Standard Operating Procedures for HIV & Syphilis Screening of Pregnant Women at VHSND Sites

Maternal Health Division
Ministry of Health and family Welfare
Government of India

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ABBREVIATION

ANC-Antenatal Care
AVD-Alternate Vaccine Delivery
ANM-Auxiliary Nurse Midwifery
CHC-Community Health Centre
DM-District Magistrate
DAPCU-District AIDS Prevention and Control Unit
EMTCT-Elimination of Mother to Child Transmission
FICTC-Facility Integrated Counseling and Testing Center
GOI-Government of India
GFATM-Global Fund to fight AIDS, Tuberculosis and Malaria
HMIS-Health Management Information System
HIV-Human Immunodeficiency Virus
ILR-Ice Lined Refrigerator
MO-Medical Officer
MCP Card-Mother Child Protection Card
NACO-National AIDS Control Organization
NHM-National Health Mission
POC-Point of Care
PIP-Programme Implementation Plan
PHC-Primary Health Centre
PPTCT-Prevention of Parent to Child Transmission
PNC-Post Natal Care
RTI-Reproductive Tract infection
RCH-Reproductive Child Health
SC-Sub Centre
STI-Sexually Transmitted Infection
SOP-Standard Operating Procedures
SA-ICTC-Standalone Integrated Counseling and Testing Centre
SAATHII-Solidarity and Action Against the HIV Infection in India
SIMS-Strategic Information Management System
SACS-State AIDS Control Society.
TISS-Tata Institute of Social Sciences
UPHC-Urban Primary Health Centre
UIP-Universal Immunization Programme
VHSND-Village Health Sanitation& Nutrition Day
WBFP-Whole Blood Finger Prick

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HIV & Syphilis screening of Pregnant Women at VHSND Sites

Introduction

It is estimated that there are 12 million people infected worldwide from Syphilis, with more than 90% of these cases bei ng from the developing countries. Each year nearly 1.5 million pregnant women around the world are infected with active syphilis. Due to widespread availability of Penicillin in the 1940s there was dramatic decrease in the rates of infection, which have again increased since the turn of the millennium in many countries, often in combination with HIV infection. Data on the incidence and prevalence of STI in the South- East Asia Region (SEAR) are limited. WHO estimates approximately 600,000 pregnant women are infected with syphilis and 230,000 associated adverse outcomes occur every year in the SEAR. (WHO)

Sixty percent of pregnant women living with HIV accessed antiretroviral medicine to prevent transmission of the virus to their baby, preventing 3500 new HIV infections among newborns. Early infant diagnosis—the percentage of HIV-exposed infants tested for HIV before eight weeks of age—stood at 23% in 2017. (UNAIDS)

The Government of India (GoI) is committed to Elimination of Mother to Child Transmission (EMTCT) of HIV & Syphilis by 2020. To achieve this target, Ministry of Health & Family Welfare (MOH&FW) has taken a policy decision for universal screening of pregnant women for Syphilis &HIV during the first visit (preferably in the first trimester) at all facilities and outreach sites such as Village Health Sanitation & Nutrition Days (VHSNDs) as part of essential antenatal care (ANC) package.

In order to achieve this objective, it is crucial to ensure HIV & Syphilis screening services at all health facilities (Medical College, District Hospitals, CHCs, PHCs, APHCs, and UPHCs) and outreach sites such as VHSNDs.

Objective of this Standard Operating Procedure:

The objective of this document is to define the standard operating procedures for implementation of HIV & Syphilis screening at VHSND sites. These SOPs are an extension of the existing guidelines (National Guidelines on Prevention, Management and Control of Reproductive Tract Infections including Sexually Transmitted Infections – MoHFW; Technical and Operational guidelines of screening for syphilis in Pregnant Women - MoHFW) and specifically focus on additional activities required for ensuring screening at outreach sites. These include activities such as procurement, transportation, cold chain of testing kits, confidentiality aspect of testing and referral, recording and reporting mechanisms, along with training component.

Procurement of Kits

- **HIV Whole Blood Finger Prick (WBFP)** Kits - NACO is responsible for procurement and supply of HIV WBFP test kits to States/ UTs.
- **Syphilis Rapid Plasma Reagin (RPR) / Point of Care (POC) test kits**
    - NACO is responsible for procurement and supply of RPR (Rapid Plasma Reagin) kits at medical college level and District level and select Sub-Divisional Hospitals (Designated STI/RTI Clinics) "SURAKSHA CLINIC"
    - States/ UTs are responsible for procurement and supply of POC kits for Syphilis, using the budget provided under NHM, at the Sub-district level and below.

Transportation of Kits

- In order to maintain cold chain (2-8 degree Celsius) there is need to focus on the transportation mechanisms for the HIV/ Syphilis kits. The transportation mechanisms have been divided into two parts for ease of understanding:
- Transportation of kits up to the cold chain point
- Transportation of kits from the cold chain point up to the VHSND site.

