Pre-Exposure Prophylaxis
State of the ART

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10th International Workshop on HIV Treatment, Pathogenesis, and Prevention
Research in Resource-Limited Settings
Outline

• Evidence from Clinical Trials
• Demonstration projects
  – Incoming data addresses some implementation questions
• Scale up
**HIV PREVENTION combined interventions**

- **Male circumcision**
  - Coates T, Lancet 2000
  - Male & female condoms
  - Grosskurth H, Lancet 2000

- **Treatment of STIs**
  - Treatment of STIs

- **Microbicide gel for women**
  - Abdool Karim Q, Science 2010

- **Oral pre-exposure prophylaxis**
  - Grant R, NEJM 2010 (MSM)
  - Baeten J, NEJM 2012 (couples)
  - Thigpen, NEJM, 2012 (Heterosexuals)

- **HIV Counselling and Testing**
  - Coates T, Lancet 2000

- **Behavioural Intervention**

- **Post Exposure prophylaxis (PEP)**
  - Scheckter M, 2002

- **Intravaginal Ring**
  - Baeten, CROI 2016
  - Nel, CROI 2016
## Oral PrEP & HIV prevention: randomized trials

<table>
<thead>
<tr>
<th>Study, population</th>
<th>Strategy</th>
<th>Efficacy (95% CI)</th>
<th>Publication</th>
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<tbody>
<tr>
<td>PROUD MSM UK (n=544)</td>
<td>PrEP FTC/TDF (vs. deferred PrEP)</td>
<td>86% (64-96%)</td>
<td>McCormack et al. Lancet 2016</td>
</tr>
<tr>
<td>BTS IDUs (♀ &amp; ♂) Thailand (n=2413)</td>
<td>PrEP TDF</td>
<td>49% (10-72%)</td>
<td>Choopanya et al. Lancet 2013</td>
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<td>iPrEx MSM &amp; TGW Multicountry (n=2499)</td>
<td>PrEP FTC/TDF</td>
<td>44% (15-63%)</td>
<td>Grant et al. N Engl J Med 2010</td>
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Demonstration Projects

In 2012, WHO issued a guidance for PrEP use for discordant couples and MSM

Also called for demonstration projects

“The outcome of these demonstration projects and country experience will be used to develop guidance for the implementation and scale-up of PrEP”
## Key implementation questions

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Baeten, Haberer, Liu et al JAIDS 2013
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*HIV-negative gay man.*  
*Karuga et al, Plos One 2016*
Priority populations

• Populations most in need should be targeted urgently to get greatest impact
  – Such populations may include MSM, sex workers, young women in SSA, serodiscordant couples, others
  – Innovative approaches to identify these populations without stigmatizing them and motivate their PrEP use
  – Those who need it may be those who find it most difficult to come to a health facility
  – But we have seen that such populations take up PrEP if it is offered to them
Those at risk want PrEP

High uptake in Demonstration Projects

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<tr>
<th>PrEP Uptake</th>
<th>% Of Cohort</th>
<th>% PREP Uptake</th>
<th>Uptake P Value</th>
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<tr>
<td>Non-condom Receptive Anal Intercourse</td>
<td></td>
<td></td>
<td>0.003</td>
</tr>
<tr>
<td>No</td>
<td>68%</td>
<td>75%</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>32%</td>
<td>81%</td>
<td></td>
</tr>
<tr>
<td>HSV Seropositive</td>
<td></td>
<td></td>
<td>0.03</td>
</tr>
<tr>
<td>No</td>
<td>87%</td>
<td>75%</td>
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<tr>
<td>Yes</td>
<td>13%</td>
<td>77%</td>
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Grant et al, *Lancet Infectious Diseases*, 2014
Partners Demonstration Project Study Population Characteristics

• Higher risk characteristics than Partners PrEP Study:
  – Median age = 29 \((\text{Partners PrEP} = 33)\)
  – 2/3 of couples have no children \((\text{Partners PrEP} = 22\%)\)
  – Median monthly coital frequency = 5-7 acts \((\text{Partners PrEP} = 4)\)
  – 64\% of women and 69\% of men reported unprotected sex with study partner in the month preceding enrollment \((\text{Partners PrEP} = 26\%)\)
  – HIV-1 infected partners have median viral load of 4.6 \((4.0-5.0) \log_{10} \text{copies/mL} \) \((\text{Partners PrEP} = 3.9)\)

