Technical Consultation to Review HIV Surveillance in India

23-25 April 2008

New Delhi

World Health Organization
Regional Office for South-East Asia

NACO
National AIDS Control Organisation
Ministry of Health and Family Welfare
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Abbreviations

AIDS	acquired immunodeficiency syndrome
ANC	antenatal care
ART	antiretroviral treatment
BMGF	Bill & Melinda Gates Foundation
BSS	Behavioural Surveillance Survey
CDC GAP	Centers for Disease Control & Prevention Global AIDS Program
DNA	deoxyribose nucleic acid
FHI	Family Health International
FSW	female sex worker
GUD	genital ulcer disease
HIV	human immunodeficiency virus
HSS	HIV sentinel surveillance
IBBS	integrated bio-behavioural survey
ICTC	integrated counseling and testing centre
ICMR	Indian Council of Medical Research
IDSP	Integrated Disease Surveillance Project
IDU	injecting drug user
MSM	men who have sex with men
NACO	National AIDS Control Organisation
NACP	National AIDS Control Programme
NARI	National AIDS Research Institute
NFHS	National Family Health Survey
NIHFW	National Institute of Health and Family Welfare
NGO	nongovernmental organization
OI	opportunistic infection
PCR	polymerase chain reaction
PGIMER	Post Graduate Institute of Medical Education and Research
PPP	public–private partnership
PPTCT	prevention of parent-to-child transmission
RCH	Reproductive and Child Health
RPR	rapid plasma reagin
SACS	State AIDS Control Societies
SRS	Sample Registration System
STI	sexually transmitted infection
TB	tuberculosis
TI	targeted intervention
TPPA	treponema pallidum particle agglutination
UAT	unlinked anonymous testing
UD	urethral discharge
UNAIDS	The Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
VDRL	Veneral Diseases Research Laboratory
WHO	World Health Organization

Key points of the consultation

- Effective surveillance in populations with high-risk behaviours is a critical priority given the concentrated nature of the HIV epidemic in India.
  - The quality of targeted intervention (TI)-based surveillance can be improved by introducing informed consent in the surveillance protocol, revising guidelines for sampling, conducting refresher training of TI staff, and strengthening monitoring and supervision to ensure adherence to the protocol.
  - Behavioural surveillance survey should be replaced with an integrated bio-behavioural survey-lite (IBBS-lite) model by planning and designing a protocol for a scaled down IBBS (IBBS-lite) that prioritizes geographic areas and population groups to be surveyed and the biological and behavioural markers that should be measured. IBBS-lite can be conducted once in two or three years in selected geographical areas.
  - Potential emerging epidemics should be identified by mapping exercises to detect concentrations of populations with high-risk behaviours and by undertaking subset analyses of integrated counseling and testing clinic (ICTC) data for subpopulations (e.g. sexually transmitted infections [STI] patients). HIV surveillance in STI clinic sites should be discontinued in high prevalence areas and phased out in low prevalence areas.
- Antenatal care clinic (ANC) sentinel surveillance serves a limited purpose in low prevalence settings, and thus there is no need to expand ANC sites to these areas.
  - The current sample size of 400 per site/district is too small to conclusively monitor trends among the ANC population at the district level. Administrative and financial decisions should not be based on yearly changes in prevalence noted at the district level because these may be attributable to small sample sizes. For the high prevalence states, ANC surveillance data can be pooled to monitor trends at the state level.

- Although promising, prevention of parent-to-child transmission (PPTCT) programme data cannot immediately replace ANC sentinel surveillance. The decision can be made only after appropriate evaluation of the possible biases and improving the quality of PPTCT programme recording and reporting.

- AIDS case-reporting does not meet current programme needs and should be discontinued. HIV infection case-reporting data would provide more useful information to guide antiretroviral and opportunistic infection treatment needs estimates, to understand age-sex distribution of HIV cases and modes of transmission for directing prevention activities, as well as to monitor AIDS deaths. HIV infection case-reporting should be instituted and implemented by taking advantage of existing reporting mechanisms at the antiretroviral treatment (ART) centres and the ICTCs.

- Recent efforts to strengthen STI services are an excellent opportunity to improve STI surveillance. STI data must be collected from all STI service delivery points, including designated STI clinics, TI clinics, and primary health care facilities. Other actions include promoting syphilis screening among ANC clinic attendees and supporting the National Rural Health Mission in universal reporting of STI syndromes at sub-district level health facilities.

- The use of dried blood spots (DBS) for HIV testing instead of serum could greatly ease surveillance operations and enhance quality due to centralizing testing in a few laboratories. The technical efficacy of DBS has already been established in the National Family Health Survey-3. A switch to DBS can be made after testing its operational feasibility in routine conditions, and training of surveillance staff.

- Information requirements at the district level should be met through customized surveillance for each district based on the type of epidemic and risk/vulnerability. Top priority should be given to analyse, triangulate and use all available data for district level planning.

Introduction

Since the first HIV infection was reported in India in 1986, the epidemic continues to grow. India has the third highest HIV burden in the world with an estimated 2.5 million (range: 2–3.1 million) people living with HIV in 2006. HIV surveillance in India began in 1985 and has substantially expanded over the years. Presently, the following mechanisms are used to track the epidemic: HIV sero surveillance for different populations in 1122 sentinel sites; nationally representative behavioural surveillance surveys in a sample of 100 000 general population and 20 000 in populations with high-risk behaviours; AIDS case reporting from all states; and surveillance for STIs from more than 900 facilities across the country.

Data generated from the surveillance system have led to a better understanding of the heterogenous nature of the HIV epidemic in the country. There are multiple, diverse subepidemics in India unfolding at different rates in different populations. The overall estimated adult HIV prevalence is very low (0.36%) in the general population; however, HIV prevalence is very high among sex workers (SWs) and their clients, injecting drug users (IDUs) and men who have sex with men (MSM), ranging from 1% to 50%. There are geographical variations in the HIV prevalence, with the northeastern states (Manipur, Mizoram and Nagaland) and the southern states (Andhra Pradesh, Karnataka, Maharashtra and Tamil Nadu) reporting the highest HIV prevalence. In 2006, 118 out of a total of 609 districts had HIV prevalence >1% among ANC clinic attendees and 81 districts had HIV prevalence of ≥5% in one or more populations with high-risk behaviours. In some southern states where the overall HIV prevalence is beginning to show a decline, high HIV transmission areas still remain. Moreover, several new populations with high HIV prevalence have been detected in other parts of the country, particularly among IDUs in Kerala, Punjab and West Bengal.

India's HIV surveillance system has evolved over the years and has fulfilled several important programme needs ranging from estimating the number of people affected with HIV, targeting the highly affected geographic areas and vulnerable population groups, identifying new subepidemics, and evaluating the impact of interventions. However, the current surveillance system has

some limitations, such as insufficient coverage in some areas, selection biases that threaten the representativeness of the data in other areas, ethical issues due to unlinked anonymous testing (UAT), inadequate sample sizes, under-reporting of AIDS and STI cases, and lack of analyses of data.

With the launch of the third phase of implementation of the National AIDS Control Programme (NACP) in July 2007, information needs for district-level planning and monitoring are increasing. The many new data sources that have emerged recently owing to the scale-up of HIV services (provider initiated testing and counseling, PPTCT and ART) should be explored to supplement surveillance data. New surveillance strategies (such as IBBS) and newer technologies (such as the use of DBS and laboratory methods to measure HIV incidence) should also be examined and incorporated in the surveillance system if suitable.

In the light of the above issues, new developments in HIV services and surveillance methodologies as well as growing needs of the programme, the WHO Regional Office for South-East Asia convened a technical consultation from 23 to 25 April 2008 in New Delhi to review the HIV surveillance system in India. The meeting was attended by 54 participants including, national and international experts as well as representatives from national institutes (Indian Council of Medical Research [ICMR], National Institute of Health and Family Welfare [NIHFW], National AIDS Research Institute [NARI], Post Graduate Institute of Medical Education and Research [PGIMER]), State AIDS Control Societies (SACS) and partner agencies, Centers for Disease Control & Prevention Global AIDS Program (CDC GAP), Family Health International (FHI), Bill & Melinda Gates Foundation (BMGF), United Nations Children's Fund (UNICEF), United Nations Population Fund (UNFPA) and The United Nations Joint Programme on HIV/AIDS (UNAIDS). The participants discussed various issues in plenary sessions as well as five working groups: (i) surveillance in populations with high-risk behaviours; (ii) surveillance in the general population; (iii) surveillance for STIs; (iv) HIV/AIDS case reporting; and (v) laboratory services for surveillance. Based on the available background information, participants critiqued the current surveillance system and discussed mechanisms to increase its representativeness, coverage and validity of data and improve the use of routine programme data for surveillance. After in-depth discussions, each group presented recommendations to strengthen

the HIV surveillance system in India and increase its usefulness for guiding the national response to the HIV epidemic.

