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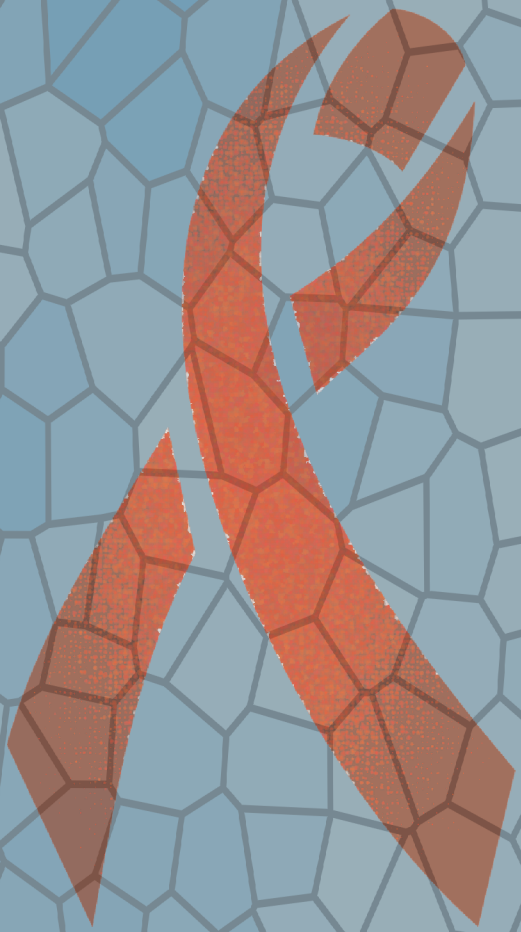
Operational Guidelines for HIV Sentinel Surveillance



NACO

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

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Operational Guidelines for HIV Sentinel Surveillance

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Abbreviations

AIIHPH . . . . . All India Institute of Hygiene and Public Health, Kolkatta

AIIMS . . . . . All India Institute of Medical Science

ANC . . . . . Antenatal Clinic

BSS . . . . . Behavioral Surveillance Survey

ELISA . . . . . Enzyme Linked Immunosorbent Assay

EQAS . . . . . External Quality Assurance Scheme

FSW . . . . . Female Sex Worker

HIV . . . . . Human Immunodeficiency Virus

HSS . . . . . HIV Sentinel Surveillance

IBBA . . . . . Integrated Biological and Behavioral Assessment

ICMR . . . . . Indian Council for Medical Research

IDU . . . . . Injecting Drug User

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 diseases, New Delhi

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

OBG . . . . . Obstetrics and Gynaecology

PGIMER . . . . . Post-Graduate Institute of Medical Education and Research, Chandigarh

PHC . . . . . Primary Health Care

RFWTC . . . . . Regional Family Welfare Training Centre

RI . . . . . Regional Institution

RPR . . . . . Rapid Plasma Reagent

RRL . . . . . Regional Reference Laboratory

SACS . . . . . State AIDS Control Society

SOP . . . . . Standard Operating Procedure

SST . . . . . State Surveillance Team

STD . . . . . Sexually Transmitted Diseases

TI . . . . . Targeted Intervention

VCTC . . . . . Voluntary Counseling and Testing Centers

VDRL . . . . . Venereal Disease Research Laboratory

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Foreword

India today has a nationwide structured Annual Sentinel Surveillance programme, launched to obtain essential information on the dynamics of the HIV epidemic, 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 activities have grown and the network of sentinel sites has expanded from a couple of centres to 180 sites in 1998, and the number stands at 1122 sentinel sites in 2006, thus establishing a progressive HIV sentinel surveillance in the country. In 2006 for the first time sentinel sites have been established in almost all the districts of the country.

National Institute of Health and Family Welfare has been identified as nodal agency for coordinating sentinel surveillance in the country. In order to maintain the quality of data five regional public health institutes in the country have been involved in monitoring and supervision of the surveillance activity including laboratory monitoring. 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.

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, NIHFW and reference laboratories. The guidelines also provide an overview of strategy, sentinel population size, inclusion criteria and the methodology for each type of sentinel population. The guidelines include formats/checklists for uniformly collecting the data and list of duties to be performed by various personnel in the surveillance activities at different levels.

The Operational Guidelines on Surveillance have been drafted by a wide consultation process including experts from all over the country and keeping in view HIV Sentinel Surveillance needs of the country. The National AIDS Control Organisation would like to acknowledge the support provided by National Institute of Health and Family Welfare and Bill & Melinda Gates Foundation (BMGF) in the development of these guidelines. Our special thanks go to Dr. Gina Dalabetta, BMGF for her support in finalizing the guidelines. These guidelines will help in standardizing the data collection and provide comprehensive guidance to persons working at sentinel sites and SACS.

The contribution of Dr. M. Bhattacharya (NIHFW), Dr. DCS Reddy (WHO India), Dr. Arvind Pandey (NIMS), Dr. Tobi Saidel (FHI), Dr. Renu Garg (WHO SEARO) and Dr. Gurumurthy Rangaiyan (UNAIDS India), who were responsible for coordinating and developing these guidelines is acknowledged. Our thanks also go to Dr. L. M. Nath, Dr. Shashi Kant, Dr. Rajesh Kumar, Dr. Girish Kumar Pandey, Dr. M.D. Gupta and Dr. S Mehendle.

The technical contribution and coordination role of Surveillance team at NACO consisting of Dr. Jotna Sokhey, Additional Project Director, Dr. Ajay Khera Joint Director, Dr. Girish Kumar Makhija and Dr. Yujwal Raj is also appreciated.

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Introduction

The HIV Sentinel Surveillance (HSS) system in India involves carrying out cross-sectional studies of HIV seroprevalence (also known as prevalence surveys) at regular intervals among selected groups of people. These populations are also referred to as "sentinel groups". With HSS, the trends in HIV infection are monitored over time by group and by place. In general, HIV surveillance is either community-based (individuals from a community are sampled in a scientific manner) or clinic/health facility- NGO based. Clinic, health facility, NGO based sampling is much more convenient, less costly and can be done more easily and this forms the basis of the our HSS. The HSS data is supplemented at intervals with community-based data but these data collection activities are difficult and expensive and are done as special studies.

Since 1998, the National AIDS Control Organization (NACO) in collaboration with the National Institute of Health & Family Welfare (NIHFW) and the National Institute of Medical Statistics (NIMS), Indian Council for Medical Research (ICMR), have been conducting annual rounds of HIV surveillance in designated sentinel sites all over the country. Over the years, the number of sentinel sites has increased from 180 in 1998 to 703 sites during 2005 to 1122 in 2006. These sites are in various high-risk population groups, antenatal clinics (ANC) and sexually transmitted diseases (STD) clinics. Additionally, from 2003, surveillance of the ANC (Rural) sites, TB sites, migrant population, eunuchs and truckers has also been initiated to understand the spread of epidemic in rural areas and other vulnerable groups of the country.

1. Objectives of HSS

The objectives of HSS are:

a) To provide an understanding of the spread of HIV infection by determining the level of infection in different States and identifying pockets of high prevalence ("hot spots");

b) To determine the geographical distribution and time trends of infection;

c) To provide information for the prioritization of resources and evaluation of the national response;

d) To estimate number of people infected with HIV in the country, utilizing the HSS data in the absence of any other reliable community based data.

e) To identify data to facilitate the integration of HIV/AIDS and Reproductive Child Health (RCH) programme under the National Rural Health Mission (NRHM).

2. Strategy

In order to meet these objectives, the surveillance system focuses on critical populations and geographical areas based on epidemiological considerations. Considering the patterns of HIV epidemic in the country and globally, high-risk groups, of whom female sex workers (FSW), men having sex with men (MSM) and injecting drug users (IDU) are the core risk groups, are infected first. Following this, the bridge population, 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 wives and girlfriends in 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, and with time HIV infection will appear in low risk individuals (general population).

For the purposes of HSS, easily and clearly defined and consistently accessible groups will be selected as sentinel populations and recruited from facilities such as ANC\STD clinics, NGO centers or other sites. From the programme point of view, sentinel sites have been selected to include all the important transmission categories in the country, e.g. sexual and parenteral transmission. Furthermore, the chosen sentinel sites are to be accessible and conveniently located and have a sufficient number of individual, either patients or individual receiving prevention services, to sample the required number for surveillance, 250 or 400 individuals according to the type of clinic/sentinel population, during the recruitment period. Sites which meet these criteria include STD clinics/obstetrics and gynecology (OBG) clinics, clinics at drop-in centers for MSMs and FSWs and drug de-addiction /harm reduction centers for IDU. ANCs are suitable for accessing pregnant women who are surrogate for the general population. In an "unlinked anonymous" manner, individuals from these sites, where blood is already being drawn for diagnosis, e.g. syphilis serologic testing, could be tested for HIV by separating some of the sera and removing all personal identifiers and testing in a separate laboratory. This strategy would protect the identity of HIV positive persons and in turn prevent participation bias. All individuals based on clearly defined selection criteria are consecutively sampled during the surveillance period to avoid selection bias. To avoid double counting of individuals, that is, individuals being tested twice during the surveillance period, only individuals showing up for the first-time during the surveillance period will be sampled. For example, pregnant women coming for their first ANC visit, STD patients with a new STI and high-risk groups being seen during their first visit to the drop in center are taken consecutively during the surveillance period. Each year is a new round of surveillance, so all individuals are eligible to participate as a "first visitor" even if they were sampled in a previous round of HSS.

2.1 Sentinel Population and Size

For surveillance purposes the sentinel populations are divided by transmission pattern into high and low-risk groups. For sampling purposes, individuals between the ages of 15 and 49 years are eligible for all sentinel groups. The different risk groups to be included in HSS are depicted in Table 1. At sites where attendees are few at main site and the likelihood of achieving the sample size is low, satellite sites of the same sentinel category, 2 to 3 in number with a prefixed sample size of 50 and above may be taken to complete sample size (termed "composite sampling"). For this, private clinics may be considered and included. If satellite sites are chosen, these must be included in all subsequent rounds of HSS.

