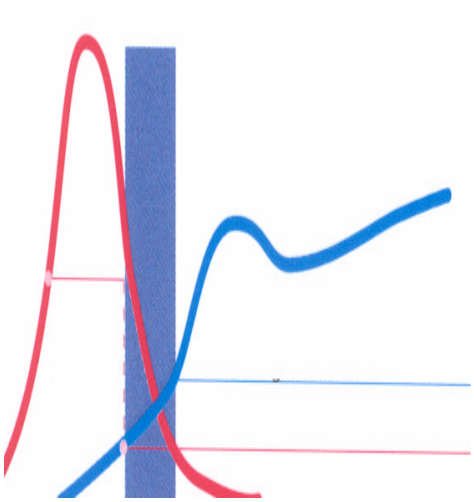
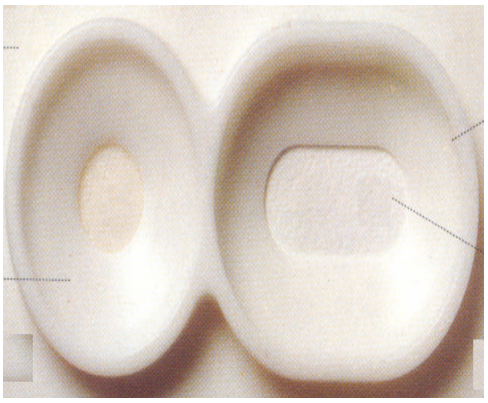
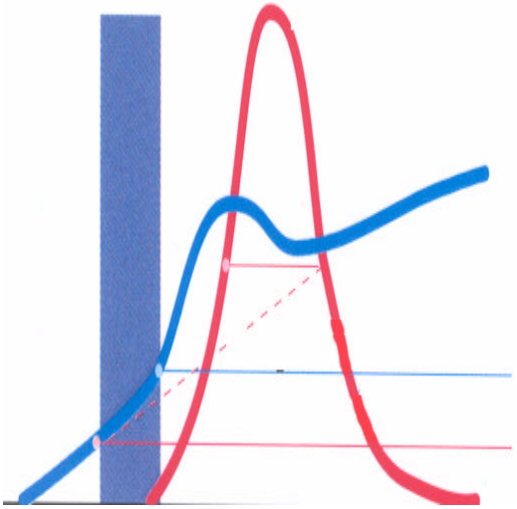
HIV/AIDS LABORATORY CAPACITY

An Assessment Report of the Capacity of Laboratories to Support HIV/AIDS Prevention and Care Programmes in the WHO/AFRO Region.

REGIONAL PROGRAMME ON HIV/AIDS

Division of Prevention and Control of Communicable Diseases

WORLD HEALTH ORGANISATION
Regional Office for Africa

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EXECUTIVE SUMMARRY

The HIV/AIDS Laboratory Network of the WHO African Region in its 2nd meeting in Accra, Ghana 20-22 November, 2002 requested WHO to conduct an assessment of existing laboratory capacities in Africa with a view to identifying the any competences and gaps. The results of the assessment would be used as an advocacy tool for mobilizing resources to strengthen laboratory services. Subsequent to this meeting an assessment questionnaire was sent out to all countries in the WHO African Region. Over 90% of the countries responded to the questionnaire. This report presents an analysis of the data from the countries that responded.

Over 98% of the countries have a National HIV Reference Laboratory. The majority of these (84%) are in the public sector while the rest are affiliated to either universities or research institutions. Over 53% receive more than half of their funding from the public sector.

Although 69% of the countries have an action plan for the laboratory there is poor correlation between the plan and the activities on the ground. This is an indication that the plans may not be appropriate to the actual situation in the country.

ELISA is mainly used in the public sector (57%) and is limited mainly to the central level (100%) and is little used at district level. The low utilization of ELISA at the periphery is due to its complexity and inappropriateness for this level. In contrast Simple/Rapid assays are increasingly being used in all sectors and all levels but more at district level (54%). This reflects an increased usage of simple assays due to their appropriateness for VCT and PMTCT programmes.

The erratic supply of reagents continues to be a major challenge. All countries reported supply interruptions with 55% reporting 1-2 interruptions in a year and the rest 6-8 interruptions. The WHO Bulk Procurement Scheme is introduced in the report and recommended as a remedy to the problem.

In 91.9% of the countries the National Reference Laboratory defines the testing algorithm for use. It is however noteworthy that 42%, 50%, 55% of the countries do not follow the recommended WHO testing strategy for blood safety, diagnosis, and surveillance respectively. Western Blot facilities are available in all countries but are limited to one or two laboratories at the central level. These are mainly used (83%) for HIV confirmatory testing.

1.0 INTRODUCTION.

The HIV/AIDS epidemic is a major public health challenge for the world in general and Africa in particular. Of the more than 42 million people infected globally 70% live in sub-Saharan Africa even though it accounts for only 10% of the global population. This has many health and socio-economic implications. Response to the epidemic in Africa is hampered by poverty, poor health infrastructure and a critical paucity of qualified personnel.

Laboratory services are a critical component in the delivery of high quality health care system. They not only provide the basis for good clinical diagnosis but also provide an objective means to monitor patient care and disease trends. The role of the laboratory in HIV prevention and intervention strategies is increasingly being recognized. The capacities of the laboratories will, therefore, need to be strengthened as African countries scale up HIV intervention programmes.

The WHO/AFRO Regional HIV/AIDS Public Health Laboratories Network second meeting in Accra, Ghana (20-22 November, 2002) requested WHO to assess the capacities of the laboratories within the region to provide support to the HIV/AIDS epidemic response. This information would provide an inventory of capacity and competence and a directory of the laboratory network to be shared with member countries. Subsequent to the meeting an assessment questionnaire was sent out to all member states. The questionnaire was completed by in country laboratory focal persons who are members of the HIV Laboratory Network in Africa. The majority of the countries, over 90%, responded to the questionnaire. The data was analysed by a consultant with the support of the Data Manager at the RPA Unit, WHO/AFRO, Harare. In calculating the percentages the number of responding countries to any given response formed the working denominator. This document presents an analysis of the responses by countries to the questionnaire.

Objectives of the document

- To provide an inventory of the laboratory infrastructure, capacity, and competence within the region
- To provide countries with baseline information for scaling up laboratory capacity to support prevention and care activities
- To act as an advocacy tool for mobilizing resources and improving laboratory services

This report has been presented in a graphic format using maps, pie charts, and histograms with supporting narrative. The graphics are intended to provide a quick visual impact of the prevailing situation. This report is primarily intended for policy makers, administrators, and laboratory managers to use as an advocacy tool for mobilizing resources for the laboratory. Consequently use of technical language has been kept to a bare minimum.

Did you know?
That the laboratory Play a key role in

- VCT programme
- PMTCT programme
  - diagnosis
  - surveillance
  - blood safety

It pays to invest in a quality laboratory service

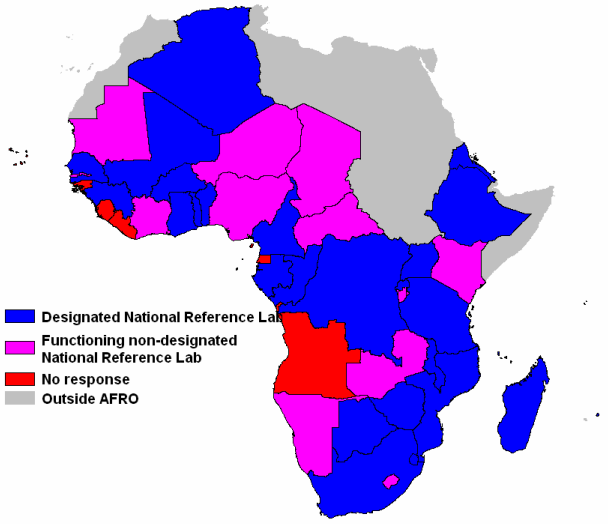
2.0 METHODS.

