

# **Session 3: Methodology of HIV Sentinel Surveillance at ANC sites**

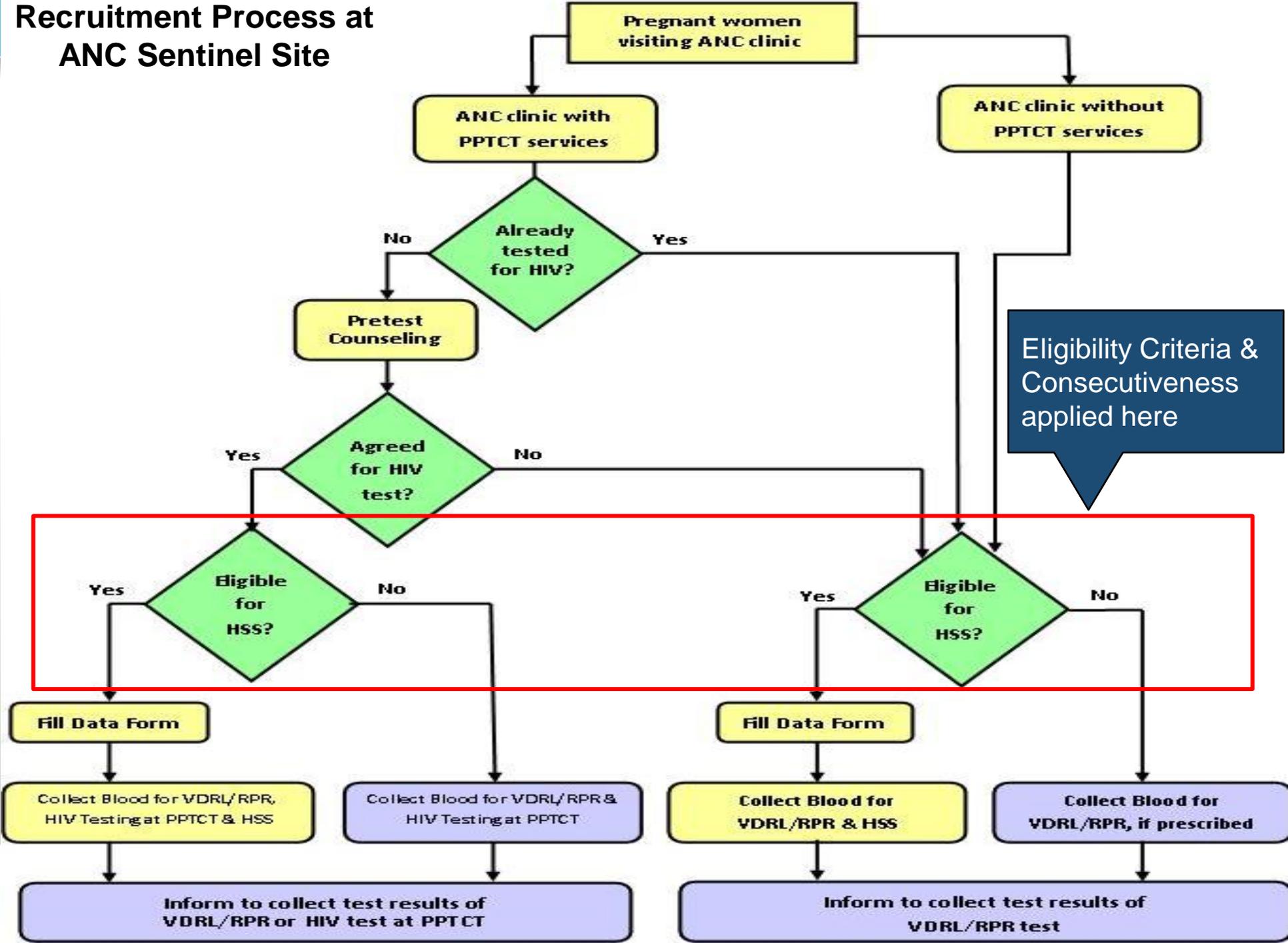


## Session Objectives

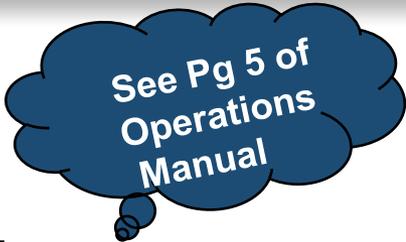
- ▶ At the end of this session, participants should be able to:
  - ▶ List the eligibility criteria for ANC surveillance
  - ▶ Define the method of sampling for ANC surveillance (Consecutive sampling) – how, why
  - ▶ Factors that may affect consecutive sampling and their implications
  - ▶ Define the testing strategy for ANC surveillance (Unlinked Anonymous Testing Strategy) - how, why

