



Implementation Science Study Designs Overview



Implementation Science Study Designs

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Background Information

- Most study designs used in implementation science were developed decades ago in other disciplines and are being applied to implementation science
- A few (e.g., effectiveness-implementation hybrid designs) are unique to implementation research
- Addressing equity has typically been an implicit objective in implementation science
- Promoting health equity is a foundational driving force in implementation science that shapes sustained impact, and warrants initial and ongoing adaptation
- Explicit consideration of equity is needed in implementation science study designs
 - Broadening the scope of phase 2 studies
 - Testing disparity-reducing implementation strategies in phase 3 studies

Equitable Implementation

Occurs when strong equity components (including explicit attention to the culture, history, values, and needs of the community) are integrated into the principles and tools of implementation science to facilitate quality implementation of effective programs for a specific community or group of communities.

(NIRN)



Reframing Implementation Science to Address Inequities in Healthcare Delivery (beyond representative inclusion)

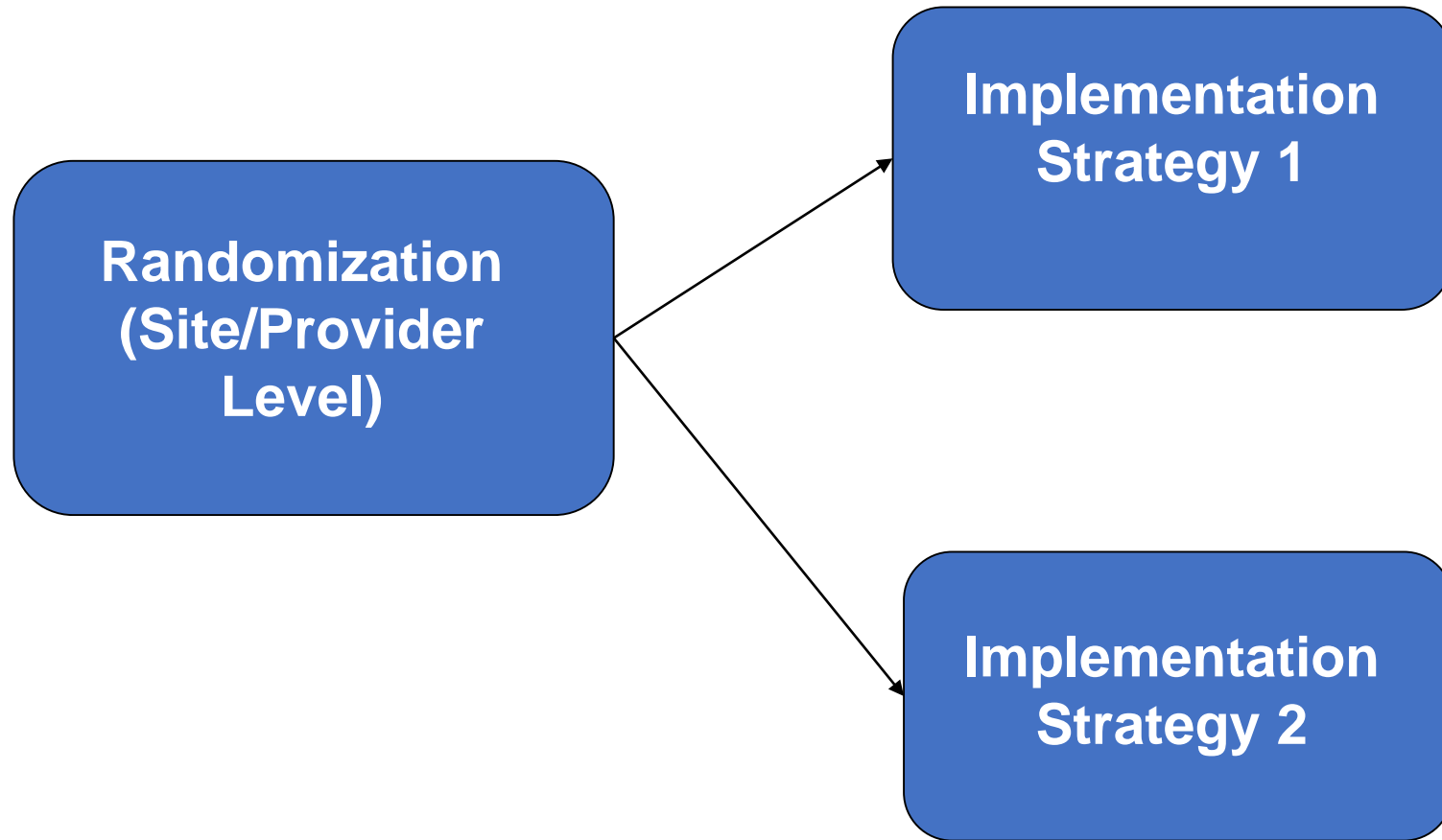
(Bauman and Cabassa 2020)