Questionnaires were sent to focal persons in national HIV reference laboratories of countries in the African Region. The questionnaires focused on general information, financing, laboratory facilities, equipment and expertise, storage conditions, transportation and shipment of samples within and outside the country, quality assurance, and information and communication systems. The data from completed questionnaires were analyzed by Epi Info software.

3.0 GENERAL OVERVIEW

Over 98% of the countries in Africa have a designated or functional National HIV/AIDS Reference Laboratory linked either to the Ministry of Health or to a University or Research Institution. The rest have either a private or commercial laboratory playing the role of a reference laboratory.

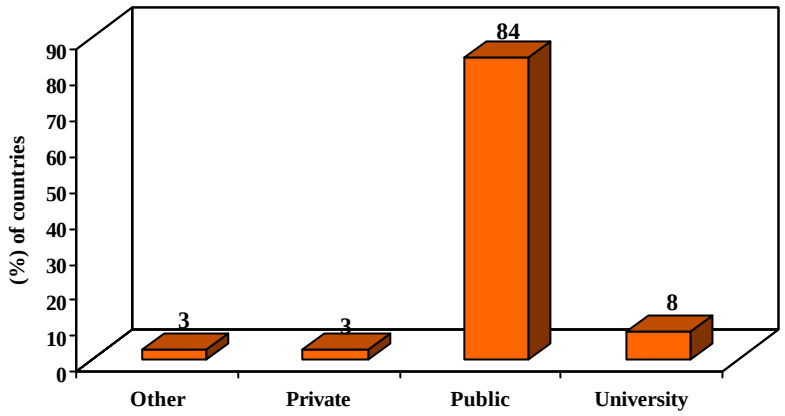
Countries with designated or functioning National Reference Laboratory



National Reference Laboratories play a key role in supporting in-country HIV/AIDS programmes to establish standardized testing protocols based on local experience and conditions, provide a supportive framework for quality assurance and staff development. This role is especially critical for the designated Reference Laboratories where linkage to the Ministries of Health may not be clear.

There exists capacity, up to district level, in all countries to screen for HIV antibodies. However a laboratory network within the district level or to higher levels exists in only 68.4% of the countries. This explains the weak support supervision mechanisms within countries.

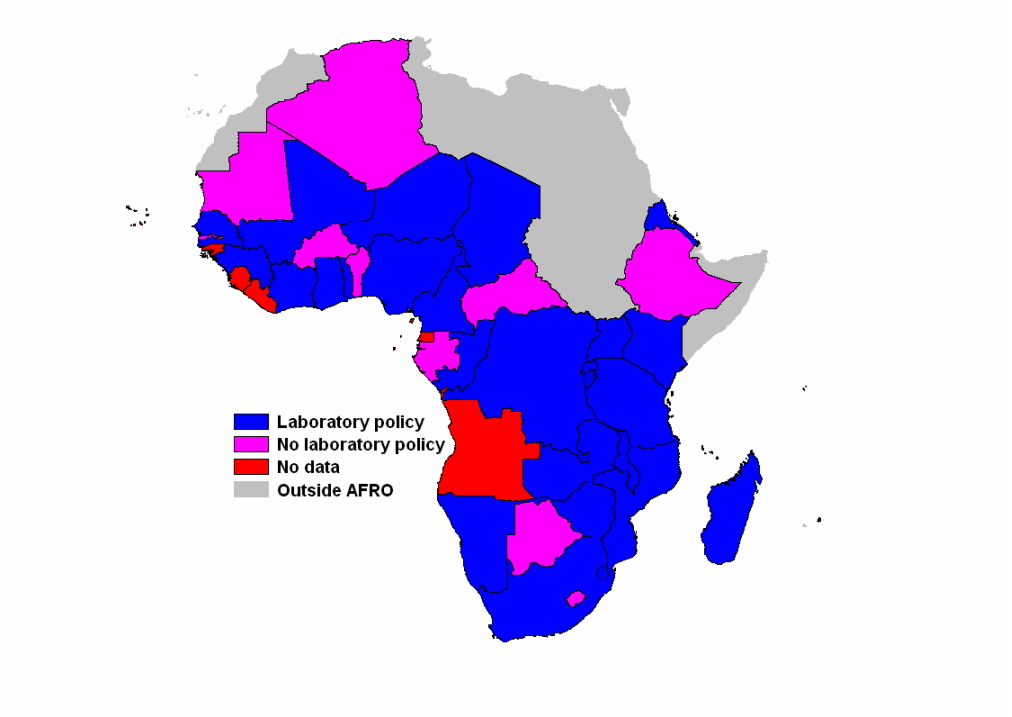
Affiliation of the National Reference Laboratory



3.1 Policy and Plan.

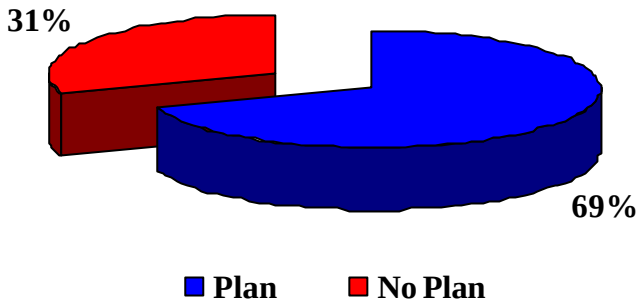
National policies and plans are critical in ensuring that services provided throughout the country are uniform. They also provide a framework for resource mobilization and distribution and help map out strategies to be employed in the provision of services.

Countries with written laboratory policies



Over 74.3% of the countries have a written laboratory policy. Only 52.7% of the countries with a policy have translated it into an action plan for laboratories while 16.7% had neither a policy nor a plan of action for HIV public health laboratories.

Proportion of Countries with National HIV/AIDS Plan for the Laboratory



Of the countries with an action plan for the laboratory, 89.4% have already incorporated the plan into the overall HIV/AIDS National Strategic Plan for the country. Although 69% of the countries have developed an action plan for the laboratories, this is not reflected in what is happening on the ground. In many countries delivery of laboratory services is still very weak and of poor quality. This is an indication that the plans may not have been appropriate for the country or may not be linked to the available resources. WHO/AFRO has already put in place systems to assist countries develop appropriate plans of action for the laboratory.

3.2 Financing.

Over the years there has been reduced resource allocation to the health sector. This has affected health care delivery especially in resource poor countries. The funds available have been directed towards provision of curative services. This has tended to starve the other services, the laboratory included, of funds. This reduction means that the laboratory finds it difficult to adequately meet the needs of the various HIV/AIDS prevention and care programmes.

Initial investment in a fully equipped laboratory, to offer a comprehensive package for HIV/AIDS prevention and care programme, may range from US$ 150 000.00 to US$ 300 000.00 with yearly running costs of $ 10 000.00. Many countries in Africa are likely to afford only one or two such laboratories.