# Eligibility Criteria

# Recruitment Process at ANC Sentinel Site



# Eligibility Criteria



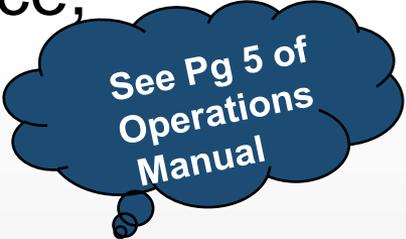
See Pg 5 of  
Operations  
Manual

## **Inclusion Criteria for ANC sentinel surveillance:**

- ▶ Age group 15-49 years
- ▶ Pregnant women attending the antenatal clinic for the first time during the current round of surveillance

## Remember:

- ▶ If the pregnant woman becomes eligible by the above criteria, she should be included in surveillance, irrespective of:
  - ▶ Date of antenatal registration
  - ▶ HIV positivity status, (if known to counselor or treating doctor)
  - ▶ Participation in previous rounds of surveillance
  - ▶ Whether she is being tested for HIV under PPTCT (or not)
- ▶ A pregnant woman should be recruited only once during a round of surveillance. To ensure this, verify the date of her previous visit to ANC clinic. If the date of her previous visit to ANC clinic falls during the current round of surveillance, she should be excluded from the sample.



See Pg 5 of  
Operations  
Manual

# Case Discussion 1



21 year old Geeta is studying in 2nd year BA. She is 7 months pregnant and has come to the ANC OPD on 12th March 2013. This is her second visit and she had earlier come to the ANC clinic on 19th December 2012. Surveillance at your ANC clinic started from 1<sup>st</sup> January 2013. Her husband is a clerk in a local bank and they live in the same town. Is this woman eligible for surveillance?

## Case Discussion 2



A 17 year old woman in her 8th month of pregnancy presents to the ANC on 12<sup>th</sup> January 2013 for the first time. She had a spontaneous abortion in the second month of pregnancy last year, but this time she says she had no problems/complaints. Her husband is a farmer and she is a house wife. The hospital has as an ongoing PPTCT program. Is this woman eligible for surveillance?

## Case Discussion 3



A 14 year old tribal girl is brought to the ANC OPD on 15<sup>th</sup> January 2013 by her mother with 5 months amenorrhea. She is unmarried, does not go to school and helps her mother in the house. This is her first pregnancy. This is her first visit to the clinic. Is this woman eligible for surveillance?

# Sampling Method

# Components of Sampling Methodology

- ▶ For each sentinel site, the same approach must be applied during every round of surveillance:
  - ▶ Sample size – the number of people to be recruited for HSS
  - ▶ Sampling method - the approach adopted at the sentinel site for recruiting eligible individuals in HSS
  - ▶ Duration of sampling - how long to recruit for HSS

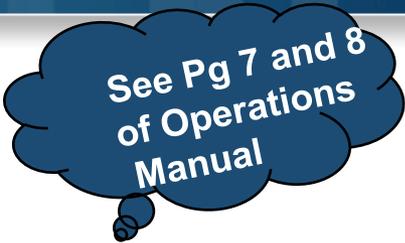
## Sample Size

- ▶ The recommended sample size for ANC surveillance per site is 400
- ▶ This sample size is feasible to be achieved in a period of three months
- ▶ This sample size is adequate for monitoring HIV trends

## Sample Size at Composite Sites

- ▶ In certain cases where 400 samples cannot be collected from a single ANC clinic due to low OPD utilization rates, composite sites are constituted by identifying 2-5 ANC clinics in a district that contribute towards achieving the target of 400
- ▶ In such cases, each sub-site in a composite site will have a pre-determined sample size which will be less than 400. This sample size will be provided by SACS.

