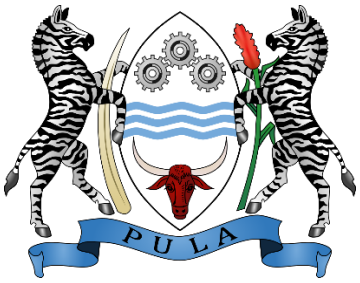
Standard Operating Procedures

Data Collection Plan for the Botswana HIV Case Based Surveillance Protocol



Republic of Botswana

MINISTRY OF HEALTH & WELLNESS

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Reviewed by: Akeem Ketlogetswe and Chris Serumola	**Current Version:** 1.0
Approved by: Penny Makuruetsa	**Effective Date:** 01/07/2021

Date of Development: July 2021
Updated: October 2021

1. TITLE

Data Collection Standard Operating Procedures for the Botswana HIV CBS Protocol

2. PURPOSE

2.1 Purpose

The purpose of this document is to define a comprehensive scope of processes and procedures that will be used in collecting data from HIV care facilities nationwide and through other sources to implement HIV case surveillance in Botswana. This will include the clarification of procedures and processes involved in the transmission of HIV case defining data and surrounding key events from the facility to the national data warehouse (NDW), a repository for medical and laboratory data. HIV case-based surveillance (CBS) consists of key events often referred to as sentinel events and include: new HIV diagnosis; initial CD4 count test result; ART initiation; initial and follow up viral load test results; opportunistic infections; new ART regimen (2nd and 3rd line); pregnancy status including outcomes; TB preventive treatment and tuberculosis infection and death.

2.2 Case Definitions

(1) A newly diagnosed HIV case:

An individual who has a confirmed diagnosis of HIV infection using the national testing algorithm according to a national HIV case definition (Appendix A for individuals aged ≥18 months, and Appendix F for children aged <18 months).

(2) Mother-to-child HIV transmission case:

a) Aged <5 years
b) Had a confirmed diagnosis of HIV infection using a national testing algorithm (Appendix E for individuals aged ≥18 months, and Appendix B for children aged <18 months); and
c) Their mother was HIV-positive during pregnancy or breastfeeding

(3) A TB case: An individual who meets the following criteria

a. Has a confirmed diagnosis of TB disease using a national clinical evaluation algorithm; or

b. Has a confirmed previous diagnosis of TB that was treated

3. USERS

3.1 This standard operating procedure is intended for use by all who have direct involvement in data collection, data transmission, data monitoring, data analysis and data dissemination during the lifetime of the case-based surveillance activities. This will include health facility staff (MOHW and Implementing partners), NDW officers (MOHW and Implementing partners), Monitoring & Evaluation officers (MOHW and Implementing partners), district focal persons, district IT persons, all CBS trainees (Master Trainers and District ToTs) and CBS TWG members.

3.2 Facility Level Staff

All health facility staff who play a part in caring for people living with HIV (PLHIV) at the facility level are required to adhere to and support the execution of the procedures delineated in this document. The following field staff must make every effort to document clinical events either in the electronic medical record (EMR) or on the CBS case report form (CRFs) and store all client records securely and confidentially:

3.2.1 *HCA/Lay Counselors/Nurse*

Provide HIV testing services, and collect and document results of the HIV test in either the Case Report Forms for Newly Diagnosed Persons Living with HIV Infection (Appendix A) or directly into DHIS-2 instance on a tablet, a computer, or in the EMRs used at the health facility. An HIV test resulting in a positive HIV diagnosis triggers a sequence of HIV care related activities. HIV diagnosis is the entry point into the HIV CBS. Capturing a newly diagnosed HIV case and all relevant information at diagnosis including demographic information is extremely important and should be correctly documented using the tools identified above. HCAs will also be involved in the Data Quality Improvement (DQI) processes as

will be described in the CBS Data Management SOP. Ensure all paper CRFs in the facility are correctly stored in a locked cabinet and packed in sealed envelopes before being transported to the mother facility or DHMT office for entry into DHIS-2.

3.2.2 *Data Clerks/Data Support Officers (DSOs)*

Capture all data into any EMR used by the facility or DHIS2 where, there is no EMR. Ensure all records have been captured in the relevant electronic system. Ensure completeness, accuracy, and timeliness of data collection and entry. Ensure all paper CRFs in the facility are correctly stored in a locked cabinet and packed in sealed envelopes before transportation to mother facility or DHMT office for entry into DHIS2.

3.3 District Level Staff

All District level staff who play a role in the implementation of the HIV CBS protocol are required to adhere to and support the execution of the procedures outlined in this document. The following district level staff must make every effort to store all study records securely and confidentially:

3.3.1 *District TOTs*

Responsible for the implementation of HIV CBS in the district. Trains facility staff on the HIV CBS protocol and documents. Develops a district specific implementation plan and monitors its implementation. Conducts district data review sessions and participates in data quality improvement processes for CBS data from the district.

3.3.2 *Community Health Nurses*

Responsible for district community health activities and coordinates such activities among the community partners. Must be aware of all community health programs such as HIV testing services (HTS), antiretroviral therapy (ART), prevention of mother to child transmission (PMTCT), etc. and report on these.

3.3.3 District M&E Officers

Provide supervision to DSOs and data clerks. Serve as the first stratum of oversight to ensure adherence to procedures delineated in this document. Collect paper CRFs from sites where EMRs are not available and ensure timely entry into DHIS-2 instance at either mother facility or at the district office. Communicates between the facility and the DHMT to resolve any data related issues. The district M&E officer is also part of the district TOT team.

3.3.4 DHMT Coordinators

DHMT coordinators will oversee the implementation of CBS in their districts. They will receive reports and be involved in the district data review sessions to ensure that the findings and actions improve HIV service provision in the district.

3.4 National Level Staff

MOHW program officers and technical partners involved in the implementation of the HIV CBS protocol will have the following roles to play in the implementation of the HIV CBS protocol.

3.4.1 CBS Master Trainers

Responsible for training district TOTs on the HIV CBS protocol and documents. Works with the district TOTs to develop the district specific implementation plan and monitors its implementation. Conducts district data review sessions and participates in data quality improvement processes.

3.4.2 *National Data Warehouse Administrators and Developers*

Responsible for ensuring seamless data transmission from facility EMRs into the NDW. Ensures extraction of required data elements from NDW into the CBS dataset for analysis by the data analysis team. Crossmatch and de-duplicate submitted cases to ensure that unique cases are only counted once. Develop

DHIS2 instance for data capture for sites without EMRs and provide maintenance support. Facilitate development of dashboards for data reviews at site and national level. Preparation of the CBS dataset for analysis.

3.4.3 *CBS Data Managers*

Provide feedback and work with the NDW administrators and M&E officers to resolve any data issues identified by the analysis team. Ensure that data is being pushed into the CBS database as expected, report any issues to the NDW and assist with trouble shooting. Develop and maintain the CBS data dictionary. Collaborate with analysis teams to develop products for dissemination including summary reports and national epidemiology profile.

3.4.4 *National Datawarehouse M&E Officers*

Responsible for reviewing CBS data on a monthly basis for completeness, producing frequency tables to check for completeness of data, validity of data, and providing feedback to sites on data quality gaps. Ensure the timeliness of data submissions both from the HIV care facilities and to the CBS database. Representativeness of case data (i.e., are all the health facilities submitting data?) and prioritize follow-up activities for health facilities.

3.4.5 *Data Analysis Team*

This team consists of the MOHW surveillance officer and implementing partner data analysis support in the form of data analysts, biostatisticians, and epidemiologists who will be responsible for monitoring, analysis, and dissemination of CBS data as described in the Data Analysis SOP. This team will guide the development of the CBS data analysis plan and provide guidance to the NDW team on the development of dashboards. This team will prepare and submit quarterly and annual CBS reports to the CBS TWG and to identified stakeholders.

3.4.6 CBS TWG

CBS TWG is comprised of MOHW and IP program officers who will review and sign off on documents and reports prepared by the data analysis team. The data will be used for decision making.

4. HIV CBS IMPLEMENTATION PHASES

4.1 Phase One Facilities

Phase one facilities will include all facilities with IPMS or PIMS with ownCloud client software installed. Data collection will be done routinely using existing EMRs and transmitted automatically to the NDW monthly.

4.2 Phase Two Facilities

Phase two facilities will include all facilities with PIMS but not connected to the ownCloud server. Data collection will be done routinely using existing EMR. Data collected at these Phase-2 facilities will be transmitted into the NDW manually. This will be done by transporting the PIMS backup from each facility to the closest DHMT or hospital with ownCloud client software for transmission to the NDW. These facilities will submit data on a monthly basis to the NDW.

4.3 Phase Three Facilities

Phase three facilities will include the rest of the facilities in Botswana without any form of EMR (IPMS or PIMS). These facilities will use paper CRFs for data collection, which will then be captured on DHIS2 for transmission to the NDW. These facilities will submit data bi-weekly or monthly to the NDW via DHIS2.

5. HIV CBS Training

Each staff involved in the HIV CBS data collection is to receive relevant training on the CRF and EMR being used in their facility.

IPMS/PIMS Training

Training gaps will be identified through facility and staff assessment. Gaps will be addressed in collaboration with MoHW and the relevant IP. Training will be done in a workshop setting for large groups or in person at each facility (on-the-job training).

CRF/DHIS2 Training

This will be arranged with the CBS TOT or Master Trainer. Training will be done in a workshop setting for large groups or in person at each of the facilities. CBS TOT should provide training or arrange for the training.

6. System Support

The district informatics officer is to provide all EMR related technical assistance required by the facilities. Contacts of the informatics officers are available at each of the facilities and should be contacted in cases of any technical issues in data collection. They can escalate those technical issues to the MOHW informatics and IT team.

DHIS-2 related technical issues should be referred to the district informatics officers, MOHW informatics office, and the MOHW IT department.

7. District Mentoring

Both the CBS TOT & Master trainers are to provide quarterly mentoring visits to the districts. The visits can cover refresher training on data collection, EMR, CRF, or DHIS2. A data management checklist should be completed at each visit to assess the district and facility implementation of CBS.

8. HIV CBS DATA SOURCES

Required variables for HIV case surveillance.

An HIV case has a minimum set of variables that are required for reporting and initiating the HIV case-based surveillance process. These include: first name, last name; date of birth; sex at birth; identification, current place of residency, HIV test date, HIV test results and HIV test place.