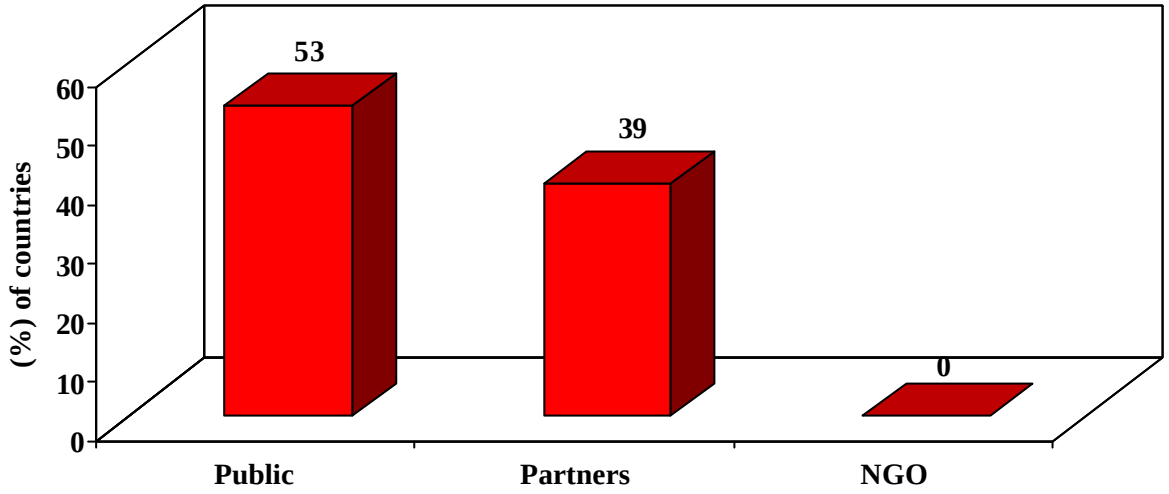
Source: The Implications of Antiretroviral Treatments, Informal Consultation April 1997 UNAIDS/WHO WHO/ASD/97.2

Few countries in Africa will have or allocate from national budgets the necessary financial resources to mount effective laboratory upgrading programmes. Governments will need to work with other development partners to mobilize additional resources for strengthening the laboratory services. In addition, countries should build internal capacity to sustain initiated programmes. WHO/AFRO will support countries in advocating for laboratory support among development partners.

3.3 Source of funding

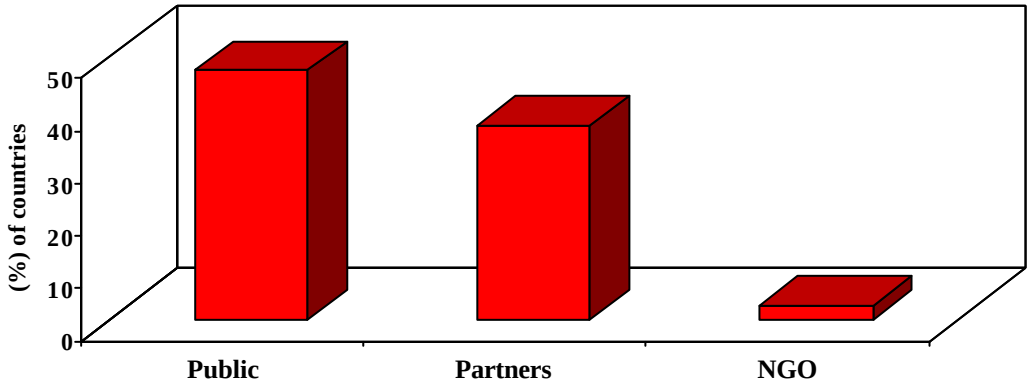
Data obtained from different countries show that both the National Reference Laboratory and the HIV Public Health Laboratories receive financial support from many sources. In particular, in 13% of the countries, development partners provide more than three quarters of the financial support to the reference laboratory.

Level of Funding by Sector for the National Reference Laboratory



Development partners and NGOs continue to provide significant financial support to National Reference Laboratories. This underscores the need for collaboration between the public sector and the other partners and for a policy framework for such collaboration. It is significant to note that in 3% of the countries NGOs provide more than 50% of the funding to HIV Public Health Laboratories.

Level of Funding by Sector of the HIV Public Health Laboratories



3.4 Personnel

Response from countries shows a general lack of adequate numbers of trained personnel and a paucity of technical skills at all levels and especially at doctoral and masters levels. Continued loss of skilled manpower poses challenges to many countries. There is a net migration of the highly skilled personnel from Africa to more developed countries and from the public to the private sector. This has tended to create an inequitable health care delivery system. The AIDS epidemic is currently a major depletor of the human resource capital in many African countries.

The epidemic has also drastically reduced, through illness and death, the productive years of many skilled personnel. This high personnel turnover and the need to expand services underscores the need to increase the output of training institutions as well as retrain the staff and rebuild the critical mass of experienced personnel to support services. Countries need to factor in HIV/AIDS into their human capacity building strategies.

The need for technical personnel in Africa is too great to leave their emergency to chance.

Adapted from – Institute of Medicine, USA, 1988

4.0 LABORATORY SERVICES

4.1 HIV Serological Diagnosis.

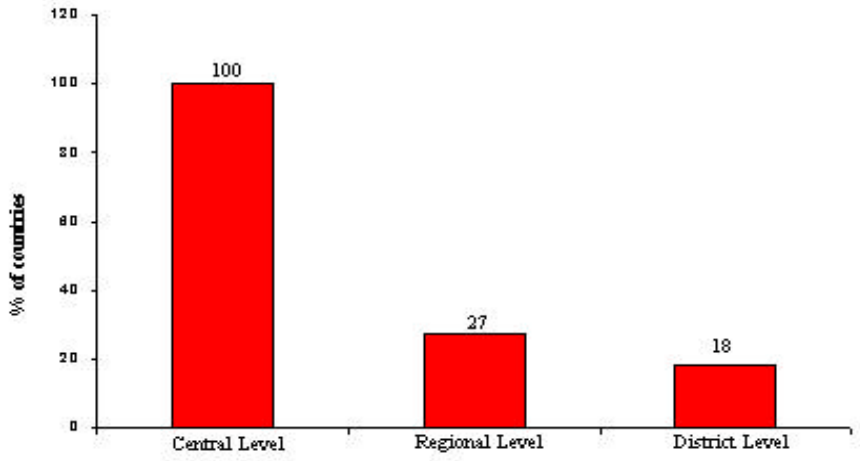
HIV testing forms the backbone and a major entry point to many of the HIV prevention and care programmes. The main objectives of HIV serological testing include serosurveillance, safety of blood transfusions, and diagnosis of HIV infections (for prevention and care intervention). This, therefore, underscores the need to ensure a quality laboratory testing infrastructure within the country.

There has been a very rapid evolution of HIV serological diagnosis since the first ELISA tests were commercially available in 1985. A wide range of different assays is now available. There are three main categories of HIV antibody tests; ELISA tests, Simple/Rapid tests, and Confirmatory tests. Over the years the simple/rapid tests have improved in sensitivity and specificity. They are increasingly being used in Voluntary Counselling and Testing and Prevention of Mother to Child Transmission Programmes because of their many advantages including ease of use and provision of same day accurate results.

4.1.1 ELISA

In 57% of the countries more than half of the public sector laboratories use ELISA for serological diagnosis. ELISA tests require expensive equipment, a reliable electricity supply, and trained manpower to perform the tests. The reagents require a cold chain thus posing logistical problems in distribution. In addition, the need for batch testing limits their use to high volume laboratories. ELISA is thus more likely to be suitable to public laboratories at
Central and regional levels.

