

## **LABORATORY NETWORK FOR HIV INFECTION IN ETHIOPIA**

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**ABSTRACT:** One of the main objectives of the Short Term Plan of the Ethiopian AIDS Control Programme was the establishment of screening laboratories in blood banks in the country and strengthening the Immunology Laboratory of the National Research Institute of Health. As a result, HIV screening laboratories were established in all five blood banks and the National Referral Laboratory for AIDS (NRLA) was established during the first half of the short term plan. Based on the Medium Term Plan of the programme which envisaged establishment of HIV screening laboratories in all regional hospitals where a substantial amount of blood transfusion took place, HIV screening laboratories were established. To date there are 24 HIV screening laboratories throughout the country. Nineteen of these laboratories use ELISA tests and 5 use simple/rapid assays. There is a well established quality control and supervision system where each laboratory is visited twice a year and characterized panels of sera are sent to each laboratory three times a year from the NRLA. The plan of the National AIDS Control Programme is to establish screening laboratories in all establishments where blood transfusion is carried out.

### **INTRODUCTION**

The first cases of AIDS were reported from the USA, Haiti and parts of Africa in the early 1980's (1,2,3,4). By 1983 sufficient evidence was accumulated to consider the communicable nature of the disease AIDS (5,6). The intensive work done on retroviruses in France and the United States led to the discovery of the causative agent, which was later on called the Human Immunodeficiency virus or HIV. Research done in 1984 showed that HIV infects T-helper cells (7,8) and by Early 1985 blood tests were developed which enabled the recognition of anti-HIV antibodies in an infected individual. Thus the enzyme linked immunosorbent assay (ELISA) became a very important technique in the screening and prevention of HIV transmission through blood transfusion.

The first seropositive cases in Ethiopia were reported in 1986 among hospital patients (9) and in 1986 a sharp increase in the prevalence of HIV among the same group was noted (10). Several findings were the basis for the Government of the Peoples Democratic Republic of Ethiopia to recognize that the AIDS epidemic poses a potential threat to the health, social and economic development of the country. The Department of AIDS Control therefore was established under the Ministry of Health in September 1987 to coordinate the prevention and control efforts in an integrated multi-disciplinary approach. As the laboratory service is an essential component of the AIDS Control Programme a specialized division was established within the Department. An advisory sub-committee consisting of six members (immunologist, hematologist, laboratory expert, blood bank

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specialist and two microbiologists) was set up to provide technical advice and guidance on matters related to HIV screening and blood banking. According to till: Short Term Plan for AIDS Control

in Ethiopia priority was given to strengthening the Immunology laboratory at the National Research Institute of Health (NRIH). Equipment necessary for blood screening and confirmatory assay were received from WHO and installed at the Laboratory .Five additional biologists and chemists were assigned and separate rooms for the laboratory have been furnished and made available. Thus the Laboratory in the NRIH was promoted to a level of National Referral Laboratory for AIDS (NRLA). The main purposes were:

- to develop strategies, improve and maintain the quality of testing;
- to establish country-wide information exchange network;
- to serve as a training center for medical laboratory technicians involved in HIV screening;
- to supervise the performance of technicians involved in HIV screening;
- to support clinicians in the diagnosis of HIV infection and AIDS;
- to support surveillance and research on HIV.

### **PROVISION OF HIV SCREENING FACILITIES TO BLOOD BANKS AND REGIONAL HOSPITALS**

In the effort to decrease the spread of HIV infection through blood, blood transfusion establishments were assessed based on the strategies of the Short and Medium Term Plans for AIDS Control in Ethiopia. According to the first five year plan for AIDS control in Ethiopia, priority was given to the five blood banks in which a minimum of 1000 units of blood were collected per year .This was followed by regional hospital laboratories where emergency transfusions were taking place.

