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Protocol Of HIV/Syphilis Sentinel Survey in High Risk Groups in Nigeria

(Female Sex Workers; Long Distance Transport Workers; Patients with sexually transmitted Diseases and Pulmonary Tuberculosis).

BY THE

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Chapter 1

Executive Summary

The increasing magnitude of HIV/AIDS world-wide, and Nigeria in particular make HIV SURVEILLANCE A HIGH PRIORITY PROJECTS. APART FROM THE FACT THAT SURVEILLANCE IS A RELIABLE MEANS OF MONITORING THE TREND OF THE EPIDEMIC, IT ALSO ENABLES EFFECTIVE PLANNING AND RE-PLANNING AND ALSO CAN BE USED AS ADVOCACY TOOL.

The following facts further lay more credence to the urgency on the need to embark on HIV Sentinel Surveillance Survey:
Nigeria is the second worst affected country in Africa second to South Africa in terms of absolute number of people infected with HIV. Its epidemic is now at the generalized and explosive phase. The age range most affected is ages less than 25years. The country currently has hot and cold spots in relation to the sero-prevalence. A little window of hope exist at the moment especially with the current political commitment led by Mr President.

While the National AIDS and STD Control Programme have long recognized the need for continuous monitoring of the disease among high-risk groups. The survey on high-risk groups was last conducted in 1995; since then it has not been logistically possible to provide data for monitoring the epidemic, impact of interventions and advocacy. The four groups included in the study as high risk groups are the Female commercial sex workers, patients with PTB and STD, and long distance truck drivers. The PTB have been included because of the dual relationship belween TB and AIDS epidemics

The National Action Committee on AIDS and Federal Ministry of Health (NASCP) and other developrnent partners have deem it necessary to harmonize the protocol in order to conduct the surveillance survey among these groups through the support of the Department of International development (DFID)

The survey is planned to be managed by central management committee made up of representatives from NACA, FMOH, tertiary research institutions, and other development partners.

Syphilis screening shall be used as entry point in most groups except PTB where HB is planned. HIV screening is expected to be centrally done. Funds shall be managed according to the financial regulations of the donor and by accounting officers of donor agencies. However, where an agency so requests, NASCP may manage the funds based on criteria to be set up by the funding agency.

Four sentinel groups shall be covered as usual but restricted to only two sites per zone. These two sites shall be maintained in the future for the country in the trend analysis of HIV epidemic and its dynamics. The sites were chosen base on existing programmes by

NGOs and other stakeholders around the different sentinel population. The need to link sexual behavioral pattern among the sentinel population cannot be over-emphasized. We are therefore linking the survey on sex workers and long distance transport workers to Behavioral Sentinel surveillance.

The State coordinators of the chosen State Ministry of Health shall be required to supervise the entire survey along with others from each sentinel site: the attendant physician, a state laboratory technologist and the NGO coordinator where applicable, and 2 site nurses. A central training workshop shall be organized for field workers in order to have abreast with the survey protocol and also as training for trainers. We will also require further training of the remaining field workers on site.

The importance of supervisory visits in the success of any sentinel surveillance programme can be over emphasized. The essence of the supervision is to ensure strict adherence by field officers to the protocol; payment of allowances of staffs and retrieving data shall be carried out during the supervisory visits. Finally, also to ensuring that materials provided for the survey are utilized for that purpose.

A minimum of 250 samples is required from each of the selected sites per groups. Syphilis screening shall be done on site while HIV screening shall be done at the central level along with data management. The HIV samples shall be collected in filter paper blots from the site. All the samples for HIV testing shall be done with Genscreen and Recombigen kits

Filter paper, Gloves, cotton wool, disinfectants, needles and syringes, note books, standard forms and biros etc shall be supplied to the sentinel sites and laboratory staff for use during the sentinel surveillance.

Based on the experience of the 1999 Survey, we would require availing ourselves consultancy services of Prof. E.E Ekaneem (Epidemiologist and Biostatiscian) to manage the data and also Prof D Olaleye (Virologist) to manage the laboratory services.
During the survey, several meetings of the central management committee shall be convened to review data and provide framework for report writing.

