The Choice Agenda
November 3, 2022

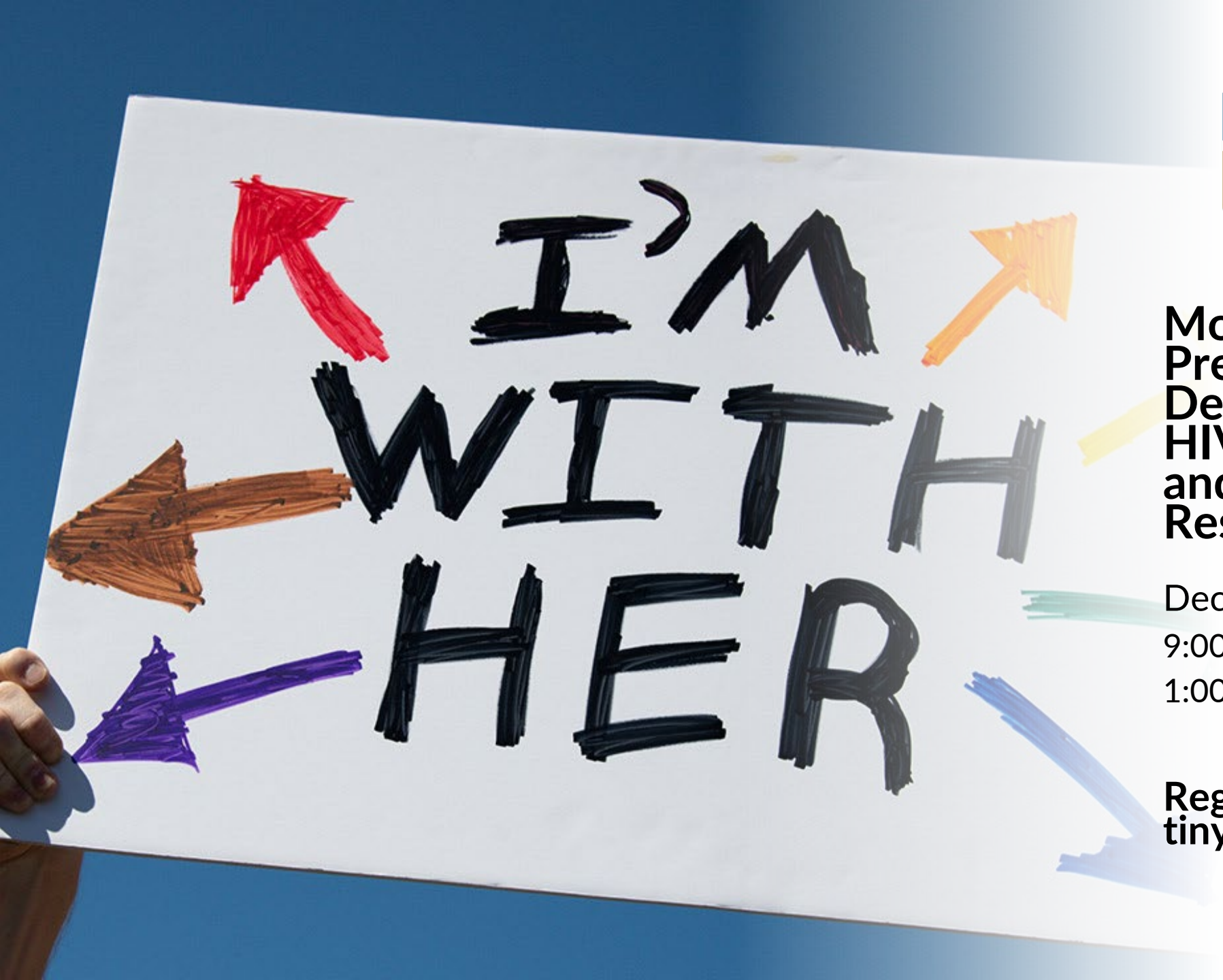
PEP needs some

PEP

Addressing PEP Neglect in HIV Prevention Research, Programming and Uptake

THE CHOICE AGENDA

Rest in peace Dr. Dawn K. Smith – your impact is everlasting



THE CHOICE AGENDA

HIV prevention research – a new forum for advocacy on the latest

More than Vessels: Pregnant People Deserve Inclusion in HIV Prevention Clinical and Implementation Research

December 14, 2022

9:00am-10:30am ET

1:00pm-2:30pm GMT

Register now: tinyurl.com/morethanvessels

Webinar Speakers

- Dr. Ken Mayer
- Dr. Njambi Njiguna
- Dr. Julie Fox
- Drs. James Ayieko and Catherine Koss
- Ace Robinson

THE FENWAY INSTITUTE

RATIONALE FOR POST-EXPOSURE PROPHYLAXIS

Kenneth H. Mayer, MD

PEP Needs PEP

November 3rd, 2022

thefenwayinstitute.org

Post-Exposure Prophylaxis (PEP)

- The use of therapeutic agents to prevent infection following exposure to a pathogen
- Types of exposures include percutaneous (needlestick), splash, bite, sexual
- For health-care workers, PEP commonly considered for exposures to HIV and Hepatitis B

Exposure Risks (average, per episode, involving HIV-infected source)

Percutaneous (blood)	0.3%
Mucocutaneous (blood)	0.09%
Receptive anal intercourse	1 - 2%
Insertive anal intercourse	0.06%
Receptive vaginal intercourse	0.1 – 0.2%
Insertive vaginal intercourse	0.03 – 0.14%
Receptive oral (male)	0.06%
Female-female orogenital	4 case reports
IDU needle sharing	0.67%
Vertical (no prophylaxis)	24%

Risk Factors for Seroconversion

Risk Factor	Odds Ratio*	95% CI
Deep injury	15	6.0 – 41
Visibly bloody device	6.2	2.2 – 21
Device in artery/vein	4.3	1.7 – 12
Terminally ill SP	5.6	2.0 – 16
AZT PEP	0.19	0.06 – 0.52

*$p<0.01$ for all

Cardo DM et al. NEJM 1997;337:1485-90

Evidence of Efficacy of PEP

- Animal models: high level of protection when started within 24 hours[1]
- OR = 0.19 for zidovudine use in HCW case-control study[2]
- Two drugs, three drugs:
  - No direct human evidence that more effective than 1 drug; animal studies suggestive
  - Cases of seroconversion despite 3-drug PEP imply efficacy less than 100%[3,4]

1. Tsai C-C et al. J Virol 1998;72:4265-73.
2. Cardo DM et al. NEJM 1997;337:1485-90.
3. Jochinsen EM et al. Arch Int Med 1999;159:2361-3.
4. MMWR June 29, 2001 / 50(RR11);1-42

Is PEP effective for non-occupational exposures?

- Brazilian non-randomized trial of PEP following sexual assault: rate of HIV transmission was 2.7% in control subjects compared with 0% in those who received PEP ($P < .05$).

- Buenos Aires study involving MSM: HIV transmission occurred in 4.2% of 131 men who did not receive PEP, compared with 0.6% of 66 men who received PEP ($P < .05$).

Schechter M. Program and abstracts of the Sixth International Congress on Drug Therapy in HIV Infection; November 17-21, 2002; Glasgow. Abstract PL6.1.

