Original article

The status of HIV screening laboratories in Ethiopia: achievements, problems encountered and possible solutions

Belete Tegbaru[1], Hailu Meless[2], Wegene Tamene[1], Negussie Gezahegn[1], Zinet Ahmedin[1], Hiwot Birhanu[1], Desalegn Tesema[1], Tsehaynesh Messele[2]

Abstract

Objectives: To know the status of HIV screening laboratories in different parts of the country, to identify the major problems encountered and to suggest and recommend possible solutions to the policy makers at different levels.

Materials and methods: Forty-two out of 74 government and non-government owned HIV screening laboratories were supervised in December 2001. A cross sectional study using a detailed questionnaire and an on-site observation /supervision to assess the technical issues, safety procedures, laboratory management and other related issues to quality assurance was conducted. These laboratories were selected randomly and at least one laboratory from each region has been included.

Results: Most laboratories, 27(64.3%) were capable of performing ELISA and Rapid tests. Majority of them (62%) do not follow a specific testing algorithm, only in 50% were confirmatory tests performed, while 21% send their specimen to the regional laboratories and the remaining 29% do not confirm their results at all. In only 29% of them were safety guidelines practiced. In 58.4% and 54.7% of them, there was a shortage of reagents and protective materials, respectively. Problems related to maintenance, weak referral system, poor laboratory management, lack of follow-up resulting in delay of issuing results to clients were identified.

Recommendations: It is suggested that the problems of regional laboratories should be alleviated through collaborative approach among different stakeholders and there is a need to encourage them to fully participate in NEQUAS. Strengthening in equipment and trained human resource, and close follow-up of Regional Laboratories, timely ordering of supplies and reagents, continuous training programs on HIV screening methods, quality assurance and maintenance were recommended. [*Ethiop.J.Health Dev.* 2002;16(2):209-215]

Introduction

Laboratory service is an essential component of the health care. Diagnostic support for the investigation of epidemics and surveillance of endemic diseases cannot be successful with out adequate and organised laboratory facilities and trained human resource (1,2). Thus, the quality of the work, the effectiveness, reputation and possibly even the accreditation of the laboratories is largely dependent on the appropriate infrastructure and technical personnel.

The validity of a diagnostic test result produced in each laboratory is entirely dependent on the quality of the measures employed before, during and after each assay. Measures to control the quality of the results in an HIV diagnostic laboratory are extremely important, because the consequences of either false positive or false negative results are huge (3,4). A good quality assurance program can monitor this. Quality assurance is a process whereby the quality of laboratory reports can

[1]Ethiopian Health and Nutrition Research Institute-National Referral Laboratory for AIDS (EHNRI-NRLA), P.O. Box 1242, Addis Ababa, Ethiopia; [2]EHNRI-Ethio-Netherlands AIDS Research Project (EHNRI-ENARP)

be guaranteed: producing the right result at the right time on the right specimen from the right patient with the right interpretation based on correct reference data and equipment. This helps to achieve a good laboratory standard (5-11). Quality assurance includes quality control and quality assessment schemes and must be supported with effective safety procedures, decontamination and sterilisation process and equipment maintenance (12-15).

Infection of HIV can only be confirmed with serological and other tests such as culture, antigen detection assays, polymerase chain reaction (PCR), etc. The reproducibility, accuracy and reliability of such diagnostic tests are however, very essential for voluntary counselling and testing services (VCT), blood donations and case management of individuals and patients. For these reasons, a quality assurance program practised in the laboratory is highly important (3,10). In developing countries where resources are often scarce, problems associated with diagnostic laboratories should always be assessed and monitored. For monitoring and evaluating the performance of HIV screening laboratories establishment of a network of quality assurance program including supervision is essential.

