Northwestern

Implementation Science

An Introductory Workshop for Researchers, Clinicians, Policy Makers and Community Members

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COMMUNITY | SERVICE DELIVERY | RESEARCH

Center for Prevention Implementation Methodology
FOR DRUG ABUSE AND HIV

NIDA: Center for Prevention Implementation Methodology for Drug Abuse and HIV Ce-PIM (P30DA027828, Brown, Mustanski PD)

NIDA: Measuring Sustainment in Prevention Programs and Initiatives (R34DA037516, Palinkas PI)

NIAID: Third Coast Center for AIDS Research (P30AI117943, D'Aquila, Moskowitz, Bouris PD)

NIMH: PrEP Implementation Science Research to Inform an Integrated Public Health Model for Biomedical HIV Prevention (Supplement, Greene PI)

NCATS: Northwestern CTSA (NUCATS; UL1TR001422, Lloyd-Jones PI)

Third Coast CFAR
Center for AIDS Research in Chicago

Institute for Sexual and Gender Minority Health and Wellbeing

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Northwestern Medicine
Feinberg School of Medicine
Institute for Public Health and Medicine

Center for Prevention Implementation Methodology for Drug Abuse and HIV

CCHE
The Chicago Center for HIV Elimination

Northwestern University
NUCATS
Clinical and Translational Sciences Institute

Workshop Outline

A. Introduction to Implementation Science
   - PrEP: Example of a Single Intervention to Prevent HIV Infection
   - Motivation, Definitions, and Systems Orientation

B. Implementation Science Methods
   - Frameworks, Strategies, Measures, Testing
   - Example: PrEP in an STD Clinic

C. Partnerships for Implementation Research
   - 5 Core Steps
   - Example: PrEP Implementation in multiple STD clinics in a large urban area

PrEP
Example of an Evidence-Based Practice

Nanette Benbow, MAS

and

Introduction to Implementation Science

C. Hendricks Brown, PhD

Introduction Outline

1. Pre-Exposure Prophylaxis (PrEP) to prevent HIV infection Background

2. Motivation, Definitions, and Systems Orientation

3. Core Takeaways

What is PrEP?

- Pre-Exposure Prophylaxis

- When **taken consistently**, PrEP has been shown to reduce the risk of HIV infection in high-risk populations by up to 92%. PrEP is much less effective if it is not taken consistently

Who should take PrEP?

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)**
  - 1 in 4 MSM
- **Adult heterosexually active men and women**
  - 1 in 200
- **Adult injection drug users (IDU)**
  - 1 in 5 IDU

Note: When guidelines were released, data on efficacy and safety of PrEP among adolescents were insufficient and thus did not make a recommendation for this population

https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf

How should PrEP be delivered?

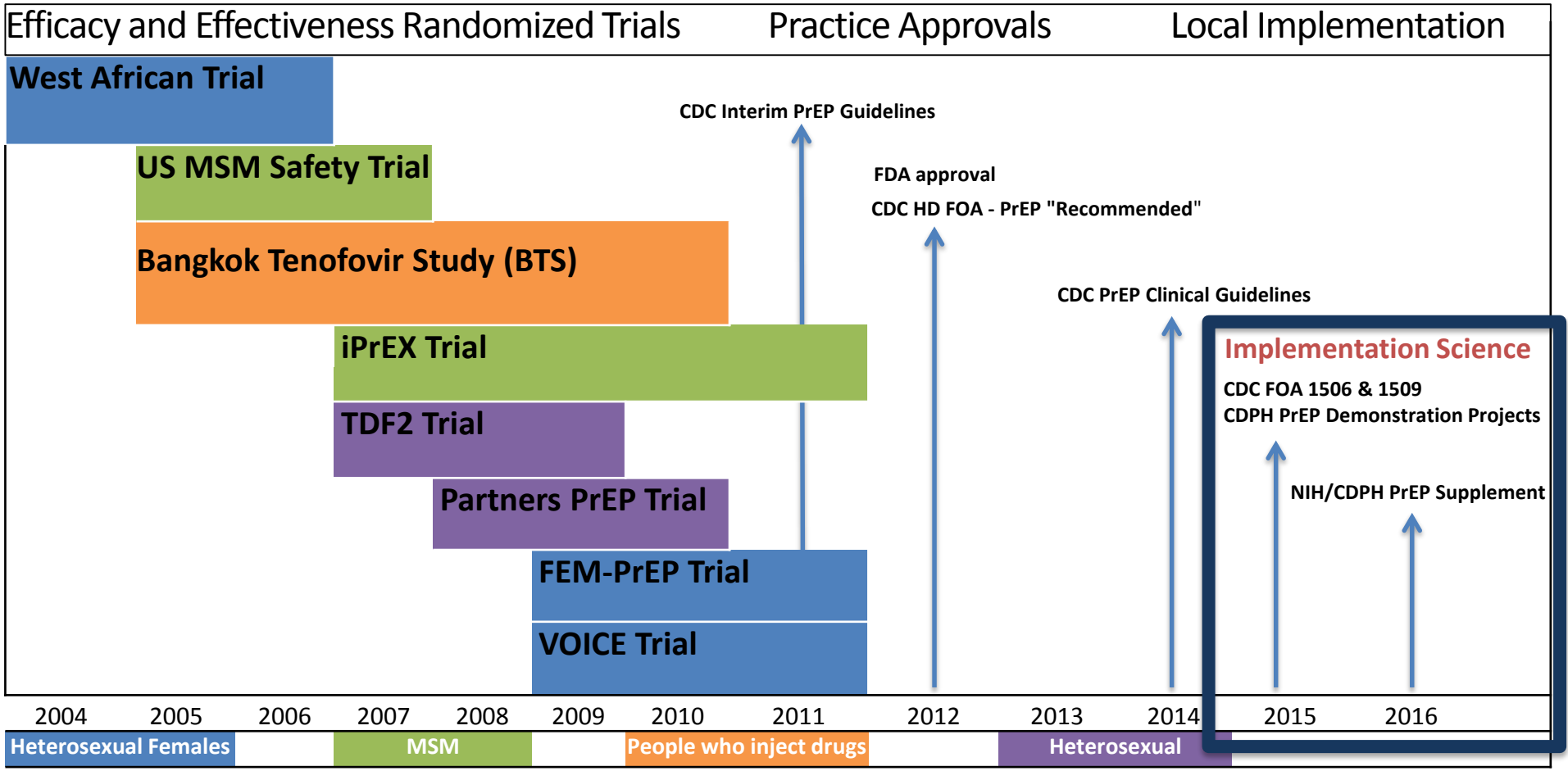
Patients on PrEP must be HIV negative in order to initiate PrEP and should be seen as follows:

- Every 3 months to:
  - **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

- At least every 6 months to:
  - Assess renal failure (monitoring eCrCl)
  - Conduct STI testing recommended for sexually active adolescents and adults (i.e. syphilis, gonorrhea, chlamydia)

https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf

Pre-Exposure Prophylaxis (PrEP) Research-> Practice Timeline 2004 - 2016



As of November 2016, there are currently 45 on-going (N=30) and planned (N=15) Open Label Demonstration and Implementation Projects (a total of 6 are in the U.S.). The populations of focus include: MSM (18 projects); Adolescents (13), female sex workers (6); transgender women (5); and heterosexuals (4).

Source: AVAC, www.avac.org/pxrd.

Settings for PrEP Implementation

- PrEP implementation can take place at various levels:
  - Nationally through partnerships between national funders, state and local public health departments, associations, advocacy groups, and policy experts
  - City or statewide through public health departments, community advocates and provider partnerships
  - Clinic-based (e.g. **STD clinics**, family planning clinics, HIV primary care, FQHCs)

PrEP Implementation Readiness in Local Health Departments (LHD) (1)

Assessment of LHD Engagement in PrEP

- 500 LHDs sampled in 2015; 284 respondents
- 109 LHDs (38%) currently engaged in PrEP implementation, 62% not yet
  - Higher among LHDs serving a large population size (67%)
  - 53% anticipate that the HD will expand its level of engagement in PrEP
- Among LHDs not currently engaged in PrEP implementation:
  - 18% expect to become engaged over the next 4 years
  - **36% report that it is unlikely they will become engaged**
  - 46% are undecided

Weiss, 2015 and 2016

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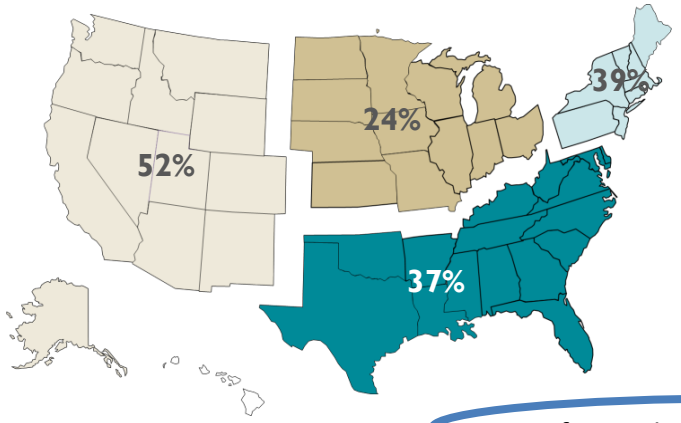
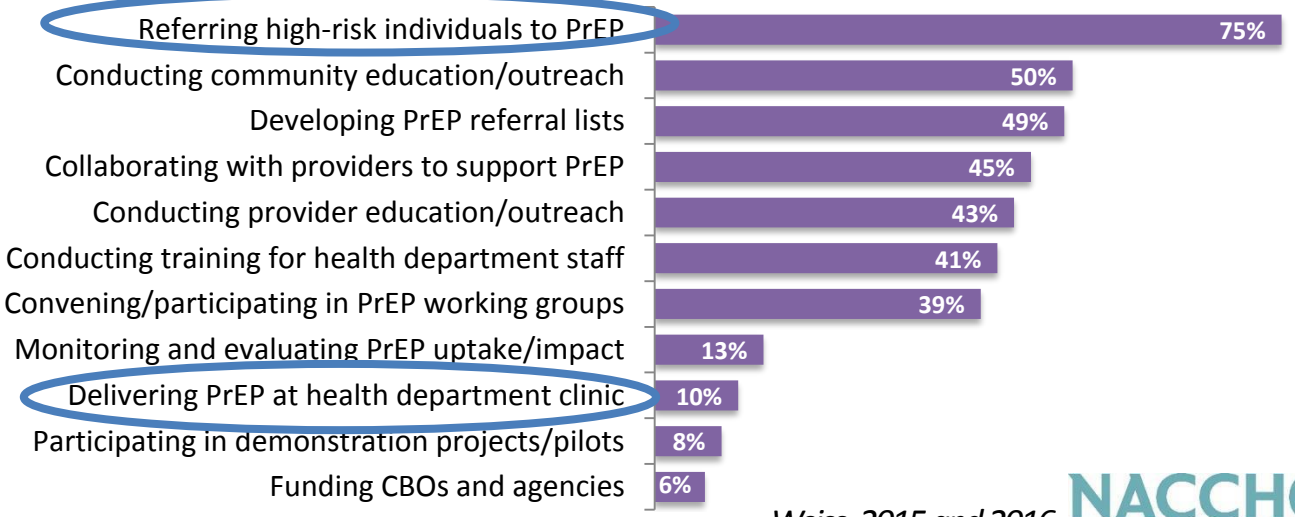
PrEP Implementation Readiness in Local Health Departments (LHD) (2)

