

OPTIONS, EpiC and RISE PrEP Learning Network M&E Considerations

> Regional Workshop Blantyre, Malawi

> November 12, 2019







TABLE EXERCISE & GROUP DISCUSSION (2 QUESTIONS) 1) WHAT ESSENTIAL DATA COLLECTED BY ROUTINE M&E? 2) WHY ARE THESE DATA COLLECTED/HOW ARE DATA USED?



U.S. President's Emergency Plan for AIDS Relief

Prep Pepfar Mer Indicators

Robyn Eakle, USAID Malawi PrEP Learning Collaborative Nov 2019 Slide Credit – Kimi Sato and Erin Schelar

PEPFAR MER v2.3 PrEP Indicators

Indicator Code	Indicator Name	Reporting Frequency	Reporting Level
PrEP_NEW	Number of individuals who have been newly enrolled on (oral) antiretroviral pre-exposure prophylaxis (PrEP) to prevent HIV infection in the reporting period	Semi-Annually	Facility
PrEP_CURR	Total number of individuals, including those newly enrolled, receiving (oral) PrEP during the reporting period	Semi-Annually	Facility
new			

Resources to learn more about PrEP MER indicators

- MER v2.4 indicator reference guide
- <u>https://www.pepfar.gov/documents/organization/288731.pdf</u>



PrEP_NEW and **PrEP_CURR**

PrEP_NEW

Description:	Number of individuals who have been newly e prophylaxis (PrEP) to prevent HIV infection in	enrolled on antiretroviral pre-exposure the reporting period						
Numerator:	Number of individuals who have received (oral) antiretroviral pre-exposure prophylaxis (PrEP) to prevent HIV infection	The numerator is generated by counting the number of people newly enrolled in oral PrEP (including WHO specified regimens "tenofovir-containing PrEP" which could be TDF alone, TDF/FTC, or TDF/3TC) during the reporting period, in accordance with the demonstration project guidance or the nationally approved protocol (or WHO/UNAIDS standards).						
Denominator:	N/A							
Indicator changes (MER 2.0 v2.2 to v2.3):	 Age/sex disaggregates updated. KP disaggregations updated to align with other KP-related indicators. 							
Reporting level:	Facility							
Reporting frequency:	Semi-Annually							

What's new for the PrEP MER?

- Requirement to report the KP disaggregate
- Nothing else

Some of the Issues

- PrEP_CURR how to report end of year
- Potential under and/or over-counting
- HIV test at 3 months (?)

PrEP_CURR

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Description:	Number of individuals, inclusive of those newly enrolled, that received oral antiretroviral pre- exposure prophylaxis (PrEP) to prevent HIV during the reporting period							
Numerator:	Number of individuals that received oral PrEP during the reporting period	N/A						
Denominator:	N/A	N/A						
Indicator changes (MER 2.0 v2.2 to v2.3):	New indicator							
Reporting level:	Facility							
Reporting frequency:	Semi-Annually							

- Implementing partners tracking own program data
- USAID PrEP custom indicators
- CDC PrEP monitoring
- Key Population Interagency custom indicators
- Soon to come USAID/CDC PrEP M&E recommendations
- And don't forget WHO PrEP indicators!
- <u>SEND THOUGHTS ON COP GUIDANCE!!!!!</u>







Thank you!

PrEP_NEW (additional)

How to use:	 The indicator measures the ongoing growth of PrEP services. This measure is critical to assess progress in the program's response to the epidemic in specific geographic areas, and the uptake and utility of PrEP among persons at substantially increased risk of HIV infection. This indicator permits monitoring trends in use but does not attempt to distinguish between different modes or regimens of PrEP or to measure the cost, quality or effectiveness of PrEP provided. These will each vary within and between countries and are liable to change over time. PrEP has been shown to reduce incident infections among several populations including serodiscordant heterosexual couples, MSM, FSW, and transgender people (TG). The WHO now recommends that oral PrEP containing tenofovir should be offered as an additional 										
	prevention choice for people at substantial risk, defined as HIV incidence > 3/100 person- years.										
How to review for data quality:	Numerator ≥ subtotal of the age/sex disaggregation: The total number people newly enrolled on PrEP (numerator) should be greater or equal to the subtotal of the age/sex disaggregate group.										
How to calculate annual total:	Sum results across quarters.										
Disaggregations:		Numerator Disaggregations:									
	Disaggregate Groups	Disaggregates									
	Age/Sex [Required]	 15-19 F/M, 20-24 F/M, 25-29 F/M, 30-34 F/M, 35-39 F/M, 40-44 F/M, 45-49 F/M, 50+ F/M, Unknown Age F/M 									
	Key Population Type: [Optional]	 People who inject drugs (PWID) Men who have sex with men (MSM) Transgender people (TG) Female sex workers (FSW) People in prison and other closed settings 									
	Denominator Disaggregations:										
	Disaggregate Groups	Disaggregates									
	N/A	N/A									



