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Monitoring, Evaluation, and Reporting (MER) Guidance (v.2.7): LAB_PTCQI

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Training Outline

Section 1: Overview of the Technical Area

Section 2: Indicator Changes in MER 2.7

Section 3: Overview of Indicators

Section 4: Data Use

Section 5: Additional Resources and Acknowledgments

Section 1: Overview of Lab



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PEPFAR Laboratory Support

- Laboratory tests are essential for both **diagnosing & monitoring** HIV and TB patients.
- PEPFAR-supported laboratory activities aim to expand the **availability** of laboratory services and ensure **quality** test results.
- Monitoring for PEPFAR-supported laboratory programs focuses on:
 - Engagement in continuous quality improvement (CQI)
 - Engagement in proficiency testing (PT)
 - Number of specimens received for testing

1st 95 (HIV Status)

- **HIV Testing Services**
 - HIV rapid testing
 - HIV recency testing
- **PMTCT**
 - Early Infant Diagnosis (EID)

2nd 95 (On ART)

- **TB Services**
 - TB mWRD
 - TB LF-LAM
 - TB AFB (smear microscopy)
 - TB Culture
- **Advanced HIV Disease**
 - CD4 testing

3rd 95 (Suppressed)

- **HIV Care & Treatment**
 - HIV Viral Load testing

Section 2: Indicator Changes in MER 2.7



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Indicator Changes in MER 2.7

Indicator	Change	Programmatic Rationale
LAB_PTCQI	<ul style="list-style-type: none"> Reduced the number of CQI disaggregates to only capture information on participation in CQI and certification/accreditation and no longer capture information on external audits or audit scores. 	<ul style="list-style-type: none"> Reduce reporting burden and improve analytic output of the indicator
	<ul style="list-style-type: none"> Reduced the number of PT disaggregates to only capture information on participation in PT and no longer capture information on PT performance. 	<ul style="list-style-type: none"> Reduce reporting burden
	<ul style="list-style-type: none"> Changed the testing category of TB Xpert to TB molecular WHO-recommended diagnostic (mWRD). 	<ul style="list-style-type: none"> New language adopted by WHO Broadens the category to capture data on new molecular instruments
	<ul style="list-style-type: none"> Added testing category TB LF-LAM. 	<ul style="list-style-type: none"> PEPFAR has been recommending and supporting scale-up of LF-LAM for several years. Adding this category will allow us to monitor the scale-up and quality of TB LF-LAM testing

Section 3: Overview of Indicator



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Indicator Definition: LAB_PTCQI

Indicator Definition: Number of PEPFAR-supported laboratory-based testing and/or Point-of-Care Testing (POCT) sites engaged in continuous quality Improvement (CQI) and proficiency testing (PT) activities.

LAB_PTCQI captures data on three metrics at two types of testing sites

↓
CQI engagement
PT engagement
of specimens received

↓
Laboratory-based
Point-of-care (POC)

Numerator:

- Number of PEPFAR-supported laboratory-based testing and/or Point-of-Care Testing sites engaged in CQI activities.
- Number of PEPFAR-supported laboratory-based testing and/or Point-of-Care Testing sites engaged in PT activities.
- Number of specimens received for testing at all PEPFAR-supported laboratory-based testing and/or Point-of-Care Testing sites within a testing category.

Numerator Disaggregates: LAB_PTCQI

Disaggregate Groups	Disaggregates
<p>CQI at laboratory-based testing sites by test category: HIV serology/diagnostic testing, HIV IVT/EID, HIV Viral Load, TB mWRD, TB LF-LAM, TB AFB, TB Culture, CD4, Rapid Test for Recent Infection) [Required]</p>	<ul style="list-style-type: none"> • How many sites perform this test but do not participate in CQI? • How many sites perform this test, participate in CQI, but are not fully accredited? • How many sites perform this test, participate in CQI, and are fully accredited?
<p>CQI at point-of-care-based testing sites by test category: HIV serology/diagnostic testing, HIV IVT/EID, HIV Viral Load, TB mWRD, TB LF-LAM, TB AFB, CD4, Rapid Test for Recent Infection) [Required]</p>	<ul style="list-style-type: none"> • How many sites perform this test but do not participate in CQI? • How many sites perform this test and participate in CQI, but are not fully certified/accredited? • How many sites perform this test, participate in CQI, and are fully certified/audited?