Among LHD currently engaged in PrEP implementation





Weiss, 2015 and 2016

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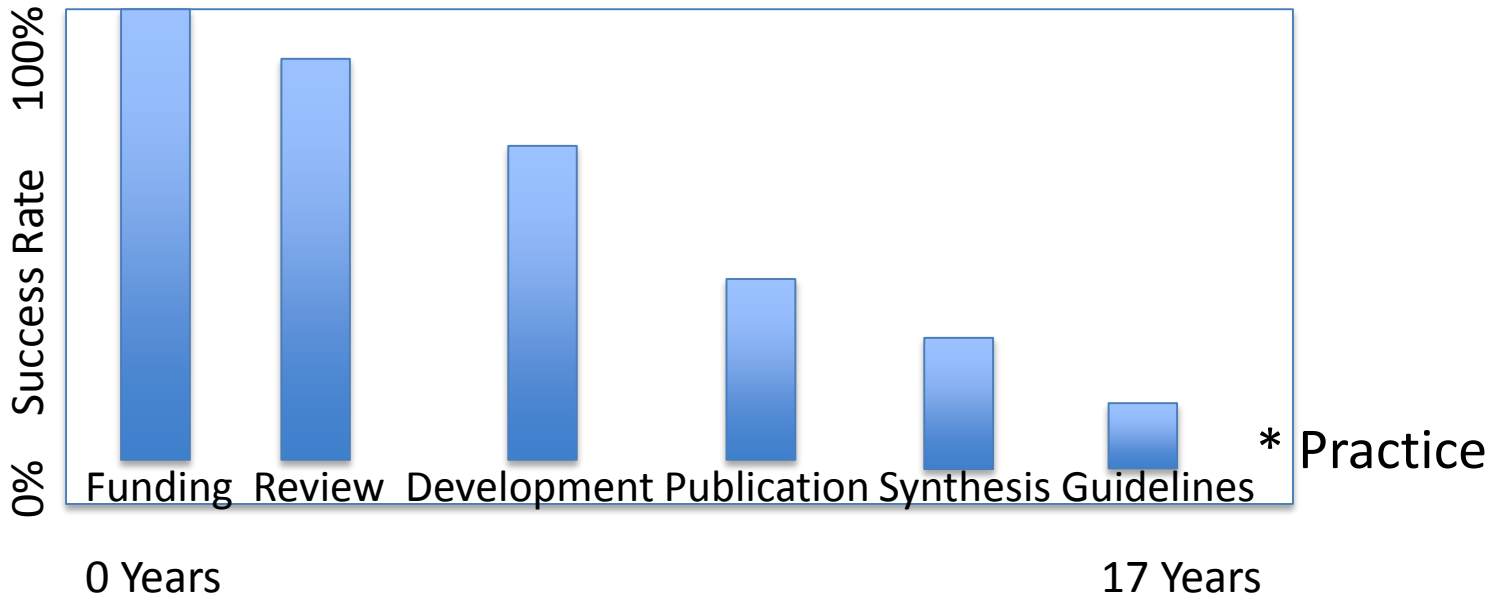
Introducing Implementation Science – Where we are headed today

- What, not How, to do Implementation Science
- References to key material

Motivation:
Closing the Gap between What We "Know" Works and What We Do

"17 Year Gap" in Health Care, 14% of original research benefits patients' care" Bales & Borman, 2000



Motivation

- **Translational Issues:**
  - 14% of Interventions succeed
  - 17 Years to move into practice
- **Implementation Issues:**
  - Currently 38% of LHDs providing PrEP
  - Currently 3% of the eligible 1.2M are taking PrEP

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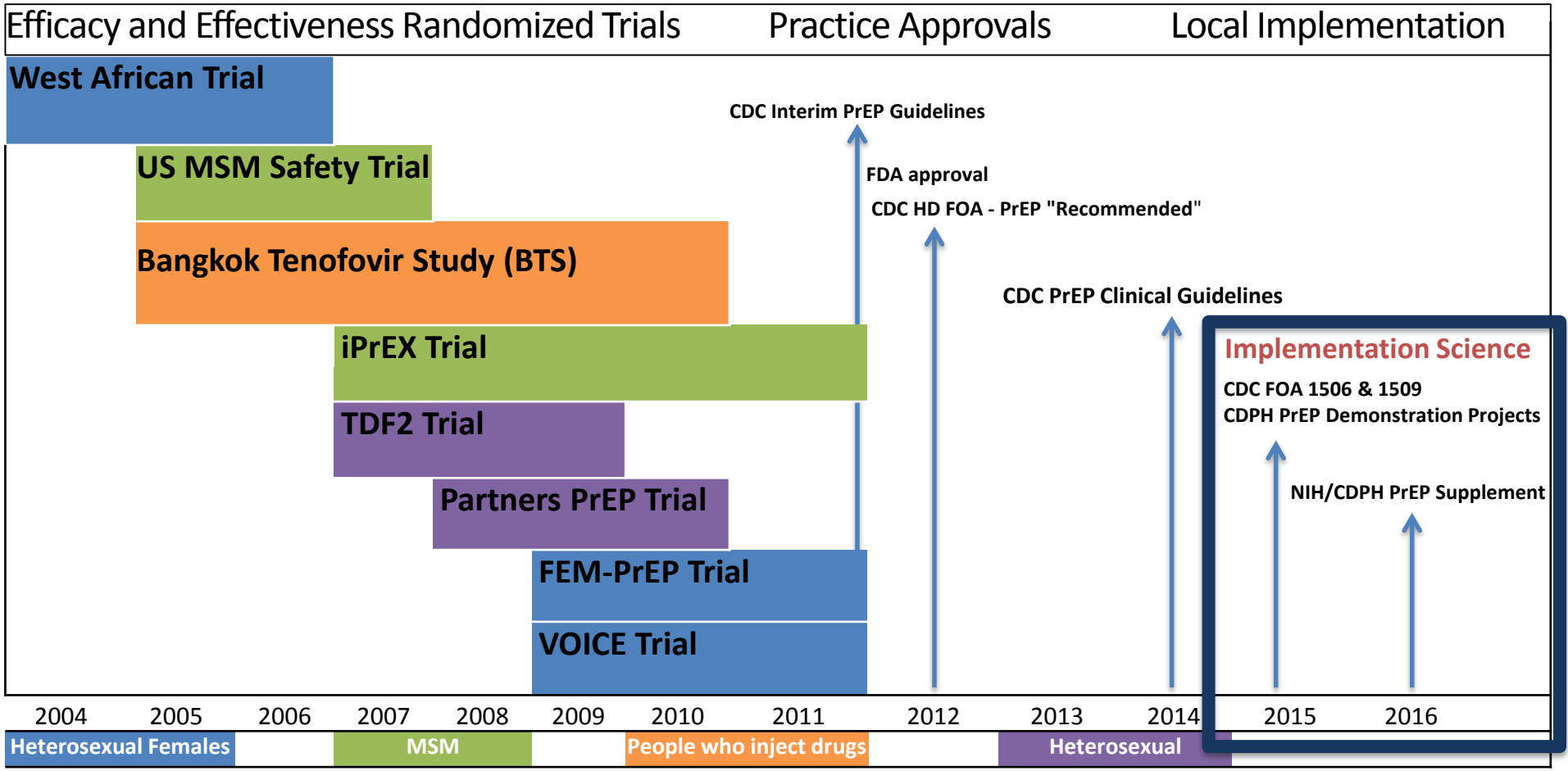

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Terminology for Implementation
(NIH Definitions)

- **Implementation Science** is the study of methods to promote the integration of research findings and evidence into healthcare policy and practice
  - **Methods: Frameworks, Measurement, Modeling, Testing**

- **Implementation Science** Produces Generalizable Knowledge

- **Implementation Practice** Produces Local Knowledge

- **Implementation research** is the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings to improve patient outcomes and benefit populations

- **Implementation research studies should allow us to answer questions like** Is delivery of PrEP more effective under Strategy A (PrEP provided within the clinic) vs. Strategy B (Referral to a PrEP service provider outside the clinic)?

Interventions vs. 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 all people living with HIV)
  - Procedures (male circumcision)

- System-Level **Strategy** for Implementing the Clinical/Preventive Intervention
  - Logic Model
  - Feedback Mechanisms
  - 9 Broad Categories (Waltz et al., 2015)

Brown et al., in press

Three Interacting and Evolving Components of Implementation

1. **Intervention: 7 P's**

2. **Practice Setting/Context:**
   - Delivery Support System
     - Implementation Readiness

3. **Macro Level Ecological System:**
   - Population HIV viral load
   - Policies on PrEP access

Chambers et al., 2013

The Delivery System Matters in Implementation

"The use of effective interventions without 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

PrEP Implementation Readiness in Local Health Departments (LHD)

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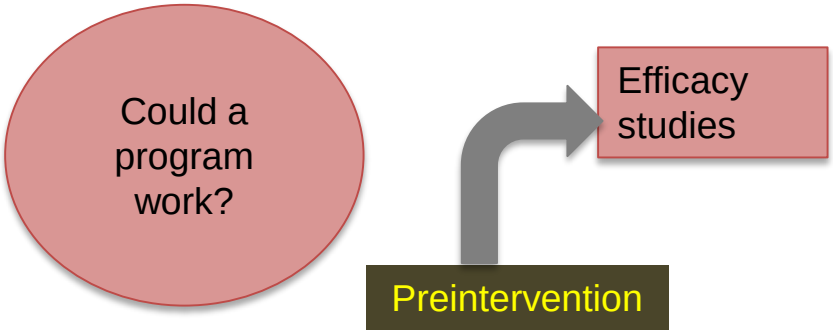
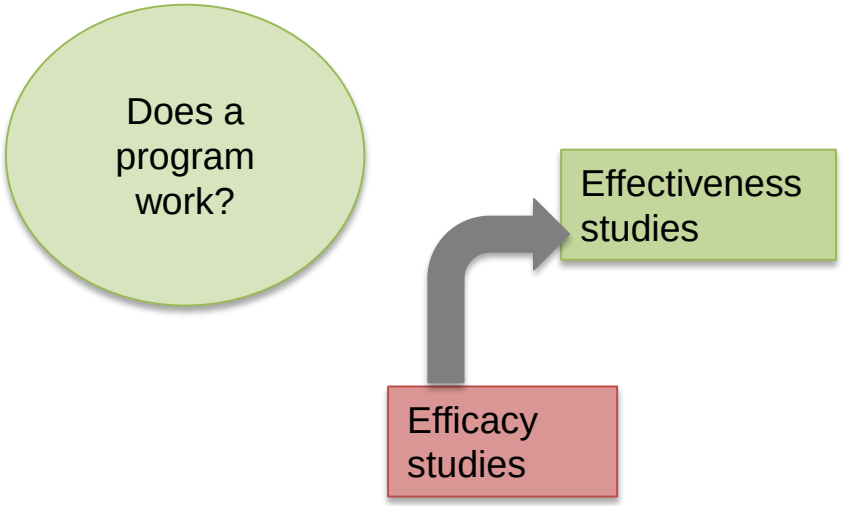
NIH Traditional Translational Pipeline
Efficacy Research Studies



Efficacy: Testing under optimal conditions,

High adherence to PrEP

NIH Traditional Translational Pipeline
Effectiveness Research Studies



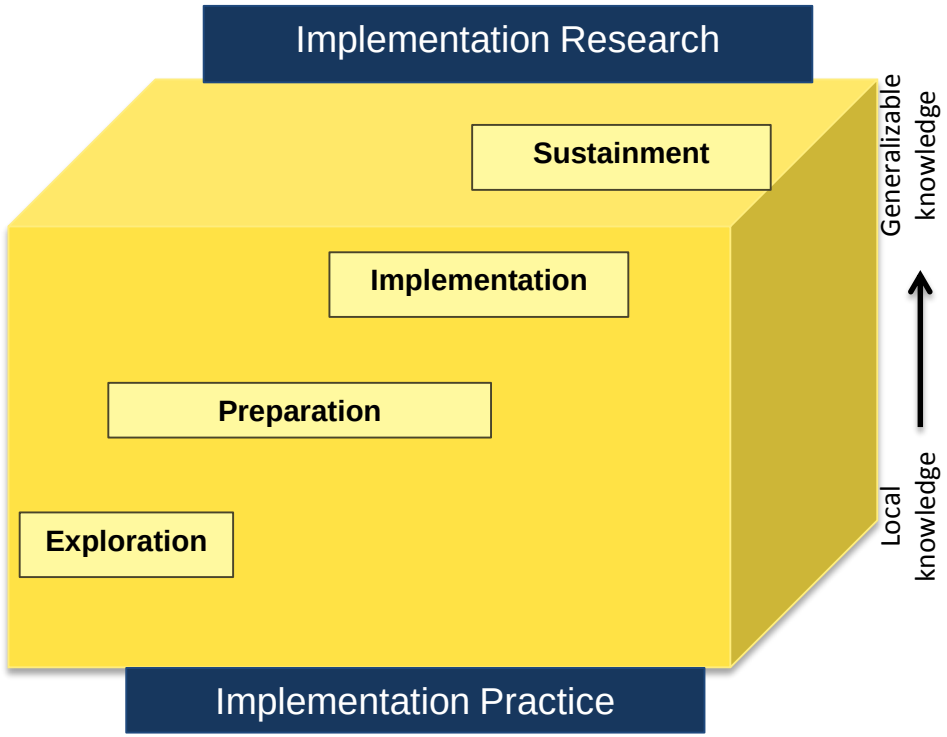
Effectiveness: Testing more realistic conditions,

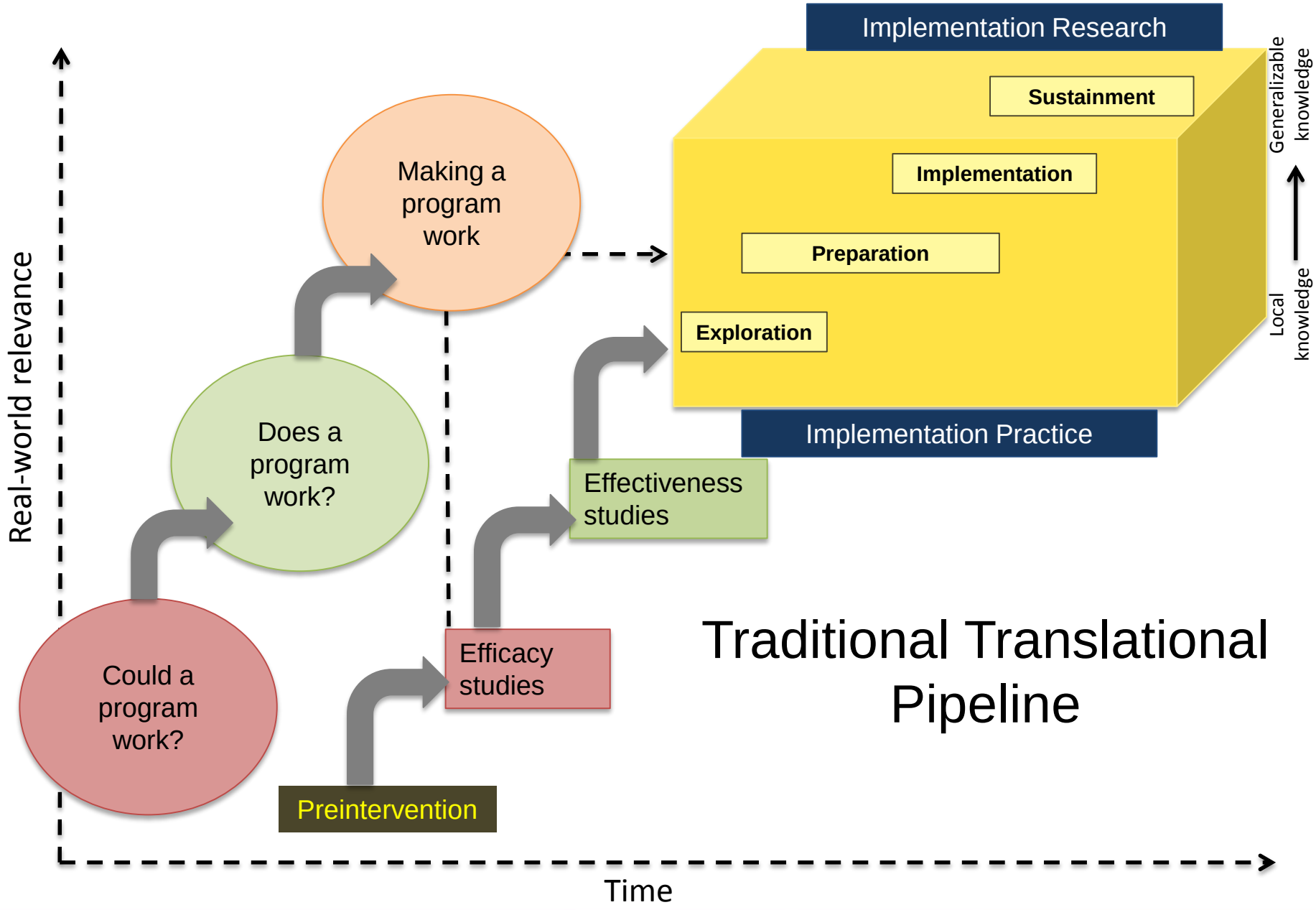
Varying adherence to PrEP

Comparison groups routinely using condoms

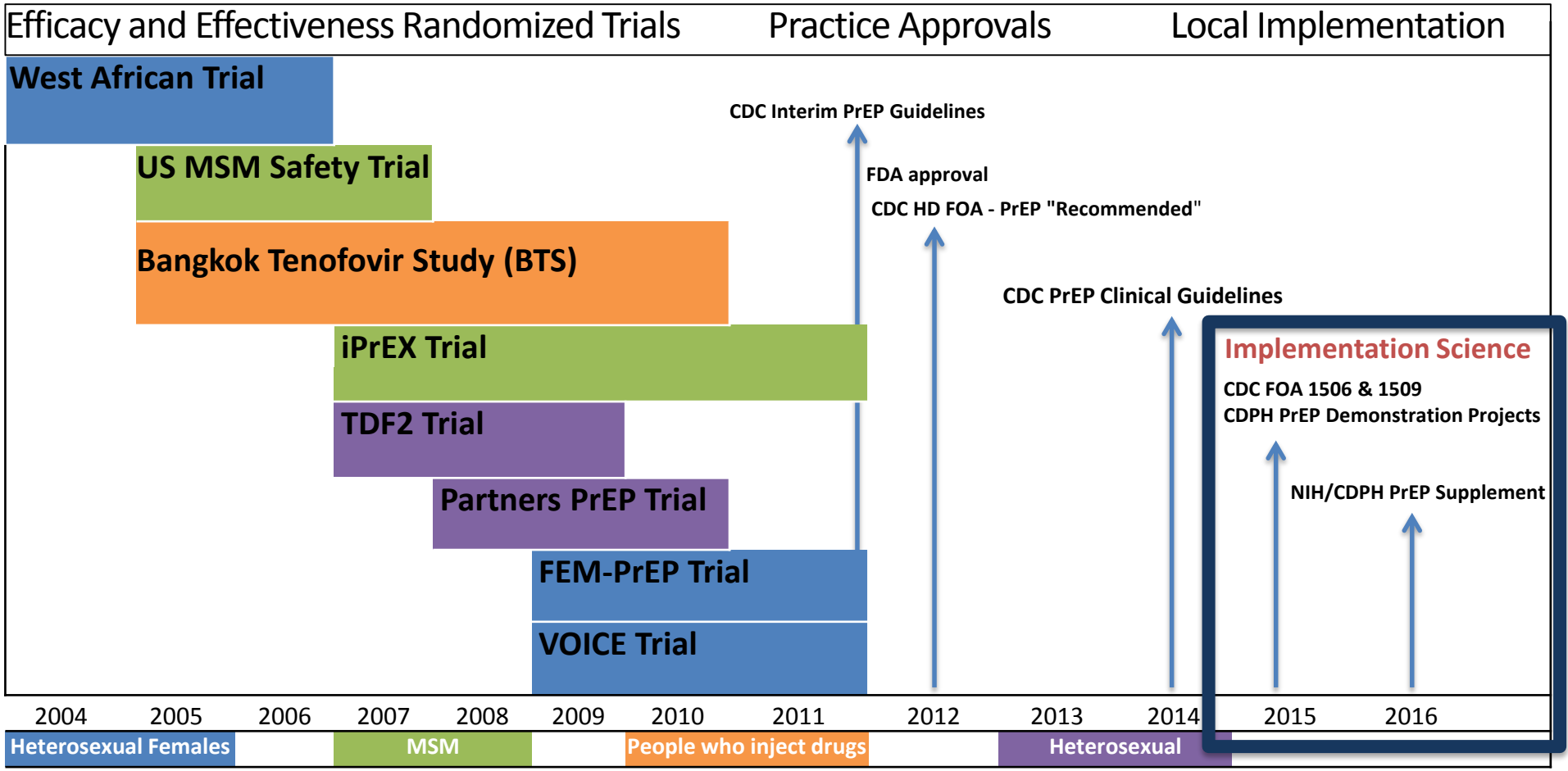
Implementation Research Studies

Making a program work




Implementation Research
Sustainment
Implementation
Preparation
Exploration
Implementation Practice
Generalizable knowledge
Local knowledge
Making a program work
Does a program work?
Could a program work?
Effectiveness studies
Efficacy studies
Preintervention
Real-world relevance
Time
Traditional Translational Pipeline

Pre-Exposure Prophylaxis (PrEP) Research-> Practice Timeline 2004 - 2016



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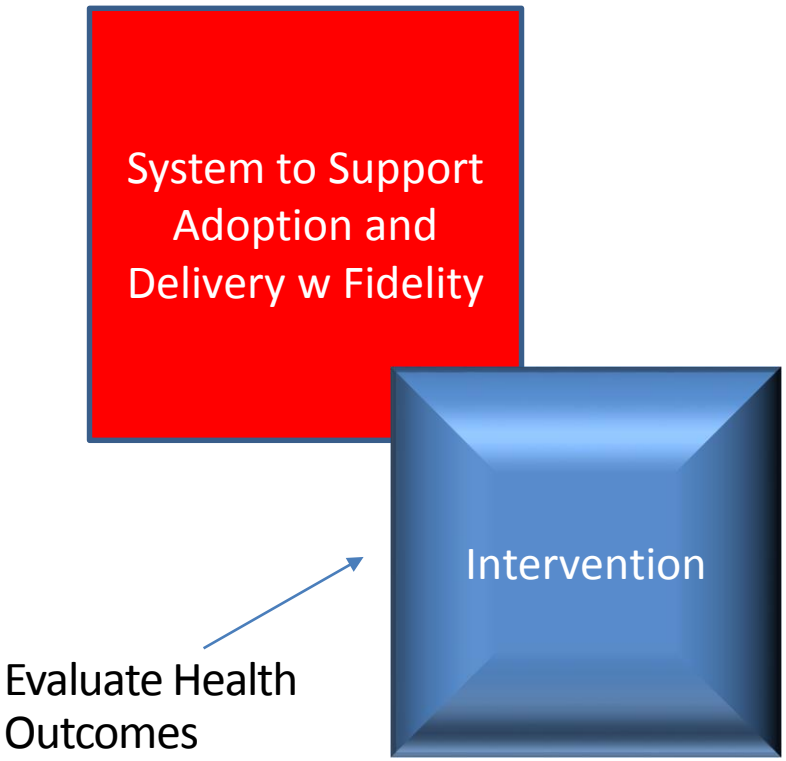
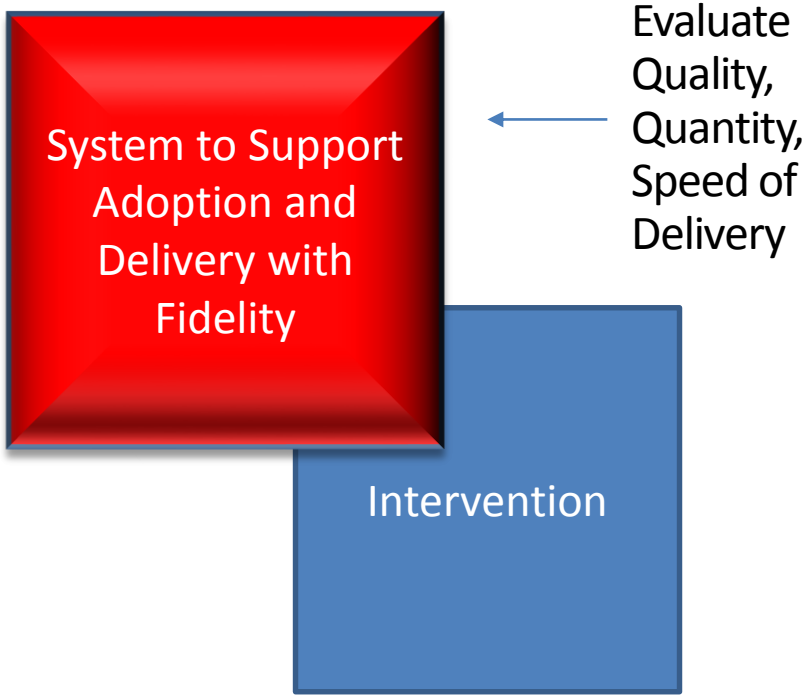
Source: AVAC, www.avac.org/pxrd.

Implementation Research Has a Different Emphasis Than Other Types of Research

Effectiveness vs. Implementation





Carries over into what to Measure, what to Model, What to Test or Evaluate

Illustrations of Implementation Research Questions

- What are the primary barriers and facilitators of implementing PrEP in Local Health Departments?
- Under what conditions does implementation Strategy A work better, faster, more efficiently than Strategy B?
- What are the characteristics of research/service/community partnerships that are sustained over time?
- Does implementation Strategy A or Strategy B more efficiently take an EBP to scale?

Proctor et al. 2012

As Yet Few Implementation Research Studies

Classification of Published Biomedical Intervention Trials for HIV Testing, PrEP, or ART Involving Efficacy/ Effectiveness and/or Implementation Questions

***N* = 107**

	Efficacy	Effectiveness	Implementation
N	79	18	Implementation = 5 Hybrid = 1
%	74	17	Implementation = 5% Hybrid = 1%

Source: Ce-PIM (unpublished)

Core Takeaways

- **Implementation Science** aims to produce **generalizable knowledge**, applicable to diverse settings
    - Delivery systems
    - Strategies of implementation
    - Populations
    - Clinical/preventive interventions

- **Implementation Research** addresses ways to improve the delivery of evidence-based interventions in diverse service systems and communities

System Thinking in Implementation Science

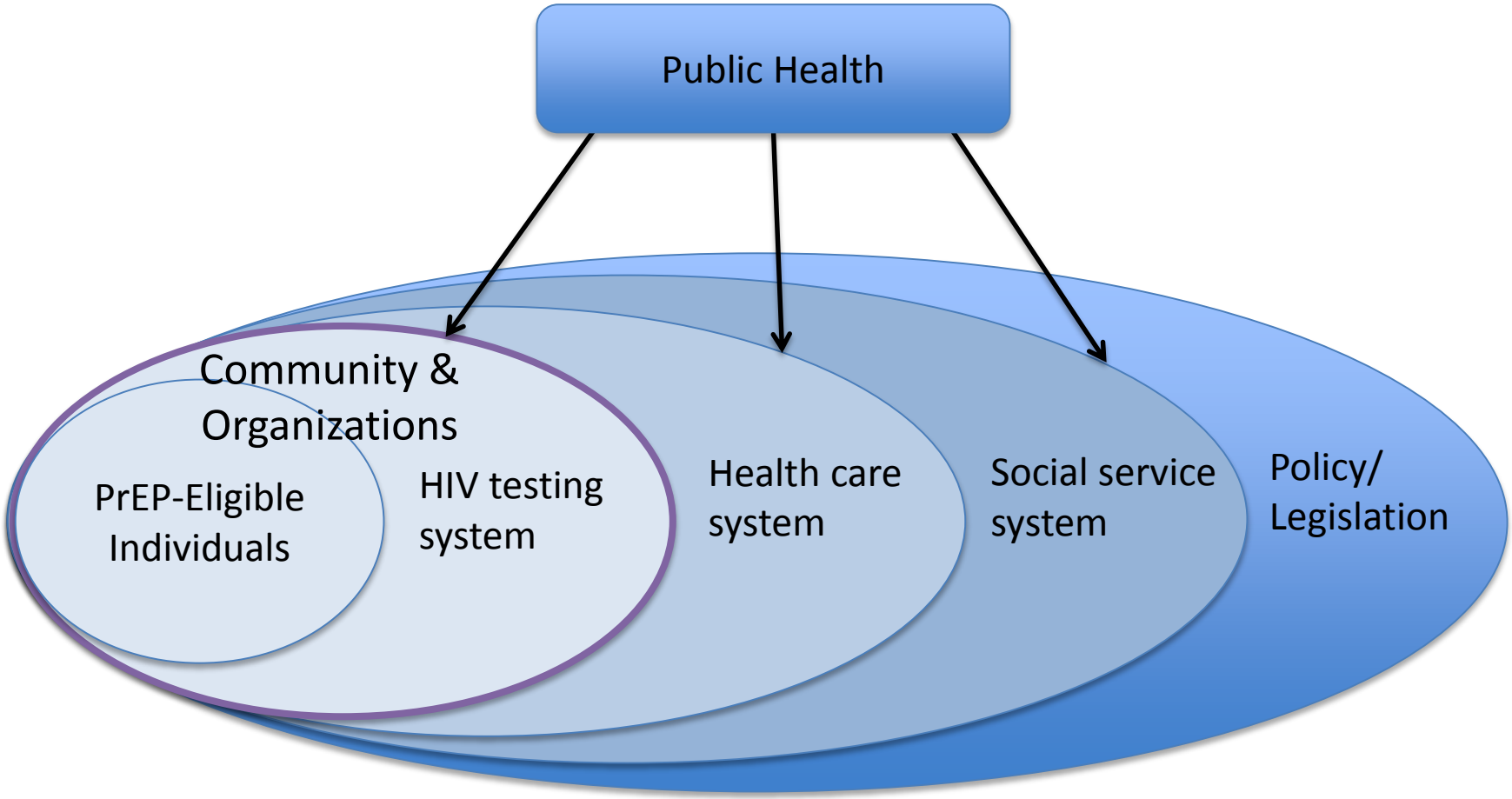
System: Implementation involves interacting components

3 Components:

- Intervention: long acting injectable HIV PrEP medication
- Delivery (sub)System: non-refrigerated truck
- Ecological (sub)System: weather, transportation system

Example: Serum degrades over 85 degrees F

A Small Portion of the PrEP Implementation System



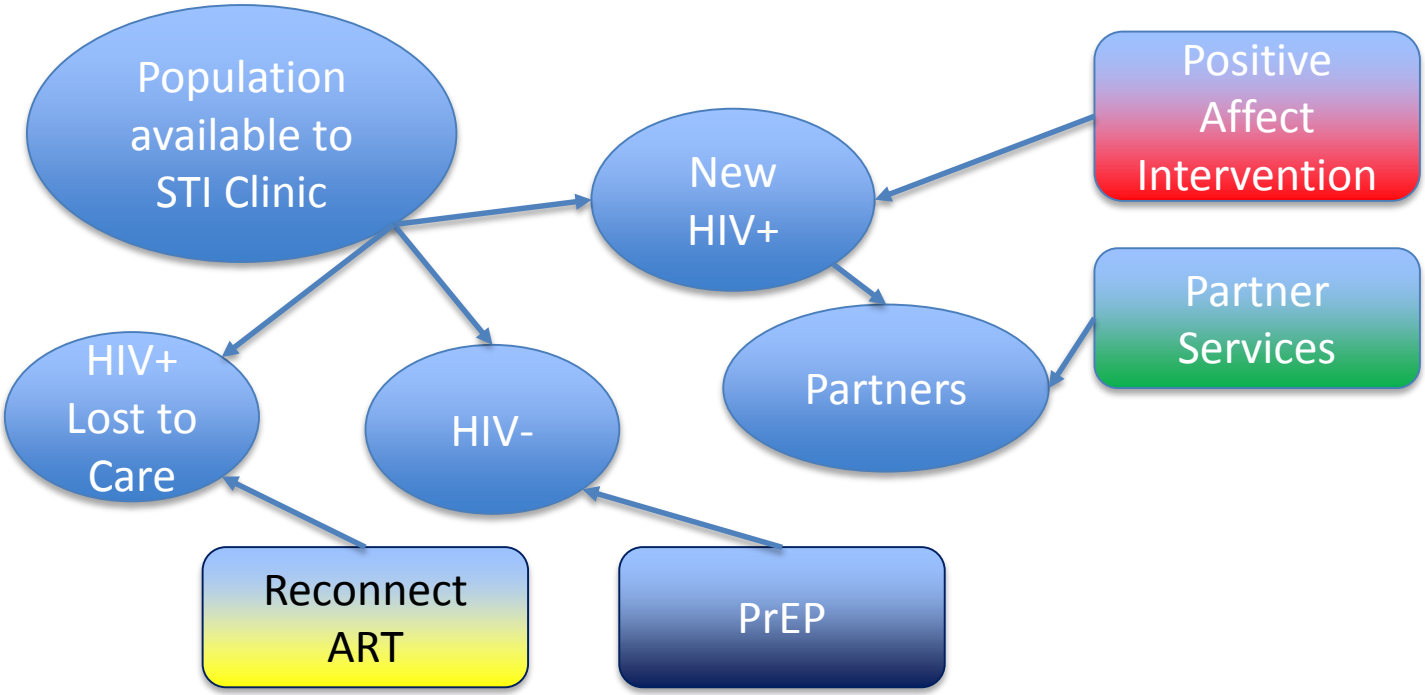
A Systems View of Implementation

- Dynamic network *(Chambers et al., 2013; Valente et al., 2015)*
- Breakdowns can occur in many places
- Data driven decision-making requires
- Monitoring and Feedback measurement system *(Brown et al., 2013; Wang et al., 2016)*
    - Timeliness
    - Accurate
    - Accessible
    - Interpretable

Contrasting Efficacy and Implementation Research

Efficacy: Focus on a small component

Implementation: Focus on system integration



Core Takeaways

- Implementation research needs to take a systems perspective

- Implementation research uses methods to improve and evaluate interactions such as feedback loops

Methods for Implementation Science

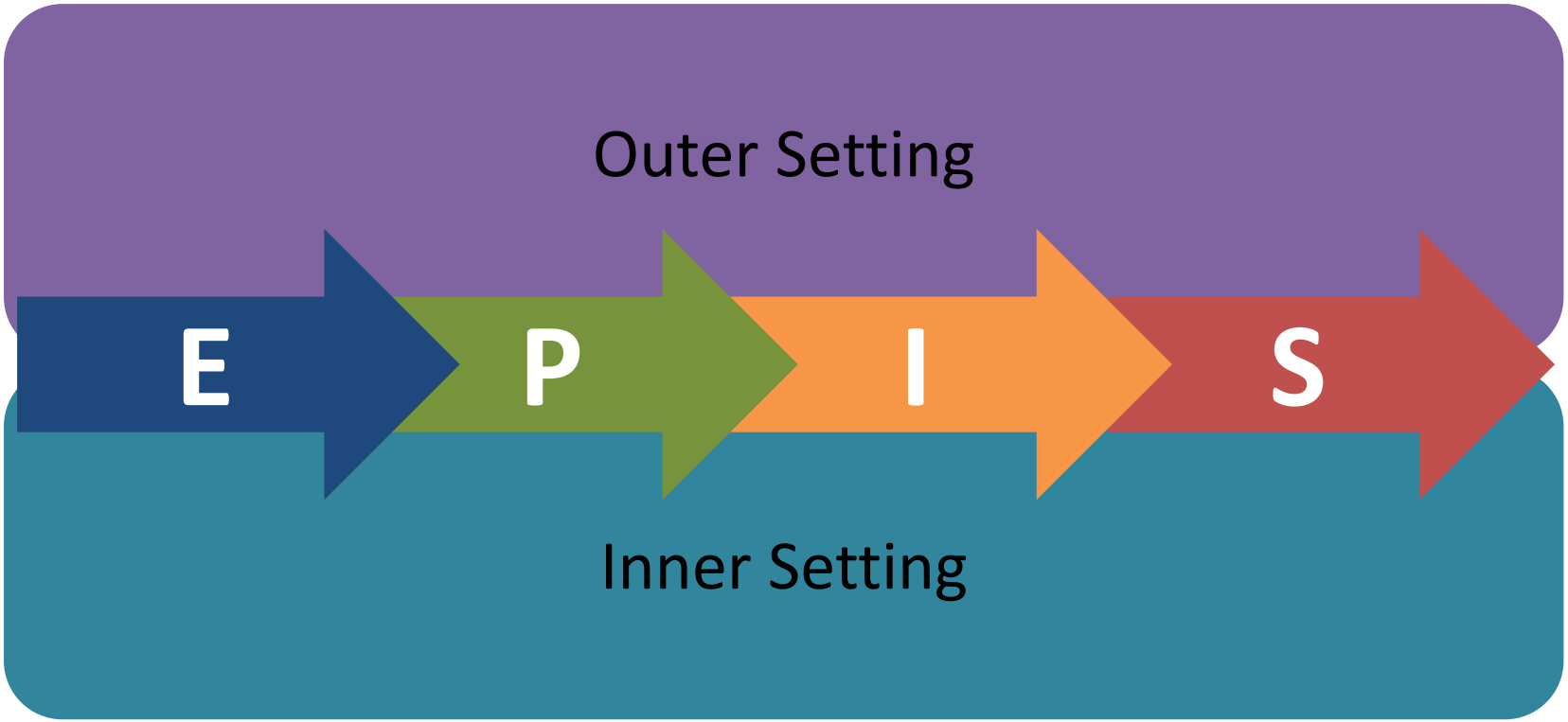
Frameworks, Strategies, Outcomes, Measures, Testing

J.D. Smith, Ph.D.

Methods Outline

- Implementation Frameworks
- Implementation Strategies
- Implementation Outcomes
- Implementation Measures
- Implementation Research Designs
- Example: PrEP in STD clinic

Implementation Framework



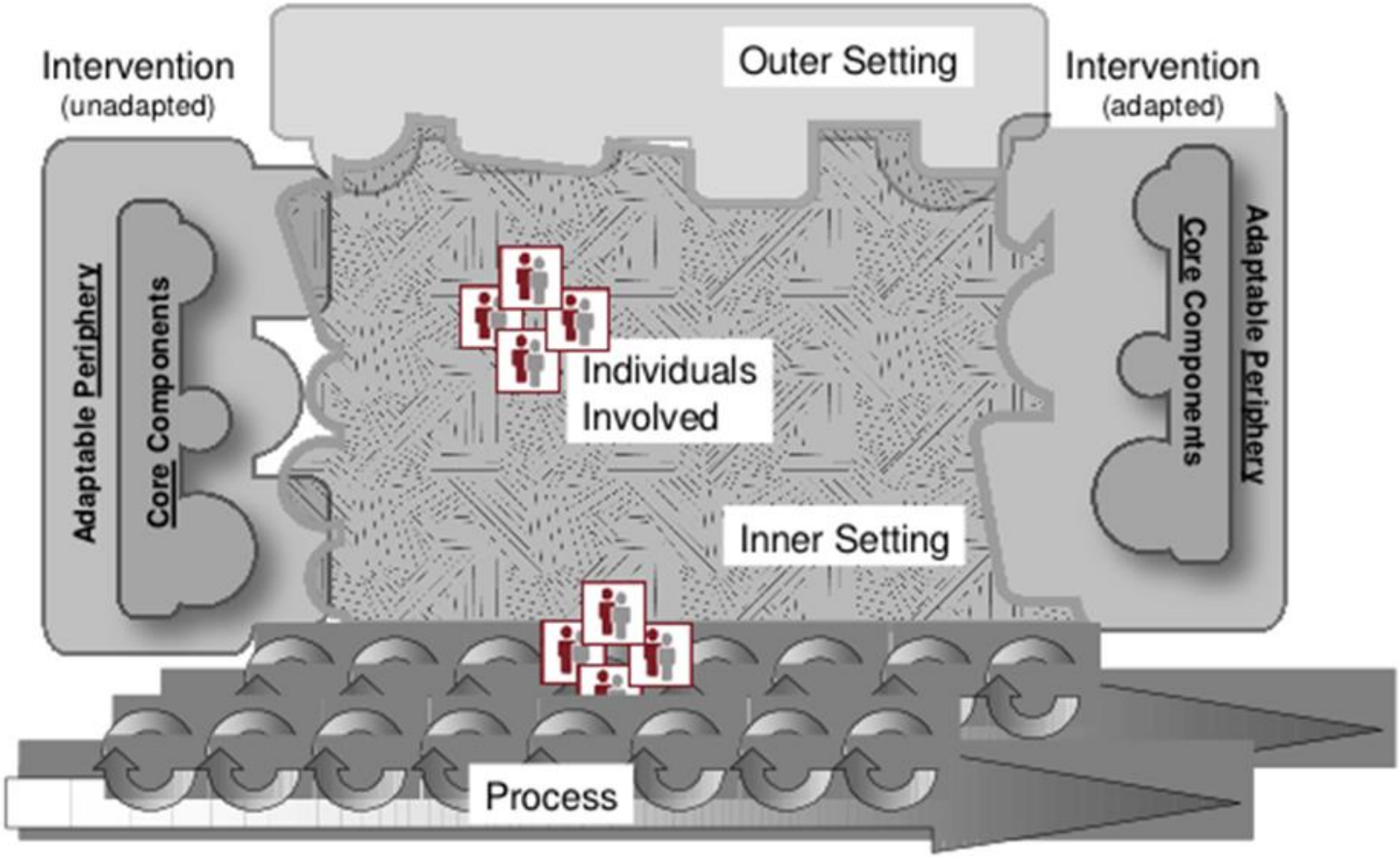
Exploration, Preparation, Implementation, Sustainment

Aarons et al. 2011

EPIS Phases
Description and Key Activities

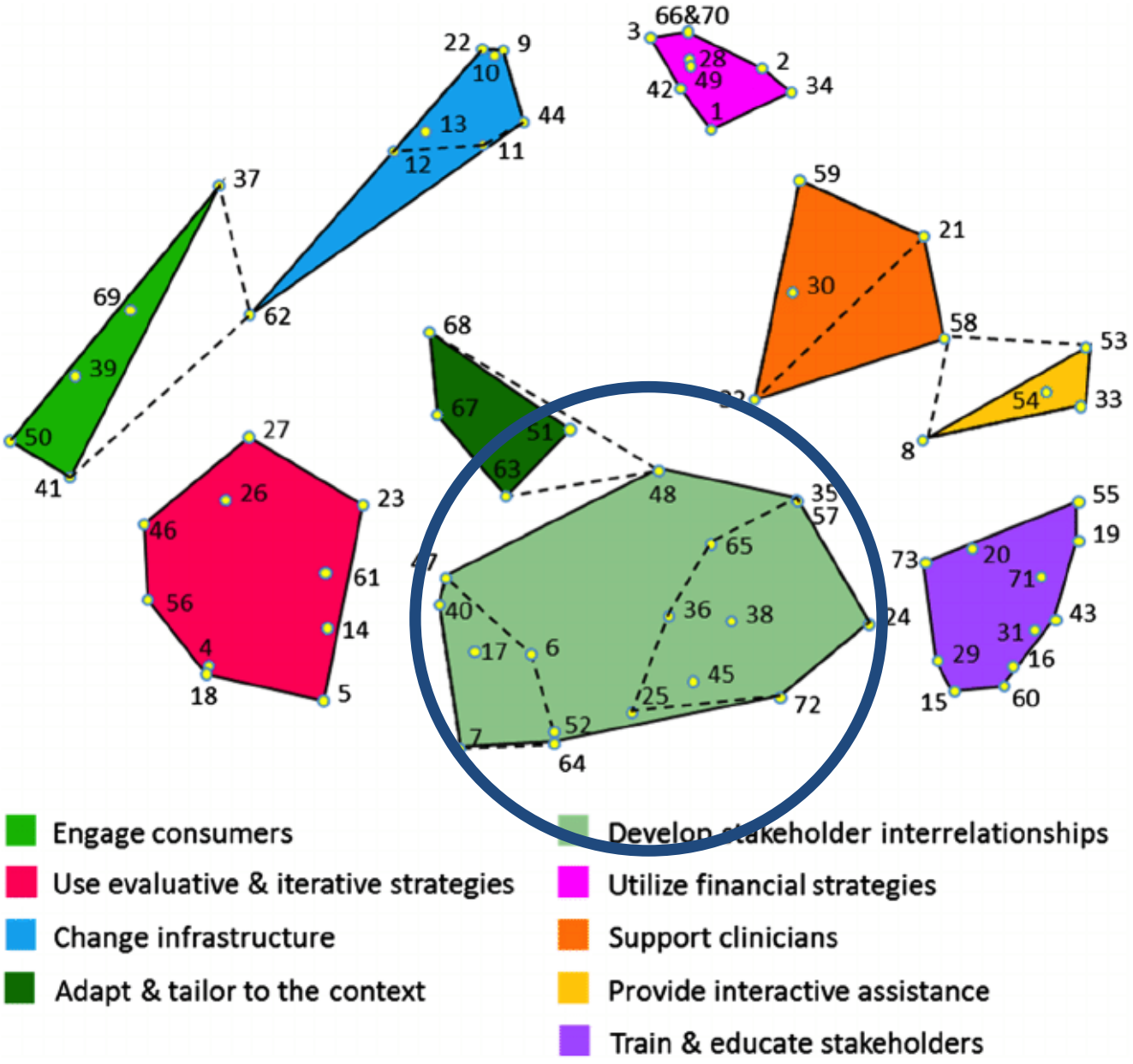
- **Exploration:** involves the awareness of a system's need for change and an investigation into appropriate strategies to address known and hypothesized barriers; identification of key stakeholders; intervention selection
- **Preparation:** decision to adopt a new practice; formal evaluation of organizational capacity (barriers and facilitators); activities to prepare for implementation; identification of key outcomes, selection of measures and ways to monitor
- **Implementation:** enactment of the implementation plan; monitoring and feedback; remediation as indicated
- **Sustainment:** supporting ongoing implementation and responding to changes (inner and outer settings); outcome monitoring and feedback

Consolidated Framework for Implementation Research (CFIR)



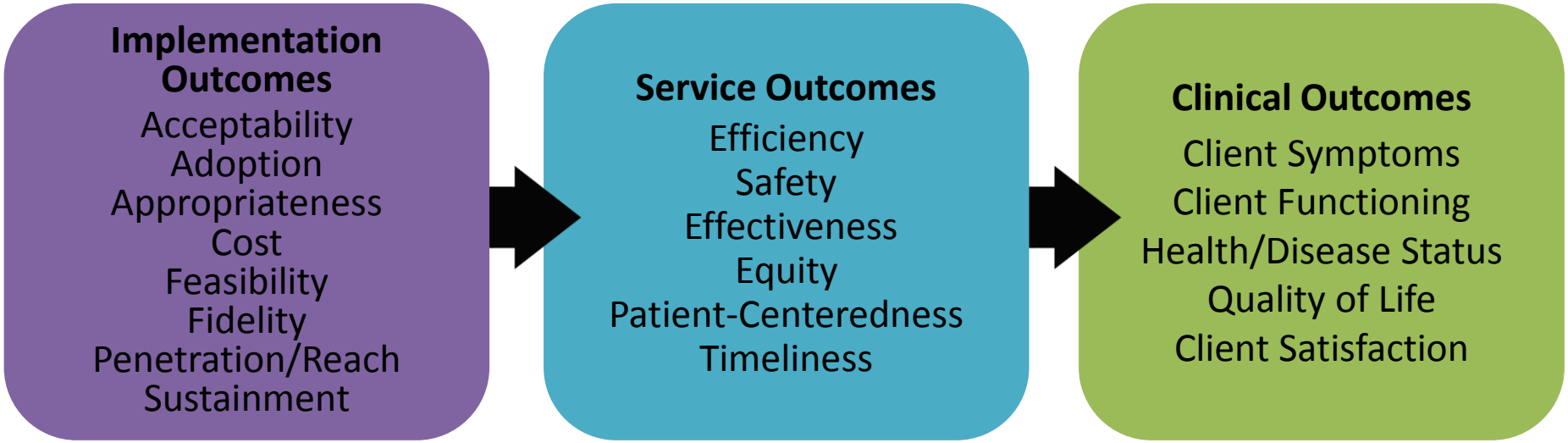
Damschroder et al. 2009

Taxonomy of Implementation Strategies



Waltz et al. 2015

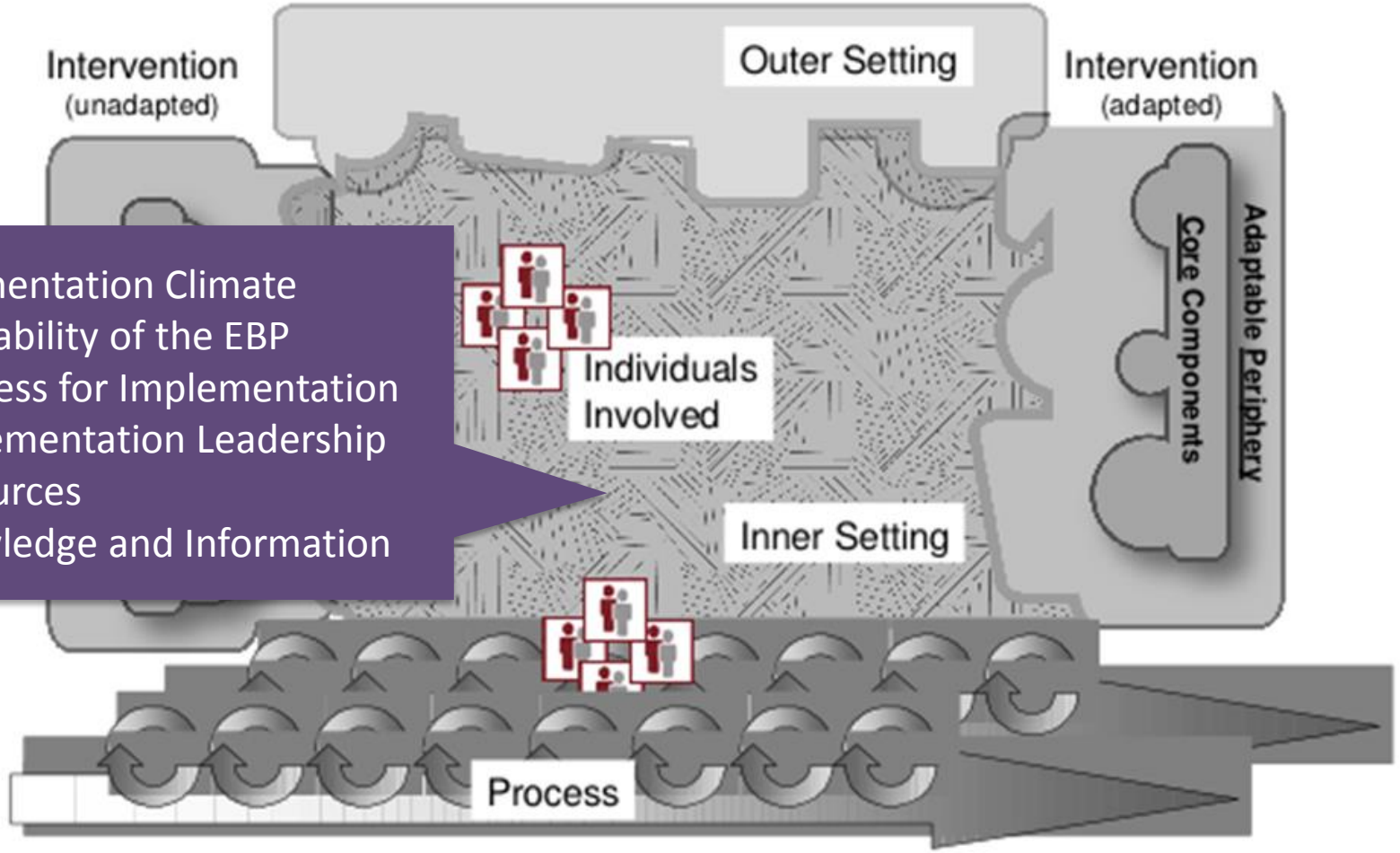
Taxonomy of Implementation Research Outcomes



Definition: Implementation outcomes are the effects of deliberate and purposive actions (strategies) to embed new treatments, practices, and services into real-world systems of care.

Proctor et al. 2011

Consolidated Framework for Implementation Research (CFIR)



Implementation Climate
Acceptability of the EBP
Readiness for Implementation
– Implementation Leadership
– Resources
– Knowledge and Information

Damschroder et al. 2009

Implementation Outcome Measures

- Implementation Leadership Scale (ILS)
- Implementation Climate Scale (ICS)
- Stages of Implementation Completion (SIC)
- Adaptation Coding
- Fidelity to Implementation Strategy(ies)
- Cost Benefit/Budget Impact Analysis
- Reach rates

$$\text{Ratio: } \frac{\#\text{prescribed PrEP}}{\#\text{eligible/indicated}}$$

Testing and Modeling of Implementation

- Examine how EBPs are adopted, scaled up, and sustained in community or service delivery systems

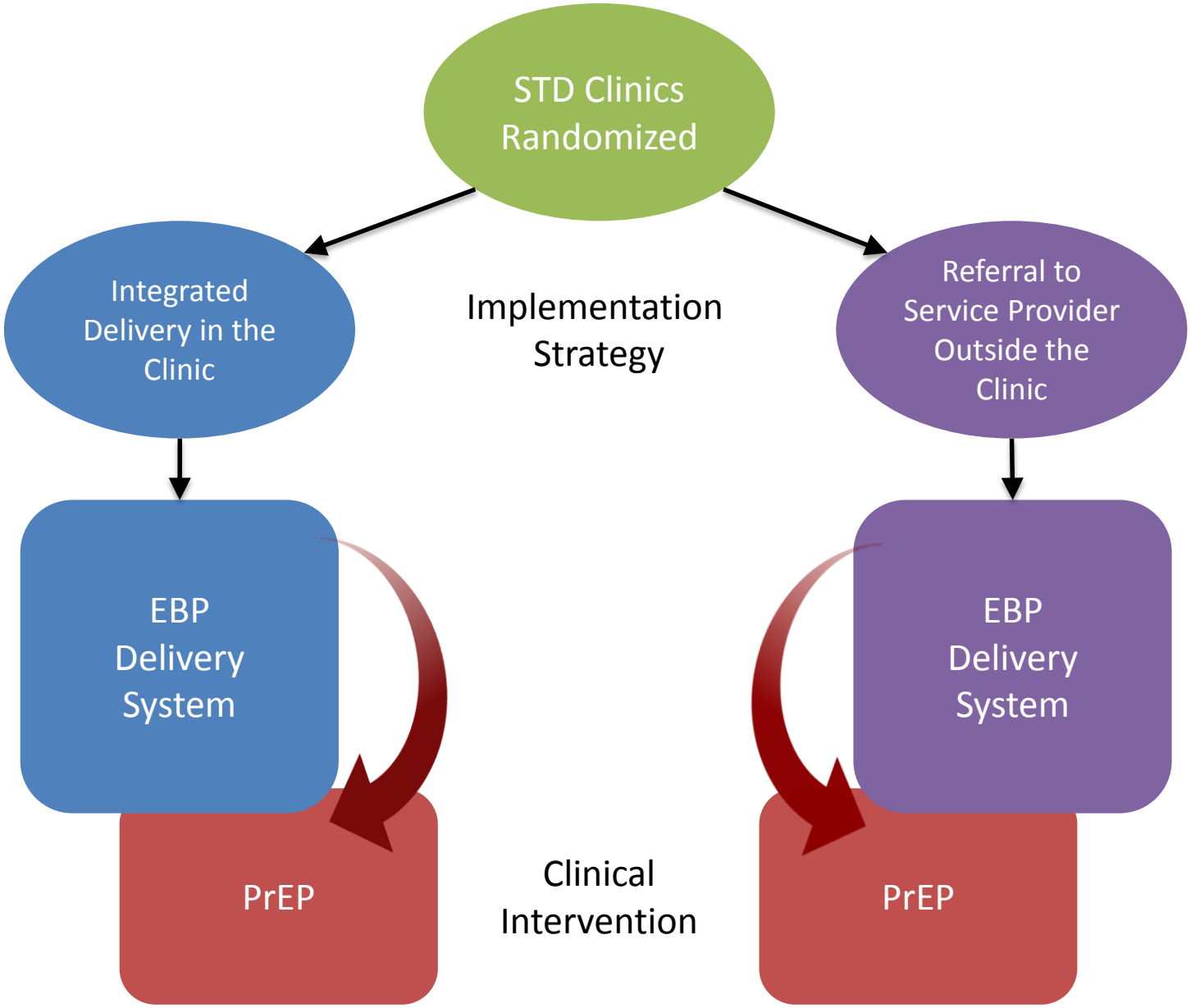
- Test the effect of implementation strategies to improve the adoption, adaptation, scale-up, and sustainability of interventions (NIH, 2016 in PAR 16-236, 237, 238)

  - Randomized and non-randomized designs
  - Hybrid effectiveness-implementation trials
  - Quality improvement designs for local knowledge
  - Simulation modeling

Example: Head-to-head randomized implementation trial

Brown et al., 2017

Design for a Head-to-Head Randomized Implementation Trial involving One Evidence-Based Intervention

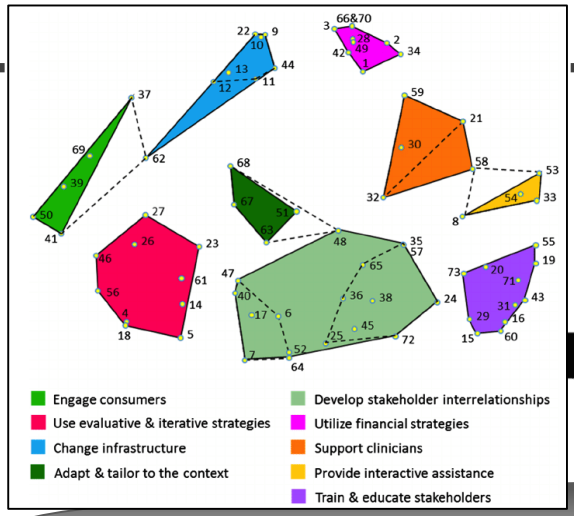


Brown et al., 2014; in press

Some Common Characteristics of Implementation Research Designs

- External validity > internal validity
- Mixed methods
- Randomization at “higher levels” of the service system (e.g., provider, clinic, county, etc.)
- Researcher manipulates and controls the implementation strategy/strategies

