Widening Options: Accelerating PrEP Uptake within a Consumer Choice Context

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Consumer perspective vs Programmatic perspective
Outline

• Implementation challenges
• The importance of choice
• Current options and choices
  • Products
  • Modalities of use
  • PrEP programs
• Conclusions
Implementation challenges

- A **wide variety of key groups** with varying needs
- Within individuals **varying needs over time**
- **Contextual/societal situation**
- **Costs** of PrEP products and PrEP-care
Implementation challenges

- On a **global** level, current PrEP uptake is insufficient to *Fast Track* the decrease of new HIV infections\(^1\)
- On a **country** level, stopping PrEP provision, even in a declining state of the epidemic, will result in an immediate increase in transmission\(^2\)
- On the **individual** level, continuing PrEP use, even while one can benefit, may be challenging
  - 41% discontinued <6 months\(^3\)
  - NL: about 42% stopped/were lost to follow-up over 3.5 years\(^4\)
    - 15% had only one visit

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1 UNAIDS. 2021 Global AIDS update slideset
2 Xiridou and Reitsema, personal communication
3 Zhang et al, Lancet HIV 2022
4 RIVM year report 2022
People want, need, and deserve choice
Choice is necessary for effective programming

- PrEP discontinuation rates are lower if both daily and event-driven regimens are offered for MSM/TGW

- One size does NOT fit all!

Zhang, Lancet HIV 2022
The HIV Prevention Pipeline

**Currently available**
- HIV treatment for people living with HIV/U=U
- Male & female condoms
- Voluntary medical male circumcision
- Syringe exchange programs
- Daily oral PrEP
  - Event-driven for some populations.

**Newly Approved and Recommended**
- Dapivirine vaginal ring
- Long-acting injectable

**In development: Efficacy trials under way**
- Long-acting injectable
- Preventive vaccines
- Daily & monthly oral PrEP
- Combo oral PrEP
  - Possible dual pill to market by 2024.¹

**In development: Preclinical and clinical**
- Long-acting implants
- Preventive vaccines
- Multipurpose vaginal ring
- Broadly neutralizing antibodies
- Vaginal/Mucosal Inserts
- Patches
- Long-acting vaginal ring
- Vaginal Gel

¹In Oct 2019, US FDA approved F/TAF for adults and adolescents who have no HIV risk from receptive vaginal sex; still in development for cisgender women.
²Efficacy trials not required; bioequivalency of the two approved products when dosed together may be all that is required.

Avac, September 2023
The Balance:

- We need products and programs that appeal to key users
- AND
- We need programs that decrease and not increase health disparities
- We need products that are fair priced and cost-effective
- We need programs that are feasible for already burdened health facilities
What are PrEP choices from a consumer perspective?

- Choice of PrEP product and modality of use
- Choice of PrEP program set-up
- Communication about sexual health
PrEP products
PrEP products-oral PrEP

- F/TDF
  - Effectivity proven in trials for several key populations
  - 2012 FDA-approved
  - Generic products broadly available
- F/TAF
  - Discover Trial: non-inferiority to F/TDF
  - Slightly less kidney related adverse events
  - 2019 FDA-approved for anal sex

Emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (DISCOVER): primary results from a randomised, double-blind, multicentre, active-controlled, phase 3, non-inferiority trial
Weight gain related to F/TAF (versus F/TDF)

- Discover trial: 1 kg weight gain over 48 weeks in F/TAF

- ADVANCE trial (among PLWHIV): 6 kg weight gain compared to 3 kg over 48 weeks; more obesity and metabolic syndrome

Mayer, Lancet 2020; Venter, NEJM 2019
PrEP products-injectable PrEP

- Cabotegravir
  - HPTN083 and 084 in MSM, TGW and cis women: non-inferior or superior to oral PrEP
  - Interestingly: good results in black MSM, TGW, and young people
  - Two-monthly injections
  - 2022 FDA-approved and 2023 EMA approved
WHO recommends the dapivirine vaginal ring as a new choice for HIV prevention for women at substantial risk of HIV infection
# Dual Prevention Pill

## Market Preparation and Introduction Strategy

<table>
<thead>
<tr>
<th>DPP Persona</th>
<th>Description</th>
<th>Trigger Moment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elsie</td>
<td>Is seeking enjoyment outside of her primary relationship and prioritizes individual values such as enjoyment or career goals.</td>
<td>Discovered male partner having extramarital affair, then began her own affair to get even.</td>
</tr>
<tr>
<td>Vicky</td>
<td>New mother who is motivated to use SRH products to perform this role, in a way that adheres to the social norms of motherhood.</td>
<td>After giving birth to her first child, wants to space births of subsequent children.</td>
</tr>
<tr>
<td>Lindiwe</td>
<td>Wants to maintain her romantic relationship, in which she often has limited decision-making power and has to rely on her male partner.</td>
<td>Discovered partner was secretly living with HIV; does not want to lose security and social status that comes with a partner.</td>
</tr>
<tr>
<td>Thandiwe</td>
<td>Has experienced or is at risk of unintended pregnancy, often compounded by low awareness of SRH options and limited locus of control with use of prevention products.</td>
<td>Unintended pregnancy postponed her plans to complete her studies and start a career.</td>
</tr>
<tr>
<td>Faith</td>
<td>Has unfaithful male partner and is motivated to protect her health, but finds it difficult to negotiate safe sex with her partner.</td>
<td>Suspected partner of infidelity; wanted to protect herself without the need for her partner’s consent.</td>
</tr>
</tbody>
</table>
PrEP use modalities
Daily oral PrEP, F/TDF

