



Research to Real-World: Implementation Science in HIV Prevention

Joseph “Greg” Rosen, PhD, MSPH
Brown University Warren Alpert Medical School

Continuum 2025 • June 10-12, 2025 • San Juan

Disclosures

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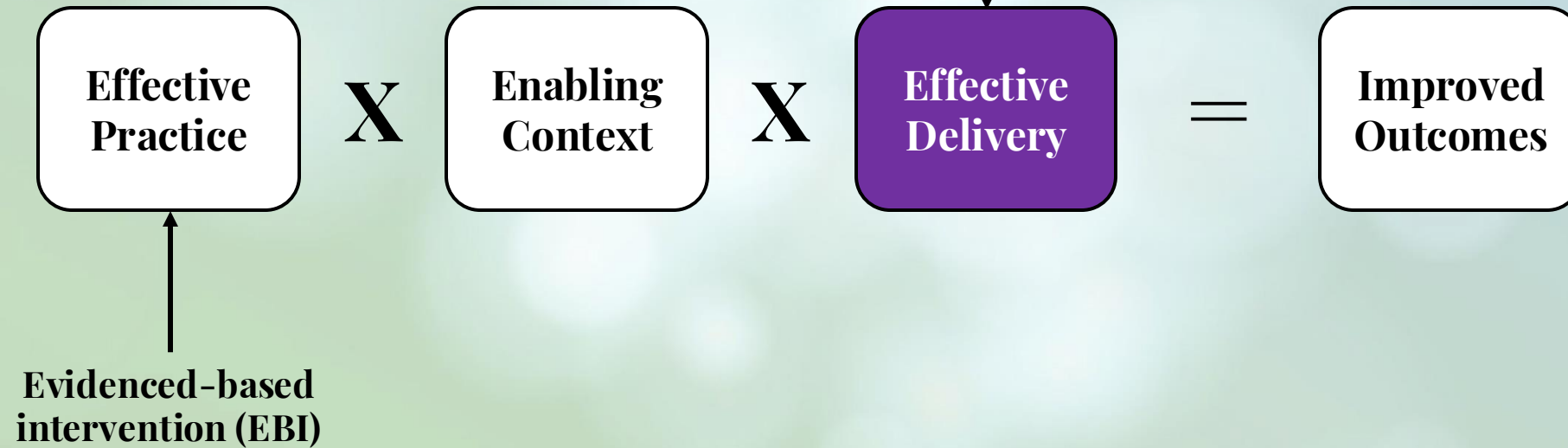


- Paid consultant to the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF)
- No commercial conflicts of interest to disclose

IS in HIV Prevention

Closing the “know-do” gap

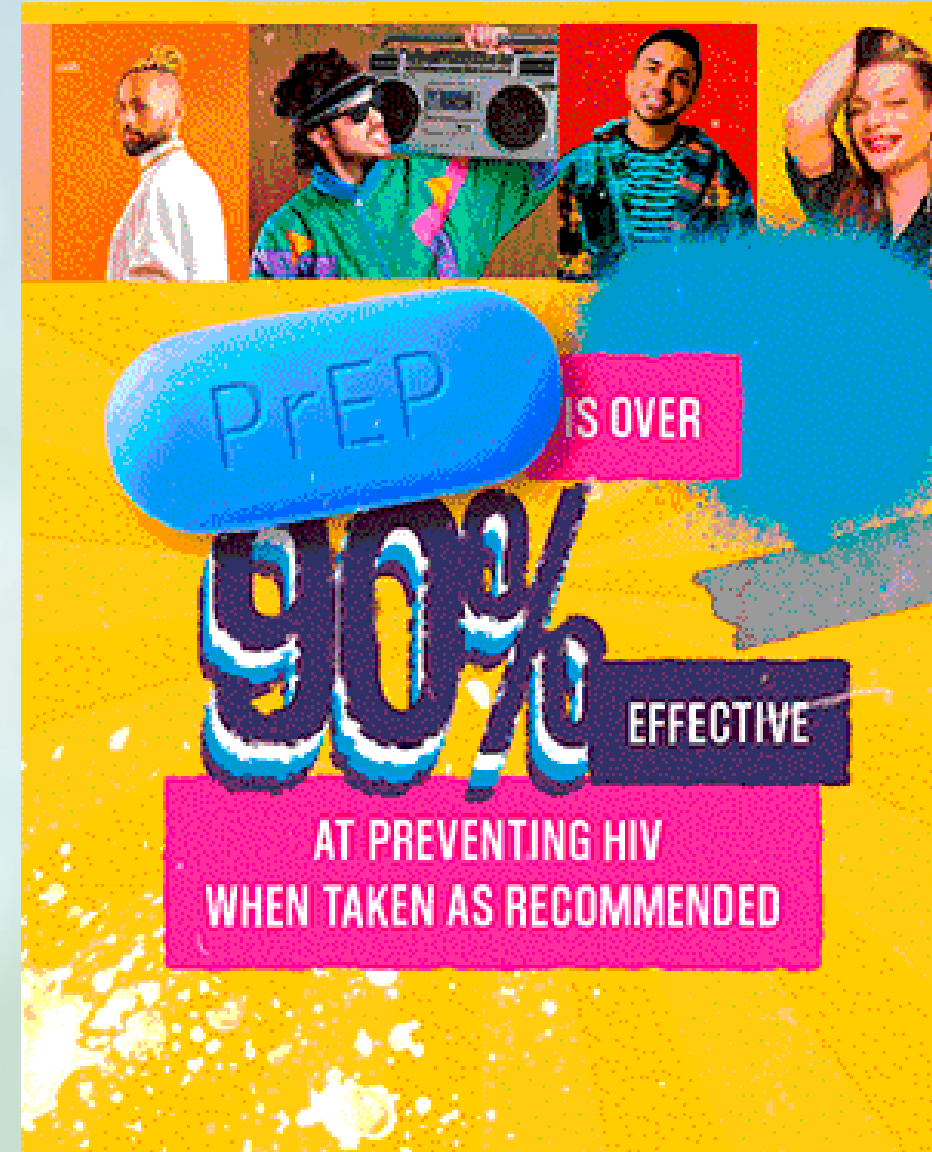
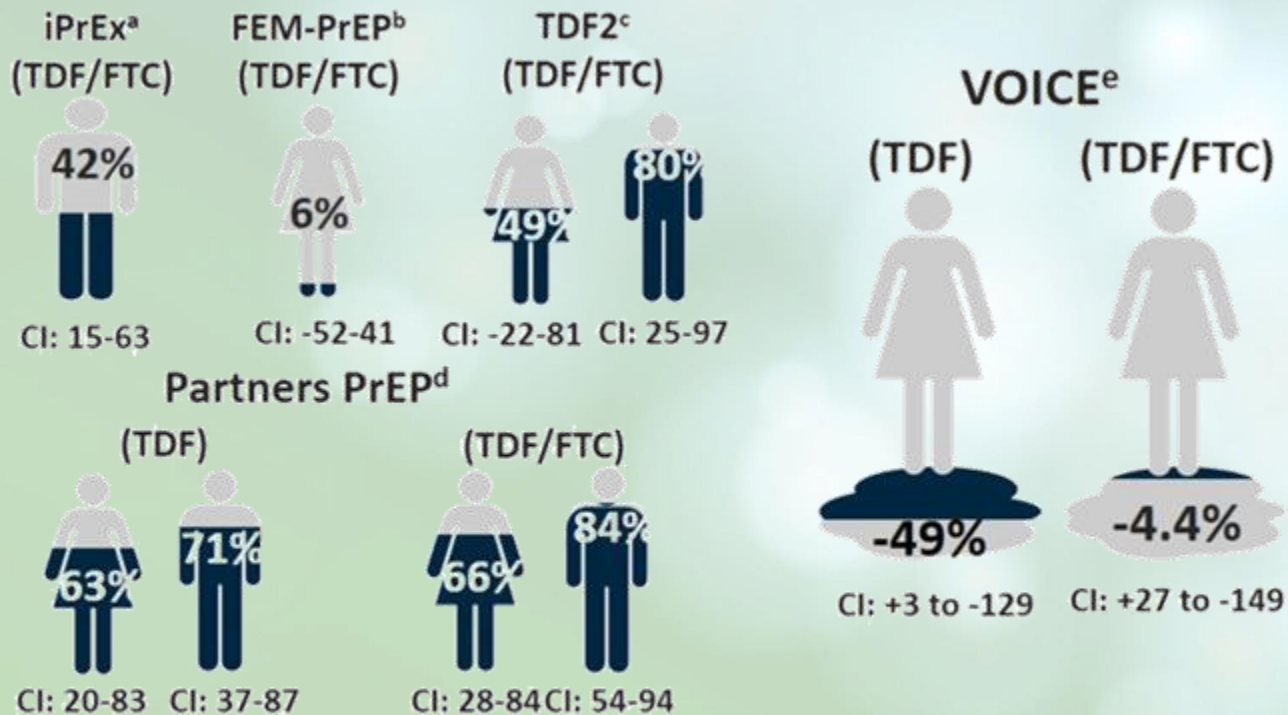
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IS in HIV Prevention: PrEP

What do we “know”?

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a. Grant RM, et al. *N Engl J Med.* 2010;363:2587-2599^[1]; b. Van Damme L. *N Engl J Med.* 2012;367:411-422^[2]; c. Thigpen MC, et al. *N Engl J Med.* 2012;367:423-434^[3]; d. Baeten JM, et al. *N Engl J Med.* 2012;367:399-410^[4]; e. Marrazzo J, et al. *N Engl J Med.* 2015;372:509-518.^[5]

IS in HIV Prevention: PrEP

What do we “know”?