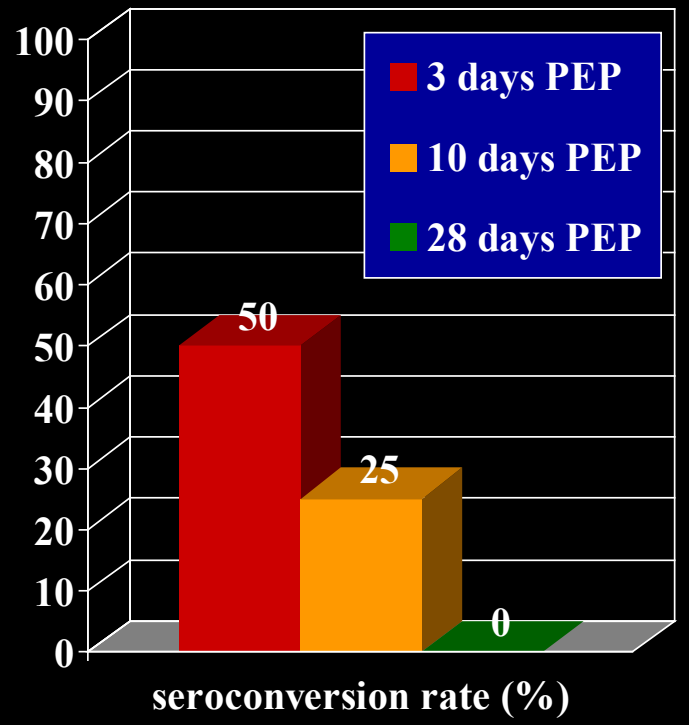
Timing of PEP: what's the evidence?

- Animal PEP studies: suggest substantially less effective beyond 24 - 36 hours[1,2]
- Case-control study: most subjects in each group received PEP within 4 hours[3]
- Analysis of PEP failures does not suggest a clear cut-off[4]
- 72 hour window is a guestimate
- "PEP should be initiated as soon as possible, preferably within hours rather than days of exposure."

1. Tsai C-C et al. J Virol 1998;72:4265-73.
2. Shih CC et al. JID 1991.
3. Cardo DM et al. NEJM 1997;337:1485-90.
4. MMWR June 29, 2001:50(RR11);1-42.

How Long Should PEP be Administered?

- N = 24 macaques inoculated with SIV intravenously
- PEP initiated 24 hours post-inoculation
- PEP administered for 3, 10, or 28 days
- 28 days used in case-control study and recommended by CDC guidelines



Tsai C-C et al. J Virol; MMWR June 29, 2001

PEP Regimens

- Rationale for 3 vs. 2 drugs is based on extrapolation and observational case series, not on head to head clinical trials.

  -newer drugs are better tolerated

  -boosted PI caused significant side effects

  -Nevirapine associated with hepatotoxicity

  -single pill regimens make adherence easier
- TDF/FTC is the preferred backbone, but AZT/3TC is an alternative (e.g. ↓ renal function)
- INSTI is preferred 3rd drug (with specific recs for Raltegravir or Dolutegravir
  -Darunavir/r is an alternative

  -Data on Bictegravir look good

CDC NPEP Updated Guidelines, 2016

Relative Tolerability of Newer Regimens

Adverse Events, %	BIC/FTC/TAF 2018-2020 (n = 52)	Historical Comparator					
		PI + 3TC/ZDV 2000-2004 (n = 119)	*P* Value	RAL + FTC/TDF 2008-2010 (n = 100)	*P* Value	EVG/COBI/FTC/ TAF 2013-2015 (n = 100)	*P* Value
Diarrhea/ loose stool	7.7	58.8	<.001	21.0	<.05	38.0	<.001
Fatigue	9.6	48.5	<.001	14.0	NS	28.0	<.01
Nausea/ vomiting	15.4	58.8	<.001	27.0	NS	28.0	NS
Headache	1.9	11.8	<.05	15.0	<.01	14.0	<.01
Dizziness/ lightheaded ness	0.0	8.4	<.05	10.0	<.01	6.0	NS
Myalgia/ arthralgia	1.9	10.9	<.05	8.0	NS	2.0	NS

Mayer. KH et al J Acquir Immune Defic Syndr. 2022

Key Take-home Points

- Multiple lines of evidence suggest that PEP can decrease HIV incidence, albeit no definitive RCT
- Current guidelines recommend HIV PEP be initiated within 72 hr of a high risk exposure with an INSTI-based regimen.

  -The sooner the better
- Regimens using earlier 3rd agents (e.g. PI or NNRTI) with 2 NRTIs have greater risk of intolerance and/toxicity than INSTI regimens
- Following a 28-day course of ART for PEP, PrEP should be considered if indicated

PEP Policy Synthesis

PRESENTED TO THE CHOICE AGENDA – NOVEMBER 3, 2022

NJAMBI NJUGUNA, FHI 360, MOSAIC

PEPFAR

USAID
FROM THE AMERICAN PEOPLE

MOSAIC
Maximizing Options to Advance Informed Choice for HIV Prevention

1 BACKGROUND & METHODS

Background

- Guidelines from the World Health Organization (WHO) recommend the use of post-exposure prophylaxis (PEP) by individuals potentially exposed to HIV for the prevention of HIV.
- Evidence supporting the use of antiretrovirals (ARVs) for HIV PEP dates to 1990, but it remains an underutilized part of HIV combination prevention.
- In addition to playing a vital role in HIV prevention on its own, PEP can act as bridge from potential exposure to uptake of other HIV prevention strategies, including pre-exposure prophylaxis (PrEP).

- The PEP policy analysis, synthesized in this PEP policy brief, aimed to:
  - Summarize the PEP policy landscape in 8 countries
  - Illustrate how to address policy and implementation barriers
  - Recommend ways to increase access to and uptake of PEP as part of HIV prevention

Methods

19 policies collected from 8 countries

17 policies selected for data extraction

Analysis

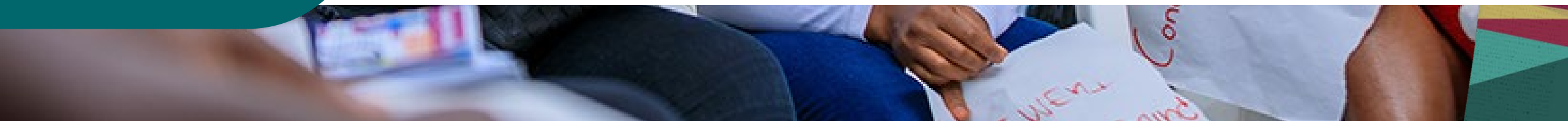
Contextualization

- Do these policies reflect what you know to be the reality of PEP access and service delivery?
- What are the barriers to PEP access generally? For adolescent girls and young women (AGYW) specifically?
- Where do you see opportunities to strengthen PEP access generally? For AGYW specifically?

Policies included in analysis

Country	Policy Name	Date Issued
Eswatini	DRAFT PEP Section Guidelines	2022 (not public)
	Clinical Implementation Guide for PrEP Provision in Eswatini	2019
	Swaziland Integrated HIV Management Guidelines	2018
Kenya	Guidelines on Use of Antiretroviral Drugs for Treating and Preventing HIV in Kenya	2018
	Pre-exposure Prophylaxis for the Prevention of HIV Infection: A Toolkit for Providers	2017
Lesotho	National Guidelines on the Use of Antiretroviral Therapy for HIV Prevention and Treatment, Sixth Edition	2021
Nigeria	National Guidelines for HIV Prevention, Treatment and Care	2020
	Guidelines for Providing Post Exposure Prophylaxis	2020
South Africa	National Clinical Guidelines of Post-Exposure Prophylaxis (PEP) in Occupational and Non-occupational Exposures	2020
	Guideline on the Management of Occupational and Non-occupational Exposure to HIV and Recommendations for PEP (2015 update)	2015
	Corrigendum PEP Guidelines	2015
Uganda	Consolidated Guidelines for the Prevention and Treatment of HIV and AIDS in Uganda	2020
Zambia	Consolidated Guidelines for HIV Care & Treatment	2020
	Implementation Framework & Guidance for Pre-Exposure Prophylaxis Of HIV Infection	2018
Zimbabwe	Zimbabwe National HIV & AIDS Strategic Plan 2021–2025	2021
	Addendum to the Guidelines for the Antiretroviral Therapy for the Prevention & Treatment of HIV in Zimbabwe	2020
	Guidelines for ART for the Prevention & Treatment of HIV in Zimbabwe	2016

2 FINDINGS & KEY RECOMMENDATIONS



PEP Eligibility

- WHO recommends that PEP be offered to "all individuals with exposure that has the potential for HIV transmission."