- 1) Focus on reach from the very beginning
- 2) Design and select interventions with implementation in mind
- 3) Implement what works
- 4) Develop the science of adaptations
- 5) Use an equity lens for implementation outcomes

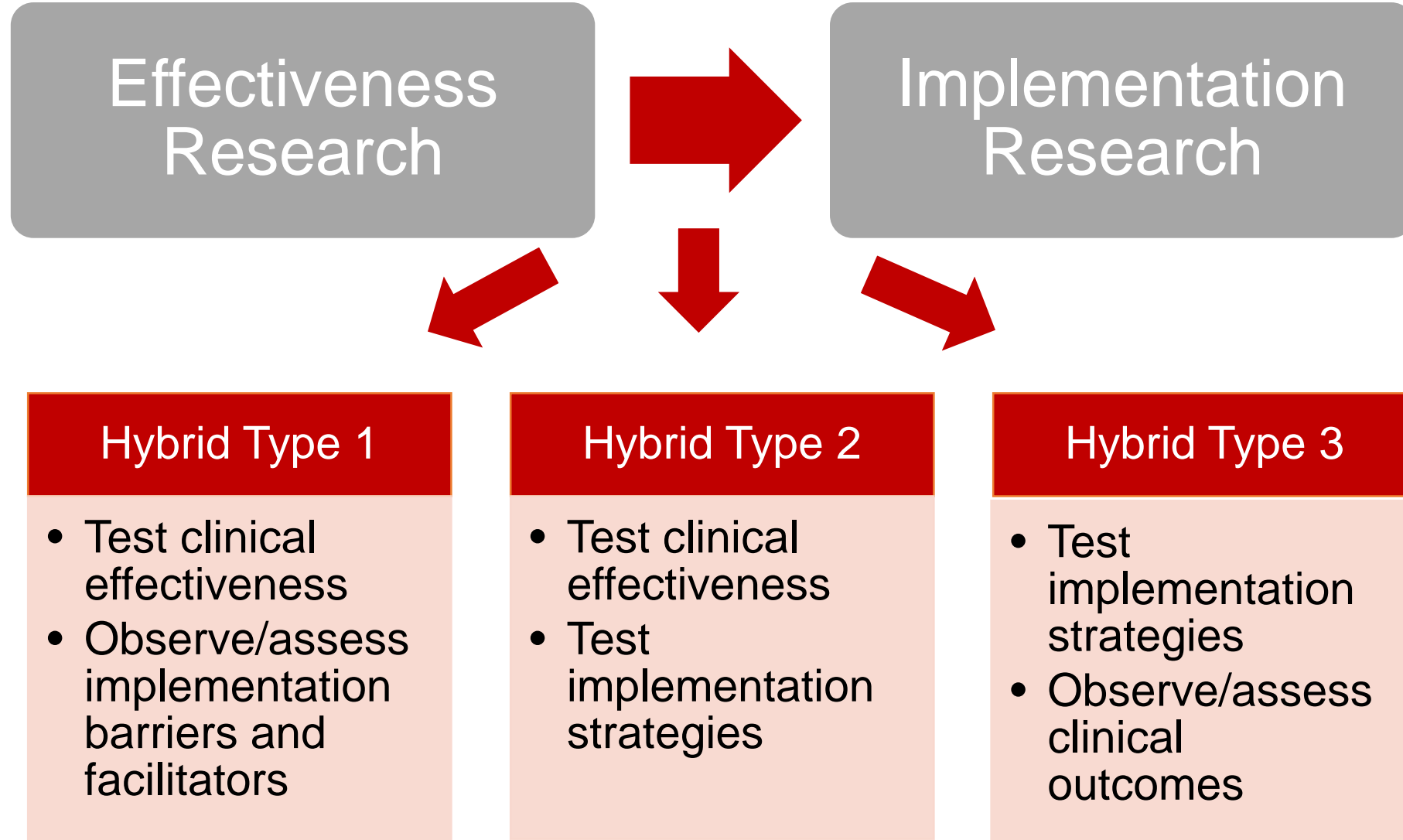
How do conventional implementation research designs potentially conflict with (or complement) the principles and goals of achieving health equity?

