Study Designs in Implementation research

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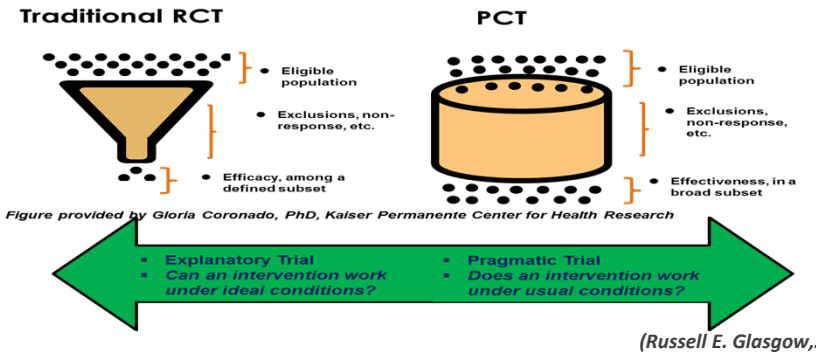
Overview

- 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



(Russell E. Glasgow,2013)

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)**

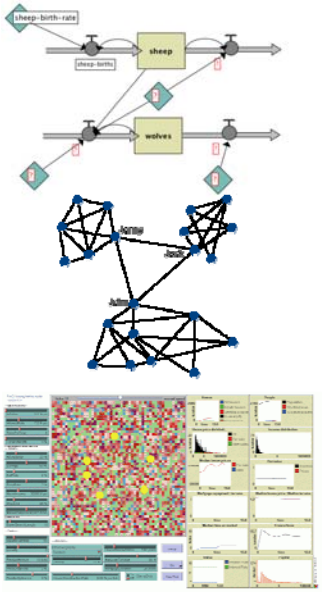
❖ **Mixed-Methods Designs**

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)

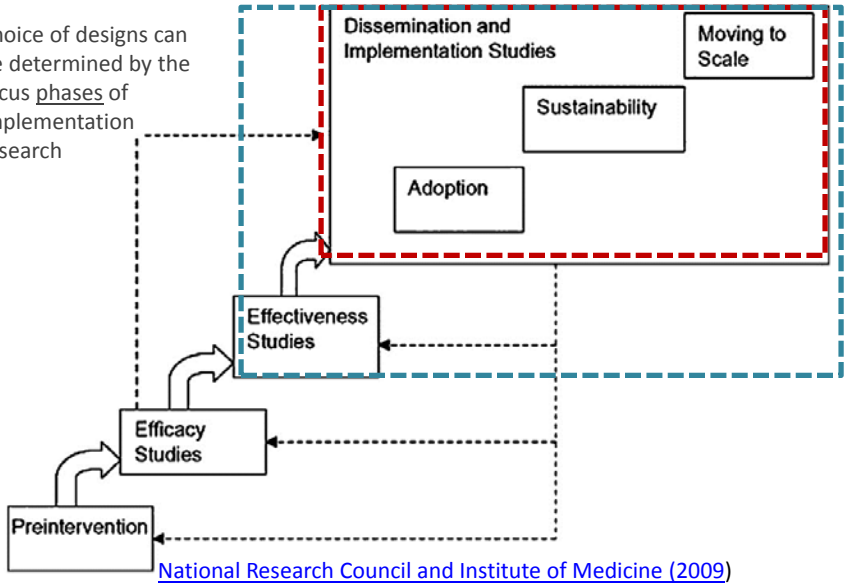
Systems science designs

- 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



Selection of Implementation Designs

Choice of designs can be determined by the focus phases of implementation research



National Research Council and Institute of Medicine (2009)

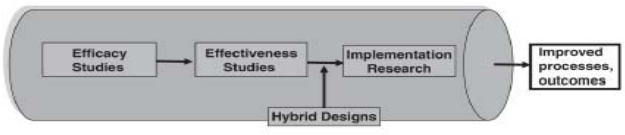
Utilizing Effectiveness-Implementation "Hybrid Designs"

- 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:

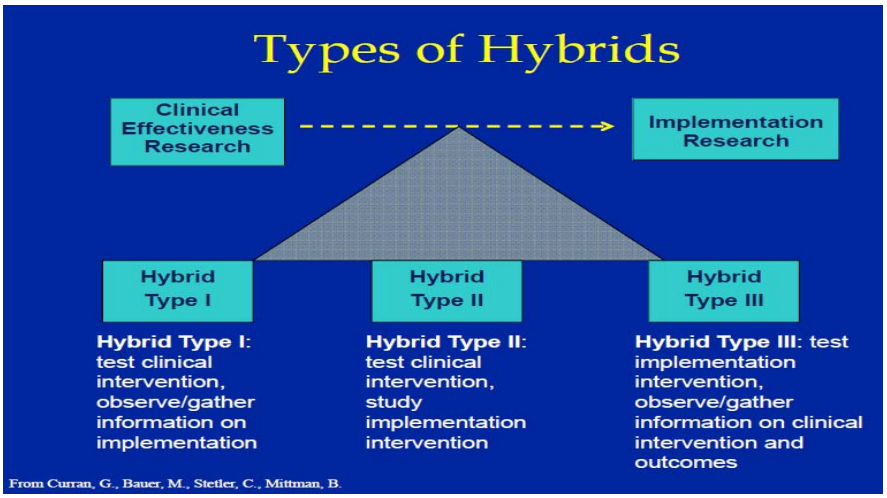
  1) testing effects of intervention while observing and gathering information on implementation;

  2) dual testing of intervention and implementation strategies; and

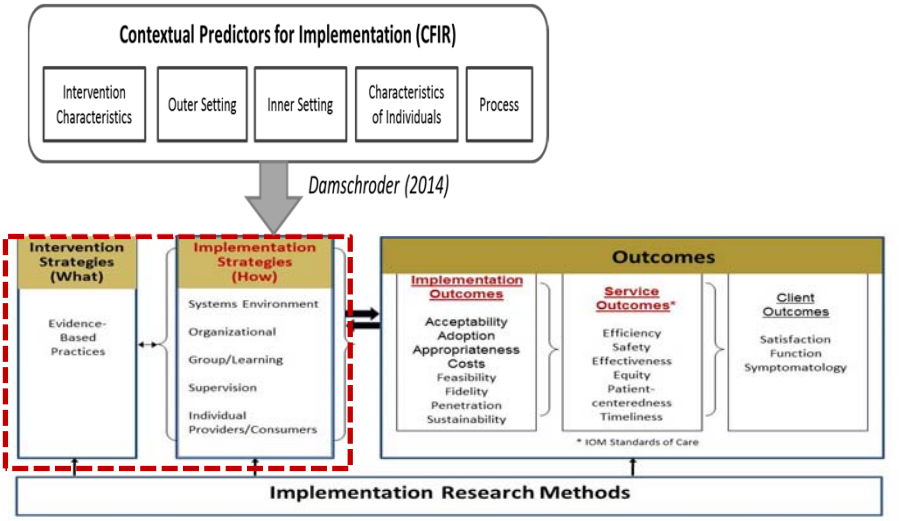
  3) testing an implementation strategy while observing and gathering information on the intervention's impact on relevant outcomes



Curran GM, Bauer M, Mittman B, Pyne JM, Stetler C et al. Medical Care 2012; 50: 217-226.

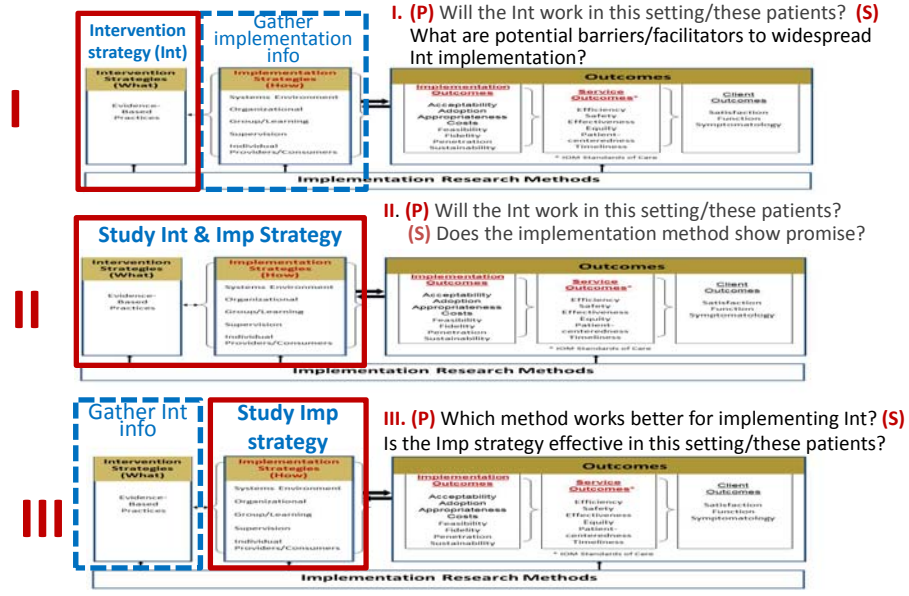


Choosing a Hybrid Design: What is the research question?