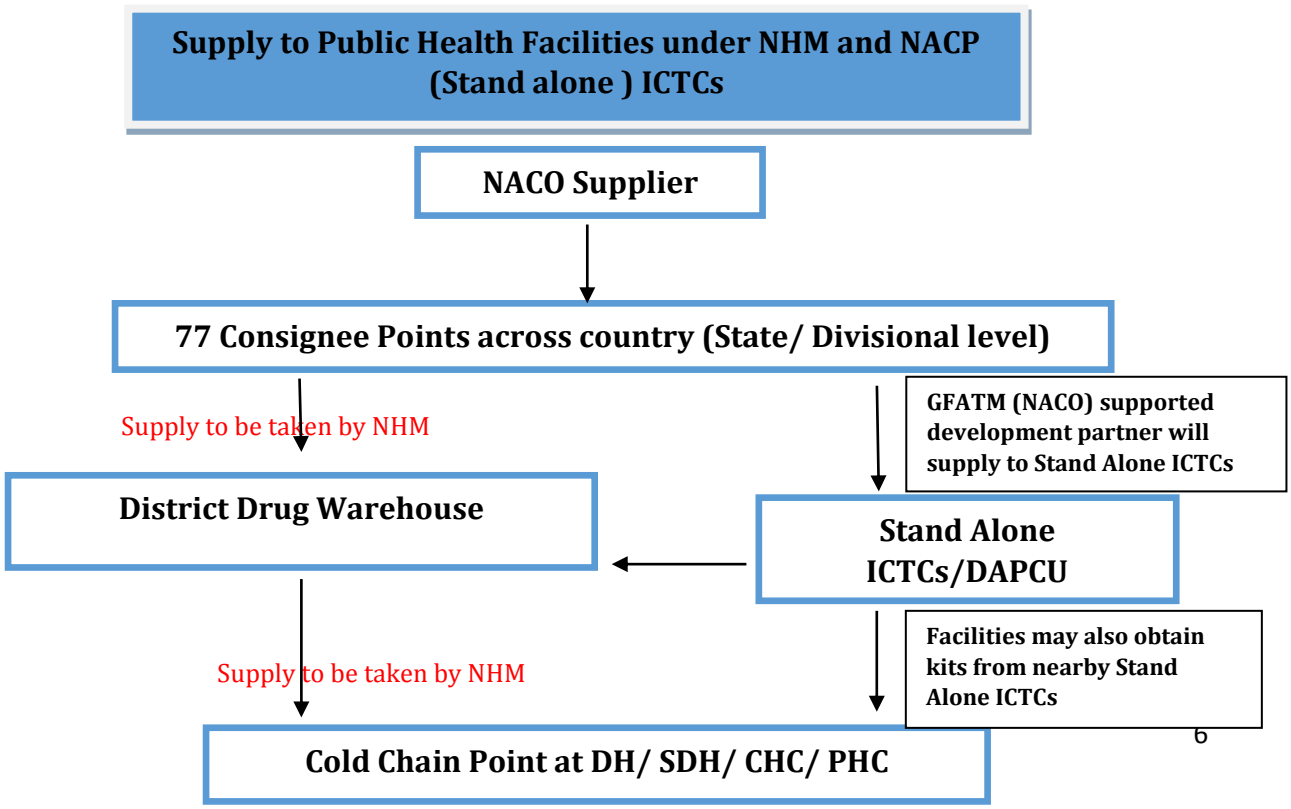
1. Transportation of kits up to the cold chain point

The transportation mechanisms up to the cold chain points are different for the different types of kits and are outlined below.

Transportation of HIV Kits up to the cold chain point

The process for transportation of HIV (Whole Blood Finger Prick Test) kits up to the cold chain points is outlined in Figure 1 below:

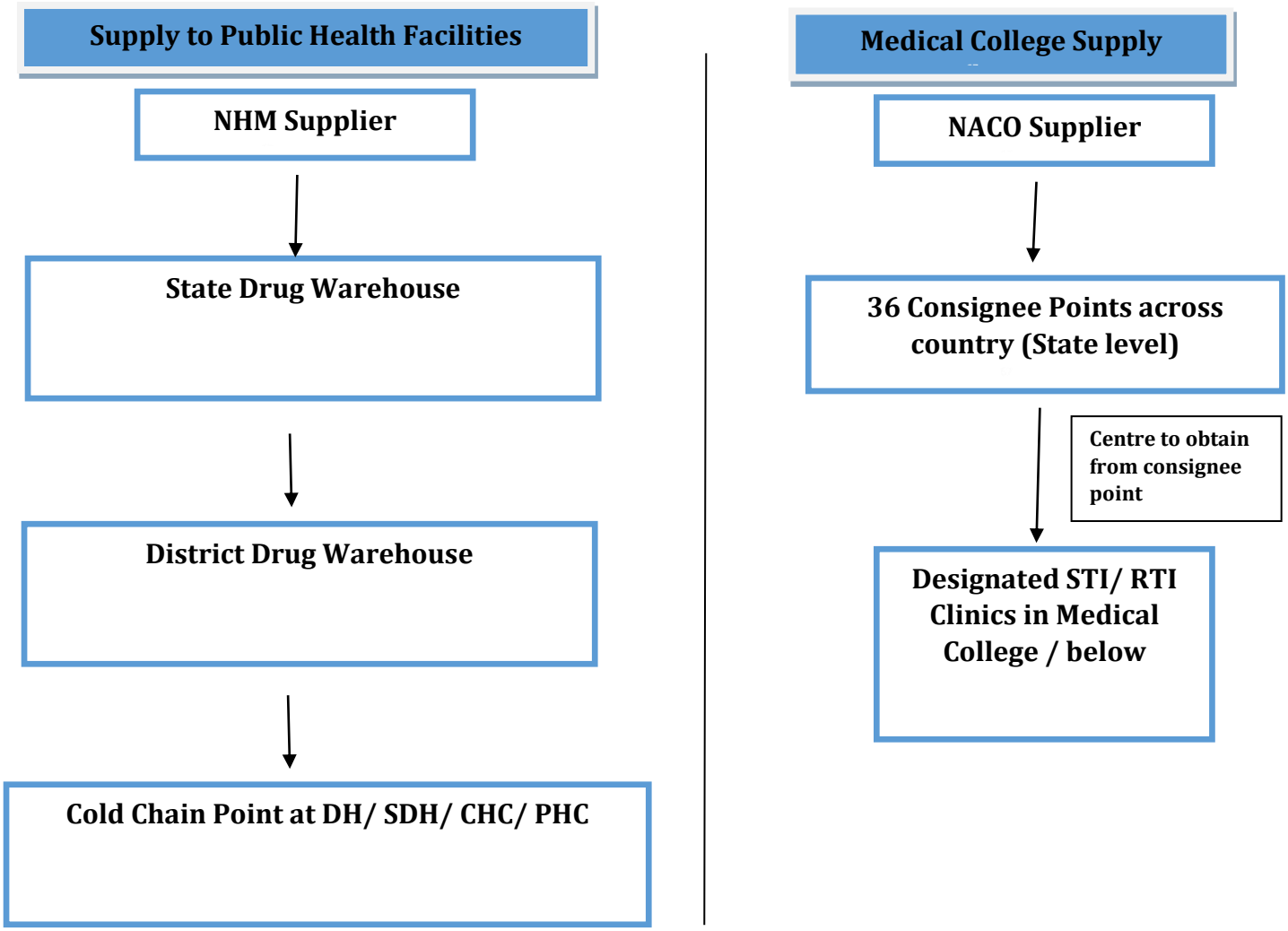
Figure1: Transport of HIV kits up to cold chain point



Transportation of Syphilis Kits up to the cold chain point

The process for transportation of Syphilis is different for Medical Colleges/ Designated RTI/STI Centres and for public health facilities as supply for the former will be from NACO whereas that for the later would be through the NHM budget and procured by the States/UTs themselves. The process is outlined in ***Figure 2*** **below:**