Policy element	Country
PEP access to anyone who has a potential exposure to HIV, with no restrictions on PEP eligibility by age and no mention of required parental consent	ALL
Use of PEP by survivors of sexual assault	ALL
Use of PEP by individuals who may be occupationally exposed	ALL
Use of PEP by those with other potential sexual exposures	Kenya, Lesotho, Uganda, Zambia
Use of PEP by those who may be exposed through injection-related practices outside of occupational settings	South Africa
Differentiated services for individuals based on type of exposure	Eswatini, Kenya, Lesotho, Nigeria
PEP should not be offered to individuals if the HIV status of the potential source is established to be negative*	Eswatini, Kenya, Lesotho, South Africa, Uganda, Zimbabwe

*Three policies clarified that if the potential source has had recent exposure or may be in the window period, PEP can be considered (Eswatini, Kenya, South Africa). One policy recommends laboratory ELISA test if the potential source can be tested (South Africa).

PEP Eligibility – Key Recommendations

- Explicitly including people with injection-related potential exposures in policies may raise awareness and increase access to and uptake of PEP among these individuals.
- Including individuals with nonoccupational injection-related potential exposures would be beneficial.
- Policies that are comprehensive and cover differentiated services for different types of exposure, as well as making PEP available to those seeking PEP, may expand access.
- National policies and global recommendations may best serve people with recent HIV exposures by explicitly allowing for PEP access regardless of the HIV status of a potential source.

Time Frame of Provision

- WHO recommends that PEP be accessed “ideally within 72 hours” of potential HIV exposure

Policy element	Country
Eligible individuals are required to access PEP within 72 hours of potential exposure*	ALL

* Nigeria had two slightly different policies. One states PEP needs to be accessed within 72 hours and one recommends within 2-72 hours

** Uganda’s policies clarifies that PEP would ideally be accessed within the first two hours of potential exposure

Time Frame of Provision – Key Recommendation

- Potential PEP users may benefit from adoption of national policies that align with WHO recommendations and allow PEP access immediately after a potential exposure, without delay and with flexibility around the latest someone can access PEP, provided with clear information about the time frame in which PEP can be provided.

Recommended Drug Regimen for Adults and Adolescents

- WHO acknowledges that a PEP regimen with two ARV drugs is effective, but three drugs are preferred. For adults and adolescents taking PEP, WHO recommends tenofovir disoproxil fumarate (TDF) + lamivudine (3TC) or emtricitabine (FTC) as the preferred backbone regimen, with dolutegravir (DTG) as the preferred third drug.

Policy element	Country
TDF/3TC/DTG as the preferred drug regimen for PEP	Eswatini, Kenya, Lesotho, Nigeria, South Africa, Uganda, Zimbabwe
TDF (or TAF) + FTC (or 3TC) + DTG	Zambia
Two-drug regimen	NONE

Recommended Drug Regimen for Adults and Adolescents – Key Recommendations

- As national policies are updated, policies that provide flexibility for application as per WHO guidelines may improve PEP completion and effectiveness
- Procurement of drugs for PEP needs to be included in national procurement plans and long-term support for PEP procurements must be established, with one-month supply supported by donors.

Linkages between PEP and PrEP

- WHO recommends offering PrEP to individuals after the completion of PEP if they are HIV negative and potential exposure to HIV is expected to continue after PEP completion

Policy element	Country
Recommendations for connecting PEP user to PrEP	Eswatini, Lesotho, Kenya, Zambia
“PEP to PrEP” mentioned in PEP-specific section	Eswatini, Kenya
“PEP to PrEP” mentioned in PrEP-specific section	Lesotho, Zambia
PrEP recommended for repeat PEP users	Eswatini, Kenya, Zambia

Linkages between PEP and PrEP – Key Recommendations

- Establishing stronger “PEP to PrEP” policies that support bidirectional referrals in service delivery settings may better enable informed choice and increase access to comprehensive HIV prevention.
- Repeated PEP use can be an indication that a client may benefit from PrEP, but offering PrEP only to those repeatedly returning for PEP may prevent the offer of PrEP to some potential users and contribute to limited access more broadly.
- Expanding PEP policies to allow for the preemptive provision of PEP in special situations may fill key gaps in HIV biomedical prevention and support more effective use of other prevention products.

Additional findings: Non-policy barriers

Barriers to PEP Access

- For adolescent girls and young women (AGYW) specifically:
  - Traditional cultural norms and existing stigma shape and limit discussions with parents or other adults about sexual encounters or ways to seek sexual health
  - Lack of AGYW-responsive centers
  - Negative provider attitudes towards AGYW exposure
  - Clinic and school hours do not align
- Limited provider knowledge and training
- Confusion about PEP and PrEP
- Required prescription for pharmacy provision
- Testing requirements or diagnostic elements
- Parental or guardian consent
- Limited monitoring systems for PEP use, distribution and follow-up
- Stigma, especially when the exposure is due to sexual assault or rape
- Late reporting of exposures by those experiencing intimate partner or gender-based violence

Barriers to PEP Use

- Fear of side effects
- Lack of integrated sexual and reproductive health and HIV prevention services
- Gaps in follow-up for PEP adherence
- Lack of information on when PEP is appropriate to take (limiting timely access)
- PEPFAR recently stopped procuring TDF/3TC/DTG in bottle sizes appropriate for the 28-day course of PEP, opting for 90-day count bottles as it focuses on supporting multimonth dispensation of ARVs for people living with HIV, leaving the responsibility of procurement of PEP-appropriate bottles to national programs and other donors
- No inclusion of provision of PEP proactively (sometimes called PEP in Pocket)

Additional findings (non-policy barriers): Key Recommendations

- Supporting sensitization, training, and mentorship efforts to familiarize both users and providers with PEP as part of the comprehensive HIV prevention package may address these barriers.
- Developing, testing, and codifying models for community-based distribution may elevate PEP awareness and elucidate opportunities for expanding differentiated service delivery.
- As other policy elements are strengthened to better support access to PEP, complementary efforts could be made to standardize monitoring and evaluation of PEP effective use and dispensation.

3 CONCLUSION

Final take-aways

- Key aspects of PEP access present rich opportunity for improvement.
- The brief summarizes a list of **thirteen recommendations** for country policies to strengthen PEP access as part of the comprehensive HIV prevention package.
- By leveraging these concluding recommendations, actors in the HIV prevention space, including ministries of health, donors, and program implementers could be well positioned to support uptake and integration of these recommendations to facilitate strengthened and sustained access to and choice of PEP.
- The PEP policy synthesis brief can be accessed here.

ACKNOWLEDGMENTS

Thank you to Katie Williams and Chris Obermeyer for the development of the *Synthesis of PEP Policies in MOSAIC Countries* brief. Thank you to Njambi Njuguna for her presentation of the findings.