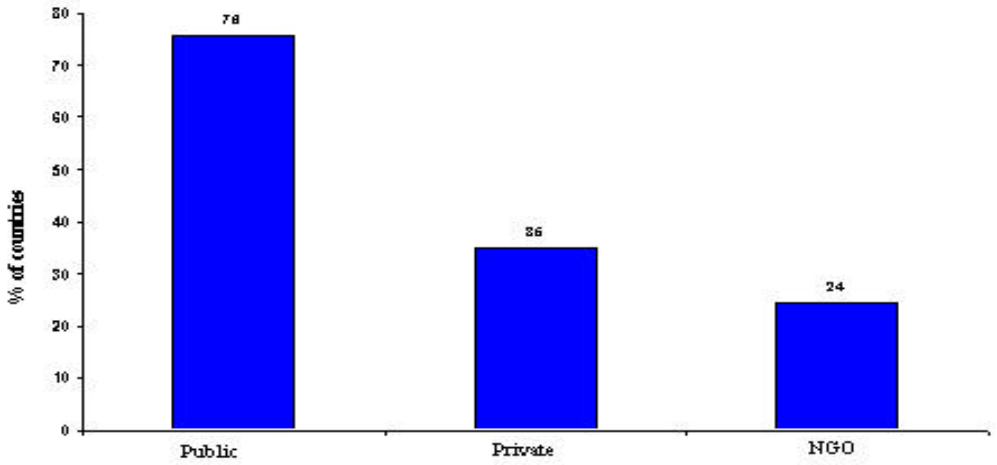
Level of Usage of ELISA Test by Health Care Level



4.1.2 Simple/Rapid Assays

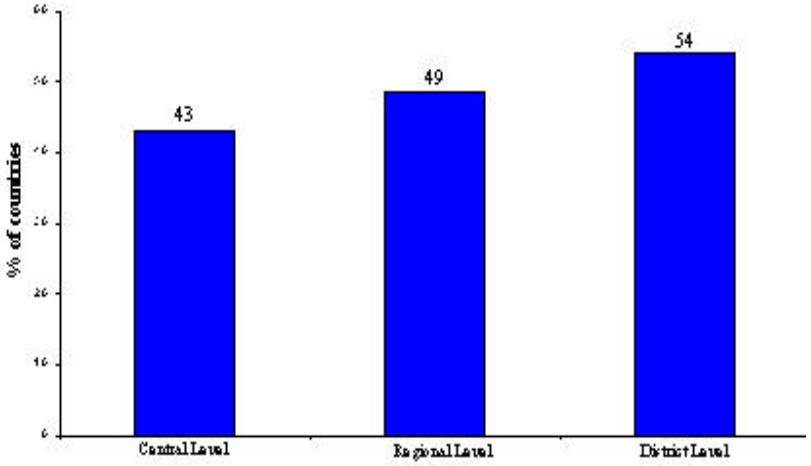
The level of use of Rapid/Simple assays has rapidly increased in many countries. In 76% of the countries more than half of the laboratories in the public sector use the assays, while the usage in the private and NGO sectors is 35% and 24% respectively. The increased usage is also reflected at different health care levels. In 54% of the countries more than half of the laboratories at district level use rapid assays.

Level of Usage of Rapid Test by Sector



In many countries ELISA equipment, installed many years ago, is in most cases non-functional. This has, therefore, given rise to the increasing use of rapid assays at all levels including the central level. All countries reported some level of use of rapid assays at all health care levels.

Level of Usage of Rapid Test by Health Care Level



The many advantages of Simple/Rapid assays over ELISA have made possible their use on a much wider scale and in many settings. They do not require highly sophisticated laboratory infrastructure. They are now extensively used at all levels of health care delivery in both the public and private sector. Their simplicity and ability to offer same day HIV results have made them suitable for use in VCT and PMTCT programmes. This is reflected in their increasing use to meet the growing demand for VCT and PMTCT services.

Advantages of the Simple/Rapid Tests

- *Sensitivity/Specificity comparable to that of ELISA*
- *The assays are NOT dependent on the cold chain*
- *Require less expertise to be performed, compared to ELISA*
- *Do NOT require expensive equipment*
- *Possibility of providing rapid (same day) results*

4.1.3 Reagent Supply

All countries experience interruptions with supply of reagents, 93.3% report 1-5 interruptions per year and the rest 6-10 times per year. In 2002 alone 55% of the countries reported at least two interruptions while the rest had 2-8 supply interruptions. Erratic test kit supplies affect the timely delivery of services, reduce the momentum of programmes, and sometimes impact negatively on quality of testing. It is important that countries plan and budget for the regular and timely procurement of reagents. ***WHO has in place a Bulk Procurement Scheme, which countries can access for quality reagents at reasonable cost.***

4.1.4 WHO Bulk Procurement Scheme

WHO established the Bulk Procurement Scheme in 1989 to assist countries access high quality reagents at low cost and on a regular basis to minimize supply interruptions.

4.1.5 Easy Purchase Procedure

The HIV Test Kit Bulk Procurement Scheme accepts purchase requests from programmes/institutions/organizations in 3 categories:

- Category A – WHO programmes and UN Agencies
- Category B – WHO member states and NGOs in official relations with WHO
- Category C – Other clients such as donor supported AIDS projects

The HIV Test Kit Bulk Procurement Scheme provides an easy to follow purchase procedure. Details on how to order are available from any of the WHO offices worldwide.

The HIV Test Kit Bulk Procurement Scheme provides an easy to follow purchase procedure. Details on how to order are available from the following addresses;

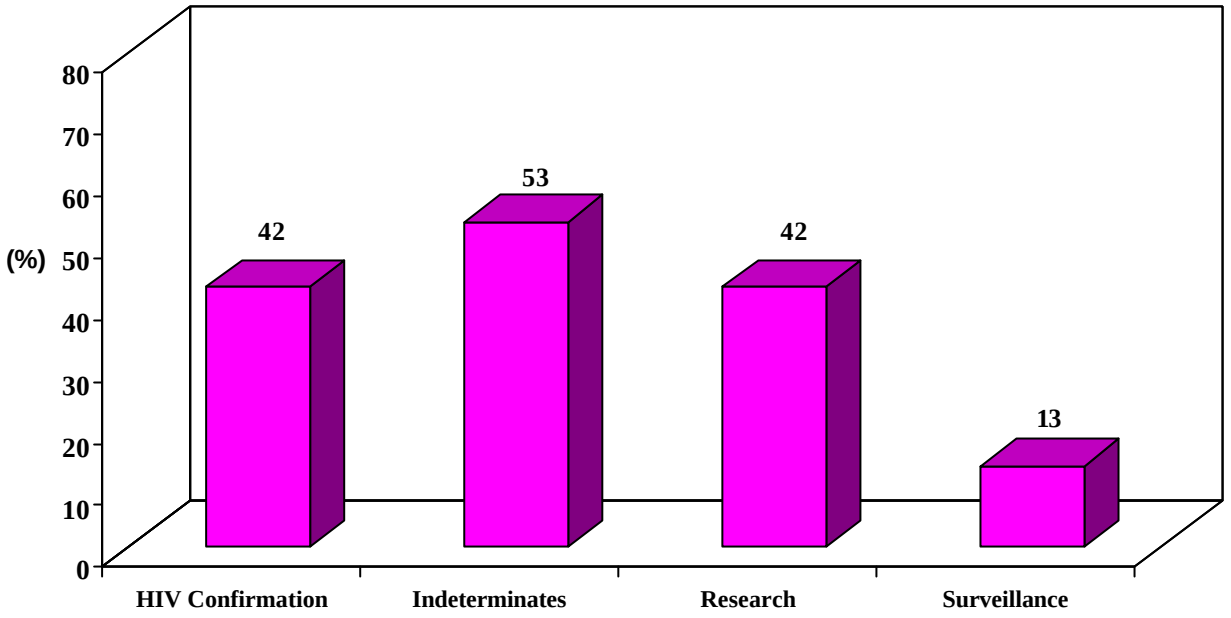
Email: procurement@who.int
Internet: www.who.int/bct and follow the links to Key Initiatives, HIV Diagnostics, HIV Test Kit Bulk Procurement Scheme

All HIV tests available through this scheme have been evaluated by WHO and meet specific and rigorous criteria. Each country will find, in this scheme, test kits that meet their requirements and testing strategies.

4.1.6 Western Blot (HIV Confirmatory Testing)

Serological tests for identifying antibodies to HIV can generally be classified into screening tests (ELISA and Simple/Rapid assays) and confirmatory tests. Western Blot, until recently, has been the most commonly used confirmatory test. It is, however, expensive and requires skilled manpower to perform the test, read, and interpret the results. Studies have shown that combinations of ELISA and/or Simple/Rapid assays can provide results as reliable as Western Blot at a much lower cost. This has further limited the use of Western Blot. It is still of value in the determination of discordant results following initial ELISA testing. Its availability will be limited to a few select laboratories

Percentage of Countries using Western Blot



Most of the countries (83%) use Western Blot to confirm discordant results by ELISA. The number of tests done in countries is still very low as discordance rates using two or three ELISA tests are below 1%.