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?

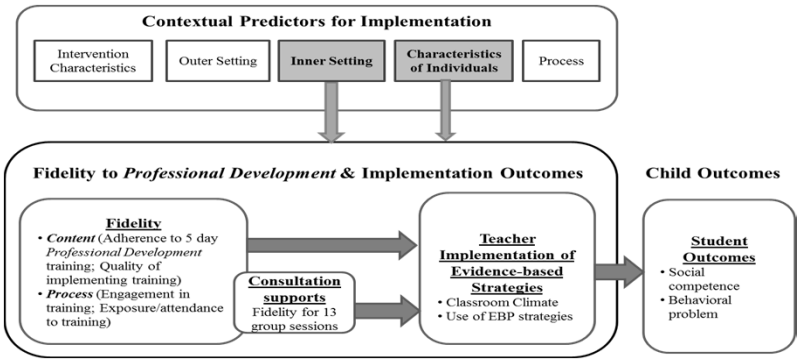
II. (P) Will the Int work in this setting/these patients? **(S)** Does the implementation method show promise?

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);

EBI Implementation Conceptual Model



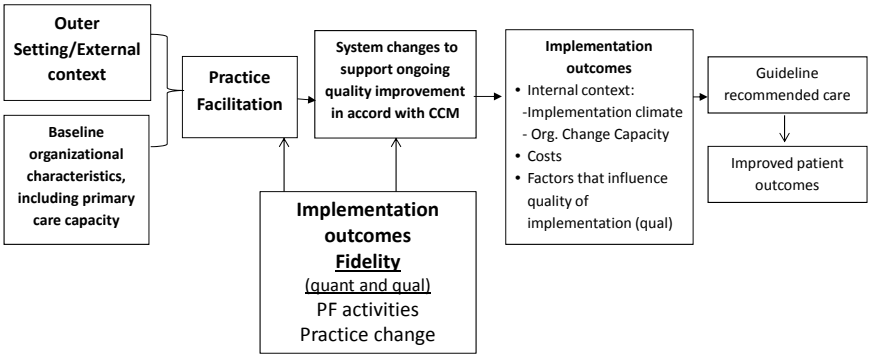
- Including both imp & effectiveness outcomes
- CFIR: Study multi-level factors that may influence quality and outcome of implementation
- Including Implementation Process testing (mediation & moderation)

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)

	YEAR 1				YEAR 2				YEAR 3			
Clusters	3	6	9	12	15	18	21	24	27	30	33	36
	Time period											
1 (80 sites)		C	X	X	X	X	F	F				
2 (80 sites)		C	C	X	X	X	X	F	F			
3 (80 sites)		C	C	C	X	X	X	X	F	F		
4 (60 sites)		C	C	C	C	X	X	X	X	F	F	

Conceptual model and implementation outcomes



Qualitative 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

- Curran G, Bauer MS, Stetler CB, Mittman BS. **Effectiveness-implementation hybrid designs**: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical Care* 2012;50: 217–226. (PMID: 22310560)
- **Dissemination &Implementation Models in Health Research and Practice** http://www.dissemination-implementation.org/ http://www.dissemination-implementation.org/content/resources.aspx
- **QUERI-Quality Enhancement Research Initiative** http://www.queri.research.va.gov/implementation/
- **Health Services Research & Development** http://www.hsrd.research.va.gov/research_topics/implementation_science.cfm#cs
- **National Collaborating Centre for Methods and Tools** http://www.nccmt.ca/resources/registry
- **NIH Implementation Science Archived Webinars** https://cyberseminar.cancercontrolplanet.org/implementationscience/
- **The National Implementation Research Networks' Active Implementation Hub** http://implementation.fpg.unc.edu/modules-and-lessons

Qs & As