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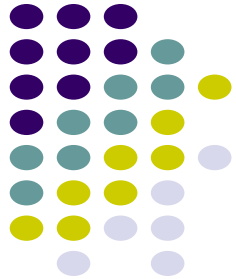
Photo Credit: MOSAIC Consortium



HIV Post Exposure Prophylaxis in the era of PrEP

Julie Fox

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Agenda

- why PEP needed in people on PrEP
- Current guidance on PEP use in people using PrEP
- Discuss lessons from PrEP that may improve PEP use

Introduction

- ART is extremely effective in HIV prevention
  - First PEP
  - Now PrEP (oral and injectable)

- Understanding how people can move from PEP to PrEP is straightforward and in guidelines. And PEP is a perfect place to start PrEP.
- BUT understanding when to take PEP in people on PrEP is not always simple, really due to a lack of data and difficulty designing studies to address these questions

Introduction:

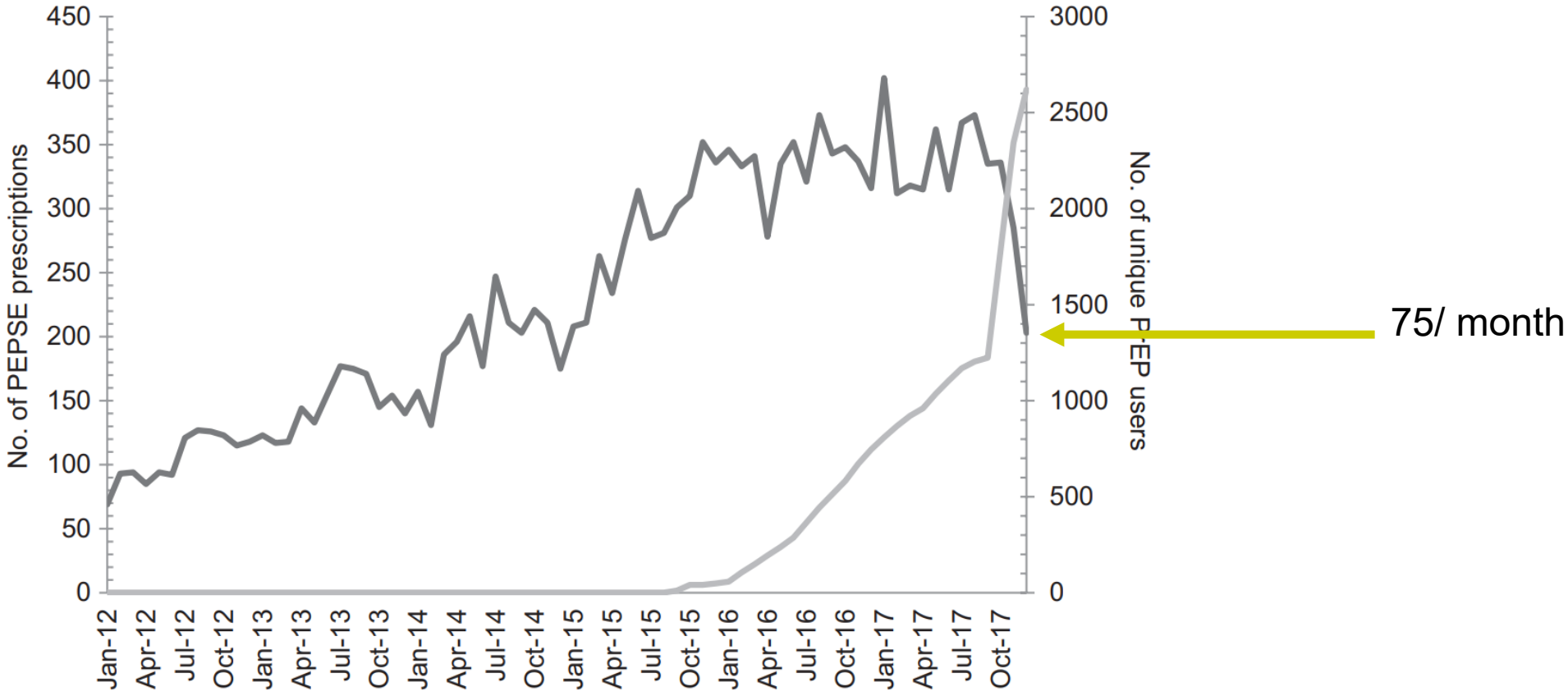
- Practical level:
  - People prescribing PrEP are often not the same people as those prescribing PEP
  - Often PEP and PrEP services are not located together, accessing the 3rd drug in rural PrEP settings problematic

"can we restart daily 2-drug PrEP instead of accessing 3rd drug"

"What can the PrEP service advise a person who needs PEP (immediate management)"

  - People on PrEP, tend to have tablets : what should they be advised to do?

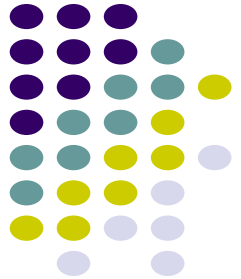
PEP still being used despite PrEP available



PEP and PrEP use over time at 56 Dean Street jan 2012 to dec 2017

Girometti HIV Medicine 2021

Reasons people need PEP in era of PrEP

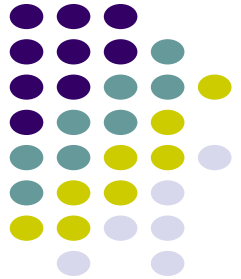


1. **On PrEP but**
   a. missed tablets
   b. Run out of tablets
   c. Not prepared for sex

2. **Don’t want to take PrEP**
   a. don’t see themselves at on-going risk
   b. afraid of stigma from taking prevention pills

3. **Do not have access to PrEP**

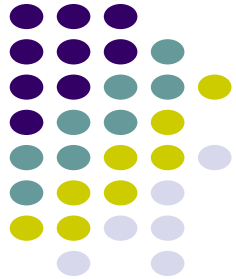
PEP timing



- Effectiveness correlates with speed of uptake following sex:[1]
  - Not much evidence for taking after 24 hours
  - In the UK, average time from exposure to first dose is 24 hours[2] - not improved despite National campaigns to increase PEPSE awareness[3]
- Most guidelines :
  - Taken up to 72 hours after sex

1. Tsai C. J Virol 1998; 72:4265–73 2: Benn HIV Med 2006: 3. Reeves 2008: 4. Schechter M. JAIDS. 2004;35-48

PrEP experience changing views on PEP



- PrEP very effective despite adherence not always good
- On demand PrEP shows pericoital ART highly effective (Molina)
  - Missed pre-coital dosing occurs yet infections v rare

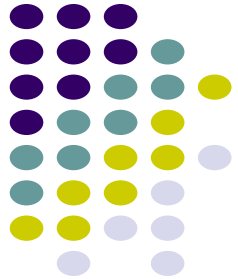
Therefore, should we rethink PEP?

- would a shorter course be effective
- are 3 drugs really required

} Need trials to explore this

McCormack S et al. Lancet. 2016 Jan 2;387(10013):53-60
Molina J-M et al. N Engl J Med. 2015 Dec 3;373(23):2237-46

When is PEP needed in people taking PrEP?