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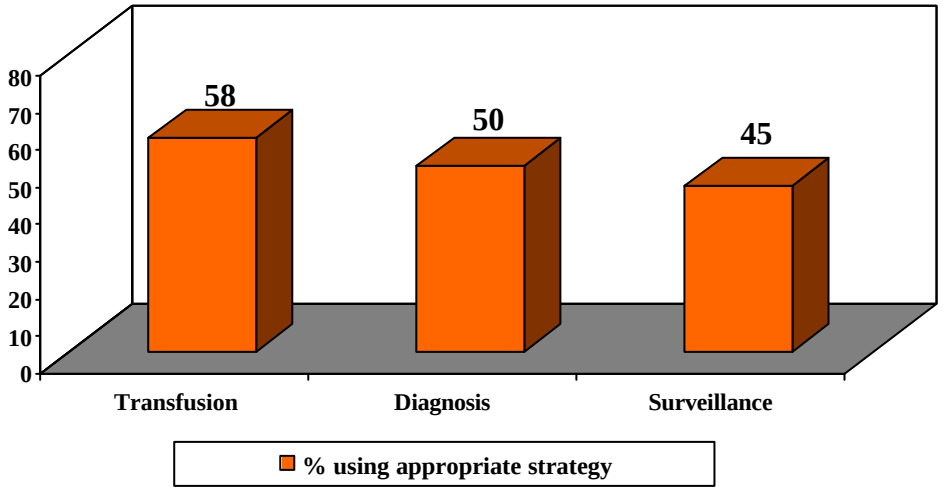
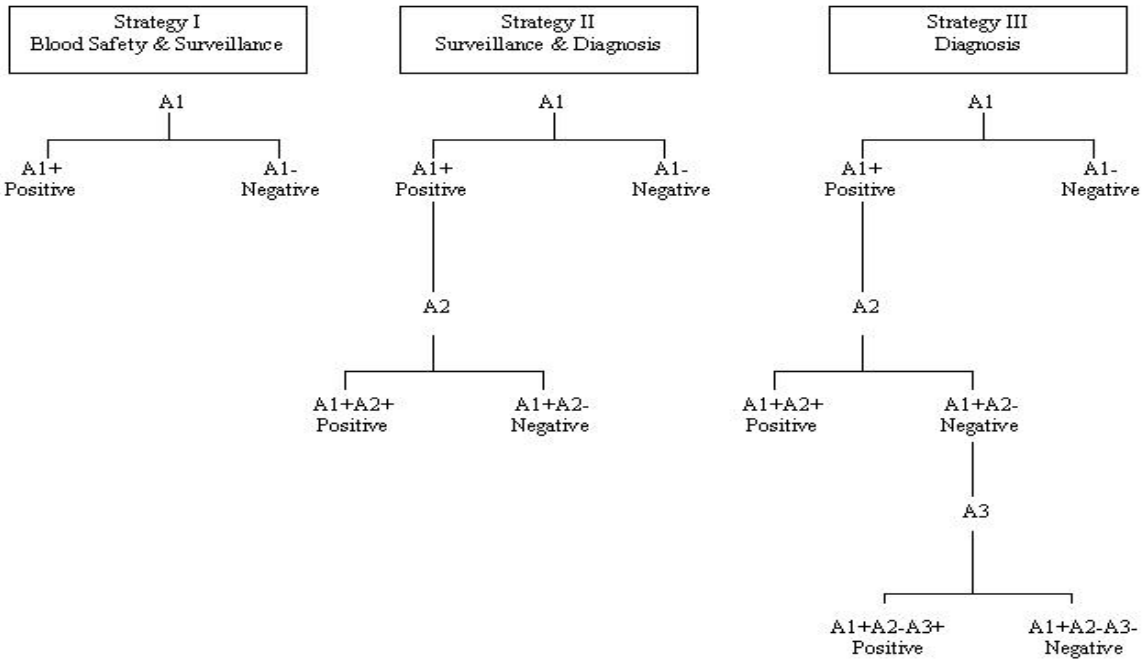
4.1.7 Testing Strategy.

The National Reference Laboratory defined the testing algorithm for use in 91.1% of the countries. However 42%, 50%, 55% of the countries respectively did not follow the WHO recommended testing strategies for blood safety, diagnosis or surveillance. The WHO testing strategy provides countries with proven and cost effective algorithms for any particular situation. Adopting this testing strategy will save countries a lot of money in reagent costs.

Percentage of countries using appropriate WHO Testing Strategy



UNAIDS and WHO recommendations for HIV testing strategies according to test objective and prevalence of infection in the sample population



Source: *WHO/CDC/UNAIDS. 2001. Guidelines for using HIV testing technologies in surveillance: Selection, Evaluation, and Implementation. Geneva: WHO/UNAIDS*

UNAIDS and WHO recommend three testing strategies. The decision on which strategy to use will depend on the objective of the test and the prevalence of HIV in the population.

Strategy I
All serum/plasma is tested with one ELISA or simple/rapid assay. This strategy is suitable for blood/transplant safety in all prevalences and for surveillance where the prevalence is >10%.

Strategy II
All serum/plasma is first tested with one ELISA or simple/rapid assay. Any reactive sample on the first assay is retested with a second ELISA or simple/rapid assay based on a different antigen preparation or test principle. This strategy is suitable for surveillance where the prevalence is equal to or less than 10% and for diagnosis where the prevalence is >10%.

Strategy III
As in strategy II. However, this strategy requires a third test based on a different antigen or test principle from the first two. The strategy is suitable for diagnosis of asymptomatic cases where the prevalence is is equal to or less than 10%.

It is noteworthy that 83.8% of the countries have a designated laboratory that selects and validates tests for use in the country. However, in selecting test kits for use, countries should realize that no single test kit is suitable for all testing objectives (diagnosis, blood safety, VCT, PMTCT, surveillance) in all settings or conditions. It is important to choose the test kit that will produce the best working performance in actual and routine use.

When selecting a test kit, the following issues should be considered:

- *The number of samples to be tested*
- *The laboratory facilities available*
- *The level of laboratory staff training*
- *The objective of the testing*
- *The testing strategy being followed*

Source: World Health Organisation, 2002

4.1.8 P24 Antigen Testing.

Only 43.2% of the HIV Reference Laboratories do p24 antigen testing. However, in 51.3% of the countries p24 antigen testing is done in laboratories other than the Reference Laboratory. Some of these countries have 1-2 laboratories (68.4%) doing p24 antigen testing while others have 2-4 (31.6%). The majority of these laboratories (57.9%) are in the public sector.

P24 antigen testing is a promising alternative to PCR for early diagnosis of HIV in infants. It has several advantages: it is cheaper than PCR, easy to perform, potentially as sensitive as PCR and can provide quantitative data. The main disadvantages are that it is instrument based and requires a cold chain making it difficult to decentralize to lower levels. However, more research still needs to be done to define its role and validate it as an alternative to PCR.

4.2 HIV Molecular Methods.

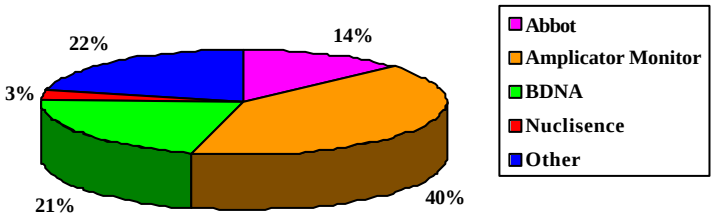
HIV molecular assays such as PCR play a role in the diagnosis of HIV especially during infancy and also assist in determining initiation of ARV therapy and the monitoring of patients on therapy.