Figure2: Transport of Syphilis kits up to cold chain point



All storage points should have refrigerator with electricity backup

Note-States/UTs who have purchased dual kit for HIV & Syphilis, the logistic supply and cold chain maintenance should be done as per the figure 2(transportation of syphilis kits)

Critical points to be remembered during transportation and storage of kits up to cold chain point:

1. All transportation of HIV and Syphilis kits should be carried out under proper cold chain process.
2. **Most Important:** *Under no circumstances cold chain equipment for vaccination under UIP and HIV-Syphilis should be mixed. Both should follow their independent cold chain system.*
3. HIV & Syphilis Kits can be stored in the common cold chain equipment/Refrigerator. However, both the kits should be labelled separately for the ease of identification and avoiding mix-ups.
4. Kits stored at divisional drug warehouse may be transported to District drug Warehouse in cold chain using cold boxes with conditioned[1] ice packs.
5. At district level, if separate cold chain storage facility not available then it should be created by installing cold chain equipment / Refrigerators with electricity backup.
6. From district store house, kits may be transported to last storage point at CHC / PHC / SC in cold boxes with conditioned ice packs.
7. At cold chain storage points at CHC / PHC / SC, the pharmacist / ANM will be responsible for storage and distribution of the kits along with required record maintenance.
8. At CHC / PHC / SC, the kits may be stored in refrigerators /domestic refrigerators with electricity backup.
9. All costs required for transportation and cold chain equipment should be budgeted under respective state PIPs under relevant budget head.

2. Transportation of kits from the cold chain point up to the VHSND site

- From the last cold chain point at facility level (CHC / PHC / SC), kits may be transported to VHSND site through Alternate Vaccine Delivery (AVDs) in vaccine[2] carrier which should be **green** in colour.
  a. The green colour should be part of the specifications for procurement so that green colour kit carrier is supplied by the manufacturer as per the specifications (Annexure 4). This is to ensure the separate identity of the carrier carrying kits.
  b. Procurement of green coloured kit carriers may be budgeted under NHM PIP.
- Pharmacist / ANM will maintain a list of the number of kits used. The used kits shall be disposed following Bio Medical Waste Management guidelines. Any excess kits leftover after testing at VHSND may be transported back to the cold chain point from where it was sent.

[1]For conditioning the ice packs, the ice packs should be removed from deep freezer and placed on a flat surface/ table top. After 15-20 minutes when sweat appears on the surface of the ice pack, shake it and if crackling sounds are there it means ice pack is conditioned.

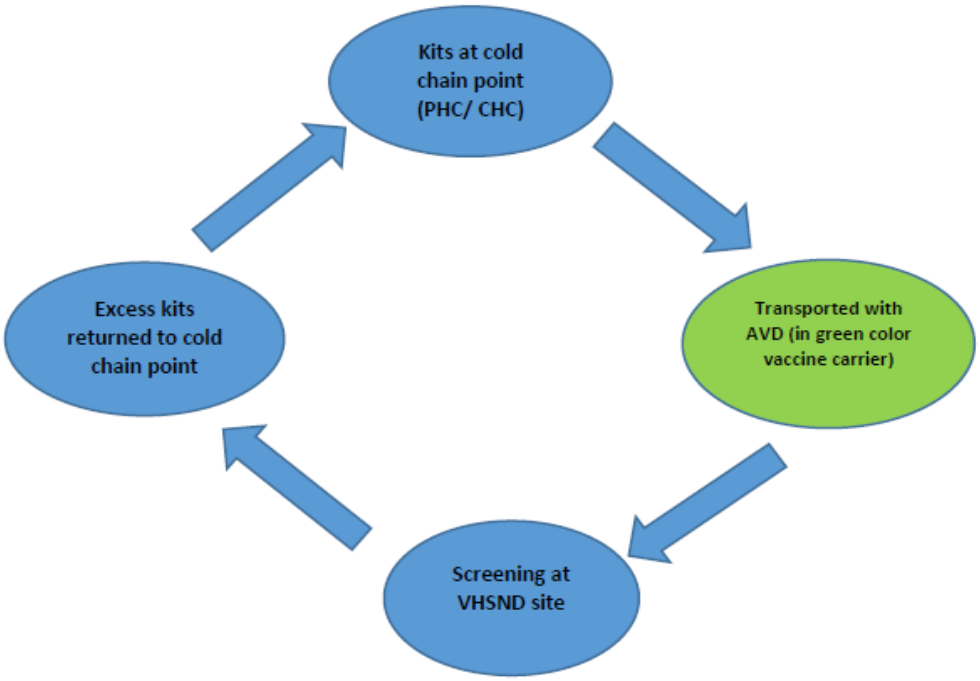


Figure 3: Transportation to and from VHSND site

- Budgeting for Alternate Vaccine Delivery of HIV & Syphilis kits
    a. State may budget for Alternate Vaccine Delivery at 50% of the rate prescribed for AVD under UIP. Accordingly, the following must be budgeted for AVD per VHND session[3]:
        i. Rs 225 in very hard to reach areas especially notified by the State/districts)
        ii. Rs 100 for AVD for hard to reach areas
        iii. Rs 45 for AVD in other areas

State can propose the budget for AVD (HIV& Syphilis) under FMR head 6.2.1.1 (RTI /STI drugs and consumables)

[3]The norms proposed in PIP will be on average basis and disbursement of fund should be on actual expenditure after verifying the AVD plans.

Screening and Referral of Pregnant women for HIV & Syphilis

Who should be screened?

- **All pregnant women** attending ANC services preferably at first ANC visit.

Who will conduct the screening?

- Any ANM trained as per National STI / RTI module for 2 days or trained by TISS on HIV & Syphilis counselling and testing can undertake HIV & Syphilis screening using Point of care (POC) / WBFP test kits or dual HIV Syphilis kits (wherever available).
- Confidentiality of reactive clients must be maintained as per national guidelines.

What mechanism should be followed for referral of pregnant women found to be reactive?

- If any pregnant woman is found reactive for HIV, then the ANM should write on the MCP card "**Referred to SA-ICTC" and refer the pregnant woman to SA- ICTC.** She must also share details with the linked In-charge PHC MO (**Refer to figure 4 below**).
- If any pregnant woman is found reactive for Syphilis, then the ANM should write on the MCP card for the pregnant women "**Reactive for Syphilis" and refer the pregnant woman to nearest PHC.** She must also share details with the linked In-charge PHC MO (**Refer to figure 4 below**).

