Rigorous Implementation Research

The Implementation Research Logic Model and Key Design Considerations

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HEALTH
UNIVERSITY OF UTAH

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Goals

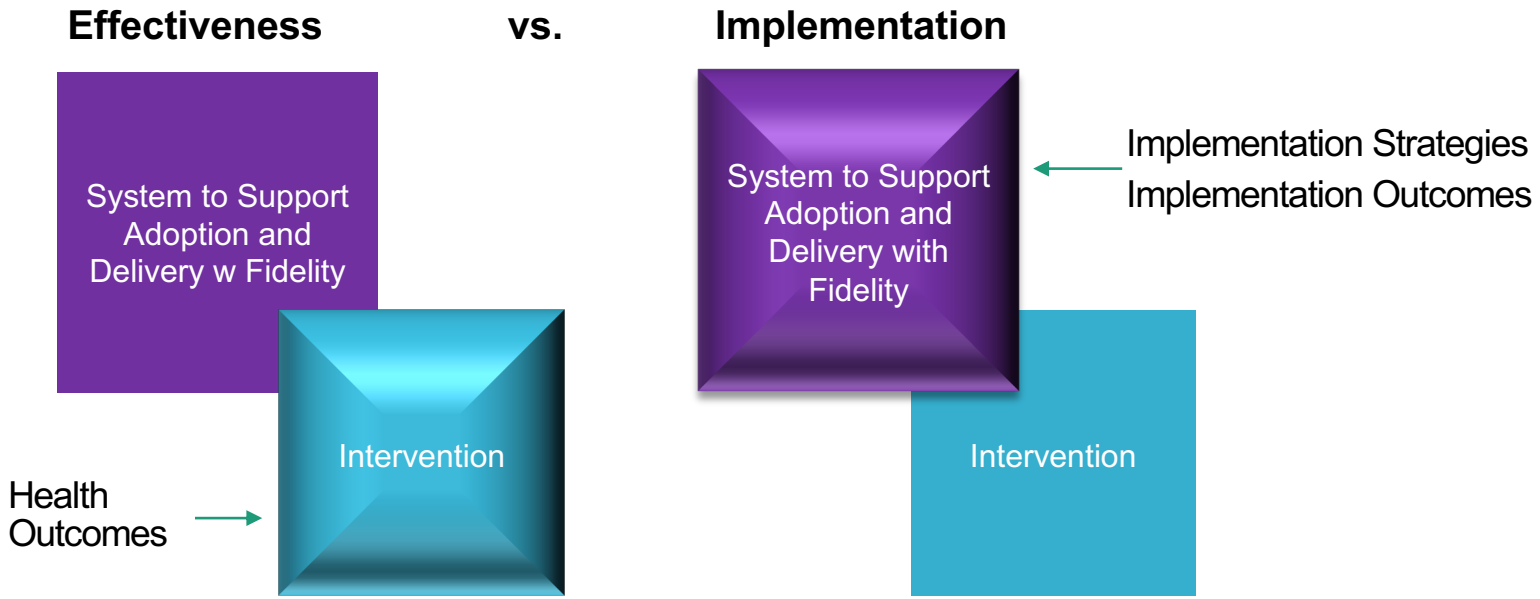
- Implementation research questions
- Designs to test implementation research questions
  - Basics of within-site, between-site, and within- and between-site designs
  - Key design considerations
  - Selecting the appropriate design
- Introduction to the Implementation Research Logic Model (IRLM)
  - Uses: Planning, Executing, Reporting, Synthesizing
  - Principles and resources for use of the IRLM

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**

Curran, 2020, *Implementation Science Communications*

Implementation Research Has a Different Emphasis Than Clinical Research



Smith & Hasan, 2020, *Psychiatry Research*

Common Implementation Research Aims

1) understand barriers and facilitators to implementation
2) adapt an EBI
3) evaluate the impact of an adapted EBI
4) select/develop/adapt implementation strategies
5) evaluate the feasibility/acceptability of strategies
6) evaluate the impact of a strategy
7) compare the impact of implementation strategies

Smith et al. 2020, *AIDS and Behavior*

Illustrations of Implementation Research Questions

- **Derived from the research-to-practice gap**
- **Implementation research should allow us to answer questions like:**
  - Is delivery of PrEP more effective when PrEP is provided within the clinic versus referring to a PrEP provider outside the clinic?
  - Under what conditions does implementation Strategy A work better, faster, more efficiently than Strategy B for getting patients on PrEP and maintaining adherence over time?
  - What contextual barriers are related to low adoption of new intervention X in Y setting?

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?

Research Question

Educate

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?

Restructure

IV

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

Other implementation outcomes that might be of interest?

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 the most effective practice for reaching PrEP eligible patients (i.e., integrated within routine care or referral to specialty STI/HIV clinics).

Designs for Implementation Research

Within-site, between-site, within- and between-site designs

Experimental/non/quasi, randomized/non-randomized

Design Terminology

- As used here, **design** refers to the planned set of procedures to
  - select subjects or larger units for study
  - assign these to or measure their naturally chosen conditions
  - assess measures before, during, and after assignment in the conduct of a study.

Hwang, Birken, Melvin, Rohweder, & Smith, 2020, *JCTS*

Community and Organizations Need to be Involved in Design Decisions and their Ownership

- Legal responsibility
- Moral responsibility
- Ethical responsibility

Key Areas

- developing and maintaining partnerships with diverse stakeholders
- recognizing under-resourced communities or other vulnerable populations have substantial historical trust concerns
- leadership is within a partnered participatory research framework
- methodological and design strategies that may apply when D&I research is conducted from a participatory, stakeholder perspective

Mensah, Cooper, Siega-Riz, Cooper, **Smith**, Brown et al. 2018, *Circulation Research*

Implementation Preparation

Implementation preparation: research in preparation for a formal evaluation or test

1) understand implementation processes and barriers/facilitators
2) explore the feasibility/acceptability of novel strategies
3) develop or tailor novel strategies
4) adapting an EBI
5) modeling that has potential to inform IR

Common Methods: field study, observational, CBPR, dynamic systems modeling, surveys, key stakeholder interviews/focus groups

Smith et al. 2019, *AIDS and Behavior*

Characteristics and Challenges of Implementation Research Trials

- External validity > internal validity
- Minimize disruptions to and burden on the systems
- Randomization occurs at “higher levels” of the service system (e.g., provider, clinic, county, etc.)
  - Often have a small number of “units”
  - Nesting within multiple levels of the system(s)
  - Interactions between levels
- Experimental Designs: The implementation strategy/strategies are manipulated (serve as the independent variable)

Hwang, Birken, Melvin, Rohweder, & Smith, 2020, *JCTS*

An Overview of Research and Evaluation Designs for Dissemination and Implementation

Annual Review of Public Health
Vol. 38:1-22 (Volume publication date March 2017)
DOI: 10.1146/annurev-publhealth-031816-044215

C. Hendricks Brown,[1] Geoffrey Curran,[2] Lawrence A. Palinkas,[3] Gregory A. Aarons,[4] Kenneth B. Wells,[5] Loretta Jones,[6] Linda M. Collins,[7] Naihua Duan,[8] Brian S. Mittman,[9] Andrea Wallace,[10] Rachel G. Tabak,[11] Lori Ducharme,[12] David A. Chambers,[13] Gila Neta,[13] Tisha Wiley,[14] John Landsverk,[15] Ken Cheung,[16] and Gracelyn Cruden[1,17]

- Within-Site Designs
  - Evaluating change within a single site
- Between-Site Designs
  - Compares outcomes between 2 or more sites
- Within- and Between-Site Designs
  - Sites Begin as One Implementation Condition and Move to Another