Over 64.9% of the countries have facilities for diagnostic PCR with 72.3% of these facilities being in the public sector. The majority of these facilities (81.8%) use commercial PCR kits and 58.8% of them perform 50 or more tests per month. However only 51.4% of the countries perform viral load assays with only 47.4% of these able to perform 25 or more assays per week. The currently existing capacity will not meet the needs of countries for scaling up programmes. Countries should, therefore, endeavour to strengthen the capacities of viral load assay laboratories to meet the expected demand.

4.2.1 Types of Viral Load Assays Used by Countries.

More than half the countries are using either Amplicor Monitor or BDNA or Abbot tests. The other assays in use are Cavidi, PCR, and various modifications of p24 antigen testing.

Distribution of Viral Load Assays

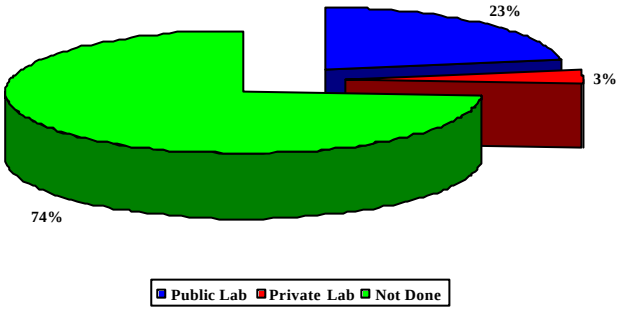


4.3 Heteroduplex Mobility Assay (HMA).

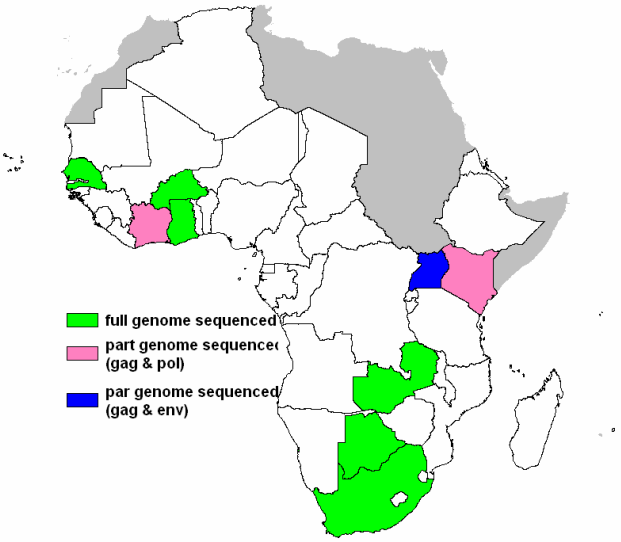
Heteroduplex Mobility Assays (HMA) are done in only 26% of the countries with 88.9% of the facilities located in the public sector. The majority of the countries (70%) perform less than 25 sequences per week. The availability of Heteroduplex Mobility Assay facilities will be critical in antiretroviral drugs resistance monitoring. While virological failure can be confirmed by closely monitoring the plasma viral load, there is minimal capacity in Africa for monitoring of HIV resistance at molecular level.

Development of resistance to antiretroviral drugs is a major concern that countries must take into account. WHO recommends that countries planning to implement antiretroviral therapy programmes establish HIV drug resistance surveillance system. As countries plan to have more AIDS patients accessing antiretroviral drugs, there is, therefore, need to invest in drug resistance monitoring facilities.

Proportion of Countries with Laboratory Performing HMA Tests



Countries performing sequencing, AFRO



Only six of the 9 African countries have managed to fully identify the order of arrangement (sequence) of the building blocks that make the genetic material (genome) of the virus. Sequencing the genome has made it possible to map out the genetic variations of the virus that causes AIDS. So far, several subtypes of HIV have been identified. Some of these subtypes are prevalent and to date have been limited to particular areas of the world. These variations between populations allow us to track the spread of the epidemic across continents. Fortunately, all subtypes of HIV-1 are responsive to antiretroviral drugs. These genetic variations and the

constant mutations of the virus pose challenges to vaccine development and vaccine trials relevant to Africa. Enhancing sequencing capability in Africa will help us further understand the HIV subtypes and variants circulating in the continent.

4.4 Immunological Testing.

The majority of African countries (81%) have facilities to perform CD4 counts but most (51%) have capacity for less than 100 assays per month.

CD4 enumeration is important in assessing the effect of the HIV infection in the immune system of an individual. It is also, together with viral load estimation, a good indicator of disease prognosis. Regular CD4 monitoring is essential in assessing immunological reconstitution after initiation of therapy.

CD4 enumeration facilities in most countries in Africa are limited to one or two laboratories at the central level. Apart from the limited capacity of these few laboratories there is also the compounding logistical problem of the timely transportation of samples to the testing sites. Samples have to be tested within 24 hours of collection; addition of a blood stabliser at time of specimen collection may extend sample life to a maximum of 72 hours. As seen elsewhere in this report, countries rely mainly on the road network system to transport their samples. This is often unreliable and subject to delays.

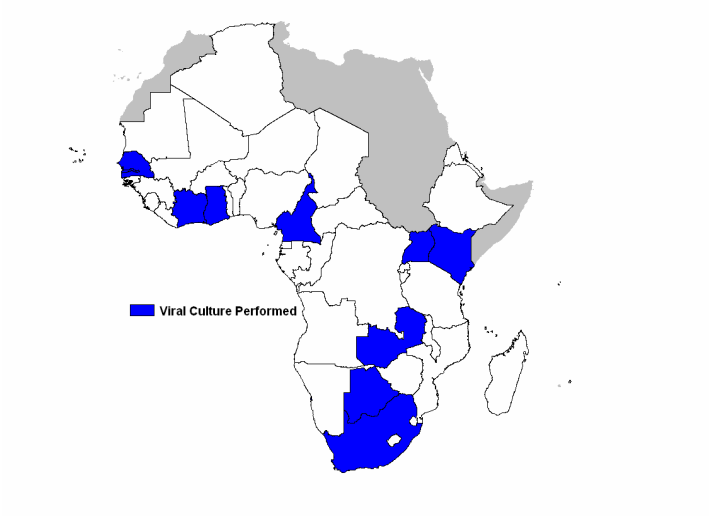
The high cost of conventional CD4/CD8 assays has tended to discourage many countries from scaling up services. However, cheaper enumeration alternatives are currently available. Countries may wish to consider these alternatives while programming.

Technologies Available for CD4 Enumeration			
Technology	**Method**	**Capital Cost**	**Reagents (Costs/test)**
Microscopy	1. Dynabeads 2. Cytospheres	UV-Microscope Haemocytometer US$ 2000.00 Microscope	Magnetic Beads & Monoclonals US$ 5.00 Latex Spheres
ELISA	1. Capcellia	ELISA Reader US$ 10 000.00	Peroxidase Conjugate Monoclonals US$ 28.00
Flow Cytometry	1. FACScount 2. FACScan 3. FACSCalibur 4. Coulter 5. CyFlow	US$ 33 000.00 US$ 75 000.00 US$ 102 000.00 US$ 79 000.00 US$ 20 000.00	Dual Platform (Coulter) Calibration Beads Monoclonals (US$ 15-20) US$ 12.00 Single Platform Monoclonals (US$ 2-5)

4.5 HIV Virus Isolation and Characterisation.

The majority of these countries (90.9) perform less than 10 cultures per week and only 26.7% do biological phenotyping using co-receptor in 70% of the facilities. Only 13.3% of the countries perform neutralizing antibody assays.