PrEP_CURR (additional)

How to collect:	The numerator can be generated by counting the number of individuals that have received PrEP during the reporting period, in accordance with national guidelines or WHO standards, including both those individuals newly initiating on PrEP and those continuing to receive PrEP. PREP_CURR reflects all persons receiving PrEP during the reporting period.
	 An individual newly initiating on PrEP will be counted under both PREP_NEW and PREP_CURR during the reporting period. If an individual tests positive at his or her three-month PrEP follow-up appointment and is then initiated on PEPFAR-supported treatment in the same reporting period, that individual could be counted as PREP_CURR in addition to TX_NEW and TX_CURR (given successful transfer into the ART program) within that reporting period. They would not be counted under PREP_CURR in subsequent reporting periods. The reporting level for this indicator is the facility level only. If PrEP is being provided at community-based sites, these sites should be connected to or have a relationship to a clinical facility. The community sites providing PrEP programming should count the number of individuals currently on PrEP being served through the community service delivery point, and then those data should be reported through the facility connected to that community site.

How to calculate annual total:	This is a snapshot indicator. Results are cumulative at each reporting period and should include anyone who received PrEP at ANY TIME during the reporting period.									
Disaggregations:	Numerator Disaggregations:									
	Disaggregate Groups	Disaggregates								
	Age/Sex [Required]	 15-19 F/M, 20-24 F/M, 25-29 F/M, 30-34 F/M, 35-39 F/M, 40-44 F/M, 45-49 F/M, 50+ F/M, Unknown Age F/M 								
	Three-month Test Result [Required]	 Positive Negative Less than three months since PrEP initiation 								
	Key Population Type [Optional]	 People who inject drugs (PWID) Men who have sex with men (MSM) Transgender people (TG) Female sex workers (FSW) People in prison and other closed settings 								
	1	Denominator Disaggregations:								
	Disaggregate Groups	Disaggregates								
	N/A	N/A								



Example: How to Count an individual- Negative



Example: How to Count an individual- Positive



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Monitoring PrEP Initiations

Njambi Njuguna, FHI 360/LINKAGES/EpiC



- Data use is critical in identifying gaps and planning on mitigation measures to increase PrEP uptake
- To improve performance, data must be analyzed and the results used to inform strategy and decisions
- Uptake of PrEP can increase rapidly over time as more people begin to use PrEP and demand creation and word-of-mouth increase awareness





- All the bars before 'initiate' determine the number of initiations. Therefore gaps between each bar will result in low initiations
- Programs need to minimize the gaps between each bar to help increase initiations



*Only to the point of PrEP initiation



LINKAGES Kenya PrEP cascade, FY19



- Low screening rates
- High numbers eligible and aware of PrEP but uptake is low
- Low Month I return

LINKAGES South Africa – Scale up of PrEP for MSM in Q3 and Q4 FY19





PrEP Cascade among MSM in South Africa, FY19 Apr-Sept 2019



Analysis of Gaps

Gaps identified vary but key among them include:

- Despite high numbers of HIV negative individuals, lower numbers initiate PrEP
- Not everyone who has screened and was found to be at high risk eventually initiate (why are people lost between screening and PrEP initiation?)
- PrEP initiation is only available within a few geographies (need for scale up at national level)
- Low uptake despite high numbers being eligible (need to understand the reasons why clients refuse to initiate even when eligible)



- PrEP providers trained? Yes
 - Sometimes not all providers at a facility are trained on PrEP
- PrEP availability?
 - Some period of PrEP shortage nationwide accounting for some numbers of high eligibility and low uptake
 - PrEP not available in all regions and DICs. Thus, screening for PrEP was not done where PrEP is not available or if done, no access to PrEP
 - PrEP may not be available during outreaches
- Screening

