SITE LEVEL CEE NARRATIVES

Version 4.2

October 13, 2022

Contents

Overview

Narrative Purpose: The Site level CEE narrative provides additional information on the organization of the Site Level Master CEE Library and descriptions of individual SIMS 4.2 Sets and CEEs that within the tool.

Organization of the Site Level Master CEE Library: The library of SIMS 4.2 CEEs is grouped into 16 Sets that are based on program or technical area except for Sets 1A, 1B, 1C, and 1D which are cross-cutting:

- SET 1A: All Sites – General
- SET 1B: All Sites – Commodities Management
- SET 1C: All Sites – Data Quality
- SET 1D: All Site – Infection Prevention Control
- SET 2A: Care and Treatment-General Population
- SET 2B: Care and Treatment for HIV Infected Children
- SET 3A: Key Populations – General CEEs
- SET 3B: Care and Treatment for HIV-Infected Key Populations (KP)
- SET 4A: PMTCT-ANC, Postnatal and Labor and Delivery
- SET 4B: HIV Exposed Infants (HEI)
- SET 5: Voluntary Medical Male Circumcision (VMMC)
- SET 6: Adolescent Girls and Young Women (AGYW), Gender Based Violence (GBV), and Orphans and Vulnerable Children (OVC)
- SET 7: HIV Testing Services (HTS)
- SET 8: TB Treatment Service Point
- SET 9: Methadone or Buprenorphine Medication Assisted Treatment
- SET 10: Laboratory

Assessment Points: Previous versions (v1.0, v2.0, and v3.0) of SIMS include three separate assessment tools; Facility, Community, and Above Site. SIMS v4.0 and v4.1 retained the Above Site Tool but combined the Facility and Community CEEs into the Site Level Master Tool. For SIMS v4.2, the Site Level Master CEE Library was updated to align with current standards and the Above Site CEEs were retired.

Required and Supportive CEEs: SIMS 4.2 include two types of required CEEs (All Sites Required and Minimum Program Requirement (MPR) Required. Required CEEs must be assessed at every Comprehensive assessment provided those services are offered or activities supported. Supportive CEEs are selected by the assessor and may be used to provide additional information on site level performance, program needs, and program gaps.

Chart Review: Individual record review is an integral component of select site level CEEs because these records provide direct evidence of service provision. The Narrative summary tables at the beginning of each set description denote which CEEs require chart or other documentation review. Chart review and other worksheets are provided for select sets to maximize efficiency of the review process (See SIMS 4.2 Implementation Guide).

Document Review: Some questions within a CEE call for the assessor to review a specific document. To guide the assessor in assessing these elements, a list of suggested documents for the questions that require document review is included in the document pull list. Implementing partners and site staff should be familiar with which documents may be requested for review and where possible 'pull' those documents in advance so that the documents are easily accessible during the SIMS assessment.

Explanation of Icons in the SIMS Assessment Tools

Icon	Description of Icon	Explanation
	Eyes	Question requires visual inspection of documents, charts/registers, or materials/space
	Pink Square	Question requires Chart or Register review
	Gray Circle	Question requires Materials/Space review
	Blue Triangle	Question requires Document review
	Remote	CEE can be assessed remotely (without USG physically present on site).
	Remote conditional	CEE can be assessed remotely if specified conditions in instructions are met
	Required (MPR)	Required CEE in Comprehensive Assessments used to inform progress against PEPFAR Minimum Program Requirement (MPR) in COP Guidance

SET 1A: ALL SITES-GENERAL				
CEE #	*Abbreviated Title*	*Required/MPR*	*Supportive*	*Remote*
S_01_01	Stakeholder Engagement	X		Yes
S_01_02	Condom Availability*	X		Yes
S_01_03	Client Rights, Stigma and Discrimination Policies			Yes
S_01_04	Child Safeguarding	X		Yes
S_01_05	Support and Assessment of Staff Performance	X		Yes
S_01_06	TB Infection Control			Yes
S_01_07	Waste Management*	X		Yes
S_01_08	Injection Safety*	X		Yes
S_01_09	Provision of PrEP Services			Yes
S_01_31	Elimination of User Fees			Yes
S_01_32	Evidence of Treatment and Viral Load Literacy			Yes

** Assess dependent on the services being offered at the site (e.g., if the site does not generate waste, then S_01_07 is not considered required)*

SET 1A: ALL SITES-GENERAL

Set Overview: Set 1A is composed of 11 CEEs that assess cross-cutting factors integral to provision of HIV-related services. These cross-cutting factors include stakeholder engagement, condom provision, client rights, stigma, and discrimination policies, child safeguarding, and staff performance support, PrEP provision, elimination of user fees and evidence of treatment and viral load literacy. Set 1A also include 3 CEEs, TB Infection Control [S_01_08], Waste management [S_01_07], Injection Safety [S_01_08], that have observational components that must be assessed throughout the site. The final score is based on any instance at the site where the observations do not meet the requirements. This requires that the SIMS assessment team convene prior to the Outbrief to ensure that all individual observations are considered, and the final score determined and updated in the site assessment tool.

SET 1A TECHNICAL BACKGROUND

S_01_01: Stakeholder Engagement: This CEE assesses whether the site has developed a written strategy/defined process for stakeholder engagement that includes eliciting stakeholders' (Civil Society Organizations (CSO) and beneficiaries) feedback and engage them in data review. All prevention and treatment services should engage stakeholders especially where Community-Led Monitoring (CLM) efforts overlap with supported sites. This CEE also includes a **document review** for examples of CSO and beneficiary engagement in program planning or review of activities as well as documentation of change in delivery approaches, procedures, or systems.

- *Remote Eligible:* Yes
- *Required:* R All-Sites Required with NA option

S_01_02: Condom Availability: WHO Standards (2008 Essential Interventions for PLHIV) states that people with HIV who choose to be sexually active should be counselled about safer sex interventions to prevent HIV transmission to other and how to avoid acquisitions of sexually transmitted infections (STI) and should be provided with condoms. Risk reduction counseling and condom provision equips people living with HIV (PLHIV) with the knowledge and skills necessary to protect their own health and the health of their partner(s) and families. Risk reduction counseling should include information on condoms and water-based lubricants, alcohol and other drug reduction, and HIV serostatus disclosure. Clients should also be told that adhering to their anti-retroviral medications can significantly reduce their risk of transmitting HIV to HIV-negative partner(s) and infants. This is also known as "treatment as prevention". For sites serving key populations, clients should also be provided with information on and access to post-exposure prophylaxis or PEP and pre-exposure prophylaxis or PREP.

This CEE assesses whether non-expired condoms are available and easily accessible to patrons/clients (i.e., in a bowl on the counter, in a dispenser, or distributed during the visit). Assessors should check the packaging confirm the condoms being provided have not exceeded their expiry date.

Some implementing partners may have a clause in their funding mechanism known as the "conscience clause" that exempts them from having to directly provide condoms. For sites to invoke the "conscience clause", this clause **must be written** into the partner's funding mechanism. Before traveling to the health facility, the project officer should review the partner's funding mechanism to determine if the clause is written into the mechanism. Where the conscience clause is applicable, the Assessor should make a note in the comment field of the CEE and not assess the CEE at the site.

- *Remote Eligible:* Yes
- *Required:* R All-Sites

S_01_03 Client Rights, Stigma and Discrimination Policies: In line with international human rights obligations and HIV-related human rights commitments made by governments in the 2011 United Nations Political Declaration on HIV and AIDS, countries are strongly encouraged to incorporate planning and programming that: a) identify social and legal barriers to health services; b) design health services using an evidence-informed, human rights based approach; c) invest in programs that support the removal of social and legal barriers to services; and d) invest in community system strengthening, including through programs that support HIV-related human rights.

This CEE also includes a **document review** and assesses not only whether the site has a written statement, policy or other written tools that describes the rights of client and the protection of all clients from stigma and

discrimination, but also that all staff have been trained on the policy, and the site can show evidence for a reporting process for discrimination (with evidence of response, if applicable)

- *Remote Eligible:* Yes
- *Required:*  All-Sites MPR Required

S_01_04: Child Safeguarding: Children affected by HIV face a range of risks due to the loss of their parents and caregivers, stigma, and discrimination; a fragile household economy potentially leading to high-risk behaviors such as transactional sex and child labor. In addition, poor child protection safeguards within programs intending to mitigate the impact of HIV may also place vulnerable children at further risk. Research clearly demonstrates that by putting in place specific safeguards, the risk of child abuse can be reduced in organizations of any setting and size. The measures include a comprehensive child protection policy that includes the following:

(1) Clear and effective reporting procedures, including locally accessible mechanisms to enable children and their families to report abuse without fear or repercussion

(2) Strong recruitment, selection and screening procedures, including verbal references and criminal checks

(3) Codes of behavior for interacting with children and consequences for breaches of these codes

(4) Child protection awareness training for all employees

This CEE is assessed at sites where PEPFAR-supported services are provided to children, or where personnel and volunteers come into regular contact with children. The site should have a written child safeguarding policy for preventing and responding to abuse, exploitation, or neglect by personnel or as a result of PEPFAR-supported programming and all personnel should be trained on this policy.

This CEE includes **documentation requirements** for written child safeguarding policy, and evidence of training. There is also a **visual check** for a confidential way for children to report abuse, exploitation and neglect.

- *Remote Eligible:* Yes
- *Required:* R All-Sites Required with NA option

S_01_05: Support and Assessment of Staff: Although many performance management systems in countries are nascent, key performance management functions at the site level should exist that support assessment of health worker performance. These include: 1) performance reviews that follow national plans/guidelines, 2) routine supervisory support, and 3) quarterly collection of client feedback.

This CEE include a **document review** and assesses whether the site has job descriptions in place for all staff as well as adequate measures in place to monitor and support health worker performance.

- *Remote Eligible:* Yes
- *Required:* R All-Sites Required

S_01_06: TB Infection Control: Tuberculosis (TB) is a communicable disease that was the leading cause of death from a single infectious agent, ranking above HIV/AIDS, until the coronavirus (COVID-19) pandemic. Approximately 10 million people developed TB in 2020. PLHIV are more vulnerable to the risk of TB transmission. The COVID-19 pandemic has reversed years of progress in providing essential TB services and reducing TB disease burden. There was a large global drop (18%) in the number of people newly diagnosed with TB and reported, resulting in an increase in TB deaths. Therefore, actions to mitigate and reverse these impacts, such as TB infection prevention and control (IPC), are urgently required. (WHO Global TB Report 2021)

WHO updated guidelines in TB IPC stress the importance of implementing IPC measures in a systematic and objective way that considers the hierarchy of IPC controls. Therefore, interventions must be considered as an integrated package to prevent TB. The 2019 guidelines lay out core components, general recommendations, and good practices to establish effective IPC programs. WHO recommends that TB IPC measures (Administrative, Environmental and Respiratory Protection) should be implemented in inpatient and outpatient facilities (including health facilities providing HIV and TB care), congregate settings, and penitentiary facilities. (WHO guidelines on TB IPC, 2019 update).

This CEE has both a **document review** and **visual check to** assess if the site has a TB infection control plan to minimize the risk of TB transmission to clients and health care workers and if a person has been assigned to monitor IPC activities. The following core elements are assessed: segregation and fast tracking of coughers, patient cough etiquette instruction, well-ventilated waiting, and clinic areas. The CEE is assessed as part of the site walkthrough. Results for all areas visited are reviewed and results for the lowest scoring area are entered in the assessment tool. Assessors should enter a comment in the comment box of the CEE to indicate which locations in the site lead to the low score. Recording the location provides useful information to target remediation activities to the underperforming area.

It is recommended that this CEE is assessed with other infection prevention and control CEEs (set 1D) to ensure there are core components of IPC programs to reduce HAI and AMR including TB. This new set also allows monitoring the availability of PPE, an important part of the respiratory protection needed to prevent TB. This TB IPC CEE and other IPC CEEs can be considered as part of a concentrated assessment to monitor all IPC activities during technical or CQI visits.

Summary of recommendations

Administrative controls

Recommendation 1: Triage of people with TB signs and symptoms, or with TB disease, is recommended to reduce *M. tuberculosis* transmission to health workers (including community health workers), persons attending health care facilities or other persons in settings with a high risk of transmission. *(Conditional recommendation based on very low certainty in the estimates of effects)*

Recommendation 2: Respiratory separation / isolation of people with presumed or demonstrated infectious TB is recommended to reduce *M. tuberculosis* transmission to health workers or other persons attending health care facilities. *(Conditional recommendation based on very low certainty in the estimates of effects)*

Recommendation 3: Prompt initiation of effective TB treatment of people with TB disease is recommended to reduce *M. tuberculosis* transmission to health workers, persons attending health care facilities or other persons in settings with a high risk of transmission. *(Strong recommendation based on very low certainty in the estimates of effects)*

Recommendation 4: Respiratory hygiene (including cough etiquette) in people with presumed or confirmed TB is recommended to reduce *M. tuberculosis* transmission to health workers, persons attending health care facilities or other persons in settings with a high risk of transmission. *(Strong recommendation based on low certainty in the estimates of effects)*

Environmental controls

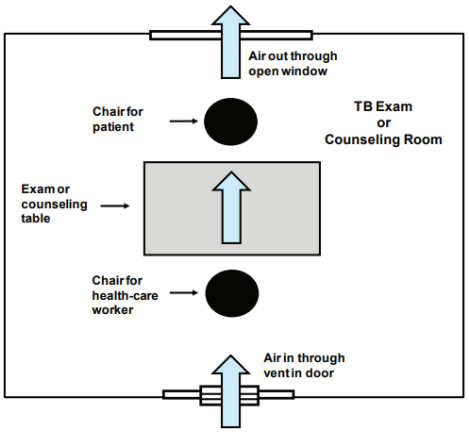
Recommendation 5: Upper-room germicidal ultraviolet (GUV) systems are recommended to reduce *M. tuberculosis* transmission to health workers, persons attending health care facilities or other persons in settings with a high risk of transmission. *(Conditional recommendation based on moderate certainty in the estimates of effects)*

Recommendation 6: Ventilation systems (including natural, mixed-mode, mechanical ventilation and recirculated air through high-efficiency particulate air [HEPA] filters) are recommended to reduce *M. tuberculosis* transmission to health workers, persons attending health care facilities or other persons in settings with a high risk of transmission. *(Conditional recommendation based on very low certainty in the estimates of effects)*

Respiratory protection

Recommendation 7: Particulate respirators, within the framework of a respiratory protection programme, are recommended to reduce *M. tuberculosis* transmission to health workers, persons attending health care facilities or other persons in settings with a high risk of transmission. *(Conditional recommendation based on very low certainty in the estimates of effects)*

The correct ventilation in a clinic is as follows:



Global tuberculosis report 2021 (who.int)
WHO guidelines on tuberculosis infection prevention and control: 2019 update

This CEE has both a **document review** and **visual check to** assess if the site has a TB infection control plan to minimize the risk of TB transmission to clients and health care workers. The following core elements are assessed: segregation and fast tracking of coughers, patient cough etiquette instruction, well-ventilated waiting and clinic areas. The CEE is assessed as part of the site walkthrough. Results for all areas visited are reviewed and results for the lowest scoring area are entered in the assessment tool. Assessors should enter a comment in the comment box of the CEE to indicate which locations in the site lead to the low score. Recording the location provides useful information to target remediation activities to the underperforming area.

- *Remote Eligible:* Yes
- *Required:* All-Site, MPR Required with NA options

S_01_07 Waste Management: Appropriate healthcare waste management is essential to prevent exposure and harm to healthcare workers, clients, and the public. Types of healthcare waste:

- **Common Waste:** Waste that does not pose any biological, chemical, radioactive, or physical hazard
- **Infectious Waste:** Waste suspected of containing pathogens and that poses a risk of disease transmission, this includes:
    - Sharps: Used or unused sharps (e.g., needles, hypodermic needles, auto-disable syringes, infusion sets, scalpels, pipettes, knives, blades, broken glass)
    - Pathologic Waste: Human tissues or fluids (e.g., body parts, organs, blood and other body fluids)

This CEE assess if the site implements approved procedures for collection, storage, and disposal of infectious waste to prevent exposures to workers, clients, and the public. These procedures include segregation of infectious waste, posted waste disposal guidance, and secure storage of infectious waste outside the site.

This CEE is assessed as part of the site walkthrough. Results for all areas visited are reviewed and results for the lowest scoring area are entered in the assessment tool. Assessors should enter a comment in the CEE comment box to indicate which locations in the site lead to the low score. Recording the location provides useful information to target remediation activities to the underperforming area.

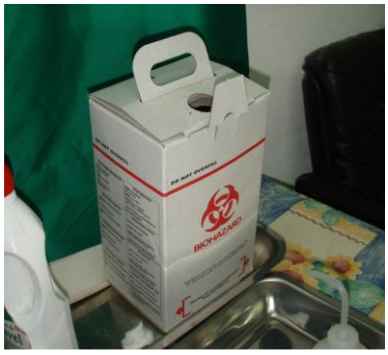
Example Job Aide

Proper waste segregation

- *Remote Eligible:* Yes
- *Required:* R All-Sites Required with NA option

S_01_08 Injection Safety: Safe injection practices and equipment/supplies such as gloves and sharps containers are essential to reduce the risk of blood borne pathogen exposure to clients and healthcare workers. This CEE assesses if the site is using appropriate injection and phlebotomy equipment/supplies and written, standardized safety procedures (including for PEP provision). PEP drugs or starter packs also need to be available on site.

This CEE has both a **document review** and **visual check** that is assessed as part of the site walkthrough. Results for all areas visited are reviewed and results for the lowest scoring area are entered in the assessment tool. Assessors should enter a comment in the CEE comment box to indicate which locations in the site lead to the low score. Recording the location provides useful information to target remediation activities to the underperforming area.



Example Sharps Containers

- *Remote Eligible:* Yes
- *Required:* R All-Sites Required with NA option

S_01_09 Provision of PrEP Services: Pre-exposure prophylaxis (PrEP) can help prevent HIV infection in people who don't have HIV but who are at high risk of becoming infected. PrEP currently comes in the form of one pill that contains two HIV medicines combined. WHO recommends that PrEP should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches. For individuals at high risk for HIV, PrEP can significantly reduce the risk of HIV infection if medication is taken consistently each day. Proper adherence to PrEP can lower the risk of getting HIV from sex by more than 90% and from injection drug use by more than 70%.

This CEE has both a **document review** and **visual check** and assesses whether HIV-uninfected men and women at substantial risk of infection can access PrEP through high quality, safe, and friendly services. In addition to whether these services exist, this CEE also assess whether site staff have been trained on the provision of PrEP.

- *Remote Eligible:* Yes
- *Required:*  All-Sites MPR Required with NA option

S_01_31 Elimination of User Fees: Sites should not charge formal or informal user fees for client registration, Clinical Treatment services [HIV services, cervical cancer screening, advanced HIV services, STI (sexually transmitted infection), or TB services], or Prevention services [condoms, OI (opportunistic infection) prophylaxis, pre and post exposure prophylaxis (PEP, PrEP), PMTCT, TB preventative therapy (TPT), and voluntary male medical circumcision (VMMC)]. This CEE has **document review** to verify if user fees are being assessed. User fees should be posted and visible to clients in the site. Assessors may also check documentation in in accounting registers, receipts, and client records for evidence of formal and informal user fees charged.

- *Remote Eligible:* Yes
- *Required:*  All-Sites MPR Required

S_01_32 Evidence of Treatment and Viral Load Literacy: Messaging (e.g., U=U- Undetectable = Untransmissible) and activities to reduce stigma and encourage HIV treatment and prevention should be provided to enhance treatment and viral load literacy.

This CEE has a **document review for Q2.** Evidence of activities include registers, calendars, or monitoring forms that document topics of health talks, support groups, clubs, or other educational discussions at the site. For remote CEE collection, assessors must ensure that any PII of beneficiaries is not visible when viewing meeting logs or other documents that may contain this PII.

- *Remote Eligible:* Yes
- *Required:*  All-Sites MPR Required with NA Option

SET 1B: ALL SITES -COMMODITIES MANAGEMENT				
CEE #	*Abbreviated Title*	*Required*/ MPR*	*Supportive*	*Remote*
S_01_10	Supply Chain Management*	X		Yes
S_01_11	Medication Dispensing*	X		Yes
S_01_12	Supply Chain Reliability-Adult ARVs*	X		Yes
S_01_13	Supply Chain Reliability-Cotrimoxazole*	X		Yes
S_01_14	Supply Chain Reliability- TB Preventive Therapy*	X		Yes
S_01_15	Supply Chain Reliability-Pediatric ARVs*	X		Yes
S_01_16	Supply Chain-Pediatric Cotrimoxazole*	X		Yes
S_01_17	Supply Chain Reliability-Pediatric TB Preventive Therapy*	X		Yes
S_01_18	Supply Chain Reliability-Rapid Test Kits*	X		Yes
S_01_33	Supply Chain Reliability-Personal Protective Equipment	X		Yes

SET 1B: ALL Sites- COMMODITIES MANAGEMENT

Set Overview: SET is composed of 10 CEEs, including 1 new CEE for SIMS v4.2. The role of facilities in the HIV supply chain is to safely store all HIV commodities, responsibly order commodities from the above-site entity which supports pharmaceutical distribution services, report stock on hand and any waste, and accurately document dispensing of medication to clients. The CEEs in Set 1B assess the important responsibilities outlined above regarding inventory ordering, reporting, management, and medication dispensing; in addition, the CEEs inquire about low stock status or stock-outs of key HIV-related commodities and TB-related commodities (antiretrovirals (ARVs), cotrimoxazole (CTX), rapid test kits (RTKs), isoniazid preventive therapy (IPT), TB preventive treatment (TPT)) so that any challenges in the supply chain can be highlighted and remediated.

Set 1B should be assessed at sites that provides one of the applicable commodities to PEPFAR clients, even if PEPFAR does not directly support the procurement of those commodities. Every CEE in the set has a Not Applicable (N/A) box to account for the variation in types of commodities provided at different sites.

To streamline assessment, all commodities CEEs will be asked only at the storage area. Because of this, it is important to remind the site staff member(s) to consider all areas of the site when answering the questions so that it can be determined whether the specific commodity was available for all intended clients or whether rationing within the site was necessary. The last 8 CEEs in the set cover stock-outs or low stock status of specific commodities. Because usage of the term 'stockout' varies among countries and IPs, it is recommended that CEEs S_01_11 through S_01_33 be read aloud exactly as written to ensure consistent interpretation of the questions.

Additional resources for Set 1B:
WHO Supply and Management of commodities, 2019
https://www.who.int/hiv/topics/vct/toolkit/components/supply/en/

SET 1B TECHNICAL BACKGROUND

S_01_10 Supply Chain Management: Good inventory management helps ensure limit stock-outs of medicine and test kits. As the maximum and minimum levels are defined in the national SOP, site staff being interviewed about this activity should be familiar with what the max and min stock levels are for their site, typically expressed as months of stock (defined as a rolling average of consumption by product).

This CEE assesses whether the site has an inventory management protocol for ARVs, CTX, IPT/TPT and RTKs and submits routine and accurate orders to maintain adequate stock (between established minimum and maximum stock levels). The CEE requires both **document review** and **visual checks** that involve review of inventory management tools and order forms as well as direct observation of the commodity storage area to ensure proper handling of the commodities.

- *Remote Eligible:* Yes
- *Required:* R All-Sites Required with NA option

S_01_11 Medication Dispensing: A medication dispensing process ensures that pharmaceuticals dispensed are well documented. Maintaining a medication dispensing tool can also help identify clients who have missed medication pick-ups.

The CEE requires **document review** and assesses if the site has a standard dispensing protocol and maintains complete and updated dispensing registers. Assessors should assess these CEEs in the main area where HIV-related medications are dispensed to clients such as the pharmacy.

- *Remote Eligible:* Yes
- *Required:* R All-Sites Required with NA option

S_01_12 to S_01_18 (see list below): A reliable supply of commodities can only be provided if the supply chain is working. Sites should be able to order products and receive them on-time and in full. Anything less can result in low stock or stock-out situations. Each of the CEEs is formatted similarly and assess whether the stock-outs have occurred for the specified products that resulted in treatment interruption (ARVs, Cotrimoxazole, IPT/TPT), drug substitution or shorter appointment intervals (ARVs, IPT/TPT), or clients not getting tested for HIV (RTK).