Figure 4: Screening at VHSND level-Referral flow diagram

S.No.	Result of Screening Test		Referral Action
	HIV	*Syphilis*	
1	Reactive	Reactive	Refer to SA-ICTC (for HIV reactive); Refer to MO-PHC (for Syphilis reactive)
2	Reactive	Non-Reactive	Refer to SA- ICTC and ensure institutional delivery
3	Non-Reactive	Reactive	Refer to MO-PHC and ensure institutional delivery
4	Non-Reactive	Non-Reactive	No referral required

- PHC MO to assist with all referrals.
- States may also utilise field coordinator of Svetana (SAATHII) or Ahana Project (PLAN) to ensure accompanied referral of all HIV pregnant women

cases to the SA-ICTC & PHC-MO (for Syphilis reactive PW) for confirmatory testing and/or treatment.

- In case of Syphilis and/or HIV reactive pregnant women, ANM should only inform PLAN/SAATHII field coordinators regarding support required for linking pregnant women to SA-ICTC over phone but would not divulge any information on her status (reactive
- Follow-up and treatment of reactive pregnant women for syphilis and/or HIV should be done by the linked SA-ICTC counsellor.
- Confirmed HIV positive pregnant women to be also followed up by SAATHII/PLAN field coordinator during her PPTCT service uptake, if possible.

Reporting Mechanism for HIV & Syphilis

Overview of Reporting Mechanisms:

- Overall, HIV & Syphilis screening services are to be recorded and reported through the following platforms:

  For HIV and Syphilis screening -
    - MCP Card
    - RCH register
    - F-ICTC SIMS report
    - RCH portal / ANMOL
    - HMIS
    - Reporting Format for pregnant women referred after HIV & Syphilis screening(Annex 1 & 2)
    - Monthly Reporting format for F-ICTC (Annex 3)

Reporting by ANM:

- HIV & Syphilis screening services are to be recorded in RCH register and MCP Card.
    - Based on the RCH register, the screening details must be submitted on a monthly basis to MO- PHC. (If the ANM is using ANMOL, these details may be directly entered into the RCH portal by the ANM).
- Recording results of Pregnant Women found reactive on the MCP card:
    - Since privacy and confidentiality are associated with HIV test, in case of the reactive result, it should be recorded as 'Referred to ICTC'. It should not be recorded as "Reactive". In non-reactive cases, ANM to write "Tested for HIV".
    - Pregnant women screened reactive for Syphilis to be recorded as 'Reactive for Syphilis'.
- ANM should fill the 'Reporting Format for pregnant women referred after HIV & Syphilis screening (Annex 1)' for all pregnant women found reactive for HIV & Syphilis and also share the list with MO, PHC.

Reporting by MO- PHC

- Details of HIV & Syphilis screening of all pregnant women are to be recorded in RCH portal, HMIS and Strategic Information Management System (SIMS):
    - Based on the RCH register submitted by the ANMs, these screening details must be incorporated in the RCH portal, HMIS and SIMS report on a monthly basis through the concerned PHC.
    - HIV & Syphilis testing details of all pregnant women should be incorporated in the RCH portal and SIMS & HMIS formats. Preferably the same person who is responsible for data entry in SIMS portal should also be made responsible to upload the data in HMIS to maintain data parity.
    - PHC MO should share line list of reactive pregnant women (HIV/ Syphilis) with CHC / Block PHC MO and nearest FICTC. (Use Reporting Format for pregnant women referred after HIV & Syphilis -Annex 2)
    - MO- PHC must submit monthly reporting formats for F-ICTC to nearby F-ICTC (Annex 3)

Reporting by Block PHC / CHC

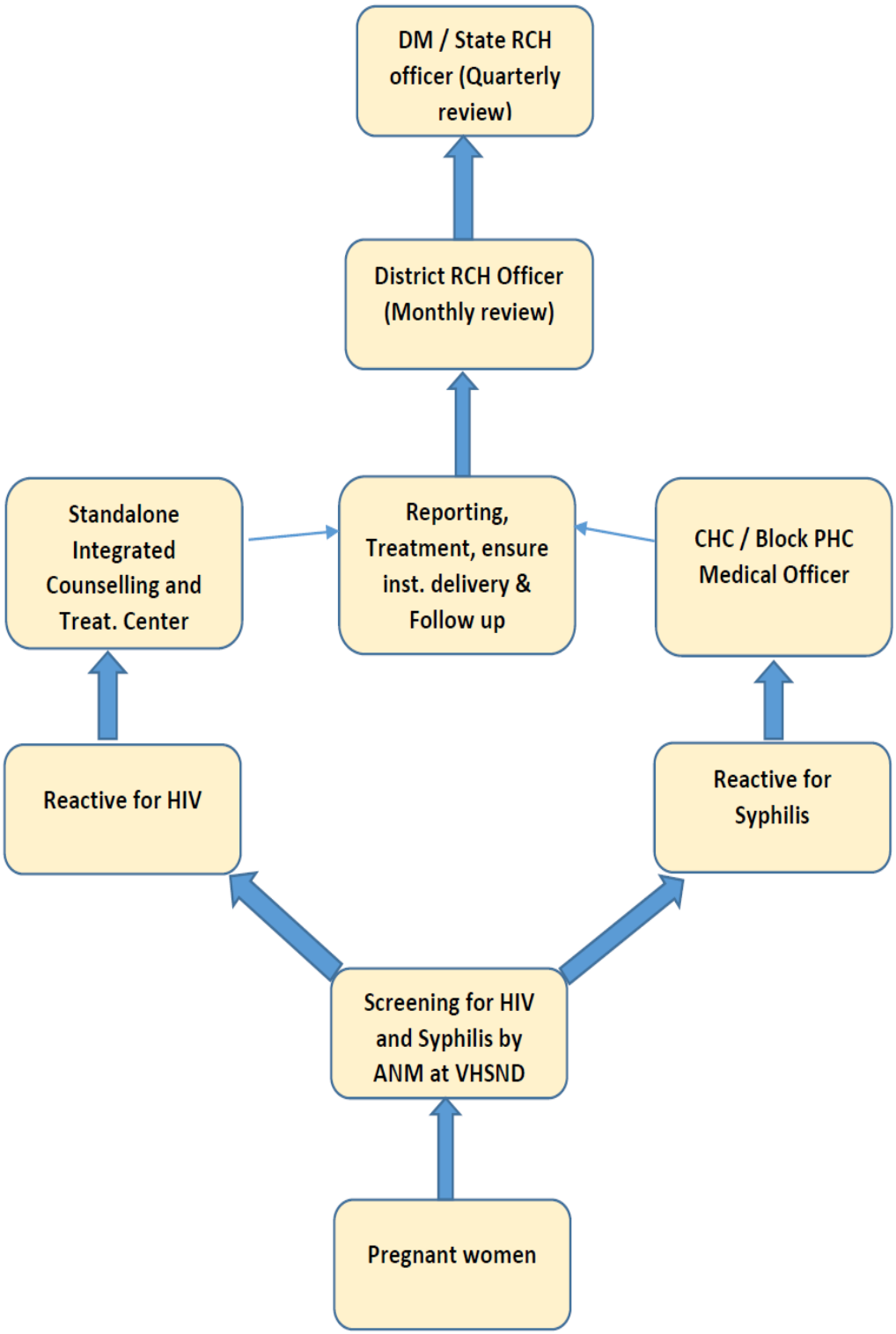
- At the end of each month, In-charge Block Medical Officer or designated officer by the State should share line list of reactive pregnant women (Syphilis/HIV) for all VHSNDs with each linked SA- ICTC centre for Syphilis & HIV reactive pregnant women.

