

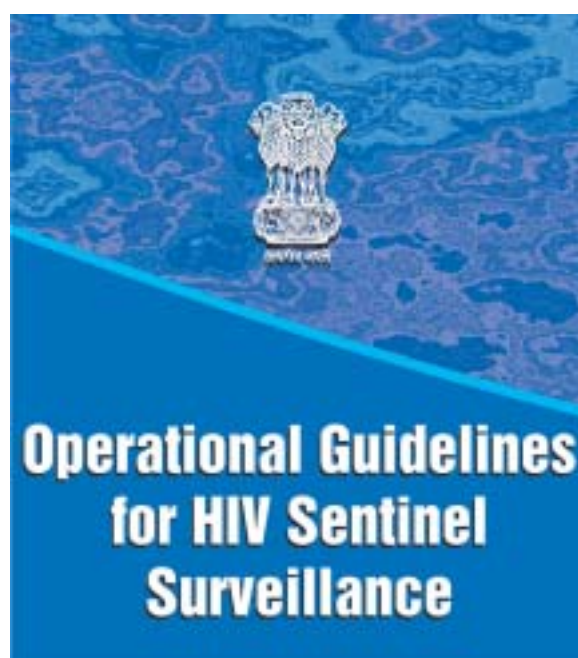


Operational Guidelines for HIV Sentinel Surveillance



National AIDS Control Organisation
Ministry of Health and Family Welfare
Government of India
New Delhi

2008



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Ministry of Health and Family Welfare
Government of India
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The annual nationwide HIV Sentinel Surveillance (HSS) programme in India provides essential information on the dynamics of the HIV epidemic and helps monitor trends and foresee the type of inputs needed to strengthen the prevention and control activities for different population groups and geographical regions. The surveillance activities have been scaled up in a phased manner and the network of sentinel sites has expanded from a couple of centres through 164 sites in 1998, to 1134 sentinel sites in 2007. In 2006, sentinel sites were established in almost all the districts of the country. In the current round of HSS in 2008, the focus is on expansion of surveillance among high risk groups.

The National Institute of Health and Family Welfare has been coordinating this national effort since inception. To maintain the quality of surveillance activities and outputs, since 2006, five regional institutes - Post Graduate Institute of Medical Education and Research, Chandigarh; All India Institute of Medical Sciences, New Delhi; All India Institute of Hygiene and Public Health, Kolkata; National AIDS Research Institute, Pune; National Institute of Epidemiology, Chennai - have been involved in planning, monitoring and supervision of the surveillance activities. This year two new institutes- Regional Institute of Medical Sciences, Imphal; and National Institute of Cholera and Enteric Diseases, Kolkata- have been identified as additional Regional Institutes to strengthen surveillance activities in the Eastern and North-Eastern regions respectively. Adequate attention is being given to External Quality Assurance System (EQAS) to provide regular feedback for instituting corrective measures as well as to understand the quality of the results from various testing sites.

NACO, with the support of WHO SEARO, convened a consultation process including national and international experts in April 2008 to review the HIV surveillance in India. Based on the recommendations from these consultations, the current Operational Guidelines on HIV Surveillance have been re-drafted. The methodology for HSS at the targeted intervention [TI] sites has been changed with effect from HSS 2008 and these have been

included in this document. The Operational Guidelines on Surveillance have been developed to ensure uniformity in the implementation of Surveillance programme, with clearly delineated function of SACS, Regional Institutions, NIHFV and reference laboratories. The guidelines also provide information on the HSS strategy, sentinel population type, eligibility criteria and the detailed methodology to be followed at the surveillance sites and the testing centres. These guidelines will help standardize the data collection and provide comprehensive guidance to persons working at all levels.

The National AIDS Control Organisation gratefully acknowledges the support, initiative and guidance provided by Dr. D.C.S. Reddy and Dr. Partha Haldar, WHO India and Dr. M. Bhattacharya, NIHFV in finalising the Operational Guidelines. Dr. Sanjay Mehendale and his team, Dr. Sheela Godbole, Mr. Rajesh Yadav and Mr. Mycal Pereira at National AIDS Research Institute, Pune has done a commendable work in revising and improving the guidelines. We also appreciate the efforts of Dr. Shashi Kant and his team at AIIMS, New Delhi in evaluating the operational feasibility of introducing the new strategies in HSS. The contributions of Dr. Virginia Loo, Dr. Arvind Pandey, and Dr. Renu Garg are also acknowledged. Our sincere thanks also go to all the members of Regional Institute teams and State AIDS Control Societies for their participation in the process of finalisation of this document. The technical contribution and coordination by the Surveillance team at NACO consisting of Dr. S. Venkatesh, Additional Project Director, Dr. Ajay Khera, Joint Director (Basic Services) and Dr. Yujwal Raj, Sr. Technical Officer (Surveillance) are highly appreciated.



(K. Sujatha Rao, IAS)



Abbreviations

AIHPH	All India Institute of Hygiene and Public Health, Kolkata
AIIMS	All India Institute of Medical Science, New Delhi
ANC	Antenatal Clinic
ART	Anti Retroviral Treatment
BSS	Behavioral Surveillance Survey
CMO	Chief Medical Officer
CMHO	Chief Medical Health Officer
DHO	District Health Officer
DBS	Dried Blood Spot
ELISA	Enzyme Linked Immunosorbent Assay
EQAS	External Quality Assurance Scheme
FSW	Female Sex Worker
GYN	Gynaecology
HCP	Health Care Personnel
HIV	Human Immunodeficiency Virus
HSS	HIV Sentinel Surveillance
HRG	High Risk Group
IBBA	Integrated Biological and Behavioral Assessment
ICMR	Indian Council for Medical Research
ICTC	Integrated Counselling and Testing Center
IDU	Injecting Drug User
LDT	Long Distance Trucker
M&E	Monitoring and Evaluation
ml	Milliliter
MC	Medical College
MSM	Men who have Sex with Men

NACO	National AIDS Control Organization, New Delhi
NARI	National AIDS Research Institute, Pune
NICD	National Institute of Communicable Disease, New Delhi
NICED	National Institute of Cholera and Enteric Diseases, Kolkata
NIE	National Institute of Epidemiology, Chennai
NIHFW	National Institute of Health and Family Welfare, New Delhi
NIMS	National Institute of Medical Statistics, New Delhi
NGO	Non-Governmental Organization
NRL	National Reference Laboratory
PEP	Post Exposure Prophylaxis
PGIMER	Post-Graduate Institute of Medical Education and Research, Chandigarh
PHC	Primary Health Center
PMO	Principal Medical Officer
PPTCT	Prevention of Parent to Child Transmission
QA	Quality Assurance
RFWTC	Regional Family Welfare Training Centre
RI	Regional Institute
RIMS	Regional Institute of Medical Sciences, Imphal
RPR	Rapid Plasma Reagent
RRL	Regional Reference Laboratory
SACS	State AIDS Control Society
SOP	Standard Operating Procedure
SST	State Surveillance Team
STD	Sexually Transmitted Disease
TI	Targeted Intervention
UAT	Unlinked Anonymous Testing
VCTC	Voluntary Counseling and Testing Center
VDRL	Venereal Disease Research Laboratory



**Operational Guidelines
for HIV Sentinel
Surveillance**

Introduction

Chapter



I



1

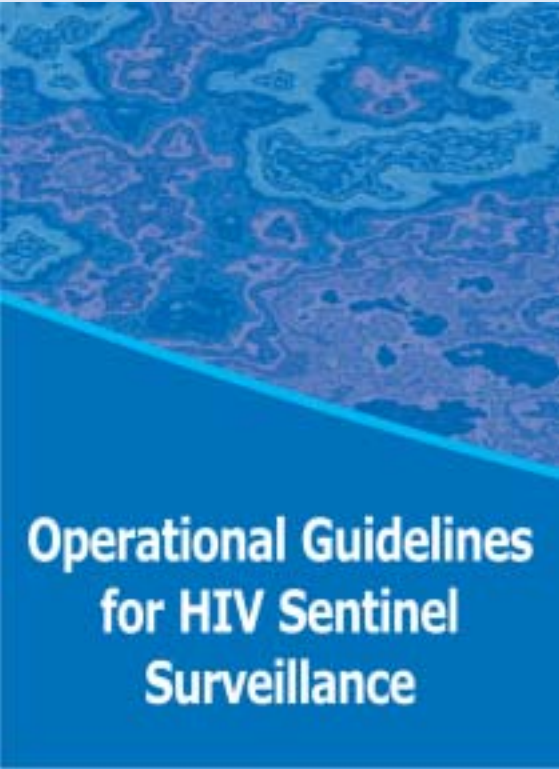
The HIV Sentinel Surveillance (HSS) system in India involves carrying out cross-sectional facility and Targeted Intervention (TI) based HIV sero-prevalence surveys at regular intervals among selected population groups. These populations are also referred to as "sentinel groups". With HSS, the trends in HIV infection are monitored over the period of time by group and by site.

The HSS system is one of the components of the second generation HIV surveillance in India. Over the years, the emphasis of HSS in India was on heterosexual transmission, so, the sentinel sites were mainly at Antenatal Clinics (ANC) and Sexually Transmitted Disease (STD) clinics, to observe the trends and levels of HIV in general population and among people with high risk behavior, respectively. Primarily from 2003 onwards, the sentinel surveillance started tracking the trends and levels in core risk groups, namely, Men having Sex with Men (MSM), Female Sex Worker (FSW) and Injecting Drug Users (IDU). Surveillance was gradually introduced in other population groups at risk such as, single male migrants and long distance truckers. Additionally, from 2003 surveillance was initiated in some ANC clinics at sub district level as well. The number of sentinel sites have increased from 164 in 1998 to 1134 in 2007.

The HIV surveillance system in India was reviewed in an international consultation convened by NACO with support from WHO in April 2008. Several recommendations were made in response to issues identified. NACO adapted the recommendations for HIV sentinel surveillance and they are scheduled to be introduced from the current round of HSS 2008. There has been a change in the strategy of surveillance of populations with high risk behavior. This has called for separate sections on methods in the operational guidelines for facility based surveillance (ANC attendees and STD patients) and TI based

surveillance (high risk behavior populations). Methodology of blood specimen collection in these specific risk behavior groups at HRG sites have been revised and the specimens will be collected in the form of Dried Blood Spots (DBS) on special papers. Data will be entered both at Regional Institute (RI) and SACS and will be validated by matching the electronic files for inconsistency.

These operational guidelines capture the aforementioned changes in detail and therefore are crucial for effective and uniform implementation of HSS. It has been specially structured keeping in mind the people implementing HSS at the different types of sites who may use this for ready reference, in addition to stakeholders at different levels.



**Operational Guidelines
for HIV Sentinel
Surveillance**

**Overview of HIV
Sentinel Surveillance**

Chapter





2

2.1 Objectives of HSS

The objectives of HSS are:

- To find the prevalence of HIV infection in different population subgroups and in different geographical areas
- To monitor trends in the prevalence of HIV infection over the period of time
- To generate data for use in HIV estimations and projections

Aim of HSS is to provide data to assist in public health decision making including:

- Advocacy
- Targeting and prioritizing prevention and care programs
- Monitoring and evaluating prevention and care programs
- Resources allocation and program planning

To achieve these aims, data collected and analyzed through the HSS are triangulated with data from other HIV surveillance activities and complementary data sources.

2.2 Frequency and Period of HSS

HIV sentinel surveillance is carried out once a year in designated sentinel sites for twelve weeks. HSS 2008 will be carried out from 1st November 2008 to 31st January 2009 for the ANC and STD sites and from 1st December 2008 to 28th February 2009 for the HRG (TI) sites.

2.3 Site selection strategy for HSS 2008

2.3.1 New sites

The number of sites was increased significantly in the HSS 2006 round with an aim to increase geographical coverage. As a result, almost every

district in the country now has a sentinel site from one or more of the sentinel groups. NACO does not anticipate adding large numbers of additional ANC sites during subsequent rounds. However, if there is a perceived need of establishing ANC sites to capture the level and trends of HIV among spouses of single male migrants, the decision should be taken only after due consultation with the respective RIs. As a guiding factor, the RIs may consider the following points to inform their decision about the relevance and feasibility of such a site:

1. Such ANC sites should be at source of migration
2. Whether the transmission dynamics are related to out migration
 - a. Who are the out migrants
 - b. ANC care utilization pattern of the spouses
3. Whether other sources of data, such as Prevention of Parent to Child Transmission (PPTCT) and Voluntary Counseling and Testing Centre (VCTC) data are available, and analysis of which rationalizes setting up such a center
4. At the prospective ANC site
 - a. Review of records should be done to note number of ANC cases attending the clinic
 - b. Whether sample size could be reached during the three month period of surveillance

The current need, however, is for inclusion of additional high-risk group sites for FSW/ MSM/ IDU. Thus State AIDS Control Societies (SACS) with documented low HIV prevalence areas are encouraged to add new high-risk group sites based on the results of mapping exercises. A decision tree for selection of new sites for high risk groups is given in Annex. 1.

2.3.2 Composite sites

In some geographic areas, where members of the target population are spread among multiple facilities such that placing a sentinel site at any single location for a type of sentinel category, is not likely

to achieve the recommended sample size of 400 for ANC or 250 for STD, additional sites termed “sub-sites”, to recruit individuals from the same sentinel category (ANC/ STD) may be included. Such sub-sites together constitute one composite site. In such cases up to 3 sub-sites may be added that are capable of contributing at least 50 samples each. Since each sub-site chosen is considered to be representative of its catchment area, sub-sites once chosen must be included in all the subsequent rounds of HSS and also the contribution of sample size from each sub-site should remain constant over time. Sites may be established in the private clinics or hospitals if the assessment teams feel reasonably confident that they will be able to collect adequate number of samples and continue to participate in HSS programme over subsequent years. In no case, there should be any kind of change of the sub-sites.

Figure 1 : Organization and Implementation Chart of HSS

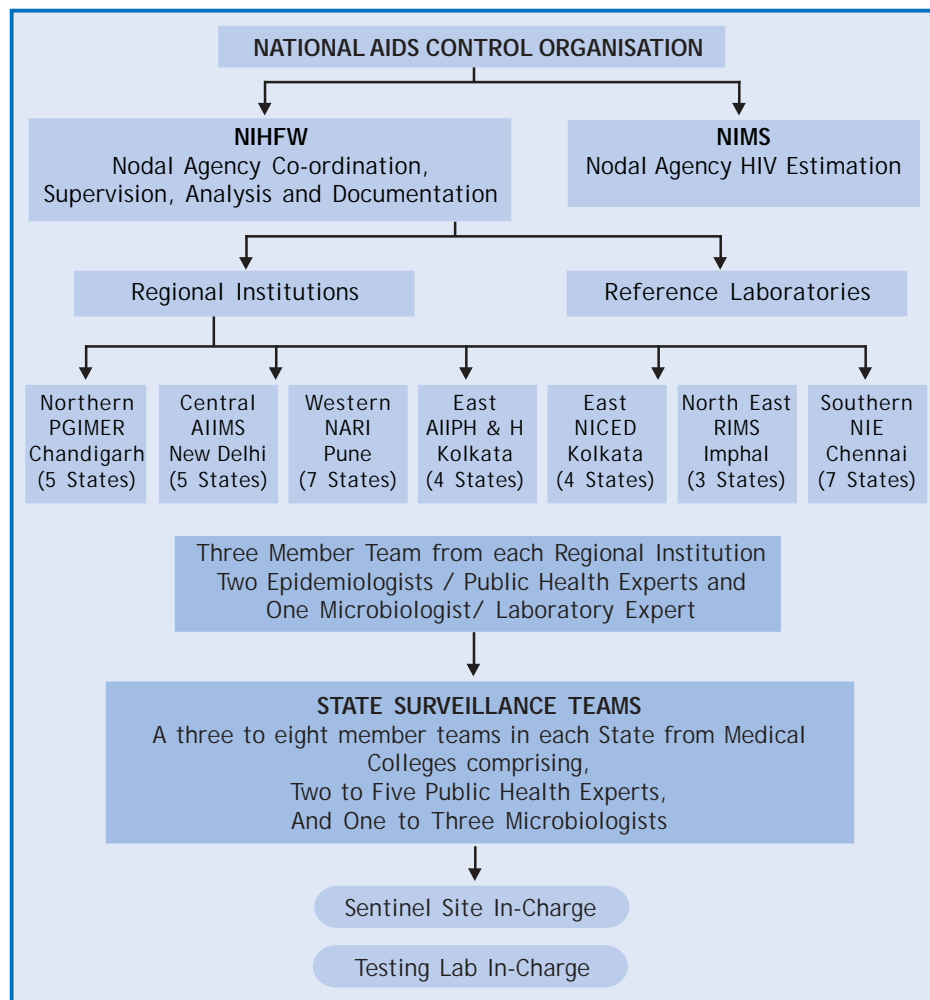


Table 1. Regional Institutes identified in different regions with the States assigned

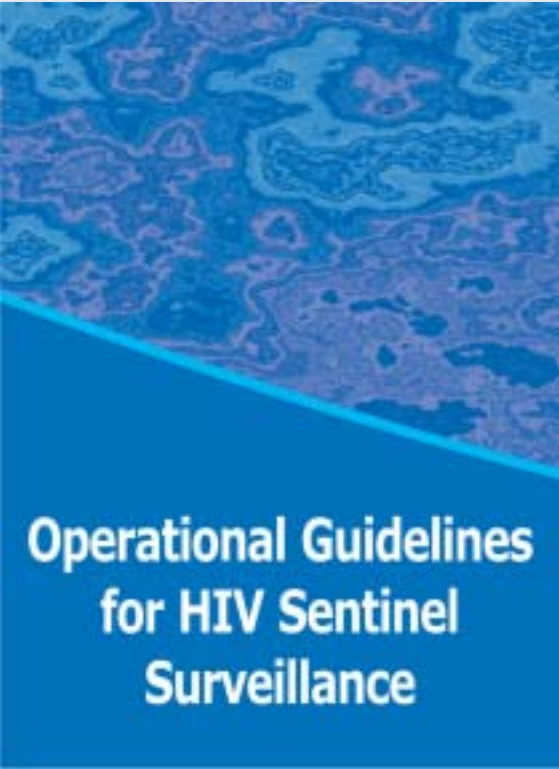
Name of Regional Institution	States of Responsibility
Central Zone: All India Institute of Medical Science, New Delhi (5 States)	Uttar Pradesh, Bihar, Jharkhand, Uttaranchal, and Delhi.
North Zone: Post-graduate Institute of Medical Education and Research, Chandigarh (5 States)	Haryana, Himachal Pradesh, Jammu & Kashmir, Punjab and Chandigarh.
East Zone: National Institute of Cholera and Enteric Diseases, Kolkata (4 States)	West Bengal, Chhattisgarh, Sikkim and Andaman & Nicobar Islands.
East Zone: All India Institute of Hygiene and Public Health, Kolkata (4 States)	Assam, Meghalaya, Arunachal Pradesh and Nagaland
North East Zone: Regional Institute of Medical Sciences, Imphal (3 States)	Manipur, Mizoram, and Tripura.
West Zone: National AIDS Research Institute, Pune (7 States)	Maharashtra, Gujarat, Goa, Madhya Pradesh, Rajasthan, Daman & Diu, and Dadra Nagar Haveli.
South Zone: National Institute of Epidemiology, ICMR, Chennai (7 States)	Andhra Pradesh, Tamil Nadu, Karnataka, Kerala, Orissa, Pondicherry and Lakshadweep.

The NIHFV and NIMS-ICMR, will act as nodal agencies for coordination and centralized data management with support from NACO. The regional institutes (RI) will be responsible for training, supervision, monitoring, data entry (data entry in addition to SACS) and analysis of regional and state level data. The state and national reference laboratories will be responsible for HIV testing and Quality Assurance (QA) procedures in coordination with regional institutes. The implementation of surveillance activities (Figure1) will be carried out by the SACS who will be provided technical support from identified RI and State Surveillance Teams (SST). The SST will be identified by RI for each state and will consist of three to eight member teams in each state from medical colleges comprising, two to five public health experts and one to three microbiologists.

NACO will provide facilitation, guidance and budget for each level in order to accomplish the task of HSS all over the country. An organizational chart for HSS at different levels of health care is shown in Figure 1 and the activities and responsibilities of each member at every level are listed in Tables 2, 4, 5 and 6 below:

Table 2: Activities at different levels during HSS

Agency		Function
National level		
National Institute of Health & Family Welfare, New Delhi	(1)	Coordination of surveillance, maintaining information on finalization of sites, data collection, analysis and reporting at national level.
National Institute of Medical Statistics, New Delhi.	(2)	Monitoring of data quality and HIV estimation.
Regional Level		
Regional Institutes (RIs)	(1)	Orientation and training of State Surveillance Teams
	(2)	Conduction of regional review meetings with SACS, SSTs
	(3)	Separate data entry in addition to SACS
	(4)	Identification of testing laboratories and orientation of microbiologists
	(5)	Assistance to State Surveillance Teams for: <ul style="list-style-type: none"> - identification and confirmation of new sites - monitoring and supervision - quality control at all levels - monitoring data quality - data entry and analysis for the assigned states and report generation
National Reference Laboratory (NRL)	(1)	External quality assurance of testing at each HIV testing center.
	(2)	Supply of panel to sera testing laboratories
State Level		
SACS	(1)	Operationalization of surveillance activities in the state
	(2)	Timely submission of proposals for new sites for validation by RI and approval by NACO
	(3)	Training in-charges and staff of sentinel sites and testing centers for HSS
	(4)	Preparation of periodic (preferably fortnightly) progress report for submission to RI and NACO
	(5)	Constitution of supervisory teams for visits within the state during the round
		<i>(Detailed list available in National Action Plan for HSS)</i>
SST	(1)	Technical support to RI and SACS in training of in-charges and staff of sentinel sites and testing centers for surveillance
	(2)	Technical support to SACS for timely implementation of surveillance activities
	(3)	Supervision and monitoring of data collection and reporting
	(4)	Submission of summary report of activities undertaken at the end of surveillance round to respective RIs
Site Level		
Sentinel Site In-charge, Nurse/ Counselor Laboratory Technician		See Tables 4 & 5
Testing Laboratory		
HIV Testing Laboratory In-charge, Laboratory Technicians		See Table 6



**Operational Guidelines
for HIV Sentinel
Surveillance**

**Organization and Implementation
of HSS 2008**

Chapter





3

Sentinel sites and Testing Centers: Responsible individuals at each site will be identified and designated by the local institutional heads to carry out work till the HSS 2008 round is over. It is important that the staff identified and trained for this round of HSS should be retained at the respective sites for the entire duration of HSS. It is also important that SACS should conduct orientation meetings with senior health officers in the state including PMO/ CMO/ CMHO/ Civil Surgeon/ DHO etc to seek their cooperation in this regard. Regional institutes and SACS will ensure that training of all the staff at all sites is done before the initiation of current round of HSS. It is suggested that the following categories of staff members should be designated and adequately trained well in advance to carry out various activities of HSS. The human resources involved in HSS at different levels are detailed in Annex 2.

