

How Do We Implement Interventions in Complex Health Care Systems?

Panel 4: Critical Questions for Pragmatic Clinical Trialists: Insights From the NIH Pragmatic Trials Collaboratory's First Decade



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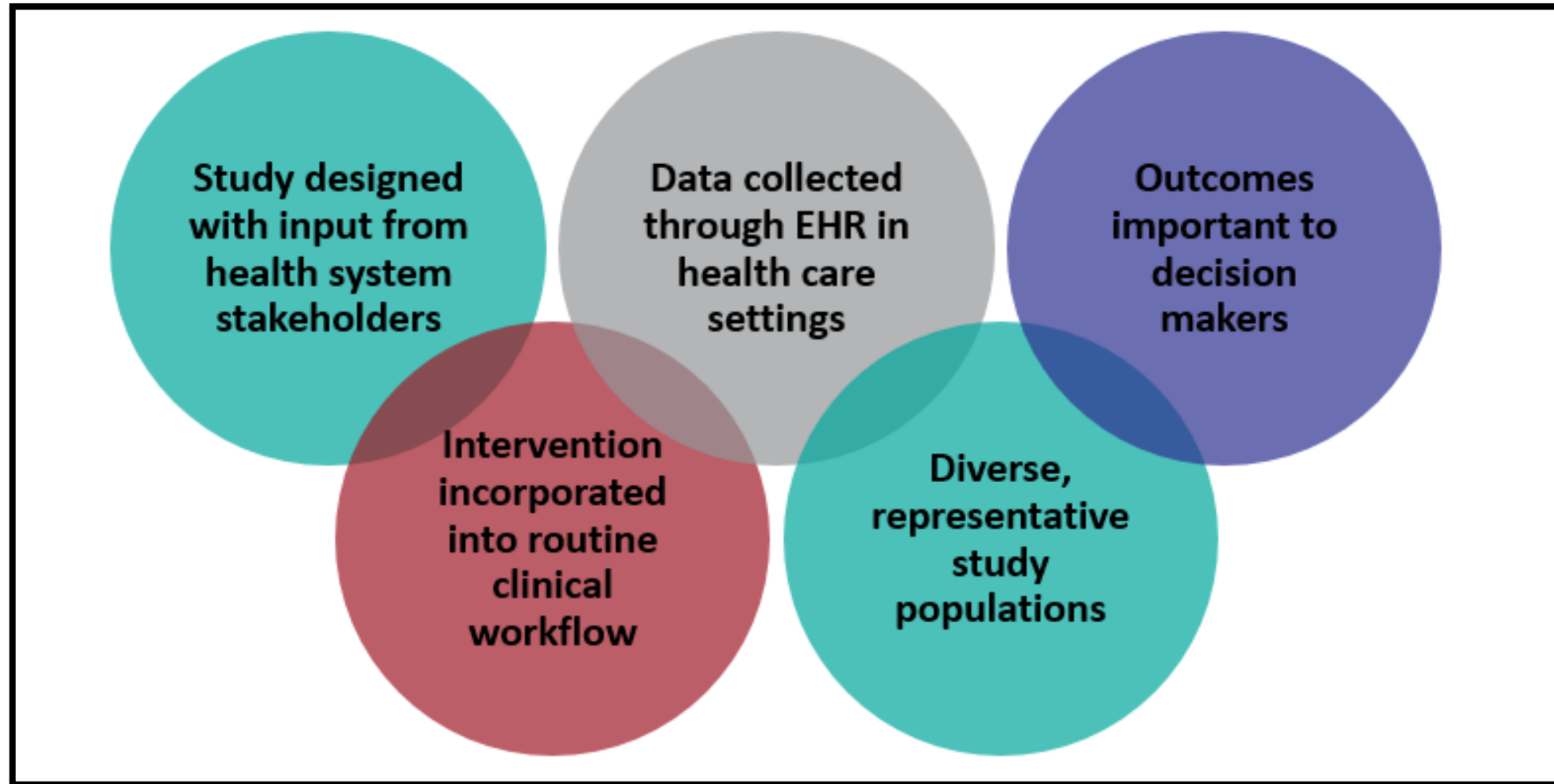
Role Call

- Moderator
 - Steven Z. George, PT, PhD
 - (Duke University)
- Panel
 - Gloria Coronado, PhD
 - (Kaiser Permanente Center for Health Research)
 - Miriam O. Ezenwa, PhD, RN, FAAN
 - (University of Florida)
 - Margaret Kuklinski, PhD
 - (University of Washington)
 - Miguel A. Vazquez, MD
 - (University of Texas Southwestern Medical Center)

Overview

- Brief Introduction
- Panel Discussion Around 5 Key Questions
- Selected Questions from Chat

