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Ministry of Health & Family Welfare
Government of India



HIV SENTINEL SURVEILLANCE 2017

Operational Manual for Antenatal Clinic Sites



National AIDS Control Organisation
Ministry of Health & Family Welfare
Government of India

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CONTENTS

LIST OF ABBREVIATIONS	i
FOREWORD	ii
GLOSSARY OF TERMS	iii
1. INTRODUCTION	1
2. ROLES & RESPONSIBILITIES	2
2.1 Sentinel site in-charge	2
2.2 Nurse/ Counsellor	3
2.3 Laboratory technician	3
3. MATERIALS REQUIRED AT ANC SENTINAL SITE	5
4. ELIGIBILITY CRITERIA	6
5. RECRUITMENT PROCESS	7
5.1 ANC sites with PPTCT services	8
5.2 ANC sites without PPTCT services	9
6. DOCUMENTATION	14
6.1 General instructions	14
6.2 Data forms	14
6.2.1 <i>General instructions for handling data forms</i>	14
6.2.2 <i>Instructions to fill the data forms</i>	18
6.3 HSS register	21
6.4 Data form transportation sheet	22
6.5 Sample transportation sheet	23
6.6 Supervisory visit register	23
6.7 Examples of wrong practices of filling data form of ANC and sample transportation sheet	24
7. STANDARD OPERATING PROCEDURES FOR BLOOD SPECIMEN COLLECTION AT ANC SITES	26
7.1 Consumables required for blood collection	26
7.2 Blood specimen collection	27
7.3 Sample processing	29
7.4. Packaging and transporting ofspecimens	30
7.5 Examples of wrong practices of specimen processing	31
8. BIOWASTE MANAGEMENT	33
9. MANAGEMENT OF NEEDLE STICK INJURY	34
10. ANNEXES	35
Annex 1: HSS 2016: Data forms for antenatal clinic attendees (ANC)	35
Annex 2: Data form transportation sheet	37
Annex 3: Sample transportation sheet	38

LIST OF ABBREVIATIONS

AIDS	acquired immunodeficiency syndrome
ANC	antenatal clinic
ANM	auxiliary nurse midwife
ASHA	Accredited Social Health Activist
ART	antiretroviral treatment
CHC	community health centre
DFTS	data form transportation sheet
DBS	dried blood spot
HIV	human immunodeficiency virus
HRG	high risk group
HSS	HIV sentinel surveillance
IBBS	integrated biological and behavioural surveillance
ICTC	Integrated Counselling and Testing Centre
IFA	iron & folic acid
LCT	linked confidential testing
NACO	National AIDS Control Organisation
NGO	nongovernmental organisation
OBG	obstetrics & gynaecology
OPD	outpatient department
PEP	post exposure prophylaxis
PHC	primary health centre
PNC	postnatal care
PPTCT	prevention of parent to child transmission
RI	Regional institute
RPM	rotations per minute
RPR	rapid plasma reagin
SACS	State AIDS Control Society
SOP	standard operating procedure
STD	sexually transmitted disease
STI	sexually transmitted infection
STS	sample transportation sheet
VDRL	Venereal Disease Research Laboratory

FOREWORD

HIV Sentinel Surveillance (HSS) has been the core in the tracking of HIV/AIDS epidemic under National AIDS Control Programme. With surveillance sites in almost every district, HSS aims to provide accurate and consistent information about the level and trend of HIV epidemic and helps in fine-tuning the responses to the epidemic by the programme.

The backbone for HIV Sentinel Surveillance is the wide network of 8 Regional institutes, 130 Laboratories and more than 1300 sentinel sites involved in managing, implementing, testing and quality management of HSS. HSS is implemented through a set process that includes training of more than 5000 personnel using standardized manual as the reference guideline for operational and technical aspects of HIV surveillance. This is consistent with NACO's commitment to systematic evidence-based planning and its readiness to adapt to emerging patterns of HIV epidemic.

Constant efforts are made to improve the mechanisms and methods of HIV surveillance to ensure better quality of data. In continuation to this endeavor, NACO organized 'Expert Group Consultation for HIV Estimations and Surveillance' in September 2016 which had participation of national and international experts including those from WHO Geneva, UNAIDS Geneva, CDC Atlanta etc. Representatives from countries of China, Vietnam and Philippines also participated in the consultation. There were three recommendations from consultations which were adopted as immediate action points: (i) scale-up of ANC surveillance sites in the northern and eastern states, (ii) sharing of test results from HSS to enable offering of HIV/AIDS counseling, testing and treatment to those in need, and (iii) adding up questions and laboratory test enabling treatment cascade surveillance. This manual has included the guidance on implementation of immediate action points as applicable.

This manual is in series of rounds of operational manual that is released before each round of surveillance with an objective to simplify the processes and to make them user-friendly. The manual, published separately for ANC and HRG & bridge population sites, describes the eligibility criteria and sampling process to be followed for surveillance among respective groups. The steps and precautions to be taken while collecting, drying, packing and transporting the specimens are also outlined in this manual and explained with the help of graphics wherever necessary.

The data coming out from surveillance have been robust. They have guided the programme in responding to the epidemic effectively. The robustness is the result of many good practices; however, standardized operational manual is the core of the system.

I hope that this operational guideline will help in strengthening the implementation of HIV sentinel surveillance.


(Dr Arun Kumar Panda)

GLOSSARY OF TERMS

In order to standardize the terminology used in HIV sentinel surveillance (HSS) and to enable correct interpretation of different words, the key words used in this document are explained below.

ANC attendees refer to pregnant women visiting antenatal clinics.

Data form is a brief questionnaire seeking information related to socio-demographic characteristics and vulnerabilities of the eligible individual.

HSS testing lab is the laboratory where serum specimens collected under HSS are tested for HIV and syphilis. This term is used to differentiate it from other laboratories or testing centres where routine tests are done in a health facility or where HIV test is done in an Integrated Counselling and Testing Centre (ICTC).

Recruitment is including an eligible individual in HSS by filling a data form and collecting blood specimen.

Sample refers to the individual/ respondent who is found to be eligible for inclusion in HSS as per specified criteria.

Sample number is the unique number given to each eligible individual recruited in HSS at a sentinel site. It is a three digit number starting with '001'. Sample number of an eligible individual is mentioned on the data form as well as on the blood specimen of the corresponding individual.

Sampling method is the approach adopted at the sentinel site for recruiting eligible individuals in HSS. Consecutive sampling is the sampling method adopted in HSS at ANC sentinel sites.

Sentinel site is a designated service point or facility where a fixed number of eligible individuals from a specified population group are recruited over a fixed period of time for the purpose of monitoring the epidemic.

Sentinel site code refers to a unique number given to each sentinel site. It is an eight digit number comprising codes for state (2 digits), district (3 digits) and site type (2 digits) followed by site number (1 digit).

Specimen is the blood collected from the eligible individuals or serum separated from it.

Subsite number is the serial number given to each subsite in a composite site, starting with 1. For a single site, the subsite number will be '0'.

Testing strategy is the approach adopted for testing the blood specimens collected during HSS. Linked anonymous testing strategy is adopted in HSS.

Testing protocol indicates the number of HIV tests conducted on the blood specimen collected during HSS. The two-test protocol is adopted in HSS (1st test of high sensitivity and 2nd test of high specificity, if 1st test is positive).

Consumables used for blood specimen collection and processing:

Aliquot is the portion of serum separated into a vial after centrifugation of blood specimen.

Centrifuge tube is a plastic/ glass tube into which the blood specimen is transferred from syringe and placed in centrifuge machine.

Cryovials/ Serum vials/ Screw capped vials with O-ring are plastic tubes into which a portion of serum is transferred using a pipette from centrifuge tube after centrifugation.

Parafilm is a flexible film, available in several different lengths and widths. It is commonly used for sealing or protecting vessels (such as flasks or cuvettes). It is stretchable, mouldable, waterproof, odourless, thermoplastic, semitransparent and self-adhering. It is also used to further seal a lidded container against moisture for long term storage. Parafilm is used to seal the vials to prevent leakage during transportation. A film should be tightly wrapped on the junction of the cap and body of the vial.

Vacutainer is a plastic/ glass tube with vacuum, used with vacutainer holder for collection of venous blood from an eligible individual.

1. INTRODUCTION

The national HIV sentinel surveillance (HSS) is mainstay of second generation human immunodeficiency virus (HIV) surveillance in India. This is one of the largest HSS systems in the world which helps to understand the dynamics of the HIV epidemic and monitor the trends among different population groups and geographical areas. It provides inputs to programme for strengthening prevention and control activities. The sentinel sites have been scaled up in a phased manner from 176 in 1998 (including 92 ANC sites) to 1359 in 2010-11 (including 696 ANC sites). The HSS 2015 was implemented at 776 ANC sites.

As a strategic focus to strengthen surveillance among high risk groups (HRG) and bridge population, given the low level and concentrated nature of the HIV epidemic in the country, the Integrated Biological and Behavioural Surveillance (IBBS) was being implemented among HRGs and bridge population in 2013-15. The 15th round of HSS is proposed to be implemented at around 800+ ANC and 500+ HRG sites during 2017. Almost every district in the country is now covered under surveillance.

Under HSS, an antenatal clinic in government or private hospitals is designated as an ANC sentinel site where 400 pregnant women (ANC attendees) are recruited. Surveillance is carried out over a period of three months. Three staff members at each facility are given the responsibility to implement the surveillance activities. They include a doctor, who is designated as the sentinel site in-charge, a nurse or counsellor who assists in data collection and a laboratory technician responsible for collection of blood specimens.

This Operational Manual has been prepared for easy reference of the staff at sentinel sites and provides the guidance on operational as well as technical aspects, for efficient implementation of HSS. It details the roles and responsibilities of the staff, recruitment process, and documentation, including instructions on filling of data forms and blood specimen management. The site in-charge should be aware of the entire set of functions and responsibilities of all the designated staff involved in surveillance activities at the sentinel site. This ensures better coordination and uninterrupted implementation of surveillance activities at the sentinel site.