Table 3: Staff details at sentinel sites and testing laboratories

Sentinel sites	In-charge sentinel site	1
	Nurse/Counselor	1
	Laboratory technician	1
HIV testing laboratory	In-charge, HIV testing laboratory	1
	Laboratory technician	1

Table 4: Roles and Responsibilities of Staff at ANC/STD Sentinel Sites of HSS

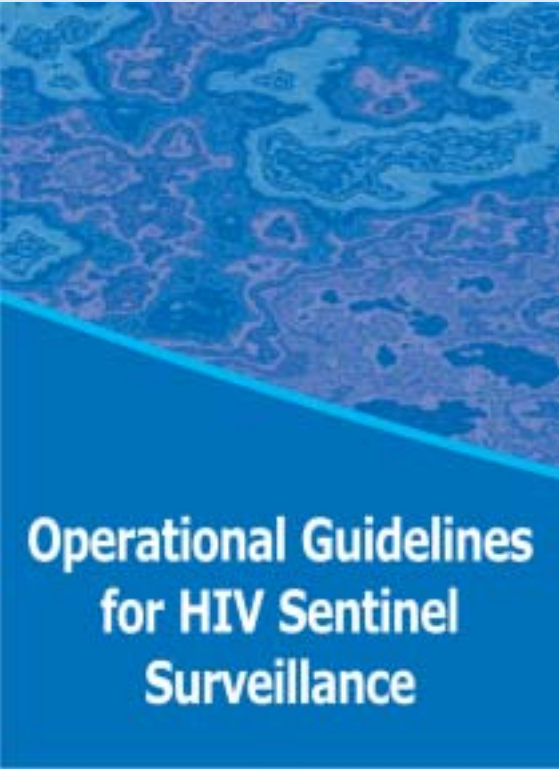
Staff member	Roles and responsibilities
Sentinel Site In charge	<ol style="list-style-type: none"> 1. Overall responsible for entire surveillance activities at her/his site 2. Ensures receipt of consumables/ data forms and prepares for surveillance 3. Obtains instructions for: <ul style="list-style-type: none"> • Start / end date for sampling to begin • Code for site • Sampling period 4. Attends training conducted by SACS and is well versed with eligibility criteria for the respective center 5. Trains all staff who might be involved in the clinic about eligibility criteria and HSS procedures on site. 6. Ensures that guidelines are available for ready reference on site and other reference material such as flow charts/ booklets are made readily available to site personnel. 7. Informs the clinic staff when to start collection of blood samples and data 8. Ensures eligibility criteria are being followed stringently 9. Ensures consecutive sampling 10. Ensures unlinked anonymous testing strategy 11. Makes provision for back up in case she/he is off duty during surveillance period including their training and sensitization 12. Ensures completion of data forms, checks and signs thereafter 13. Sends participants for venepuncture for syphilis screening (Routine procedure) after filling up individual data form and ensures that this step is not missed by any participant. 14. At end of each day, count number of data forms filled, ensures completeness of information, and duly signs each form
Nurse/ Counselor	<ol style="list-style-type: none"> 1. Follows the direction of site in-charge 2. Assists site in-charge in identifying eligible people 3. Ensures that eligible person attends the site of blood collection, without fail 4. Ensures consecutiveness
Laboratory Technician (ANC/STD sites only)	<ol style="list-style-type: none"> 1. Checks that the data form is complete and no item is missing 2. Collects blood specimen (Obtains 5ml of blood) 3. Separates sera from collected blood as per guidelines 4. Ensures separate tips/ pipettes are used for each sample 5. Divides the sera obtained into two specimen vials <ul style="list-style-type: none"> • for syphilis testing on site and result (Labeled routinely per site procedures) • for unlinked anonymous HIV testing at testing centre (labeled with HSS code number, date of collection, age and sex only) 6. Ensures unlinked anonymity of specimens 7. Stores coded vials at "+4°C", in a special box marked with sentinel site code and dates of collection for a maximum of 7 days only. They can not be stored at this temperature for more than 7 days (see section 6.2.1) 8. Arranges for transport box with sera in icebox to HIV testing laboratory at end of week or daily if laboratory is nearby along with Transport Sheet in duplicate. 9. Ensures cold chain is maintained 10. Ensures that biosafety procedures are followed at all times 11. Obtains (from the laboratory) a receipt for the sera transported on a copy of Transport Sheet

Table 5: Roles and Responsibilities of Staff at HRG (TI based) sentinel sites for HSS

Staff member	Roles and responsibilities
Sentinel Site In charge	<ol style="list-style-type: none"> 1. Overall responsible for entire surveillance activities at her/his site 2. Ensures receipt of consumables/ data forms and prepares for surveillance 3. Instructions received for: <ul style="list-style-type: none"> • Start / end date for sampling to begin • Code for site • Sampling period 4. Attends training conducted by SACS and is well versed with eligibility criteria at that type of center 5. Trains all staff who might be involved in the surveillance about eligibility criteria and HSS procedures on site. 6. Ensures that guidelines are available for ready reference on site and other reference material such as flow charts/ booklets are made readily available to site personnel. 7. Informs the concerned staff when to start collection of blood samples and data 8. Ensures eligibility criteria/ HRG case definition is being followed stringently 9. Ensures that all who qualify for HSS as per case definition are approached for Informed consent and no selection criteria be applied. 10. Ensures that Informed Consent form is administered correctly as per procedures. 11. Ensures that all who are approached for informed consent have been given vouchers/ referrals for HIV testing at nearest VCTC 12. Ensures all informed consent forms are sent to respective SACS at the end of HSS 13. Ensures unlinked anonymous with informed consent testing strategy 14. Ensures completion of the data forms, checks and signs thereafter 15. Ensures that site staff are trained in collection of blood using the Dried Blood Spot technique as outlined in section 5.6 16. At end of each day, count number of data forms filled, ensures completeness of information, and duly signs each form 17. Makes provision for back up in case she/he is off duty during surveillance period including their training and sensitization
Nurse/ Counselor	<ol style="list-style-type: none"> 1. Follows the direction of site in-charge 2. Assists site in charge in identifying eligible people 3. Ensures that all consenting participants are sent for finger-prick after filling up individual data form and ensures that this step is not missed by any participant. 4. Ensure completion of the data forms, checks and signs thereafter 5. Ensures consecutiveness
Laboratory Technician	<ol style="list-style-type: none"> 1. Checks that the data form is complete and no item is missing 2. Collects Dried Blood Spot sample by finger-prick method as outlined in section 5.6 3. Ensures unlinked anonymity of specimens 4. DBS specimens should be coded appropriately, dried packed, stored and transported as per guidelines outline in section 5.6 5. Ensures that bio-safety procedures are followed at all times 6. Obtain (from the laboratory) a receipt for the sera transported on a copy of Transport Sheet

Table 6: Roles and Responsibilities of Staff at testing centers for HSS

Staff member	Roles and responsibilities
Testing Centre in-charges	<ol style="list-style-type: none"> 1. Ensures testing centre preparedness for the surveillance, 2. Checks the availability of equipment, supplies and kits in appropriate amounts and in proper conditions 3. Follows the guidelines issued by NACO/ NIHFW for HIV and syphilis testing 4. Carries out and complete the testing at shorter intervals to prevent back logs 5. Trains all the staff involved in HIV and syphilis testing 6. Participates in re-training of site lab technicians in case of deficiencies noted during surveillance period 7. Enters HIV/ Syphilis test reports on data forms and transfer to SACS 8. Participates in quality assurance by periodically sending samples to NRLs as per guidelines 9. Informs the clinic staff when to end blood and data collection 10. Forwards the completed forms to SACS/RI/NIFHW as directed
Lab Technician	<ol style="list-style-type: none"> 1. Follows the direction of testing center in-charge 2. Ensures quality of specimens received and checks the data forms received for completeness 3. Reports back to the survey site (through center in-charge) if poor quality of specimens received. 4. Stores the samples as per guidelines 5. Fills the data forms for test results



**Operational Guidelines
for HIV Sentinel
Surveillance**

**Clinic-Based Sentinel Groups
ANC and STD Sentinel Sites**

**Chapter
IV**





4

4.1 Strategy

India is a large and epidemiologically diverse country with regions that are primarily experiencing low level and concentrated epidemics. In order to meet the objectives of sentinel surveillance the focus is on critical population groups that are selected on the basis of epidemiological considerations and the current understanding of local HIV transmission dynamics.

From the programme point of view, sentinel sites should be selected to include the populations of greatest importance to local epidemic from both sexual and parenteral transmission perspective. For the purpose of HSS, clearly defined and consistently accessible groups will be selected as sentinel populations. People recruited from ANC and STD sites act as proxy for general population and people with high risk behavior respectively. These sites are easily accessible and operationally feasible. The unlinked anonymous testing strategy is feasible to implement since these clinics as part of preventive and curative services provide syphilis testing for which routinely blood specimen has to be collected. A part of serum obtained from this blood specimen is separated without any individual identifiers for the purpose of HIV testing. Sero-prevalence data from ANC/STD sites provide different perspectives as detailed below.

4.1.1 Use of the data from ANC sentinel sites

Prevalence in women who attend ANC is most often used as a proxy for general population prevalence under generalized epidemic conditions. In low level and concentrated epidemics ANC attendees represent women who do not typically engage in risk behaviour themselves. These women often are the terminal end of a chain of transmission that starts through commercial sex or unsafe injections; as such they are not useful as an early warning

system of a potential local HIV epidemic. It is likely that by the time ANC prevalence reaches 1%, the need for prevention programmes would have been long established due to the identification of established HIV infection in high risk groups. At the same time, consistent HIV prevalence of greater than 1% among ANC attendees does provide evidence that HIV has taken roots in a specific area and signals the need to prioritize the area for prevention as well as care, support, and treatment programmes. One transmission scenario for which ANC sentinel sites can be particularly important is to identify the areas where large numbers of high risk / high-prevalence male migrants may originate. In an area where HIV may otherwise be unexpected due to the absence of high risk group members, ANC sentinel sites may provide the first indication of returning migrants transmitting infection to their regular partners.

4.1.2 Use of the data from STD sentinel sites

Patients who attend STD clinics generally have symptoms of an STD or have been referred by a sexual partner who has recently been diagnosed with an STD. For this reason, STD clinic attendees can be considered as a proxy for the group of individuals who may engage in high risk sexual behaviour. It is presumed that this population is also at risk for HIV infection. In the absence of a site for a more specifically defined group engaging in high risk sexual behaviour like FSW, MSM, or clients of sex workers; STD sites may serve as a good source for picking up pockets of HIV infections in an area believed to be low prevalence and are most useful when no other source of high risk groups is available.

4.2 Salient points of Surveillance at ANC and STD sites

To ensure the highest quality of data and to minimize selection and participation bias, protocols for carrying out HSS are carefully defined. The salient points are:

1. Sentinel sites should be located at facilities which regularly have a sufficient number of individuals or patients receiving preventive or curative services to meet the required sample size during the surveillance period.
2. Specimens should be collected following an "unlinked anonymous testing strategy" i.e. when blood is already routinely drawn for other diagnostic purposes, such as testing for syphilis. This strategy ensures participants' anonymity and in turn prevents participation bias.
3. To prevent selection bias, all individuals attending the sentinel site facility who meet the defined selection criteria should be consecutively sampled during the surveillance period.
4. Blood specimen collection (drawing of blood), should be arranged close to the surveillance site or at the surveillance site itself to minimize loss of participants following the use of an off-site laboratory. This type of referral will cause inconvenience to the respondents especially if the laboratory is far away from the surveillance site, as high drop-out rate leads to participation bias.
5. To avoid double counting of individuals, that is, individuals being tested twice during the surveillance period, only those visiting the clinic for the first-time during the surveillance period should be recruited. Hence pregnant women coming for the first time during the period of surveillance for their ANC visit; or STD patients with a new STI should be recruited. If an individual visits the clinic twice for follow up or with new episodes during the period of surveillance, (s)he will be recruited during the first episode only.

If a pregnant woman has visited ANC clinic on 15th October and is visiting again on 15th November, that happens to be the second ANC visit for her current pregnancy, she is eligible to be recruited for surveillance since this is her first visit during the period of surveillance.

6. Each year is a new round of surveillance, so all individuals are eligible to participate as "first visitors" during the period of surveillance even if they were sampled in a previous round of HSS.
7. Any referral should not be excluded. If a referred case is recruited, the source of referral should be mentioned in the data form against the appropriate question.

4.3 Methodology

4.3.1. Sentinel Group of Pregnant Women: Surveillance at ANC sites

- **Site:**

Typical recruitment site for pregnant women is the ante-natal clinic in government or private sector.

- **Sampling:**

Consecutive first time visitors are to be included to attain a total sample size of 400. It is advised that the number of consecutive attendees recruited per day be determined by the patient flow numbers and the number of days the clinic functions. The study staff and site in charges should ensure that the surveillance activity is of high quality and does not interfere with the quality of patient care.

In general, it is recommended that not more than 20 consecutive attendees should be included per day to maintain quality of data collection. However, it is recognized that there will be exceptions to this recommendation. The overarching criteria are

consecutive sampling, attainment of desired sample size of 400, non-compromised patient care and high-quality surveillance.

At some ANC sites, where PPTCT is functional sample recruitment may pose operational difficulty. Care should be taken not to link routine testing/HSS activity to PPTCT. Refer Annex. 3 for flow chart that explains this situation.

- **Inclusion criteria:**

The collection of samples at ANC sites must be based strictly on the inclusion criteria and defined sampling procedure. Consistent implementation with clear definitions allows for more accurate monitoring of trends over years.

Pregnant women visiting ante-natal clinics during the surveillance period are included if they are between the ages of 15 to 49 years. Women who have been recruited once and are attending the clinic again during the current surveillance period should be excluded. Those women who have already registered with the ante-natal clinic but are reporting to the clinic after the initiation of HSS for the first time are eligible for inclusion. This is true even if they have been included in previous rounds of HSS.

Explaining the purpose for blood specimen collection at ANC surveillance sites:

All the pregnant women to be included in HSS following their eligibility assessment will be informed that their blood sample is being collected for syphilis serology. HSS data forms should be filled for such patients and they should be directed to blood collection. [As per the protocol of unlinked anonymous testing, blood drawn for testing for syphilis serology can be tested for HIV with identifiers removed.] As such, test results for syphilis and treatment, if necessary, must be provided to the participant in all cases. Returning syphilis results and treatment to the pregnant women and their partners should be incorporated into routine ANC clinical practices.

4.3.2 Sentinel Group of STD patients: Surveillance at STD sites

- **Site:**

The STD sentinel sites consists of two clinic sources - STD clinic and GYN clinic, in the same hospital or in two different hospitals designated by SACS for HSS in the same city/ town.

- **Sampling:**

A total of 150 samples from attendees of STD clinics and 100 samples from attendees of GYN clinics should be recruited by taking consecutive new cases reporting with STD's. Samples from the STD and GYN clinics should be reported and analyzed separately, but should be interpreted in context of each other for a more cohesive assessment of the local epidemic. Please see flow chart in annex 4.

- **Inclusion criteria:**

Only consecutive new cases of STDs with genital ulcers, urethral discharge, cervical discharge and ano-genital warts should be included.

GYN clinic attendees

To determine eligibility of women, visualization of the cervix is necessary to determine the presence of cervical discharge. Women with complaints of vaginal discharge who have not had cervical discharge confirmed by physical examination are not eligible. Women presenting with genital ulcers/ ano-genital warts to the GYN clinic are included in the survey. Only persons between the ages of 15 and 49 years are eligible.

STD clinic attendees

"New cases" are those that are reporting with new STI episode during the HSS period. Cases that have been prescribed treatment for their STI and called for follow up

and who report for the first time during HSS can also be included. Individuals with recurrent or new STDs who have visited the STD or GYN clinic in the previous years who may or may not have been included in the previous rounds are eligible for recruitment in the present round if they present with a new STD episode. Referrals from private providers to the survey sites need not be excluded from HSS.

Explaining the purpose for blood specimen collection at STD sentinel sites:
All the STI patients to be included in HSS following their eligibility assessment should be informed that their blood sample is being collected for syphilis serology. HSS data forms should be filled for such patients and they should be directed to blood collection. [As per the protocol of anonymous unlinked testing, blood drawn for testing for syphilis serology can be tested for HIV with identifiers removed.] As such, test results for syphilis and treatment, if necessary, must be provided to the participants in all cases. Syphilis screening test results for STD patients will be returned through the usual clinic channels and patient follow-up mechanism.

4.3.3 Composite site

The required sample size for each ANC and STD groups included in HSS are shown in Table 7. In some geographic areas, where members of the target population are spread among multiple facilities such that placing a sentinel site at any single location is likely to result in failure to achieve the recommended sample size of 400 (ANC) and 250 (STD), additional sites termed “subsites” to recruit individuals from the same sentinel category (ANC/ STD) may be included. Such subsites together constitute one composite site. In such cases up to 3 sub sites may be added that are capable of contributing at least 50 samples each. Sub sites once chosen must be included in all the subsequent rounds of HSS and the contribution of sample size from each sub-site should remain constant over time. Sub-sites may be established in the private clinics or hospitals if the assessment teams feel reasonably confident that they will be able to collect adequate number of samples and continue to participate in HSS programme over subsequent years. In the event that a sentinel surveillance site does not meet the required sample size through sequential sampling of people coming to facility, data from this site is still valuable and can be analyzed. Interpretation of the data will be contingent

on the exact sample size and prevalence estimated.

Sites should NOT artificially increase the number of people recruited for surveillance by special campaigns or drives to increase attendance or hold camps. Data from sentinel sites are much more useful and reliable when recommended strategy of clinic based sequential sampling is strictly adhered to.

Table 7: Risk Groups included in HSS (Clinic/Facility based)

Sentinel group	Number of Samples per group
Pregnant women	400
Patients with STD (males and females)	250

4.4 Data Collection

The HIV sentinel surveillance protocol dictates that the specimen for HIV testing is unlinked to any identifiers of the individual concerned. All personnel involved in data collection should ensure that the protocol is adhered to. A minimal amount of socio-demographic information is collected on individuals tested in the surveillance activity. This data is collected for each individual and accompanies each serum sample. The data forms for the different clinic based sentinel groups are provided in Annex. 5 - A (ANC sentinel group), B (STD sentinel group).

Note, the individual request form should accompany the serum sample to the testing centre. Only a unique code number will link the information on the data forms to the laboratory result. A summary list of duties at sentinel site clinic is given in Table 4. Sufficient quantity of these reporting forms must be made available for use during the surveillance period to all the sites. Adequate training will be given to all designated staff by RI, State Level Trainers and SACS in filling up the data forms appropriately.

4.5 Collection of blood samples from clinic/ facility based sentinel sites (ANC and STD)

Blood should be collected following the standard operating procedure (SOP), so that the separated sera samples are made into aliquots in adequate volume for the serology tests (HIV and syphilis including EQAS of HIV) and are not allowed to be haemolysed (damage to the clot that tinges the serum red) or contaminated.

Method

1. Appropriate universal precautions must be observed at all times while handling biological samples.
2. Select patients/ subjects to be included in the HSS round as per the recruitment and selection procedures outlined in this document. Each of them should be accompanied with the anonymous HSS data collection form specific for the particular sentinel site.
3. The technician should check that all required sections of the data form are complete before collecting blood.
4. Collect 5 ml blood with sterile syringe/ needle/ vacutainer (whichever is available), in sterile tubes following appropriate bio-safety precautions
5. Allow the blood to coagulate at room temperature on the laboratory bench top.
6. The sera should be separated on the same day following good laboratory practices.
7. **IMPORTANT:** Use specified vials to store blood specimens. Centrifuge and collect clear supernatant and transfer at least 0.5 ml serum into two 2 ml plastic sterile storage vials. Vials with screw cap fitted with '**O**' rings should be used. It is very important that sterile vials as specified must be used for this purpose; otherwise, there are documented evidences of serum samples getting contaminated/ infected/ showing growth of fungus.

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8. **IMPORTANT:** Use separate Sterile Pasteur pipettes or micropipettes with disposable plastic tips for each sample. Separate tips must be used for each sample to avoid cross contamination.
 9. Label the first vial with patient identity. This sample carrying all personal identifications is to be sent for routine syphilis serologic testing, e.g. VDRL or RPR, the results of which will be communicated to the person tested.
 10. Label the second vial with sample and site code numbers, age, sex & date and store at +4°C for a maximum of seven days. If you know that the storage will be longer than seven days the specimen should be stored at -20°C.
 11. Send the coded sera along with the data forms, to laboratory daily if laboratory is nearby or once a week if laboratory is far away.

4.5.1 Storage and transport of serum specimens

1. The screw capped storage tube for syphilis serology / HIV testing must contain a minimum of 0.5 ml. of serum.
 2. The serum vial should be properly labeled and stored in the refrigerator at +4°C for maximum seven days and sent to the HIV testing laboratory in batches in vaccine carrier or ice box with sufficient pre-cooled icepacks to maintain cold chain following bio-safety precautions (ref to section 7 for detailed bio-safety guidelines). The samples should be sent with an accompanying sample transport sheet (Annex. 6) and the corresponding data forms to the designated testing center.
 3. In case storage is required for more than a week, the sample should be stored in the freezer section of the refrigerator at -20°C. Samples should not be frozen and thawed repeatedly. In order to prevent spillage during transportation the vials
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with O rings to be used; should be capped appropriately and sealed with parafilm. (Please see flow chart in Annex. 4.)

4.5.2 Syphilis serology testing

- Sera for routine syphilis testing (ANC/ STD sites) should be routed to the usual on-site laboratory for syphilis testing with the appropriate requisition laboratory slip. The sample used for this test is the uncoded serum vial that displays patient identifiers.
- Results of the syphilis test should be returned to the participating clinic. The clinic is responsible for getting the results back to the participants and providing treatment if required.
- NOTE: Where the sentinel site testing and the HSS testing centre are in the same facility, the Testing Centre in-Charge should take all precautions to ensure that there is no linking of samples. Syphilis testing on HSS sample should be done separately on the coded sample once again as per protocol and no linking of RPR/VDRL data between coded and uncoded samples should be attempted.

4.5.3 Quality Control of Data forms

The site in-charge is responsible for the completeness of data forms filled during the HSS round. All the data forms should be checked and signed by the site in-charge as well as the person completing the form. Please see detailed list of roles and responsibilities (Table 4)

4.5.4. Bio Safety Precautions and Waste Disposal

Universal Safety Precautions refer to the precautions consistently used on the presumption that all blood and body fluids are potentially infectious for blood borne pathogens. Safety precautions are essential and should be followed at all points in the testing process from specimen collection, transport, testing, storage and disposal of

biohazard wastes so as to minimize occupational risk of HIV transmission. Proper disposal of all the biomedical / laboratory waste is essential.

Refer to Section 7 for detailed description of bio-safety procedures to be followed at sentinel sites and testing centers.

4.5.5. Post Exposure Prophylaxis (PEP)

PEP refers to the comprehensive management given to minimize the risk of infection following potential exposure to blood-borne pathogens (HIV, HBV, HCV). This includes counseling, risk assessment, relevant laboratory investigations based on informed consent of the source and exposed person, first aid and depending on the risk assessment, the provision of short term (4 weeks) of antiretroviral drugs, with follow up and support.

"Health Care Personnel (HCP)" is defined as any person, paid or unpaid; working in healthcare settings who are potentially exposed to infectious materials (e.g. blood, tissue, and specific body fluids and medical supplies, equipment, or environmental surfaces contaminated with these substances). HCP include: emergency care providers, laboratory personnel, autopsy personnel, hospital employees, medical and nursing students and health care professionals of all levels. If required, PEP can also be given to public safety workers, including law enforcement personnel, prison staff, fire-fighters, workers in needle exchange programs and workers in international HIV programs.