Table 1: Risk Groups included in HSS

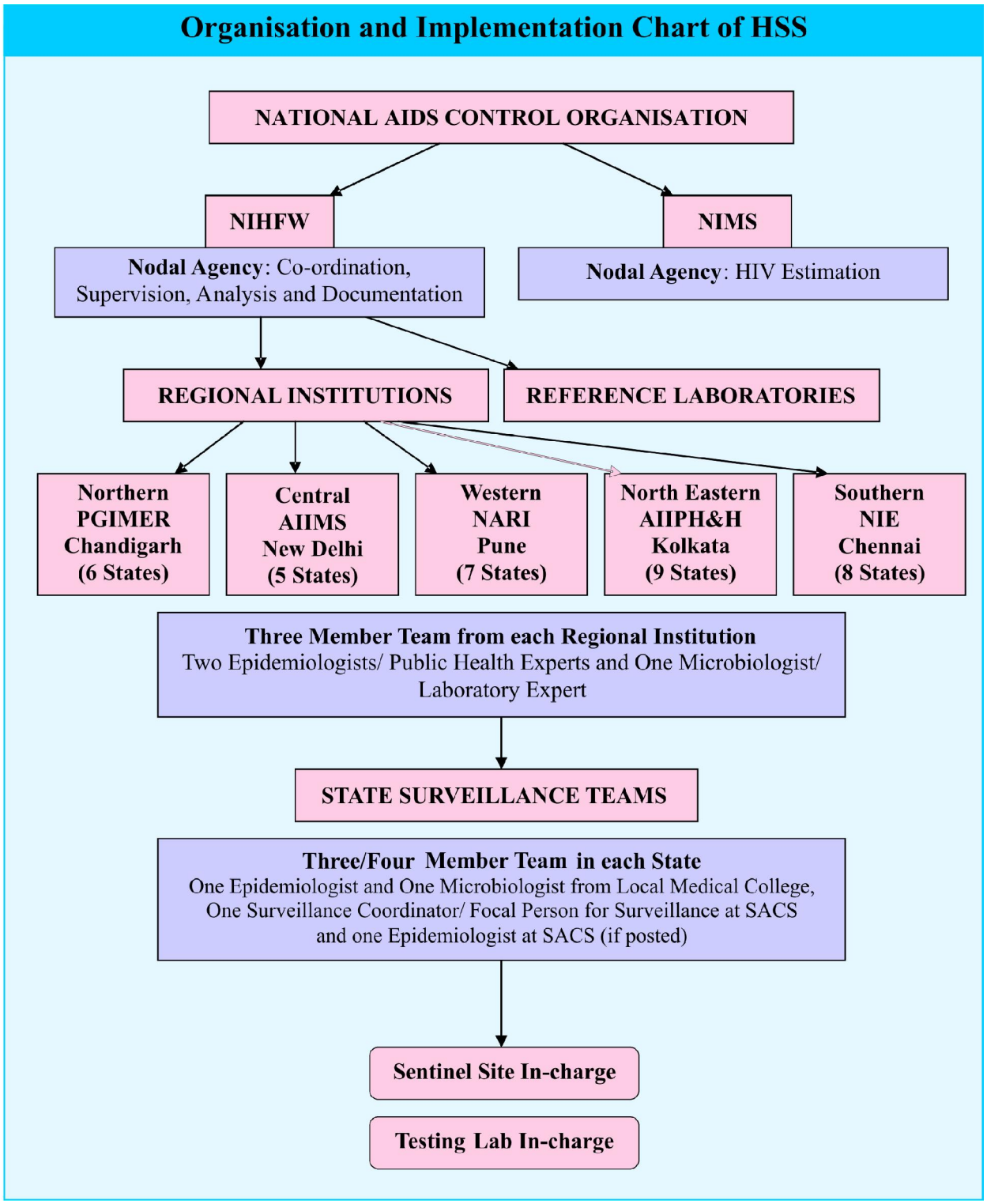
Groups	Description	Number of Samples
High Risk	Female sex workers	250 from each site
	Men who have sex with men	250 from each site
	Injecting drug users	250 from each site
	Eunuchs / Transgenders	250 from each site
General Population	Pregnant women	400 from each site
Special Groups	Patients with STD (males and females)	250 from each site
	Truckers	250 from each site
	High-risk migrants (males only)	250 from each site
	Patients with TB	250 from each site

2.2 New Sites

The number of sites was increased significantly in the 2006 HSS round with an aim to represent the vulnerable states in Northern India and other high risk areas in the country. As a result, every district in the country now has a sentinel site from one or more of the sentinel groups outlined in Table 1 above. While NACO does not anticipate adding large numbers of additional ANC sites during subsequent rounds, there is need for additional high-risk group sites given the focus on the National AIDS Control Program - 3 (NACP) and State AIDS Control Societies (SACS) are encouraged to add new high-risk group sites. A decision tree for selection of new sites is given in Annexure I. New sites must be submitted by the Regional Institutes and SACS to NIHFW. Please note that once a site is added it must be included in all subsequent HSS rounds as it is the trends of HIV infection that are important to monitor.

3. Organization and Implementation of HIV Sentinel Surveillance 2006

3.1 Organizational Structure



The NIHFW and NIIMS -ICMR, will act as nodal agencies, with support from NACO. The implementation of surveillance activities (Figure1) will be carried out by the SACS who will be provided technical support from identified Regional Institutions (RI) and State Surveillance Teams (SST). The State Surveillance Team will be identified by Regional Institutions and will consist of three\four member team in each state, one epidemiologist and one microbiologist from local medical college, one surveillance co-ordinator/focal person for surveillance at SACS and one epidemiologist at SACS (if posted).

NACO will provide facilitation, guidance and budget for each level in order to accomplish the task of HSS all over the country. An organization 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 Table 2 below:

Table 2: Activities at different levels during HSS

Agency	Function
National level	
National Institute of Health & Family Welfare, New Delhi	(1) Coordination, preparation of guidelines for surveillance, finalization of sites, monitoring and supervision, data collection and analysis, reporting at national level.
National Institute of Medical Statistics, New Delhi.	(2) Monitoring of data quality and HIV estimation.
Regional Level	**Role of RegionalRegional Institutes**
Regional Institutes (RIs) Regional Reference Laboratory (RRL)	(1) Orientation of State Surveillance Teams (2) Assistance to State Surveillance Teams for: ❑ identification of news sites ❑ monitoring and supervision ❑ quality control at all levels ❑ data quality and analysis at state level (3) External quality assurance test at each HIV testing center. (4) Supply of panel sera to sentinel sites.
State Level	
State Surveillance Teams - three/four member team in each state, one epidemiologist and one microbiologist from local medical college, one surveillance coordinator/focal person for surveillance at SACS and one epidemiologist at SACS (if posted).	1) Operationalize surveillance in the state 2) Training of incharges of sentinel sites and HIV testing sites and other paramedical staff. 3) Supervision and monitoring of data collection and reporting 4) Submit state Report to SACS, RI and NACO
Site Level	
Sentinel Site In-charge, Laboratory Technician and other paramedical staff	(1) Data collection at sentinel site and transfer of samples to testing sites
Testing Laboratory	
HIV Testing Laboratory In-charge and Sentinel Site In-charge.	(1) HIV and syphilis serologic testing (e.g, VDRL, RPR) (2) Recording of results (3) Transfer of results to SACS.

In order to identify high risk sites, Regional Institutes and State Surveillance Teams will assist SACS in carrying out epidemiological assessment of the districts for finalizing the sites. The work of State Surveillance Teams will be coordinated by the Regional Institutes. The Regional Institutes and SACS will submit the final list of sentinel sites to NIHFW, New Delhi. The Regional Institutes identified in different regions with the States assigned to them are shown in *Table 3* below:

Table 3: Regional Institutes Identified for Coordinating HSS

Name of Institutions	States
National Institute of Epidemiology, ICMR, Chennai	Orissa, Andhra Pradesh, Tamil Nadu, Karnataka, Kerala, Pondicherry, Lakshadweep, and Andaman & Nicobar Islands.
All India Institute of Hygiene and Public Health, Kolkata	Assam, Arunachal Pradesh, Manipur, Meghalaya, Mizoram, Nagaland, Sikkim, Tripura and West Bengal
Post-graduate Institute of Medical Education and Research, Chandigarh	Haryana, Himachal Pradesh, Jammu & Kashmir, Punjab, Chandigarh and Chattisgarh.
National AIDS Research Institute, Pune	Maharashtra, Gujarat, Goa, Madhya Pradesh, Rajasthan, Daman & Diu, Dadar Nagar Haveli
All India Institute of Medical Science, New Delhi	Uttar Pradesh, Bihar, Jharkhand, Uttaranchal, Delhi

3.2 Designated Individuals at Sentinel Sites

The responsible individuals at each site will be identified and designated to carry out their respective work till the HSS round is over. It is suggested that the following category of staff must be designated and adequately trained well in advance to carry out the various activities, with emphasis to follow the given criteria for choosing samples at all sites.

At sentinel sites	In-charge sentinel site	1
	Nursing assistant	1
	Laboratory technician	1
At HIV testing laboratory	In-charge HIV testing lab	1
	Laboratory technician	1

The activity plan for a typical HSS round is given in **Annexure 2.**

4. Frequency and Period of Survey

HIV sentinel surveillance is carried out once a year to look at HIV infection trends. The annual round of HSS will be conducted in designated sentinel sites for twelve weeks during the last quarter of the year or dates specified by NACO.

5. Training and Capacity Building

Nation-wide training of designated staff at different levels would be conducted for all engaged in HSS, including the staff at proposed new sites. The programme of capacity building will be according to the training plan of NACO (see Annexure 3) and is briefly outlined below:

a) Orientation of five regional institutions at NIHFW, New Delhi by the Task Force Members, on the strategy for conducting the HSS will be done. This will include training in the overall HSS goals, data collection, data recording, monitoring and supervision at different levels, laboratory testing and biosafety precautions.

b) Orientation / refresher training of State Surveillance Teams including the Joint Director (Surveillance) or focal person for surveillance at the respective regional institutes will be done.

c) Following this training of the State Surveillance Teams, they will conduct training on the appropriate procedures for implementing sentinel surveillance to all categories of workers in the State involved in the surveillance activities. In order to adequately appraise the designated staff on the guidelines for HSS, the training for staff will be for two days for new sites and one day for old sites.

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, re-training of old staff to be carried out.

e) A uniform training curriculum outlined by RIs in Annexure 3 must be followed by all.

f) For data entry operators and monitoring and evaluation (M&E) officers who will need to work with offline and online software for data entry and analysis training, this training will be conducted at NIHFW, New Delhi.

6. Methodology

6.1 Surveillance Protocol

6.1.1 The Surveillance Site

The protocol for sample collection from the surveillance site is to collect consecutive blood samples from the start of the surveillance activity till the predetermined sample size is reached or the surveillance period is over. The surveillance sites are clinical settings in the case of ANC and STD samples. They, however, may be NGO TI sites, drop-in centers, or detoxification centers in the case of high-risk groups (see section 6.1.2). Often, some patients attending a surveillance site may opt to drop out if referred for blood testing to the laboratory. The referral will cause inconvenience to the patient especially if the laboratory is far away from the surveillance site. This drop-out leads to participation bias. As such, sample collection, e.g., the drawing of blood, should be arranged at the surveillance site.

6.1.2. The Inclusion Criteria for sampling are defined for each sentinel group as follows. The collection of samples in these sites must be based strictly on the inclusion criteria and sampling procedure. Consistent implementation with clear definitions allows for more accurate monitoring of trends.

- **STD Sentinel Group:**
  - **Site:** The sites for the STD sentinel group consists of two clinic sources - STD clinic and OBG clinic, in the same hospital or a hospital designated by SACS for HSS
  - **Sampling:** A total of150 samples from STD clinics and 100 samples from OBG clinics should be collected from consecutive new cases with STD complaint. The sample is combined for a total sample size of 250 individuals.
  - **Inclusion criteria:** Only consecutive new cases of STDs with genital ulcers, urethral discharge, cervical discharge and ano-genital warts should be included. Note, for women in order to determine eligibility 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. Only persons between the ages of 15 and 49 years are eligible. "New cases" are those that are new STI episode during the reporting period. Individuals with repeat STDs in the past who have come to STD or OBG clinic in the past who may or may not have been included in previous rounds are eligible for recruitment during each round if they present with a new STD episode. Sites are encouraged to include private providers in a composite approach.
  - **Treatment for reactive syphilis serology:** 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 syphillis and treatment, if necessary, must be provided to the participant. Syphilis screening test results for STD patients will be returned through the usual clinic channels and patient follow-up.

- **IDU Sentinel Group:**
  - **Site:** Typical recruitment sites for the IDU sentinel group are both de-addiction as well as TI sites which usually have drop-in centers run by NGOs. Alternatively, a health camp approach is also acceptable. The health camp approach involves organizing an event over one to several days that will attract large numbers of the target community where health services such as medical examinations, simple laboratory tests, treatment and health counseling are provided. In order for such an approach to be successful there must be enough advance notice and community mobilization efforts to get large numbers of the target community to attend. Any other potential recruitment strategies must be discussed and approved by the regional institute.
  - **Sampling:** Consecutive first time visitors are to be included for a total sample size of 250.
  - **Inclusion criteria:** First time visitors 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 15 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-addition 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. The rationale for "new first time visitors" during the time period is to avoid double counting individuals by recruiting them twice during any surveillance round.
- **FSW Sentinel Group:**
  - **Site:** Typical recruitment site for the FSW sentinel group is a TI site which usually has drop-in centers run by NGOs. Alternatively, a health camp approach is also acceptable. The health camp approach involves organizing an event over 1 to several days that will attract large numbers of the target community where health services such as medical examinations, simple laboratory tests, treatment and health counseling are provided. In order for such an approach to be successful there must be enough advance notice and community mobilization efforts to get large numbers of the target community to attend. Any other potential recruitment strategies must be discussed and approved by the regional institute.
  - **Sampling:** Consecutive first time visitors are to be included for a total sample size of 250.
  - **Inclusion criteria:** First time visitors during the surveillance period are included if they are active female sex workers defined as a woman aged 15 to 49 years who has sold sex for money at least once in the previous 6 months, engages in consensual sex for money or payment in kind, as her principal means of livelihood. “New first time visitors”

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* 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. opoids (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.

