Designs for Dissemination and Implementation Research for Small Populations

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Outline

Implementation and dissemination science overview

Intervention study designs for implementation research, e.g.,

- Hybrid designs
- Stepped-wedge
- Sequential Multiple Assignment Trial (SMART) designs

Setting the Stage

- ***Dissemination research*** is the scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to understand how best to spread and sustain knowledge and the associated evidence-based health interventions.

- ***Implementation research*** is the scientific study of the use of strategies to promote the uptake of evidence-based health interventions in clinical and community settings in order to improve patient/population outcomes.

From: NIH PAR 16-238: Dissemination and Implementation Research in Health (R01)

Designs for Implementation & Dissemination Intervention Research

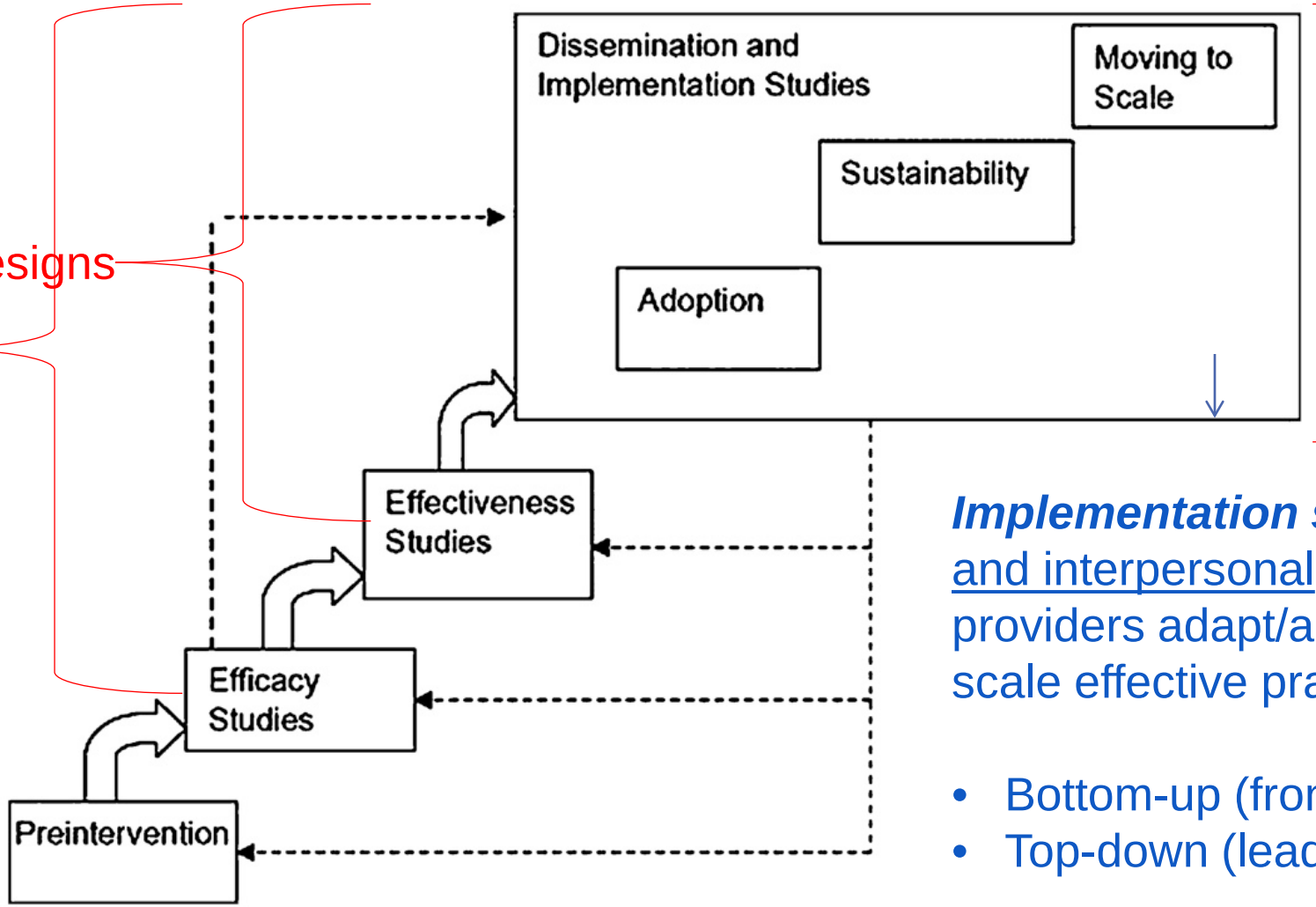
- Randomized controlled trial (RCT)
- Pragmatic clinical trials (PCT)

- Interrupted time series (ITS)
- Dynamic wait list design (DWLD)

- Regression point displacement design (RPDD)
- Stepped-wedge designs

- Hybrid Effectiveness/Implementation Designs
- Sequential Multiple Assignment Randomized Trial/adaptive designs

Study Designs for Implementation Strategies



Hybrid Designs

SMART & Adaptive Designs

Stepped-wedge

Implementation strategies: technical and interpersonal methods that help providers adapt/adopt, sustain, and scale effective practices into routine care

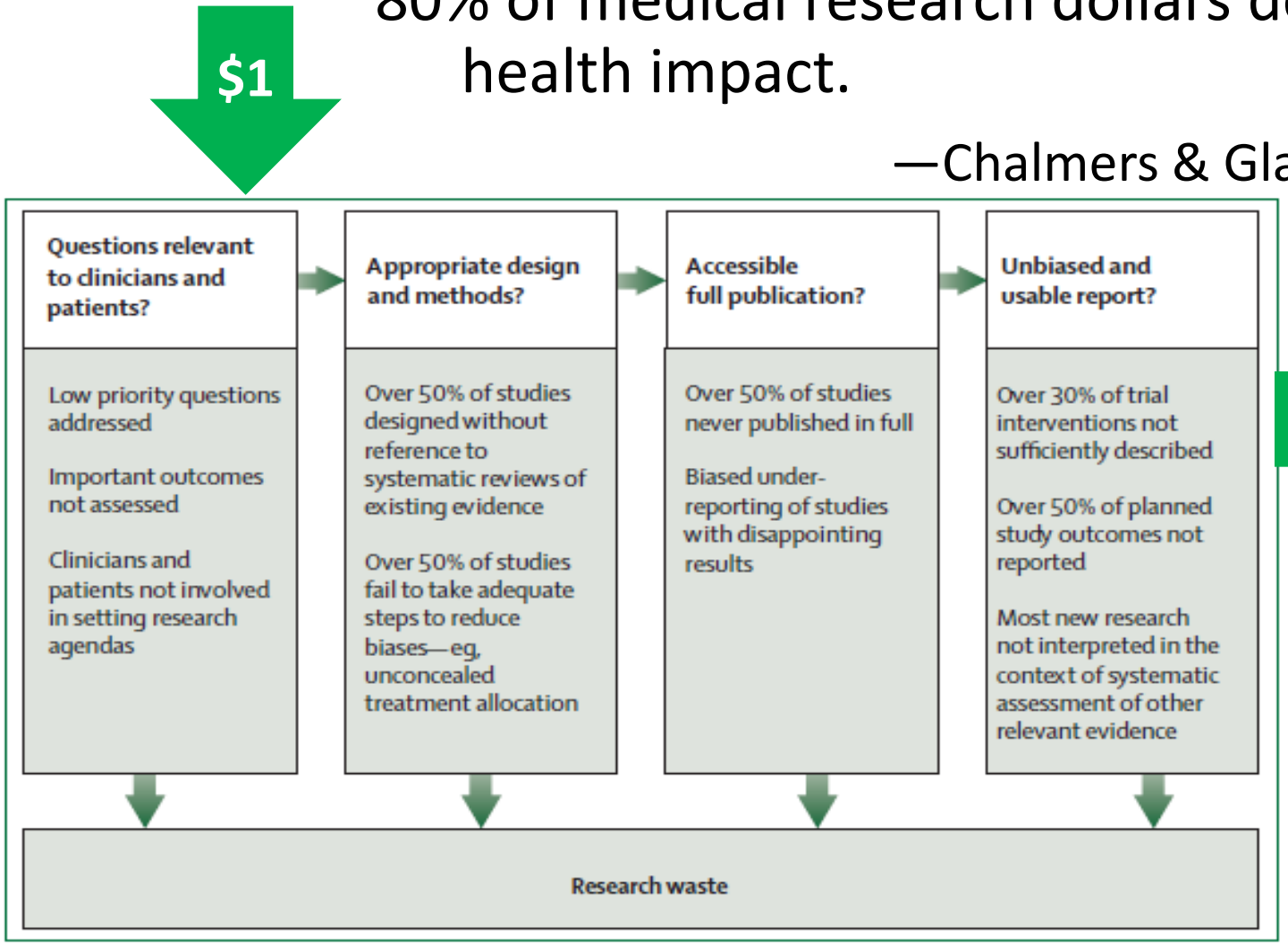
- Bottom-up (frontline engagement)
- Top-down (leadership engagement)