"Exposure" which may place an HCP at risk of blood-borne infection is defined as a percutaneous injury (e.g. needle-stick or cut with a sharp instrument), contact with the mucous membranes of the eye or mouth, contact with non-intact skin (particularly when the exposed skin is chapped, abraded, or afflicted with dermatitis), or contact with intact skin when the duration of contact is prolonged (e.g. several minutes or more) with blood or other potentially infectious body fluids.

Ref: Guidelines for Post Exposure Prophylaxis nested within the document: "Antiretroviral Therapy Guidelines for HIV infected Adults and Adolescents including Post-exposure" section B.

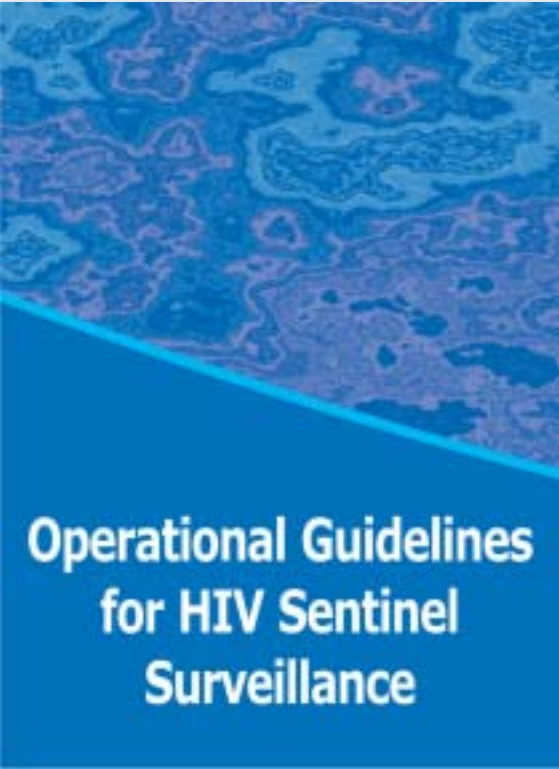
The document is downloadable at

http://www.nacoonline.org/Quick_Links/Publication/Treatment_Care__Support/

All site in charges should familiarise themselves with the above mentioned document of the National AIDS Control Organization. Please contact your SACS for hard copies of the same.

Some relevant sections of this document have been included in Annex : 7-A and Annex 7-B.

Adherence to good practices (Dos and Don'ts) given in Annex-8 will ensure high quality of HSS.



**Operational Guidelines
for HIV Sentinel
Surveillance**

**Targeted Intervention-Based
Sentinel Groups (High Risk)**

Chapter
V





5

5.1 Strategy

In order to meet its objectives, the surveillance system focuses on including selected critical populations and geographical areas selected on the basis of epidemiological considerations and the current understanding of HIV transmission dynamics. India is a large diverse country with regions that are primarily experiencing low level and concentrated epidemics. In these types of epidemics infections are most likely to emerge among high-risk groups, such as female sex workers (FSW), men having sex with men (MSM) and injecting drug users (IDU), who constitute the core risk groups, and are the most effective populations to target for surveillance and prevention activities. Following transmission among core groups, the infection spreads in the bridge population, i.e. persons who acquire infection from individuals in the core risk groups such as clients of sex workers, and in turn, transmit the infection to individuals without high-risk behaviors such as their wives and girlfriends in the general community. Hence in any given geographic area, HIV will appear first among people who are exposed to the virus at a higher rate or an earlier time, i.e. the higher risk groups, such as core and bridge populations (concentrated epidemics) and subsequently HIV infection will appear in low risk individuals or general population (generalized epidemics).

For the purpose of HSS, easily and clearly defined and consistently accessible groups will be selected as sentinel populations. Such groups are recruited from clinics at drop-in centers for MSMs and FSWs and drug de-addiction/ harm reduction centers for IDU. Seroprevalence data from different types of high risk groups provide different types of insights into the epidemic. In some cases, multiple sentinel sites of different populations in the same district provide better understanding of the transmission dynamics in the area. From the programme point of view, sentinel sites should be selected to include the

populations of greatest importance to local epidemic from the perspective of both sexual and parenteral transmission.

To ensure the highest quality of data and to minimize various forms of selection or participation bias, protocols for carrying out HSS are carefully defined. In brief, the chosen sentinel sites have to sample the registered members in the sentinel groups they are serving to achieve the desired sample size ensuring prevention of selection bias. Specimens should be collected following Unlinked Anonymous Testing with informed consent (UAT with consent), where informed consent from participants is taken but no identifier is recorded and HIV test results are not returned. This strategy maintains the ethical integrity of the surveillance while preserving participants' anonymity.

All individuals registered at the sentinel site facility who meet the defined selection criteria should be consecutively sampled during the surveillance period to further minimize selection bias. Each year is a new round of surveillance, so all individuals are eligible to participate even if they were sampled in a previous round of HSS.

5.2 Sample size and Composite sites

The different types of risk groups included in HSS and the required sample size for each group are shown in Table 8. The sample size required for high risk groups is lower than that specified for ANC populations due to the generally higher prevalence found among high risk groups and in recognition that the size of the high risk group population may be relatively small in some geographic areas.

Targeted intervention sites are defined as sites run by Non Governmental Organizations (NGOs) that serve to high risk populations like MSM, FSW, IDU, Trans-genders, LDTs and migrants. Traditionally such sites have been participating in HSS by recruiting clients from their clinics, drop-in centers and through specially arranged camps. A sample size of 250 is recommended for such sites. While this recommendation will be considered valid for all such NGOs that have

memberships above 250, there has been a change in the strategy in recruitment of high risk populations at small TI sentinel sites from HSS 2008. It is recommended that the NGOs that have fewer than 250 clients registered with them (small TI sentinel sites) should include all the beneficiaries registered under them in HSS programme who are eligible for surveillance i.e, "take all" approach. In some geographic areas, where members of the target population are spread among multiple facilities such that placing a sentinel site at any single location will result in a low likelihood of achieving the recommended sample size of 250, additional centers to recruit individuals from the same sentinel category (high risk group) may be included (termed "composite/ sub sites"). In such cases up to 3 composite or sub sites may be added that are capable of contributing at least 50 samples each. Sub sites once chosen must be included in all subsequent rounds of HSS. In the event that a TI sentinel surveillance site does not meet the required sample size, data from this site is still valuable and can be analyzed. Interpretation of the data will be contingent on the exact sample size and prevalence estimated. Data from sentinel sites are much more useful and reliable when the recommended strategy of sequential sampling or "take all" approach is strictly adhered to and refusal rates are clearly noted.

At sites that have memberships above 250, it is recommended that they work with their RI/SACS to develop a sampling strategy. The HRG (TI based) sites should attempt to enroll participants keeping in mind:

- All eligible participants visiting a service point must be approached consecutively for informed consent and subsequent participation in HSS. Where multiple service points exist, proportionate sampling should be used to ensure appropriate representation to beneficiaries. It is essential to have mapping, size estimations and line listing data.
- Recruitment for HSS must be spread out over the three month period of surveillance and not more than 10-20 individuals must be approached for informed consent in a day/ at a service point

- An individual should be enrolled in HSS only once in a single surveillance period. Those who have participated in previous round of HSS can participate if still eligible. Sites must devise their own strategies in order to ensure this.
- Avoiding purposive sampling: by purposively enrolling or excluding people with known HIV status

Table 8: Risk Groups included in HSS (TI based)

Sentinel groups	Number of Samples per group
Female Sex Workers	250 or "Take all" approach
Men who have Sex with Men	250 or "Take all" approach
Injecting Drug Users	250 or "Take all" approach
Eunuchs / Transgenders	250 or "Take all" approach
Single Male Migrants	250 or "Take all" approach
Long Distance Truckers	250 or "Take all" approach

* "Take all" approach: This strategy is applicable only to small TI sites (registered beneficiaries less than 250) where all the beneficiaries registered under the NGOs should be included in HSS programme. Composite/ satellite site should be added to achieve the desired sample size.

The most valuable type of sentinel site would be a targeted intervention site that serves FSW, IDU, MSM, or trans-gender populations. In low HIV prevalence areas where there are no functional TI sites, it is recommended that the Regional Institutes may submit proposal for operations research during the inter-surveillance period to generate/ update evidence or identify areas with substantial concentrations of high risk populations in the states assigned to them on high risk behavior groups. Regional Institutes may do this activity with the help of respective SACS. This type of data will serve the primary purpose of identifying areas where new TI sites may be added in HSS 2009 in keeping with the objective of NACP-III to strengthen and expand surveillance programme in high risk populations.

5.3 Methodology

5.3.1 Surveillance Site

The protocol for sample collection from the surveillance site is to collect consecutive blood samples from target group members visiting the NGO clinical centre or drop-in centre from the start of the surveillance activity till the predetermined sample size is reached or the surveillance period is over. In case of small TI sentinel sites collection of samples from all the registered beneficiaries at the NGOs during the surveillance period is advised. They may collect samples at their drop-in centers, detoxification centers, clinics or other specially set up facilities.

The inclusion criteria for sampling are defined for each sentinel group and are described in the following section. The collection of samples in these sites must be based strictly on the inclusion criteria and defined sampling procedure. Consistent implementation with clear definitions allows for more accurate monitoring of trends over years. The data forms for various high risk sentinel groups are provided in Annex. 9: A- (FSW), B- (MSM), C- (IDU), D- (Eunuch/TG), E- (Single Male Migrants) and F-(Long Distance Truckers).

5.3.2 FSW Sentinel Group

- Use of the data from FSW sites: This data has some limitations because FSW who access services at a drop in center or clinic run by an NGO are by definition, the segment of the population who are reached by the intervention; are more likely to be in contact with outreach staff and exposure to behavior change communication and/ or who use free condom distribution and STI services, and also more likely to represent direct SWs or those who are more comfortable identifying as sex workers. Part-time or home based SW may be less likely to be represented in these types of sentinel sites.

However, HIV prevalence data from this high risk population, especially in low HIV prevalence settings can give an early indication of HIV transmission in the area and potential for becoming generalized epidemic.

- **Site:**

- 1) Typical recruitment sites for the FSW sentinel group are Drop-in centers, clinics or other specially set up facilities run by NGOs.
- 2) All FSWs who come to the drop in center, TI clinic or other specially set up facilities during the surveillance period should be invited to participate in the surveillance round. In case of small TI sites, all registered FSW should be contacted and encouraged to participate in HSS 2008. Any type of health camp approach for recruitment leads to selection bias and should not be used
- 4) FSWs even with their previously known HIV status (positive / negative) should be included in the survey if they are registered with the NGOs. However no special efforts should be made to selectively include known positive or negative FSW.
- 5) Care should be taken to ensure that these FSW fulfill all the inclusion/eligibility criteria for participation in the survey:
 - Sold sex for money /engaged in consensual sex for money or payment in kind as a principal means of livelihood in the last 6 months
 - Between 18-49 years of age
 - Have not been included previously in current round of HSS (2008)
- 6) Participants should be asked for consent to participate. HIV testing should be voluntary and anonymous.
- 7) Individuals should only participate once in the current surveillance round; however people who have participated in surveillance in previous years should not be excluded from participating in the current year.

- 8) The objective is to ensure that a sample, which is representative of the general FSW community, is obtained and the sample size is as close to 250 as possible.
- 9) In compliance with international guidelines and HSS operational guidelines, informed consent (Annex. 10) will be obtained for HIV testing. Regional Institutes will train NGO staff with the help of SACS in HSS 2008 to ensure compliance with this requirement.

Sampling: Consecutive sampling till a total sample size of 250 is reached.

- **Inclusion criteria:** First time visitors during the surveillance period are included if they are active female sex workers defined as women aged 18 to 49 years engaged in consensual sex for money or payment in kind, as a means of livelihood in the previous 6 months.

“New first time visitors are those FSW that visit the sentinel site for the first time during the surveillance period. Individuals that have an ongoing relationship with the NGO, have visited previously are eligible for inclusion in this surveillance round if they are active FSWs. This is true even if they have been included in previous rounds of HSS and are known HIV positive. The rationale for "new first time visitors" during the time period is to avoid double counting of individuals during any single surveillance round.

- **Informed Consent for HIV Testing:** Following their eligibility assessment of a FSW to be included in HSS will be informed that their blood sample is being collected for HIV serology following informed consent. It should be informed to the participants that they will not be provided their individual HIV test reports since HIV testing is voluntary and anonymous. HSS data forms should be filled for such patients and they should be directed to blood collection.

5.3.3 MSM Sentinel Group

- **Use of the data from these sites:** This data has some limitations because the MSM who access services at a drop in center or clinic run by an NGO are by definition, the segment of the population who are reached by the intervention. They are more likely to be in contact with outreach staff and exposure to behavior change communication and/or who use free condom distribution and STI services, and also more likely to be kothis/ receptive partners or male sex workers. However, HIV prevalence data from this high risk population, especially in low HIV prevalence settings can give an early indication of HIV transmission in the area and potential for becoming generalized epidemic.

The term "men who have sex with men" (MSM) is used to denote all men who have sex with other men as a matter of preference or practice, regardless of their sexual identity or sexual orientation and irrespective of whether they also have sex with women or not. Coined by public health experts for the purpose of HIV/STI prevention, this epidemiological term focuses exclusively on sexual practice. This term does not refer to those men who might have had sex with other men as part of sexual experimentations or very occasionally depending on special circumstances. It should be noted that all who engage in male-to-male sex do not necessarily identify themselves as homosexuals or even men

- **Site:**
 - 1) Typical recruitment sites for the MSM sentinel group are Drop-in centers, clinics or other specially set up facilities run by NGOs.
 - 2) All MSM who come to the drop in center, TI clinic or other specially set up facilities during the surveillance period should be invited to participate in the surveillance round. In case of small TI sites, all registered MSM should be contacted and encouraged to participate in HSS 2008. Any type of health camp approach for recruitment leads to selection bias and should not be used
 - 3) MSMs even with their previously known HIV status (positive/negative) should be included in the survey if they are registered with the NGOs. However no special efforts should be made to selectively include known positive or negative MSM.

- 4) Care should be taken to ensure that these MSM fulfill all the inclusion/eligibility criteria for participation in the survey:
 - Men who have engaged in sex - anal or oral - with another male at least once in the previous month
 - Between 18-49 years of age
 - Have not been included previously in current round of HSS (2008)
- 5) Participants should be asked for consent to participate. HIV testing should be voluntary and anonymous.
- 6) Individuals should only participate once in the current surveillance round; however people who have participated in surveillance in previous years should not be excluded from participating in the current year.
- 7) The objective is to ensure that a sample, which is representative of the general MSM community, is obtained and the sample size is as close to 250 as possible.
- 8) In compliance with international guidelines and HSS operational guidelines, informed consent (Annex. 10) will be obtained for HIV testing. Regional Institutes will train NGO staff with the help of SACS in HSS 2008 to ensure compliance with this requirement.
 - **Sampling:** Consecutive sampling till a total sample size of 250 is reached.
 - **Inclusion criteria:** First time visitors during the surveillance period are included if they are active men aged 18 to 49 years, who have sex with men, who have engaged in sex - anal or oral - with another male at least once in the previous month.

"New first time visitors" are those MSM that visit the sentinel site for the first time during the surveillance period. Individuals that have an ongoing relationship with the NGO and have visited previously are eligible for inclusion in this

surveillance round if they are active MSM. This is true even if they have been included in previous rounds of HSS and are known HIV positive. The rationale for "new first time visitors" during the time period is to avoid double counting of individuals during any single surveillance round.

- **Informed Consent for HIV Testing:** All the MSM to be included in HSS following their eligibility assessment will be informed that their blood sample is being collected for HIV serology following informed consent. It should be informed to the participants that they will not be provided their individual HIV test reports since HIV testing is voluntary and anonymous. HSS data forms should be filled for such patients and they should be directed to blood collection.

5.3.4 Eunuch / Trans-genders Sentinel Group

- **Use of the data from Transgender sites:** This data has some limitations because Eunuch[@] / Trans-genders who access services at a drop in center or clinic run by an NGO are by definition, the segment of the population who are reached by the intervention; are more likely to be in contact with outreach staff and exposure to behavior change communication and/or who use free condom distribution and STI services. However, HIV prevalence data from this high risk population, especially in low HIV prevalence settings can give an early indication of HIV transmission in the area and potential for becoming generalized epidemic.

[@] Eunuchs belong to a distinct socio-religious and cultural group, a "third gender" (apart from male and female). They dress in feminine attire (cross-dress) and are organised under seven main gharanas (clans). Among the eunuchs there are emasculated (castrated, nirvan) men, non-emasculated men (not castrated, akva/akka) and inter-sexed persons (hermaphrodites). While one sub-set of eunuchs is involved in blessing and gracing during births, marriages and ceremonies, another is involved in begging, and a third group is involved in sex work. For the purposes of TI, eunuchs are covered under the term "transgenders" or TGs

Site:

1. Typical recruitment sites for the Eunuch / Trans-genders sentinel group are Drop-in centers, clinics or other specially set up facilities run by NGOs.

2. All Eunuch / Trans-genders who come to the drop in center, TI clinic or other specially set up facilities during the surveillance period should be invited to participate in the surveillance round. In case of small TI sites, all registered Eunuch / Trans-genders should be contacted and encouraged to participate in HSS 2008. Any type of health camp approach for recruitment leads to selection bias and should not be used.
3. Eunuch / Trans-genders even with their previously known HIV status (positive / negative) should be included in the survey if they are registered with the NGOs. However no special efforts should be made to selectively include known positive or negative Eunuch / Trans-genders.
4. Care should be taken to ensure that these Eunuchs/transgenders fulfill all the inclusion criteria for participation in the survey:
 - Participants who self-identify themselves as 'Eunuchs/ Transgenders'
 - Between 18-49 years of age
 - Have not been included previously in current round of HSS(2008)
5. Participants should be asked for consent to participate. HIV testing should be voluntary and anonymous.
6. Individuals should only participate once in the current surveillance round; however people who have participated in surveillance in previous years should not be excluded from participating in the current year.
7. The objective is to ensure that a sample, which is representative of the general Eunuch / Transgenders community, is obtained and the sample size is as close to 250 as possible.
8. In compliance with international guidelines and HSS operational guidelines, informed consent (Annex. 10) will be obtained for HIV testing.

9. Regional Institutes will train NGO staff with the help of SACS in HSS 2008 to ensure compliance with this requirement.

- **Sampling:** Consecutive sampling till a total sample size of 250 is reached.
- **Inclusion criteria:** First time visitors during the surveillance period are included if they are aged 18 to 49 years and self-identify as eunuchs/ transgenders.

"New first time visitors" are those eunuchs/ transgenders that visit the sentinel site for the first time during the surveillance period. Individuals that have an ongoing relationship with the NGO and have visited previously are eligible for inclusion in this surveillance round if they are eunuchs/ transgenders. This is true even if they have been included in previous rounds of HSS and are known HIV positive. The rationale for "new first time visitors" during the time period is to avoid double counting of individuals during any single surveillance round.

- **Informed Consent for HIV Testing:** All the Eunuch / Trans-genders to be included in HSS following their eligibility assessment will be informed that their blood sample is being collected for HIV serology following informed consent. It should be informed to the participants that they will not be provided their individual HIV test reports since HIV testing is voluntary and anonymous. HSS data forms should be filled for such patients and they should be directed to blood collection.

5.3.5 IDU Sentinel Group

Use of data from IDU sites: This data has some limitations because IDU who access services at a drop in center or clinic run by an NGO are by definition, the segment of the population who are reached by the intervention; are more likely to be in contact with outreach staff and exposure to behavior change communication and/or who use free condom distribution and STI services. However, HIV prevalence data from this high

risk population, especially in low HIV prevalence settings can give an early indication of HIV transmission in the area and potential for becoming generalized epidemic.

- **Site:**

- 1) Typical recruitment sites for the IDU sentinel group are TI sites which usually have drop-in centers, detoxification centers, other specially set up facilities or clinics for IDU run by the NGOs. When such NGO sites are not in place it may be possible to use outpatient drug treatment centers as another sentinel surveillance site.
- 2) All IDUs who come to the drop in center, TI clinic or other specially set up facilities during the surveillance period should be invited to participate in the surveillance round. In case of small TI sites, all registered IDU should be contacted and encouraged to participate in HSS 2008. Any type of health camp approach for recruitment leads to selection bias and should not be used
- 3) IDUs even with their previously known HIV status (positive / negative) should be included in the survey if they are registered with the NGOs. However no special efforts should be made to selectively include known positive or negative IDU.
- 4) Care should be taken to ensure that these IDU fulfill all the inclusion criteria for participation in the survey:
 - Participants who are either current or shadow drug users who have injected at least once in the previous six months
 - Between 18-49 years of age
 - Have not been included previously in current round of HSS (2008)
- 5) Participants should be asked for consent to participate. HIV testing should be voluntary and anonymous.
- 6) Individuals should only participate once in the current surveillance round; however people who have participated in

surveillance in previous years should not be excluded from participating in the current year.

- 7) The objective is to ensure that a sample, which is representative of the general IDU community, is obtained and the sample size is as close to 250 as possible.
 - 8) In compliance with international guidelines and HSS operational guidelines, informed consent (Annex. 10) will be obtained for HIV testing.
 - 9) Regional Institutes will train NGO staff with the help of SACS in HSS 2008 to ensure compliance with this requirement.
- **Sampling:** Consecutive sampling till a total sample size of 250 is reached.
 - **Inclusion criteria:** First time visitors (*IDUs; current injectors and shadow users) during the surveillance period are included if they are active injectors defined as having injected at least once in the previous six months. Only persons between the ages of 18 and 49 years are eligible.

"New first time visitors" are those IDU that visit the sentinel site for the first time during the surveillance period. Individuals that have an ongoing relationship with the NGO or the de-addiction centers and have visited previously are eligible for inclusion, if they are active injectors. This is true even if they have been included in previous rounds of HSS and are known HIV positive. The rationale for "new first time visitors" during the time period is to avoid double counting of individuals by recruiting them twice during any surveillance round.

* IDUs are not injectors at all times in their injecting life-span. They may inject, then fall back into non-injecting (e.g. oral) drug use, or abstinence, and then return to injecting. Thus IDUs are classified in two categories for the purpose of programming:

*Current injectors: IDUs are those who used any drugs through injecting routes in the last three months.

*Shadow users: When injecting drugs, e.g. opioids (tidigesic), are not available, some IDUs switch over to oral or inhalation drugs or vice-versa. Conversely, when oral or inhalation drugs are not available, some users shift temporarily to injectables. Drug users who have done so in the last six months are called shadow users.