Two important notes on these CEEs: 1) unlike the majority of other yes/no questions in CEEs, a NO answer advances you to the next question and 2) Q1 is focused on interruption of treatment; therefore even if a stock-out occurred, if the site was able to provide treatment on schedule through use of a back-up system, the assessor should score NO and proceed to the next question.

- **S_01_12 Supply Chain Reliability-Adult ARVs**
- **S_01_13 Supply Chain Reliability-Cotrimoxazole**
- **S_01_14 Supply Chain Reliability- TB Preventive Therapy**
- **S_01_15 Supply Chain Reliability-Pediatric ARVs**
- **S_01_16 Supply Chain-Pediatric Cotrimoxazole**
- **S_01_17 Supply Chain Reliability-Pediatric TB Preventive Therapy**
- **S_01_18 Supply Chain Reliability-Rapid Test Kits**

- *Remote Eligible:* Yes
- *Required:* R All-Site Required with NA option

S_01_33 Supply Chain Reliability-Personal Protective Equipment: Ensuring that medical professionals are able to protect themselves from contracting any infectious disease is vital to maintaining the health care system and preventing the spread of disease. Personal protective equipment is one of the crucial tools needed to sustain the health of medical professionals. For this reason, sustaining an adequate supply of personal protective equipment is critical. Continuous supply of PPE is dependent upon many things, not the least of which are: budget allocation, including PPE on order forms, sites ordering of PPE, SOPs for ordering, restocking and using PPE, distribution processes for PPE, inventory management and records or documentation of PPE distribution. The CEE included herein will assess many of these factors to attempt to identify a root cause for any lack of PPE.

Q1 of this CEE has a **document check** to confirm availability of SOPs, protocols and documentation of PPE distribution. Q3 has a **visual check** of current PPE supplies as well as checking stock-outs in the past 3 months.

- *Remote Eligible:* Yes
- *Required:* R All-Site Required

SET 1C: ALL SITES –DATA QUALITY				
CEE #	*Abbreviated Title*	*Required*(MPR)*	*Supportive*	*Remote*
S_01_19	Data Quality Assurance (Routine Activities)			Yes
S_01_20	Assessment & Utilization of Performance Data in QI Activities			Yes
S_01_21	Data Reporting Consistency – TX_NEW-C&T*	X		Yes
S_01_22	Data Reporting Consistency – HTS_TST*	X		Yes
S_01_23	Data Reporting Consistency – PMTCT_STAT*	X		Yes
S_01_24	Data Reporting Consistency – VMMC_CIRC*	X		Yes
S_01_25	Data Reporting Consistency – TX_CURR*	X		Yes
S_01_26	Data Reporting Consistency – PMTCT_EID*	X		Yes

**If applicable to the services being supported by the Implementing Partner at the site.*

SET 1C: ALL SITES – DATA QUALITY

Set Overview: High quality data is an essential component impacting the quality of services provided to clients and ultimately patient outcomes. Quality management systems have two intertwined components, quality assurance (QA) and quality improvement (QI). QA is focused on compliance with standards, whereas QI is a continuous process of making changes which lead to better patient outcomes. This set contains CEEs that assess the quality assurance and quality improvement activities supported at the site. The last 4 CEEs in the set are designed to assess data reporting consistency by comparing site level results with results submitted to DATIM for the corresponding time period.

SET 1C TECHNICAL BACKGROUND

S_01_19 Data Quality Assurance (Routine Activities): Data quality assurance involves methodologies and activities meant to maintain high levels of data quality. Sites should follow routine data quality assurance (DQA) procedures to verify the accuracy and completeness of reported HIV program data on at least a quarterly basis.

This CEE includes **documentation review** and assesses if the site has written standard procedures available, is conducting data quality activities, and if the site has documented their data quality findings and highlighted discrepancies and/or data quality concerns.

- *Remote Eligible:* Yes
- *Required:*  All-Sites MPR Required

S_01_20 Assessment & Utilization of Performance Data in QI Activities: Quality Management systems has two intertwined components, quality assurance (QA) and quality improvement (QI). QA is focused on compliance with standards, whereas QI is a continuous process of making changes which lead to better patient outcomes.

This CEE includes **documentation review** and assesses whether the site:

a) routinely reviews key programmatic/performance indicators at least quarterly over the last 12 months at a minimum;
b) has a Quality Management/Quality Improvement plan and a system for performance and outcome measurement.

A good quality management system is reliant on the staff and leadership collecting and reviewing performance data to identify gaps and initiate quality improvement activities, and has a **documentation check** for a site-level QI plan.

- *Remote Eligible:* Yes
- *Required:*  All-Sites MPR Required
-

S_01_21 to S_01_26: These CEEs monitor whether the numbers extracted from DATIM for each of 6 different indicators (TX_NEW-C&T, HTS_TST, PMTCT_STAT, VMMC_CIRC, TX_CURR, PMTCT_EID) match the summary reports maintained at facility level for the same reporting period.

These CEE require **document review**. To assess these CEEs, the data should be extracted from DATIM prior to the assessment visit and the results from site reports compared with the number that was entered in DATIM for the same reporting period.

NOTE: It is critical that the individual who extracts the information from DATIM is familiar with how to complete this activity and has cross-checked with the assessment team to confirm the reporting time periods to avoid potential issues with the site generated number not matching the number extracted from DATIM.

S_01_21 Data Reporting Consistency – TX_NEW-C&T

S_01_22 Data Reporting Consistency – HTS_TST

S_01_23 Data Reporting Consistency – PMTCT_STAT

S_01_24 Data Reporting Consistency – VMMC_CIRC

S_01_25 Data Reporting Consistency – TX_CURR

S_01_26 Data Reporting Consistency – PMTCT_EID

- *Remote Eligible:* Yes
- *Required:* R All-Sites Required with NA option

SET 1D: ALL SITES- INFECTION PREVENTION AND CONTROL (IPC)				
CEE #	*Abbreviated Title*	*Required (MPR)*	*Supportive*	*Remote*
S_01_27	Infection Prevention and Control Program			Yes
S_01_28	Environmental Cleaning Procedures			Yes
S_01_29	Availability of Personal Protective Equipment (PPE)			Yes
S_01_30	Decontamination and Reprocessing of Medical Devices			Yes

SET 1C: ALL SITES – INFECTION PREVENTION AND CONTROL (IPC)

Set Overview: Over the last decade, major outbreaks such as Ebola virus disease and the Middle East respiratory syndrome coronavirus (MERS-CoV), and the coronavirus disease 2019 (COVID-19) pandemic, have demonstrated how epidemic-prone pathogens can spread rapidly through health care settings. Tuberculosis (TB) is an important pathogen in individuals with HIV, and PEPFAR encourages screening for and treatment of TB in individuals under care and in health care workers who may have increased exposure. Infection Prevention and Control (IPC) programs, including integrated, well-coordinated and multi-sectorial actions towards TB IPC, are therefore critical to the safe operation of health care facilities. Furthermore, other less-visible health emergencies are also a compelling reason to address gaps in IPC, such as the silent endemic burden of health care-associated infections (HAIs) and antimicrobial resistance (AMR), which harm clients every day across all health care systems.

SET 1D TECHNICAL BACKGROUND

CEE #: S_01_27 Infection Prevention and Control Program: The gold standard in any country is to achieve the full implementation of all requirements of the WHO core components of IPC programs. However, it is recognized that countries may be at different levels of progress, with different capacities, available opportunities, and resources. Whether applying the minimum requirements or full requirements, the implementation of the IPC core components should always be done based on a careful assessment of the status of the IPC program and activities.

This CEE requires that at a facility level there is a functional IPC program with a dedicated, trained IPC focal point or team in place for the purpose of preventing healthcare-associated infections (HAI) and combating antimicrobial resistance (AMR) through IPC good practices.
Evidence of an active IPC program requires visual confirmation of supporting documents such as:

- National IPC guidelines, policies, protocols, and SOPs based on IPC national guidelines
- IPC program site -specific plan
- Training certificates from IPC focal points
- Annual IPC training for HCW (e.g., participants' list, agenda, certificates)
- Documentation of assessment of IPC activities: IPC monitoring and assessment reports
- Dedicated time and resources for IPC activities
- HCW registry of annual screening and vaccinations
-

Note that some facilities may have an IPC focal point, others may have an IPC committee. In many circumstances, evidence may not be available on site when facilities depend on a health center or hospital's IPC program/team. In that case, electronic documents or copies are acceptable. It is recommended that the

facility's IPC focal point has representation in the larger IPC team to ensure the site-specific plan is implemented. Refer to CEE #: S_01_06 TB Infection Control [ALL SITES-GEN] for detailed information for a TB infection control plan.

This CEE requires a **document review** for both Q1 and Q2. The HCW registry should include staff TB screening, relevant vaccines (influenza, CVID-19, HepB), and staff exposures (TB, COVID-19, Varicella). When reviewing IPC training, the training may occur in person, virtually, or through self-study. IPC activities may include quality improvement for IPC, capacity building activities, and/or improvement interventions.

- *Remote Eligible:* Yes
- *Required:*  All-Site, MPR Required

References:

- who_ipc_global-report_executive-summary.pdf
- Global report on infection prevention and control (who.int)
- Minimum requirements for infection prevention and control programmes (who.int)
- Guidelines on core components of infection prevention and control programmes at the national and acute health care facility level (who.int)
- TB Infection Control in Health Care Settings | Health Care Settings | TB |CDC
- WHO guidelines on tuberculosis infection prevention and control: 2019 update

CEE #: S_01_28 Environmental Cleaning Procedures: Maintaining a clean environment during healthcare delivery is essential to protecting clients and healthcare workers from healthcare-associated transmission of infectious pathogens. As part of the minimum requirement for the Core Components for IPC, WHO highlights that 1. all levels of healthcare facilities should have facility SOPs for environmental cleaning, and 2. staff, including cleaners, should receive the appropriate education and training to facility SOPs. According to WHO's core global WASH indicators, key indicators for monitoring environmental cleaning in healthcare contexts include the availability of facility specific cleaning protocols, staff with dedicated cleaning responsibilities, and training.

This CEE requires **document review** of written procedures and protocols for environmental cleaning, documentation of training on environmental cleaning methods (e.g., participants' list, agenda, certificates), documentation of monitoring cleaning practices, and availability of cleaning supplies. Written procedures and protocols should be available and easily accessible by staff. The essential cleaning supplies are listed in the instructions section of the CEE. Availability of all essential cleaning supplies (see list in instructions) should be confirmed via visualization of the cleaning supply storage space and contents.

The following link includes steps on how to create and store 0.1% chlorine solution to disinfect frequently touched surfaces and items: *chlorine-solution-healthcare-settings.pdf (cdc.gov).* Posters like these may be helpful to have strategically posted throughout the facility, allowing cleaners to have easy access to instructions for making effective disinfection solutions.

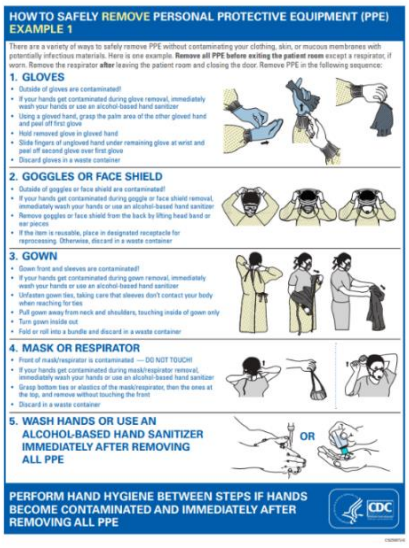
- *Remote Eligible:* Yes
- *Required:*  All-Site, MPR Required

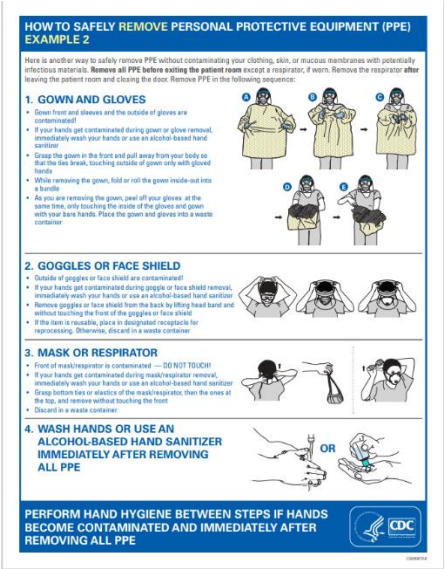
References:

- Best Practices for Environmental Cleaning in Healthcare Facilities: in Resource-Limited Settings Version 2 (cdc.gov)
- Core questions and indicators for monitoring WASH in health care facilities in the Sustainable Development Goals (who.int)
- Water and sanitation for health facility improvement tool (WASH FIT) (who.int)
- Additional Tools and Resources | CDC

CEE #: S_01_29 Availability of Personal Protective Equipment (PPE): The use of personal protective equipment (PPE) is one of several infection control measures that help protect healthcare workers and clients from contracting infectious pathogens. The level of protection achieved by PPE depends on the availability of supplies and the correct usage of each item. In line with the minimum requirements highlighted in the WHO Core Component for IPC, healthcare facilities should ensure the availability of essential PPE at all times and in sufficient quantities to facilitate safe healthcare delivery and healthcare worker (including cleaners and waste handlers) compliance with standard and transmission-based precautions. If used incorrectly, PPE can increase risk of transmission of pathogens. Staff should receive training on what PPE to wear based on the healthcare activities in which they are engaging in, how to use PPE, and finally, how to don and doff PPE.

This CEE requires **visual check** of PPE supply as well as hand hygiene stations, functionality, and locations. The essential PPE are outlined in the first question. With regards to ensuring the correct use of PPE, job aides for safely donning and doffing PPE should be strategically placed throughout the facility. This CEE also required a **document review** for Q3. An example of a job aide is included below:





ppe-sequence.pdf (cdc.gov)

Depending on site type, not all PPE listed in Q1 may be required. For example, N95 respirators are not required to be stocked at VMMC sites.

- *Remote Eligible:* Yes
- *Required:* All-Site, MPR Required

References:

- Minimum requirements for infection prevention and control programmes (who.int)
- Rational use of personal protective equipment (PPE) for coronavirus disease (COVID-19) (who.int)
- Additional Tools and Resources | CDC

CEE #: S_01_30: Decontamination and Reprocessing of Medical Devices: Medical equipment reprocessing involves a complex series of steps with multiple potential failure points. If not correctly done every time, clients are at risk for infectious complications. Ensuring the use of appropriate and successful cleaning and reprocessing methods is required to prevent healthcare-associated transmission of bloodborne pathogens between clients, including HIV, hepatitis B and hepatitis C. Strict adherence to cleaning and sterilization procedures eliminates infectious microorganisms, including bacterial spores (e.g., Clostridium tetani), that can lead to a surgical site or wider systemic infection. Furthermore, in many low-resource settings there is inappropriate reuse of disposable medical devices and the procedures to clean and decontaminate these devices are inadequate and not standardized. PEPFAR's COP guidance has some information on decontamination and reprocessing and specific information is available for PEPFAR supported procedures such as VMMC and cervical cancer screening.

This CEE requires a **document review** of written procedures and protocols for decontamination and reprocessing of medical devices, documentation of training for staff on appropriate decontamination and reprocessing of medical equipment practices (e.g., participants' list, agenda, certificates), documentation of safety and monitoring measures (e.g., Sterilizer validation, use of appropriate biological or chemical indicators of sterility (e.g., autoclave tape), validation of the sterilization process and ensure that the reprocessed medical device has met the validated process parameters EVERY time), documentation of proper service of equipment.

Q3 applies only to sites conducting sterilization. If a site practices high-level disinfection of medical equipment, but not sterilization, assessors should select NA option for each tick-box in Q3.

- *Remote Eligible:* Yes
- *Required:*  All-Site, MPR Required with NA option

References:

- Decontamination and reprocessing of medical devices for health-care facilities (who.int)

SET 2A: CARE AND TREATMENT-GENERAL POPULATION (NON-KEY POPS FACILITIES)				
CEE #	*Abbreviated Title*	*Required (MPR)*	*Supportive*	*Remote*
S_02_01	Retesting for Verification before/at ART Initiation		X	Yes Conditional
S_02_02	Client Tracking-ART Clients			Yes Conditional
S_02_03	Rapid ART Initiation			Yes Conditional
S_02_04	Viral Load Access and Monitoring			No
S_02_05	Management of High Viral Load			Yes Conditional
S_02_06	Provision of Differentiated Service Delivery (DSD) Models			Yes
S_02_07	Partner Notification Services		X	No
S_02_08	Routine HIV Testing of Children of Adult Clients			Yes Conditional
S_02_09	TB Screening		X	No
S_02_10	TB Preventive Treatment (TPT)			No
S_02_11	Cotrimoxazole (CTX)			No
S_02_12	TB Diagnostic Evaluation Cascade			Yes Conditional
S_02_13	Community-Based Linkage and Retention Support Services		X	Yes
S_02_14	Service Referral and Linkage System		X	Yes Conditional
S_02_15	Family Planning / HIV Integration Service Delivery		X	Yes
S_02_16	Community-Based Delivery of Family Planning Services		X	Yes
S_02_17	Cervical Cancer Screening Capacity		X	Yes Conditional

SET 2A: CARE AND TREATMENT-GENERAL POPULATION (NON-B+ AND NON-KEY POPS FACILIITIES)

Set Overview: Set 2A contains 17 CEEs and assesses care and treatment services for HIV-infected adults. This set should be assessed at sites where PEPFAR supports HIV care and treatment services to adults in a general ART clinic. This set should *not* be used to assess services in clinics specifically targeted to key populations (see Set 3B) or to clinics that provide ART only to pregnant/breastfeeding women and their families (see Set 4A).

As noted in the table above, several CEEs in this set require review of client **charts/records**. Please see Adult Care and Treatment Chart Review Worksheet.

SET 2A TECHNICAL BACKGROUND

S_02_01 Retesting for Verification before/at ART Initiation: WHO recommends retesting all newly diagnosed HIV positive individuals prior to or at ART initiation using the national HIV testing algorithm on a new specimen and preferably by a different provider to rule out potential misdiagnosis.

This CEE includes both **document review** and **chart review** and assesses whether the site is conducting and documenting retesting for verification prior to or at ART initiation (verified using register entries or charts). Retesting should not be done on individuals already on ART. For chart/register review, the assessor should review 10 records of adults and adolescents ≥15 who newly initiated ART in the last 3 months to confirm that retesting prior to or at ART initiation is documented. **Note** that the numerator and denominator are collected as part of Q3, the final response is percentage.

- *Remote Eligible:* Yes Conditional
- *Required:* No

S_02_02 Client Tracking-ART Clients: Tracking of clients has been shown to decrease the duration of interruptions in treatment (IIT) and loss-to-follow-up among PLHIV. Client tracking systems can take various forms including: 1) Phone calls or text messages to clients who have missed appointments or medication pick-ups and 2) Home visits by trained individuals who follow-up with clients in the community. Client tracking systems rely on a functional and updated appointment and/or refill system that allows timely and efficient identification of those clients who have interrupted treatment.

Providers should also have a system for updating clients' addresses and phone numbers at each visit, as clients often change these and if not updated it could lead to failure to track client who have missed appointments.

Furthermore, individuals who have previously initiated ART and are re-engaging after ≥12 months should be assessed for advanced HIV disease, including CD4 testing, and should be offered the advanced HIV disease package as appropriate (COP 22 Guidance).

This CEE includes a **documentation review** and assesses if the ART site has a standard procedure for identifying and tracking ART client (both adults and children) who have missed their appointments. To assess this CEE, the assessor needs to review appointment logbooks/registers and any missed appointments/tracking and tracing tools to determine the percentage of client with missed appointments have been contacted (Q2), and whether the result of tracking is documented (Q3).

- *Remote Eligible:* Yes Conditional
- *Required:*  All-Site, MPR Required

S_02_03 Rapid ART Initiation: WHO guidelines (2021) now recommend ~~-~~treating all PLHIV as soon as an HIV diagnosis is confirmed. Research has shown that rapid ART initiation can improve program outcomes, particularly by reducing interruptions in care prior to beginning ART. There are also clinical benefits associated with~~-~~rapid ART Initiation. Since HIV can attack the immune system within days of infection, early treatment can halt ~~the~~ further progression of ~~d~~isease. In clients with advanced immunosuppression, rapid ART initiation can be lifesaving. Rapid ART initiation is defined as starting ART within 7 days of HIV diagnosis. WHO recommends ART initiation on the same day as HIV diagnosis based on the person's willingness and readiness to start treatment. Further, WHO's 2021 recommendations specify that ART should be initiated as soon as possible within two weeks of starting TB treatment, regardless of CD4 cell count, for adults, adolescents, children and infants living with HIV.

Early engagement remains a challenge across PEPFAR programs. Providers are responsible for ensuring successful early engagement for clients on ART for <3 months and reducing interruptions in treatment during this period. They should work collaboratively with the testing partner to create synergies, so that no one is left behind, especially individuals who did not expect to test HIV positive, are reluctant to start ART, or have been avoiding testing.

All eligible individuals with newly diagnosed HIV should be offered same-day or rapid (within 7 days) start of optimized treatment, regardless of how and where they are diagnosed. The only medical contraindication to rapid ART start is central nervous system infection. A pending TB workup should not delay ART initiation. Those clients, or parents/guardians of children, who are unable or unwilling to start therapy on the same day should be offered the opportunity again within 7 days of diagnosis and be actively but sensitively tracked and supported to prevent interruptions in care, particularly within the first three months after treatment initiation or re-initiation.

Of note, client transfers can be challenging to document and can lead to misclassification of active clients as having interrupted treatment, particularly if clients self- transfer to a new site without disclosing that they were already on treatment elsewhere. Facilities should assess whether clients are already on treatment at another site and are self- transferring to a new facility, and should have a clear protocol in place for this process.

All efforts should be made to coordinate timing of early clinical appointments, drug pick-ups and viral load monitoring, when possible, at the same facility for all members of a family or household on ART. Programs are also encouraged to actively use CLM feedback to be responsive to the needs of each sub-population (PEFPAR, COP22 Guidance).

This CEE assesses if the site offers HIV-infected individuals the option of rapid or same-day ART initiation according to guidelines and national policy. Question 2 has a **chart review component** of 10 register entries or client charts of HIV positive clients who were initiated on ART. If the site is NOT offering rapid or same-day ART, check N/A and skip CEE.

- *Remote Eligible:* Yes Conditional
- *Required:*  All-Sites MPR Required

S_02_04 Viral Load Access and Monitoring: The 2016 WHO guidelines and literature point to the necessity of laboratory-based monitoring to determine treatment response/failure in clients on ART as part of clinical monitoring. Clients on ART should be receiving routine monitoring for virologic suppression through assessment of viral load, per national guidelines. These results should then be documented in the medical record.

This CEE assesses whether sites providing ART are able to monitor their clients using point-of-care (where available) viral load. It also scores if providers are ordering and documenting viral load results in the intervals recommended in the national guidelines, so the CEE should be adapted to align with the national guidelines if necessary. The CEE has a **chart review component**, please see chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews for Q2 and Q3 can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool.

- *Remote Eligible:* No
- *Required:*  All-Site, MPR Required with NA option if there are NO clients on ART >=12 months

S_02_05 Management of High Viral Load: Non-suppressed VL results require urgent action because clients with non-suppressed VL are at risk of progression of HIV disease, transmission of HIV, as well as accumulation of HIV drug resistance mutations with lower chances for re-suppression on 1st or 2nd line therapy. The return of non-suppressed VL results from the lab to the facilities should be prioritized. Clinicians and adherence counselors should document and monitor each step in the care of an individual with non-suppressed VL, from the date of VL sample collection to the date of return of result to facility to the date that the VL result was shared with the client. Clients with non-suppressed VL need to be tracked and followed closely to ensure that they receive timely interventions in care, such as enhanced adherence counseling (EAC) at every visit, follow-up VL testing after improved adherence, and potential switches to new ARV regimens.