Strategies



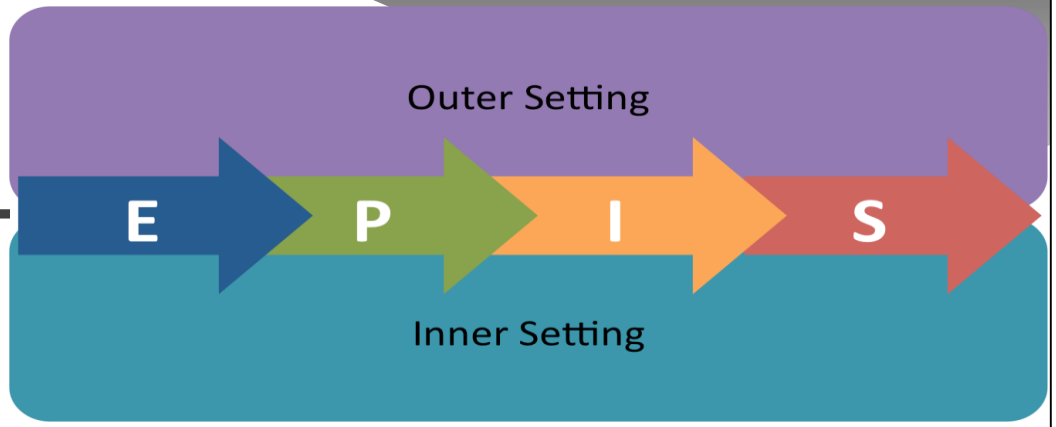
Measures

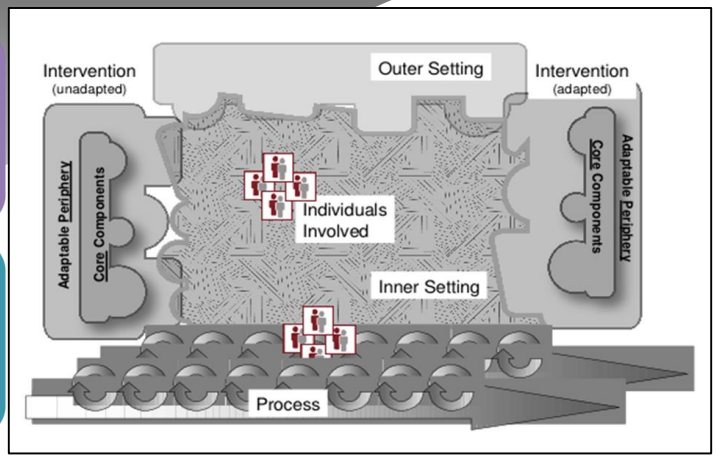
Outcomes

Implementation Outcomes
Acceptability
Adoption
Appropriateness
Cost
Feasibility
Fidelity
Penetration/Reach
Sustainment

Service Outcomes
Efficiency
Safety
Effectiveness
Equity
Patient-Centeredness
Timeliness

Clinical Outcomes
Client Symptoms
Client Functioning
Health/Disease Status
Quality of Life
Client Satisfaction



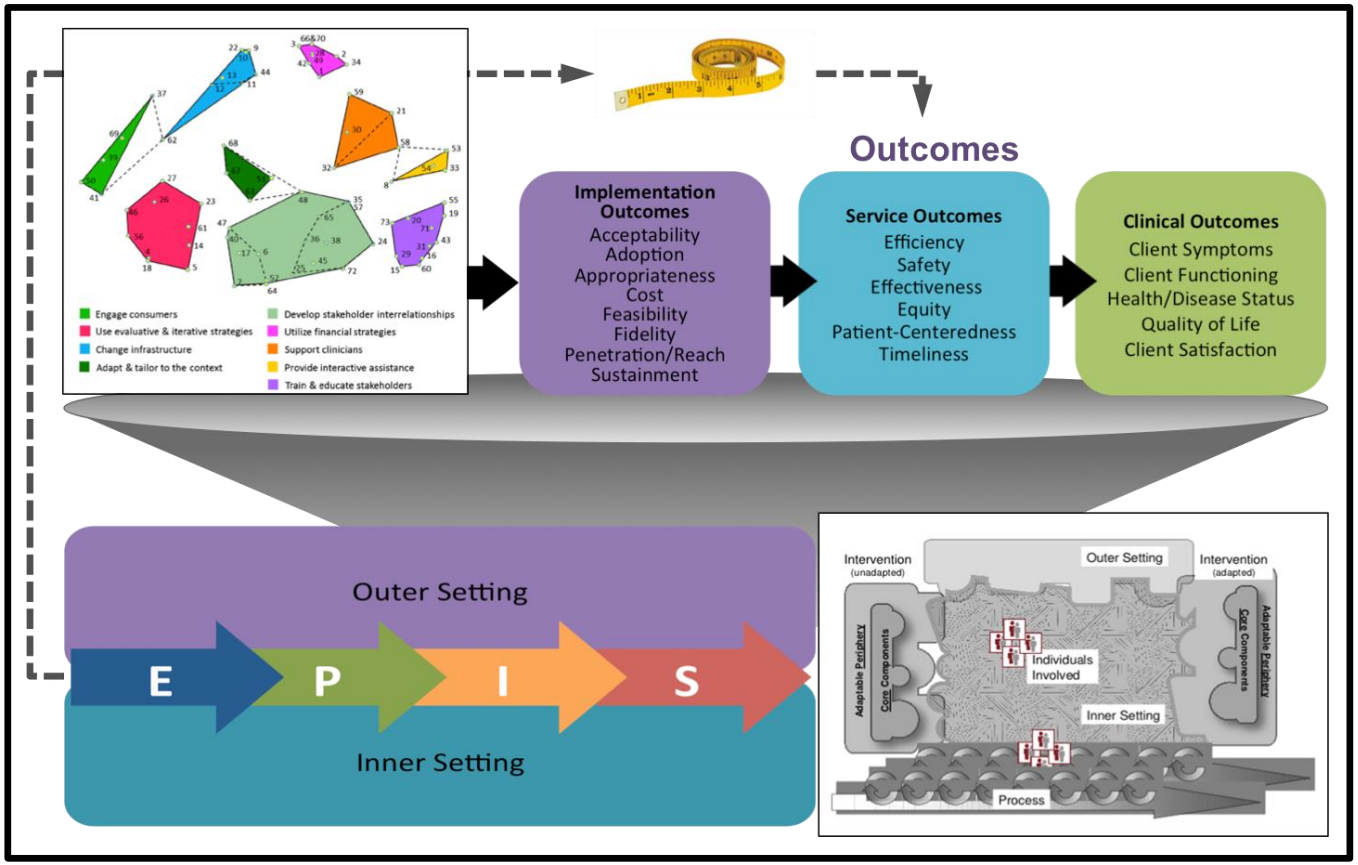


Frameworks and Models

from Smith & Polaha, under review

Example: Applying concepts to PrEP implementation in an STD Clinic

Role Play of the Implementation Facilitation Process (J.D. and Nanette)



Inner Setting

- Provider knowledge and acceptance of PrEP
- Staffing (skills, training, and capacity)
- Procedural reorganization
- Leadership (support, commitment)
- Medical record system readiness to monitor outcomes
- Capacity to (continually) fund PrEP implementation

Outer Setting

- Legislation/policies (Medicaid, ACA)
- Funding and Reimbursement Streams
  - Private and government health insurance
  - Uninsured
- HIV stigma and discrimination
- Client Awareness of PrEP
- Attitudes toward PrEP
- Key stakeholders (need for partnerships)

Barriers to PrEP Implementation

Weiss, 2016

Exploration

- Is PrEP in alignment with STD clinic mission and vision? (appropriateness)
- Is there organizational support for PrEP? (IR -capacity)
- Do providers know about PrEP? (IR - knowledge)
- Is there clinic-level leadership commitment to implement PrEP? (leadership support)
- Does the clinic serve the population who will benefit from PrEP? (appropriateness, feasibility)

Preparation

- Develop **implementation plan**
  - Assess potential barriers to implementation and strategies to address them
  - Determine costs associated with PrEP delivery and how they will be funded
  - Identify possible changes in PrEP delivery and ways to adopt/incorporate such changes
- Identify implementation outcomes and develop mechanisms and data collection tools to monitor them
- Conduct provider and support staff training

Example – Implementation Planning

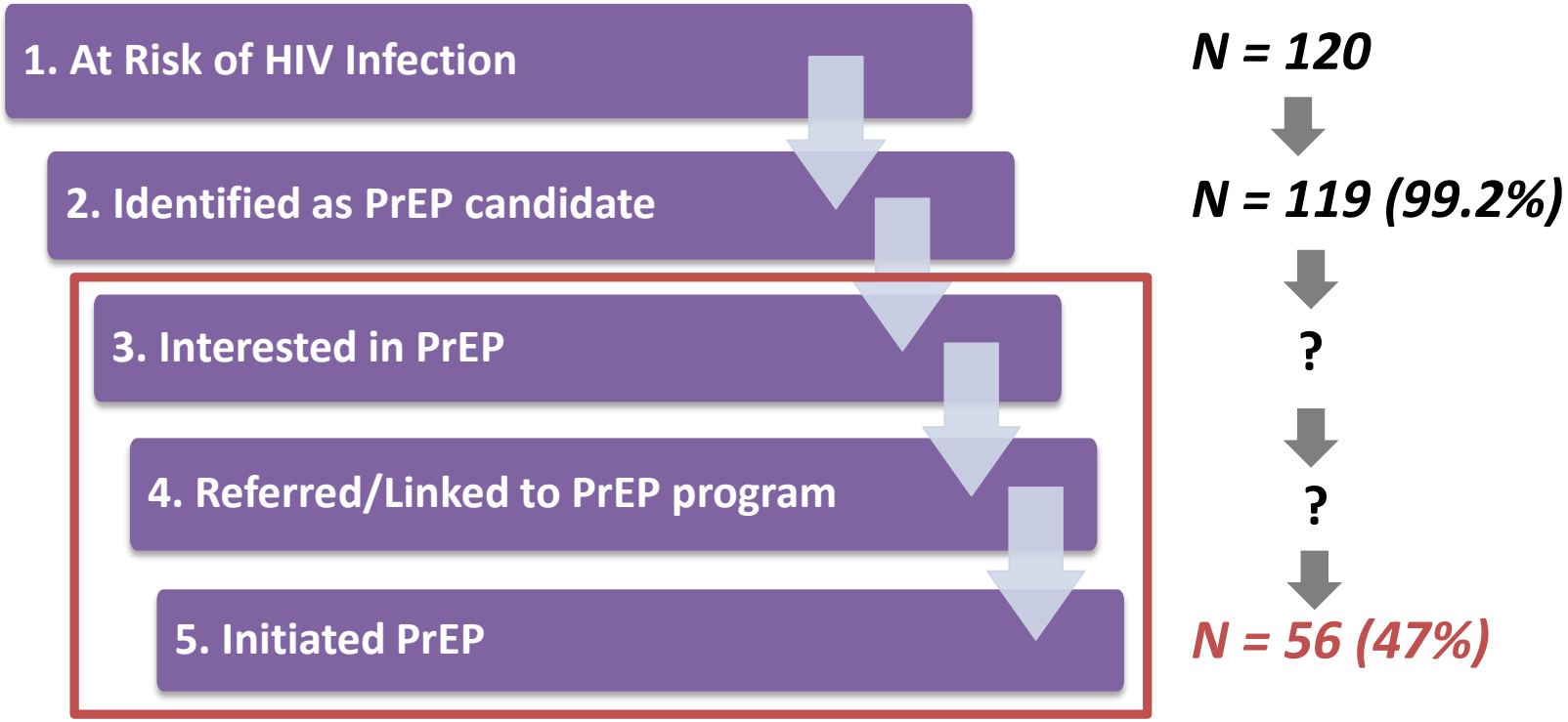
Provider Knowledge

- Assessment: provider knowledge of PrEP
- Identify Barrier(s): providers lack knowledge and understanding of who should be prescribed PrEP, the potential effects of PrEP, and potential complications
- Identify a Strategy: Educational materials distributed to providers and in-person trainings are conducted
- Identify a Measure: Pre-post survey of knowledge and acceptability of PrEP

Implementation

- Delivery of PrEP begins with patients in the clinic
- Monitor implementation outcomes and make adjustments to implementation plan based on feedback
  - Example: Low patient initiation of PrEP
  - Low acceptability? Description by provider? Cost?
  - – Repeat steps: assess→strategy→monitor

Abbreviated PrEP Cascade



Implementation science provides tools to help explain why we observe drops from one step to the next and the strategies needed to address it.

Sustainment

- Conduct routine quality assurance by continual monitoring and feedback of implementation outcomes
- Repeat steps as necessary: assess→strategy→monitor
- Adapting to emerging PrEP modifications (long-acting injectable, adolescent guidelines, funding/policy changes)

Core Takeaways

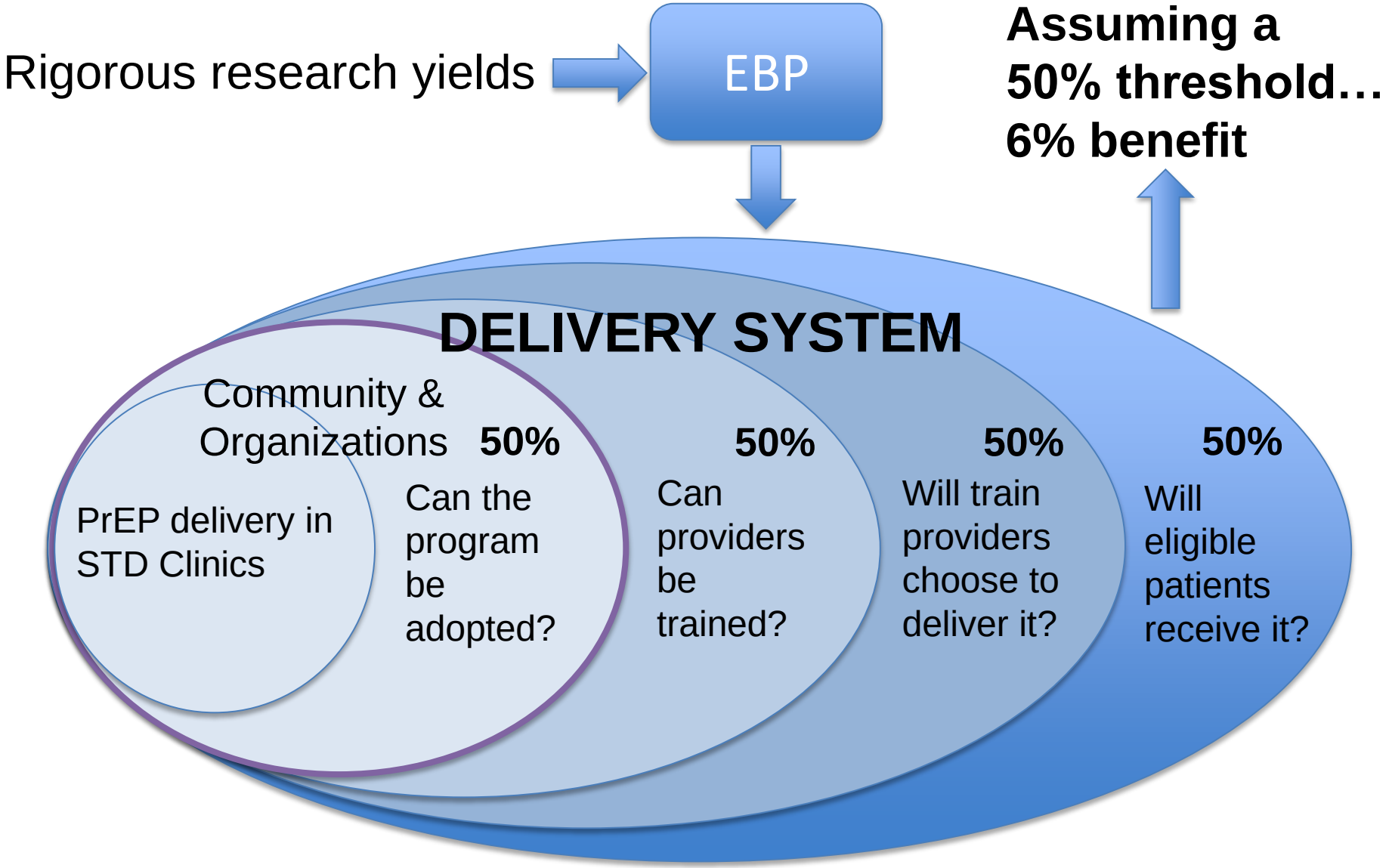
- Processes and outcomes of implementation can be measured, modeled, and tested
- Frameworks guide the implementation and help inform the selection of outcomes to measure
- Strategies are manipulations to the system for the implementation of new innovations
- The success of implementation research can be tracked by using appropriate outcome measures
- Implementation research can be rigorously evaluated and contribute to generalizable knowledge through rigorous research designs

Partnerships to Support Implementation

Juan Villamar, M.S.Ed.

Partnerships Outline

- Role of partnerships in Implementation and Implementation Research
- Terminology
- Steps to build partnerships to support implementation
- Mutual self interest in Implementation Research
- Core Takeaways



Successful partnerships improve quality of implementation

Chambers, Nov 2016 (PSMG Presentation)

Terminology

- **Partnerships** = implementation strategy
- **Partners** = stakeholders, leaders/leadership, movers & shakers, champions
- Can also be:
  - Collaboration/Collaborators
  - Coalition
  - Alliance
  - Consortium
- **Use the term that is the most appropriate, so long as steps are covered**

Partnership Example

- I am an Implementation Researcher
- Sought out by: the STD Medical Director of a public health department in charge of multiple STD clinics
- STD Medical Director wants **all** STD clinics to deliver PrEP as a **new** service
- My role: facilitate partnership development for implementation and develop generalizable knowledge from STD clinics
    - Implementation Broker *(Fixsen et al, 2005)*

Partnership Building Steps

1. Analyze who is required for support
   - Community stakeholders and leaders
   - External PrEP Providers
   - Union leaders
   - Other Health Department Leadership
2. Learn AND work through trust
   - Meet in their offices
   - Do not sell them anything
   - Do more listening than talking. Listen for: mission, priorities, fears

Kellam, 2012; Brown et al. 2012

Partnership Building
(con't)

3. Search for mutual self-interest
   - Where do priorities overlap?
   - Will your work further the interests of your partners?
   - Can your partners see themselves in the agenda you are creating?
4. Form an operation group with oversight
   - Group composed of partners with **power**
   - Critical decision: where does this group sit?

Kellam, 2012; Brown et al. 2012

Partnership Building
(con't)

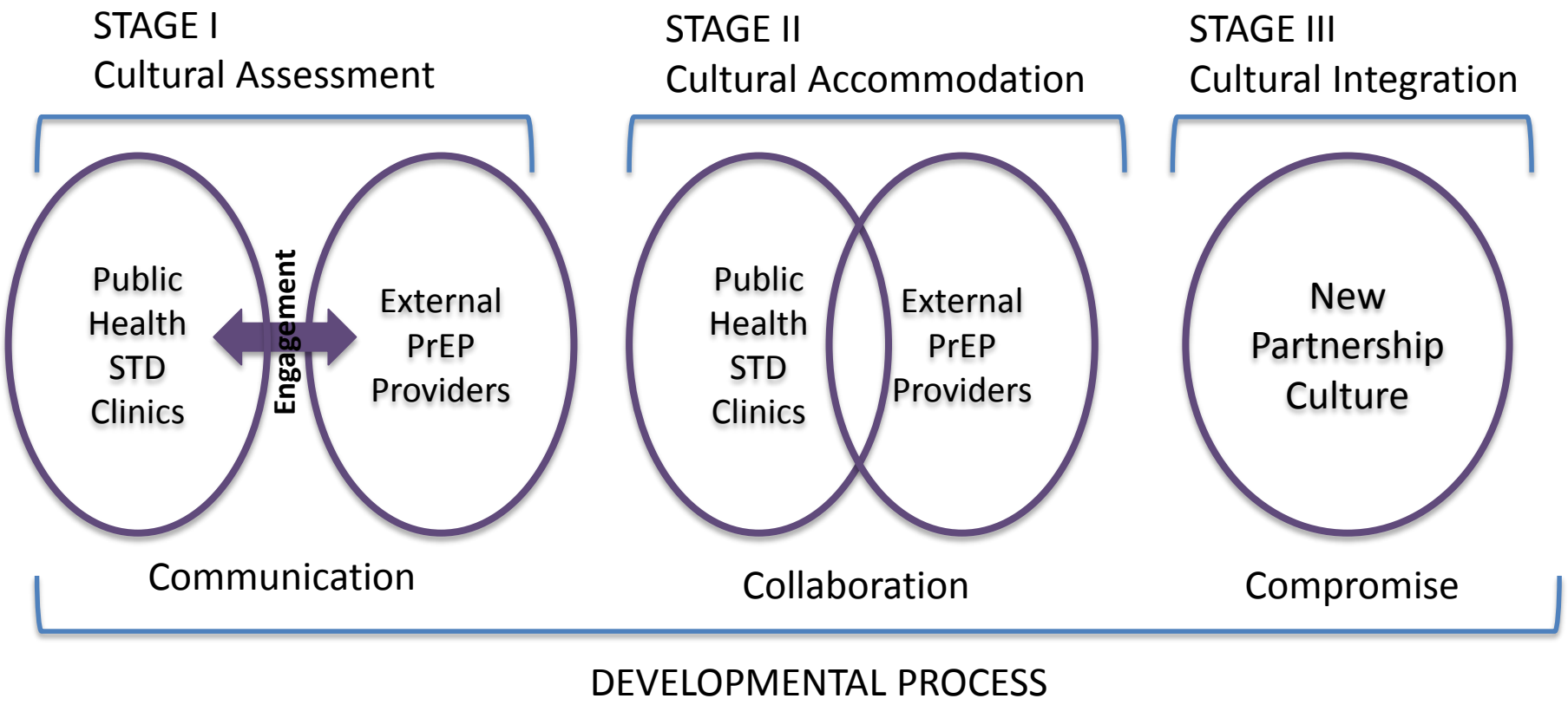
5. Plan and carry out mutual self-interest programs
   - Partnership agenda expands beyond the initial work
   - Partnership flexible to address priorities as they are identified
   - Implementation research as a service to the partnership

Kellam, 2012; Brown et al. 2012

What does mutual self-interest look like in implementation research?

- Research conducted under the oversight of partnership members
- Implementation researcher serves as facilitator between research and partnering systems
- Research integrity is enhanced not compromised through Implementation Science

What success looks like: Cultural Exchange



Palinkas, et.al. 2009

Core Takeaways

- Partnerships are built around trust, shared understanding, power, and mutual benefit
- Partnerships are a developmental process, not an end in itself
- Partnerships could be between:
  - A researcher who wants to implement an evidence-based intervention within the health department
  - A community based organization interested in building the evidence of a homegrown intervention

Implementation Science Resources

Training

- Training Institute in Dissemination and Implementation Research in Health (TIDIRH)
- Implementation Research Institute (IRI)
- Mentored Training in Dissemination and Implementation Research in Cancer (MT-DIRC)
- Certificate Program in Implementation Science (UCSF CTSI)
- Prevention Science and Methodology Group (PSMG)
- NCI D&I Webinar Series
- Brownson RC, Colditz GA, Proctor EK, eds. *Dissemination and Implementation Research in Health: Translating Science to Practice.* London: Oxford University Press; 2012:225-260.

Articles, Measures, News, etc.

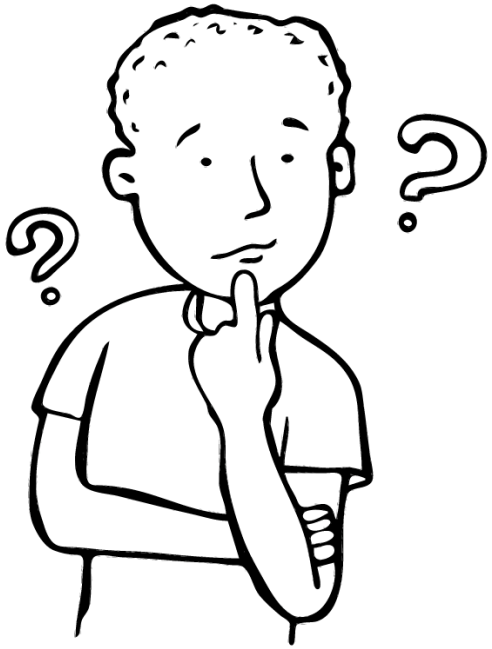
- Ce-PIM/Bridges Websites at NU
- *Implementation Science*
- SIRC instrument repository
- NIH Resources on Dissemination and Implementation Research in Health
- Knowledge Translation Resources from Canadian Institutes of Health Research
- WHO's Implementation Research Platform
- UNC Chapel Hill's North Carolina Translational and Clinical Sciences Institute: D&I portal
- UNC Chapel Hill's Active Implementation Hub
- NIH Fogarty International Center's Implementation Science site

Next Steps

- Series of implementation research workshops and training opportunities by Ce-PIM/CFAR
- Tailored to your needs
- Let us know!

Web: cepim.northwestern.edu

Email: bridges@northwestern.edu



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