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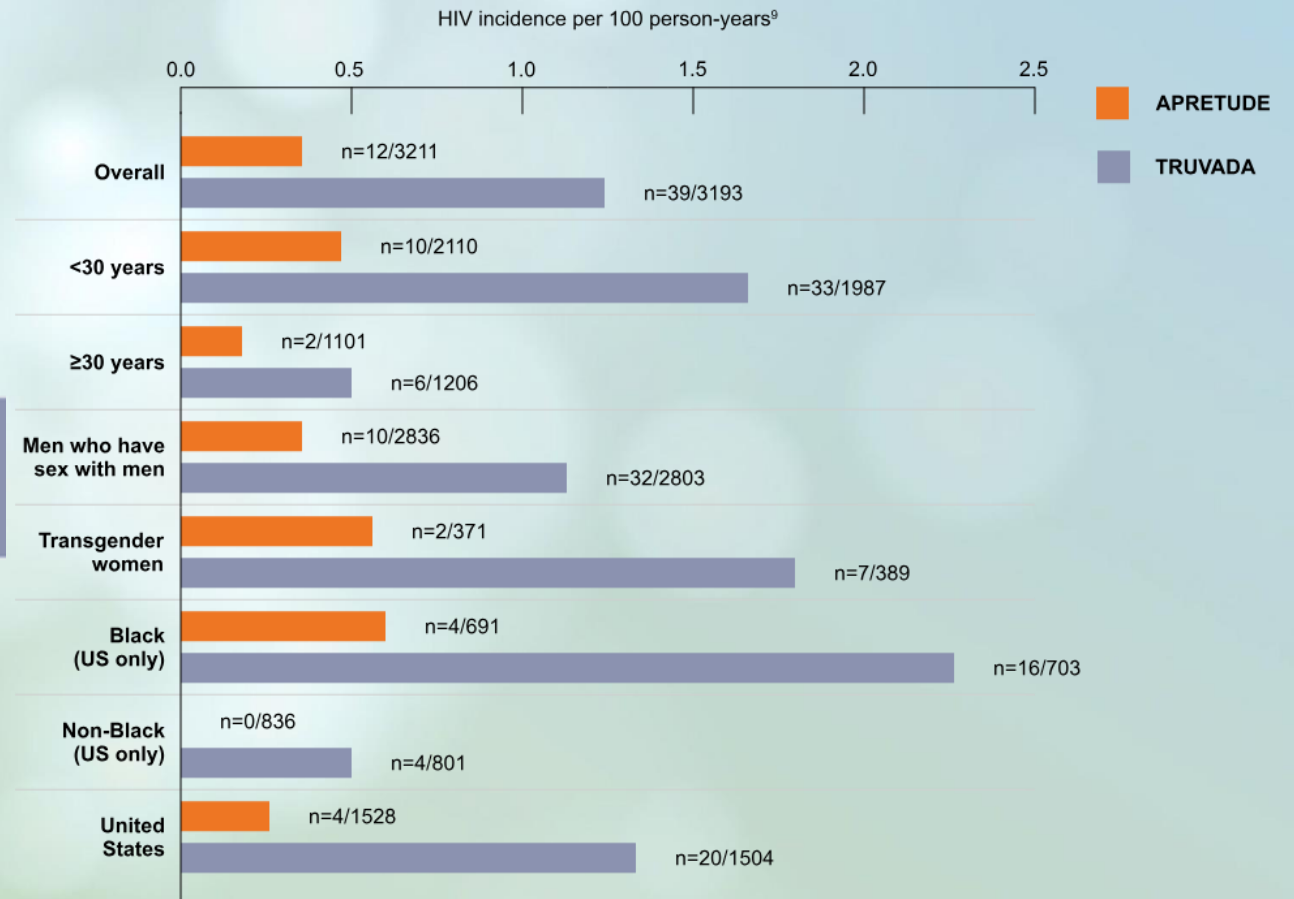
39 PEOPLE (OF 2281) ACQUIRED HIV-1 WHILE ON TRUVADA

VS



12 PEOPLE (OF 2278) ACQUIRED HIV-1 WHILE ON APRETUDE

HIV-1 ACQUISITIONS OCCURRED
>3x LESS OFTEN
WITH APRETUDE



IS in HIV Prevention: PrEP

What are we failing to “do”?

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~40% discontinuation within the first month of PrEP initiation

PLOS ONE

RESEARCH ARTICLE

Persistence on oral pre-exposure prophylaxis (PrEP) among female sex workers in eThekweni, South Africa, 2016–2020

Amrita Rao^{1*}, Hlangwe Mhlophe², Carly Comins¹, Katherine Young³, Mfeki Masingane², Catherine Lesosky³, Ntombi Mulumba², Stefan Baral¹, Harry Haesler³, Sheree Schwartz²

¹ Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland, United States of America, ² TB HIV Care, Durban, South Africa, ³ TB HIV Care, Cape Town, South Africa

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Abstract

Background

Despite the established efficacy of PrEP to prevent HIV and the advantages of a user-controlled method, PrEP uptake and persistence by women in both trials and demonstration projects has been suboptimal. We utilized real-world data from an HIV service provider to describe persistence on oral PrEP among female sex workers (FSW) in eThekweni, South Africa.

Methods

We examined time from PrEP initiation to discontinuation among all FSW initiating PrEP at TB HIV Care in eThekweni between 2016–2020. We used a discrete time-to-event data setup and stacked cumulative incidence function plots, displaying the competing risks of 1) not returning for PrEP, 2) client discontinuation, and 3) provider discontinuation. We calculated hazard ratios using complementary log-log regression and sub-hazard ratios using competing risks regression.

Results

The number of initiations increased each year from 155 (9.3%, n = 155/1659) in 2016 to 1224 (27.5%, n = 1224/4446) in 2020. Persistence 1-month after initiation was 53% (95% CI: 51%–55%). Younger women were more likely to discontinue PrEP by not returning compared with those 25 years and older. Risk of discontinuation through non-return declined for those initiating in later years. Despite the COVID-19 pandemic, a greater number of initiations and sustained persistence were observed in 2020.

Conclusions

Low levels of PrEP persistence were observed, consistent with data among underserved women elsewhere. Encouragingly, the proportion of women persisting increased over time, even as the number of women newly initiating PrEP and staff workload increased. Further



OPEN ACCESS

Citation: Rao A, Mhlophe H, Comins C, Young K, Masingane M, Lesosky C, et al. (2022) Persistence on oral pre-exposure prophylaxis (PrEP) among female sex workers in eThekweni, South Africa, 2016–2020. PLOS ONE 17(3): e025434. <https://doi.org/10.1371/journal.pone.0254344>

Editor: Catherine E. Oldenburg, University of California, UNITED STATES

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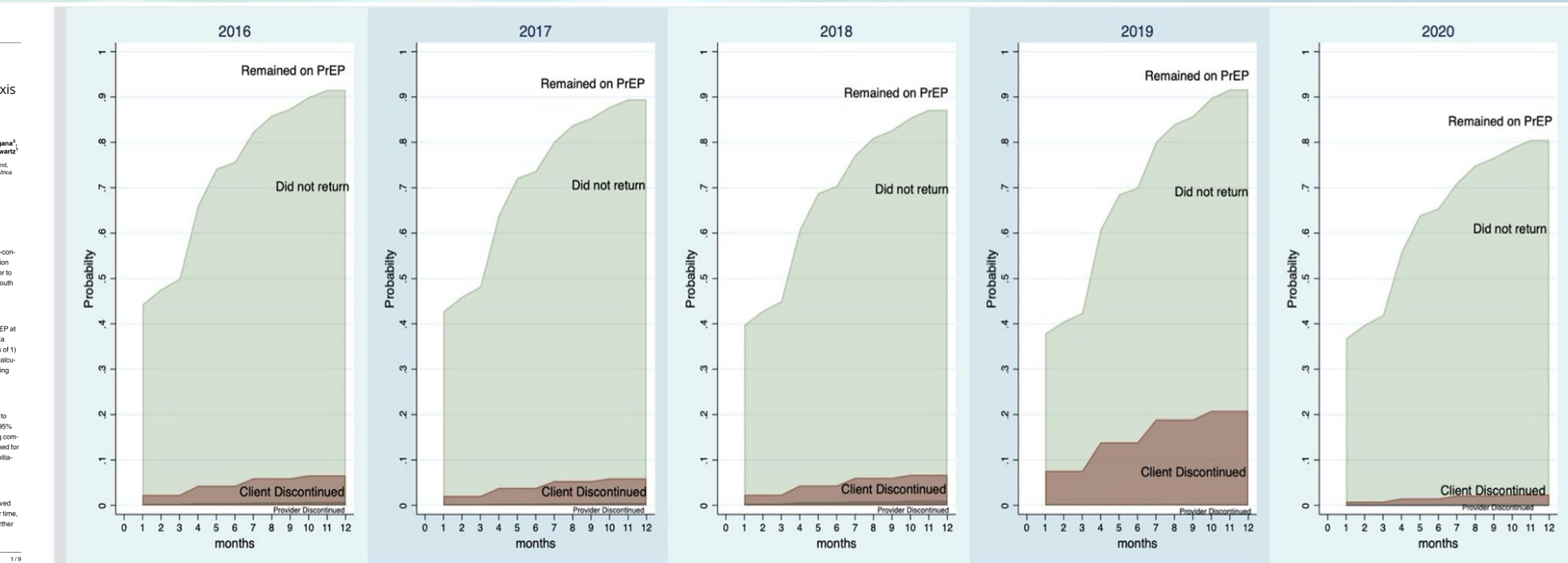
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Data Availability Statement: This analysis leveraged program data that the research team does not have ownership over. Data are protected under the Protection of Personal Information Act



IS in HIV Prevention: PrEP

What are we failing to “do”?

#continuum2025



Stoebenau et al. BMC Public Health (2024) 24:1617
<https://doi.org/10.1186/s12889-024-19152-y>

BMC Public Health

RESEARCH

Open Access



Barriers and facilitators to uptake and persistence on prep among key populations in Southern Province, Zambia: a thematic analysis

Kirsten Stoebenau^{1*}, Godfrey Muchanga², Sacha St-Onge Ahmad³, Chiti Bwalya¹, Mwangala Mwale³, Samara Toussaint¹, Choolwe Maambo³, Carson J. Peters¹, Caitlin Baumhart^{4,5}, Linah K. Mwangi⁶, Marie-Claude C. Lavoie^{2,4,5} and Cassidy W. Claassen^{3,4,5,7}

Abstract

Background Especially in high HIV prevalence contexts, such as Zambia, effective biomedical prevention tools are needed for priority populations (PPs), including key populations (KPs), who are at higher risk. HIV pre-exposure prophylaxis (PrEP) has been scaled up nationally in Zambia, but little is known about barriers to PrEP use among specific PPs to date.