Embedded trials bridge clinical care and research

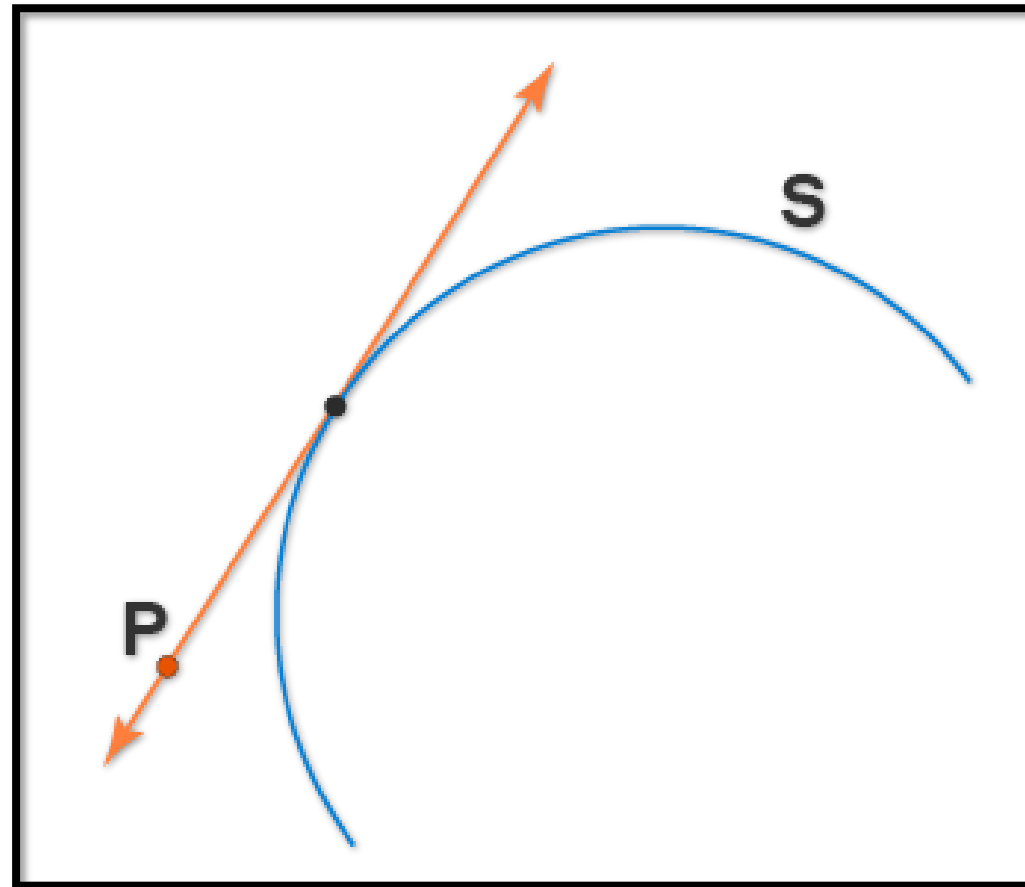


Introduction to the Topic

- Underestimating complexity is a common challenge in embedded PCTs
- This session will examine how trialists have thought during trial planning and conduct about complexity of:
 - Their interventions
 - The systems they will be delivered
- We plan to highlight implementation science strategies that bolstered success

Introduction to the Topic

- But first a very brief tangent



Introduction to the Topic

- One of the reasons complexity may be underestimated is that it is hard to measure
- The NIH Pragmatic Trials Collaboratory is working on a tool to address this issue

Introduction to the Topic

- Key components of complexity from this tool:
 - Disruption to existing workflow or tasks
 - Training burden
 - Number of clinics and health systems
 - How dependent or specific the setting needs to be
 - Intervention components (quality and quantity)
 - Number of steps between intervention and outcome

Introduction to the Topic



Level Setting on the Trials

Study Acronym	Panel Rep	Design	Population	Intervention	Primary Outcomes
GGC4H	Kuklinski	CR	Adolescents in primary care	Guiding Good Choices	Substance Use Initiation with 4 indicators (Alcohol, Cannabis, E-cigarettes, Cigarettes)
GRACE	Ezenwa	HEI	Patients with sickle cell disease	Guided Relaxation and Acupuncture	Pain control

CR = Cluster Randomization

HEI = Hybrid Effectiveness Implementation

IR = Individual Randomization

SW = Stepped Wedge Design

Level Setting on the Trials

Study Acronym	Panel Rep	Design	Population	Intervention	Primary Outcomes
STOP CRC	Coronado	CR	40,000+ patients in 26 federally qualified health center clinics due for colorectal cancer screening	Real-time EHR tools and training to deliver mailed FIT outreach	FIT test completion within 12 months of patient identification

CR = Cluster Randomization

HEI = Hybrid Effectiveness Implementation

IR = Individual Randomization

SW = Stepped Wedge Design

Level Setting on the Trials

Study Acronym	Panel Rep	Design	Population	Intervention	Primary Outcomes
ICD-Pieces	Vazquez	CR	11,000 patients with kidney disease, DM and high BP in 4 health systems	IT tool and nurses/ pharmacists assisting to deliver evidence-based care	1-year hospitalization rate

CR = Cluster Randomization

HEI = Hybrid Effectiveness Implementation

IR = Individual Randomization

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Introduction

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

In planning your trial - how did you think about intervention and health system complexity? How did this change during trial conduct?

Question 1



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How did you incorporate what is known about implementation science strategies in your trial?

Question 2



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Where did you find implementation science expertise for your trial?

Question 3



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What is the value of mapping out workflow before you start a trial?
And how were these maps used during the trial?

Question 4



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How can pragmatic trials be conducted to reduce health disparities?

Question 5



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Summary

- All roads for PCTs run through implementation science
- Pragmatic trials often strike a balance between being adaptive enough to make intervention work for the PCT vs. being true to the core components of the intervention to be delivered
- Is what we did for this PCT actually going to be sustainable after the trial?