Introduction to Implementation Science & the Implementation Research Logic Model

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Agenda

- Introduction to core concepts of implementation research (IR)
- Implementation Research Logic Model
  - Why IR needs a unique logic model
  - Components of the IR Logic Model
    - Determinants
    - Implementation Strategies
    - Mechanisms of Action
    - Outcomes
  - Example of the IR Logic Model to a hypothetical study of HIV intervention implementation

Introduction to Implementation Science

Core concepts and definitions

The Research-to-Practice "Chasm"

Institute of Medicine, 2001

- **17 years** to move effective interventions into practice
- **14%** of interventions reach their intended population in the real-world

Balas et al., 1998

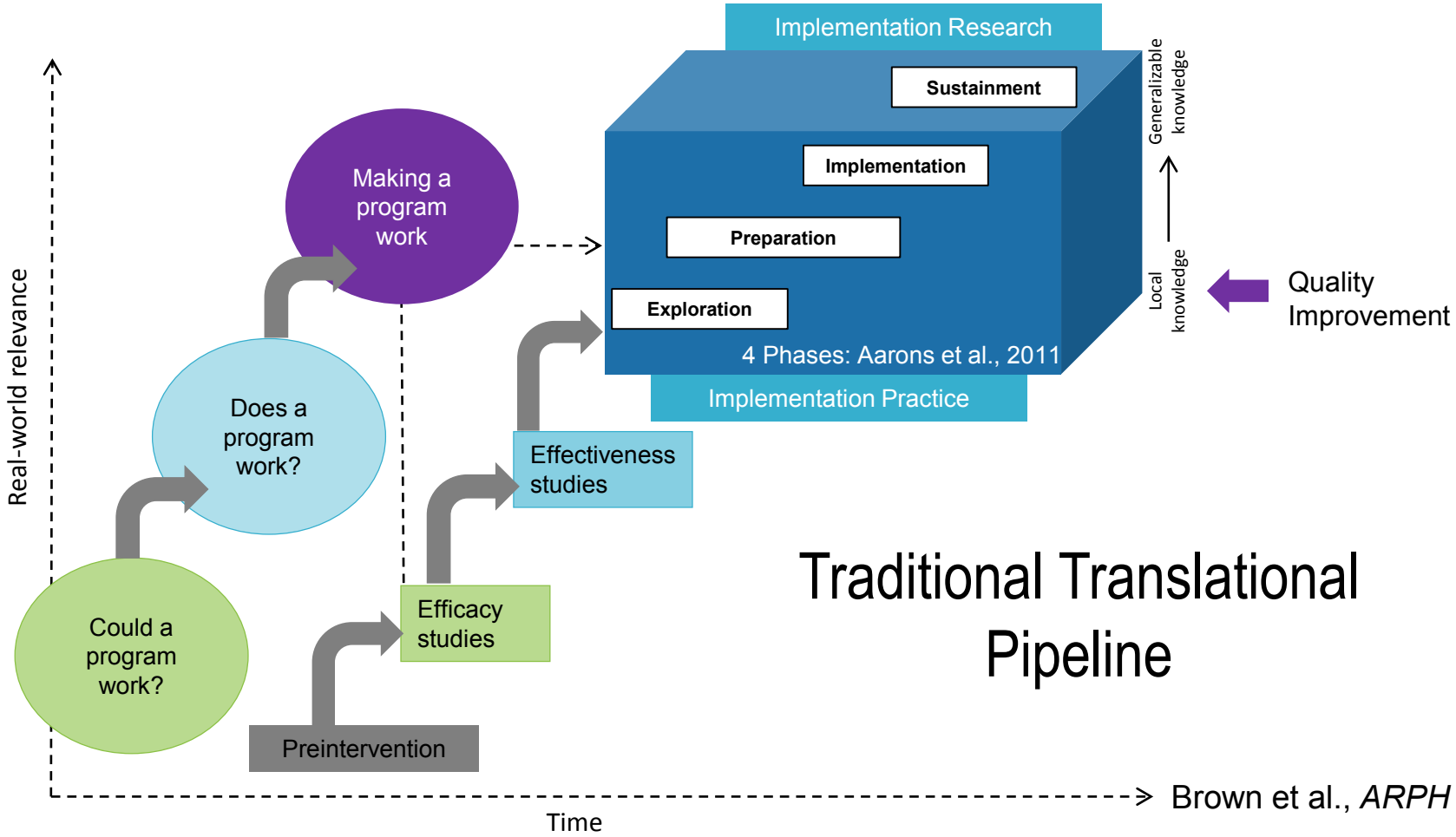
Let's Start Very Non-Scientific

- The intervention/practice/innovation is **THE THING**
- Effectiveness research looks at whether THE THING works
- D&I research looks at how best to help people/places **DO THE THING**
- *Implementation strategies* are the stuff we do to try to help people/places **DO THE THING**
- Implementation outcomes are **HOW MUCH** and **HOW WELL** they **DO THE THING**

Terminology

- **Implementation practice** is the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within and across specific systems (local knowledge)
- **Implementation research** evaluates of the use of strategies to integrate interventions into real-world settings to improve patient outcomes (generalizable knowledge)
- **Implementation science** is the study of methods to promote the integration of research findings and evidence into healthcare policy and practice

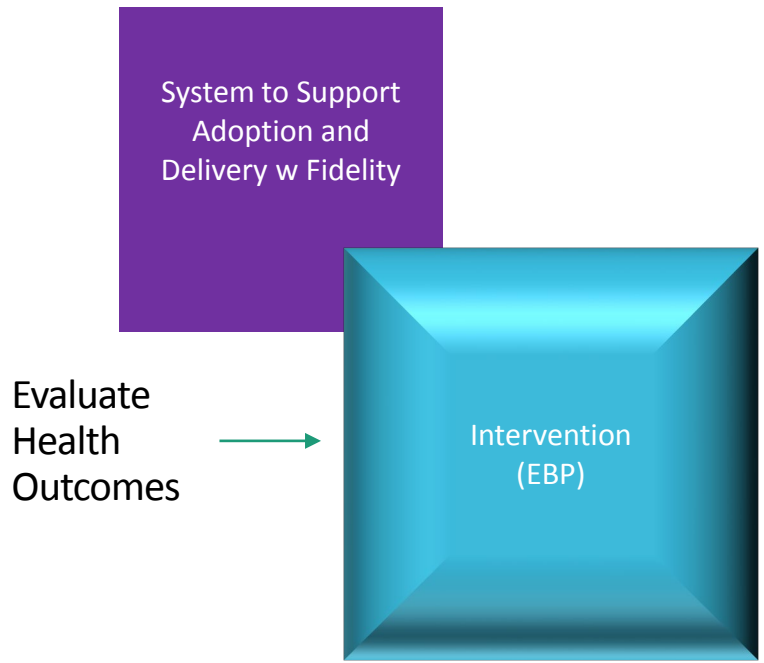
Brown et al. 2017; NIH, 2019

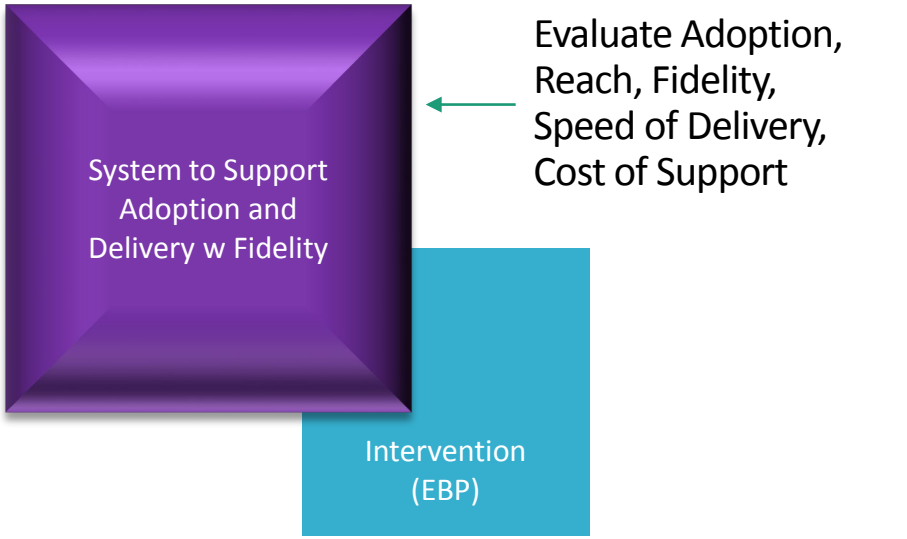


Traditional Translational Pipeline

IR has a Different Emphasis Than Other Types of Research

Effectiveness **vs.** **Implementation**





Influences what to measure, what to model, how to test, and what to evaluate

The Delivery System Matters in Implementation

"The use of effective interventions without [effective] implementation strategies is like a serum without a syringe; the cure is available, but the delivery system is not."