This CEE that both **documentation** and **chart review**; the CEE assesses whether sites are tracking individuals with virologic non-suppression and giving enhanced adherence counseling and repeat VL monitoring according to their national guidelines to assess for virologic failure and inform ART switch decisions.

- *Remote Eligible:* Yes Conditional
- *Required:*  All-Site, MPR Required with NA options if the site does not offer these services

S_02_06 Provision of Differentiated Service Delivery (DSD) Models: Differentiated service delivery describes the continuum of adaptations that can be made to HIV service (including ART delivery) to streamline care in the context of limited human resources and infrastructure, while addressing the needs of defined groups of clients, including:

- **Eligible Client** – country specific description of a client who may qualify for multi-month dispensing and appointment spacing.
- **Multi-month dispensing**–providing clients with three* or more months of ART to reduce the need to return to the site between clinic visits.
- **Fast-tracking pharmacy pick-up** – process which allows individuals to quickly pick-up ART at dispensing facilities.

This CEE includes **documentation review** and assesses if the site offers appointment spacing and multi-month drug dispensing to meet the needs of stable ART clients.

Of note, six-month dispensing is preferred, but there may be circumstances where three-month dispensing is necessary. Requirements such as a minimum time on ART or a documented suppressed viral load are barriers to the successful scale-up of this intervention. At a minimum, most clients at ART treatment sites including adults, children, adolescents/youth, pregnant and breastfeeding women, members of key populations, and

foreign nationals should be offered six months of ART. COP guidance states that Individuals newly on ART and those re-engaging in treatment should be offered MMD.

- *Remote Eligible:* Yes
- *Required:*  All-Sites, MPR Required with NA option

S_02_07 Partner Notification Services: Partner services, also referred to as index testing/partner notification services, is an approach whereby the exposed contacts (i.e., sexual partners, biological children and anyone with whom a needle was shared) of an HIV-positive person (i.e., index client), are elicited and offered HIV testing services. It is important to offer partner HIV testing and counseling within HIV treatment programs because sex partners and injection drug partners are at high risk for HIV, yet, few PLHIV know their partner(s)' HIV status. Integrating partner HTS into ART services can improve access to HIV prevention, care, and treatment for the partner(s) because *negative* partners can be linked to prevention services (e.g. male circumcision), *positive* partners can be linked to HIV care and treatment services.

This CEE has a **chart review component** to identify where partner testing is documented within the client medical chart. This may be on an ART "patient card" or on a sheet inserted into the medical chart, or in an associated Index Testing Log/Register. As this information may be difficult to identify within the client record, assessors should be familiar with the layout and format of client records and field-based Care and Treatment staff can assist with familiarizing SIMS teams with client record format and content. Please see the chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool.

NOTE: both the numerator and denominator are referring to the number of CHARTS of HIV-positive clients. In most cases, the denominator should be equal to 10.

- *Remote Eligible:* No
- *Required:* No

S_02_08 Routine HIV Testing of Children of Adult Clients: HIV testing for children of adults living with HIV is a key way to identify and diagnose children living with HIV. This is an element of index testing services noted above under partner services. This key entry point for case identification in children is often neglected, despite high yield for results. Chart documentation that is consistently used (such as a 'family history' or 'family matrix') can improve testing coverage; it may require providers to keep addressing this beyond the initial patient visit until the HIV status of all of the patient's children is known.

This CEE has a **chart review component** to identify where partner testing is documented within the client medical chart. This may be on an ART "patient card" or on a sheet inserted into the medical chart, or in an associated Index Testing Log/Register. As this information may be difficult to identify within the client record, assessors should be familiar with the layout and format of client records, field-based Care and Treatment staff can assist with familiarizing SIMS teams with client record format and content. Please see the chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool.

NOTE: For the numerator and denominator, the totals are referring to the number of CHARTS, not total number of children. In most cases, the denominator will be 10 (charts) and the numerator is equal to the number of charts of clients with children where all biological children have documented HIV testing status.

Special challenges may exist when assessing this CEE for institutionalized clients (correctional facilities). The Comments box should be used to contextualize any responses that result in a low score.

- *Remote Eligible:* Yes Conditional
- *Required:* All-Site, MPR Required with NA option

S_02_09 TB Screening: As TB often goes undiagnosed among PLHIV, screening and early diagnosis of TB among PLHIV facilitates timely TB treatment and ART initiation. WHO recommends that all PLHIV should be screened at each clinical encounter for the following symptoms: cough, fever, weight loss or night sweats. Those who report any one of the symptoms may have active TB and should be evaluated for TB and other diseases. Xpert MTB/RIF should be used as the initial diagnostic test in adults and children suspected of having HIV-associated TB.

This CEE assesses whether the site has a protocol for performing and documenting the screening for active tuberculosis on intake and at each clinical visit for all HIV-infected clients. The screen should review all 4 of the following symptoms: cough, fever, night sweats, and weight loss. This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

Example Job Aide

- *Remote Eligible:* No
- *Required:* No

S_02_10 TB Preventive Treatment (TPT) TPT has been demonstrated to prevent TB among PLHIV. WHO recommends that PLHIV without active TB should receive a full course of TPT (alternative TPT regimens with shorter duration are available) as part of a comprehensive package of HIV care.

This CEE and assesses whether all eligible HIV-infected clients who screened negative for active TB have received TPT per national guidelines. The SIMS team should determine prior to SIMS visit if the site is expected to provide TPT per national guidelines and implementation plans; if not, then the NA option should be selected. This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

- *Remote Eligible:* No
- *Required:* All-Sites MPR Required with NA option

S_02_11 Cotrimoxazole (CTX): Extensive evidence shows that CTX reduces mortality and morbidity (complications) in PLHIV. For ART clients the greatest benefit is for sickest clients (CD4 <200, or WHO Stage 3 or 4). Country guidelines on use of CTX vary. Most countries define eligibility based on immune status (CD4 or WHO stage); however some countries recommend universal CTX for all PLHIV. Some countries define criteria for stopping CTX ("stopping criteria") for clients on long-term ART with stable CD4 above a defined level.

This CEE is used to assess whether all HIV clients have documented prescription of cotrimoxazole (CTX) according to national guidelines. To assess this CEE, SIMS teams need to be familiar with national guidelines re: CTX eligibility to assure the assessment focuses on eligible clients. This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

NOTE: the numerator and denominator are both referring to the number of charts or register entries where the conditions are met. In most cases the denominator will be 10 (charts).

- *Remote Eligible:* No
- *Required:*  All-Sites MPR Required with NA option

S_02_12 TB Diagnostic Evaluation Cascade: Early diagnosis of TB among PLHIV with TB facilitates timely TB treatment and ART initiation. WHO recommends that all HIV-positive clients with a positive TB symptom screen should undergo diagnostic evaluation for active TB and receive immediate treatment.

This CEE has a documentation review (register/line list) and assesses if the site has a protocol for documenting PLHIV with presumptive TB (using a line list or register) and a referral and follow-up mechanism to ensure TB diagnostic evaluation**.** This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

- *Remote Eligible:* Yes, Conditional
- *Required:*  All-Sites MPR Required with NA option

S_02_13 Community-Based Linkage and Treatment Support Services: Community-based care and support interventions are critical for successful HIV care and treatment. A growing body of evidence indicates that community interventions can increase continuity in care and adherence to ART. As HIV treatment programs begin initiating PLHIV earlier in the disease stage, especially for same-day ART initiation in community settings for KP, an increasing number of ART clients will need community-based services to address their physical, psychosocial, and prevention needs.

This CEE assesses whether each site that provides care and support services has a standard protocol for providing and documenting all the following core elements:

1. Support for Continuity/adherence and ART beneficiaries/clients
2. Referral and linkage to health facilities providing comprehensive HIV care

3. Basic beneficiary/client assessments, documenting psychosocial needs with linkage/referral to services as appropriate

This CEE includes a **documentation review** for written SOPs for linkage and retention services.

- *Remote Eligible:* Yes
- *Required:* No

S_02_14 Service Referral and Linkage System: Individuals living with and affected by HIV need access to a number of HIV prevention and care services to maintain their physical and mental health, including:

- HIV testing and counseling,
- STI screening and treatment,
- PLHIV support groups,
- OVC programs,
- PMTCT services,
- TB diagnosis and treatment programs,
- Male circumcision,
- Condom and lubricant provision, and
- Post-violence care

Community programs should refer their clients to these services and track the successful completion of these referrals to ensure that all clients have access to these high-impact services.

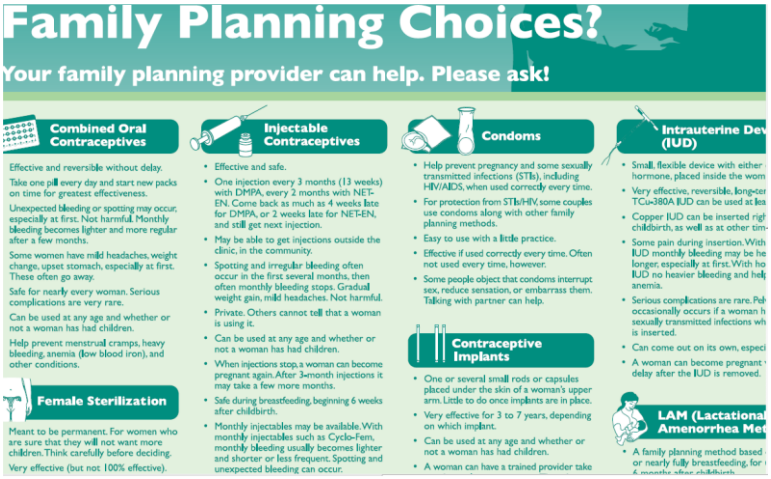
This CEE assesses whether service delivery points supporting prevention and care outreach programs refer beneficiaries/clients to other high-impact HIV services and track those referrals to support successful completion. This CEE contains a **documentation review** of referral tools and a **chart review** of 10 referrals made in the last three months.

- *Remote Eligible:* Yes, Conditional
- *Required:* No

S_02_15 Family Planning / HIV Integration Service Delivery: Family planning (FP) counselling and services, based on a broad range of contraceptive choices, should be provided to couples, and individual men, women and young people living with HIV, to prevent unintended pregnancies and mother-to-child transmission of HIV. Assessing and assisting individuals and couples living with HIV with desires for children should be part of family planning counselling and services. FP services for people living with HIV (PLHIV) are directly linked to improved health outcomes, including reduced rates of maternal mortality and vertical transmission of HIV. Evidence indicates, however, that PLHIV continue to face high unmet need for FP services, resulting in high rates of unintended pregnancy. Moreover, PLHIV who wish to have children may face stigma and discrimination from their communities and providers. Clinics providing HIV services should offer comprehensive FP counseling, including education on all available contraceptive methods, to clients who wish to delay or prevent pregnancy. This education should include information on ALL FP methods, not just those that are available at the site. If a client chooses a method that is not available at the site, a referral should be made and safer conception and pregnancy counseling should be offered to clients who wish to get pregnant.

This CEE has a **document review** and assesses if all clients attending HIV services have access to high quality voluntary family planning counseling and services, including safer pregnancy counseling and contraceptives, depending upon their fertility intentions. Common methods of contraception include fertility awareness

methods, male and female condoms, oral contraceptive pills, injectables, implants, intra-uterine devices (IUDs), and sterilization/permanent methods (e.g. vasectomy, tubal ligation). Clients should have access to at least three of the contraceptive methods listed above either directly at the HIV clinic or through referral to nearby clinic or health facility, as well as education materials. If the site scores a yellow on Q5, assessors should provide guidance to the implementing partner on how to work with USAID's Population and Reproductive Health program, the Ministry of Health, and other agencies that procure contraceptives (e.g. DfID, UNFPA) to address recurring stock-outs.



Example Contraceptive Poster

- *Remote Eligible:* Yes
- *Required:* No

S_02_16 Community-Based Delivery of Family Planning Services: Reproductive rights rest on the recognition of the basic right of all couples and individuals, including those living with and affected by HIV, to decide freely and responsibly the number, spacing and timing of their children. Access to voluntary family planning (FP) services and information is critical for individuals to exercise their reproductive health rights and should be offered to all individuals living with and affected by HIV as part of HIV prevention, care, and treatment services. According to the WHO 2008 Essential Interventions for PLHIV, family planning counselling and services, based on a broad range of contraceptive choices, should be provided to couples, and individual men, women and young people with HIV, to prevent unintended pregnancies and mother-to-child transmission of HIV.

Assessing and assisting individuals and couples living with HIV who are interested in having children should be part of family planning counselling and services. Access to voluntary family planning (FP) services and information is critical for individuals to exercise their reproductive health rights and should be offered to all individuals living with and affected by HIV as part of HIV prevention, care, and treatment services.

This CEE includes a **document review** and assesses whether each site supporting services for this population provides access to high quality family planning (FP) education and services, directly or through referrals. If the service is provided via referrals, a process must be in place for tracking them. Also, the quality of the provision of these services are monitored at least quarterly.

- *Remote Eligible:* Yes
- *Required:* No

S_02_17 Cervical Cancer Screening Capacity: Cervical cancer can be cured with screening early diagnosis and treatment of precancerous cervical lesions. Women living with HIV have a higher risk of pre-cancer and invasive cervical cancer. Therefore, WHO recommends that all women living with HIV should be monitored closely for development of precancerous changes in the cervix.

This CEE requires **chart review** to identify where cervical cancer screening and/or precancerous lesion treatment services is documented within the clients medical chart. This CEE assesses whether each site provides cervical cancer screening and/or precancerous lesion treatment services for all women living with HIV. It assesses the quality of the services provided and referral for follow up services not provided at the site.

- *Remote Eligible:* Yes, Conditional
- *Required:* No

Additional Resources for Set 2A:

- WHO. 2021. Updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring.
- WHO consolidated guidelines on tuberculosis. Module 2: screening – systematic screening for tuberculosis disease. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.
- WHO consolidated guidelines on tuberculosis. Module 1: prevention – tuberculosis preventive treatment. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO.
- WHO. 2021. WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention. Second edition.

SET 2B: CARE AND TREATMENT FOR HIV-INFECTED CHILDREN				
CEE #	*Abbreviated Title*	*Required (MPR)*	*Supportive*	*Remote*
S_02_18	Retesting for Verification before/at ART Initiation		X	Yes Conditional
S_02_19	Client Tracking-ART Clients			Yes Conditional
S_02_33	Rapid ART Initiation			Yes Conditional
S_02_34	Optimized ART Regimen for Young Children			No
S_02_21	Dosing of Pediatric and Adolescent ARVs		X	Yes
S_02_22	Viral Load Access and Monitoring			No
S_02_23	Management of High Viral Load			Yes Conditional
S_02_24	Provision of Differentiated Service Delivery (DSD) Models			Yes
S_02_25	Routine HIV Testing for Children and Adolescents			Yes Conditional
S_02_26	TB Screening		X	No
S_02_27	TB Preventive Therapy (TPT			No
S_02_28	Cotrimoxazole (CTX)			No
S_02_29	TB Diagnostic Evaluation Cascade			Yes Conditional
S_02_30	Support Services for Adolescents Living with HIV		X	Yes
S_02_31	Community -Based Linkage and Retention Support Services		X	Yes
S_02_32	Service Referral and Linkage System		X	Yes Conditional

SET 2B: CARE AND TREATMENT FOR HIV INFECTED CHILDREN

Set Overview: Set 2B consists of 16 CEEs that focus on the quality of care and treatment services for HIV infected children and adolescents. This set should be assessed at sites where PEPFAR supports HIV testing and antiretroviral therapy (ART) for children and adolescents.

The CEEs S_02_28 and S_02_26 assess cotrimoxazole provision and TB screening. These CEEs require review of 10 charts. It is ideal to have a mix of younger (<5 years of age) and older (5-15 years of age) clients when reviewing charts for these CEEs. CEE (S_02_21) that assesses dosing of Pediatric ARVs in the ART clinic by ensuring each ART site providing treatment services to children is equipped with current pediatric ARV weight band dosing tools at the point of care. CEE (S_02_30) in this set assesses support services for HIV-infected adolescents. This CEE may be assessed in the ART clinic or in a specific clinic/area where care is provided to adolescents. A **chart review worksheet** can be found in the SIMS Implementation Guide appendix.

SET 2B TECHNICAL BACKGROUND

S_02_18 Retesting for Verification before/at ART Initiation [DUP S_02_01]: WHO recommends retesting all newly diagnosed HIV positive individuals prior to or at ART initiation, using the national HIV testing algorithm with a new specimen and preferably by a different provider to rule out potential misdiagnosis.

This CEE includes both **document review** and assesses whether the site is conducting and documenting retesting for verification prior to or at ART initiation (using register entries or charts). This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

- *Remote Eligible:* Yes, Conditional
- *Required:* No

S_02_19 Client Tracking-ART Clients [DUPS_02_02]: Tracking of clients has been shown to decrease the duration of interruptions in treatment (IIT) and loss-to-follow-up among PLHIV. Client tracking systems can take various forms including: 1) Phone calls or text messages to clients who have missed appointments or medication pick-ups and 2) Home visits by trained individuals who follow-up with clients in the community. Client tracking systems rely on a functional and updated appointment and/or refill system that allows timely and efficient identification of those clients who have interrupted treatment.

Providers should also have a system for updating clients' addresses and phone numbers at each visit, as clients often change these and if not updated it could lead to failure to track client who have missed appointments.

Furthermore, individuals who have previously initiated ART and are re-engaging after ≥12 months should be assessed for advanced HIV disease, including CD4 testing, and should be offered the advanced HIV disease package as appropriate (COP 22 Guidance).

This CEE includes a **documentation review** and assesses if the ART site has a standard procedure for identifying and tracking ART client (both adults and children) who have missed their appointments. To assess this CEE, the assessor needs to review appointment logbooks/registers and any missed appointments/ tracking and tracing tools to determine the percentage of client with missed appointments have been contacted (Q2), and whether the result of tracking is documented (Q3).

- *Remote Eligible:* Yes, Conditional
- *Required:*  All-Sites MPR Required

S_02_33 Rapid ART Initiation: WHO guidelines (2021) now recommend ~~-~~treating all PLHIV as soon as an HIV diagnosis is confirmed. Research has shown that rapid ART initiation can improve program outcomes, particularly by reducing interruptions in care prior to beginning ART. There are also clinical benefits associated with rapid ART Initiation. Since HIV can attack the immune system within days of infection, early treatment can halt ~~the~~ further progression of disease. In clients with advanced immunosuppression, rapid ART initiation can be lifesaving. Rapid ART initiation is defined as starting ART within 7 days of HIV diagnosis. WHO recommends ART initiation on the same day as HIV diagnosis based on the person's willingness and readiness to start treatment. Further, WHO's 2021 recommendations specify that ART should be initiated as soon as possible within two weeks of starting TB treatment, regardless of CD4 cell count, for adults, adolescents, children and infants living with HIV.

Early engagement remains a challenge across PEPFAR programs. Providers are responsible for ensuring successful early engagement for clients on ART for <3 months and reducing interruptions in treatment during this period. They should work collaboratively with the testing partner to create synergies, so that no one is left behind, especially individuals who did not expect to test HIV positive, are reluctant to start ART, or have been avoiding testing.

All eligible individuals with newly diagnosed HIV should be offered same-day or rapid (within 7 days) start of optimized treatment, regardless of how and where they are diagnosed. The only medical contraindication to rapid ART start is central nervous system infection. A pending TB workup should not delay ART initiation. Those clients, or parents/guardians of children, who are unable or unwilling to start therapy on the same day should be offered the opportunity again within 7 days of diagnosis and be actively but sensitively tracked and supported to prevent interruptions in care, particularly within the first three months after treatment initiation or re-initiation.

Of note, clients transfers can be challenging to document and can lead to misclassification of active clients as having interrupted treatment, particularly if clients self- transfer to a new site without disclosing that they were already on treatment elsewhere. Facilities should assess whether clients are already on treatment at another site and are self- transferring to a new facility, and should have a clear protocol in place for this process.

All efforts should be made to coordinate timing of early clinical appointments, drug pick-ups and viral load monitoring, when possible, at the same facility for all members of a family or household on ART. Programs are also encouraged to actively use CLM feedback to be responsive to the needs of each sub-population (PEFPAR, COP22 Guidance).

Children and adolescents newly diagnosed with HIV should be offered rapid ART initiation. Untreated HIV-infected children have high rates of mortality, so early ART initiation is key to prolonging life. When assessing this CEE, records should only be from newly diagnosed C/ALHIV <15y. When initiating a child or adolescent on treatment, it is imperative that an optimized first line regimen is started. The first-line regimens typically prolong life, have a low pill burden and currently have the lowest cost. These WHO recommended regimens include:

- *<3 kg AZT/3TC +RAL granules or NVP liquid*
- *3. 0 – 19.9 kg: ABC/3TC + DTG 10 mg DT*
- *20 – 29.9 kg: ABC/3TC + DTG 50 mg FCT*
- *30+ kg: TLD FDC*

Once a neonate is 4 weeks of age and 3 kg, he/she should be immediately switched to ABC/3TC + DTG 10 mg DT.

- *Remote Eligible:* Yes, Conditional
- *Required:*  All-Sites MPR Required

S_02_34 Optimized ART Regimen for Young Children: As new Dolutegravir (DTG) formulations have become available as a standard optimal antiretroviral treatment for all children greater than 3 kg and 4 weeks of age, COP 22 guidance requires that all children are transitioned to a DTG containing regimen. Depending on a child's weight, different formulations of DTG should be used:

- *3. 0 – 19.9 kg: ABC/3TC + DTG 10 mg DT*
- *20 – 29.9 kg: ABC/3TC + DTG 50 mg FCT*
- *30+ kg: TLD FDC*

It is important to look at charts of children <5 years of age and 5-9 years of age as they will likely be on different formulations of DTG based on their weight. DTG formulation for children 20 kg and greater were approved and available before the formulations for smaller kids so it is important to evaluate both age groups.

This CEE assesses if the site offers childing living with HIV the option of rapid or same-day ART initiation according to guidelines and national policy. Question 2 has a **chart review component** of 10 register entries or client charts of HIV positive clients who were initiated on ART. If the site is NOT offering rapid or same-day ART, check N/A and skip CEE.

- *Remote Eligible:* Yes Conditional
- *Required:*  All-Sites MPR Required

S_02_21 Dosing of Pediatric ARVs: Assessing a child's weight and prescribing ARV medications accordingly using weight band dosing is essential to ensure children are adequately treated during ongoing growth and development. Weight band dosing is easier to use than calculating mg/kg dosing. ARV refills that are prescribed at the same dosage over time to a growing child, without regular weight-based dose adjustment, will risk under-dosing, lack of viral suppression, and increase potential for developing drug resistance.

- **Weight band dosing:** ARV drug dose prescribed according to a specified weight range which has been evaluated to provide therapeutic effect. Efforts are made to standardize the many pediatric ARVs to a fixed set of weight ranges or "bands".
- **Fixed-dose combination (FDC):** Fixed-dose combinations of antiretrovirals are multiple antiretroviral drugs combined into a single pill, which helps reduce pill burden. They may combine different classes of antiretrovirals or contain only a single class.

This CEE includes **document review** and assesses if the site providing treatment services to children is equipped with current pediatric ARV weight band dosing tools at the point of care, and includes a documentation check for whether there is a place on the register or client chart to document the child's weight and ART dose.