Countries performing Viral Culture



HIV viral culture is useful in the early diagnosis of HIV in infants and children and in identifying variants of the virus that may exist in the population. It is important for countries to fully understand the HIV variants circulating in the country for them to fully participate and benefit from the vaccine development and trials initiatives. Virus isolation techniques, however, require highly sophisticated laboratories with appropriate infrastructure to ensure safety to laboratory personnel, the general public, and the environment. **Due to the costs involved in establishing these laboratories, WHO will identify existing regional capacities and assist countries access them. Capacity for viral isolation already exists in at least one country in each sub-region.**

4.6 Storage.

Many countries have several –20 C deep freezers albeit unevenly distributed throughout the country. There are a few –70 C deep freezers; these are mainly found at the central level. These are, however, not adequate to store the increasing number of samples.

Although 63.9% of the countries indicated the local availability of liquid nitrogen only 58.3% of the laboratories have nitrogen tanks. Dry ice is locally available in 59.5% of the countries. Caution must however be exercised in the interpretation of these figures as most of these facilities are available only at the central level.

4.7 Transportation and Shipment of Samples.

The bulk of in country transportation of samples is by road (64.1%) and air (32.1%) either as fresh samples (37.0%) or as frozen samples (35.2%) or using dry ice (22.2%). The efficiency of this system is highly dependent on the road network and the transport system.

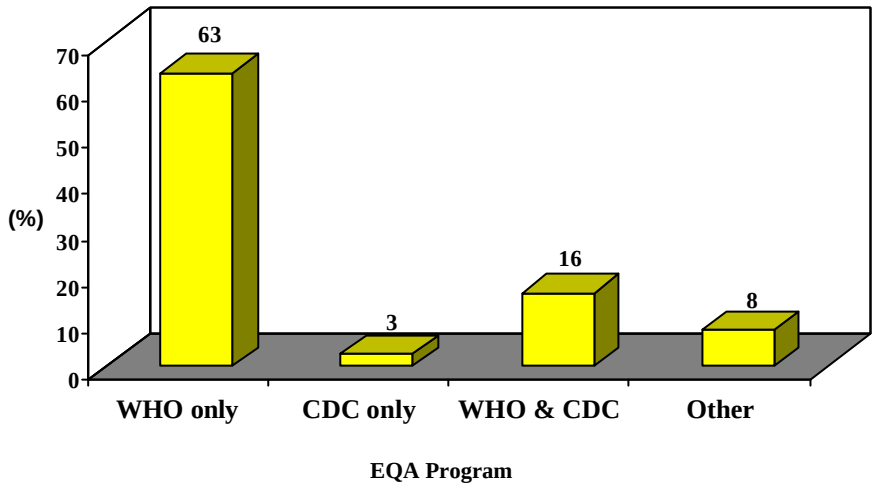
Transportation of samples outside the country is almost exclusively by air (99%) either as fresh samples (27.0%) or as frozen samples (21.6%) or using dry ice (43.3%). The majority of the countries (81.8%) use both national government clearance mechanisms and IATA Guidelines. 18.2% of the countries do not have specific guidelines for shipment of samples outside the country.

5.0 QUALITY ASSURANCE.

Quality Assurance has been defined as "assuring compliance with standards". A good Quality Assurance system ensures that laboratory results are accurate, reliable, and reproducible. The system helps build confidence in the laboratory, reduces the cost of performing tests and contributes immensely to a quality health care delivery system.

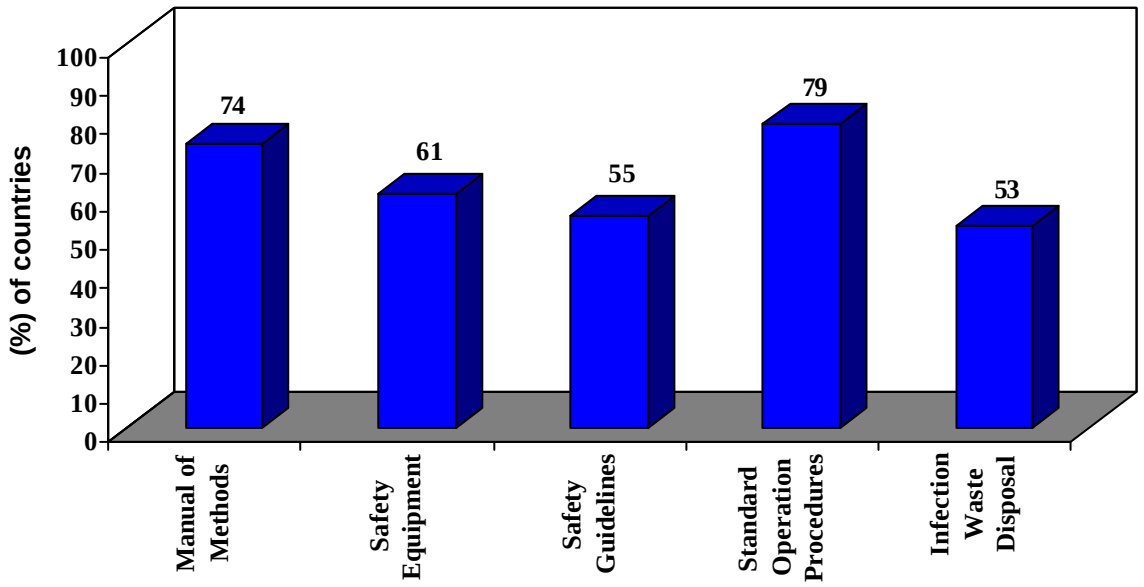
51.4% of the countries have a National Quality Assurance Programme in place with participation limited mainly to the public sector laboratories (>90%). Proficiency testing is conducted at least once a year in 55.6% of the countries with a response rate of over half of the participating laboratories in 80% of the countries. The proficiency testing is complemented in 80.6% of the countries by supervisory visits from the national level.

Participation of Laboratories in EQA Schemes



The majority of countries participate in the WHO supported External Quality Assurance Scheme. In about 50% of the countries this is the only form of quality assurance programme. The WHO supported EQAS therefore plays an important role in laboratory quality assurance in Africa. This role will become more critical as countries scale up HIV response programmes. **There is, therefore, need for WHO to not only sustain the support but also to expand its scope.**

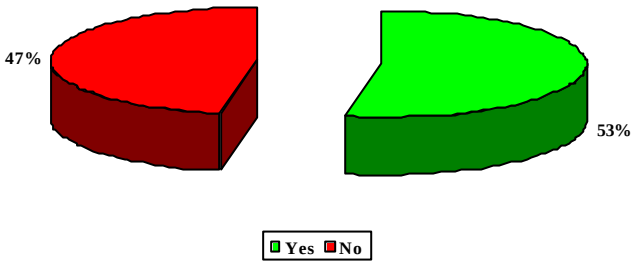
Availability of Operational Guidelines for the National Refe re nce Laboratory



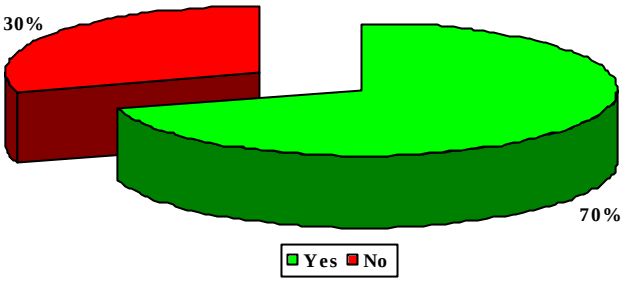
It is noted that at least half the countries do not have a National Quality Assurance Programme in place. **It is essential for countries to develop such programmes and put in place mechanisms for their implementation. There are many advantages, such as reliability of test results and reduced cost of testing, to countries in establishing quality assurance programmes.**

6.0 INFORMATION AND COMMUNICATION.

Laboratory Information System



Internet Access



Slightly more than half of the countries (53%) have a communication facility at reference laboratory, and 70% have access to the internet. While access to the internet may enhance networking within the region there is likely to be little exchange of useful information if the in-country information system is not in place and functional. There is need, therefore, for countries to strengthen the laboratory information system with particular emphasis on investing in data entry, management, analysis, and applications development. This will assist countries to have informed policy development, planning, and decision making processes.