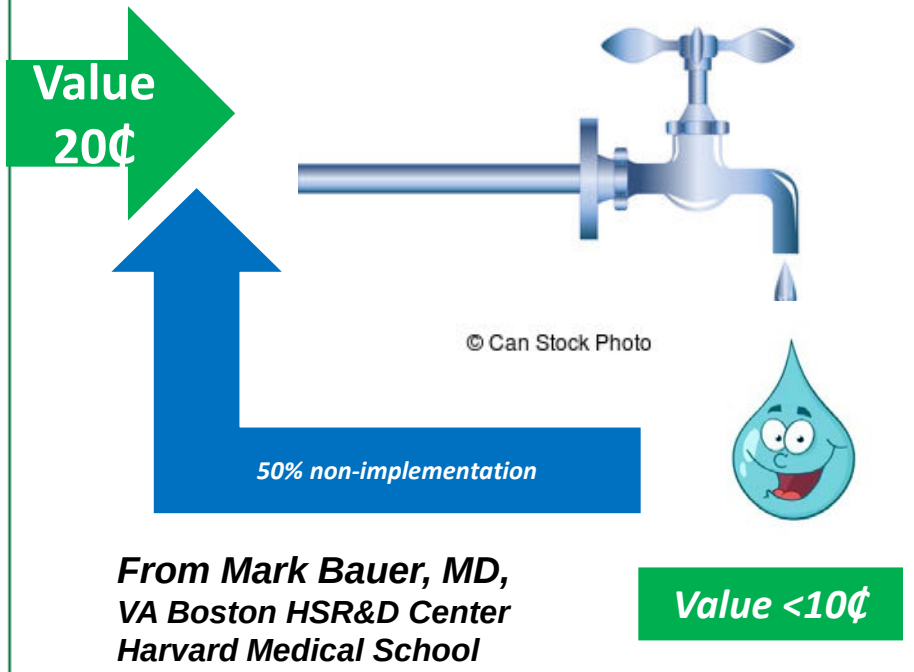
Why Research on Implementation Strategies?

Effective Practices are Not Routinely Implemented for Small Populations

80% of medical research dollars do not result in public health impact.

—Chalmers & Glasziou, *Lancet* 2009





From Mark Bauer, MD,
VA Boston HSR&D Center
Harvard Medical School

Value <10¢

Implementation Science Addresses the Research-to-Practice Gap

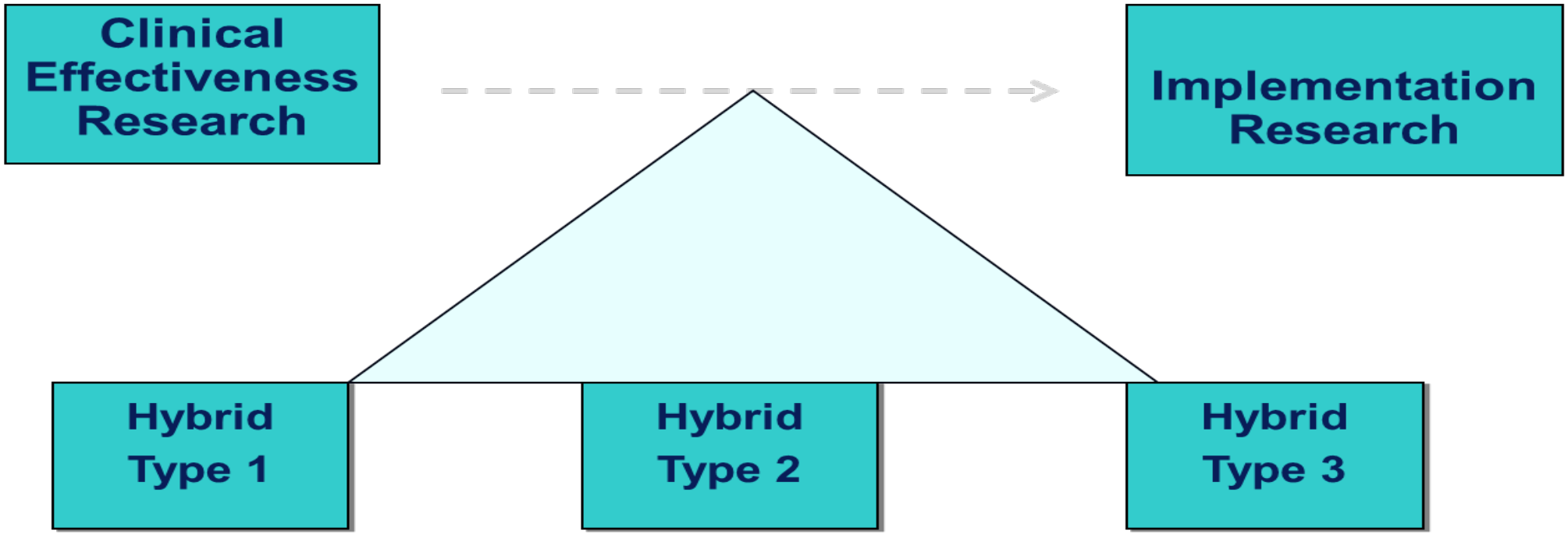
Challenge	Implementation Strategies to Consider	Design Barrier
Interventions not designed for small populations	Tools to adapt to local settings/populations	Sufficient numbers of sites
Interventions rolled out with limited planning	Provider training, facilitation, community engagement	Policy imperative, urgency to “do something”
Intervention reach hard to sustain	Policy incentives, organizational change	Data access/reliability

Hybrid Effectiveness/ Implementation Designs

- Compare implementation strategies
- Address limits of step-wise research (speed research → practice)
- Promote external validity
- Blend effectiveness, implementation stages

Curran, et. al. Effectiveness-Implementation Hybrid Designs. Med Care 2012

Types of Hybrid Designs



Hybrid Type 1: test clinical intervention, observe/gather information on implementation

Hybrid Type 2: test clinical intervention, test implementation strategy

Hybrid Type 3: test implementation strategy, observe/gather information on clinical intervention outcomes

Hybrid Effectiveness/Implementation Designs

	Type I	Type II	Type III
Design Characteristic	Test clinical intervention	Test clinical & implementation strategies	Test implementation strategy
Question	Is treatment effective versus usual care (UC)?	Is treatment delivered through tailored provider coaching effective vs UC?	Does provider coaching vs. training alone improve treatment uptake?
Unit of analyses	Patient	Providers/clinics	Providers/clinics
Primary outcomes	Health outcomes	Process measures	Provider Uptake, Sustainability
Key Advantage	“Cleanest” in determining intervention effectiveness	Ideal when there is time-sensitive need to roll out intervention	All participants get intervention, focus on what will it take to sustain