Table A1.2 Simplified dosing of child-friendly solid formulations for once-daily dosing for infants and children four weeks and older[a] (continued)

Drug	Strength of paediatric tablet	Number of tablets or capsules by weight band once daily					Strength of adult tablet	Number of tablets or capsules by weight band once daily
		3–<6 kg	6–<10 kg	10–<14 kg	14–<20 kg	20–<25 kg		25–<35 kg
DTG[h]	Film-coated tablet 50 mg	–	–	–	–	1	50 mg	1
	Dispersible tablet 5 mg	1	3	4	5	6		
	Dispersible scored tablet 10 mg	0.5	1.5	2	2.5	3		

Table A1.3 Simplified dosing of child-friendly solid and oral liquid formulations for twice-daily dosing for infants and children four weeks of age and older[a]

Drug	Strength of paediatric tablets	Number of tablets or mL by weight-band morning (AM) and evening (PM)										Strength of adult tablet	Number of tablets by weight band	
		3–<6 kg		6–<10 kg		10–<14 kg		14–<20 kg		20–<25 kg			25–<35 kg	
		AM	PM	AM	PM	AM	PM	AM	PM	AM	PM		AM	PM
Solid formulations														
AZT	Tablet (dispersible) 60 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300 mg	1	1
ABC	Tablet (dispersible) 60 mg	1	1	1.5	1.5	2	2	2.5	2.5	3	3	300 mg	1	1
LPV/r[b]	Tablet 100 mg/25 mg	–	–	–	–	2	1	2	2	2	2	–	3	3
	Pellets 40 mg/10 mg	2	2	3	3	4	4	5	5	6	6		–	–
	Granules 40 mg/10 mg sachet	2	2	3	3	4	4	5	5	6	6		–	–
DRV[c]	Tablet 75 mg	–	–	–	–	–	–	5	5	5	5	400 mg	1	1
RTV[d]	Tablet 25 mg	–	–	–	–	–	–	2	2	2	2	100 mg	1	1
	Tablet 50 mg	–	–	–	–	–	–	1	1	1	1			
RAL[e]	Chewable tablets 25 mg	1	1	2	2	3	3	4	4	6	6	400 mg	1	1
	Chewable tablets 100 mg	–	–	–	–	–	–	1	1	1.5	1.5			

arv_guidelines-2018-annex3a_dosages-for-arv-drugs.pdf (who.int)

Child's Weight	No. of pDTG 10mg Daily Tablets *90-count bottle*	No. of ABC/3TC 120/60 mg Daily Tablets *30-or 60-count bottle*
3 to 5.9 kg	0.5	1
6 to 9.9 kg	1.5	1.5
10 to 13.9 kg	2	2
14 to 20 kg	2.5	2.5

2022gapfdtgguidance_english.pdf (who.int)

NOTE: Q2 is designated as a chart/register review question, however the assessor is checking charts/register content to determine if there is a specific space to document child's weight and ART dose as each clinic rather than if the chart is completed.

- *Remote Eligible:* Yes
- *Required:* No

S_02_22 Viral Load Access and Monitoring [DUP S_02_04]: The latest guidelines and literature point to the necessity of laboratory-based monitoring to determine treatment response/failure in clients on ART as Clinical monitoring. Clients on ART should be receiving routine monitoring for virologic suppression through assessment of viral load, per national guidelines. These results should then be documented in the medical record.

This is CEE and assesses whether sites providing ART are able to monitor their clients using point-of-care (where available) viral load. It also scores if providers are ordering and documenting viral load results in the intervals recommended in the national guidelines, so the CEE should be adapted to align with the national guidelines. The CEE has a **chart review component**, please see chart review worksheet for additional guidance

on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool.

- *Remote Eligible:* No
- *Required:*  All-Sites, MPR Required with NA option if there are NO clients on ART >=12 months

S_02_23 Management of High Viral Load [DUP S_02_05]: Non-suppressed VL results require urgent action because clients with non-suppressed VL are at risk of progression of HIV disease, transmission of HIV, as well as accumulation of HIV drug resistance mutations with lower chances for re-suppression on 1st or 2nd line therapy. The return of non-suppressed VL results from the lab to the facilities should be prioritized. Clinicians and adherence counselors should document and monitor each step in the care of an individual with non-suppressed VL, from the date of VL sample collection to the date of return of result to facility to the date that the VL result was shared with the client. Clients with non-suppressed VL need to be tracked and followed closely to ensure that they receive timely interventions in care, such as enhanced adherence counseling (EAC) at every visit, follow-up VL testing after improved adherence, and potential switches to new ARV regimens.

This CEE includes **document review** and assesses whether sites are tracking individuals with virologic non-suppression and giving enhanced adherence counseling and repeat VL monitoring according to their national guidelines to assess for virologic failure and inform ART switch decisions. The CEE has a **chart review component**, please see chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool.

NOTE: pay careful attention to the age bands for chart selection.

- *Remote Eligible:* Yes Conditional
- *Required:*  All-Sites, MPR Required with NA options if the site does not offer these services

S_02_24 Provision of Differentiated Service Delivery (DSD) Models [DUP S_02_06]: Differentiated service delivery describes the continuum of adaptations that can be made to HIV service (including ART delivery) to streamline care in the context of limited human resources and infrastructure, while addressing the needs of defined groups of clients. COP 22 guidance states that children living with HIV (CLHIV) two years of age and older are eligible for MMD of ART. Weight increases requiring dosing changes occur infrequently and thus should not preclude providing MMD to CLHIV. For the average child, only six weight-based ART dosing changes are anticipated to occur before ten years of age.[1] ART refills can be delinked from clinical consultation visits, provided outside of health facilities, and managed by trained lay providers (including OVC workers in cases where children face challenges in accessing ART). Programs should make every effort to supply all CLHIV 2 years and older with a 3-month supply (3MMD) at initiation of treatment. Children 5 years of age and older who are already on treatment should be supplied with a 6-month supply.

- **Multi-month dispensing**–providing clients with three* or more months of ART to reduce the need to return to the site between clinic visits.
- **Fast-tracking pharmacy pick-up** – process which allows individuals to quickly pick-up ART at dispensing facilities.

This CEE includes **documentation review** and assesses if the site offers appointment spacing and multi-month drug dispensing to meet the needs of stable ART clients.

This CEE assesses if the site offers different aspects of differentiated service delivery to meet the needs of ART clients.

- *Remote Eligible:* Yes
- *Required:*  All-Site, MPR Required with NA option

S_02_25 Routine HIV Testing for Children and Adolescents: While it is best for any HIV-infected child to be diagnosed in early infancy, many children are not, and the majority of children living with HIV in most PEPFAR-supported countries remain undiagnosed. This becomes the first and most dire barrier to providing good treatment coverage for children. There are predictable entry points at which HIV-infected children can be expected to present, and routine HIV testing policies are necessary in these entry points (ex: TB clinic, malnutrition clinics, outpatient departments and pediatric inpatient ward). To make sure testing at these entry points is optimized, registers should track the HIV status of all children presenting to each entry point. All children with unknown status should receive an HIV test, and the test result documented in the register. This will improve case identification efforts, and avoid missed opportunities to diagnose and treat these children.

- **Key entry points**: Parts of the site where children are seen for a variety of medical issues—testing children here will help in identifying those who are HIV-infected and are sick
- **Case identification**: Finding the first 90 of 90-90-90. Testing in the appropriate locations so that we can locate HIV-infected children who are not yet diagnosed or in treatment services.

This CEE include **document review** and assesses if routine, systematic HIV testing of all children of unknown HIV status is conducted at key entry points to maximize identification of children with HIV so that rapid enrollment into care and ART initiation can occur before complications ensue. This CEE also contains a **chart review component** to review registers/charts for documented HIV status of children. WHO: 2010 Policy Requirements for HIV Testing and Counseling of Infants and Young Children in Health Facilities also states that HIV testing of children is endorsed for all entry points. Please see chart review worksheet for additional guidance on selection of charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool.

- *Remote Eligible:* Yes
- *Required:*  All-Site

S_02_26 TB Screening [DUP S_02_09]: TB is a major source of morbidity and mortality for children living with HIV. Many programs focus on adult TB screening and do not perform this essential task for children, especially those too young to answer questions for themselves. Official (WHO-defined) four-symptom TB screening is **DIFFERENT** in children and adults:

- *Adults:* cough, fever, weight loss, and *night sweats*
- *Children:* cough, fever, weight loss (or inadequate weight gain), and **contact with a known TB patient**. A positive screen is yes if any of the above symptoms or contact with known TB patient.

If TB screening in children does not include TB contact status, then an adequate TB screen has not been performed. Likewise, if TB contact status is only assessed for "TB suspects" – those who have another symptom – this is not adequate. This distinction often leads to low scores in this element, but it affords a key opportunity to improve pediatric care.

- **TB screening:** Assessing if a client has any risks for having TB.
- **TB testing:** Ascertaining if a person who has screened positive has TB.
- **4-symptom TB screen (for children):** Review of signs and symptoms of possible TB: cough, fever, weight loss and history of TB contact.

This CEE assesses if the site performs and documents screening for active TB on intake and at each clinical visit for all HIV-infected children. This CEE has a **chart review component**- please see chart review worksheet (Appendix A) for additional guidance on selection of charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

- *Remote Eligible:* No
- *Required:* No

S_02_27 TB Preventive Therapy (TPT) [DUP S_02_10] TPT has been demonstrated to prevent TB among PLHIV. WHO recommends that PLHIV without active TB should a full course of TPT (alternative TPT regimens with shorter duration are available) as part of a comprehensive package of HIV care.

This CEE and assesses whether all children living with HIV who screened negative for active TB have received TPT per national guidelines. The preferred regimen for CLHIV is six months of daily isoniazid/IPT given known drug-drug interactions of newer, shorter TPT regimens with certain ART regimens and unknown interactions with DTG. The SIMS team should determine prior to SIMS visit if the site is expected to provide TPT per national guidelines and implementation plans; if not, then the NA option should be selected. This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

- *Remote Eligible:* No
- *Required:*  All-Sites, MPR Required with NA option

S_02_28 Cotrimoxazole (CTX) [DUP S_02_11]: Extensive evidence shows that CTX reduces mortality and morbidity in children living with HIV. This benefit is seen for ART clients with the greatest benefit in the youngest (under 2 years) and sickest clients (CD4 <200, or WHO Stage 3 or 4). Newer evidence suggests the benefit may extend to all children, regardless of age or immune status. WHO recommends CTX prophylaxis for infants, children, and adolescents with HIV, irrespective of clinical and immunological conditions. Prioritization should be given to all children less than 5 years old regardless of CD4 cell count or clinical stage, and children with severe or advanced HIV clinical disease**.** In settings where malaria and/or severe bacterial infections (SBIs) are highly prevalent, CTX prophylaxis should be continued until adulthood irrespective of ART provision. In settings of low prevalence for both malaria and SBIs, CTX prophylaxis may be discontinued for children 5 years of age and older who are clinically stable and/or virologically suppressed on ART for at least 6 months and with CD4 >350 cells/mm^3.

Country guidelines on use of CTX vary; most countries define eligibility based on immune status (CD4 or WHO stage); however some countries recommend universal CTX for all children living with HIV, and usually at least for all children under a certain age (typically 5 years). Some countries define criteria for stopping CTX

("stopping criteria") for clients on long-term ART with stable CD4 above a defined level. It is important for the assessor to be familiar with national guidelines to assure the assessment focuses on eligible children.

- **Morbidity and mortality:** bad health effects or death that result from a particular illness
- **Co-trimoxazole:** an antibiotic that helps prevent and or treat certain opportunistic infections in PLHIV
- **Appropriate use of cotrimoxazole:** refers to prescription of cotrimoxazole to children deemed eligible/in need as per national guidelines
- **Advanced clinical disease:** CD4 count of <350, or WHO Stage III/IV
- **SBI:** Serious bacterial infections, such as meningitis

This CEE assesses whether all eligible pediatric clients have documented prescription of co-trimoxazole (CTX) according to national guidelines. This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score. Documentation should show that the child was recently prescribed and/or received CTX if that child was eligible. Correct dosing does not need to be verified. If there is documentation that CTX was *intentionally* avoided because the child did not qualify by the country guidelines, or because of clinical justification (e.g., allergy, adherence complications), then that client is not considered 'eligible' for CTX. The denominator will only include those truly eligible when determining the proportion who were supplied with CTX.

- *Remote Eligible:* No
- *Required:*  All-Site, MPR Required with NA option

S_02_29 TB Diagnostic Evaluation Cascade [DUP S_02_12]: Early diagnosis of TB among PLHIV with TB facilitates timely TB treatment and ART initiation. WHO recommends that all HIV-positive clients with a positive TB symptom screen should undergo diagnostic evaluation for active TB. TB can be challenging to diagnose in children due to difficulty collecting sputum specimens, so follow-up and documentation of completed diagnostic testing is a key step.

This CEE includes **document review** and assesses if the site has a protocol for documenting PLHIV with presumptive TB (using a line list or register) and a referral and follow-up mechanism to ensure TB diagnostic evaluation**.** This CEE has a **chart review component**- please see chart review worksheet) for additional guidance on selection of charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

- *Remote Eligible:* Yes, Conditional
- *Required:*  All-Site, MPR Required with NA option

S_02_30 Support Services for HIV-Positive Adolescents: Adolescents living with HIV are becoming increasingly recognized as a neglected population—they are the only group where HIV mortality rates are still increasing**.** , and have lower rates of linkage to ART, retention in care, adherence to ART, and viral load suppression when compared to adults. Younger adolescents are at especially high risk of developing HIV drug resistance (low adherence)**.** Older adolescents are at especially high risk of loss-to-follow-up (low clinic retention). Services targeting the unique needs of adolescents have shown improved outcomes in this population. For these reasons, clinic services tailored to adolescent clients are critical to their success

- **Adolescent:** a person between the ages of 10-19 (WHO definition); Younger adolescents are 10-14 years old; Older adolescents are 15-19 years old
- **Youth or young people:** a person between the ages of 10-24 (WHO definition)

This CEE and assess if adolescent-friendly clinical services are provided to cater to the specific treatment, support and general health needs of adolescents living with HIV. Q1 includes **documentation review** to ensure systems are in place to track disclosure to HIV-infected children and adolescents, policy for consent for treatment in adolescents, and training provided to ART staff on adolescent-friendly health services. Q2 includes a subjective component, but follow-up questions ("In what way is this service provided at this site?" or "Can you give an example of that?") can help identify which services are actually being provided and should be credited to the site. The written policies under request (age of consent for HIV treatment) may be clinic-specific or (more likely) national; either one is acceptable. Sexual and reproductive health services do not need to be adolescent-specific, but adolescents do need to be able to access them. Adolescent-specific peer leaders/mentors should be adolescents/youth living with HIV.

- *Remote Eligible:* Yes
- *Required:* No

S_02_31 Community-Based Linkage and Treatment Support Services [DUP S_02_13]: Community based care and support interventions are critical for successful HIV care and treatment. A growing body of evidence indicates that community interventions can increase continuity in care and adherence to ART. As HIV treatment programs begin initiating PLHIV earlier in the disease stage, an increasing number of ART clients will need community-based services to address their physical, psychosocial, and prevention needs.

This CEE assesses whether each service delivery point that provides care and support services has a standard protocol for providing and documenting all the following core elements:

1. Referral and linkage to health facilities providing comprehensive HIV care
2. Basic beneficiary/client assessments, documenting psychosocial needs with linkage/referral to services as appropriate
3. Support for continuity/adherence and ART beneficiaries/clients

This CEE includes a **documentation review** for written SOPs for linkage and retention services.

- *Remote Eligible:* Yes
- *Required:* No

S_02_32 Service Referral and Linkage System [DUP S_02_13]: Individuals living with and affected by HIV need access to a number of HIV prevention and care services to maintain their physical and mental health, including:

- HIV testing and counseling,
- STI screening and treatment,
- PLHIV support groups,
- OVC programs,
- PMTCT services,
- TB diagnosis and treatment programs,
- Male circumcision,
- Condom and lubricant provision, and
- Post-violence care.

Community programs should refer their clients to these services and track the successful completion of these referrals in order to ensure that all clients have access to these high-impact services.

This CEE assesses whether service delivery points supporting prevention and care outreach programs refer beneficiaries/clients to other high-impact HIV services (both community and facility) and track those referrals to support successful completion. Data on successful completion of referrals are reviewed by service delivery point staff at least monthly to track and improve performance. This CEE contains a **documentation review** of referral tools, a **chart review** of 10 referrals made in the last three months.

- *Remote Eligible:* Yes, Conditional
- *Required:* No

SET 3A: KEY POPULATIONS-GENERAL				
CEE #	*Abbreviated Title*	*Required (MPR)*	*Supportive*	*Remote*
S_03_01	Lubricant Availability at Site		X	Yes
S_03_02	STI Screening and Management for Key Populations		X	No
S_03_03	Peer Outreach Management		X	Yes
S_03_04	Family Planning/HIV Integration Service Delivery		X	Yes
S_03_05	Ability to Produce KP-specific Program Data		X	Yes Conditional
S_03_06	Human-centered Approaches to Providing Sensitized Services		X	Yes
S_03_07	Provision of PrEP Services			Yes

SET 3A: KEY POPULATIONS-GENERAL CEES

Set Overview: Set 3A covers general services for key populations (KPs) regardless of serostatus and should be assessed at all facilities that target KPs. Set 3A contains CEEs that are unique to KPs; these include lubricant availability, STI screening for both HIV-positive and HIV-negative KPs, Peer Outreach Management, and safeguards against sharing of personal information on referral forms.

Note that S_03_02 requires client chart review for monitoring STI screening practices and documentation; see SIMS Implementation for the applicable worksheet.

SET 3A TECHNICAL BACKGROUND:

S_03_01 Lubricant Availability at Site: Lubricants should be packaged in discreet, easy-to-carry sachets (such as those available through USG bulk purchasing). Lubricants should be displayed in visible locations and co-displayed with condoms for reinforcement of co-use.

This CEE assesses if a site targeting key populations has a reliable supply of water- or silicone-based lubricants and associated materials. Lubricants have at least one month of shelf life before expiration, and are displayed so that they are easily accessible to patrons/clients. This CEE includes a **visual check**; lubricants should be visible to the eye (not hidden under a counter, in a drawer or cabinet) at the time of the assessment. They should be offered at multiple places where clients frequent – registration desk, pharmacy, bathrooms, etc. Observe for places that you might easily access condoms or lubricant if *you* were a client.

- *Remote Eligible:* Yes
- *Required: No*

S_03_02: STI Screening and Management for Key Populations: Sex workers, men who have sex with men, and transgender people (SW, MSM, and TG) are at increased risk of sexually transmitted infections (STIs), thus, it is important to offer clinical management of STIs in line with WHO guidance. People who inject drugs (PWID) may also engage in sex work, and male PWID may have sex with other men and thus face higher STI risks. STI services can be funded through PEPFAR funds for both HIV positive and negative members of a key population. While laboratory STI screening is preferred, syndromic management (SM) is used to treat STI among KP where this is the default national approach to STI control. STI testing and treatment should always be voluntary and free from coercion. The majority of STI cases are asymptomatic, particularly in women.

- **Syndromic management:** This approach is based on the identification of consistent groups of symptoms and easily recognized signs (syndromes), and the provision of treatment that will deal with the majority of, or the most serious, organisms responsible for producing a syndrome. Syndromes are a combination of self-reported symptoms and signs detected at physical examination. Most common syndromes are urethral discharge (UD) in men, vaginal discharge (VD) in women, lower abdominal pain (LAP) in women, genital ulcer disease (GUD) in both men and women.

This CEE include **document review** and assesses if sites that target Key Populations regardless of HIV serostatus have a protocol for performing and documenting STI screening. All facilities should offer STI management and treatment in line with national or WHO STI guidelines either onsite or through referral. Specifically, syphilis screening is offered at every clinical visit. This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

- *Remote Eligible:* No
- *Required: No*

S_03_03: Peer Outreach Management: Peers should represent the community they are serving (i.e. peers should be from the KP community and be known by those they are reaching). Peers need training and exposure on how services work to explain to others. Outreach programs need work plans that list activities, define roles and responsibilities, and define goals and targets for peers. Peers need training on work plans and how to interpret data around targets and performance. Outreach coordinators need training on mentoring peers, standard criteria to evaluate good peer performance and performance reviews need to be scheduled.

This CEE assesses whether each site provides peer educators with standardized supportive supervision, including mentorship and training to better perform their role in outreach. Supervision results are shared with peer educators to improve their outreach efforts

This CEE includes a **documentation review** of the outreach supervision checklists, peer evaluations sheets, or any performance reviews as well as of the record books documenting meetings, performance reviews, etc.

- *Remote Eligible:* Yes
- *Required: No*

S_03_04: Family Planning/HIV Integration Service Delivery: Reproductive rights rest on the recognition of the basic right of all couples and individuals, including those living with and affected by HIV, to decide freely and responsibly the number, spacing and timing of their children. Access to voluntary family planning (FP) services and information is critical for individuals to exercise their reproductive health rights and should be offered to

all individuals living with and affected by HIV as part of HIV prevention, care, and treatment services. According to the WHO 2008 Essential Interventions for PLHIV, family planning counselling and services, based on a broad range of contraceptive choices, should be provided to couples, and individual men, women and young people with HIV, to prevent unintended pregnancies and mother-to-child transmission of HIV.

Assessing and assisting individuals and couples living with HIV with desires for children should be part of family planning counselling and services.

This CEE include **document review** and assesses whether site supporting services for this population provide access to high quality family planning (FP) education and services, directly or through referrals. If referrals are offered, there is a documentation review for tracking of referrals. The quality of the provision of these services should be monitored at least quarterly.

- *Remote Eligible:* Yes
- *Required: No*

S_03_05 Ability to Produce KP-specific Program Data: Each site providing services to key populations should be documenting each client's KP classification according to the current MER Reference Guide. By classifying clients according to KP membership, programmatic achievements for will be available to monitor success along the HIV services cascade over time for KP and in comparison with non-KP groups. Appendix A was created to be used in both community and facility health care settings for the purpose of helping providers identify the types of services needed by the individual client. KP-specific and general population sites should offer classification by KP to all clients, regardless of providers' assumptions about whether the client is a key population member or not.

While most sites can collect and retain KP classification data in a safe and secure manner, there are some settings that cannot guarantee KP classification data will be secure. In these instances (e.g., criminalization of KP groups without adequate legal protection for health data), this CEE should be marked N/A with a note to indicate the lack of protection for KP data collection.

This CEE include **document review** and assesses whether all providers conducting client assessments have received training on screening clients for KP classification as well as whether client registers have a place to indicate KP classification. This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

NOTE: the numerator and denominator should be of the number of records reviewed (10), the denominator in most cases should be 10 (records)

- *Remote Eligible:* Yes, Conditional
- *Required: No*

S_03_06 Human-centered Approaches to Providing Sensitized Services: Providing services in a friendly and sensitive manner is always preferred in health settings. However, it is especially important when dealing with key populations such as sex workers, men who have sex with men, people who inject drugs, people in closed settings, and transgender persons. Around the world, key populations face much higher rates of HIV compared to the general population. Barriers such as police harassment, stigma, societal discrimination and insufficient community-based HIV services prevent these populations from readily accessing the programs they need.

This CEE includes **document review** and assesses whether site staff have the ability to take a standard training covering information about the barriers these key populations face and how they impact their needs and risks surrounding HIV. This CEE will also look into whether clients are able to provide anonymous feedback about unfair or discriminatory treatment received to the site.

- *Remote Eligible:* Yes
- *Required: No*

S_03_07 Provision of PrEP Services: Pre-exposure prophylaxis (PrEP) can help prevent HIV infection in people who don't have HIV but who are at high risk of becoming infected. PrEP currently comes in the form of one pill that contains two HIV medicines combined. WHO recommends that PrEP should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches. For individuals at high risk for HIV, PrEP can significantly reduce the risk of HIV infection if medication is taken consistently each day. Proper adherence to PrEP can lower an individual's risk of getting HIV from sex by more than 90% and from sharing injection drug use equipment by more than 70%.

This CEE includes **document review** and assesses whether HIV-uninfected men and women at substantial risk of infection can access PrEP through high quality, safe, and friendly services. In addition to whether these services already exist, this CEE will also assess whether site staff have been trained on the provision of PrEP.