- Most studied
- Highly effective if used consistently
- Effective for all populations
- FDA approved in 2012, broadly approved elsewhere
- Generic products widely available
Daily vs non-daily oral PrEP

- **On demand or event-driven PrEP**
  - 2-1-1
  - Is effective for anal sex
  - Is preferred by some GBMSM
  - Some GBMSM will not take daily PrEP but will use this modality
- **Ts and Ss**: 4 pills a week (Tuesday, Thursday, Saturday, Sunday)
  - Based on studies from daily PrEP with no infections in those using at least 4 tablets/week; for anal sex only
- **Holiday PrEP**: 7-7-7
  - Start with 7 tablets, then enjoy holiday/sex for 7 days with daily pills, after holiday continue for 7 days
- **Safe starting and stopping**
  - 2 pills (anal sex) or 7 days before sex; 2 times 1 tablet (anal sex) or 7 days after sex

"Because event-driven PrEP makes you think [about your sex life], and then you don’t go all crazy"

"[I am] afraid I might forget a pill when using it on a daily basis"

Individuals need information about effective use of non-daily PrEP regimens

Counselling about HIV prevention after stopping PrEP

Zimmermann et al, 2019

- We offered **choice** between daily and event-driven PrEP
- For MSM and TGW
- 27% chose event-driven use
- Switching occurred often: 29% switched in first 2 years

Men who have sex with men more often chose daily than event-driven use of pre-exposure prophylaxis: baseline analysis of a demonstration study in Amsterdam

Elke Hooimenborg1,2, Roel CA Achterberg1,2, Maarten F Schim van der Loeff1,3, Udi Davidovich1,3, Jannie J van der Helm1, Arjan Hoexwoning2,4, Yvonne THP van Duinovens1, Gerard JB Sonder1, Henrey JC de Vries1,2,5, and Maria Prins1,2,5 on behalf of the Amsterdam PrEP Project team in the HIV Transmission Elimination AMsterdam Initiative
PrEP programs
Program set-up: Five options to maximise uptake and continuation

1. Co-located services associated with higher PrEP uptake\(^1\)
2. Peer (co)-led services vs public health professional-led vs hospital-based
3. Key group-tailored services
4. Online PrEP services
5. Costs and navigation

Tanner et al, JAIDS 2023
Co-located services

- **Examples**
  - Provision of PrEP tablets on premises
  - With STI services and free condoms
  - With HIV treatment services

- **Promising** in some settings:
  - With harm reduction services for PWUD
  - With gender affirming care for transgender persons
  - With services for sex workers
Co-led Clinic by Community and professionals:

**Services:**
- Hormone Support
- Sexual Health Services
- Psychosocial Support

**Provided for:**
People from the trans and gender diverse community who experience barriers to access regular care
- Asylum seeker/ Undocumented status
- Homelessness
- Active as sex worker
- Migrant background
Key-group-tailored services

Amsterdam Center for Sex Workers
Online PrEP services

- Increased during COVID-19 restrictions
- Many reports from all over the world
- Offers choice *and* effective programming

- Is it as good as face-to-face care?

- In Amsterdam: Ezi-PrEP trial
Ezi-PrEP trial design

Primary outcome: adherence to PrEP pills
Let's Talk Confidentially

As a Nurx patient you can message with our medical or customer support teams any time with questions or concerns about your medications or tests. Simply log in to your Nurx account and click Messages to access your private inbox. To update your address, payment method or delivery schedule, log in and click Account. You can also email support@nurx.co or reach out by phone Monday-Friday (9am–9pm EST) at (800) 321-NURX.
Policy makers should keep in mind to make prevention choices accessible: capacity, costs, culture, navigation.
Communication about sexual health (and PrEP)
Non-judgemental communication

Shared decision making

Sex-positive and PrEP-positive communication

Motivational interviewing

Concern-based versus risk-based conversation

Estcourt et al, Sex health 2023
Dangerfield et al, Prevention Science 2023
Mueller Johnson et al, AIDS and behaviour 2023
Conclusion

• Several PrEP-related choices and other prevention options are valuable and needed
• Let’s stop talking about risk - let's talk about concern, needs, preferences, and keep it positive
• We should work together with all our stakeholders and communities to ensure PrEP reaches all who can benefit
• PrEP implementation needs to be tailored to local community needs and resources and will likely change over time - so revise and adjust regularly
• Adopting a consumer or marketing perspective can generate innovative insights and programs that keep people at center
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