To integrate HIV screening facilities into the existing health care delivery system, assessment of the five blood banks and twenty regional hospitals was made using a questionnaire which included information on the number of inpatients, surgery performed, blood transfusion given (units of blood collected), availability of equipment, space and trained manpower. As soon as the laboratory establishments were assessed and areas for HIV testing identified, medical laboratory technicians were selected on the basis of the recommendation by the hospitals or blood bank directors, indicating the educational background, year of service and professional interest.

### **TRAINING**

To ensure the uniformity of training, a course syllabus was developed consisting of both theoretical and intensive practice on HIV screening by ELISA and simple/rapid assays. The following topics were included in the syllabus:

- A) Basic knowledge on AIDS
  - virology
  - pathogenesis and pathology
  - immunology of mode of transmission
  - prevention and control
- B) Sterilization and disinfection
- C) Laboratory safety and precautions
- D) Blood banking
- E) Ethics and confidentiality in recording and reporting
- F) Specimen collection, handling, transportation and storage

- G) Demonstration ELISA, simple/rapid assays
- H) Practical laboratory work -ELISA, simple/rapid assays
- 1) Evaluation of the techniques
- J) Evaluation of the performance

The selected laboratory technicians were given intensive training for a period of two weeks by the staff of the NRLA. The trainees who showed good performance were assigned to be responsible for the HIV screening laboratory in their respective regions.

### **ESTABLISHMENT OF PERIPHERAL HIV SCREENING LABORATORIES**

At the end of the training the technicians return to their regions accompanied by one of the NRLA staff and all the necessary equipment and reagents required to set up an HIV screening laboratory. The staff of the NRLA remained on site until the newly trained technicians could perform testing independently.

### **SAMPLE COLLECTION AND LABORATORY TESTING FOR HIV**

The specimens tested by the HIV laboratories are from several target groups identified through various strategies of the National AIDS Control Programme. Suspected AIDS patients. Coded blood samples from suspected AIDS patients are sent to the NRLA along with the test request format signed by the designated physician responsible for the diagnosis of AIDS. The criteria used in the laboratory for specimens from suspected AIDS patients is the revised WHO criteria on the standardization of western blots for HIV -1, HIV-2 and HTLV-1 (11).

Blood donors. All units of blood from donors are screened either in the blood banks or in the regional hospital HIV screening laboratories. If the sample is positive twice, the unit of blood is discarded. Serosurveys. Specimens are collected through various surveys from the different population groups like female sex workers, long distance truck drivers and attendants of antenatal clinics. Screening of the population at the sentinel surveillance sites is delegated to the regional screening laboratories. The first line screening test performed in regional HIV screening laboratories, blood banks and NRLA is Enzyme Linked Immunosorbent Assay (ELISA). Currently second generation ELISA assays based on recombinant DNA technology or synthetic peptide antigens with high sensitivity and specificity are used for initial screening. All double ELISA positive samples are confirmed by western blot at the NRLA. Confirmatory tests are usually done for AIDS patients and other subjects requiring post-test counselling.

According to the present strategy all blood bank laboratories that screen large units of blood use ELISA. Laboratories at the regional hospitals (which transfuse less than twenty units of blood per month) use simple/rapid assays. This is not only cost effective but also minimizes the danger of using untested blood.

### **RECORDING, REPORTING AND CONFIDENTIALITY**

All samples that come to the laboratory are coded, and the identity of the patient is kept with the physicians, or individuals responsible for a particular survey or study that required HIV testing. The laboratory results are then reported back to the individual who requested the test. This way the confidentiality of the test is maintained. At the end of each month, the total number of AIDS patients and of units of blood collected and tested for HIV is reported

from each screening laboratory to the Department of AIDS Control in the pre-designed monthly report form.

### **SUPERVISION AND QUALITY CONTROL**

Once the laboratories have been established the built-in mechanism for quality control (figure I) starts operating. The technician in each laboratory sends all positive samples and 10% of all negative samples to NRLA every three months. These samples are tested at the referral laboratory and, if there is a discrepancy, actions are taken to identify the reasons for default. The actions vary from a telephone contact to a site visit.

