FEDERAL MINISTRY OF HEALTH IN COLLABORATION WITH THE CENTER FOR DISEASECONTROL (CDC); THE WORLD HEALTH ORGANIZATION (WHO) AND UNAIDS

# NATIONAL HIV/SYPHILIS SERO-PREVALENCE SURVEILLANCE SURVEY PROTOCOL

FOR

## WOMEN ATTENDING ANTENATAL CLINIC

October 2000

## INTRODUCTION

The purpose of HIV sentinel sero-surveillance is to track HIV infection levels in populations accessed through "watch-post" institutions. These institutions are selected because they provide access to populations that are either of particular interest in the epidemic, or representative of the larger population.
In general, sentinel institutions are already drawing blood for other purposes. Where blood is taken for other purposes, leftover blood can be stripped off all identifying markers and tested for HIV infection without the consent of the individual concerned. This method is particularly applicable for Antenatal clinic attendees, Tuberculosis, Psychiatric, prison inmates and STD patients respectively.

Surveillance systems set up to track the course of the HIV epidemic test all samples taken in a specified time frame, usually point prevalence is adopted since it takes a minimum of six to eight weeks for all sites to generate enough acceptable and statistically meaningful results.

Active Surveillance system can be used to assess public response to the HIV epidemic. The data can also be used for planning, monitoring of the success of intervention as well as for advocacy.

Currently, Nigeria has over 2.6 million people living with HIV. This estimate was made using the 1999 sentinel survey done in 37 states. So far, four (4) active surveillance using sentinel groups have been done in selected states. The first survey was done in1991 in 9 states; the second survey was done in 1993 covering17 states (64 sentinel sites, the third survey was done covering 21 states (72 sentinel sites) in 1995 while the fourth survey was done in two sites per state in 37 states of the Federation.

The current state of the epidemic in the country required annual sentinel sero-prevalence surveys in all sites with an expansion of sentinel sites in every large city like Lagos, Kano and Ibadan etc. This shall obviously increase the total number of sentinel sites to 84 sites.

We are obviously belated in the statistics of 1999 and are overdue for the 5th round of survey this time covering all 36 States and Abuja (in 74 sites).

### Objectives

The general objective of conducting the survey is to provide information that will lead to eventual prevention and control of HIV/AIDS.

The specific objectives are:

- To monitor the spread of HIV and STDs in the country.
- To determine the prevalence of HIV infection in among women attending Antenatal clinic by selected demographic characteristics and geographical location.
- To monitor trends of HIV infection among women attending Antenatal clinic.
- To make estimates and projections on HIV in the country.

# Methodology

## SENTINEL POPULATION

The sentinel population for the year 2000 survey shall be women attending antenatal clinics in public hospitals in the country. This sentinel group is at best considered suitable for extrapolations in the general population.

### SAMPLING SITES

Sampling sites will be selected according to the following criteria:

- 1999 HIV sentinel results
- Availability of staff, facilities and procedure for drawing blood from antenatal clinic attendees on their first visit of the current pregnancy
- Provision of services to a relatively large number of pregnant women per week.
- Qualified personnel and willingness of on-site staff to cooperate,
- Location of sites in different geographical areas of the country.
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**Sample Inclusion criteria**

Each woman attending the antenatal clinic for the first time for the current pregnancy during the sampling period will be enrolled for the study.

### SAMPLE SIZE, SAMPLING SCHEME AND DURATION OF SAMPLING

It is recommended that for high-risk groups, a sample size of 100 is adequate for a prevalence study.

All sites should aim at collecting a minimum amount of demographic data, e.g. age, education, occupation, and behavioral pattern, duration of stay in the catchment area. Sentinel sites where adequate sample sizes cannot be obtained within 6-8 weeks shall be excluded.

