Study Designs in Implementation research

Keng-Yen Huang, PhD, MPH
Donna Shelley, MD, MPH
Department of Population Health
NYU Langone Medical Center

Overview

• Spectrum of Implementation study designs
• “Hybrid Designs” for Effectiveness-Implementation Studies
• Examples (Hybrid I, II, III)
Pragmatic Perspective in Imp Research

- **Explanatory/Efficacy** trials or efficacy trials: concerned with evaluation of intervention under optimal conditions that maximize treatment fidelity and adherence.
- **Pragmatic/Effectiveness** research: concerned with answering real-world questions of relevance to practitioners, policymakers, administrators, and citizens.

Types of Implementation Designs

- **Experimental/Quasi experimental**
  - RCTs/Cluster RCTs
  - Controlled Clinical Trials (CCTs): quasi-random allocation method
  - Quasi-Experimental Designs
    - Controlled before and after studies (CBAs)
    - Interrupted time series (ITS)
- **Dynamic wait-listed design/ Stepped-wedge design**
- **Adaptive design (SMART)**
- **Mixed-Methods Designs**
How to decide when to use mixed methods?

- When seeking answers to same question - corroborate one set of data with another
- Seeking answers to related questions - complementarity
- When findings based on one methods raises questions that can be answered by use of the other method - expansion
- When findings based on one method are prerequisite to use of the other method (development)

Systems science designs

- System dynamics
  - Models and computer simulations used to understand endogenous sources of complex system behavior
- Network analysis
  - The study of relationships and flows among social actors, including people and organizations
- Agent-based modeling
  - Use of computer simulations to examine how elements of a system behave as a function of their interactions with each other and their environment
Choice of designs can be determined by the focus phases of implementation research.

Selection of Implementation Designs

Dissemination and Implementation Studies
Moving to Scale
Sustainability
Adoption

Effectiveness Studies
Efficacy Studies
Preintervention

National Research Council and Institute of Medicine (2009)

Utilizing Effectiveness-Implementation “Hybrid Designs”

- Hybrid designs take a dual focus a priori in assessing intervention effectiveness and implementation.
- Advantages: speed translation and more useful information for researchers and decision makers
- Three types:
  1) testing effects of intervention while observing and gathering information on implementation;
  2) dual testing of intervention and implementation strategies; and
  3) testing an implementation strategy while observing and gathering information on the intervention’s impact on relevant outcomes

Choosing a Hybrid Design: What is the research question?

Proctor et al., *Adm Policy Ment Health*, 2009, 36:24-34
“Hybrid Designs” for Varying Imp Qs

I. (P) Will the Int work in this setting/these patients? (S) What are potential barriers/facilitators to widespread Int implementation?

II. (P) Will the Int work in this setting/these patients? (S) Does the implementation method show promise?

III. (P) Which method works better for implementing Int? (S) Is the Imp strategy effective in this setting/these patients?

Hybrid I Example

- **Transporting an EBI (ParentCorps) to Uganda**
- **Conditions**: Need assessments demonstrate strong face validity and evidence for the EBI that would support applicability to the new/Uganda setting, population, and delivery method; and there is minimal risk associated with the EBI
- **Imp Research Aim**: (P) Will ParentCorps work in Uganda school setting and populations (teachers, children, parents). (S) What are potential barriers/facilitators to widespread ParentCorps Implementation
- **Study Design**: A Hybrid Type I + Cluster RCT wait-listed + Mixed Methods design (Primary Quantitative & Secondary Qualitative);
• Including both impact & effectiveness outcomes
• CFIR: Study multi-level factors that may influence quality and outcome of implementation
• Including Implementation Process testing (mediation & moderation)

**Type III: HealthyHearts NYC: Study Design**

- **Implementation Research Aim:** Does practice facilitation (PF) (the implementation strategy) increase implementation of cardiovascular disease prevention and treatment guidelines (the evidence based intervention)?
- **Study design:** Mixed methods, Stepped wedge cluster RCT (all 290 sites receive 12 month PF intervention)
- **Primary outcome:** ABCS process and outcome measures (obtained from EHR)
Conceptual model and implementation outcomes

Quality data collection:
1) Interviews with practices and site visits to assess inner/outer setting factors that influence implementation and sustainability
2) Observing PF meetings and site visits

Methodology and Related Web References

- Dissemination & Implementation Models in Health Research and Practice [http://www.dissemination-implementation.org/](http://www.dissemination-implementation.org/) [http://www.dissemination-implementation.org/content/resources.aspx](http://www.dissemination-implementation.org/content/resources.aspx)
- Health Services Research & Development [http://www.hsrdrresearch.va.gov/research_topics/implementation_science.cfm#cs](http://www.hsrdrresearch.va.gov/research_topics/implementation_science.cfm#cs)
- National Collaborating Centre for Methods and Tools [http://www.nccmt.ca/resources/registry](http://www.nccmt.ca/resources/registry)
- NIH Implementation Science Archived Webinars [https://cyberseminar.cancercontrolplanet.org/implementationscience/](https://cyberseminar.cancercontrolplanet.org/implementationscience/)
Qs & As