# Consecutive Sampling (1)



See Pg 7 and 8  
of Operations  
Manual

- ▶ From the start of surveillance, all individuals attending the sentinel site facility who are eligible for inclusion in surveillance as per the defined criteria, should be recruited in the order they attend the clinic
- ▶ Every successive individual should be recruited in HSS till designated sample size of 400 is achieved or the designated period of three months is over, whichever is earlier
- ▶ This sampling method removes all chances of selection or exclusion based on individual preferences and other reasons, and hence reduces selection bias
- ▶ It is convenient and easy to follow

## Consecutive Sampling (2)

- ▶ In clinics with large daily attendance, it is recommended that not more than 20 consecutive eligible attendees be recruited per day (to ensure quality of surveillance data collection)
- ▶ In such cases, the first 20 eligible attendees on a given day should be recruited
- ▶ However, there may be site-specific exceptions to this recommendation. In such cases, decision about number of consecutive samples to be collected per day should be taken in consultation with RI/SACS
- ▶ However, the exception should not compromise the principles of consecutive sampling, desired sampling size, high quality patient care and surveillance

## Consecutive Sampling (3)

- ▶ Sample collection should be stopped once the target of 400 has been achieved or at the end of three month period, even if the target of 400 is not achieved
- ▶ In order to reach the target, sentinel sites **SHOULD NOT recruit pregnant** women admitted in the hospital/labor ward or through special campaigns to increase OPD attendance or by holding special camps or by any other means. Data from sentinel sites are much more useful and reliable when the strategy of consecutive sampling is strictly adhered to.

## Implications of not doing Consecutive Sampling

- ▶ There may be chances of selection bias in enrolling the women by sentinel site staff
- ▶ There may be a chance of including or excluding individuals with a specific characteristic that may affect HIV prevalence. (E.g. If women with known HIV status get preferentially enrolled or eliminated, the HIV prevalence in the women sampled may be over-estimated or under-estimated)

# Scenarios that may affect Consecutive Sampling

# 1. Distance between point of assessing eligibility, filling data form & sample collection

- ▶ A pregnant woman visits a facility where the point of filling data form and/or point of specimen collection is situated far away from the ANC clinic
- ▶ There is a possibility that the pregnant woman may drop out after being assessed as eligible by the attending doctor. In this case, the principle of consecutiveness may not be followed
- ▶ Therefore the recommendation is to make arrangements for filling data form and blood specimen collection at the ANC clinic itself or have someone accompany every eligible pregnant woman to point of data form filling or point of specimen collection

## 2. Self-exclusion at ANC Sentinel Site with PPTCT Services

- ▶ A pregnant woman who knows her HIV status visits a maternity hospital which also offers PPTCT services. If the attending doctor finds her eligible for surveillance and refers her to PPTCT centre for filling of data form, the pregnant woman may decide not to go to the PPTCT as she already knows her status. This will violate consecutiveness.
- ▶ Therefore the recommendation is to make arrangements for filling data form and blood specimen collection at the ANC clinic itself or have someone accompany every eligible pregnant woman to the PPTCT centre and subsequently to the laboratory

### 3. Patient flow at sentinel site with PPTCT services

- ▶ In a hospital where a pregnant woman visits ICTC/PPTCT centre first and then proceeds to the ANC clinic, and if assessment of eligibility and filling of data form are done in PPTCT centre, the following possibilities may arise:
  - ▶ Confirmation of pregnancy needs doctor's consultation. Hence, eligibility criteria may not be followed.
  - ▶ Those women who were already registered at PPTCT centre may not visit the centre during their subsequent visits, and thereby consecutiveness may be affected.
  - ▶ No. of aliquots to be prepared from the blood specimen will be determined only after doctor's consultation. Hence, filling form and collecting blood at PPTCT centre may subject her to multiple punctures.
- ▶ Hence, it is recommended that in such a scenario, the patient flow should be in such a way that the pregnant woman first visits the doctor for eligibility and then the data form is filled by the nurse/counselor, if eligible.

## 4. Recruitment from Maternity Ward or Labor Room

- ▶ A pregnant woman is admitted to the maternity ward due to pregnancy complications or admitted for delivery in the labor room. She meets the eligibility criteria of HSS, and is enrolled for surveillance by the nurse/counselor.
- ▶ This clearly violates the principle of consecutiveness because this woman is not a ANC clinic attendee.
- ▶ Therefore, only pregnant women who visit antenatal clinic should be assessed for their eligibility and recruited for surveillance.

## Case Discussion 4: Sample Size and Duration



An ANC surveillance site has not managed to get the requisite sample size at the end of three months of surveillance period. The site in-charge decides to continue recruiting till they achieve the target sample size of 400. Is this the right approach?

## Case Discussion 5: Sample Size & Duration



After completion of the requisite sample collection at the end of 3 months, the site in-charge is informed by the testing lab that 30 of the last few samples sent the previous week are rendered unusable due to haemolysis. The site collects 30 samples beyond 400. Is that acceptable? What else could the site in-charge do?