Fixsen, Blase, Duda, Naoom, Van Dyke, 2010

Interventions vs. Implementation Strategies

- Evidence-Based **Clinical or Preventive Intervention: 7 P's**
  - **Pill** (PrEP)
  - **Program** (PROMISE)
  - **Practice** (routine HIV screening in clinical settings)
  - **Principle** (HIV Treatment as Prevention)
  - **Product** (condom)
  - **Policy** (housing for people at high risk for HIV)
  - **Procedures** (male circumcision)

Brown et al., 2017

Interventions vs. Implementation Strategies

- Implementation Strategies are an intervention on the system to increase adoption of evidence-based innovations into usual care
  - 9 categories derived from 75 discrete evidence-informed strategies

ERIC Study
Powell et al. 2015

Powell et al. 2012

Plan | Educate | Finance | Restructure | Quality Management | Policy Context

Assumptions about IR

- There is sufficient evidence to implement one of the P's
- Implementation needs to be evaluated as a P is rolled out
- IR is about the context of implementation
  - Service delivery system and agents
  - Defined population(s) served

Nilsen *Implementation Science* (2015) 10:53
DOI 10.1186/s13012-015-0242-0

IMPLEMENTATION SCIENCE

DEBATE Open Access

Making sense of implementation theories, models and frameworks

Per Nilsen

Abstract

Background: Implementation science has progressed towards increased use of theoretical approaches to provide better understanding and explanation of how and why implementation succeeds or fails. The aim of this article is to propose a taxonomy that distinguishes between different categories of theories, models and frameworks in implementation science, to facilitate appropriate selection and application of relevant approaches in implementation research and practice and to foster cross-disciplinary dialogue among implementation researchers.

Discussion: Theoretical approaches used in implementation science have three overarching aims: describing and/or guiding the process of translating research into practice (process models); understanding and/or explaining what influences implementation outcomes (determinant frameworks, classic theories, implementation theories); and evaluating implementation (evaluation frameworks).

Summary: This article proposes five categories of theoretical approaches to achieve three overarching aims. These categories are not always recognized as separate types of approaches in the literature. While there is overlap between some of the theories, models and frameworks, awareness of the differences is important to facilitate the selection of relevant approaches. Most determinant frameworks provide limited "how-to" support for carrying out implementation endeavours since the determinants usually are too generic to provide sufficient detail for guiding an implementation process. And while the relevance of addressing barriers and enablers to translating research into practice is mentioned in many process models, these models do not identify or systematically structure specific determinants associated with implementation success. Furthermore, process models recognize a temporal sequence of implementation endeavours, whereas determinant frameworks do not explicitly take a process perspective of implementation.

Keywords: Theory, Model, Framework, Evaluation, Context

Bridging Research and Practice

Models for Dissemination and Implementation Research

Rachel G. Tabak, PhD, Elaine C. Khoong, BS, David A. Chambers, DPhil, Ross C. Brownson, PhD

Context: Theories and frameworks (hereafter called models) enhance dissemination and implementation (D&I) research by making the spread of evidence-based interventions more likely. This work organizes and synthesizes these models by (1) developing an inventory of models used in D&I research; (2) synthesizing this information; and (3) providing guidance on how to select a model to inform study design and execution.

Evidence acquisition: This review began with commonly cited models and model developers and used snowball sampling to collect models developed in any year from journal articles, presentations, and books. All models were analyzed and categorized in 2011 based on three author-defined variables: construct flexibility, focus on dissemination and/or implementation activities (D/I), and the socioecologic framework (SEF) level. Five-point scales were used to rate construct flexibility from broad to operational and D/I activities from dissemination-focused to implementation-focused. All SEF levels (system, community, organization, and individual) applicable to a model were also extracted. Models that addressed policy activities were noted.

Evidence synthesis: Sixty-one models were included in this review. Each of the five categories in the construct flexibility and D/I scales had at least four models. Models were distributed across all levels of the SEF; the fewest models (n=8) addressed policy activities. To assist researchers in selecting and utilizing a model throughout the research process, the authors present and explain examples of how models have been used.

Conclusions: These findings may enable researchers to better identify and select models to inform their D&I work.

(Am J Prev Med 2012;43(3):337–350)

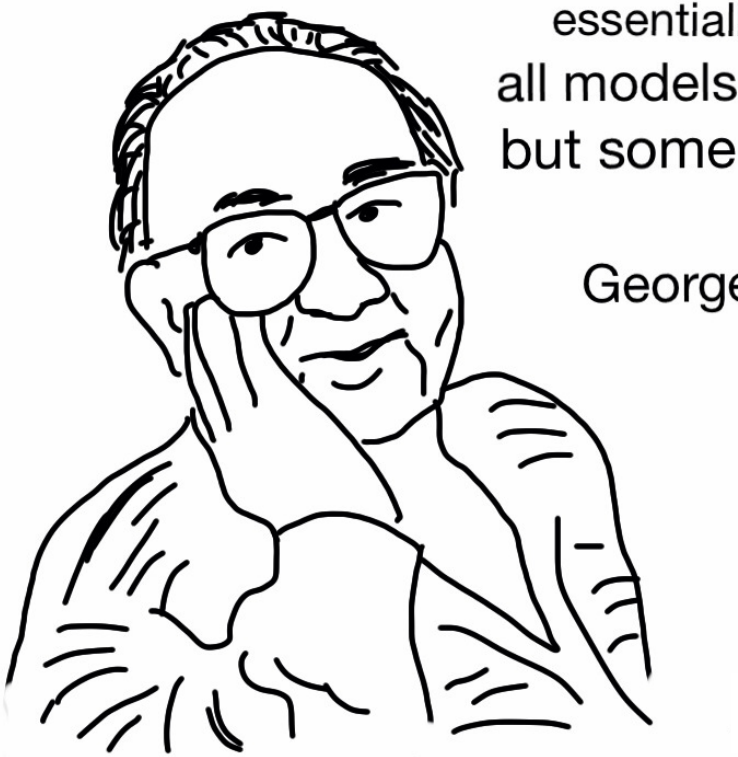
Theories, Models, and Frameworks

- Determinant frameworks: barriers and facilitators of implementation process/outcomes (CFIR, PARIHS, Theoretical Domains Framework)
- Process models: specifies stages/phases of implementation (EPIS, Knowledge-to-Action, Ottawa Model)
- Evaluation frameworks: aspects of implementation that can be measured to determine success of implementation (RE-AIM, PRECEDE-PROCEED, Proctor et al. 2009)
- Classic theories: theories originating in other fields (Diffusion of Innovation, social networks, behavior change, organizational)
- Implementation theories: developed by implementation researchers (Implementation Climate, Absorptive Capacity, Organizational Readiness)

