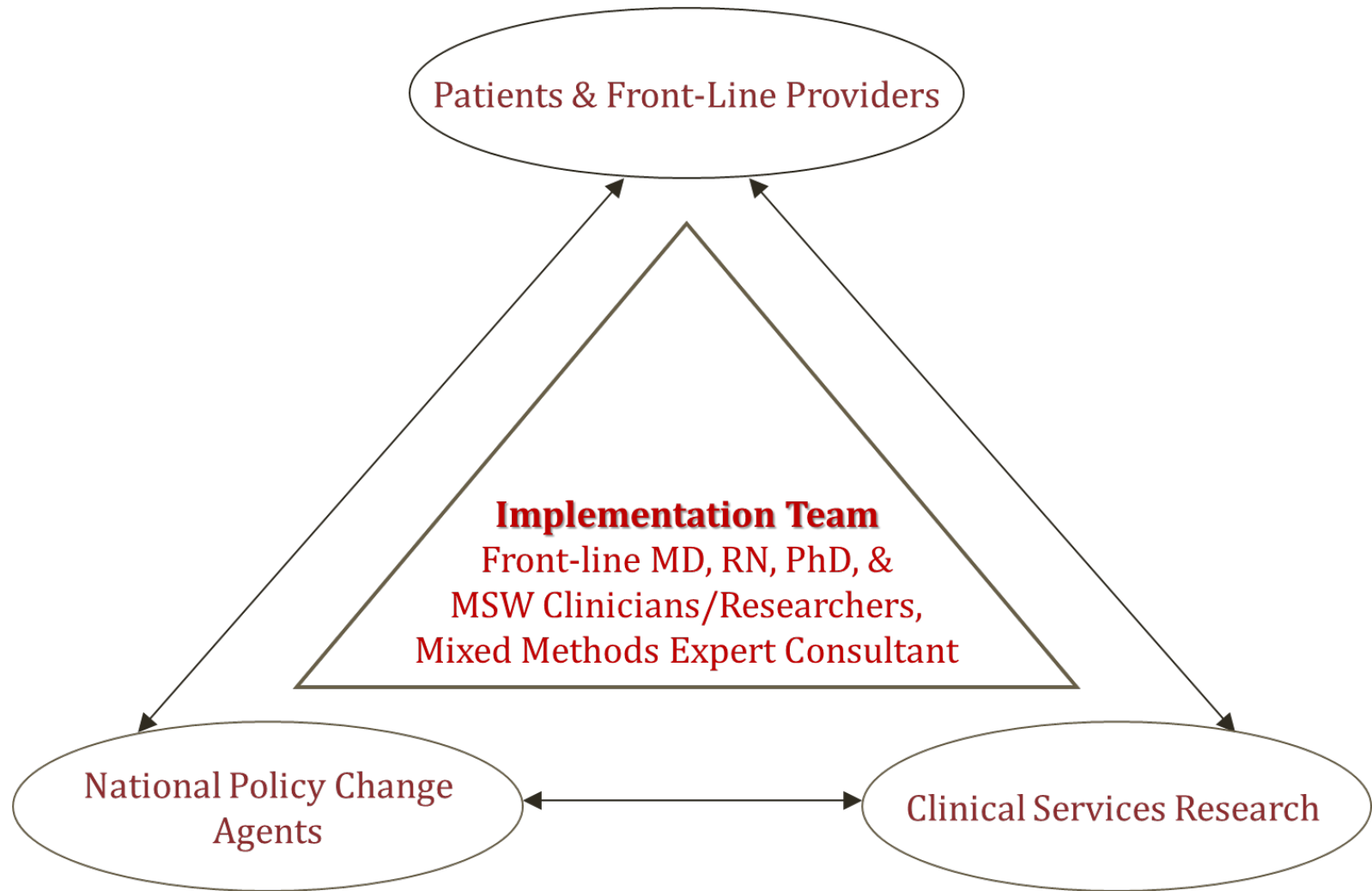
Novel embedded mixed methods: Rapid Assessment Procedure Informed Clinical Ethnography (RAPICE)

- 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

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?

5 min

10 min