Implementing/Delivering Interventions Across HealthCare Organizations and Stability of Control

April 21, 2022

Bethesda, MD

NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Role Call

- Moderator
  - Steven George, PT, PhD (Duke University)
- Panel
  - Corita Grudzen MD, MSHS, FACEP (NYU School of Medicine)
  - Mitch Knisely, PhD, RN (Duke University)
  - Karen Sherman, PhD, MPH (Kaiser Permanente Washington Health Research Institute)
  - James Tulsky, MD (Dana-Farber Cancer Institute)

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Overview

- Very Brief Introduction
- Panel Responses to 5 Questions
- Questions from Audience

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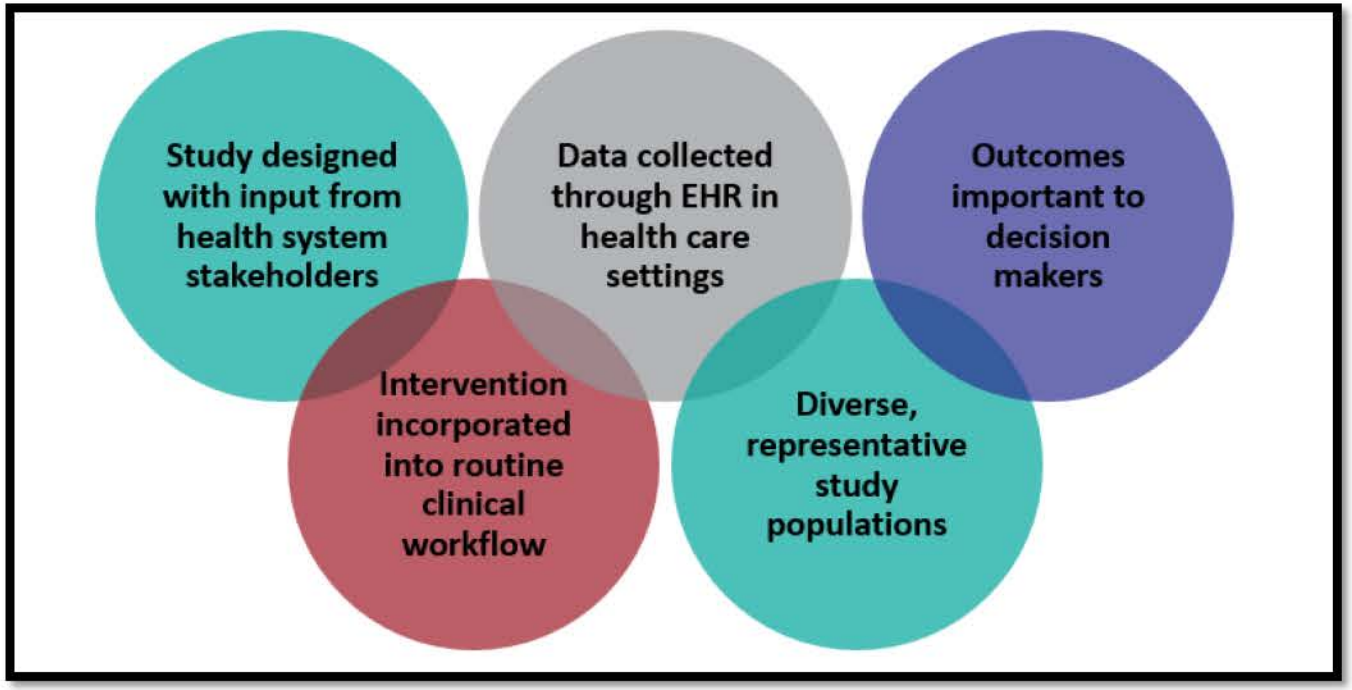
Introduction to the Topic

- Embedded trials attempt to bridge clinical care and research:



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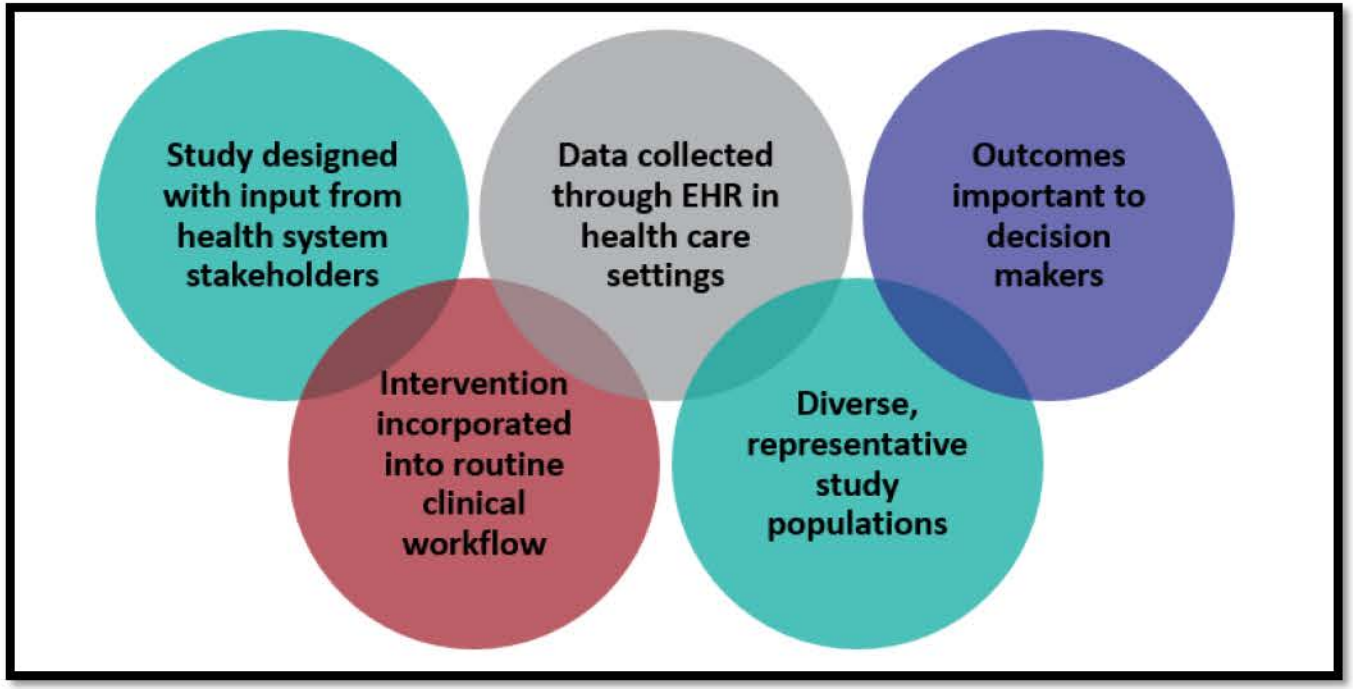

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Level Setting on the Trials

Study Acronym	Panel Rep	Design	Population	Intervention	Primary Outcomes
ACP PEACE	Tulsky	CR, SW	Patients > 65 with advanced cancer	Training for communication (clinicians) and video decision aids (patients)	Advance care planning
BackInAction	Sherman	IR	Adults >/= 65 with chronic LBP	Acupuncture	Functional status Pain intensity

CR = Cluster Randomization
IR = Individual Randomization
SW = Stepped Wedge Design

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Level Setting on the Trials

Study Acronym	Panel Rep	Design	Population	Intervention	Primary Outcomes
GRACE	Knisely	HEI	Patients with sickle cell disease	Guided Relaxation and Acupuncture	Treatment sequencing Pain control
PRIM-ER	Grudzen	CR, SW	Patients >/= 66 in the ED with life limiting illness	Palliative care education, training, and technical support	Hospital admissions

CR = Cluster Randomization
HEI = Hybrid Effectiveness Implementation
IR = Individual Randomization
SW = Stepped Wedge Design

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Introduction

- Each team has faced challenges in getting these interventions implemented for a pragmatic trial

- Panel met before the session to identify questions that would showcase themes of interest

How much should you trust the electronic health record for capture of a) treatment processes and/or b) study endpoints?

Question 1

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How did you successfully obtain “buy in” for delivery of an intervention (or comparator) and what were the key elements of the success?

Question 2

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What is the one very practical, concrete piece of advice you would give to the person on the street that says “I am thinking of conducting a pragmatic trial”?

Question 3

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How does the comparison group work in your pragmatic trial? Did you find any benefits or constraints with this compared to comparison groups you used in other trials?

Question 4

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How do the implementation barriers and challenges we all know and love impact the interpretation of a null pragmatic trial?

Question 5

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