5.3.6 Long Distance Truckers (LDT) Sentinel Group

- **Use of data from LDT sites:** This data has some limitations because LDT who access services at a drop in center or clinic run by an NGO are by definition, the segment of the population who are reached by the intervention; are more likely to be in contact with outreach staff and exposure to behavior change communication and/or who use free condom distribution and STI services. However, HIV prevalence data from this high risk population, especially in low HIV prevalence settings can give an early indication of HIV transmission in the area and potential for becoming generalized epidemic.
- **Site:**
 1. Typical recruitment sites for the LDT sentinel group are truck halts/stops, truck loading/unloading depots, Trans-shipment Locations (TSL) where TI sites (run by the NGOs) have interventions like drop-in centers for LDT.
 2. All LDTs presenting at truck stops/ truck loading-unloading points/Trans-shipment Locations which are intervention sites for the TI site/NGO during the surveillance period should be invited to participate in the surveillance round consecutively. Any type of health camp approach for recruitment leads to selection bias and should not be used
 3. Even LDTs with previously known HIV status (positive / negative) should be included in the survey if they are registered with the NGOs. However no special efforts should be made to selectively include known positive or negative LDT.
 4. Care should be taken to ensure that these fulfill all the inclusion for participation in the survey:

-
- Truckers who travel more than 800 km one way between source and destination
 - Between 18-49 years of age
 - Have not been included previously in current round of HSS (2008)
5. Participants should be asked for consent to participate. HIV testing should be voluntary and anonymous.
 6. Individuals should only participate once in the current surveillance round; however people who have participated in surveillance in previous years should not be excluded from participating in the current year.
 7. The objective is to ensure that a sample, which is representative of the general LDT community, is obtained and the sample size is as close to 250 as possible.
 8. In compliance with international guidelines and HSS operational guidelines, informed consent will be obtained for HIV testing.
 9. Regional Institutes will train NGO staff with the help of SACS in HSS 2008 to ensure compliance with this requirement.

Sampling: Consecutive sampling till a total sample size of 250 is reached.

- **Inclusion criteria:** Long Distance Truckers who are first time visitors/attendees at the designated places during the surveillance period are included if they are LDT's defined as Truckers who travel more than 800 km one way between source and destination, and between the ages of 18 and 49 years. "New first time visitors" are those LDT who visit the sentinel site for the first time during the surveillance period. Individuals who have an ongoing relationship with the NGO or the service centers and have visited previously are eligible for inclusion, if they are LDT. This is true even if they have been included in previous rounds of HSS and are known HIV positive. The rationale for "new first time visitors" during the

time period is to avoid double counting of individuals by recruiting them twice during any surveillance round.

Informed Consent for HIV Testing:

All the LDT to be included in HSS following their eligibility assessment will be approached for Informed consent and explained that their blood sample is being collected for HIV serology following informed consent.

It should be informed to the participants that they will not be provided their individual HIV test reports since HIV testing is voluntary and anonymous.

HSS data forms should be completed for such patients and they should be directed to blood collection.

5.3.7 Male Migrants Sentinel Group

- **Use of the data from Migrant sites:** Male migrants* may be more vulnerable to HIV. This includes men in the transport industry, agriculture, quarry, or other factory work. These men may be more prone to have sex with FSW or MSM due to the separation from their regular partners. For this reason, populations of migrant males who have these characteristics serve as a proxy for the bridge population of male clients of sex workers. This data has some limitations because Male Migrants who access services at a drop in center or STD clinic run by an NGO are by definition, the segment of the population who are reached by the intervention; are more likely to be in contact with outreach staff and exposure to behavior change communication and/or who use free condom distribution and STI services. However, HIV prevalence data from this high risk population, especially in low HIV prevalence settings can give an early indication of HIV transmission in the area and potential for becoming generalized epidemic.

* Men who are living at a place other than "place of usual residence" without spouse or family members for more than 6 months for purposes of work

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- **Site:**
 - 1) Typical recruitment sites for the Male Migrants sentinel group are Drop-in centers, clinics or other specially set up facilities run by NGOs.
 - 2) All Male Migrants who come to the drop in center, TI clinic or other specially set up facilities during the surveillance period should be invited to participate in the surveillance round. In case of small TI sites, all registered Male Migrants should be contacted and encouraged to participate in HSS 2008. Any type of health camp approach for recruitment leads to selection bias and should not be used
 - 3) Male Migrants even with their previously known HIV status (positive / negative) should be included in the survey if they are registered with the NGOs. However no special efforts should be made to selectively include known positive or negative Male Migrants.
 - 4) Care should be taken to ensure that these 'Male Migrants' fulfill all the inclusion/eligibility criteria for participation in the survey:
 - Men who are living at a place other than "place of usual residence" without spouse or family members for more than 6 months for purposes of work
 - Between 18-49 years of age
 - Have not been included previously in current round of HSS (2008)
 - 5) Participants should be asked for consent to participate. HIV testing should be voluntary and anonymous.
 - 6) Individuals should only participate once in the current surveillance round; however people who have participated in surveillance in previous years should not be excluded from participating in the current year.
-

- 7) The objective is to ensure that a sample, which is representative of the general Male Migrants community, is obtained and the sample size is as close to 250 as possible.
 - 8) In compliance with international guidelines and HSS operational guidelines, informed consent (Annex. 10) will be obtained for HIV testing. Regional Institutes will train NGO staff with the help of SACS in HSS 2008 to ensure compliance with this requirement.
- **Sampling:** Consecutive sampling till a total sample size of 250 is reached.
 - **Inclusion criteria:** First time visitors during the surveillance period are included if they are aged 18 to 49 years and self-identify as migrants.

"New first time visitors" are those migrants that visit the sentinel site for the first time during the surveillance period. Individuals that have an ongoing relationship with the NGO have visited previously are eligible for inclusion in this surveillance round if they are migrants. This is true even if they have been included in previous rounds of HSS and are known HIV positive. The rationale for "new first time visitors" during the time period is to avoid double counting of individuals during any single surveillance round.

- **Informed Consent for HIV Testing:** All Male Migrants to be included in HSS following their eligibility assessment will be informed that their blood sample is being collected for HIV serology following informed consent. It should be informed to the participants that they will not be provided their individual HIV test reports since HIV testing is voluntary and anonymous. HSS data forms should be filled for such patients and they should be directed to blood collection.

5.4 Data Collection

The HIV sentinel surveillance protocol dictates that the specimen for HIV testing is unlinked to any identifiers of the individual concerned. All personnel involved in the data collection should ensure that the protocol is adhered to. A minimal amount of socio-demographic information is collected on individuals tested in the surveillance activity. This data is collected for each individual and accompanies each dried blood spot (DBS) sample. The data forms for the various high risk sentinel groups are provided in Annex. 9A to 9F.

- Note, data form completed for every participant should accompany the DBS sample to the testing centre. Only a unique code number will link the information on the data forms to the laboratory result. Sufficient quantity of reporting forms must be made available for use during the surveillance period to all the sites. Adequate training will be given to all the designated staff by Regional Institutions, State Level Trainers and SACS in filling up of data forms appropriately.

5.4.1 Quality Control of Data forms

- The site in charge is responsible for the completeness of data forms filled during the HSS round. All the data forms should be checked and signed by the site in charge.

5.5 "Unlinked Anonymous Testing with Informed Consent":

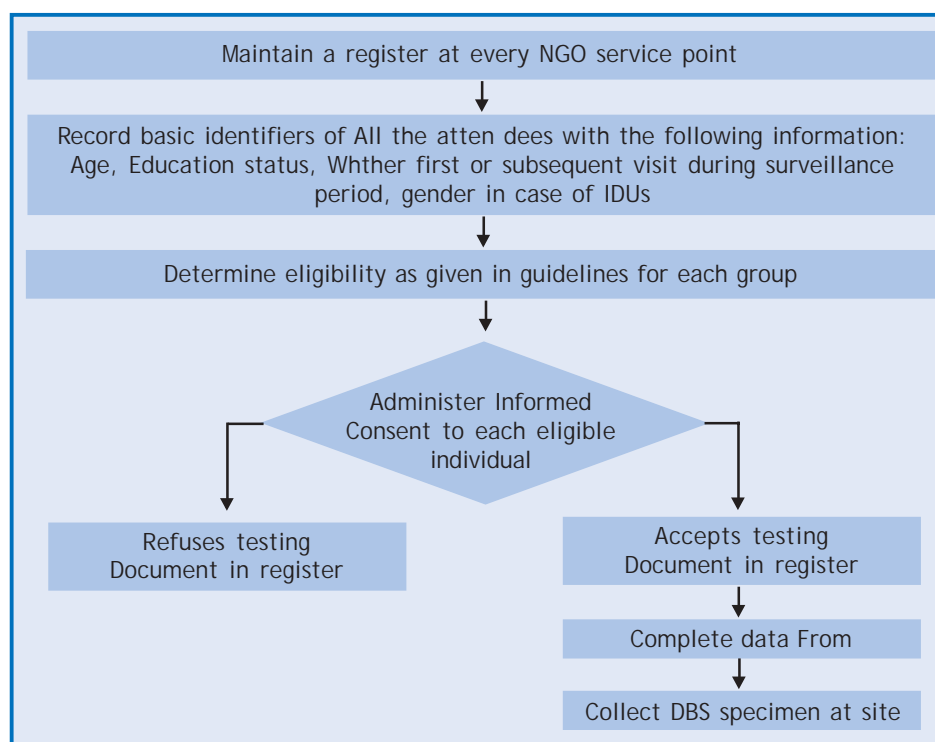
Unlinked Anonymous Testing with Informed Consent requires obtaining informed consent from participants, which includes making patients aware that HIV testing will be done on the specimen, and it will be done in a way that makes it impossible to link the test result to the participant. People who consent should understand that their HIV test result will not be returned to them.

Obtaining Informed Consent:

- It is the responsibility of the SACS and site-in-charge to ensure that their members are adequately trained in the process of informed consenting of eligible individuals and the process remains voluntary.
- It is the responsibility of the site-in-charge to ensure that all eligible individuals for HSS at that site are consecutively approached for informed consenting. The site in charge must periodically review the process with their staff.
- The informed consent forms (Annex. 10) must be stored separately and carefully at the sentinel site and sent to SACS at the end of the survey period. No copies are to be made.
- A register is to be maintained at each site documenting how many participants were approached for informed consent and whether they accepted. A format for the register is shown below:

S.No	Eligible for HSS as per case definition? (Yes/No)	Age	Education status	Gender (for IDUs)	Is this the first visit during current surveillance period? (Yes/No)	Whether Informed Consent was signed?	If no: Reason for refusal
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Box 1 : Flowchart of the procedure for obtaining Informed consent is outline in the flow chart below



Note: All eligible persons approached for HIV blood collection under HSS in the TI groups should be given a voucher for free HIV testing at a nearby VCTC regardless of whether they gave consent and sample for testing.

5.6 Collection of Blood specimens for Unlinked Anonymous Testing with informed consent at HRG (TI) sentinel sites using the Dried Blood Spot technique:

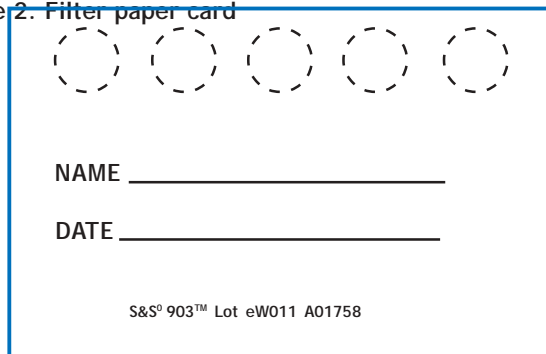
Blood samples for HRG (TI) groups under UAT with informed consent will be collected using the 'Dried Blood Spot' technique. In order to ensure that the HIV testing is anonymous, no names or other contact information would be recorded with the dried blood spot (DBS) samples. After the consent is obtained from an eligible respondent, a code with same ID would be given on the filter paper card (figure 2) and the individual data form.

Materials required:

1. Disposable Gloves
2. DBS card with five circles (No. 903, Schleicher and Schuell)
3. Alcohol swabs and dry gauze pads

4. Tissue paper
5. Safety Lancet
6. Small Band aids
7. Sharps disposal container
8. Sodium Hypochlorite solution

Figure 2. Filter paper card



5.6.1 Procedure for collection of blood for DBS:

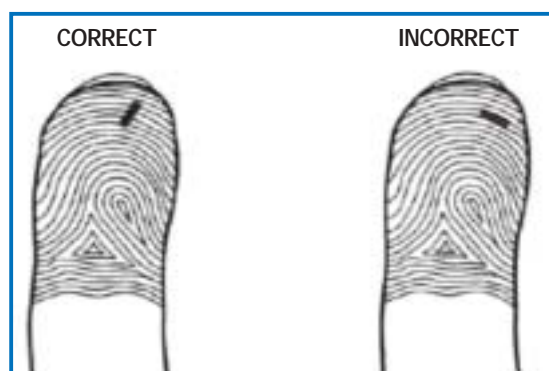
Procedure for making finger-prick

The retractable lancet provided is to be used; they are sterile and for one time use only. It is spring-loaded and the lancet retracts into the body of the device after skin puncture and gets locked and cannot be used there after. The recommended depth of puncture is 2.5 mm for adults.

1. Position the patient. The patient should sit in a chair, lie down, or sit up in bed. Hyperextend the patient's arm.
2. Massage the finger to increase blood flow. This may be done by gently squeezing the finger from hand to fingertip 5 or 6 times. Do not overuse this maneuver as it may cause erroneous results due to concentration of tissue fluids.
3. Cleanse fingertip with alcohol swabs. Wipe dry with a clean, dry piece of gauze or cotton. Be sure that the finger is thoroughly dry otherwise blood will not well up and form a drop at the puncture site of a moist finger.
4. Remove the lancet from its package and grasp the lancet

-
- between the thumb and forefinger.
- Using the sterile lancet, make a skin puncture just off the center of the finger pad
 - The puncture should be made perpendicular to the ridges of the fingerprint so that the drop of blood does not run down the ridges(See fig.3)
 - Wipe away the first drop of blood, which tends to contain excess tissue fluid.
 - Collect drops of blood on the labeled filter paper card as outlined below.

Figure 3 : Line of Puncture should be perpendicular to ridges of finger print



5.6.2 Collecting the sample on the Filter paper card

- For each subject one filter paper card will be used.
- Label the filter paper card.
- Place the card close to the lancet area but do not touch it. Apply gentle pressure to the base of the finger and allow the second LARGE blood drop to fall from the tip of the finger onto surface of the filter paper.
- The filter paper cards come with printed circles, apply blood to the inside of each of the circles in the centre. Attempt to fill the circle completely with a single drop before moving to the next empty circle (see fig.4).
- Apply blood to only one side of the filter paper (the side with

printing).

6. Avoid excessive pressure that may squeeze tissue fluid into the drop of blood.
7. When all circles are filled (or client no longer bleeds) : Have the patient hold a small gauze pad over the puncture site for several minutes to stop the bleeding
8. Apply adhesive band aid over the puncture site
9. Dispose all contaminated materials in designated containers and follow bio-safety precautions.
10. Avoid touching the part of the card with the blood spot
11. Air dry the specimen for at least 3 to 4 hours on the dry racks provided. Depending on the climate it might be necessary to allow spots to dry over night. For drying the DBS card, drying racks supplied must be used.
12. Do not allow the blood collection card to be exposed to direct sunlight or extreme temperature or humidity.

Figure 4 : Collecting drops of blood on filter paper card



5.6.3 Packaging the DBS Specimens

Materials required (Supplied in the kit with the DBS card):

1. Low-gas permeable sealable small plastic (zip-lock) zip-lock bags (one bag for each sample)
2. 5-10 desiccant packs
3. Bigger zip lock bag (big enough to pack 10 small zip lock bags)

with DBS cards)

4. Desiccant Packs-1gram desiccant pack with blue indicator that turn pink with high humidity
5. Biohazard labels
6. Glassine Paper envelopes
7. Padded envelopes
8. Humidity Indicator cards

Procedure for packaging the filter paper card

- 1) Each filter paper card with DBS (well dried) should be packed in a separate small zip lock bag by, inserting one card each into one glassine paper envelope so that blood spot cards from different patients are not touching each other.
- 2) Add desiccants (this will remove any residual moisture from the cards) to each bag. Push the desiccant to the bottom of the bag
- 3) Add a humidity indicator card

The humidity indicator cards and desiccant packs have a color indicator which changes from blue to pink as humidity increases. If the color of the desiccant / humidity indicator cards changes to pink, they should be replaced by new ones.

Ensure that sufficient quantity of humidity indicator cards and desiccants are stored at each blood collection site.

- 4) Push as much air out of the bag as possible.
- 5) Double check that the bag is sealed completely.
- 6) Avoid exposing the DBS to sunlight and high temperature.
- 7) Pack 10 small zip lock bags in one big zip lock bag.
- 8) Samples should be stored at room temperature and are

transported to testing laboratory on weekly basis.

5.6.4 Storage and transport of DBS specimens

1. Place the bigger ziplock bag containing the DBS inside the paper envelope.
2. Place the paper envelope inside a padded labeled envelope to avoid damage to the DBS during transportation.
3. Place the data forms in a separate ziplock bag and place it in this padded envelope.
4. Samples can be transported either
 - a. Daily : by hand (staff) if the testing centre is near the collection centre or
 - b. Weekly: through a tested courier / mailing system if the testing centre is at a distant place and daily transport is not possible.
5. Samples should be stored at room temperature till they are transported to testing laboratory.
6. A transport sheet should be filled in for DBS samples collected and sent to testing laboratory along with the samples. The transport sheet should be filled in duplicate, (one copy each for the site and testing lab), signed by the site staff and acknowledged by the testing laboratory staff.

The format for transport sheet is given in Annex. 6.

5.7 Bio Safety Precautions and Waste Disposal

Universal Safety Precautions refer to the precautions consistently used on the presumption that all blood and body fluids are potentially infectious for blood borne pathogens. Safety precautions are essential and should be followed at all points in the testing process from specimen collection, transport, testing, storage and disposal of biohazard wastes so as to minimize occupational risk of HIV transmission. Proper disposal of all the biomedical/ laboratory waste is essential.

Refer to Section 7 for detailed description of Bio-safety procedures to be followed at sentinel sites and testing centres.

5.8 Post Exposure Prophylaxis (PEP)

PEP refers to the comprehensive management given to minimize the risk of infection following potential exposure to blood-borne pathogens (HIV, HBV, HCV). This includes counseling, risk assessment, relevant laboratory investigations based on informed consent of the source and exposed person, first aid and depending on the risk assessment, the provision of short term (4 weeks) of antiretroviral drugs, with follow up and support.

"Health Care Personnel (HCP)": is defined as any persons, paid or unpaid; working in healthcare settings who are potentially exposed to infectious materials (e.g. blood, tissue, and specific body fluids and medical supplies, equipment, or environmental surfaces contaminated with these substances). HCP include: emergency care providers, laboratory personnel, autopsy personnel, hospital employees, medical and nursing students and health care professionals of all levels. If required, PEP can also be given to public safety workers, including law enforcement personnel, prison staff, fire-fighters, workers in needle exchange programs and workers in international HIV programs.

"Exposure" which may place an HCP at risk of blood-borne infection is defined as: a percutaneous injury (e.g. needle-stick or cut with a sharp instrument), contact with the mucous membranes of the eye or mouth, contact with non-intact skin (particularly when the exposed skin is chapped, abraded, or afflicted with dermatitis), or contact with intact skin when the duration of contact is prolonged (e.g. several minutes or more) with blood or other potentially infectious body fluids.

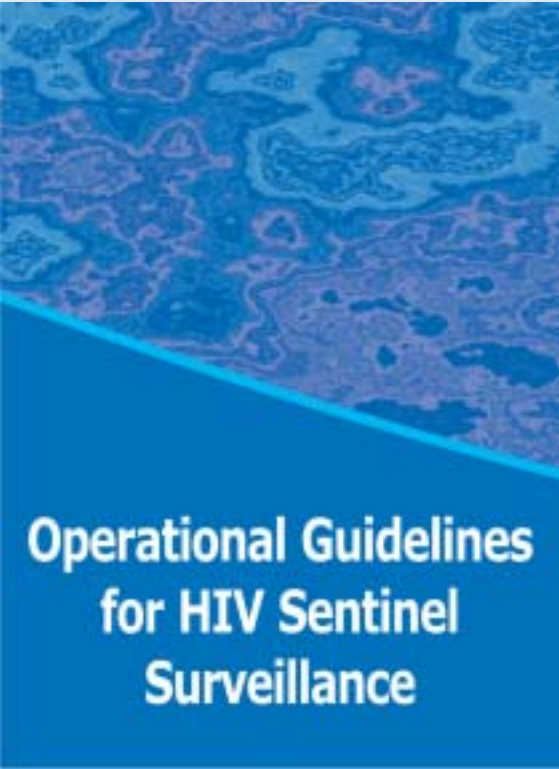
Ref: Guidelines for Post Exposure Prophylaxis nested within the document: "Antiretroviral Therapy Guidelines for HIV infected Adults and Adolescents including Post-exposure" section B, The document is downloadable at

http://www.nacoonline.org/Quick_Links/Publication/Treatment_Care__Support/

All site in charges should familiarise themselves with the above mentioned document of the National AIDS Control Organization. Please contact your SACS for hard copies of the same.

Some relevant sections of this document have been included in Annex 7-A and 7-B

Adherence to good practices (Do's and Don'ts) given in Annex 8 will ensure high quality of HSS.



**Operational Guidelines
for HIV Sentinel
Surveillance**

HIV Testing Centers

Chapter
VI





6

Please refer to Annex. 11 for flowchart for activities at Testing Centre

6.1 Sample Receipt and Verification at Testing Centers

TCs will receive the samples along with the data forms from the survey sites on a weekly basis. On receipt of the samples, the designated staff should check for -

- number of samples
- quality of samples (eg. haemolysed)
- adequacy of samples
- leaking vials
- labels on vials
- maintenance of cold chain
- details on the transport sheet
- matching of data with the samples
- the number and details on the data forms

The findings should be entered on the verification checklist in duplicate (Refer: Annex. 12 A and 12 B) and one copy should be handed over to the person bringing the samples. Acknowledgement of receipt of sample be made on the transport sheet.

6.2. Laboratory Procedures

After verification, the samples should be tested on the same day.

If they are not tested on the same day, the samples should be stored at -20 degree C until testing.

6.2.1 Storage of serum samples

- Serum samples are to be stored at +4°C for only one week from the day of collection.
- If testing is to be carried out beyond this period, freeze at -20°C.

6.2.2 Storage of DBS Specimens

DBS should be tested within one week of receiving the samples. Till then samples should be stored at room temperature. After the DBS samples are tested, filter papers with remaining spots should be stored in a freezer (-20°C).

6.3 HIV Testing

All the sera /DBS samples collected at any one sentinel site during any one sampling period should be tested in the same HIV testing laboratory, recognized by SACS/NACO. ELISA/ Rapid Test (E/R) assay for serum and ELISA 1/ ELISA 2 (E1/E2) assay for DBS should be performed for detecting HIV antibodies, using the strategy outlined below: Validated and approved HIV test kits will be supplied by NACO to respective SACS. SACS should supply these kits to all the testing labs in the state (Annex.-13).

- Testing procedures described in the test kits, must be strictly followed and test results should be appropriately recorded in laboratory registers.
- Good laboratory practices should be strictly followed.