2. ROLES & RESPONSIBILITIES

2.1 Sentinel site in-charge should:

1. Be responsible for all the arrangements and activities for HIV surveillance at the site.
2. Attend trainings conducted for surveillance by the State AIDS Control Societies (SACS).
3. Conduct a pre-surveillance on-site training of the staff participating (or expected to participate) in surveillance activities, including other medical officers, staff nurses and others.
4. Inform every pregnant woman and display the message at appropriate places in a suitable language at the ANC clinic about the essential package of services and ongoing HSS.
5. Ensure offering of Prevention of Parent to Child Transmission (PPTCT) services as per the national HIV counselling and testing guidelines.
6. For the clinics which do not have the facility of HIV counselling and testing, get the list of the nearest HIV counselling and testing facilities from SACS.
7. Correctly identify eligible respondents as per the inclusion criteria and recruit each successive eligible individual to ensure consecutive sampling.
8. Ensure that individual identifiers like name and mobile number are not recorded anywhere, thus maintaining anonymity of respondents recruited under HSS.
9. Ensure that 'HSS register' linking HSS sample number with ANC registration number is maintained in a secure and confidential manner.
10. The site-in charge will review the details of each of the pregnant women recruited in HSS for their HIV testing status under the PPTCT programme. If there are some cases which were not tested in PPTCT, s/he will take appropriate follow-up action to offer HIV testing to such pregnant women.
11. Ensure that the standard operating procedures (SOP) are complied with by the staff while collecting, processing and storing of blood specimens.
12. Check the forms filled on a particular day for completeness and discuss issues, if any, with the concerned staff, guide them and sign the filled forms. Never sign blank data forms in advance.
13. Monitor progress in sample collection on a daily basis.

14. Arrange for transport of blood specimens under proper cold chain along with sample transportation sheet (STS) every week and file the returned copy of STS at the site.
15. Ensure that results of tests, for which blood specimen is collected, are provided to the respondent subsequently.
16. Arrange for transportation of details of relevant records from 'HSS register' to the ICTC in-charge at SACS in a secure and confidential manner every fortnight.
17. Contact the nodal person at SACS for any clarification/ problem regarding staff, availability of the listed consumables, user manuals, flow charts, data forms and stamps/ pre-printed stickers or any methodological issues.

2.2 Nurse/ Counsellor should:

1. Assist the site in-charge in recruitment of eligible respondents.
2. Fill the data form and "HSS register" for each eligible respondent as per the instructions given.
3. Ensure that the data form does not carry any personal identifiers.
4. Assist the site in-charge in ensuring that every pregnant woman is offered HIV counselling and testing under PPTCT as per the national HIV counselling and testing guidelines.
5. Assist the site in-charge to offer HIV/STI counselling and testing services to pregnant women who are recruited in HSS but not tested under PPTCT as per existing guidelines for counselling and testing services under the programme.
6. Assist the site-in charge for keeping the 'HSS register' in a confidential and secure manner.
7. Ensure that the completed data form and the respondent reach the laboratory technician for blood collection.
8. Ensure proper storage of data forms and weekly transportation of data forms to the RI, along with the data form transportation sheet.
9. Assist the site in-charge in the overall implementation of surveillance at the site

2.3 Laboratory technician should:

1. Verify completeness of the data form before taking the blood specimen; refer back to the nurse/counsellor immediately if any fields are missing or illegible in the data form.
2. Collect blood specimen following universal safety precautions and inform the respondent about details to collect the test results.
3. Separate sera from blood specimens, label it and store it as per the SOP.

4. Take all the care and precautions to avoid damage to specimens (haemolysis, contamination, leakage etc).
5. Strictly follow instructions for labelling and ensure appropriate labelling of specimens for routine testing and surveillance.
6. Assist the site in-charge in storing, packing and transporting of blood specimens every week and help complete all documentation.
7. Strictly adhere to all prescribed biosafety measures.

3. MATERIALS REQUIRED AT ANC SENTINAL SITE

Table 1: List of materials

S. No.	Materials/ Consumables	ANC sites
	Documents	
1	Operational manual	3*
2	Wall charts/Flow charts	1*
3	Data forms	450
4	Data form transportation sheets	20-30
5	Sample transportation sheets	20-30
6	Stamp/stickers with site details	2*/500
7	HSS register	1*
8	Supervisory visit register	1*
	Consumables/Equipment	
1	Apron/Tourniquet	2*
2	Gloves & adhesive tapes	450
3	Spirit swabs	450
4	Sterile syringes & needles /vacutainers (5ml)	450
5	Centrifuge tube	20-30
6	Centrifuge machine	1*
7	Micro-pipette – Sterile disposable pipette tips OR	1*-450 OR
8	Cryovials/ Serum vials/ Screw-capped vials with O ring	450
9	Labels	500
10	Water proof marking pens for labelling	2*
11	Test tube stands/storage racks	5*
12	Refrigerator	1*
13	Sample transportation box with lid	5*
	Material for waste disposal	
1	Needle destroyer	1*
2	Puncture proof containers(Jar for disposal of sharps)	1*
3	Colour-coded waste disposal bags (Red, blue and black)	3 per day*
4	Hypo chlorite solution	1*

* Quantity required per site; in the case of a composite site, for every subsite.

4. ELIGIBILITY CRITERIA

It is essential to follow uniform eligibility criteria for recruiting individuals in every round of surveillance to facilitate comparison of HSS results over time for determining trends. The inclusion criteria for ANC attendees has been described in Box 1 below.

Box 1. Eligibility criteria for inclusion of ANC attendees in HSS

Inclusion criteria:

1. Pregnant women of age 15-49 years; and
2. Attending the ANC clinic for the first time during the current round of surveillance.

Exclusion criteria:

1. Pregnant women not in the age group of 15-49 year; or
2. Any pregnant woman attending the antenatal clinic for the 2nd or more time during the current round of surveillance.

Note:

1. If the pregnant woman is found eligible by conforming to the above criteria, she should be included in the surveillance, irrespective of:
 - a) Date of antenatal registration;
 - b) HIV positivity status, if known;
 - c) Participation in previous rounds of surveillance; and
 - d) Whether tested under PPTCT or not.
2. A pregnant woman should be recruited only once during a round of surveillance. To ensure this, verify the date of her previous visit to the ANC clinic. If the date of her previous visit to the ANC clinic falls during the current round of surveillance, she should be excluded from the sample.
3. Women, who are already registered with the ANC clinic but are visiting the clinic for the first time during the current round of surveillance, are eligible for inclusion.

5. RECRUITMENT PROCESS

The sampling method adopted at the ANC sentinel sites is that of consecutive sampling. It is crucial to understand the flow of individuals at these sites to maintain consecutive sampling.

The following box explains the concept of consecutive sampling.

Box 2. Consecutive sampling method

- After the start of surveillance, pregnant women attending the ANC sentinel site (ANC clinic), who are eligible for inclusion in surveillance as per the defined criteria, should be recruited in the order in which they attend the clinic;
- This sampling method removes all chances of selection or exclusion based on individual preferences and other reasons, and hence reduces any scope for selection bias; and
- It is convenient, feasible and easy to follow.

The following general instructions on sample recruitment at ANC sentinel sites may be noted:

1. From the notified date of start of the surveillance round, every individual attending the ANC clinic should be assessed for eligibility for inclusion in HSS.
2. Starting with the first individual, every successive eligible individual should be recruited in HSS till the designated sample size is achieved or the designated period of three months is over, whichever is earlier.
3. The specified sample size for an ANC sentinel site is 400.
4. In case of composite sites, the sample size will be specified for each subsite and this should be obtained from SACS.
5. In clinics with large daily attendance, it is recommended that NOT MORE THAN 20 consecutive eligible attendees should be included per day to ensure quality of surveillance data collection. In such a case, the first 20 eligible attendees on a given day should be included.
6. However, there may be exceptions to the above recommendation. In such cases, the decision about number of consecutive samples to be collected per day should be taken in consultation with RI/SACS, without compromising the overarching principles of consecutive sampling, attainment of desired sample size of 400, non-compromised patient care and high-quality surveillance.
7. Sample collection should be stopped once the target of 400 has been achieved or at the end of the three month period, even if the target of 400 is not achieved.

8. In order to reach the target, sentinel sites SHOULD NOT recruit pregnant women admitted in the hospital/labour 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.
9. The OPD where the medical officer conducts antenatal check-up and assesses eligibility for HSS, the place where nurse/counsellor fills the data form and the place of blood specimen collection should be arranged as close to one another as possible. This will help in completing all steps of recruitment and ensuring there is no loss of eligible individuals between one step and the next.
10. If these are situated at a distance, someone at the facility (nurse/hospital attendant) should accompany the eligible individual. If no one accompanies her, there is a chance that she may not go to the nurse or laboratory technician, thereby affecting the consecutive sampling.
11. Similarly in some hospitals where the ICTC is situated at a distance from the ANC clinic, it may be appropriate to arrange for filling of data forms and blood specimen collection at the ANC clinic itself and then send the pregnant woman to the counsellor in the ICTC. In such cases, if the woman needs to be tested at the ICTC, arrangements should be made to ensure that the blood specimen collected earlier is used and a second specimen is not collected at the ICTC. Three serum aliquots should be prepared and one should be used for HIV testing at the ICTC.

Following the expansion of the ICTC programme, PPTCT services have been made available in almost all hospitals. So, most of ANC sentinel sites may also have an ICTC in the same facility providing PPTCT services, while few may not have PPTCT services. While the conceptual framework for recruitment of pregnant women in HSS remains same as outlined below, there will be minor variation in steps as per availability of PPTCT services at the site (Flow chart 1 and 2). It is important to adhere to the steps outlined, in order to avoid selection bias as well as facilitation of universal screening of pregnant women for HIV.

5.1 ANC sites with PPTCT services (Flow chart 1)

1. The pregnant woman coming to the clinic for ANC check-up will go to the doctor. She will be provided information about the essential package of ANC services as well as HSS. The information provided shall communicate that blood samples drawn for clinical purposes may be tested for HIV/syphilis under HSS as well as potential of follow-up referral for HIV/syphilis counselling and testing services to keep the pregnant woman healthy and protect the unborn baby (Box 3).
2. Following antenatal check-up and provision for routine ANC/PPTCT services, the doctor will assess her eligibility for inclusion in HSS and send her to the counsellor/nurse for the purpose of PPTCT and HSS.
3. The counsellor/nurse will offer PPTCT services as applicable and reassess her eligibility for inclusion in HSS.
 - a) If found eligible, the counsellor will fill the HSS data form as well as 'HSS register' and then send the pregnant woman to the Laboratory technician (LT) to collect blood specimen under routine programme (for testing of haemoglobin/syphilis/HIV etc as applicable). LT will take blood specimen and then prepare the separate aliquots for routine tests and HSS (Flow chart 1); and

- b) If the woman is not eligible for HSS, she is not recruited in HSS and data form or HSS register is not filled. However, she is referred to the laboratory technician for blood specimen collection for routine testing as mentioned above (Flow chart 1).
4. In all cases where blood specimen is collected from the pregnant woman, she should be informed by the Laboratory technician about the time and other details to collect the test results of routine testing being done under programme as applicable. Test results for all routine tests should be provided to the pregnant woman subsequently.