- *Remote Eligible:* Yes
- *Required:*  All-Site, MPR Required with NA option

SET 3B: CARE AND TREATMENT-KEY POPULATIONS (C&T KEY POPS)				
CEE #	*Abbreviated Title*	*Required (MPR)*	*Supportive*	*Remote*
S_03_08	Retesting for Verification before/at ART Initiation		X	Yes Conditional
S_03_09	Client Tracking-ART Clients*			Yes conditional
S_03_10	Rapid ART Initiation			Yes Conditional
S_03_11	Viral Load Access and Monitoring			No
S_03_12	Management of High Viral Load			Yes Conditional
S_03_13	Provision of Differentiated Service Delivery (DSD) Models			Yes
S_03_14	Partner Services		X	No
S_03_15	Routine HIV Testing of Children of Adult Clients			Yes Conditional
S_03_16	TB Screening		X	No
S_03_17	TB Preventive Treatment (TPT)			No
S_03_18	Cotrimoxazole (CTX)			No
S_03_19	TB Diagnostic Evaluation Cascade			Yes Conditional
S_03_20	Community-Based Linkage and Retention Support Services		X	Yes
S_03_21	Service Referral and Linkage System		X	Yes conditional
S_03_22	Family Planning / HIV Integration Service Delivery		X	Yes
S_03_23	Community-Based Delivery of Family Planning Services		X	Yes
S_03_24	Cervical Cancer Screening Capacity		X	Yes Conditional

SET 3B: CARE AND TREATMENT FOR HIV-INFECTED KEY POPULATIONS (KP)

Set Overview: Set 3B should be assessed at HIV care and treatment facilities that specifically target key populations. It is intended to ensure that sites providing ART for key populations have the same quality of services as ART clinics for the general population. Examples of sites in which set 3B should be scored include an ART clinic for commercial sex workers, a methadone clinic for people who inject drugs that also provides HIV care and treatment services, and an ART site for MSM/TG. A **chart review worksheet** for Set 3B can be found SIMS Implementation Guide Appendices. As Set 3B contains the same CEE content as Set 2A, please refer to Set 2A narratives for the relevant CEE.

SET 4A: PMTCT-ANC, POSTNATAL, and L&D				
CEE #	*Abbreviated Title*	*Required (MPR)*	*Supportive*	*Remote*
S_04_01	Retesting for Verification before/at ART Initiation		X	Yes Conditional
S_04_02	Client Tracking-ART Clients			Yes Conditional
S_04_03	Viral Load Access and Monitoring			No
S_04_04	Management of High Viral Load			Yes Conditional
S_04_05	Provision of Differentiated Service Delivery (DSD) Models			Yes
S_04_06	Support Services for HIV-Positive Pregnant Adolescents in ANC		X	Yes
S_04_07	Partner Services		X	No
S_04_08	Routine HIV Testing of Biological Children of Adult Clients			Yes Conditional
S_04_09	TB Screening		X	No
S_04_10	TB Preventative Treatment (TPT)			No
S_04_11	Cotrimoxazole (CTX)			No
S_04_12	TB Diagnostic Evaluation Cascade			Yes Conditional
S_04_13	PITC for Maternity Clients		X	Yes Conditional
S_04_14	ARVs at Labor and Delivery		X	Yes Conditional

SET 4A: PMTCT-ANC, POSTNATAL, and L&D

Set Overview: Set 4A assesses the quality of services provided in maternal child health (MCH) settings and should be assessed at sites where PEPFAR supports TB testing and therapy (TPT/IPT), HIV testing, and antiretroviral therapy (ART) provision for pregnant and breastfeeding women.

A portion of this set focuses on M&E and ART provision in the MCH setting. Because ART retention and early loss-to-follow-up (LTFU) has been recognized as a major issue in PMTCT settings, S_04_06 (ART Retention in PMTCT facilities) assesses not only whether enrolled women are prescribed ART but also whether they have received ART within the last 2 months. This is designed to determine whether HIV-infected women are returning to the clinic after enrollment. Documentation of ART receipt may not be documented longitudinally in the ANC register; therefore, review of either the ART register or client records may be necessary to score this CEE.

The remainder of the CEEs in Set 4A assess care and treatment services provided to HIV-infected pregnant and breastfeeding women. All HIV-infected pregnant women in PEPFAR facilities now receive ART through at least the end of breastfeeding (Option B); most are receiving lifelong ART (Option B+). Therefore, many MCH clinics

are serving as ART clinics for a prolonged period. Note that S_04_13 (PITC for Maternity Clients) assesses provision of PITC for all *eligible* women, not necessarily all women. WHO guidelines have different recommendations depending on the type of epidemic, and retesting is recommended for some settings; therefore, it is critical to know the guidelines for your particular setting.

It is important to note that in some facilities, pregnant women receive their ART services within the general ART clinic at that site; this is especially true in smaller facilities. In that case, it would be redundant to score certain CEEs since the general ART clinic would be assessed in Set 2A.

To decide which of the required CEEs 04_01 through 04_12 should be scored, consider where pregnant women receive ART services:

1) If the women receive ART services within the MCH clinic: **Select from ALL Set 4A CEEs**
2) If the women receive ART services in the general ART clinic: **Select from the following CEEs**
    - S_04_06 Support Services for HIV-Positive Pregnant Adolescents in ANC (if applicable)
    - S_04_07 Partner Notification Services
    - S_04_08 Routine HIV Testing of Children of Adult Clients
    - S_04_13 PITC for Maternity Clients
    - S_04_14 ARVs at Labor and Delivery

SET 4A TECHNICAL BACKGROUND

S_04_01 Retesting for Verification before/at ART Initiation [DUP S_02_01]: WHO recommends retesting all newly diagnosed HIV positive individuals prior to or at ART initiation, using the national HIV testing algorithm with a new specimen and preferably by a different provider to rule out potential misdiagnosis.

This CEE includes **document review** and assesses whether the site is conducting and documenting retesting for verification prior to or at ART initiation (using **register entries or charts**). This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

- *Remote Eligible:* Yes Conditional
- *Required:* No

S_04_02 Client Tracking-ART Client Tracking of clients has been shown to decrease the duration of interruptions in treatment (IIT) and loss-to-follow-up among PLHIV. Client tracking systems can take various forms including: 1) Phone calls or text messages to clients who have missed appointments or medication pick-ups and 2) Home visits by trained individuals who follow-up with clients in the community. Client tracking systems rely on a functional and updated appointment and/or refill system that allows timely and efficient identification of those clients who have interrupted treatment.

Providers should also have a system for updating clients' addresses and phone numbers at each visit, as clients often change these and if not updated it could lead to failure to track client who have missed appointments.

Furthermore, individuals who have previously initiated ART and are re-engaging after ≥12 months should be assessed for advanced HIV disease, including CD4 testing, and should be offered the advanced HIV disease package as appropriate (COP 22 Guidance).

This CEE includes a **documentation review** and assesses if the ART site has a standard procedure for identifying and tracking ART client (both adults and children) who have missed their appointments. To assess this CEE, the assessor needs to review appointment logbooks/registers and any missed appointments/tracking and tracing tools to determine the percentage of client with missed appointments have been contacted (Q2), and whether the result of tracking is documented (Q3).

- *Remote Eligible:* Yes Conditional
- *Required:*  All-Sites, MPR Required

S_04_03 Viral Load Access and Monitoring [DUP S_02_04]: The latest guidelines and literature point to the necessity of laboratory-based monitoring to determine treatment response/failure in clients on ART as Clinical monitoring. Client on ART should be receiving routine monitoring for virologic suppression through assessment of viral load, per national guidelines. These results should then be documented in the medical record.

This CEE assesses whether sites providing ART are able to monitor their clients using point-of-care (where available) viral load. It also scores if providers are ordering and documenting viral load results in the intervals recommended in the national guidelines, so the CEE should be adapted to align with the national guidelines. For example, if the guidelines call for viral load to be assessed every 6 months for ART clients, then charts would be reviewed for a viral load result documented within the past 8 months. The CEE has a **chart review component**, please see chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool.

- *Remote Eligible:* No
- *Required:*  All-Site, MPR Required with NA option if there are NO clients on ART >=12 months

S_04_04 Management of High Viral Load: Non-suppressed VL results require urgent action because clients with non-suppressed VL are at risk of progression of HIV disease, transmission of HIV, as well as accumulation of HIV drug resistance mutations with lower chances for re-suppression on 1st or 2nd line therapy. The return of non-suppressed VL results from the lab to the facilities should be prioritized. Clinicians and adherence counselors should document and monitor each step in the care of an individual with non-suppressed VL, from the date of VL sample collection to the date of return of result to facility to the date that the VL result was shared with the client. Clients with non-suppressed VL need to be tracked and followed closely to ensure that they receive timely interventions in care, such as enhanced adherence counseling (EAC) at every visit, follow-up VL testing after improved adherence, and potential switches to new ARV regimens.

This is CEE that includes **document review** and assesses whether sites are tracking individuals with virologic non-suppression and giving enhanced adherence counseling and repeat VL monitoring according to their national guidelines to assess for virologic failure and inform ART switch decisions. This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

- *Remote Eligible:* Yes Conditional
- *Required:*  All-Site, MPR Required with NA options if the site does not offer these services

S_04_05 Provision of Differentiated Service Delivery (DSD) Models [DUP S_02_06]: Differentiated service delivery describes the continuum of adaptations that can be made to HIV service (including ART delivery) to streamline care in the context of limited human resources and infrastructure, while addressing the needs of defined groups of clients, including:

- **Eligible Client** – country specific description of a client who may qualify for multi-month dispensing and appointment spacing.
- **Multi-month dispensing**–providing client with three* or more months of ART to reduce the need to return to the site between clinic visits.
- **Fast-tracking pharmacy pick-up** – process which allows ~~stable~~ individuals to quickly pick-up ART at dispensing facilities.

This CEE includes **documentation review** and assesses if the site offers appointment spacing and multi-month drug dispensing to meet the needs of stable ART clients.

Of note, six-month dispensing is preferred, but there may be circumstances where three-month dispensing is necessary. Requirements such as a minimum time on ART or a documented suppressed viral load are barriers to the successful scale-up of this intervention. At a minimum, most clients at ART treatment sites including adults, children, adolescents/youth, pregnant and breastfeeding women, members of key populations, and foreign nationals should be offered six months of ART. COP guidance states that Individuals newly on ART and those re-engaging in treatment should be offered MMD.

- *Remote Eligible:* Yes
- *Required:*  All-Sites, MPR Required with NA option

S_04_06 Support Services for HIV-Positive Pregnant Adolescents in ANC: Pregnant adolescents living with HIV and their infants have poorer health outcomes for themselves when compared to outcomes among adult women living with HIV. Since this is a particularly vulnerable group, they require special attention and enhanced support to optimize maternal and infant outcomes.

This CEE assesses the availability of adolescent-friendly clinical services available at the site to cater to the specific treatment and general health needs of HIV-positive adolescents under the age of 20. his CEE considers whether the site a trained health care provider in this specific area, dedicated time or space, and appropriate support such as peer leaders, champions for AGYW, mentor mothers, OVC case management, gender based-violence and response services, pregnancy crisis counseling and support groups to provide adolescent friendly services.

- *Remote Eligible:* Yes
- *Required:* No

S_04_07 Partner Notification Services [DUP_S_02_07]: Partner services, also referred to as index testing/partner notification services, is an approach whereby the exposed contacts (i.e., sexual partners, biological children and anyone with whom a needle was shared) of an HIV-positive person (i.e., index client), are elicited and offered HIV testing services. It is important to offer partner HIV testing and counseling within HIV treatment programs because sex partners and children of PLHIV are at high risk for HIV, yet, few PLHIV know their partner(s)' HIV status. Integrating index HTS into ART services can improve access to HIV prevention, care, and treatment for the partner(s) and children of PLHIV because *negative* partners can be linked to prevention services (e.g. male circumcision), *positive* partners can be linked to HIV care and treatment services.

To assess this CEE the SIMS team will need to review clients' charts and identify where partner testing is documented within the client medical chart. This may be on an ART "patient card," on a sheet inserted into the medical chart or in an associated Index Testing Log/Register. As this information may be difficult to identify within the patient record, assessors should be familiar with the layout and format of client records, field-based Care and Treatment staff can assist with familiarizing SIMS teams with client record format and content. The CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool.

NOTE: the numerator and denominator reflect the number of entries review, therefore the denominator in most cases will be 10 (entries)

- *Remote Eligible:* No
- *Required:* No

S_04_08 Routine HIV Testing of Children of Adult Clients [DUP S_02_08]: HIV testing for children of adults living with HIV is a key way to identify and diagnose children living with HIV. This is an element of index testing services noted above under partner services. This key entry point for case identification in children is often neglected, despite high yield for results. Chart documentation that is consistently used (such as a 'family history' or 'family matrix') can improve testing coverage; it may require providers to keep addressing this beyond the initial client visit until the HIV status of all of the client's children is known.

To assess this CEE the SIMS team will need to review client charts and identify where partner testing is documented within the client medical chart. This may be on an ART "patient card," on a sheet inserted into the medical chart or in an associated Index Testing Log/Register. As this information may be difficult to identify within the client record, assessors should be familiar with the layout and format of client records, field-based Care and Treatment staff can assist with familiarizing SIMS teams with client record format and content.

This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. NOTE: special challenges may exist when assessing this CEE for institutionalized clients (correctional facilities). The Comments box should be used to contextualize any responses that result in a low score.

NOTE: the numerator and denominator reflect the total register entries or charts that were reviewed, in most cases the denominator will be 10 or less (entries)

- *Remote Eligible:* Yes Conditional
- *Required:*  All-Site, MPR Required with NA option

S_04_09 TB Screening [DUP S_02_09]: As TB often goes undiagnosed among PLHIV Screening and early diagnosis of TB among PLHIV facilitates timely TB treatment and ART initiation, WHO recommends that all PLHIV should be screened at each clinical encounter for the following symptoms: cough, fever, weight loss or night sweats. Xpert MTB/RIF should be used as the initial diagnostic test in adults and children suspected of having HIV-associated TB

This CEE assesses whether the site has a protocol for performing and documenting screening for active tuberculosis on intake and at each clinical visit for all HIV-infected clients. The screen should review all 4 of

the following symptoms: cough, fever, night sweats, and weight loss. This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

Example Job Aide

- *Remote Eligible:* No

Required: No

S_04_10 TB Preventative Treatment (TPT) [DUP S_02_11] TPT has been demonstrated to prevent TB among PLHIV. WHO recommends that PLHIV without active TB should receive a full course of TPT (alternative TPT regimens with shorter duration are available) as part of a comprehensive package of HIV care.

This CEE and assesses whether all eligible HIV-infected clients who screened negative for active TB have received TPT per national guidelines. The SIMS team should determine prior to SIMS visit if the site is expected to provide TPT per national guidelines and implementation plans; if not, then the NA option should be selected. This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

- *Remote Eligible:* No
- *Required:* All-Site, MPR Required with NA option

S_04_11 Cotrimoxazole (CTX) [DUP S_02_11]: Extensive evidence shows that CTX reduces mortality and morbidity (complications) in PLHIV. For ART clients the greatest benefit is for sickest clients (CD4 <200, or WHO Stage 3 or 4). Country guidelines on use of CTX vary. Most countries define eligibility based on immune status (CD4 or WHO stage); however some countries recommend universal CTX for all PLHIV. Some countries define criteria for stopping CTX ("stopping criteria") for clients on long-term ART with stable CD4 above a defined level.

This CEE is used to assess whether all HIV clients have documented prescription of cotrimoxazole (CTX) according to national guidelines. To assess this CEE, SIMS teams need to be familiar with national guidelines re: CTX eligibility to assure the assessment focuses on eligible clients. This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

NOTE: the numerator and denominator are both referring to the number of charts or register entries where the conditions are met. In most cases the denominator will be 10 (charts).

- *Remote Eligible:* No
- *Required:*  All-Site, MPR Required with NA option

S_04_12 TB Diagnostic Evaluation Cascade [DUP S_02_12]: Early diagnosis of TB among PLHIV with TB facilitates timely TB treatment and ART initiation. WHO recommends that all HIV-positive clients with a positive TB symptom screen should undergo diagnostic evaluation for active TB and receive immediate treatment.

This CEE has a documentation review (register/line list) and assesses if the site has a protocol for documenting PLHIV with presumptive TB (using a line list or register) and a referral and follow-up mechanism to ensure TB diagnostic evaluation**.** This CEE has a **chart review component**- please see chart review worksheet for additional guidance on selection of ART charts for review. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool. The Comments box should be used to contextualize any responses that result in a low score.

- *Remote Eligible:* Yes, Conditional
- *Required:*  All-Site, MPR Required with NA option

S_04_13 PITC for Maternity Clients: 2019 Consolidated WHO Guidelines recommend that "all pregnant women should be routinely offered HIV Testing Services at least once and as early as possible during pregnancy" as a component of the basic package of care in antenatal, childbirth, postpartum and pediatric care settings. When HIV testing is delayed or missed in early pregnancy or during the third trimester visit, women should receive catch-up testing at the earliest possible point, including during admission to labor and delivery. Re-testing is recommended in the third trimester, during labor and during the postpartum/breastfeeding period in high HIV burden settings and among pregnant key population groups or women at continued high risk for HIV acquisition. Targeted retesting can be considered in pregnant women in low HIV burden settings.

- **Potential testing scenarios at maternity:**
  - Testing of women with unknown HIV status AND/OR
  - Retesting of women with previous HIV negative result

This CEE is assessed to determine if routine PITC is provided to all eligible women attending maternity for labor and delivery. Note that the CEE standard dictates PITC for all eligible women, **not all women**, and WHO guidelines have different recommendations depending on the type of epidemic. Retesting is recommended for some settings, so it is critical to know the guidelines for your particular setting. This CEE has a **register review component**- please see chart review worksheet for additional guidance.

- *Remote Eligible:* Yes, Conditional
- *Required:* No

S_04_14 ARVs at Labor and Delivery: ARVs provided to pregnant women living with HIV and their exposed infants are primarily to reduce maternal viral loads and to prevent vertical transmission of HIV. In HIV exposed infants, prophylaxis should begin at birth or when HIV-exposure is first identified during the postpartum (6 weeks post delivery) or breastfeeding period. Assessors should be familiar with national guidelines regarding use of ART during labor and delivery, particularly in women who are not virally suppressed at time of delivery.

This CEE assesses if ART for pregnant women with HIV infection and ARV prophylaxis for their exposed infants are provided at maternity/L&D and contains a **register review** component to verify provision to mother-infant pairs.

- *Remote Eligible:* Yes, Conditional
- *Required:* No

SET 4B: HIV EXPOSED INFANTS (HEI)				
CEE #	*Abbreviated Title*	*Required (MPR)*	*Supportive*	*Remote*
S_04_15	Early Infant Diagnosis Provided to Caregiver		X	Yes conditional
S_04_16	Tracking HIV-Exposed Infants			Yes
S_04_17	Collection of a Second Specimen for Confirmatory Testing		X	No
S_04_18	CTX for HIV-Exposed Infants			No
S_04_19	HEI Follow-up and Final HIV Status			Yes Conditional
S_04_20	Enrollment of HIV-Infected Infants into ART Services			No
S_04_21	Supply Chain Reliability (Early Infant Diagnosis) DBS or POC		X	Yes

SET 4B: HIV EXPOSED INFANTS (HEI)

Set Overview: Set 4B assesses the quality of services provided for HIV-exposed infants (HEIs) and should be assessed at sites where PEPFAR supports clinical services for HEIs. Registers are usually the initial source where HEIs are identified. Ideally, all of the information needed to complete this set can be found in one register, but multiple registers and/or patient charts may be required.

It is important to note that the review of the register for HEIs should not go further than 12 months prior to the SIMS visit. HEIs also have high rates of lost to follow-up LTFU and it is essential to ensure sites are tracking HEIs until final HIV status is known; S_04_16 focuses on identifying and tracking HEIs who have defaulted on their appointments.

S_04_20 assesses enrollment of HIV-infected infants into ART. The last CEE in this set, S_04_21, ensures each PMTCT site has a reliable supply of DBS supplies. This CEE should be assessed at the place within the site where DBS supplies are managed (e.g. the central store, pharmacy, or laboratory).

SET 4B TECHNICAL BACKGROUND

S_04_15 Early Infant Diagnosis Provided to Caregiver: The risk of mortality in the first year of life is very high among HIV-infected infants, especially those infected perinatally and WHO strongly recommends that HIV virological testing be used to diagnose HIV infection in infants and children below 18 months of age. Early diagnosis (within the first 2 months of life) is critical for reducing this mortality.

This CEE assesses whether all HIV-exposed infants (HEIs) have a specimen collected for early infant diagnosis (EID) and infant virologic testing (IVT). This CEE will ensure that there is also documented return of HIV results to caregivers within one month of sample collection and contains a **register review component** to verify status of the most recent HEIs.

- *Remote Eligible:* Yes, Conditional
- *Required:* No

S_04_16 Tracking HIV-Exposed Infants: Having a tracking system of this nature can improve EID outcomes, including timely reporting of EID results and tracking of HIV-infected infants for early initiation of ART. In order for the tracking system to be effective, it should include procedures for client identification and tracking, standardized documentation showing evidence of more than one attempt to bring the client back into care and results of tracking efforts.

This CEE includes **document review** and assesses whether sites are providing services for HIV-exposed infants (HEIs) that have a standard procedure for identifying and tracking HEIs who have missed appointments.

- *Remote Eligible:* Yes
- *Required:*  All-Site, MPR Required with NA option

S_04_17 Collection of a Second Specimen for Confirmatory Testing: The types of tests used for early infant diagnosis can lead some HIV-uninfected infants to be incorrectly identified as HIV-infected. Therefore, confirmatory testing not only prevents misdiagnosis of HIV in infants but is also cost-saving.

This CEEs assesses whether all infants with an initial positive virologic test result have a second specimen collected for confirmatory testing and contains a **register/chart review component** to verify.

- *Remote Eligible:* No
- *Required:* No

S_04_18 CTX for HIV-Exposed Infants: Data has shown the effectiveness of cotrimoxazole in reducing morbidity and mortality among individuals living with HIV. WHO recommends cotrimoxazole for all HIV-exposed children born to mothers living with HIV starting at 4-6 weeks after birth and continuing until the infant is no longer at risk of acquiring HIV through breastfeeding and HIV infection has been excluded.

This CEE assesses whether all HIV-exposed infants (HEIs) initiate cotrimoxazole by eight weeks of age and contains a **register/chart review component** to verify.

- *Remote Eligible:* No
- *Required:*  All-Site, MPR Required with NA option

S_04_19 HEI Follow-up and Final HIV Status: Since more than 50% of infant HIV infections now occur in the postpartum period, follow-up of HEI throughout the entire breastfeeding period and assuring their final HIV status after weaning is critical to optimizing outcomes. By providing a comprehensive continuum of antenatal, postnatal, and HEI care, health centers can lower the rate of mother-to-child transmission of HIV among their clients.

This CEE includes a **document review** that assesses whether there is a system in place to track HIV-exposed infants through the end of breastfeeding and documentation of infant final HIV status by 24 months of age and contains a **register/chart review component** to verify.

- *Remote Eligible:* Yes
- *Required:*  MPR Required with NA option

S_04_20 Enrollment of HIV-Infected Infants into ART Services: Early identification and entry into care is critical to reducing morbidity and mortality in infants with HIV.

This CEE includes a **document review** and assesses whether HIV-infected infants are enrolled into ART services and also contains a **register/chart review component** to verify.

NOTE: Records should only be from **HIV-infected infants. Note that paper version of the tool currently shows Q2 response as #, but this should be %**

- *Remote Eligible:* No
- *Required:*  MPR Required with NA option

S_04_21 Supply Chain Reliability (Early Infant Diagnosis) DBS or POC: A reliable supply of commodities can only be provided if the supply chain is working. Sites should be able to order products and receive them on-time and in full. Anything less than that performance can result in low stock or stock-out situations.

This CEE assesses whether each PMTCT site has a reliable supply of Early Infant Diagnosis (EID) collection supplies for specimens (including dried blood spot (DBS)) obtained for conventional laboratory-based testing or for point-of-care testing (POCT) and has fully functional platforms for testing.

- *Remote Eligible:* Yes
- *Required:* No

SET 5: VOLUNTARY MEDICAL MALE CIRCUMCISION (VMMC)				
CEE #	*Abbreviated Title*	*Required (MPR)*	*Supportive*	*Remote*
S_05_01	Precision and Safeguarding of VMMC Surgical Records		X	No
S_05_02	Adverse Event (AE) Prevention and Management		X	Yes
S_05_03	VMMC Adverse Event (AE) Register		X	Yes Conditional

SET 5: VOLUNTARY MEDICAL MALE CIRCUMCISION (VMMC)

Set Overview: Set 5 should be scored at sites where voluntary medical male circumcision (VMMC) services are supported by PEPFAR. Refer to the DATIM Site List for a list of sites where VMMC is offered. This set reflects whether crucial components are in place to ensure the health and safety of VMMC clients such as good record keeping practices, emergency preparedness and adverse event management,.

