Trial Objectives and Design:
An Overview of Hybrid Designs

Devon Check, PhD
Assistant Professor
Department of Population Health Sciences
Duke University School of Medicine

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Learning goals

- Review 3 types of effectiveness-implementation hybrid trial designs and when they may be appropriate for ePCTs

Hybrid trial design

- Trials with a focus on both clinical (i.e., patient) and implementation outcomes

Why hybrid trial designs?

- Let's go faster!
  - Sequential looks at effectiveness and implementation are slower
- Don't wait for perfect effectiveness data before moving to implementation research
- We can backfill effectiveness data while we test/evaluate implementation strategies
- How do clinical outcomes relate to levels of adoption and fidelity?
  - How will we know this without data from both sides?

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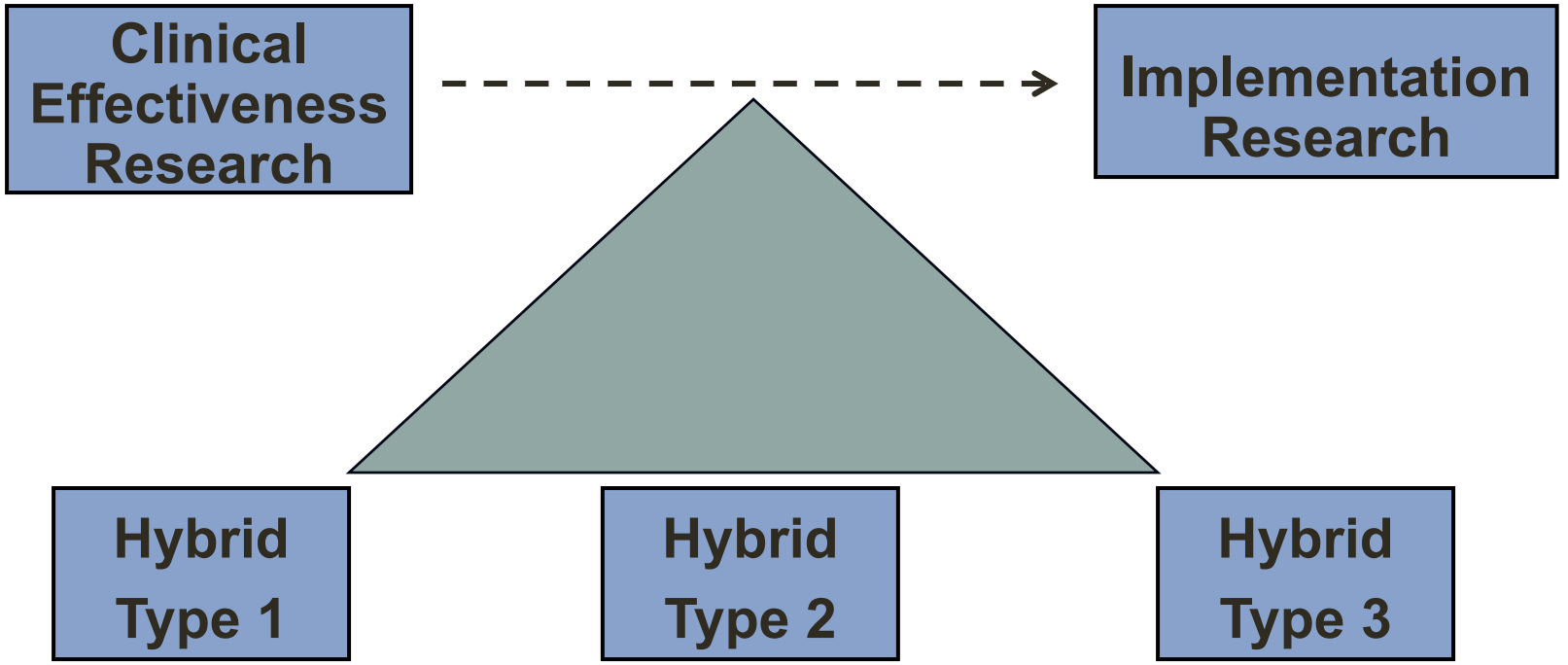
Types of hybrids



Hybrid Type 1: test a clinical intervention, observe/gather information on implementation

Hybrid Type 2: test a clinical intervention, test/study an implementation strategy

Hybrid Type 3: test an implementation strategy, observe/ gather information on intervention's effectiveness

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Type 1

- Clinical Trial PLUS
  - Implementation-focused process evaluation
  - Usually mixed method study of what worked/didn't
  - Revise intervention? Implementation strategies needed?