. Counseling shall be provided where necessary but an unlinked anonymous method of testing shall be used - e.g. testing HIV antibodies in aliquot of samples meant for syphilis

Samples will be collected on daily basis from the sentinel group during the specimen collection period of 8 weeks. The supervising nurse or outreach health worker fills in the initial demographic information of the client on arrival. After the routine protocols, 5mls of blood will be collected from the subject into sterile Vacutainer tube from which 200 micro-liter will be dispensed into two spots of CDC blood collection blotting paper. The sample bottle is labeled and transported to the State central HIV screening laboratory HIV test.

Aliquot of sample will be used for on-site syphilis screening.

Results of syphilis test are thereafter sent back to attending Doctor/Health worker for appropriate follow-up treatment.

**The On-Site laboratory officer will remove initial label on samples and code after separating the sera and then store them in the freezer compartment of the refrigerator**

The coding system of specimens is based on four variables: State, sentinel site, age and serial number.

The appropriate completed data collection form should accompany each specimen. For each sample, the following data should be collected: State, site, institution and age

The code on data collection forms and the one labeled on respective individual specimen bottles should be the same.

E.g [K][D] [K][F [S] [F] [2][1] [0][0][5]

Since anonymous unlinked method of testing will be used, no one will be able to link the results of the HIV screening to the individual subject. The person who puts labels on individual specimen and the one who does the screening should be in different locations.

## LABORATORY SCREENING OF SAMPLES

At the State laboratory, each sample will be initially screened with RAPID HIV testing kits (Determine). All samples which result **"non reactive"** will be reported as negative, while all samples that are reactive in the initial screening test will be further tested using Genie II for confirmation and differentiation of antibodies to HIV-I and/or HIV-2.

Samples, which result negative in the first test, shall be reported as **negative** for HIV antibodies. Samples that are reactive in both test will be considered positive for HIV antibodies. Any sample that is reactive in the first test but negative in the second test shall be considered indeterminate.

Dried blot spots will collect during supervision visit for quality control at the department of virology, University College Hospital, Ibadan. All blood spots from samples that tested positive and 20th negative sample at the state laboratory will be further tested using the same procedure.
Similar screening procedure will be done for syphilis using RPR and TPHA kits.

The data collection form will be used as a guide to decide which sample should be stored for QC purposes.
In order to get a point prevalence, sampling period shall not exceed 8-10 weeks.

## TRAINING OF FIELD STAFFS

It is assumed that all laboratory staff is qualified to do HIV testing. However, at least one-day briefing session on basic laboratory techniques and standardization of operational procedures of the survey shall be organized for all staff. Briefing sessions will be conducted for 2 sets of staffs that will actively be involved in the survey: Laboratory staff at the State and on-site field staffs.
The briefing sessions for the laboratory Staffs will focus on screening techniques and procedures of the survey, while the one planned for field staff will be mainly operational procedures, such as specimen collection, confidentiality, coding. Etc.
SAPCs shall be briefed on the implementation process, supervision modalities and logistic issues during the central training.

The following table describes the type of training required by staff at all levels:

TABLE 2: TYPE OF TRAINING REQUIRED BY FIELD STAFF

| | TYPE OF PERSONNEL | AREAS TO BE COVERED DURING TRAINING |
|---|---|---|
| 1 | **On-site staff:**<br>**Laboratory technician**<br>**Nurse and doctor** | **All staff at the site should be taught about:**<br>**a) Objectives of sentinel Sero surveillance**<br>**b) Sample inclusion criteria and specimen collection techniques**<br>**c) Labelling and storage methods**<br>**d) Anonymous unlinked and confidential testing methods** |
| 2 | **State Laboratory technologists** | **Same as above. In addition, they should be briefed on quality control and standardization procedure.** |
| 3 | **NASCP\|State AIDS Programme Coordinators** | **Same as above; Data compilation, analysis, interpretation and reporting; feedback mechanisms.** |

## SUPERVISION OF THE SURVEILLANCE SYSTEM

On-site supervision during specimen collection period is under the responsibility of the on-site survey Co-ordinator. He/She will supervise daily collection of specimen according to the given protocol and guidelines. At this stage, emphasis should be placed on compliance with the recommended method of collecting the desired number of samples (i.e. anonymous unlinked), proper coding and storage of samples, appropriate filling of data collection forms ... etc. The zonal facilitators who surveillance experts based in the training institution located in the respective health zones shall also be involved in providing complimentary supervision in the zone.
Central technical supervisors have also been identified to visit the field for about three times during the period of the survey.