Numerator Disaggregates: LAB_PTCQI (cont.)

Disaggregate Groups	Disaggregates
<p>PT at laboratory-based test category: HIV serology/diagnostic testing, HIV IVT/EID, HIV Viral Load, TB mWRD, TB_LF-LAM, TB AFB, TB Culture, CD4, Rapid Test for Recent Infection) [Required]</p>	<ul style="list-style-type: none"> • How many sites performed this test but do not participate in PT? • How many sites perform this test and participate in PT?
<p>PT at Point-of-Care testing sites by test category: HIV serology/diagnostic testing, HIV IVT/EID, HIV Viral Load, TB mWRD, TB_LF-LAM, TB AFB, CD4, Rapid Test for Recent Infection) [Required]</p>	<ul style="list-style-type: none"> • How many sites performed this test but do not participate in PT? • How many sites perform this test and participate in PT?
<p>Testing Volume by laboratory vs. point-of-care testing and test category: HIV serology/diagnostic testing, HIV IVT/EID, HIV Viral Load, TB mWRD, TB LF-LAM, TB AFB, TB Culture, CD4, Rapid Test for Recent Infection) [Required]</p>	<ul style="list-style-type: none"> • Number of specimens received for testing at all PEPFAR- supported laboratory-based testing sites within a testing category

Definitions of Disaggregates: LAB_PTCQI

- For both CQI and PT disaggregate groups, testing category disaggregations are only applicable if specific test category is performed by the laboratory.
- Please see the MER Reference Guide for specific definitions of each disaggregate.

How to Collect: LAB_PTCQI

- PEPFAR-supported testing sites may receive:
 - DSD or TA from PEPFAR
 - Specimens from PEPFAR-supported clinics
 - PT panels via PEPFAR-support
- Testing sites may be laboratory-based or point-of-care



Laboratory-based testing sites:

- Dedicated laboratory infrastructure
- Laboratorians performing testing



POCT sites:

- At or near place of interaction with the patient
- No dedicated laboratory infrastructure
- May not have laboratorians performing testing

Facilities may have ≥ 1 laboratory-based testing sites, ≥ 1 POCT sites or both lab-based and POCT sites.

How to Collect: LAB_PTCQI

	How many sites perform this test but do not participate in CQI?	How many sites perform this test, participate in CQI, but are not fully accredited?	How many sites perform this test, participate in CQI, and are fully accredited?	Total Number of Sites
CQI: Lab & POCT				
HIV Serology/Diagnostic				
HIV IVT/EID				
HIV Viral Load				
TB mWRD				
TB LF-LAM				
TB AFB				
TB Culture*				
CD4				
Rapid Test for Recent Infection				

How to Collect: LAB_PTCQI

PT: Lab & POCT	How many sites perform this test but do not participate in PT?	How many sites perform this test and participate in PT?	Total Number of Sites
HIV Serology/Diagnostic			
HIV IVT/EID			
HIV Viral Load			
TB mWRD			
TB LF-LAM			
TB AFB			
TB Culture			
CD4			
Rapid Test for Recent Infection			

*TB Culture is only reported under laboratory-based testing

How to Collect: LAB_PTCQI

	How many specimens were received for testing?
Test Volume: Lab & POCT	
HIV Serology/Diagnostic	
HIV IVT/EID	
HIV Viral Load	
TB mWRD	
TB LF-LAM	
TB AFB	
TB Culture	
CD4	
Rapid Test for Recent Infection	

*TB Culture is only reported under laboratory-based testing

How to Use: LAB_PTCQI

Counting the Number of Facilities with a PEPFAR-Supported Lab and/or Point of Care (POC) Site

- How many labs is PEPFAR supporting?