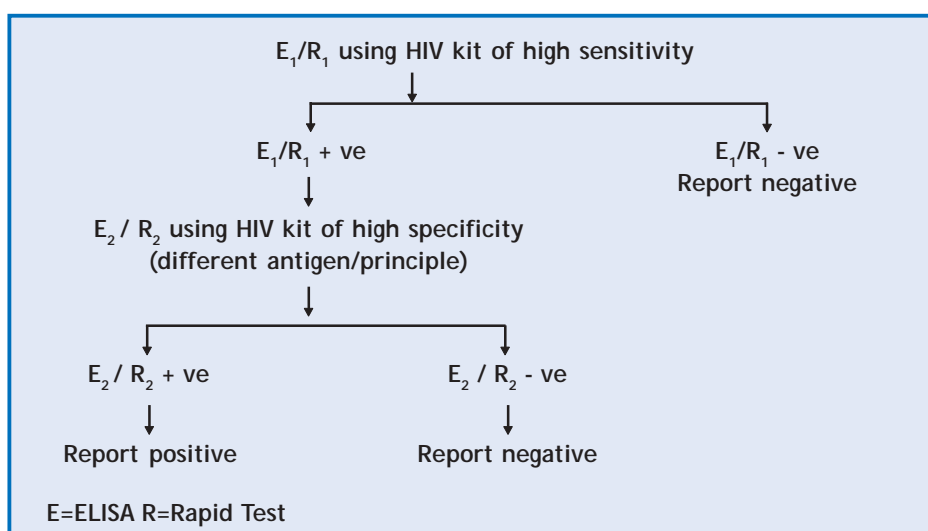
To maintain anonymity strict test results recording procedures should be followed so that there is no linking of the HIV testing results to the tested individual.

6.3.1 HIV Testing Strategy for Serum samples

- The Testing Strategy of NACO for surveillance, i.e. use of two HIV tests, should be followed. (See Figure 5).
-

- The HIV test protocol to be used may be: either ELISA based or rapid test.
- The serum should be first tested for HIV antibodies with one ELISA or Rapid test with high sensitivity.
- Any serum found reactive on the first assay should be retested with a second assay of high specificity, based on a different antigen preparation and/ or different test principle, from the first test.
- Serum that is reactive in both the tests is interpreted as "antibody positive".
- Serum that is reactive in the first test but non-reactive in the second test or non-reactive in the first test should be considered "antibody negative".
- The results of the two HIV tests should be entered in the individual data form.

Figure 5 : Flow Diagram for HIV Testing Strategy

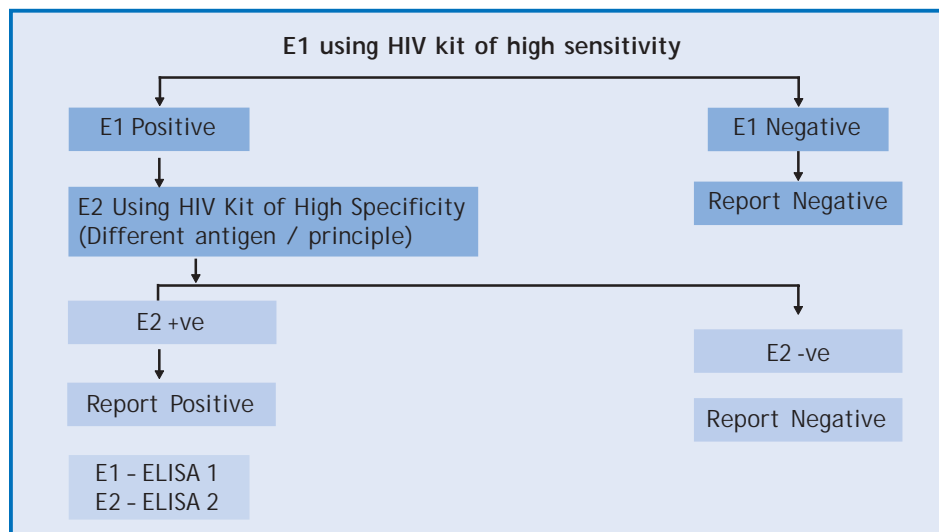


6.3.2. HIV Testing Strategy for DBS Specimens

- The Testing Strategy of NACO for surveillance, i.e. use of two HIV tests, should be followed. (See Figure 6).
- The eluted DBS sample to be first tested for HIV antibodies with one ELISA with high sensitivity.

- Any DBS sample found reactive on the first assay should be retested with a second assay of high specificity, based on a different antigen preparation and/ or different test principle, from the first test.
- DBS sample that is reactive in both the tests is interpreted as "antibody positive".
- DBS sample that is reactive in the first test but non-reactive in the second test is considered "antibody negative".
- The HIV test protocol to be used is ELISA based or rapid test.
- The results of the two HIV tests should be entered in the individual data form.

Figure 6 : Flow Diagram for HIV Testing Strategy for DBS samples



6.4 Syphilis serology for surveillance testing

- Testing is carried out on the coded vial that does not contain any patient identifiers.
- Qualitative syphilis serologic testing with undiluted sera samples is to be carried out first.
- Quantitative syphilis serologic testing with diluted sera on reactive sera samples in the first test to be carried out according to standard procedure (as supplied with the kit).

- Syphilis serology test results should be appropriately entered on the data form along with HIV test results.
- Standard laboratory practices should be strictly followed.

6.5 External Quality Assurance Scheme (EQAS) in HIV testing

EQAS is the periodic check and validation of proficiency of the testing laboratory by an external agency. It comprises primarily of:

- a) the proficiency panel testing of the testing laboratory before the start of the surveillance activity, and
- b) cross-check of positive and negative samples sent by the testing laboratory during the course of the sentinel surveillance activity to the NRL.

Project Directors, SACS should ensure that each centre involved in testing of sentinel site samples is linked to the respective reference laboratory (Table 9). The in-charge of the laboratory should be informed about the arrangement with a copy to NACO.

In order to carry on the process of the EQAS the following measures must be followed:

Proficiency Panel Testing:

- The entire activity for proficiency panel testing should be over before the HIV sentinel surveillance activity commences i.e. in the pre-surveillance period. Panel of coded sera for proficiency testing will be sent from the reference laboratories to the testing laboratories. The testing laboratories should then send the reports of the panel tested in their laboratories, back to the reference laboratories.
- The reference laboratories should verify the proficiency testing results, report to the respective testing labs with a copy to respective SACS, RIs and NACO.
- This activity should be repeated every year before surveillance starts. However, those testing labs that have

already undergone proficiency panel testing as part of the NACO's EQAS need not redo this. Thus, the proficiency panel testing should be carried out for those labs which do not routinely participate in NACO's proficiency panel testing.

- For the discordant results arising out of the coded panel sera, repeat testing of the panel to be done by the participating laboratory, till correct result is obtained.

Cross check of positive/ negative samples:

- The testing centers should submit all the positives and 5% of the negative HIV tested sera samples to the reference laboratory on a regular basis - specifically at an interval of 15 days during the surveillance period for cross checking.
 - This 5% of the negative samples should be chosen by systematic random sampling. The starting random number would be informed by the reference laboratory to the testing site in-charges, and then from there onwards every 20th sample should be selected.
 - The samples to be sent to the reference laboratories should be treated as far as possible in same way as other samples. There should be no special attention, no special testing by any separate kit/ separate lab personnel.
 - The testing labs should append the site name and the code number of the samples being sent to the reference laboratories. The forms specially designed for this activity should be used (Annex. 14).
 - The reference laboratories should in turn examine the specimens sent from the testing labs, as soon as possible after receipt. The person from the testing centers bringing the samples should be given one copy of the verification checklist (Annex. 15) duly completed by TC staff in duplicate and acknowledgement of receipt of samples by putting in signature by the TC staff on the duplicate copy of
-

the transport sheet. They should further communicate the results of EQAS regularly (within 1-2 weeks), during the surveillance period, preferably before the receipt of the next lot. This communication should be sent to the testing laboratories with a copy each to the respective SACS, NIHF, RI and NACO.

- Discordant results: All the discordant results along with the code number and site name should be reported to the respective SACS with a copy to NIHF, New Delhi, respective RI and NACO.

6.6 Storage of Samples

Guidelines for storage are currently under review and until new guidelines are circulated by NACO. The testing centers should store all samples at least until all EQAS related issues are settled and Regional Institute permits destruction of samples. All positive samples should be stored indefinitely until informed otherwise by RI.

6.7 Quality Control of Data Form Entries

- 1) 10% entries of HIV test results on data forms should be cross checked with the entries in the laboratory test registers.
- 2) 10% of HIV test results in the laboratory test register should be cross checked with the HIV test results entries made in the data forms.
- 3) All positive HIV tests results entries made in the data forms should be cross checked with the HIV test results entries made in the laboratory test registers.

Table 7 : Expected timeline of EQAS sample submission and reporting

	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;">First lot of samples should reach the ref lab from testing center for cross checking</div>		<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;">The feedback report of the first sample should reach the testing center from ref lab</div>			
Sentinel Surveillance Starts (Days)	15	30	45	60	75	90
Sending samples for cross-checking from testing labs or Ref labs						
Reference lab should report back by				The same schedule will be observed in subsequent fortnights		

6.8 Bio Safety Precautions and Waste Disposal

Universal Safety Precautions refer to the precautions consistently used on the presumption that all blood and body fluids are potentially infectious for blood borne pathogens. Safety precautions are essential and should be followed at all points in the testing process from specimen collection, transport, testing, storage and disposal of biohazard wastes so as to minimize occupational risk of HIV transmission. Proper disposal of all the biomedical/ laboratory waste is essential.

Refer to Section 7 for detailed description of bio-safety procedures to be followed at sentinel sites and testing centers.

A list of good practices (Do's and Don'ts) given in Annex. 8 will ensure high quality of HSS.

Table 9 : List of National Reference Laboratories and the States allotted

Name of National Reference Laboratory	States allocated
Institute of Preventive Medicine , Hyderabad	Andhra Pradesh
Dr TN MGR University, Chennai	Andaman & Nicobar Islands, Tamil Nadu, Puducherry
National Institute of Biologicals (NIB), Noida	Uttar Pradesh, Uttaranchal
National Institute of Communicable Diseases (NICD), Delhi	Jammu & Kashmir, Haryana, Rajasthan, Delhi
All India Institute of Medical Sciences (AIIMS), New Delhi	Chandigarh, Punjab, Himachal Pradesh
Institute of Immunohaematology (IIH), Mumbai	Mumbai, Madhya Pradesh, Daman and Diu, Dadra Nagar Haveli
National Institute of medical & Neuro Sciences (NIMHANS), Bangalore	Karnataka
National AIDS Research Institute (NARI), Pune	Goa, Gujarat, Maharashtra
National Insitute of Cholera & Enteric Diseases (NICED), Kolkata	Meghalaya, Orissa, Assam, Jharkhand
School of Tropical Medicine, (STM), Kolkata	Sikkim, West Bengal, Bihar, Chhattisgarh
Regional Institute of Medical Sciences Nagaland, (RIMS, Imphal), Imphal	Manipur, Mizoram, Tripura, Arunachal Pradesh
Christian Medical College (CMC), Vellore	Kerala, Lakshadweep
Madras Medical College (MMC), Chennai	Tamil Nadu



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Biosafety

Chapter
VII





7

Safety precautions are essential and should be followed at all points in the testing process from specimen collection to testing, storage, and disposal of biohazard wastes-so as to minimize occupational risk of HIV transmission. Proper disposal of all the contaminated laboratory waste is essential.

Universal Safety Precautions refer to the precautions consistently used on the presumption that all blood and body fluids are potentially infectious for blood borne pathogens.

7.1 Laboratory Bio-safety Practices

- The laboratory should be kept neat, clean and free of materials that are not pertinent to the work
- All blood samples are to be treated as potentially infectious samples
- Exposure may occur during blood collection, handling, processing, testing, disposal of waste, transport
- Laboratory aprons must be worn at all times for the work in the laboratory
- Gloves must be worn for all procedures that may involve direct or accidental contact with blood, body fluids and other potentially infectious materials. After use, gloves should be removed and hands must be washed
- Personnel must wash their hands thoroughly after handling infectious materials and before they leave the laboratory working areas(see fig.8).

Figure 8. Hand washing

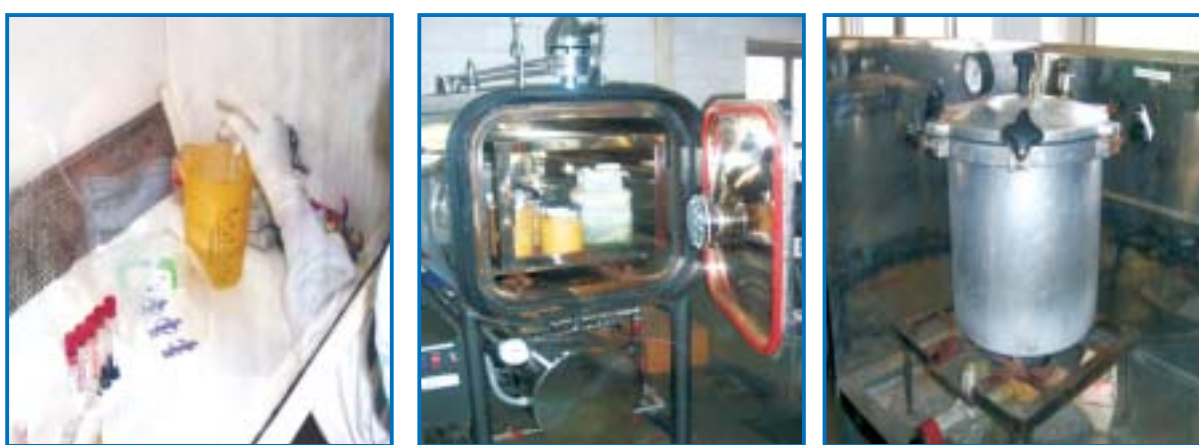


- All spills, accidents and overt or potential exposures to infectious materials must be reported to the laboratory supervisor. A written record of such accidents and incidents should be maintained
- Written procedures for the clean -up of all spills must be maintained
- Contaminated liquids must be decontaminated before discharge to the sanitary sewer
- Work surfaces must be decontaminated after any spill of potentially dangerous material and at the end of the working day
- Safe handling of sharp items and prevention of accidents with sharps
- Safe handling of specimens (blood etc) during collection, processing and transport
- Whenever possible avoid the use of sharps
- Never recap a used needle
- Ensure sharps container is nearby, well placed, and not over-filled
- Keep one bottle with 70% ethanol, one with 10% hypochlorite solution ready

- Replace container with hypochlorite solution used for discarding contaminated pipettes & tips everyday
- Work surface to be wiped with 70% ethyl alcohol
- Open toed foot wear must not be worn in laboratories
- Eating, drinking, smoking, applying cosmetics and handling of contact lenses is prohibited in the laboratory working areas
- Storing foods or drinks anywhere in the laboratory working areas is prohibited
- Pipetting by mouth must be strictly forbidden
- It is prohibited to wear protective laboratory clothing outside the laboratory, e.g, in canteens, coffee rooms, offices, libraries, staff rooms and toilets
- Decontamination and their ultimate disposal are closely interrelated
- Before disposal, the objects or materials should be effectively decontaminated or disinfected by an approved procedure
- Steam autoclaving is the preferred method for all decontamination processes. Materials for decontamination and disposal should be placed in containers, e.g, autoclavable plastic bags, that are color coded according to whether the contents are to be autoclaved and or incinerated
- After use, hypodermic needles should not be recapped, clipped or removed from disposable syringes. The complete assembly should be placed in a sharp disposal container and incinerated with prior autoclaving if required
- Sharps disposal containers must be puncture proof and must not be filled to capacity. When they are three-quarters full, they should be replaced with new containers
- Discard containers, pans or jars preferably unbreakable (e.g. plastic) should be placed at every work station

-
- When disinfectants are used, waste materials should remain in intimate contact with the disinfectant for the appropriate time according to the disinfectant used
 - Discard containers should be decontaminated and washed before reuse

Figure 9 : Decontamination and autoclaving



7.2 Bio-safety in HSS

In the following situations, specific precautions need to be taken:

1. Sample Collection:

- Personal protective devices like aprons, face mask and gloves must be worn while working in the laboratory
- Cotton swabs and gloves should be discarded in appropriate container
- Discarding of used needles in a puncture proof container containing freshly prepared 1% sodium hypochlorite solution
- Any spillage of potentially dangerous material should be properly cleaned and decontaminated following standard procedures
- Needle stick injuries, should be reported to the concerned authorities and PEP should be given, if necessary

2. Sample Handling and Testing

- Proper decontamination of the Pasteur pipettes used for serum separation and testing should be done
- Work surfaces must be decontaminated before and after working
- The decontaminated materials should be steam autoclaved before disposal

3. Sample Storage and Transport

- The samples should be stored in a refrigerator (up to a maximum 7 days) and in deep freezer (if storage required for more than 7 days)
- The samples should be properly sealed to avoid any leakage
- The serum samples should be transported in a proper carrier such as vaccine carrier
- The sample carrier must be held up right at all times and should always be in the custody of the person transporting it.
- The sample carrier should not be opened between the place of dispatch & delivery.

7.3 Management of spills and accidents

Management of spills:

- Wear gloves throughout.
- Cover spill with absorbent material and pour disinfectant around the spill and over the absorbent material. Leave for 30 min. Remove the absorbent material and place in the biohazard bag for infectious waste.
- Wipe the surface again with disinfectant.
- Sweep broken glass etc with a brush and discard into the waste container.
- Report the spills to the laboratory in-charge.

- Keep a written record of all such accidents.

Management of Needle stick injury:

- Needle stick, puncture wounds, cuts, open skin contaminated by spills or splashes should be washed thoroughly with soap and water.
- Report the injury to the laboratory in-charge.
- Keep a written record of all such accidents.
- Appropriate medical evaluation, treatment and counseling should be provided.

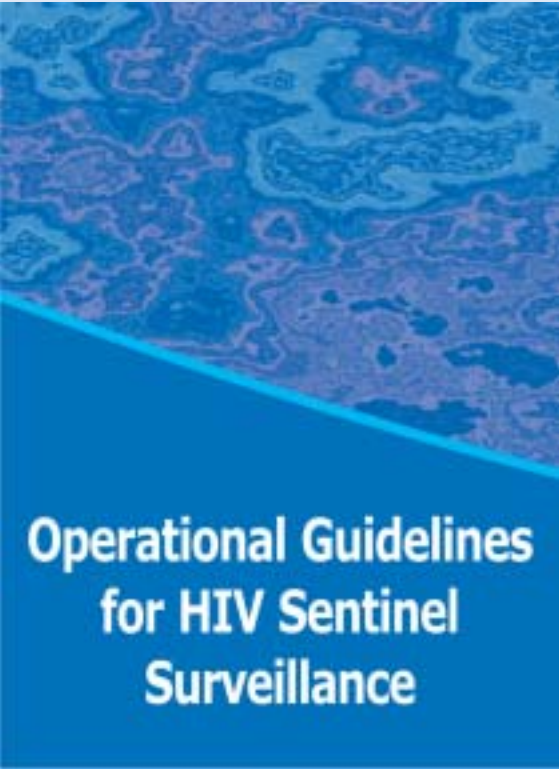
Table 10: Preparation of different concentration of Sodium Hypochlorite solution

Required strength Solution	4% stock Solution	5% stock Solution	10% stock Solution	15% stock
0.1% (1g/L- 1000 ppm)	1:40*	1:50	1:100	1:150
0.5% (5g/L- 5000 ppm)	1:20	1:25	1:50	1:75
1% (10g/L- 10,000 ppm)	1:4	1:5	1:10	1:15

*parts of stock solution: parts of water
Always use freshly prepared diluted hypochlorite solution every day

Table 11: Recommended strength of the sodium hypochlorite for various purposes

Purpose	Strength
Spills	1%
Surface decontamination	1% (smooth surface) 10% (porous surface)
Cleaning of discard bins	2.5%
Treatment of liquid infectious waste (with large amount of organic matter)	10%
Discarding of sharps	1%



**Operational Guidelines
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**Programme
Management**

Chapter
VIII





8

8.1 Training and Capacity Building

Nation-wide training of designated staff at different levels would be conducted for all engaged in HSS 2008. The programme of capacity building will be according to the training plan of NACO (see document on Action Plan) and is briefly outlined below:

- a) Orientation of Seven RI is conducted by NIHFW, New Delhi on the strategy for conducting the HSS. This will include orientation in the overall HSS goals, data collection, data recording, monitoring and supervision at different levels, laboratory testing, EQAS and biosafety precautions.
- b) Training of State Surveillance Teams including the Joint Director (Surveillance) or focal person for surveillance at the respective RI will be done by RIs for HSS 2008. RI may decide to conduct this training in various states assigned to them with a view to train additional state level trainers.
- c) Trained State Level Trainers will conduct training for staff of sentinel sites and testing centers involved in HSS 2008. They will be expected to refer to the guidelines for HSS 2008 and use the standard training modules developed by National AIDS Research Institute, Pune and NACO.
- d) For the HIV testing laboratories, "hands-on" training (training by a qualified technician that includes actually running the tests that will be used in the laboratory) and if required, retraining of old staff should be carried out.

For data entry operators and monitoring and evaluation (M&E) officers' from SACS and RI the training will be conducted by NIHFW.

8.2 Logistic Management

All logistics must be organized well in advance and as per the activity plan for the HSS 2008 round by SACS/ NACO. All the necessary equipment required for collection, processing and storage of samples must be made available well in advance to clinics/ sentinel sites and/ or testing laboratories for the HSS. (A checklist is given in Annex. 17). HIV Testing Kits and data forms should be procured by SACS well in advance to ensure timely start of the HSS round from the last quarter of the year or dates specified by NACO. In 2008, the data forms will be printed centrally by NIFHW and distributed to SACS.

8.3 Monitoring and Supervision

To ensure timely completion of preparatory activities and smooth organization of the HSS round, supervisory visits must be conducted during the round as per the action plan prepared by the Regional Institutions in consultation with the SACS. SACS must arrange and conduct state level monitoring plan in consultation with RI, independent of the monitoring by the RI and SST and send timely report of the same to RI.

At least one visit for the old sites and two visits for the new sites are to be conducted during the active round of surveillance. It is suggested that Regional Institutions take a monthly review of the progress of sample collection at various sites in their area of work, identify poorly performing sites and make additional visits to such sites or take measures to improve their performance with the help of SACS and SSTs. Identified supervisory teams of central observers or Technical Resource Group members will conduct visits as per schedule prepared by NACO or NIHFHW. The central observers will send their reports to RI as early as possible manner so that corrective actions can be made in a timely fashion even during the surveillance period. The monitors will record their findings using specified check lists (Annex. 18 and 19). Supervisory visits by teams from nodal agencies to the selected sentinel sites will also be carried out.

