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OPTIONS REVIEW AND DOCUMENTATION OF M&E INDICATORS FOR ORAL PrEP



Overview of this review

Goals of this work

- Summarize **current M&E efforts** for oral PrEP at the global, country and demonstration project levels
- Compile a **list of indicators** being recommended by **WHO** and for reporting under **PEPFAR/OGAC**
- Describe the national M&E structure and processes in **South Africa, Kenya and Zimbabwe**
- Present next steps for **prioritizing and positioning indicators**

Collect Information

WHO

is contributing to oral PrEP M&E development at the global, country and demonstration project levels?

WHAT

specific indicators are those stakeholders collecting or recommending?

HOW

is or will monitoring and evaluation data be collected and used?

The Critical Importance of “Getting it Right”

- **Monitoring** can improve current clinical and programmatic services by identifying when indicators of delivery or quality are not meeting expectations, so that corrective action can be taken
- **Evaluations** of key indicators can occur periodically or at the end of a project period. Key indicators can include process (# aware of oral PrEP, # using oral PrEP), impact indicators (# of HIV infections averted), and pharmacovigilance (# of seroconversions on oral PrEP, # of serious adverse events on oral PrEP)

The goal of M&E is to improve quality and optimize outcomes, but overly ambitious or ill-aligned M&E plans can:

- delay initiation of services
- result in data collection requirements that are burdensome for providers
- result in data collection requirements that are inconvenient and/or off-putting to clients

What do we NEED to know at WHAT levels to effectively introduce and rollout oral PrEP?

WHO is engaged, WHAT are they doing and HOW are they doing it?

GLOBAL/INTERNATIONAL LEVEL

WHO?	WHAT?	HOW?
World Health Organization	Providing global guidance on M&E for oral PrEP	WHO Implementation Guidance for PrEP includes Chapter 11 for “Program Monitors and Evaluators” Convening small working group for oral PrEP M&E
OGAC/PEPFAR	Establishing MER indicators for oral PrEP rollout under DREAMS/PEPFAR	Implementing partners offering oral PrEP will report on PrEP_NEW M&E working group will consider recommending broader range of indicator reporting in COP 17
BMGF: Prevention Market Manager (PMM)	Capturing data in early implementation phases to learn from and guide rollout plans regionally	Technical support to South Africa on early implementation M&E, and possibly to Zimbabwe, Kenya, Malawi

WHO is engaged, WHAT are they doing and HOW are they doing it?

COUNTRY/NATIONAL LEVEL			
COUNTRY	WHO?	WHAT?	HOW?
South Africa	NDOH	Detailed monitoring of early rollout of sex worker (SW) oral PrEP program including tracking clients cycling on and off oral PrEP	Electronic Medical Records (EMR) at all implementation sites, with technical support from CHAI/PMM
		Designing M&E of AGYW prevention programs	Through AGYW TWG
Zimbabwe	MOHCC	Identifying key indicators for tracking oral PrEP service delivery at national level through DHIS_2	Through oral PrEP and M&E TWGs, and OPTIONS-supported implementation planning
		Possible monitoring of early rollout as in South Africa	TBD, with technical support from CHAI/PMM
Kenya	MOH/ NASCO	Detailed monitoring of oral PrEP rollout through DREAMS and Bridge-To-Scale (B2S)	TBD, with technical support from UCSF
		Identifying key indicators for tracking oral PrEP service delivery at national level through DHIS_2	Through oral PrEP and M&E TWGs, and OPTIONS-supported implementation planning

Note: USG is engaged on M&E at national-level through missions in all three countries

WHO is engaged, WHAT are they doing and HOW are they doing it?