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. The rationale for "new first time visitors" during the time period is to avoid double counting individuals during any single surveillance round.

- **Treatment for reactive syphilis serology:** 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 participant. NGOs participating in HSS will need to put in place procedures for FSW participants to learn their syphilis screening results and receive treatment, if necessary. Ensuring treatment for reactive syphilis serology is an ethical requirement of this approach and is also important given the high prevalence of syphilis among FSWs.

MSM Sentinel Group:

- **Site:** Typical recruitment site for the MSM sentinel group is an intervention (TI) site which usually has drop-in centers run by NGOs. Alternatively, a health camp approach is also acceptable. The health camp approach involves organizing an event over 1 to several days that will attract large numbers of the target community where health services such as medical examinations, simple laboratory tests, treatment and health counseling are provided. In order for such an approach to be successful there must be enough advance notice and community mobilization efforts to get large numbers of the target community to attend. Any other potential recruitment strategies must be discussed and approved by the regional institute.
- **Sampling:** Consecutive first time visitors are to be included for a total sample size of 250.
- **Inclusion criteria:** First time visitors during the surveillance period are included if they are active men aged 15 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 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. The rationale for "new first time visitors" during the time period is to avoid double counting individuals during any single surveillance round.
- **Treatment for reactive syphilis serology:** 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 syphillis and treatment, if necessary, must be

[#] 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.

provided to the participant. NGOs participating in HSS will need to put in place procedures for MSM participants to learn their syphilis screening results and receive treatment, if necessary. Ensuring treatment for reactive syphilis serology is an ethical requirement of this approach and is important given the high prevalence of syphilis among MSMs.

- **Eunuch / Transgenders Sentinel Group:**

  - **Site:** Typical recruitment site for the eunuch / transgender sentinel group is a TI site which usually has drop-in centers run by NGOs or CBOs. Alternatively, a health camp approach is also acceptable. The health camp approach involves organizing an event over 1 to several days that will attract large numbers of the target community where health services such as medical examinations, simple laboratory tests, treatment and health counseling are provided. In order for such an approach to be successful there must be enough advance notice and community mobilization efforts to get large numbers of the target community to attend. Any other potential recruitment strategies must be discussed and approved by the regional institute.

  - **Sampling:** Consecutive first time visitors are to be included for a total sample size of 250.

  - **Inclusion criteria:** First time visitors during the surveillance period are included if they are aged 15 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 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. The rationale for "new first time visitors" during the time period is to avoid double counting individuals during any single surveillance round.

  - **Treatment for reactive syphilis serology:** 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 sypilisand treatment, if necessary, must be provided to the participant. NGOs participating in HSS will need to put in place procedures for eunuch / transgender participants to learn their syphilis screening results and receive treatment, if necessary. Ensuring treatment for reactive syphilis serology is an ethical requirement of this approach and is important given the high prevalence of syphilis in this group.

- **High-risk Migrants Sentinel Group:**

  - **Site:** Typical recruitment site for the migrant sentinel group is a TI site which usually has drop-in centers run by NGOs. Alternatively, a health camp approach is also acceptable. The health camp approach involves organizing an event over 1 to several days that will attract large numbers of the target community where health services

[@] 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.

such as medical examinations, simple laboratory tests, treatment and health counseling are provided. In order for such an approach to be successful there must be enough advance notice and community mobilization efforts to get large numbers of the target community to attend. Any other potential recruitment strategies must be discussed and approved by the regional institute.

- **Sampling:** Consecutive first time visitors are to be included for a total sample size of 250.
- **Inclusion criteria:** First time visitors during the surveillance period are included if the individual is a male, aged 15 to 49 years and who has moved between source community and destination community within India once or more in the previous year. "New first time visitors" are those male migrants that visit the sentinel site for the first time during the surveillance period. This is true even if they have been included in previous rounds of HSS. The rationale for "new first time visitors" during the time period is to avoid double counting individuals during any single surveillance round. High-risk migrants are those that live near and interact with FSW populations.
- **Treatment for reactive syphilis serology:** 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 participant. NGOs participating in HSS will need to put in place procedures for high-risk migrant participants to learn their syphilis screening results and receive treatment, if necessary. Ensuring treatment for reactive syphilis serology is an ethical requirement of this approach and is important given the high prevalence of reactive syphilis serology in this group.

Pregnant Women Sentinel Group:

- **Site:** Typical recruitment site for pregnant women is the ante-natal clinic run by government or private sector.
- **Sampling:** Consecutive first time visitors are to be included for 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, the number of days the clinic occurs and the personnel available is to 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 but it is recognized that there will be exceptions to this recommendation. The overarching criteria is non-compromised patient care and high-quality surveillance.
- **Inclusion criteria:** Pregnant/ antenatal mothers during the surveillance period are included if they are between the ages of 15 to 49 years and first time visitors to the ANC clinic for the current pregnancy. Antenatal mothers who have an ongoing relationship with the ANC site and have visited previously are eligible for inclusion in this surveillance round if they are currently pregnant. This is true even if they have been included in previous rounds of HSS. The rationale for "new first time visitors" during the time period is to avoid double counting individuals during any single surveillance round.
- **Treatment for reactive syphilis serology:** 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 participant. Returning syphilis results and treatment the pregnant women and her partner can be incorporated into routine ANC clinical practices.

Recruitment criteria for area specific special groups such as truckers and TB patients should be coordinated with the regional institutes.

6.1.3 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 serum sample. The proforma for the various sentinel groups are provided in Annexure 4 - 4A (STD sentinel group), 4B (ANC sentinel groups) and 4C (IDU/ MSM/ FSW/ other sentinel groups). Note, only ONE form is to be completed and it should accompany the serum sample. Only a unique code number will link the information on the proforma form to the laboratory result. A summary list of duties at sentinel site clinic is at Annexure 5. Sufficient quantity of these reporting forms must be made available for use during the surveillance period at all sites and testing laboratories. Adequate training will be given to all designated staff by Regional Institutions, Sentinel Surveillance Teams and SACS.

6.1.4 "Unlinked Anonymous" Testing

"Unlinked anonymous" testing is the approach to HIV testing being used in HSS, as it minimizes participation bias. In this type of testing, a part of the blood sample originally collected for other purposes is used for testing for HIV but all personal identifiers that could link the result back to the individual are removed. For example, when blood sample is collected for syphilis serologic testing at the STD clinic, a part of it should be separated and sent to the HIV testing laboratory after removing all personal identifiers, e.g. name, address, etc., so that the HIV test results cannot be linked with the individual whose blood has been taken for testing. Implicit in this strategy is the notion that participants will receive some benefit. For all of the participants in the HSS, syphilis serologic screening is being provided. Procedures must be in place to ensure that ALL participants from all survey groups get their syphilis results back and are provided appropriate treatment if the test is reactive.

6.1.5 Collection of Blood

A total of 5 ml of blood should be collected with sterilized blood drawing equipment, e.g. syringe and needle / vacutainer tube and needle. The sera should be separated on the same day using good laboratory technique and appropriate universal precautions. Care should be taken to avoid haemolysis (damage to the clot that tinges the serum red) of the sample. Individual pipette tips for each serum sample should be used, which is then divided into two samples with at least 0.5 ml of serum in each screw-capped vial (See Annexure 6 for details). One sample with all personal identifications is to be sent for routine syphilis serologic testing, e.g. VDRL or RPR, for diagnosis and communication of results to the person tested. The second sample marked with only the code/age/sex for syphilis serology and HIV testing along with the proforma is to be sent to the designated surveillance testing sites.

6.1.6 Storage and Transport of Serum Samples

The screw capped storage tube for syphilis serology / HIV testing must contain a minimum of 0.5 ml. of serum, properly labeled and stored in the refrigerator at +4° C for maximum seven days and sent to the HIV testing laboratory in batches with proper cold chain and bio-safety precautions. If storing more than a week, it is to be kept in freezer section at -20° C. Samples should not be frozen and thawed repeatedly.

6.2 Laboratory Procedures at HIV Testing Laboratory

6.2.1. Storage of sera samples

- Store at +4^0 C for only one week from the day of collection.
- If testing is to be carried out beyond this period, freeze at -20^0 C.

6.2.2. HIV Testing

All the sera samples collected at any one sentinel site during any one sampling period should be tested in the same HIV testing laboratory, recognized by SACS. ELISA/Rapid Test (E/R) assay to be performed for detecting HIV antibodies, using the strategy outlined below. Following points should be carefully observed:

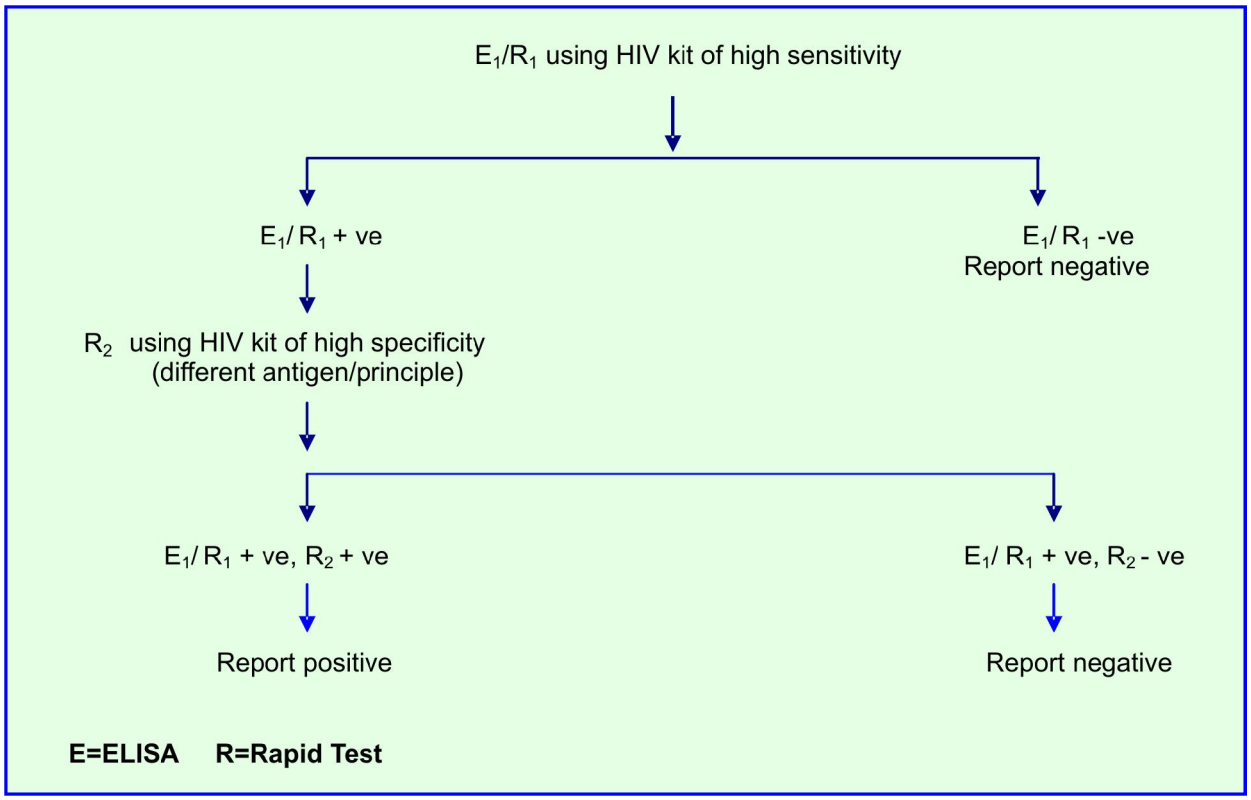
- Respective SACS should utilize and supply NACO approved kits, to all the testing labs in the state (Annexure-7).
- Only validated kits should be used for HSS.
- Testing procedures described in the test kits, using all the necessary controls, to be strictly followed and appropriately recorded in laboratory manuals consistent with good laboratory practices.
- Strict testing and result recording procedures should be followed to maintain anonymity in order to make the linking of the HIV testing results to the tested individual, impossible.