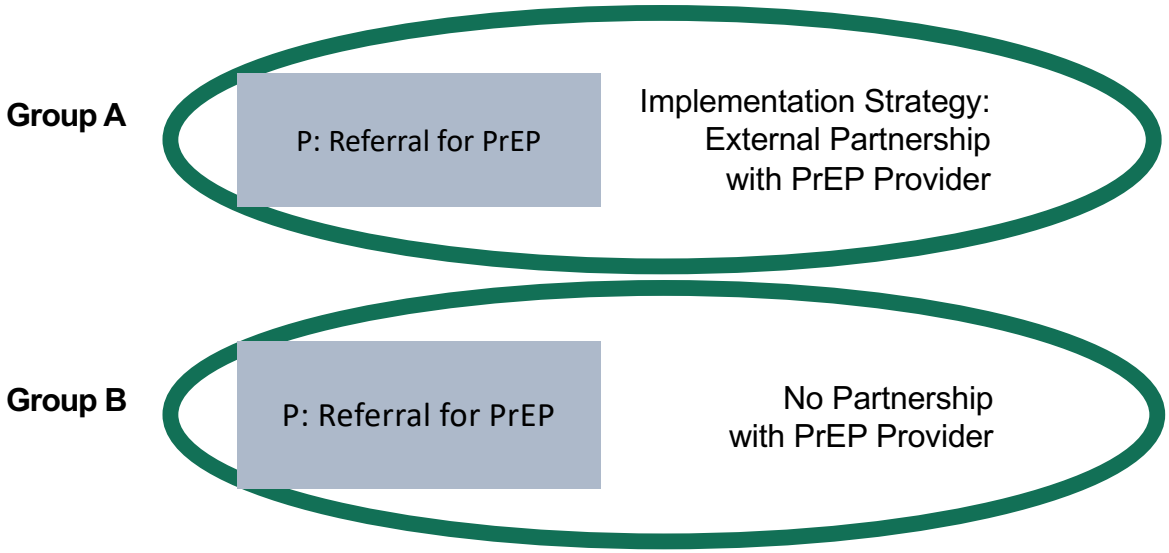
Within-Site Design Types and Definitions

- Post Design
  - Only measure implementation outputs after a new EBP is adopted
  - Common in quality improvement
- Pre-Post Design
  - Compare implementation outputs before and after a new strategy is used to deliver an EBP
- Interrupted Time-Series
  - Single unit experiments with multiple baselines
  - Single site can demonstrate feasibility and initial impact
  - Multiple sites for full evaluation
- Rarely randomized (but possible when multiple units/people)
- Simple and useful
- Best for local knowledge/QI-type questions

Between-Site Design Types and Definitions

- Novel implementation strategy vs routine practice
  - Non-Randomized or Randomized
- Head-to-Head Implementation Trial
  - Two novel implementation strategies for the same clinical/preventive intervention (7 Ps)
  - Equipoise
  - Randomization increases internal validity

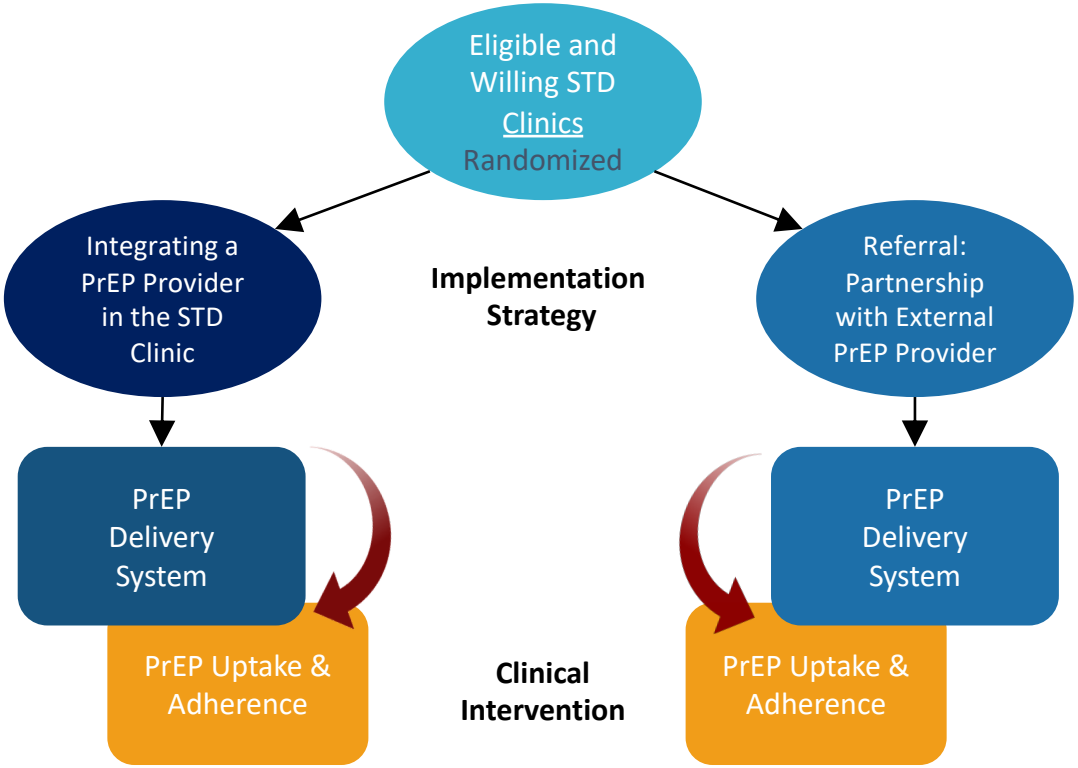
Novel Implementation Strategy vs Routine Practice using a Non-Randomized Implementation Design



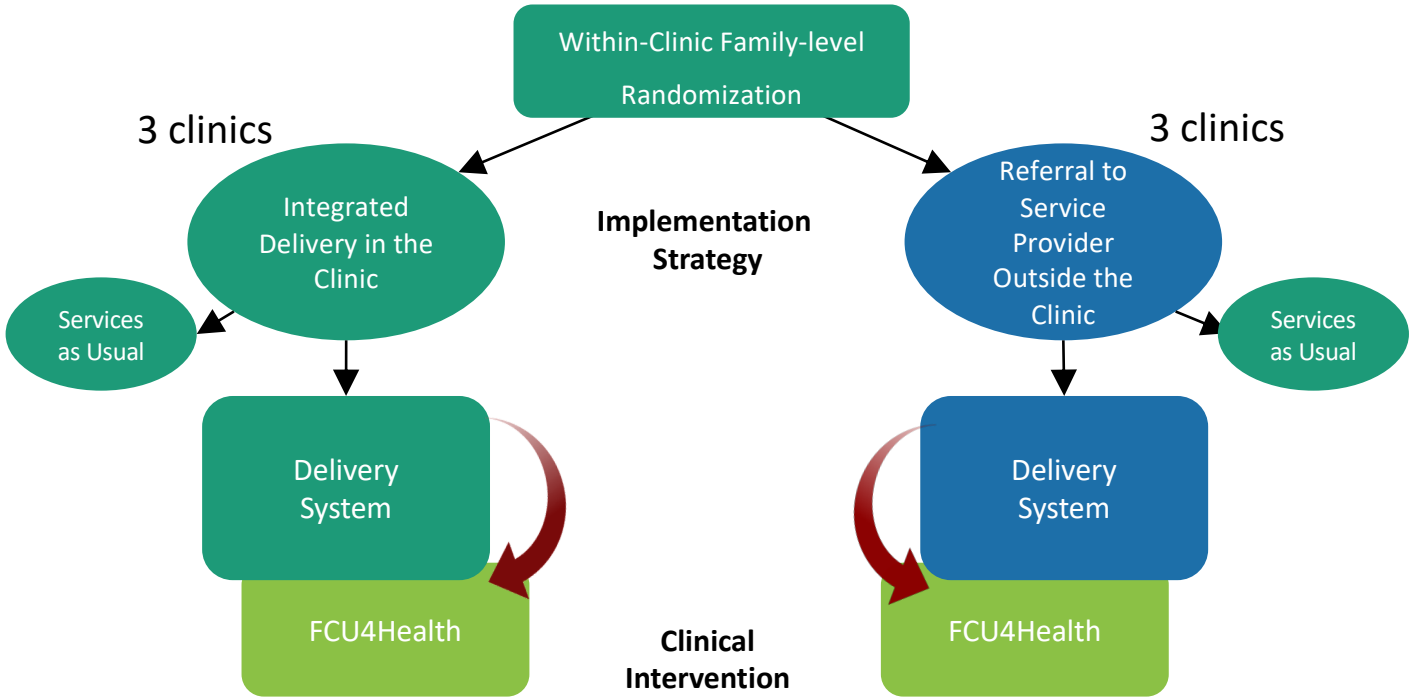
Group A determined through self-selection/readiness, selective invitation, RFA

