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
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

- Study designed with input from health system stakeholders
- Data collected through EHR in health care settings
- Outcomes important to decision makers
- Intervention incorporated into routine clinical workflow
- Diverse, representative study populations
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

<table>
<thead>
<tr>
<th>Study Acronym</th>
<th>Panel Rep</th>
<th>Design</th>
<th>Population</th>
<th>Intervention</th>
<th>Primary Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>GGC4H</td>
<td>Kuklinski</td>
<td>CR</td>
<td>Adolescents in primary care</td>
<td>Guiding Good Choices</td>
<td>Substance Use Initiation with 4 indicators (Alcohol, Cannabis, E-cigarettes, Cigarettes)</td>
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<tr>
<td>GRACE</td>
<td>Ezenwa</td>
<td>HEI</td>
<td>Patients with sickle cell disease</td>
<td>Guided Relaxation and Acupuncture</td>
<td>Pain control</td>
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</tbody>
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CR = Cluster Randomization
HEI = Hybrid Effectiveness Implementation
IR = Individual Randomization
SW = Stepped Wedge Design
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<td>STOP CRC</td>
<td>Coronado</td>
<td>CR</td>
<td>40,000+ patients in 26 federally qualified health center clinics due for colorectal cancer screening</td>
<td>Real-time EHR tools and training to deliver mailed FIT outreach</td>
<td>FIT test completion within 12 months of patient identification</td>
</tr>
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<td>ICD-Pieces</td>
<td>Vazquez</td>
<td>CR</td>
<td>11,000 patients with kidney disease, DM and high BP in 4 health systems</td>
<td>IT tool and nurses/pharmacists assisting to deliver evidence-based care</td>
<td>1-year hospitalization rate</td>
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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
How did you incorporate what is known about implementation science strategies in your trial?

Question 2
Where did you find implementation science expertise for your trial?

Question 3
What is the value of mapping out workflow before you start a trial? And how were these maps used during the trial?

Question 4
How can pragmatic trials be conducted to reduce health disparities?
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?