Synthetic Example of Implementation Research in HIV

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Center for Prevention Implementation Methodology
FOR DRUG ABUSE AND HIV

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Purpose

- Demonstrate application of implementation research frameworks/ models/theories, metrics, and research designs to HIV-related implementation studies

Research Questions, Hypotheses, Specific Aims

Selection and application of Frameworks/Models/Theories
How to determine (research designs) and rigorously evaluate the impact of implementation strategies

Setting the Stage

- Frameworks, models, and theories guide the implementation process, inform the selection of outcomes to measure, and help the implementer/researcher anticipate and proactively address barriers through implementation strategies.
- Implementation strategies are manipulations to the system to support adoption, implementation, and institutionalization of new innovations.
- Implementation can be rigorously evaluated through use of rigorous research designs and the use of appropriate outcome metrics.

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

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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.

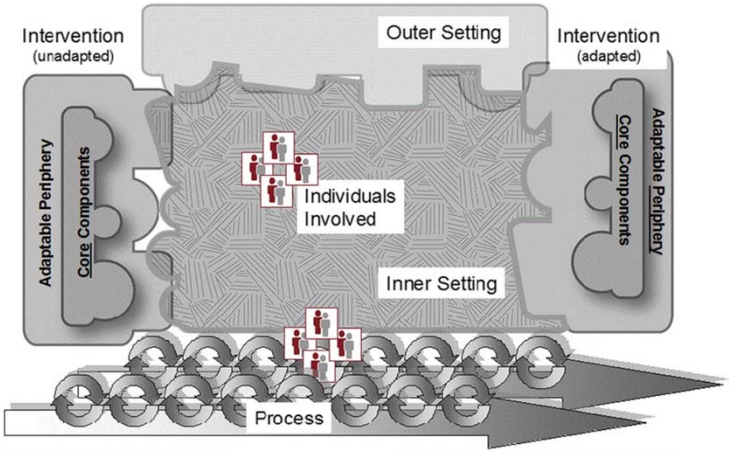
H_2: Improving leadership support of provider delivery of PrEP will improve rates of adoption.

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

Hypothesis 1

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

Determinants Framework



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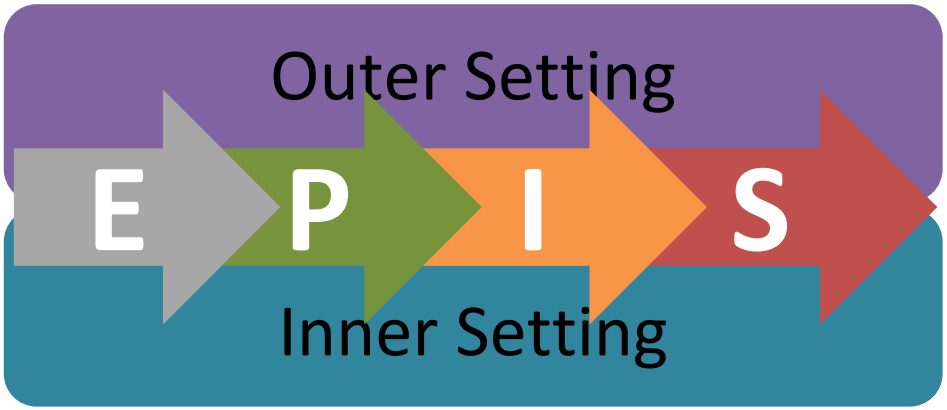
Hypothesis 1