- High potential for introduction bias due to capacity/readiness

Design for a Clinic-Level Randomized Comparative Implementation Trial



Design for a Comparative Implementation Trial
Involving Within-Arm Patient-Level Randomization



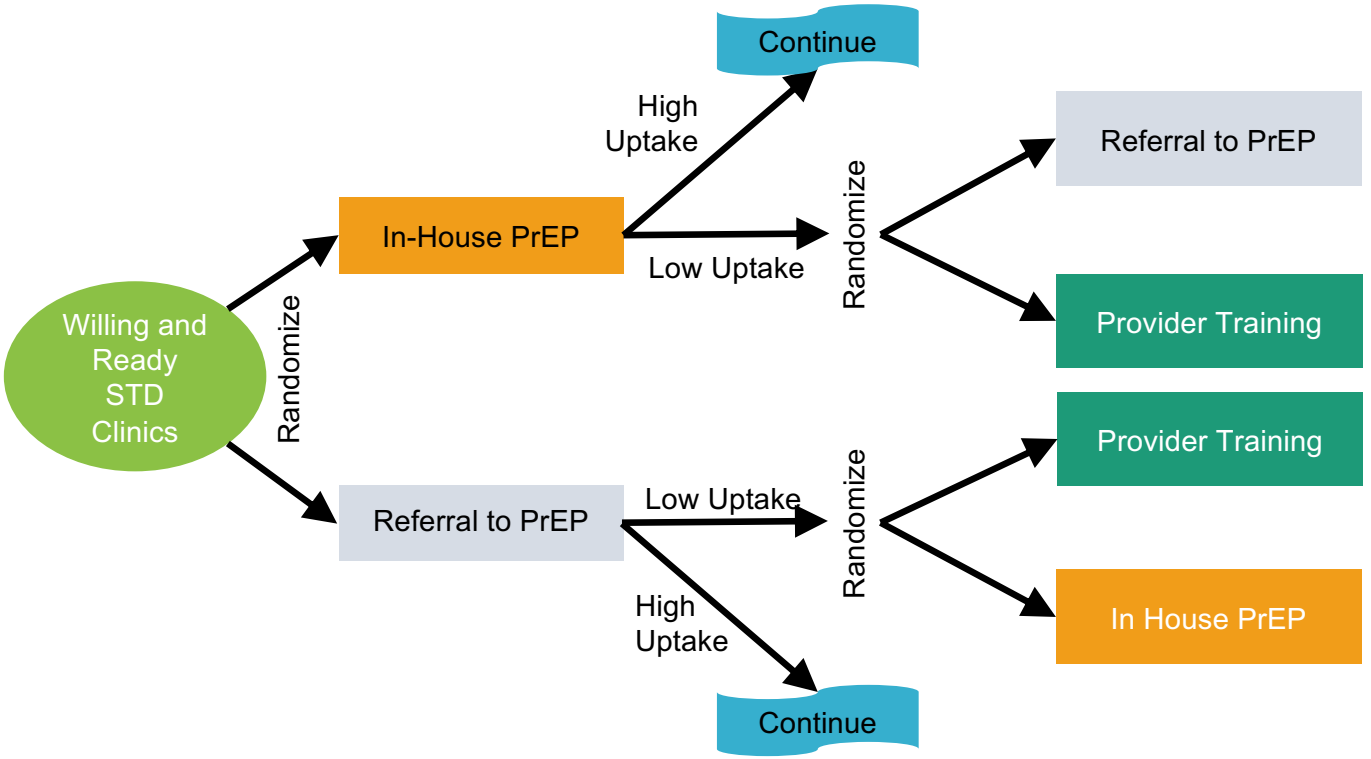
Smith et al 2018, *Implementation Science*

Testing and Optimizing Implementation Strategies: SMART Designs

- Sequential, multiple assignment, randomized trial (SMART)
- Optimization of dynamic and adaptive multicomponent implementation strategies
- SMART designs allow implementation strategies to be evaluated while responding to clinic's failure to achieve impact
  - Adapt to address differential response to implementation strategies
  - Randomization required (twice!)

Collins, et al. 2014

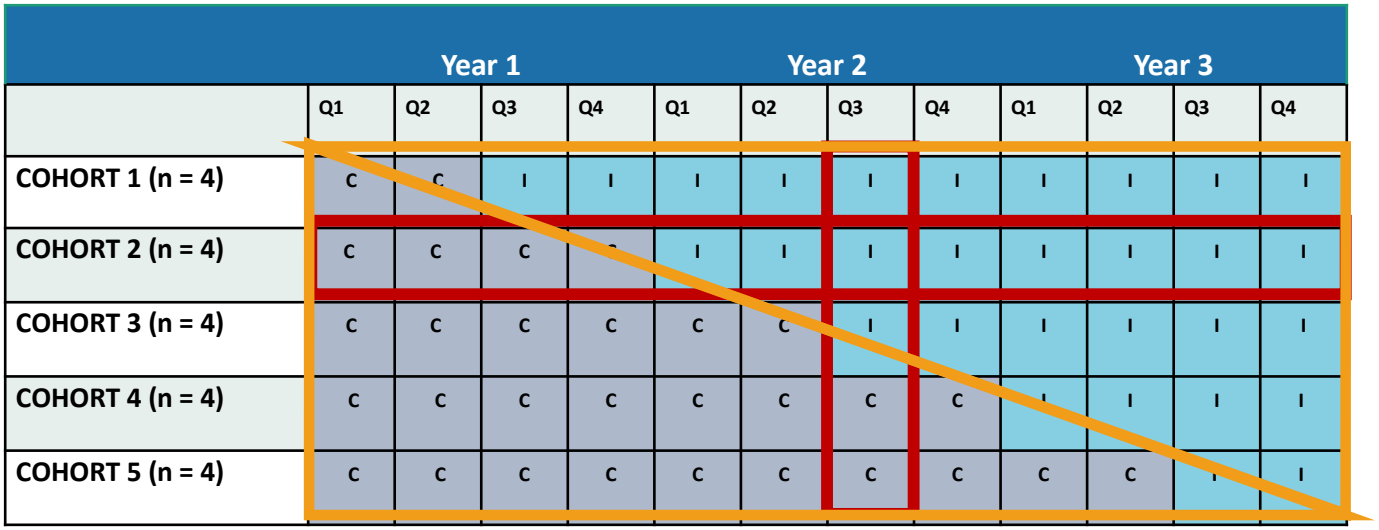
SMART Design for PrEP Implementation in STD Clinics



Within- and Between-Site Designs
Roll-Out Designs for Implementation Research

- Stepped Wedge, Dynamic Wait-List Design
- All assign units randomly to when and what implementation strategy is used
- Benefits of roll-out designs
  - Reduce the logistic demands in delivering new implementation strategies across multiple units
  - Equity (benefits for earlier and later start)
  - Beneficial to statistical power by using within and between comparisons of impacts

Randomized Stepped Wedge Implementation Trial
Comparing Two Strategies (n=20 STD clinics)



	Year 1				Year 2				Year 3			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
COHORT 1 (n = 4)	C	C	I	I	I	I	I	I	I	I	I	I
COHORT 2 (n = 4)	C	C	C	C	I	I	I	I	I	I	I	I
COHORT 3 (n = 4)	C	C	C	C	C	C	I	I	I	I	I	I
COHORT 4 (n = 4)	C	C	C	C	C	C	C	C	I	I	I	I
COHORT 5 (n = 4)	C	C	C	C	C	C	C	C	C	C	I	I

- Cohorts of 4 STD Clinics each (2 Refer to PrEP Provider, 2 provide in-house PrEP)
- Implementation staggered by 6 months for successive cohorts

Randomized Roll Out Implementation Trial Design (modified stepped wedge)

7 clinical oncology units in a single health system

	Year 1				Year 2				Year 3				Year 4				Year 5			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Cluster 1	C	C	I	I	I	I	I	I												
Cluster 2	C	C	C	C	I	I	I	I	I	I										
Cluster 3			C	C	C	C	I	I	I	I	I	I								
Cluster 4					C	C	C	C	I	I	I	I	I	I						
Cluster 5							C	C	C	C	I	I	I	I	I	I				
Cluster 6									C	C	C	C	I	I	I	I	I	I		
Cluster 7											C	C	I	I	I	I	I	I		

Smith et al. 2020, *American Society for Clinical Oncology*

Choosing a Design

- What design type is required to answer your implementation research question(s)?
  - Consider at what level in the system the primary outcome is measured (aligned with the level the strategy is targeting)
- Do you have sufficient units to answer your implementation research question(s)?
- Can you randomize the units?
- Is “implementation as usual” acceptable to your community/clinical partners?