Hybrid Type I Example:

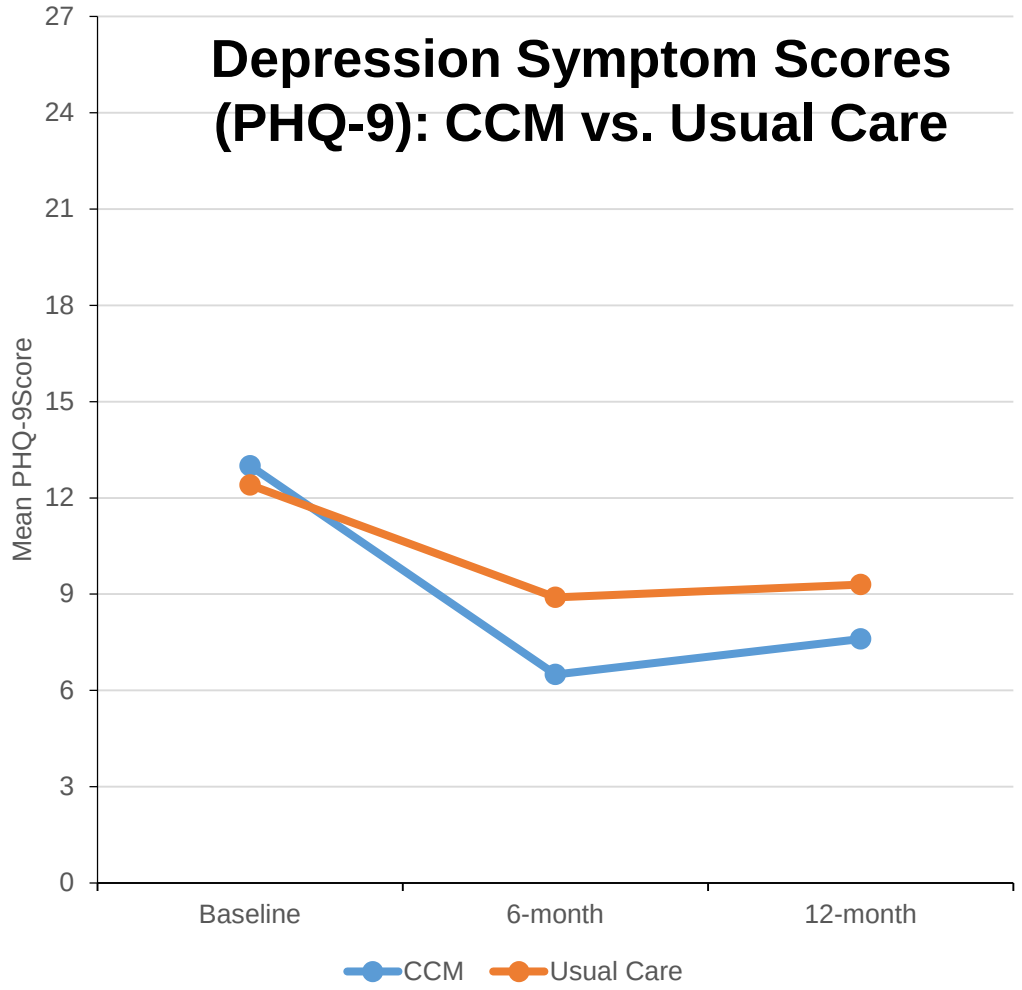
National Implementation of Collaborative Care Model (CCM) for Aetna Enrollees with Mood Disorders from Small Group Practices

Collaborative Care Model

- Care Management
- Self-management support

Usual Care

- Wellness mailings



Kilbourne AM et al, BMC Psychol, 2014

Hybrid Type II Example:

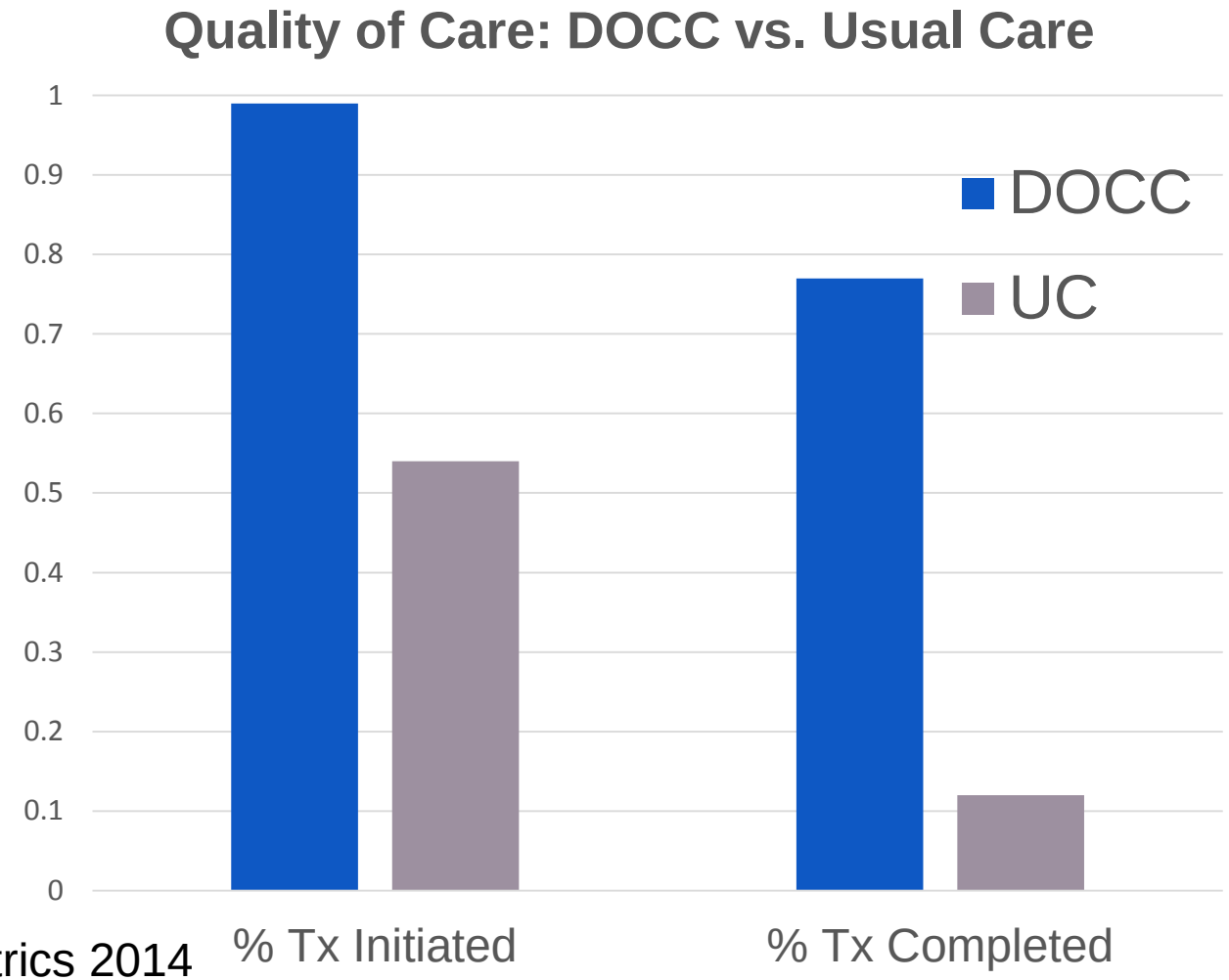
Implementing Doctor-Office Collaborative Care to Improve Pediatric Behavioral Health Outcomes