6.2.3. HIV Testing Strategy

- The Testing Strategy of NACO for surveillance, i.e. use of two HIV tests, should be followed. (See Figure 2 below).
- The serum to be first tested for HIV antibodies with one ELISA or Rapid test with **high sensitivity.**
- Any serum found reactive on the first assay to 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 is considered “antibody negative”.
- The HIV test protocol to be used may be: either ELISA based or rapid test

- The results of the two HIV tests should be entered in the individual proforma.

Figure 2: Flow Diagram for HIV Testing Strategy



6.2.4. Syphilis Serologic Testing

Routine testing:

- Sera for routine syphilis testing should routed to the usual laboratory for syphilis testing with the appropriate requisition laboratory slip. The sera used for this test is the uncoded serum vial and contains patient identifiers.
- Results of the syphilis test should be returned to the participating clinic or NGO. The clinic and NGO is responsible for getting the results back to the participants and providing treatment if required.

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 (supplied with the antigen). Low titer reactive sera is interpreted as negative to exclude biologic false positives and sero-fast treated individuals.
- Following good laboratory procedures always include positive, negative and antigen control.

- Report positive if the titre is ≥ 8
- The results of the syphilis serologic testing should be filled in the proforma along with HIV test results.

6.2.5. External Quality Assurance Scheme Programme (EQAS) in HIV testing

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

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.

Project Directors, SACS should ensure that each centre involved in testing of sentinel site samples is linked to the respective reference laboratory as listed in Table 4. 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 needs to 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, report to the respective testing labs and copy to respective SACS and NACO.
- This activity should be repeated every year before surveillance starts. However, those testing labs that already underwent 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 lab, till correct result is obtained.

Cross check of positive/ negative samples:

- The testing labs should submit all the positives and 5% of the negative HIV tested sera samples to the reference lab 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. This procedure is also known as Quality Check (QC).
- The samples to be sent to the reference labs 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 labs.
- The reference laboratories should in turn examine the specimens sent from the testing labs, as soon as possible after receipt. 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, NIHFW 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 NIHFW, New Delhi and NACO.

Figure 3: Expected timeline of EQAS sample submission and reporting

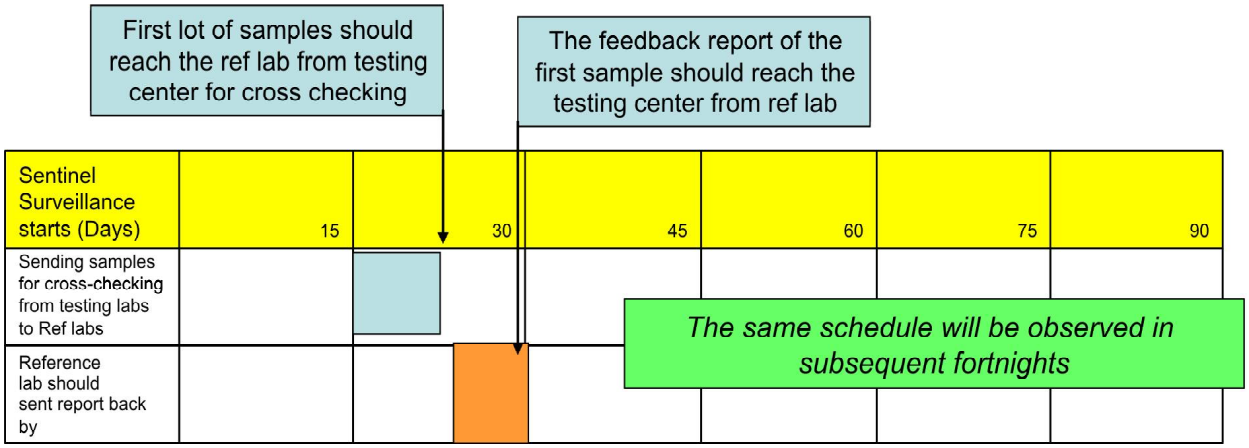


Table 4: List of Reference Centers and Distribution of States

National Reference Center	States
National Institute of Biologicals, Noida	Uttar Pradesh and Uttaranchal
National Institute of Communicable Diseases, New Delhi	Delhi, Jammu & Kashmir
All India Institute of Medical Sciences, New Delhi	Himachal Pradesh, Chandigarh, Punjab
National Institute of Mental Health and Neuro Sciences, Bangalore	Karnataka
National Institute of Hematology, Mumbai	Mumbai, Madhya Pradesh and Chattishgarh
National AIDS Research Institute, Pune	Maharashtra, Goa, Gujarat, Daman & Diu, D&N Haveli
School of Tropical Medicine, Kolkata	West Bengal, Bihar, Jharkhand and Sikkim
National Institute of Cholera and Enteric Diseases, Kolkata.	Assam, Orissa, Andaman & Nicobar Islands, Meghalaya
Dr. MGR University, Chennai.	Andhra Pradesh
Madras Medical College, Chennai	Tamil Nadu, Pondicherry
Christian Medical College, Vellore	Kerala, Lakshadweep
Regional Institute of Medical Sciences, Manipur	Manipur, Tripura, Arunachal Pradesh, Mizoram, Nagaland

6.2.6 Bio Safety Precautions and Waste Disposal

All bio-safety procedures must be followed for blood collection, sera separation, storage, transport of sera and serologic testing for HIV and syphilis. Biomedical waste disposal procedures should be followed strictly at each site and laboratory.

A list of salient Do's and Don'ts for high quality HSS is given at Annexure 8.

7. Logistic Management

All logistics must be organized well in advance and as per the activity plan for the 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 Annexure 9). HIV Testing Kits and proforma 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.

8. 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 and as per the action plan prepared by the Regional Institutions in consultation with the SACS. 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. Identified supervisory teams will conduct visits as per schedule prepared by NACO/ NIHFW/ Regional Institutions with a check list (Annexures 10A and 10B). Supervisory visits by teams from nodal agencies to the selected sentinel sites will also be curried out.

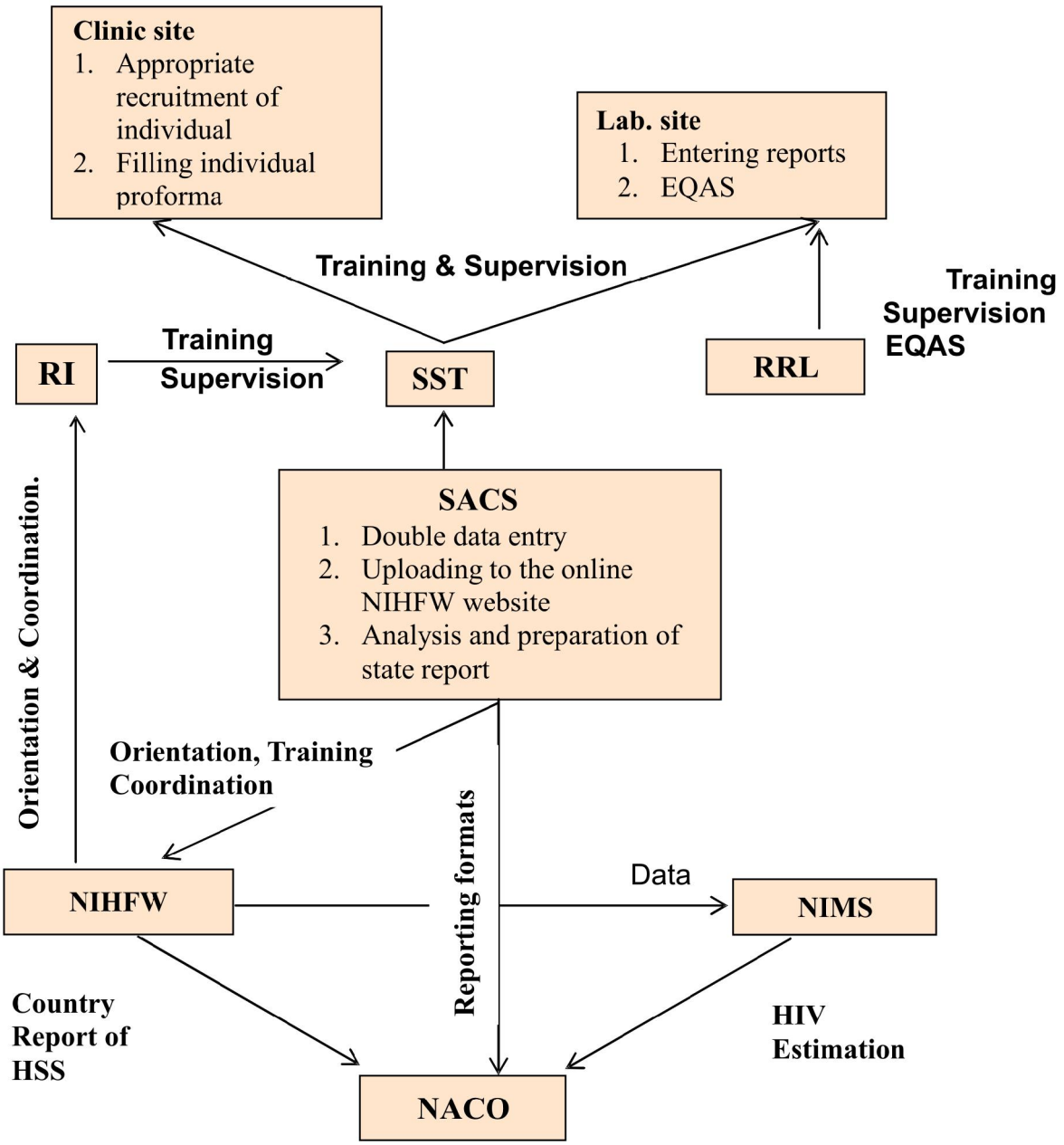
9. Data Reporting and Analysis

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 proformae are to be sent by the laboratories to SACS for data entry, after checking for completion. Double data entries are to be made directly from the proforma to the offline web-based data entry system by professionals and then uploaded on to the online NIHFW web site **(www.nihfw.org / HIV software)**. This data is to be checked by the Regional Institutions and SACS at the data entry point. NIHFW is to monitor the data at the website. The data is to be analyzed at SACS and aggregated at 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. All data should be downloaded, checked and report prepared at the national level by NIHFW. The data is also to be given to NIMS to carry out HIV estimation.

10. 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.