The site-in charge will review details of each of the pregnant women recruited in HSS for their HIV testing status under the PPTCT programme. The site in-charge will do it by going through the “HSS register” with the help of nurse/counsellor. If there are some cases which were not tested in PPTCT, the ANC site team will take appropriate follow-up action to offer HIV testing to such pregnant women.

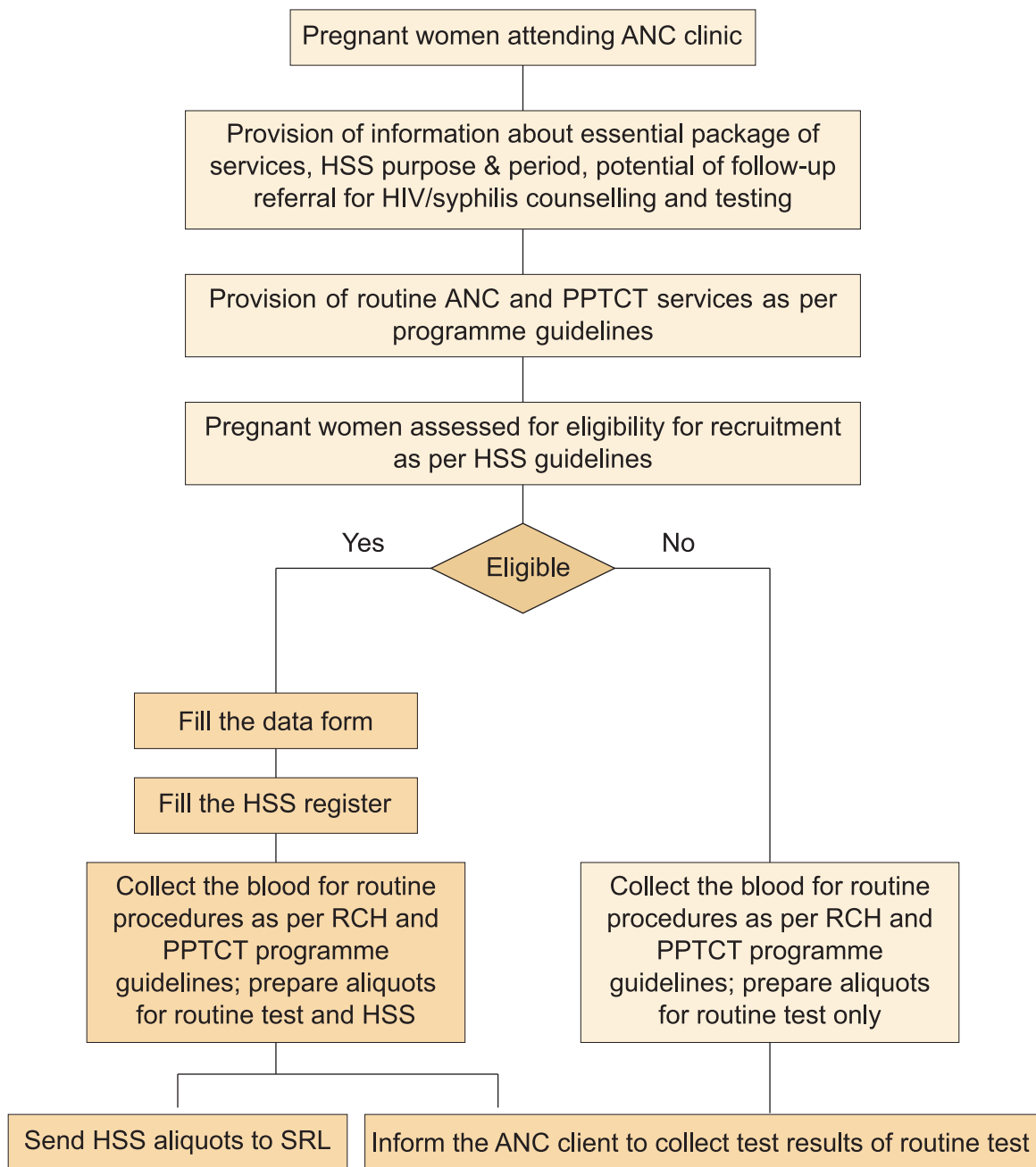
5.2 ANC sites without PPTCT services (Flow chart 2)

Pregnant women coming to the clinic for the ANC check-up will go to the doctor and be provided information on the essential package of services as well as HSS. The information provided shall communicate that blood samples drawn for clinical purposes may be anonymously tested for HIV/syphilis under HSS as well as have potential of follow-up referral for HIV/syphilis counselling and testing services. This will keep the pregnant woman healthy and protect the unborn baby too (Box 3).

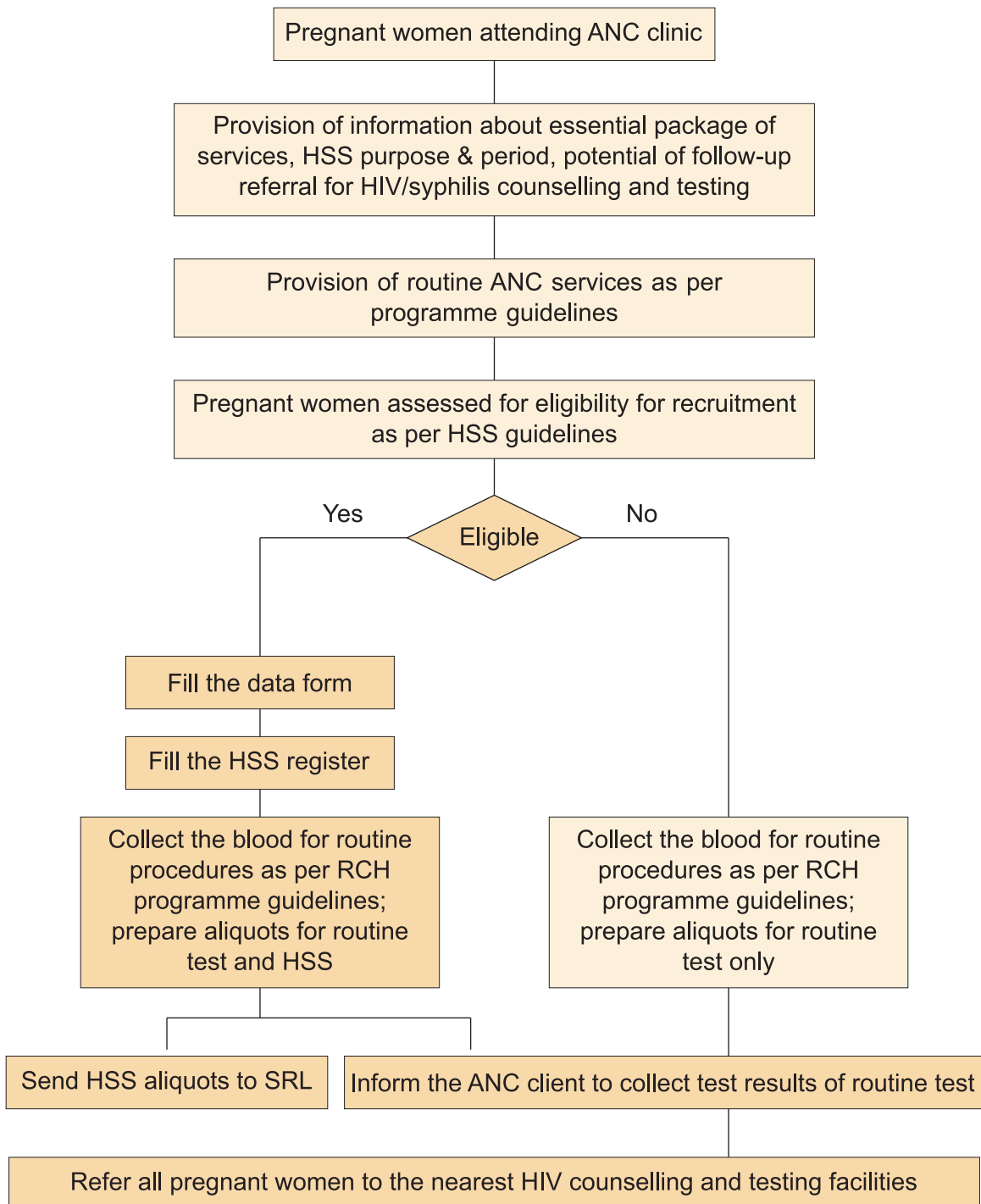
1. Following the antenatal check-up, the doctor will assess her eligibility for inclusion in HSS and send her to the counsellor/nurse for the purpose of HSS.
2. The counsellor/nurse will reassess her eligibility for inclusion in HSS. If found eligible, the counsellor will fill the HSS data form as well as HSS register and send her to LT to collect the blood specimen under the routine programme (for testing of haemoglobin, syphilis and other conditions, as per applicability). The LT will take the blood specimen and prepare separate aliquots for routine tests/HSS (Flow chart 2).
3. If the woman is not eligible for HSS, she is neither recruited in the HSS and nor is data form or HSS register filled. However, she is referred to the LT for blood specimen collection for routine testing, such as haemoglobin and syphilis, as per applicability (Flow chart 2).
4. All the pregnant women attending the ANC clinic without PPTCT services will be referred to the nearest facility which has HIV counselling and testing services.
5. In all cases where the blood specimen is collected from the pregnant woman, she should be given some key information. This includes, the time and other details related to collection of test results of routine testing that was done under the programme (haemoglobin, syphilis and other conditions as applicable).
6. Test results for all routine tests should be provided to the pregnant woman subsequently.

The site-in charge will review details of each of the pregnant women recruited in HSS for their HIV testing status. The site in-charge will do it with the help of the nurse/counsellor. If there are some cases which were not tested for HIV, the ANC site team will take appropriate follow-up action to refer HIV testing to such pregnant women.