In addition, the NRLA sends properly controlled panels of sera to HN screening laboratories every four months. After determining the antibody status of each serum by the screening laboratories the results are sent back to the NRLA along with the quality control information format. Then the test is checked and compared by the Quality Control Officer and the results communicated to the laboratories.

For monitoring blood screening activities each laboratory is visited at least twice a year. During the unannounced supervisory visits a specially designed questionnaire is used to collect information on the general set up of the laboratories with special emphases to the standard of biosafety in the laboratory, handling of specimens, blood collection and storage, condition of test kits, performance of tests, confidentiality of test results, recording and reporting, disposal of laboratory waste, habit of using

**TABLE Development of HIV screening laboratory network in Ethiopia Activities 1987**

Activities	1987	1988	1989	1990	TOTAL
Laboratories Established at:					
-NRLA	1	-	-	-	1
-Blood banks	1	4	-	1	6
-Reg. hospital	-	3	-	9	12
-Reg. hospital (Simple/rapid assay)	-	-	5	-	5
-Total Labs established	2	7		10	24
Personnel Trained					
-Biologist	4	-	-	-	4
- Lab technicians	1	7	17	16	41
- Total	5	7	17	16	45
Samples tested					
-Truck drivers, assistnces and mechanics	-	995	557	371	1923
MPSC females	-	6564	4754	2433	13751
-Scholarship winners	-	1142	1535	760	3437
AIDS suspected patients	-	756	1696	2222	4674
Blood donors	-	20462	19658	26291	66411
Total	-	29919	28200	32077	90196

protective clothing and condition of laboratory equipment. Problem faced by the technicians are examined and solutions given on the spot.

## **RESEARCH**

Research is one of the regular activities of the NRLA. Research on diagnostics is one of the major research questions addressed in collaboration with WHO/GPA and supported by the national laboratory networks. Some of the topics addressed include:

- a. field evaluation of simple/rapid assays;
- b. standardization of the interpretation of immunoblot assays;
- c. evaluation of alternative confirmatory strategies such as consecutive use of different antibody screening assays;
- d. field testing of the quality control system developed by WHO/GPA.

## **DISCUSSION**

There have been a number of developments in the HIV Laboratory Network in Ethiopia. The Immunological Laboratory at the National Research Institute of Health (NRIH) has been strengthened both in equipment and manpower and upgraded to a National Referral Laboratory for AIDS (NRLA). Currently the NRLA has the capability to perform different types of screening and confirmatory assays including the polymerase chain reaction (PCR).

A number of training seminars were conducted on HIV screening by the NRLA. A total of 45 laboratory technicians were trained on ELISA, simple/rapid assays and western blot techniques.

A total of 24 laboratories have been established up to the end of this year (table 1 and figure 2). More than 101,622 specimens have been tested until December 1990. The majority, 77,837 (76.6%) were specimens from blood donors. Of these 2994 (3.8%) units of blood have been discarded. Although the transmission of HIV through blood transfusion is efficient, the contribution of blood transfusion towards the transmission of HIV in developing countries might not be significant. Considering the ELISA false positivity rate at 30% , over two thousand acts of HIV transmissions through donors blood have been prevented in Ethiopia. The figure apparently is not very high if compared to the number of persons infected through other ways. It was estimated (12) that in the year of 1989 alone, over 70,000 adults had been infected in Ethiopia. HIV transmission through donated blood might have contributed less than one percent to the tall of newly infected persons. However, even in the areas where HIV prevalence among blood donors is below one percent, the screening of blood was found cost efficient (13). The cost of prevention of one transmission episode through donors blood in Ethiopia is estimated at EBirr 240 (US\$ 120), which is relatively low, considering social and economic losses an AIDS patient and the family suffer from the disease and eventual death.