The State AIDS Programme Coordinator shall on weekly basis, visit each site in order to collect samples and to assure proper implementation of the operational procedures within the context of the given protocol. Before transporting back the collected sera, the SAPC should make sure that specimen bottles are properly labeled/closed and data collection forms are appropriately filled.

The state laboratory technologists have the responsibility of assuring the reliability of syphilis and HIV screening results. Randomized site supervision shall be used with spot checklist to monitor the procedure in the field by the National facilitators.

### Personnel Requirements

Availability of motivated staff at all levels is very crucial to the success of the HIV sentinel exercise. The SAPC should select sites based on availability of such staff at the site level.
The following table describes the type and number of staff needed at each level of implementation:

**TABLE 3: TYPE OF PERSONNEL REQUIRED PER ACTIVITY**

| DESCRIPTION OF ACTIVITY | TYPE AND NUMBER OF STAFF NEEDED |
|---|---|
| Blood collection, serum separation and storage | In each site, the Medical officer should identify one reliable lab technician and one nurse to execute such an activity. The role of the nurse is to ensure that the subject selected for the exercise belongs to the right sentinel group. |
| Transportation of specimens to the laboratory | Each SAPC should have access to appropriate means of transporting collected specimens from selected HIV sentinel sites. The NASCP will provide limited funds for such purposes. |
| Performing screening tests | At the State laboratory, laboratory staff should be involved in conducting all the tests. If more than 2 staff are involved, the SAPC should divide that allotted sum to those involved in the activity |
| Data compilation, analysis, interpretation and feedback | At State level the SAPC will do data compilation and analysis for his/her State. At Federal level, one data manager and two data entry officers will be needed. |
| On-site supervision | The doctor on-site will supervise methods of collecting specimens, anonymous unlinked, coding and labeling |
| State level Supervision | The NASCP Epidemiology and Surveillance staff and the National/or zonal facilitators have the responsibility of supervising project implementation at the State level. |

## EQUIPMENT NEEDS

It is anticipated that all HIV sentinel sites are equipped to conduct basic laboratory tests. The FMOH in collaboration with the Center for Disease Control (CDC) will provide kits for HIV testing and the necessary consumables .

## DATA COMPILATION, ANALYSIS, PRESENTATION AND FEEDBACK

Results of screening will be recorded on the presented data collection form (annex 2). The State AIDS Programme Coordinators will collate individual data at the State level. The NASCP will organize data entry and analysis with Epi-info version 2000 for windows at Federal level for all sites.

The completed report of the 5th phase of the HIV sentinel survey should be ready within 2-4 weeks after completion of data entry and analysis. The report would be widely disseminated to all departments of the Federal Ministry of Health, all Federal

Ministries and Parastatals, State Ministries, Teaching Hospitals, Civilian Governors, Traditional Leaders, Mass Media networks, active NGOs in Health, Members of National Action Committee on AIDS, International Donors and Stakeholders, LGA Chairmen and PHC Coordinators at all levels.

At the end of the sero-surveillance activities, a report shall be compiled to describe the trend of HIV infections among ANC attendees. A meeting of the technical committee on HIV/AIDS/STD Epidemiology, Surveillance and Research, which is within the National AIDS Committee on AIDS, shall be convened to review the report.

Afterwards, a National seminar of data producers and users shall be organized to agree on the report. This will be immediately be followed by a press conference by the Hon. Minister of Health.

Then, NASCP will put together a detailed surveillance report, which will be sent to all the States.

In addition, presentations, advocacy and technical articles, kits covering the results of the HIV sero-surveillance system may be published in reputable journals and media.