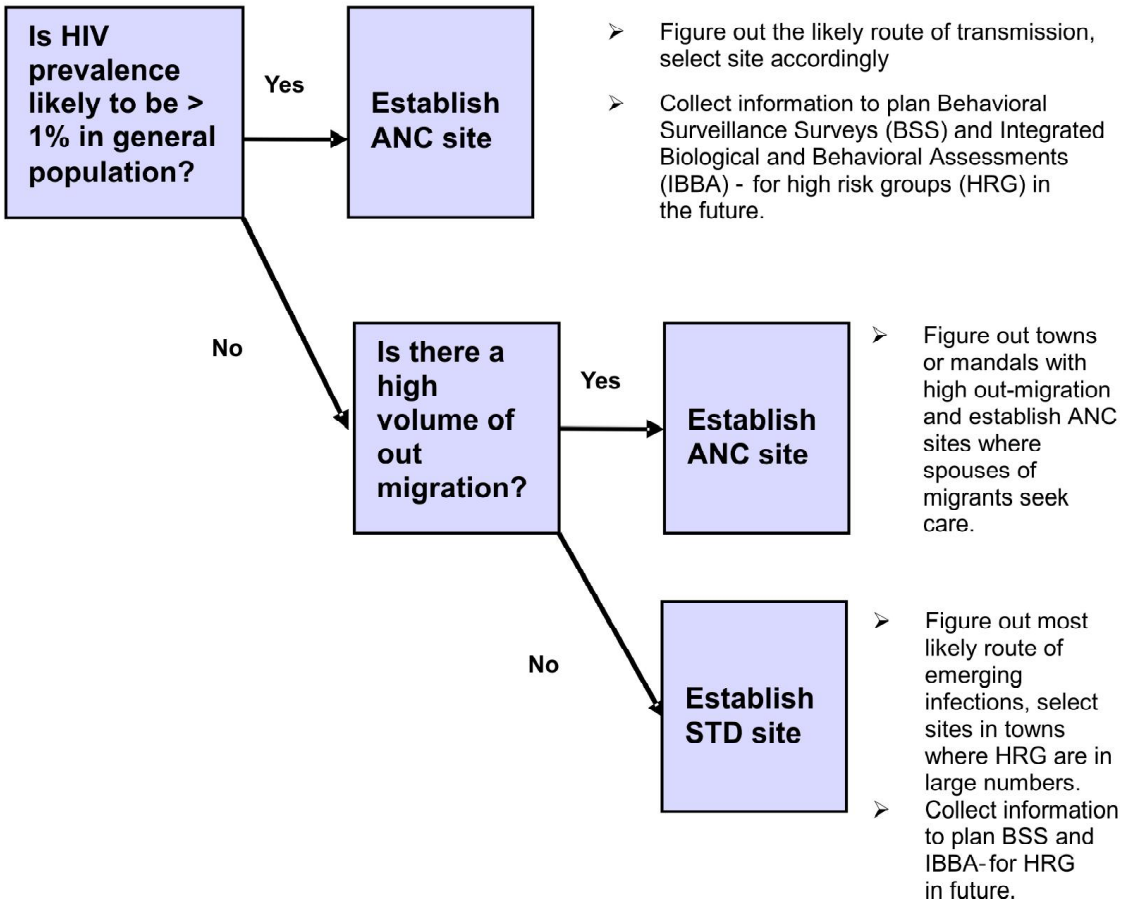
Figure 43: HSS Data Quality Assurance



Annexure 1

Decision Tree for New Sites

Decision Tree for New ANC and STD sites



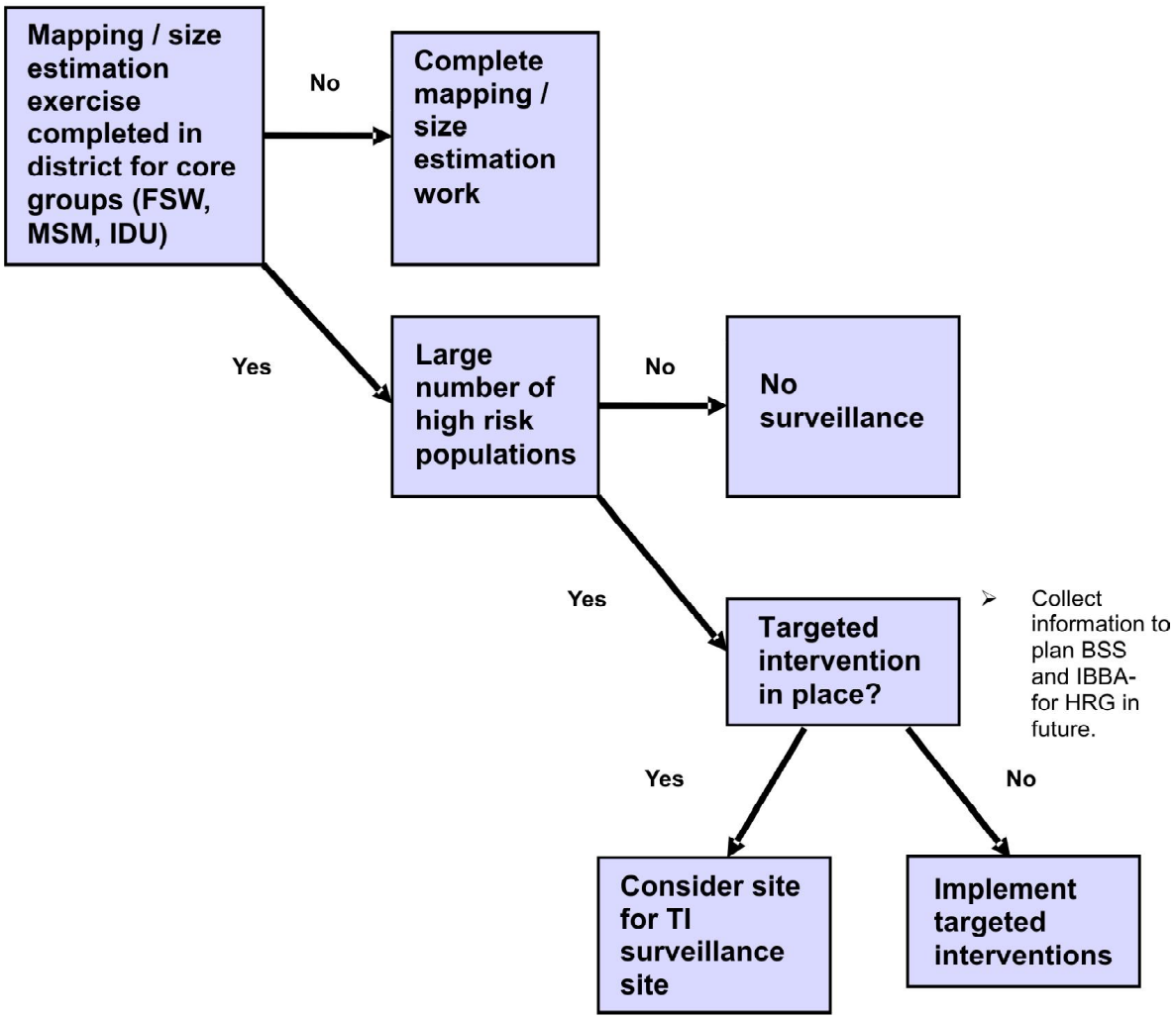
For all candidate sites: Assess feasibility criteria for establishing site

For all selected sites: Collect background information necessary to interpret data on site

For all areas where HRG are present:

- Consider inclusion of sites for TI surveillance (see next decision tree)
- Initiate pre-surveillance activities to plan community based surveys (i.e., BSS or IBBA)

Decision Tree for New High Risk Group Sentinel Sites



For all candidate sites: Assess feasibility criteria for establishing site. Includes:

- Size of HRG under TI.
- Infrastructure of TI - is there a community center (drop in center)
- Capability or linkages to provide syphilis results and treatment if necessary to participants.

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)

Annexure 2

Activity Plan for HSS

Activity	Responsibility
Technical meeting of Regional Surveillance Institutions and Central Surveillance team members	NIHFW /NIMS
Orientation training of State Surveillance teams at regional centers for HIV Surveillance: 1) PGI, Chandigarh; 2) NIE, Chennai; 3) AIIPH, Kolkatta; 4) NARI, Pune; 5) AIIMS, Delhi;	Regional institutions
Field visits of State Surveillance teams for confirmation of additional sites and site assessment in coordination with SACS.	Regional institutions
Finalization of list of sites in the States / Union Territories	NIHFW
Identification of testing laboratories and orientation of Microbiologist	Regional Institutions
Training of Sentinel Sites in-charge	State Surveillance teams/SACS
Training of lab technicians working in the testing laboratories	State Surveillance teams/SACS
Training of data entry operators on web based soft ware for collection of data	NIHFW
Meeting of National Reference laboratories for quality assurance	NICD
Procurement of consumables, HIV & VDRL kits & formats and other logistic management	SACS
HSS round	SACS
Visit to Sites/testing centre by state surveillance teams	Regional institution
Regional review meetings with Nodal officer SACS & state surveillance teams	Regional institutions
Reporting to NIHFW	SACS/ SST / RIs
National HIV estimation process	NIMS
Preliminary Report	NIHFW / NIMS
Final report including printing and dissemination	NACO

Annexure 3

Training Plan for Surveillance

SR. NO	TRAINING CATEGORY	STATE-WISE NUMBER	DURATION	PLACE OF TRAINING	TRAINERS	BATCHES
1	Orientation of regional institutions	5x4=20	2 days	NIHFW	Central Surveillance Team	Four
2	Orientation training of SST	38X4 =152	2 days	1.PGI Chandigarh 2. NIE, Chennai 3. AIIPH, Kolkata 4. NARI, Pune 5.AIIMS, New Delhi	Faculty of Regional Institutions	Four
3	Sentinel Site I/c	1122	1 day	RFWTC Medical College	State Surveillance Team	Fifty
4	Testing Lab. Microbiologists	182	1 day	Medical Colleges	State Surveillance Team	Seven
5	Testing Lab. Technicians	182	1 day	Medical Colleges	Microbiology Deptt. of Medical Colleges	Seven
6	Data Entry Operators / M&E Officers	38	2 days	NIHFW	NIHFW	Two
7	Quality Assurance Microbiologists	10	1 day	NICD	Apex Reference Laboratory	One

Annexure 4A

HSS REQUEST FORM FOR STD SENTINEL GROUP

Name of the State **Name of Sentinel Site**

1. **Sentinel Site code** _____ _____ _____
2. **Sample Number** _____ _____ _____ _____
3. **Date** _____ _____/ _____ _____/ _____ _____
4. **Age in years** _____ _____

5. Sex (circle one) 1. Male 2. Female

6. Place of Residence (circle one) 1. Urban 2. Rural

7. Whether Migrant* (circle one) 1. Yes 2. No

8. Educational Status (circle one)

1.Illiterate 2.Literate and till 5th Class 3.Till 12th Class 4.Graduate and above

9. Current Occupation (Self) (circle one)

1. Agriculture /Unskilled worker
2. Truck /Auto/Taxi Driver and helper
3. Industrial and Factory worker
4. Hotel Staff
5. Service
6. Business
7. Unemployed
8. Student
9. Housewife
10. Sex worker
11. Other (specify)

10. Current Occupation of Spouse (circle one)

1. Agriculture /Unskilled worker
2. Truck /Auto/Taxi Driver and helper
3. Industrial and Factory worker
4. Hotel Staff
5. Service
6. Business
7. Unemployed
8. Student
9. Housewife
10. Other (specify) †
99. Not applicable

11. Syndromic Diagnosis of STDs

Male		Female
Ano-genital ulcer……	1	Ano-Genital Ulcer ……..…..1
Urethral discharge ……	2	Cervical discharge ……..2
Genital Ulcer & Urethral Discharge …….	3	Genital Ulcer & Cervical Discharge ……..3
Ano-genital Warts ……..	4	Ano-genital Warts ……....4

Name: _____ **Signature**_____
(Person completing form)

Name: _____ **Signature**_____
(In-charge of the sentinel site)

12. Laboratory results			
a) HIV Testing			
Screen: first Test		**Confirm:** Second Test	
1. Positive	2. Negative	1. Positive	2. Negative
		9. Not applicable if first test is negative	
b) Syphilis Serologic Testing			
Qualitative: First test		**Quantitative:** Second test	
1. Reactive	2. Non-reactive	1. Dilution Titer <8	2. Dilution Titer ≥8
		9. Not applicable if first test is non-reactive	
		If 2 (>8) report as syphilis positive)	

Name: _____ **Signature**_____

(In-charge of HIV testing lab)

- Fill appropriate code
- This request from must be sent to HIV testing laboratory alongwith coded sample.
- **Blood samples should be taken only once from all STD cases included during the period of surveillance.**

Annexure 4B

HSS REQUEST FORM FOR PREGNANT WOMEN SENTINEL GROUP

Name of the State **Name of Sentinel Site**

1. **Sentinel Site code**_____ _____ _____
2. **Sample Number**_____ _____ _____
3. **Date**_____ _____ / _____ _____ / _____ _____
4. **Age in years**_____ _____

5. **Place of Residence** (circle one) 1. Urban 2. Rural

6. **Whether Migrant*** (circle one) 1. Yes 2. No

7. **Educational Status** (circle one)
   1.Illiterate 2. Literate and till 5th Class 3. Till 12th Class 4. Graduate and above

8. **Order of Pregnancy**
   1. First 2. Second 3. Third 4. Forth or more

9. **Current Occupation (Self)**
   1. Agriculture /Unskilled worker
   2. Truck /Auto/Taxi Driver and helper
   3. Industrial and Factory worker
   4. Hotel Staff
   5. Service
   6. Business
   7. Unemployed
   8. Student
   9. Housewife
   10 Other (specify)
   99. Not applicable

10. **Current Occupation of Spouse.**
    1. Agriculture /Unskilled worker
    2. Truck /Auto/Taxi Driver and helper
    3. Industrial and Factory worker
    4. Hotel Staff
    5. Service
    6. Business
    7. Unemployed
    8. Student
    9. Housewife
    10. Other (specify)
    99. Not applicable

Name: _____ **Signature**_____
(Person completing form)

Name: _____ **Signature**_____
(In-charge of the sentinel site)

11. Laboratory results			
a) HIV Testing			
Screen: First Test		**Confirm:** Second Test	
1. Positive	2. Negative	1. Positive	2. Negative
		9. Not applicable if first test is negative	
b) Syphilis Serologic Testing			
Qualitative: First test		**Quantitative:** Second test	
1. Reactive	2. Non-reactive	1. Dilution Titer<8	2. Dilution Titer ≥8
		9. Not applicable if first test is non-reactive If 2 (≥ 8 report as syphilis positive)	

Name: _____ **Signature**_____

(In charge of HIV testing Lab)

- Fill appropriate code
- This request form must be sent to HIV testing laboratory along with coded sample.
- **Inclusion criteria:** all pregnant women attending antenatal clinic to be tested only once during the current surveillance round.