DOCC

- Care Management
- Family Support
- **Provider Training & Consultation**

Usual Care

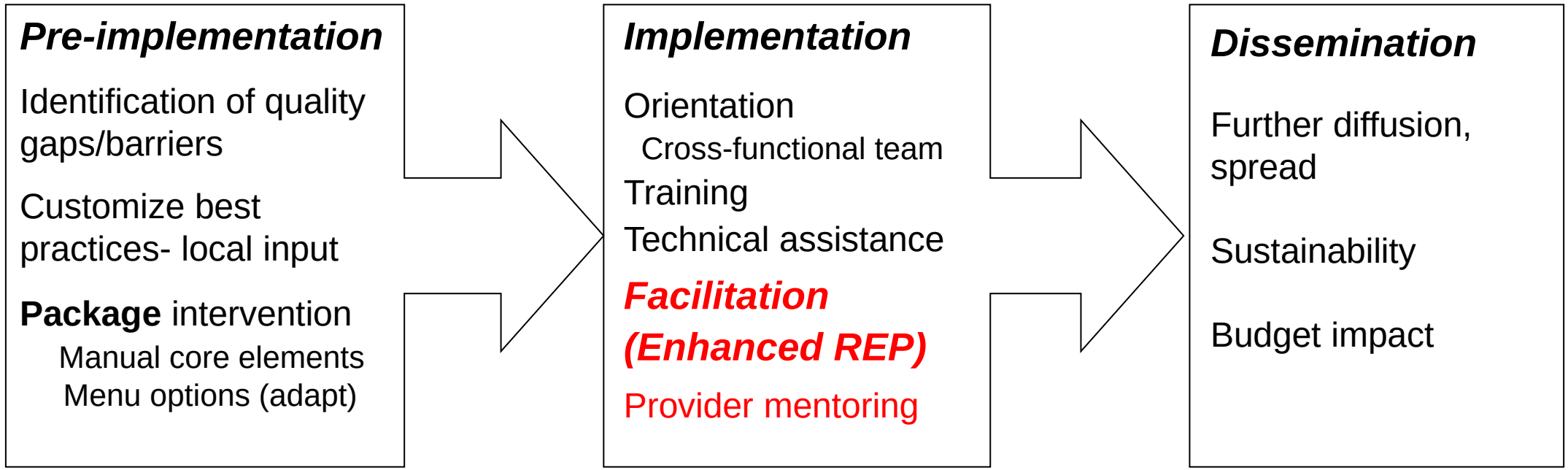
- Standard primary care



Kolko DJ et al, Pediatrics 2014

Hybrid Type III Examples:

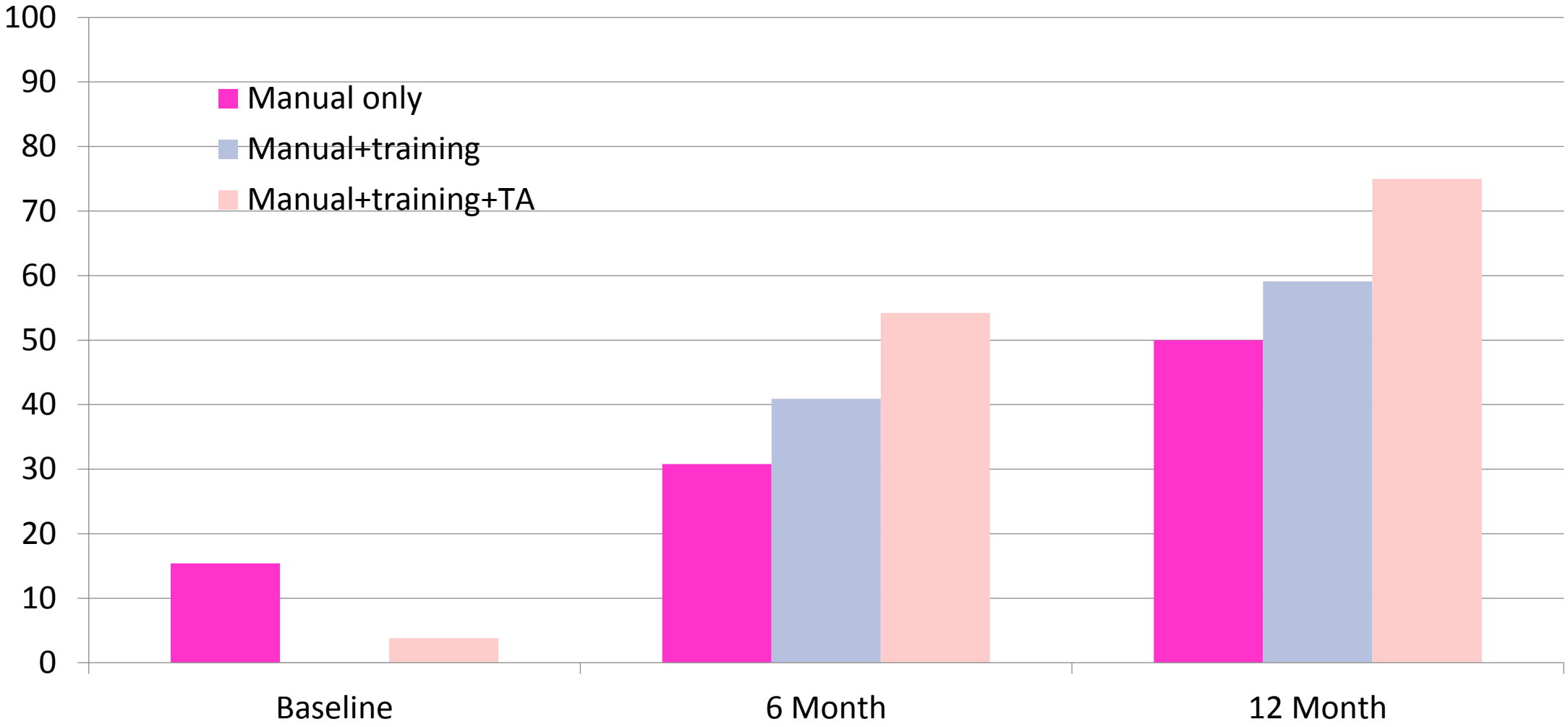
Enhanced Replicating Effective Programs (REP) Implementation Strategy



- *REP was developed by the Centers for Disease Control to rapidly translate prevention programs to community-based settings (Social Learning Theory, Rogers' Diffusion model) (Kegeles 2000; Kilbourne 2007)*
- *Enhanced REP added Facilitation (regular coaching by implementation expert) to support providers in implementation self-efficacy through identifying/mitigating barriers to adoption, building coalitions at sites, and enhancing communication with leaders (Kilbourne et al Implementation Science 2014)*

Hybrid Type III Example #1:

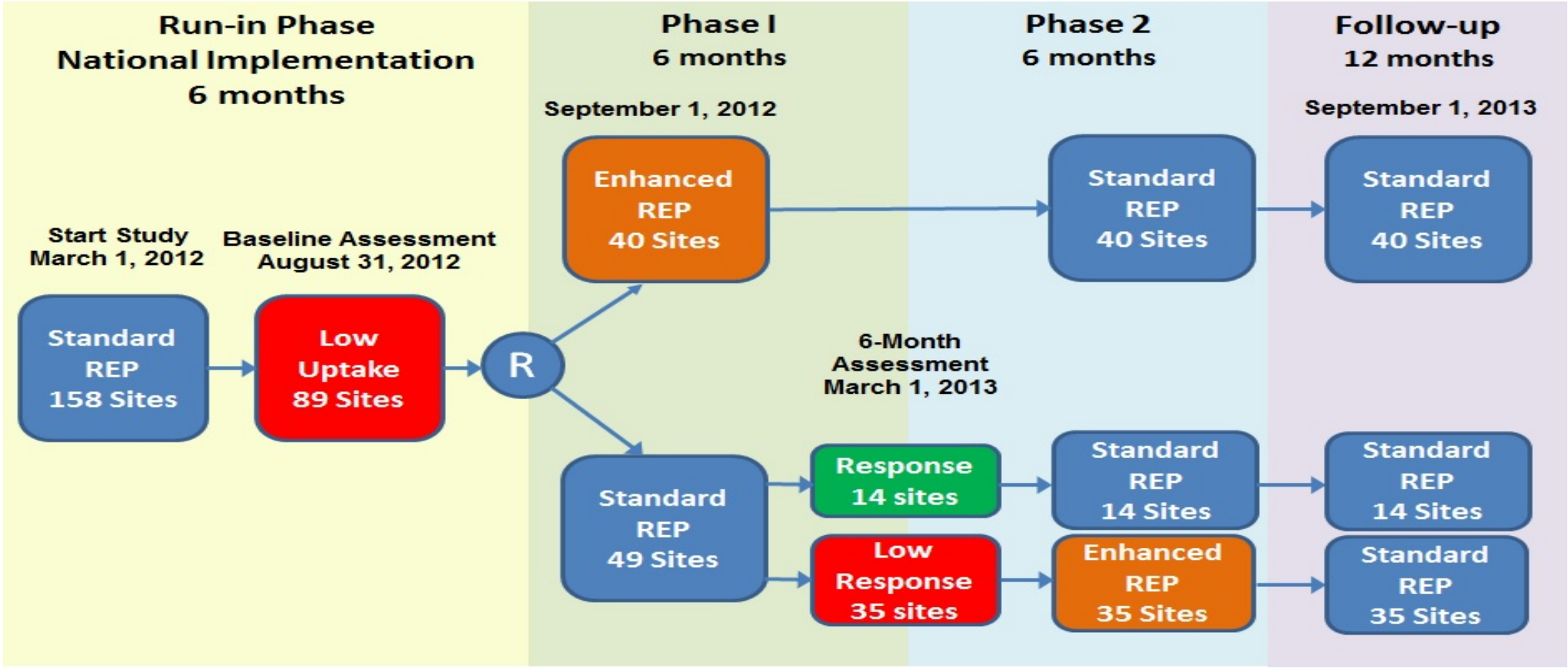
Implementation Strategies and Uptake of HIV Prevention Interventions in AIDS Service Organizations



Kelly J, et al. AJPH 2000

Hybrid Type III Example #2:

Immediate vs. Delayed Enhanced REP Implementation Strategy to Improve Uptake of Outreach Program for Veterans with SMI



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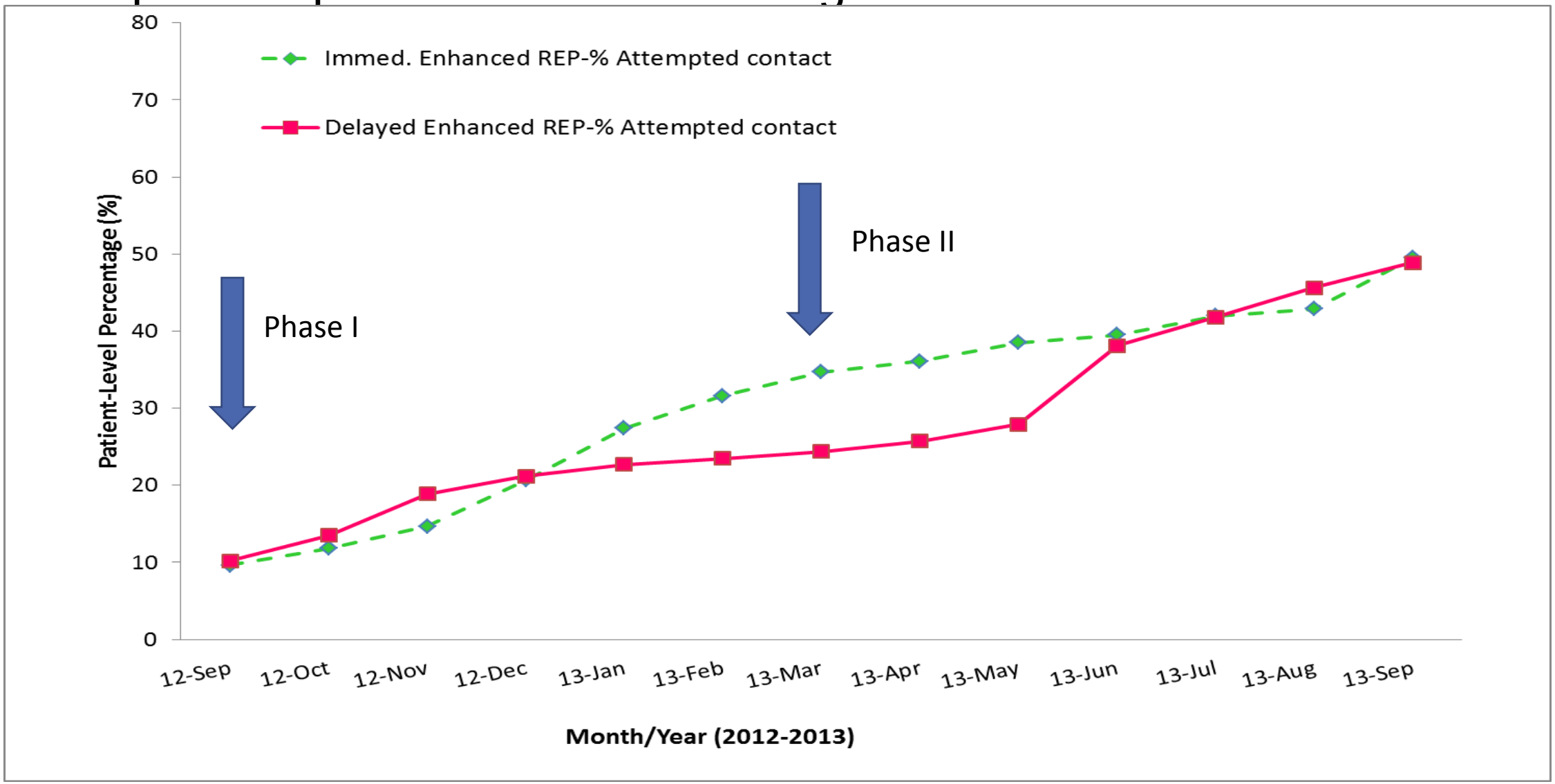
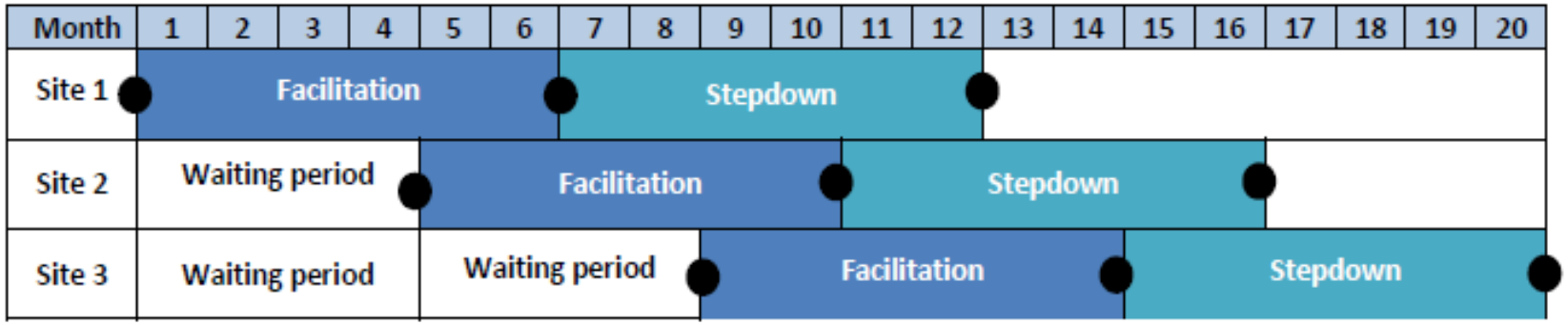