- **VMMC site:** describes any location where VMMC is provided. It is often in an operating theater in a health clinic or hospital, but VMMC may be performed in a mobile tent, community health center, or another temporary location.
- **Surgical VMMC:** VMMC performed using only standard surgical instruments (usually prepacked together, in a single-use VMMC kit or as a reusable set).
- **Device based VMMC:** VMMC performed using a device specifically designed for male circumcision. As of 2021, ShangRing is the only device supported by PEPFAR.

SET 5 TECHNICAL BACKGROUND

S_05_01 Precision and Safeguarding of VMMC Surgical Records: Maintaining and safeguarding of surgical records is an integral component of quality healthcare and essential for the continuity of care in clients.

This CEE assesses whether each site retains accurate, complete, and updated VMMC patient records in a secure location. This CEE contains a **register review** to ensure that a standard register is kept, and that entries are complete and secure.

- *Remote Eligible:* No
- *Required:* No

S_05_02 Adverse Event (AE) Prevention and Management: VMMC is a safe procedure if established guidelines are followed by all clinical staff. However, rare emergencies can occur during procedures, and a small percent of adverse events (complications) are expected to occur during or shortly after VMMC procedures. These are usually minor in nature, and if managed appropriately by clinicians do not result in any long-term disability. This CEE reflects VMMC site and service processes:

Q1 includes a **visual inspection** of medical devises and supplies. For electronically powered items (glucometers, some blood pressure cuffs), check to see that they are operational.

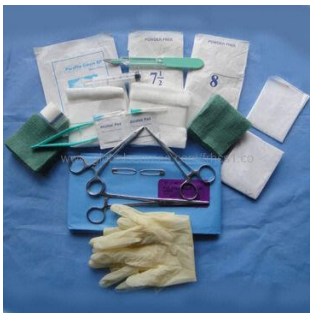
Q2 contains a **visual inspection** that these supplies are inventoried on a list in areas where VMMC occurs.

Q3 also contains a **documentation review** for a written procedure or algorithm to classify, documents and manage adverse events. It also requires a review of monthly written or electronic meeting minutes (notes) from the site that cover review of all VMMC moderate and severe adverse events that occurred at this site in the past month, any corrective actions taken, and the outcome.

Example images of emergency supplies

Sphygmomanometer /Blood pressure cuff

IV Infusion tubing



Emergency kit supplies

Ambu bag - adult

IV catheters

Oropharyngeal airways

- *Remote Eligible:* Yes
- *Required:* No

S_05_03 VMMC Adverse Event (AE) Register: AE surveillance is a critical component to a VMMC program's overall strategy to improve service quality and client safety. Site level surveillance is accomplished by recording standardized information on AEs of all severities (mild, moderate, severe) in an on-site register.

Q1 includes visual inspection to confirm that an AE register is present on site.

Q2 includes documentation of review of the AE register to determine the proportion of entries that have documented intermediate or final outcomes (i.e., what happened to the client from a clinical perspective such as "completely healed", "bleeding stopped", or "pain improved"). An outcome is "final" when the client no longer needs follow-up, an outcome is "intermediate" when the provider wants the client to return for another follow up visit to assess clinical response to treatment.

- *Remote Eligible:* Yes Conditional
- *Required:* No

Additional resources for Set 5:

Adverse Event Action Guide: For VMMC by Surgery or Device, 2nd edition

https://project-iq-resources.jhpiego.org/resource/adverse-event-action-guide-for-vmmc-by-surgery-or-device-2nd-edition/

SET 6: AGYW, GBV and OVC				
CEE #	*Abbreviated Title*	*Required (MPR)*	*Supportive*	*Remote*
S_06_01	Capacity to Provide Post-Violence Care Services		X	Yes
S_06_02	Availability of Post-Violence Care Services		X	Yes
S_06_03	Gender Norms		X	Yes
S_06_04	Case Management Services			No
S_06_05	Case Management Workforce Strengthening		X	Yes
S_06_07	Services to support HIV Testing for OVC			No
S_06_08	Services to support HIV Treatment Linkage, Engagement, and Viral Suppression for OVC			No
S_06_09	DREAMS Mentoring		X	Yes

SET 6: Adolescent Girls and Young Women (AGYW), Gender Based Violence (GBV) and Orphans and Vulnerable Children (OVC)

Set Overview: Set 6 consists of 8 CEEs that assess post-violence care, HIV prevention programs for AGYW, and gender norms and OVC programs at PEPFAR supported sites.

CEEs S_06_01 and S_06_02 assess sites capacity to provide post-violence clinical care to children, AGYW, and adults and availability of the minimum package of PEPFAR post-violence care services. These two CEEs should only be administered at facilities that provide post-violence clinical care.

CEE S_06_03 should only be administered at sites that have received funding to provide gender norms interventions.

CEE S_06_06 should only be administered at sites (community and facility) that provide HIV prevention programs to AGYW.

Note: Each DREAMS country has a layering table that identifies the set of interventions and curricula (if applicable) DREAMS sites should offer to AGYW participants. The country-specific layering tables are available on the DREAMS page on the PEPFAR SharePoint site.

CEEs S_06_04, S_06_05, S_06_07, and S_06_08 assess case management, HIV testing and treatment, and viral suppression for OVCs. All these CEEs require case files/chart reviews.

SET 6 TECHNICAL BACKGROUND

S_06_01 Capacity to Provide Post-Violence Care Services: Based on WHO guidelines, health care providers delivering post-violence care services should be trained in intimate partner AND sexual violence through pre- or in-service training. Training should enable providers to deliver first-line support (i.e., LIVES) **and** teach providers the following:

- Basic information about violence
- Existing supportive services for victims of violence
- Appropriate ways to interact with victims of violence and provide trauma-informed care
- When and how to enquire about violence, in alignment with PEPFAR guidance
- When and how to collect forensic evidence, where appropriate
- Different components of responding to violence (e.g., safety planning, clinical skills, case documentation, making referrals)
- Give advanced training on emergency contraception (EC), where applicable and legal, PEP for HIV, and STI prophylaxis, HEP B vaccination, and the importance of timely intervention.

According to COP 22 guidance, implementing partners who provide post-violence care services must:

- Provide training **and** supportive supervision to both providers and organizations on first-line support (i.e., the WHO LIVES approach including empathetic listening, inquiring about needs and concerns, validating survivors' experiences, enhancing safety, and connecting survivors to other support, which may include referrals to additional services). Providers should work to provide immediate, trauma-informed, survivor-centered support to meet the overall emotional, physical, safety, and support needs of survivors.

Based on UN and PEPFAR technical considerations, specific training of health care providers on the care of children who have experienced sexual violence is critical and should (in addition to the above):

- Orient to sexual violence/post-rape care clinic and referral protocols specific to children
- Address age- and developmentally appropriate provision of first-line support and post-violence clinical care
- Advanced emergency contraception (EC) training including proper dosing for children and other child-centered care approaches should be provided
- Include site-based prophylactic (PEP, EC, STI prophylaxis) and response services related to sexual, physical, and emotional health in response to sexual violence against children and adults, physical and emotional intimate partner violence, and physical and emotional violence against children. For more information on WHO standards for violence response services, refer to the Gender-Based Violence Quality Assurance Tool below.

This CEE includes **document review** and assesses whether the site providing post-violence care services has written procedures for provision of these services for adults, adolescents, and children. Post-violence care should be accessible and affordable. There should be no service charges or user fees of any kind, including for clinical services, transportation fees, fees for filling out, filing, or copying forms, etc. All staff providing post-violence care services are trained on the provision and documentation of those services, and documentation is adequate, without compromising anonymity.

- *Remote Eligible:* Yes
- *Required:* No

S_06_02 Availability of Post-Violence Care Services: Based on WHO and PEPFAR guidelines, sites that provide post-violence care, should provide immediate access to and provision of the full minimum package of comprehensive and age-appropriate post-violence services.

For sexual violence:

- Initial assessment of patient needs/psychosocial and trauma-informed counseling
- Treatment of serious or life-threatening medical issues (e.g., lacerations, broken bones) and the necessary forensic interviews and examinations
- Post Exposure Prophylaxis (PEP) for HIV, if the person is reached within the first 72 hours
- Rapid HIV Testing and referral to care and treatment as necessary
- Emergency contraception (EC) where legal and appropriate, if the person is reached within the first 120 hours
- STIs screening/testing and treatment and/or prophylactic treatment

For physical and/or emotional violence, sites should offer the following minimum package of services:

- Initial assessment of patient needs/ psychosocial and trauma informed counseling, (other than counseling for testing, PEP, STI, and EC)
- Treatment of serious or life-threatening medical issues (e.g., lacerations, broken bones) and the necessary forensic interviews and examinations
- Rapid HIV Testing and referral to care and treatment as necessary
- STIs screening /testing and treatment

Forensic interviews and examinations are critical components of post-violence response; however, some sites will be more equipped than others to provide this type of service. While it is encouraged, it is not required.

In addition to the minimum package of services listed above, sites should also be partnering with and making referrals to other community services, including:

1. Longer term psycho-social support
2. Legal counsel
3. Police (e.g., investigations, restraining orders, etc.)
4. Child Protection Services (e.g., emergency out of family care, reintegration into family care when possible, permanency options when reintegration not possible)
5. Emergency shelter
6. Economic empowerment referrals, in this context, are referrals to entities that provide critical financial and non-financial support to individuals experiencing violence:
   - Financial support can include programs to build the capacity of individuals to change their economic status, such as savings and loans programs and training on resource management.
   - Non-financial support can include (but may not be limited to) assistance for individuals needing to leave their homes and vouchers for food, transportation, or services.

   Note: as feasible, economic empowerment referrals should be paired with gender norms activities (as described in S_06_03).

This CEE that includes **document review** and assesses if the site providing post-violence care services (for sexual violence among children and adults, physical and emotional intimate partner violence, and physical and emotional violence against children) provides the minimum package of services and referrals. For Q2: If the site does not provide emergency contraception because it is not legal, and it is the ONLY one of the post-violence services NOT provided, you should answer Y to Q2 and move on to Q3.

- *Remote Eligible:* Yes
- *Required:* No

S_06_03: Gender Norms: Changing harmful gender norms is a cross-cutting effort and contributes to results across a range of PEPFAR program areas, including prevention, care, and treatment. PEPFAR Gender Strategy (December, 2013) includes 6 key activities for PEPFAR programs:

1) Provide gender equitable HIV prevention, care, treatment & support
2) Implement GBV prevention activities
3) Provide services for post-GBV care
4) Implement activities to change harmful gender norms & promote positive gender norms
5) Promote gender-related policies and laws that increase legal protection
6) Increase gender equitable access to income and productive resources, including education

This CEE assesses whether sites providing or supporting gender norms interventions have staff trained in these interventions and their performance monitored at least quarterly. These interventions use a standard curriculum and are more than a single stand-alone session.

- **Gender norms intervention:**
  An intervention that seeks to:
  (a) identify and change harmful traditional, cultural, and social norms that contribute to behaviors that increase HIV/AIDS risk in both men and women and that impede access to care and treatment services for those who need them including, gender-based violence; and
  (b) identify and promote positive traditional, cultural, and social norms that facilitate and support gender equality.

- **Standard curriculum:**
  Defined as having a strong theoretical base or as an evidence-based curriculum focused on or with a strong emphasis on gender norms or violence prevention (e.g., SASA!, Program H, One Man Can, No Means No Worldwide, Coaching Boys into Men, Every Hour Matters).

This CEE contains **documentation requirements** for an intervention manual, curriculum, participation guide or other materials. Certification of training or attendance sheets for staff is also required, along with performance evaluations of staff and gender norm interventions.

- *Remote Eligible:* Yes
- *Required:* No

S_06_04 Case Management Services: Case management is the process of identifying vulnerable children and families; assessing their needs and resources; working together to establish specific, realistic objectives and goals and planning actions to achieve objectives and goals; implementing plans through completing specific actions and receiving services; monitoring both the completion of actions (including the receipt of services in a timely, context-sensitive, individualized, and family-centered manner) and progress toward achievement of objectives/goals (e.g., child protection and well-being, including HIV prevention, treatment, and adherence). It helps to ensure a high-quality health journey for OVC beneficiaries and can improve client satisfaction, decrease the unnecessary utilization of resources and reduce morbidity, mortality, and re-admission rates.

This CEE assesses whether sites have standard procedures for supporting case management for OVC and families affected by HIV including standard procedures to support identification, assessment, case plan development, case plan monitoring, case plan achievement/graduation, case closure, case file confidentiality, and minimize attrition. This CEE also includes **chart/register review**.

- *Remote Eligible:* No
- *Required:*  MPR Required

S_06_05 Case Management Workforce Strengthening: To effectively carry out case management services, sites need to have trained OVC case managers who are well supervised and supported.

This CEE assesses whether sites have standard procedures for planning, developing and supporting community workers responsible for case management. This CEE has a **documentation review** for HR files of case workers.

- *Remote Eligible:* Yes
- *Required:* No

S_06_07 Services to Support HIV Testing for OVC: Case management plays a critical role in linking/referring OVC beneficiaries who are at high risk of being or becoming HIV infected to HIV testing and counselling services.

This CEE assesses whether sites providing OVC services have a case management system that captures important information related to HIV risk screening, HIV testing referral where applicable and HIV status for children and their caregivers.

- *Remote Eligible:* Yes
- *Required:*  MPR Required

S_06_08 Services to support HIV Treatment Linkage, Retention and Viral Suppression for OVC: Case management is instrumental in facilitating support for HIV Treatment Linkage, Retention Adherence, and Viral Suppression for children and their caregivers. Children and adolescents continue to lag significantly behind adults in regard to achievement of the three 95's (UNAIDS World AIDS Day report 2021). To improve treatment outcomes for children, PEPFAR COP22 guidance promotes multi-month dispensing for all children who are stable, and routine viral load testing. PEPFAR COP 22 guidance further specifies that OVC programs play an instrumental role in advocating for all eligible children to have access to MMD and VL testing, and for OVC programs to monitor children's access to both.

This is a **required** CEE that includes **document review** and assesses whether sites providing OVC services have case management procedures to capture pertinent information related to OVC HIV treatment linkage, retention into care, adherence to treatment, multi-month dispensing, viral load testing, and viral load suppression. This CEE also includes **chart/file** review of families with either a caregiver or child living with HIV from the site roster.

- *Remote Eligible:* No
- *Required:*  MPR Required

S_06_09 DREAMS Mentoring: This CEE allows for regular monitoring of the mentoring component of DREAMS. In COP22, OUs should strengthen mentoring in DREAMS by enhancing or establishing systematic processes to recruit and support mentor training, supportive supervision and equitable compensation. These components contribute to mentors providing DREAMS participants with the most effective, evidence-informed mentoring possible. Priority areas in mentoring programming include:

- Mentors should be provided standardized tools/SOPs and job descriptions explicitly outlining roles, responsibilities and expectations of supervisors, mentors and mentees. These should be shared with mentors during onboarding and reviewed regularly to ensure alignment.
- OUs should have a comprehensive onset and refresher training plan for mentors that includes technical information, facilitation & mentorship skills, and first-line support to strengthen mentors' capacity to respond to disclosures of violence.
- Support to perform their duties including access to resources (job aids, tools, cell phones)
- Mentors should receive remuneration and resources (i.e., wages, transport stipend, airtime allowances) representative of the level of engagement and service delivery provided to DREAMS AGYW.
- Routine supportive supervision both to oversee the conduct of specific responsibilities as well as ensure the well-being of mentors must be prioritized.

This CEE that includes **document review:**

- Standard operation procedures for recruitment
- Mentor job description
- Standardized training package that includes what it means/ how to be a mentor, training for first-line support, and training on social asset building. *Note: A standardized package is defined as a set of core training activities that are provided to all DREAMS Mentors (e.g., communication, leadership, group facilitation, safety and security).*
- Plan for mentors to access resources (community guides, job aids, and support with communication such as cell phone/airtime /data.
- Plan and process for remuneration, Compensation/pay should always be provided at a similar amount to wages in the community for comparable work (i.e., government extension workers, CHWs). Cash payments are discouraged especially for program accounting, and it often puts mentors at risk. Mentors should open bank accounts for depositing pay after turning in monthly accounting/reports.
- Documentation of routine supportive supervision

Additional Resources for Set 6:

- WHO. Gender-Based Violence Quality Assurance Tool https://static1.squarespace.com/static/5a29b53af9a61e9d04a1cb10/t/5f087452fa4efb0134eafaab/1594389591515/GBV-QA+tool_Jan+2018.pdf
- https://www.who.int/reproductivehealth/publications/post-violence-care-in-health-facilities/en/.
- PEPFAR Guidance for Orphans and Vulnerable Children Programming (2012) https://www.pepfar.gov/documents/organization/195702.pdf
- MER 2.0 (Version 2.3) Reference Guide 2018: Appendix D: Illustrative eligible services and Appendix E: Global OVC Graduation Benchmarks
- https://ovcsupport.org/wp-content/uploads/2018/10/MER-Indicator-Reference-Guide-Version-2.3-FY19.pdf
- DREAMS Guidance
- https://www.pepfarsolutions.org/resourcesandtools-2/2021/8/19/pepfar-dreams-guidance

- https://www.state.gov/2022-country-operational-plan-guidance/#:~:text=COP%2FROP%202022%20guidance%20for,enduring%20national%20health%20systems%20and

SET 7: HTS				
CEE #	*Abbreviated Title*	*Required (MPR)*	*Supportive*	*Remote*
S_07_01	Compliance with National Testing Algorithm and Strategy		X	Yes Conditional
S_07_02	Quality Assurance of HIV Testing Services		X	Yes
S_07_03	HTS Linkage to HIV Care and Treatment at the Site Level		X	Yes Conditional
S_07_04	Site Level HIV Proficiency Testing		X	Yes
S_07_05	HTS Safety Measures at the Site		X	Yes
S_07_06	Confidentiality of HIV Testing Services at the Site		X	Yes
S_07_07	HIV Self-Testing			Yes
S_07_08	Index Testing Training and Supportive Supervision			Yes
S_07_09	Monitoring Adverse Events			Yes
S_07_10	Secure Handling and Storage of Index Testing data			Yes
S_07_11	Intimate Partner Violence Risk Assessment and Support for Index Testing			Yes
S_07_12	Supporting Clients who Disclose Intimate Partner Violence			Yes
S_07_13	HTS Linkage to HIV Prevention Services			Yes

SET 7: HTS

Set Overview: HIV rapid testing is a critical tool in the HIV response, as knowledge of HIV serostatus is necessary to access evidence-based interventions including ART, prevention of mother-to-child HIV transmission (PMTCT), and VMMC. Quality assurance measures for HIV rapid testing are critically important to reduce the risk for misdiagnosis and to ensure that all individuals who receive an HIV diagnosis are linked to life-saving treatment.

As there may be more than one location where HTS is conducted at a given location, assessors should select up to 3 locations to assess. Where more than one service delivery points are assessed, the Set 7 Worksheet can be used to capture the results for each service delivery point. The results for the lowest scoring location should be enter for each CEE and a comment entered in the Comment box to designate which area accounted for the low score.

SET 7 TECHNICAL BACKGROUND

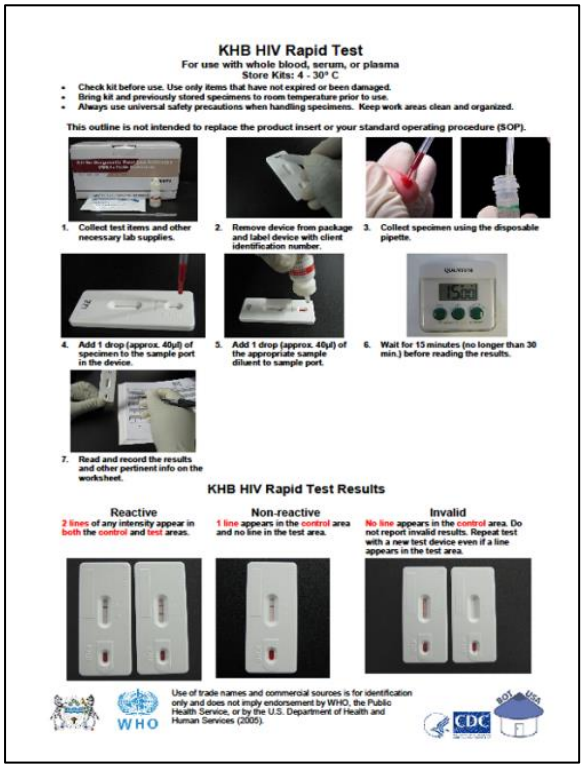
S_07_01 Compliance with National Testing Algorithm and Strategy: WHO standard (2019 HTS Consolidated Guidelines): The combination of assays used in a testing algorithm(s) should be validated at the national or regional level. The number of algorithms used in a country should be limited, with back-up assay options in the case of lot failures or stock-outs and to respond quickly to recalls or corrective actions recommended by the manufacturer. The types of records required for a quality system are: testing/laboratory logbook should record details to identify the person undergoing testing (client identifier, name [optional], date of birth [optional]), the assays used (with lot numbers and expiry dates), the test results (preferably, band intensity when using RDTs), both readers' results (when using rapid diagnostic tests (RDTs)), date of test run, name of operator and QC results, and overall status as given to the individual who received HTS.

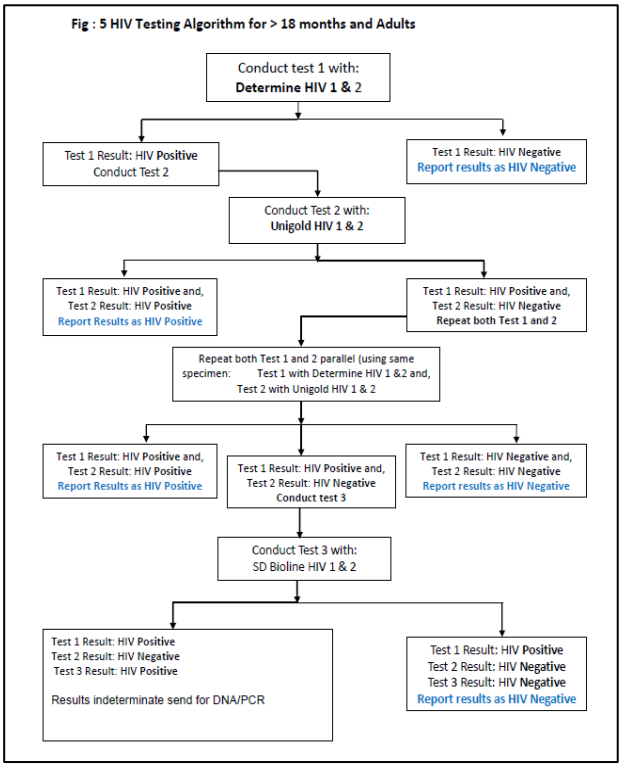
- **Algorithm:** refers to a defined combination of specific assays within a testing strategy

- **Testing Strategy:** refers to the sequence in which diagnostic tests are used for a specific objective, taking into consideration the presumed HIV prevalence in the population tested

This CEE requires a **document review** and assesses whether the site performs rapid HIV testing in accordance with national testing algorithms and strategies. This includes a visual inspection and a **register review** to determine if the algorithm was conducted correctly. Q1 requires the assessor to determine if there are written or printed testing protocols and job aides available. Below are examples of what an assessor should expect to find at any testing point.