All over Ethiopia, there were 90 screening laboratories (as of January 2002). Of these, 74 were governmental and Non-Governmental, and 16 were privately owned (all of them capable of performing an ELISA assay and located in Addis Ababa). The distribution was: ten in Tigray, ten in Amhara, twenty in Ormiya, one in Afar, two in Somali, five in Hararri, one in Dire Dawa Administration council, one in Gambella, two in Benshangul Gumuz, six at the centre (those under Ministry of Health), twelve in Southern Nations and Nationalities Region and four in Addis Ababa. Of these 74 laboratories, 44 have a capacity of doing both ELISA and rapid test while the others perform only rapid tests. From those capable of doing ELISA and Rapid tests, 7 were Regional Referral and 8 Blood Bank laboratories. To monitor the performance of these screening laboratories, a National Quality Assurance Scheme (NEQUAS) within the National Referral Laboratory for AIDS (NRLA) of the Ethiopian Health and Nutrition Research Institute (EHNRI) has been initiated in collaboration with the Ministry of Health since 1992. Proficiency testing was commenced on 15 selected Blood Bank and Regional Referral laboratories. At the end of 2001, twenty-nine screening laboratories were participating in NEQUAS. Thus, NEQUAS for HIV screening laboratories in Ethiopia is the first of its kind in assessing and monitoring the HIV screening laboratories in the country.

Therefore, the objectives of the study were: to know the status of HIV laboratories in different parts of the country, to identify the major problems encountered, to attract the attention of relevant bodies towards the issues of quality in diagnostic laboratories as a whole for future concern and discussion and to suggest and recommend possible solutions, for the problems identified, to the policy makers at different levels.

Methods

Of the 74 screening laboratories, 42 (27 of them doing both ELISA and Rapid, and 15 of them only Rapid) were visited/supervised in December 2001. The laboratories were selected randomly and at least one laboratory from each region has been supervised. Private laboratories were not included in the assessment since these laboratories were not NEQUAS participants. Two teams from NRLA, each composed of one technical and one scientific staff, supervised these laboratories (21 laboratories by each team). Methods of assessment were: on-site supervision and interviewing using a detailed structured questionnaire regarding the general conditions of the laboratories, types and performances of tests, specimen collection and analysis, quality assurance and control, confidentiality of test results, recording and reporting, waste disposal, disinfection and safety, relationship of the laboratories with the Health Bureaux and Zonal Health Departments and availability of test regents/kits. Furthermore, the supervision team had a general discussion with the head of the laboratories, laboratory technicians who were involved directly in the screening, medical director/head of the institutions, head of the Regional Health Bureaux and Zonal Health Departments. In the National External Quality Assurance Scheme (NEQUAS), which is

conducted by NRLA, distribution of proficiency testing panel (8 well-characterized specimens) for 29 HIV screening laboratories is regularly done every six months. Those NEQUAS participant HIV screening laboratories respond within one to two months of time and the feedback from these laboratories is be analysed and distributed to them so that early detection of errors can be done, if any.

Results

Participant laboratories and personnel

Out of the 42 supervised laboratories, 32(76.2%) were hospital based, 7(16.7%) Regional Referral Laboratories and 3(7.1%) were Blood Bank Laboratories. Of all, 27(64.3%) of them were found to be technically and logistically capable of conducting both ELISA and rapid tests. Junior laboratory technologists (59.5%) followed by senior (35.7%) and graduate technologists (4.8%) were available laboratory personnel in the laboratories at the time of supervision. In 37(88.1%) of the laboratories, at least one technician trained on HIV screening methodologies was available (Table 1). Most of the training was given at NRLA (78.4%) while 21.6% was given at the Regional Referral Laboratories.

Observed conditions of the supervised laboratories

Observation was also made on the availability of electricity, water supply and space for testing in the screening laboratories. Of the supervised laboratories, 36/42 (85.7%)of them had separate rooms for testing and in 38/42 (90.5%) of them electric city and water supply was available. Seventeen out of twenty-seven (62.9%) ELISA capable laboratories experienced power interruptions for more than 24 hours. Eventhough the capacity of the generators found in the health institutions was variable and small in some of them, 16/17(94.1%) of them could alleviate the problem using generators. More than 60% of the laboratories tested less than 60 samples (either blood donors or patients) at an average per month. However, 23/42(58.4%) of the screening laboratories were complaining of frequent reagent shortages (Table 2).