Note: Taking into consideration the low prevalence of HIV and Syphilis, the number of reactive pregnant women for HIV and Syphilis will be few, and hence it is critical to follow up with all screened reactive in a timely manner

Supervision Mechanism

The State RCH officer should be responsible for conducting quarterly reviews to ensure that (a) all registered ANC are screened for Syphilis & HIV, and (b) those who are screened reactive for HIV are linked to SA-ICTC and those screened reactive for Syphilis are linked with PHC-MO for testing / treatment. Ensure institutional delivery and follow-up of all positive pregnant women. District RCH officer should be made responsible to review monthly and track all cases. DM/Collector should review every quarter. Joint State level reviews should be conducted for NHM & SACS.

Supervisory Mechanism



Privacy, Confidentiality and Respectful Maternity Care during VHSND for HIV & Syphilis test

Confidentiality in HIV Counselling and Testing Services (HCTS)

HIV testing services must be confidential, meaning that the HIV testing provider and the client should not be disclosed to anyone else without the expressed consent of the person being tested. HCTS give utmost importance to audio-visual privacy and confidentiality. Confidentiality is essential for ensuring respect for the privacy and rights of an individual and to protect them from victimization, discrimination, and stigmatization.

General Principles

- **Informed Consent:** Informed consent as per guidelines to be taken for all ANCs. As per the HCTS guideline 2016 and HIV AIDS Act 2017, each individual should give informed consent for HIV testing with an opt-out option. Written consent is not mandatory, but the program does maintain a record of the same in the services register. For VHND testing, the same method of recording consent in a services register by the ANM may be followed. However, there is no separate consent form required for HIV testing.

- **Group/ Individual Counselling**:
  - Counselling to inform all pregnant women about the ante natal routine screening tests haemoglobin (Hb %), Urine albumin/sugar, VDRL/RPR, blood grouping & typing and the benefits of testing for HIV.
  - Nurse/ Counsellors to provide information on the antenatal screening comprehensive package including HIV testing through both individual counselling and group counselling information sessions.

    OPT OUT OPTION: During counselling, pregnant women should be provided an option of opting out of the HIV testing. However, pregnant women who opt-out of HIV testing should be offered repeat counselling to explore the reasons for opting out, address any misunderstandings and encourage her to reconsider her decision. These women should be offered routine HIV testing at each subsequent visit.

- Ensure that all tests are conducted using a single prick.

- **Post Test Counselling:** Post-test counselling for all pregnant women is very important. Pregnant women with non- reactive tests must be counselled to remain uninfected. Pregnant women with reactive results must be referred to SA-ICTC and counselled to visit the SA-ICTC for further confirmatory testing.

- **Procedure at Stand Alone ICTCs**: Pregnant women who have been referred by ANMs after whole blood screening tests must undergo pre-test counselling and follow the usual HIV testing protocol similar to the regular antenatal cases at the stand-alone ICTCs for confirmatory tests

- **Disclosure of HIV Status:** Disclosure of HIV status is to be done only at stand-alone ICTCs after appropriate confirmatory testing as per laboratory guidelines (post-test counselling) and only by trained health staff (MO, Nurse or Counsellor)

- **Follow up of Pregnant Women:** All pregnant women referred to other HIV services including ART Centre, should be tracked to ensure that they actually avail the services, and have been registered at the respective centres.

- **Husband Involvement:** Partner (Husband) involvement during the pregnancy and thereafter must be encouraged. Husband involvement for PPTCT interventions and family planning methods to be encouraged e.g., couple counselling for mutual psycho-social support, linking mother to ART and baby to ARV, Family planning counselling etc.

- **Confidentiality of Data:** As per the Act, every establishment keeps the records of HIV-related information shall adopt data protection measures. The measures shall include procedures for protecting information from disclosure, accessing information, security, accountability and liability of persons in the establishment.
    - Recording the result on MCP card: Privacy and confidentiality are associated with HIV test. In case the pregnant woman is found reactive, record the result as 'Referred to ICTC'. It should not be recorded as "Reactive". In non-reactive cases, ANM to write "Tested for HIV".

What are Do's for confidentiality in HIV testing?

- Informed consent should be taken before performing the HIV testing of any person.

- Maintain utmost confidentiality of personal information shared by individuals accessing HIV Counselling & testing Services, including his/ her HIV test results.
- The confidentiality of the HIV test results should be maintained for both positive and negative reports.
- The test results should be handed over directly to the person concerned, to a person authorized by the patient,

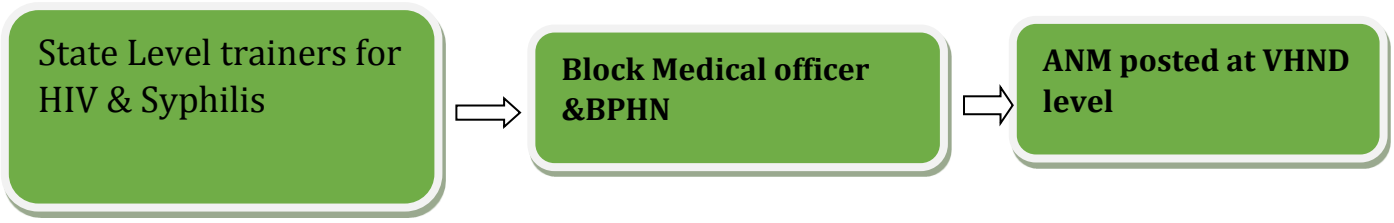
- However, in certain circumstances when discloser of an individual's HIV status to another person is required by law or ethical consideration, the HIV test results may be shared.
- Wherever warranted, in the medical interest of an individual, their HIV status may be shared with her health-care provider(s) involved in the treatment and care of that individual. The purpose of sharing information is to ensure that the individual receives better treatment and care. Confidentiality should be maintained during the process.
- All the concerned functionaries (Health care provider) need to ensure privacy, confidentiality and safe custody of the personal information and test results of the individual.
- Health care provider will ensure, that all HIV screened positive person will be linked to SA-ICTC for further HIV confirmation.
- Confidentiality applies not only to the test results and reports of HIV status but also to any personal information, such as information concerning sexual behaviour and the use of illegal drugs.