Example Job Aides and SOP for HTS





Example Job Aides

Q2 requires a review of the HTS register or rapid testing logbook to check for compliance with appropriate documentation. Q3 requires the assessor to review the 20 most recent HIV positive entries in the appropriate site/intervention point level registers and/or rapid testing logbooks to determine if the

algorithm was conducted correctly for each patient/client. Count the number of HIV-positive entries that are compliant with the national testing algorithm. In the response column, enter the percent of entries that are compliant with the national algorithm:

> What percent these entries are compliant with the national testing algorithm?
>
> ***Numerator**: ____number of reviewed entries that were fully compliant with the national testing algorithm.*
> ***Denominator**: ____number of reviewed entries within the past 12 months where the final HIV test result was HIV positive in the HTS register/rapid testing logbook*

- *Remote Eligible:* Yes Conditional
- *Required:* No

S_07_02 Quality Assurance of HIV Testing Services: WHO standard (2019 HTS Consolidated Guidelines): Any program considering the expansion of HIV Testing Services (HTS), including site-based testing (laboratories, clinical facilities), community-based testing and testing conducted at point of care should have the following elements in place:

1) a national HIV testing policy that is regularly updated and linked to the national laboratory policy and strategic plan
2) access to quality-assured in vitro diagnostics with adequate pre-market and post-market regulatory controls
3) validated national testing algorithm(s) with back-up options in accordance with the appropriate WHO-recommended testing strategy
4) quality management systems for all HIV testing, irrespective of where testing takes place
5) adequate training and supportive supervision of HIV testing providers, with requirement for certification
6) accreditation (or registration/certification) of testing sites, where applicable
7) accurate forecasting and therefore quantification, with procurement systems in place to avoid stock-outs of test kits and critical consumables.

HTS site/intervention points should a) use a rapid testing logbook or incorporate key variables into an HTS register to track test performance, b) have a focal person who conducts routine direct observation of HTS counseling sessions, and c) have a feedback loop for both the quality of testing and quality of counseling.

This CEE includes **document review** and assesses whether quality assurance procedures are in place to monitor the quality of HIV rapid testing through oversight by a manager or laboratorian. This person must observe and document each tester conducting a HIV rapid test at least once a year, review the logbook at least monthly, and review assurance variables at least quarterly.

- *Remote Eligible:* Yes
- *Required:* No

S_07_03 HTS Linkage to HIV Care and Treatment at the Site Level: Effective linkage of HIV-positive clients to HIV-related clinical services is critical to minimize HIV-related morbidity and mortality as well as transmission to uninfected partner(s). HTS sites should have interventions to facilitate linkage of HIV-positive clients into HIV care and treatment services including procedures or systems for tracking HIV-positive clients, and for following-up with those who have not linked to care and treatment. According to the WHO, the success of linkage should be measured by enrolment in care and not by intermediary process indicators such as the

number of referral cards issued. Tracking systems should be established to monitor and evaluate the success of linkage to care approaches and identify areas for improvement.

This CEE assesses whether all sites that provide HTS have a standardized system for tracking successful referrals of HIV-infected beneficiaries/clients to HIV care and treatment services. This CEE contains a **document review** for forms, vouchers, and SOPs for facilitating linkage to care, as well as tracking forms and logbooks. This CEE also includes a **register review.** Q4 requires the assessor to review 10 clients identified as HIV positive within the last 3 months from the HTS register to determine the percentage of HIV positive clients who were successfully linked to treatment services. In the Response column, indicate the percentage of clients that were successfully linked to treatment.

***Numerator**: ___number of reviewed records of clients who were successfully linked to treatment and returned for their next appointment (i.e., the site knows the client or beneficiary was successfully initiated on ART and engaged early int treatment)*

***Denominator**: ____number of reviewed files of clients who identified as HIV positive within the last 3 months*

- *Remote Eligible:* Yes Conditional
- *Required:* No

S_07_04 Site Level HIV Proficiency Testing: WHO standard (2019 HTS Consolidated Guidelines): At the country level the national reference laboratory, with mandate from the ministry of health, should plan and implement a variety of quality assurance activities to monitor and improve the quality of testing. These activities may be decentralized at the provincial or district level depending on the scope of the activities. These activities include promoting the use of standardized logbooks or registers, implementing external quality assurance (EQA) schemes, extraction and analysis of EQA data and implementation of corrective actions. These key activities should be systematically planned and implemented to maximize their impact on the accuracy of HIV testing.

This CEE assesses whether the site participates in (and passes) HIV proficiency testing (where proficiency testing is part of the national guidelines) via a **document review**.

For Q2, calculate the percentage of HTS providers at the site that completed and submitted proficiency testing panels in the last 12 months. If proficiency testing is not part of the national guidelines for HTS, check NA, and SKIP this CEE. Q2 calculate the percentage:

***Numerator**: _____# of reviewed records of HTS providers who completed and submitted proficiency testing panels in the last 12 months*

***Denominator**: _____# of reviewed records of HTS providers who received a proficiency testing panel in the last 12 months*

Example proficiency test panel

- *Remote Eligible:* Yes
- *Required:* No

S_07_05 HTS Safety Measures at the Site: It is critical to guard against harm to any client, HIV testing provider or other person at the testing site. This means that a safe working environment must be maintained by and for all staff, with necessary procedures in place. These procedures include universal precautions (assuming that all specimens are potentially infectious), prevention of and/or response to needle-stick injuries or other occupational exposures, chemical and biological safety, spill containment, waste disposal and use of personal protective equipment.

This CEE assesses whether each site ensures that appropriate safety measures are in place at all HTS service delivery points, and whether there is oversight and training for HTS safety measures. These measures include use of disposable gloves, personal hygiene, and proper waste management. Q1 contains a **visual inspection** that safety measures are in place and being used by all testing providers. Q2 requires confirmation that a supervisor or manager has visited the site within the last six months to document implementation of HTS safety measures, and Q3 assesses if all HIV testing providers have received appropriate training on HTS safety measures, including waste management.

- *Remote Eligible:* Yes
- *Required:* No

S_07_06 Confidentiality of HIV Testing Services at the Site: All HTS must be conducted in accordance with WHO's 5 Cs (consent, counseling, confidentiality, correct test results, and connection to appropriate HIV prevention and treatment services). Lack of confidentiality discourages people from using HIV testing services (HTS). HTS must be confidential, meaning that what the provider and the client discuss will not be disclosed to anyone else without the expressed consent of the person, couple, or family being tested. Shared confidentiality with a partner or family members – trusted others – and healthcare providers is often highly beneficial. Counsellors should discuss whom the person may wish to inform and how they would like this to be done. HTS should avoid practices that can inadvertently reveal a client's test results, or HIV status, to others where testing is conducted. Such practices might include counselling all people diagnosed HIV-positive in a special room or by a specific provider or lengthy post-test counselling offered only to clients diagnosed as HIV seropositive.

This CEE assesses whether HIV testing services at the site are provided in a manner that protects the privacy and confidentiality of the beneficiary/client and if reporting systems are in place for beneficiaries/clients to make anonymous report violations. Information discussed during the HTS session should not be disclosed to anyone else without the expressed consent of the person, couple, or family being tested.

Q1 includes confirmation that all HTS staff have received training on the importance of maintaining privacy and confidentiality. Q2 contains a **visual inspection** that testing is conducted in a space that protects the privacy of the beneficiary/client (i.e., where others cannot overhear). Q3 assesses if the beneficiary/client is aware of how violations of privacy or confidentiality can be reported anonymously.

- *Remote Eligible:* Yes
- *Required:* No

S_07_07 HIV Self-Testing: As of 2021, across PEPFAR-supported countries, there were an estimated 5.7 million people living with HIV and who are not on ART (COP22 Guidance, Section 2.3.1. Therefore, countries are looking for ways to rapidly increase uptake of and decentralize HIV testing services, especially for hard(er)-to-reach populations. One approach is HIV self-testing (HIVST), where a person receives an HIV self-testing kit to collect his or her own specimen (oral fluid or blood) and then performs the HIV self-test and interprets the

result. HIV self-testing is a screening test and requires self-testers with a reactive (preliminary positive) result to receive further testing from a trained provider using a validated national testing algorithm. WHO recommends HIVST to be offered as an additional approach to HIV testing services.

This CEE assesses the distribution and use of HIV self-test kits, and whether HTS providers are documenting in a HTS register or logbook if a client is presenting for confirmatory HIV testing services due to prior use of an HIV self-test. If HIV self-testing is not part of the national HIV Testing Services guidelines, check NA and skip this CEE.

Q1 includes a **document review** to determine if there is a standardized protocol for assessing reason for HIV testing and if HIVST is included in the reasons for testing). Q2 requires the assessor to review the register or logbook to determine if reason for seeking an HIV test on the date of service includes the option of confirmatory HIV test after HIVST

- *Remote Eligible:* Yes
- *Required:*  MPR Required

S_07_08 Index Testing Training & Supportive Supervision: PEPFAR remains committed to implementing safe and ethical index testing services.

This CEE assesses whether staff providing index testing services have been trained using a standardized national training curriculum that covers WHO's 5Cs (consent, confidentiality, counseling, correct test results, and connection to treatment and/or prevention services).

Q1-Q3 include a **document review.** Specifically, Q1 assesses if all staff who provide index testing services have been trained according to a standardized, national training curriculum that covers WHO's 5Cs and minimum standards for index testing, including intimate partner violence. Q2 and Q3, respectively, assess for the presence of standardized materials to conduct supportive supervisory visits and if supportive supervisory visit feedback is documented and shared with staff.

- *Remote Eligible:* Yes
- *Required:*  MPR Required

S_07_09 Monitoring Adverse Events from Index Testing: This CEE assesses whether PEPFAR supported index testing services have procedures and processes in place to assess, mitigate and reduce potential risk for social harm or impact arising from. partner notification.

Q2 and Q3 include **register/chart and document review** to determine if reports of social harm following index testing services have been documented in the client charts or index testing register and to visualize the SOP for investigating social harms following index testing services.

- *Remote Eligible:* Yes
- *Required:*  MPR Required

S_07_10 Secure Handling & Storage of Index Testing Data: This CEE assess whether the site retains accurate, complete, and updated index testing records in a secure location and maintains a shared confidentiality agreement with any outside organization that assists with the testing of sex partner(s), needle-sharing partners, and biological child(ren) of index clients.

For Q1 the assessor will need to visualize the space where index testing records/registers are stored to ensure the files are kept in a secure and confidential manner. Q2 and Q3 include a **document review** including review of confidentiality agreements and SOPs.

- *Remote Eligible:* Yes
- *Required:*  MPR Required

S_07_11 Intimate Partner Violence Risk Assessment and Support for Index Testing: This CEE assesses whether sites offering index testing services have an appropriate system in place for testing service providers to identify and respond to clients who disclose their fear of or experience with Intimate Partner Violence (IPV) from (a) named partner(s).

Q1 assesses how a site implements and records IPV assessments.

Q2 includes a **document review** of a SOP to assess for and address reports of IPV as part of the provision of index testing services. The SOP should outline the roles/responsibilities of site staff. For example, the testing provider will assess for intimate partner violence (IPV) for each named partner during the recall period. If a client discloses violence, the testing provider provides immediate psychosocial support, conducts an immediate safety check, and does not pursue notification methods for the IPV involved partner(s), but may continue with other partner(s). The provider then may refer to another staff member for referrals and follow up to other services, as well as document the client's experience in their medical chart as IPV-related support should be addressed in their care and treatment plan. The SOPs outline these roles, so it is clear for everyone at the site

- *Remote Eligible:* Yes
- *Required:*  MPR Required

S_07_12 Supporting Clients who Disclose Intimate Partner Violence: This CEE assesses if sites that offer index testing services have an appropriate system in place for HTS providers to respond to and support clients who disclose their fear of or experience with intimate partner violence from a (a) named partner(s).

Q1 assesses if index testing providers have been trained on how to assess and respond to concerns/reports of IPV. Q2 specifically assesses if index testing providers are offering first-line support to clients who disclose violence.

- *Remote Eligible:* Yes
- *Required:*  MPR Required

S_07_13 HTS Linkage to Quality Prevention Services: UNAIDS call for "95% of people at risk of HIV infection [to] use appropriate, prioritized, person-centered and effective combination prevention options by 2025" (UNAIDS. (2021). 2025 AIDS TARGETS. https://aidstargets2025.unaids.org/). HIV testing services (HTS) directly contribute to HIV prevention outcomes when individuals with a seronegative HIV status are offered appropriate HIV prevention services and linking individuals who test HIV negative to person-centered prevention services is essential. HTS can also be a valuable tool to monitor and refine prevention programming.

This CEE assesses that HTS sites have a standardized protocol or process for linking adults and adolescents who test HIV seronegative to high quality HIV prevention services for which they are eligible. Q1 confirms the presence of a documented and systematic process to proactive offer and link individuals who test HIV seronegative to high quality, person-centered HIV prevention services. Q2 assesses if all site staff are routinely trained on offering and providing HIV prevention services to clients who are HIV seronegative.

- *Remote Eligible:* Yes
- *Required:*  MPR Required

Additional Resources for Set 7:

WHO. (October 2014). *WHO Information Note: Reminder to retest all newly diagnosed HIV-positive individuals in accordance with WHO recommendations*. http://www.who.int/hiv/pub/vct/retest-newly-diagnosed-plhiv-full/en/

WHO (2016) *HIVST and Partner Notification Guidelines*. http://www.who.int/hiv/pub/vct/hiv-self-testing-guidelines/en/

WHO (2019) *Consolidated Guidelines on HIV Testing Services.* https://www.who.int/publications/i/item/978-92-4-155058-1PEPFAR (July 2020) *Guidance on Implementing Safe and Ethical Index Testing Services*.

https://www.pepfarsolutions.org/resourcesandtools-2/2020/7/10/pepfar-guidance-on-implementing-safe-and-ethical-index-testing-services

SET 8: TB TREATMENT SERVICE POINT				
CEE #	*Abbreviated Title*	*Required (MPR)*	*Supportive*	*Remote*
S_08_01	Routine PITC for Clients with TB or Presumptive TB		X	No
S_08_02	ART Provision for PLHIV with TB		X	No

SET INSTRUCTIONS: The following CEEs are assessed at sites where TB treatment is the entry point for clients receiving HIV services and where these HIV services are PEPFAR supported.

SET 8: TB TREATMENT SERVICE POINT

Set Overview: Set 8 contains two CEEs and should be assessed at facilities where TB treatment is the entry point for clients (adults and children) and PEPFAR supports HIV testing and/or ART provision for those clients. The CEEs assess PITC for TB patients entering TB treatment and ART provision for TB clients co-infected with HIV. The TB clinic register is the primary source of review for this set.

SET 8 TECHNICAL BACKGROUND

Tuberculosis (TB) is the leading cause of mortality among people living with HIV (PLHIV) in high-burden countries. Implementation and scale-up of collaborative TB/HIV activities in countries with high TB and HIV burden is essential to achieve HIV epidemic control and meet UNAIDS 90-90-90 targets. Strategic interventions to accomplish this goal include

- Provider-initiated HIV testing for all TB clients and suspects
- Provision of ART to all HIV-positive TB clients
- Intensified TB case finding among PLHIV
- Scale-up of rapid TB diagnostics, including Xpert® MTB/RIF
- Provision of Isoniazid Preventive Therapy to PLHIV without active TB
- Implementation of TB infection control measures
- Integrated TB and HIV service delivery
- Monitoring and Evaluation of TB/HIV activities.

S_08_01 Routine PITC for Clients with TB or Presumptive TB: Provider-initiated testing and counseling (PITC) is aimed at identifying unrecognized HIV infection in persons presenting for care at health facilities. As TB clients and TB suspects may have undiagnosed HIV infection, WHO recommends provider-initiated HIV counseling and testing for all TB clients, and provision of antiretroviral therapy for all HIV-infected TB clients.

This CEE assesses if routine provider-initiated testing and counseling (PITC) is provided to all TB clients. This CEE should be assessed at sites where TB treatment is the entry point for clients receiving HIV services and where these HIV services are PEPFAR supported. This CEE requires the assessor to select the ONE option to indicate the age bracket of the clients served by the site. This CEE has a **register review component.** For Q2 the assessor will need to look through the TB registers for documentation of HIV status among TB clients newly registered in clinic.

- *Remote Eligible:* No
- *Required:* No

S_08_02 ART Provision for PLHIV with Active or Presumptive TB : As there is a survival benefit for HIV-infected clients with TB from early initiation of ART, WHO recommends that all HIV-positive TB clients receive ART within 8 weeks of TB treatment and all HIV-positive TB clients with profound immunosuppression (CD4 <50) should receive ART within the first 2 weeks of initiating TB treatment.

This is CEE assesses whether all TB clients diagnosed with HIV are initiated on ART, regardless of CD4 count. This CEE has a **register review component.** For Q2, the assessor should look through the TB register for documentation of ART initiation among TB clients diagnosed with HIV Review the register of clients diagnosed with HIV 3-12 months prior to the SIMS visit. This allows time for ART initiation after start of TB treatment. If no HIV-infected individuals are found in the specified period, enter '100%' for the response.

For Q2, calculate the percentage of PLHIV with active or presumptive TB reviewed have documentation of ART initiation.

- *Remote Eligible:* No
- *Required:* No

SET 9: METHADONE OR BUPRENORPHINE MEDICATION ASSISTED TREATMENT (MAT)				
CEE #	*Abbreviated Title*	*Required (MPR)*	*Supportive*	*Remote*
S_09_01	Intake Treatment Plan Development		X	No
S_09_02	TB screening and Management in MAT Facilities		X	No
S_09_03	Dose Reduction and Termination		X	Yes
S_09_04	HIV Testing		X	No
S_09_05	Supply Chain Reliability (methadone and buprenorphine)		X	Yes

SET 9: METHADONE OR BUPRENORPHINE MEDICATION ASSISTED TREATMENT (MAT)

Set Overview: Set 9 covers key quality domains of an MAT site and applies to both buprenorphine and methadone programs. This set assesses eight CEEs on client intake practices, stabilization, dose reduction and termination, HIV testing and supply chain reliability. The majority of these CEEs require chart review; see **Appendix A** for the Set 9 **Chart review worksheet**.

SET 9 TECHNICAL BACKGROUND

S_09_01 Intake Treatment Plan Development: Intake assessment is the initial assessment a client undergoes *prior* to initiating methadone or buprenorphine. It can include: medical history related to opioid dependence, health and psycho-social examination and assessment, diagnosis of opioid dependence, and laboratory testing. The purpose is to identify a client's clinical status and level of opioid dependence, co-morbidities, psychosocial factors that may influence the treatment process, and any urgent physical and psychosocial issues that need addressing**.**

- **Opioid dependence:** a medical condition that is characterized by the compulsive use of opioids (morphine, heroin, codeine, etc.) in spite of consequences of continued use and the withdrawal syndrome that occurs when opioid use stops.
- **Treatment plan:** A treatment plan should be individualized to the client and should identify the level and extent of services needed, clarify the involvement of health staff and supportive systems for the client, and describe needed linkages to other services and support.

This is a CEE that includes **document review** and assesses if an intake treatment plan is developed for every client to reflect the physical and mental health, and social needs as identified by the intake assessment. S_09_01 has a **chart review component.** For Q3 the assessor will review the charts of 10 clients who started MAT within the past 12 months and determine the percentage of charts that document treatment plans. The same charts can be used for S_09_01, S_09_02, and S_09_04. The results from chart reviews can be documented in the relevant Chart Review Worksheet and then transferred to the assessment tool.

- *Remote Eligible:* No
- *Required:* No

S_09_02 TB screening and Management in MAT Facilities: Drug use is associated with increased rates of tuberculosis (TB) disease and infection. HIV positive injecting drug users are at greater risk of TB infection and disease, compared with other HIV positive individuals and tuberculosis is one of the common AIDS-defining conditions and the leading cause of death among people living with HIV.

This CEE that includes **document review** and assesses if sites providing MAT have a protocol for performing and documenting screening for active tuberculosis (TB) on intake and at each clinical visit. The screen reviews all 4 of the following symptoms: cough, fever, night sweats, and weight loss. MAT clients with TB have access to TB treatment either onsite or through referral. S_09_02 has a **chart review component.** For Q3 the assessor reviews 10 charts of clients who started MAT within the past 12 months (the same charts can be used for S_09_01, S_09_02 and S_09_04) and determine what percent of reviewed charts document TB screening results at the last clinical visit.

- *Remote Eligible:* No
- *Required:* No

S_09_03 Dose Reduction and Termination: Clients leave treatment abruptly for a variety of non-therapeutic reasons due to incarceration, hospitalization, transportation reasons, etc. Other clients may be involuntarily tapered because of behavioral issues affecting staff and/or clients. The physician's role is to weigh the risks and benefits for the client remaining in treatment vs. involuntary discharge.

A smaller number of clients request MAT tapering and discharge. Clients should be advised that few are able to maintain abstinence after tapering off MAT and reminded that a successful outcome of the attempt at tapering is ongoing, sustained abstinence from opioid use, whether the client is able to discontinue MAT or not. A successful taper is one that does not destabilize the client, which may mean proceeding very slowly or stopping and restarting the taper as needed to control symptoms of withdrawal or craving. Clients should be closely monitored for symptoms of withdrawal and signs of destabilization. A comfortable taper will rarely take less than six to eight weeks and will more often take months to years. When developing a taper schedule, it is helpful to remember **that clients are generally able to discern a difference when the dose is adjusted by ten percent.** For this reason, a taper will be more comfortable to the client if the taper rate is based **on percent of dose**, rather than number of milligrams.

This CEE assesses whether clients who decide to voluntarily discontinue MAT are guided by the clinical staff through standardized tapering and termination procedures over several weeks. A decreasing dosage schedule should be agreed upon by the clinician and client and monitored over time.

- *Remote Eligible:* Yes
- *Required:* No

S_09_04 HIV Testing: Some country guidelines recommend more frequent HIV testing than 12 months; ensure MoH re-testing guidelines for persons who inject drugs are followed. The key is to ensure HIV testing is voluntary and not conditional to receiving methadone or buprenorphine. Clients should never be discharged or refused MAT service in the event a client refuses an HIV test

This is a CEE that assesses whether all MAT clients are offered voluntary HIV testing during client intake assessment. HIV uninfected clients are offered voluntary retesting at least every 12 months**.** Q2 has a **chart review component;** the assessor should review 1- chart of clients who have been on MAT ≥12 months, and determine what percent of reviewed charts document HIV testing within the last 12 months (either from MAT site or from other site).

- *Remote Eligible:* No
- *Required:* No

S_09_05 Supply Chain Reliability (methadone and buprenorphine): When supply of methadone and buprenorphine is interrupted or insufficient to treat clients at therapeutic levels, a variety of negative consequences can occur. These may be the inability to enroll new clients, under-medicating current clients, and/or early involuntary discharge. A quality supply chain system will identify early on, potential stock interruptions so that a contingency plan can be enacted.

This CEE includes **document review** and assesses if the site has a reliable supply of methadone and buprenorphine.

- *Remote Eligible:* Yes
- *Required:* No

SET 10: LABORATORY				
CEE #	*Abbreviated Title*	*Required (MPR)*	*Supportive*	*Remote*
S_10_01	Quality Management Systems		X	Yes
S_10_02	Laboratory Biosafety		X	Yes
S_10_03	Test SOP		X	Yes
S_10_04	Quality Testing Monitoring		X	Yes
S_10_05	Testing Interruptions		X	Yes
S_10_06	Waste Management		X	Yes
S_10_07	Injection Safety		X	Yes
S_10_08	HIV Viral Load Laboratory Capacity		X	Yes
S_10_09	HIV Viral Load Specimen Referral and Results Management		X	Yes

SET 10: LABORATORY

Set Overview: PEPFAR programs depend on laboratories to provide quality diagnostic testing to meet PEPFAR goals for prevention, treatment, and care of HIV-infected persons, so it is critical that the laboratory is capable of delivering test results that are accurate and reliable

Set 10 applies to laboratories defined by the following:

A. Having dedicated physical laboratory infrastructure
B. Having dedicated laboratory personnel
C. Conducting one or more of the core HIV-related tests

Set 10 applies to laboratories performing any of the following HIV-related tests: HIV viral load, HIV diagnostics (including rapid tests, EID, EIA, and Western blots), recency tests, TB diagnostics (including Xpert, AFB microscopy, and TB cultures), CD4, and HIV drug resistance.

The two CEEs in Set 10, S_10_08 and S_10_09 apply only to laboratories involved in referring or testing HIV viral load specimens.