* Fill migration as 'Yes', when the person is living at a place other than his place of residence for more than 6 months with out spouse/family.

Annexure 4C

HSS REQUEST FORM FOR IDU /FSW / MSM / TRANSGENDER / MIGRANT SENTINEL GROUP

Name of the State **Name of Sentinel Site**

1. Sentinel Site code_____ _____ _____

2. Sample Number_____ _____ _____

3. Date_____ _____ / _____ _____ / _____ _____

4. Age in years_____ _____

5. Sex (circle one) 1. Male 2. Female

6. Place of Residence (circle one) 1. Urban 2. Rural

7. Whether Migrant* (circle one) 1. Yes 2. No

8. Educational Status (circle one)

1. Illiterate 2. Literate and till 5th Class 3. Till 12th Class 4. Graduate and above

9. Current Occupation (Self) (circle one)

1. Agriculture /Unskilled worker
2. Truck /Auto/Taxi Driver and helper
3. Industrial and Factory worker
4. Hotel Staff
5. Service
6. Business
7. Unemployed
8. Student
9. Housewife
10. Sex worker
11. Other (specify)

10. Current Occupation of Spouse (not to be filled for FSW and MSM) (circle one)

1. Agriculture /Unskilled worker
2. Truck /Auto/Taxi Driver and helper
3. Industrial and Factory workeR
4. Hotel Staff
5. Service
6. Business
7. Unemployed
8. Student
9. Housewife
10. Other (specify)
99. Not applicable

Name: _____ **Signature**_____

(Person completing form)

Name: _____ **signature**_____

(In charge of the sentinel site)

11. Laboratory results			
a) HIV Testing			
Screen: First Test		**Confirm:** Second Test	
1. Positive	2. Negative	1. Positive	2. Negative
		9. Not applicable if first test is negative	
b) Syphilis Serologic Testing			
Qualitative: First test		**Quantitative:** Second test	
1. Reactive	2. Non-reactive	1. Dilution Titer<8	2. Dilution Titer ≥8
		9. Not applicable if first test is non-reactive If 2 (≥ 8 report as syphilis positive)	

Name: _____

Signature_____
(In charge of HIV testing Lab)

- This request form must be sent to HIV testing laboratory along with coded sample.
- Inclusion criteria: IDUs attending drug de-addiction clinic/NGO drop-in centres or health camp to be tested only once during the current surveillance round.
- MSM/FSW/Transgenders/migrants attending NGO clinic/drop-in centres or health camp to be tested only once during the current surveillance round.

* Fill migration as 'Yes', when the person is living at a place other than his place of residence for more than 6 months but less than 1 year with out spouse/family.

Annexure 5

Summary List of Duties at Sentinel Site Clinic for HSS

A list of duties to be performed at the sentinel site clinic as part of HSS is as follows. Responsibility for execution (E) and supervision (S) of the various duties are marked out:

1.	Supplies for Annual Sentinel surveillance received at site.	
(a)	Receipt of consumables and HIV Kits well before start of round -	In-charge of HIV testing site
(b)	Instructions received for:· • Start / end date for sampling to begin • Code for site • Sampling period	In-charge of both clinic site and HIV testing site
2.	Inform the clinic staff that collection of blood samples and data will begin	In-charge Clinic Site
3.	Send selected patients for VDRL screening for venepuncture (Routine procedure)* after filling up individual data sheet.	In-charge Clinic Site
4.	Obtain 5-10 ml of blood.	In-charge Clinic Site, Lab Tech
5.	Separate sera from collected blood	In-charge Clinic Site, Lab Tech
6.	Divide the sera obtained into two specimen tubes	In-charge Clinic Site, Lab Tech
	One tube for syphilis serology marked as per routine. Second tube marked with code number, age and sex only.	In-charge Clinic Site, Lab Tech
7.	Coded sera tubes stored in a special box at 4-8^{o} C in clinic refrigerator in a box marked with code for sentinel site and sampling period	In-charge Clinic Site, Nurse
8.	At end of each day, count number of tubes with data correctly marked. Record number on special form attached to box; sign.	In-charge Clinic Site, Lab Tech, Nurse
9.	Transport box with sera in icebox to HIV testing laboratory at end of week or daily if laboratory is nearby.	In-charge Clinic, Attendant
10.	Obtain (from the laboratory) a receipt for the sera transported. Receipt lists with date, no. of sera code for site etc. and note the quality of samples received.	In-charge HIV Testing site, Attendant

11.	Handover the receipt from the lab for the sample sent, to clinic In-charge	In-charge Clinic, Attendant
12.	Inform the clinic staff when to end blood and data collection	In-charge HIV Testing site, Lab Technician

*Routine procedure is one already practiced in the clinic like syphilis serologic testing round the year and it contains Name/Age/Sex/Registration Number of the patient.

Annexure 6

Method of Blood Collection and Transport for HSS

Blood should be collected following this standard operating procedure (SOP), so that the separated sera samples are liquidated in adequate volumes for the serology tests (HIV and syphilis including EQAS of HIV) and are not haemolysed or contaminated.

Method

1. 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 proforma specific for the concerned site.
2. Collect 5-10 ml blood with pre sterile syringe/needle/vacutainer (whichever is available), in sterile plastic 10 ml screw capped tubes following biosafety precautions
3. Allow the blood to coagulate at room temperature on the lab bench top.
4. Separate sera using separate glass/plastic pasteur pipettes or micropipettes with plastic tips and transfer into another centrifuge tube.
5. Centrifuge and collect clear supernatant and transfer into two 2 ml plastic sterile storage tubes, each containing at least 0.5 ml serum.
6. Label the first tube with patient identity and process through routine testing for syphilis serology.
7. Label the second tube with the code number and age/sex and store at +4° centigrade for a maximum of 7 days. If you know that the storage will be longer than 7 days or if it had been in the refrigerator for 7 days, the specimen should be frozen at -20°C
8. Send the coded sera to laboratory daily if laboratory is nearby or once a week if laboratory is far away.

Annexure 7

SELECTED HIV RAPID TEST KITS*

S. No.	Name of kit	Antigen	Principle	Manufacturer	Sensitivity	Specificity
1	HIV Tridot	Recombinant proteins	Immuno filtration	Biotech Inc, Himachal Pradesh India	100%	100%
2	Pareekshak	Recombinant proteins	Immuno filtration	Bhat Biotech India (P) Ltd.	Not mentioned	Not mentioned
3	Immunocomb II HIV 1 & 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	Comb AIDS-RS	Recombinant & Synthetic peptides	Dot Immunoassay / Immuno Chromotographic	Span Diagnostics Ltd., G.I.D.C. Sachin 394260, Surat, India	100%	98.7%/ 100%
6	Capillus HIV 1 & 2	Recombinant proteins	Latex agglutination	Trinity biotech. ISA	99.6%	100%
7	NEVA HIV	Recombinant molecules having RBC binding sites	Particle agglutination	Cadila Pharmacenticals, “Cadila Corporate Campus”, Sarkhej Dholke Road, Bhat, Ahmedabad 382210, Gujrat	99%/ 99.9%	95%/ 98.5%
8	SD Bioline HIV ½ 3.0	Recombinant	Immuno Chromatographic	SD Standard Diagnostics Inc 575/34 Pajang /Dang JanGanKu Suwon / Sikyong Do. Korea	100%	99.8% /100%
9	Retrocheck HIV	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	Immuno Comb II	Synthetic	Synthetic	Orgenics, P.O. Box 360, YAVNE 70650, Israel	100%	98.4%

Selected ELISA Test Kits

Sl. No.	Name of the kit	Antigen	Principle	Manufacturer	Sensitivity	Secification
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 lisa HIV	Recombinant Protein	Indirect Elisa	J. Mitra & Co. Ltd. A-180, Okhla Area, Ph- 1, New Delhi-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	HIV ASE 1+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.

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:

a). (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.

b). 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.

c) 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

Comment:

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

Annexure 8

Salient Do's and Don'ts for a High Quality HSS

Do's

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 proforma completely.

3 Ensure correct labels and codes, and maintain confidentiality

4 Label the blood collection tube with code number/age/sex for each attendee at every site.

5 Fellow universal precautions and good laboratory practice for collection of blood, separation of sera, storage and transport.

6 Report any accidental needle stick injury.

7 Store the sera samples at +4° C for maximum one week, and sera should be frozen after one week.

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

11 Send sera of all HIV positive and 5% negative samples to reference laboratories for EQAS. Enter verified results in the proforma.

12 Follow biosafety precautions at each step and discard waste according to national guidelines.

13. Perform double data entry for cross checking.

Don'ts

1 Do not send the patient for blood collection to a laboratory far away from the clinic site. [Arrange to draw blood at the site.]

2 Do not write patient identity, either on proforma 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.]

3 Do not use same pipette/tips for separation of different sera. [Use a new pipette for each sample].

4 Do not leave sera in the refrigerator more than a week. [Freeze at -20oC if 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 but at +40 C.

7 Do not use haemolysed or contaminated sera for HIV or syphilis serologic testing.

8 Do not report incorrect syphilis or HIV results in the proformae. [Double check your work.]

9 Do not wait to send the proformae together to the SACS. [Send completed, checked proformae in batches regularly to facilitate data entry.]

Annexure 9

Check list of Supplies at Sentinel Site Clinic and Laboratory Settings for HSS*

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
4.	Spirit swabs
5.	Needle destroyer/ puncture proof containers
6.	Hypo chlorite solution
7.	Plastic/glass pasteur pipettes/ micropipettes with plastic tips
8.	Centifuge tubes - 15 ml capacity
9.	Centifuge
10.	Labels/stickers and marking pens
11.	Color coded bags for disposal
12.	Gloves / aprons
13.	Refrigerator

At Testing Site

For HIV Serology Test

1.	Micropipettes for conducting ELISA/Rapid Test
2.	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)

For Syphilis Serology Test

1.	Glass slides
2.	Ring template
3.	Wax
4.	Syphilis testing reagents (VDRL antigen or RPR)
5.	Micropipettes/glass graduated pipettes (0.5 ml.)
6.	Tuberculin syringe with 18 gauge needle.
7.	Rotator for syphilis serology
8.	Timer
9.	Microscope

General Laboratory

1.	Gloves / aprons / masks
2.	1% hypochlorite solution / other disinfectant
3.	Refrigerator with freezer
4.	Sterilizer **(Footnotes)**

* Individual Proforma (to be photocopied according to need)

Annexure 10A
(Part A)

CHECKLIST FOR MONITORING OF SENTINEL SITE

PART A

I. General Information

1.	Names and designations of Coordinators a) b)		
2.	Date of supervisory visit		
3.	State	City	Institute
4.	Type of sentinel site	ANC / STD / IVDU / MSM / FSW / Any other-specify	
5.	Location of Site	Urban / Rural	
6.	Days of service	Daily / Twice a week / Thrice a week / Once a week	
7.	Since when functioning as Sentinel Site	Year	

II. Personnel involved in HIV Sentinel Surveillance

S.No.	Name	Designation	Experience	Trained for HSS 2006 Yes / No
1.				
2.				
3.				
4.				