Table 1: **General information on the supervised HIV screening laboratories**

Characteristics	Number (%)
Methods used for HIV testing	
ELISA and Rapid test	27(64.3)
Rapid test only	15(35.7)
Types of health institutions where laboratories are located	
Hospital	32(76.2)
Regional Referral Laboratory	7(16.7)
Blood Bank Centres	3(7.2)
Qualification of technicians who are involved in the screening	
Junior Laboratory technicians	25(59.5)
Senior laboratory technicians*	15(35.7)
BSc and above	2(4.8)
Presence of trained technicians on HIV screening methods	37(88.1)

* Senior laboratory technicians are those with a qualification of Diploma (two Years training) plus one year further training.

Table 2: **Observed conditions of supervised HIV screening laboratories**

Characteristics	Number (%)
Presence of separate room for the laboratory for screening	36(85.7)
Good water supply for the laboratory	38(90.5)
Good electricity supply for the laboratory	42(100.0)
Place of training for the technicians who were involved in the screening	
National Referral Laboratory for AIDS-EHNRI	29(78.4)
Regional Referral Laboratories	8(21.6)
Shortage of test kits/reagents	
Rapid test kits for rapid test testing laboratories (n=15)	10(66.7)
ELISA test kits for ELISA level Laboratories (n=27)	13(48.1)
Total	23(58.4)
Average number of specimens analysed per month (<60)	26(65.0)
Power interruptions for more than 24 hours (n=27)	17(62.9)

Safety procedures, waste disposal and disinfection

Over 70% of the specimen sources for screening were patients and blood donors. Of the total laboratories visited during the supervision, 23/42 (55%) were using incinerators for solid waste disposal and in 25/42 (58.5%) of them liquid waste coming out of the laboratory is released to the sewerage system without any pre-treatment with chemicals or other sterilisation techniques. Over 60% of the laboratories were

using alcohol (at a concentration of 70%) and sodium Hypochlorite (ready made by factories) for disinfection purposes. However, 23/42 (54.8%) of them had shortage of protection materials such as gloves and only 29% of them strictly followed safety manuals (some of them adopted from WHO) (Table -3).

Table 3: **Waste disposal, disinfecting and safety methods practiced in the laboratories**

Characteristics	Number (%)
Source of sample for HIV screening	
Suspected patients and blood donors	16(38.1)
Suspected patients	13(30.9)
Others	13(30.9)
Presence and use of safety manuals (adopted from WHO, etc)	12(28.6)
Disposal of solid waste from the laboratory	
Incineration	23(54.8)
Damping to wells and burning	19(45.2)
Disposal of liquid waste from the laboratory	
Directly to the sewerage system without pre-Treatment	25(58.5)
To the sewerage after treatment with Disinfectants	14(33.3)
Pit	3(7.1)
A availability of sufficient protective materials Such as gloves, etc.	19(45.2)

Quality assurance, Quality control, Recording and Reporting

Of the 42 laboratories, 25(59.5%) (85.2% of those capable of doing ELISA and rapid tests, and 13.3% of those with capacity of rapid test only) were participating in NEQUAS and only 15(35.7%) of them gave feedback on the specimen distributed in NEQUAS. Testing algorithm (NRLA type or adopted from World Health Organization (WHO), See-Annex-1) usage in the laboratories was very low and was only 38%. ELISA/ ELISA and/or ELISA-Rapid test combination for the confirmation of the results according to the recommendation of WHO, was conducted in only 50% of the laboratories assessed. Twenty-nine percent of them had no means to confirm a result coming out of their laboratories. Almost all of the laboratories were suffering from a maintenance problem. In 4/15(26.7%) of the rapid test laboratories, ice-boxes were used for transporting specimens to Regional Referral Laboratories for confirmation. Monthly/ quarterly report either to the Regional Health Bureau/ Zonal Health Departments or to their Hospital data section was practical in only 50% of the laboratories. The majority of them complain either of not having a direct relation or follow up and supervision by their immediate RHB and ZHDs (Table -4).