Providing Overview of Laboratory Support and Context for Testing Results:

- LAB_PTCQI monitors proxy indicators of laboratory quality and can provide context to testing results reported in other indicators such as HTS_TST, TX_PVLS, PMTCT_EID, and TX_TB. If a country is at 95% viral load coverage and 95% viral load suppression, we should also check to ensure the VL testing sites are enrolled in CQI and PT

Monitoring Availability of Laboratory Services:

- The number of specimens received for each testing category assesses the extent to which PEPFAR-supported laboratories and/or POCT sites are maintaining or expanding laboratory services. The number of specimens received may also be used to monitor the capacity of testing sites and scale-up efforts over time.



How to Review for Data Quality: LAB_PTCQI

How to Review for Data Quality:

- There is no total numerator for this indicator. Subtotals are automatically summed across the CQI and PT data elements for each laboratory-based or POCT testing category.
 - Subtotals should represent the number of testing sites per facility. CQI and PT status categories are mutually exclusive, so only the highest status should be selected per testing site.

How to Calculate Annual Total: N/A. Data is reported only once annually at Q4.

Guiding Narrative Questions: LAB_PTCQI

1. In the narrative, please define how the specimen volume was counted (i.e., specimen log, LIS, etc.).

Section 4: Data Use

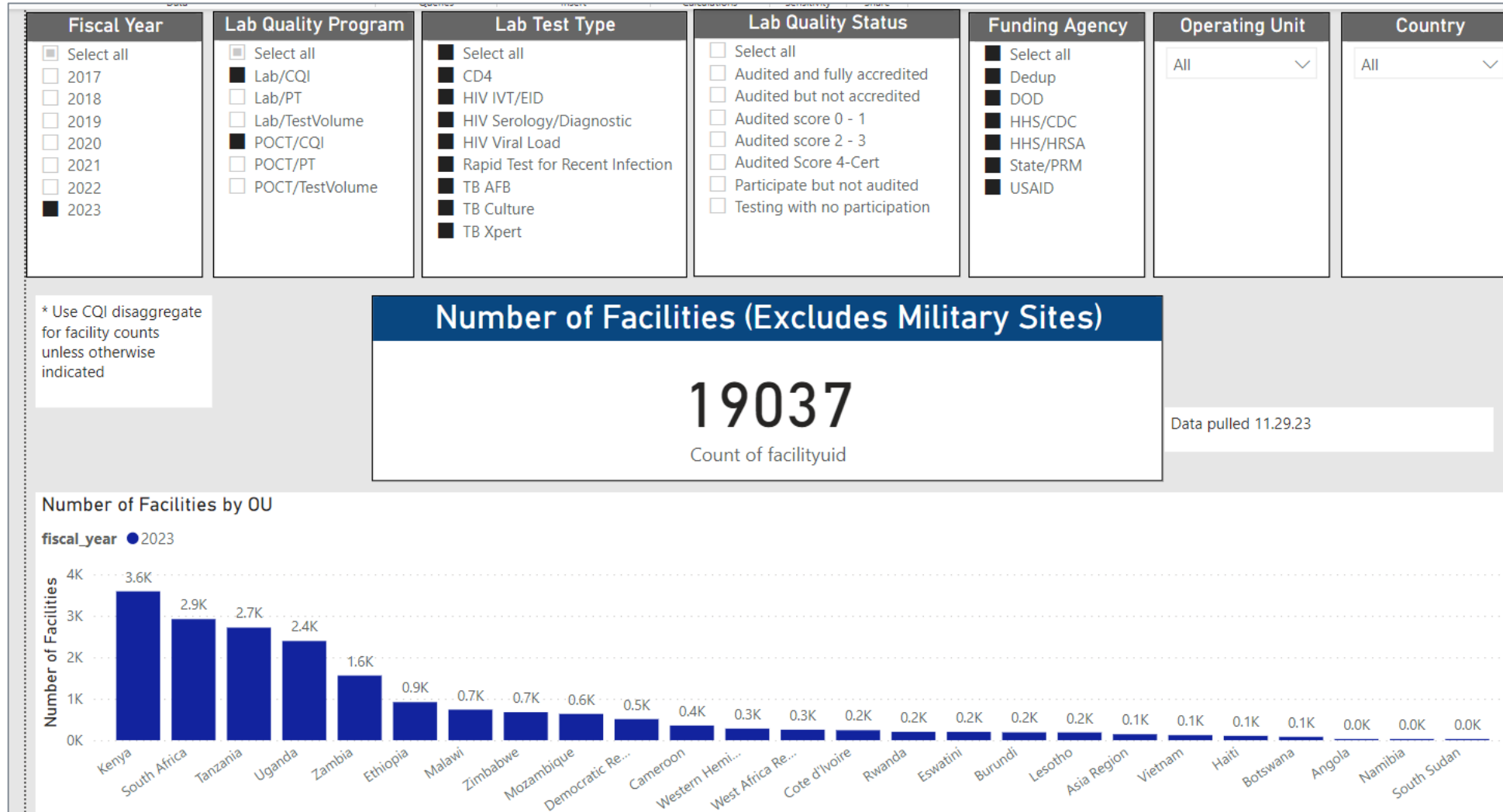


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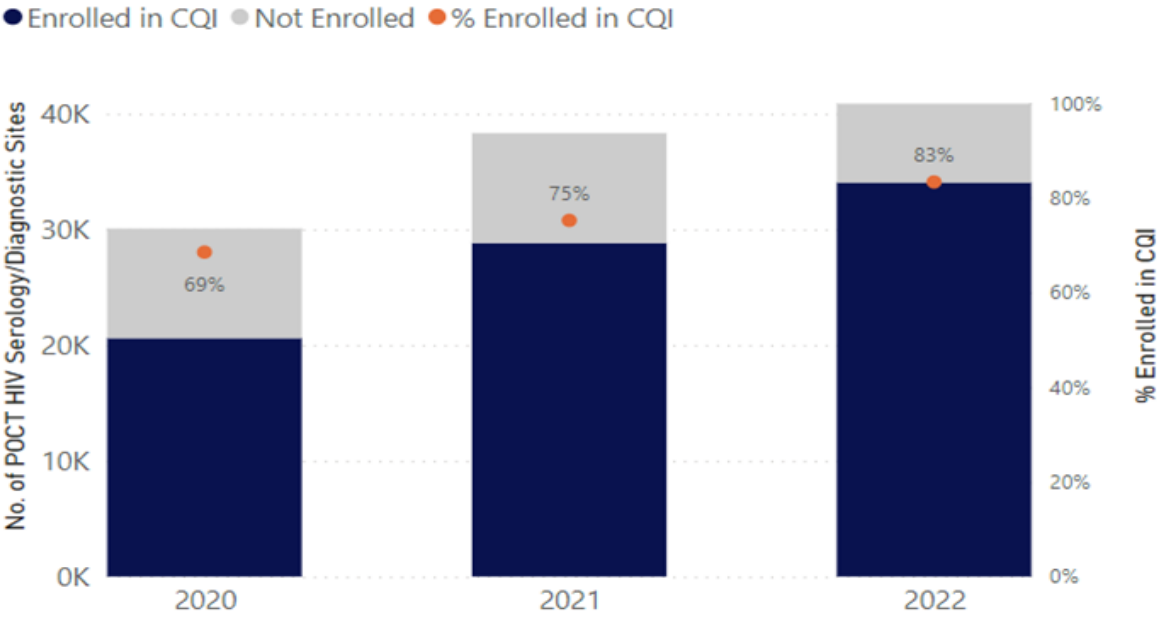
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Data Visualization and Use Examples: LAB_PTCQI