Unique Identification

A unique identification is required for CBS activities. The omang number is a unique identification issued to citizens of Botswana and will be used to uniquely identify HIV cases. For children under 16 years of age without an omang, a birth certificate will be used as a unique identifier. For non-citizens, the passport number will be used as a unique identifier.

SUID

This will be a system auto generated ID and will be used to uniquely identify individuals in the CBS de-identified dataset and link them back to the NDW. The SUID will also be used for clients who do not have an omang or passport number.

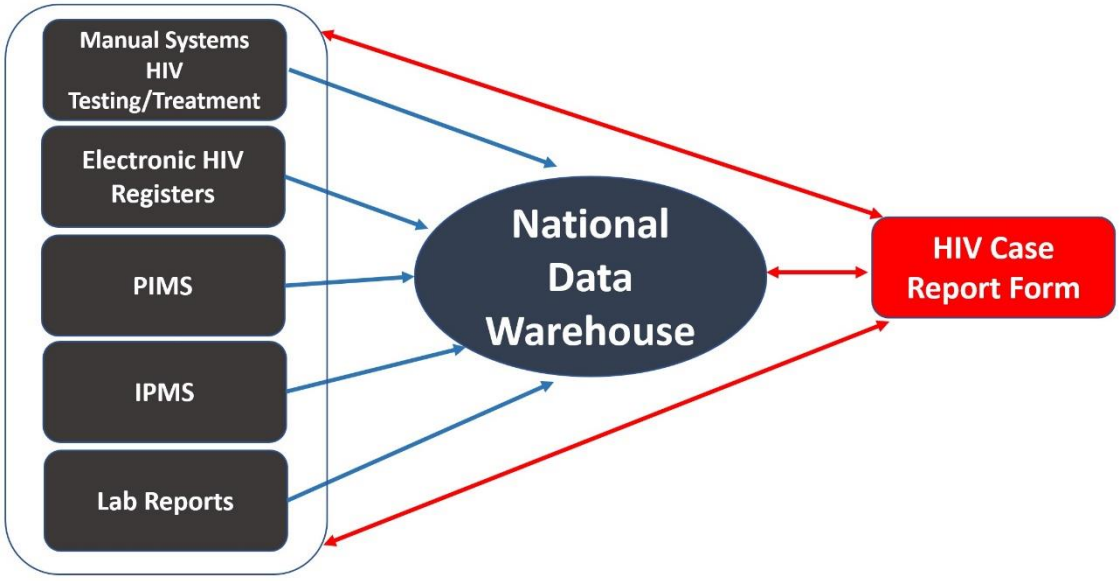


Figure 1. NDW Data Sources

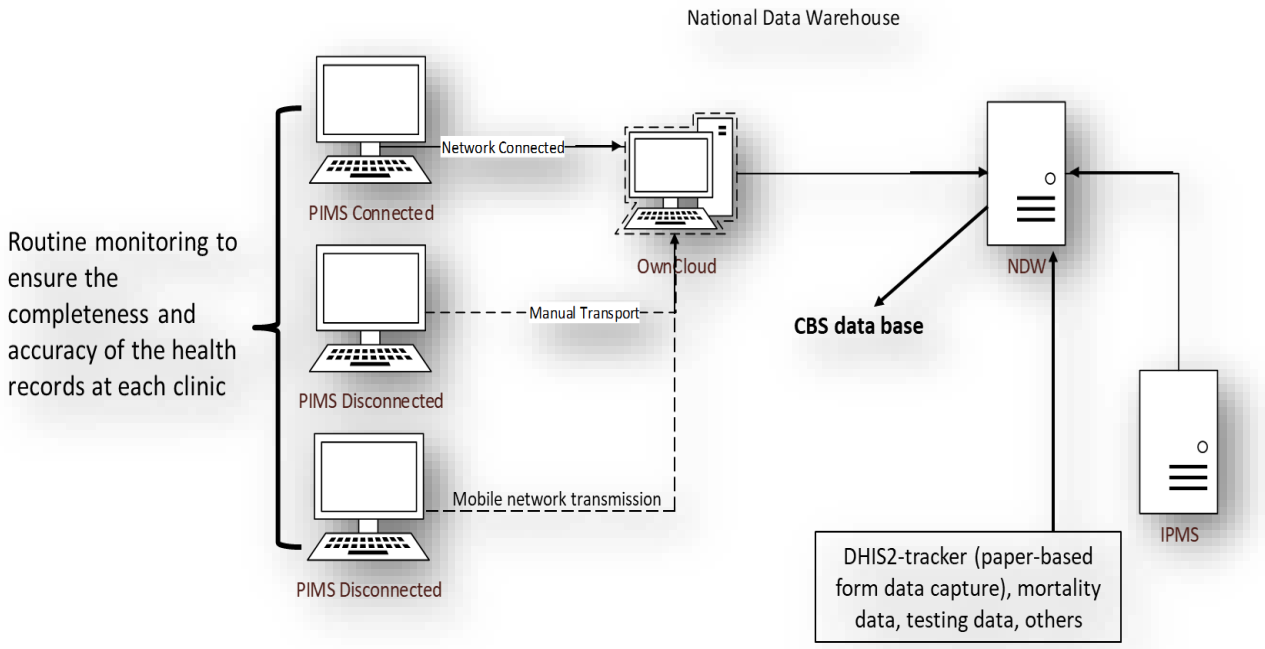
Table 1. CFR Data Sources

CRF Section	Data Source
Client Demographic	Patient File, HTS Daily Register, ART Register, PMTCT Register, Maternity Register, Baby Testing and Follow Up Register
HIV Testing	Patient File, HTS Daily Register, ART Register, PMTCT Register, Delivery Register, Child Follow Up
Clinical Information at Diagnosis	Patient File, HTS Daily Register, ART Register, PMTCT Register, Delivery Register, Child Follow Up
Care & Treatment	Patient File, ART Register
Laboratory Information	Patient File, IPMS, Lab Order Form
Clinical Information During Reporting Period	ART Register, Transfer form, Client Tracking Register, Presumptive TB Register, ARV Encounter Register

9. DATA COLLECTION PROCESSES

Current existing EMR (PIMS & IPMS) will be used to capture and collect all patient data for HIV case reporting and follow up sentinel events. These patient data are available on the EMR across various program areas and forms are collected routinely and progressively as the patient visits the health facility. Where there is no EMR, a paper-based CRF will be used to capture patient data from various existing facility patient registers and files.