This report summarizes the discussions and recommendations of the *Technical Consultation to Review HIV Surveillance in India*.

HIV surveillance among populations with high-risk behaviours

In a concentrated epidemic, HIV is usually first detected among populations with high-risk behaviours (such as SWs and their clients, MSM and IDUs). Tracking the epidemic in these groups also provides most information about where new infections may emerge and the potential for spread in new geographic areas. Therefore, effective surveillance among these populations is most critical.

In India, HIV sero surveillance in MSM, IDUs, and SWs is done at sentinel sites, such as nongovernmental organization drop-in centres and de-addiction centres. The protocol for sentinel surveillance calls for UAT on 250 consecutive eligible respondents. In addition to these clearly defined population groups, the surveillance system also tracks trends among male and female STI patients seeking care in government health facilities as a proxy for people with high-risk behaviours. The national behavioural surveillance survey (BSS) for populations with high-risk behaviours is conducted periodically (one round was done in 2001 and a second round in 2006) by the NACP with consultation from multiple national and international technical agencies. In BSS, time location cluster sampling is used with a sampling frame constructed for each of the 25 state/multi-state zones. This is in contrast to the HIV sentinel surveillance system, which by-and-large functions at a district level.

The main objectives of surveillance in populations with high-risk behaviours are to: detect emerging epidemics; monitor HIV trends; evaluate programme impact; and make estimations and projections.

Detecting emerging epidemics

Surveillance activities for populations with high-risk behaviours are critical for detecting emerging epidemics in low prevalence areas. Detection of emerging epidemics involves identifying a geographic area that currently has non-existent or very low HIV prevalence, but has the potential to become an area with a concentrated epidemic (HIV prevalence among

populations with high-risk behaviours >5%) because of the presence of one or more core or bridge population groups that are sufficiently large and active (i.e. engaging in risk behaviours).

In low prevalence areas, TI programme data or surveys of groups with high-risk behaviours are not usually available to examine biological or behavioural markers of risk directly. Instead, detection of emerging epidemics must rely on triangulating other sources of information. Mapping or rapid assessment exercise are a proactive way to detect concentrations of populations with high-risk behaviours (both core and bridge populations) that can signal the potential for an emerging epidemic. Due to the highly variable and mobile nature of populations with high-risk behaviours, this kind of exercise should be done frequently (e.g. annually for areas where there is substantial mobility or limited understanding). Mapping exercises should not only estimate the size of the at-risk population, but also gather information to characterize the risk profile of the population to assess likelihood of an epidemic. These data sources need to be followed up by further investigation and local confirmation and corroboration. Anecdotal evidence at the local level from individuals who interact with high-risk populations may also be useful for prompting further investigation. Other helpful sources of programmatic data that can be used to trigger further investigation include higher numbers (spikes) of positive HIV test results from ICTC, including referrals from STI and tuberculosis (TB) clinics or inpatient populations. Rates of other STIs also serve as markers for HIV transmission and can be used as early warning indicators of HIV emergence.

HIV surveillance at STI clinic sites can be useful in providing an early indication of the presence of HIV in a district where no other data are available. However, as referral of STI patients to ICTC becomes routine in low prevalence areas, ICTC data can take over this function. Appropriate systems and mechanisms need to be developed to ensure that the ICTC data are analysed and used meaningfully. HIV surveillance among STI patients does not provide further insight on the HIV epidemic once an emerging epidemic has been identified in a geographic area.

Detecting epidemics through ANC sentinel surveillance is “too late”, in the sense that by the time an epidemic affects pregnant women, many opportunities to prevent spread from the high-risk groups who were infected earlier have already been lost. The exception to this would be in areas where the epidemic is driven by migrants periodically returning to

their families from higher prevalence areas. In these "source" migration areas, "early" detection among ANC women is critical.

In summary, secondary data sources can play an important role in detecting emerging epidemics in low prevalence areas. Some of the most useful sources are mapping/rapid assessment data (to identify core or bridge populations with high-risk behaviour); TI clinic data (where STIs may be a marker of HIV transmission); ICTC, TB patients, and hospital inpatients (as an early indication of the presence of HIV) data; and STI clinic patient data (where a rising numbers of STIs can signal HIV transmission). Areas with potential emerging epidemics are numerous, and it is not possible to look everywhere. Therefore exploration of secondary data sources, followed by local investigation of corroborative evidence should be the basis for prioritizing intervention and surveillance sites.

Monitoring HIV trends among populations with high-risk behaviours

Monitoring trends among populations with high-risk behaviours is useful for (i) evaluating the impact of programmes in the intervened populations and to (ii) describe the current epidemic trajectory and predict what may happen in the future in a specific geographic area.

Using targeted interventions site surveillance for monitoring trends

It is useful to implement TI surveillance in sites where monitoring programme interventions are important. TI sentinel surveillance, in theory, can provide internally valid measurements in an intervened population, that are useful for monitoring trends in populations with high-risk behaviours for purposes of programme evaluation. However, the quality of TI surveillance should be improved to ensure adherence to protocol, particularly on the issue of obtaining a sequential sample of people who would normally come to the TI site for services. The quality and interpretability of current TI surveillance is compromised by non-adherence to protocol. Also, some TI sites do not conduct routine syphilis testing. When syphilis testing is not routinely done and UAT is not appropriate, introduction of an informed consent process is needed. Some TI sites in southern states have adopted this approach with good success.

Some of the problems with reliability of data from TI sentinel surveillance sites relate to the potential bias introduced when the programme is pressured to recruit a sample size that is greater than the number of people who normally come to the site during the surveillance period routinely. One of the ways TI sites address the inability to obtain enough samples through the drop-in system is to hold special camps to collect surveillance data. This means it is not possible to follow the consecutive sampling approach or even the UAT approach. Sometimes camps recruit the required sample selectively, and this selective inclusion or exclusion of HIV-positive persons can affect the validity of the results. These problems may reflect a poor understanding or insufficient training regarding the purpose and methodology of sentinel surveillance for the programme staff who implement the sentinel surveillance activity on a day-to-day basis.

A modification to the recruitment protocol may also be required for small TI sites. While using statistical measures for a point estimate of people who come to a particular TI site, the sample size should have reasonable confidence intervals to view trends. Areas with a large number of people with high-risk behaviours attending the TI site can continue to follow the traditional sample size requirement. However, a “take all” approach during the surveillance period for small TI sites is a good alternative if the sentinel site represents a particular segment of the population (i.e. people who come to the TI site during a fixed period of time) and is not expected to be representative of a larger population. A “take all” sample gives a valid measurement for this group, and need for a “required” sample size is thus not important. However, while considering this approach, it might become necessary to compromise the national timeframe of HIV sentinel surveillance (HSS) and thus implementing this approach would require careful thinking.

Using IBBS for monitoring trends

To make estimates and projections and to describe the current epidemic in a specific geographic area, measurements with sufficient external validity are required that can be obtained by probability-based samples that are representative of populations with high-risk behaviours in a specific geographic area. Probability-based samples to obtain behavioural data only or integrated biological and behavioural data are resource-intensive and time-consuming. Therefore, it may not be possible to conduct these surveys in all areas where populations with high-risk behaviours are concentrated.

To simplify the IBBS and make it more manageable and cost efficient, an "IBBS lite" survey can be designed. The IBBS can be made "lighter" by: (i) prioritizing and limiting the number of biological markers, (ii) reducing the questionnaire to collect only critical behaviour indicators to serve the surveillance objectives, while maintaining the consistency with data generated through BSS, (iii) prioritizing the geographic areas where it is important to track trends for overall understanding of the epidemic (including for estimates/projections), (iv) identifying the relevant population groups to be surveyed, and (v) reducing the frequency of surveys. In other words, IBBS is not required in every geographical area and need not be done every year. Instead, it could be staggered, e.g. conduct surveys in one-third of the sites each year to cover all the sites over a three-year period.