III. Facilities at the clinic site

1.	**General Infrastructure**	
a.	Reception & Waiting space Adequate / Inadequate	Yes / No
b.	Separate Examination Room	Yes / No
c.	If no, then curtained area for examination of patients	Yes / No
d.	Privacy maintained	Yes / No
e.	Examination table	Yes / No
f.	Light adequate	Yes / No
g.	Electricity supply	Regular / Irregular

h.	Stand by generator	Yes / No Functioning / Not functioning
i.	IEC material	Available / Not available Displayed / Not displayed
j.	Blood collection facilities available in the clinic site	Yes / No
k.	If No, then how far is the laboratory from the Sentinel Site?	Nearby/ Far away
2.	**Facilities for Blood Collection, separation and storage at Collection Centre**	
l.	Individual Request Formats for report	Available / Not available
m.	No. of formats	Adequate / Inadequate
n.	Personal protective devices Aprons / Gloves in adequate number	Yes / No
o.	Disposable needles & Syringes	Available / Not available
p.	Number of Needles and Syringes available: ANC (500), STD, FSW, MSM, IDU, etc (300)	Yes / No
q.	Needle Destroyer used	Yes / No
r.	If No, why? State reasons	
s.	Disinfectants 1% (Sodium Hypochlorite Solution/Bleach) available for decontamination	Yes / No
t.	Sterile, plastic screw capped 10 ml blood collection tubes available in adequate number	Yes / No
u.	Sterile plastic screw capped 2 ml storage vials available in adequate number	Yes / No
v.	Plastic/glass pasteur pipettes/micropipettes with plastic tips available	Yes / No
w.	Centrifuge machine	Present / Absent / Functioning / Not functioning
x.	Centifuge tubes-15 ml capacity available	Yes / No
y.	Refrigerator	Present / Absent / Functioning / Not Functioning

Annexure 10A (contd...)
(Part B)

CHECKLIST FOR MONITORING OF SENTINEL SITE

PART-B

IV. Practices followed at Clinic Sites

1.	Selection of new attendees based on inclusion criteria	Yes / No
2.	Daily attendance at clinic of STD/ANC / IDU/MSM/FSW Attendees. Each counted once during surveillance	(Specify number).
3.	Total attendees since start of HSS activity.	(Specify number).
4.	Blood sample taken from all consecutive attendees. If No why? Give reasons	Yes / No
5.	Formats filled up for all first time attendees during September 1 to November 30. If No, why? Give reasons	Yes / No
6.	Who is filling up the forms?	Trained / Untrained
7.	Whether properly filled. If No, give reasons:	Yes / No
8.	Blood collected at	Clinic site / Hospital Lab/ Testing Centre
9.	Amount of blood collected - 5 ml	Yes / No
10.	Blood collected by	Lab. Technician / Nurse
11.	Time taken between collection of blood and serum separation	3 hrs/6 hrs/18 hrs/ >18 hrs
12.	Storage of serum sample	Refrigerator / Deep freezer
13.	Labeling/coding of serum samples done	Yes / No
14.	Frequency of dispatch	Daily / Twice a week/ Once a week / whenever convenient / other (Specify)
15.	Mode of dispatch	Vaccine Carrier/ Other/ without cold chain
16.	Method of decontamination of used	Bleach solution / 1% hypo consumables chlorite sol /2% cidex soln.
17.	Needle destroyer used. If no why?	Yes / No
18.	Method of final disposal used syringes & needles	Burnt / Buried /incinerator/Others
19	a) Proper records maintained at clinic Site. If no why? Give reasons	Yes / No
	b) Reports. Confidentiality of reports maintained	Yes / No
20.	Support system Adequate / Inadequate	
Suggestions for improvement:		

_____
Name (Member of supervisory team)

_____
Signature

Annexure – 10B
(Part A)

CHECKLIST FOR MONITORING AT HIV TESTING CENTRE

PART-A

I General Information

1. Name of Centre
2. Number and Name of Sentinel Sites attached to the Centre

II Personnel Involved in HIV testing:

S.No	Name	Designation	Experience	Training Status for HSS 2006
a.				
b.				
c.				
d.				
e.				

III Facilities at the Testing Site

1. General infrastructure

a.	Reception & Waiting space	Adequate / Inadequate
b.	Collection area	Yes / No
c.	Testing area	Yes / No
d.	Area for washing and disposal	Yes / No
e.	Illumination sufficient	Yes / No
f.	Adequate water supply:	Yes / No
g.	Alternate arrangement for Electricity	Yes / No

2. HIV and Syphilis Serologic Testing

A	Equipments	Available	Not available	Functioning	Non functioning
a.	Micropipettes				
b.	Sterilisers				
c.	Refrigerator				
d.	Centrifuge				
e.	Deep freezer (-20^0 C)				
f.	ELISA Reader & Washer				
g.	VDRL Rotator				
h.	Microscope				
i.	Timer				

B Consumables

a. Disposable syringes and needles	Adequate / Inadequate
b. Disinfectants available - Name & Concentration	Adequate / Inadequate / Used / Not used
c. Masks	Adequate / Inadequate / Used / Not used
d. Gloves	Adequate / Inadequate / Used / Not used
e. Aprons (Plastic)	Adequate / Inadequate / Used / Not used
f. Screw capped plastic vials for collection and storage	Adequate / Inadequate / Used / Not used
g. Disposable plastic tips	Adequate / Inadequate / Used / Not used
h. Pasteur pipette	Adequate / Inadequate / Used / Not used
i. Glass slides for syphilis testing	Adequate / Inadequate
j. Wax	Adequate / Inadequate
k. Ring Template	Adequate / Inadequate

C Kits

a. HIV Kits	**Name of Kit**	**Source**	**Batch Number**	**Expiry Date**
i) ELISA				
ii) RAPID				
b. VDRL Antigen				
c. Storage of Kits		Satisfactory/Not Satisfactory		
d. Kits Sufficient				
i) HIV ELISA		Yes/No		
ii) HIV RAPID		Yes/No		
iii) VDRL		Yes/No		

Annexure – 10B (Contd...)
(Part B)

CHECKLIST FOR MONITORING AT HIV TESTING CENTRE

PART-B

IV Practices followed at Laboratory

A. HIV Testing Methodology	
a. Standard procedure followed (2ER)	Yes / No
b. ELISA/ Rapid test	Test 1 / Test 2
c. Quality Control – control in House	Yes / No
d. Reading of results by Microbiologist	Yes / No
e. Ext: Quality Assurance guidelines followed	Yes / No
f. Panel sera received (from Ref. lab.)	Yes / No
B. Syphilis Serology Testing Methodology	
a. Whether VDRL/RPR used	Specify
b. Standard procedure followed	Yes / No
c. Whether 2 VDRL/RPR done	Yes / No
d. Qualitative or Quantitative test done	Specify
e. Quantitative test done on how many sera	specify number
C. Universal Precautions followed	
a. Handling Sharps	Proper / Improper
b. Handling spillage of blood	Proper / Improper
c. Washing of hands	Proper / Improper
d. Pipette technique	Proper / Improper
e. Decontamination before disposal	Yes / No
f. Final Waste Disposal	Burning/Incineration/Deep burial

V Details of HSS

a. Samples Received	Daily / Once a Week / Any Other (Specify)
b. Cold chain maintained during transport	Yes / No
c. Nature of sample	Serum / Whole Blood
d. Quantity of serum	Adequate / Inadequate
e. Condition of Sample on day of visit	Haemolysed / Contaminated
f. No. of unsatisfactory samples, and total samples	
g. Unsatisfactory samples discarded	Yes / No
h. Mode of storage of Sera	Refrigerator / Deep freezer
i. Duration of storage before testing	Immediate/1 Week/2 weeks/1 month/ other
j. Tests Done	Daily / Twice a week / Any Other (Specify)
VI Record Maintenance	Maintained / Not maintained
VII Problems faced	
VIII Suggestions for improvement	

_____

Name (Member of supervisory team)

_____

Signature

Annexure 11

Pattern of Financial Assistance to Sentinel Sites for HIV Sentinel Surveillance

I. For new sites (For first round of HSS)

S.No	Details	Amount (Rs.)
1	Honorarium for personnel at the sentinel site, HIV testing laboratory and secretarial assistance	10,000.00
2	Equipments, Centrifuge machine, hot air oven, domestic refrigerator etc. as may be required	40,000.00
3	Consumables (HIV testing kits, VDRL Kits, Gloves, Disposable syringes, Racks for storage of vials, labels, plastic apron, test tubes, stationery etc.	40,000.00
4	Expenditure on POL for transportation of blood samples and TA/DA and other contingency expenditures etc.	10,000.00
5	Training session for doctors, nurses, Lab Technicians and other staff	10,000.00
	TOTAL	**1,10,000.00**

II. For old sites (For subsequent rounds of HSS)

S.No	DETAILS	Amount (Rs.)
1	Honorarium for personnel at the sentinel site, HIV testing laboratory and secretarial assistance	10,000.00
2	Consumables (HIV testing kits, VDRL Kits, Gloves, Disposable syringes, Racks for storage of vials, labels, plastic apron, test tubes, stationery etc.	40,000.00
3	Expenditure on POL for transportation of blood samples and TA/DA and other contingency expenditures etc.	10,000.00
	TOTAL	**60,000.00**

Annexure 12

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 New Delhi.	Member
4.	Dr. M.D. Gupte, Director National Institute of Epidemiology, Chennai.	Member
5.	Dr. M. Bhattacharya Department of CHA, NIHFW, 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. Muliyal 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 & Melinda 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

Annexure 13

Directory of Focal Persons

S.No	Name	Designation	Address	Contact Numbers	E-Mail
National AIDS Control Organisation, Ministry of Health & Family Welfare, Government of India (NACO)					
1	Ms. K. Sujatha Rao	Additional Secretary & Director General	NACO 9th Floor, Chandralok Building, 36 Janpath, New Delhi 110011	Ph: 23355331	asdg@nacoindia.org
2	Dr. Jotna Sokhey	Additional Project Director	NACO 9th Floor, Chandralok Building, 36 Janpath, New Delhi 110011	Ph: 23325337, 43509913	apd@nacoindia.org
3	Dr. Ajay Kumar Khera	Joint Director (AK)	NACO 9th Floor, Chandralok Building, 36 Janpath, New Delhi 110011	Ph: 23736851, 43509916	ajaykhera@nacoindia.org, ajaykheranaco@gmail.com
4	Dr. Girish K Makhija	Programme Officer (Surveillance)	NACO 9th Floor, Chandralok Building, 36 Janpath, New Delhi 110011	Ph: 4350 9927, M: 9312223866	hrdnaco@gmail.com
5	Dr. Yujwal Raj P	Senior Technical Officer (Surveillance)	NACO 9th Floor, Chandralok Building, 36 Janpath, New Delhi 110011	Ph: 2332 5343 Ext. 925, 9350566003	pyraj@yahoo.com
National Institute of Health & Family Welfare, Ministry of Health & Family Welfare, Government of India (NIHFW)					
6	Dr. Deoki Nandan	Director	NIHFW, Main Road Munirka, New Delhi 110 067.	Ph: 2616 5959, extn: 301	director@nihfw.org
7	Dr. M. Bhattacharya	Prof. & Head, Dept. of CHA & Project Coordinator	NIHFW, Main Road Munirka, New Delhi 110 067.	Ph; 26188485, Ext. 349 M: 9871257894	cha_nihfw@yahoo.co.in
National Institute of Medical Statistics, Indian Council of Medical Research, Government of India (NIMS)					
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9	Dr. M. Thomas	Asst. Director	NIMS, ICMR Campus, Ansari Nagar, New Delhi 110029	Ph: 26588868 Fax. 26589635, 9810349793	mariat@operamail.com