While NASCP /NACA staffs shall not be entitled to any Honorarium, state officials involved with the sentinel surveillance shall be entitled to some token honorarium as incentive.
One thousand five hundred copies of the sentinel surveillance report shall be published by the NASCP and distributed widely. The NASCP shall be encouraged to present findings at national and international fora.

It is expected that from the time funds are made available, it will take twenty- four weeks from commencement to the end of the survey.

The detail of the budget is attached on the annex and the summary of the cost implications is as follows:

STD Sero-survey	N7, 826,0.50.00
FSW survey	
	N8,546,050.00

LDTW survey	₦3,546,050.00
PTB SURVEY	N7,826,050
MEETING OF CENTRAL MANAGEMENT COMMITTEE	N560,000.00
COST OF BSS AMONG FSW AND LDTW	Yet to be determined
TOTAL	**N22,293,000.00 plus**

Chapter 2

2.1 Introduction

The purpose of HIV sentinel sero-prevalence 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, these sentinel institutions should already be drawing blood routinely 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 need to seek consent of the individual concerned. This method is particularly applicable for Tuberculosis, and STD patients respectively. Other sentinel groups such as CSW, LDTW require services linked to the survey that might require consent for initial test.

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 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 sexually active adults 15-49years people living with HIV. This estimate was made using the 1999 sentinel survey done in 36 states plus FCT. So far, four (4) active surveys 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 (i.e 84 sentinel sites) and in 1999, it covered all the 36 states and the Federal capital Territory, Abuja.

In each of the above surveys except for the 1999 survey, high-risk population groups were included. The last time determination of magnitude and trend monitoring of HIV were done among high-risk sub-population groups was in 1995. It is definitely long over due to provide an updated HIV/Syphilis data for advocacy, planning interventions and monitoring of the epidemic among these groups in the country.

It is in the light of this that, the year 2000 HIV/Syphilis Sentinel Sero-Prevalence Survey will concentrate on four (4) High Risk groups – FSW, PTB, STDs and LDTW. It is envisaged that a survey in these groups using some selected representative zonal sites will suffice in depicting a clear picture of the epidemic. HIV Infection among these groups has been known to have direct or indirect effect in fueling and sustaining the epidemic in the general population.

2.2 General Objectives:

The general objective of conducting this survey is to provide information for advocacy, planning and evaluation of the impact of the response to the epidemic among these identified high-risk population groups: female sex workers, patients with sexually transmitted diseases and long distance transport workers. Patients with pulmonary tuberculosis have also been targeted in order to assess the dual epidemics.

Specific objectives are:

- To determine the prevalence of HIV infection among female sex workers, patient with sexually transmitted diseases, long distance transport workers and patients with pulmonary tuberculosis
- To monitor trends of HIV infection among female sex workers, patient with sexually transmitted diseases, long distant truck drivers and finally patients with pulmonary tuberculosis
- To identify the link between sexually behavioral pattern and HIV sero-prevalence among female sex workers, long distant transport workers and patient with sexually transmitted diseases.

Chapter 3

3.0 METHODOLOGY

Due to the variability of the settings of the sentinel groups such as female sex workers, patient with sexually transmitted diseases, long distant truck drivers and finally patients with pulmonary tuberculosis, the methodology of the groups are addressed separately.

3.1.0 Methodology of the different Sentinel Groups

3.1.1 Patients with Sexually Transmitted Diseases

Sentinel population

The sentinel population for the survey shall be male and female patients with sexually transmitted diseases

Sampling sites

Two sites per zones shall be used. The two sites shall be identified in one hot spot and also in one cold spot. The selection of the site will be based on the following:

- Availability of functional STD clinic,
- Laboratory support for syphilis screening,
- Qualified health care providers Physicians,
- Availability of adequate trained laboratory scientist and technologist; trained STD counselors and nurse
- Adequate inflow of STD patient at least 100 patient/month

Sample inclusion criteria

All patients with the following syndromes shall be included:
Abnormal vaginal discharge in women, lower abdominal pain in women, urethral discharge in males, genital ulcers in both male and females, inguino-scrotal swelling. The attending physician will be required to establish STD diagnosis based on syndromic approach. All sites must be trained on syndromic management. Patients with vaginal discharge are excluded because of its non-specific nature.