The next highest number of specimens have been specimens from serosurveys 15,674 (17.38%). Through this the prevalence of the disease in the different population groups has been established. This has become the basis for prevention and control strategies especially the planning of IEC activities for the population groups at risk. The number of specimens from cases that show signs and symptoms of HIV/AIDS infection has shown a tremendous increase during the last two years. This is due to the training that has been given to physicians on clinical diagnosis. As a result 4674 specimens which make up 5.18% of the total have come from hospitals. Three quarter of these specimens are attributed to the last one year. Though passive, this has also contributed towards the monitoring of disease progression.

There have been several problems encountered in the process of establishing the network of HIV laboratories. Some of these problems were:

- limited numbers of properly organized blood banks;
- shortage of laboratory technicians in the regional and district hospitals;
- inadequate laboratory space for HIV screening in some hospitals;
- lack of facilities for transporting the samples from the periphery to the NRLA for confirmation.

All problems identified during supervisory visits and quality control check up were discussed with the technicians and medical directors on the spot for finding immediate solutions. Problems that were found to be beyond the capacity of the peripheral laboratory officials were referred to the regional health administration and the Department of AIDS Control for further considerations.

The issues that are going to be addressed in the future include:

- Strengthening the already established laboratories through provision of equipment, reagent, protective clothing and training of manpower.
- Expansion of HIV screening facilities to additional 16 peripheral hospitals by the end of 1991 and to the remaining 60 hospitals within the second five year plan (1992 -1996).
- As the ELISA technique becomes a tool for laboratory diagnosis of other sexually transmitted diseases the integration of the laboratory facilities for HIV screening system with that of STD laboratories.
- In order to indicate the stage of development of HIV infection in individual subjects the NRLA will be strengthened by including assays for T<sup>4</sup> and T<sup>8</sup> lymphocyte subset determination.
- In order to meet the growing demands for identification of suspected sero-negative AIDS patients and children born to HIV infected mothers, it is planned to use the recently developed gene amplification technique known as the polymerase chain reaction (PCR).