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10	Dr. D. Sahu	Asst. Director	NIMS, ICMR Campus, Ansari Nagar, New Delhi 110029	Ph.: 26588803 Ext.222 Fax. 26589635, 9810292017	Sahu_m@hotmail.com
All India Institute of Medical Sciences, New Delhi (AIIMS)					
11	Dr. Shashi Kant	Professor	Centre for Community Medicine, AIIMS, Ansari Nagar (West), New Delhi-110029	Ph.: 26594908, M: 9810464064	skant76@hotmail.com
12	Dr. Lalit Dhar	Addl. Professor	Centre for Community Medicine, AIIMS, Ansari Nagar (West), New Delhi-110029	Ph.: 26588700 Ext. 3367	
13	Dr. Sanjay Rai	Asst. Professor	Centre for Community Medicine, AIIMS, Ansari Nagar (West), New Delhi-110029	Ph: 26594908 M. 9868397358	sanjayrai@rediffmail.com
All India Institute of Public Health & Hygiene, Kolkata (AIIPHH)					
14	Dr. Girish Kumar Pandey	Prof & HOD, Dept of Epidemiology	All India Institute of Public Health and Hygiene 110 Chittaranjan Avenue Kolkatta - 700 073	M: 9433048478 Ph: 033-2241383 Fax: 033-22418717	drgkpandey@gmail.com
15	Dr. D. Pal	Prof & HOD, Dept. of Microbiology	All India Institute of Public Health and Hygiene 110 Chittaranjan Avenue Kolkatta - 700 073	M: 098308-31015, Ph: 033-2241383 / 22412860	debaprasadpal@hotmail.com
16	Dr. T.K. Dey	Field Epidemiologist	All India Institute of Public Health and Hygiene 110 Chittaranjan Avenue Kolkatta - 700 073	Ph: 033-22413831 Ext.249 Fax: 033-22418717 M: 09231657113	aiihphepid@rediffmail.com, drtushar.dey@gmail.com
Post Graduate Institute of Medical Education and Research, Chandigarh					
17	Dr. Rajesh Kumar	Prof. HoD, Deptt. of Community Medicine	School of Public Health PGIMER, Chandigarh - 160012	Tele - 0172-2744993, 2744401 M: 9876017948	rajeshkum@sancharnet.in

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19	Dr. Sunil Arora	Addl. Prof. Deptt. of Immunopathology	School of Public Health PGIMER, Chandigarh - 160012	Tele - 0172-2755193	
National AIDS Research Institute, Pune (NARI)					
20	Dr. Sanjay Mehendale	Deputy Director	NARI 73, G Block, M.I.D.C. Bhosari, Pune - 411026	Tel:020- 7121072 / 71221, M-09422088135	smehendale@nariindia.org
21	Dr. Sheela Godbole	Deputy Director	NARI 73, G Block, M.I.D.C. Bhosari, Pune - 411026	Ph: 020-27121342/43, 27121071(Fax) Mob: 9422087972	sgodbole@nariindia.org
22	Dr. Arun Risbud	Deputy Director	NARI 73, G Block, M.I.D.C. Bhosari, Pune - 411026	Tel:020- 7121072	arispud@nariindia.org
National Institute of Epidemiology, Chennai (NIE)					
23	Dr. M. D. Gupte	Director	Post Box No. 2577. Mayor VR Ramathan Road Chetpet Chennai - 600 031	Ph.28360025/2308(o), 9444039344 Fax.26357464/26357465	mohangupted@yahoo.com
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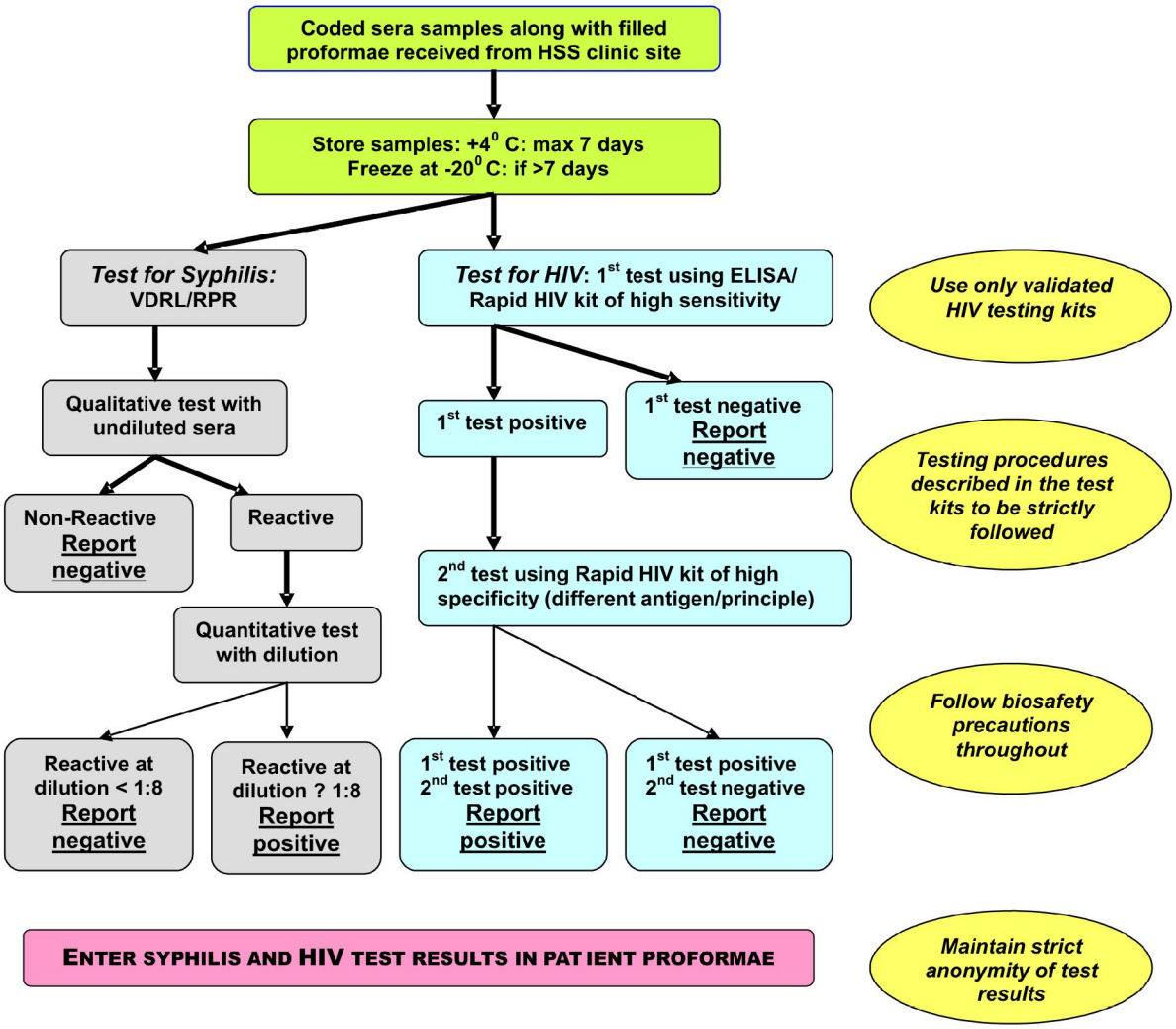
25	Dr. Joseph K David	Microbiologist,	Post Box No. 2577. Mayor VR Ramathan Road Chetpet Chennai - 600 031	Fax No. 26357464 26357465 (o), M: 9444713717	joseph_david@rediffmail.com

Annexure 14

FLOWCHART for DESIGNATED HIV TESTING LABORATORIES PARTICIPATING in HIV SEN TINEL SURVEILLANCE (HSS)



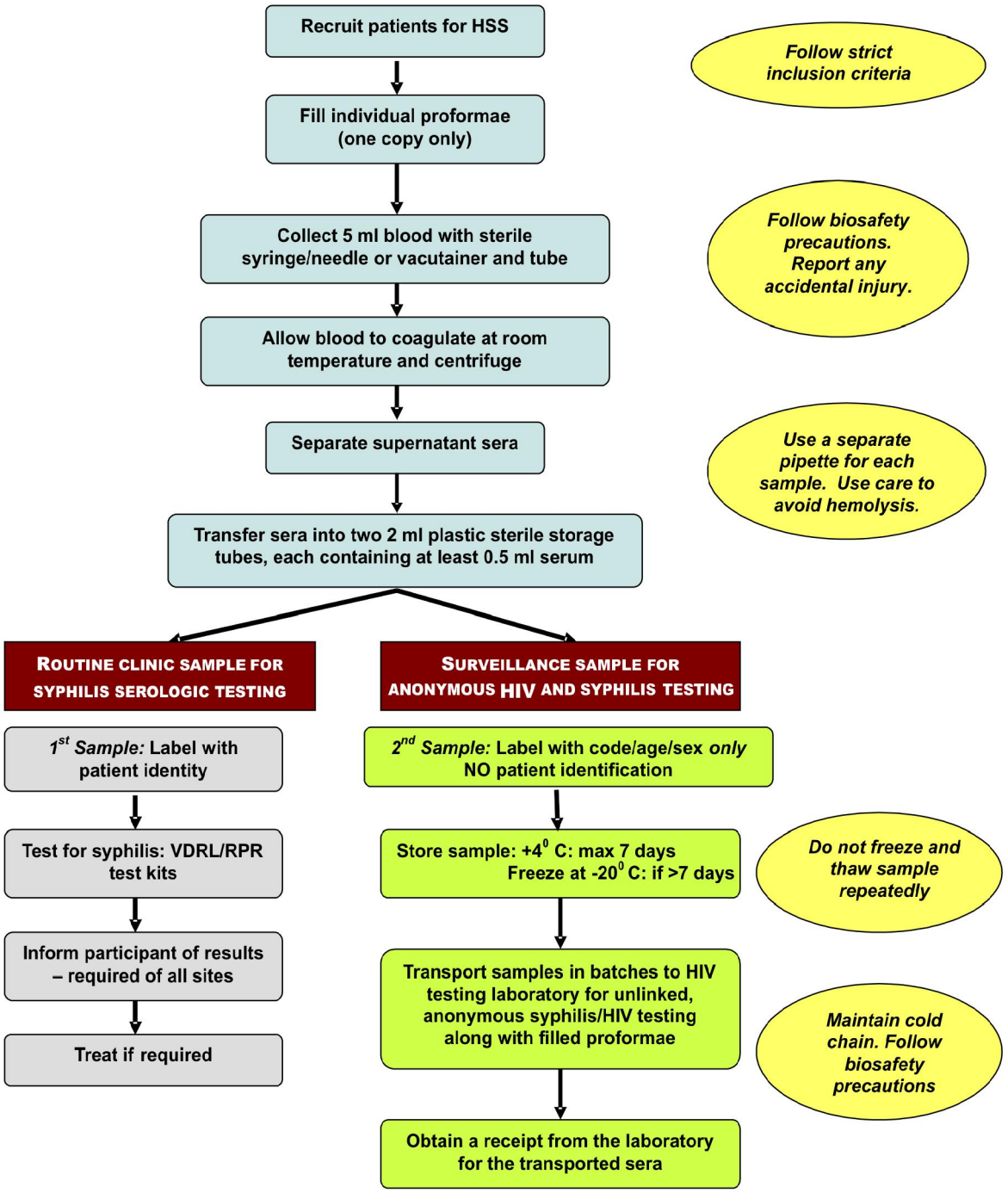
External Quality Assurance Scheme (EQAS) Procedures:

Pre-surveillance: Participate in proficiency panel testing prior to surveillance activity.
During surveillance:

- Send sera of all HIV positive samples and 5% negative samples, chosen by systematic random sampling, to the reference laboratory at 15-day intervals during the surveillance period.
- Expect report from external laboratory every 15 days.

Annexure 15

FLOWCHART FOR DESIGNATED SURVEILLANCE SITES PARTICIPATING IN HIV SENTINEL SURVEILLANCE (HISS)



Total sample size of different sentinel groups from each site: *ANC women:* 400; *STD:* 250 (STD clinic 150 + OBG clinic 100); *all other groups (FSW, IDU, MSM, truckers, migrants, etc):* 250