- Some providers consider screening clients for PrEP as additional burden



- Mentorship of providers to continually screen and offer PrEP to all eligible clients
- Outreaches screening of PrEP at outreaches with dispensing and linking of KPs to the DICs or clinical sites
- Working with outreach workers to dispel myths and misconceptions of PrEP including addressing other barriers to PrEP initiation
- Working with providers to counsel on potential side effects of PrEP*
- A monitoring and reporting strategy should maximize data quality and minimize the burden on health workers by collecting and reporting only data and indicators at site, sub-national and national levels that are necessary for decision-making at each of those levels.
- The PrEP cascade to Initiation, should make sure that "initiation is defined clearly" and that perhaps there should be a step that is "PrEP Distributed" followed by "PrEP Start". Initiation is an ART term giving the sense of once you initiate it is for life. Thus new terminology is needed to differentiate from ART and call it more of what it is. Thus perhaps Started PrEP (starting taking, first pill) is a better language.

Monitoring PrEP Continuation

Patricia Ongwen, Jilinde/Jhpiego

Monitoring PrEP Continuation

- After INITIATING PrEP, clients' follow-up status broadly categorized according to ongoing use (or lack of)
 - DISCONTINUED: client has not returned at all for additional PrEP supply
 - ONGOING USE: client has returned for additional PrEP supply
 - Follow-up visits further sub-classified (according to timeliness of return):
 - o "REFILL": on-time return for additional PrEP supply
 - number of contiguous months with REFILLs (1, 3, 6, 12 months, etc) = 'continuation' at 1, 3, 6, 12
 - o "RESTART": delayed return for additional PrEP supply

Determining Follow-up Visit Type (REFILL vs. RESTART)

- Visit type categorization
 - -Categorization automated; computer algorithm calculates duration between visits and classifies timeliness of follow-up (REFILL vs. RESTART)
 - -Requires collection of 2 variables for every visit
 - o Visit date
 - o # pills dispensed



Chukua kontrol

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Data Source JDS

Case study: PrEP Continuation Rates in 8 ICRHK Drop-In-Centers



Feb to Mar 2017 Apr to June 2017 July to Sept 2017 Oct to Dec 2017 Jan to Mar 2018 Apr to June 2018 july to Sept 2018 Oct to Dec 2018 Jan to Mar 2019

Q/FY PrEP Initiated



Monitoring Episodic PrEP Use (users that cycle on and off PrEP repeatedly)

Jason Reed, Jane Mutegi, Brian Wakhutu Jhpiego/Jilinde



- Many clients take PrEP episodically: use limited to periods of risk, followed by stop(s) and restart(s) when risk resumes
 - Current indicator only monitor continuation duration of first use; does NOT measure continuation after restart(s)
 - PREP_CURR does NOT quantify duration of use (continuous or otherwise); merely specifies clients receiving follow-up prescription that initiated PrEP in a prior year
- Client-level longitudinal data:
 - Enable monitoring of use duration across multiple episodes (not just 1st episode)
 - Allows for identification of users characteristics associated with early discontinuation and highly episodic use (for program improvement if needed)

Example client: Jill Received 9 PrEP prescriptions in 2018



Jill's Prescriptions DATE/(# Dispensed) JAN 31 (30) MAR 1 (30) APR 16 (30) MAY 31 (30) JUL 1 (30) AUG 1 (30) AUG 31 (30) NOV 1 (30) DEC 14 (30)

Only 2 variables needed for each visit

- Visit Date
 - Volume dispensed (# pills)



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Jill's **Prescriptions** DATE/(# **Dispensed**) JAN 31 (30) MAR 1 (30) APR 16 (30) MAY 31 (30) JUL 1 (30) AUG 1 (30) AUG 31 (30) NOV 1 (30) DEC 14 (30)



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Determine deadline for return by adding to Initiation Date the # PILLS dispensed (30) + "forgiveness" factor (default = 15 days)

2nd Visit Return Deadline: Jan 31 + 30 (pills) + 15 (forgiveness days) = March 17



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Determine deadline for return by adding to Initiation Date the # PILLS dispensed (30) + "forgiveness" factor (default = 15 days)

- If follow-up on or before 3/17, Rx classified as <u>REFILL</u>
- If follow-up 3/17, Rx classified as
 <u>RESTART</u>



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Jill's Prescriptions DATE/(#) JAN 31 (30) MAR 1 (30) APR 16 (30) MAY 31 (30) JUL 1 (30) AUG 1 (30) AUG 31 (30) NOV 1 (30) DEC 14 (30)