What are Don'ts for confidentiality in HIV testing?

- No results, under any circumstances, should be communicated via telephone, fax, email, etc.
- What the HIV testing provider and the client discuss should not be disclosed to anyone else without the express consent of the person being tested.
- Don't discriminate or stigmatization the clients irrespective of HIV test result.

Training Program for HIV & Syphilis -

Training will be provided through a cascade model. Initial training will be imparted by State level Master trainers to Block Medical officers which in turn will train the field level workers (ANM).



Duration of training

Duration of the training programme will be for 1 day for both BMO level and for ANM level.

Site of training

State level trainer will provide training to BMO & Block Public Health Nurse(BPHN) at State level/regional site. Block medical officer will provide training to ANM (posted at VHND) at Block level.

Training Budget-

States/UTs can propose the budget for training for HIV, Syphilis in the PIP.

Training Budget

Annexure 1

Budget for 1 day training for Field Level Workers for HIV & Syphilis Batch size of 30

Trainers – Block Medical officers & Block Public Health Nurse (BPHN)
Trainees- ANM

Sr.NO	Head	Unit Cost	Number of Participants	Days	Total	Budget per person
1.	Venue hiring(**In absence of training Institute)**	5000/day at district level		1	Rs 5,000/-	
2.	DA to participants	Rs. 700/day	30	1	Rs. 21,000/-	700/-
3.	Food to participants	Rs. 250/day	35	1	Rs.8,750/-	250/-
4.	Honorarium to State Faculty	Rs. 1000/ day	2	1	Rs. 2000/-	
5.	Honorarium to District Faculty	Rs 600/day	2	1	Rs 1200/-	
6.	Incidental expenses (photocopying, job aids, flip chart, Audio Visuals etc.)(Subject to actuals)	Rs 300/ person/day	30	1	9,000/	300/-
	Sub Total				**46,950**	
9.	TA to partcipants(to&fro)(As per state Government Rules)	Rs 1000/day	30		Rs 30,000/-	1000/-
10.	Travel to trainers from the state(to&fro)(As per state Government Rules)	Rs2000/day	2		Rs4000/-	
	Grand Total/Batch				**80,950**	**2250/-**

Note: TA to be given as per state Norms.

The state needs to adjust the training norms as per the training load of the district and state.

Budget for 1 day training of Block Medical officer and BPHN for HIV & Syphilis. Batch size of 30

Trainers – State level trainers from SIHFW, Regional Institute, NIHFW & Medical Colleges.
Trainees- Block Medical officers & Block Public health Nurse

Sr.NO	Head	Unit Cost	Number of Participants	Days	Total	Budget per person
1	Venue hiring(**In absence of training Institute)**	3000/day at block level		1	Rs 3,000/-	
2	DA to participants	Rs. 400/day	30	1	Rs. 12,000/-	400/-
3	Food to participants	Rs. 250/day	35	1	Rs.8,750/-	250/-
4	Honorarium to district faculty	Rs. 600/ (per day)	2	1	Rs. 1,200/-	
7	Incidental expenses (photocopying, job aids, flip chart, Audio Visuals etc.)(Subject to actuals)	Rs 200/ person/day	30	1	6,000/-	200/-
8	**Sub Total**				**30,950**	
9	TA to participants (to&fro)(As per state Government Rules)	Rs 1000/	30		30,000/-	1000/-
10	TA to trainers(to&fro)(As per state Government Rules)	Rs 2000/	2		4,000/-	
	Grand Total/Batch				**Rs 64,950/-**	**1850/-**

Annexure 1:

Reporting Format for pregnant women referred after HIV & Syphilis screening

(To be filled by ANM for every VHSND and shared with MO-PHC)

	Pregnant woman/ Client 1	**Pregnant woman/ Client 2**	**Pregnant woman/ Client 3**
Name of District			
Type and Name of Public Health Facility			
FICTC PID (Only Last 5 Digits – For HIV &Syphilis only)			
Name of the client			
Type of Case ((1 =ANC, 2= PNC, 3= General client), 4–other-please specify)			
Age			
Complete Address			
Block/Village			
District			
Phone Number			
Mobile Number			
RCH / MCTS Number (if available)			
Date of Screening			
Screened for HIV (Yes/ No)			
Screened for Syphilis (Yes/ No)			
Whether woman referred to SA-ICTC (Yes or No) /PHC-MO for Syphilis reactive			
Name of SA-ICTC of referral			
District of SA-ICTC of referral			
Results of Syphilis Screening			
Result of Syphilis Screening (Reactive/ Non- Reactive)			

Annexure 2:

ReporFor ting mat for pregnant women referred after HIV & Syphilis screening

(To be filled by MO- PHC and shared with BMO & nearby F-ICTC)

	Pregnant woman/ Client 1	**Pregnant woman/ Client 2**	**Pregnant woman/ Client 3**
Name of District			
Type and Name of Public Health Facility			
FICTC PID (Only Last 5 Digits – For HIV & Syphilis only)			
Name of the client			
Type of Case ((1 =ANC, 2= PNC, 3= General client), 4–other-please specify)			
Age			
Complete Address			
Block/Village			
District			
Phone Number			
Mobile Number			
RCH / MCTS Number (if available)			
Date of Screening			
Screened for HIV (Yes/ No)			
Screened for Syphilis (Yes/ No)			
Whether woman referred to SA-ICTC (Yes or No)			
Name of SA-ICTC of referral			
District of SA-ICTC of referral			
Results of Syphilis Screening			
Result of Syphilis Screening (Reactive/ Non- Reactive)			