Figure 2. CBS EMR Data Flow



9.1 IPMS

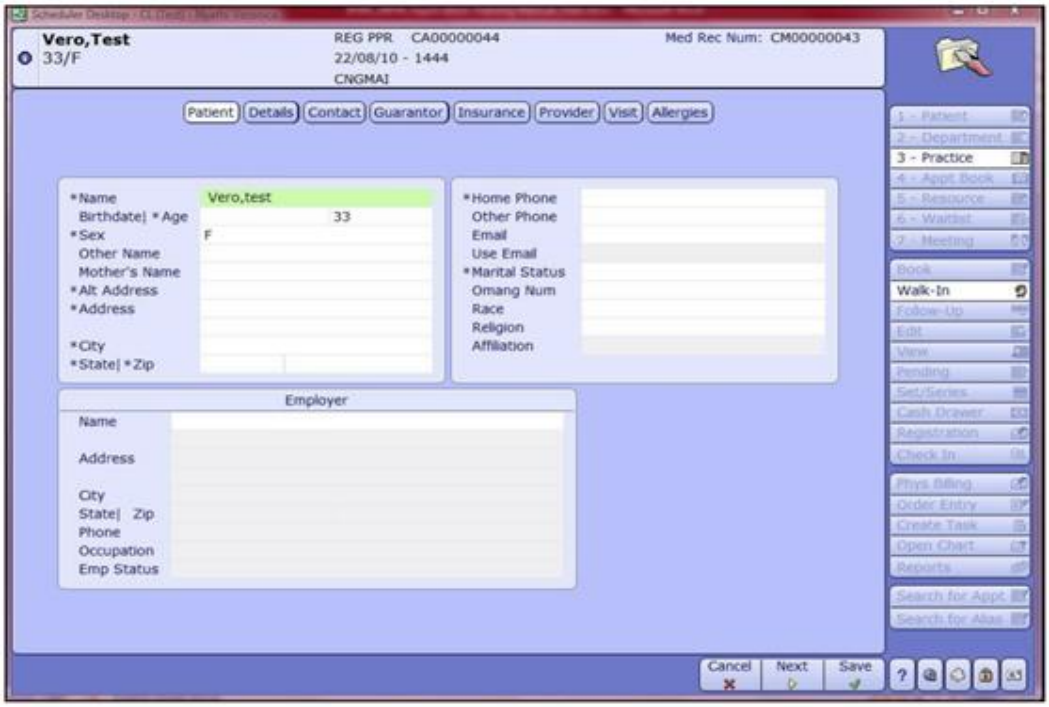


Figure 3. Enrolling new clients on IPMS

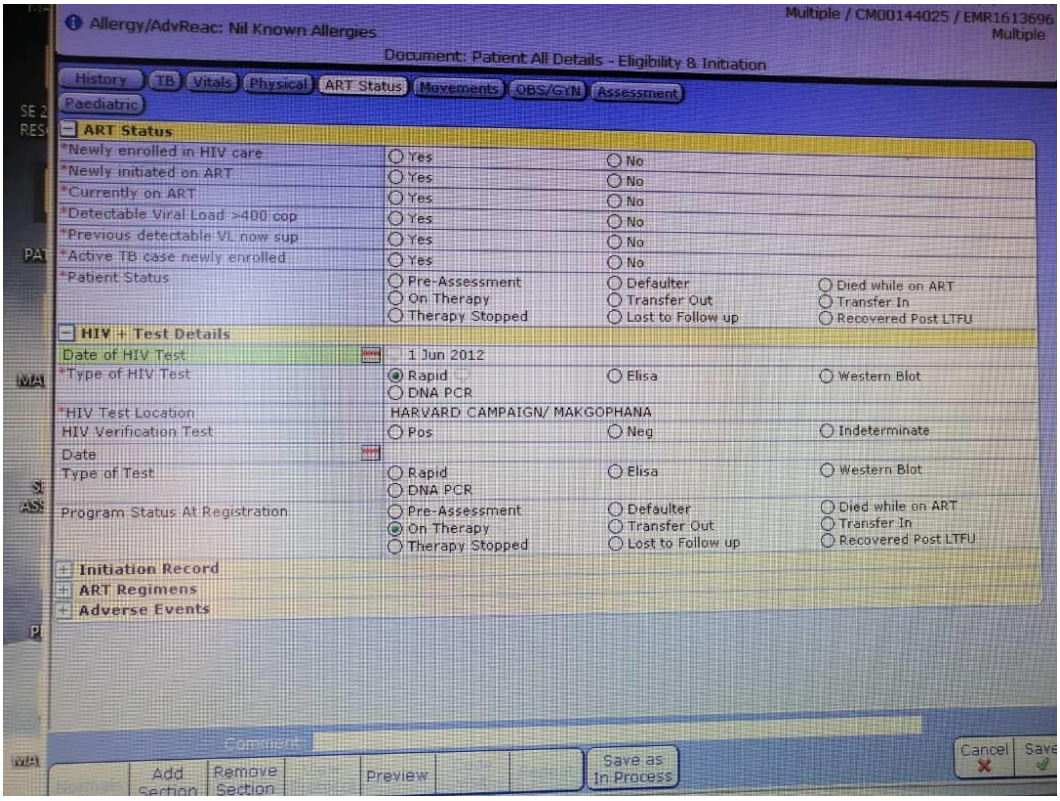


Figure 4. Capturing client testing and treatment details on IPMS

Facility staff shall collect and update data using IPMS as they have been doing, the data will then be pushed to the NDW at preset times. This process, requiring internet connection, pushes the data to the NDW automatically once it is captured on IPMS. (*See IPMS manuals for more details*).

1.1 PIMS

PIMS (Patient Information Management System) is another EMR that is currently being used at facilities (Clinics and Health Posts) that do not have IPMS installed.

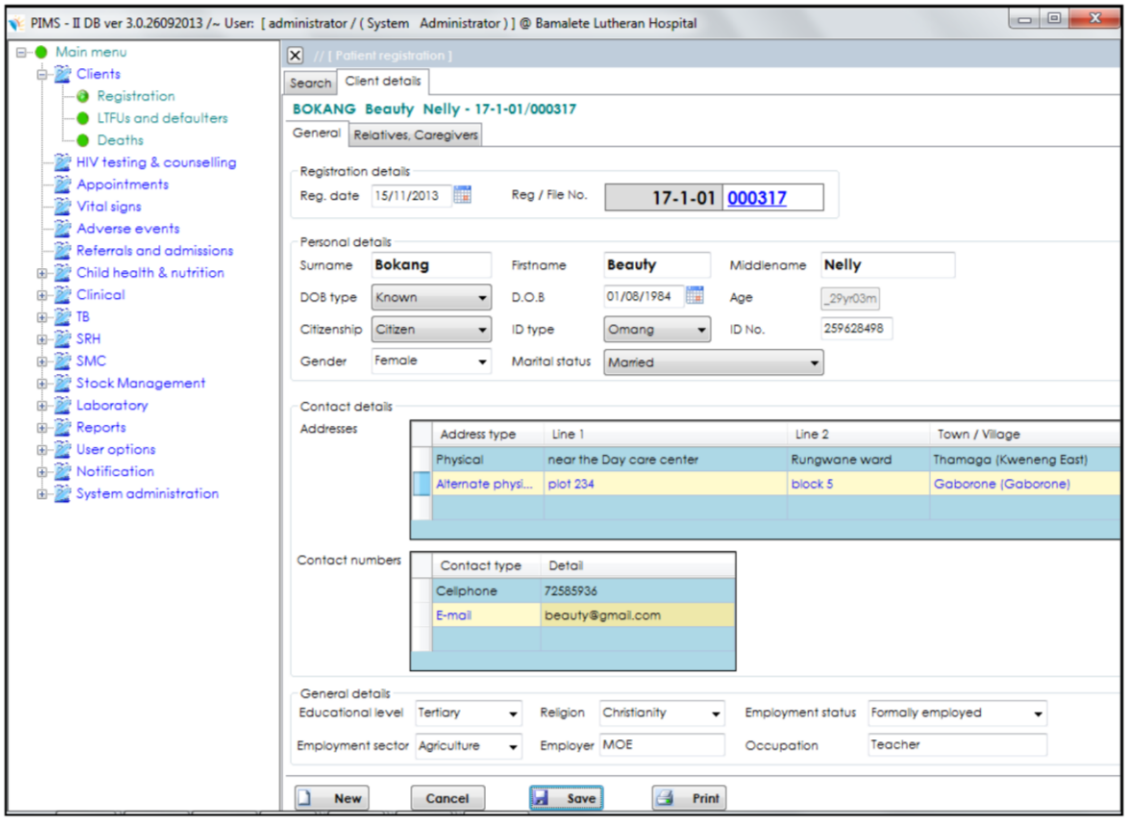


Figure 5. Capturing new clients on PIMS

Facilities using PIMS shall continue collecting and updating data as they have been doing all along. Data collected on PIMS will then be sent to the NDW either through OwnCloud, if available at the facility, or transportation shall be arranged for the manual transmission of the PIMS backup to a facility connected to NDW. (See PIMS manual for full description of how data is collected on PIMS).

9.2 CRF/DHIS2

Where there is no EMR, a paper based CRF (See Appendix C & D) and DHIS-2 Tracker Capture will be used to collect and send data to NDW. All such facilities are to use the paper based CRF, but the DHIS-2 Tracker will only be installed at centralized mother facilities where all CRF forms will be sent for capture.

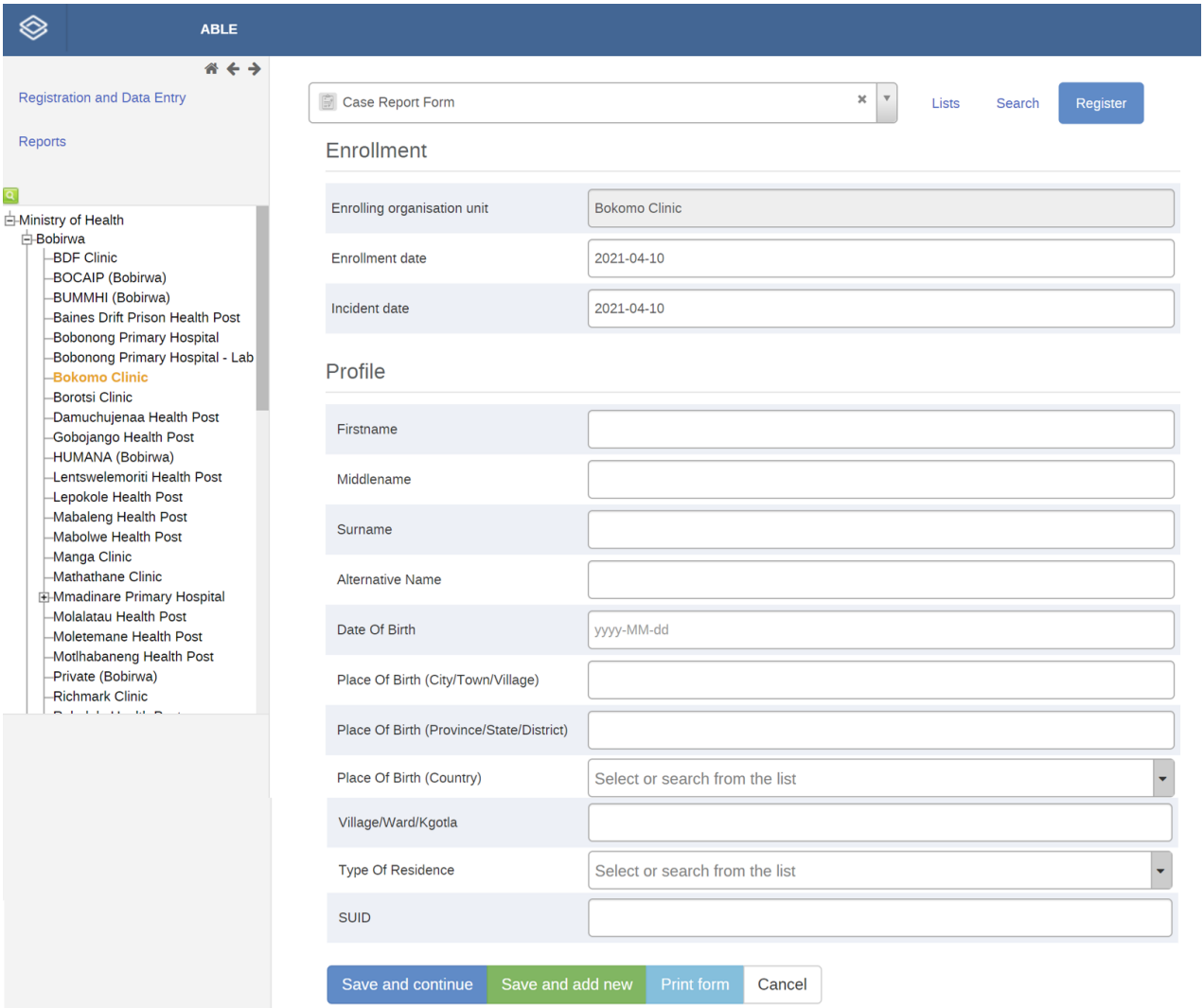


Figure 6. Capturing client demographics on DHIS-2.

10. COMPLETING A CASE REPORT FORM (CRF)

The following steps describe the process of completion of the CRFs; it refers to both the CRF for the newly diagnosed cases and for capturing subsequent sentinel events (See Appendix E & F).

1. The CRF for newly diagnosed persons living with HIV (Appendix C) is used to capture information on an individual following a verified new positive HIV diagnosis at the various testing points.
2. The CRF must include enough information for the surveillance program to describe the HIV epidemic according to person, place, and time.
3. A completed CRF form must include
    a. **Client Unique Identifiers** and **Client Demographics** section must all be completed with "Not Available" ticked if the information is not available.
    b. **Facility Information** section must all be completed.
    c. **Data Management** Section must all be completed.
    d. **HIV Testing** section must all be completed.
    e. Either **Client Clinical History (Age < 5)** or **Client Clinical History (Age > 5)** must all be completed.
    f. For all other sections, tick "**Not Done**" if the section was not done, if it was done complete all variables collected in that section.
4. The CRF will be completed by extracting information from service registers, patient charts, and various standard national tools.
5. Data elements from these tools will be mined to generate a CRF for each client.
6. Newly diagnosed pregnant mothers and DNA-PCR positive exposed infants, at ANC/PMTCT clinic, will have their CRFs generated from the ANC and PMTCT cohort registers, since all the required information for the HIV case report is contained in these registers.
7. See Appendix E & F for full description of the CRF data elements.
8. CRF form is **NOT** to be completed when the client is at the facility getting HTS or ART services, and it does not replace any currently used patient register or file.