FIGURE 1 : HIV SCREENING QUALITY CONTROL SYSTEM

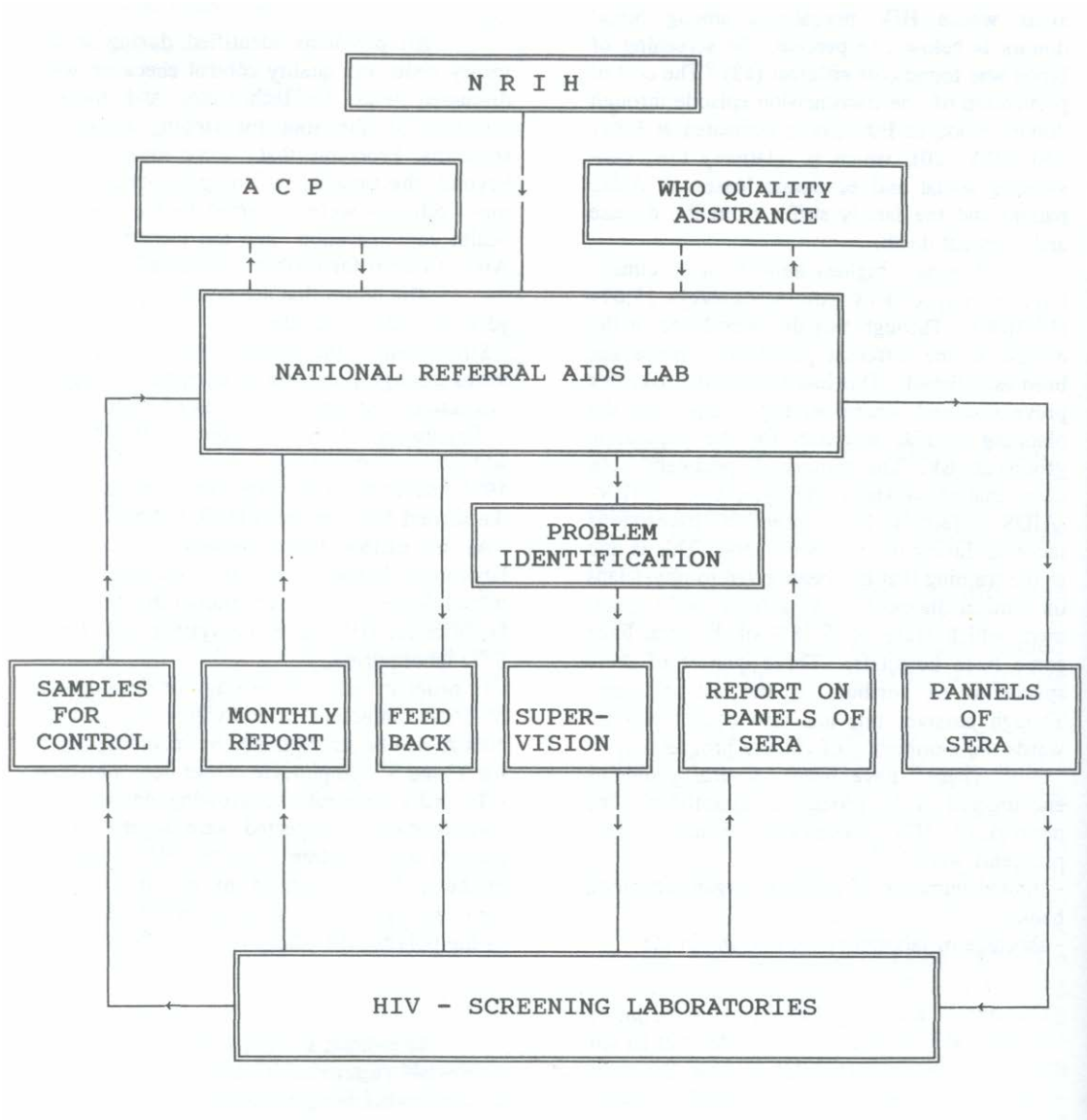
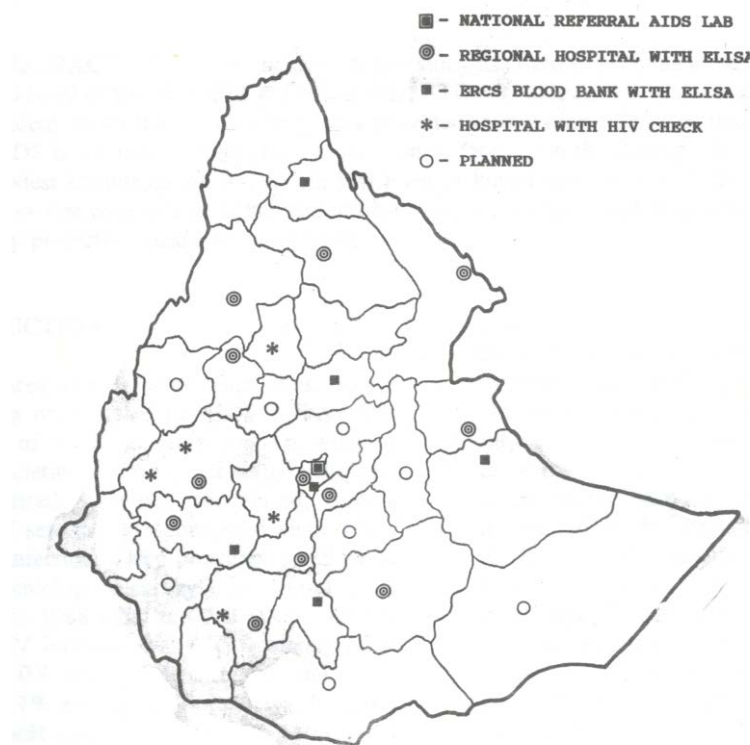


FIGURE 2: DISTRIBUTION OF HIV-1 SCREENING LABORATORIES IN ETHIOPIA, AUGUST 1990



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