Table 4: **Quality assurance, quality control, recording and reporting of results in the supervised laboratories**

Item	Number (%)
Participation in NEQUAS	25(59.5)
Presence of test procedure/manuals in the laboratory for both rapid and ELISA tests	42(100.0)
Presence of testing algorithm in the laboratory	16(38.1)
Laboratories that use internal controls for both rapid and ELISA test	42(100.0)
Use of cold chain/ice-box for transporting samples for confirmations/referral system (from peripheral)	7(77.7)
Locking of recording logbooks after registration of results (confidentiality)	34(80.9)
Confirmation of HIV test results by the Laboratory	
Double ELISA or ELISA/Rapid	21(50.0)
Referring to regional Laboratories	9(21.4)
No means to confirm results	12(28.6)
Monthly or quarterly report to RHB/ZHD or Hospital data section	21(50.0)

Discussions

Following the decentralisation of health services in Ethiopia, NRLA has established Regional Referral HIV laboratories in all the Regions to strengthen HIV screening in the country. These laboratories have objectives of being immediate problem solving centres for the nearby health institutions and peripheral laboratories. They can also serve as centers for the collection of essential epidemiological data of passive and active surveillance activities conducted in the regions. Moreover, they can be used as appropriate sites to conduct refresh-training courses for the laboratory personnel in the regions. However, lack of close follow-up and supervision affect the performances of these laboratories. Apparently this was the situation, as 64% of the laboratories had no close follow up and supervision. Thus, there is a need for an urgent and special attention to this problem by the respective RHB and ZHDs.

Equipment maintenance was one of the major problems noticed in almost all the supervised laboratories. In most of the laboratories, different brands of either donated or purchased equipment were available without the technical knowledge how to maintain them. Hence, ordering of identical brand, training on the operation and proper handling of equipment, and training of maintenance technicians were strongly recommended to alleviate such constraints as suggested by WHO (9).

According to the present information, more than 60% of the samples for screening were

obtained from HIV suspected patients and blood donors. However, the non availability of safety guidelines (available only in 29%), and the absence of a sufficient amount of protective materials (in 55% of them) indicate that there could be a high risk of infection through occupational exposure in the health personnel working in the area. Such situation should be well handled before happening, as described elsewhere (16), since prophylaxis after exposure is not currently available in the country. Therefore, timely ordering, purchasing and periodic distribution of protective materials and strengthening of safety precautions should be considered.

Shortage of reagents or test kits for the screening process was observed in more than half of the laboratories (58.4%). This may lead to the use of unscreened blood for donation, poor case management and poor counselling services. Continuous supply of reagents is one means to alleviate the problem for the laboratories by the concerned institutions/ authorities.

Even though the percentage of trained human resource in the HIV screening laboratories during the time of supervision was high (88.1%), high turn over of trained human resource from government to private sectors in the profession in general and in HIV screening laboratories in particular is still a problem, as described by RHBs/ZHDs. This could partially be solved by organising continuous training programs, including HIV screening methods and quality assurance in the regular curriculum for laboratory technicians and creating a conducive working environment by providing incentives to the professionals in the field.

WHO recommends that either ELISA/ELISA or ELISA/rapid or rapid/rapid test combinations can be used to confirm results in HIV screening laboratories (17,18). In this study, however, as show in Table-4, 28.6% of the laboratories had no means of confirming their results. This indicates a weak referral system and/or the nonavailability of test kits. Of the total number of governmental and non-governmental laboratories (74) in the county, 30 of them need referral system. This is due to the capacity of these laboratories to do the confirmation assay and/or due to the non-availability of test kits. Hence, to improve the situation, we feel that either the existing referral system should be strengthened or at least two rapid assays, as recommended by different studies (19), should be in place.

Underreporting of the number of HIV positive cases in the country is always a major concern to the MOH and other concerned bodies. This could be improved by strengthening the reporting system at the bottom level, such as laboratories to their respective RHBs, ZHDs or Hospitals.

As seen from the assessment, the use of safety procedures and safety guidelines in the field was very low. One entry point to solve the problem could be by developing safety guidelines and protocols, and training of the professionals in the area.