Determine deadline for return by adding to Initiation Date the # PILLS dispensed (30) + "forgiveness" factor (default = 15 days)

- If Jill's 2nd visit on or before 3/17, Rx classified as REFILL
- If Jill's 2nd visit after 3/17, the Rx classified as RESTART
- Jill's actual 2nd visit/return date was 3/1, so this visit is classified as a REFILL





Jill's Prescriptions DATE/(#) JAN 31 (30) MAR 1 (30) APR 16 (30) MAY 31 (30) JUL 1 (30) AUG 1 (30) AUG 31 (30) NOV 1 (30) DEC 14 (30)

 Jill's actual 3rdnd visit/return date was 4/16, so this visit is classified as a RESTART



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CONTINUATION = contiguous months' REFILLS

USE CYCLE = every RESTART results in a new use cycle; every use cycle has its own continuation duration



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Jill received 9 prescriptions across 3 cycles of use (initiation and two restarts)

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Jill's Prescriptions DATE/(#) JAN 31 (30) MAR 1 (30) APR 16 (30) MAY 31 (30) JUL 1 (30) AUG 1 (30) AUG 31 (30) NOV 1 (30) DEC 14 (30) INITIATION

> REFILI RESTART

Jill received 9 prescriptions across 3 cycles of use (initiation and two restarts)



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5 6 7 8

19 20 21 22 26 27 28 29

12 13 14

S

JIL

Jill received 9 prescriptions *across 3 cycles of use* (initiation and two restarts)





Jill's Prescriptions DATE/(#) JAN 31 (30) MAR 1 (30) APR 16 (30) MAY 31 (30) JUL 1 (30) AUG 1 (30) AUG 31 (30) NOV 1 (30) DEC 14 (30)



First Use is Only the Beginning of the Story

- Which continuation duration is most important?
 - -A client's first use
 - -A client's most recent use
 - -A client's longest use

First Use is Only the Beginning of the Story

- Which continuation duration is most important?
 - ✓A client's first use?
 - ✓A client's most recent use?
 - ✓A client's longest use?
 - ✓ ALL OF THE ABOVE!



<u>M&E APPROACH</u>: PREP_CURR ≠ TX_CURR <u>INTERPRETATION</u>: PREP CONTINUATION ≠ ART RETENTION

Mirroring ART retention may lead to faulty conclusions; doesn't consider prevention effective use

Measuring What Matters

- Importance of long-term contiguous days' use difficult to gauge for PrEP, especially early in scale-up
- Instead measuring what we want to better understand:
 - -"Who" stops early or never returns and why
 - "Who" frequently stops and restarts (cycles on/off) and why
- Appeal: Avoid prematurely selecting indicators that are ambiguous and potentially harmful to assessment of program viability (even if convenient/familiar)

Continuation vs. Effective Use

- Reminder: though 'continuation' is the indicator measured
 - -Non-continuous use may still be effective, depending upon use pattern and association with risk
 - -Continuous **refills** not necessarily associated with effective/protective use



PrEP-it: Cascade Module

November 12











Initiation outputs

- Generates 2 cascades
- Dynamic can look at by priority population or by year
- Can be used to examine program performance





- Users select which of the monthly indicators they are collecting and then enter the data in each month for up to 60 months, by priority population
- Most users will have a subset of the possible monthly metrics listed
- The essential metric to effectively use the tool is # initiated PrEP, including reinitiations, which can also be tracked separately

Monthly Metrics

- \Box # testing for HIV
- \Box # testing HIV negative
- # screened for PrEP (1 vs. 2stage scring
- # screened deemed eligible for PrEP
- # eligible offered PrEP
- # initiated PrEP
 (including reinitiations)
- □ # reinitiated PrEP
- □ # seroconversions on PrEP
- □ # serious side effects
- □ # 3 custom indicators



Define priority populations

_	_	

Enter monthly data on initiations and other metrics

Enter or calculate continuation rates



Link to other modules: targetsetting, costs, and impact

- View uptake and initiation measures by priority population and identify areas for improvements
- Forecast number of PrEP clients expected in the near future
- Track progress against targets
- Estimate costs and impacts associated with PrEP delivery
- Examine how impact and effectiveness could be improved via higher continuation rates

ROUTINE M&E: PANEL DISCUSSION

SPECIAL M&E TOPICS: PANEL DISCUSSION