8.4 Data Reporting and Analysis

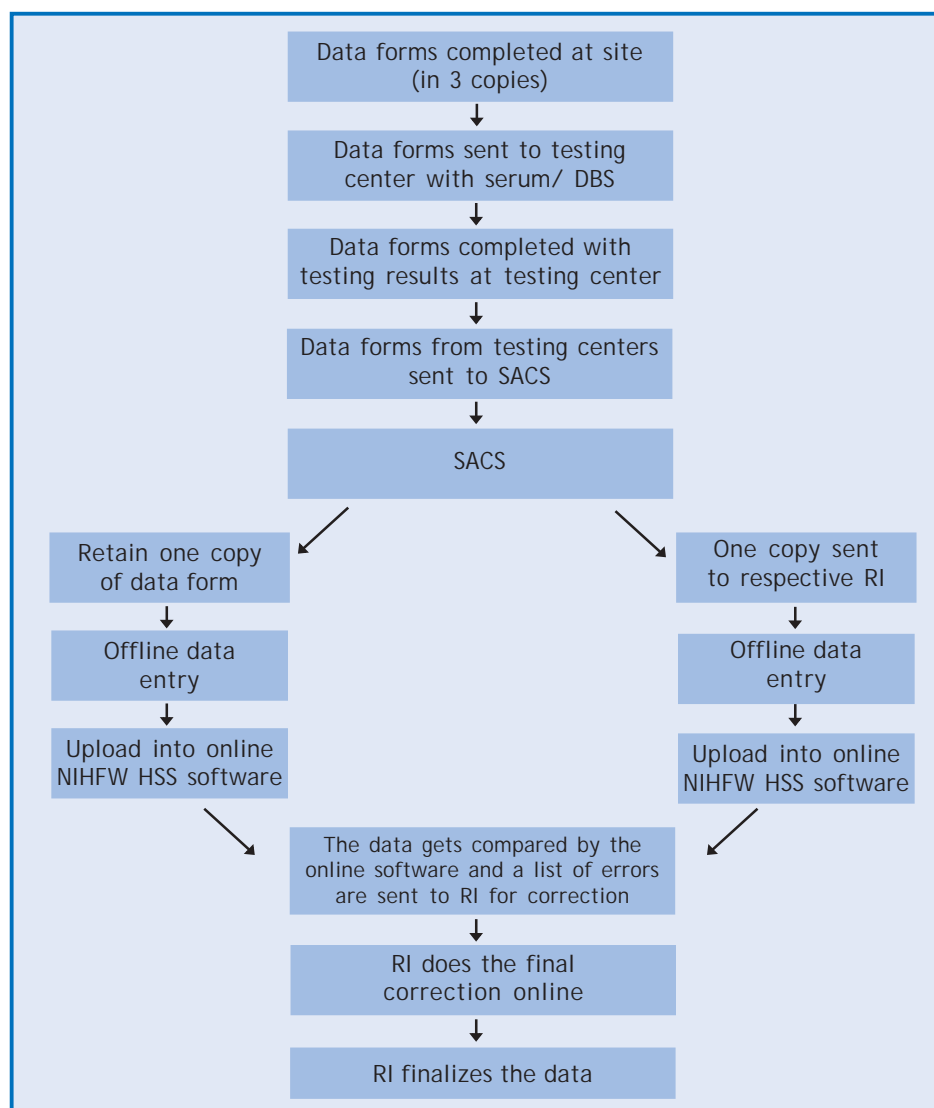
Data collected at each HIV sentinel site and for each sentinel group at that site should be reported in the prescribed format and as per the reporting schedule. All individual forms (individual data forms) will be sent along with the matching number of samples to testing laboratories. The persons receiving the samples should also check the Data Forms for completeness and provide feedback to the sentinel site accordingly. As such, the forms would have been checked by the technician/nurse collecting the blood sample as well as site in-charge before forwarding to the TC. However this check at the TC will ensure continuous quality check and timely feedback to the site and SACS will help application of corrective actions at sites where data forms completion is found to be a problem.

Testing Centre In charges will ensure that HIV and syphilis serology (ANC and STD sites only) results are appropriately entered on the data forms. Quality control procedures will be adopted at testing centers to ensure that data on the laboratory registers is accurately transcribed on the data forms. A 100% quality control mechanism is highly desirable.

The testing centers will make arrangements to send all the data forms with duly completed entries after laboratory testing to respective SACS. SACS, in turn would send one copy to the designated RI. All Regional Institutes will carry out data entry for their assigned states on the offline NIHFWS software. Similarly, the States would do the data entry for the same forms at SACS using offline NIHFWS software. Once the data entry is finished by the SACS, the SACS would upload the offline data entered by them into the NIHFWS -online software. The RIs would upload the offline data entered by them into NIHFWS online software. The software is so designed to compare the data for a same site that has been uploaded by SACS and RI separately. The software would compare the electronic files and provide a list of errors identified by it. This list of errors generated by the software would be

accessible to RIs (through their administrative control). The RIs would review the errors and do the necessary correction. The final entry (after review of errors) would be done by the RIs on the NIHFW -online software.

Figure10: Flow of data from sentinel sites



Quality control procedures will be adopted at the data management department of the SACS and Regional Institutes to ensure that data on the data forms is accurately entered in the database. A 100% quality control mechanism is highly advisable. Quality control of data forms should be done as follows:

- a) 10% of data forms should be cross checked with the computer data entry

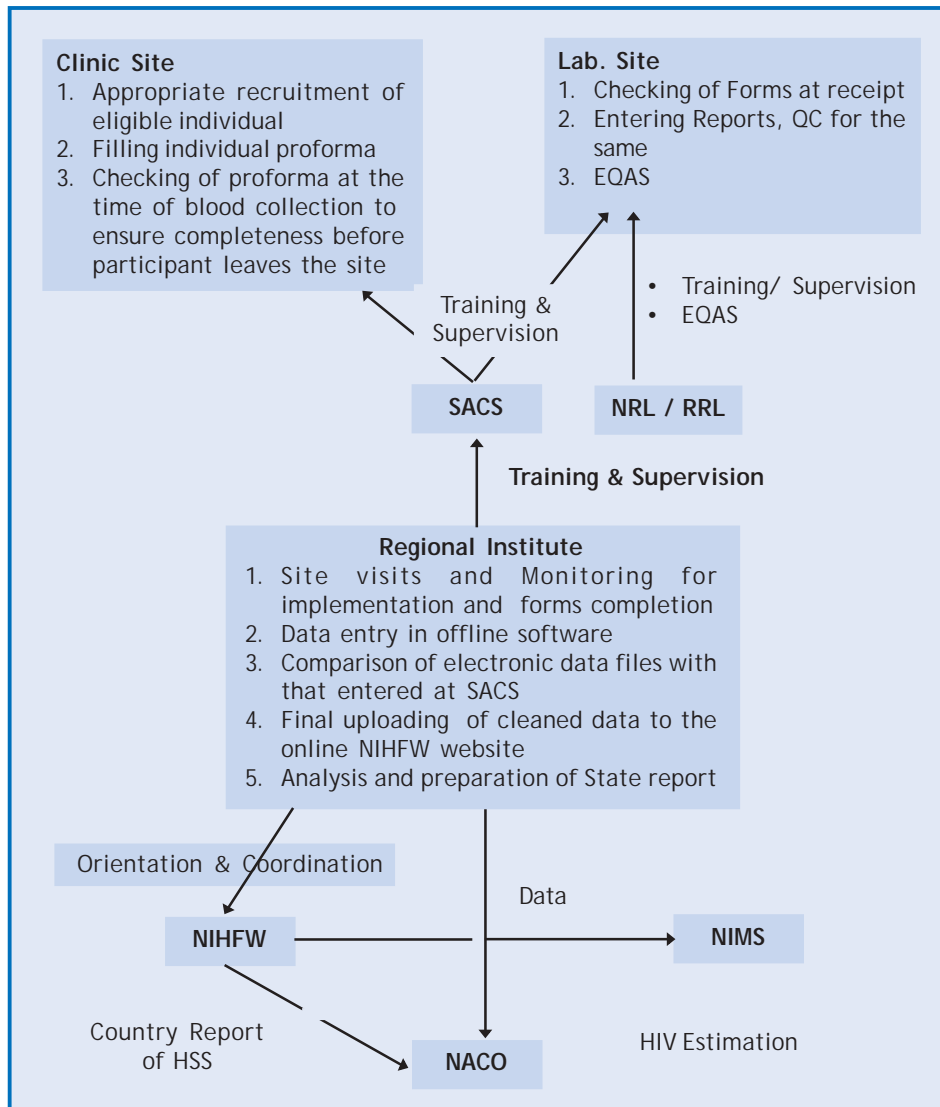
- b) 10% of computer data entry should be cross checked with the data forms.
- c) All positive result entries in the data form should be cross checked with the computer data entry.

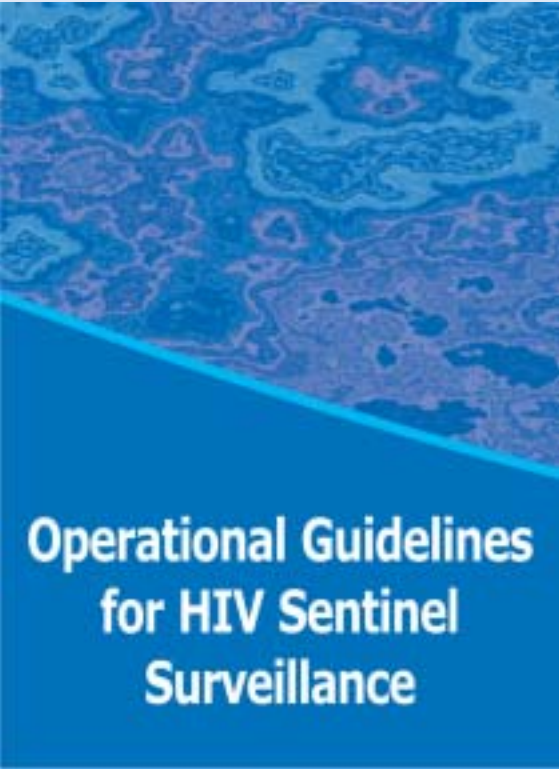
NIHFW will monitor the data at the website and generate periodic and timely reports for circulation to Regional Institutes, SACS and NACO. The data will be analyzed by the Regional Institutes taking district as a unit for each state and finally prepare a report aggregated at the state level to calculate median and confidence interval (90%), separately for each population group using the NIHFW software. State and site-wise trends may be obtained along with analysis of socio-demographic variables. The NIHFW software can be used for generating the reporting formats for sending to NACO. NIHFW will download, check and generate report at the national level and submit the same to NACO as well as NIMS to carry out HIV estimation.

8.5 Interpretation and Use of Data

The HSS data is to be interpreted to assess the changing trends of HIV prevalence as well as the rapidity of spread in different groups and areas, in order to determine the target population group needing priority attention with respect to interventions and to understand the nature of the epidemic. The data is also to be used to estimate the number of people currently infected and the number expected to develop AIDS in the future. The results of sentinel surveillance is to be disseminated not only to those responsible for formulating policy but also to staff of sentinel sites and testing centres, supervisory teams, health care providers, NGOs and other stakeholders, working for the control and prevention of HIV/AIDS in the country.

Figure 11: HSS Data Quality Assurance





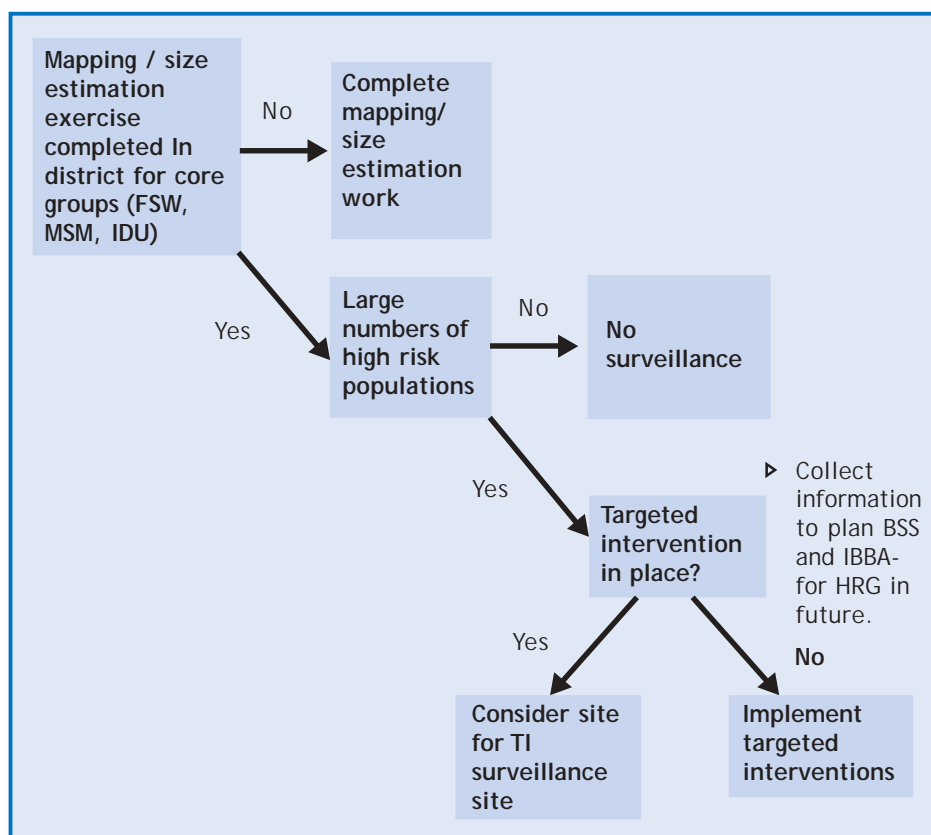
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Annexes



Annex 1: Decision Tree for New High Risk Group Sentinel Sites

Box 2 : Flow chart for establishing new high risk group sentinel sites.



For all candidate sites: Assess feasibility criteria for establishing site, which include:

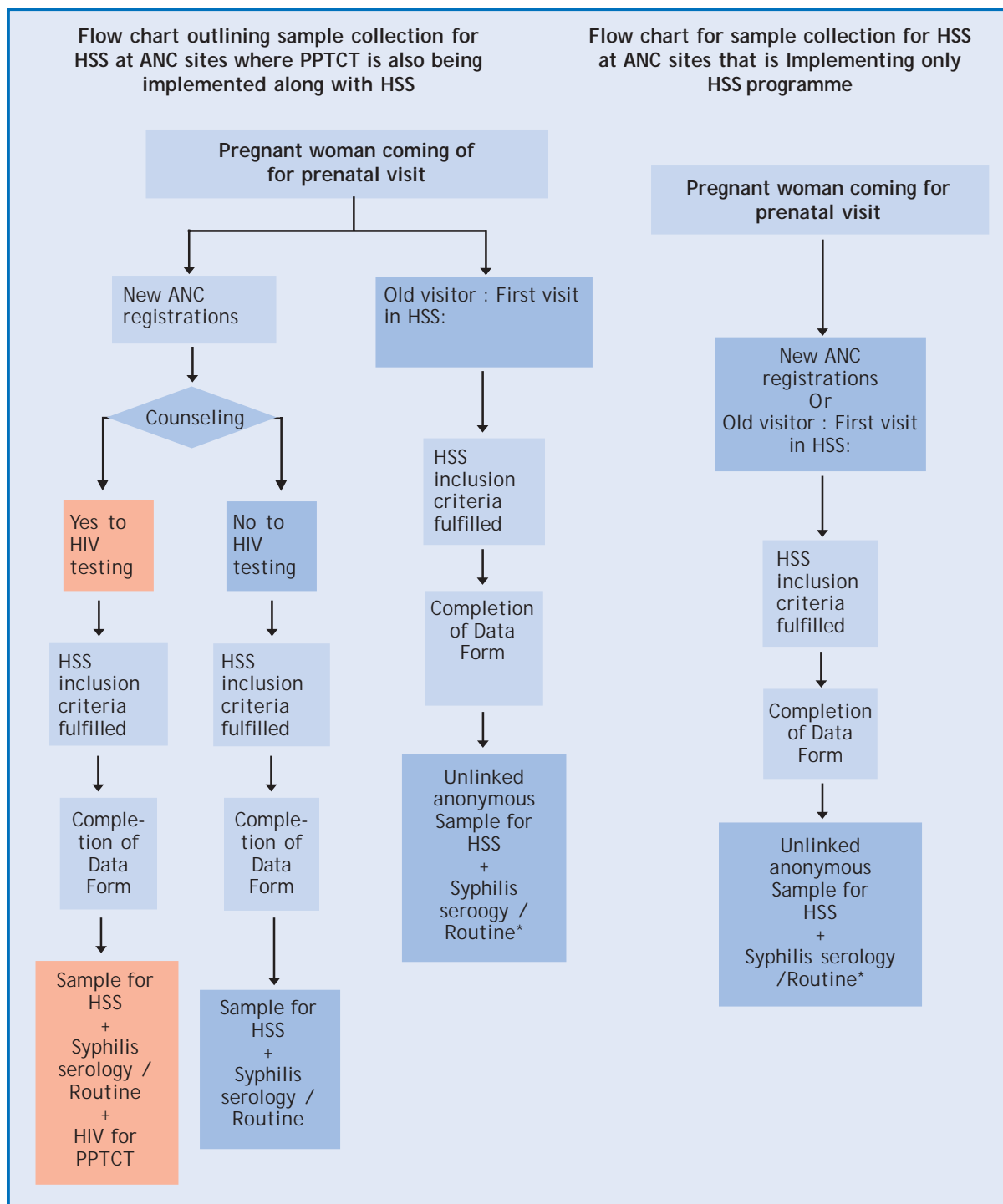
- Size of HRG under TI.
- Infrastructure of TI - is there a community center (drop in center).
- If more than one TI is working in district and none of them have population adequate to provide required sample size of 250, initiate "take all"
- Mapping work is updated by NACO. Also, in inter surveillance period, RI may submit proposals for operations research to identify such population, if required.

For all selected sites: Collect background information necessary to interpret data on site. For all areas where large numbers of HRG are present: Initiate pre-surveillance activities to plan community based surveys (i.e., BSS or IBBA).

Annex 2: Human Resources involved in HSS at different levels

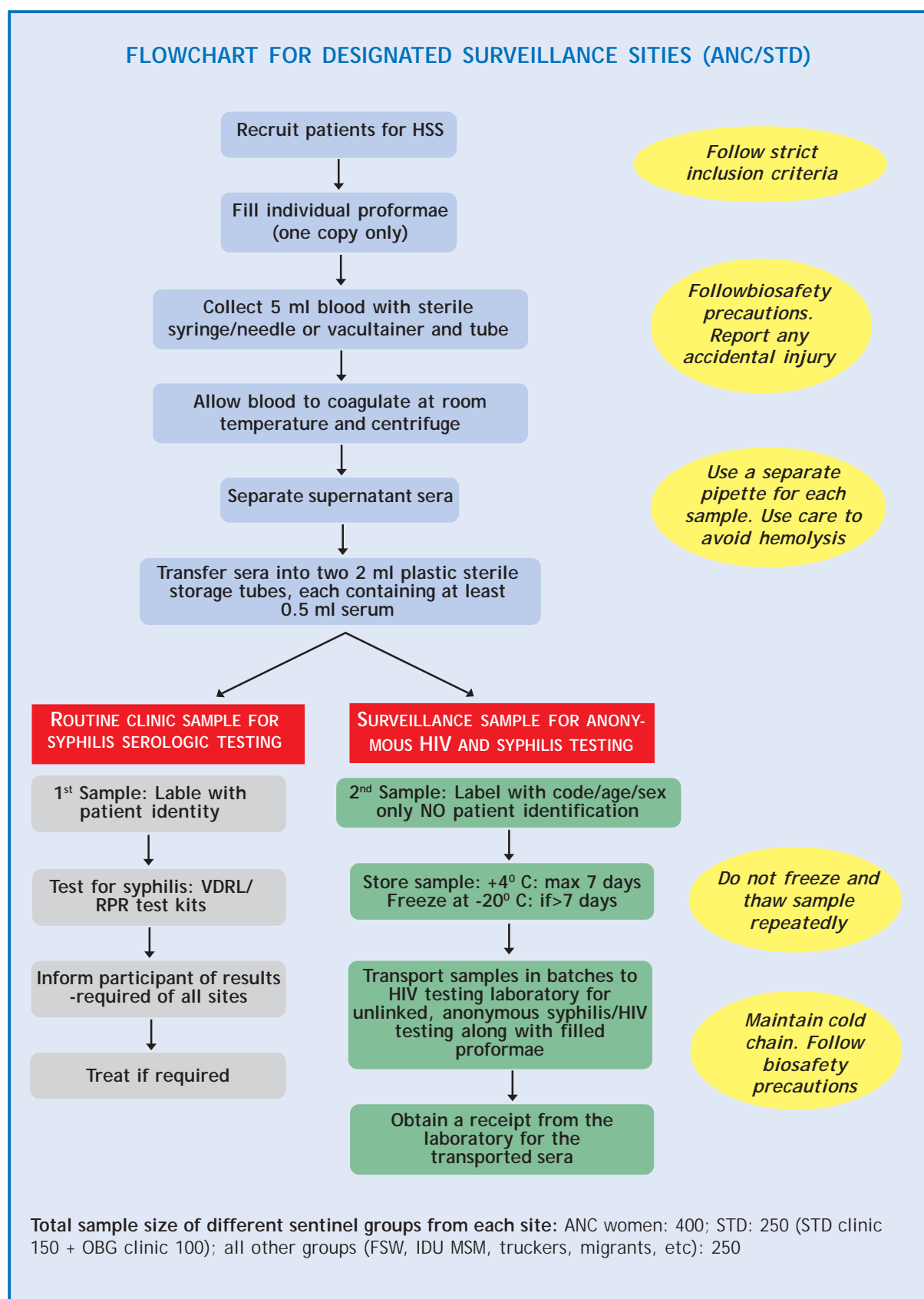
S.No	Institution Involved	Cadre Involved
1	National AIDS Control Organisation	Joint Director (Basic Services Division) Technical Officer (Surveillance)
2	Technical Resource Group for Surveillance	As constituted
3	National Institute of Health and Family Welfare, New Delhi	Nodal Person for HIV Sentinel Surveillance Epidemiologist Project Coordinator/ Research Officer Data Manager/ GIS Technician Computer Assistant
4	National Institute of Medical Statistics, New Delhi	Director, NIMS, New Delhi Deputy Director, NIMS, New Delhi Consultant for HIV Estimation
5	Central Team Members	As constituted
6	Regional Institutes (Seven)	Two Public Health Experts/ Epidemiologists One Microbiologist Project Coordinator/ Epidemiologist Two Research Officers - Field and Lab Computer Assistant/ Office Assistant Data Entry Operators (Based on Requirement)
7	State Surveillance Teams (One in each State)	Two to Five Public Health Experts One to Three Microbiologists
8	State AIDS Control Society	Deputy Director (Surveillance) State Epidemiologist Focal Person at SACS for TI Programme Constituted Team for Supervisory Visits
9	Sentinel Sites	Site In-charge (Medical Officer/ NGO In-charge) Lab Technician Nurse/ Assistant
10	Testing Labs in states	Lab In-charge (Medical Officer) Lab Technician
11	National Reference Laboratories for EQAS of venous samples from Testing Labs in States	Lab In-charge (Medical Officer/ Professor) Lab Technician
12	Designated Laboratories for Testing DBS Sampels	Lab In-charge (Medical Officer/ Professor) Lab Technicians (Based on Requirement)
13	NARI, Pune for EQAS of DBS Samples	Lab In-charge (Medical Officer/ Professor) Lab Technicians (Based on Requirement)

Annex 3: Flow chart for recruiting participants at ANC sentinel site



*Routine - Other routine tests as decided by the treating medical officer.