Fundamental Challenges

- Developing a strong design that satisfies the needs and obligations of key stakeholders
  - Building and maintaining partnerships
- Sufficient statistical power
  - Smarter ways to:
    - Balance
    - Randomize
    - Analyze
- How to conduct an implementation trial

Hybrid Effectiveness-Implementation Designs

Why Hybrid Designs?

- Don't wait for "perfect" effectiveness data before moving to implementation research
- We can "backfill" effectiveness data while we test implementation strategies
- How do clinical outcomes relate to levels of adoption and fidelity?
  - How will we know this without data from "both sides"?

Curran, Landes, & **Smith**, 2019, *AcademyHealth ARM*

Remember…

- All effectiveness trials use “implementation strategies” to support the delivery of the intervention; we just usually don’t call them that…
- The are normally resource-intensive
  - Paying clinics, paying interventionists, paying for care, frequent fidelity checks and intervening when it goes south…
- We “know” that some/many the strategies used in effectiveness trials are not feasible for supporting wide-spread adoption
- BUT, we can learn from the use of those strategies during the trial!

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

- Power and level of randomization are key considerations

Curran et al. 2012; Hwang et al. 2020; Landsverk, Brown, Smith et al. 2017

What Hybrids are NOT

- Hybrids are **NOT** ”the way” that the intervention/implementation will be tested/evaluated—only tells you what you will focus on (or the relative focus between the two) and extends to what is measured
- Always accompanied by a quasi/experimental/observational trial/study design (e.g., cluster RCT, SMART)

The Implementation Research Logic Model (IRLM)

A tool for increasing rigor and reproducibility of implementation research

Smith, Li, & Rafferty, 2020, *Implementation Science*

An IR specific logic model is needed

- Integrating the necessary conceptual elements of implementation research, which often involves multiple models, frameworks, and theories, is an ongoing challenge
- Transparency, Rigor, Openness, Specification, & Reproducibility
  - Rigor—the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results
  - Improving the specification of phenomena in implementation research is necessary to inform our understanding of how implementation strategies work, for whom, under what determinant conditions, and on what implementation and clinical outcomes (Smith, Li, & Rafferty, 2020)
  - Testable way of explaining phenomena by specifying relations among variables, thus enabling prediction of outcomes (Glanz & Bishop, 2010)

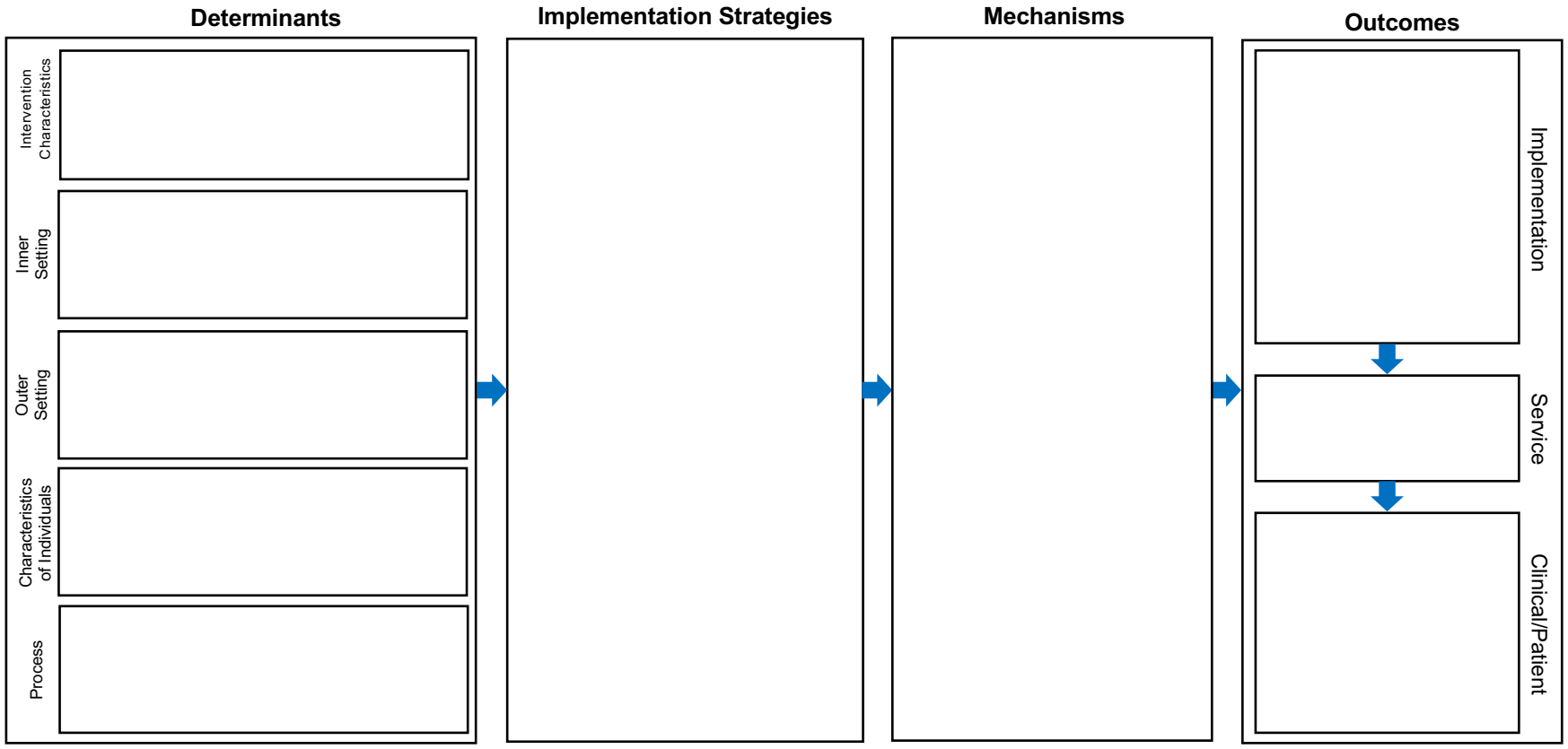
Theory and Elements of the IRLM

- Generalized theory of the IRLM :
  - (1) implementation strategies selected for a given EBP are related to the implementation determinants (context-specific barriers and facilitators)
  - (2) strategies work through specific mechanisms of action to change the context or the behaviors of those within the context
  - (3) implementation outcomes are the proximal impacts of the strategy and its mechanisms, which then relate to the clinical outcomes of the EBP
- IRLM: Aid in the specification of the relationship between foundational elements of an IR study