11. GUIDELINE FOR COMPLETING CRFS

Table 2. Completing CRF Guideline

Items	Description
Who should fill the CRF	The HCA, data clerk or any assigned facility staff completes the relevant CRF and this will be transcribed to an electronic form on DHIS-2.
When to fill the form	The CRF form is filled daily immediately a new case is identified or after a routine clinical visit for a known HIV positive client
Submission **due date** and timeline	Bi-weekly to mother facility or DHMT
Where to send the completed report	Identified mother facility or DHMT
Where to **store** the completed form	The CRF should be kept securely in a file cabinet that is accessible to only authorised persons/staff at the service delivery points or designated location. Electronic copy to be completed on DHIS2
Source of information	Various patient registers

12. SUBMITTING A CASE REPORT FORM (CRF)

CRFs will be submitted on a bi-weekly basis by the designated facility staff to a designated mother facility, the district M&E officer, or a CBS TOT in sealed envelopes for entry into a designated computer/tablet with a web-based DHIS-2 Tracker that links to the NDW. Existing channels of movement of paper documents will be used. A chain of custody form (Appendix G) will be completed to document the handover process. Each CRF will be kept at the facility in a secure cabinet for at least 3 months before destruction by the district CBS TOT. The CRF is kept, allowing time for data entry and verification; after three months the forms will be collected by the district CBS TOTs and will be destroyed by shredding.

1. Completed CRFs are to be stored in secure, locked cabinets in the implementing facilities with access restricted to authorized individuals only (site-level staff & CBS TOT/Officers).
2. Completed forms are to be submitted bi-weekly to a designated mother facility, district M&E officer, or CBS TOT in signed and sealed envelopes for entry into a designated computer/tablet with a web-based DHIS2 Tracker that links with the NDW.

3. Sealed envelopes containing CRFs to be hand delivered and clearly addressed (Full Name, Position, Department, Facility) to the receiving officer (CBS TOT, District M&E, etc.). Delivery can be made by CBS personnel or authorized facility drivers.
4. A chain of custody form (Appendix G) is to be completed to document the hand over process of the CRFs.
5. In the event of an open envelope, this should be reported as an incident as per the Regulatory SOP.
6. All CRF forms at the designated facility will be kept in a secure cabinet for at-least three months from the date of capture into DHIS2 before destruction by the CBS Personnel (CBS TOT, District M&E, etc.).
7. Where there is no lockable cabinet, this should be reported to the CBS TOT.
8. CRF forms must be destroyed by shredding.

13. CAPTURING CRF ON DHIS2

Completed CRF forms are to be captured into DHIS2 at designated facilities or location by authorized personnel with access to DHIS2.

1. Retrieve completed CRF forms from their secured cabinets as scheduled.
2. Capture all information on the CRF form into DHIS-2. (*See DHIS-2 Job Aid for full steps*)
3. When done with each CRF form, complete the “Data Management” section, indicating the “Date the Report was Entered”.
4. Return all CRF forms captured in DHIS2 to their secure cabinets for storage for three months before their destruction by shredding.

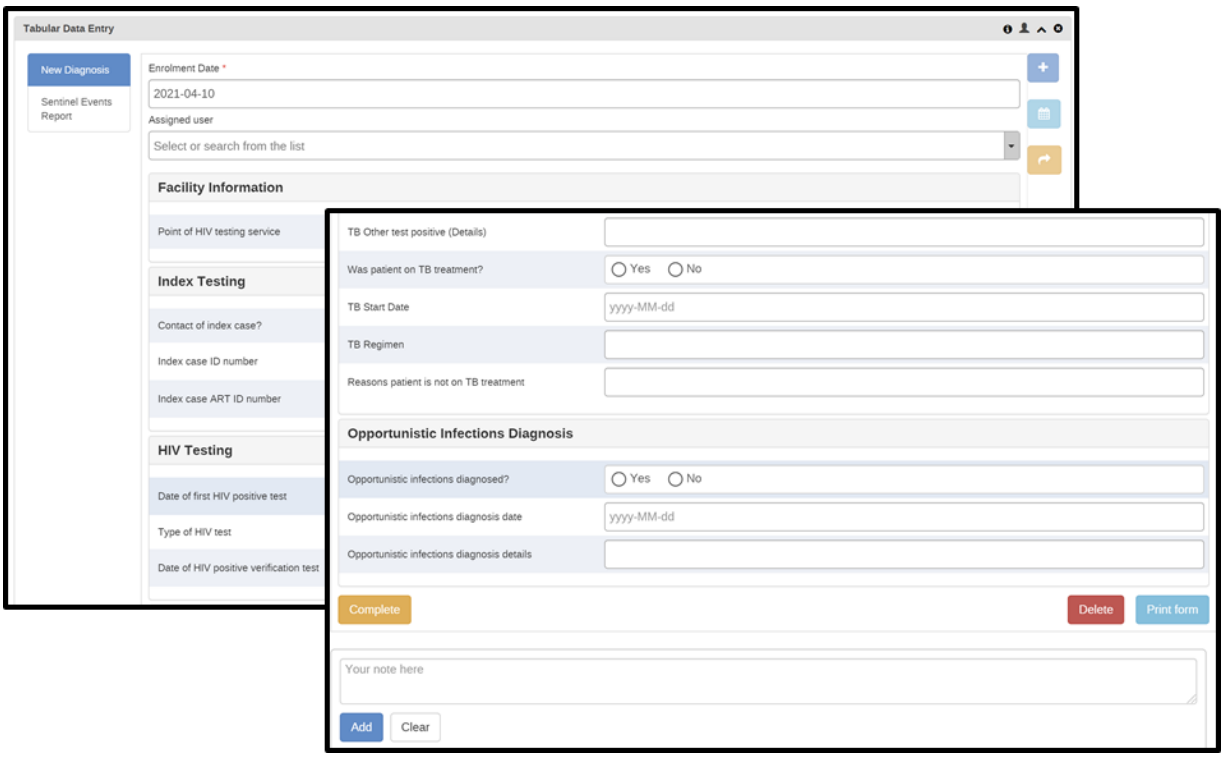


Figure 7. Capturing sentinel events on DHIS-2.