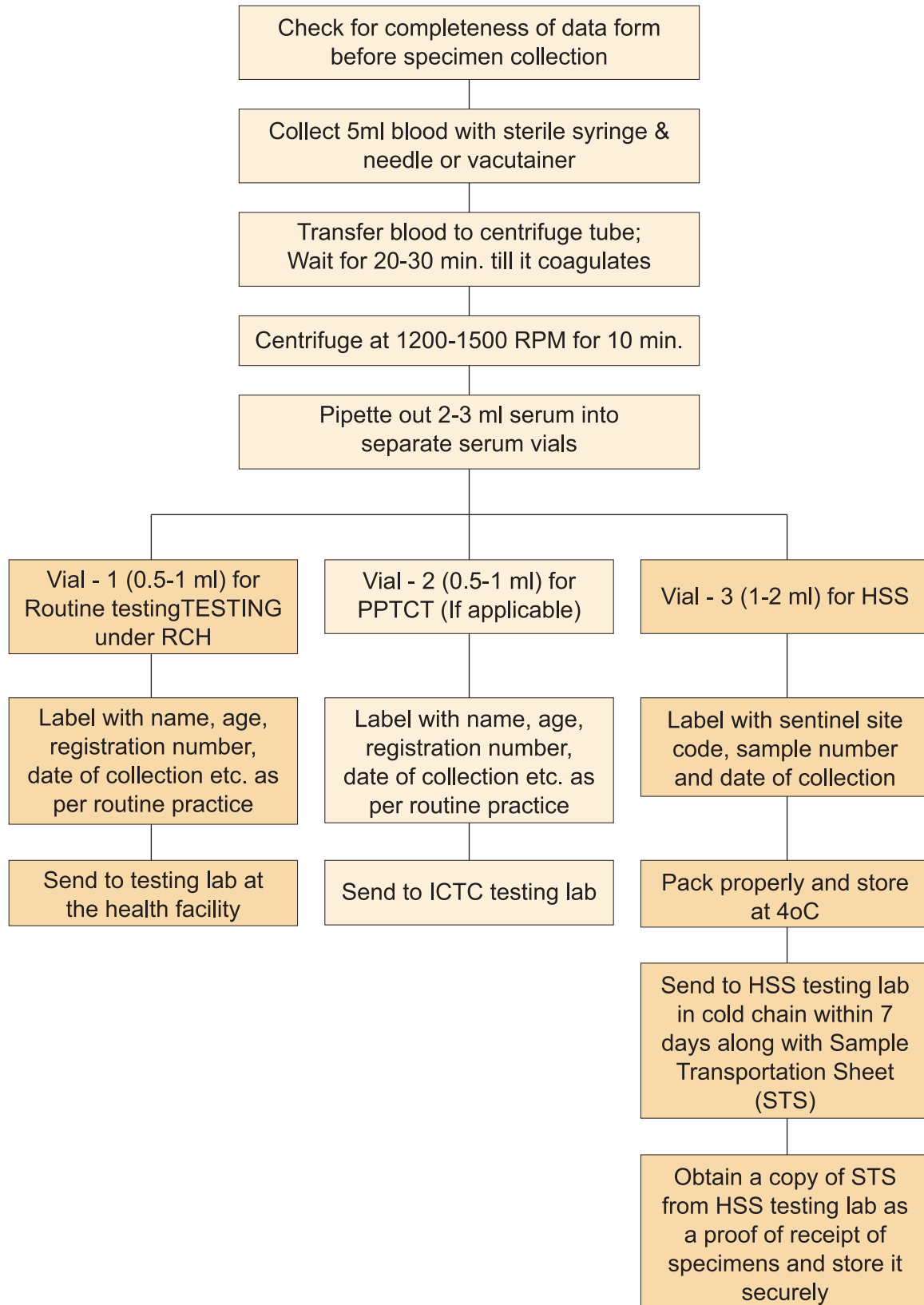
Flow chart 1. Recruitment process at ANC sentinel site with PPTCT services



Flow chart 2. Recruitment process at ANC sentinel site without PPTCT services



Flow chart 3. Blood specimen management for an eligible individual at ANC sentinel sites



Box 3. ANC site information sheet

The Government of India is committed to providing assured and comprehensive antenatal care to all pregnant women through an essential ANC package. The package includes a minimum of at least four ANC visits, including early registration and first ANC in first trimester along with physical and abdominal examinations, haemoglobin estimation and urine investigation, two doses of T.T Immunization, consumption of Iron and Folic Acid (IFA) tablets (6 months during ANC & 6 months during postnatal care or PNC) and universal screening/testing of pregnant women for HIV and syphilis. All ANC clinics aim to provide the services under the essential ANC package. In cases of few clinics where HIV screening/ testing facilities are not available, pregnant women are referred to the nearest HIV counselling and testing facilities for HIV.

This centre is also currently implementing HSS. This surveillance system is an essential activity for the measurement of the burden of HIV infection in different population groups in order to help the government to make good policies for public health. The information generated will help our country to eliminate transmission of two important infectious diseases (syphilis and HIV) from parents to children. Under surveillance, a small part of blood samples collected routinely as part of clinical antenatal care may be tested for these infections (HIV/syphilis). The surveillance portion of specimen is coded. No other personal identifier or name is put on vial containing this specimen.

Please note, all pregnant women are routinely requested to get screened/tested for HIV and syphilis by the government of India and this is done free of cost at all ICTC facilities.

In the rare case of a pregnant woman not getting tested in the ICTC or failing to collect the report, she may be found to be reactive under HSS testing, indicating a high likelihood of having syphilis or HIV infection. In such a situation, in order to keep the pregnant woman healthy and to protect the unborn baby, the doctors and counsellor may reach out to her and offer free HIV/STI counselling and testing services. This will help her and the unborn baby to stay healthy. It will also facilitate meeting India's goal towards elimination of mother to child transmission of syphilis and HIV.

Thank you.

6. DOCUMENTATION

6.1 General instructions

1. Documentation to be maintained at ANC sentinel sites; norms for submission are provided in Table 2 below.
2. Only designated and trained personnel should maintain the documentation at the sentinel site.
3. Site in-charge should ensure that all the documentation at the sentinel site is properly maintained and completed.
4. All the documents should be stored securely and confidentially at the site.
5. At the end of HSS, except for 'HSS registers' and one copy of the STS and DFTS, none of the **other documents** should be retained or photocopied for retention at the site. All documents should be dispatched from the site as per the instructions given below.
6. Linked Confidential Testing (LCT) strategy should be adopted at the sentinel site in all its documentation. The concept of LCT is described in Box 5.

Table 2. Documentation to be maintained at ANC sentinel sites and norms for submission

S. No.	Document	Managed by	Verified by	Norms for submission
1.	Data forms	Nurse/Counsellor	Site-in charge	Send to RI every week along with data form transportation sheet
2.	HSS register	Nurse/Counsellor	Site-in charge	Retained at ANC site in a confidential and secure manner
3.	Data form transportation sheet (DFTS)	Nurse/Counsellor	Site-in charge	Send to RI every week along with data forms
4.	Sample transportation sheet (STS)	Lab technician	Site-in charge	Send to HSS testing lab every week along with serum specimens
5.	Supervisory visit register	Nurse/Counsellor	Site-in charge	Send to SACS at the end of HSS

6.2 Data forms

6.2.1 General instructions for handling data forms

1. The Data form is a brief tool recording information related to socio-demographic characteristics and vulnerabilities as well as service uptake history of the eligible individual.

2. The Nurse/ Counsellor should fill the data form for each individual respondent.
3. Only designated and trained personnel should complete the data form.
4. Only one data form should be completed per eligible individual.
5. Data forms should be filled only after confirmation of the eligibility of the attendee by the medical officer/ sentinel site in-charge.
6. Data forms should be completed before blood specimen collection.
7. Stamps/stickers with site details including state, district, site name, subsite number and site code should be obtained from SACS. They should be stamped or pasted in the space provided on each data form before filling the data form.
8. The sample number should be manually written in the appropriate boxes provided in the data form. The same sample number should be mentioned by the lab technician on the blood specimen sent to the HSS testing lab.
9. To ensure confidential testing, any personal identifiers such as name, address, OPD/ANC registration number etc., which could link the data form to an individual, should not be mentioned anywhere on the data form.
10. Data forms should be filled neatly and legibly, without any overwriting and strike marks. In case of an error while filling the form, use a fresh data form.
11. The person completing the form is advised to use a hard ball point pen to complete the data form. Ink pens may cause seepage, making entries illegible.
12. Each question on the form should be completed.
13. Except for one question (age) where the appropriate number of years should be written, for the remaining questions, responses should be recorded by CIRCLING the appropriate option.
14. Only one appropriate option should be circled (except for question no 12 on management of HIV which is a multiple option question). Circling more than one option in rest of the question will make this question invalid in the analytical phase.
15. Other than the specified information, nothing else should be written on the data forms.
16. Data forms should not be handed over to the participants.
17. The person completing the data forms should check for completeness and write his/her name, before putting signature and date.
18. The Laboratory technician must check that all questions in the data form are completed, before collecting blood specimen. If a response is not recorded for any question, it should be sent back to the nurse/counsellor so that the information may be collected while the individual is still in the facility.

19. Completed data forms should be kept securely at the sentinel site.
20. The site in-charge should verify the completed data forms every day before signing and putting the date. Blank data forms should NEVER be signed in advance.
21. If there are any issues or mistakes in filling the data forms, the site in-charge should discuss with the concerned staff and guide them.
22. Completed data forms should be sent to the respective RI every week.

Box 4. Subsite number & sample number

Subsite number:

In case of composite sites, write the subsite number allotted by SACS from 1-5, in case of a single site, write '0'.

Sample number:

The sample number at each site and subsite should begin from '001'. If some of the samples are found to be invalid at the testing lab and the site is asked to collect additional samples, these additional samples should be given fresh sample numbers after 400/x (where x is the sample size allotted to a subsite). The sample number of the invalid sample should not be given to these additional samples. The following example illustrates these points:

Eg 1. At a subsite with the allotted number '2', and with an allotted sample size of 050, the subsite number should be mentioned as '2' and sample numbers should be given from 001 to 050, successively. Suppose sample numbers 020, 034 & 042 are found to be invalid at HSS testing lab, the three additional samples that will be collected at subsite no.2 should be given the sample numbers 051, 052 & 053.

Eg 2. At an ANC single site (not composite), the subsite number should be mentioned as '0' and sample numbers should be from 001 to 400, successively. If four samples were found to be invalid, the additional four samples should be given sample numbers 401, 402, 403 & 404.