Annex 4 : Flow chart for activities at sentinel site



Annex 5A: HSS 2008 Data form for antenatal clinic attendees

(Circle appropriate options, complete where options are not available)

Date: __ __ / __ __ / __ __ __ __		State	District	
1. Name of Sentinel Site:				
2.1 Sentinel Site Code:		2.2 Sub-Site Number: 0, 1, 2, 3, 4, 5 (Circle appropriately. Circle 0 if the site is not a composite site)		
3. Sample Number				
4. Age in completed years				
5. Education				
1. Illiterate		2. Literate and till 5th	3. Till 12th Standard	
4. Till Graduation		5. Graduate and above		
6. Order of current Pregnancy				
1. First	2. Second	3. Third	4. Fourth	
5. Greater than fourth				
7. Source of referral to ANC clinic				
1. Self Referral		2. Family/Relatives/ Neighbors/ Friends	3. NGO	
4. Private Doctor		5. Govt Doctor/Health Centre		6. ICTC/VCTC
8. Current place of residence				
1. Urban (Municipal Corporation/Council/Cantonment)			2. Rural	
9. Duration of stay at current place of residence: _____ years _____ months				
10. Current occupation of the Respondent				
1. Agricultural labourer	2. Non-agricultural labourer	3. Domestic servant		
4. Skilled/ Semiskilled worker	5. Petty business/ small shop	6. Large Business/Self employed		
7. Service (Govt./Pvt.)	8. Student	9. Truck Driver/helper		
10. Local transport woker/ (auto/taxi driver, handcart pullers, rickshaw pullers etc)	11. Hotel Staff		12. Agricultural cultivator/ landholder	
14. Housewife				
11. Current Occupation of the Spouse				
1. Agricultural labourer	2. Non-agricultural labourer	3. Domestic servant		
4. Skilled/ Semiskilled worker	5. Petty business/ small shop	6. Large Business/Self employed		
7. Service (Govt./Pvt.)	8. Student	9. Truck Driver/helper		
10. Local transport woker/ (auto/taxi driver, handcart pullers, rickshaw pullers etc)	11. Hotel Staff		12. Agricultural cultivator/ landholder	
13. Unemployed	99. Not Applicable (For Never married/ Widows)			
12. 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/ never married)		
Signature _____		Signature _____		
Name _____		Name _____		
(Person completing the form)		(In charge of the Surveillance Site)		
To Be Completed at Testing Center				
Laboratory results				
13 a) Testing for HSS (Please circle the appropriate number)				
First test	1. Positive	2. Negative		
Second test	1. Positive	2. Negative	9. Not applicable (if first test is non-reactive)	
13 b) Syphilis Serologic Testing (Please circle the appropriate number)				
Qualitative Test :	1. reactive	2. non reactive		
Quantitative Test :	1. <1: 8	2. ≥1: 8	9. Not applicable (if first test is non-reactive)	
Signature _____		Signature _____		
Name _____		Name _____		
(Person completing the form)		(In-charge of the Testing Center)		

Annex 5B : HSS 2008 Data form for patients attending STD/ GYN clinics

(Circle appropriate options, complete where options are not available)

Date: __ __ / __ __ / __ __ __ __		State	District
1. Name of Sentinel Site			
2.1 Sentinel Site Code:		2.2 Sub-Site Number: 0, 1, 2, 3, 4, 5 (Circle appropriately. Circle 0 if the site is not a composite site)	
3.1 Sample Number		3.2 Sentinel Site type: 1. STD clinic 2. GYN clinic	
4.1 Age (in completed years):		4.2 Sex: 1. Male 2. Female	
5. Marital Status: 1. Never married 2. Married 3. divorced/separated/widowed			
6. Education:		1. Illiterate 2. Literate and till 5th	
3. Till 12th		Till Graduation	5. Graduate and above
7. Source of referral to STD clinic			
1. Self Referral		2. ICTC/ VCTC	3. NGO
4. Private doctors		5. ART center	6. Other OPDs
7. Referred by spouse having STD			
8. Current place of residence of the Respondent			
1. Urban (Municipal Corporation/Council/Cantonment)		2. Rural	
9. Duration of stay at current place of residence? _____ year _____ months			
10. Current occupation of the Respondent			
1. Agricultural labourer		2. Non-agricultural labourer	3. Domestic servant
4. Skilled/ Semiskilled worker		5. Petty business/ small shop	6. Large Business/Self employed
7. Service (Govt./Pvt.)		8. Student	9. Truck Driver/helper
10. Local transport woker/ (auto/taxi driver, handcart pullers, rickshaw pullers etc)		11. Hotel Staff	12. Agricultural cultivator/ landholder
13. Unemployed		14. Housewife	
11. What is the Occupation of the Spouse?			
1. Agricultural labourer		2. Non-agricultural labourer	3. Domestic servant
4. Skilled/ Semiskilled worker		5. Petty business/ small shop	6. Large Business/Self employed
7. Service (Govt./Pvt.)		8. Student	9. Truck Driver/helper
10. Local transport woker/ (auto/taxi driver, handcart pullers, rickshaw pullers etc)		11. Hotel Staff	12. Agricultural cultivator/ landholder
13. Unemployed		14. Housewife	
99. Not Applicable (For Never married/ widows/ widowers)			
12.1 SYNDROMIC DIAGNOSIS OF STD (Circle the appropriate number(s))			
Ano-genital Ulcer		1	
Urethral discharge/ Cervical discharge		2	
Genital Ulcer & Urethral Discharge/ Cervical discharge		3	
Ano-genital Warts/		4	
"Q 13" is ONLY FOR FEMALE RESPONDENTS (if respondent is male, encircle code "99")			
13. Does husband 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/ married/ male respondent)	
Signature_____		Signature_____	
Name_____		Name_____	
(Person completing the form)		(In charge of the Surveillance Site)	

To Be Completed at Testing Center

Laboratory results		
14 a) Testing for HSS (Please circle the appropriate number)		
First test	1. Positive	2. Negative
Second test	1. Positive	2. Negative 9. Not applicable (if first test is non-reactive)
14 b) Syphilis Serologic Testing (Please circle the appropriate number)		
Qualitative Test:	1. reactive	2. non reactive
Quantitative Test:	1. <1: 8	2. ≥1: 8 9. Not applicable (if first test is non-reactive)
Signature_____	Signature_____	
Name _____	Name _____	
<i>(Person completing the form)</i>	<i>(In-charge of the Testing Center)</i>	

Annex 7A : Flow chart for Management of Occupational Exposure

Occupational Exposure Management-sample Flow Chart					
Services provided	Day 0*	Day 3*	Week 4	Month 3	Month6
1. Immediate management steps					
• First aid	X				
• Reporting to designated PEP officer	X				
• Risk assessment	X				
2. PEP discussion					
• Discuss PEP*	X				
• Obtain informed consent	X				
• Give first dose of PEP medication if required	X				
3. Source assessment					
• Consent for HIV test or information of HIV treatment history	X				
• Rapid testing if available	X				
• Risk assessment-consider window period, population prevalence, risk behaviour	X				
4. PEP prescription					
• PEP eligibility confirmation	X				
• Assess prior HIV risk	X				
• Dispense PEP medications	X	X			
Adherence counselling		(if 3-day starter pack given)			
• Side effect counselling					
• Informed consent for PEP	X				
• Consider pregnancy	X		X		
• Arrange special leave from duty (2 weeks initially)	X	X			
	X	X			
5. HIV testing and counselling					
• Crisis counselling	X				
• HIV counselling and testing with informed consent (with further visit for results when available)##	X	X (If not done on day 0)	X	X	X (If PEP taken)
• Consider counselling/support for significant others	X	X	X	X	
• Advice on prevention of transmission	X	X			

Source: - www.nacoonline.org/Quick_Links/Publication/Treatment_Care__Support/

Annex 7B : Information Sheet for Health Care Providers on PEP

Information Sheet for Health Care Providers on Post-exposure Prophylaxis (PEP) and Follow-up after an Accidental Exposure to Blood (AEB)

This is to be given to the exposed person, for information only.

The doctor assessed that there is a risk of transmission of HIV infection as a result of this accidental exposure and the you and start antiviral prophylaxis, if you agree.

1. You must understand that this preventive medication (PEP):
 - Must be started, if possible, within 2 hours of the accidental exposure (within 72 hours at the latest) for maximum benefit.
 - Although there is strong evidence that PEP may prevent infection with HIV, but this preventive intervention is not 100% effective.
 - May cause minor side-effects (as with any medication), especially digestive problems, headache, fatigue, malaise, muscle ache or joint ache.
 - Must be taken regularly in two doses per day for 4 weeks (28 days)
 - Must be backed up by regular laboratory check-up
 - Requires the use of condoms during the period of PEP treatment until the results of the HIV testing at 3 months are known
 - Requires the use of efficient contraception during the period of treatment until the results of the HIV test at 6 months are known
 - If you stop taking PEP at any time, you will not get the full benefit of the medicaton
 - It is your choice whether or not to take PEP. You will be asked to sign a consent form.
2. The following is proposed as laboratory investigations and follow-up, if you agree:

Timing	In persons taking PEP (standard regimen)	In persons not taking PEP	Follow-up dates
Baseline (within 8 days after AEB)	HIV Hepatitis B and C Complete blood count Liver function test	HIV Hepatitis B and C	
Week 2 and 4	Liver function test Complete blood count	clinical monitoring for hepatitis	
Week 6	HIV	HIV	
Month 3	HIV Hepatitis B and C Liver function test	HIV Hepatitis B and C	
Month 6	HIV Hepatitis Liver function test	HIV Hepatitis B and C	

Source: www.nacoonline.org/Quick_Links/Publication/Treatment_Care__Support/

Annex 8 : Good Practices- (Do's and Dont's) for High Quality HSS

Do's	Dont's
<ol style="list-style-type: none"> 1. Ensure availability of all items required by HSS well in advance. 2. Follow strict inclusion criteria for individual selection at each site and fill the data forms completely. 3. Ensure correct labels and codes, and maintain confidentiality 4. Label the blood collection tube with site and sample code numbers, age, sex and date for each attendee at every site. 5. Follow universal precautions and good laboratory practice for collection of blood, separation of sera, storage and transport. 6. Report any accidental needle stick injury to Clinic / Site In charge. 7. Store the sera samples at +4°C for maximum one week, and freeze the sera after one week (-20°C). 8. Label one portion of serum in a storage tube with patient identity for routine syphilis serologic test and the second one with HSS codes for HIV and syphilis serology. 9. Perform syphilis serology and HIV test from the coded tube. 10. Follow correct HIV testing strategy and enter verified results on the data forms 11. Send sera of all HIV positive and 5% negative samples to reference laboratories for EQAS. 12. Follow biosafety precautions at each step and discard waste according to national guidelines. 	<ol style="list-style-type: none"> 1. Do not use blood collection sites/ laboratories far away from the clinic site. [Arrange to draw blood at the site.] 2. Do not write patients' identity, either on data forms or on the blood collection vials meant for HIV testing and do not try to link patients with their HIV status. [Ensure anonymous unlinked protocol is maintained for ANC and STD sites.] 3. Do not use same pipette/ tips for separation of different sera. [Use a new pipette for each sample to avoid cross contamination]. 4. Do not leave sera in the refrigerator more than a week. [Freeze at -20oC if storage required for more than 7 days]. 5. Do not repeat freeze thawing of sera. [Once frozen keep frozen until testing.] 6. Do not store HIV kit in the freezer compartment. [Store at +4oC]. 7. Do not use haemolysed or contaminated sera for HIV or syphilis serologic testing. [Testing centre in charges to inform the clinic/ site in charges the number of haemolysed sera; so that additional samples can be collected in time] 8. Do not report incorrect syphilis or HIV results in the data forms. [Double check your work and insist on 100% quality control] 9. Do not wait to send the data forms and samples to the testing centres till the end of the survey. [Send completed, checked data forms and samples in batches regularly to facilitate lab testing] 10. Do not wait for sending the data forms with lab entries to Regional Institute till the end of the survey. [Testing in charges should send completed, checked data forms in batches regularly to facilitate data entry.]

Annex 9A : HSS 2008 Data form for FSW Sentinel Group

(Circle appropriate options, complete where options are not available)

Date: __ __ / __ __ / __ __ __ __		2. State	3. District
1. Name of Sentinel Site:			
2.1 Sentinel Site Code:		2.2 Sub-Site Number: 0, 1, 2, 3, 4, 5 (Circle appropriately. Circle 0 if the site is not a composite site)	
3. Sample Number			
4. Age in completed years			
5. Education			
1. Illiterate		2. Literate and till 5th	3. Till 12th
4. Till Graduation		5. Graduate and above	
6. Reason for coming to the service point			
1. STD Treatment	2. Other Medical Care	3. Other	
7. Current place of residence			
1. Urban (Municipal Corporation/Council/Cantonment)		2. Rural	
8. Duration of stay at current place of residence: _____ year _____ months			
9. Type of sex work involved in? (Multiple options are allowed)			
1. Brothel based	2. Street based		
3. Home based	4. Others		
10. Duration of involvement in Sex Work			
1. < 6months	2. 6 months to 1 year	3. 1-3 years	
4. 3-5 years	5. >5 years		
11. Any other source of Income, apart from sex work?			
1. Yes	2. No		
If yes, specify _____			
12. Has she ever for pleasure injected drug without prescription?			
1. Yes	2. No		
Signature _____		Signature _____	
Name _____		Name _____	
(Person completing the form)		(In charge of the Surveillance Site)	
To Be Completed at Testing Center			
Laboratory results			
13. Testing for HSS (Please circle the appropriate number)			
First test	1. Positive	2. Negative	
Second test	1. Positive	2. Negative	9. Not applicable (if first test is non-reactive)
Signature _____		Signature _____	
Name _____		Name _____	
(Person completing the form)		(In-charge of the Testing Center)	

Annex 9B : HSS 2008 Data form for MSM Sentinel Group

(Circle appropriate options, complete where options are not available)

Date: __ __ / __ __ / __ __ __ __		State	District
1. Name of Sentinel Site:			
2.1 Sentinel Site Code:		Sub-Site Number: 0, 1, 2, 3, 4, 5 (Circle appropriately. Circle 0 if the site is not a Composite site)	
3. Sample Number			
4. Age in completed years			
5. Education			
1. Illiterate	2. Literate and till 5th	3. Till 12th Standard	
4. Till Graduation	5. Graduate and above		
6. Reason for coming to the service point			
1. STD Treatment	2. Other Medical Care	3. Other	
7. Current place of residence of the respondent			
1. Urban (Municipal Corporation /Council /Cantonment)		2. Rural	
8. Duration of stay at current place of residence: _____ year _____ months			
9. Current occupation of the Respondent			
1. Agricultural labourer	2. Non-agricultural labourer	3. Domestic servant	
4. Skilled/ Semiskilled worker	5. Petty business/ small shop	6. Large Business/Self employed	
7. Service (Govt./Pvt.)	8. Student	9. Truck Driver/helper	
10. Local transport woker/ (auto/taxi driver, handcart pullers, rickshaw pullers etc)	11. Hotel Staff	12. Agricultural cultivator/ landholder	
13. Unemployed			
10. Type of MSM			
1. Kothi	2. Panthi	3. Double Decker	4. No response
11. Did the respondent have any sexual intercourse with any female partner in last 6 months?			
1. Yes	2. No		
12. Has the respondent ever received money or payment in kind for sex?			
1. Yes	2. No	3. No response	
13. Has he ever for pleasure injected drug without prescription?			
1. Yes	2. No		
Signature_____		Signature_____	
Name _____		Name _____	
(Person completing the form)		(In charge of the Surveillance Site)	
To Be Completed at Testing Center			
Laboratory results			
14. Testing for HSS (Please circle the appropriate number)			
First test	1. Positive	2. Negative	
Second test	1. Positive	2. Negative	9. Not applicable (if first test is non-reactive)
Signature_____		Signature_____	
Name _____		Name _____	
(Person completing the form)		(In-charge of the Testing Center)	

Annex 9C : HSS 2008 Data form for IDU Sentinel Group

(Circle appropriate options, complete where options are not available)

Date: __ __ / __ __ / __ __ __ __		State	District
1. Name of Sentinel Site:			
2.1 Sentinel Site Code:		2.2 Sub-Site Number: 0, 1, 2, 3, 4, 5 (Circle appropriately. Circle 0 if the site is not a Composite site)	
3. Sample Number			
4. Age (in completed years)		5. Sex : 1. Male 2. Female	
6. Marital Status : 1. Never Married 2. Married 3. Divorced/separated/widowed			
7. Education			
1. Illiterate	2. Literate and till 5th	3. Till 12 th	
4. Till Graduation	5. Graduate and above		
8. Reason for coming to the service point			
STD Treatment		2. Other Medical Care	3. Other
4. Needle Exchange Program		5. Oral Substitution Therapy/ de-addiction	
9. Current place of residence of the respondent			
1. Urban (Municipal Corporation /Council /Cantonment)		2. Rural	
10. Current Occupation of the Respondent			
1. Agricultural labourer	2. Non-agricultural labourer	3. Domestic servant	
4. Skilled/ Semiskilled worker	5. Petty business/ small shop	6. Large Business/Self employed	
7. Service (Govt./Pvt.)	8. Student	9. Truck Driver/helper	
10. Local transport woker/ (auto/taxi driver, handcart pullers, rickshaw pullers etc)	11. Hotel Staff	12. Agricultural cultivator/ landholder	
13. Unemployed		14. Housewife	
11. Is the respondent a Shadow User? 1. Yes 2. No			
*Shadow users: IDUs who switch over to injectable drugs from oral or inhalational and have injected in the last six months			
12. Average frequency of injecting drugs			
1. once a week or less	2. Twice a week	3. Thrice a week	4. More than thrice a week
13. Duration of injecting drug use			
1. < 6months	2. 6 months to 1 year	3. 1-3 years	4. 3-5 years
5. >5 years			
Signature_____		Signature_____	
Name _____		Name _____	
(Person completing the form)		(In charge of the Surveillance Site)	
To Be Completed at Testing Center			
Laboratory results			
14. HSS testing (Please circle the appropriate number)			
First test	1. Positive	2. Negative	
Second test	1. Positive	2. Negative	9. Not applicable (if first test is non-reactive)
Signature_____		Signature_____	
Name _____		Name _____	
(Person completing the form)		(In-charge of the Testing Center)	

Annex 9D : HSS 2008 Data form for Eunuchs/TG Sentinel Group

(Circle appropriate options, complete where options are not available)

Date: __ __ / __ __ / __ __ __ __		State	District
1. Name of Sentinel Site:			
2.1 Sentinel Site Code:		2.2 Sub-Site Number: 0, 1, 2, 3, 4, 5 (Circle appropriately. Circle 0 if the site is not a Composite site)	
3. Sample Number			
4. Age in completed years			
5. Education			
1. Illiterate		2. Literate and till 5th	3. Till 12 th Standard
4. Till Graduation		5. Graduate and above	
6. Reason for coming to the service point			
1. STD Treatment	2. Other Medical Care		3. Other
7. Current place of residence of the respondent			
1. Urban (Municipal Corporation /Council /Cantonment)		2. Rural	
8. Duration of stay at current place of residence: _____ year _____ months			
9. Current Occupation of the Respondent			
1. Agricultural labourer	2. Non-agricultural labourer	3. Domestic servant	
4. Skilled/ Semiskilled worker	5. Petty business/ small shop	6. Large Business/Self employed	
7. Service (Govt./Pvt.)	8. Student	9. Truck Driver/helper	
10. Local transport woker/ (auto/taxi driver, handcart pullers, rickshaw pullers etc)	11. Hotel Staff	12. Agricultural cultivator/ landholder	
13. Unemployed			
10. Has the respondent ever received money or payment in kind for sex?			
1. Yes	2. No	3. No response	
11. Has respondent ever for pleasure injected drug without prescription?			
1. Yes	2. No		
Signature _____		Signature _____	
Name _____		Name _____	
(Person completing the form)		(In charge of the Surveillance Site)	
To Be Completed at Testing Center			
Laboratory results			
12. Testing for HSS (Please circle the appropriate number)			
First test	1. Positive	2. Negative	
Second test	1. Positive	2. Negative	9. Not applicable (if first test is non-reactive)
Signature _____		Signature _____	
Name _____		Name _____	
(Person completing the form)		(In-charge of the Testing Center)	

Annex 9E : HSS 2008 Data form for Single Male Migrants Sentinel Group

(Circle appropriate options, complete where options are not available)

Date: __ __ / __ __ / __ __ __ __		State	District
1. Name of Sentinel Site:			
2.1 Sentinel Site Code:		2.2 Sub-Site Number: 0, 1, 2, 3, 4, 5 (Circle appropriately. Circle 0 if the site is not a Composite site)	
3. Sample Number			
4. Age (in completed years)			
5. Marital Status : 1. Never Married 2. Married 3. Divorced/separated/widowed			
6. Education			
1. Illiterate	2. Literate and till 5 th	3. Till 12 th	
4. Till Graduation	5. Graduate and above		
7. Reason for coming to the service point?			
1. STD Treatment	2. Other Medical Care	3. Other	
8. Current place of residence of the respondent?			
1. Urban (Municipal Corporation /Council /Cantonment)		2. Rural	
9. Since when has respondent migrated to current place? _____ year _____ months			
10. 1 State of origin		10. 2 District of origin	
10.3 : Place of Origin? 1. Urban (Municipal Corporation/Council/Cantonment)			2. Rural
11. Current Occupation of the Respondent			
1. Student	2. Non-Agricultureal/labourer		
3. Domestic Servent	4. Hotel Staff	5. Agricultureal labor	
6. Skilled/ Semiskilled worker		8. Petty business/ small shop	
11. Service (pvt/ govt)	12. Professional/ self employed		
14. Local transport worker (auto/ taxi driver, handcart pullers, rickshaw pullers etc) and trucker			
Signature_____		Signature_____	
Name _____		Name _____	
<i>(Person completing the form)</i>		<i>(In charge of the Surveillance Site)</i>	
To Be Completed at Testing Center			
Laboratory results			
12. Testing of HSS (Please circle the appropriate number)			
First test	1. Positive	2. Negative	
Second test	1. Positive	2. Negative	9. Not applicable (if first test is non-reactive)
Signature_____		Signature_____	
Name _____		Name _____	
<i>(Person completing the form)</i>		<i>(In-charge of the Testing Center)</i>	

Annex 9F : HSS 2008 Data form for Long-Distance-Truckers Sentinel Group

(Circle appropriate options, complete where options are not available)

Date: __ __ / __ __ / __ __ __ __		State	District
1. Name of Sentinel Site:			
2.1 Sentinel Site Code:		2.2 Sub-Site Number: 0, 1, 2, 3, 4, 5 (Circle appropriately. Circle 0 if the site is not a Composite site)	
3. Sample Number			
4. Age (in completed years)			
5. Marital Status : 1. Never Married 2. Married 3. Divorced/separated/widowed			
6. Education			
1. Illiterate	2. Literate and till 5th	3. Till 12 th	
4. Till Graduation	5. Graduate and above		
7. Reason for coming to the site			
1. STD Treatment	2. Other Medical Care	3. Other	
8. Current place of residence of the respondent			
1. Urban (Municipal Corporation /Council /Cantonment)		2. Rural	
9. Average number of days in a month that are spent at home with family? _____ days			
Signature_____		Signature_____	
Name _____		Name _____	
<i>(Person completing the form)</i>		<i>(In charge of the Surveillance Site)</i>	
To Be Completed at Testing Center			
Laboratory results			
11. Testing for HSS (Please circle the appropriate number)			
First test	1. Positive	2. Negative	
Second test	1. Positive	2. Negative	9. Not applicable (if first test is non-reactive)
Signature_____		Signature_____	
Name _____		Name _____	
<i>(Person completing the form)</i>		<i>(In-charge of the Testing Center)</i>	

Annex 10 : Informed consent form for participating in HIV Sentinel Surveillance

This form explains the purpose for which blood sample is being collected and the method of blood collection. On reading/ understanding the following information, if you are willing to provide blood sample, you are requested to sign or make a thumb impression at the end of form. If you have any questions/ queries, you can ask us before giving the consent.