14. HIV CBS DATA FLOW

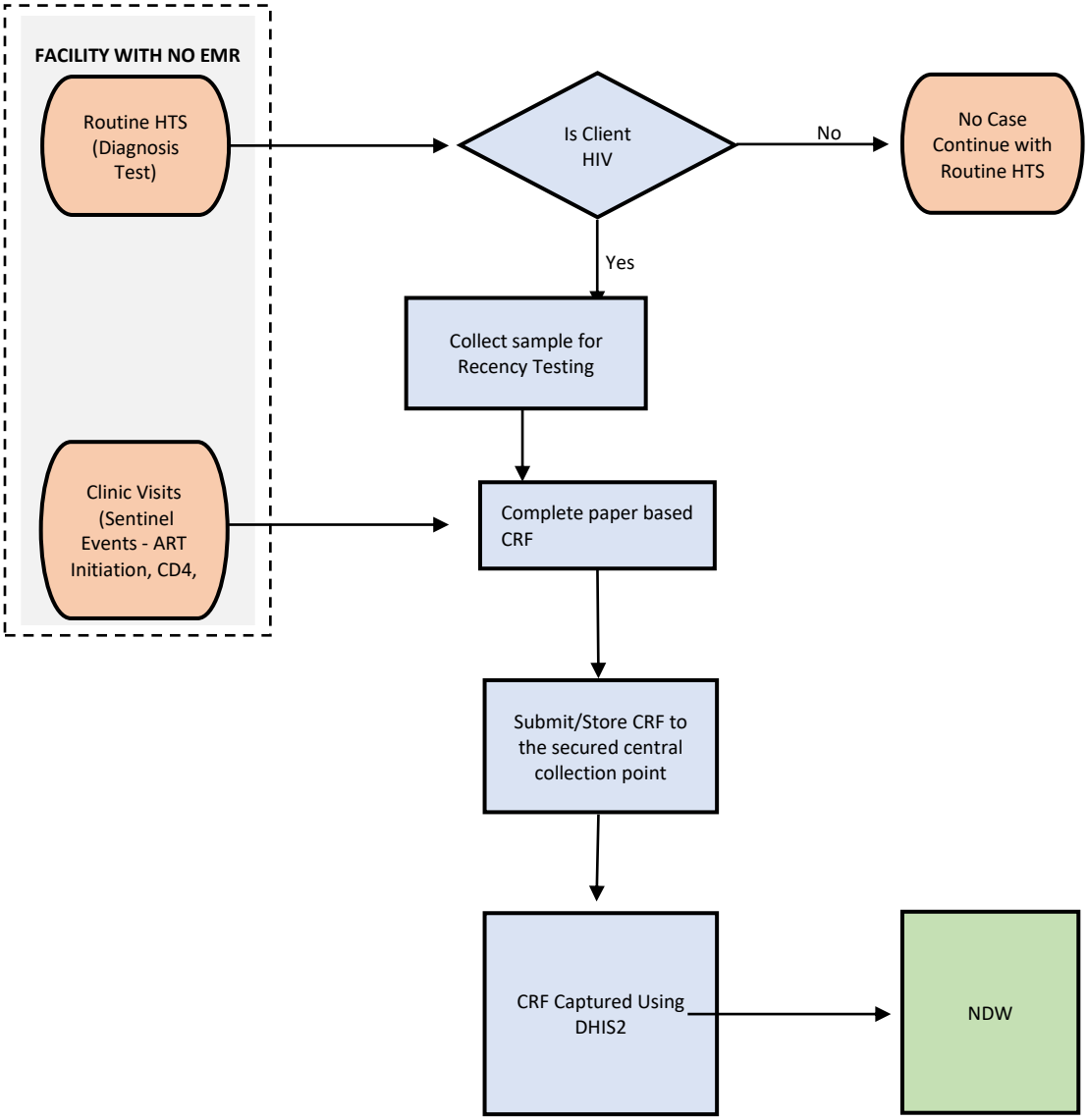


Figure 8. HIV CBS Data Flow

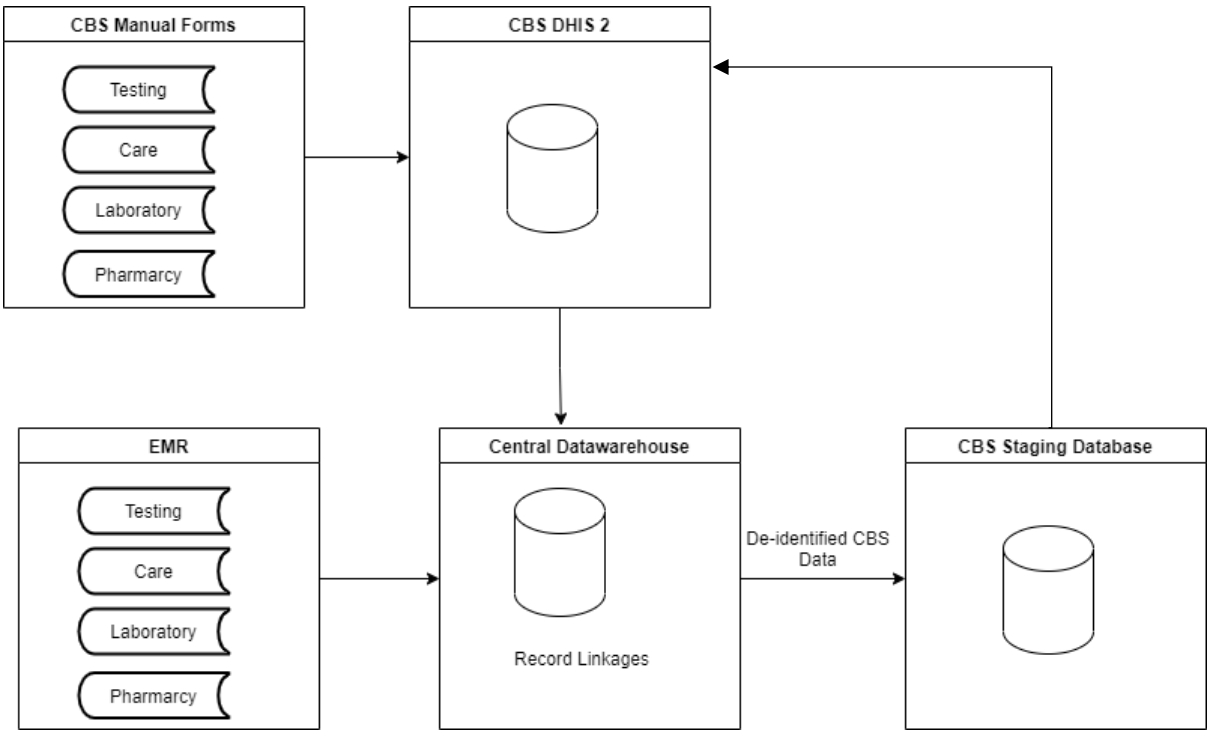
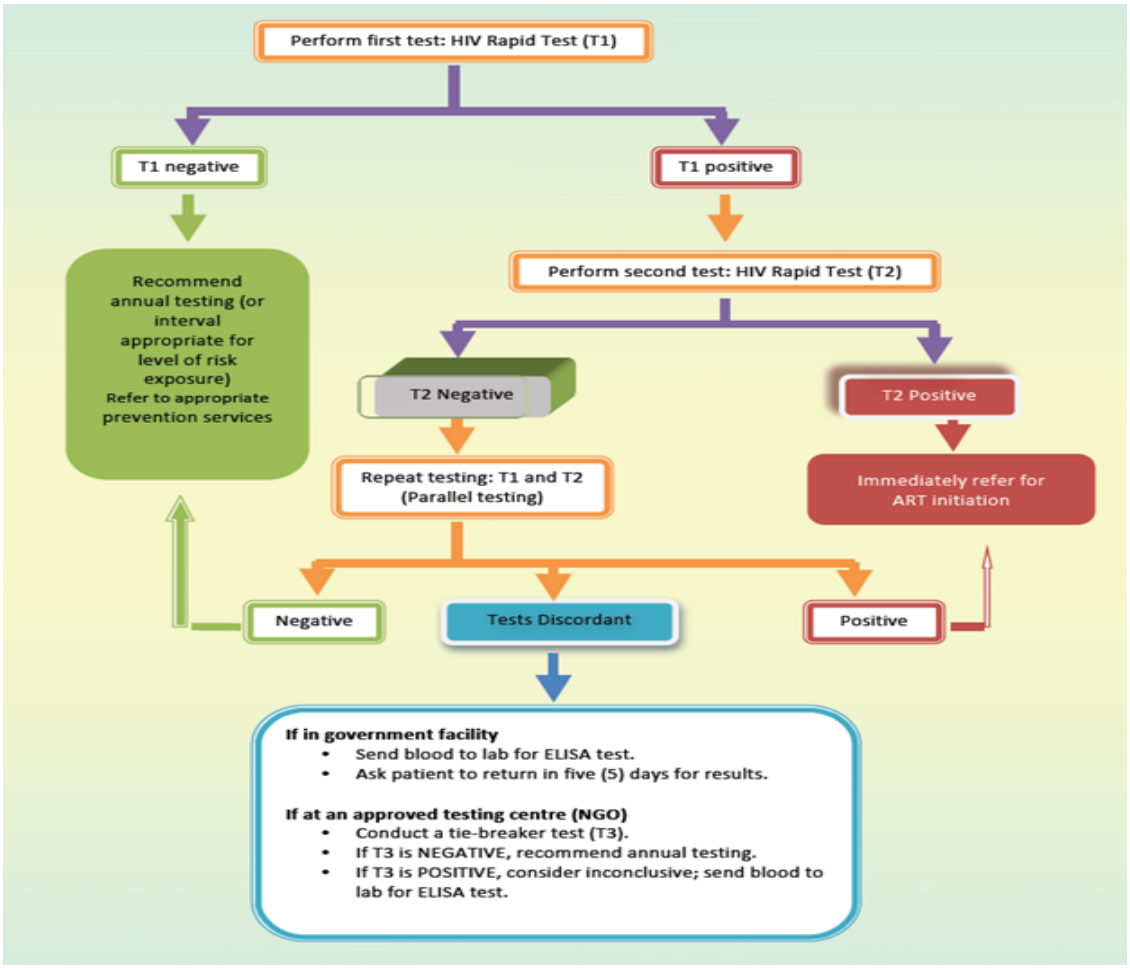
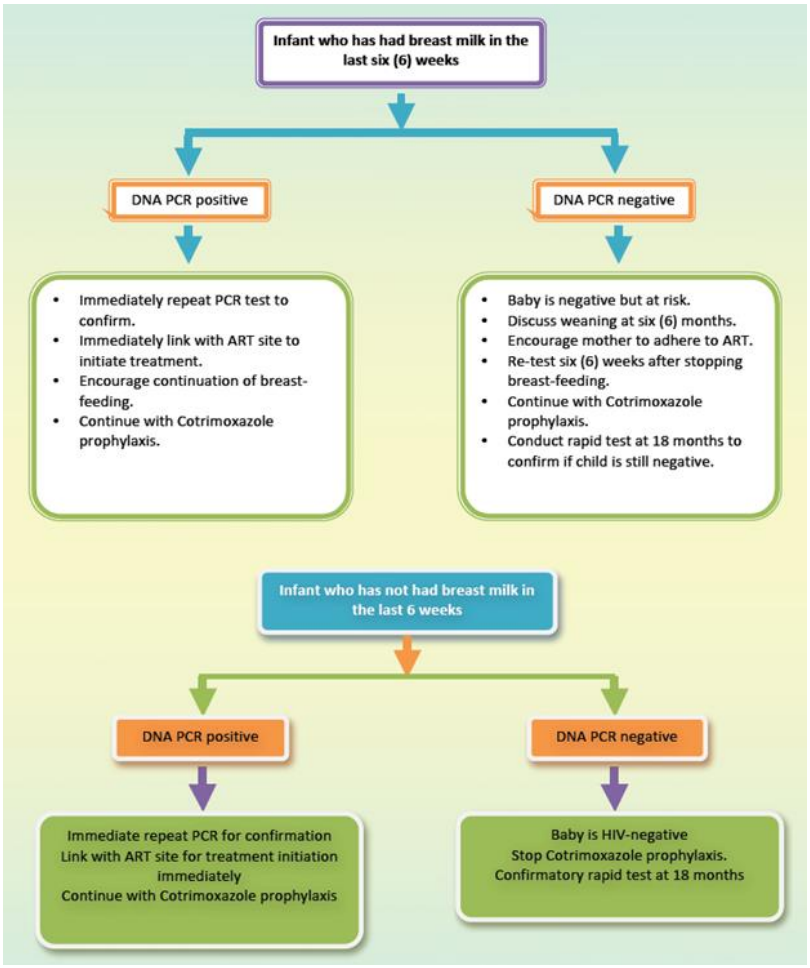


Figure 9. HIV CBS Database Data Flow

Appendix A: Botswana HIV Testing Algorithm



Appendix B: HIV Diagnosis in infants less than 18 months of age



Appendix C: Case Report Form for Newly Diagnosed Persons Living with HIV Infection.

Botswana Ministry of Health and Wellness

Case Report Form for Newly Diagnosed Persons Living with HIV infection

This form may be completed by a health care provider on the day of HIV diagnosis or within 7 days.