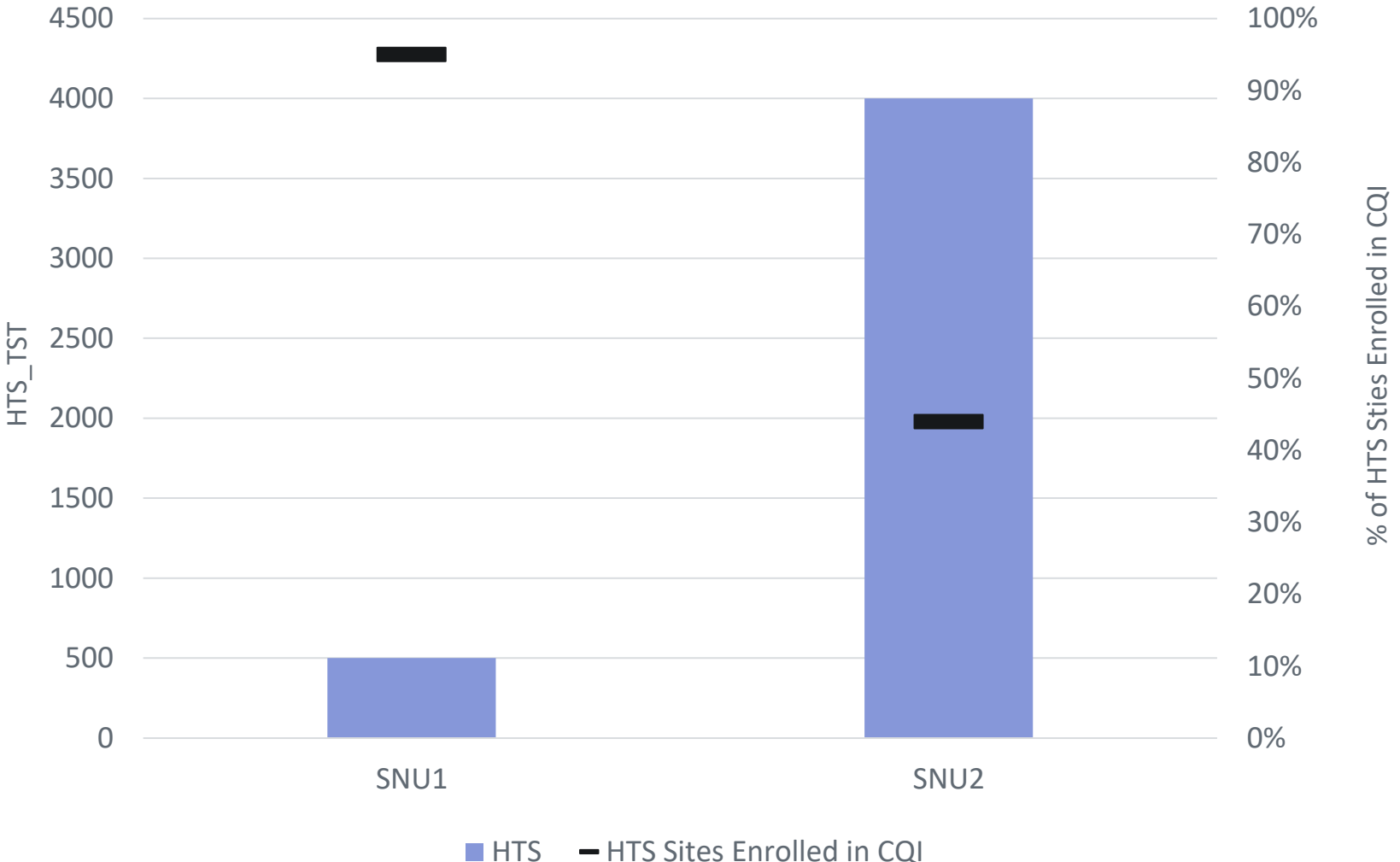
Data Visualization and Use Examples: LAB_PTCQI