HIV trends among STI patients

STI patients are intended to represent populations with high-risk behaviours. However, surveillance of HIV among STI patients at governmental facilities is fraught with major limitations. Patients attending STI sites represent a highly selective group that by definition is known to continue risk behaviours. Many STI patients remain inaccessible to health care systems as they take available over-the-counter drugs. Of those who seek care, three-fourths access the private sector. Currently, all the surveillance sites are located at tertiary care governmental facilities. Due to the small number of STI patients accessing the public sector, it has increasingly become more difficult to recruit an adequate sample of STI patients during the surveillance period; last year, nearly 40% of the sites were unable to recruit a sample of 250 during the surveillance period. Additionally, sampling women with STIs is a major issue as they are often asymptomatic. Also, because many STI sites are referral sites for more serious or chronic infections, these STI patients may have a higher likelihood of HIV infection than the typical group of STI patients. For these reasons, HIV surveillance data from STI patients are highly biased. Moreover, these data have little utility for monitoring trends or evaluating the success of prevention interventions because populations that are positively influenced by the interventions are excluded.

Making HIV estimates and projections

In the past, overall estimates and projections for India (through WHO/UNAIDS/National AIDS Control Organisation; NACO) were derived

for the entire country. In addition to being useful for advocacy purposes, estimates and projections are used for planning and resource allocation in terms of knowing the source of new infections, the size of the HIV problem, and the relative contribution of different populations with high-risk behaviours to the number of infections in the "general population". Some of the data required for this type of planning and resource allocation may be obtained by reviewing local data, such as mapping, health facility or programme data. This is part of the district planning process currently used to produce district action plans. However, generating estimates and projections to provide useful and in-depth information, especially for mature epidemics, requires a more intensive effort. In a low prevalence setting, the estimates and projections process may not be as effective as using secondary data and mapping for planning and resource allocation.

Defining the geographical unit for surveillance in populations with high-risk behaviours

The administrative unit for HSS is generally the district and the surveillance system tries to ensure that there is at least one surveillance site in every district. In 2006, there were 386 districts (out of a total of 609), which had at least one sentinel site for either a defined population with high-risk behaviour or STI patients. Thus, there is no information on populations with high-risk behaviours for half the districts, and nearly two-thirds with no information for defined groups (such as IDUs, MSM and SWs or their clients, i.e. migrants or truckers). While information is required for each district, it is not necessary to set up each type of surveillance for every group in each district. Rather, surveillance should be tailored to each district according to its risk/vulnerability. For detecting emerging epidemics, a district-level unit would be best for identifying risk groups and potential risk of transmission. For monitoring trends in intervened populations for programme evaluation, the geographic unit should be relevant to the way the TI sites implement activities. For truckers, the relevant unit of analysis/data collection is the region or source-destination corridor, rather than the district. For determining estimates and projections it is best to first identify useful epidemiologic zones at the state level and select districts that would be "representative" of a zone for data collection. Actual data collection may be done at the district level, and the data from that district may be used for modelling the epidemic for other districts in the same epidemiologic zone.

Surveillance in other populations

In neighbouring countries in the South-east Asia Region, prisoners are greatly affected with HIV. In some instances, as in Thailand, prison populations have seeded epidemics in geographic areas to which they return when they are released. Since prison populations form a large group in India, information about this group can help in planning services for this population. There is limited information on the situation of prisoners in India, but it is an important area to explore by undertaking special surveys to understand the burden. Uniformed personnel are another population group that is at high risk of contracting HIV and it may be worth examining data for this population.

Key conclusions

- Given the concentrated nature of the HIV epidemic in India, effective surveillance in populations with high-risk behaviours is critical as it provides the most information about where new infections may emerge and the potential for spread in new geographic areas.
- TI surveillance can be useful for monitoring the impact of interventions in the intervened populations but its quality needs to be improved, particularly with regards to sampling, adherence to protocol and introducing informed consent.
- Probability-based sampling methods (such as IBBS) would be useful in selected geographical areas to provide measurements with sufficient external validity.
- It may not be practical or even necessary to conduct HIV surveillance for groups with high-risk behaviours in every district. Instead, it would be useful to identify/define epidemiologic zones at the state level and select districts that would be “representative” of a zone for data collection. Actual data collection may be done at the district level, and the data from that district may be used as representative of other districts in the same epidemiologic zone.
- In the absence of other data in low prevalence areas, HIV surveillance in STI clinics may be useful for detecting emerging epidemics; however, HIV surveillance among STI patients is not useful for monitoring HIV trends either in low or high prevalence areas and are no longer used for estimations.
- To detect emerging epidemics in low prevalence areas, mapping data as well as subset analyses of ICTC data for populations with high-risk

Recommendations

- Strengthen TI-based surveillance by:
  - Introducing informed consent to the TI sentinel surveillance protocol. Informed consent is considered compatible with voluntary unlinked anonymous approach to testing.
  - Using mapping data to assess whether TI sites are located in areas with high concentrations of populations with high-risk behaviours (including bridge populations). Conversely, assess districts without TI sites and determine whether the lack of data from populations with high-risk behaviours is justified, or should be addressed by additional data collection for surveillance.
  - Revising TI guidelines to introduce informed consent, clarify sample size issues, and emphasize avoiding the camp approach.
  - Strengthening monitoring and supervision for adhering to the revised TI sentinel surveillance protocol.
  - Ensuring annual refresher training for implementers of TI based surveillance and strengthen monitoring and supervision of TI HSS sites.
- Replace BSS with IBBS-lite model. Develop a plan, design and protocol for a scaled down IBBS (IBBS-lite) that prioritizes geographic areas and population groups as well as biological and behavioural markers that should be measured. IBBS lite can be conducted once in two to three years in selected geographical areas.
- Discontinue HIV surveillance in STI clinic sites in high prevalence states as these data serve little purpose and can be misleading. Phase out HIV surveillance in STI clinics in low prevalence states as ICTC data become available in these states. Improve the quality of data collection, data management and analyses at ICTCs to allow its effective and immediate utilization.
- Develop guidance on appropriate methods for collecting data among bridge populations for surveillance purposes (e.g. establishing sentinel sites for truckers, migrants).
- Establish a system of mapping that is more routine and covers the entire country even where HIV is not yet thought to be present. Incorporate

elements of qualitative profiling of populations with high-risk behaviours in addition to doing hotspot-based size estimations. Develop guidelines for analysis of mapping and programme data to systematically detect emerging infections.

- Develop standard operating procedures to investigate and respond to any unusual changes in HIV prevalence in an area.
- Develop guidance on the second-generation surveillance system design, clarifying the use of TI HSS, STI HSS, BSS and IBBS, among others in meeting surveillance objectives.
- Explore the importance of military and prison populations as potential contributors to the HIV epidemic.

HIV surveillance in the general population

HIV surveillance among ANC clinic attendees is used as a proxy for the general population. ANC sentinel surveillance, which started in 1998 with 92 sites expanded to 628 sites in 453 districts by 2006. Surveillance at each sentinel site (usually one in each district in the northern low prevalence states and two in each district in the southern higher prevalence states) is carried out among 400 consecutively recruited pregnant women through the UAT approach. The ANC clinic population is used for surveillance because it is easy to access.

However, ANC sentinel surveillance captures data only from women who access health services. Majority of the ANC sites are located in governmental facilities in towns/periurban areas, and thus a large proportion of the rural populations and those who do not access governmental facilities do not get captured in the surveillance system. Moreover, the women attending ANC clinics are young and sexually active and do not use protective measures. For these reasons, data generated from ANC surveillance are biased and need to be interpreted and used with caution.

Objectives of ANC surveillance in a low level/concentrated epidemic

The main purposes of ANC surveillance are to understand the extent of HIV spread among the general population, to monitor HIV trends, to estimate HIV burden and identify high burden geographical areas for resource allocation.

In a concentrated epidemic, HIV is likely to be first seen among populations with high-risk behaviours, and later spreads to their low-risk partners (general population). Therefore, in a low level/concentrated epidemic, such as in India, surveillance in populations with high-risk behaviours is a critical first priority. Relying on the ANC sentinel group for detecting the emergence of HIV could be misleading and gives a false security. Therefore,

in low prevalence settings, the limited available resources should not be used to expand ANC surveillance; instead several homogenous districts should be combined and considered as a single epidemiological zone for the purpose of planning and estimating burden.

Currently, ANC sentinel surveillance data are being used to divide districts into A, B, C and D categories in descending order of HIV prevalence. This facilitates in planning and administrative decisions for the allocation of funds. For programme planning purposes, not just ANC data but all available programme data sources should be used (e.g. PPTCT, blood bank, STI, IBBS /BBS, ICTC, ART, and any community based surveys, such as demographic and health survey, National Family Health Survey [NFHS] or Reproductive and Child Health survey). A central team should analyse all available data to prepare a comprehensive "District Report Card on HIV". Also, there should be central guidance on the use of multiple data sources and local capacity building for triangulation of data.

Monitoring HIV trends using ANC sentinel surveillance data

According to the national surveillance guidelines, a sample size of 400 pregnant women should be consecutively recruited at each sentinel site. The required sample size for monitoring changes in HIV prevalence over time depends on two variables: (i) the baseline HIV prevalence, and (ii) the magnitude of change in prevalence that the programme wants to detect from one time point to another. The smaller the baseline prevalence, the larger is the required sample size; the smaller the magnitude of change in prevalence that the programme wants to detect over time, the larger is the sample size to detect a statistically significant difference.

In India, even among the high HIV prevalence states and districts, the prevalence is usually between 1% and 2%. To detect a 30% decrease in prevalence (from 1% to 0.7%) in areas with a baseline prevalence of 1%, at 95% confidence level and 80% power, a sample size of 14 000 is required; and to detect a 20% decrease (from 1% to 0.8%) with the same baseline prevalence, the required sample size would be 34 000.* Thus, the sample size of 400 tested at ANC sites does not have enough power for monitoring

* UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance (2003). Guidelines for conducting HIV sentinel sero surveys among pregnant women and other groups.

site-wise and district-level trends even in high prevalence areas. However, data for all the districts in a state can be pooled to get a sufficiently large sample size to monitor trends at the state level. In pooling the data, appropriate adjustments should be made for any differences in socio-demographic characterstics of the populations.

As explained above, the year-to-year fluctuations observed in a district thus reflect variations attributed to the small sample size rather than to real changes in prevalence. Thus, administrative decisions at the district level should not be based on changes in prevalence noted from one year to the next. The interpretation of trends as well as the decisions for administrative reclassification of districts requires careful analyses and understanding of data and should be done at the central level. At least three data points over three years should be used for drawing conclusions. Central guidance is required to investigate unusual fluctuations in HIV prevalence at a site (increase or decrease). For this, a standard protocol should be developed.

Using PPTCT programme data for surveillance

As HIV testing is unlinked and anonymous (i.e. women are not aware that they were tested for HIV) in ANC sentinel surveillance, the data are not biased due to refusal of HIV testing unlike data from PPTCT programmes. However, due to the unlinked nature of HIV testing, the UAT HIV test results cannot be communicated to the participants, which denies them an opportunity to know their HIV status and receive HIV services, such as PPTCT, ART, and care and support services. With the rapid expansion and increased availability of PPTCT and care and treatment services, women have a right to know their HIV status. Thus, it is ethically difficult to justify UAT unless all UAT sites are also providing PPTCT services.

PPTCT programmes also collect HIV testing information from the same pregnant women as collected by UAT sentinel surveillance. Therefore, PPTCT programme data could be used for HIV surveillance and could replace UAT sentinel surveillance. However, the PPTCT programme collects monthly aggregated data and reporting is usually incomplete and prone to errors, which could affect the use of PPTCT data for surveillance. Additionally, HIV prevalence estimates from PPTCT programme data could be biased if some women refuse to take the HIV test.

PPTCT programme data offer several advantages if used for HIV surveillance:

- The number of sites far exceeds that used for UAT sentinel surveillance.
- It could provide greater coverage and representativeness than UAT data as the programme expands further.
- The number of women tested is much larger than that tested by UAT sentinel surveillance. Larger sample sizes would improve the precision of HIV prevalence estimates.
- It may save costs incurred for UAT sentinel surveys.

A comparison of UAT and PPTCT data from 2003 to 2006 in India shows that: (i) though the completeness of PPTCT programme data has improved from 2% in 2003 to 60% in 2006, a large number of PPTCT centres still do not regularly report data every month; (ii) the acceptance rates of HIV test in PPTCT centres varies among states though a trend towards increasing acceptance is noted in most states; (iii) the correlation between PPTCT and ANC sentinel surveillance increases as HIV acceptance increases and is quite high in sites/states where HIV test acceptance is >90%; (iv) the quality of PPTCT data is inferior to that of ANC sentinel surveillance data.

As the PPTCT programme expands and its quality improves these data can be used for monitoring trends in HIV prevalence and for estimating prevalence at the district and state levels. However, before discontinuing ANC sentinel surveillance, potential biases in the PPTCT must be evaluated. An operational study at selected sites in each state should be conducted to test the feasibility of using PPTCT data and to characterize any biases introduced by women refusing HIV testing. The utility of PPTCT data for surveillance could be increased if regular reporting of PPTCT programme data from all centres is ensured and their quality is systematically checked. Also, ANC sentinel surveillance data can be used for evaluation of the quality of PPTCT by adding some questions about PPTCT in the ANC questionnaire, such as whether referred and reasons of referral, offered voluntary counseling, accepted the test, test result.

Obtaining representative data for HIV estimates

Data available from the ANC surveillance tend to overestimate HIV prevalence in the general population. In 2006, the availability of population-based NFHS-3 helped in calculating a calibration factor to adjust the ANC sentinel surveillance data for the purpose of estimates.

The representativeness of ANC surveillance data is largely compromised by absence of the male population and the limited inclusion of rural populations. Potential sources of obtaining data for the male population are blood donors, military recruits and potential government employees undergoing general health check-up before recruitment. However, each of these data sources have some limitations. Data from blood donors is based on a single HIV screening test and is also subject to selection bias. Before considering blood donor data for use in surveillance, it is important to characterize the magnitude and direction of the bias in using these data as a proxy for the general population. In some countries, potential military recruits serve as an important group to provide data on the young male population. However, these data are usually sensitive and may not be easily accessible. Private laboratories are another option for obtaining a representative sample of the general population. However, this group is unlikely to truly represent the low-risk general population — rather it is likely to be a mix of low-risk and high-risk populations. As NACO scales-up PPTCT in the private sector (in selected states), PPTCT sites should be included for surveillance. Access to rural populations for surveillance will remain challenging unless HIV testing services are further decentralized.

Obtaining a truly representative general population sample is difficult without a community-based probability sampling approach. In order to make appropriate adjustments to surveillance data, operations research is needed to determine differences between populations who are captured in the surveillance systems and those who are not. The ANC sentinel surveillance/PPTCT forms could be slightly modified to include a limited number of pertinent questions to help in making appropriate adjustments to the surveillance data. For example, published studies indicate that HIV-positive women are more likely to be referred to governmental facilities.

Including a question in the surveillance form on whether the women were referred from another health facility, can help in making appropriate adjustments to the facility-based surveillance data. Finally, for the purpose of estimating HIV burden, periodic population based surveys that use probability sampling would be needed to calculate appropriate calibration factors to adjust surveillance data.

Key conclusions

- In areas with low HIV prevalence, ANC sentinel surveillance serves limited purpose; in these areas, surveillance among populations with high-risk behaviours is most critical and useful.
- In low prevalence states, every district *does not* require an ANC sentinel site; and thus there is no need to expand ANC sites to every district of the country. Similar/homogenous districts may be combined and considered as a single epidemiological zone for the purpose of planning and estimations.
- It is ethically difficult to justify UAT unless all UAT sites are also providing PPTCT services.
- The current sample size of 400 per site/district is too small to conclusively monitor trends at the district level. However, for the high prevalence states, data could be pooled to monitor trends at the state level.
- Year-to-year changes in prevalence at the district level should not drive administrative and financial decisions. At least three data points (over three years) suggesting trends in the same direction are required for concluding change in trends.
- Although promising, PPTCT programme data cannot immediately replace UAT surveillance. The decision can be made only after appropriate evaluation of the possible biases and improving the quality of PPTCT programme recording and reporting.
- The current surveillance system for the general population focuses on young women accessed through ANC clinics and is not truly representative of the general population. For the purpose of HIV estimates, periodic population surveys would be needed to calibrate facility-based data from ANC clinic attendees.

Recommendations

- Offer PPTCT services at all UAT surveillance sites.
- Strengthen the PPTCT programme, and particularly, improve quality of recording and reporting.
- Conduct multi-site operations research using individual-level primary data to characterize bias among women who do not accept HIV test in the PPTCT programme. After ensuring the quality of the PPTCT programme regarding above issues and reviewing the operations research data, decide on replacing the three-month sentinel surveillance sample for ANC with the year-round PPTCT sample.
- Use all available data sources for programme planning purpose at the district level, such as PPTCT, ANC sentinel surveillance, BSS, ICTC, blood donor. Use at least three data points (over three years) to make conclusions about HIV prevalence trends; do not base administrative and financial decisions on year-to-year changes in prevalence.
- Develop central guidelines and tools on data analyses and triangulation from multiple sources and produce a report card on HIV for each district.
- Modify the ANC sentinel surveillance form to include a limited number of questions that will help in understanding and adjusting potential biases in these data.
- Explore the possibility of obtaining data on “potential military recruits” and from government pre-employment health check-ups to capture surveillance data representing young men.
- Undertake operations research to characterize the magnitude and direction of bias in using blood donor data as a proxy for the general population.
- Conduct periodic population-based surveys that can capture more representative data from the general population to calibrate ANC data for estimations.
- Strengthen human resource and institutional capacity in surveillance and build local capacity for data analyses and interpretation.

HIV/AIDS case-reporting

AIDS case-reporting was initiated in India in 1985 as a means for tracking HIV infection early in the course of the epidemic. Due to the lack of other reliable methods of surveillance and monitoring at that time, AIDS case-reporting served as one of the few available methods to monitor HIV/AIDS trends and plan resources for clinical and laboratory facilities.

Over the years, multiple significant changes in the national response to the HIV epidemic, such as the development of sentinel surveillance for HIV infection, the expansion of ICTC, and the implementation of a detailed monitoring and evaluation system have contributed valuable data that have improved the understanding of the prevalence, trends and changes in the HIV epidemic in India. Recently, the roll-out and ongoing scale-up of free ART services in the public sector have underscored the importance of collecting accurate data to estimate resource needs and plan effective interventions for HIV prevention and treatment.

Utility of AIDS case-reporting in the context of ART scale-up

With the increased availability of effective first-line ART, new priorities have taken precedence in the national AIDS programme. As the programme continues to progress towards universal access for HIV prevention, care and support, it is becoming increasingly important to identify people earlier in the course HIV infection through effective HIV testing to ensure that they are enrolled in appropriate care and treatment services in a timely manner. The value of continuing AIDS case-reporting thus needs to be revisited in this context.

The key programme requirements include estimating resource needs for ART services and opportunistic infections' (OI) treatment, planning interventions for HIV prevention and understanding AIDS-related mortality. Because AIDS case-reporting focuses on persons already given a clinical diagnosis of AIDS, it is not useful for predicting near and mid-term ART needs. Furthermore, AIDS case-reporting relies on data from multiple disparate reporting units across undefined lines of authority, making the reporting inconsistent, incomplete and poorly representative. These

limitations further preclude useful prediction of resource needs for ART and OI treatment, and are of limited use for monitoring trends or AIDS-related mortality. Clearly, the current AIDS case-reporting system does not meet the present programme requirements. Therefore, it is recommended that AIDS case-reporting be discontinued in favour of initiating other reporting mechanisms that can better meet programme needs.

HIV infection case-reporting

In an ideal setting, the collection of complete data on HIV infection, advanced HIV infection (including AIDS), TB and non-TB OIs, and deaths due to AIDS would be desired to provide accurate information to plan resource allocation and programme priorities.

In 2006, WHO recommended *HIV infection case-reporting* to capture more complete data on persons infected with HIV at all stages of infection. HIV infection case-reporting data can be potentially useful for monitoring the epidemic, understanding age–sex distribution of HIV cases and modes of transmission, estimating resource and treatment needs, and monitoring AIDS deaths. Because HIV infection case-reporting involves reporting of HIV infections both among persons with early- and late-stage HIV infection (clinical stage 1 and 2; clinical stage 3 and 4), and those who have developed AIDS, it can be more readily used to predict ART needs. In India, the two main existing sources of data on HIV infection are the ART centres and ICTCs.

HIV infection case-reporting from ART centres

Persons who are diagnosed with HIV infection are routinely referred to ART centres for HIV care and treatment. Persons who access ART centres are initially registered in pre-ART care, where individual patient demographic data, HIV clinical staging data and CD4 cell count are all routinely collected and recorded. Thus, existing reporting mechanisms from ART centres can be modified for HIV case-reporting purposes to incorporate monthly data on HIV-infected persons newly registered for pre-ART care. The data included for HIV case-reporting from the pre-ART centre can therefore include HIV status, demographic data, clinical stage and CD4 count. Clinical data on OIs (both TB and non-TB) are also routinely collected at both pre-ART and ART centre levels. Data can be collected from all patients

newly registering for pre-ART services at ART centres. Reporting would thus encompass persons with HIV and AIDS (*refer Box 1 for case definitions*). One of the drawbacks of HIV infection case-reporting from ART centres is that at present, only an estimated 35% of persons diagnosed with HIV at ICTCs gain timely access to care and treatment at an ART centre. Thus, the population reported represents a proportion of all those diagnosed with HIV, and may perhaps be skewed to include more patients with advanced (stage 3 or 4) HIV infection and those more likely to require clinical care and treatment. However, the advantage is that it will be logistically easy to implement case reporting from ART centres as most of the data is already being collected systematically. Another advantage is that since each patient is provided an individual ID, duplication in data is much less of a concern than in ICTC reporting.

Operations research is warranted to determine the reasons for and barriers to successful linkages between ICTCs and ART centres for persons who are newly diagnosed with HIV infection. Tightening and improving the referral and linkages between ICTCs and ART centres is an important activity to strengthen both HIV treatment and care services and the quality of HIV case-reporting. Additionally, CD4 testing and HIV clinical staging can be piloted using operations research to obtain more complete HIV clinical information among all ICTC clients, including both those who are linked to ART care, and those who are not linked to ART care. These data would provide data for programme planning of ART needs, as well as allow a better understanding of the limitations of HIV case-reporting data.

HIV infection case-reporting from ICTC

The other existing key data source for HIV infection case-reporting is the ICTC, of which there are now over 4000 centres across the country. Existing reporting mechanisms through ICTCs can provide data on the number of persons detected with HIV infection. However, these reports provide aggregated and not individual client data. Clients diagnosed with HIV infection at one ICTC may subsequently access services at a different ICTC to “confirm” results. Thus, the issue of duplication in reporting may arise, and should be considered when assessing HIV infections reported from ICTCs. Possible methods to address duplications in HIV reporting data include name-based reporting, which the Indian programme does not favour at present, or a coding system that would allow de-duplication. The latter, while an effort-intensive and potentially complicated process, has

Box 1: Proposed case definitions for HIV case-reporting for surveillance of HIV infection and advanced HIV infection for adults and children

Case definitions: adults

HIV infection in adults (15 years and older):

- Positive HIV antibody testing (ELISA/Rapid/Simple)
- Confirmed by a second antibody (E/R/S) relying on a different antigen in symptomatic individuals
- Confirmed by a third antibody (E/R/S) relying on a different antigen in asymptomatic individuals

The above definition shall be used for *HIV infection reporting*
Reporting unit: Any facility that has HIV testing and counseling capacity (ICTCs)

Advanced HIV infection in adults (15 years and older):

- Confirmed HIV infection and clinical diagnosis (presumptive or definitive) of any stage 3 *or* 4 condition

or

- Confirmed HIV infection and first ever documented CD4 count below 350 cells/mm^3

This would be *newly* instituted for routine reporting in the monthly ART centre report. Encompasses *both* advanced HIV and AIDS cases

AIDS case-definition in adults (15 years and older)

- Confirmed HIV infection and clinical diagnosis (presumptive or definitive) of any stage 4 condition

or

- Confirmed HIV infection and first ever documented CD4 count below 200 cells/mm^3

This replaces the existing AIDS case definition. *However, this would no longer be reported separately*

Case definitions: children

- HIV infection in *children* younger than 18 months
  - Positive virological test for HIV (HIV RNA, HIV-DNA, or HIV p24 Ag) confirmed by a second virological test obtained from a separate determination taken more than 4 weeks after birth
- HIV infection in children 18 months–14 years
  - Positive HIV antibody testing (E/R/S), confirmed by a second HIV antibody test (E/R/S) relying on different antigens

Advanced HIV infection in children

- Confirmed HIV infection *and* presumptive or definitive diagnosis of stage 3 or 4 condition.
- Confirmed HIV infection *and*
  - % CD4 <30 among those <12 months
  - % CD4 <25 among those 12–35 months
  - % CD4 <20among those 36–59 months
  - CD4 count less than 350 cells/mm^3 among those five years and older

These data would be *newly* instituted for reporting from the ART centres.

been implemented in other South-east Asian countries successfully, and could be investigated in the Indian setting. The extent of duplication in ICTC data has not been quantified, and can be evaluated in select sentinel ICTC sites by instituting line-listing of ICTC data. A simple method of de-duplication based on key demographic criteria to be performed at the state level can be devised and piloted. Depending on the pilot results, this could be evaluated for further expansion in the coming years. Even in the absence of specific de-duplication procedures, routinely reported data from ICTCs provide a rich source which in combination with information collected from other surveillance components can provide information on modes of transmission, demographics and clinical characteristics of the infected cases, epidemic trends in infected sub-populations and detection of emerging epidemics, as well as guide planning of HIV preventions, care and treatment activities.

TB-HIV programme data

At present, key TB-HIV programme collaborative activities include risk-based referral of TB patients for HIV testing and intensified case-finding for TB at ART centres. Under this scheme, HIV testing for TB patients takes place at ICTCs. TB status is routinely reported from ICTC records. Therefore, analyses of ICTC records can provide information on the proportion of clients with HIV and TB co-infection. For patients who are already in HIV care, data on OIs including TB is recorded in the pre-ART and ART records. It is important to strengthen the diagnosis, recording and reporting of TB status among HIV-infected patients at the ART centres to enhance the quality of both treatment services and OI reporting. Furthermore, in high prevalence states an intensified TB-HIV package would be implemented in the coming year, involving routine referral of all TB patients to ICTCs for HIV testing, co-trimoxazole prophylaxis for all co-infected patients, and expanded reporting of HIV status on TB treatment cards and reports. Analysis of these data over the next two years would provide information on HIV prevalence among registered TB patients, and other useful programme information for planning and implementing TB and HIV programmes.

HIV mortality

Information on HIV-related deaths is useful for: measuring the impact of HIV-related care and treatment programmes; demonstrating the relative impact of HIV-related mortality as compared with other causes of death; and estimating the number of years of productive life lost. In developing countries like India with weak vital registration systems and the widespread HIV-associated stigma, it is challenging to measure HIV associated mortality.

As the number of HIV-infected persons receiving ART increases, the number of deaths attributable to HIV should decline. This can provide a good marker of the impact of ART on HIV-related mortality. Routine ART programme cohort data analysis allows the calculation of mortality (case-fatality) among patients who are on treatment. Results of these analyses would be important indicators of programme performance and would help to inform further scale-up of ART services. For a more complete measurement of HIV associated mortality, data should be obtained from special surveys, including the verbal autopsy methods used by Sample Registration System (SRS).

Key conclusions

- AIDS case-reporting provides incomplete and poorly representative data, and does not meet current programme requirements for treatment needs' estimations and resource allocation.
- HIV infection reporting is much better suited to current programme requirements of estimating ART and OI treatment needs, and planning interventions for HIV services. Pilot-testing of HIV case-reporting would provide experiences for further expansion throughout the country.
- Analysis of mortality data among patients receiving ART would also be useful for continued monitoring and evaluation of programme services. To determine the burden of AIDS-related deaths in India, estimates may be best obtained from modelling as well as special studies.
- Data collected at TB sites and HIV care and treatment sites are useful both for TB programme activities as well as HIV treatment and support activities, and the systematic analyses and expansion of such activities should be explored.

Recommendations

- Discontinue the current AIDS case-reporting system.
- Institute HIV infection reporting systems using revised WHO case definitions.
  - Pilot test the implementation of HIV infection case-reporting in 10 ART centres over the next 12 months, collecting data from each newly registered patient for clinical stage, OIs, and CD4 status. The pilot implementation of HIV case-reporting should inform and guide the expansion of HIV case-reporting to additional ART centres in the coming 12–18 months.
  - Pilot test HIV infection case-reporting from 10 ICTCs. This data will include line listing on individual cases including demographic, clinical and risk behaviour information.
- Continue ART cohort analyses among patients on treatment. This will provide data on HIV/AIDS related mortality and will be useful to evaluate the impact of the ART programme. Collaborate with the Office of the Registrar General of India to obtain HIV/AIDS mortality data collected through verbal autopsy from SRS.
- Systematically analyse HIV/TB data collected at TB and HIV facilities to monitor and improve TB and HIV care and treatment activities.
- Undertake operations research to evaluate referrals between ICTCs and ART centres. This research will help in improving linkages to care, increase the proportion of persons diagnosed in care, and also improve the quality of HIV case-reporting.
- Pilot test clinical staging and CD4 staging at selected ICTCs to obtain more complete HIV clinical information among all ICTC clients. These data would provide information for programme planning of ART needs, as well as allow a better understanding of the limitations of HIV case-reporting data.

Surveillance for sexually transmitted infections

Surveillance for STIs is an important component of the second-generation HIV surveillance system. STI data are useful for planning, monitoring and evaluation of both STI and HIV programmes. As STIs are markers of HIV risk behaviours, surveillance for STIs serve as an early warning of the emergence of HIV.

According to the national STI surveillance guidelines, the key components of STI surveillance are: (i) STI syndromic and etiological case-reporting; (ii) Syphilis screening among pregnant women; (iii) Syphilis screening in donated blood; (iii) Population-based STI prevalence assessment and monitoring; (iv) Assessment of STI syndrome and etiologies; and (v) Antimicrobial resistance monitoring.

However, in practice, the systematic collection, analyses and use of STI data has received very low priority. Reporting of STI data is inconsistent, irregular and incomplete. While 10–20% STI clinics report high volume of patients, 30% do not report at all. Standard case definitions are not used for reporting and there is little training of staff in the use of standard recording and reporting tools. Each year, syphilis screening is done among pregnant women and blood donors but these data are rarely analysed, reported or used. Systematic analyses and feedback of data for action is almost non-existent. Thus, the current STI surveillance system does not fulfill its intended objectives and needs to be revived.

Proposing a STI surveillance framework for HIV surveillance

Similar to the framework for HIV surveillance, STI data should be captured from three distinct population groups: populations with high-risk behaviours, bridge populations (e.g. truckers) and the general population. A basic STI surveillance framework should include: (i) STI case-reporting from sentinel STI clinics (one per district); (ii) syphilis screening for all pregnant women and populations with high-risk behaviours at TI sites; and (ii) universal reporting on key syndromes among men and women at all sub-

district level health facilities and TI clinics. As basic STI surveillance is built around routine services, which are recommended as a standard of care, it should be logistically easy to implement. In addition to the basic system, advanced laboratory-based surveillance is needed for monitoring selected STI etiologies and antimicrobial resistance. The proposed framework for STI surveillance for the three population groups is given below:

Core populations with high-risk behaviours

- Syphilis screening is recommended for populations with high-risk behaviours at first visit and subsequently every six months. Biannual syphilis screening data provides trends in serological syphilis among populations with high-risk behaviours, which can be useful for planning, monitoring and evaluating the impact of TIs.
- Syndromic STI case-reporting should be done at all high-risk TI clinics using NACO's syndromic reporting forms.
- Periodic community-based etiologic surveys should be undertaken among populations with high-risk behaviours in conjunction with other surveys.

Bridge populations

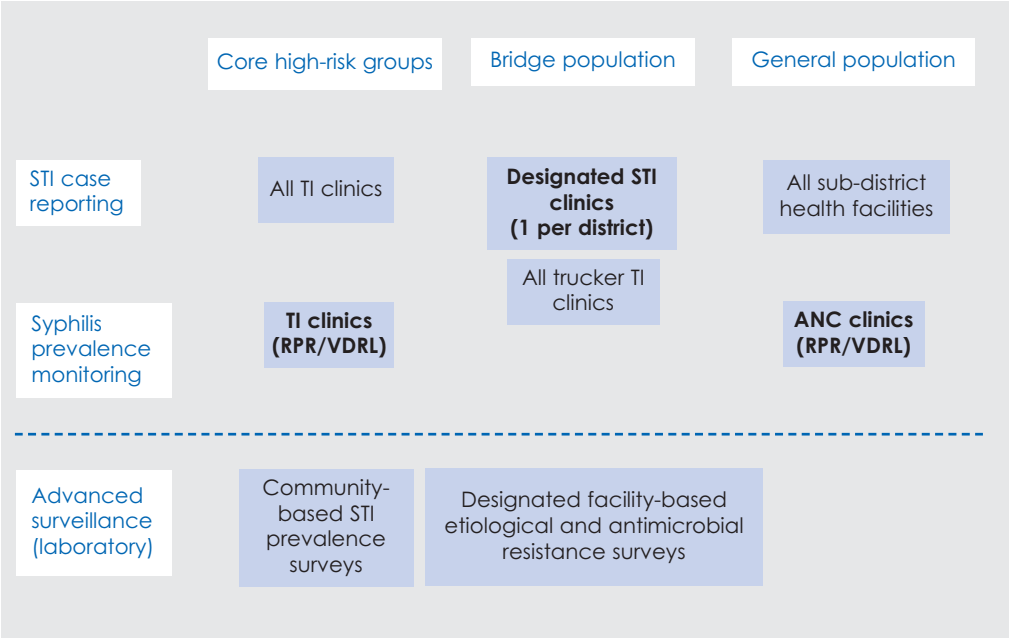
- STI case-reporting from designated STI clinics (one in each district) should be strengthened. Since designated STI clinics presumably cater to bridge populations, a separate surveillance system is not required for them at this time. Syndromic reporting with periodic etiological surveillance should be done at these clinics.
- STI case reports should be collected from trucker TI clinics. These clinics should also follow the national guidelines and use the same report formats.
- STI data on migrants can be captured from designated STI clinics located in areas with high migrant density.

General population

Women attending ANC clinics serve as an easily accessible group for surveillance. Syphilis screening is recommended for all pregnant women at

their first ANC clinic visit. There is a need to promote widespread screening of syphilis among pregnant women at all clinics that are capable of performing rapid plasma reagin / veneral diseases research laboratory (RPR/VDRL) tests. Syphilis screening and surveillance should progressively extend screening and surveillance to more peripheral levels. The Centers for Disease Control and Prevention, Atlanta is field-testing a new rapid test kit, which will detect both nontreponemal and treponemal antibodies simultaneously, thus increasing the sensitivity as well as specificity of the test and facilitating syphilis screening at peripheral sites.

Framework for STI surveillance



Note: Bold text indicates higher priority

Choice of STI syndromes and etiologies

The key STIs to be monitored on priority are genital ulcer disease (GUD) among men and women and urethral discharge (UD) among men. GUD and UD trends among men are most useful markers of sexual transmission of HIV among the bridge population. Bacterial causes of GUD (chancroid, syphilis) are markers of poor STI control and high HIV vulnerability.

Gram stain used for diagnosing chancroid lacks sensitivity and should be stopped. At centres of excellence, highly specific and sensitive laboratory tests (such as polymerase chain reaction; PCR) should be used to provide the best possible data on STI aetiologies. CDC has developed a DNA capture card which facilitates transfer of specimens easily even from remote areas. Operational research should be undertaken to field test this.

As presumptive treatment is advocated across high-risk group clinics, there should be provision for periodic laboratory-based surveillance for gonococci and chlamydia. Additional testing for herpes simplex virus type II (HSV II) may not yield programmatically useful information if applied universally, and instead can be used in low HIV-prevalence districts (category C and D) to identify emerging hot spots.

Improving the completeness and quality of STI surveillance data

Improvements in STI surveillance occur in conjunction with improvements in STI service delivery. The current weaknesses in the system are mainly due to operational constraints, such as lack of staff, training and feedback mechanisms. Improving the completeness of reporting will require focusing on capacity building and operational support. Vacancies of STI focal persons at several SACS should be addressed urgently. High priority should be given to developing and institutionalizing data analysis and feedback system. Other ways to improve completeness of reporting should be explored including starting a newsletter that could also be disseminated periodically; electronic data entry form with inbuilt analysis; and using cell phones for data capture. Steps should be taken to converge reporting from sources, such as Integrated Disease Surveillance Project (IDSP) and Reproductive and Child Health (RCH) II project, with NACO reports to a generate a holistic / comprehensive picture of STIs. The five existing regional STI reference research and training centres need to be strengthened to function as centres of excellence with specific terms of reference (drafted) and accountable to NACO. At least one microbiology department needs to be upgraded per state to provide laboratory support to designated STI clinics to ensure quality syphilis screening. Regional and state laboratory strengthening should prioritize: capacity building and quality control for syphilis testing; high quality laboratory testing to inform and improve syndromic guidelines; and routine support for select etiologic testing.

Capturing STI surveillance data from the private sector

Since three-quarters of the STIs are treated in the private sector, it is important to capture data from private STI service providers. However, caution is required as there are few successful examples of private sector involvement for STIs; collecting surveillance data from the private sector is especially challenging. The recently introduced public-private partnership scheme of NACO is an opportunity to collect STI surveillance data from the private sector. The feasibility of collecting STI surveillance data from the private sector should be tested in a few districts before rolling out to all sites. Simplified methodology and reporting forms should be developed for surveillance in the private sector (e.g. reducing the number of reportable STI syndromes, using a pre-paid postcard). STI surveillance data should be collected from the clinics of the private medical colleges and their faculty should be involved in supervision/ monitoring of STI programmes and surveillance.

Key conclusions

- The current STI surveillance system provides incomplete, irregular and non-representative data and has been used sparingly to monitor the HIV and STI epidemics.
- STI surveillance should be improved in conjunction with strengthening of other aspects of STI services.
- There is a need to capture STI data from different population groups, namely, populations with high-risk behaviours, bridge populations (such as truckers) and the general population.
- Detection of GUD among men and women and UD among men are priorities for the AIDS control programme.
- Most of the weaknesses of the current STI surveillance system are of operational nature and can be corrected by filling up vacancies, providing training, and instituting a feedback mechanism to reporting units.
- The current surveillance system captures data mainly from the public sector though more than three-fourths of the patients with STIs seek care from the private sector. Thus, engaging the private sector in surveillance is important but challenging and should be attempted on a small scale with careful evaluation.

Recommendations

- Implement a basic STI surveillance system in designated STI clinics, TI clinics and ANC clinics. Also, support the National Rural Health Mission in universal reporting of STI syndromes at sub-district level health facilities.
- Undertake special studies periodically to monitor STI etiologies and antimicrobial resistance patterns.
- Ensure that all reporting sites (including TI sites and trucker TI sites) use the standardized STI case-reporting format.
- Provide staffing and operational support to build the required systems at all levels to ensure completeness and timeliness of reporting. Address the key issue of STI focal persons vacancy at many SACS.
- Strengthen the five existing regional sexually transmitted diseases reference research and training centres as centres of excellence with specific terms of reference. Upgrade at least one microbiology department per state to provide laboratory support to designated STI clinics to ensure quality syphilis screening.
- Conduct operations research to field-test the new rapid test kit covering RPR + TPPA on a single strip for syphilis screening.
- Undertake operations research to evaluate the use of DNA capture for sample collection from patients with GUD from remote sites.
- Evaluate carefully the planned strengthening of private providers through PPP. Consider simplified reporting formats with key syndromes and innovative reporting (such as pre-paid post cards). Explore the role of medical colleges in supporting STI reporting by private providers.
- Ensure that all available STI data including syphilis data from ANC clinic attendees and blood donors is analysed, reported and used. Also, analyse data from other sources (such as IDSP, RCH II) to arrive at a more complete representation of STI burden and trends.
- Map the many organizations and donors working in the field of STI in India, and hold biannual meetings to be mutually beneficial. The shared data may be used for planning /monitoring purposes.

Laboratory services in surveillance

Efficient and high quality laboratory services are the cornerstone of HIV surveillance. In recent years, HIV testing both for the purpose of diagnoses and surveillance has expanded markedly, thereby increasing the workload on laboratories. In this context, there is a need to strengthen existing laboratories (national reference laboratories, and other HIV testing laboratories involved in surveillance) in terms of equipment, and manpower, as well as to ensure that external quality assurance is conducted consistently and regularly.

Approximately 350 000 specimens are tested in the HIV sentinel surveillance round, each year. At each site, whole blood is collected and HIV testing is done on serum specimens either at the same location or after they are transported to a laboratory for testing. Operationally, it is a huge undertaking and requires cold chain, plastic ware, logistics of transporting serum and quality control procedures at more than 200 laboratories across the country. The use of DBS instead of serum for HIV testing could greatly ease surveillance operations and enhance quality by centralizing testing to a few laboratories. DBS was used in the NFHS-3 survey and its feasibility and efficacy has been established in India. However, the operational feasibility of using DBS from multiple surveillance sites and by staff with varying skills should be established.

Recommendations

- Ensure that external quality assurance is conducted and reported consistently and regularly.
- Switch to DBS for HIV surveillance after testing its operational feasibility.
- Strengthen existing laboratories (national research laboratories and other HIV testing laboratories involved in HSS) in terms of equipment and manpower, in view of the expanding role of laboratories.
- Constitute an advisory committee comprising experienced microbiologists and epidemiologists to proactively plan and advise on different laboratory testing issues in STIs, HIV and associated diseases.

HIV incidence surveillance

The current surveillance system measures HIV prevalence in different population groups. With the expanding ART coverage and increasing life span of patients, the pool of HIV-infected persons is likely to increase in the future; therefore, measuring HIV prevalence alone may not accurately reflect the trends and current dynamics of the epidemic. For a better understanding of the current spread of infection, it is important to think about and make preparations to measure HIV incidence. For a concentrated epidemic, it is more important to measure incidence in populations with high-risk behaviours than in the general population. The current technology/ laboratory methods to measure incidence are still evolving but NACO could start planning and building systems for HIV incidence testing in the future.

Recommendations

- Plan for HIV incidence surveillance by building capacity, infrastructure and cold chain logistics, and storage of positive specimens for future testing.
- Develop a design suitable to perform incidence assays as a part of surveillance among populations with high-risk behaviours, including considerations for sample size, additional survey questions and type of specimen to be collected.
- Explore the possibility of using stored NFHS-3 specimens for HIV incidence testing.
- Conduct research to determine the correction factor for laboratory-based HIV-1 BED incidence assay in the Indian context.

Cross-cutting recommendations

- Meet information requirements at the district level through customized surveillance for each district based on the type of epidemic and risk/vulnerability factors.
- Prepare a road map and action plan for improving design, collection, analyses and use of HIV surveillance data.
- Develop central guidelines and tools on data analyses and triangulation from multiple sources, such as mapping of high-risk groups, TI surveillance, ICTC, PPTCT programme, ANC sentinel surveillance, behavioural surveys, and blood donor data.
- Produce an HIV Report Card for each district summarizing key information including the size of the affected populations and the biological and risk behaviour markers; this should serve in district-level planning for prevention, care and treatment services for different population groups.
- Strengthen human resource and institutional capacity at the national and state levels in surveillance, data management and data analyses. Build district- and programme-level capacity for understanding and using data.
- Consistently follow-up each programme reporting unit to ensure that data are regularly reported to NACO. Develop standardized data analysis and automatic feedback mechanisms to inform back to the programme reporting units.
- Develop standard operating procedures to investigate and respond to any unusual changes in HIV prevalence in an area.
- Continue to undertake periodic desk reviews and field supervision of surveillance activities.

Annex 1: Programme schedule

Day 1: Wednesday 23 April 2008		
09.00–09.45	Opening session	
	Welcome and introductory remarks	Dr Poonam Khetrapal Singh, Deputy Regional Director, WHO/SEARO
	Opening remarks	Ms Sujatha Rao, Additional Secretary and Director General, NACO
	Objectives and expected outcomes of the meeting	Dr Jotna Sokhey, Addl. Project Director, NACO
09.45–10.15	Tea / Coffee	
10.15–13.00	Chairpersons	Dr Jotna Sokhey, Additional Project Director, NACO and Dr Tasnim Azim, ICDDR, Bangladesh
	Overview of HIV/AIDS, STI and behavioural surveillance in India	Dr Ajay Khera, NACO and Dr Bhattacharya, NIHFW
	HIV surveillance in the general population: utility of prevention of parent-to-child transmission of HIV programme data	Dr Rajesh Kumar
	HIV sentinel surveillance in populations with high-risk behaviours: current status and issues	Dr Tobi Saidel
	Facility-based HIV/AIDS case-reporting	Dr Partho Haldar
	STI surveillance in India: current status and issues	Dr Shashikant
	Discussions	
13.00–14.00	Lunch	
14.00–17.00	Group work (Four working groups) Group 1: HIV surveillance in core high-risk populations and bridge populations Group 2: HIV surveillance in the general population Group 3: HIV/AIDS case reporting and HIV surveillance among TB patients Group 4: STI surveillance	

Day 2: Thursday 24 April 2008	
09.00–10.00	Group work (contd.)
10.15–10.30	Tea / Coffee
10.30–13.00	Group work (contd.)
13.00–14.00	Lunch
14.00–15.00	Group work (contd.)
15.00–15.15	Tea / Coffee
15.15–17.00	Group work (contd.)

Day 3: Friday 25 April 2008		

Chairpersons: Dr Jai P. Narain, Director Communicable Diseases, WHO/SEARO
Dr Jotna Sokhey, Additional Project Director, NACO

Group work presentations and discussions

08.30–10.00	Recommendations of Group 1: HIV surveillance in core high-risk populations and bridge populations	Dr Virginia Loo
10.00–10.30	Tea / Coffee	
10.30–11.30	Recommendations of Group 2: HIV surveillance in general population	Dr Sudhir Bunga
11.30–12.30	Group 3: Recommendations of HIV/AIDS case reporting and HIV surveillance among TB patients	Dr Padmini Srikantiah
12.30–13.30	Lunch	
13.30–14.30	Group 4: Recommendations of STI surveillance	Dr Shashikant
14.30–15.00	Recommendations of the group on laboratory issues	Dr Usha Baweja
15.00–15.15	Tea / Coffee	
15.15–16.00	Discussion (open)	
16.00	Closing remarks	Dr Jotna Sokhey Additional Project Director, NACO Dr Jai P. Narain WHO/SEARO

Annex 2: Terms of reference for the groups

Group 1: Key questions about HIV surveillance in core high-risk populations and bridge populations

- How to increase the representativeness and quality of surveillance among populations with high-risk behaviours ? What should be the geographical unit for surveillance for each group, as relevant? How to capture the urban/rural dichotomy?
- How to better capture data from the bridge populations, namely clients of sex workers and mobile populations? Do we need to set up surveillance among new groups, e.g. prisoners?
- What are the biases in surveillance data collected from TI sites? Is it ethical to continue unlinked anonymous testing in TI-based surveillance?
- What is the utility/relevance of HIV surveillance among STI? Does it add value to monitor HIV trends in populations with high-risk populations? Should it be phased out?
- Should we consider replacing HIV sentinel surveillance among populations with high-risk behaviours by integrated bio-behavioural surveillance (IBBS)? Are there any simpler models of IBBS for use? What should be the minimal essential behavioral and biological markers for surveillance in each risk group?
- Can we better use routine programme data, such as counseling and testing data, for surveillance?

Group 2: Key questions about HIV surveillance in general population

- Is the ANC clinic sentinel surveillance useful for monitoring site-specific, district-specific and state-specific HIV trends? What should be the geographical unit for monitoring trends in the general population, including urban/rural dichotomy?
- Are the prevention of parent-to-child transmission of HIV (PPTCT) data and the ANC sentinel surveillance data comparable in India? Can we phase out ANC sentinel surveillance and replace with PPTCT programme data in selected states were PPTCT coverage and uptake is high?
- What are the other options to capture data for general populations, especially for groups missed out by ANC surveillance, e.g. low-risk males, older women and rural populations?
- Can private laboratories be used to collect data for the general population?

Group 3: Key questions for HIV/AIDS case reporting and HIV surveillance among TB patients

- What purpose does AIDS case reporting serve in the context of ART scale-up? Is it worthwhile to continue reporting and monitoring AIDS cases?
- Should AIDS case reporting be replaced by HIV case reporting? Can HIV case reporting be used for HIV and ART needs estimations?
- Should HIV case surveillance definitions be revised as per the new WHO definitions?
- How can we bettter use routine programme data, such as those collected at ART and TB clinics to improve case reporting?
- Can the data collected at the TB clinics be used for HIV surveillance among TB patients?

Group 4: Key questions for STI surveillance

- How to improve the quality of STI surveillance and make it more relevant for monitoring STI and HIV epidemics?
- What should be the framework for the national STI surveillance in India to capture STI data from (a) core-high risk groups; (b) bridge populations; (c) general population?
- Which are the priority etiological STI infections (laboratory-diagnosed) to be monitored?
- Which are the most useful/specific STI syndromes to monitor? How to improve the completeness of STI syndromic case reporting in the public sector?
- Is it necessary to capture STI data from the private sector? If so, how?

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