Sentinel Size

The sample size shall be minimum of 250 per site.

Sampling Inclusion Criteria

12 weeks shall be used to generate data from the sentinel site.

Sampling Scheme

All patients attending STD clinics shall be included. An unlinked anonymous method shall be used. Syphilis screening shall be used as entry point.

Samples will be collected on daily basis from the sentinel group during the specimen collection period of 16 weeks. The supervising nurse or outreach health worker fills in the initial demographic information of the client on arrival. About 5mls of blood will be collected from the patients as part of routine diagnostic procedure. The sample bottle is labeled and transported to the laboratory on site for syphilis testing. Results are thereafter sent back to attending Doctor/Health worker for appropriate management.

Few drops of blood left over shall be collected and stored in filter paper for HIV screening centrally.
For each sample, the following data should be collected: State, site, sex, marital status, type of STD syndromes and age.

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. This group shall not be linked to sexual behavioral study (BSS)

Laboratory Screening of Samples

Centralized (national) HIV screening shall be used. Syphilis screening shall be done at the site level

Training of Field Staff

The following training needs have been identified for field workers:

- STD Counselling
- Syndromic diagnosis and management
- Laboratory training

2-3 days training is recommended to cover these needs

Supervision of the Surveillance System

Supervision should be done centrally, zonal and at the site level

Personnel Requirements

The following field personnel will be required: Laboratory scientist, Nurse, and physician.

3.1.2 Patient with Pulmonary Tuberculosis

Sentinel population

The sentinel population to be covered are male and female patients with confirmed pulmonary tuberculosis

Site selection

One site per zone shall be used covering six zones. This is because specialized TB are large geographical coverage as referrals are sent from the catchments area. It is well known that sampling of TB patient therefore fairly represents the PTB sub-population in the zone due to referral status of facilities and free drug policy that operates in some sites. The facilities identified for sampling shall the infectious Disease Hospital, Missionary hospitals and leprosy and tuberculosis hospital

Sample inclusion Criteria

The sample inclusion criteria are as follows:

- Confirmed PTB (smear positive patient)
- Close or open case not beyond 9 months of onset treatment

Sample size

The sample size shall be 250/site/zone ie one site per zone. A total of 1500 samples shall be required for this study in six sites in the country

Duration of sampling

The duration of the survey of PTB shall be 16 weeks. All sites are expected to start at the same time

Sample of questionnaires

The following demographic information shall be used in the data collection form: age, sex, marital status, and parity

Training Needs

Training shall cover the following field officers : State Aids Programme Coordinator, State TB/leprosy coordinators, Laboratory scientists, Laboratory technicians, Medical Doctors, and Nurses

Sample Scheme

Specialized treatment centers for tuberculosis shall be listed and sampling frame calculated. PTB patients are sampled based on inclusion criteria. Informed consent shall be received from included patients and basic demographic information collected such as age, and sex. Blood collection shall be linked up to routine heamoglobin collection used for monitoring treatment response. The remaining liquor shall be used for central screening of HIV stored in filter paper.

Supervision

There is an urgent need to develop and use standard checklist for supervision. Also on site daily supervision by medical officer will be required. The State AIDS Programme coordinator shall coordinate and supervise the survey at the state in collaboration with health workers providing services in PTB treatment centers.

Possible interventions

Results of the survey shall be used for advocacy and planning of interventions using the DOTS strategies in collaboration with the National Tuberculosis and Leprosy center.

3.3.1 Long Distance Transport Workers

Sentinel Population

Long distance transport workers shall be sampled for this survey.