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

Process Model



Exploration, Preparation, Implementation, Sustainment

Hypothesis 2

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

Theory

Hypothesis 3

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

… lead to provider adoption and to reaching more eligible patients…

Evaluation Framework

Acceptability
Feasibility
Appropriateness

Metrics

Adoption: Providers' prescribing PrEP

Reach: Proportion of eligible patient's prescribed PrEP

Acceptability: Providers' perspective

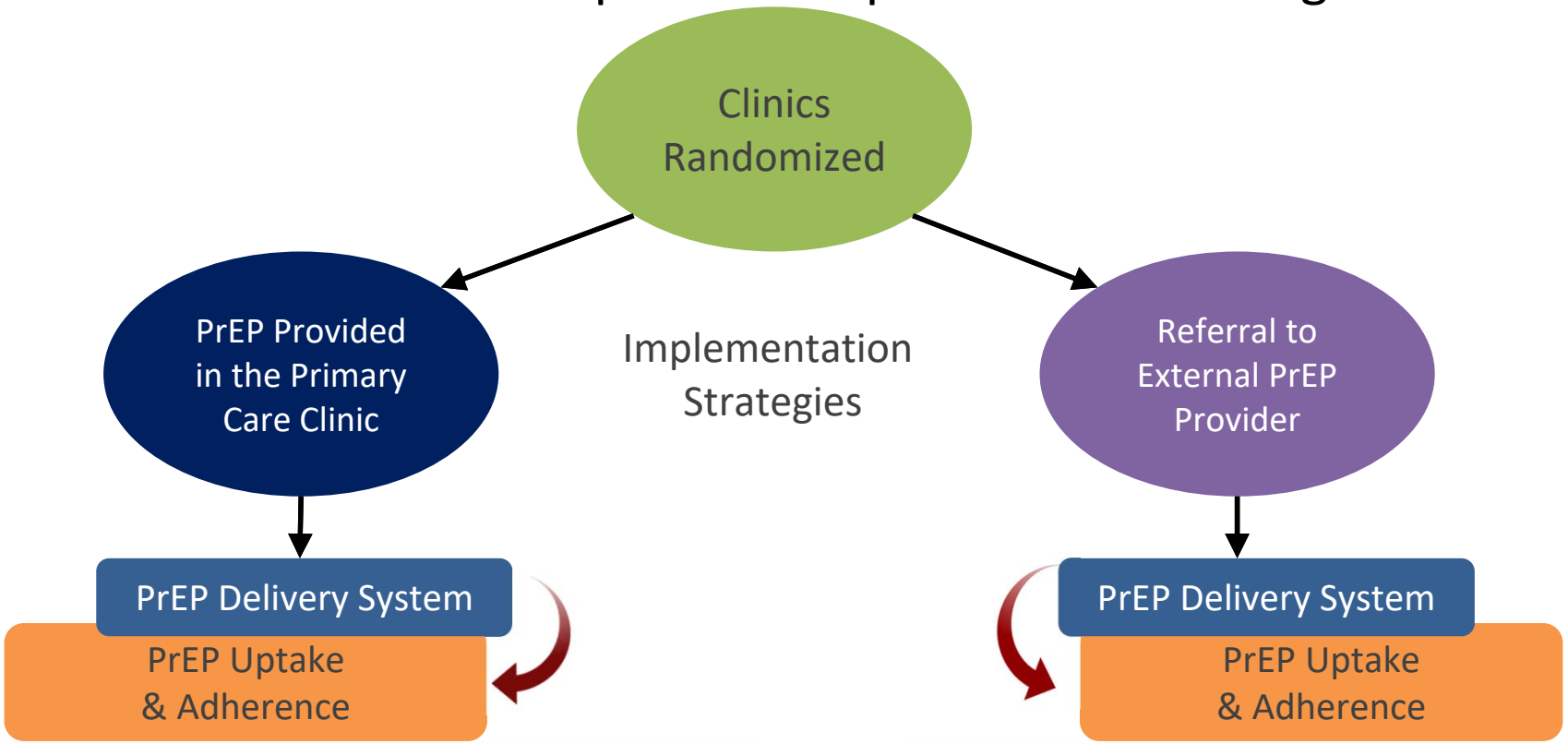
Appropriateness: Provider and patient perspectives

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?

Trial Design 1

Between-site comparative implementation design



Trial Design 2

Randomized Roll Out Implementation Trial

(n=28 Clinics, 4 clusters, 7 clinics each)

	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		

Trial Design 3

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

Take Homes

- Research question(s), specific aims, and hypotheses drive the selection of:
  - Which and what type of framework, model, or theory
  - Inform the evaluation and process plan
  - Research design and metrics
  - Example: Smith & Polaha (2017, *Families, Systems & Health*)
- Patient outcomes?
  - None in true IR studies
  - Hybrid Effectiveness-Implementation trials collect both simultaneously

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Thank you!

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