Sample code: (12 digits)	Sentinel site code (8 digits)	+	Subsite number (1 digit)	+	Sample number (3 digits)
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Box 5. Linked confidential testing

1. Every pregnant woman in India is expected to receive services as per the essential antenatal care package. The package includes minimum of at least four ANC visits, including early registration and first ANC in first trimester along with physical and abdominal examinations, haemoglobin estimation and urine investigation, 2 doses of T.T immunization, consumption of IFA tablets (6 months during ANC & 6 months during PNC) and universal screening/testing of pregnant women for HIV and syphilis.
2. A portion of blood specimen collected for routine clinical diagnostics is separated for HIV surveillance purpose after removing all personal identifiers. The surveillance portion of the specimen is coded. No personal identifier like name, address and mobile number is put on the vial containing HSS aliquot.
3. This surveillance code is linked with ANC registration/OPD code in a separate register (HSS register) which is kept confidentially at the ANC HSS site.
4. Report of the routine diagnostics tests (haemoglobin/syphilis/HIV etc) is communicated to the participant at the ANC site.
5. The surveillance specimen is sent to the HSS testing lab (usually a SRL) for HSS purposes. The HSS testing lab tests the surveillance specimen for both of HIV and Syphilis. Results of surveillance specimen reactive either for HIV or syphilis are shared with SACS ICTC in-charge at the earliest. SACS ICTC in-charge I coordinate with respective ANC site in-charge to refer cases for PPTCT services which were reactive in surveillance but not tested under the programme. This will facilitate offering of counselling, testing and/or treatment services to pregnant women, in order to keep them healthy and to protect their unborn baby.

6.2.2 Instruction to fill the data form

Table 3: Instructions to fill the data form

S. No	Question/Field	Description/Instructions
	Box with site and sample details	<p>Stamp or place the sticker in the empty box on the right with details of state, district, site name, site code and sub site number.</p> <p>Write the following 2 items manually:</p> <p>1. Sample number 2. Date of sample collection</p> <p>If stamp/stickers are not provided by SACS, manually enter all these details in the box on the left.</p>
1.	Age	Write the age of the participant in years
2.	Literacy status	<p>Circle the appropriate educational category using the explanation given below:</p> <ol style="list-style-type: none"> 1. Illiterate: Without any formal or non-formal education. 2. Literate and till 5th standard: Those with non-formal education or those who joined school but not studied beyond 5th standard. 3. 6th to 10th standard: Those who studied beyond 5th standard but not beyond 10th standard. 4. 11th standard to Graduation: Those who studied beyond 10th standard but not beyond graduation. Includes those with technical education/ diplomas. 5. Post graduation: Those who studied beyond graduation.
3.	Order of current pregnancy	The order of pregnancy denotes the number of times a woman has become pregnant. It includes the number of live births, still births and abortions. Enquire about each of the above and add them to arrive at the order of pregnancy. Circle the appropriate number.
4.	Duration of current pregnancy	<p>Duration of pregnancy is usually measured in terms of three trimesters; each of them of about three month's duration. Circle the appropriate trimester as explained below:</p> <ol style="list-style-type: none"> i. First trimester: The first trimester of pregnancy is from conception to 12th week of pregnancy. ii. Second trimester: The second trimester of pregnancy is from 13th to 27th week of pregnancy. iii. Third trimester: The third trimester of pregnancy spans from week 28 to birth.
5.	Prior receipt of antenatal care services during her current pregnancy	<p>This refers to any prior (before today i.e. day of recruitment into HSS) receipt of antenatal care services from a health care facility (PHC/CHC/District hospitals/Maternity hospitals/Private health care facilities/NGO health care facilities) by the pregnant women during her current pregnancy.</p> <p>This refers to receipt of antenatal care services and should not include seeing a doctor or nurse for other reasons.</p>
6.	Source of referral	Enquire about who referred the woman for ANC visit. Government health care providers include ANM, ASHA, doctors/ nurses at PHC, CHC, etc. Circle the appropriate option.

7.	Current place of residence	<p>Enquire if the current place of residence of the respondent (the place she is living with her husband) falls under Municipal Corporation/ Municipal Council/Cantonment area.</p> <ul style="list-style-type: none"> - If yes, circle the first option (urban) - If no, circle the second option (rural) <p>Do not write the name of the place</p>
8.	Occupation of respondent	<p>Circle the appropriate current occupation of the respondent using the explanations given below. Only categories which need some elaboration are explained below:</p> <ol style="list-style-type: none"> 1. Non-agricultural labourer: Includes workers at construction sites, quarries, stone crushers, road or canal works, brick-kilns, etc. 2. Skilled/ semi-skilled worker: Includes workers in small scale or cottage industries; industrial/ factory workers; technicians such as electricians, masons, plumbers, carpenters, goldsmiths, iron-smiths, those involved in automobile repair works; artisans such as weavers, potters, painters, cobblers, shoemakers, tailors etc. 3. Petty business/small shop owners: Includes vendors selling vegetables, fruits, paan shop, milk, newspapers, etc. 4. Large business/ self-employed: Includes professionals and businessmen. 5. Service: Those working on salary basis in government, private or institutional sector excluding drivers and hotel staff.
9.	Occupation of spouse	<p>Same as occupation of the respondent (Question no. 8). If the person in question was never married/ was widowed/ divorces/separated, circle option '99' (Not applicable)</p>
10.	Migration status	<p>This question is asked to understand migration status of the spouse. If the spouse usually happens to live away from the wife for longer than 6 months in a year, then circle 'Yes', otherwise, circle 'No'. If the woman is widowed or never married/ divorced/separated, circle the third option 'Not applicable'.</p>
11.	HIV testing history	<p>This refers to the HIV testing history of pregnant women.</p> <p>If she has been ever tested for HIV, irrespective of when, please circle the option "1" ("Yes").</p> <p>If she has been never tested for HIV, please record as option "2" ("No").</p> <p>Please note that, for the pregnant women who reported to be never tested for HIV (i.e. for whom option "2" was encircled), response code "99" (i.e. "Not applicable") shall be encircled for subsequent question number 12 to 15.</p>

12.	Time of last testing	<p>This question aims to understand the timing of last HIV testing of respondents in reference to current pregnancy.</p> <p>For pregnant women, who were last tested for HIV during the current pregnancy, option “1” (“Tested previously during current pregnancy”) to be encircled.</p> <p>For those pregnant women, whose last HIV testing was done before current pregnancy, option “2” (“Tested before current pregnancy”) to be encircled.</p> <p>For the respondents who were never tested for HIV (i.e. option “2” under question no 11), option “99” (“Not applicable”) to be encircled.</p>
13.	Result of last HIV test	<p>This refers to the result of the last HIV test of the respondent. The responses shall be recorded carefully to avoid invalid entry; only option code “99” will be applicable for those who reported to be never tested for HIV in previous questions (i.e. option “2” under question 11 and option “99” under question 12”).</p> <p>For those who have been tested at least once (i.e option “1” encircled under question 11 and any option between “1” - “2” in question 12), one of the option as per indicative guidance below shall be selected for them are as below:</p> <p>Option “1” (“Positive”) shall be encircled for respondents whose HIV test result for last test was positive</p> <p>If respondent's last HIV test result was indeterminate, please record it as “Negative” i.e. encircle option “2”.</p> <p>There may be few who do not collect the result of their last test. Please encircle option “3” (“did not collect the test result”) for them.</p> <p>There may be some respondents who do not want to disclose their status and hence either do not provide any information regarding the result of their last HIV test result or refuse to do so. Please record such responses under “No response” i.e. circle option “4”.</p>
14.	Management of HIV infections	<p>This refers to the enrolment of HIV positive respondents in HIV care, either for pre-ART or ART services, at the time of surveillance. The options are self-explanatory and shall be circled appropriately.</p> <p>For all those respondents who were not positive when tested last (i.e any of option “2-4” or “99” is encircled under question 13), please encircle option “99” i.e “Not applicable”</p> <p>This is a multiple option question and in instances where respondents are seeking care from more than one service delivery points; all appropriate options shall be encircled.</p> <p>If the respondent is not seeking any care for management of HIV, then please encircle option “7” i.e. “Not seeing care for HIV management”.</p>

15.	ART uptake	<p>This refers to the current uptake of 'antiretroviral therapy' by HIV positive respondents. Carefully enquire about it by choosing a term for HIV treatment that is understandable in the local context, whether that is a complete phrase such as 'antiretroviral therapy', an acronym, such as ART, or another term.</p> <p>For all those respondents who were not positive when tested last (i.e any of option "2-4" or "99" is encircled under question 13), please encircle option "99" i.e "Not applicable")</p> <p>If she has been currently taking ART, please circle option "1" ("Yes"). If she was not currently taking ART, please record as option "2" ("No").</p>
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6.3 HSS register

1. The objective of 'HSS register' is to facilitate offering of universal HIV and syphilis screening/testing services to all pregnant women recruited under HSS. This is consistent with the existing guidelines for HIV counselling and testing services under the programme.
2. HSS register shall be maintained only for respondents who were recruited under HSS. For respondents who were not eligible for HSS, as per the prescribed procedure, their details shall not be recorded in this register.
3. This register shall only contain the columns as per format prescribed under Table 4. No other information and personal identifier (like name, mobile number) shall be recorded in this register.

Table 4. Format of HSS register

1.	2.	3.	4.	5.	6.	7.	8.
S.No.	Date	ANC registration number	HSS sample number	Whether tested for HIV under PPTCT during current pregnancy (Yes/No)	If 'no' under column 5, reasons thereof	Follow-up action	Remarks

4. The HSS register shall be filled by the nurse/counsellor for every respondent recruited under HSS. The site In-charge shall review the HIV testing status of each and every pregnant woman and take necessary action for those cases who have not been tested for HIV under the programme.

Column1: Serial number is the number allotted to each ANC recruited under surveillance. It shall start with '1' and continue subsequently from the start of surveillance;

Column 2: It refers to the date of recruitment of pregnant women in surveillance;

Column 3: ANC registration number refers to the unique ID provided by the ANC clinic to the pregnant women;

Column 4: HSS sample number refers to the unique HSS ID provided to the pregnant women recruited in surveillance;

Column 5: This refers to the status of pregnant women who have been tested for HIV under the programme. Status of all the pregnant women, who have been tested under PPTCT, either in earlier visit or current visit, shall be recorded as “Yes”;

Column 6: This column shall be filled only for the pregnant women who were recruited under HSS but have been never tested under PPTCT during her current pregnancy. The reason for not testing under PPTCT shall be clearly mentioned under this column;

Column 7: This column shall be filled only for those pregnant women who were not tested for HIV in their current pregnancy. The follow-up action taken by the site to offer counselling and testing of HIV/STI to such pregnant women shall be recorded here; and

Column 8 (Remarks): This refers to any specific observations which the site in-charge wishes to record. It will include updating the testing status of cases which were not tested for HIV at the time of recruitment in surveillance but which were tested later on.