Site Selection

The site selection criteria are as follows: major truck routes, adequate number of drivers to participate, site with on going project- Onitsha, Port-Harcourt, Makurdi, Kebbi, Yola and Sagamu

Sample Inclusion Criteria

The inclusion criteria for subjects are the following

- All truckers available at site

Supervision/Logistics Issues

The following logistics issues shall be emphasized during the survey:
Site supervision, State level supervision
Federal level supervision
Transport stipends
Remuneration of personnel

consent for syphilis on site and those positive are provided with on site treatment or linked to existing facilities for treatment. Samples for HIV screening shall be collected from syphilis samples already collected on filter paper and stored in fridge for onward transportation to the central screening laboratory. An anonymous unlinked method shall be used in other to avoid ethical issues. This survey shall be linked with behavioral survey

Duration of sampling

The duration of sampling shall be 16 weeks.

TRAINING NEEDS.

Members of Sex workers association, brothel managers, laboratory personnel, site supervisors and NGOs shall be trained on the study protocol and basic counseling before commencement of the survey.

Logistic issues

The logistic requirement for the survey are : transport for laboratory Technicians; condoms for respondents; haematenics for respondents; supervision logistics (Checklist shall be used during supervision of the supervision)

Possible Interventions

The data shall be used to provide interventions on condom use skills and other behavioral change interventions as well as advocacy. Possibilities of linkages to existing treatment facilities within the locality may be feasible as post survey programmes.

3.2 CENTRAL TRAINING OF FIELD WORKERS

This is applicable for the following key officers: State AIDS Programme; the Medical Officer or focal Officer in charge of NGO providing interventions and laboratory scientist.

Field Officers trained shall required to conduct training of trainers workshop for the site staffs.

3.3 BLOOD SAMPLE COLLECTION, TRANSPORTATIONLABOARATORY TESTS, QUALITY ASSURANCE AND CONTROL

BLOOD SAMPLE COLLECTION

About 5mls of various bloods will be collected using syringe and needle from each individual recited into each of the studies. About 50ml (2drops) each of the whole blood will be dispensed onto two spots of a used labeled coded blotting paper strip per person. The remaining blood sample will be transferred into a 5mls plain plastic tube with clean identifiers of the subject.

The blotting paper impregnated with the blood sample will be allowed to dry at room temperature (for about 10-15 minutes). The paper will then be transferred into a nylon bag (such as medicine dispensing sachet) and stored at a cool (non moist) condition (4 – 8°C or preferably – 20°C) until ready for shipment to the Virology Laboratory at UCH, Ibadan. The sample will be allowed to clot at room temperature for serum separation into a sterile 2mls vials. The serum samples will be used for syphilis testing immediately or stated at – 20°C until ready to be used.

TRANSPORTATION

Depending on size and standard of storage facilities as well as stability of electricity supply at the sample collection sites, coded filter paper blot will be moved at least once in two weeks or once per month to the central facility for HIV laboratory test.

The zonal supervisors and the central laboratory supervisor will coordinate transportation of samples.

Frozen filter paper will be transported in insulated boxes with adequate cold packs from the collection sites to the laboratory.

NB In sites where storage facilities are not available, arrangements will be made to transport whole blood or sera to a laboratory within the same locality where such samples will be processed and stored properly.

HIV-1 and HIV-2 tests

HIV testing will be done centrally in the Department of Virology, UCH, Ibadan. All the filter papers with the dot blood samples will be sent to Ibadan by courier. Strips from each of the four study groups will be registered and stored separately at – 20°C until ready to be tested. In order to avoid deterioration (penetration) of the antibody level in any positive samples testing will be done progressively as enough samples are received to utilize at least one screening kit.

One of the two blood spots from each person will be cut from the blotting paper strip and transferred into a well labeled khan to be or plastic test tube. Evaluation buffer will be added to achieve a dilution of 1:10 or 1:100 depending on the test kit. The blood in the blotting paper will be eluted into the buffer by gentle rocking for 30 – 60 minutes. The paper will be removed from the tube into a biohazard container for incineration.