Development of the IR Logic Model

Uses and Elements

Disclaimer

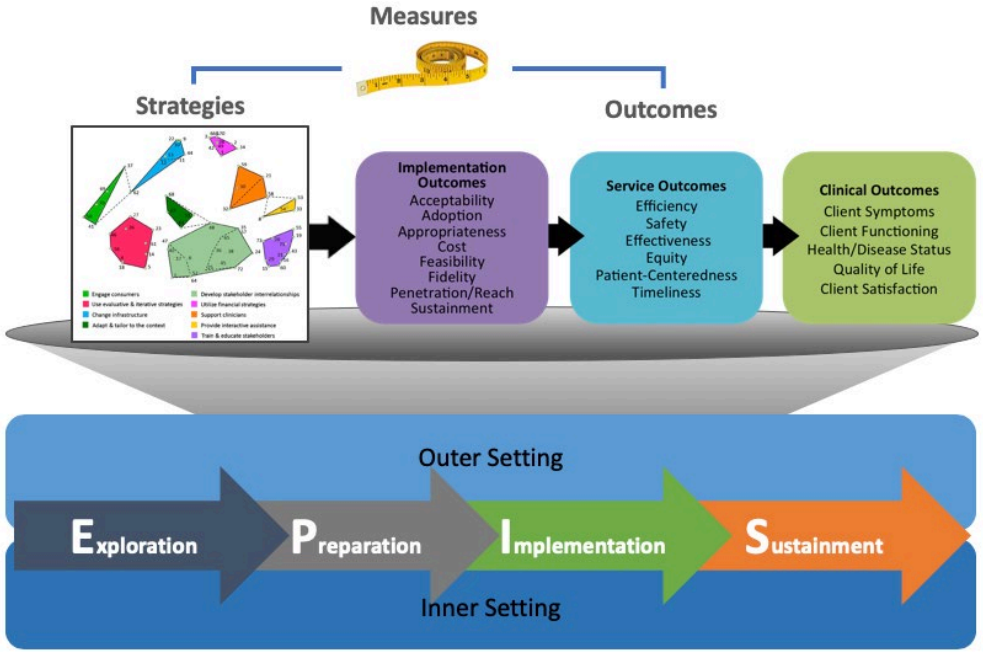


essentially,
all models are wrong,
but some are useful

George E. P. Box

Development of the IR Logic Model

- Based on the CDC and AHRQ logic model format and components
- Pipeline model
  - Other: Outcome chains
- Leverage existing frameworks, models, and taxonomies by focusing on their integration in a new logic model
- Pilot work
  - Ce-PIM/AbilityLab
  - Keep It Up! 3.0 (Brian Mustanski)
  - Emory (Patrick Sullivan & Aaron Siegler)
  - Raising Healthy Children Study (CORD 2.0)
- Principled use, not rule-governed
- Model from Smith & Polaha (2017)



Logic Models (in general)

- Develop agreement among diverse stakeholders of the “what” and the “how”
- Improve planning by highlighting theoretical and practical gaps
- Support the development of meaningful process indicators for tracking
- Reproduce successful studies / identify failures of unsuccessful studies
- Uses:
  - Planning the project
  - Organizing a project proposal/grant application/study protocol
  - Presenting findings from a completed project (post hoc application)
  - Synthesizing the findings of multiple projects

Petersen, Taylor, & Peikes, 2013

Related Approaches

- **Program Theory** (Funnell & Rogers, 2011)
  - Explicit model on how a project/strategy contributes to a chain of intermediate results and finally to the intended or observed outcomes
    - **Theory of Change** — central processes or drivers by which change comes about; formal theory or tacit understanding
    - **Theory of Action** — explains how projects/strategies are constructed to activate the Theory of Change
- **Implementation Mapping** (Bartholomew, Fernandez, et al.)
  - Primarily focused on the design and selection of implementation strategy(s)
  - Series of matrices

Elements of an IR Logic Model

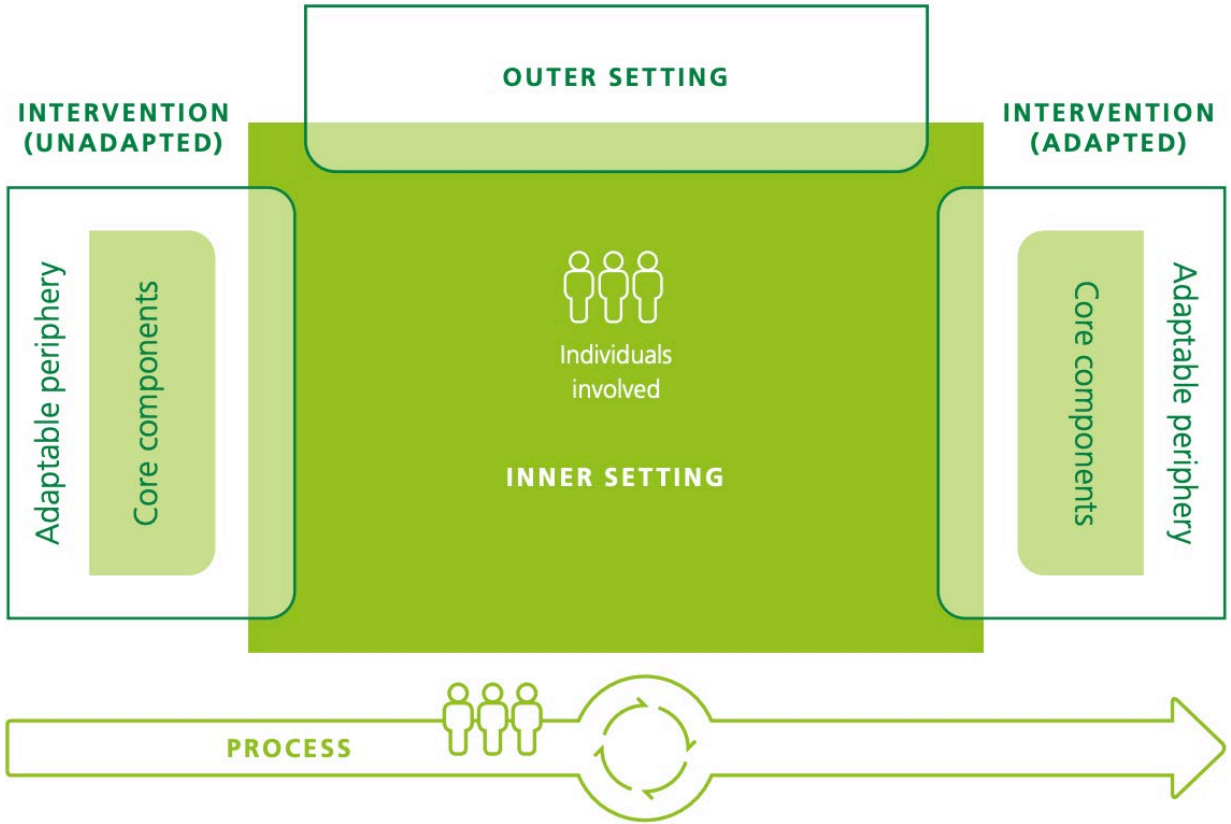
1. Determinants of practice
2. Implementation strategies
3. Mechanisms of action
4. Outcomes

- IR Logic Model: Specification of the relationship between components of an IR study

  Determinant(s) → Implementation Strategy → Mechanism of Action → Outcomes

Elements of an IR Logic Model

Determinants
Factors that might prevent or enable improvements (barriers & facilitators); may act as moderators or 'effect modifiers,' or as mediators; indicating that they are links in a chain of causal mechanisms (CFIR, Damschroder et al. 2009; TICD, Flottorp et al. 2013)