\text{Heffron et al. R4P 2014}
PrEP uptake at enrollment in the Partners Demonstration Project

Kabwohe, Uganda: 96.6%
Kampala, Uganda: 98.1%
Kisumu, Kenya: 94.6%
Thika, Kenya: 95.5%

Heffron et al. CROI 2014
Those at risk want PrEP

• **What PrEP takers say PrEP offers** (Gilmore et al. IAPAC 2014; Ware et al. JAIDS 2012; Ware et al. AIDS & Beh 2014; Grant & Koester Curr Opin HIV AIDS 2016)
  
  – decreased anxiety
  
  – Increased sexual pleasure and intimacy
  
  – empowerment

PrEP would allow me to have sex without fear for the first time in my life

*HIV negative gay man.*
Grant et al, Curr Opin HIV AIDS 2016
Those at risk want PrEP

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  - Increased sexual pleasure and intimacy
  - Empowerment

Since we started taking [PrEP] we feel like we have a good future, earlier on we had seen death.

HIV negative woman in serodiscordant relationship
Ngure et al, AIDS Patient Care and STDs 2016
### Key implementation questions

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*Baeten, Haberer, Liu et al JAIDS 2013*
PrEP Works if You Take It — Effectiveness and Adherence in Trials of Oral and Topical Tenofovir-Based Prevention

Effectiveness (%)

Percentage of participants' samples that had detectable drug levels

- CAPRISA 004 (tenofovir gel, BAT-24 dosing)
- FEM-PrEP
- IPERGAY (TDF/FTC)
- iPrEx
- Partners PrEP (TDF)
- Partners PrEP (TDF/FTC)
- PROUD (TDF/FTC)
- TDF2
- VOICE (TDF)
- VOICE (TDF/FTC)
- VOICE (tenofovir gel, daily dosing)
Will users adhere?

In coming data suggest that adherence is high
– Knowledge that PrEP works may influence adherence

<table>
<thead>
<tr>
<th>HIV Discordant Couples</th>
<th>MSM</th>
<th>Young women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trials</td>
<td>82% (Partners PrEP, TDF2)</td>
<td>51% (iPrEx)</td>
</tr>
<tr>
<td>Demonstration Projects</td>
<td>86% (Partners Demo)</td>
<td>71% (iPrEx OLE)</td>
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* Adherence by drug detection

*Important points:
- Periods of high risk should be protected by PrEP
Study months with prevention-effective adherence

Total N = 3,220 study months

<table>
<thead>
<tr>
<th>Sufficient adherence (doses/week)</th>
<th>Risk of HIV acquisition</th>
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<tbody>
<tr>
<td></td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>N visits</td>
<td>% high risk visits</td>
</tr>
<tr>
<td>4+</td>
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Haberer, to be presented, 2016
Partners Demonstration Project

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Take home points:
- People know how to adhere when they are at risk
- Achieving sufficient adherence is easier with a lower threshold
Adherence

Scale up should:

– Prioritize PrEP for those that adhere
– Provide support for non-adherers
  • e.g young women
– Assist identification of risk and seasons of high risk

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Empiric data on risk compensation in those receiving active PrEP

Partners PrEP Study, no increase in unprotected sex, STIs, or pregnancy after July 2011 (when placebo stopped and all received active PrEP)
The US Demo Project among MSM and transgender women

– The number of anal sex partners declined over time
– Proportion practicing condomless receptive sex remained stable
– STI incidence was high, but did not increase over time

Those reporting condomless anal sex with many partners had protective drug levels

Suggesting that those at greatest risk may be more adherent
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Baeten, Haberer, Liu et al JAIDS 2013
Delivery

• Very few delivery models have been tested

This review summarizes PrEP delivery in a health maintenance organization, an STI clinic, and a primary care practice.
• The authors conclude that PrEP can be successfully delivered across a variety of settings.
PrEP as a bridge to ART
(an example of a delivery model)

• For couples initiating ART at enrollment, PrEP is offered through 6 months, then stopped:

• For couples in which the infected partner delays or declines ART, PrEP is continued until 6 months after ART initiation:

• This strategy is supported by mathematical modeling as potentially highly effective and cost-effective (Hallett et al. PLoS Med 2011; Ying et al. CROI 2015, abstract #1106)
Possible PrEP Delivery Avenues

• In Africa
  – Learning from ART experience  -  Driven by public sector delivery, enhanced by private practitioners
  – Consider various vulnerable populations
    – MSM, FSW, young women, fisher folk

• Possible venues
  – Clinics that offer PEP
  – Clinics offering FP, including emergency contraception
  – Youth friendly clinics
  – Clinics devoted to sex workers, STI and Cervical cancer screening clinics
Health providers

- Providers’ lack of information, unclear messaging, and judgment and discomfort in talking about sex have limited the achievement of best prevention benefits.
- Consider training needs and capacity building
Consider health providers

- Willingness to prescribe PrEP has been associated with knowledge of PrEP
- Uptake may be higher when recommended by a health provider

I just don’t believe anything I see on TV or in a newspaper. I’d rather hear it from a doctor, in person, one-on-one.... or therapists, people that are more involved in it

HIV negative, gay man in HIV discordant partnership

Brooks et al, AIDS Care, 2011
Delivery model

• Users will prefer a delivery model free of barriers

What are the steps I have to go through to get it? I mean, can I just go and say ‘can I have this pill’ to my doctor or pharmacist... What are the requirements, or do I have to jump through hoops to get the pill?”

• However regular HIV testing is required
  – Creatinine, Hep B testing

Brooks et al, AIDS Care, 2011
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Baeten, Haberer, Liu et al JAIDS 2013
PrEP is for a season

• PrEP is not for everyone, all of the time
• Adolescent women present a season of vulnerability
  – High HIV incidence East and Southern Africa ages 16-24 years
• HIV serodiscordant couples trying to conceive
• Young men who have sex with men
• Partners of migrant workers during periods of increased exposure
Costs and cost-effectiveness

• PrEP will be cost effective if offered to most at risk population
  – WHO recommends where HIV incidence >3/100 person years
• The NNT to avert 1 HIV infection
  – 13 for high risk MSM
  – 30 for high risk discordant couples
• Partners Demonstration Project – estimates costs of PrEP provision -  <$100/year per couple
• For policy makers, data are needed on
  – on cost savings made from provision of HIV PrEP to ART programs,
  – cost effectiveness data that includes various populations and various service delivery settings.
Remember..

• Cost of drugs for PrEP are lower than cost of drugs for treatment
  – Shorter duration of treatment
  – Fewer drugs required
Ultimately, it is about coverage and delivery

- Public health impact will come when PrEP (and ART and other highly effective strategies) are implemented effectively and at scale.
- UNAIDS has called for 3 million persons on PrEP by 2020.

![Projected annual number of new HIV infections globally, Fast-Track versus business as usual, 2010–2030](image)
Where are we with scale up?

- Early Clinical work
- Clinical trials
- Demonstration Projects
- Pilot Delivery
- Wide-scale Implementations
Oral PrEP containing TDF should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches (strong recommendation, high-quality evidence).
Regulatory Approvals

FDA Approves First Medication to Reduce HIV Risk

“‘It is still better to prevent HIV than to treat a life-long infection of HIV.’”

Deborah Birnkrant, director of the Division of Antiviral Products, US FDA, 16 July 2012

Press release

Medicines Control Council approves fixed-dose combination of tenofovir disoproxil fumarate and emtricitabine for pre-exposure prophylaxis of HIV

From: Registrar of Medicines, Medicines Control Council

Approvals obtained in Canada, France, Israel, Peru
Clinical guidelines are urgently needed

- They educate and guide health providers on how to provide PrEP
- Will act as a point of reference in M&E as PrEP rolls out
• Financing is a big question
  – For most countries may require donor funding

• Begin with low lying fruit -
  – high risk populations that are ready and willing and where there is social acceptability, depending on context
DREAMS is a partnership to reduce HIV infections among adolescent girls and young women in 10 sub-Saharan African countries. 

PrEP is endorsed as a priority within the DREAMS initiative.
Conclusion

• We have evidence that PrEP works, when taken

• Data from Demonstration projects continue to provide some information on what the ‘real world’ implementation of PrEP will be

• We may not have all the answers (and do not need to), but we really should scale up PrEP now
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