- Experimental designs (e.g., randomized controlled trials)
- Quasi-experimental designs (e.g., interrupted time series)
- Observational (e.g., cross-sectional surveys)
- Qualitative (e.g., semi-structured interviews)
- Mixed methods (e.g., explanatory)
- Hybrid effectiveness-implementation designs (Type 1, 2, 3)
- Adaptive/ SMART trials

Example: Parallel Group RCT Design



Example: Hybrid Effectiveness-Implementation Trials



Examples of Health Equity Research Design Challenges

- Are “usual care” comparisons or usual implementation strategies acceptable?
- How do quasi-experimental/observational designs incorporate potential mechanisms contributing to health inequities and social determinants of health?
- Type 2 and Type 3 Hybrid Designs: What minimal level of evidence is adequate for the intervention or the implementation strategy ? How much uncertainty?
- Adaptation: How do research designs incorporate cultural adaptations of strategies or interventions *during the study*?
- Outcomes: Achieving equity is a long-term, multiply determined goal: What proximal indicators might be valid indicators?
- Vulnerable populations: disproportionately affected by large-scale social, public health, and economic events - conflict with fixed IS research designs?

Defining the Scope

- Increasing interest in health equity within implementation science to ensure the equitable implementation of evidence-based programs/ interventions across a range of diverse populations and settings.
- Health equity researchers can apply implementation science study designs to promote more widespread dissemination and implementation, and sustainment of evidence-based interventions to address health inequities.
- The group will:
 - Consider key study designs used in implementation science
 - Identify examples of potential models for promoting health equity in IS study designs
 - Guidance for incorporating implementation science designs into disparities research

Overarching Discussion Questions

How should **Implementation Research Study Designs** be reconsidered and specifically adapted to meet the challenges of advancing equity-focused implementation research?

What is the most important thing that the Consortium should do in study designs?

Goal for today ! ~ 70 mins

- Part 1: Idea generation ~25 mins
 - Mentimeter link (next slide)
- Part 2: Moving ideas forward ~ 45 mins
 - Refining idea and leading



ISCC

Implementation Science Study Designs Recap



ISCC

Implementation Science Study Designs

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Brief Overview: IS Study Designs Group

- Many study designs used in IS were developed decades ago in other disciplines and are being applied to IS
- A few (e.g., effectiveness-implementation hybrid designs) are unique to IS
- Addressing equity has typically been an implicit objective in IS
- Explicit consideration of equity is needed in IS study designs
- Reframing IS to address inequities in healthcare (Baumann & Cabassa, 2020)
 - Focus on reach from the very beginning
 - Design and select interventions with implementation in mind
 - Implement what works; develop imp. strategies that help reduce inequities
 - Develop the science of adaptations
 - Use an equity lens for implementation outcomes
- Examples of conventional implementation research designs that potentially conflict with the principles and goals of achieving health equity
- **Our Question:** How should Implementation Research Study Designs be reconsidered and specifically adapted to meet the challenges of advancing equity-focused implementation research?

Major Ideas from Day One Discussion

- Stakeholder Engagement: What study designs engage stakeholders in identifying/tailoring strategies/interventions while maintaining rigor?
 - Designs that engage stakeholders and communities across the IS spectrum
 - Acceptable methods for co-designing implementation strategies and choices
- Adaptation: How do research designs incorporate adaptations of strategies or interventions *during* the study?
 - Need for methods for rapid adaptations; rapid cycle research
 - Flexibility to meet target population needs while balancing scientific rigor
 - Adaptation and flexibility in agile research designs
 - COVID as a case study in addressing inequities, adaptability, and flexibility
- Methods/measures to study equity-based implementation and proximal indicators
- Methods/measures to study equitable sustainability and proximal indicators
- Role of team science in developing and applying equity-based IS designs
- Ideas for public goods:
 - Developing guidelines/best practices for optimal designs that advance health equity
 - Literature review(s), systematic/scoping
 - White paper, modeled after “Qual Methods in IS”

Additional Ideas to Explore in Day Two

- Are "usual care" comparisons or usual imp. strategies acceptable?
- How do quasi-experimental/observational designs incorporate potential mechanisms contribute to health inequities and SDH?
- Types 2 and 3 hybrids: what minimal level of evidence is adequate?
- Vulnerable populations are disproportionately affected by large-scale social, public health, and economic events. Conflict with fixed IS designs?
- Identifying potential public goods to help guide the field (and the review process)
- Collaboration with other groups
 - Context and Equity in IS
 - Community Participation in IS
 - Implementation of Complex/Multilevel Interventions
 - Learning Healthcare Systems
 - IS in Global Health