5. Column 1-4 shall be updated at the time of recruitment while 5-7 may be updated later.
6. This register shall be maintained in a secure and confidential manner by the site in-charge. It will not be available to any other except the site in-charge and nurse/counsellor.

6.4 Data form transportation sheet

1. As mentioned earlier, the responsibility of sending the data forms along with the DFTS is primarily that of the nurse / counsellor.
2. A properly filled DFTS (Annex 2), in duplicate, should accompany each set of data forms. One more copy should be retained at the sentinel site.
3. Clearly write the name and complete address of the sentinel site/subsite, including name of district and state.
4. Mention the type of sentinel site (ANC), and write the site code and subsite number.
5. The period of sample collection i.e the period for which data forms are being sent, should be written in dd/mm/yy format.
6. Write the total number of data forms and the number of envelopes (containing the data forms) being sent.
7. In the table, write the date of collection and sample number of each sample, whose data forms are being sent.
8. If the space provided in the table is not sufficient, please attach another sheet.
9. The sender should write legibly his/ her name and telephone number and sign at the designated place before sending the data forms.
10. Also write the date of dispatch of the data forms.

11. The name, signature of the person receiving the data forms and date of receiving the data forms at the RI will be written by the recipient and one of the two sheets will be returned to sentinel site.
12. The signed copy of DFTS received from the RI should be securely stored for any future reference.

6.5 Sample transportation sheet

1. The responsibility of sending the blood specimens and the STS is primarily that of the laboratory technician.
2. A properly filled STS (Annex 3), in duplicate, should accompany each set of blood specimen sent to the HSS testing lab. One more copy should be retained at the sentinel site.
3. Clearly write the name and complete address of the sentinel site, including the name of district and state.
4. Mention the type of sentinel site (ANC) and write the site code as well as subsite number.
5. The period of sample collection i.e the period for which the current batch of blood specimens are being sent, should be written in dd/mm/yy format.
6. Write the total number of blood specimens and the number of sample transportation boxes (containing the blood specimens) being sent.
7. In the table, write the date of collection and sample number of each blood specimen being sent.
8. If the space provided in the table is not sufficient, please attach another sheet.
9. The sender should write legibly his/ her name and telephone number and sign at the designated place before sending the blood specimens.
10. Also write the date of dispatch of the blood specimens.
11. The name, signature of the person receiving the blood specimens and date of receiving the blood specimens at HSS testing laboratory will be written on the STS by the recipient at the lab and one of the two sheets will be returned to the sentinel site.
12. The signed copy of the STS received from the HSS testing lab should be securely stored for any future reference.

6.6 Supervisory visit register

1. Every site and sub-site should maintain one register where supervisors who visit the site/subsite can record their observations and recommendations.
2. The supervisor should provide specific observations and recommendations and provide unambiguous guidance for quality implementation of HSS at the site.

3. The site/subsite personnel should take corrective action as recommended in the register.
4. This will also enable supervisors, who visit the site/subsite subsequently, to know previous observations and verify if suitable action has been taken or not.
5. Please refer to Annex-4 for the implementation structure of HSS.

6.7 Examples of wrong practices of filling data form of ANC and sample transportation sheet

Fig 1: The age field should not be left blank in the data form.

Fig 2: The age mentioned in this form does not fall within the inclusion criteria of HSS i.e. 15-49 years.

Fig 3: It is mandatory to fill the site code, subsite number, sample number and dd/mm/yy format in the data form.

9. Does spouse reside alone in another place/ town away from wife for work for longer than 6 months?
 1. Yes 2. No 99. Not Applicable (For widows /unmarried women)

Signature _____ Signature _____
 Name _____ Name _____
 (Person filling the form) (In charge of the Surveillance Site)

Fig 4: The data form should be duly signed by the in-charge of the surveillance site. Otherwise it is considered as an incomplete form.

HSS 2010: Data Form for Antenatal Clinic Attendees (ANC)
 (Please fill the site details in the box below OR Paste the sticker with site details/ Stamp the site details in the empty box.)

State: _____ District: _____
 Site Name: _____
 (Site Code) (Subsite No.) (Sample No.) (Date - DD/MM/YY)

1. Age (In completed years) 27

2. Literacy Status
 1. illiterate 2. Literate and till 5th standard 3. 6th to 10th standard 4. 11th to Graduation 5. Post Graduation

3. Order of Current Pregnancy
 1. First 2. Second 3. Third 4. Fourth or more

4. Source of Referral to the ANC clinic
 1. Self Referral 2. Family/ Relatives/ Neighbors/ Friends 3. NGO
 4. Private (Doctor/ Nurses) 5. Govt (including, ASHA/ ANM) 6. CTC / ART Centre

Fig 5: Data form should be filled without over writing and strike mark. In case of an error while filling the form, use a fresh data form.

HIV SENTINEL SURVEILLANCE 2010 DATA FORM TRANSPORTATION SHEET
 (To be sent in duplicate along with the samples)

1. Name and Complete Address of the Sentinel Site: _____
 District: _____ State: _____

2. A) Type of Site: 1 B) Site Code: 157492031

3. Period of Sample Collection: 26-10-10 (dd/mm/yy) to 1-11-10 (dd/mm/yy)

4. Total No. of Data Forms: 2

5. Total Number of Envelopes: 1

6. Details of Sample Numbers whose data forms are being sent:

S. No.	Date of Collection	Sample No.	S. No.	Date of Collection	Sample No.	S. No.	Date of Collection	Sample No.	S. No.	Date of Collection	Sample No.
1	26-10-10	1	26		51			76			
2	28-10-10	6	27		52			77			
3	29-10-10	3	28		53			78			
4	30-10-10	3	29		54			79			
5	1-11-10	6	30		55			80			
6			31		56			81			
7			32		57			82			

Fig 6: In Data Form Transportation Sheet, total number of forms should tally with details of sample numbers whose data forms are being sent. Sample number should not be repeated at the site.

7. STANDARD OPERATING PROCEDURES FOR BLOOD SPECIMEN COLLECTION AT ANC SITES

7.1 Consumables required for blood collection

Table 5: List of consumables

Cotton with spirit	Needle destroyer
Vacutainer tube & tube holder or needle & syringes	Puncture proof sharp disposal container
Centrifuge tube	Pipette/Micro-pipette with tips
Latex hand gloves	Pipette/Micro-pipette with tips
Tourniquet	Labels
Adhesive bandages	1% Sodium hypochlorite solution
Test tube stand	

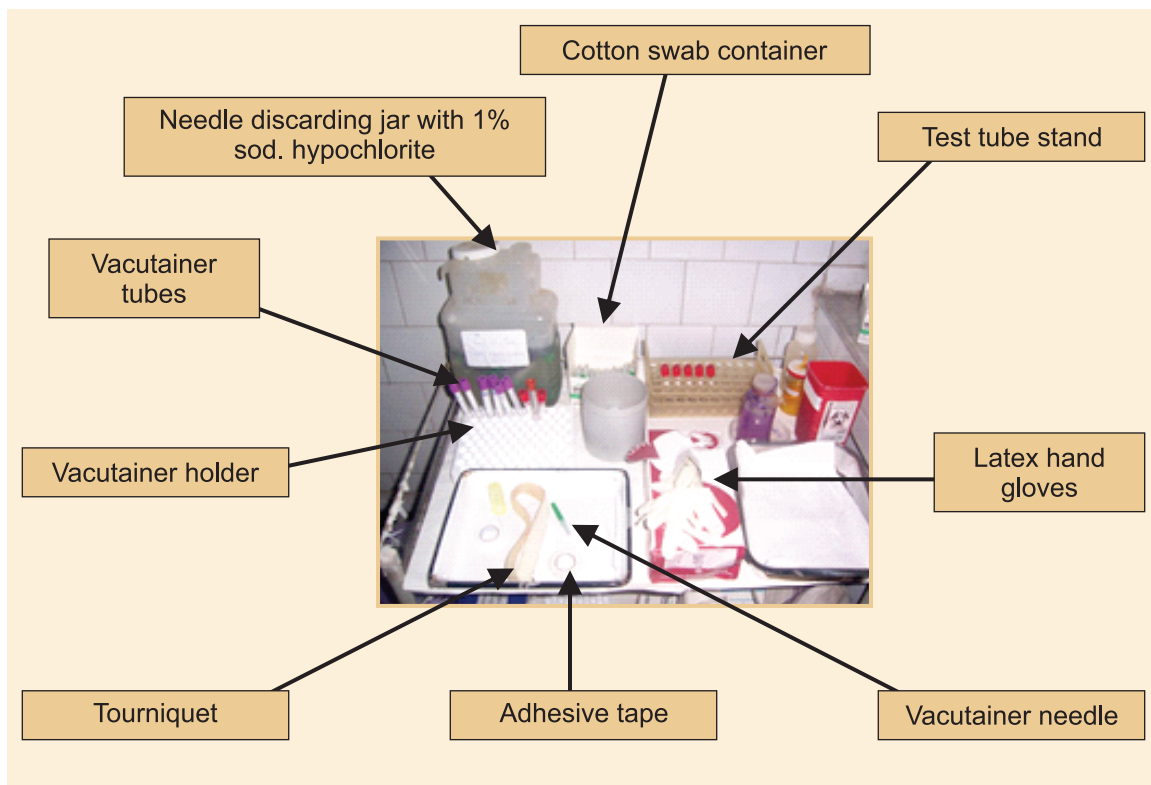
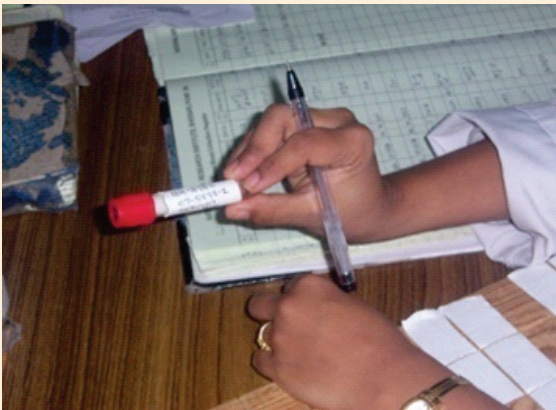






Fig 7: Consumables required for blood collection.