- Men
  - 2 doses before and 2 days After (IPERGAY)
  - OR 4 doses in past 7 days (IPREX)

- Women
  - 6 days before and 7 days afterwards (HPTN066)
    - Drug level data in vaginal/ cervix tissue shows slower uptake of drug suggesting more drug is needed
    - Cottrell PK results need greater discussion around this
  - No on demand PrEP studies to facilitate discussion

Few PEP guidelines provide guidance on starting PEP in PrEP users

- Not on WHO
- UK PEP guidelines do, PrEP guidelines in development- trying to address issues more pragmatically

UK BASSH PEP guidelines

- Anal sex:

- daily PrEP: where <4 pills have been taken in last 7 days then take PEP
- on demand PrEP: take PEP is if missed a PrEP dose (cf IPERGAY analysis)

- Vaginal (much stricter):

Take PEP if > 48 h since last dosing or if fewer than six tablets have been taken within the previous 7 days.

- ALL PEP for 28 days

In reality, this doesn't happen. Mismash of recommendations- Double dose, restart daily 2-drug asap

Cresswell HIV medicine 2021

Cases to discuss with your services

	Offer 4- week PEP	Advise re- start daily PrEP	Advise take double dose Truvada and continue daily PrEP
A man had condomless sex yesterday. He had taken 4 doses in past week, but these were 4, 5,6,7 days ago	☐	☐	☐
A woman had condomless sex yesterday. She had taken 4 doses in past week, and these were in the last 4 days	☐	☐	☐
A man taking on demand PrEP had his pre-coital dosing and then one dose after sex but forgot the 48hr dose. It is now 60 hours after sex	☐	☐	☐
A man taking on demand PrEP had one tablet before sex and one after. It is now 60 hours after sex	☐	☐	☐
A man had sex 20 hours ago and reported taking five PrEP tablets within the previous 7 days	☐	☐	☐
A women had sex 24 hours ago and reported taking five PrEP tablets have been taken within the previous 7 days.	☐	☐	☐

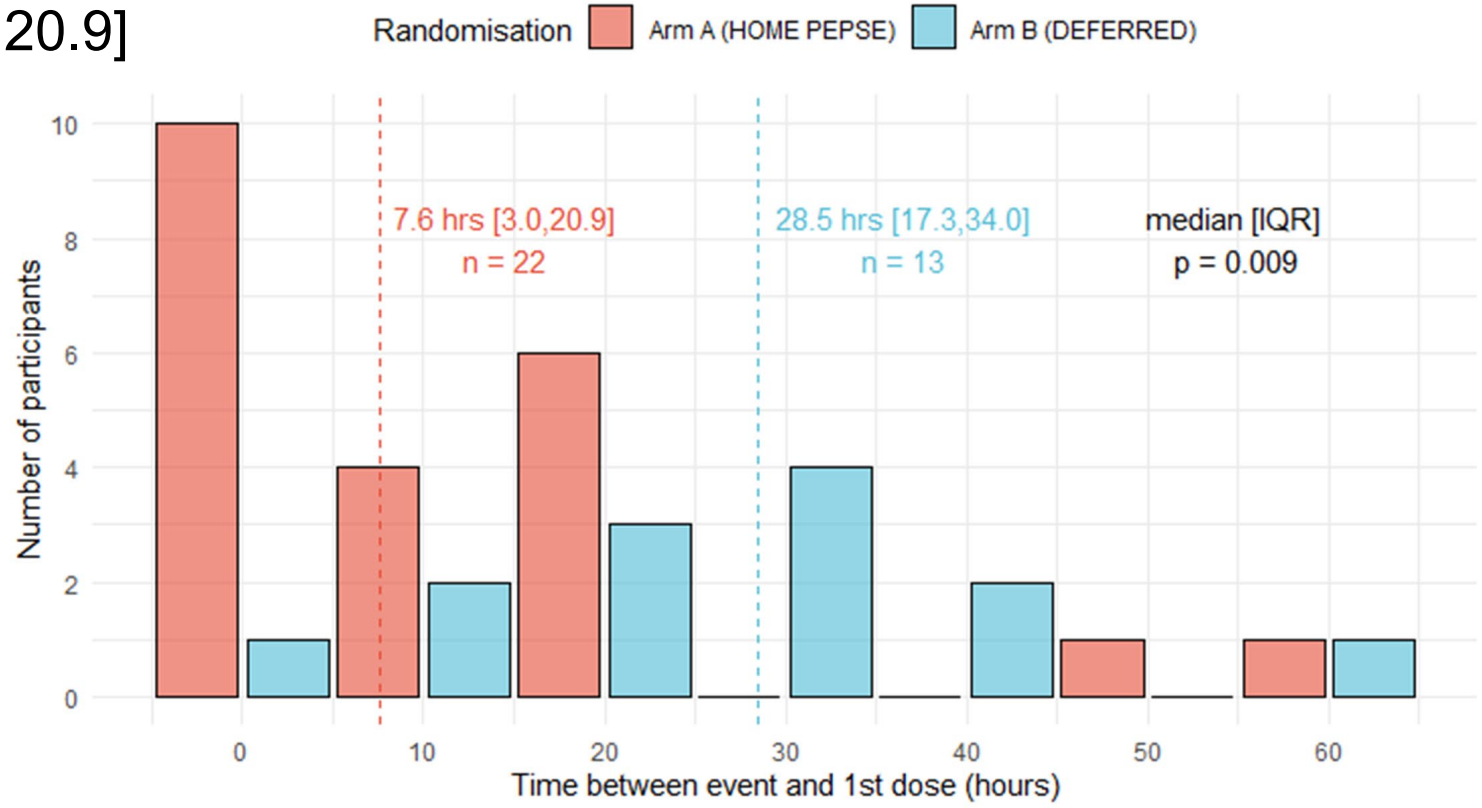
Can lessons from PrEP improve PEP

1. Reduce time to first dose eg start PEP at home
2. Is it possible to take a shorter course (<28 days)
3. Are 3 drugs needed

Taken quicker: HOME PEPSE reduces time to first dose by 21 hours

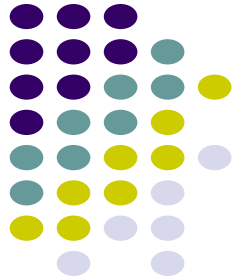
Median time::
HOME PEPSE 7.6 hours [3.0,20.9]
SOC 28.5 hours [17.3,34.0]
($p < 0.01$)

I.e. almost a 21 hour reduction in time to first dose



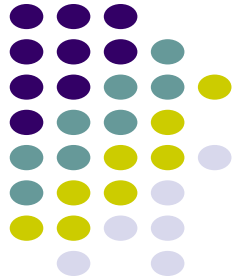
Fox CROI 2022

Taken for <28 days?



- For men, on demand PrEP data suggests yes esp if first dose very very close to sex
- Macaque data suggested 28 days needed
- Need an efficacy study…

Can we have 2 –drug PEP



- Rationale for 3 drugs is that works for starting ART in HIV infection
- BUT : Dolutegravir/3TC trials show newer drugs more powerful
- should 2-drug PEP be explored again?
  - Would mean people on PrEP could self-manage from home if 2 drug ok.

Conclusion

- PrEP and PEP are becoming closer and closer
- When to initiate PEP needs review on individual basis based on PrEP adherence, type of sex and hours since exposure
- Self-start double dose TDF/FTC pragmatic
- Currently a full 28-days is indicated
- More data needed

Thank You!

“Possible missed opportunities in reducing new HIV infections using PEP”

Lessons from the SEARCH studies

James Ayieko MBChB, MPH, PhD

Kenya Medical Research Institute-Kenya

Catherine Koss, MD

University of California, San Francisco-USA

Acknowledgement

Background

- Post-exposure prophylaxis (PEP) developed decades ago as biomedical HIV prevention option
  - underutilized for decades, especially in low- and middle-income settings
  - largely reserved for occupational exposures among healthcare workers
- *Why expand PEP?*
  - Only prevention option for adults that can be started after (vs. before) HIV exposure
  - Current INSTI-based PEP regimens are well-tolerated and can be delivered outside of occupational exposure settings, including in settings, such as rural sub-Saharan Africa (SSA), when operational barriers are addressed
  - Both a *gateway* to other prevention options for persons with ongoing exposure or a *bridge* for persons who have needs for short-term protection
- Collectively, including more options can enhance the success of the prevention armamentarium.

Rationale

- PrEP is expanding in generalized epidemic settings, but additional prevention options are needed for individuals with **unanticipated, periodic, high-risk sexual exposures.**
- In Africa, awareness of and access to **PEP** for sexual exposures are limited.

PEP Pilot in SEARCH Study

- SEARCH Studies in rural SW Uganda and western Kenya (UCSF/KEMRI/IDRC; PIs: Havlir, Kamya, Petersen)
  - Aim to reduce HIV burden and improve community health
- Population-level HIV testing with universal access to PrEP for persons at elevated HIV risk
    - Same day start, flexible delivery system

Observations about PrEP from some participants

- Pill burden/fatigue; less frequent potential HIV exposure (e.g. every 3 months); less predictable; unplanned one-off exposures; may be difficult to predict seasons of risk
- Can start PrEP ahead of certain events – but can be hard to predict;
  - One-off sports day
  - Stop PrEP and spouse returns without notice
  - Alcohol use, new partner, e.g. barmaid or women engaged in sex work
  - 2-1-1 may not be an option

→Could PEP be preferred by some individuals?

Methods

- Within the SEARCH trial (NCT01864603), we conducted a pilot PEP study in five rural communities in Kenya and Uganda between December 2018 and May 2019.
- Community sensitization, health leader and provider training
- PEP package: available 7 days/week; hotline; option for out-of-facility medication delivery

SEARCH
SUSTAINABLE EAST AFRICA RESEARCH IN COMMUNITY HEALTH

Ayieko, JIAS, 2021

Results

1

- 124 people sought PEP
- **1/3** were male
- **1/4** were<25 years
- **41%** were fisherfolk

2

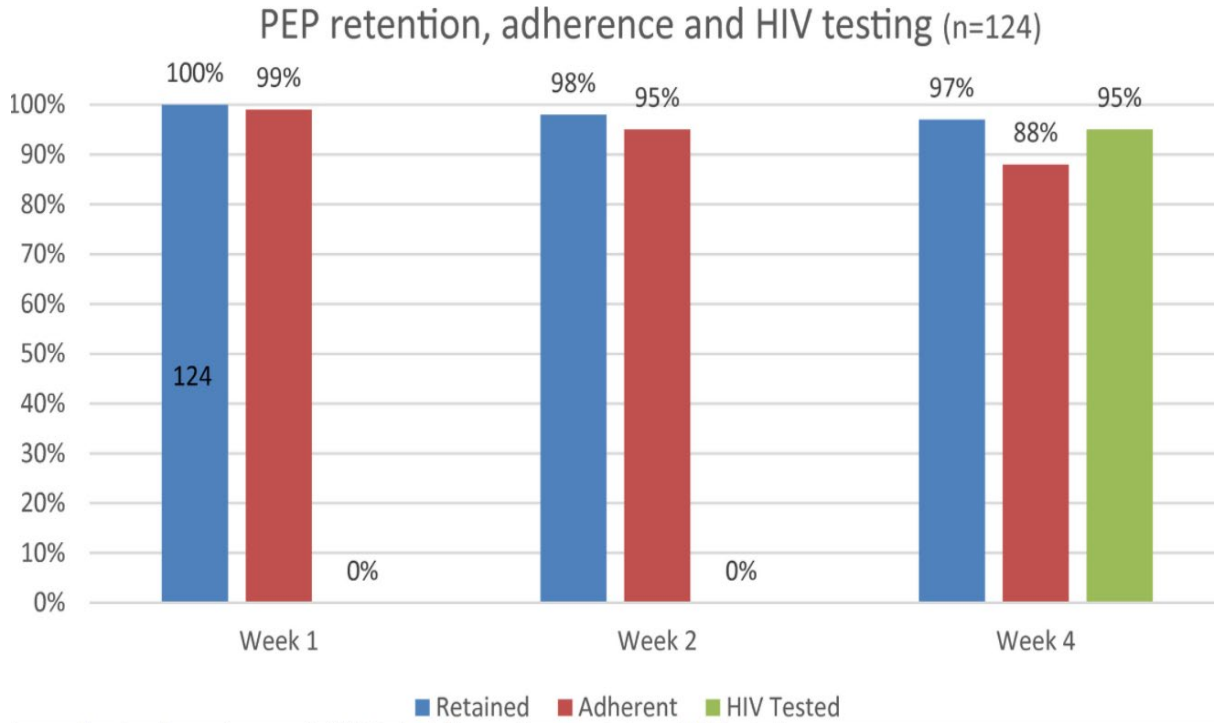
Exposures

- **20%** reported exposure with a sero-different partner
- **72%** with a new or existing relationship
- **7%** from transactional sex

Visits

- 12% of all visits conducted at out-of-facility sites
- 35% of participants had ≥1 out-of-facility visit.

3



4

No SAEs reported
No Seroconversions

Ayieko, JIAS, 2021

Lessons Learnt

- **HIV PEP is implementable and useful beyond occupational exposure in rural Uganda and Kenya.**
  - **Patient centred approaches with flexibility to enhance convenience improve engagement**
  - **Appeal for this option among individuals with occasional one-off encounters.**
  - **We found high completion and adherence rates of the 28-day course**

SEARCH SAPPHIRE – expanding choices in HIV prevention

Testing multi-disease and multi-sector HIV treatment and prevention interventions (NCT04810650)

- aimed at reducing HIV burden and improving health in rural southwestern Uganda and western Kenya

3 ongoing randomized trials of **Dynamic Choice Prevention Intervention** using a patient-centered delivery model (N ~1200 participants, 600 per arm)

- Antenatal clinics, outpatient departments, and out-of-clinic community settings

PRODUCT CHOICE
(+ option to switch products)
- Oral PrEP (TDF/XTC)
- PEP (pill in pocket option)

