

Research Methods for Dementia Care and Services

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#DementiaCareSummit

Dementia Methods Pre-Summit, June 7-8, 2017 Steering Committee

PCORI Methodology Committee Co-chairs:

David Meltzer, University of Chicago

Brian Mittman, VA Greater Los Angeles Healthcare System; Kaiser Permanente

Arlene Bierman, Agency for Healthcare Research and Quality (AHRQ)

Chris Callahan, Indiana University-Purdue University Indianapolis

Elena Fazio, National Institute on Aging (NIA)

Laura Gitlin, Johns Hopkins School of Nursing; Johns Hopkins School of
Medicine

Lisa Gwyther, Duke University

Lee Jennings, University of Oklahoma Health Sciences Center

Ian Kremer, LEAD Coalition

Katie Maslow, Gerontological Society of America

Darby Morhardt, Northwestern University

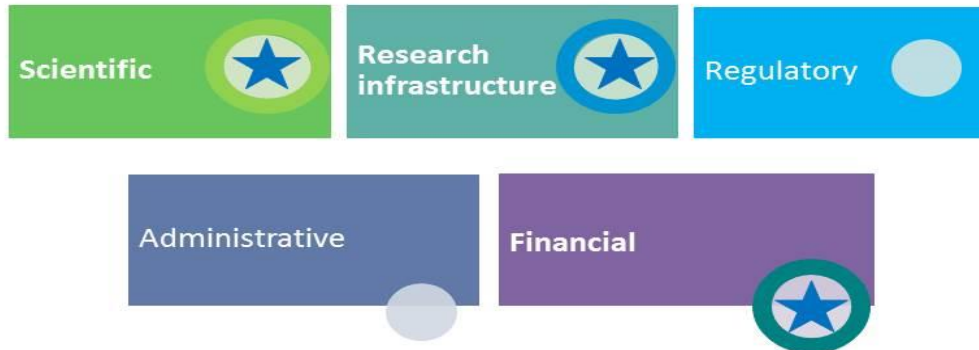
David Niebuhr, AHRQ

Kim Wittenberg, AHRQ

Mary Kay Margolis and Lori Frank, PCORI

1. Dementia Methods Pre-Summit;
2. PCORI Methodology Committee Standards for Studies of Complex Interventions

Pre-Summit: Five areas of recommendations



Methods standards: public release of draft standards expected by October 31

Characteristics of complex interventions

Simple interventions:

- *Single fixed (stable, homogeneous) targeting*
- *A single (relatively) stable process to achieve*
- *A distinct goal within*
- *Stable, (relatively) homogeneous settings*
- *Relative simplicity, homogeneity, stability*

Complex interventions:

- *Multiple varying activities, components deployed at*
- *Multiple levels targeting*
- *Multiple structures and processes to achieve*
- *Multiple (conflicting) goals within*
- *Dynamic, heterogeneous settings*
- *Extreme complexity, heterogeneity, instability*

Challenges in studying complex interventions

Heterogeneity

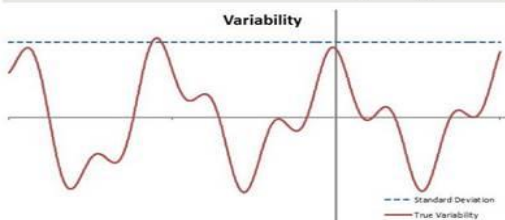
- individuals, families, institutions, systems, communities
- settings, context
- underlying pathologies addressed by intervention
- pathologies' etiology, root causes
- intervention (*program*) design, content



Challenges in studying complex interventions

Instability, variability, adaptability

- intervention targets (individuals, families, institutions, systems, communities)
- settings, context
- intervention (*program*) design, content



Challenges in studying complex interventions

Causal complexity

- multiple components; multi-step causal chains (proximal, distal impacts)
- strength of contextual vs. “intervention” main effects



Policy/practice decision makers' questions



Does it work? Is it “effective”?

- *Should it be approved? Funded? Promoted? Mandated?*
- *Included in the formulary?*
- *Should I use it?*

Policy/practice decision makers' questions

Does it work? Is it "effective"?

- For some drugs, the answer is "Yes, for many/most patients" (but *cf* precision medicine)
- For *robust* complex interventions (e.g., some health promotion programs, healthcare delivery innovations) the answer is "Yes, often enough"
- For *most* complex interventions, the answer is "sometimes"... "it depends"



Support for policy/practice leaders: evidence vs. insights and guidance

- Support for dichotomous approval or selection decisions (FDA and formulary, treatment):
 - *Is it effective? Does it work? Which is more effective?*
- Insights and guidance for practice:
 - *How does it work? Why? Where? When? For Whom?*
 - *How can we enhance its effectiveness?*

Policy/practice decision makers' questions

- How do I choose an appropriate program given my context?
- How do I implement (deploy) the program to increase effectiveness?
- How do I adapt and customize the program to increase effectiveness (initially and over time)?
- How do I modify/manage the organization or setting to increase effectiveness (initially and over time)?
- **How, why, when and where does it work?**
- **How can I make it work?**

Support for policy/practice leaders: evidence vs. insights and guidance

- Support for dichotomous decisions, selection decisions (FDA and formulary, treatment):
 - *Is it effective? Does it work? Which is more effective?*
- Insights and guidance for practice:
 - *How does it work? Why? Where? When? For Whom?*
 - *How can we enhance its effectiveness?*
- **Impact focus vs. process focus (mediators, moderators, mechanisms, adaptation, managing context)**

Studying complex interventions: *mediators, moderators, mechanisms*

- Mediation analysis, structural equation modeling, other approaches to study mediators, moderators, mechanisms
- Qualitative comparative analysis (QCA)
- Process evaluation
- Theory-based evaluation, realistic/realist evaluation
- Approaches to adaptation

Other research approaches

- Observational, quasi-experimental designs (time series, stepped-wedge design)
- Statistical process control
- Simulation modeling, systems dynamics models
- Complexity theory, complex systems