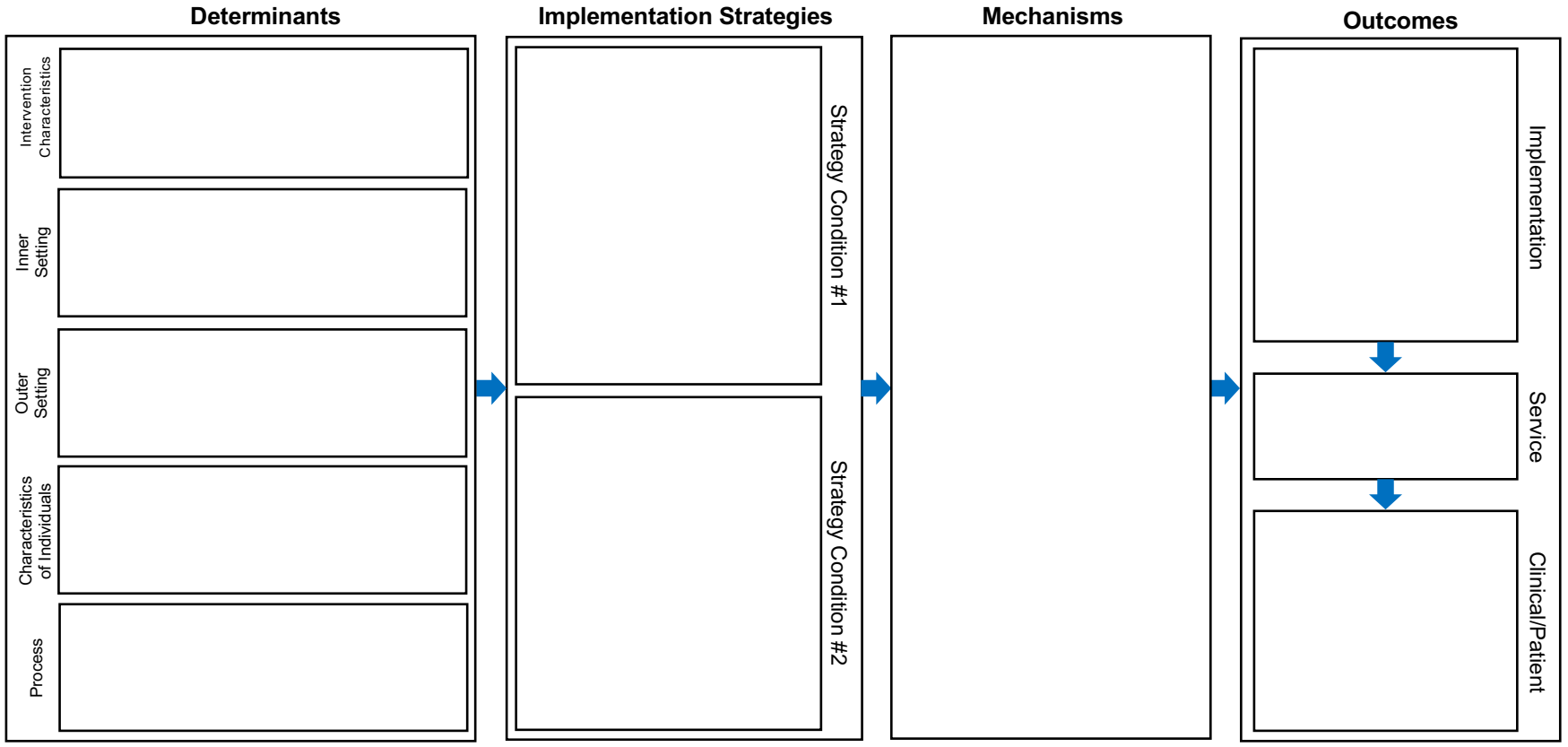
  Determinant(s) → Implementation Strategy → Mechanism of Action → Outcomes

IRLM Formats

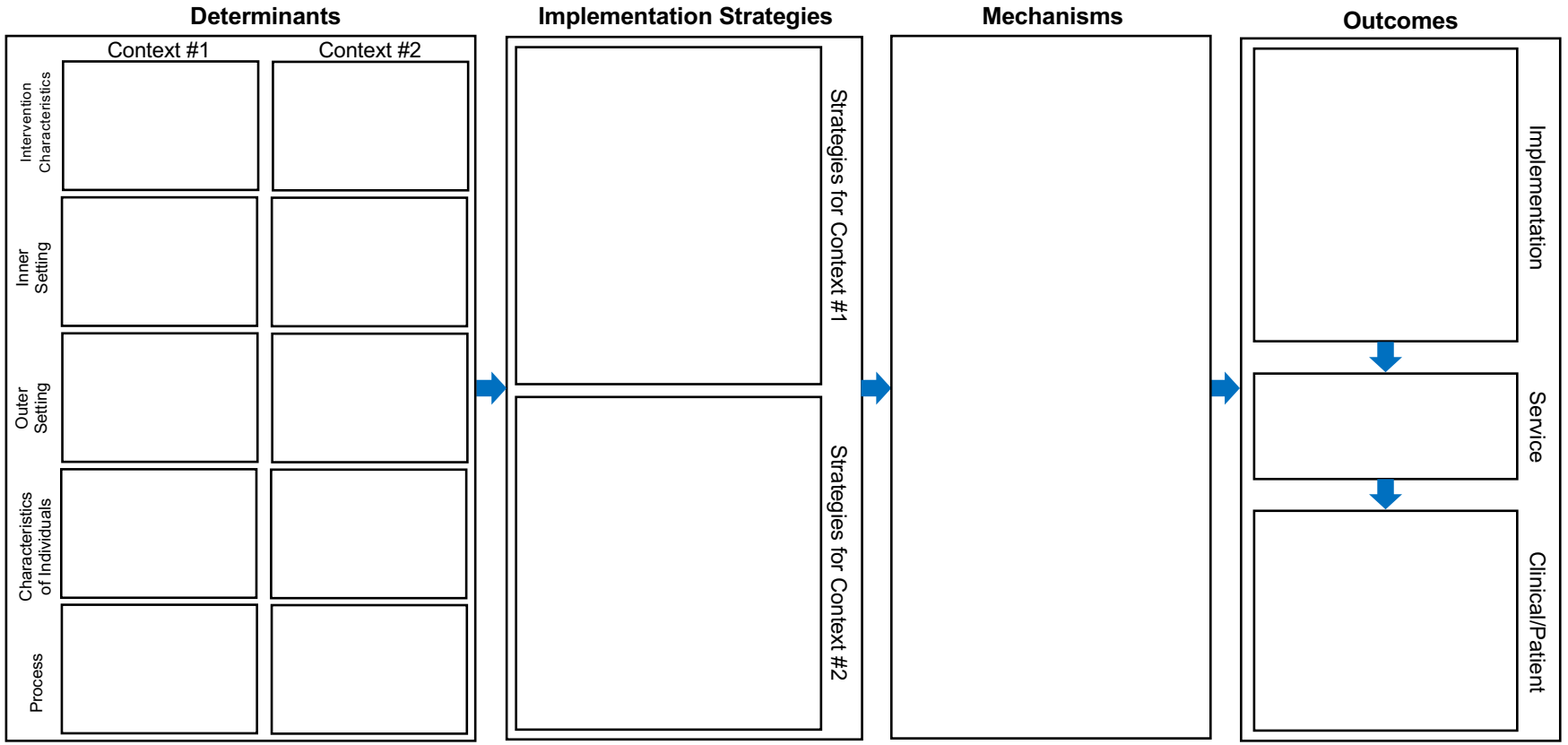
The Implementation Research Logic Model (IRLM)