Monthly reporting format

F-ICTC Code							
MONTHLY REPORTING FORMAT: FACILITY INTEGRATED / PPP ICTC							
SECTION A. IDENTIFICATION							
1. Name of Centre:				Type of F-ICTC			
2. Address:							
Pin Code:		Block/ Mandal/ Taluka:		District:		State:	
3. Reporting Period:		Month:		Year:			
4. Name of Officer In-charge (F-ICTC):							
5. Contact number (phone):							
6. Email Address:							
7. F-ICTC Location:							

SECTION B. BASIC INDICATORS							
1. PROGRESS MADE DURING THE MONTH							
	Pregnant Women			General Clients			
	ANC	Direct in Labour	Total	Male	Female	TS / TG	Total
1. Total ANC Clients registered during the month			0				
2. Number of Clients provided pre-test counseling			0				0
3. Number of Clients tested for HIV			0				0
4. Number of Clients provided post-test counseling			0				0
5. Number of Clients detected HIV reactive after 1st Test			0				0
6. Number of ANC Clients tested for Syphlis (VDRL/RPR Test)			0				
7. Number of ANC Clients found reactive for Syphlis			0				

2. LINKAGE & REFERRAL		
Department/ Organisation	In Referral	Out Referral to Stand Alone ICTCs for confirmation
1. OBG / GYN (ANC)		
2. Targeted Intervention NGOs		
3. Link Worker		
4. RNTCP		
5. STI Clinc		
6. Others		

3. STOCK STATUS OF HIV TEST KITS (Number of Tests)										
Consumables	Name of Kit	Batch No.	Expiry Date dd/mm/yyyy	Opening Stock	Received	Consumed	Control	Wastage / Damage	Closing Stock	Quantity Indented
1. HIV 1st Test										
2.Whole Blood Test										

SECTION C. STI/RTI MONTHLY INDICATORS			
	Male	Female	Total
1. Number of patients diagnosed and treated for various STI/RTI			0
2. Number of STI/RTI patients tested for Syphlis (VDRL/RPR Test)			0
3. Of Above, Number found reactive for syphilis			0
4. Availability of essential STI/RTI drugs (Yes/ No)	Yes		

Annexure 4

Specification of Vaccine Carrier (Green coloured) for Transportation of HIV and Syphilis Kits

1 Description of Function	
Sl	**Name**
1.1	Vaccine carriers are used to safely carry the HIV and Syphilis Kitsduring transportation. The colour of the carrier should be Greentoensure the separate identity of the carrier carrying HIV and Syphilis kits

2 Operational Requirements	
Sl	**Name**
2.1	Small vaccines carriers, short range are required to safely transport the HIV and Syphilis Kitsunder cold conditions for short distances.

3 Technical Specifications	
Sl	**Name**
3.1	Storage Capacity 1- 2 litres(any capacity within this range is acceptable
3.2	Weight fully loaded should be less than 5 Kg
3.3	Weight empty with empty ice pack should be less than 3 kg
3.4	**External surface being HDPE-(High Density Polyethylene) and internal lining of HDPE/HIPS.**
3.5	Insulation material CFC-free Polyurethane
3.6	Insulation thickness: 30-50 mm
3.7	Cold Life without opening 36 hours at 43 deg C (OR BETTER)
3.8	Each vaccine carrier/HIV and Syphilis Kit carrier shall contain ice packs of WHO PQS Performance specification, E-05/IP01.1 The specifications are as given below: Water Content: 0.3 Litres.

	External Dimensions: 163x90x33 mm +/- 1 mm. Empty weight-75 to 80 gms Robustness: The Ice Packs samples shall withstand a two metre drop on every face,edge and corner when in a frozen state (-10 deg C to -20 deg C). It will then successfully pass the leakage test after thawing. Leakage Test: No leaks when 80 Kg lateral force is applied. Features: Effective reinforcements to restrain walls against swelling.Removable cap for filling ;cap to have effective internal water seal to resist 80 kg lateral force with no leakage. Manufacturer's recommended filling line to be clearly indicated. Freezing Characteristics: Shall not display super cooling characteristics when filled with de mineralised water and frozen in flat, horizontal contact with evaporator at - 8 deg C. Maximum thickness of the icepack, when frozen solid and laid flat on an evaporator surface, shall not exceed the unfrozen thickness by more than 10%. The internal dimension of the unit should be sufficient to accommodate the largest tolerances of the standard ice packs.
3.9	In addition to the existing lid of the carrier a foam pad to be provided to serveas a temporary Lid to hold the carrier vials during VHND sessions. The pad will: * be soft foam , minimum 30 mm thickness; * fit tightly inside the neck of the carrier on top of the ice packs, under the Lid *Have a maximum of 5 slits cut into it to allow for vaccine vials to be inserted (no other holes shall be cut into it)

4 System Configuration Accessories, spares and consumables

Sl	Name
4.1	Vaccine Carrier-01
4.2	Ice Packs-04
4.3	Foam Pad-01

5 Power Supply

Sl	Name
	None

6 Standards, Safety and Training

Sl	Name

6.1	The equipment should Conform to WHO PQS Performance Specifications, E-04/VC 01.2. The equipment should preferably be listed on the PQS Information sheet of WHO.
6.2	The system should be tested as per WHO Product Verifications Protocol E004/VC 01-VP.2 for Vaccine Carriers and E005/IP01- for Ice Packs.
6.3	Warranty- The manufacturer must provide unconditional replacement warranty for two years

7 Documentation

Sl	Name
7.1	Manufacturer's certification of compliance of test procedures as per WHO Standards Test Procedures.
7.2	Certificate of Type Testing as per WHO Product Verification Protocol to be provided prior to dispatch. Type-testing will be carried out by an independent ISO/IEC 17025 testinglaboratory, accredited for Type Testing of COLD BOXES and VACCINE CARRIERS by WHO/ UNICEF/ STQC/ NABL."

Annexure 5

Frequently Asked Questions- Screening for HIV

Should we advocate for informed consent or informed and written consent?

As per the HCTS guideline 2016 and HIV AIDS Act 2017, each individual should give informed consent for HIV testing with an opt-out option. Written consent is not mandatory, but the program does maintain a record of the same in the services register. For VHND testing, the same method of recording consent in a services register by the ANM may be followed. However, there is no separate consent form required for HIV testing.