DEMONSTRATION PROJECT/PROGRAM LEVEL

WHO?	WHAT?	HOW?
OPTIONS	Tracking completed and ongoing oral PrEP trials and implementation projects including: population, study design/key questions, what data is collected and current status. This can serve as a resource for data-use at country-level	Through surveys and interviews with oral PrEP trial and implementation project staff. Posted online at PrEPWatch: (http://www.prepwatch.org/about-prep/research/)
South Africa	15 ongoing or planned oral PrEP trials and implementation projects with SWs, MSM, young people, and AGYW	See PrEPWatch for details (http://www.prepwatch.org/about-prep/research/)
Zimbabwe	Two oral PrEP trials with AGYW and two implementation projects with SWs and AGYW.	See PrEPWatch for details (http://www.prepwatch.org/about-prep/research/)
Kenya	Four implementation projects of PrEP with MSM, SWs and young people, and one completed project with sero-discordant couples	See PrEPWatch for details (http://www.prepwatch.org/about-prep/research/)

Note: OPTIONS is warehousing available information on PrEPWatch for ALL demo projects from countries across the region, and data collection tools and data reported from the relevant projects (<http://www.prepwatch.org/about-prep/research/>). See also <http://www.avac.org/resource/ongoing-and-planned-prep-demonstration-and-implementation-studies>)

What **policy-level** indicators are being considered by the **World Health Organization**?

Indicator	Measurement	Data Collection	Priority
Medicines Registration	Registration of TDF containing regimens for oral PrEP (including Truvada)	Tracking of registration processes and formal approvals	High
Professional Society Guidelines for oral PrEP	Recommendations from professional societies for the use of oral PrEP	Published/approved guidelines with sufficient detail to guide use	High
Public Sector Guidelines for oral PrEP	National recommendations by government agencies (e.g. MOH)	Published/approved guidelines with sufficient detail to guide use	High
Public Services and/or Insurance	Universal access, defined co-pay and/or insurance schemes covering oral PrEP	Published guidance, insurance policies	High
Total Costs	Amount paid by public agencies, donor organizations and oral PrEP users	National budgets, donor reports	Moderate

Note: Indicators and priority ranking adapted from WHO PrEP Implementation Guidance, Chapter 11

What **implementation** indicators are being considered by the **World Health Organization**?

Indicator	Measurement	Data Collection	Priority
Clinical capacity to deliver oral PrEP	# of clinics with capacity to deliver oral PrEP, # of potential clients served	Site readiness tools, estimated target population in catchment areas of capacitated clinics	Moderate
# of people informed about oral PrEP	# informed disaggregated by age, sex and risk group	Outreach tracking, clinic registers/summary return forms	Moderate
# of potential users reached who did not initiate oral PrEP	# and reasons why oral PrEP was not initiated, by age, sex and risk group	Outreach tracking, clinic registers/summary return forms	High
# of people initiating oral PrEP	# initiating by age, sex and risk group	Clinic registers/summary return forms	High
# of people continuing oral PrEP	#s continuing by age, sex and risk group (at monthly or clinically appropriate intervals)	Clinic registers/summary return forms	Moderate
# of people discontinuing oral PrEP	# and reasons for discontinuation, by age, sex and risk group	Clinic registers/summary return forms	Moderate
# of people re-starting oral PrEP	# and reasons for re-starting, by age, sex and risk group	Clinic registers/summary return forms	Moderate

Note: Indicators and priority ranking adapted from WHO PrEP Implementation Guidance, Chapter 11

What **individual/behavioral** indicators are being considered by the **World Health Organization**?

Indicator	Measurement	Data Collection	Priority
Behavioral risk prior to starting oral PrEP	# of sex partners 3 months before starting oral PrEP	Behavioral surveys/clinic records	Moderate
	Condom-less-sex 3 months before starting oral PrEP	Behavioral surveys/clinic records	High
Behavioral risk while on oral PrEP	# of sex partners 3 months after starting oral PrEP	Behavioral surveys/clinic records	Moderate
	Condom-less-sex 3 months after starting oral PrEP	Behavioral surveys/clinic records	High

Note: Indicators and priority ranking adapted from WHO PrEP Implementation Guidance, Chapter 11

What **impact** indicators are being considered by the World Health Organization?