Stepped-Wedge Designs Overview

- All participants receive uniform intervention
- Start-time is randomized
- Ideal when resources are too limited to intervene at same time



Stepped-Wedge Design Advantages

Budgetary:

- Resources too limited to intervene at the same time at all participants/sites

Policy:

- Policy imperative to have all participants receive intervention

Pragmatic:

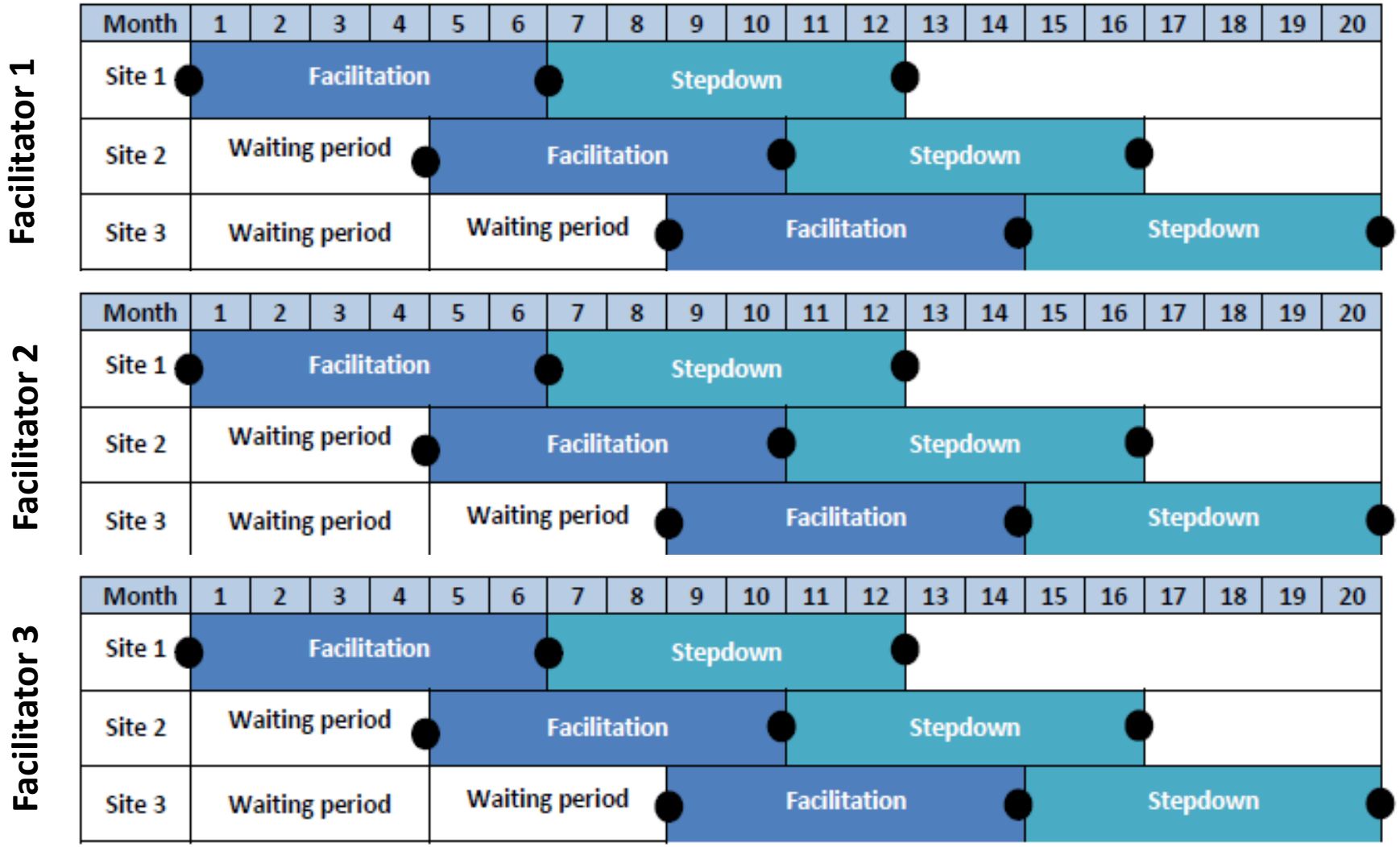
- Advantageous for recruiting & retention to have all participants receive intervention

Ethical:

- Intervention clearly causes more good than harm for participants, rather than equipoise

Stepped-Wedge Design Example:

Provider Facilitation -Collaborative Care in Mental Health Clinics



Sequential Multiple Assignment Trials (SMART)

Towards Precision Implementation

- Multi-stage trials; same subjects throughout
- Each stage corresponds to a critical decision point
- Pre-specified measure of responsiveness
- Treatment options at randomization restricted depending on history of responsiveness
- Subjects randomized to set of treatment options

The goal of a SMART is to inform development of adaptive intervention strategies

When to Use SMART Designs for Implementation

Often insufficient evidence/theory to decide:

- Which implementation strategy(ies) should I **start with**?
- What should I do for sites that are ***non-responsive*** to first-line implementation strategy?
- What should I do for sites that are ***responsive*** to first-line implementation?

SMART designs

can help to answer these questions.

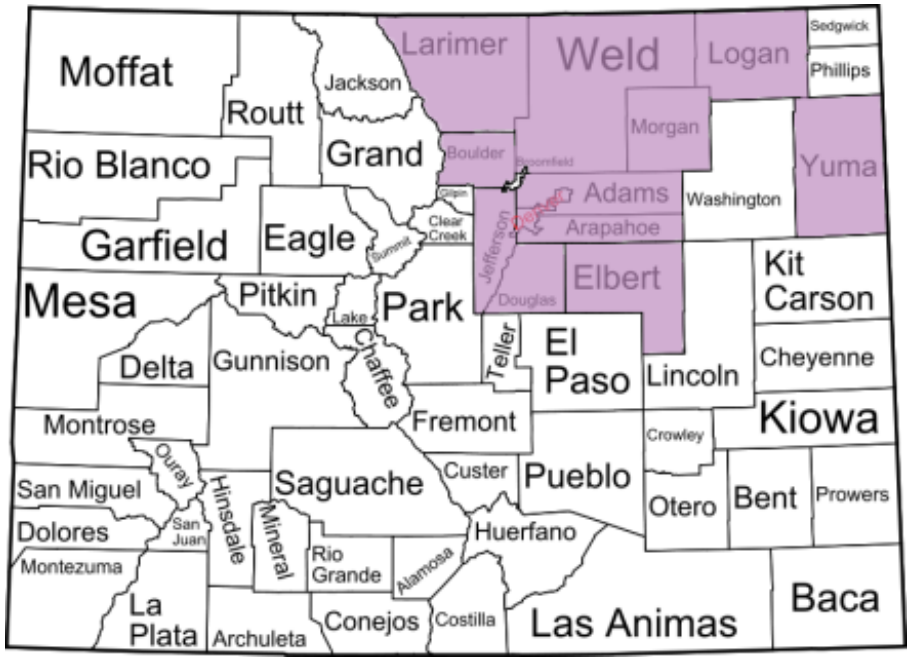
Adaptive Implementation Interventions: Example: Adaptive Implementation of Effective Programs Trial (ADEPT) Study