After Screening for HIV:

- **What should be written in the RCH Register?**
  - Tested for HIV: Yes/No
  - Next Steps: If Non-Reactive then "NR" and if Reactive then "Referral to SA-ICTC"

- **What should be told to the pregnant woman?**
  - If Results is Non-Reactive: HIV screening result is Non-Reactive (NR)
  - If Results is Reactive: The current form of result delivery after screening should be followed wherein PW is not told the result, only that further testing is required at a SA-ICTC.

- **What should the ANM tell the ASHA?**
  - No communication required if HIV screening result is NR
  - If screened reactive, ASHA may be asked to accompany PW SA-ICTC for further testing, but the reactive result need not be disclosed.

- **Is a written report signed by MO mandatory for HIV? Should the non-reactive report be shared back with the pregnant woman?**
  - A written report signed by MO is not mandatory in the case of screening for HIV, regardless of the result. The PW may however be advised of the next steps. Signed reports are only shared at SA-ICTC after confirmatory testing, where counsellor will hand over the test result after providing the counselling to the PW.

After Confirmatory Tests for HIV:

- **What should be written in the RCH Register?**
  - Next Steps after SA-ICTC referral: If not reactive then "NR", if reactive then "Refer to ART"

- **What should be told to the pregnant woman?**
  - The ANM is not responsible for reporting the result to the PW. SA-ICTC counsellor will hand over the test result after providing appropriate counselling to the PW.

- ANM may support the PW to reach the ART, if confirmed HIV positive.

- **Is the SA-ICTC expected to inform the concerned ANM of the result?**
  - If the woman requires follow-up testing or support to reach ART Center, the ICTC counsellor may inform the ANM at his/her discretion.
  - As per the HCTS guidelines, in the medical interest of an individual, their HIV status may be shared with other health care provider(s) involved in the treatment and care of that individual. The purpose of sharing information is to ensure that the individual receives better treatment and care. Confidentiality should be maintained during the process.

- **Is the SA-ICTC expected to inform the concerned MO of the result?**
  - Yes, the ICTC counsellor may inform the MO at his/her discretion.
  - As per the HCTS guidelines, in the medical interest of an individual, their HIV status may be shared with other health care provider(s) involved in the treatment and care of that individual. The purpose of sharing information is to ensure that the individual receives better treatment and care. Confidentiality should be maintained during the process.

- **What should be written on the MCP card?**
  - HIV tested- Yes/No

- **What should be written in the RCH Register?**
  - Next Steps after SA-ICTC referral: If not reactive then "NR", if reactive then "Refer to ART"

- **What should the ANM tell the ASHA?**
  - Test result will be shared directly to PW by SA-ICTC counsellor after post-test counselling. ANM need not disclose results to ASHA, but may ask for support in accompanying PW to ARTC if needed.

Annexure: 6

Guidance note on Bio-medical Waste Management mechanism for HIV and Syphilis screening at VHSND site

Scope:

The guiding rules will be applicable for Management of WBFP kit/RPR kit/POC kit/Dual kit of HIV & Syphilis waste.

Type of Waste	Type of Bag or Container to be used	Disposal options
Plastic waste such as gloves, rapid card, any other contaminated plastic waste	Red-colored closed containers having 1% freshly prepared hypochlorite solution	Immerse the collected waste in the hypochlorite solution for 30 min. Thereafter, the contents should be sent in a sealed and labelled bag to nearest PHC for further treatment and disposal, as per schedule I of BMW Rules 2016.
Sharp waste such as lancet/needle, glass, any other contaminated sharp object that may cause puncture and cuts	Puncture proof, Leak proof, tamper proof container	Send to nearest PHC for further treatment and disposal, as per procedure given in BMW Rules 2016.
Sterile gauze, cotton swabs contaminated with blood, Mask	Yellow colored non-chlorinated bag	Send to nearest PHC for further treatment and disposal/ Deep burial in rural area (not having access to Common Waste Treatment Facility) as per standards given in the BMW Rules 2016.

Annexure – 7:

Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (Prevention and Control) Act, 2017

Informed Consent

The Act states that no HIV test shall be undertaken or performed upon any person; or no positive person shall be subject to medical treatment, medical interventions or research, except with the informed consent.

In the act the term 'informed consent' is defined as *consent given by any individual or his representative specific to a proposed intervention without any* ***coercion****, undue influence, fraud, mistake or misrepresentation and such consent obtained after informing such individual or his* ***representative****, such* ***information*** *relating to risks and benefits of, and alternatives to, the proposed intervention in such* ***language*** *and in such manner as understood by that individual or his representative ,as the case may be.*

The act also contains provisions where informed consent for conducting an HIV test shall not be required- when a court determines by an order; for procuring, processing, distribution or use of a human body; for epidemiological or surveillance purposes and for screening purposes in any licensed blood bank.

Disclosure of HIV status:

As per the act, no person shall be compelled to disclose HIV status except by an order of the court that the disclosure of such information is necessary. Also no person shall disclose or be compelled to disclose the HIV status or any other private information of other person imparted in confidence.

The act also includes areas where informed consent for disclosure is not required-

- *By a healthcare provider to another healthcare provider who is involved in the care of such person, when such disclosure is necessary to provide care or treatment to that person.*
- *By an order of a court that the disclosure of such information is necessary in the interest of justice.*
- *In suits or legal proceedings between persons, where the disclosure of such information is necessary.*
- *If it relates to statistical or other information of a person that could not reasonably be expected to lead to the identification of that person; and*
- *to the officers of the Central Government or the State Government or State AIDS Control Society of the concerned State Government for the purposes of monitoring, evaluation or supervision*

Disclosure of HIV positive status to partner

The act states that No healthcare provider, except a physician or a counsellor, shall disclose the HIV-positive status of a person to his or her partner. Disclosure can happen <u>only after completion of four probabilities:</u>

a. reasonably believes that the partner is at the significant risk of transmission of HIV from such person; and

b. such HIV-positive person has been counselled to inform such partner; and

c. is satisfied that the HIV-positive person will not inform such partner; and

d. has informed the HIV-positive person of the intention to disclose the HIV- positive status to such partner:

The act also provides that disclosure to the partner shall be made in person after counselling and that a healthcare provider shall have no obligation to identify or locate the partner of an HIV-positive person:

With respect to partner notification of woman, the act takes an exception and provides that a healthcare provider shall not inform the partner of a woman where there is a reasonable apprehension that such information may result in violence, abandonment or actions which may have a severe negative effect on the physical or mental health or safety of such woman, her children, her relatives or someone who is close to her.