Update on roll out of PrEP

Dr Rachel Baggaley, Michelle Rodolph, Dr Shona Dalal, Dr Ioannis Hodges-Mameletzis

WHO HIV Department
Geneva, Switzerland

Regulatory pathways and clinical trial design for long-acting PrEP

Monday, 5 March, 18:00-21:30, Fenway Health
Oral PrEP: 7 yrs - from 1st RCT → increasing implementation

- **2010**: Fem-PrEP (SA, Kenya, Tanzania) PrEP 44% ↓ HIV (MSM)
- **2010**: Partners (Kenya & Uganda) PrEP 73% ↓ HIV (MSM)
- **2011**: BBK TDF PrEP 49% ↓ HIV (PWID)
- **2011**: CAPRISA 004 Tenofovir gel
- **2012**: iPergay (France) PrEP 86% ↓ HIV (MSM)
- **2012**: TDF2 (Botswana) PrEP 62% ↓ HIV (M&W)
- **2013**: Proud (UK) PrEP 86% ↓ HIV (MSM)
- **2013**: Voice PrEP & gel no ↓ HIV (MSM)

**WHO PrEP KP rec for PrEP for KP (except PWID) (as part of KP GL)**

**WHO enabling PrEP rec for all at 'substantial HIV risk' PWID) (as part of KP GL)**

**Numerous demo projects and OLE**

- **2014**: EML inclusion of TDF; TDF/FTC & TDF/3TC for PrEP
- **2015**: US FDA approval of TDF/FTC for PrEP
- **2015**: EMA approval of TDF/FTC for PrEP
- **2016**: EML inclusion of TDF; TDF/FTC & TDF/3TC for PrEP

**WHO update on PrEP use during pregnancy & BF**

**WHO PrEP issues for adolescents**

**WHO PrEP implementation tool**

**WHO PrEP KP rec for demo projects MSM, TG & SDC**

**WHO update on PrEP use during pregnancy & BF**

**First WHO PrEP GL for demo projects MSM, TG & SDC**
Evolution of WHO PrEP recommendations

**2012** PrEP for SDC, MSM and TG (*conditional recommendation in the context of demo projects*)

**2014** PrEP for MSM (*strong recommendation*)
Other KP (*conditional recommendation; no recommendation for PWID*)

**2015** PrEP for people at substantial HIV risk (≈3 per 100 person years) (*strong recommendation*)

**2016** PrEP drugs on EML (*TDF/FTC; TDF/3TC; TDF*)

**2017** WHO PrEP implementation tool

**2017** WHO update on PrEP use during pregnancy & BF

**2018** WHO update on PrEP and adolescents
PrEP M&E
Oral PrEP scale-up is a reality

- **February 2018**
  - Over 19 countries have approved TDF-FTC for oral PrEP
    - Gilead Sciences, Mylan, Cipla, Teva, and other manufacturers in the PrEP market space

- Implementation largely focused in MSM
  - (e.g. USA, France, Australia, UK, Thailand, Brazil, Philippines, Malaysia)

- Some implementation for sex workers
  - (South Africa national programme, India, Kenya, etc)

- Large scale-up for women underway in SSA (SA, Kenya), DREAMS and others (e.g. Lesotho national programmes, AGYW, SDC, others)

- Informal use – increasing but how to capture
### PrEP incorporated in ≈ 30 national ARV guidelines

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**In preparation**

- Lesotho
- Swaziland

**Updated:** February 26, 2018
Which countries are currently offering PrEP outside the context of demonstration projects (i.e. state-funded PrEP)?