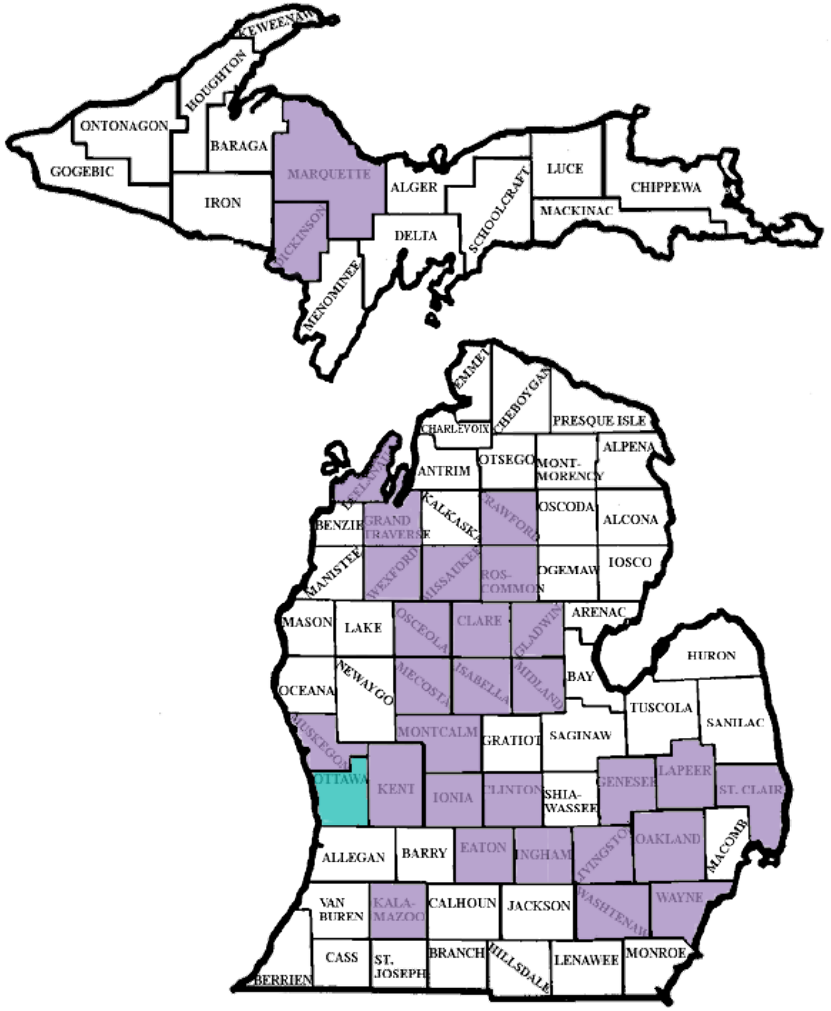
The question:

What is the best way to implement a collaborative care model (Life Goals) in community-based practices to improve patient mental health outcomes?

Kilbourne AM et al. (2014). Implementation Science, 9(1), 132; R01 MH 099898

ADEPT Setting:
Small Practices in Michigan & Colorado

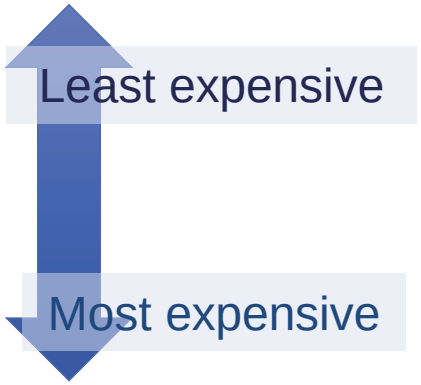




Example: Adaptive Implementation of Effective Programs Trial (ADEPT)

Implementation strategy options:

- Replicating Effective Programs (REP)
- External Facilitation (EF)
- External + Internal Facilitation (EF/IF)



Adaptive Implementation Interventions: Rationale for ADEPT

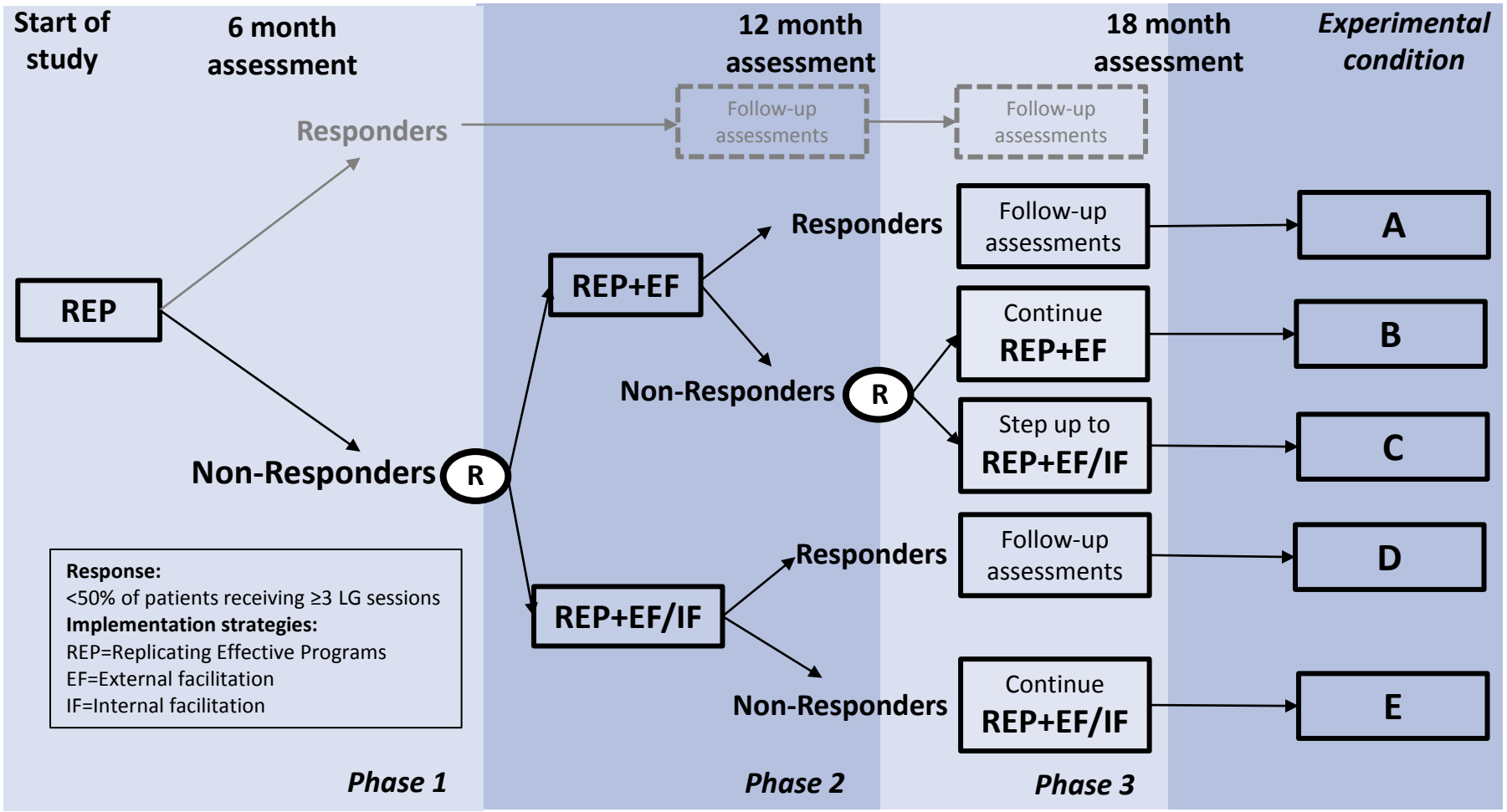
Prior evidence says:

- **REP** will work for **some** sites, but likely not **most**
  - But we don’t really know which…
- Most sites will need **more support than REP**

But we don’t know:

- What do we do when **REP doesn’t work**?
  - Step up directly to **EF/IF** or to **EF**? (Aim 1)
  - What if we step up to **EF** but sites still don’t respond? (Aim 2)