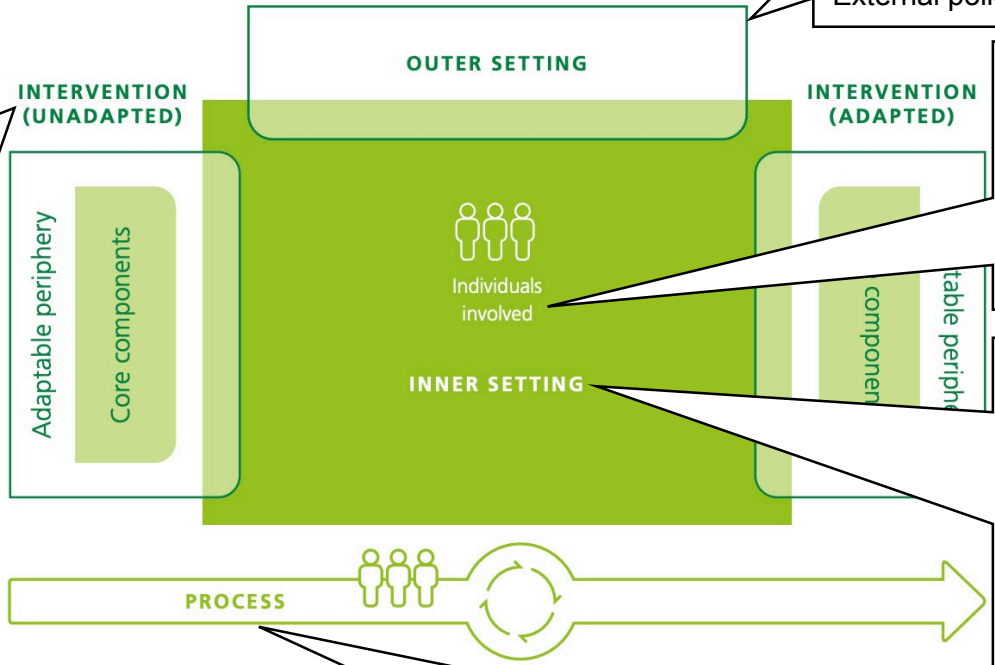


Damschroder et al. 2009

Determinants

Patient needs and resources
Cosmopolitainism
Peer pressure
External policies and incentives

Intervention source
Evidence strength and quality
Relative advantage
Adaptability
Trialability
Complexity
Design quality and packaging
Cost



Knowledge/Beliefs about the Intervention
Self-efficacy
Individual stage of change
Individual identification with the organization
Other personal attributes

Structural characteristics
Networks and communication
Culture
Implementation climate
- Tension for change
- Compatibility
- Relative priority
- Organizational incentives/rewards
- Goals and feedback
- Learning climate

Readiness for implementation
- Leadership engagement
- Available resources
- Access to knowledge/information

Engaging
- Opinion leaders
- Formal internal implementation leaders
- Champions
- External change agents

Planning
Executing
Reflecting and Evaluating

For definitions visit:
https://cfirguide.org/constructs/

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Elements of an IR Logic Model

Implementation Strategies

- interventions on the system to increase adoption of evidence-based innovations into usual care (Powell et al. 2015)
- Theory- or logic-driven connection between the implementation strategy and the barriers (that it will attempt to overcome) and the facilitators (that it will attempt to leverage) (CFIR → ERIC study)
- Rarely 1-to-1 (i.e., 1 strategy often is linked to multiple determinants; > 1 strategy to address 1 barrier; increasing 1 implementation outcome could be the result of ≥1 determinant and require ≥ strategy)
- Characteristics of the Strategy
  - The Actor, the Action, the Action Target, Temporality, Dose, Outcome Affected, Justification for use (Proctor, Powell, & McMillen, 2013)
  - Fidelity to the strategy itself

Elements of an IR Logic Model

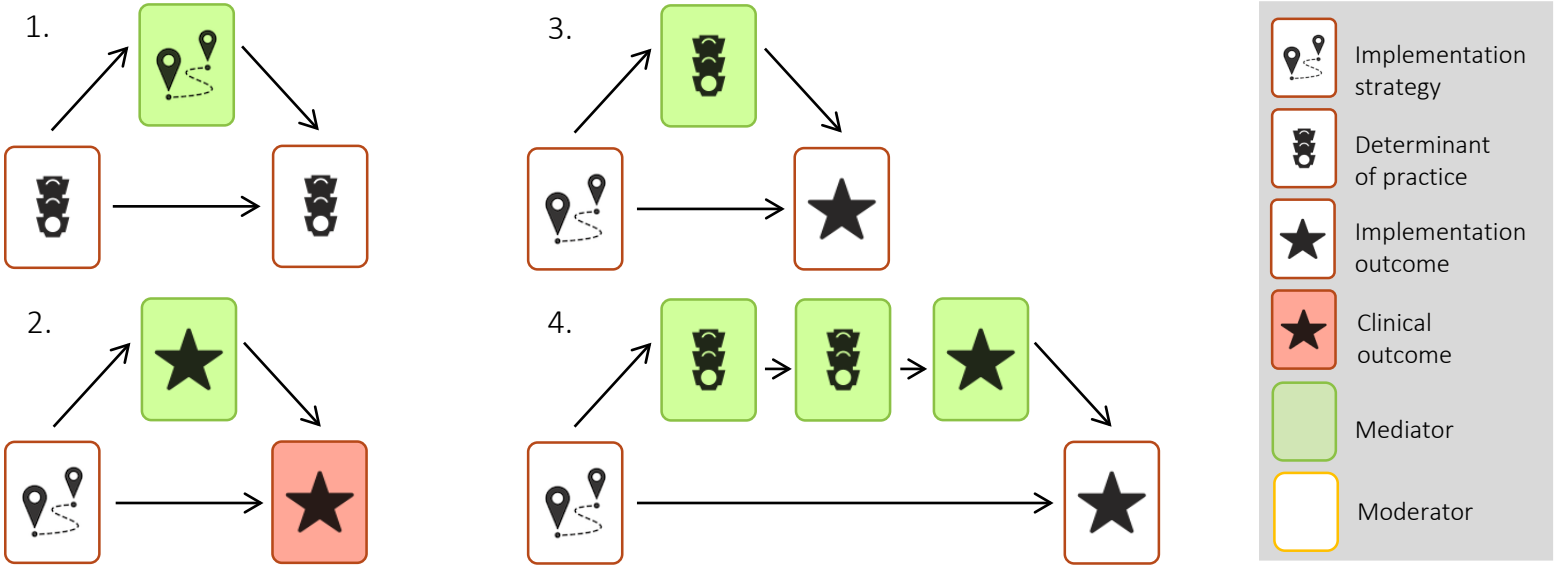
Specifying Implementation Strategies in the IR Logic Model

- Comprehensive
  - Strategies already in place (pre)
  - Strategies added/used that were unplanned (during; post)
- Single-arm studies
  - Non-experimental: identify those of interest (pre); identify those with greatest relevance/impact (post)
  - Experimental: identify those added/manipulated for the trial (the IV)
- Multi-arm studies
  - Non-experimental: identify differences between arms (pre and post)
  - Experimental: identify those added/manipulated for the trial (the IV) for each arm/condition
  - Comparative implementation: identify those added/manipulated AND those that differ between arms/conditions

Elements of an IR Logic Model

Mechanisms of action

- Process or event through which an implementation strategy operates to affect desired implementation outcomes (Lewis et al. 2018)



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Slide courtesy of Cara Lewis (April 2019)