Please record all date as dd/mm/yyyy

Section A: Client Unique Identifier

(Personal identifying information from this section will not be included in the surveillance database)

1. **Name:** First_____ Surname _____ Middle _____
2. **Alternative name:** _____ Not available ☐
3. **Place of birth:** City/town/village_____ province/state/district _____ Country/code _____
4. **DOB**: / /
5. **National identification** (check all that apply):
   National ID (OMANG) : _____ Birth certificate number: _____
   Driver licence : _____ Passport number : _____ Not available ☐
6. **HIV care/ART ID number:** _____ Not available ☐
7. **Index case number**: _____ Not available ☐

Section B: Client Demographic Information

1. **Marital status:** Never married/single ☐ Married-monogamous ☐ Co-habiting ☐ Married-polygamous ☐ Divorced/separated ☐ Widow/Widower ☐
2. **Location and type of residence:**
   District name: _____ Village/ward/kgotla:_____
   Residence (check one only): House/apartment/flat ☐ Prison ☐ Temporary house ☐ Homeless ☐ Shelter ☐
3. **Age**: year(s) month(s)
4. **Sex at birth:** Male ☐ Female ☐

SECTION C: Facility information

1. **District:** _____ **2. Testing Site Name/Code:** _____
5. **Reporting Site/Code:** _____
6. **Point of HIV testing service where the case was diagnosed:**
   HTS ☐ ANC ☐ Maternity ☐ IDCC ☐ TB ☐ VMMC ☐
   A&E ☐ Inpatient Ward ☐ STI ☐ OPD ☐ Child Welfare ☐
   Other ☐, specify:_____

SECTION D: Report reception/Data management information

1. Date Form Completed: / /
2. Date Report Received: / /
3. Date Report Entered: / /

Section E: Index Testing

1. **Contact of index case?** Yes ☐ Index case ID number _____ Not available ☐
   Index case ART ID number _____ Not available ☐
   No ☐ Refuse ☐

(If client aged < 5 years and identified through PMTCT: HTS and ART ID number of the biological mother should be used)

Section F: HIV Testing

1. **Date of first HIV positive test (dd/mm/yyyy):** / / **Type of HIV test:** ☐ Rapid Test ☐ PCR (EID testing)
2. **Date of HIV positive verification test (dd/mm/yyyy):** / /

Section G: Client Clinical History Information (client aged ≤ 5 years)

1. **Birth weight:** ____kg **Gestation at birth:** ____ weeks
2. **Maternal ART:** Yes ☐ No ☐ Don't know ☐
   If yes, ART initiation: Before pregnancy ☐ During pregnancy ☐ During birth ☐
   After giving birth ☐ Don't know ☐
   ART regimens taken before or during pregnancy or during or after giving birth (list all): _____
3. **Infant ARV prophylaxis:** Yes ☐ No ☐ Don't know ☐
   If yes, NVP ☐ NVP & AZT ☐ Other ☐ specify:_____ Duration:____weeks
4. **Birth defects (ICD-10):** Yes ☐ No ☐ Don't know ☐
   If yes, specify_____

Section H: Client Clinical History Information (client aged > 5 years)

1. **Date of most recent HIV-negative test**: / / or ____ months ago Never been tested ☐
2. **Ever been on PREP** Yes ☐ No ☐ Refuse ☐ Unknown ☐
3. **Ever been on ART** Yes ☐ No ☐ Refuse ☐ Unknown ☐
4. **Ever received ARV/ART prophylaxis to prevent mother to child HIV transmission?**
   Yes ☐ No ☐ Refuse ☐ Unknown ☐
5. **If the client is a girl/woman ≥12 years of age**: a. Pregnant ☐, *Gestation (weeks)*: ____
   b. Breastfeeding ☐, Post-delivery (months): ____ (Up to 24 months)
   c. Not pregnant or breastfeeding ☐

Section I: Client Clinical Information at the time of HIV Diagnosis

1. **Was the WHO clinical stage assessed?**
   No ☐ Yes ☐ → date: / /
   Result: Stage I ☐
   Stage II ☐
   Stage III ☐
   Stage IV ☐

2. **1st CD4:** Not done: ☐
   Sample collection date: / /
   Sample test date: / /
   Result count: ____
   Result percent: ____

3. **ART initiation**
   No ☐ → Referral ☐ Refused ☐
   Yes ☐ Initiation date: / /
   Regimen: _____

4. **Was cryptococcal infection diagnosed?**
   No ☐ Not done ☐
   Yes ☐ → date / /
   Results: CrAg positive ☐
   CM/disseminated ☐

5. **Was Tuberculosis diagnosed?**
   No: ☐ → Was TB preventive therapy (TPT) given?
   Yes ☐ → date: / /
   Regimen: _____
   (e.g., INH, 3HP)
   No ☐ → Reason: ☐ Client refused
   ☐ Contraindication
   ☐ Already completed TPT
   ☐ No drug supply
   Yes: ☐ → date / /
   Symptom screening positive ☐
   Sputum positive ☐ Xray positive ☐
   Other test positive ☐, specify _____
   Was the patient on TB treatment?
   Yes ☐ → Start date: / /
   Regimen: _____
   No ☐ → Why? _____
   Not done: ☐

6. **Were any other opportunistic infections diagnosed?**
   No ☐
   Yes ☐ → date / /
   If yes, specify _____

Appendix D: Case Report Form for Sentinel Events for a Previously Reported Case

Botswana Ministry of Health and Wellness

Case Report Form for Sentinel Events for a Previously Reported Case

This form may be completed by a health care provider every 3 months (or 6 months) from the date of HIV diagnosis per country guidelines. Please record all date as dd/mm/yyyy

Section A: Client Unique Identifier/Client Profile

(Personal identifying information from this section will not be included in the surveillance data repository)

1. **Name:** First_____ Surname _____ Middle _____
2. **Alternative name:** _____ Not available ☐
3. **Place of birth:** City/town/village_____ province/state/district _____ Country/code _____
4. **DOB:** / / **Age:** year(s) month (s)
5. **Sex at birth:** Male ☐ Female ☐
6. **National identification** (check all that apply):
   National ID (Omang): _____ Birth certificate number: _____
   Driver's license: _____ Passport number: _____ Not available ☐
7. **HIV care/ART ID number:** _____ Not available ☐

SECTION B: Care and Treatment Facility Information

1. **District:** _____
2. **Village/city:** _____
3. **Care and Treatment Facility Name/Code:** _____

SECTION C: Report Reception/Data Management Information

1. **District:** _____
2. **Reporting facility/Code:** _____
3. **Date Form Completed:** / /
4. **Date Report Received:** / /
5. **Date Report Entered:** / /

Section D: Client Latest Demographic Information

1. Location and Type of Resident

a. District name: _____

b. Village/ward/kgotla: _____

2. Marital Status

Never married/single ☐ Married-monogamous ☐

Co-habiting ☐ Married-polygamous ☐

Divorced/separated ☐ Widow/Widower ☐

Section D: Client Testing and Treatment History

1. **Date of HIV diagnosis:** / / **Testing site name/code:** _____
2. **Date first enrolled in care/treatment:** / / **Care/treatment clinic name/code:** _____

3. **Transferred in:**
   No ☐, skip to Section E
   Unknown ☐, skip to Section E
   Yes ☐, →Question 4

4. **Transfer in date:** / /
5. **Previous facility name/code:** _____
6. **Patient was on ART:** No ☐ Unknown ☐
   Yes ☐, HIV Care/Treatment ID number _____
7. **Date of ART initiation in previous facility:** / / Unknown ☐
8. **Regimen** _____ Unknown ☐

Section E: Antiretroviral Treatment (ART) during the reporting period

Current **HIV Care/Treatment ID number:** _____ (Note: a patient could receive more than one regimen)

On 1st line: ☐ Date started on 1st line / / Regimen: _____

2nd line: ☐ Date started on 2nd line / / Regimen: _____

3rd line: ☐ Date started on 3rd line / / Regimen: _____

On a special (prescribed by a doctor) regimen (not 1st or 2nd or 3rd line):

No ☐ Yes ☐ → Date started on the special regimen: / / Regimen: _____

Reasons to switch a new ART regimen:

Treatment failure (Viral load not suppressed or drug resistance) ☐ Adverse drug reaction ☐ Gastrointestinal ☐

Skin ☐ CNS ☐ Haematological ☐ Hepatic dysfunction ☐ Metabolic ☐ Headache ☐

Kidney dysfunction ☐ Bone dysfunction ☐ Fatigue ☐ Treatment guideline change ☐

ARV shortage/stockout ☐ Drug-drug interactions ☐ Pregnancy/planning to become pregnant ☐

Other ☐, Specify: _____

Section F: Women and Child Health during the reporting period (for female patient only)

1. Was she pregnant?
   - Yes ☐ →
   - No ☐, skip to G
   - Don't know ☐, skip to G

a. Last day of menstrual period / / Don't know ☐
b. Due date / / Don't know ☐
c. Attend antenatal care? No ☐ Don't know ☐
Yes ☐ → Date of 1st ANC visit: / / Gestation (weeks): ____

2. Did she give birth?
   - Yes ☐, →
   - No:
     Miscarriage ☐, skip to G
     Stillbirth ☐, skip to G
     Abortion ☐, skip to G
     Don't know ☐, skip to G

The child's date of birth: / / Don't know ☐
Gestation at delivery: ___ weeks **Birth weight:** ___ kg
Birth defects (ICD-10): Yes ☐ No ☐ Don't know ☐
If yes, Specify _____
Was the baby diagnosed with HIV?
- No ☐ Don't know ☐
- Yes ☐ → Date of the diagnosis / / Not available ☐
  Was the child initiated on ART? No ☐ Yes ☐
  ART ID number? _____ _ Not available ☐

Section G: Laboratory Test Information

CD4 T cell count and percentage during the reporting period

Date of sample collection: / / CD4 count _____ cells/µL CD4 percentage _____%
Date of sample collection: / / CD4 count _____ cells/µL CD4 percentage _____%

HIV viral load RNA test during the reporting period

Date of sample collection: / / Detectable copies _____ copies/mL
Detectable copies _____ log Undetectable ☐

Date of sample collection: / / Detectable copies _____ copies/mL
Detectable copies _____ log Undetectable ☐

HIV Drug Resistance during the reporting period

Date of sample collection: / / Date of sample tested: / / Sample rejected ☐ Not done ☐
Major mutation results: NRTI ☐ NNRTI ☐ PI ☐ INI ☐ Other ARV class ☐, specify ART name_____

Section H: Clinical Information During the Reporting Period

Was Tuberculosis diagnosed?
No ☐ Not done ☐
Yes ☐ → date / /
Symptom screening positive ☐
Sputum positive ☐
Xray positive ☐
Other positive ☐,
specify _____
Was the patient on TB treatment?
Yes ☐ → Start date: / /
Regimen: _____
No ☐ → Why? _____

Was TB preventive treatment (TPT) completed?
No ☐ → Why? Non-adherence ☐
Developed active TB ☐
No drug supply ☐
Adverse drug reaction ☐,
specify _____
(e.g., rash, neuropathy, liver toxicity)
Yes ☐ → Start date: / /
End date: / /
Regimen: _____
(e.g., INH, 3HP)