1. USA (government-funded schemes, e.g. Medicaid)
   - Certain states are moving towards offering PrEP under state budgets, e.g. Florida most recently made that announcement
2. South Africa (NDoH)
3. Kenya
4. Canada
5. France
6. Norway
7. Belgium
8. Scotland
9. Brazil (newly launched programme December 2017, SUS)
10. Lesotho (SDC, KP inc people in prisons, AGYW)

Note: Other countries planning scale-up access in 2018
   - Thailand will include it by October 2018 into its national health insurance (NHSO), currently PrEP is available in limited government hospitals
   - Australia, Portugal, Netherlands, Vietnam

Updated: January 2018 (WHO HQ)
Oral PrEP global roll-out, 2018

**National roll-out** - Australia, Belgium, Brazil, Canada, Kenya, New Zealand, Norway, Scotland NHS, South Africa (?US)

**Other implementation** (e.g. demonstration projects, pharmacy access, DREAMS)
How many people are on PrEP right now?
Number of people taking PrEP globally

Cumulative number starting PrEP

Estimated active users
Feb 2018
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<th>Country</th>
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| Canada        | ?>2500         | Targets stated in November 2017 presentation by Julio Montaner  
• 1,000 PrEP treatments by Dec 31st 2017  
• up to 2,500 PrEP by March 31st 2018, up to 5,000 PrEP by March 31st 2019 |
| Brazil        | TBD            | For new national rollout, estimating 7,000 for 1st year of implementation in SUS + 3,000 on ImPrEP study (throughout 3 years)                                                                                 |
| Other PAHO    |                | Haiti, Peru, Mexico – planned                                                                                                                                                                                  |
| France        | 6000-7000      | Dec 2017, JM Molina reported 5352 persons started PrEP (Jan 1st 2016 - July 31st 2017), ANSM report. Approx. 400 start every month.                                                                           |
| UK            | 6000           | PrEP Scotland and PrEP Wales – free on NHS  
PrEP England PrEP IMPACT Trial for 10,000 in 200 sexual health clinics                                                                                                                                |
| Other Europe  | ? >1000        | Netherland AMPrEP 370- fully recruited  
Norway- free since Oct 2016 >500  
Denmark, Ireland                                                                                                                   |
| South Africa  | 4000           | January 2018, based on initiations since start of national roll-out                                                                                                                                           |
| Kenya         | 7000           |                                                                                                                                                                                                            |
| DREAMS        | 15-19yrs 1,330 | >400 in Kenya; >500 in South Africa and Kenya, small scale in Uganda, Zambia.                                                                                                                             |
|               | 20-24yrs 4,396 |                                                                                                                                                                                                            |
| Other Africa  | ? >1000        | Lesotho – national targets 26,000, Swaziland, Namibia, 100 + 500 SW Mozambique                                                                                                                             |
| Australia     | 11000 (at least) | Based on WHO Global PrEP webinar February 2018 (under-estimate). March 2018 national reimbursement likely to being.                                                                                       |
| Other Asia    | ? >5000        | India SW >1000  
Philippines Preppy 200, Malaysia 200, Indonesia, Taiwan  
Thailand >1000  
Vietnam >400                                                                                                                                  |
Private sector & “informal” PrEP use

How do we measure?


- 7% of respondents currently taking PrEP, prior to the Brazilian rollout, inc through clinical trials and ordering online.
- 36% were likely to use PrEP in the next six months

Blued on line survey
- 24 million users in China
- From survey increasing demand and informal use
What issues are limiting or preventing the implementation of PrEP?

- Cost of PrEP
- Cost of service delivery
- Feasibility
- Increases in STIs
- Adherence
- Other/Not licensed
- Lower condom use
- Eligibility
- Drug resistance

Number of countries (n=36)

High importance | Medium importance | Low importance

- Cost of PrEP
- Cost of service delivery

The future issues re planning and forecasting for PrEP roll out: Some successes some concerns

- **Sex worker programmes**
  - Benin – very poor uptake and retention; no impact
  - South Africa – national programme growing traction; impact beyond PrEP
  - Zimbabwe – increasing interest and use

- **AGYW**
  - Early uptake relatively low; adherence and retention issues likely significant challenges

- **SDC**
  - Acceptable as a ‘starter population’ – Nigeria, and Lesotho; early success in Kenya

- **MSM**
  - Huge interest in all regions; adherence and retention ?even better in OLE etc., ?impact in HIC; concern about STIs

- What about **Transgender women**
- What about **PWID (PWUD)**
What does this mean for forecasting for LA products?

- Replacement of current users
- New users
- What about adolescents (15-19) (inc AGYW and young KP)
- What about pregnancy and breastfeeding safety
- What about heterosexual men