The Laboratory CEEs in Set 10 do not apply to point of care testing (POCT) sites or HTs sites in which testing is performed near client and outside of the physical laboratory infrastructure

Set 10 TECHNICAL BACKGROUND

S_10_01 Quality Management Systems: This CEE is an indication of the status of a laboratory Quality Management System (QMS) and commitment to continual quality improvement and**/or accreditation.** Quality Management System (QMS) has elements to ensure the quality and reliability of the test results. The QMS must encompass all management activities and processes relating to quality assurance. QMS elements can be categorized into twelve quality system essentials:

1) Organization
2) Personnel
3) Equipment
4) Purchasing and inventory
5) Process control
6) Documents and records
7) Information management

8) Investigation of non-conformities
9) Assessment
10) Process improvement
11) Service and satisfaction
12) Facilities and safety

QMS Program: A program that provides tools, mentorship, or trainings to strengthen a laboratory QMS. Examples include:

- SLMTA: Strengthening Laboratory Management Toward Accreditation
- SLIPTA: Stepwise Laboratory Improvement Process Toward Accreditation
- GLI Tool: Global Laboratory Initiative Stepwise Process Toward TB Laboratory Accreditation
- LQMS: Laboratory Quality Management Systems

Clinical Laboratory Accrediting Agencies: International or national organizations which assess laboratories according to a standardized set of criteria and give formal recognition that the laboratory is competent to carry out clinical laboratory testing. Examples include:

- ISO: International Standards Organization
- CAP: College of American Pathologist
- SANAS: South African National Accrediting Scheme
- KENAS: Kenya National Accrediting Scheme

This CEE includes **document review** and assesses three of the quality system essentials: personnel, equipment, and purchasing and inventory. As part of a QMS, each laboratory must:

- Provide and documents routine (e.g., annual) personnel training
- Perform and documents routine (e.g., daily) equipment maintenance
- Have an inventory control system for supplies and reagents

This CEE assess if the site laboratory has documentation of accreditation by international laboratory quality standards (e.g., ISO 15189, SANAS, CAP, KENAS) and/or is implementing a QMS program working towards continuous quality improvement.

- *Remote Eligible:* Yes
- *Required:* No

S_10_02 Laboratory Biosafety: Safety also is assessed in laboratories by applying the waste management CEE S_10_06. Safety procedures and precautions are designed to protect laboratory staff, maintenance and other site staff, the client, and the community. This CEE is designed to ensure that the laboratory has the supplies and training to safely conduct testing and dispose of biohazardous waste.

- **Personal Protective Equipment (PPE):** Items worn to protective the staff from infectious materials and hazardous materials (e.g., gloves and lab coats).
- **Biohazard waste:** Waste that has the potential to expose individuals or the environment to infectious agents (e.g., blood tube, needles, testing cartridges, gloves, slides, pipette tips, etc.).

- **Biohazard waste containers:** Clearly marked bins (large or small) for biohazard waste that may also contain a biohazard bag.
- **Sharps containers:** Clearly marked hard-sided containers for biohazard objects such as needle, capillary tubes, scalpels, etc.

This CEE is assessed at laboratories as defined in the Set 10 overview. Assess this elective CEE to address any safety issues that arise before or during a SIMS site visit.

This CEE includes **document review** and assesses if the site laboratory has a biosafety program that is fully implemented and includes the following elements:

- Availability and proper use of Personal Protective Equipment (PPE) and waste containers
- Training on biosafety for laboratory personnel
- Laboratory biosafety SOPs and/or biosafety manual

Before entering the laboratory testing areas, ask the laboratory staff about any safety practices you, as an assessor, need to observe. For Q1, visually inspect the laboratory testing areas to observe if the indicated safety supplies are available in all testing areas. For Q2, biosafety SOPs or manuals must be current and readily available to laboratory personnel. For Q3, ask which laboratory staff conduct core HIV-related testing. Review biosafety training records for at least 2 of these staff members.

- *Remote Eligible:* Yes
- *Required:* No

S_10_03 Test SOPs: Standard operating procedures (SOPs) are critical for maintaining consistent testing performance and reducing errors associated with variation in the testing. Each laboratory must have up-to-date and practical SOPs for all laboratory activities to ensure the consistency, quality, and integrity of the generated results. To maintain the quality of testing, current SOPs must be readily available in the work areas, accessible to all testing personnel, and strictly followed. Laboratory managers, supervisors, and testing personnel must understand and review the SOPs annually.

- **Standard Operating Procedure (SOP):** Documents that specify all of the steps involved in conducting a specific procedure or test.
- **Job Aide:** Documents taken from a SOP to provide a quick aide on specific steps of the procedure.

This elective CEE includes **document review** and assesses if a laboratory has current and accessible SOPs for all core HIV-related tests, as define in the Set 10 overview, performed at the laboratory. For Q1 of this CEE, a written SOP for each core HIV-related test performed at the laboratory must be provided. Note that HIV-related tests include those listed in the MER LAB_PTCQI indicator (HIV serology diagnosis (Rapid Test, ELISA, and Western Blot), Recency Testing, HIV Viral Load, Early Infant Diagnosis (EID), CD4, TB Diagnosis: Xpert, AFB, and/or culture. The SOPS should be located at site of testing at the time of the assessment. For Q2, Assessors should review if the SOP is current (usually meaning approved or review by laboratory management within the last two years) and ask about the review process for approving or revising SOPs.

- *Remote Eligible:* Yes
- *Required:* No

S_10_04 Quality Testing Monitoring: Monitoring the quality of the laboratory testing is important to ensure accurate and reliable results and is a responsibility of laboratory staff and management. Performing and monitoring QC testing can identify abnormal trends and problems with the instruments or reagents so that the problems can be addressed or corrected as soon as possible. Proficiency Testing (PT)/External Quality Assessment (EQA) programs provide a means to monitor the quality of test results for a number of laboratories.

- **Quality Control (QC):** Materials with known result values that are used to monitor the quality of the testing system on the day of testing.
- **Proficiency Testing (PT):** Involves sending identical specimen or panel of specimens to each enrolled laboratory à laboratory tests PT panel à Result returned to PT provider for analysis and scoring à Scores and feedback provided to laboratory à Corrective action if needed.

This CEE include **document review** and assesses if a laboratory monitors the quality for of testing for all core HIV-related tests, as define in the Set 10 overview, performed at the laboratory. The CEE assesses if the site laboratory performs and monitors routine quality control (QC) testing on all core HIV-related tests and whether the site laboratory participates in proficiency testing (PT) or external quality assessment (EQA) programs for all core HIV-related tests that they perform. PT/EQA results and feedback should be available onsite.

- *Remote Eligible:* Yes
- *Required:* No

S_10_05 Testing Interruptions: Optimal client care depends on having laboratory results readily available and in time to make an informed medical decision. When laboratory testing is interrupted, laboratory results either will be unavailable or delayed for client care. To ensure reliable laboratory results, reagents and supplies must be available at all times and within their expiration date, and all equipment must be functional, the testing environment adequate for testing, and the staff available to perform testing

This CEE assesses if a laboratory can provide reliable results for all core HIV-related tests, as defined in the Set 10 overview, performed at the laboratory. The CEE assesses if the site laboratory provides continuous and reliable services. There should be minimal to no testing interruptions as a result of any of the following: a) Supply or reagent stock outs b) Expired supplies or reagents c) Equipment failures d) Staff shortages and e) Infrastructure issues.

- *Remote Eligible:* Yes
- *Required:* No

S_10_06 Waste Management: This CEE is assessed at laboratories as defined in the Set 10 overview. Assess this elective CEE to address any waste management issues that arise before or during a SIMS site visit. Safety also is assessed in laboratories by applying the waste management CEE S_10_02. Appropriate healthcare waste management is essential to prevent exposure and harm to healthcare workers, clients, and the public. Types of healthcare waste:

- **Common Waste:** Waste that does not pose any biological, chemical, radioactive or physical hazard
- **Infectious Waste:** Waste suspected of containing pathogens and that poses a risk of disease transmission, this includes:

- **Sharps:** Used or unused sharps (e.g., needles, hypodermic needles, auto-disable syringes, infusion sets, scalpels, pipettes, knives, blades, broken glass)
- **Pathological Waste**: Human tissues or fluids (e.g., body parts, organs, blood and other body fluids)

This CEE assess if the laboratory is implementing approved procedures for collection, storage, and disposal of infectious waste to prevent exposures to workers, clients, and the public. These procedures include segregation of infectious waste, posted waste disposal guidance, and secure storage of infectious waste outside the site. Like TB infected control, this CEE should be assessed at all areas of the laboratory and the score from the lowest scoring area should be reported. See S_01_06 Waste Management in Set 1A for additional information.

- *Remote Eligible:* Yes
- *Required:* No

S_10_07 Injection Safety: This CEE is assessed at laboratory that also provide phlebotomy services. Safe injection practices and equipment/supplies such as gloves and sharps containers are essential to reduce the risk of blood borne pathogen exposure to clients and healthcare workers. See S_01_07 Injection Safety in Set 1A for additional information.

- *Remote Eligible:* Yes
- *Required:* No

S_10_08 HIV Viral Load Laboratory Capacity: This CEE is for all laboratories that test for HIV viral load. These are laboratories with instruments, personnel, and infrastructure to test for the quantification of the HIV virus in blood specimens.

This CEE includes **document review** and assesses whether HIV viral load testing laboratory has the capacity and systems to meet the testing demands for HIV viral load scale-up.

Q1 assesses if the laboratory has the necessary capacity to meet the demands of HIV viral scale-up for all the clinical sites which the laboratory services. Assessors should determine the expected HIV viral load testing demand for the clinical sites serviced by the laboratory. Assessors should determine if the laboratory has sufficient capacity to meet the demand in regarding:

· Personnel to perform testing

· Testing instruments (e.g., Roche, Abbott, Hologic, and/or GeneXpert instruments) and ancillary equipment

· Laboratory infrastructure to perform HIV viral load testing

· Keeping up with demand (i.e., no backlog of specimens).

Ask laboratory management and personnel about HIV viral load testing workloads and any issues or needs to meeting the demands of testing. Assessor should determine if the capacity of all the HIV viral load instruments in the laboratory is capable of meeting the expected HIV viral load scale-up demands. Determine if laboratory space is sufficient for all testing needs including specimen handling and results management, and storage of specimen and testing reagents and supplies. Assessors should determine if the HIV viral load testing backlog is minimal by reviewing specimen and result reporting logs or information obtain from laboratory personnel.

Q2 assesses if the laboratory has the necessary systems in place to meet the demands of HIV viral scale-up for all the clinical sites which the laboratory services.

- Assessors should determine if the HIV viral load testing laboratory has specimen transport and results reporting systems which are sufficient and reliable to meet the HIV viral load testing demands.
- Assessors should review the laboratory turn-around time for HIV viral load testing as defined as time from specimen received in the laboratory to time results reported. The standard is ≤ 14 days.
- Assessors should determine if systems are in place at the laboratory and clinical sites for notification of clients with non-suppressed HIV viral loads (e.g. ≥ 500 cp/m) as defined by country's guidelines.

  - *Remote Eligible:* Yes
  - *Required:* No

S_10_09 HIV Viral Load Specimen Referral and Results Management: This CEE is assessed at laboratories, as defined in the Set 10 overview, which offer referral services to laboratories that perform HIV viral load testing. Laboratories that do not perform HIV viral load testing, should have capacity and systems to handle referrals.

This CEE includes **document review** and assesses whether these laboratories have systems to accommodate referred specimen and handling results to ensure specimen integrity and achievement of established acceptable turnaround time for referral testing services.

- *Remote Eligible:* Yes
- *Required:* No

SIMS Site Level CEE Glossary

Appropriate use of cotrimoxazole: refers to prescription of cotrimoxazole to adults, children, and infants who deemed eligible/in need as per national guidelines. [Set 2A, 2B, 3B, 4A, 4B]

Advanced clinical disease: There are several characteristics that can define an advanced clinical disease. For HIV, having a CD4 count of <350 cells/mm^3, or CD4% <25% in children less than 5 years, or WHO Stage III/IV are the standard definitions. [Set 2B]

Adolescent: A person between the ages of 10-19 years (WHO definition). Younger adolescents are 10-14 years old; older adolescents are 15-19 years old. [Set 2B]

Adverse event rate: This is the calculation of the percentage of clients who had at least one moderate or severe AE. For post-operative AEs, the rate is determined by dividing the total number of clients who had at least one moderate or severe AE by the total number of VMMC clients who have returned for at least one post-operative follow-up visit within 14 days of VMMC surgery. Post-operative AE rates are generally around 2%; it is a concern if the AE rate is higher than this or if it is 0, as this would suggest poor reporting. [Set 5]

Algorithm: Refers to a defined combination of specific assays within a testing strategy. [Set 7]

ART Clients: clients that have enrolled in HIV care and have initiated ART. [Set 2A, Set 3B, Set 4A]

Biohazard waste: Waste generated in the laboratory that has the potential to expose individuals or the environment to infectious agents. (e.g., blood tube, testing cartridges, gloves, pipette tips, etc.) [Set 1A, Set 10]

Biohazard waste containers: Clearly marked bins (large or small) for biohazard waste that can contain a biohazard bag. [Set 1A, Set 10]

Case identification: The process of identifying undiagnosed HIV infections through testing. This represents the first 90 of the 90-90-90 strategy. [Set 2B]

Clinical Laboratory Accrediting Agencies: International or national organizations which assess laboratories according to a standardized set of criteria and give formal recognition that the laboratory is competent to carry out clinical laboratory testing. Examples of accrediting agencies include: ISO: International Standards Organization; CAP: College of American Pathologist; SANAS: South African National Accrediting Scheme; KENAS: Kenya National Accrediting Scheme. [Set 10]

Cotrimoxazole (CTX): an antibiotic that helps prevent and or treat certain opportunistic infections in PLHIV (e.g., Pneumocystis jiroveci pneumonia (PCP) (formerly Pneumocystis carinii pneumonia) and toxoplasmosis). Also known as Septrim, Bactrim, CTX, or sulfamethoxazole/trimethoprim. The drug is widely available in both syrup and solid formulations. [Set 1B, 2A, 2B, 3B, 4A, 4C]

Data quality assurance procedures: Assures that the five criteria for data quality are met; completeness, validity, consistency, timeliness and accuracy. These procedures (activities) are done by staff as part of routine data entry or reporting. Additionally, staff should take steps to address identified limitations and document, resolve and retain the assessment. [Set 1A]

Data reporting validation exercise: Includes the following: Periodically verify/validate data to ensure 'reasonable' quality in source data; Systematic verification of program source data and reported result which may be done by National or District Health Offices, Implementing Partners or PEFPAR Offices**;** Steps taken to address identified limitations**;** Document, resolve and retain the assessment. [Set 1A].

DATIM: Data for Accountability, Transparency, and Impact (DATIM) is a software system to simplify and streamline data collection and reporting at the field level for implementing partners and field-staff. Additionally, the tool allows for the improvement of data quality, program transparency and accountability. The system captures and manages MER program targets and results and SIMS. [Set 1A]

DNA PCR: Most common virologic test used for testing HEIs and performed on DBS. [Set 4C]

Economic empowerment referrals: In this context, referrals to entities that provide critical financial and non-financial support to individuals experiencing violence are included. Financial support can include programs to build the capacity of individuals to change their economic status, such as savings and loans programs and training on resource management. Non-financial support can include (but may not be limited to) assistance for individuals needing to leave their homes and vouchers for food, transportation, or services. [Set 6]

Eligible: referring to eligibility by national guidelines and also clinical appropriateness of CTX use See also 'Appropriate use of cotrimoxazole' above. [Set 2A, 2B, 3B, 4A, 4C]

Fixed-dose combination (FDC): Fixed-dose combinations of antiretrovirals are multiple antiretroviral drugs combined into a single pill, which helps reduce pill burden. They may combine different classes of antiretrovirals or contain only a single class [Set 2B]

HTS_TST: This is a PEFAR MER indicator and represents the number of individuals who received HIV Testing Services (HTS) services for HIV and received their test results. [Set 1A]

Informed consent: Written consent given by an adult for himself or by a guardian for a minor to receive VMMC, with full understanding of risks and benefits. [Set 5]

Job Aide: Document taken from a SOP to provide a quick aide on specific steps of the procedure. [Set10A, Set 11]

Job/position descriptions: A document that outlines an individual's scope of work within an organization and clarify staff roles and responsibilities. [Set 1A]

Key entry points: Areas of a facility where children are seen for a variety of medical issues. Testing children here will help in identifying those who are living with HIV and may be in need of treatment. [Set 2B]

Line list (epidemiologic context): A table that summarizes information about persons who may be associated with a particular disease or outbreak; in the SIMS example, the line listing refers to persons with suspected TB. In a typical line list, each row represents a single individual, and each column includes specific demographic, clinical, and diagnostic information (e.g., sputum microscopy results, Xpert results, etc.) [Set 2A, 3B, 4A]

Morbidity and mortality: The negative health symptoms or death that result from a particular illness. [Set 2B]

Opioid dependence: A medical condition that is characterized by the compulsive use of opioids (morphine, heroin, codeine, etc.) in spite of consequences of continued use and the withdrawal syndrome that occurs when opioid use stops. [Set 9]

Client tracking: A standardized process in which clients who have missed appointments or medication pick-ups are contacted to promote re-engagement in care and retention. Also called defaulter tracing, defaulter tracking. [Set 2A, Set 3B]

Personal Protective Equipment (PPE): Items worn to protective the staff from infectious materials and hazardous materials (e.g., gloves and lab coats). [Set 10]

Phlebotomy: The action of extracting blood from a client by venipuncture (needle into the vein of the client) or puncturing skin to extract capillary blood. [Set 1A, Set 10]

PMTCT B+: Prevention of Mother-To-Child Transmission (PMTCT) sites implementing lifelong antiretroviral therapy for all pregnant and breastfeeding women regardless of CD4 count (Option B+). [Set 2A, Set 3B, Set 4A]

PMTCT_STAT: This is a PEFAR MER indicator and represents the number of pregnant women with known HIV status (includes women who were tested for HIV and received their results). [Set 1A]

Post-operative follow-up visit: Describes the recommended visit that a VMMC client makes to the circumcising site for review and assessment after surgery. All VMMC clients are advised to return to the circumcising site two days and seven days after surgery, even if they have no complaints or complications. The nurses at the VMMC site conduct brief assessments of the circumcision wound to ensure that healing is progressing normally. [Set 5]

Post-operative adverse events: Describes complications that a VMMC client may experience after VMMC surgery. All adverse events (AEs) are graded according to severity (mild, moderate, or severe) and type (e.g., excessive bleeding, infection, wound disruption, etc.). All clinicians should have access to a guide or job aid with specific information about proper clinical management for each type and severity of AE. [Set 5]

Post-violence care services: Services include facility-based prophylactic and response services related to sexual, physical, and emotional health in response to sexual violence against children and adults, physical and emotional intimate partner violence, and physical and emotional violence against children. [Set 6]

Provider initiated testing and counseling (PITC): HIV testing that is offered/initiated by the healthcare provider (i.e., client does not request the test) [Set 4A]

Proficiency Testing (PT): Involves sending identical specimen or panel of specimens to each enrolled laboratory. The laboratory then tests the panel and returns results to the PT provider for analysis and scoring. Scores and feedback are returned to the laboratory which takes corrective actions if results are unsatisfactory. [Set 10]

Psychosocial: Refers to an individual's psychological development within a social environment (e.g. stressors a client faces – homelessness, family rejection). [Set 9]

Psychosocial support: Refers to resources that help individuals achieve life satisfaction, social participation and functioning, and psychological/personal growth. [Set 9]

QMS Program: A program that provides tools, mentorship, or trainings to strengthen a laboratory QMS. Examples of QMS programs include: SLMTA: Strengthening Laboratory Management Toward Accreditation; SLIPTA: Stepwise Laboratory Improvement Process Toward Accreditation; GLI Tool: Global Laboratory Initiative Stepwise Process Toward TB Laboratory Accreditation; LQMS: Laboratory Quality Management Systems. [Set 10]

Quality (in healthcare): Clients receive the care they need; Care is consistent with national guidelines; and the care delivered has the desired positive effect on health and well-being. [Set 1A]

Quality Assurance: Full cycle of activities and systems for maintaining the quality of client care. It is generally associated with the monitoring of compliance with standards.

Quality Assurance (QA): A range of planned activities that collectively provide confidence that the laboratory fulfills requirements for accurate and reliable testing. [Set 10]

Quality Control (QC): Materials that mimic specimens with known result values that are used to monitor the quality of the testing system on the day of testing. [Set 10]

Quality processes: Describes the procedures that each VMMC implementing partner abides by to ensure that the VMMC surgeries are performed safely and according to WHO guidance. [Set 5]

Quality Improvement (QI): The combined and unceasing efforts of everyone – healthcare professionals, clients and their families, researchers, payers, planners, and educators – to make the changes that will lead to better client outcomes (health), better system performance (care), and better professional development. [Set 1A]

Quality Management System (QMS): A system which encompasses all management activities and processes relating to quality assurance. [Set 10]

Regular: On a consistent basis, so that routine use and reporting can be accomplished. [Set 2A, Set 3B, Set 4A, 4B, 5]

Routine: Not episodically, but according to a set schedule such as weekly sign off, or monthly reporting. [Set 2A, Set 3B, Set 4B, 5]

SBI: Serious Bacterial Infections, such as meningitis. [Set 2B]

Sharps containers: Clearly marked hard-sided containers for biohazard objects such as needles, capillary tubes, scalpels, etc. [Set 1A, Set 10]

Standard Operating Procedure (SOP): Documents that specify all of the steps involved in conducting a specific procedure or test. [Set 10]

Stock-outs: When a commodity is not available at the site for a day or more. [Set 1B]

Syndromic management: A treatment approach relying on uniform treatment strategies to cover all likely pathogens responsible for various syndromes. Syndromes are a combination of self-reported symptoms and signs detected at physical examination. Most common syndromes are: Urethral discharge (UD) in men, Vaginal discharge (VD) in women, Lower abdominal pain (LAP) in women, and Genital ulcer disease (GUD) in both men and women. [Set 2A, 3A, 4A]

TB screening: Assessing if a client has any risks for having TB from a standard list of known risk factors. [Set 2A, 2B, 3B, 4A, 9]

TB diagnostic testing: Ascertaining if a person who has screened positive has TB disease confirmed by microbiologic testing. [Set 2A, 2B, 3B, 4A]

4-symptom TB screen (for children): A review of signs and symptoms of possible TB: cough, fever, weight loss and history of TB contact. [Set 2B]

Testing Algorithm: A schematic of testing which can define which client to test, when to test, what additional tests will be needed depending on the result of a previous test, and next steps in client care. [Set 7]

Testing Strategy: Refers to the sequence in which diagnostic tests are used for a specific objective, taking into consideration the presumed HIV prevalence in the population tested. [Set 7]

Treatment Failure: PLHIV receiving ART can develop resistance to their treatment. 3 types of treatment failure can occur as outlined by WHO: Clinical, Immunological, and Virological failure. [Set 2B]

TX_NEW: This is a PEFAR MER indicator and represents the number of adults and children newly enrolled on antiretroviral therapy (ART). [Set 1A]

Tuberculosis: An infectious bacterial disease characterized by the growth of nodules (tubercles) in the tissues, especially the lungs. The bacteria that cause TB are transmitted through the air. [Sets 1A, 2A, 2B, 3B, 4A, 8, 9]

Virologic test: Assays to detect viral nucleic acid (HIV DNA, RNA, or total nucleic acid). Currently, virological testing for early infant diagnosis (EID) is most commonly performed on dried blood spot (DBS) specimens, with collection at local sites which are transported to centralized laboratories for testing. [Set 4B]

VMMC_CIRC: This is a PEFAR MER indicator representing the number of males circumcised as part of the voluntary medical male circumcision (VMMC) for HIV prevention program. [Set 1A]

VMMC facility: Describes any location where VMMC is provided. It is often in an operating theater in a health clinic or hospital, but VMMC may be performed in a mobile tent, community health center, or another temporary location. Refer to the DATIM Site List for a list of sites where VMMC is offered. [Set 5]

VMMC services: Includes a combination of complementary clinical services that are provided in addition to the surgical excision of a male's foreskin. Specifically, these include offering HIV testing and counseling, excluding and treating males with symptoms of STIs, provision and promotion of male and female condoms, and counseling on risk reduction and safe sex. [Set 5]

Voluntarism: The state of freely making the decision to uptake VMMC, not resulting from coercion via pressure from others or an incentive unrelated to the procedure itself. [Set 5]

Youth or young people: A person between the ages of 10-24 (WHO definition). [Set 2B]