SERVICE LOCATION CHOICE
- Clinic
- Home/Community site
- Phone/Virtual visit

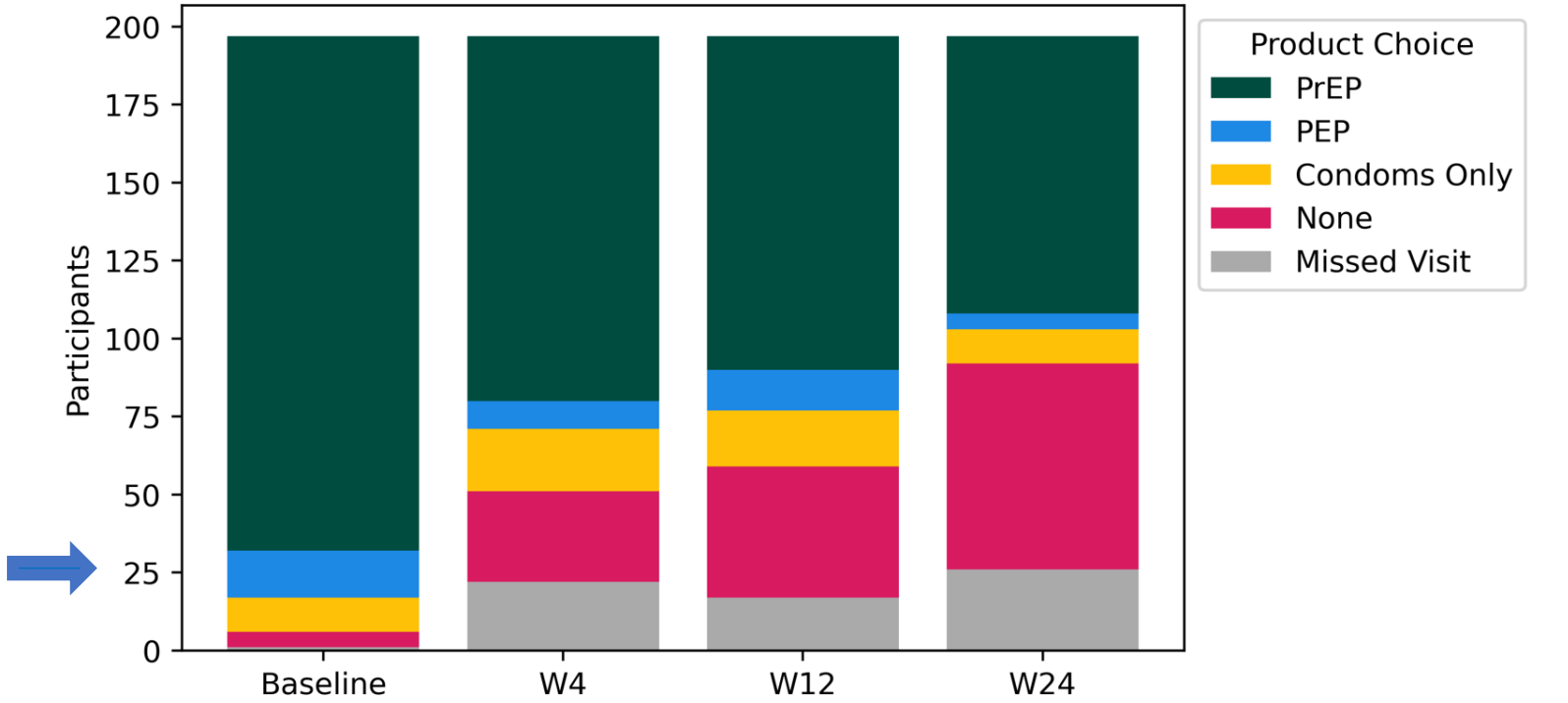
HIV TESTING CHOICE
- Rapid test
- HIV self-test option

CLIENT-CENTRED CARE

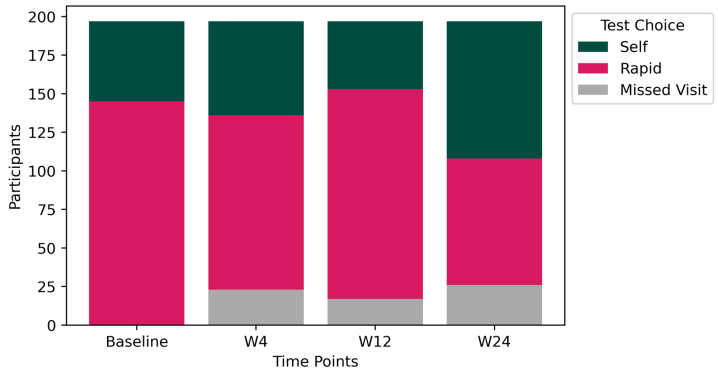
- **Structured assessment of barriers** to PrEP/PEP start/adherence, with **personalized plans** in response
- **Longer PrEP supply for start/refills (up to 3 months)**
- **Phone access to clinician** for PEP or PrEP starts, advice/questions (24hrs/7 days/week)
- **Reproductive health and/or STI service integration at ANC, OPD**
- **Psychological support** – referrals to counseling for trauma/gender-based violence

Outpatient Department Implementation

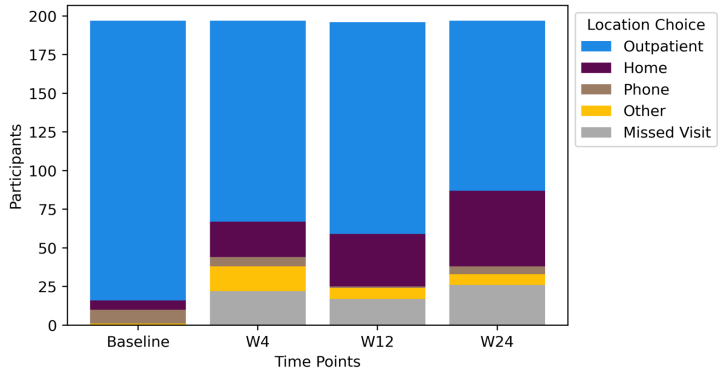
Interim data – week 24 intervention arm



Product Choice



Test Choice



Location Choice

Interest in PEP – potential missed opportunity to prevent infections if only PrEP offered

PEP as a choice to expand HIV prevention options

There is no “one size fits all” for prevention

- Additional choices are needed to serve all who may benefit from HIV prevention
- PEP is under-utilized and an entry point for other prevention options
- As new prevention options, including CAB LA PrEP, are scaled up alongside oral PrEP
    - opportunity to offer PEP as a choice to meet HIV prevention needs

Acknowledgements

- Study participants (NCT01864603)
- U.S. National Institutes of Health
- Ministry of Health Kenya
- Ministry of Health Uganda
- Kenya Medical Research Institute
- Infectious Diseases Research Collaboration
- University of California, San Francisco
- Study staff and Investigators

- AVAC, The Choice Agenda & Jim Pickett

PEP
It’s Not a Secret
(or at least it shouldn’t be)

ACE ROBINSON, MHL, MPH
HE / EL / ELE / IL
PCAF | CHIEF EXECUTIVE OFFICER
PUYALLUP | TACOMA

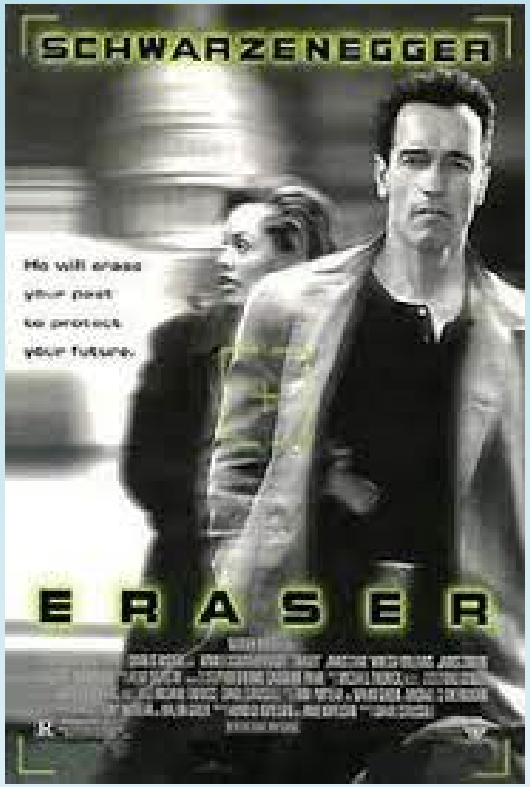
A Bit About Me

- CEO of PCAF: Largest HIV Service Provider in South Puget Sound
- Co-Chair of the Federal AIDS Policy Partnership (FAPP)
- Senior Advisor for HHS' Office of Infectious Disease Policy (OIDP)
- Master of Healthcare Leadership from Brown University | Master of Public Health from University of Cape Town | Bachelor of Chemistry from Duke University

