Implementation Matters: Unlocking Scale in HIV Prevention

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Relevant financial interests

- NIH grant funding
- Consultation with Merck

Outline

- Implementation science 101
- Generating evidence and moving it into implementation science
- Adaptation, rapid iteration, learning
- Discussion

Implementation science 101

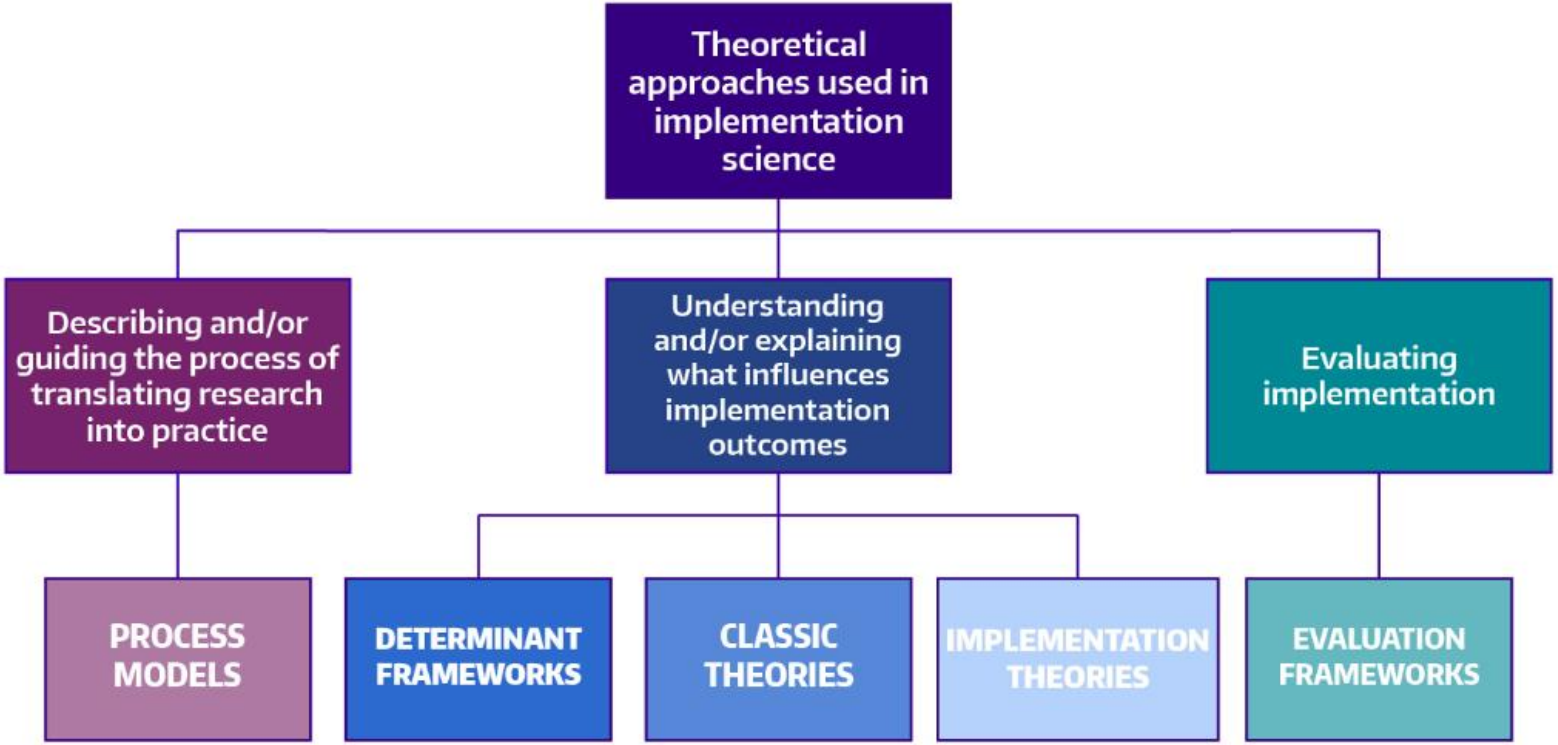
- Implementation science is the use of rigorous approaches to understanding how to improve the uptake and ongoing use of **evidence-based interventions**
- **Theories, models, and frameworks** give us a better understanding and explanation of how and why implementation succeeds or fails

Theories, models, and frameworks

- **Theory**: A set of interrelated concepts and variables that help predict outcomes and explain causal mechanisms of implementation
- **Model**: Approach used to describe and/or guide the process of translating research into practice
- **Frameworks**: Descriptions of factors believed or found to influence implementation outcomes (e.g., checklists, not explanation)

(Nilsen, Imp Sci, 2015)

- There are dozens of theories, models, and frameworks… each can be used for different purposes
- Many people use these terms interchangeably (for better or worse); the ideas are what are important



Adapted from: Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci.* 2015;10(1):1-13.

https://impsciuw.org/

The focus is on the implementation strategy (not developing the intervention)

Strategy	Example
Evaluate and iterate	Audit & feedback
Adapt to context	Tailor the EBI to local needs
Train and educate stakeholders	Inservice trainings
Engage consumers	Demand creation with clients, community
Change infrastructure	Modify physical environments
Provide interactive assistance	Hot or warm lines
Utilize financial strategies	Incentives (behavioral economics)
Develop stakeholder interrelationships	Identify and support champions, early adopters

Powell BJ et al, Expert Recommendations for Implementing Change (ERIC) project. Imp Sci 2015

A journey into implementation science…

PrEP My Way: a type 1 hybrid effectiveness-implementation RCT in Kisumu Kenya

MASSACHUSETTS GENERAL HOSPITAL
GLOBAL HEALTH

KENYA MEDICAL RESEARCH INSTITUTE
KEMRI

HARVARD MEDICAL SCHOOL

Persistence to PrEP is Low among Young Women

Monitoring PrEP in Young Adult women (R01MH109309)

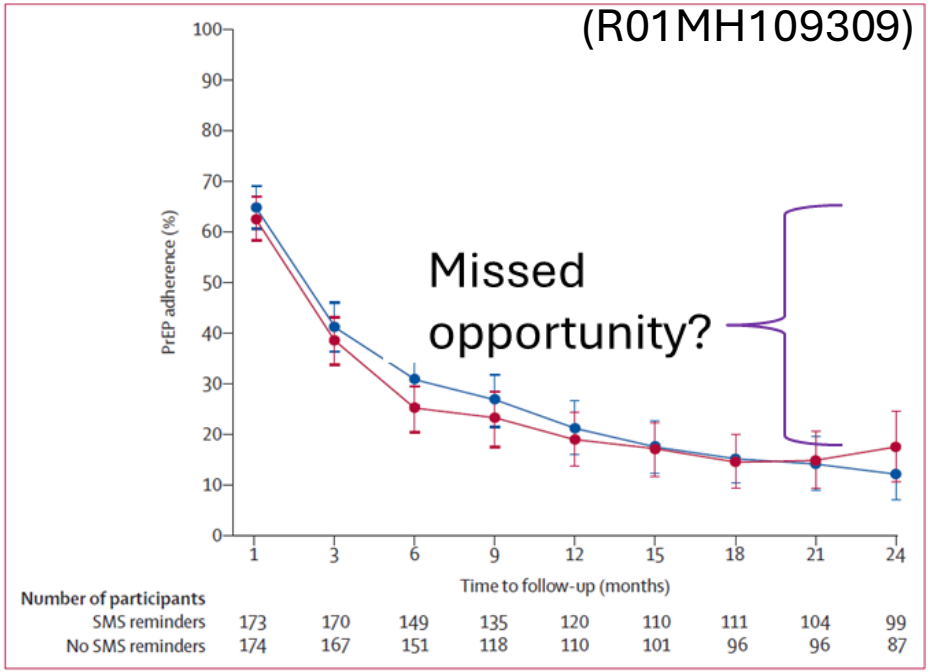
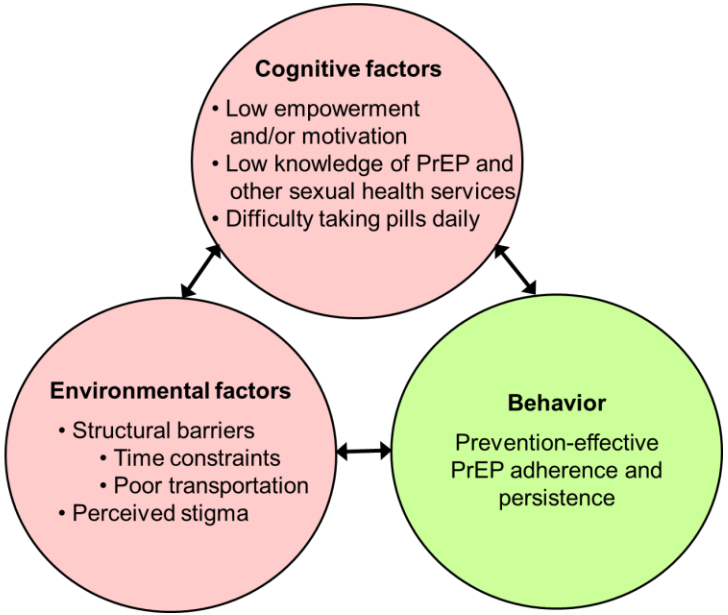


Figure 2: PrEP adherence by electronic monitoring and pharmacy refill by study group

Social Cognitive Theory



(Haberer et al, Lancet HIV 2021; Haberer et al, JIAS 2024)

The PrEP My Way Intervention Strategy

- PrEP is an evidence-based intervention
- We developed PrEP My Way to help more young women use it
- Clinic-based initiation of PrEP
- Co-packaging with desired services: STI testing, family planning options
- Community-based peer delivery of a visually appealing kit with pictorial and video guidance

(R34MH100940)

Instructional guides

1.

Geuza beseni huu upande wa chini.

2.

Fungua hivi

Simamisha chupa kwenye beseni

Usikunywe maji haya

Usimwage maji haya

3.

Usiguze upande wa chini

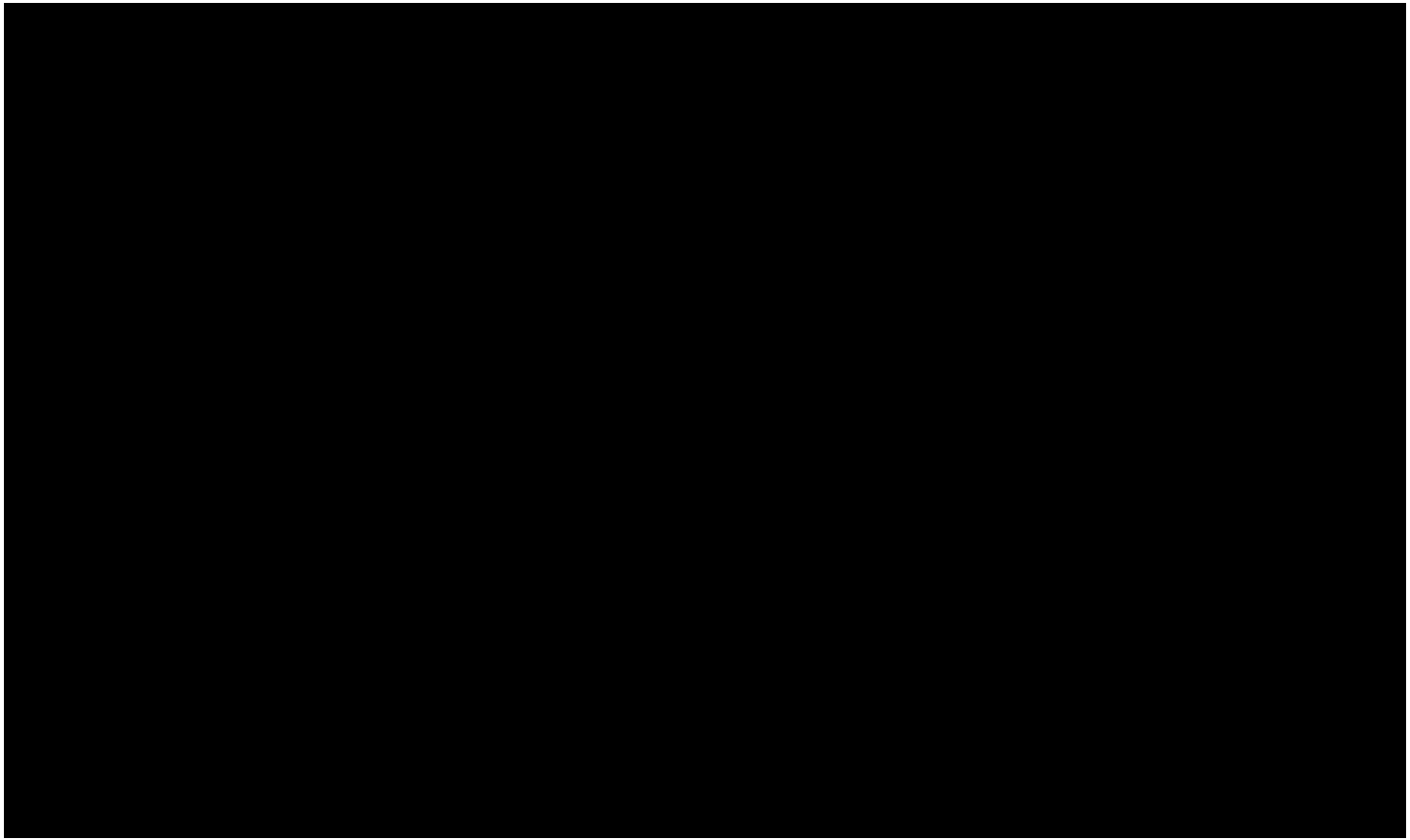
Pitisha sehemu hii mara moja kwenye gum ya juu na ya chini

Subiri Dakika 20

Mstari mmoja humaanisha uko sawa

Ukiona mistari miwili pigia peer mentor wako

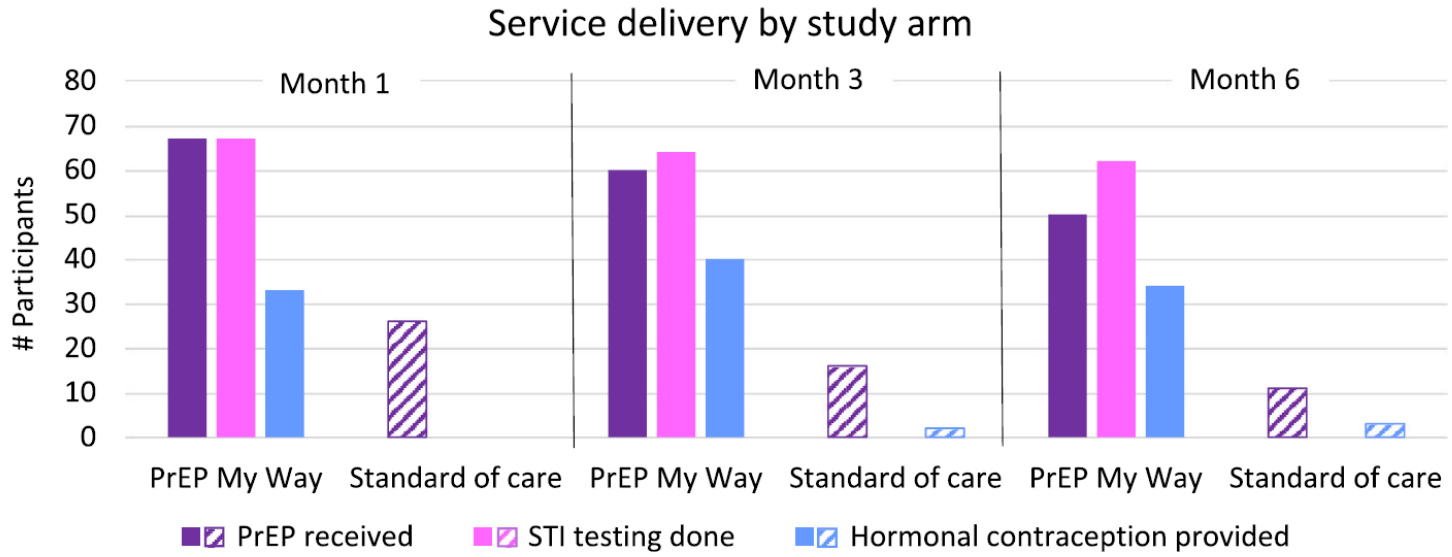
Video guidance



Evidence generation for the strategy

150 young women randomized 1:1 to My Way vs Standard of Care

High feasibility: PrEP receipt, STI testing, family planning receipt over time



(Haberer et al, JIAS 2024)

High acceptability

- 66 (88%) preferred PrEP My Way to clinical care
- 68 (91%) would use PrEP My Way in the next 12 months
- 69 (92%) found peers acceptable/very acceptable
- 95-99% using each kit component found them acceptable/very acceptable
- Median systems usability scale of 76 (IQR 68-85; N=68) indicating excellent performance

Modest persistence at 6 months by TFV-DP

Persistence:

- 12/75 (**16%**) PrEP My Way
- 4/75 (**5%**) SoC; p=0.04

Prevention-effective persistence:
(self-reported PrEP use, >1 partner, condomless sex, a lot of concern about HIV)

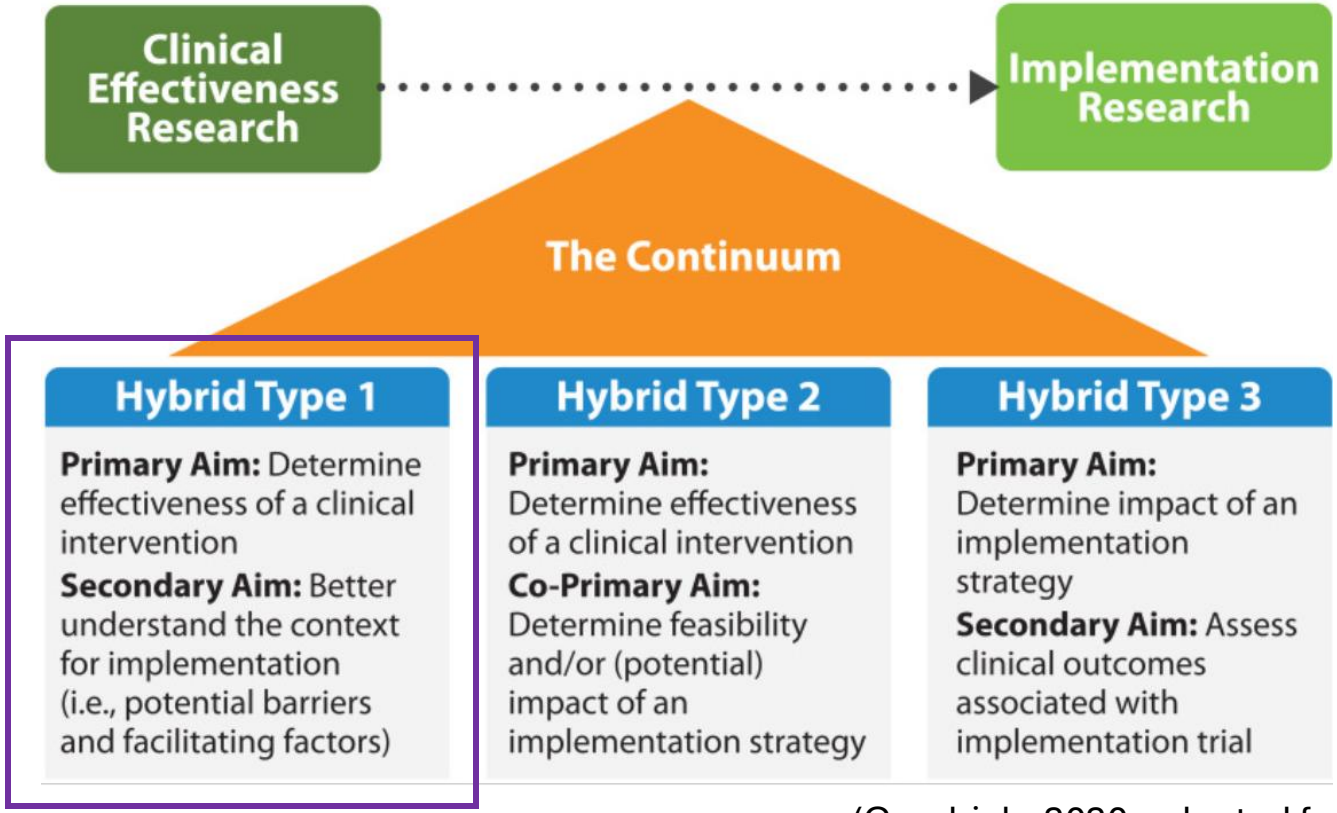
- 12/67 (**18%**) PrEP My Way
- 4/56 (**7%**) SoC; p=0.08

Overall assessment of PrEP My Way

- Highly effective, evidence-based intervention = PrEP
- Highly feasible and acceptable delivery strategy = PrEP My Way

- PrEP My Way: a type 1 hybrid effectiveness-implementation RCT in Kisumu Kenya (R01MH138255; PIs: Haberer, Bukusi)
- Augmented initial work with additions of **choice** (REACH/MTN-034; PURPOSE 1):
  - PrEP formulation (oral, vaginal ring, CAB-LA, LEN)
  - Adherence support strategies (SMS, WhatsApp, live calls)
- Intervention vs enhanced standard of care in 432 young women in partnership with Kenya Ministry of Health

Hybrid implementation-effectiveness designs



(Goodrich, 2020; adapted from Curran)

Outcomes

- **Primary outcome**: PrEP persistence at 5-7 months in women with ongoing HIV prevention needs (i.e., self-reported desire for PrEP, self-reported HIV risk, condomless sex, and/or multiple sexual partners)
- **Secondary outcomes**: PrEP persistence and adherence at other time points and with alternative definitions of HIV prevention needs, STI testing, and family planning use.
- **Implementation outcomes (per Proctor's framework)**:
  - Implementation metrics: acceptability, adoption, appropriateness, feasibility, fidelity, penetration, sustainability
  - Service metrics: efficiency, equity, timeliness
  - Client metrics: satisfaction, function
- **Cost and cost-effectiveness analysis**

Adaptation

- **ADAPT-ITT**: Assessment, Decision, Adaptation, Production, Topical Experts–Integration, Training, and Testing (Wingood & DiClemente, JAIDS 2008)
- **CFIR**: Consolidated Framework for Implementation Research (Damschroeder et al, Imp Sci 2022)
- **FRAME**: Framework for Reporting Adaptations and Modifications to Implementation Strategies (Miller, Imp Science, 2021)
- **Human centered design** (Brown & Wyatt. Ann *Rev Policy Design* 2015)

ADAPT-ITT

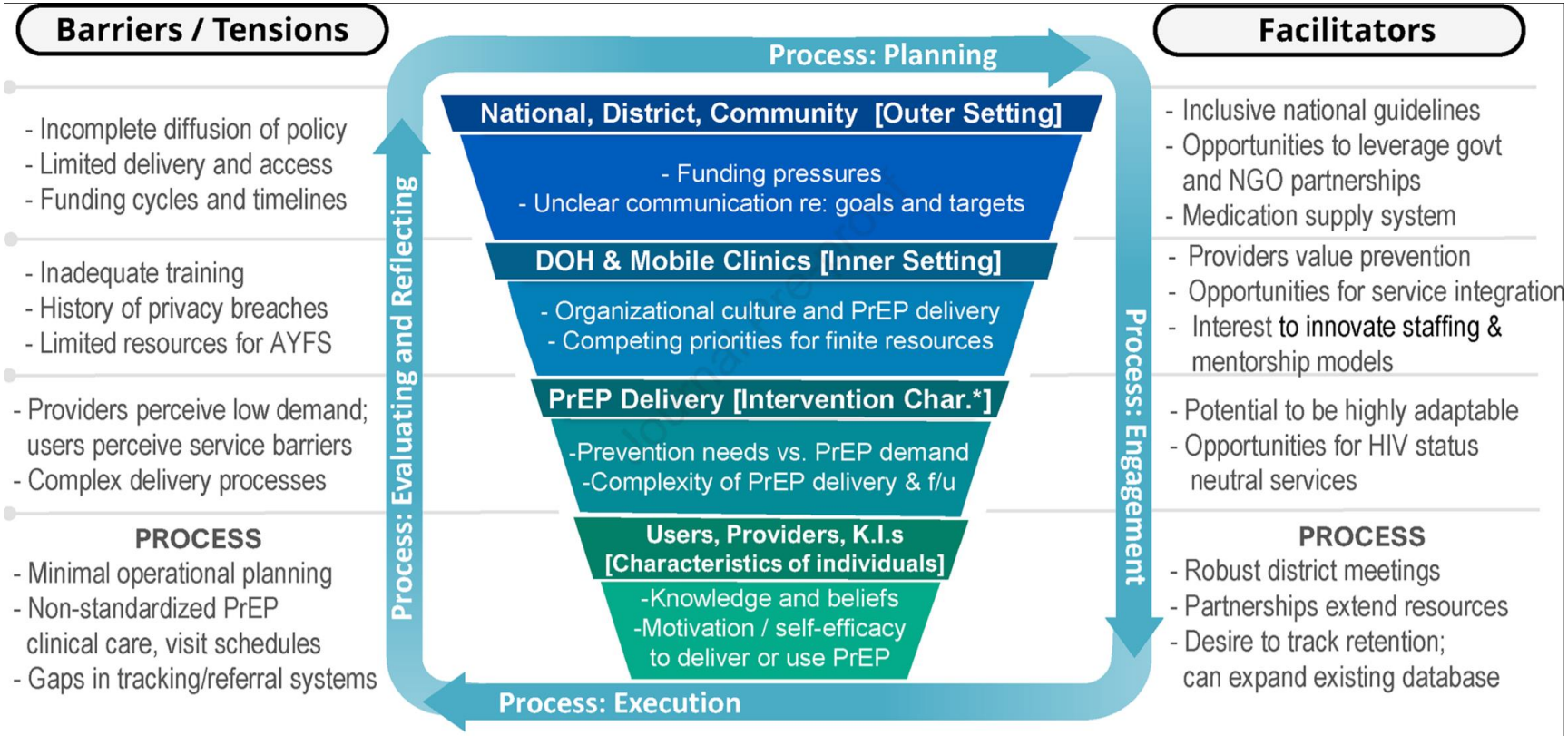
Adaptation and Reach of a PrEP Social Marketing Campaign (PrEP4Love) for Latino, Latina, and Latinx Populations

(Shah et al, JMIR FR, 2024)

Phase	Methodology used for the PrEPárate campaign
Assessment	• Focus groups, stakeholder interviews, and surveys with Latino/a/x sexual minority men and transgender women were conducted
Decision	• We decided to adapt the evidence-based intervention PrEP4Love for Latino/a/x sexual minority men and transgender women in Cook County, Illinois
Adaptation	• The campaign name was selected through a crowdsourcing open contest • We contracted 4 local Latino/a/x designers to develop campaign materials • We "theatre tested" different design schemes with Latino/a/x sexual minority men and transgender women over Instagram (Meta Platforms Inc) and with CQL[c] Collaborative members
Production	• We arranged photo and video sessions with 7 local Latino/a/x sexual minority men and transgender women social media "influencers" (people with large social media followings among our target audience) • We developed a website [35] • We contracted a social media agency to create and manage advertisements
Topical experts	• The CQL Collaborative was involved in every phase of the project including the review of all campaign materials and study design
Integration	• We integrated feedback from CQL Collaborative members and a survey of Latino/a/x LGBTQ+[d] youth to refine campaign materials prior to dissemination
Training	• The investigative team completed training in running and evaluating social media advertisements through the Center for AIDS Research Digital Bootcamp • The social media agency and web developer were already trained in their respective fields
Testing	• We tested campaign advertisements in April 2022 and launched the full pilot intervention from May to July 2022 using social media (including dating apps), posters at Latino/a/x-focused CBOs[e] and clinics, and train and bus advertisements

Consolidated Framework for Implementation Research

PrEP delivery in rural South Africa (Baron et al, SSM 2024)



FRAME-IS: Framework for Reporting Adaptations and Modifications to Implementation Strategies

Module 1: BRIEFLY DESCRIBE the EBP, implementation strategy, and modifications

Module 2: WHAT is modified?

Module 3: What is the NATURE of the content, evaluation, or training modification?

Module 3, OPTIONAL Component: Relationship to fidelity/core elements?

Module 4: Part 1: What is the GOAL?

Module 4: Part 2: What is the LEVEL of the rationale for the modification?

Using FRAME to Adapt an Evidence-Based HIV Prevention Intervention for Zambian AGYW

(Sissoko et al, AIDS & Behavior, 2026)

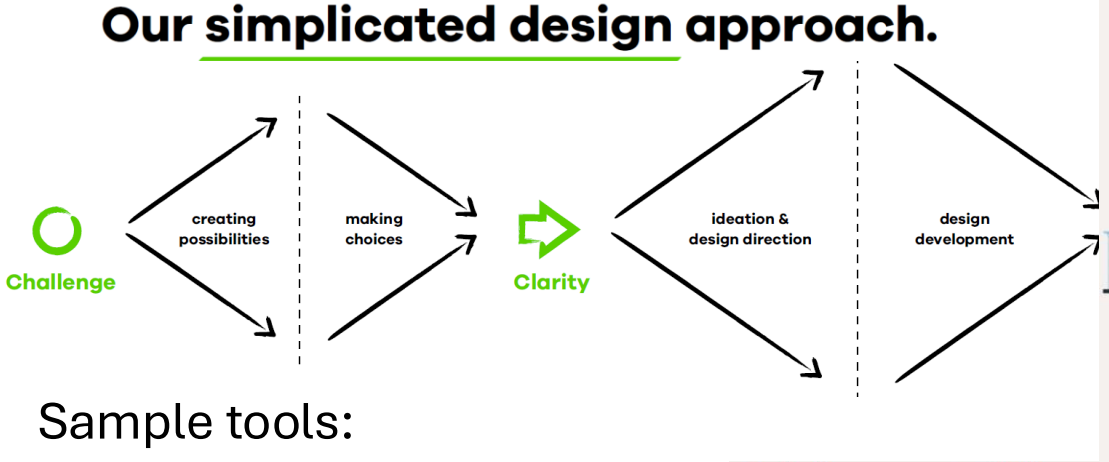
Informed Motivated Aware and Responsible Adolescents and Adults (IMARA) program (US -> South Africa)

"…provided a transparent, systematic method to maintain cultural relevance with fidelity to an evidence-based intervention"

Table 2 Modifications for ZAIMARA using FRAME

	Modification	Why/goal
1	Language change to Bemba	Fit
2	Curriculum Motto was changed	Fit Cultural Factors
3	IMARA poem was changed	Fit Cultural Factors
4	IMARA theme song was changed	Fit Cultural Factors
5	Intervention terms were changed (i.e., assertive to effective communication)	Cultural Factors Satisfaction Retention Effectiveness/outcomes
6	Names and scenarios changed to Zambian context	Fit Cultural Factors
7	Increase session length on communication to 150 min	Reach/engagement Effectiveness/outcomes
8	Mother figure recipients were expanded to include younger female caregivers	Reach/engagement

Human centered design



Sample tools:

- Individual interviews
- Multi-stakeholder workshops
- Use of personas
- Creation of story boards

(Ark Africa, Julita Bhagat)

Rapid iteration

Integrating HIV PrEP into Family Planning Care: A RE-AIM Framework Evaluation

(Washington DC; Brant et al, *AIDS Patient Care STDS* 2020)

- **Reach:** % of women receiving HIV counseling / PrEP screening
- **Effectiveness:** PrEP uptake among eligible women
- **Adoption:** Provider participation and willingness to discuss PrEP
- **Implementation:** Fidelity to workflows, barriers, workflow adaptations
- **Maintenance:** Sustainability after formal implementation period

- Repeated evaluation increased PrEP screening 10% -> 65%

Putting it all together: Learning

Points for Discussion

- What is working well for you with implementation science?
- What is challenging?
- How can we better use implementation science for HIV prevention (and other EBIs)?

Thank you!

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