Was the patient LTFU?
No ☐
Yes ☐ → date / /

Was the patient transferred out?
No ☐
Yes ☐ → date / /

Did the patient die?
No ☐
Yes ☐ → date / /
Cause of death:
_____

Was cryptococcal infection diagnosed?
No ☐ Not done ☐ Yes ☐ → date / /
Results: CrAg positive ☐ CM/disseminated ☐
Was the patient on treatment? No ☐ → Why? _____
Yes ☐ → Start date: / / Regimen: _____

Was the WHO clinical stage assessed?
No ☐ Yes ☐ → date: / /
Result: Stage I ☐ Stage II ☐
Stage III ☐ Stage IV ☐

Were any other opportunistic infections diagnosed? No ☐ Yes ☐ → date / /
Specify:_____

Appendix E: Completing a Case Report Form for Newly Diagnosed PLHIV

SECTION A: CLIENT IDENTIFIER
The variables in this section are all required for case-based surveillance (CBS) and must all be completed. If the client has a government issued identification document, please use that to correctly capture the spelling of the clients' name.
1. NAME: This variable includes the Surname, First Name and Middle Name. At a minimum, you must capture the client's surname (usually a family name and sometimes referred to as the last name) **AND** their first name. If the middle name is available, please capture this too. **2. PLACE OF BIRTH:** The country where the client was born, the district of birth and the town or city or ward where client was born. **3. DOB (Date of Birth):** This must be completed in the DD/MM/YYYY format, starting with two digits for the day, two digits for the month and four digits for the year. *E.g., if the client was born 2nd February 1980, then the person completing the form should enter 02/02/1980.* **4. CONTACT DETAILS**: This is the telephone number of a close relative who can be contacted on the occasion that the facility cannot reach the client. The next of kin is usually a spouse, a sibling or some other relative. Confidentiality must always be maintained, and client information must not be disclosed without prior consent from the client. **5. NATIONAL IDENTIFICATION:** This should be taken directly from an original government issued document and not word of mouth, the Omang is a national unique identification number provided to all citizens of Botswana. This is the gold standard for identification and should be captured if the client is a citizen of Botswana. If the client is a non-citizen, please capture the passport number as written. Some passports are alphanumeric and contain both letters and numbers, please capture this correctly. Other identification documents can be used if client has them available and as additional identification. **6. HIV CARE/ART FILE NUMBER:** **7. INDEX CASE NUMBER:** This is the number assigned to the client if they are offered partner notification services. Not all clients will have an index case number. **8. CBS UNIQUE IDENTIFIER:** **9. TODAY'S DATE:** Today's calendar date, this is to be completed using the format -DD/MM/YYYY
SECTION B: CLIENT DEMOGRAPHIC INFORMATION
The variables in this section are all required for case-based surveillance (CBS) and must all be completed.
1. MARITAL STATUS: What is the current marriage status of the client. **2. MARRIED:** If the client has stated that they are married, are they in a polygamous or monogamous marriage.

3. CO-HABITING: If the client is single or separated, determine if they are co-habiting (living together but not married) with a partner. They can either be single or separated.
4. DISTRICT: This is the district of diagnosis
5. AGE: Current age of the client, this is not a date but a number.
6. SEX AT BIRTH: The gender of the client at their birth.

SECTION C: FACILITY INFORMATION

The variables in this section are all required for case-based surveillance (CBS) and must all be completed.

1. DISTRICT: This is the district in which the facility is located
2. TESTING SITE NAME/CODE: This is the name of the testing site or the code used for the testing site
3. REPORTING SITE/CODE: This is the name of site where the results are being
4. POINT OF HIV TESTING SERVICE:

SECTION D: CASE REPORT FORM/DATA MANAGEMENT INFORMATION

The variables in this section are all required for case-based surveillance (CBS) and must all be completed.

1. DATE CRF COMPLETED: This is the date when the CRF is fully completed and should adhere to the following format- (DD/MM/YYYY). *E.g., if the CRF is completed on 20th June 2005, then the date CRF completed is 20/06/2005.*

COMPLETED BY: This is the full name (first name and last name) of the person completing the CRF.

CONTACT NUMBER: This is the telephone contact number of the person completing the CRF.

2. DATE CRF RECEIVED: This is the date the CRF is received at the designated clinic or district level for entry into the DHIS-2. The (DD/MM/YYYY) format must be used. *E.g., if the CRF is received on 25th June 2005, then the date CRF received is 25/06/2005.*

RECEIVED BY: This is the full name (first name and last name) of the person receiving the CRF at the designated clinic or district level facility.

CONTACT NUMBER: This is the telephone contact number of the person receiving the CRF at the designated clinic or district level facility.

3. DATE DATA ENTERED: This is the date the data from the CRF is entered into the DHIS-2 at the designated clinic or district level facility. The (DD/MM/YYYY) format must be used. *E.g., if the CRF is entered on 27th June 2005, then the date CRF entered is 27/06/2005.*

ENTERED BY: This is the full name (first name and last name) of the person entering data from the CRF into the DHIS-2
CONTACT NUMBER: This is the contact number of the person entering the data from the CRF into the EMR.

SECTION E: INDEX TESTING

The variables in this section are all required for case-based surveillance (CBS) and must all be completed.

If the client is less than five years of age and is identified through PMTCT, use HTS and ART ID number of the biological mother.

1. CONTACT OF INDEX CASE: This is a client (contact) who has tested HIV positive, this client (contact) has been referred for testing by an index case. An index case is a client who previously tested positive for HIV, has a relationship with the contact, provided details about the contact for the purposes of HIV testing.

I**NDEX CASE ID NUMBER:** This is the number assigned to the index client by the testing facility and is used to link the index cases with their contacts for public health purposes only.

INDEX CASE ART ID NUMBER:

SECTION F: HIV TESTING

The variables in this section are all required for case-based surveillance (CBS) and must all be completed.

1. DATE OF FIRST HIV POSITIVE TEST: This is the date the client was diagnosed. The date MUST be completed and the DD/MM/YYYY format.

2. DATE OF HIV POSITIVE VERIFICATION TEST: This is the date the client was diagnosed and then verified to confirm HIV diagnosis. This date MUST be completed and DD/MM/YYYY format used.

SECTION G: CLIENT CLINICAL HISTORY INFORMATION

The variables in this section are all required for case-based surveillance (CBS) and must all be completed. If client is older the five years of age, move to section H.

1. BIRTH WEIGHT: The weight of the baby at birth measured in kilograms.

GESTATION AT BIRTH – This is the amount of development time of the baby before delivery and is measured in weeks

2. MATERNAL ART: Select one of the three options (Yes, No, Don't Know) depending on the mother's ART status. If mother is on ART, then select the correct option and list ALL ART regimen.

3. INFANT ARV PROPHYLAXIS: Select one of the three options (Yes, No, Don't Know) if the infant is on ARV prophylaxis to prevent mother to child transmission. If yes, select or list the medication in use and how long (in weeks) it has been used.

4. BIRTH DEFECTS (ICD-10): Select one of the three options (Yes, No, Don't Know) if medical records indicate the baby has birth defects. If yes, please indicate as documented in the records.

SECTION H: CLIENT CLINICAL HISTORY INFORMATON (Client age > 5 years)

The variables in this section are all required for case-based surveillance (CBS) and must all be completed.

1. DATE OF MOST RECENT HIV NEGATIVE TEST: This can be a date (DD/MM/YYYY) if available or provided in number of months prior to positive HIV diagnosis. If client has never been tested, please select this option or if client does not know, select Don't Know.

2. EVER BEEN ON PrEP: Pre-exposure prophylaxis (PrEP) is a pill taken by those at risk of getting HIV. Select one of the four options (Yes, No, Refuse or Unknown).

3. EVER BEEN ON ART: Please select one of the four options (Yes, No, Refuse or Unknown).

4. EVER RECEIVED ARV/ART PROPHYLAXIS TO PREVENT MOTHER TO CHILD HIV TRANSMISSION: Please select one of the four options (Yes, No, Refuse or Unknown).

5. IS THE CLIENT FEMALE > 12 YEARS OF AGE: Select appropriate response
6. IF CLIENT IS FEMALE >12 YEARS OF AGE: Select all that apply

SECTION I: CLIENT CLINICAL INFORMATION – AT TIME OF DIAGNOSIS

The variables in this section are all required for case-based surveillance (CBS) and must all be completed.

1. WHO CLINICAL STAGE ASSESSED: If No, go to question 2. If an assessment was conducted, select Yes and select the result of the assessment (Stage I, II, III, IV).

2. 1st CD4 TEST CONDUCTED? If a CD4 test was conducted, select Yes and enter the sample collection date, sample test date using the date format (DD/MM/YYYY), result count and result percent.

3. ART INITIATED? If client is not initiated on ART, please document if they were referred or they refused. If client is initiated on ART, select Yes; Date of Initiation and Regimen.

4. CRYPTOCCOCAL INFECTION DIAGNOSED? Select one of three options (No, Not Done or Yes), if Yes, document date (DD/MM/YYYY) and results.

5. TUBERCULOSIS (TB) DIAGNOSED? If TB not diagnosed, select No and complete the follow up questions. If TB preventive therapy (TPT) given, select Yes, date (DD/MM/YYYY) and regimen of therapy. If TPT not given, select No and reason by selecting one of the four options provide (client refused, contraindication, already completed TPT, no drug supply).
If TB diagnosed, select Yes and complete the follow up questions. If patient was on TB treatment select Yes, start date for treatment and regimen. If patient is not on treatment, select No and document reason. Select Not Done if TB test not conducted.

6. ANY OTHER OPPORTUNISTIC INFECTIONS (OI) DIAGNOSED? In none, select No. If other OIs are diagnosed, select Yes, the date of diagnosis and specify the opportunistic infection.

Appendix F: Completing a Case Report Form for Sentinel Events of PLHIV

SECTION A: CLIENT IDENTIFIER

The variables in this section are all required for case-based surveillance (CBS) and must all be completed. If the client has a government issued identification document, please use that to correctly capture the spelling of the clients' name.

1. NAME: This variable includes the Surname, First Name and Middle Name. At a minimum, you must capture the client's surname (usually a family name and sometimes referred to as the last name) **AND** their first name. If the middle name is available, please capture this too.