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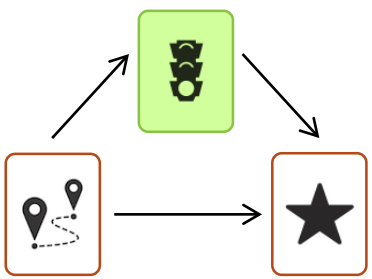
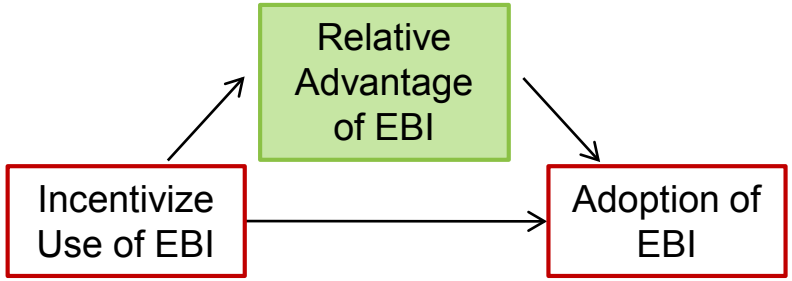
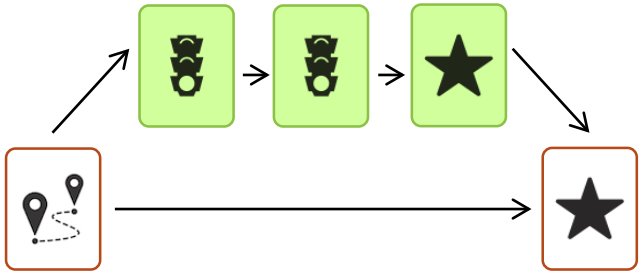
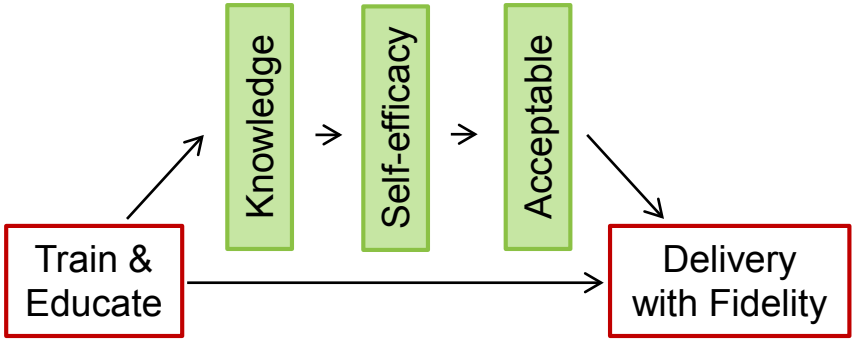
Examples of Causal Chains









Elements of an IR Logic Model

Implementation Outcomes

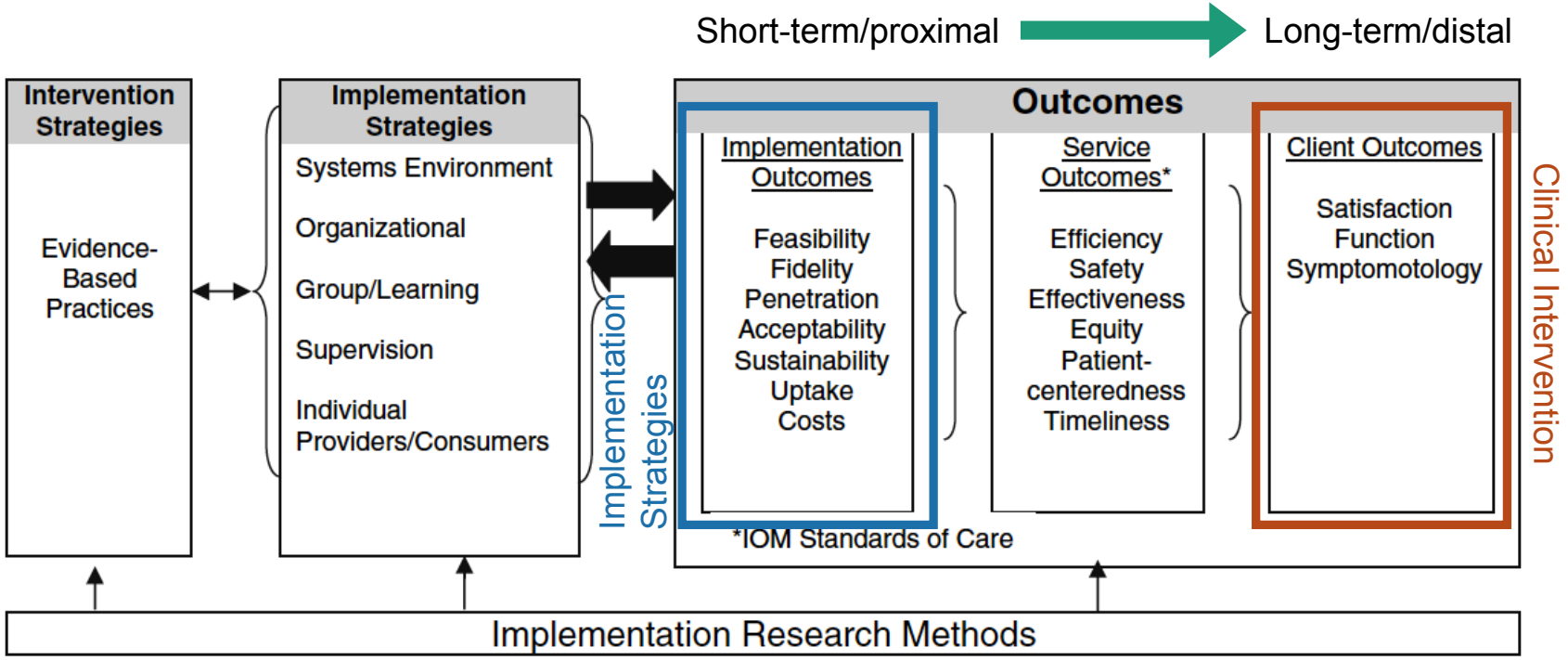
The effects of deliberate and purposive actions to implement new treatments, practices, and services (Proctor et al. 2011)

1) indicators of implementation success
2) proximal indicators of implementation processes
3) key intermediate outcomes in relation to service or clinical outcomes

Interactions among IR outcomes

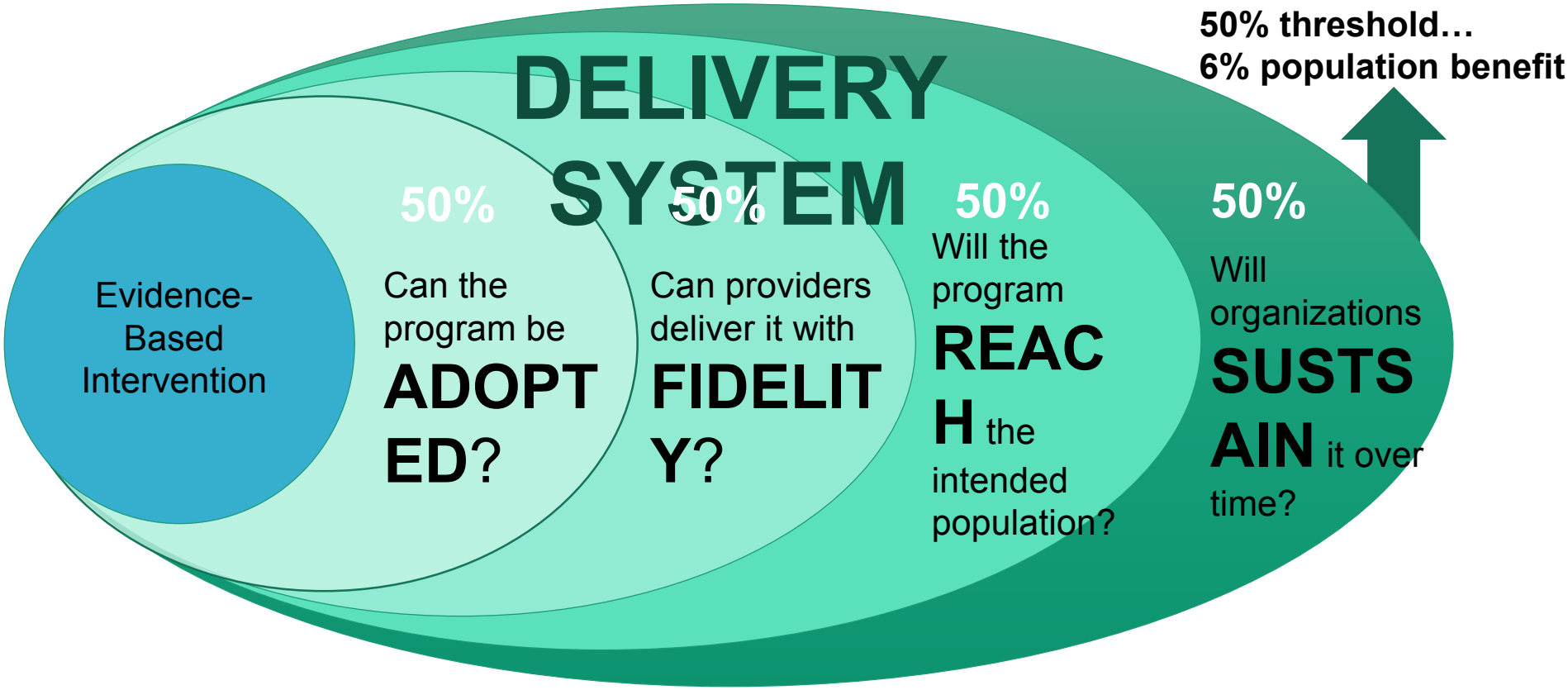
- Public health impact: effect * reach
- Figure