7.2 Blood specimen collection

<p>Step 1:</p> <ol style="list-style-type: none">1. Observe all universal precautions at all times by wearing gloves, lab coats and safety glasses.2. Collect 5ml blood by venipuncture in pre-labelled vacutainer tubes.3. Prepare and label the tube for blood collection with name, registration number etc as per routine practice; only one tube at a time.4. Keep this single labelled tube in the test tube rack to avoid picking up the wrong tube for sample collection.	 <p>Fig 8: Red top vacutainer tube.</p>
<p>Step 2:</p> <ol style="list-style-type: none">1. Remove the rear protective cover (white) of the needle.2. Fix the rear end of the needle to the holder.3. Remove the forward/ front protective cover of the needle (green).4. If blood is collected using needle and syringes, take a sterile disposable syringe and needle.	 <p>Fig 9: Assembling the vacutainer system.</p>
<p>Step 3:</p> <ol style="list-style-type: none">1. The respondent is made to sit on the chair and asked to incline the arm in a downward position. (Fig 10)2. Ask the participant to clench and unclench the fist.3. Lightly tap the vein.4. Apply tourniquet.	 <p>Fig 10: Suggested position of the arm for blood specimen collection.</p>
<p>Step 4:</p> <ol style="list-style-type: none">1. Disinfect the puncture site carefully and thoroughly.2. Wipe the skin surface with a cotton swab containing spirit or alcohol solution.4. Wipe in an outward moving circular motion. When dry, collect blood specimen. (Fig 11)	 <p>Fig 11: Disinfecting the puncture site for blood specimen collection.</p>
<p>Step 5:</p> <ol style="list-style-type: none">1. Slowly insert the needle with holder/syringe into the lumen of the vein. (Fig 12)2. Hold the puncture device firmly to avoid any jerking movement with the needle in place to avoid unnecessary pain for the patient.	 <p>Fig 12: Inserting the needle into the vein.</p>

Step 6:

1. Hold the needle holder firmly and gently insert the vacutainer tube into the holder.
2. Press the tube gently into the rear end of the needle in the holder so that the rear end of the needle penetrates the rubber top of the tube.
3. Now the blood will flow into the tube. (Fig 13)
4. Holding the puncture device firmly gently remove the tube from the holder.
5. If needle and syringes are used, gently pull the piston of the syringe to draw 5 ml blood into the syringe barrel. (Fig 14)
6. Placing the cotton on the punctured site, gently remove the needle from the vein.
7. Holding the puncture device in one hand, release the tourniquet completely.



Fig 13: Inserting vacutainer tube into needle holder.



Fig 14: Removing vacutainer tube into needle holder.

Step 7:

1. Place the vacutainer tube with blood sample in the test tube rack. (Fig 15)
2. If needle and syringes are used, remove the needle and transfer the blood into the pre-labelled centrifuge tube from the syringe. Place the centrifuge tube with blood specimen in the test tube rack.



Fig 15: Place vacutainer/centrifuge tube with blood specimen in the rack.

Step 8:

1. Cover the puncture site with a sterile adhesive bandage. (Fig 16)
2. Destroy the needle using the needle/cutter and discard it into the puncture proof discarding jar/sharp disposal container having 1% sodium hypochlorite solution. (Fig 17)
3. Discard the gloves, cotton swab and gauze pieces into the waste bucket with the yellow bag. (Fig 18)



Fig 16: Apply adhesive tape over puncture site



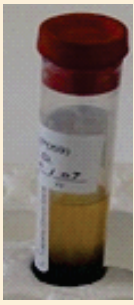


Fig 17: Discard needle in puncture proof container.



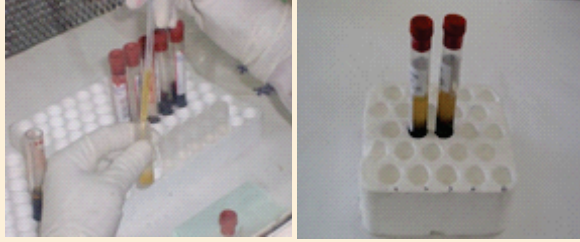

Fig 18: use appropriate waste basket.

7.3 Sample processing


<p>Step 1:</p> <ol style="list-style-type: none">1. The blood specimen is allowed to stand for at least 20-30 minutes until the formation of clot before centrifugation. (Fig 19)2. The blood specimen is centrifuged to separate the serum. Care must be taken to balance the vacutainer/centrifuge tubes in the centrifuge, in order to prevent agitation and there by hemolysis.	 <p>Fig 19: Blood specimen is allowed to stand before centrifugation.</p>
<p>Step 2:</p> <ol style="list-style-type: none">1. The specimen should be centrifuged at 1,200 to 1,500 RPM for 10 minutes. (Fig 20)2. Meanwhile label the cryovials/serum vials into which serum will be transferred after centrifugation and keep them ready. (Fig 21)3. Do not use glass tubes for storing specimens; use only plastic vials.4. Determine the number of aliquots to be prepared from each blood specimen and prepare the labels accordingly. (Box 6)	  <p>Fig 20: Centrifugation of blood specimens.</p> <p>Fig 21: Blood sample after centrifugation.</p>
<p>Step 3:</p> <ol style="list-style-type: none">1. Aliquot for routine testing (eg, VDRL/RPR) and aliquot for HIV test under PPTCT should be labelled with personal identifiers (name, registration number, age, sex, date etc.) as per routine practice.2. Aliquot for HSS should be labeled with HSS site code, sample number, subsite number and date of collection. No personal identifiers should be mentioned on HSS specimen, to ensure anonymous testing under HSS.3. Make sure that the label is placed on the side of the tube, not on the cap.4. Only water resistant markers or lead pencil only should be used for labeling. Avoid use of ink or gel pens.5. Ensure that the HSS sample number is written only on the designated vial and the data collection form. It should not be recorded in the logbook or in any other place where it could be traced back to the patient.	

Box 6. Determining the number of aliquots to be prepared (Refer Flow Charts 1, 2 & 3)

1. At an ANC sentinel site with PPTCT services, if the woman is not registered for PPTCT/not tested for HIV under PPTCT earlier and if she agrees to get tested for HIV under PPTCT:
 - a) If HSS data form has been filled for the woman, then prepare 3 aliquots - one for routine testing (eg, VDRL/RPR), second for HIV test under PPTCT and the third for HSS; and
 - b) If HSS data form has NOT been filled for the woman, then prepare 2 aliquots - one for routine testing (VDRL/RPR) and the second for HIV test under PPTCT.
2. At ANC sentinel site with PPTCT services, if the woman had already been tested for HIV under PPTCT, (ii) at ANC sentinel site with PPTCT services, if the woman does not agree for HIV test under PPTCT; (iii) at ANC sentinel site without PPTCT services:
 - a) If HSS data form has been filled for the respondent, then prepare 2 aliquots - one for routine testing (eg, VDRL/RPR) and the second for HSS.
 - b) If HSS data form has not been filled for the respondent, then prepare 1 aliquot for routine testing (VDRL/RPR).

<p>Step 4:</p> <ol style="list-style-type: none"> 1. After the specimen is centrifuged, transfer 0.5 ml of serum to the required number of sterile labeled serum vials (plastic, not glass) or cryovial (2.0 ml with screw cap) using a clean pipette (disposable plastic pipettes or micropipette with disposable tips). 2. Do not pour the serum from one tube to another. USE a pipette. 3. Use separate pipette tips for each specimen. 4. Make sure that the screw cap is tightly closed on the labeled cryovial or serum vial. 5. After serum separation, the centrifuge tube with the clot should be decontaminated by autoclaving. Subsequently, tubes can be washed, and cleaned properly. 	 <p>Fig 22&23: Aliquoting the serum.</p>
<p>Step 5:</p> <ol style="list-style-type: none"> 1. Send the vial for routine testing to the concerned testing lab at the facility and return test results to the respondent subsequently. 2. Send the vial for PPTCT to ICTC laboratory and return the test result subsequently. 3. Store the vial for HSS at 4 C in the refrigerator up to a maximum of seven days. 4. Do not freeze. Do not de-frost the refrigerator when specimens are stored. 	 <p>Fig 24: Aliquoting the serum.</p>

7.4. Packaging and transporting of specimens

<p>Step 1:</p> <ol style="list-style-type: none"> 1. Check that each vial is tightly closed and sealed. 2. Seal each vial with 'parafilm', just before transportation. 3. The surface should be dried to ensure proper sticking of the film. 4. Tightly wrap the parafilm on the junction of the cap & vial. 	 <p>Fig 25&26: Securing serum vials.</p>
<p>Step 2:</p> <ol style="list-style-type: none"> 1. Sealed vials are packed in a proper sample transportation box with a numbered lid so that the serum specimens remain upright during transportation. 2. Do not transport any other material in this box. 3. This container should be placed in a double plastic bag and sealed well. 	

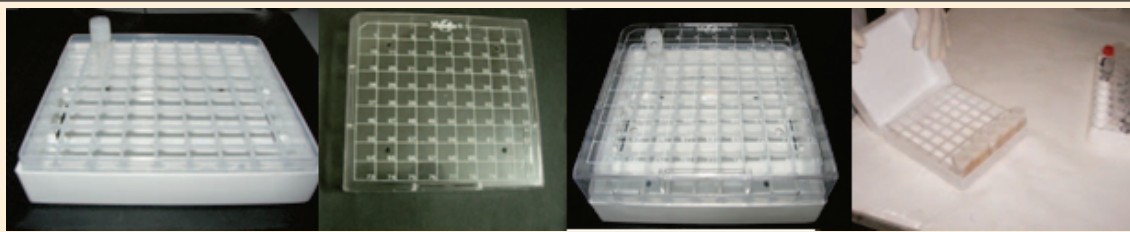


Fig 27: Proper sample transportation box.

Fig 28: Numbered lid of sample transportation box.

Fig 29&30: Proper way of transporting serum specimens.

Step 3:

1. Place the sample transportation box in a vaccine carrier/ice box containing adequate number of pre-chilled cold packs to produce an ambient temperature of 4°C within the box for the duration of the journey. (Figure 31)



Fig 31: Placing sample containers in bigger box.

Step 4:

1. The serum specimens are transported to the testing laboratory on a weekly basis.
2. Ensure that the specimens are delivered to the testing laboratory during working hours only (ensure that it is not a holiday before you leave).
3. The samples should be accompanied by a duly completed and signed sample transportation sheet in duplicate.
4. Once packed, the samples should reach the testing laboratory directly and there should be no deviation en route.
5. The samples should remain in the fridge until the last moment and should not be taken home or elsewhere.