2. PLACE OF BIRTH: The country where the client was born, the district of birth and the town or city or ward where client was born.

3. DOB (Date of Birth): This must be completed in the DD/MM/YYYY format, starting with two digits for the day, two digits for the month and four digits for the year. *E.g., if the client was born 2nd February 1980, then the person completing the form should enter 02/02/1980.*

4. CONTACT DETAILS: This is the telephone number of a close relative who can be contacted on the occasion that the facility cannot reach the client. The next of kin is usually a spouse, a sibling or some other relative. Confidentiality must always be maintained, and client information must not be disclosed without prior consent from the client.

5. NATIONAL IDENTIFICATION: This should be taken directly from an original government issued document and not word of mouth, the Omang is a national unique identification number provided to all citizens of Botswana. This is the gold standard for identification and should be captured if the client is a citizen of Botswana. If the client is a non-citizen, please capture the passport number as written. Some passports are alphanumeric and contain both letters and numbers, please capture this correctly. Other identification documents can be used if client has them available and as additional identification.

6. HIV CARE/ART FILE NUMBER:

7. INDEX CASE NUMBER: This is the number assigned to the client if they are offered partner notification services. Not all clients will have an index case number.

8. CBS UNIQUE IDENTIFIER:

9. TODAY'S DATE: Today's calendar date, this is to be completed using the format -DD/MM/YYYY

SECTION B: CARE AND TREATMENT FACILITY

The variables in this section are all required for case-based surveillance (CBS) and must all be completed.

1. DISTRICT: This is the district in which the facility is located

2. VILLAGE/CITY: This is the name of the village or city of the facility where the client is receiving their HIV care and treatment

3. CARE AND TREATMENT FACILTY NAME/CODE: This is the name of the facility where the client is receiving their HIV care and treatment.

SECTION C: CASE REPORT FORM/DATA MANAGEMENT INFORMATION

The variables in this section are all required for case-based surveillance (CBS) and must all be completed.

1. DISTRICT:

2. REPORTING FACILITY/CODE:

3. DATE CRF COMPLETED: This is the date when the CRF is fully completed and should adhere to the following format- (DD/MM/YYYY). *E.g., if the CRF is completed on 20th June 2005, then the date CRF completed is 20/06/2005.*

COMPLETED BY: This is the full name (first name and last name) of the person completing the CRF.

CONTACT NUMBER: This is the telephone contact number of the person completing the CRF.

4. DATE CRF RECEIVED: This is the date the CRF is received at the designated clinic or district level for entry into the DHIS-2. The (DD/MM/YYYY) format must be used. *E.g., if the CRF is received on 25th June 2005, then the date CRF received is 25/06/2005.*

RECEIVED BY: This is the full name (first name and last name) of the person receiving the CRF at the designated clinic or district level facility.

CONTACT DETAILS: This is the telephone contact number of the person receiving the CRF at the designated clinic or district level facility.

5. DATE DATA ENTERED: This is the date the data from the CRF is entered into the DHIS-2 at the designated clinic or district level facility. The (DD/MM/YYYY) format must be used. *E.g., if the CRF is entered on 27th June 2005, then the date CRF entered is 27/06/2005.*

ENTERED BY: This is the full name (first name and last name) of the person entering data from the CRF into the DHIS-2

CONTACT DETAILS: This is the contact number of the person entering the data from the CRF into the EMR.

SECTION D: CLIENT CURRENT DEMOGRAPHIC INFORMATION

The variables in this section are all required for case-based surveillance (CBS) and must all be completed.

1. LOCATION AND TYPE OF RESIDENT: This is the current residential location of the client. Please complete all the location information down to the plot number if it is available.

2. MARITAL STATUS: Please select one of the four options (Single, Married, Divorced/Separated, Widow/Widower) depending on the client's status.

MARRIED: If the client has stated that they are married, are they in a polygamous or monogamous marriage.
3. CO-HABITING: If the client is single or separated, determine if they are co-habiting (living together but not married) with a partner.

SECTION E: CLIENT TESTING AND TREATMENT HISTORY

The variables in this section are all required for case-based surveillance (CBS) and must all be completed.

1. DATE OF HIV DIAGNOSIS: This is the date the client first tested positive was diagnosed with HIV. The date MUST be completed using the DD/MM/YYYY format.
TESTING SITE NAME/CODE: This is the name/code of the HIV testing site where the client was first diagnosed with HIV.

2. DATE FIRST ENROLLED IN CARE/TREATMENT: This is the date the client was initiated into HIV care and treatment. This date MUST be completed using the DD/MM/YYYY format.

CARE/TREATMENT CLINIC NAME/CODE: This is the name/code of the facility where the client was first initiated into care/treatment after being diagnosed with HIV.

3. TRANSFERRED IN: Is the client transferring in from another facility, if No or Unknown then skip to section F. If Yes, go to question 4.

4. TRANSFER DATE: What date is the date of transfer, usually this would be the current calendar date and be completed using the DD/MM/YYYY format.

5. PREVIOUS FACILITY NAME: Name of the client's previous facility. If the client has been to more than one facility, this should the most recent facility where the client received care.

6.PATIENT WAS ON ART: Please select one of three response options (No, Unknown or Yes). If the response is Yes, document HIV Care/Treatment ID number.

7. DATE OF ART INITIATION IN PREVIOUS FACILITY: This is the date the client was initiated into treatment at the facility they transferred in from.

8. REGIMEN: Document the regimen the client was on at the previous facility.

SECTION F: ANTIRETOVIRAL TREATMENT (ART) DURING THE REPORTING PERIOD

The variables in this section are all required for case-based surveillance (CBS) and must all be completed. If client is older the five years of age, move to section H.

1. CURRENT HIV CARE/TREATMENT ID NUMBER:
ON: Select which line of treatment the client in currently receiving, the date they started using the format (DD/MM/YYYY) and the regimen.

2. REASONS TO SWITCH TO A NEW ART REGIMEN: If the client switched from one regimen to another, document the reason (s) why the switch was made.

SECTION G: WOMEN AND CHILD HEALTH DURING REPORTING PERIOD (Female Clients Only)

The variables in this section are all required for case-based surveillance (CBS) and must all be completed.

1. IS THE CLIENT PREGNANT: If No or Unknown, skip to section H. If Yes, tick the correct box and complete the rest of this section.

a. LAST DAY OF MENSTRUAL PERIOD: If the client's last day of their menstrual cycle is known, complete as much of the date information. It is possible they may remember just the month and year. If they know the full date, use the format (DD/MM/YYYY). If only the month and the year is known then use the format (99/MM/YYYY) where 99 is unknown date. If they do not know the date, select Don't Know.

b. DUE DATE: If the client's due date is known, document the date using the format (DD/MM/YYYY). If it is not known, select Don't Know.

c. ATTEND ANTENATAL CARE: Depending on weather the client has attended antenatal clinic, select one of three options (No, Don't Know, Yes). If Yes, document the date of their first visit for antenatal care using the format (DD/MM/YYYY) and gestation in weeks.

2. DID SHE GIVE BIRTH:

SECTION H: LABORATORY TEST INFORMATION

The variables in this section are all required for case-based surveillance (CBS) and must all be completed.

CD4 T CELL COUNT AND PERCENTAGE DURING THE REPORTING PERIOD

DATE OF SAMPLE COLLECTION: This is the day that a sample of the client's blood is drawn for testing. Please use the format (DD/MM/YYYY).

CD4 COUNT: This is the result of a CD4 count test and is displayed as a whole number.

CD4 PERCENTAGE: This is also the result of a CD4 count test and is displayed as a percentage (%)

HIV VIRAL LOAD RNA TEST DURING THE REPORTING PERIOD

DATE OF SAMPLE COLLECTION: This is the day that a sample of the client's blood is drawn for testing. Please use the format (DD/MM/YYYY).

DETECTABLE COPIES: This is the result of the viral load test and is displayed in whole numbers.

HIV DRUG RESISTANCE DURING THE REPORTING PERIOD

DATE OF SAMPLE COLLECTION: This is the day that a sample of the client's blood is drawn for testing. Please use the format (DD/MM/YYYY).

DATE SAMPLE TESTED: This is the day that the sample of the client's blood is tested. Please use the format (DD/MM/YYYY).

SAMPLE REJECTED: Tick this box is a sample was collected and submitted for testing and the laboratory rejects it.

NOT DONE: Tick this box if a sample was not collected for drug resistance testing.

MAJOR MUTATION RESULTS: If a sample is collected, tested and the results returned; please select one of the options listed and specify if other.

SECTION I: CLINICAL INFORMATION

The variables in this section are all required for case-based surveillance (CBS) and must all be completed.

1. TUBERCULOSIS (TB) DIAGNOSED? If TB not diagnosed, select No and complete the follow up questions. If TB preventive therapy (TPT) given, select Yes, date (DD/MM/YYYY) and regimen of therapy. If TPT not given, select No and reason by selecting one of the four options provide (client refused, contraindication, already completed TPT, no drug supply).

If TB diagnosed, select Yes and complete the follow up questions. If patient was on TB treatment select Yes, start date for treatment and regimen. If patient is not on treatment, select No and document reason. Select Not Done if TB test not conducted.

WHO CLINICAL STAGE ASSESSED: If No, go to question 2. If an assessment was conducted, select Yes and select the result of the assessment (Stage I, II, III, IV).

2. 1st CD4 TEST CONDUCTED? If a CD4 test was conducted, select Yes and enter the sample collection date, sample test date using the date format (DD/MM/YYYY), result count and result percent.

3. ART INITIATED? If client is not initiated on ART, please document if they were referred or they refused. If client is initiated on ART, select Yes; Date of Initiation and Regimen.

4. CRYPTOCCOCAL INFECTION DIAGNOSED? Select one of three options (No, Not Done or Yes), if Yes, document date (DD/MM/YYYY) and results.

6. ANY OTHER OPPORTUNISTIC INFECTIONS (OI) DIAGNOSED? In none, select No. If other OIs are diagnosed, select Yes, the date of diagnosis and specify the opportunistic infection.

Appendix G: Chain of Custody Tracking Log

Date of Transfer	Name of person handing over docs	Designation	District	Location of hand over	#of forms handed over	Name of forms (codify)	Signature	Name of recipient receiving document /form	Designation	District	Confirm # of forms/ docs handed over	Date of Receipt	Signature of recipient