Regional Referral Laboratories (particularly those attached to the hospitals) can be centre of excellence for referral. If they are well-strengthened in terms of human resource and equipment, they could even serve as sites to monitor ARV therapy by establishing CD4 count and viral load determinations.

Finally, having a good quality assurance program and participating in the external quality assurance schemes (programs) will assist the laboratories to improve their laboratory procedures, testing strategies and training programs. Currently the number of NEQUAS respondents is becoming very low. Therefore, we advised all HIV screening laboratories to participate in NEQUAS and the Regional Referral Laboratories to have their own quality assurance networks in their respective regions. Since private laboratories are currently participating in HIV screening for volunteers, these laboratories should be included in NEQUAS so that a maximum efficiency in HIV testing system can be attained in the country.

Acknowledgements

The authors (NEQUAS group) acknowledge the following: World AIDS Foundation (WAF), The Royal Embassy of the Netherlands-through ENARP for financial support and EHNRI for its continuous support for the sustainability of the NEQUAS program

and the ministry of Health for material support.

References

1. Kassu A and Aseffa A. Pattern of out patient laboratory service consumption in a teaching Hospital in Gondar, Ethiopia. East Afr Med J 1996;73(7):465.
2. Kassu A and Aseffa A. Laboratory service in health centres of Amhara Region in North Ethiopia. East Afr Med J. 1999;76(5):3.
3. Constantine NT, Collahan JD and Watts DM. Retroviral Testing: Essentials for quality control and laboratory diagnosis. 2nd edition, CRC Press Inc. Boca Raton, USA, 1992;121.
4. King MB. AIDS, HIV and Mental Health. Cambridge University Press, London 1993;133.
5. Cheesbrough M. District laboratory practice in tropical countries (Part-1). Tropical Health Technology UK, 1998;31-37.
6. Hoffman RG. Establishing quality control and normal ranges in the clinical laboratory. 1st edition, Exposition Press, New York, 1971; pp1-102.
7. Whitehead TP. Quality control in clinical chemistry. A Wiley Medical Publications, John Wily & Sons, New York, 1977; pp1-130.
8. Institute of Medicine, National Academy of Science. Confronting AIDS-Update-1988. National Academy Press, Washington DC, 1988;13.
9. World Health Organisation. Maintenance and repair of laboratory, diagnostic imaging, and Hospital equipment. WHO, Geneva, 1994;12-15.
10. Stewart CE and Koepe JA. Basic quality assurance practices. J.B. Lippincott Company, Philadelphia, 1987;1-5.
11. Farr AD. Quality control and assurance in clinical laboratories, three years on. Institute of medical laboratory sciences. UK, 1987; pp1-10.
12. World Health Organisation. Guidelines for organising National external Quality Assessment Schemes for HIV serological testing. WHO, Geneva, September 1990.
13. World Health Organisation. Laboratory Biosafety manual. WHO, Geneva, 1983;61.
14. World Health Organisation. Laboratory Biosafety manual. 2nd edition, WHO, Geneva, 1993; pp35-71.
15. Miller BM. Laboratory safety: principles and practices. American Society for Microbiology. Washington D.C. 1986; 292.
16. Weiss SH. Risk of Human Immunodeficiency Virus (HIV) infection among laboratory workers. Science 1988;239:60.
17. World Health Organisation and United Nations Joint Program on HIV/AIDS. Revised recommendations for the selection and use of HIV antibody tests. WHO Wkly Epidimiol 1997;72(12), March 21, 81-8.
18. World Health Organisation. Operational characteristics of commercially available assays to determine antibodies to HIV and/or HIV-2 in human sera. WHO, Geneva, January 1998 (Report 9/10, WHO/LBS/98.1).
19. Meless H, Tegbaru B, Messele t, et al. Evaluation of rapide assays for screening and confirming HIV-1 infection in Ethiopia. Ethiop Med J. 2002;40(Suppl -1):27.

Annex 1: **Testing algorithm used by National laboratory for AIDS, Adopted from WHO [18]**