Step 5:

1. On reaching the HSS testing lab, the specimens along with the STS should be handed over to the testing lab in-charge or lab technician.
2. Please wait while the samples are verified.
3. Take back with you a signed copy of sample transport sheet and verification checklist.
4. This should be handed over to the sentinel site in-charge on return and kept in a file for future reference.

7.5 Examples of wrong practices of specimen processing



Fig 32: Wrong practice of recapping the needle and allowing blood to clot in the syringe itself. After collection, blood should immediately be transferred to centrifuge tube and the tube should be allowed to stand for 20-30 minutes for clot formation, before centrifugation.

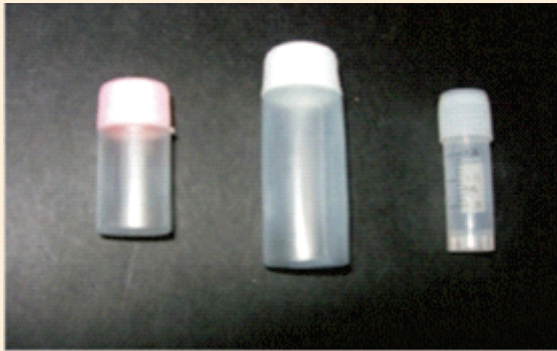


Fig 33: Serum vials used in different states; screw capped vials with O-ring should be used for holding serum.

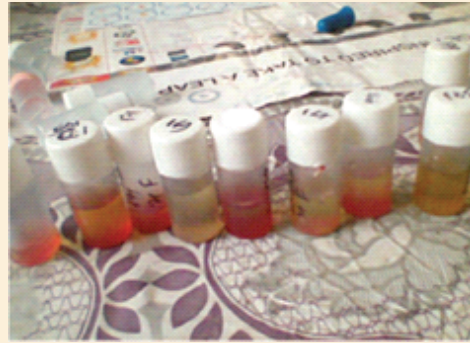


Fig 34: Varying quality of sera at the sentinel site.



Fig 35: Wrong practice of packing serum vials using rubber bands leads to chance of cross-contamination.



Fig 36: Sample transportation box or tiffin box for school kids. Use appropriate sample transportation box with numbered lid to avoid leakage of specimens during transport.



Fig 37: Sharps disposal container not used for discarding needles.

8. BIOWASTE MANAGEMENT

It is essential to follow universal safety precautions at all points in the specimen collection, storage, testing, transportation and disposal of bio-hazardous wastes. The Laboratory technician should take the responsibility of implementing safe biowaste management procedures at the sentinel site under active supervision of the sentinel site in-charge. Colour-coded waste-bags should be used as per standard specification for disposal of waste materials and contaminated sharps.

- a) Used needles and syringes should be disposed off by using a needle cutter. After crushing the hub of the needles, they should be put in a puncture proof container containing freshly prepared 1% sodium hypochlorite solution. At the end of each day's work, the contents of the container should be put in a biowaste bag (blue-bag) and disposed off as per the standard procedure at the site;
- b) Alcohol swabs, gloves and gauze pieces should be discarded into the biohazard waste bag (yellow bag);
- c) General waste such as the wrapper of gloves, papers etc. Should be discarded in the biowaste bag (black bag);
- d) The biohazard waste bags should be sent for final disposal as per the standard procedures at the site; and
- e) Any spillage of potentially dangerous material should be properly cleaned and decontaminated following standard procedures.

Table 6. Preparation of 1% sodium hypochlorite solution (10g/L- 10,000 ppm)

4% stock Solution	5% stock Solution	6% stock Solution
1:3*	1:4*	1:5*

*parts of stock solution: parts of water

9. MANAGEMENT OF NEEDLE STICK INJURY

1. Needle stick, puncture wounds, cuts, open skin contaminated by spills or splashes should be washed thoroughly with soap and water.
2. Report the injury to the laboratory in-charge or site in-charge as the case may be; the person should be assessed for post exposure prophylaxis (PEP).
3. PEP, preferably should be started within 2 hours and no later than 72 hours of the accidental exposure for maximum benefit.
4. Appropriate medical evaluation, treatment and counselling should be provided.
5. For details on PEP, please refer to office memorandum titled "Revised guidelines for post exposure prophylaxis (PEP) for HIV" dated 2nd December 2014; downloadable at [http://naco.gov.in/sites/default/files/Revised Guidelines for Post Exposure Prophylaxis \(PEP\) for HIV. pdf](http://naco.gov.in/sites/default/files/Revised%20Guidelines%20for%20Post%20Exposure%20Prophylaxis%20(PEP)%20for%20HIV.pdf)

Annex 1

HSS 2016: Data form for antenatal clinic attendees (ANC)

(Please fill the site details in the box below OR
Paste the sticker with site details/Stamp the site details in the empty box

State: District:..... Site /Subsite name: <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 2px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 2px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 2px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 2px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 2px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 2px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 2px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 2px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 2px;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; margin: 2px;"></div> </div> <div style="display: flex; justify-content: space-around; font-size: small; margin-top: 5px;"> (Site code) (Subsite No) (Sample No) (Date-DD/MM/YY) </div>	
--	--

1. Age in completed years	<input style="width: 20px; height: 20px;" type="text"/>
----------------------------------	---

2. Literacy status
1. Illiterate 2. Literate and till 5th standard 3. 6th to 10th standard 4. 11th to Graduation 5. Post graduation

3. Order of current pregnancy
1. First 2. Second 3. Third 4. Fourth/More

4. Duration of current pregnancy
1. First trimester 2. Second trimester 3. Third trimester

5. Has respondent received prior antenatal care services from a healthcare facility during her current pregnancy?
1. Yes 2. No

6. Source of referral to the ANC clinic
1. Self-Referral 2. Family/Relatives/Neighbours/Friends 3. NGO 4. Private hospital (Doctor/Nurses) 5. Government hospitals (including ASHA/ANM) 6. ICTC/ART centre

7. Current place of residence
1. Urban (Municipal corporation/Council/Cantonment) 2. Rural

8. Current occupation of the respondent
1. Agricultural labourer 2. Non-agricultural labourer 3. Domestic servant 4. Skilled/Semi-skilled worker 5. Petty business/small shop 6. Large business/Self-employed 7. Service (Government/Private) 8. Student 9. Hotel staff 10. Truck driver/Helper 11. Local transport worker (auto/taxi driver, hand cart pullers, rickshaw pullers etc) 12. Agricultural cultivator/landholder 13. Housewife

9. Current occupation of the spouse
1. Agricultural labourer 2. Non-Agricultural labourer 3. Domestic servant 4. Skilled/Semi-skilled worker 5. Petty business/small shop 6. Large business/Self-employed 7. Service (Govt./Pvt.) 8. Student 9. Hotel staff 10. Truck driver/Helper 11. Local transport worker (auto/taxi driver, hand cart pullers, rickshaw pullers etc) 12. Agricultural cultivator/landholder 13. Unemployed 99. Not applicable (for Never Married/Widowed/Divorced/Separated)

10. Does spouse reside alone in another place/town away from wife for work for longer than 6 months?

1. Yes 2. No
99. Not applicable (For Never Married/Widowed/Divorced/Separated)

11. Has respondent ever been tested for HIV?

1. Yes 2. No

12. If ever tested for HIV, when was the last she was tested for HIV?

1. Tested during current pregnancy 2. Tested before current pregnancy
99. Not applicable (For never tested)

13. What was the result of respondent's last HIV test?

1. Positive 2. Negative 3. Did not collect the test result 4. No response
99. Not applicable (For never tested)

14. If positive, is respondent seeking care from any of the following for management of HIV?

1. Government Hospital/ART centres 2. NGO doctor
3. Private Facilities (Hospital/ standalone clinic) 4. Pharmacist/ chemist
5. Alternative/non-allopathic doctor (*Ayurvedic/homoeopathic/siddha*) 6. Any other type of doctor
7. Not seeking care for HIV management
99. Not applicable (For all who were either never tested or not positive when last tested for HIV)

15. Is respondent currently taking antiretroviral medications/HIV tablets?

1. Yes 2.No
99. Not applicable (For all who were either never tested or not positive when last tested for HIV)

Signature/हस्ताक्षर:
Name/नाम:
(Person who filled the form/
व्यक्ति जिसके द्वारा फार्म भरा गया)

Signature/ हस्ताक्षर:
Name/नाम:
(Sentinel site in-charge/
सेंटिनेल साइट प्रभारी)

Annex 2

Data form transportation sheet

(To be sent in duplicate along with the data forms)

1. Name and complete address of the sentinel site/subsite:
..... District: State:
2. (A) Type of site: (B) Site code: (C) Subsite No:
3. Period of sample collection: (dd/mm/yy) to (dd/mm/yy)
4. Total no. of data forms:
5. Total number of envelopes:
6. Details of sample numbers whose data forms are being sent:

S. No.	Date of collection	Sample No.	S. No.	Date of collection	Sample No.
1			16		
2			17		
3			18		
4			19		
5			20		
6			21		
7			22		
8			23		
9			24		
10			25		
11			26		
12			27		
13			28		
14			29		
15			30		

If space provided above is not sufficient, please attach another sheet.

Data forms sent by:

.....
(Name)

.....
(Signature)

.....
(Tel/ Mobile no.)

Date of sending data forms:

Data forms received by:

.....
(Name)

.....
(Signature)

Date of receipt of data forms:

Annex 3 Sample transportation sheet

(To be sent in duplicate along with the samples)

1. Name and complete address of the sentinel site/subsite:
..... District: State:
2. (A) Type of site:(B) Site code: (C) Subsite No:
3. Period of sample collection: (dd/mm/yy) to (dd/mm/yy)
4. Total number of samples:
5. Total number of boxes:
6. Details of sample numbers:

S. No.	Date of collection	Sample No.	S. No.	Date of collection	Sample No.
1			16		
2			17		
3			18		
4			19		
5			20		
6			21		
7			22		
8			23		
9			24		
10			25		
11			26		
12			27		
13			28		
14			29		
15			30		

If space provided above is not sufficient, please attach another sheet.

Sample sent by:

.....
(Name)

.....
(Signature)

.....
(Tel/Mobile no.)

Date of sending samples:

Samples received by:

.....
(Name)

.....
(Signature)

Date of receipt of samples:

