

TECHNICAL WORKING GROUP ON SIMU FOR NACP-IV PLANNING
STRATEGY AND KEY RECOMMENDATIONS FOR NACP-IV ON SURVEILLANCE AND EPIDEMIOLOGY

(Draft Report, 13 Aug 2011)

I. REVIEW OF EXISTING SYSTEM FOR HIV/AIDS SURVEILLANCE & OTHER EPIDEMIOLOGICAL ACTIVITIES

Review of NACP-III plan document on HIV/AIDS Surveillance – Important Extracts

1. Number of surveillance sites in the northern states requires strengthening
2. Coverage in urban and rural areas and high risk populations needs expansion.
3. The information obtained in surveillance programmes needs to be more completely analyzed and more robust management systems need to be developed.
4. Under NACP-III, the surveillance system will focus on: tracking the epidemic, identifying pockets of HIV infection and estimating the burden of infection in the country.
5. Given that the PPTCT programme successfully monitors HIV among ANC attendees, NACP-III will explore the possibilities of integrating PPTCT surveillance and ANC surveillance systems.
6. The possibility of integrating HSS with Integrated Biological and Behavioural Surveillance (IBBS) every 2-3 years among High Risk Populations will also be explored.
7. Surveillance activities will involve:
 - a. BSS and HSS including measurement of HIV incidence
 - b. STI surveillance and tracking of other surrogate markers, e.g. Hepatitis B, Hepatitis C etc.
 - c. AIDS case reporting
 - d. HIV associated morbidity and mortality
 - e. Anti-retroviral and STI drug resistance surveillance
 - f. Other methods /sources of data (e.g. ongoing surveys).
 - g. Conducting two types of BSS, namely, a) annual risk assessment at the district level and b) methodologically rigorous BSS at state level, at least once in three years
 - h. Initiating sentinel surveillance of OIs
 - i. Conducting periodic studies (once in two years) to estimate mortality from AIDS to validate the results of model based estimation
 - j. Strengthening the capacity of SACS to carry out district-wise estimation using available models/software

Components of HIV/AIDS Surveillance and Current System/Practice under NACP-III

S.No	Component	Current System/Practice under NACP-III
1.	Behavioural Surveillance	- In the form of periodic surveys; - BSS 2009 conducted in six states (AP, Kar, Mah, TN, UP, Manipur); - 2 Rounds of Integrated Biological & Behavioural Assessment (IBBA) under Avahan Programme in 23 districts in High Prevalence States; - National Integrated Biological & Behavioural Surveillance (IBBS) among HRG in select districts in a phased manner to be rolled out from 2011-12
2.	STI Surveillance	- Plans underway for establishing (under STI Division)
3.	Incidence Surveillance	- Use of Proxy Indicators such as prevalence among 15-24 yrs; - Model-based Estimations using EPP/Spectrum; - Laboratory Assays on HIV Positive Samples (Plans to undertake preliminary validation studies in 2011-12);
4.	HIV Surveillance	- HIV Sentinel Surveillance (Key developments elaborated below)

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5.	AIDS Case Surveillance	- AIDS Case Reporting (earlier method)/ Reporting from ART Centres; - HIV Case Reporting (Piloting Done)
6.	Mortality Surveillance	- AIDS Death Reporting (earlier method)/ Reporting from ART Centres; - Model-based Estimations
7.	Drug Resistance Surveillance	- Cohort Studies at select ART centres (Under CST Division)
8.	Other Epidemiological Activities	- Epidemiological Profiling of HIV/AIDS Situation at District & Sub-district Level Using Data Triangulation undertaken in 25 states/560 districts. - Framework for Prioritisation of Districts using data from multiple sources developed

Status with respect to other issues mentioned in NACP-III Plan Document

1. Surveillance data has been effectively utilized under the programme for monitoring the epidemic, identifying pockets of HIV infection and estimating the burden of infection in the country.
2. Surveillance data has also been used for district categorization for priority attention under the programme.
3. Reliable estimates of HIV incidence and mortality were developed for the first time in 2010 using EPP-Spectrum based modeling of HIV epidemic using HIV Sentinel Surveillance data.
4. Adequate emphasis was not given to complete analysis of surveillance data at state levels and wider use of surveillance data at state and district levels.
5. Reviews were undertaken to analyse the usefulness of PPTCT data for HIV surveillance in general population. However, the efforts have been ad-hoc and not as a systematic approach.
6. Specific studies to validate assumptions for model-based estimations were not undertaken.
7. Capacity building of state and district level personnel in data quality checks, data analysis and use was undertaken through 'Epidemiological Profiling of HIV/AIDS Situation at District & Sub-district Level Using Data Triangulation' exercise. However, the outputs need to be further consolidated and the methods and mechanisms of regular, ongoing data analysis and use need to be institutionalized.

Key developments in HIV Sentinel Surveillance during NACP-III

HIV Surveillance in India has started from the year 1985 when Indian Council of Medical Research (ICMR), for the first time, initiated the surveillance activity among blood donors and patients with Sexually Transmitted Diseases (STDs). After National AIDS Control Organisation (NACO) was established in 1992, sentinel surveillance for HIV/AIDS in India had been initiated with sentinel sites confined to selected cities in the beginning. Surveillance was conducted at 54 sites during 1993-94. In 1998, NACO formalized annual sentinel surveillance for HIV infection in the country with 180 sentinel sites. In 2003, HRG sites were established and ANC sites were expanded to peri-urban/ rural settings. However, till 2006, the majority of sentinel sites were located in six high prevalence states.

Key developments in 2006-07

1. Major expansion of STD and ANC urban sentinel sites in low prevalence states of North India
2. Addition of some more rural ANC sites in high prevalence states
3. Initiation of special ANC sites for 15-24 year old pregnant women to monitor new infections
4. Expansion of sentinel sites among FSW, MSM & IDU
5. Initiation of sentinel sites among Long Distance Truckers, Single Male Migrants and Transgenders
6. Introduction of composite sites
7. Involvement of five leading public health institutions in the country as Regional Institutes for providing technical support, guidance, monitoring and supervision for implementing HSS

Key developments in 2008-09

1. Undertaking thorough technical validation of new sentinel sites by RIs before inclusion in HSS
2. Dropping STD sites in high prevalence states
3. Introduction of Dried Blood Spot Method (DBS) of sample collection from HRG sites
4. Introduction of Informed Assent/ Consent at HRG sites
5. Piloting random sampling method of recruitment
6. Standardisation of the training protocols
7. Decreasing the number of testing labs for ANC and STD samples
8. Initiation of Epidemiological Investigation into unusual findings
9. Strengthening of State Surveillance Teams
10. Two new Regional Institutes to strengthen HSS in the North Eastern States

Key developments in 2010-11

1. Expansion of HRG & Bridge Population sites
2. Initiation of Rural Composite ANC sites to capture effect of migration in heavy out-migration districts
3. Random Sampling Method was standardized and adopted in 8 states at HRG sites, to avoid selection bias and to ensure better representativeness
4. DBS Method used at select ANC/STD sites in remote places
5. User-specific Operational Manuals and site-specific Wall Charts developed & centrally printed
6. Strengthened Laboratory Support
 - Testing of ANC/STD samples limited to State Reference Laboratories
 - Expanded network of DBS Testing Labs
 - Streamlining External Quality Assurance Scheme (EQAS) for HSS
7. Improvements in data collection tools
 - Introduced Bi-lingual data forms for the first time in HSS - Data forms translated into Hindi and 7 regional languages
 - General Information captured in a box through stamp or pre-printed stickers
 - Instructions to fill data forms are printed overleaf for quick reference
 - Reporting of lab results de-linked with data forms
8. Data Management
 - Double Data Entry at Regional Institutes
 - Integration of Data Management System for HSS into Strategic Information Management System (SIMS)
 - Online Data entry through SIMS Application for HSS, with Data Matching functions, Data Monitoring functions, validation checks and customised report generation in-built into the system
9. Quality of data improved through strengthened supervision by RIs, Labs and DAPCUs

Key Issues/ Gaps in HIV Sentinel Surveillance

1. Problems in Central Procurement of DBS Consumables leading to delayed implementation of HRG surveillance
2. Need to streamline logistics management of central supplies
3. Need to address delays in procurement & training at state level that led to late initiation in some states
4. Less responsiveness from some SACS to the feedback and instructions from RIs

5. Incidents of acute crisis in laboratory testing due to HIV test kits giving false results and thereby leading to transfer of kits and problems in storage of specimens
6. Need to further systematise real time lab monitoring & field monitoring, feedback & corrective actions

II. RECOMMENDATIONS FOR SURVEILLANCE & OTHER EPIDEMIOLOGICAL ACTIVITIES UNDER NACP-IV

Recommendation 1: Expansion of HIV Sentinel Surveillance Network:

1. HIV Sentinel Surveillance at STD sites may be discontinued in NACP-IV in all the states for the following reasons. *(Note for readers: During the core group meeting, it was suggested by the STI division that they want to explore how STD sites under HSS can be used for developing STI surveillance. Though it was discussed that the methodology being adopted at STD sites for HIV Sentinel Surveillance is not suitable for doing STI surveillance and it needs to be completely revamped, it was recommended that a decision on this recommendation of dropping STD sites from HSS be taken after a proper discussion with the team working on STI surveillance)*
 - a. The prevalence of bacterial STIs has gone down leading to significant decrease in the number of STI cases being reported at the OPD. This in turn makes it difficult to achieve the target sample size and the data remains of no use.
 - b. STD sites under HSS are mostly located in referral and tertiary hospitals. They mostly receive complicated/long-standing cases and hence may not represent the entire gamut of STIs.
 - c. Referrals do not come from a well-defined catchment area or population and so make the sample non-representative of any geographical area or any risk group.
 - d. Inappropriate differentiation between cervical discharge and vaginal discharge among female STD patients due to lack of proper cervical examination practices at many centres leads to questionable data on female STD patients.
 - e. Since most of the STD sites are located in tertiary hospitals where ART centres have also been established, STD clinics receive disproportionate referrals of HIV positive cases from ART centres. This leads undue upward bias in HIV prevalence among STD patients in such centres.
 - f. STD data is no more being used for HIV estimations and epidemic analysis. Hence, there is no clear benefit in conducting HIV Sentinel Surveillance at STD sites.
 - g. STD patients were considered as proxy for bridge population. However, now, with an expanded ICTC programme, HIV positivity among direct walk-in clients is available for almost all districts in the country and acts as a proxy for population exposed to high risk. With proper disaggregation of ICTC data, better insights can be gained into the epidemic patterns of bridge and high risk populations.
 - h. Also, HIV testing data routinely reported from STI clinics under STI programme can be analysed for epidemic trends, provided the data collection, reporting and quality of data are standardized through improved data management practices and close supervision. With mandatory HIV testing for all STI patients, this can be a useful source of information.
 - i. In low prevalence states, it is argued that, STD sites are required where there are no HRG sites under HSS. However, the above mentioned limitations exist in low prevalence states also. Wider availability of ICTC and STI programme data should be made use of for analyzing trends among high risk and vulnerable populations in these areas.

2. There should be an expansion of MSM, IDU, Transgender and destination migrant sites under HSS as these are the risk groups with emerging epidemics and rising trends. Addition of FSW sites may be considered at specific areas based on epidemiological requirement and feasibility.
3. Expansion of rural ANC sites may be undertaken in districts with heavy out-migration. The sites should be established in such a way that they rightly capture the spouses of migrants in true rural scenario. Composite PHC/CHC based rural ANC sites may be established after adequate feasibility assessment. Private ANC sites should be added in states where there is a dominant private sector catering to a large proportion of antenatal care. However, critical situational analysis should be done to understand the need to generate the data from rural areas as well as from the private sector through sentinel surveillance. With wider availability of PPTCT data across the country [including rural areas in many states], decision for adding HSS sites in rural areas should be taken after thorough review of data from relevant PPTCT centres.

Recommendation 2: Periodicity of HSS: HSS may be conducted in alternate years. Intermittent years should be dedicated to in-depth data analysis, data use, epidemiological investigation into new findings, special district/state/region-specific studies to better explain the HIV epidemic, HIV surveillance among special groups not amenable to routine HSS, detailed analyses synthesising HSS data with programme data, HIV estimations, capacity building and publications. Three rounds of HSS may be conducted during NACP-IV in the years 2012-13, 2014-15 & 2016-17.

Explanation/ Justification:

1. Three key uses of HIV Sentinel Surveillance data are for monitoring epidemic trends, identifying emerging pockets of HIV epidemic and for estimation of HIV burden.
2. HIV prevalence usually does not change significantly on a year to year basis. Fluctuations in a single year are, anyway, not conclusively due to epidemic rise and can be due to sampling or non-sampling errors. Monitoring of epidemic trends can be done with prevalence data available for every alternate year, as well. Fluctuations can be analysed by reviewing the corresponding PPTCT data and other information on vulnerability using triangulation approaches.
3. New pockets of high HIV prevalence are identified after each round and informed to the programme. However, by the time new pockets are investigated and conclusive evidence on rising epidemic or vulnerabilities is generated for recommending to the programme, the next round of HSS will be on the cards. In some cases, proper investigation is also not done due to time constraints of consolidating the previous round of HSS and preparing for the next round.
4. Most important limitation of conducting HIV Sentinel Surveillance every year is the inadequate attention given to data analysis and use of data for the benefit of the programme. With a tight annual cycle with unexpected delays, there is hardly time for detailed data analysis, dissemination and use of data for programme. HSS data can provide many useful insights to refine and improve the programme, especially at state and district levels. Also, the capacities of the staff at state and district levels in data cleaning, quality checks and simple analyses are limited. But, there is no adequate time to plan and undertake systematic capacity building of SACS officers as well as for building a resource pool of expertise and institutional support in the country.
5. Model-based estimation of HIV burden is also an intensive exercise that takes 8-10 months after the HSS data is finalized. Availability of new data set every year forces the estimation process to prepare and start the next round with new data, instead of undertaking in-depth analysis of model outputs at national, regional and state level that will be very useful for the programme. Analysis is limited to key estimates. It

does not give time for adequate dissemination and capacity building. Also, changes in estimates and epidemic projections every year are very difficult to explain to the general public, that question the credibility of the estimates.

6. Though the implementation of HSS is only for three months, preparations for HSS including procurement, training, site selection and review before the round, testing of specimens, data entry, analysis and report preparation after the round need a lot of time. If there is a delay in any of these operational steps, the entire surveillance cycle gets disturbed, and it becomes difficult to plan and organize surveillance and estimation activities of subsequent year in synchrony with other programme components and global commitments.
7. Finally, there is nothing that is going to be lost or missed by shifting from annual to bi-annual HSS. Moreover, it greatly improves the scope for proper planning and implementation of HSS and better utilization of its outputs.

(Note to Readers: During the core group meeting, this recommendation was debated a lot. Some members of the group and the Chairperson felt that HSS should continue to be an annual exercise. Reasons mentioned for this are as follows:

1. *HSS is the only robust system that the programme has that generates critical inputs to programme planning as well as evaluation. So, such a mechanism should be annual to be more effective.*
2. *Systems, guidelines and mechanisms for implementing HSS have been standardized over years and various implementing arms are adequately oriented to the processes. So, it will be relatively easy to conduct HSS every year than undertaking other activities during the intermittent periods as proposed above.*
3. *To assess if a fluctuation in one year is valid or not, one needs to wait for the next round of data to see if the direction of the epidemic is consistent or not, over at least three data points. With HSS on alternate years, to have three data points, it will take five years and meanwhile, we may miss some important inputs. Hence, annual HSS is required.*
4. *If there are issues with capacities of implementation and analysis, build those capacities by strengthening the units, rather than making the frequency once in two years.*

Besides the above, there was also another suggestion that, since epidemic trend does not change significantly among ANC population from year to year, while it may be so among HRG, we may have HRG surveillance every year and ANC surveillance on alternate years.

The group members are requested to consider the above view points, add if you have any other point for or against any view point and give your final recommendation, so as to take a final decision as a group.)

Recommendation 3: Integrated Biological & Behavioural Surveillance (IBBS) among HRG: Behavioural Surveillance among general population may be completely integrated with NFHS. Integrated Biological and Behavioural Surveillance (IBBS) among HRG may be undertaken in a survey mode. It will not be a replacement for HSS, but it will replace BSS. District level IBBS may be conducted at the beginning (2011-12 & 2012-13) and end (2015-16 & 2016-17) of NACP-IV.

Explanation/ Justification:

1. IBBS is being conceptualized as survey to generate district level behavioural estimates for HRG, which is a major information gap under NACP-III. Design and methodology may be adopted from Avahan's IBBA which is rigorous in its scientific approach.
2. IBBS at district level is a resource intensive exercise, both in terms of financial as well as institutional resources, and hence, not feasible to be implemented every year.

3. Due to the scale of operation of IBBS, entire country cannot be covered in a single round as being done under HSS. So, country can be covered in two or three phases. This may lead to availability of HRG prevalence estimates only for a few states each year. i.e. national HRG prevalence estimates may not be available every year, as is currently available through HSS.
4. Conducting IBBS in a survey mode i.e as a specific community-based survey that can give representative estimates of prevalence, will provide data for calibration of HRG prevalence derived from HSS, and hence gives a better picture during HIV estimations. This is similar to using population-based HIV prevalence among general population from NFHS for calibrating ANC prevalence from HSS, during the process of estimation. This will provide more accurate estimates.
5. Conducting IBBS in survey mode will also allow the programme to collect more information for detailed profiling and epidemiological understanding of behaviours, vulnerabilities and HIV among HRG, which is not possible to collect under HSS. This data can be used to better interpret and explain the levels and trends of HIV among HRG observed in HSS.
6. Since behaviours do not change year by year, conducting behavioural surveys once in 3-5 years will give adequate evidence about behavioural change. Annual data on behaviours is not of much use.
7. Behavioural surveillance among general population and youth may be completely integrated with NFHS. NFHS-III had a detailed section on knowledge & awareness, STI, condoms, stigma & discrimination, sexual behaviours and condom use and HIV testing. The section on HIV/AIDS in NHFS tools may be reviewed and additions on any other area of interest to NACP may be recommended. This will give representative estimates at state level as those from BSS among general population and youth conducted by NACO.

(Note to Readers: During the core group meeting, it was suggested that before taking the decision to implement IBBS, it needs to be reviewed thoroughly whether we can piggy-back on any other surveys to do this, and what are the critical indicators that we need for which we need to do a separate survey. An attempt to this effect is being made, and a draft note on this will be shared with the group soon.

It was also suggested that if we can add curable STIs as additional bio-markers in this survey, that will obviate the need to have a separate STI surveillance or STI burden estimation survey among HRG. This needs to be discussed with STI division, modalities and cost implications need to be worked out and then finalized.)

Recommendation 4: Additional bio-markers for HIV Surveillance: Syphilis testing of HRG specimens under HSS may be resumed after validating the appropriate test kits for use on DBS specimens or with finger prick specimens. Feasibility of adding curable STIs as biomarkers in HSS may also be explored. However, laboratory implications and limitations in this regard need to be worked out. Hepatitis B & Hepatitis C testing may be added for MSM & IDU in HSS. This may act as a bio-marker and give an idea of network dynamics among these groups.

Recommendation 5: In-depth Analysis of Surveillance data: Establish mechanisms to ensure that in-depth analysis of surveillance data is undertaken at state and district levels, wherever possible, and appropriate outputs in the form of analytical reports, epidemic status reports, factsheets, policy briefs, scientific papers etc. are developed and published. Some suggested mechanisms for the same include:

1. Capacity building exercises for SIMU staff at state & district levels in analysis using surveillance data
2. More involvement of Regional Institutes and identification of local institutional support in data analysis and report preparation at SACS

3. Regular post-round workshops for data analysis and report preparation involving state level officers and personnel from identified institutions
4. Making publication of surveillance report mandatory for every state and region
5. Encourage development of scientific papers by the data analysis teams and promote their publications in peer-reviewed journals

Recommendation 6: HIV Estimations and Modeling:

1. EPP-Spectrum is used for generating national estimates on HIV. Detailed analysis of HIV estimates at national and state levels should be undertaken to make use of the outputs from estimation process for better understanding of the epidemic and focus areas for programme.
2. District level estimations may be attempted in select states where adequate data is available.
3. Capacity building activities in EPP & Spectrum should be undertaken to build regional pools of expertise in HIV modeling in the country. Adequate handholding should be provided to these teams from the national team involved in estimations.
4. This national system of estimations should be made more robust by generating Indian data to feed into the assumptions for modeling. The parameters in the model for which we currently do not have India-specific data, for which we borrow the parameters from other countries, need to be identified and specific activities should be initiated to generate them. *(Note to Readers: It was recommended that these parameters and mechanisms to generate them in India also need to be spelled out in this strategy document for NACP-IV. This will be worked out and shared with the group members soon for your inputs.)*
5. Besides the EPP/Spectrum model adopted for deriving national estimates, other robust models such as Asian Epidemic Model should be worked upon, at least for specific states or regions. Capacity building exercises should be undertaken in these models using international expertise and partner support.
6. An expert committee may be constituted to review various models available for HIV estimation, projections and impact evaluation, identify the advantages and limitations of each, understand the scenarios where each model will be more applicable and useful, identify the additional outputs that each model will give beyond the national system, and develop a systematic plan for using and building capacity in them. However, it should be a cautious approach of defining the scope of each model to ensure that they become complementary to the national system rather than generating un-resolvable contradictions.

Recommendation 7: Use of PPTCT data for Monitoring HIV Trends and Estimating Burden: PPTCT data may be used for monitoring trends and HIV estimation, **ONLY AFTER** carefully addressing the limitations which the data is fraught with and comparing the trends and estimates with HSS outputs. If the trends and estimates start looking comparable, PPTCT data may be more increasingly used for district or sub-district level analysis, which is an area of limitation of HSS data due to sample size. The road map proposed below may be adopted for using PPTCT data for surveillance purposes. *(Note to Readers: The limitations for using PPTCT data for surveillance purposes were discussed and emphasized strongly, during the core group meeting. A cautious approach, rather than a sudden shift to PPTCT-based surveillance, is recommended.)*

The relative strengths and weaknesses of the HSS vis-à-vis proposed PPTCT [program] based surveillance are summarized in the table below:

Strengths of HIV Sentinel Surveillance	Strengths of PPTCT-based Surveillance
1. Traditionally designed as surveillance. Hence, data collection and inclusion of	1. Coverage under the PPTCT program is very good in some states and rapidly expanding in other states. Denominators are very large

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<p>cases are done under controlled settings that ensure reliability and uniformity over years and across states.</p> <ol style="list-style-type: none"> 2. Data available since 1998 and has been the main stay for analysing trends and also for estimations in India. 3. Most reliable and readily available HIV data source in India. 4. Employs unlinked anonymous testing (UAT) approach and hence refusals are minimum or almost nil [sample collected during routine ANC care, for haemoglobin estimation and/ or syphilis testing is used for HIV testing]. 5. Methodology ensures that there is no duplication of cases included in surveillance. 6. Strict quality control mechanisms for laboratory testing are in place to avoid any potential testing errors. 7. Closely monitored and supervised activity with a strong supervisory structure and reporting mechanisms. 	<p>and hence if coverage is large and uniform procedures are followed, the data can be truly representative and generalizable.</p> <ol style="list-style-type: none"> 2. Year-round data is available 3. Services are offered to all the women attending ANC clinics, they are provided counseling and if they give informed consent, their blood samples are collected for HIV testing.
Limitations of HSS	Limitations of PPTCT-based Surveillance
<ol style="list-style-type: none"> 1. Uses very small sample size and sample collection period is only 3 months. This raises concerns about generalizability of the data. 2. Being UAT, the opportunity of intervention is missed 3. Methods of sampling have been reported to be non-uniform in some cases: possibility of selection bias cannot be completely ruled out [especially at ANC sites with large attendance and which are operated by many specialists] 4. Geographic coverage of the population is limited [although this has been much improved 2006 onwards] 	<ol style="list-style-type: none"> 1. PPTCT coverage (% of pregnant women visiting ANC clinics who are tested for HIV under PPTCT programme) is an important factor that determines the usability of PPTCT data for surveillance. It had been noted that, as PPTCT coverage increases, the correlation of PPTCT trends with ANC trends also tends to increase. However, the gap between ANC registrations and HIV testing under PPTCT ranges from 1% to over 50% across the states, with a national average of 16.5% during 2010-11. 2. Inclusion and exclusion of pregnant women is not controlled. It may depend on a lot of factors from availability of counselor, time taken for counseling to willingness of pregnant women. 3. Data collection is not designed for surveillance primarily. Wide variations exist in methods of data recording and entry, and reporting. Hence, even if the program coverage is expanding, the extent to which the data is utilizable is not known. Information on refusals also needs to be collected and analysed. 4. Implementation of PPTCT is affected by several programme related issues such as target setting under programme, special camps and initiatives to increase coverage, availability of test kits, quality of laboratory testing, etc. This affects the uniformity and comparability of PPTCT data over time as well as across states, as these issues are limited to specific areas and specific time points. These may add potential biases to the PPTCT data. 5. Quality control of laboratory testing is an important area of concern under PPTCT programme due to its large scale of operation. 6. There are several occasions where pregnant women are tested twice or more for HIV during her pregnancy, may be at the same of different centre in a district or state. This may affect the use of PPTCT data for surveillance purposes.

	<ol style="list-style-type: none">7. Since PPTCT programme is continuously being scaled up, any trend analysis using PPTCT data needs to be controlled for scale-up. Mechanisms to do so need to be developed.8. Other data requirements that need to be worked out before using PPTCT data for surveillance and estimations include<ul style="list-style-type: none">– Development of calibration factors for PPTCT data– Development of methods for standardization and adjustments to be made for PPTCT data– Ensuring global comparison for use in HIV estimation process9. HSS has been traditionally done since 1998 and is probably the best data source to study HIV trends over years. We have data available for comparison of trends over the last 12 years. If we shift to PPTCT based surveillance, we would lose the comparability of data.
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Proposed road map for using PPTCT data for Surveillance Purposes

1. Three key aspects need to be ensured before even attempting to validate PPTCT data for surveillance purposes.
 - a. PPTCT coverage should be high. Select states/districts where PPTCT coverage is greater than 80%. States/ districts with low PPTCT coverage are not good candidates for using PPTCT data for surveillance purposes.
 - b. Uniform, uninterrupted testing procedures and quality control of laboratory testing are ensured. Duration in a year when testing related issues are reported may be excluded from analysis and data may be adjusted accordingly.
 - c. Electronic reporting of individual level data is available and complete, including for those who refused PPTCT testing. Ensure that there are no backlogs in individual level data entry from any centre.
2. Data elements or variables collected over the years in HSS will have to be included in data collection under the PPTCT programme for retaining the ability to analyze trends over years.
3. There are challenges in managing the PPTCT data at the site, district, state and national levels. A systematic approach needs to be developed for quality checks, validation and cleaning of PPTCT data. Appropriate field level practices should be designed and strictly implemented to avoid known errors and biases in data collection and reporting, so that PPTCT data would become more and more reliable and dependable over the next few years. Thus trends and estimates based on that would be more realistic.
4. Mechanisms should be developed for removing duplicate cases from the database, before analysis.
5. Standardizations and Calibrations need to be developed for PPTCT data, to make it usable for trend analysis and HIV estimations respectively to ensure global comparability, and methods for the same need to be worked out.
6. Analysis should be carried out using the data generated through the PPTCT programme since its roll out in India, say 2005 onwards. It is possible to carry out modeling using PPTCT data to determine the trends of HIV epidemic as well as for HIV disease burden estimation.
7. The next logical step would be to compare the trends and estimates derived based on PPTCT data with those of HSS and analyse the results to arrive at appropriate interpretations.
8. There is a proportion of women who opt out of HIV testing in the PPTCT settings and a significant variation was observed in this proportion across various States. Determining the precise reasons for opting out is crucial for correct interpretation of trends and estimates before the proposed transition from HSS to PPTCT. Data should be adequately adjusted to account for the quantum and nature of refusals/ opt outs.

9. It has been observed that PPTCT data at the state level may match closely with the HSS data; but not at the district or site levels. Precise reasons for this disconnect need to be understood. Analysis should be done to find answers to this problem.
10. Modeling for trends and estimates by using both HSS and PPTCT data should be carried out simultaneously even after substantial improvement in the PPTCT data management takes place, to ensure global comparability.

Recommendation 8: Involvement of private sector in Surveillance: Expansion of ANC sites into private sector would have significant utility, particularly in districts with established high HIV prevalence ($\geq 1\%$) among ANC clients as it would not only inform about HIV prevalence across different strata of society but also make ANC surveillance data more generalizable. The focus during NACP IV may be on establishing at least one private ANC surveillance site in all districts with ANC prevalence $> 1\%$ where at least one third of pregnant women are availing ANC services from private sector.

Explanation/ Justification:

1. HIV sentinel surveillance (HSS) is the mainstay for monitoring trends of HIV epidemic in high and low risk populations and also for HIV disease burden estimation in India.
2. Ever since its introduction in 1998 in India, HSS has been carried out in pregnant women and results are considered as good proxy for general population. However, non/limited representation of private sector sites for surveillance among pregnant women has been one of major limitations of HSS programme.
3. One third of pregnant women across the country, who had received any Ante Natal Check up (ANC), has availed services from private health facility and clearly Private sector has significant share in delivering of maternal health care.
4. Round 3 of District level household survey (DLHS) have shown that there are states like Andhra Pradesh (63.6%), Goa (57.5%), Karnataka (54.8%), Kerala (67.7%) and Punjab (57.8%) where private sector is the major partner in delivering of ANC services to pregnant women.
5. The profile of pregnant women who visit the public sector is completely different than that of clients visiting the private sector. Educated class pregnant women with higher income more often opts for private sector. Obviously, for the ANC surveillance data to be more generalizable, inclusion of more sites from private sector is crucial.

ANC Surveillance sites in Private Sector - Example from Andhra Pradesh

1. Andhra Pradesh is one of states in India which is having ANC surveillance sites in private sector. Three ANC sites were initiated in 2007 round of surveillance in state and subsequent up-scale was done in 2010 round to six sites in private sector. The sites initiated in 2007 had been participated in all rounds of surveillance since then.
2. During 2010 round, the sample collection was 100% at all private sector sites. Success for continuation of private sites may be contributed to district level team whose inputs were taken in identification of sites resulting in identification of viable sites as well as ownership of supporting supervision and quick attention of issues (if any) of private sector sites.
3. A comparison of respondent profile of clients at private sector with urban public sector sites during 2007 round of surveillance corroborate that respondents of two type of sites differ significantly in socio-economic characteristics.
4. Among the total respondents recruited at private sector sites, 8.8% were illiterates while 68.8% were having secondary or higher level education. This was significantly different from respondents recruited at

public sector urban sites where 36% of respondents were illiterate while only one third of respondents were having secondary or higher level education.

5. On Occupation aspect, 90.5% of respondents at private sector sites were housewife while another 5% were in service. Two third of respondents at urban public health sector sites were housewife while another 28% were working as agri/unskilled worker. Almost two fifth (39%) of spouses of pregnant women at private sector sites were in service/business in comparison to only 15.9% of spouses at the urban public sector sites.
6. All these evidences clearly emphasize that those respondents at private sector sites are better educated and represent better offs in the society.
7. HIV prevalence at private sector sites (0.47%, 95% CI 0.06 – 0.89%) was significantly different from the prevalence at corresponding urban public health sector sites (1.23, 95% CI 1.00% - 1.45%).

Recommendation 9: HIV incidence as a part of regular national surveillance:

1. All data collection efforts under the programme should include an element of collecting data on proxy indicators for HIV incidence estimation such as prevalence among 15-19 yrs old, pregnant women at low order of pregnancy, those who are newly introduced to high risk behaviour etc. Regular analysis should be undertaken on these proxy indicators to derive meaningful conclusions on HIV incidence in different risk groups.
2. Model-based estimates of incidence should be analysed in greater detail. Alternate models should be used for generating incidence estimates and for cross-validating outputs from different models.
3. Laboratory based assays for HIV incidence should be adopted to Indian settings before using them for incidence estimation. All the possible limitations should be addressed, correction factors need to be developed and the method and tools need to be standardized before using the assays for estimation of HIV incidence. Availability of licensed manufacturers and kits in the country is a serious limitation for this process, that needs to be considered while devising the system.
4. Sample size and design issues and operational feasibility aspects need to be addressed before adding HIV incidence assay as an additional test on HIV Sentinel Surveillance. However, it is strongly recommended to initiate the process of validation and adoption of available technology for HIV incidence assays so that over the next 2-3 years, incidence assay should be an integral part of routine HIV Sentinel Surveillance.
5. TI-based cohorts may be established at select well-performing TIs by strictly controlling and standardizing methods and tools for collecting data on HIV positivity and related parameters among HRG. Mechanisms should be thoroughly integrated into the programme management systems so that they can be implemented easily. Though this cannot be a mainstay approach for surveillance among HRG, it can generate useful information to better explain patterns among HRG. If thoroughly implemented, this system can also generate reliable incidence and prevalence estimates for HIV, STIs and behaviours, besides tracking progression to AIDS and treatment requirements among HRGs.

Recommendation 10: Assessment of AIDS-related Mortality:

1. The key purpose of monitoring mortality estimates is to assess the impact of care, support & treatment programme, and to analyse mortality patterns for any useful insights towards programme improvements.
2. Assumptions used in deriving model-based estimates need to be validated with India-specific data generated through special studies.

3. Specific questions and mechanisms may be introduced under the Annual Health Survey to assess AIDS-related mortality.
4. Mechanisms may be developed to improve death reporting from ART centres.
5. NACO should work closely with Registrar General of India (RGI) for making best use of SRS data for assessment of AIDS-related mortality.
6. Any other innovative models of mortality estimation by independent expert groups should be reviewed for their merits and use in the programme.

Recommendation 11: Epidemiological Profiling using Data Triangulation

1. District Epidemiological Profiling using Data Triangulation has been one of the most important activities during NACP-III that addressed the issues of data quality, validation and cleaning, involvement of all cadre from reporting unit level to national level in data analysis and interpretation, fostered institutional linkages for data analysis, developed guidelines and simple methods for data analysis, and promoted 'data use for decision making' as an important concept in programme management.
2. This exercise should be institutionalized by developing mechanisms and guidelines for undertaking them on a regular basis and updating the district reports every year. This should also include regular capacity building exercises of the personnel at peripheral units and DAPCUs.
3. Encourage the use of data triangulation methodologies using data from different sources to provide answers to strategic questions. Data triangulation endeavors can be done quickly and efficiently when appropriate process is followed for developing questions and finding answers.
4. Use of programme data for understanding the epidemic patterns or vulnerabilities should be strongly encouraged. For Eg. PPTCT data and data on HIV positivity among HRG reported through TIs across the country should be analysed using data triangulation approaches for better understanding of HIV epidemic in different areas and risk groups.

Recommendation 12: Moving towards HIV Case Reporting:

1. The key objective of HIV Case Reporting is patient tracking from the point of detection of HIV infection till his/her death. If coverage under HIV case reporting is complete, it can provide data for analyzing epidemic patterns and levels and trends of HIV incidence and prevalence.
2. Introduction of individual level reporting from ICTC and ART centres through the upcoming SIMS provides opportunity to develop a model for HIV Case Reporting. This should be explored and mechanisms should be devised in consultation with the Basic Services & CST divisions at NACO to ensure the use of this data as HIV Case Reporting.
3. System evaluation and preparatory work for HIV Case Reporting should be undertaken at the earliest, since the SIMS Application is in the process of roll out and it gives right opportunity to make any necessary changes that are required.

Recommendation 13: Other Epidemiological Work:

1. A system for identifying Early Warning Indicators from the programme reporting, undertaking epidemiological investigations to find out the causes/reasons and giving inputs to the programme divisions, should be put in place.
2. Specific studies should be undertaken to develop new and innovative intervention models to inform the programme on key issues

3. Some suggested areas of epidemiological work include:
 - a. Mechanisms for Cohort tracking of HRG/PLHA/ART Patients etc.
 - b. Specific epidemiological studies to understand emerging epidemics such as MSM epidemics, dual risks among HRG, migration-driven epidemics, mechanisms to control spousal transmission etc.
 - c. In-depth epidemiological investigations/studies into select region-specific epidemics
 - d. Studies on newer forms of risk behaviours and sex work patterns
4. Other areas for other epidemiological work should be identified from time to time and studies should be initiated with clear timelines.

Recommendation 14: System and HR Requirements for Surveillance & Epidemiology

Current Scenario

Understanding the critical role played by surveillance in decision making, the National AIDS Control Organisation (NACO) has established a credible and robust system for annual HIV Surveillance in the country. At the national level, the program is coordinated by surveillance division of Strategic Information Management Unit (SIMU). The division is lead by Deputy Director General (Monitoring, Evaluation, Surveillance and Research) and has dedicated Program Officer (Surveillance) and Technical Officer (Surveillance). Each state has a dedicated unit, similar to national unit, to carry out the surveillance activities. The team is headed by a Deputy Director (Monitoring, Evaluation and Surveillance) and is supported by State Epidemiologist (1), Statistical Assistant (1) and data entry operators (2-3) to coordinate the implementation of surveillance activities. At the district level, there are District AIDS Prevention and Control Units (DAPCUs) in category A and B district. DAPCU has been utilized in states like Andhra Pradesh for coordination of implementation of surveillance activities, especially on logistics aspects.

Major Challenges

1. **Inadequate personnel time for data analysis:** At the national level, where the entire bulk of surveillance data, programme data and research outcomes in the country converges, and where planning and decision-making are the primary activities, there is no dedicated cadre for knowledge management (data analysis and ensuring data use). This responsibility currently lies with the existing programme staff under SIMU (Programme Officers & Technical Officers) who are primarily responsible for managerial and administrative work. Data validation and cleaning, data analysis, discussions with experts on the analytical approaches and outcomes, and preparation of reports, in itself, is a large amount of work that requires continuous focus and attention. As long as managerial work and technical work are assigned to the same cadre of the staff, the former gets higher priority due to the operational deadlines and practical implications, while the latter is limited to mandatory submissions and urgent requirements. Systematic consolidation and use of data does not take place.
2. **HR challenges for Surveillance Division at NACO:** Surveillance division at national level has been instrumental in carrying out HSS as well as Behaviour Surveillance under NACP III. Operational activities to roll out HSS involve a wide range of activities and coordination with RIs and SACS for several months before and after actual sample collection. The division has also coordinated the District Epidemiological Profiling and District Recategorisation exercises to synthesize evidence from multiple sources of data for a comprehensive and integrated understanding of both programme efforts, results and their impact on the epidemic. However, the position of Technical Officer (Surveillance) could not be filled up, lower pay scales being an important reason. With the proposed activities like IBBS, HIV incidence surveillance, HIV case reporting etc, the human resource challenges for the division are going to be very critical.

3. **Availability and retention of Epidemiologists at state level:** Availability of technical manpower, especially the state epidemiologists, has been a key constraint for surveillance and epidemiological work at many states. As a result, there are problems in taking appropriate technical decisions during implementation of surveillance and surveillance data is not analyzed enough at state level. It becomes a responsibility of already overburdened RI/national teams co-ordinating surveillance. This lack of analysis at state level, at least delayed, the transformation of data into information that can be used for action. Also, subsequent retention of state epidemiologists has been a key challenge in many states, due to lack of systematic engagement of their potential for epidemiological and analytical work. The ad-hoc pattern of their work made SACS to use them for different other works, for which they are not designated.

Recommendations

1. Create a Knowledge Management Unit under SIMU at NACO with proposed composition of two Epidemiologists, two Statisticians, one GIS analyst and one documentation/communication expert. This unit should focus exclusively on the technical work of data quality audit, analysis, dissemination and data use at national, state and district levels. Primary mandate of this unit will be to
 - a. Undertake epidemiological and analytical work at national level
 - b. Promote and mentor technical work at state and district levels
 - c. Ensure Effective Data Use at all levels
 - d. Institutionalisation of these activities through development of mechanisms and guidelines
2. Create one more post of Programme Officer (Surveillance) to handle up-coming new projects such as IBBS, Incidence Surveillance and other modeling activities.
3. In view of the shortage of qualified epidemiologists in the country, relaxation of qualifications and increase in pay packages for key PO, TO & epidemiologists positions in SIMU at NACO and SACS should be done, to ensure that the positions do not lie vacant.
4. Once recruited, systematic efforts would be made to retain the candidates through focusing on continuous professional development.

(Note to Readers: Chairperson recommended that the group should come up with the entry level qualifications that are essential for different posts and what elements of technical competence can be built through capacity building exercises after recruiting the persons. The group is also asked to work on non-financial incentives that can be built into the system to attract and retain good talent. Experts are requested to provide your views on this issue as well for compilation.)

The first point mentioned here about creation of Knowledge Management Unit or a separate unit for data analysis has been mentioned by other sub-groups on Programme Monitoring and Research also. So, this will be taken out and included under a separate theme of Knowledge Management. It is mentioned here only for completion sake.)

Recommendation 15: Use of Other General Health Surveys (NFHS, DLHS, AHS) for generating HIV related indicators:

(Note to Readers: It is recommended in the core group meeting that a matrix be prepared on what indicators can be generated by adding questions/markers to the general health surveys so that there is adequate integration of data generation efforts with broader health system. Based on this matrix, recommendations may be worked out. A sub-group of members are working on this, and it will be shared with the other members soon.)

Recommendation 16: Revised Framework for District Prioritisation using Data from Multiple Sources:

(Note to Readers: It is also suggested that the WG on SIMU should review the new framework for district prioritisation developed following data triangulation exercise and recommend, whether it should be adopted under NACP-IV. It could not be discussed in the meetings yesterday. The framework has been developed and district categorisation was attempted using data upto 2009. However, it was directed by Secretary & DG, NACO earlier that it should be updated with the latest round of surveillance and programme data upto 2010. Hence, a separate meeting of WG members and experts will be held subsequently to present and discuss the revised framework and its outputs.)