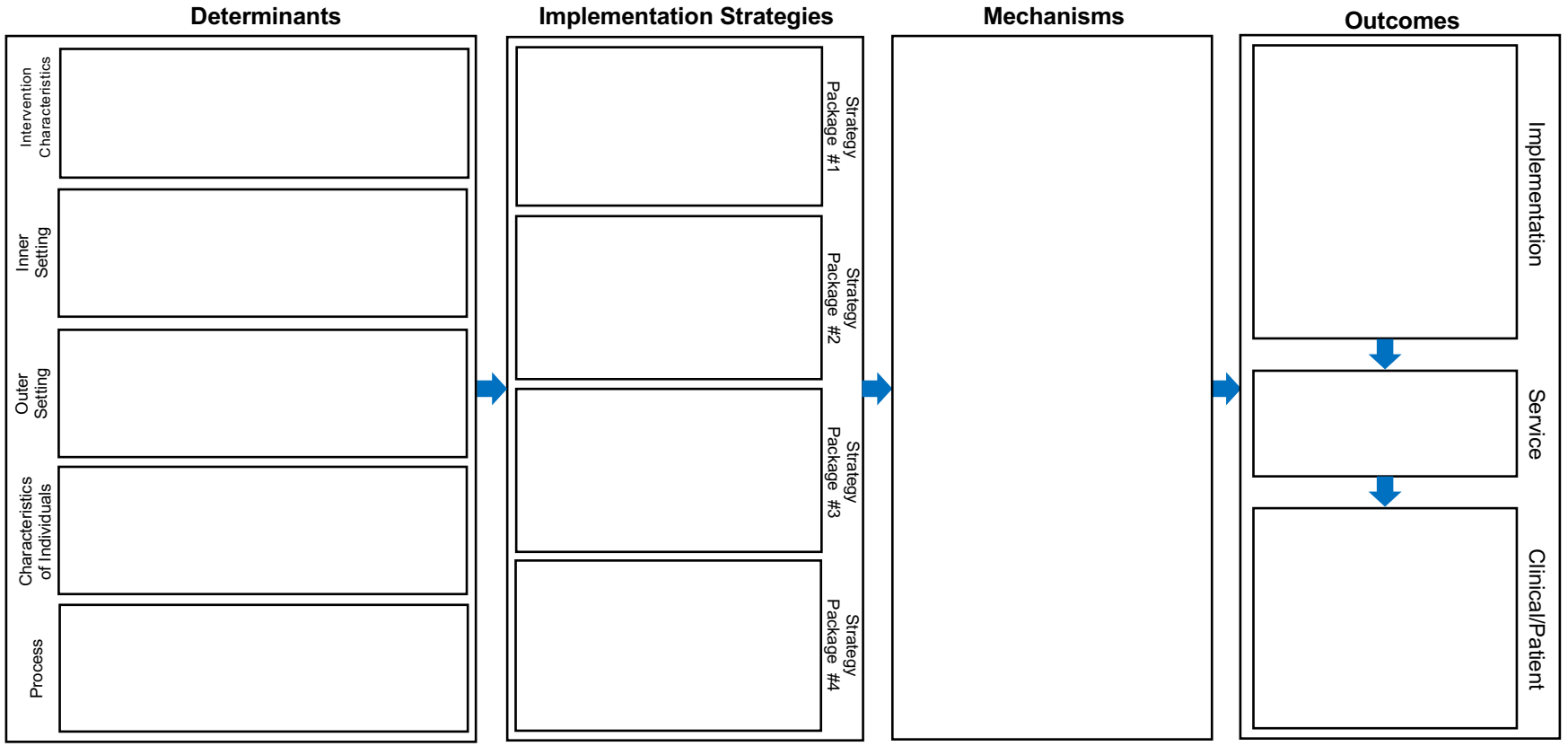
IRLM for Comparative Implementation



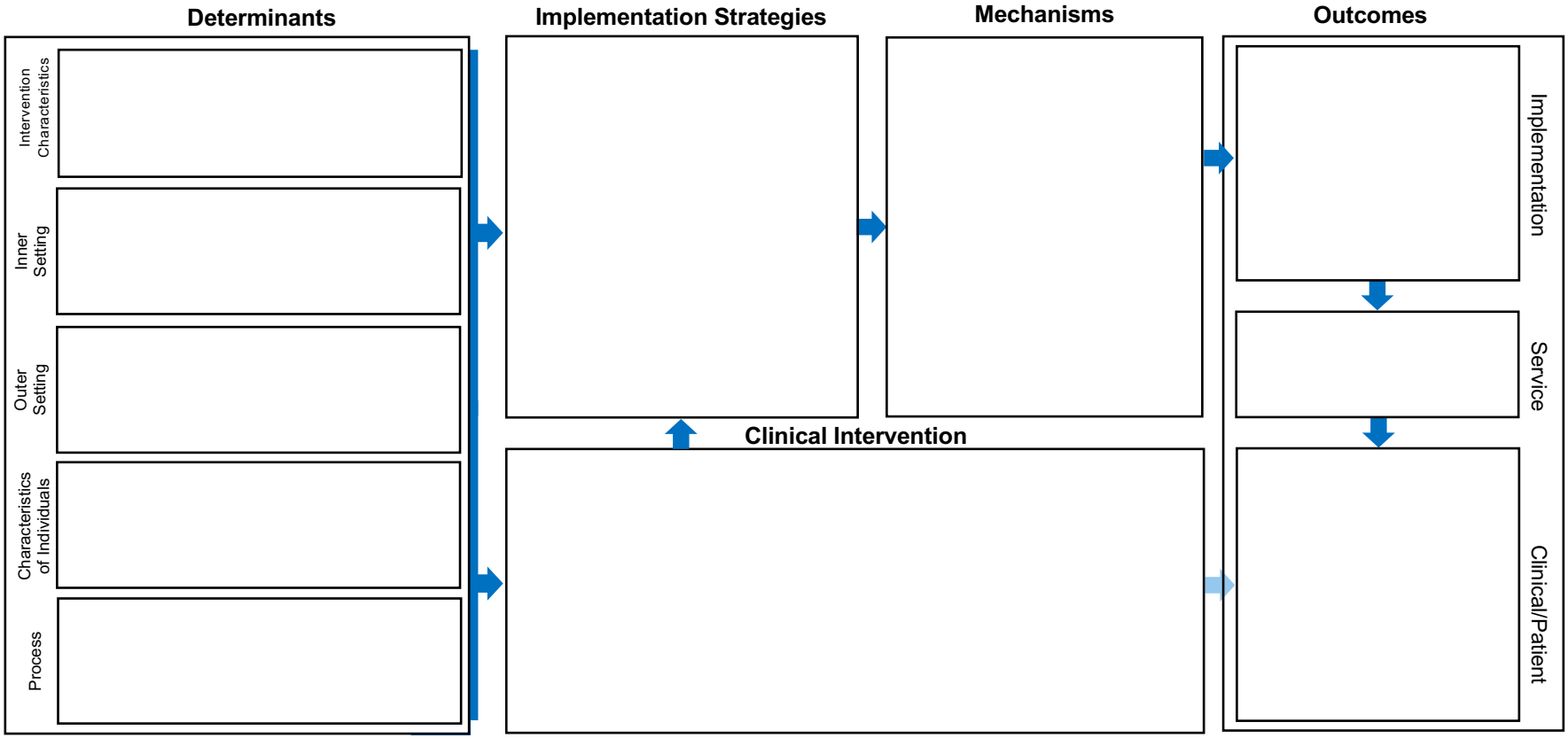
IRLM for Multi-Context Implementation of Single Intervention



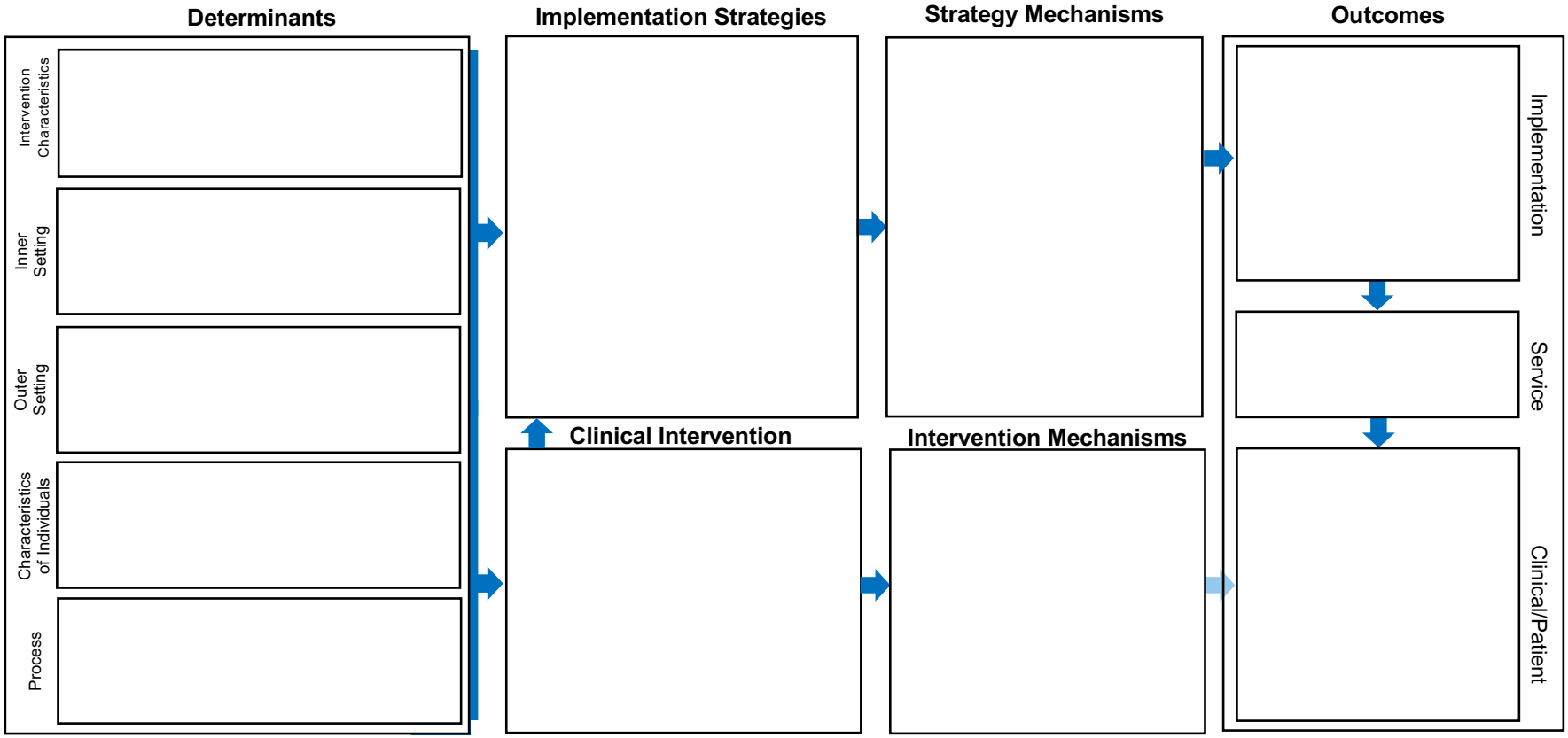
IRLM for Implementation Optimization Trial (4 clusters; 1 setting)



IRLM with Clinical Intervention



IRLM with Clinical Intervention and Intervention Mechanisms



Using the IRLM

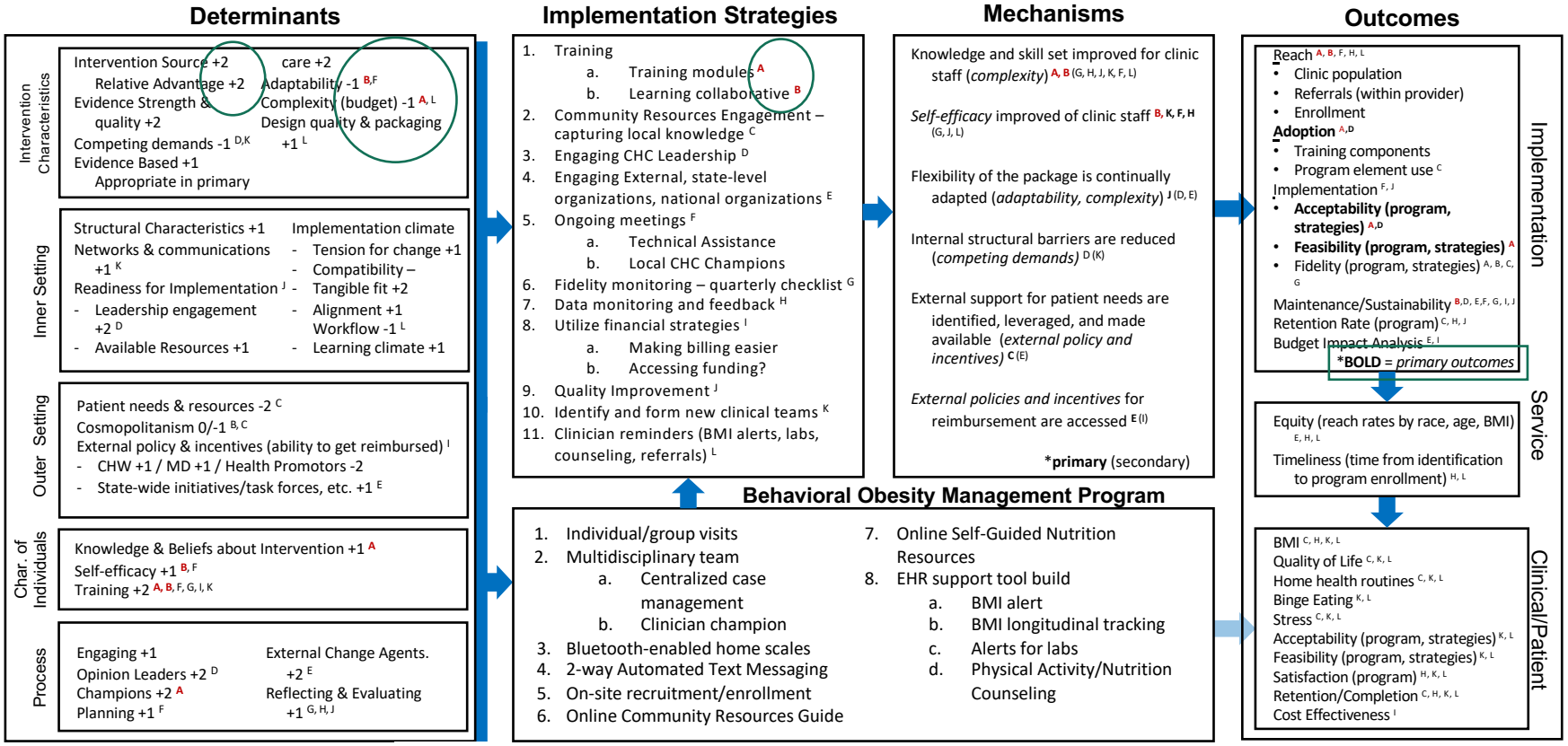
Guiding Principles

Principles-driven Approach to IRLM

- *Principle 1: Strive for Comprehensiveness*
  - All determinants, strategies, and outcomes
- *Principle 2: Indicate Key Conceptual Relationships*
  - Notations indicating relationships between elements in alignment with the specific theory of change
- *Principle 3: Specify Critical Study Design Elements*
  - Primary outcome(s), strategies in experimental condition(s), use the design-specific IRLM format

Completed Hypothetical IRLM

Obesity Management Intervention implemented in Community Health Centers (CHCs)



Supporting Text and Resources

	Text	Table	Figure
• Data re: determinants	✓	✓	✓
• Measures	✓	✓	
• Strategy specification (Proctor, Powell, & McMillen, 2013)	✓	✓	
• "Paths" supported by theory (e.g., Lewis et al. 2018)	✓	✓	✓
• Trial design description and methods	✓		✓
• Implementation plan/process model (e.g., EPIS)	✓	✓	✓

By utilizing superscripts, subscripts, color, and other notations within the IRLM, it is easy to refer to (a) hypothesized causal paths in theoretical overviews and analytic plan sections; (b) planned measures for determinants and outcomes; and (c) specific implementation strategies in text, tables, and figures.

Using the IRLM for Different Purposes and Stages of Research

Planning, Executing, Reporting, Synthesizing

- ***Planning***
  - Often begins with the known parameter(s) of the study
    - Working from the two “bookends” of the IRLM (context and outcomes often known; strategies, mechanisms, and even the EBP often are not)
  - Work with community partners and/or organization stakeholders to fill in the implementation strategies
- ***Executing***
  - Completed IRLM serves as ”protocol” and can form the basis for ongoing tracking of what occurs, what is altered, deviations, etc.
- ***Reporting***
  - Show what happened during the study; reporting of the hypothesized relationships that were observed; facilitates communication of findings
- ***Synthesizing***
  - draw conclusions for the implementation of an EBP/similar EBPs in a particular context (or across contexts) that are shared and generalizable to provide a guide for future research and implementation

Acceptability and Usability of the IRLM

Results of a Post-Training Survey of EHE Planning Project Grantees

ISC^{3}I's *Ending the HIV Epidemic* Summit

- Coordinating and technical assistance center for grantees funded under the national *EHE* plan
- 2-day in-person training in Chicago, IL, in October 2019
- *N*=132 participants from 63 projects
  - *n*=129 pre-training survey
  - *n*=66 post-training survey 6 weeks after
    - 42 investigators, 24 implementation partners; 68.2% women
    - 44.6% indicated having completed a full draft of the IRLM for their project
- 10 items related to the IRLM plus one about the general logic of implementation research
  - Rated on a 4-point scale from 1 (*not at all*) to 4 (*very much*)

IRLM was either "moderately" or "very" helpful in:

1)	**Improving the rigor and reproducibility**	**77.7%, *M*=3.05**
2)	**Serving as a "roadmap" for the project**	**74.0%, *M*=3.08**
3)	**Clearly reporting and specifying the project plan**	**67.8%, *M*=2.94**
4)	**Understanding connections between determinants, strategies, mechanisms, and outcomes**	**66.3%, *M*=2.92**
5)	**Identifying gaps in the IR logic of their project**	**64.2%, *M*=2.86**
6)	Deepening their knowledge of IR methods	62.9%, *M*=2.83
7)	Planning the project	61.3%, *M*=2.82
8)	Developing consensus and understanding of the project among diverse stakeholders involved	58.8%, *M*=2.75
9)	Identifying gaps in research questions/analyses	51.3%, *M*=2.54

Note. All *SD*s = 0.89–1.09

Additional Results

- 74.1% (*M*=3.02, *SD*=.886) said the worksheets provided during the summit were "*moderately*" or "*very*" helpful in completing the IRLM

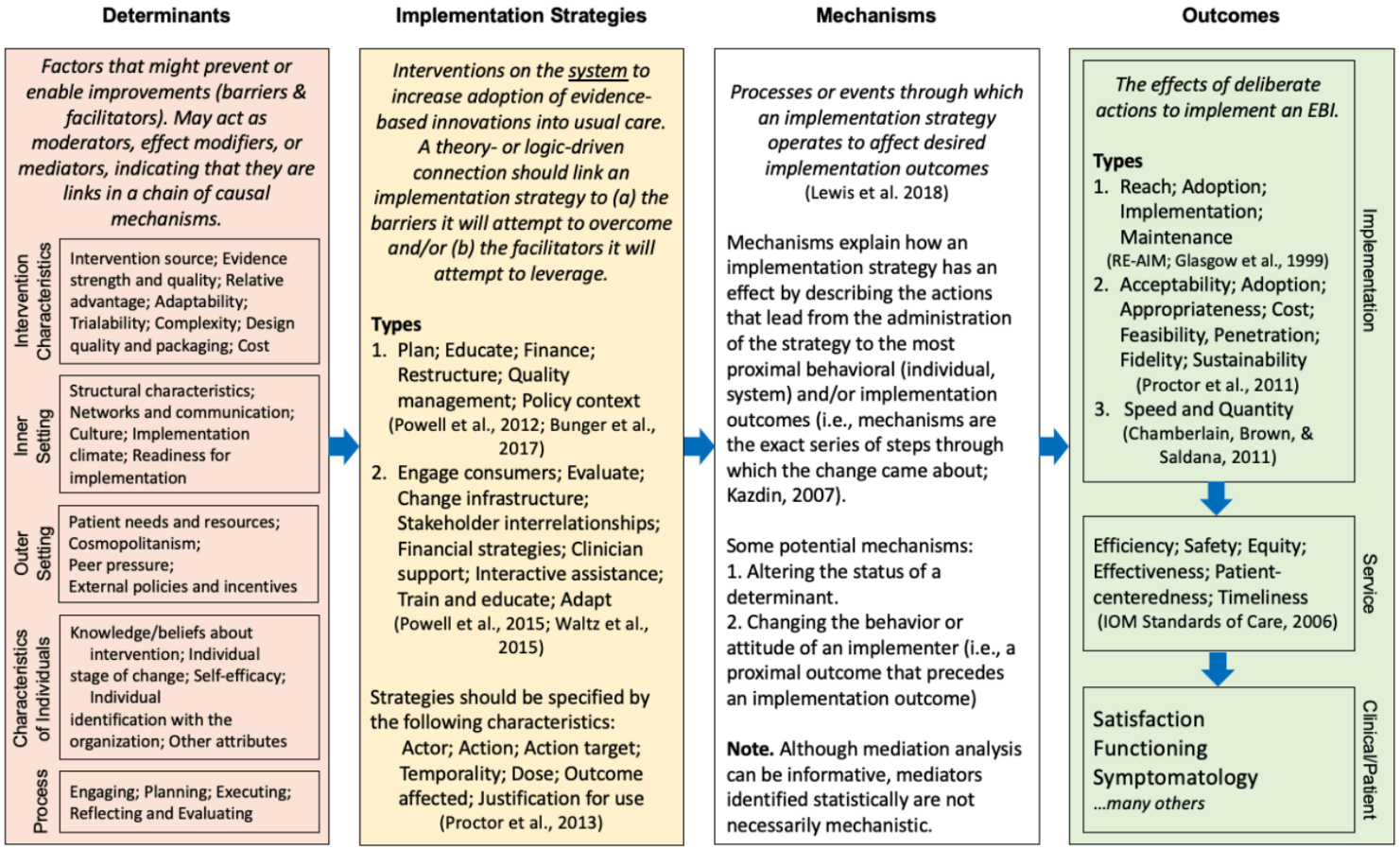
- 77.6% (*M*=3.18, *SD*=.827) said their knowledge on the logic of implementation research increased "*moderately*" or "*very much*" after the two-day training

Resources for Using the IRLM

Quick Reference Guide, Worksheets, Templates, Examples

IRLM Website

Quick Reference Guide



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Implementation Research L

IRLM — Deter

Smith, Li, & Rafferty, 2

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	Outer Setting
	Patient needs an resources
	Cosmopolitanism
	Peer pressure
	External policies incentives

	Inner Setting
	Structural character
	Networks and communication
	Culture
	Implementation clin - *Tension for char* - *Compatibility* - *Relative priority* - *Incentives & rew* - *Goals and feedb* - *Learning climate*
	Readiness for implementation - *Leadership enga* - *Available resour* - *Access to knowl*
	Characteristics of In
	Knowledge/beliefs a intervention
	Individual stage of c
	Self-efficacy
	Individual identifica with the organizatio
	Other attributes
	Process
	Engaging - *Opinion leaders* - *Formal internal implementation* - *Champions* - *External change*
	Planning
	Executing
	Reflecting and evalu

Implementation Research Logic

IRLM — Impleme

Smith, Li, & Rafferty, 2020

Implementation outcome
treatments, practices, an
success, (2) proximal indi
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v	Service outcome	
	Efficiency	A
	Safety	A
	Effectiveness	Pr re ar
	Equity	Pr as
	Patient-centeredness	Pr ne
	Timeliness	R w

3. From the list of in
to your project. F

v	Implementatio
	RE-AIM Framew
	Reach
	(Effectiveness)
	Adoption
	Implementation
	Maintenance
	Proctor et al., 2
	Acceptability
	Adoption
	Appropriateness
	Cost
	Feasibility
	Fidelity
	Penetration/Upt
	Sustainability

Implementation Research Lo

IRLM — Implen

Smith, Li, & Rafferty, 20

In implementation rese
- An evidence-based in
- An implementation i

To avoid inevitable cor

When implementing a
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1. From either taxono
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   b. A full list of
   https://impl
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v	Strategy
	Bunger et al., 2017;
	Planning
	Education
	Finance
	Restructure
	Quality manageme
	Policy

	Expert Recommendations for Implementing Change (ERIC; Powell et al., 2015; Waltz et al., 2015)	
	Use evaluative and iterative strategies	- Assess for readiness and identify barriers and facilitators - Audit and provide feedback - Develop and implement tools for quality monitoring - Conduct local need assessment - Obtain and use patients/consumers and family feedback
	Provide interactive assistance	- Facilitation - Provide local technical assistance - Provide clinical supervision - Centralize technical assistance
	Adapt and tailor to context	- Tailor strategies - Promote adaptability - Use data experts - Use data warehousing techniques
	Develop stakeholder interrelationships	- Identify and prepare champions - Organize clinician implementation team meetings - Recruit, designate, and train for leadership - Inform local opinion leaders - Build a coalition - Obtain formal commitments
	Train and educate stakeholders	- Conduct ongoing training - Provide ongoing consultation - Develop educational materials - Distribute educational materials - Use train-the-trainer strategies - Create a learning collaborative
	Support clinicians	- Facilitate relay of clinical data to providers - Remind clinicians - Develop resource sharing agreements - Revise professional roles - Create new clinical teams
	Engage consumers	- Involve patients/consumers and family members - Intervene with patients/consumers to enhance uptake and adherence - Prepare patients/consumers to be active participants - Increase demand - Use mass media
	Utilize financial strategies	- Fund and contract for the clinical innovation - Access new funding - Alter incentive/allowance structures - Make billing easier - Alter patient/consumer fees
	Change infrastructure	- Mandate change - Change record systems - Change physical structure and equipment - Change service sites

IRLM Website

https://cepim.northwestern.edu/implementationresearchlogicmodel/

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Thank you!

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