Indicator	Measurement	Data Collection	Priority
Strategic use of oral PrEP	# and proportion of clients who used oral PrEP at protective levels during weeks when sex occurred	Self-report of daily usage, drug concentrations	High
HIV diagnosed at screening	# and proportion of HIV diagnosed among those screened, # linked to care and # initiated on ART	Clinic records, registers/summary return forms	High
HIV diagnosed after initiating oral PrEP	# and rates of sero-conversions (expressed as per 100 person years of oral PrEP follow-up)	Clinic records, registers/summary return forms	High
Drug resistance	HIV-1 RT/PR genotype indicating resistance to FTC or tenofovir at time of sero-conversion	Lab results	Low
STI diagnoses among oral PrEP users	# and proportion of oral PrEP users diagnosed with STIs at screening and follow-up	Clinic/lab results and/or presumptive diagnoses	High

Note: Indicators and priority ranking adapted from WHO PrEP Implementation Guidance, Chapter 11

What **oral PrEP indicators** are being considered by **OGAC/DREAMS**?

- PEPFAR implementing partners are being asked to track and report on the indicator **“PrEP_New”**
 - New **oral** PrEP initiations among young women aged 15-24 (disaggregated by ages 15-19 and 20-24 years)
- “PrEP_New” aligns with WHO recommended global indicator “# of people initiating oral PrEP”
- OGAC M&E working group will potentially add additional oral PrEP indicators for COP 2017
 - OPTIONS can support this process and help ensure selected indicators align with global recommendations (e.g. presenting this work to the M&E working group, keeping working groups informed about global recommendations)

Considerations for global indicators

- Focus on what we need-to-know vs. what is good-to-know to prioritize critical indicators without unnecessary burden
- Some indicators may serve as overall “PrEP” indicators, that can be later disaggregated for different types of PrEP (e.g. oral PrEP, vaginal rings, long-acting injectables), while others may be specific for oral PrEP (this should be clearly specified)
- OGAC M&E working group will potentially add additional oral PrEP indicators for COP 2017
 - OPTIONS can support this process and help ensure selected indicators align with global recommendations
 - OPTIONS can present this work to the M&E working group, keeping working group informed about global recommendations, etc.

Considerations for **Data Collection** and **Analysis**

Data Collection

- Now vs. programs at scale
 - What is critical to inform program rollout now?
 - What will we need to track programs at scale?
 - What is required for pharmacovigilance?

Data Analysis

- Use of research and implementation project data analyses to inform country-level rollout
- Who will analyze M&E data collected at the national level?
- How will M&E data be used for decision-making?

National M&E Structure/Process:

South Africa

- CHAI is working with NDOH to provide M&E support for the rollout of oral PrEP for the national sex worker program
- CHAI has recommended two M&E indicators to NDOH (new initiations of oral PrEP, continuation on oral PrEP)
- NDOH will wait to integrate new indicators until next year to incorporate learning from the initial oral PrEP rollout before making final indicator selections
- At the request of the NDOH, OPTIONS will work with CHAI to adapt the sex worker oral PrEP rollout M&E tools into a simplified version for oral PrEP implementation projects to use for reporting key data into NDOH for monitoring purposes
- The technical working group on Adolescent Girls and Young Women has been tasked with planning M&E for overarching AGYW prevention programming

National M&E Structure/Process:

Kenya

- Oral PrEP indicators (beyond PrEP_NEW) will be identified through the M&E TWG convened by NASCOP in early November 2016, selection will be informed by the oral PrEP TWG
- Once agreed, changes will be made to clinic registers for all service delivery points (source documentation) and to the monthly summary return form (#731) for entry into DHIS_2
- Changes can be ad hoc, or through the regular 2-year cycle (note: regular cycle has just been completed)
- USAID SI team is working closely with NASCOP on this process, with UCSF as the technical partner for M&E under DREAMS
- There are plans to bring in WHO through the NASCOP process

National M&E Structure/Process:

Zimbabwe

- There are plans to develop recommended oral PrEP indicators as part of the OPTIONS work and national PrEP TWG/ implementation planning process once guidelines are adopted
- OPTIONS will discuss recommended indicators with the strategic information (SI) team at MOHCC and the SI team at USAID to make refinements as needed
- These agreed indicators will be presented to the M&E TWG
- Once approved, OPTIONS will work with the SI team to review/develop tools for data collection
- Tools will then be integrated into DHIS_2 and electronic patient medical record system

Note: Existing M&E tools are under review now – there is a timely opportunity to feed into this national review