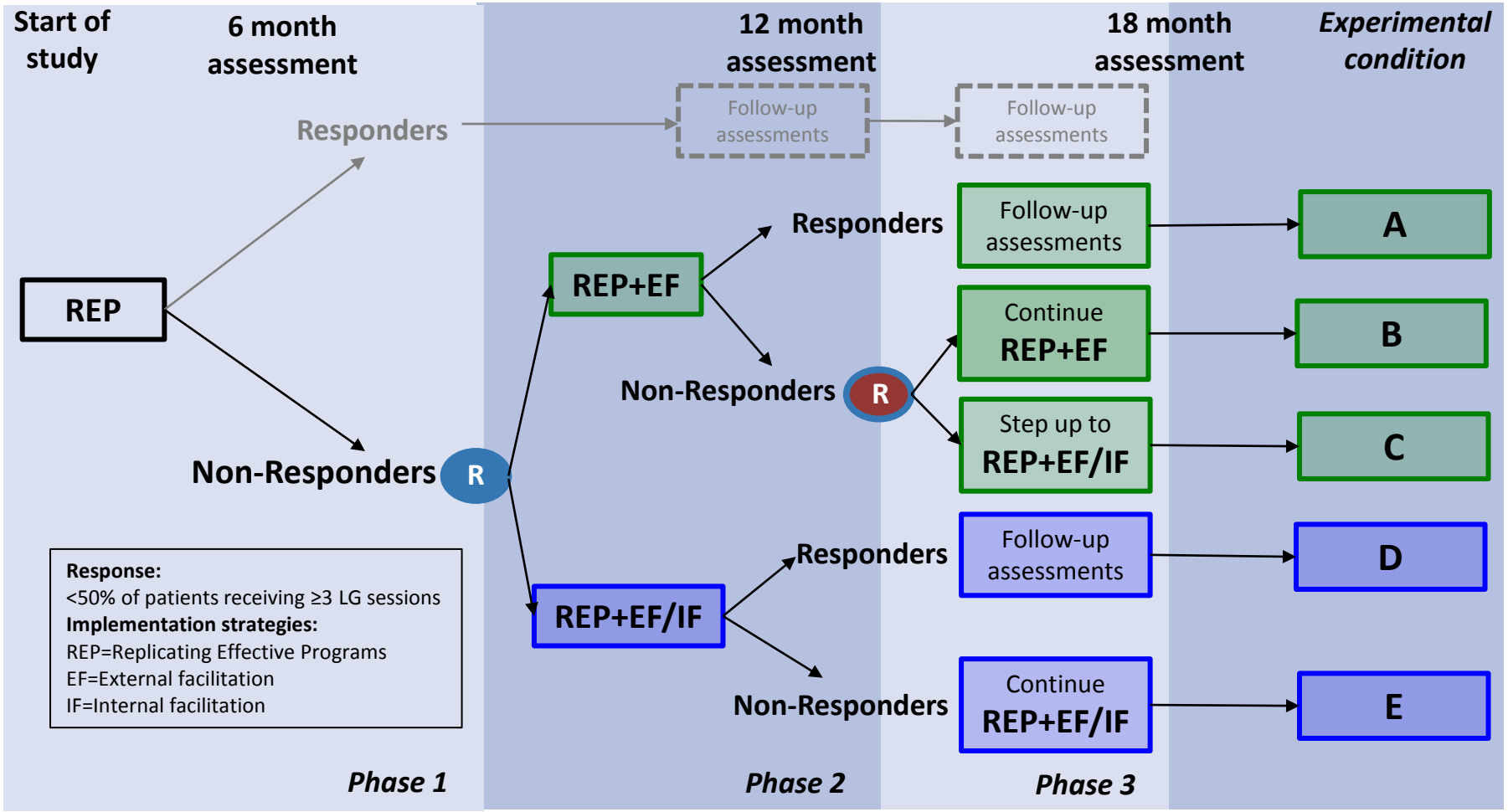
ADEPT Study Design



Kilbourne AM et al. (2014). Implementation Science, 9(1), 132.

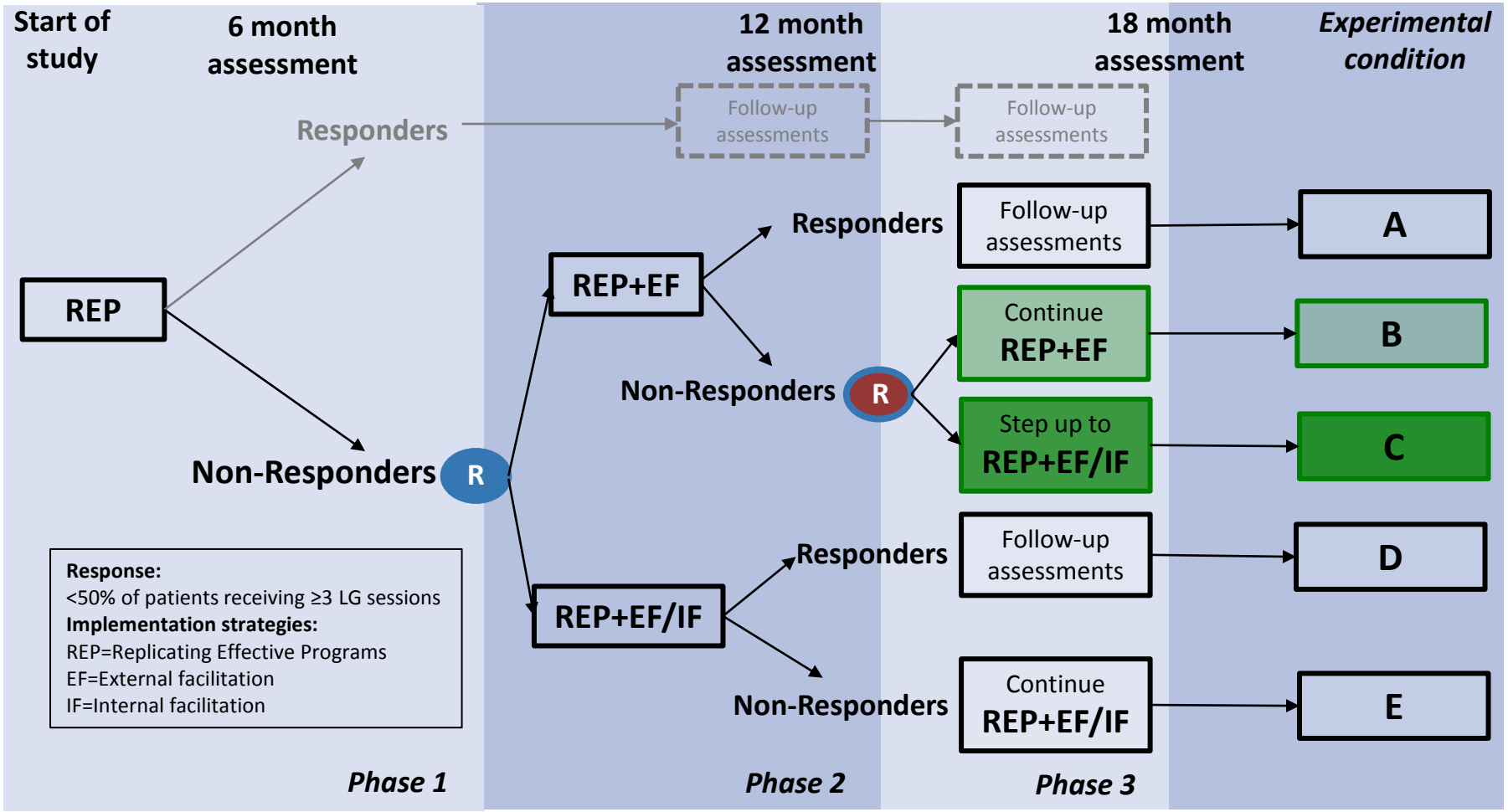
ADEPT Study Design: Aim 1

Is EF+IF better than EF alone for non-responding sites?



ADEPT Study Design: Aim 2

Is continuing EF+IF or EF alone better for non-responding sites?



Future Directions

- Enhancing reach: community organizations, schools, etc.
- Implementation strategies: everyone gets something
- Randomization: stakeholder timelines
- Data capture strategies

THANK YOU!

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