IR Outcomes are Distinct from Clinical Outcomes



Proctor et al. 2009; 2011

Implementation Outcomes = Population Benefit



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Gaglio, Shoup, & Glasgow, 2013

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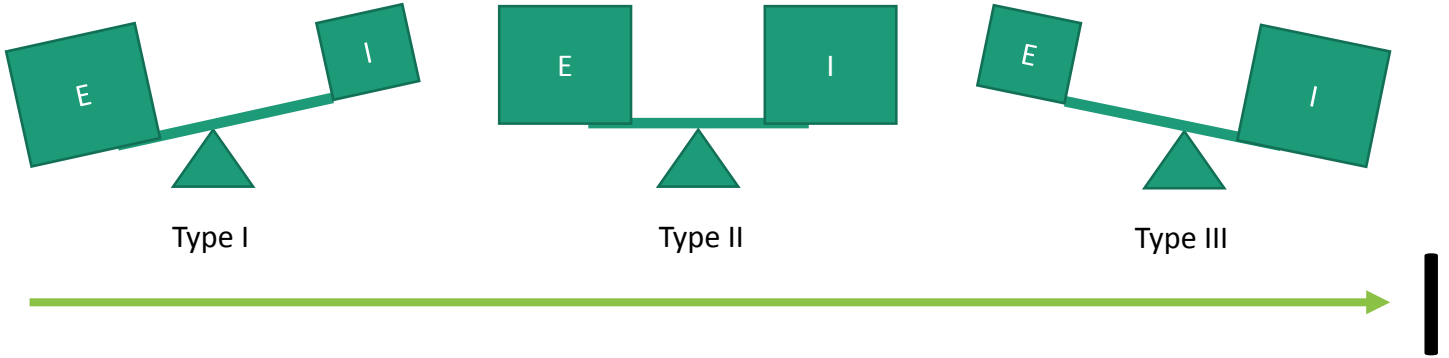
Effectiveness–Implementation Hybrid Designs

A bit of a special case

Definition and Purpose

- Simultaneous evaluation of the effectiveness of the clinical intervention and its implementation
- ≥2 levels of data collection (patient & system)
- Emphasis on E and I differentiates hybrid types (continuum)
- Speed translation and efficiently take programs to scale



Hybrid Types

- **Type I:** Explore *implementabilty* of an intervention while we are testing its effectiveness (towards real world implementation strategies)
- **Type II:** Test implementation strategies *during* effectiveness trials (simultaneous look at both)
- **Type III:** Test implementation strategies while also documenting clinical/prevention intervention outcomes (evaluating them as they relate to uptake and fidelity)

Application/Purpose of Each Type

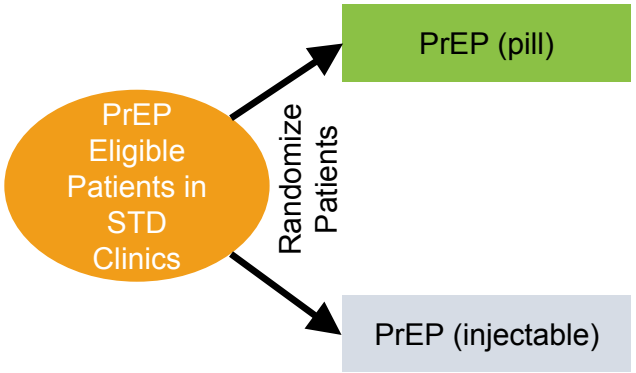
	Primary Aim:	*Secondary Aim:*
Type I	Determine effectiveness of an intervention	Better understand context for implementation
Type II	Determine effectiveness of an intervention	Determine feasibility and/ or (potential) impact of an implementation strategy
Type III	Determine impact of an implementation strategy	Assess clinical outcomes associated with implementation

- Use Type I or Type II when effectiveness of the P has yet to be established
- Allowed to “backfill” effectiveness data while testing implementation strategies
- Use Type II or III when a relationship between implementation and effectiveness is unknown or hypothesized to occur (head-to-head trial)
- Power and level of randomization are key considerations

Curran et al. 2012; Landsverk, Brown, Smith et al. 2017

Hybrid Type I Example: PrEP as a Long-Acting Injectable

- Assumption: Efficacy trials were recently completed – no effectiveness trials
- Test effectiveness of long acting PrEP provided in-house within STD clinics AND gather information about implementation



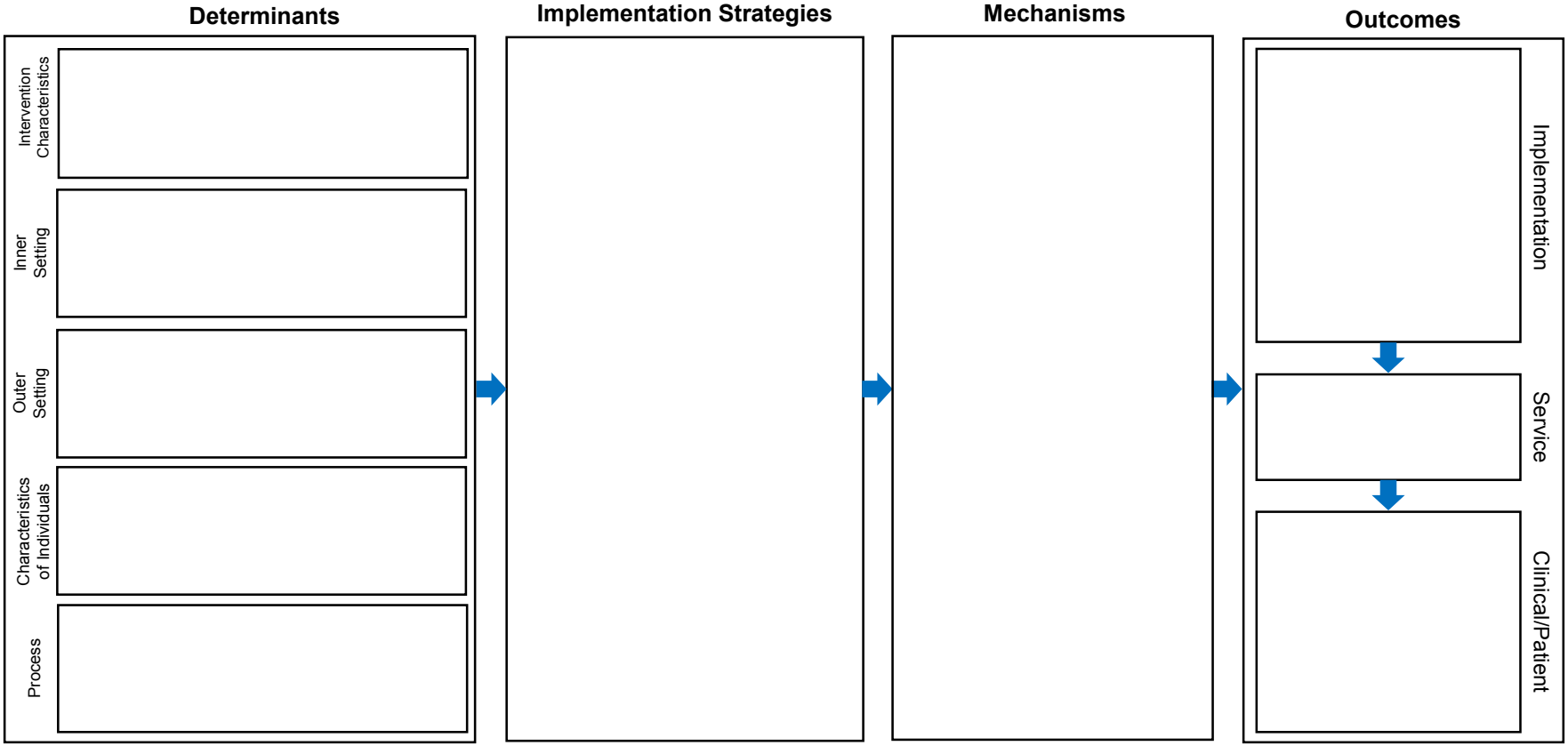
Specific Aims

Aim 1. Test the comparative effectiveness of long acting PrEP compared to one-a-day PrEP.

Aim 2. Gather information about implementation (adoption, acceptability, adherence, fidelity).

Aim 3. Evaluate relations between implementation and effectiveness (e.g., does adherence account for variation in PrEP effectiveness? Are patients more likely to remain adherent to long acting PrEP?)

Logic Model for Implementation Research



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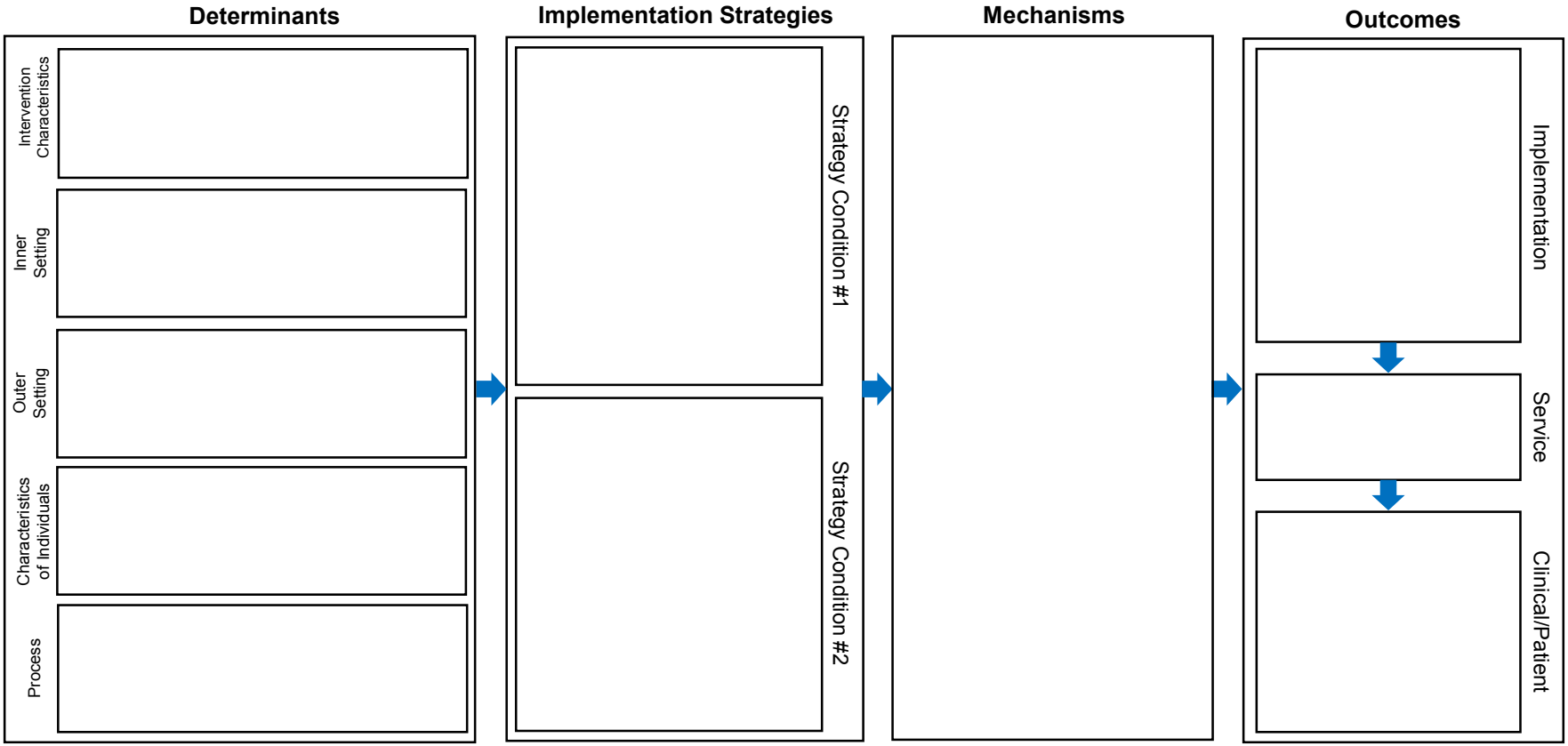
IR Logic Model for Comparative Implementation



IR Logic Model Guiding Principles

- Include all relevant determinants and strategies
  - Comprehensiveness, transparency, rigor, alternative explanations
- Indicate/Notate relationship between elements
  - Color-coding, superscript/subscript (connect to text and tables)
- Label independent variable(s) (i.e., strategies) as appropriate
- Note the Primary Outcome(s) at each level
- Operationalize the outcome(s) when space allows
- Comparative implementation trials
  - Indicate the determinants/strategies/mechanisms differentiating arms
  - Identify the shared primary outcome(s) by both arms
  - Combined when similar or 1 IR Logic Model per arm when dissimilar

Supporting Text and Resources

- Preliminary data for determinants
- Measures
- Strategy/ies (Bartholomew et al.; Powell et al., 2017; Proctor, Powell, & McMillen, 2013)
- “Paths” supported by theory (e.g., Lewis et al. 2018)
- Trial design
- Implementation plan/process model (e.g., EPIS)

Text	Table	Figure
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A (very basic) Example Application of the IR Logic Model

An urban primary healthcare system wants to increase PrEP prescribing

Pre-Exposure Prophylaxis (PrEP) (Truvada)

- When **taken consistently**, PrEP has been shown to reduce the risk of HIV infection in high-risk populations by up to 92%.
- 2014 CDC Comprehensive Clinical Practice Guidelines
  - HIV-uninfected individuals who engage in behaviors that place them at substantial risk of HIV acquisition:
    - Sexually active adult men who have sex with men (MSM)
    - Adult injection drug users (IDU)
  - Delivery
    - Every 3 months — **repeat HIV testing** to confirm patient is still HIV negative; **provide a prescription** or refill authorization for no more than 90 days (until the next HIV test); assess **adherence** and side effects
    - Every 6 months — **assess renal failure**; **conduct STI testing**

Premise for Example IR Study

- A large health system with 54 primary health care clinics in a high HIV prevalence urban area wants to increase PrEP uptake by 50%.
- Leaders in the health system have decided to compare whether referring potentially-eligible patients to specialty STI/HIV clinics for PrEP or providing PrEP in their clinics will result in better outcomes.
- Health system has partnered with an implementation scientist to devise a study to test this question.

Research Question

Does training primary care physicians to identify and prescribe PrEP as part of routine preventive care lead to provider adoption and to reaching more eligible patients compared to referring them to specialty STI/HIV clinics?

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Implementation Strategies

Research Question

Does training primary care physicians to identify and prescribe PrEP as part of routine preventive care lead to provider adoption and to reaching more eligible patients compared to referring them to specialty STI/HIV clinics?