The eluted blood sample will then be used for HIV test using the initial screening and follow up kits that will be provided for the study. The tests shall be carried out according to the manufacturers' recommendations. A sample will be regarded as positive for HIV when it is reactive with both tests.

Syphilis Tests

These tests will be carried out in the site facility laboratories (STI) or other designated laboratories in the state for the FSW and LDTW.

Experienced laboratory scientist on site using the RPR agglutination test kit will screen the serum samples from each person for syphilis antibody. All reactive samples (weak, to strongly) will then be subjected to confirmatory test using the TPHA kit. A sample will be considered reactive for syphilis when it is positive with both assays.

Results of the syphilis tests will be made available to the attending physician for treatment of positive persons.

Determination for PTB Group

Aliquots of the whole blood in EDTA from each of the patients enrolled for the study will be used to determine the Hemoglobin level of that person. The results of this test shall be made available to the attending physician to assist in the management.

QUALITY ASSURANCE MEASURES

- Highly qualified laboratory staff will be recruited for the study and retrained.
- Quality of the test kits will be ascertained and maintained
- Ensure proper storage of samples and kits
- Provide adequate storage and laboratory consumables to completely eliminate cross contamination.
- Strict adherence to the study protocol as well as test kit manufacturers; procedures
- Centralized testing of samples to minimize certain multiple Technician handling errors.
- In-built kit controls and external positive and negative controls to be included in every test plate.
- Reading of test results with ELISA reader will eliminate errors due to colour blindness that may occur with RTDs.

3.4 CENTRAL DATA MANAGEMENT

All data shall be managed centrally. The different phases of data management is as stated below:

Data Retrieved

Data from the sites will be retrieved by zonal supervisors for central data entry. States are to maintain duplicates of data sent to the central data entry point.

Quality Retrieved

Data forms will be checked for completeness, errors and inconsistencies.

EPI information software will be used for data entry, validation and analysis. Several strategies will be adopted to ensure the accuracy of data entered. First a CHECK Programme will be created. The check programme is to ensure that only legal codes and data in specified ranges are entered. Secondly, separate entry clerks will subject ten percent of all the records to double entries. The VALIDATE option of the EPI information programme will used to validate the entries.

as syphilis screening, filter paper blot, supervisory visits, BSS link with the survey and general survey management from UNAIDS, WHO AFRO, CDC and FHI.

2. Names of survey sites

ZONES	STD GROUP	PTB GROUP	FSW	LDTW
South East Abia Anambra Enugu **South West** Lagos Ogun Osun	Aba Enugu Lagos Ife	Aba Enugu Lagos Ife	Aba Onitsha Lagos Ibadan	Aba Onitsha Ijebu-ode sagamu
North West Kaduna Kebbi Jigawa Kano **North East** Adamawa Borno Taraba Yobe bauchi	Zaria Kano Maiduguri Bauchi	Zaria Hadejia Maiduguri Bauchi	Kafanchan kano Jalingo Damaturu	Benin-kebbi Hadejia Yola Maiduguri
North central Benue FCT Plateau Kwara	Jos Ilorin	Makurdi Jos Ilorin	Makurdi Abuja	Makurdi Jos
South South Rivers Edo Akwa Ibom	Port Harcourt Uyo	Port Harcourt Uyo	Port-Harcourt Uyo	Port Harcourt Benin

3. Budget on Survey monitoring meetings

S/NO	Description of activities	Cost
1	Hall hire	N10,000.00
2	Group lunch for 20 participants at N1000 x 20 participants	N20,000.00
3	Transport for three participants at N20,000.00 x 3	N60,000.00
4	Tea breaks at N500 x @ x 20	N20,000.00
5	Stationaries	N20,000.00
6	Local transport for 10 at N1000.00	N10,000.00
7	Total	N140,000.00
8	Total Number of meetings is 4/ group x N140,000	N560,00.00