90% of POCT sites should be enrolled in CQI with the end-goal of reaching 100%

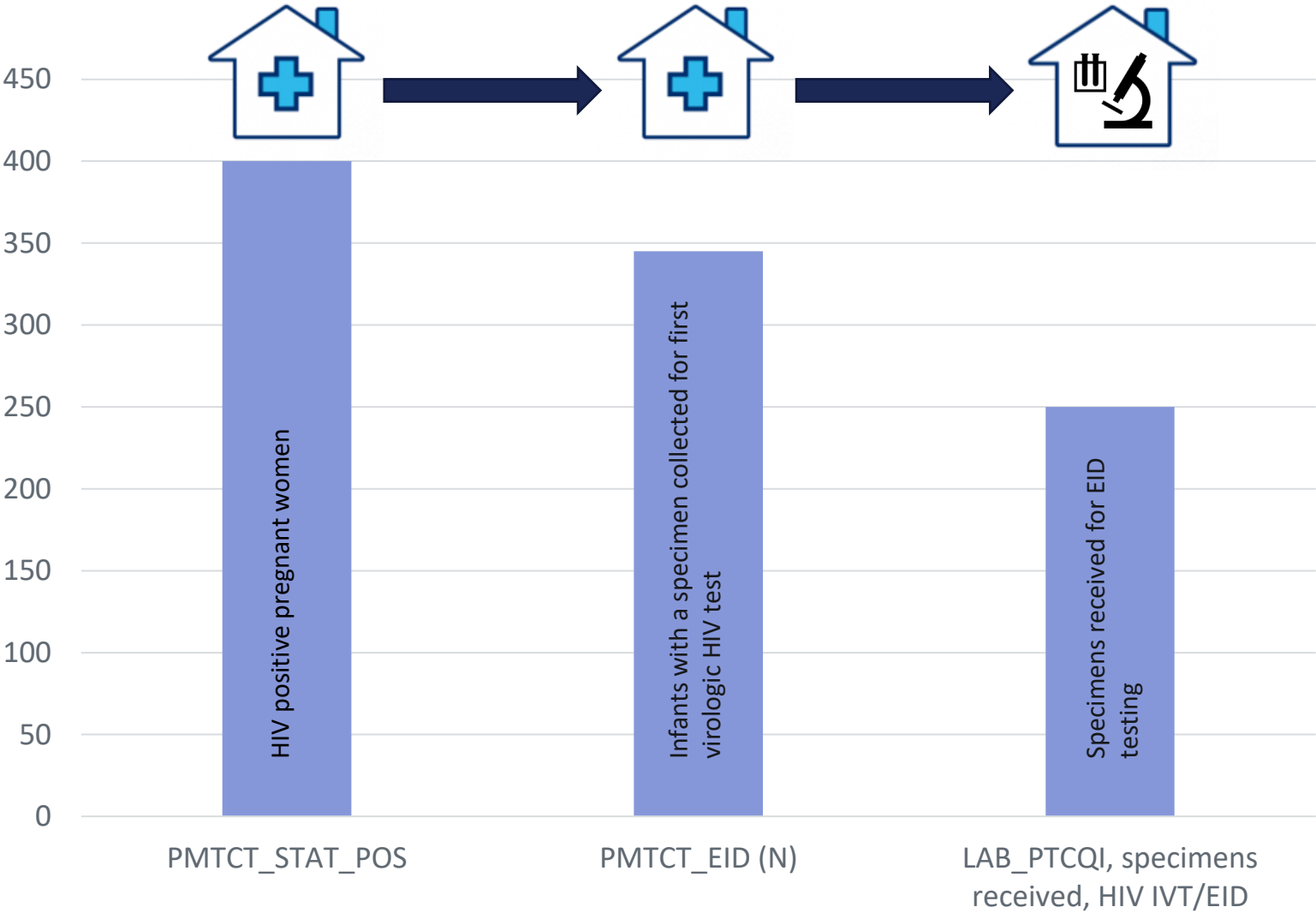


Year-over-year increases in the proportion of testing sites enrolled in CQI

Context for HTS Results



Clinic-Lab Interface



Thank you!



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