- Indications
  - Clinical effectiveness data remain limited, so "too early" for intensive focus on implementation, but…
  - Ideal opportunity to explore implementation issues, learn what's needed for future focus on implementation (study or do…)

Type 2

- Clinical trial nested within
  - Implementation trial of competing strategies
  - Pilot (one arm) study of single implementation strategy

- Indications
  - Clinical effectiveness data available, though perhaps not for your population or context of interest
  - Have data on barriers and facilitators to implementation
  - “Implementation momentum” within healthcare system

Type 3

- Implementation trial!
  - Primary test is comparing implementation strategies
  - Clinical effectiveness is a secondary analysis

- Indications
  - We sometimes proceed with roll-outs/implementation studies of interventions without strong effectiveness data
  - Interested in exploring how clinical effectiveness might vary by extent and/or quality of implementation?

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Concluding points 

- 1 This was a VERY brief summary!

- 2 ePCTs would usually be type 1 or 2, depending on
  - How ready you are to test an implementation strategy or strategies on summative implementation outcomes
    - Just want to describe implementation during the trial and prepare for more work later on real-world implementation strategies = 1
    - Ready to test the impact of real-world strategies on implementation outcomes like adoption or fidelity = 2

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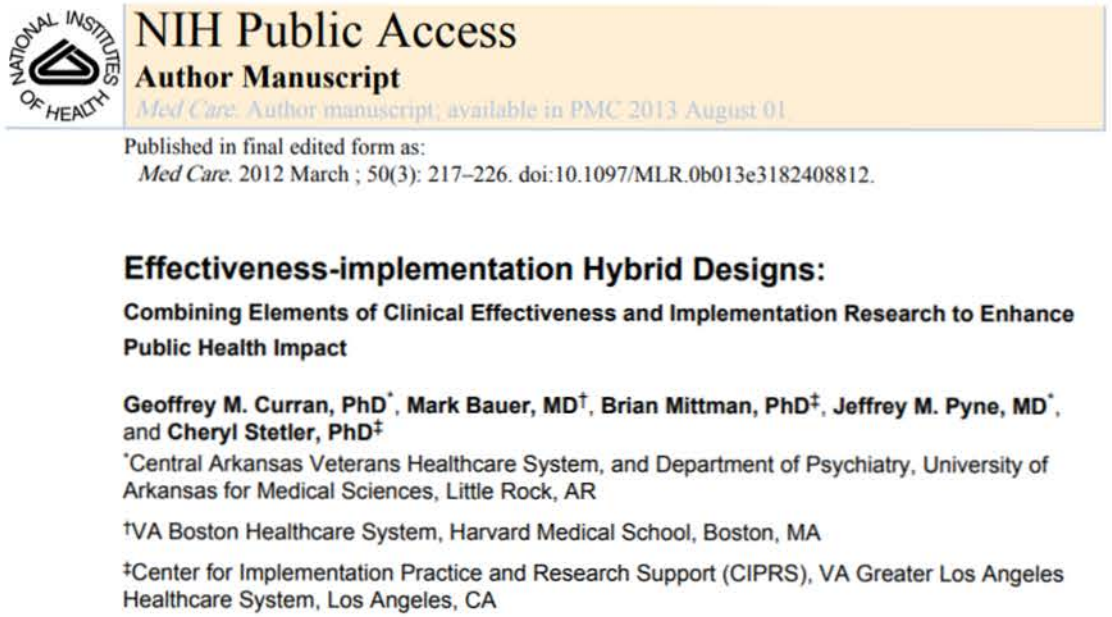
Concluding points

- 3 If you want to learn more…



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Effectiveness-implementation Hybrid Designs:

Combining Elements of Clinical Effectiveness and Implementation Research to Enhance Public Health Impact

Geoffrey M. Curran, PhD[*], **Mark Bauer, MD**[†], **Brian Mittman, PhD**[‡], **Jeffrey M. Pyne, MD**[*], and **Cheryl Stetler, PhD**[‡]

[*]Central Arkansas Veterans Healthcare System, and Department of Psychiatry, University of Arkansas for Medical Sciences, Little Rock, AR

[†]VA Boston Healthcare System, Harvard Medical School, Boston, MA

[‡]Center for Implementation Practice and Research Support (CIPRS), VA Greater Los Angeles Healthcare System, Los Angeles, CA

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An introduction to effectiveness-implementation hybrid designs

Sara J. Landes[a,b,c,*], Sacha A. McBain[b,c], Geoffrey M. Curran[b,c,d]