Implementation Outcomes

Research Question

Does training primary care physicians to identify and prescribe PrEP as part of routine preventive care lead to provider adoption and to reaching more eligible patients compared to referring them to specialty STI/HIV clinics?

Comparison-based trial design

Specific Aims

1. Train primary care physicians to identify and prescribe PrEP as part of routine preventive care.
2. Increase primary care provider adoption of PrEP screening and prescribing.
3. Identify most effective practice for reaching PrEP eligible patients (i.e., integrated within routine care or referral to specialty STI/HIV clinics).

Hypotheses

H_1: Provider, clinic, and PrEP-related factors will be related to primary care physicians' adoption. Training can overcome these potential barriers.

H_2: Improving leadership support of provider delivery of PrEP will improve rates of adoption.

H_3: Providing PrEP in primary care will lead to more prescriptions than referring out.

Implementation Outcome Metrics

Adoption: Providers' prescribing PrEP

Reach: Proportion of eligible patient's prescribed PrEP

Acceptability: Providers' perspective

Appropriateness: Provider and patient perspectives

Feasibility: Time with patients; wait times; total patients

Cost: Is PrEP provision in the clinic cost-beneficial/cost neutral for revenue as well as effects achieved?

Example: Timeline for Pre-Post Design to Evaluate Impact

- PrEP prescribing rates are low
- Referrals to PrEP are low

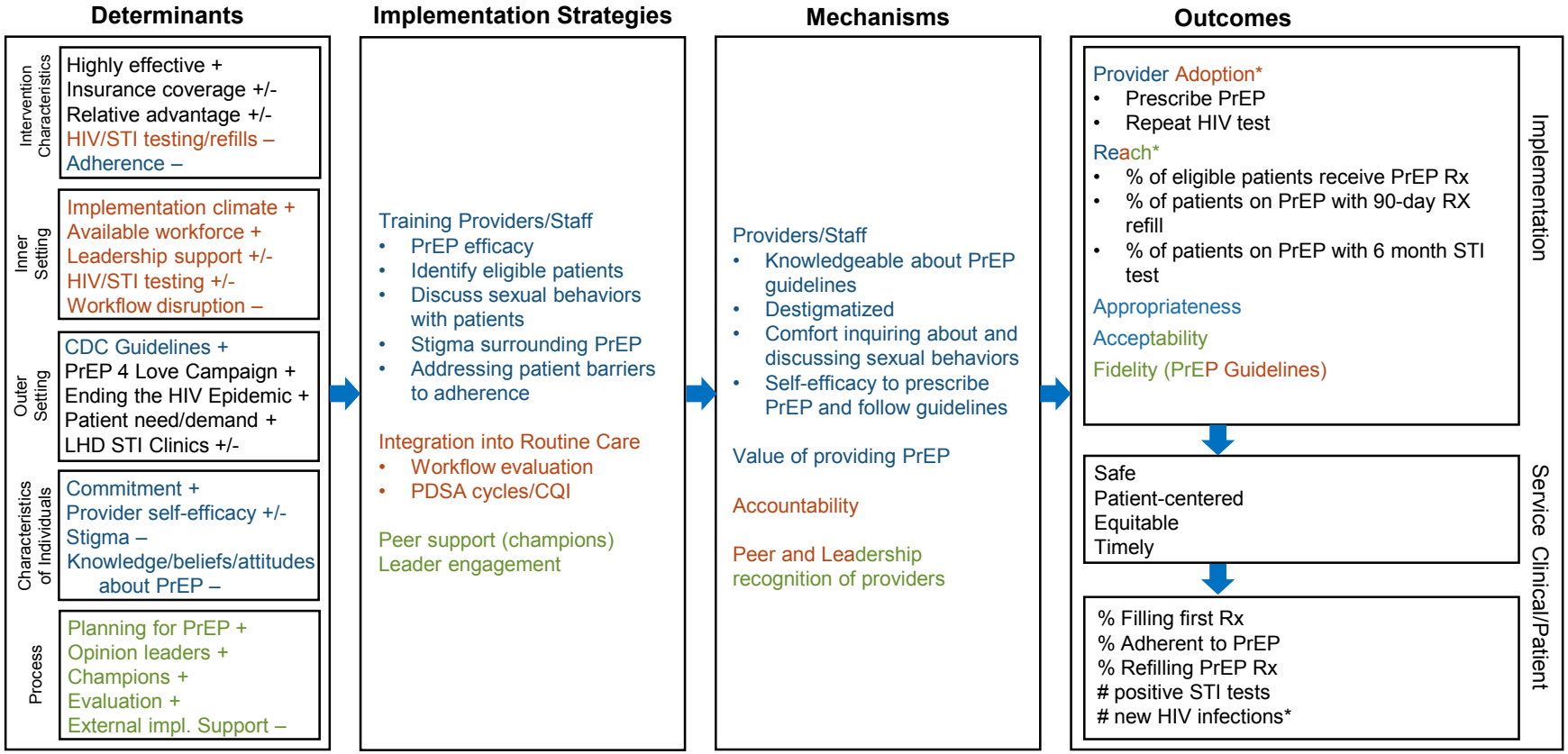
Implementation Strategies

- Training of PCPs to identify eligible patients
- Training in prescribing PrEP
- Audit and feedback (routine)

Primary Outcomes

1. PrEP prescribing (adoption)
2. Proportion of eligible patients prescribed PrEP (reach)
3. Appropriateness (PCP/patient)
4. Acceptability (PCP)
5. Feasibility (workflow etc.)
6. Cost

PrEP Implementation Project IR Logic Model



*primary outcomes

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Feedback on the IR Logic Model

- Completing the IR logic models for our project helped both study arms systematically think through the steps needed to ultimately achieve the implementation outcomes. From the researcher standpoint, delineating the mechanistic pathways between each strategy and the outcomes creates a set of hypotheses that can be further explored in the current study or tested in future research. From the practical/staff perspective, identifying relevant determinants and selecting appropriate strategies to address those determinants helped inform the development of trainings and resources needed for CBO staff (in the CBO arm) and for our own staff (in the DTC arm) to successfully implement KIU! This process, in turn, will inform how we design and scale out technical assistance for KIU! in the future.
- For our staff with limited background in IR, there was a learning curve to understand and complete the IR logic models. We found breaking it down into the smaller components/behaviors helpful for their understanding. Once trained, they agreed the exercise was useful for ensuring the comprehensiveness of their respective implementation plans.

– Brian Mustanski, PhD & Dennis Li, PhD

Concluding Thoughts

Strengths and Limitations of the IR Logic Model

- 1-2 page visual depiction of project
- Increase transparency/comprehensiveness of a complex process
- Common structure to increase consistency and transparency
- Aids in demonstrating rigor and reproducibility components
- Clearer specification of links and pathways to test theories
- Tool for academic–practice collaboration and partnership development
- Planning and tracking process over time)

- Simplified format – balance depth and detail
- May inhibit creative thinking if applied too rigidly

IR Logic Model Activity

Complete the IR Logic Model for your Project

- Work in pairs (PD and implementation partner)
- 3 sessions during this training
  - Outcomes
  - Determinants
  - Strategies & Mechanisms
- 2 worksheets/cheat sheets for quick reference
- **Goal while here:** Solid start that can be added to and refined
- Faculty will be circling to answer questions

Some Additional IR Resources

Implementation Science Trainings

Brown, Smith, Benbow, & Villamar (2016)

Basics of Implementation Science methodology with an example of its use to support diverse sexual transmitted infection (STI) clinics around the country in delivering PrEP to prevent spread of HIV infections.

Brown, Smith, & Benbow (2017)

Covers the defining characteristics of trials testing implementation, provides a basic understanding of experimental designs for implementation research, and outlines the key challenges of designing and conducting an implementation trial.

http://cepim.northwestern.edu/trainings/

The Prevention Science and Methodology Group

Mission: To reach, teach, and inspire innovations in prevention science and implementation science methodology at a national and international level.

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