National AIDS Control Organization (NACO), the nodal national agency for control of HIV in India, conducts annual HIV surveys in different population groups to know how prevalent HIV is in India in different groups and overall . If you agree to participate in the survey, a few drops of blood will be collected from your finger on a filter paper and sent to laboratory for testing. We will use disposable sterile instruments that are clean and completely safe for this procedure. You can see the instruments that we will use for taking blood sample. The results will be anonymous. This means no one, including us or this agency, will be able to trace or connect the blood sample or the result of the HIV test back to you. To ensure this, , your name or address will not be attached to the blood sample. The testing will not be done over here. Since, in order to protect your confidentiality, we are not recording any information that will identify you in this survey, we cannot give you the result of the HIV test. However, if you wish to get your blood tested for HIV and know the result, we will give you a voucher for a free HIV test at a nearby health clinic where you can get your blood tested.

We would ask you some very personal questions that some people may find difficult to answer. Your answers are completely anonymous. You do not have to answer any questions that you do not want to answer. However, your honest answer to these questions will help us better understand the risk factors associated with HIV.

I hope you would participate in the survey because your answers will immensely help NACO to develop appropriate programs to prevent HIV/AIDS in your community and region and in India as a whole.

Do you have any questions?

I, _____ am willing to give my blood for HIV test by my own wish. I know that my HIV test result will not be disclosed to me. I also know that this data will be used for the National AIDS Control Program with full confidentiality.

Participant's name _____
(To be verified if the patient is illiterate)

Signature/ thumb impression _____ Name of witness _____

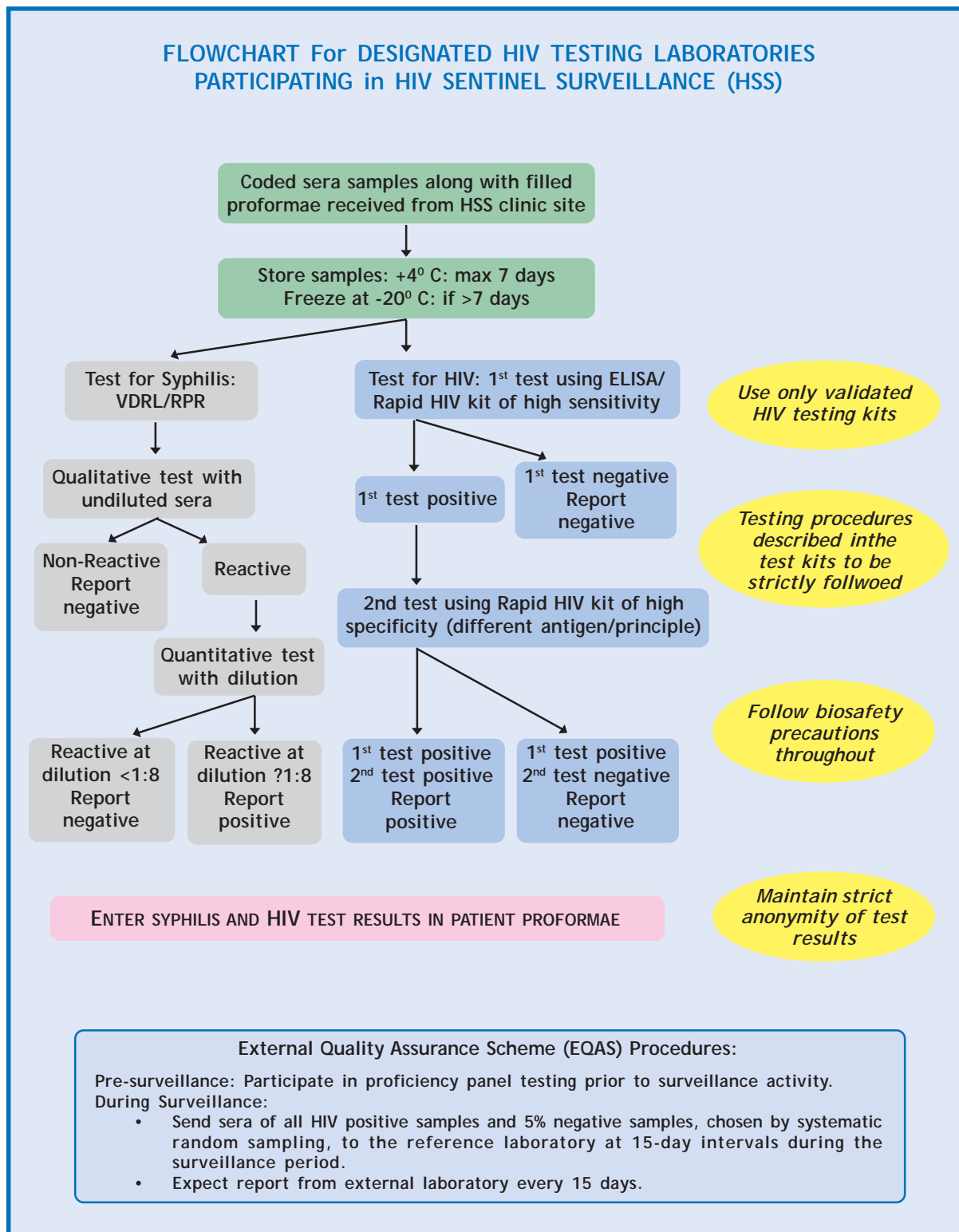
Date _____ Signature _____

Date _____

Counselor's Name _____

Signature _____ Date _____

Annex 11 : Flowchart for activities at testing center



Annex 12 A: Sample Verification Checklist (from testing centre to site)

(Fill in duplicate, one copy to be retained by the testing centre and the other copy for the site)

1. Name of the Testing centre: _____
2. Name of the site: _____
3. Date of sample received: _____
4. Total number of sample received
5. No. of samples rejected
 - Hemolysed Lipaemic Other
6. No. of vials leaking:
7. No. of vials with improper labeling:
8. Cold chain maintained: Yes No
9. Details on the transport sheet: Complete Incomplete
10. Data Forms matched with the samples: Yes No

Verified by: _____
 Name Signature with Date

Laboratory In-charge: _____
 Name Signature with Date

Annex 12 B: Sample verification Checklist for DBS samples

(Fill in duplicate, one copy to be retained by the testing centre and the other copy for the collection site)

1. Name of the Testing centre: _____
2. Date of sample received: _____
3. Total number of sample in the transport sheet :
5. No. of samples received:
6. No. of samples not received:
7. No. of samples not packed in ziplock bags:
8. No. of samples which do not contain dessiccant packs:
9. No. of samples which have less than five circles of dried blood spots:
10. No. of samples with improperly / inadequately filled circles:
11. No. of samples with colour of dessiccant / humidity indicator cards changed to pink:

Verified by: _____
 Name Signature with Date

Laboratory In-charge: _____
 Name Signature with Date

Annex 13 : Selected HIV rapid test kits*

S.No.	Name of kit	Antigen	Principle	Manufacturer	Sensitivity	Specificity
1	HIVTridot	Recombinant proteins	Immunofiltration	Biotech Inc, Himachal Pradesh India	100%	100%
2	Pareekshak	Recombinant proteins	Immunofiltration	Bhat Biotech India (P) Ltd.	Not mentioned	Not mentioned
3	ImmunoComb II HIV1 & 2 BiSpot	Synthetic Peptides	Indirect EIA	PBS Orgenics, France	100%	99.4%
4	HIV EIA Comb	Recombinant proteins	Dot Immunoassay	J. Mitra Co. Ltd.	100%	99.9%
5	CombAIDS-RS	Recombinant Synthetic peptides	Dot Immunoassay/Immuno Chromatographic	Span Diagnostics Ltd., G.I.D.C.Sachin & 394260, Surat, India	100%	98.7% 100%
6	CapillusHIV1 & 2	Recombinant proteins	Latex agglutination	Trinity biotech. ISA	99.6%	100%
7	NEVA HIV	Recombinant molecules having RBC binding sites	Particle agglutination	Cadila Pharmaceuticals, "Cadila Corporate Campus", Sarkhej Dholke Road, Bhat, Ahmedabad 382210, Gujrat	99%/99.9%	95%/98.5%
8	SD Bioline HIV 1/2 3.0	Recombinant	Immuno Chromatographic	SD Standard Diagnostics Inc 575/34 Pajang/Dang JanGanKu Suwon/Sikyong Do. Korea	100%	99.8%/100%
9	RetrocheckHIV	Recombinant	Lateral flow Immuno Chromatography	Qualpro Diagnostics, India	100%	99.8%
10	Precise	Recombinant	Immuno Chromatographic	Ranbaxy Lab. Ltd., Diagnostic Division, A-3, Okhla Industrial Area, Phase 1, New Delhi-110020	100%	99.6%
11	HIV Spot	Recombinant	Membrane filtration	Gene Lab. Diagnostics Ltd., 85 Sciences Park Division, No.04/01, Singapore Science Park	100%	99.5%
12	ImmunoComb II	Synthetic	Synthetic	Orgenics, P.O. Box 360, YAVNE 70650, Israel	100%	98.4%

SELECTED ELISA TEST KITS

S.No.	Name of the kit	Antigen	Principle	Manufacturer	Sensitivity	Specificity
1	Ani Lab. systems (Elisa based)	Synthetic peptide	Indirect Solid Phase (EIA)	Ani. Lab. Systems Ltd. OY Museekatu 13B Fin-00100 Helsinki, Finland	100%	99.5%
2	Micro Iisa HIV	Recombinant Protein	Indirect Elisa	J. Mitra & Co. Ltd. A-180, Okhla Area, Ph-1, NewDelhi-20	100%	99.5%
3	Eliscan HIV	Synthetic peptide	Indirect Solid phase	Ranbaxy Lab. Ltd. Diagnostic Division A-3, Okhla Industrial Area Phasee-1, New Delhi-110020	100%	99.5%
4	HIVASE1+2	Recombinant	Direct sandwich method	General Biological Corporation Innovation 1st Road Science Based Industrial Park HSINCHU Taiwan, Roc	Not mentioned	Not mentioned

Disclaimer :

The tables above are a listing of commonly used HIV test kits in VCTCs. The list does not attempt to be exhaustive technical purposes to illustrate different HIV testing principles.

The mention of specific companies or of certain manufacturers' products or names of HIV test kits does not imply the endorsed or recommended by NACO in preference to others of a similar nature that are not mentioned here.

The technical information provided in the table is based solely on the technical information provided by the manufacture or represent that the information in the table is accurate complete and error-free. The list will be updated regularly.

Selected HIV Rapid Test kits (document with landscape formatting as separate file) Selected ELISA test kits

Rapid Test Combination

Example (1)

Sl. No.	Name	Principle	Antigen
1	NEVA HIV	Particle agglutination	Recombinant
2	HIV Spot	Membrane filtration (Immunofiltration)	Recombinant
3	Immuno Comb II	Immuno dot (Indirect solid phase) EIA	Synthetic

Comment:

- (1) & (2) have different principles being particles agglutination and membrane filtration (immuno-filtration), (3) has synthetic antigen which is different from (1) and (2) which is recombinant.
- In case of HIV spot, the manufacturer mentioned the principles of membrane filtration although it is a type of Immunocomb. HIV Spot is both membrane filtration & dot blot type and Immunocomb is both Immunodot & Indirect solid phase.
- In case of Immunocomb, the manufacturer mentions the principles as Indirect solid phase although it is a type of immunodot.

Example (2)

Sl. No.	Name	Principle	Antigen
1	Capillus HIV 1 & 2	Latex agglutination	Recombinant Protein
2	SD bioline HIV 1 & 2 3.0	Immuno Chromatographic	Recombinant Protein
3	Immuno Comb II HIV 1 & 2 Bispot	Indirect EIA (Comb test)	Synthetic peptide

Comments:

(1) and (2) have different principles, e.g. latex agglutination and Immunochromatographic (3) has synthetic peptides which is different from (1) and (2) which is recombinant.

Example (3)

Sl. No.	Name	Principle	Antigen
1	HIV Spot	Membrane filtration	Recombinant
2	Capillus HIV-1 & 2	Latex agglutination	Recombinant
3	Comb AIDS-RS	Dot blot/Immunochromatographic	Recombinant & Synthetic peptides

Comments:

(1) and (2) have principles of membrane filtration and latex agglutination while (3) has antigen as synthetic peptides. Further (3) is immunochromatographic in principle.

Annexe 14 : Transport of samples from Testing Centre to NRL

QA Sample transport sheet

(Fill in duplicate, one copy to be retained by the testing centre after acknowledgement and the other copy for the NRL)

1. Date of sending the samples:
2. Name of the TC: Centre Code:
3. Period of sample testing: (From _____ To _____)
dd / mm / yy dd / mm / yy
4. Total number of samples:

5. Details of Samples:

HIV Negative Samples

Sr. No.	Date of collection	Sample No.	Sr. 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		

HIV Positive Samples

Sr. No.	Date of collection	Sample No.	Sr. 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 in above table is not sufficient, attach another sheet

Samples sent by: _____ (Name) _____ (Signature)

Samples received at NRL by: _____ (Name) _____ (Signature)

Annex 15 : Sample Verification Checklist (from NRL to Testing centre)

(Fill in duplicate, one copy to be retained by the NRL and the other copy for the site)

1. Name of the Testing centre:	_____		
2. Name of the Testing center:	_____		
3. Date of sample received:	_____		
4. Total number of sample received	<input type="text"/>		
5. No. of samples rejected	<input type="text"/>		
	Hemolysed	<input type="text"/>	Lipaemic <input type="text"/> Other <input type="text"/>
6. No. of leaking vials:	<input type="text"/>		
7. No. of vials with improper labeling:	<input type="text"/>		
8. Cold chain maintained:	Yes <input type="checkbox"/>	No	<input type="checkbox"/>
9. Details on the transport sheet:	Complete <input type="checkbox"/>	Incomplete	<input type="checkbox"/>
10. Data Forms matched with the samples:	Yes <input type="checkbox"/>	No	<input type="checkbox"/>
Verified by:	_____	_____	_____
	Name		Signature with Date
Laboratory In-charge:	_____	_____	_____
	Name		Signature with Date

Annex 16 : Transport of Data Forms from Testing Centre to SACS

Data forms Transport Sheet

(Fill in duplicate, one copy to be retained by the testing centre after acknowledgement and the other copy for the RIs)

1. Date of sending the DCFs:	___ / ___ / _____		
2. Name of the TC:	_____		
3. Name of the site:	_____		
4. Site code:	_____		
5. Total number of DCFs:	_____		
6. DCFs for sample numbers:	From _____	To _____	
DCFs sent by:	_____	_____	_____
	Name		(Signature)
DCFs received by:	_____	_____	_____
	Name		(Signature)

Annex 17 : Check list of Supplies at Sentinel Site Clinic and Testing Center

Laboratory Items	
At Clinic Sites	
1.	Adequate sterile syringes, needles/ vacutainers
2.	Sterile, plastic, screw capped 10 ml blood collection tubes*
3.	Sterile, plastic, screw capped 2 ml storage vials with O vials*
4.	Spirit swabs, tourniquet, adhesive tapes
5.	Needle destroyer
6.	Puncture proof containers and Hypo chlorite solution
7.	Pasteur pipettes/ micropipettes, sterile disposable plastic tips *
8.	Centrifuge*
9.	Labels/ stickers and marking pens
10.	Color coded bags for bio waste disposal
11.	Gloves, aprons
12.	Refrigerator
13.	Appropriate number and type of Data forms
#	Targeted Intervention sites must ensure that they have an adequate number of DBS collection kits before start of the surveillance
*ANC/STD sites only	
At Testing Center	
For HIV Serology Test	
1.	Micropipettes for conducting ELISA/ Rapid Test
2.	Approved HIV test kits(ELISA and/ or Rapid Test - two test kits required) and all additional reagents required
3.	Equipment for ELISA test (ELISA reader and washer)
4.	Timer
For Syphilis Serology Test	
1.	Syphilis testing reagents (RPR kits)
2.	Micropipettes/ glass graduated pipettes (0.5 ml.)
3.	Rotator for syphilis serology
4.	Timer
General Laboratory	
1.	Gloves/ aprons/ masks
2.	1% hypochlorite solution / other disinfectant
3.	Refrigerator with freezer
4.	-20° C freezers (at testing centres)
5.	Autoclave

Annex 18 : Checklist for Monitoring of Sentinel Sites

1. Date of Monitoring Visit:
2. Name of the Sentinel Site:
3. Type of sentinel site:
4. Location of the Site: Urban Rural
5. Frequency of OPD
- Comments:

6. Personnel & training

Sr. No.	Name	Designation	HSS 2008 Training	
			Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No

Comments:

.....

.....

7. Clinic infrastructure Adequate Inadequate

Comments:

.....

8. Blood collected at Clinic site Laboratory
- Distance from the clinic/ site Close to clinic Away from clinic

Comments:

.....

9. Consumables Adequate Inadequate

Comments:

.....

10. Site laboratory infrastructure Adequate Inadequate

Comments:

.....

11. Essential laboratory equipment: Adequate Inadequate

Comments:

.....

12. Personal protective devices: Adequate Inadequate

Comments:

.....

13. Data from HSS 2008

- a. No. of blood samples collected till date:
- b. Frequency & number of samples dispatched to testing center:
- c. No. of sample collected on the day of visit:
- d. Matching number of data forms with number of samples collected:

Comments:.....

14. Inclusion/exclusion criteria followed? Yes No

Comments:.....

15. Consecutiveness in sampling maintained? Yes No

Comments:.....

16. Anonymity maintained Yes No

Comments:.....

17. Total OPD attendance since the start of HSS (to be verified from the hospital register) _____

18. Whether data forms were filled properly? Yes No

19. Storage of serum samples Satisfactory Unsatisfactory

20. Labeling of serum vials Satisfactory Unsatisfactory

21. Sample transport sheets used Yes No

22. Were all records maintained properly? Yes No

Summary (important observations):

1.
2.
3.
4.
5.

Additional comments if any:

.....

.....

Problems/ concerns reported by testing centre staff (please record comments of TC staff only)

1.
2.
3.
4.
5.

Name and Signature of the Monitors

1.
2.

Annex 19 : Checklist for Monitoring of Testing Center

1. Date of Monitoring Visit:
2. Name of the Testing Center:
3. Name of the Laboratory in- Charge:
4. Number and Names of Sentinel Sites attached to the Center:

S.N.	Site Code	Type of Sentinel Site ANC/ TI/ STD/ Special	Name of the site

5. Personnel & training

Sr. No.	Name	Designation	HSS 2008 Training	
			Yes	No
			Yes	No
			Yes	No
			Yes	No
			Yes	No

Comments:

.....

6. Lab. infrastructure at testing center: Adequate Inadequate

Comments:

.....

7. Equipment

Name	Years in service	Functioning	Not functioning
ELISA Washer			
ELISA Reader			
Deep Freezer (-20°C)			
Refrigerator			
Centrifuge			
Micropipettes			
Timer			

Comments:

8. Personal protective devices

Gloves Available Not available
 Aprons Available Not available

Comments:

9. Kits

Type	Name	Manufacturer	Lot. No.	Expiry
HIV ELISA				
HIV Rapid				
RPR				

10. Storage of kits: Satisfactory Unsatisfactory

Comments:

11. HIV testing methodology

a. First test ELISA Rapid
 b. Second test ELISA Rapid

Comments:

12. Data from HSS 2008

- a. No. of samples received till date
- b. No. of sample rejected till date
- c. No. of samples tested for HIV till date
- d. No. of samples found positive by First test
- e. No. of samples found positive by Second test
- f. Were the results verified by Lab. in Charge/Supervisor? Yes No
- g. Performance in 2007 round of
- i) HIV EQAS 100% Less than 100%
- ii) HSS Quality Control 100% Less than 100%

Comments:

h. RPR testing:

- i) No. of samples tested for RPR
- ii) No. of samples positive for RPR <1:8 =>1:8

Comments:

13. Laboratory safety practices adequately followed? Yes No

Comments:

14. Storage of serum samples :

15. Whether all the documents related to HSS were properly maintained? Yes No

16. Whether the site personnel were responsive and cooperative? Yes No

Summary (important observations):

1.
2.
3.
4.
5.

Additional comments if any:

Problems/ concerns reported by testing centre staff (please record comments of TC staff only)

1.
2.
3.
4.
5.

Name and Signature of the Monitors

1.
2.

Annex 20 : A Technical Resource Group on “Surveillance and Estimation” is constituted for providing Technical support in the implementation of NACP-III

The list of Technical Resource Group is as follows:

1.	Dr. N.K. Ganguly Director General, Indian Council for Medical Research New Delhi.	Chairperson
2.	Ms. Sujatha Rao Additional Secretary & Director General, NACO.	Co-Chairperson
3.	Dr. L.M. Nath NewDelhi.	Member
4.	Dr. M.D. Gupte, Director National Institute of Epidemiology, Chennai.	Member
5.	Dr. M. Bhattacharya Department of CHA, NIHFV, New Delhi.	Member
6.	Dr. Arvind Pandey Director, National Institute of Medical Statistics Indian Council for Medical Research New Delhi.	Member
7.	Dr. J.P. Narain Director, Communicable Diseases, World Health Organization South East Asia Regional Office New Delhi.	Member
8.	Dr. D.C.S. Reddy National Programme Officer, WHO - India.	Member
9.	Dr. A. Indrayan Biostatistician, UCMS, New Delhi.	Member
10.	Dr. Meera Sharma Prof. & Head, Deptt. Of Microbiology, PGIMER, Chandigarh.	Member
11.	Dr. Shashi Kant, Prof. of Community Medicine, AIIMS, New Delhi.	Member
12.	Dr. Rajesh Kumar Professor & Head, Department of Community Medicine Chandigarh.	Member
13.	Dr. J.P. Muliya Professor & Head, Department of Community Medicine CMC, Vellore.	Member
14.	Dr. Prabhat Jha CGHR, Toronto.	Member
15.	Dr. Paul De Ley Director Evaluation, UNAIDS.	Member
16.	Dr. Peter Ghys Manager, Impact Monitoring UNAIDS.	Member
17.	Dr. Tobi Saidel Family Health International, New-Delhi	Member
18.	Dr. Gina Dallabetta Avahan-India AIDS Initiative Bill & Mel inda Gates Foundation, New Delhi.	Member
19.	Dr. Ajay Khera Joint Director NACO.	Member Secretary
Other Members:		
1.	Dr. Renu Garg SEARO, World Health Organisation, IP Marg, New Delhi 110002	
2.	Dr. Guru Murthy Rangaiyan UNAIDS- AIDS Aruna Asaf Ali Marg, New Delhi - 110067	

Annex 21 : Directory of Focal Persons

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National AIDS Control Organisation

Ministry of Health and Family Welfare

Government of India

New Delhi

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