Methods To understand barriers and facilitators to PrEP use in Zambia, we conducted a qualitative case study of PrEP services to PPs including sero-discordant couples (SDCs), female sex workers (FSWs), and men who have sex with men (MSM) in Livingstone. The study conducted in 2021 included in-depth interviews (n=43) guided by the socio-ecological model, and focus group discussions (n=4) with clinic and community-based providers and PrEP-eligible clients including users and non-users across PP groups. We used thematic analysis to analyze data using codes derived both deductively and inductively.

Results We found multilevel barriers and facilitators to PrEP use. Cross-cutting barriers shared across PP groups included amplifying effects of PrEP being mistaken for antiretroviral drugs used to treat HIV, including anticipated stigma, and concerns about side-effects based on both misinformation and experience. In addition, stigmatized identities, particularly that of MSM, served as a barrier to PrEP use. The fear of being mislabeled as having HIV was of greatest concern for FSWs. Facilitators to PrEP use primarily included the importance of confidential, KP-sensitive services, and the role of informed, supportive family, friends, and peers. Participants across all PP groups urged expanded education efforts to increase awareness of PrEP within the general population toward mitigating concerns of being mislabeled as living with HIV.

Conclusion To our knowledge, this is the first qualitative study of the PrEP cascade among multiple PPs in Zambia. This study provides important explanation for the low rates of PrEP continuation found in earlier demonstration trials among KPs in Zambia. The study also offers recommendations for programming efforts going forward such

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BARRIERS

FACILITATORS

Stigmatization of people living with HIV
Stigmatization of KP identities
Criminalization of MSM

Society

Discrimination of KP in clinic with providers
Mistrust of healthcare system
Long wait times / conflicts with work
Drug stockouts

Health System

Misinformation about PrEP
Family/Partner mistaking PrEP for ART
Partner mistrust

Interpersonal

Alcohol use
Mobility
PLHIV label avoidance
Fear of / experience side effects
Does not believe that PrEP works
Pill Size

Individual

Community-based distribution of PrEP
Trained, kind providers
Private consultation rooms

Informed and supportive family, partners, and peers

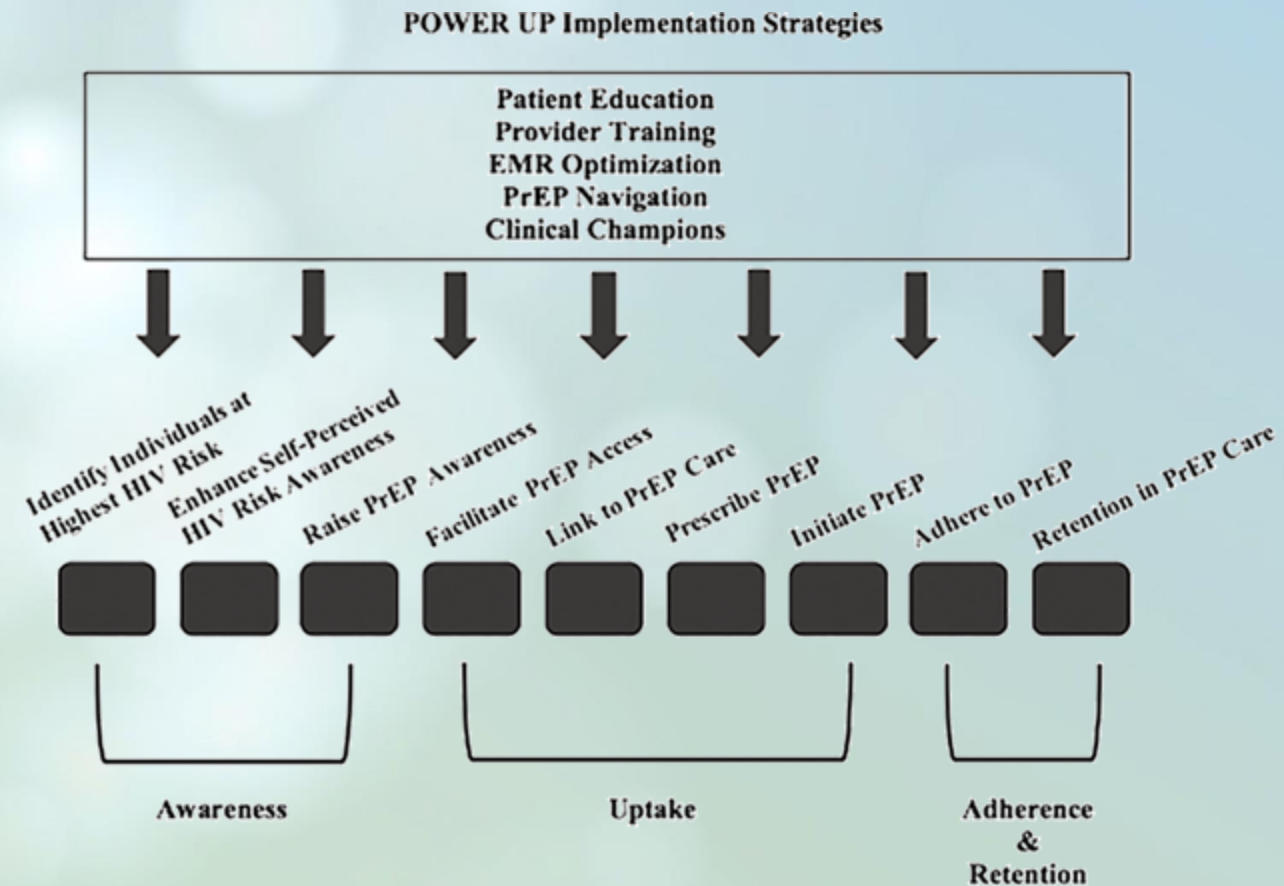
Doesn't like condoms
Can't control condom use
High risk perception
Wants to protect children and loved ones

IS in HIV Prevention: PrEP

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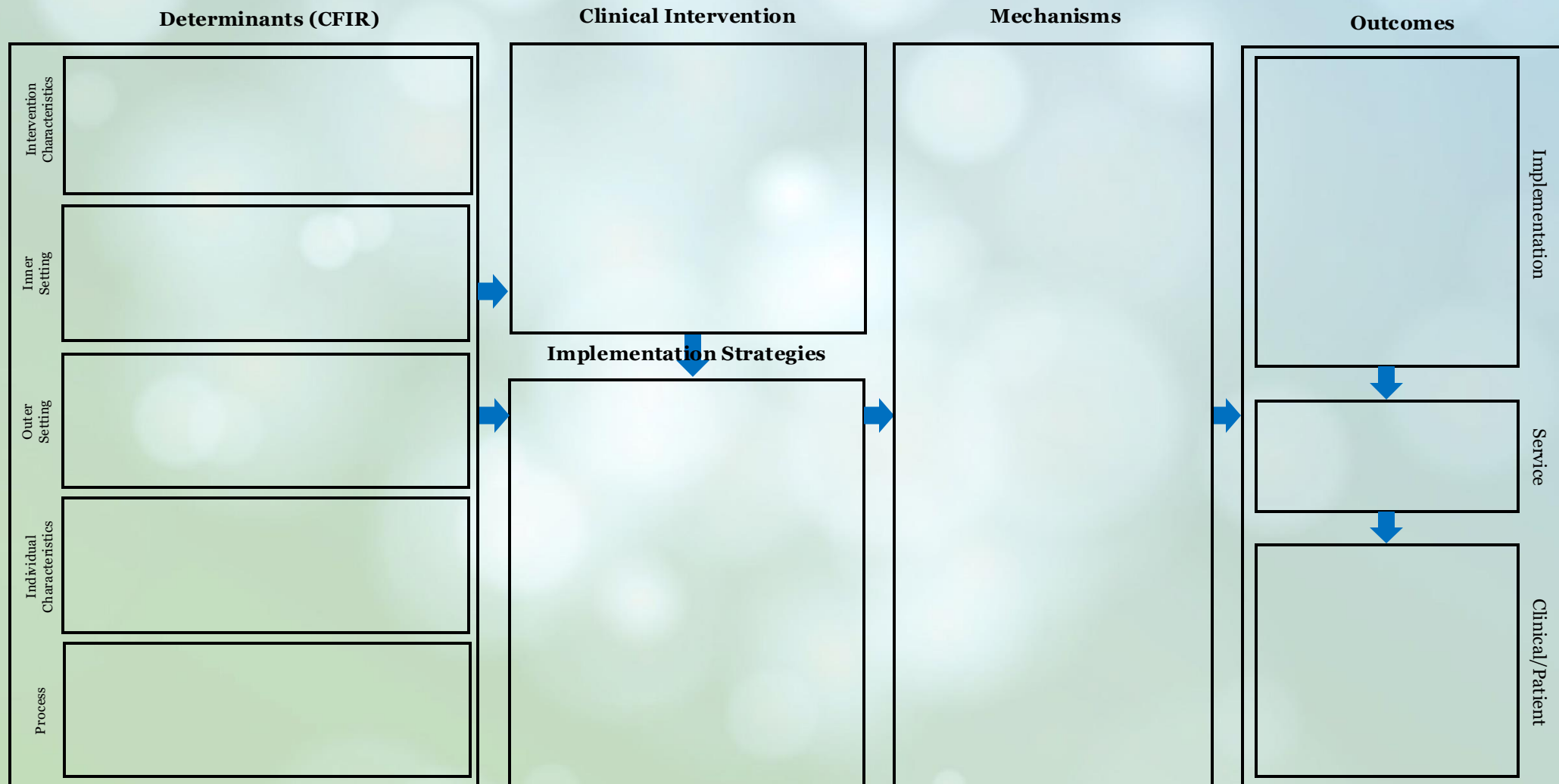


How do we deliver differently (better)?



Implementation Research Logic Model (IRLM)

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Identifying implementation determinants

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Determinants (CFIR)



Clinical Intervention

**Daily or event-driven oral
PrEP for HIV prevention**



Identifying implementation determinants

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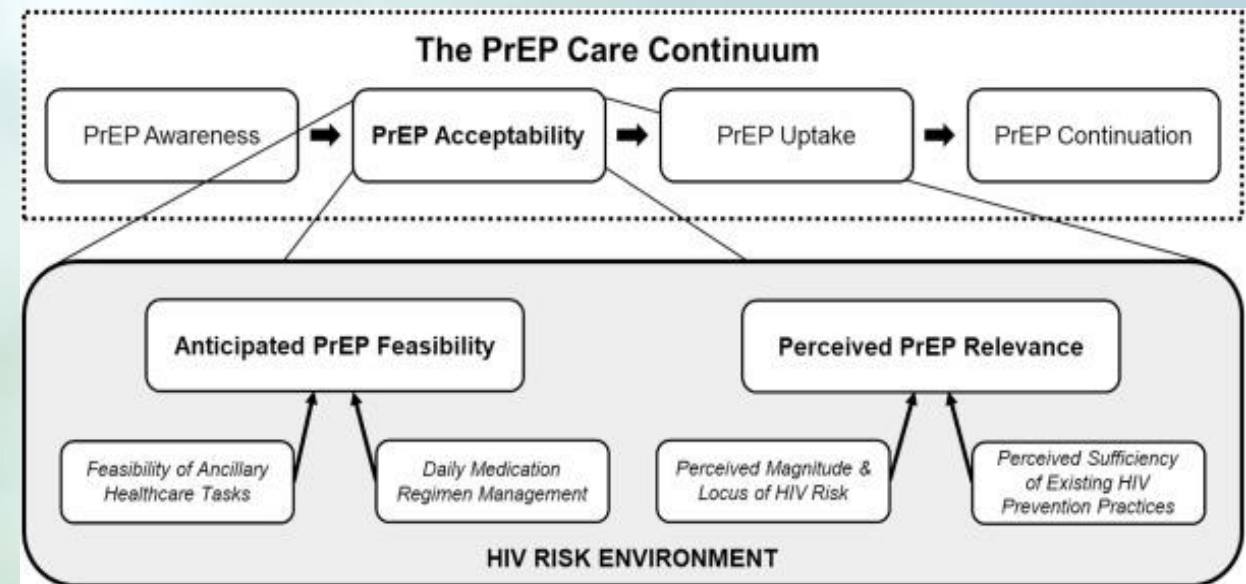
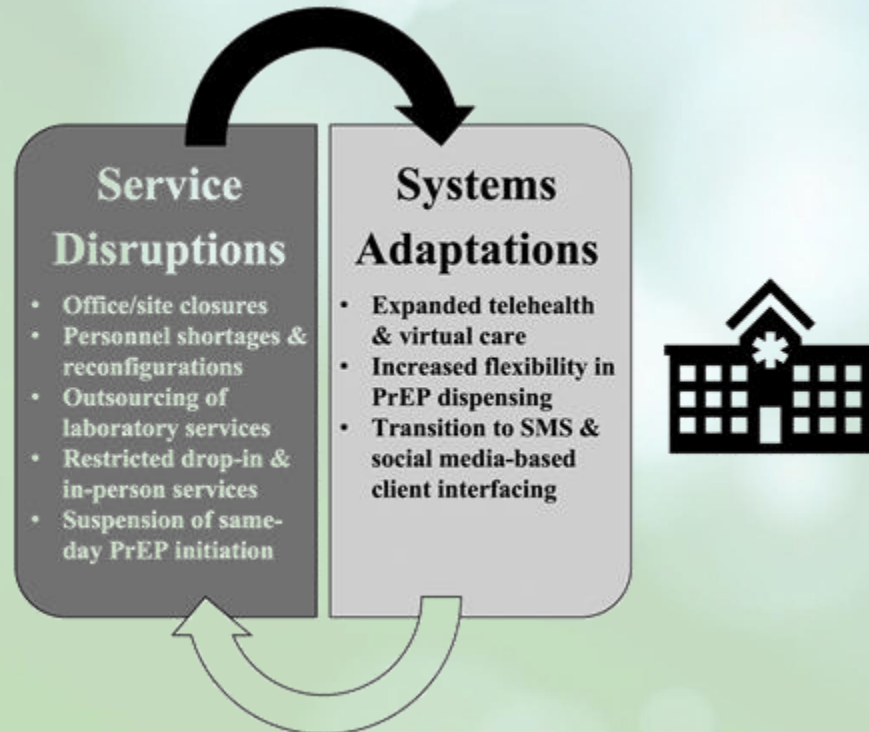
Provider Perspectives on HIV Pre-Exposure Prophylaxis Service Disruptions and Adaptations During the COVID-19 Pandemic in Baltimore, Maryland: A Qualitative Study

Joseph G. Rosen, MSPH ¹, Leanne Zhang, MSPH ², Danielle Pelaez, BA ², Jenell S. Coleman, MD, MPH ³, C To, MSPH ⁴, Lyra Cooper, MHS ², Praise F. Olatunde, MSPH ¹, Teagan Toomre ², Jennifer L. Glick, PhD ², and Ju Nyeong Park, PhD ^{2,5,6}



Interrogating perceived relevance and feasibility of HIV pre-exposure prophylaxis: A novel model of PrEP acceptability among cisgender women who inject drugs

Leanne Zhang ^{a,*}, Joseph G. Rosen ^b, Lyra Cooper ^a, Praise F. Olatunde ^b, Danielle Pelaez ^a, Susan G. Sherman ^a, Ju Nyeong Park ^{a,c,d}, Jennifer L. Glick ^a



Identifying implementation determinants

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Determinants (CFIR)

Intervention Characteristics	High efficacy/effectiveness (+) Side effects (-) Adherence requirements (-) Affordability (+/-) Convenience (+/-)
Inner Setting	Leadership commitment/support (+) Workforce rapport with VM (+) Available/trainable FHRW (+/-) Competing workplace priorities/time (-) Referral pathways to healthcare (+)
Outer Setting	Multi-modal PrEP availability (+/-) Medical mistrust and racism (-) PrEP promotion campaigns (+/-) Payment plans for PrEP prescriptions (+/-)
Individual Characteristics	Perceived PrEP relevance (+/-) Competing needs/survival priorities (-) Trust in and rapport with FHRW (+) Engagement with community partners(+) Disengagement from health services (-)
Process	Planning for PrEP promotion/referral (+) Opinion leaders (+) Change champions (+) Evaluation (+) External implementation support (+/-)

Clinical Intervention

Daily or event-driven oral PrEP for HIV prevention



Consolidated Framework for Implementation Research (CFIR) 2.0



Specifying implementation strategies

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Determinants (CFIR)

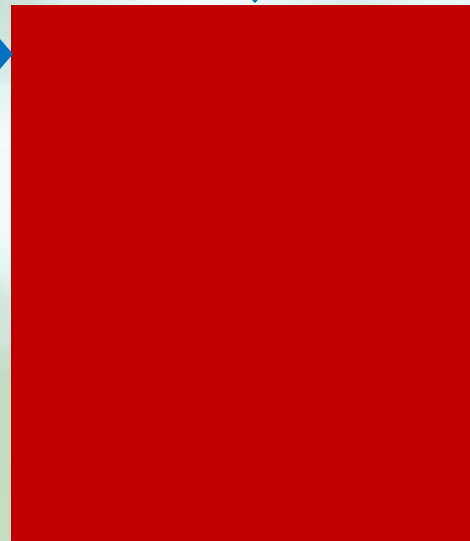
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Clinical Intervention

Daily or event-driven oral PrEP for HIV prevention



Implementation Strategies



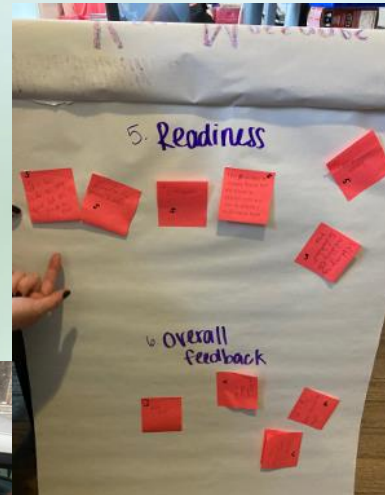
Specifying implementation strategies

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A Novel Capacity-Strengthening Intervention for Frontline Harm Reduction Workers to Support Pre-exposure Prophylaxis Awareness-Building and Promotion Among People Who Use Drugs: Formative Research and Intervention Development

Jennifer L Glick¹, PhD; Leanne Zhang¹, MPH; Joseph G Rosen², PhD; Karla Yaroshevich³, AA; Bakari Atiba³, AA; Danielle Pelaez¹, BA; Ju Nyeong Park^{4,5}, PhD



When Does PrEP Become Protective?

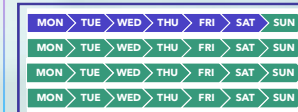
21 Days

receptive vaginal sex or receptive injection equipment sharing



7 Days

receptive anal sex

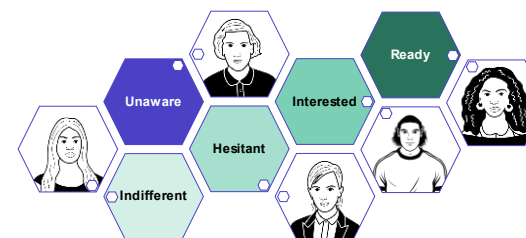


No data are currently available for insertive vaginal and anal sex, but PrEP is still protective!

Is PrEP Safe?

- ✓ Is PrEP safe to take with other medications, including birth control or gender-affirming hormones?
- ✓ Can people who use drugs take PrEP, even if they take medications like methadone or suboxone?
- ✓ Can people with underlying health conditions like Hepatitis C take PrEP safely?
- ✓ What about people who are pregnant or breastfeeding? Is it safe for them to take PrEP?

The PrEP Awareness Mosaic

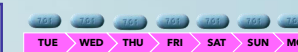


PrEP may not be for everyone. But everyone should know about it.

How is PrEP Taken?

Daily

for all populations

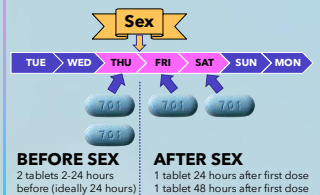


EVERY DAY

1 PrEP tablet taken daily

On-Demand ("2-1-1")

for cisgender men having receptive anal sex



BEFORE SEX

2 tablets 2-24 hours before (ideally 24 hours)

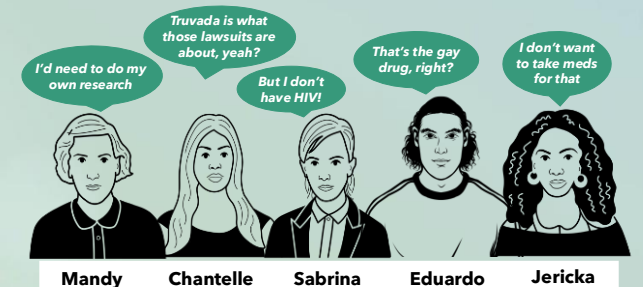
AFTER SEX

1 tablet 24 hours after first dose
1 tablet 48 hours after first dose

Where Can People Get PrEP?

- Online and telephone resources (www.prepmaryland.org, 888-788-PREP) connect clients to PrEP providers.
- Same-day (rapid) PrEP starts are available in some clinics, including the Baltimore City Health Department (SPOT Van).
- PrEP is covered by most insurance plans with no co-pay. Payment plans are available for qualifying clients.

Role Play Exercise #1: Raising Awareness



Specifying implementation strategies

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Determinants (CFIR)


Intervention Characteristics	High efficacy/effectiveness (+) Side effects (-) Adherence requirements (-) Affordability (+/-) Convenience (+/-)
Inner Setting	Leadership commitment/support (+) Workforce rapport with VM (+) Available/trainable FHRW (+/-) Competing workplace priorities/time (-) Referral pathways to healthcare (+)
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Clinical Intervention

Daily or event-driven oral PrEP for HIV prevention

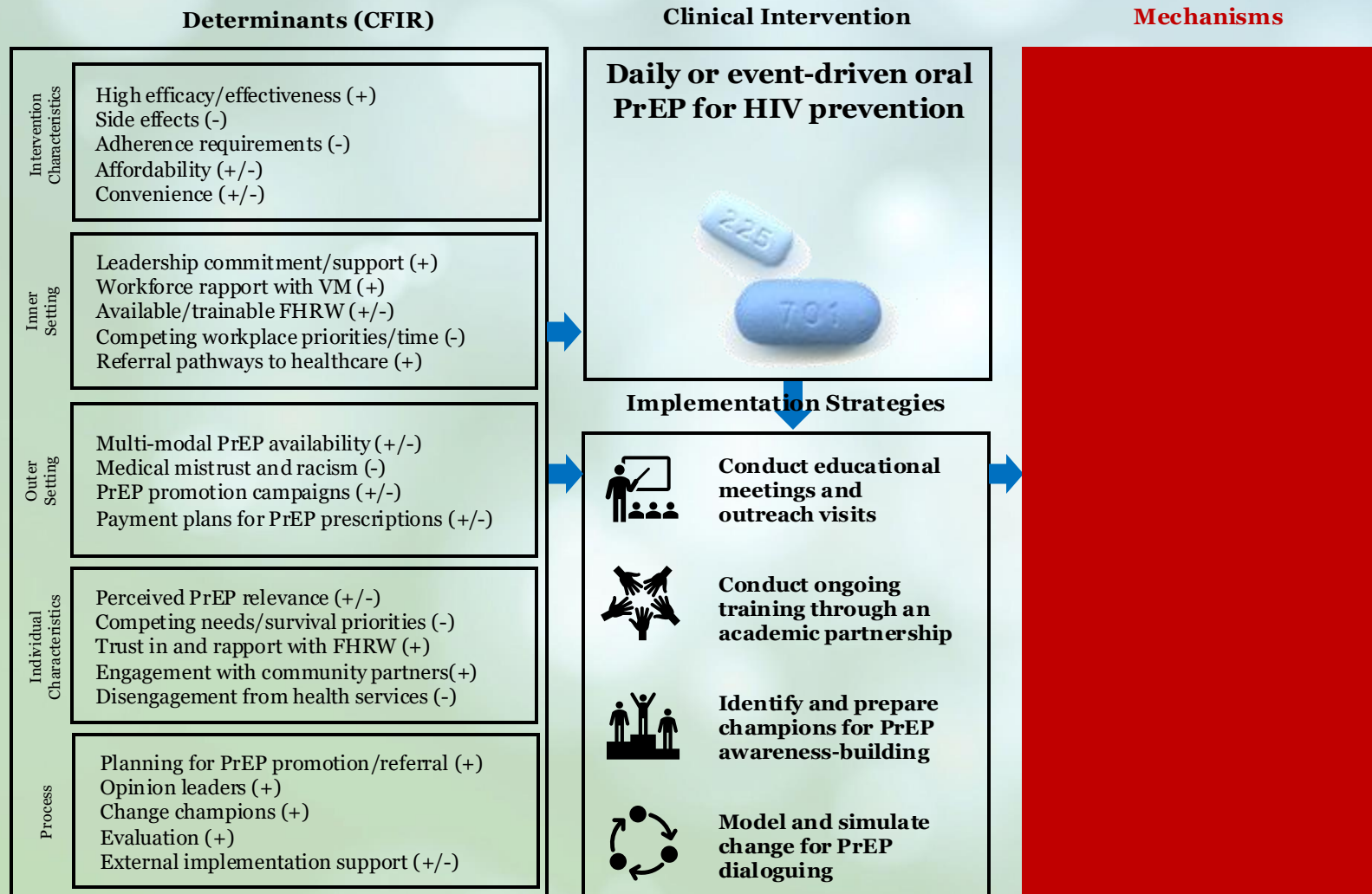


Implementation Strategies

	Conduct educational meetings and outreach visits
	Conduct ongoing training through an academic partnership
	Identify and prepare champions for PrEP awareness-building
	Model and simulate change for PrEP dialoguing

Measuring implementation mechanisms

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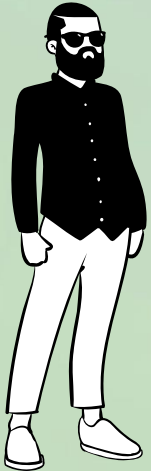


Measuring implementation mechanisms

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“Conversations on Zoom and in-person are completely different... I think the role-play scenarios would be a lot better in-person.”



“I used to work for a company selling credit cards. If I can sell you a card, I can talk to you about PrEP.”

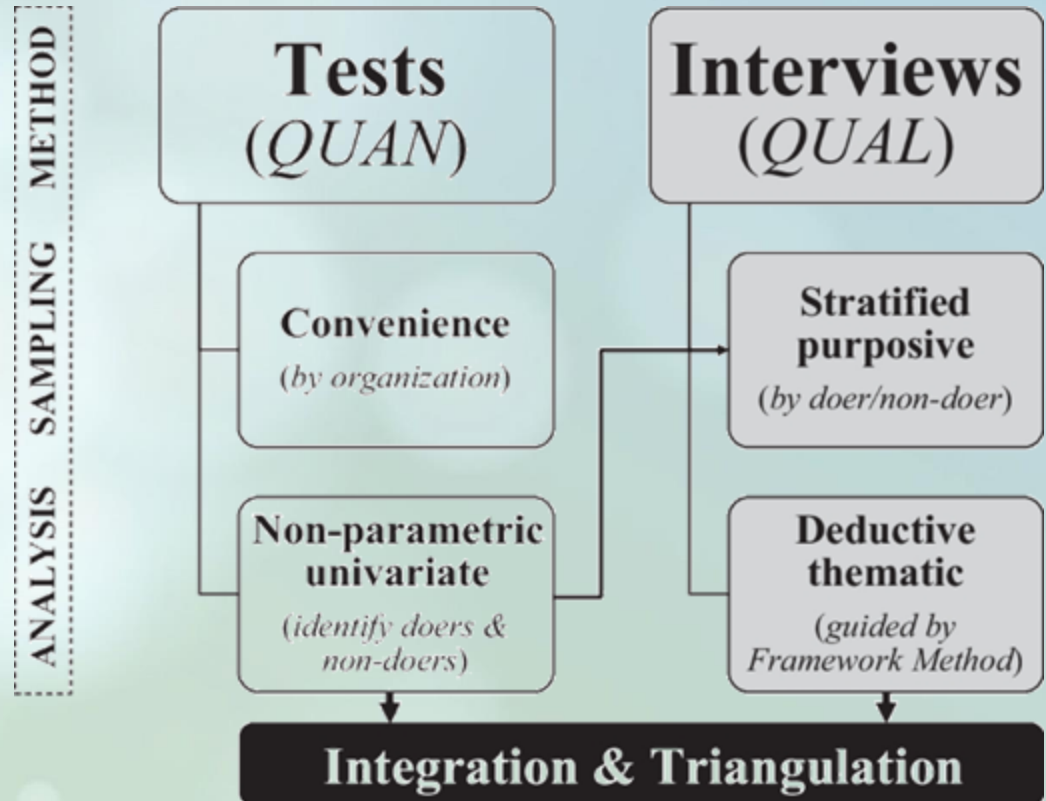


“PrEP is something we don't ask about on our assessment or treatment plans...It's something that doesn't come up in our day-to-day conversations.”



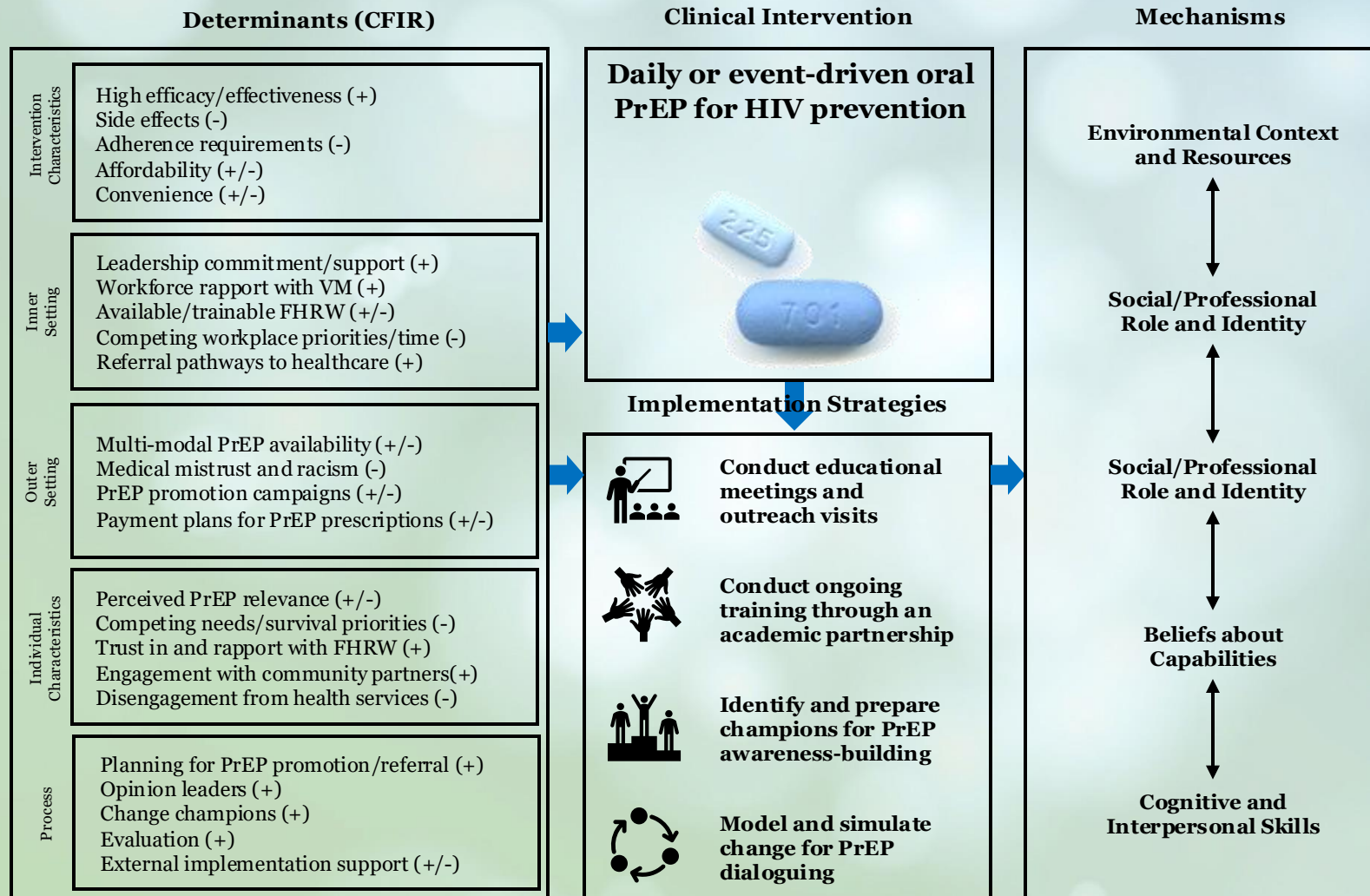
A Capacity-Strengthening Intervention to Support HIV Pre-exposure Prophylaxis (PrEP) Awareness-Building and Promotion by Frontline Harm Reduction Workers in Baltimore, Maryland: A Mixed Methods Evaluation

Joseph G. Rosen¹ · Leanne Zhang² · Danielle Pelaez² · Ju Nyeong Park^{2,3,4} · Jennifer L. Glick²



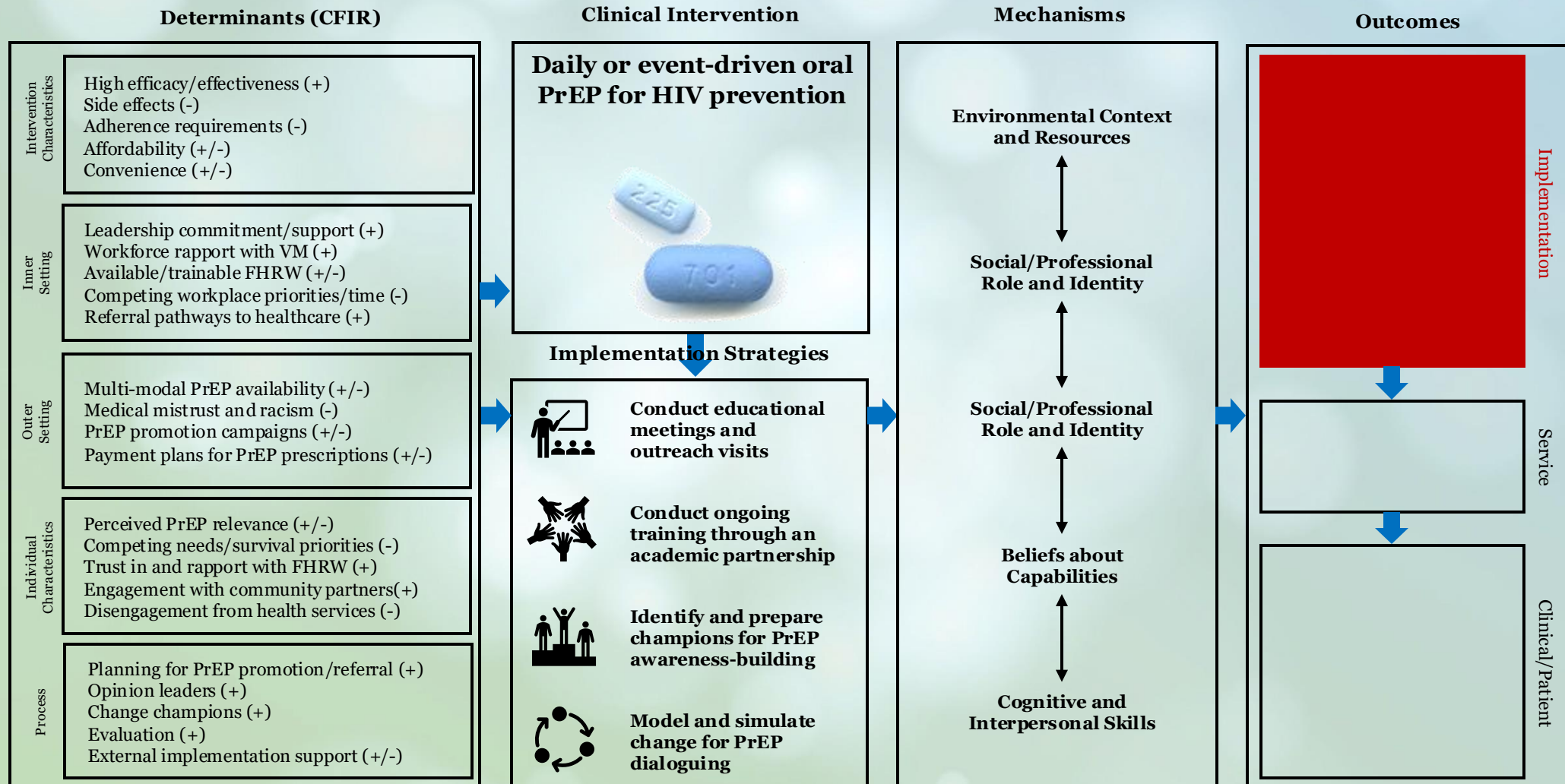
Measuring implementation mechanisms

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Evaluating implementation outcomes

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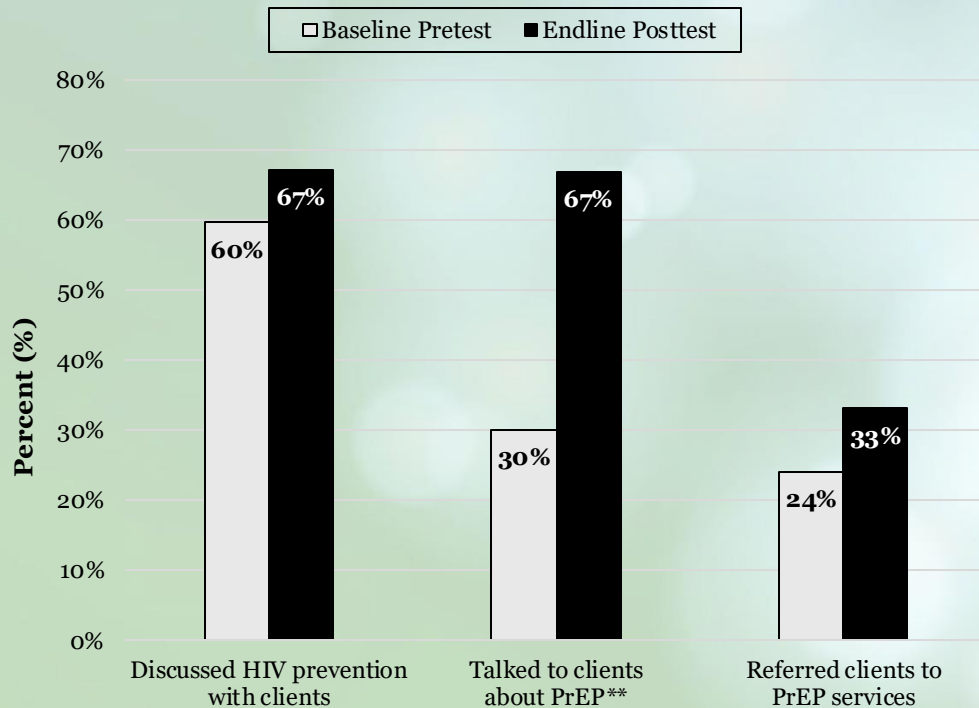


Evaluating implementation outcomes

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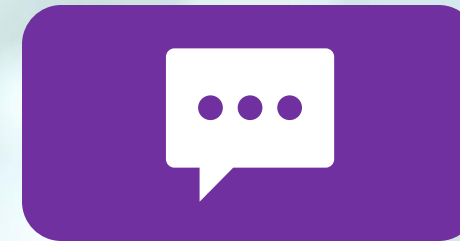


The proportion of FHRW discussing PrEP **doubled**

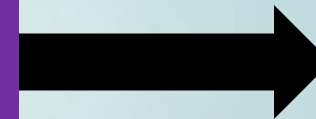


A Capacity-Strengthening Intervention to Support HIV Pre-exposure Prophylaxis (PrEP) Awareness-Building and Promotion by Frontline Harm Reduction Workers in Baltimore, Maryland: A Mixed Methods Evaluation

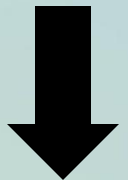
Joseph G. Rosen¹ · Leanne Zhang² · Danielle Pelaez² · Ju Nyeong Park^{2,3,4} · Jennifer L. Glick²



279
PrEP conversations
with clients



127
Client PrEP
referrals



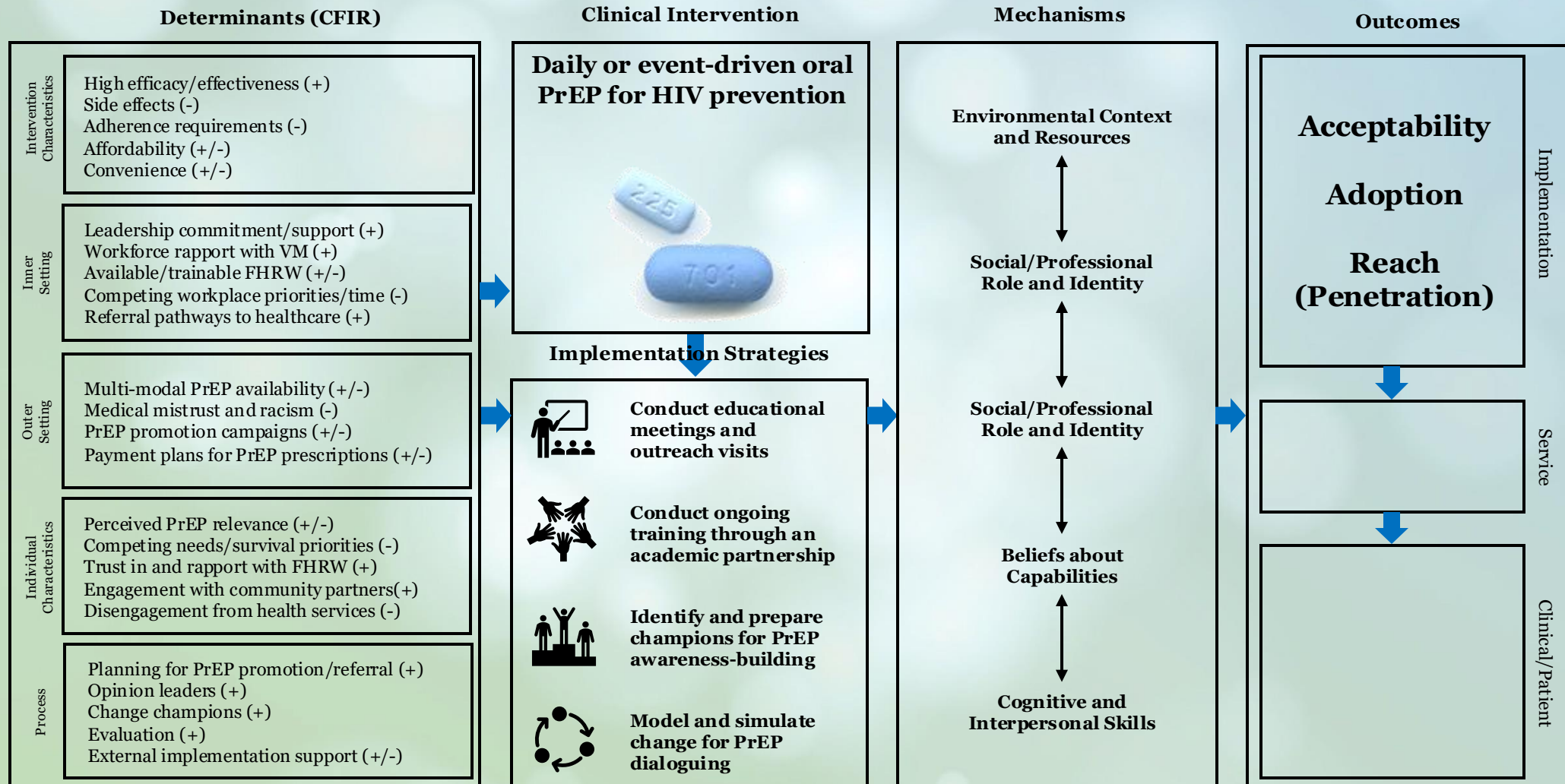
8

FHRW-reported
client PrEP initiations



Evaluating implementation outcomes

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New tools. Same problems?

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What ViiV must do to help ensure access to CAB-LA

Announced 28 July 2022!

Agree a voluntary license without further delay

...but with significant restrictions

Register the drug widely

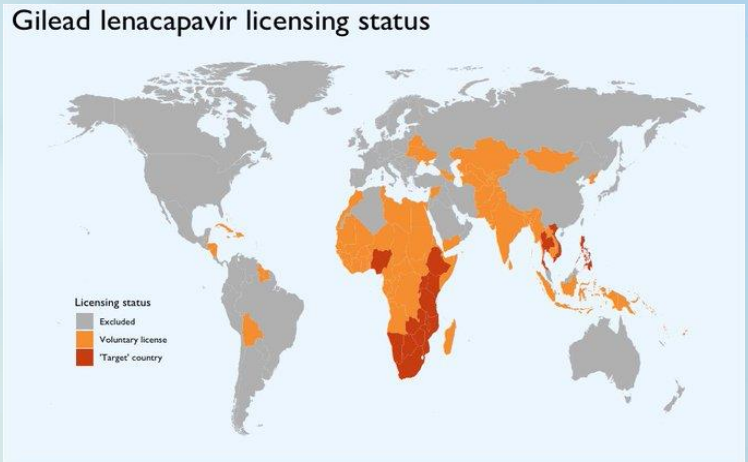
Announce its not-for-profit price

Allow organisations and national programmes to buy CAB-LA directly

Ensure sufficient manufacturing capacity to avoid shortages

Manufacturer's plans for equitable access to twice-yearly PrEP under fire

Roger Pebody | 10 April 2025 | Estimated reading time 10 minutes



Wardle et al. BMC Health Services Research 2021, 21:255

BMC Health Services Research

RESEARCH ARTICLE

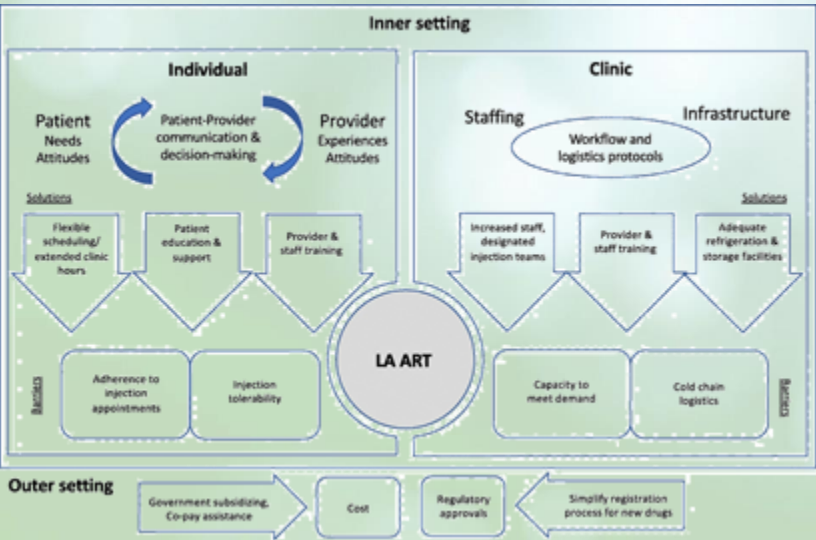
Multi-level considerations for optimal implementation of long-acting injectable antiretroviral therapy to treat people living with HIV: perspectives of health care providers participating in phase 3 trials

Abstract

Background Long-acting injectable antiretroviral therapy (LA ART) has been shown to be non-inferior to daily oral ART, with high patient satisfaction and preference to oral standard of care in research to date, and has recently been approved for use in the United States and Europe. This study explored the perspectives of health care providers participating in LA ART clinical trials on potential barriers and solutions to LA ART roll-out into real-world settings.

Methods This analysis draws on two data sources: (1) open-ended questions embedded in a structured online survey of 103 health care providers participating in the AIDS 2024 trial across 10 countries, and (2) in-depth interviews with 14 providers participating in PLAN (PLANARIS/LAART-2) trials in the United States and Spain. Both elements explored provider views and clinic dynamics related to the introduction of LA ART and were analysed using thematic content analysis. The Consolidated Framework for Implementation Research (CFIR) was used as the conceptual framework underpinning development of a model depicting study findings.

Continued on next page



Moving a Product to the Real World

October 2024 |

avac.org

Technology	Efficacy Results	1	2	3	4	5	6	7	8	9	10
<div> <div> <div>Oral TDF/FTC</div> <div>2010</div> </div> </div>			<div> </div>			<div> </div>	<div> </div>				<div> </div>
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<div> <div> <div>Injectable Cabotegravir</div> <div>2020</div> </div> </div>	<div> </div>	<div> </div>	<div> </div>					<div> </div>			
<div> <div> <div>Injectable Lenacapavir</div> <div>2024</div> </div> </div>	<div> </div>	<div> </div>	<div> </div>								

First Regulatory Approval

First African Regulatory Approval

WHO Recommendations

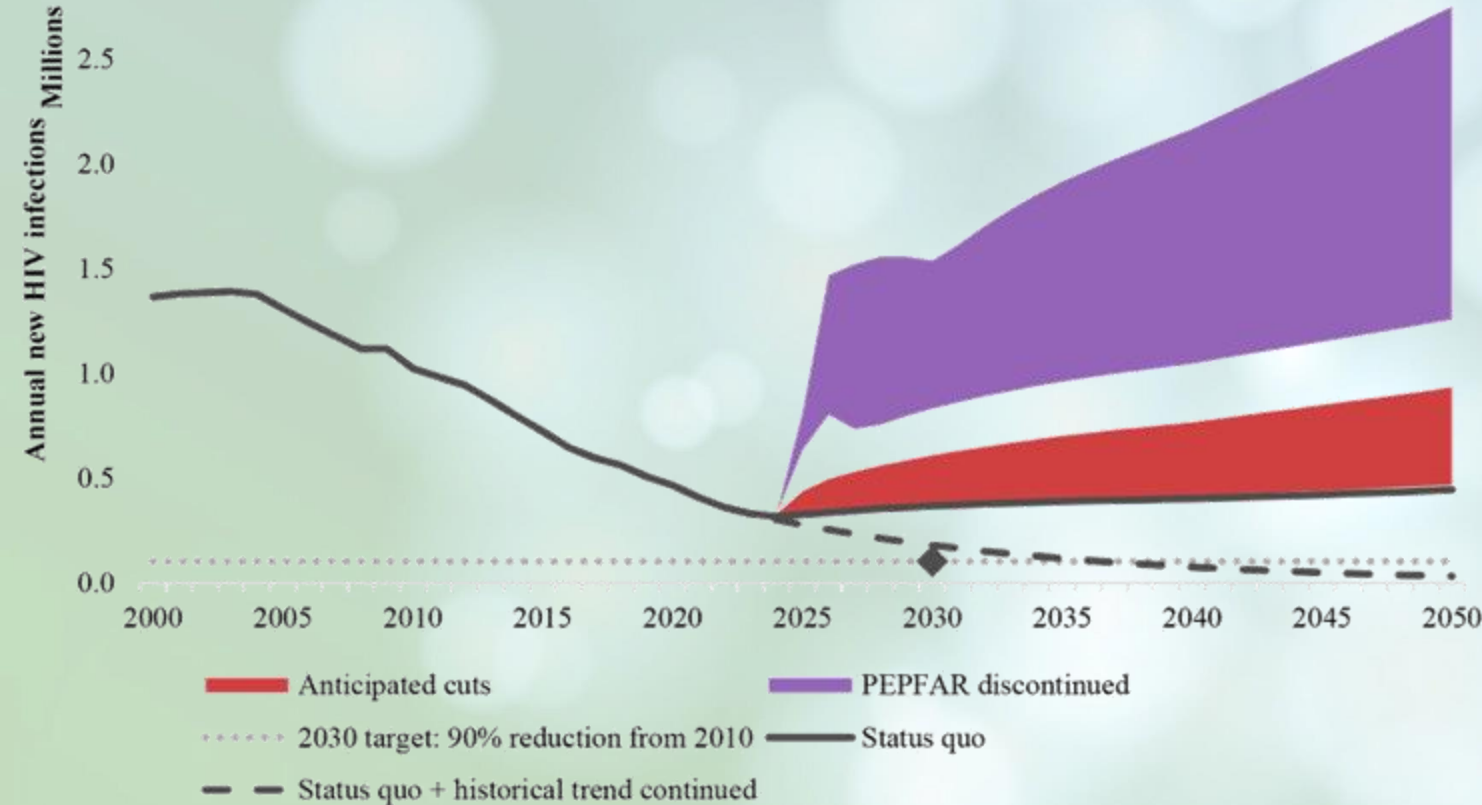
First Demo Project

Scale

Generic Access in LMICs

De-implementation?

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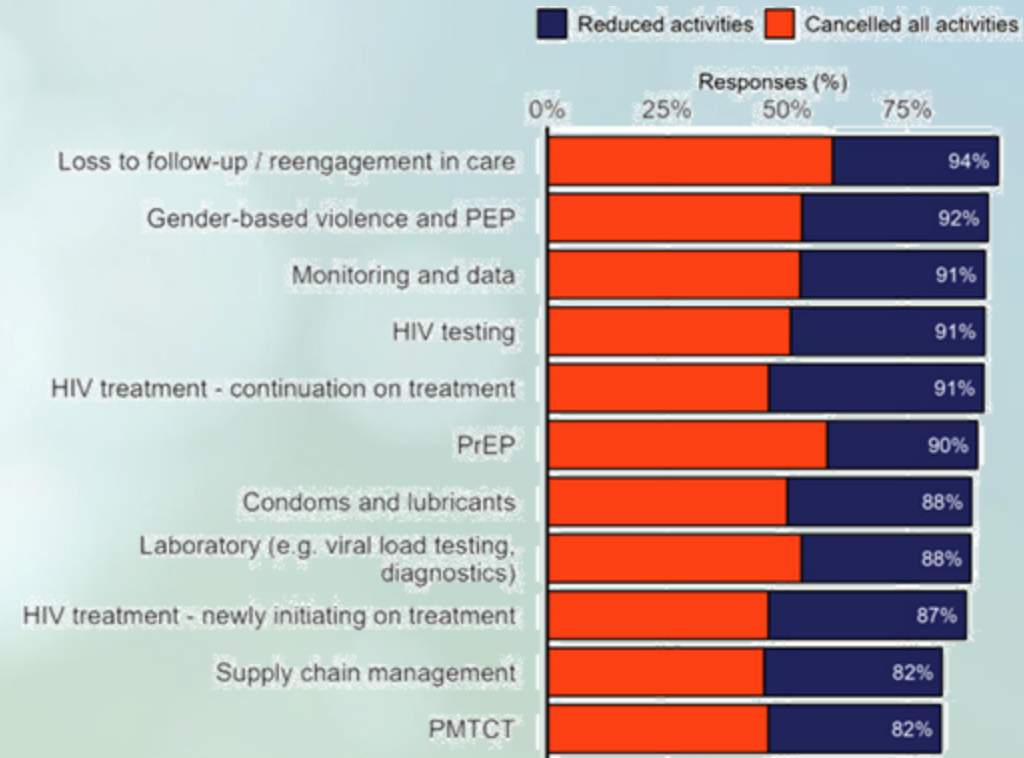
Lankiewicz E et al. *Journal of the International AIDS Society* 2025; 28:e26423
<http://onlinelibrary.wiley.com/doi/10.1002/jia2.26423/full> | <https://doi.org/10.1002/jia2.26423>



FIELD NOTES

Early impacts of the PEPFAR stop-work order: a rapid assessment

Elise Lankiewicz^{1,8,✉}, Alana Sharp^{2,✉}, Patrick Drake², Jennifer Sherwood¹, Brian Macharia³, Michael Ighodaro⁴, Brian Honermann¹ and Asia Russell⁵



Impact of an international HIV funding crisis on HIV infections and mortality in low-income and middle-income countries: a modelling study

Debra ten Brink, MD ^a ✉ · Rowan Martin-Hughes, PhD ^{a,*} · Anna L Bowring, PhD ^a · Nisaa Wulan, MPH ^a · Kelvin Burke, MSc ^a · Tom Tidhar, BSc ^a · et al. [Show more](#)



De-implementation?

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Lankiewicz E et al. *Journal of the International AIDS Society* 2025, 28:e26423
<http://onlinelibrary.wiley.com/doi/10.1002/jia2.26423/full> | <https://doi.org/10.1002/jia2.26423>

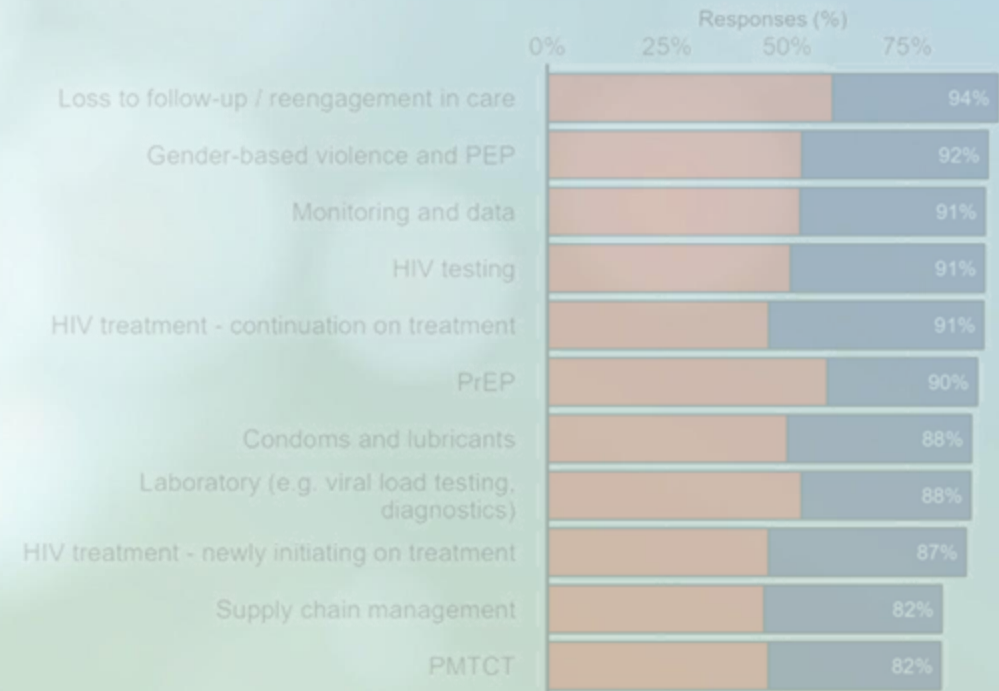
JIAS
 JOURNAL OF THE
 INTERNATIONAL AIDS SOCIETY

FIELD NOTES

Early impacts of the PEPFAR stop-work order: a rapid assessment

Elise Lankiewicz^{1,2,3}, Alana Sharp^{2,4}, Patrick Drake², Jennifer Sherwood¹, Brian Macharia³, Michael Ighodaro⁴, Brian Honermann³ and Asia Russell⁵

Reduced activities Cancelled all activities



Impact of an international HIV funding crisis on HIV infections and mortality in low-income and middle-income countries: a modelling study

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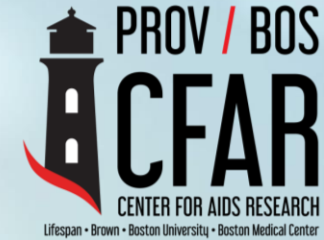
Acknowledgments



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