The Fine Print

- Disclosures
  - My organization receives unrestricted funding from ViiV & Gilead Sciences

June 21st, 1996



Ace w/ Jheri Curl

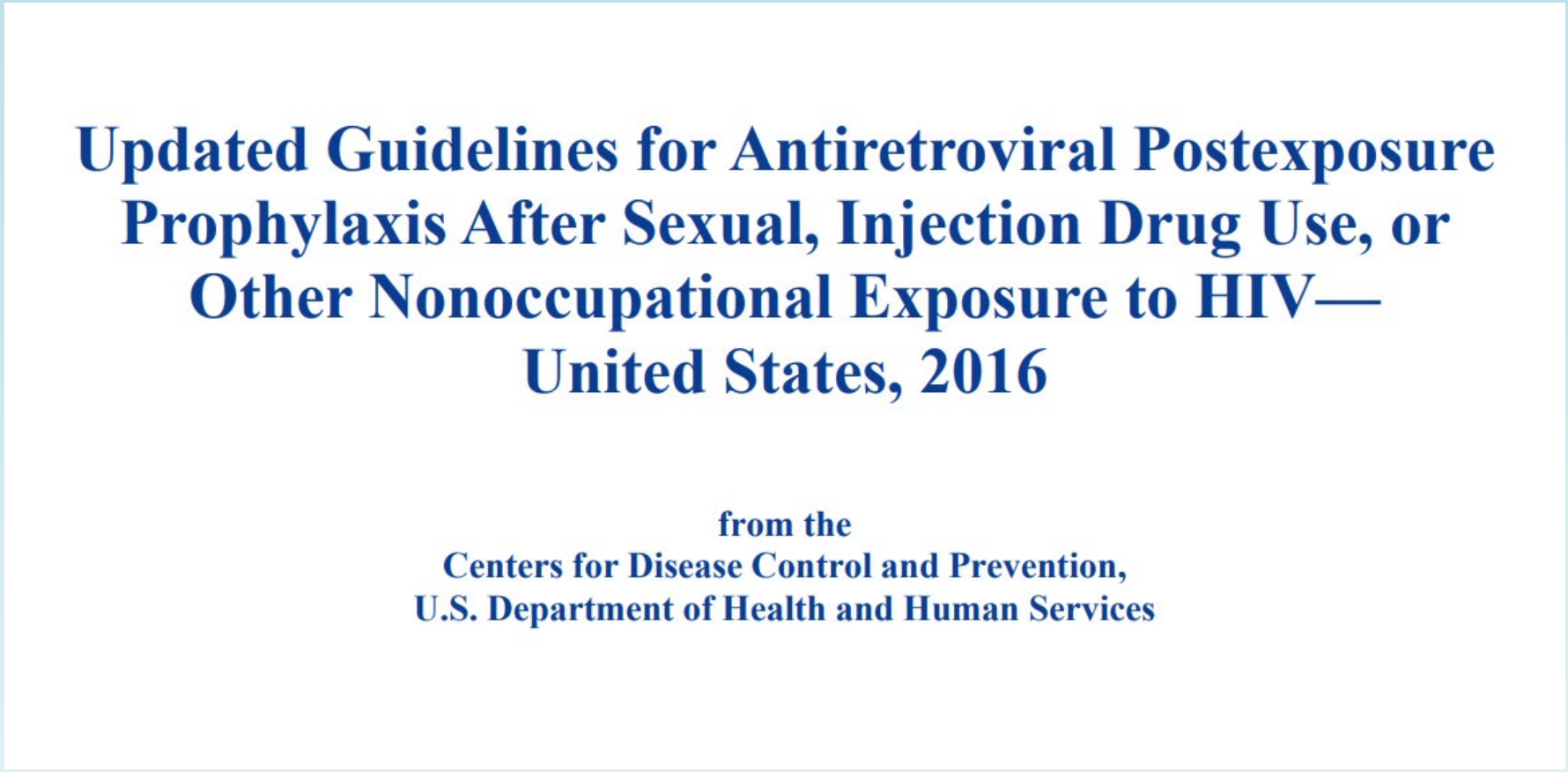
What else happened on that date?

- Viramune is approved as the first post-exposure prophylaxis regimen
- Caveat: It was only for clinicians who had an accidental fingerstick
- What else: Protease Inhibitors are shown to be effective
- Caveat: Turning point in the HIV response for certain communities

Same Story, Different Cast

- HIV Paternalism in Biomedical Prevention from Day One
- Foci remained on Babies, Mothers, Hemophiliacs, and Clinicians
- Left out: Queers, BIPOC, Substance Users

Twenty … read: 20… Years Later



Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV— United States, 2016

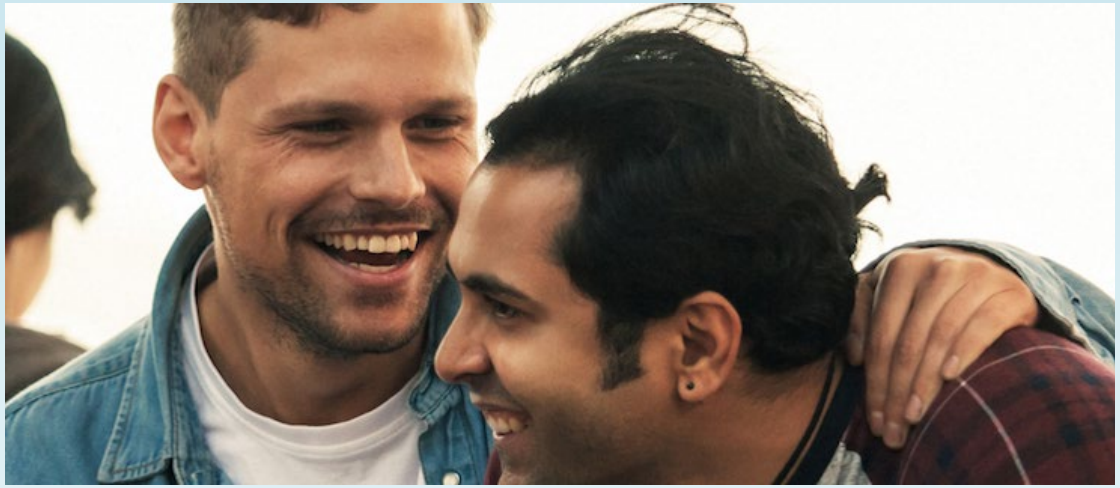
from the
Centers for Disease Control and Prevention,
U.S. Department of Health and Human Services

Impossible Is Nothing

- Where we are now…
- PEP is a proven & effective treatment
- Requirements
  - Mar/Comm
  - Staff Awareness (Sexual Health | Primary Health | Emergency Departments)
  - Standing Orders (7-day course with referral)
    - Do not require confirmed HIV-negative result
    - Train residents to work with Outreach Staff
      - Focus on medical staff who reflect the epidemic
  - Pharmacy partnerships are vital

History Doesn’t Have to Repeat Itself

Rewriting the Future's History Lesson



Did you???

- Create a protocol that can be followed in high throughput environments
- Are the staff trained on engaging communities greatly impacted by HIV
- Focus on engaging BIPOC clinicians
- Develop a marketing & communication strategy focused on QTPOC, street-involved & substance using
- Craft metrics to evaluate prevalence of HIV Paternalism within your organization
  - Evaluate metrics of differential offer & uptake across demographic populations

Remember One Thing: Public Health Is Not Rocket Science