## Case Discussion 6: Sampling Method



As soon as the nurse in CHC Sitapur (which is a surveillance site) discovers that there is a pregnant woman who has come direct-in-labor, she notifies the site-in-charge, does pre-test counseling and asks the laboratory technician to draw blood for HSS in the labor room itself. Is this the correct protocol?

## Case Discussion 7: Sampling Method



The site-in-charge at Jambhi CHC which is a sentinel surveillance site, asks the hospitals close to his facility to refer pregnant women to the CHC as sentinel surveillance is on-going. Are these instructions correct?

## Case Discussion 8: Sampling Method

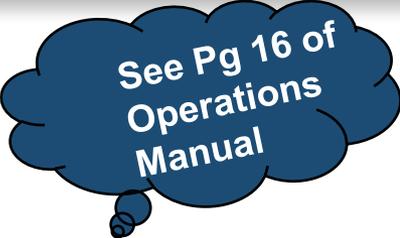


In a district hospital with an average daily OPD of 40 pregnant women at the ANC clinic, surveillance was not initiated from the designated date as doctor was on leave. Towards the end of surveillance, when the doctor joins duty, he asks the nurse to start collecting samples from all pregnant women who come to the clinic and completes the target in 10 days, within the three month period. Is this the right approach?

# Testing Strategy



# Testing strategy for ANC sentinel sites

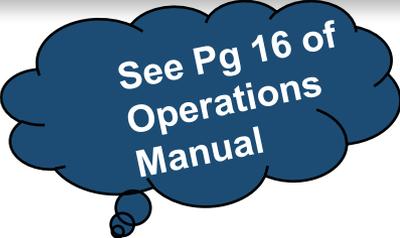


See Pg 16 of  
Operations  
Manual

## Unlinked Anonymous Testing

- ▶ HIV Testing is done on a portion of blood specimen collected for routine diagnostic purposes (such as Syphilis, Hb) after removing all personal identifiers
- ▶ The information collected in the data form, or the HIV test result from the blood specimen should **NEVER** be linked to the individual from, whom information/specimen is collected
- ▶ Neither the staff collecting the blood specimen nor the staff testing the blood specimen is able to track the results back to the individual
- ▶ Therefore personal identifiers such as name, address, OPD registration number etc. should **NOT** be mentioned anywhere on the data form, blood specimen, data form transportation sheet or sample transportation sheet

# Testing strategy for ANC sentinel groups



See Pg 16 of  
Operations  
Manual

## Unlinked Anonymous Testing

- ▶ Similarly, HSS sample number or any mark indicating inclusion in HSS should not be mentioned in the ANC register or ANC patient card/ OPD card
- ▶ Part of the blood specimen with identifiers is used on site for conducting routine test for which it has been collected. Part of the blood specimen without identifiers is sent for HIV testing under HSS
- ▶ Report of the prescribed diagnostic test (e.g. syphilis test) **MUST** be communicated to the participant

## Case Discussion 9: Testing Strategy



The laboratory technician after drawing blood for syphilis testing and HSS, labels both aliquots with the patient name and ANC registration No./OPD No. and tests required. He then sends the HSS samples to the HSS testing lab and retains the other for syphilis testing at the local lab. Is this the correct procedure?

## Case Discussion 10: Testing Strategy



The laboratory technician draws blood specimens from eligible pregnant women during the first week of surveillance. He sends the samples as per protocol to the HSS testing lab. He makes a note of the HSS sample number on the ANC/lab register and calls up the HSS testing lab to know which samples were positive. He calls the positive women to let them know so they can seek immediate medical help. Is this the correct procedure?

## Case Discussion 11



In an ANC clinic, the counselor marks “**SS**”, in the ANC registration card for all eligible attendees to make a note for ANC attendees who have been included for HSS, to avoid duplication. As attendees come in, he first checks for this mark on the registration card and includes only those that do not have the “**SS**” mark, and who meet the eligibility criteria. Is this approach violating any principles of HSS that you have learnt so far? Is so, which ones?

# Practical Exercise

## Group Work

# Exercise on 'Know Your Sentinel Site'

## Group Work

- ▶ In view of the discussions on eligibility, consecutiveness & UAT, review the formats filled by you in the Session II group work and answer the questions given in the exercise
- ▶ Discuss with resource persons while writing the actions to be taken to avoid the problems
- ▶ Submit the filled formats to the resource persons after finishing the exercise

# DISCUSSION

**END OF SESSION 3**