[a] *The Department of Veterans Affairs Quality Enhancement Research Initiative (QUERI) for Team-Based Behavioral Health, 2200 Fort Roots Drive, North Little Rock, AR 72114, USA*
[b] *South Central Mental Illness Research Education and Clinical Center (MIRECC), Central Arkansas Veterans Healthcare System, 2200 Fort Roots Drive, North Little Rock, AR 72114, USA*
[c] *University of Arkansas for Medical Sciences, Department of Psychiatry, 4301 W. Markham St, Little Rock, AR 72205, USA*
[d] *University of Arkansas for Medical Sciences, Department of Pharmacy Practice, 4301 W. Markham St, Little Rock, AR 72205, USA*

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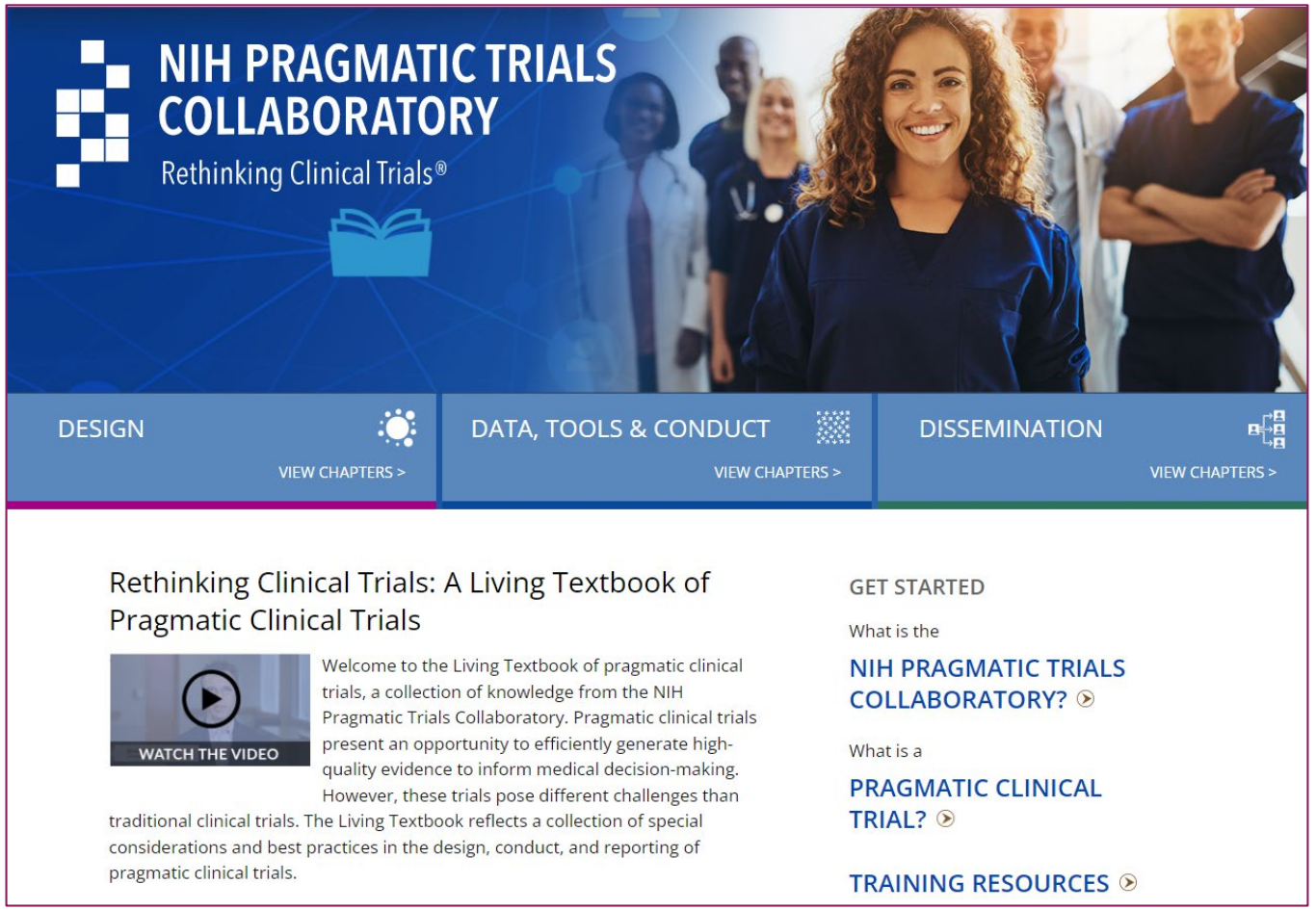

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