7.0 LABORATORY CAPACITY TO SUPPORT HIV/AIDS PROGRAMMES.

In many African countries the AIDS epidemic is posing serious health, developmental, and in some cases security challenges. Many African countries have declared HIV/AIDS a national disaster and have developed multisectoral strategic plans to stem the rapid spread of the epidemic. Pursuant to the Regional Committee Resolution (AFR/RC46/R2) many countries are already accelerating the implementation of the Regional HIV/AIDS Strategy. There is need to strengthen the laboratories to support the intended scaling up of the HIV/AIDS prevention and care programmes. Inaction or delayed action will lead to millions of new infections and unnecessary deaths, compounding an already existing crisis.

Without additional resources, expanding the current workload of existing laboratories to support scaling up of programmes will be extremely difficult.

Adapted from CDC (GAP) Strategy Document

7.1 Voluntary Counseling and Testing (VCT)

It is now recognized that VCT is a major entry point to many HIV/AIDS prevention and care programmes. It is estimated that in Africa VCT services are available to only 6% of those who need it (Source: WHO/HIV/2002.10). The majority of people seeking the services are those who perceive themselves at risk or those who wish to know their status for purposes of marriage or travel abroad. This entails allocating extra resources for training of counselors and testers and procurement of additional reagents and supplies.

The availability of simple/rapid assay, their acceptance and use by many countries has led to a tremendous increase in VCT client uptake. The simplicity of the assays has also seen the spread of VCT centers to rural areas, and many non technician staff are getting involved in HIV testing. This rapid increase now poses challenges to the health systems of instituting quality assurance systems, support supervision, and laboratory safety and proper waste disposal mechanisms.

7.2 Prevention of Mother to Child Transmission (PMTCT)

In the absence of any intervention, rates of mother to child transmission of HIV can vary from 15% to 45%. In the industrialised countries, with vigorous intervention measures, these rates have dropped to less than 2%. Africa's challenge is to use this cost effective intervention to attain the UNGASS Declaration of Commitment of reducing by 50% the proportion of infants infected by HIV by 2010.

Timely administration of antiretroviral drugs has been shown, in some African countries, to be effective in reducing mother to child transmission of HIV. These findings have facilitated the expansion of this programme to many other African countries.

Paediatric HIV/AIDS in Africa

- *Four million children have died since the epidemic began*
- *One million are currently living with HIV*
- *In 2000, 10% of new infections were reported in children*
- *90% of HIV infected children worldwide are born in Africa*

The coverage of PMTCT services in Africa is 1% (0-37%) yet it is estimated that over 27 million births occur in Africa annually (Source: Coverage of selected Health Services for HIV/AIDS Prevention and Care in Less Developed Countries in 2001, WHO). Many countries have pilot programmes with plans to significantly scale up the services. The challenge in many countries will be to offer a timely HIV test and result to initiate intervention.

7.3 Antiretroviral Therapy (ARV)

Of the 4.4 millions of AIDS patients in Africa in need of life sustaining ARV drugs less than 1% have access to them (Source: WHO/HIV/2002.10). The availability of ARV drugs, in Africa, has been limited due to the high price of drugs and the need for training and advanced testing and monitoring equipment. Recent efforts to reduce the cost of drugs are making this treatment more affordable but many obstacles still remain. Some of these are the high cost of testing and the paucity of laboratories with the required infrastructure and personnel to provide testing and monitoring services.

The Role of the Laboratory in ARV Therapy

- *Diagnosis of HIV*
- *Decision on when to initiate therapy*
- *Monitoring of treatment efficacy*
- *Monitoring of treatment toxicity*
- *Drug resistance surveillance*

The presence in the country of well equipped laboratories to provide the above support is essential for ARV programmes. As African countries budget for ARV drugs there is need to put equal emphasis on strengthening of the laboratory capacities.

The development of drug resistance is a serious concern and challenge. If left unmonitored it will negate any benefits of any ARV Programmes. It is strongly recommended that countries starting ARV Therapy Programmes should also establish drug resistance monitoring systems.

RESISTANCE MONITORING:

1) Biologic (Phenotypic) Assay.
Measures HIV growth in the presence of different concentrations of a drug or combination of drugs. It requires a sophisticated (P3 Level) laboratory and is cumbersome, time consuming and expensive.

2) Genotypic Assay.
Determines mutations within the nucleic acid of the patient's HIV genome and when the amino acid exchanges causing resistance are known, the degree of resistance can be calculated. This assay can be performed in three days but needs facilities for nucleic acid sequencing.

7.4 Blood Safety

Although coverage of screening of donated blood for Africa is estimated at 94% (Source: Coverage of Selected Health Services for HIV/AIDS Prevention and Care in Less Developed Countries in 2001, WHO), blood safety will be improved by the establishment of functional Blood Transfusion Services. In addition frequent shortages of testing reagents often disrupt screening programmes. It is estimated that 10-20% of HIV infections in Africa are transmitted via blood.

Blood saves lives only if a safe blood product is given to the right patient at the right time.

Blood will be safe if there is;

- a nationally coordinated blood transfusion service
- collection of blood only from voluntary non-remunerated blood donors
- **testing of all blood for transfusion transmissible infections**
- transfusion of the right blood to the right patient
- a comprehensive quality assurance system

7.5 Surveillance.

Over 70% of the countries in the Region have surveillance systems in place. National sentinel surveillance programmes have provided the bulk of information on the epidemic trends in the continent. They have been useful in forecasting impacts and designing intervention programmes. A quality laboratory testing system is critical to the success of the surveillance programme.

8.0 SUB-REGIONAL PROFILES

8.1 West Africa

All the countries have either an officially designated (61.5%) or a functional (38.5%) National HIV Reference Laboratory. All the laboratories dedicate more than 50% of their time to offering diagnostic support. At least 58.3% of the laboratories receive more than 50% of their financial support from the public sector. While only 61.5% of the countries have a policy guiding laboratory services, 75% have an HIV action plan and 90.9% of these have included their action plan in the national HIV/AIDS health sector plan.

Laboratory Facilities.

ELISA facilities are available at central level (80%), at regional level (15%), and at district level (<5%). Rapid assays are performed mainly at district level (80%) although they are also available at regional and central levels. Western Blot facilities are available at central level in 92.3% of the countries while only 38.5% of the countries perform p24 antigen testing.

Although mechanisms for defining HIV testing algorithms exist in 84.6% of the countries 50% or more of the countries do not conform to the WHO testing strategies for diagnosis and surveillance.

PCR and viral load assays are available in 53.8% of the countries. The majority of these (71.4%) perform less than 25 assays per week using the amplicor monitor (50%). HIV culture facilities are available in 30.8% of the countries.

Heteroduplex Mobility Assays are available in 38.5% of the countries. One of the countries has sequenced the full genome with the remaining having done parts of the genome.

Facilities for CD4 enumeration are available only at central level in 76.9% of the countries.

Only 58.3% of the countries have a National Quality Assurance Programme although 92.3% of the Reference Laboratories participate in an External Quality Assessment Scheme, 84.6% of which are supported by WHO.

8.2 Central Africa

All the countries have either an officially designated (71.4%) or a functional (28.6%) reference laboratory. All the laboratories spend more than 50% of their time offering diagnostic support to the country. Only 28.6% of the reference laboratories receive 50% or more funding from the public sector. Less than half (42.9%) of the countries have a policy guiding laboratory services and 57.1% have an HIV action plan.

Laboratory Facilities.

ELISA facilities are available at central level (80%), at regional level (20%), and at district level (<1%). Rapid assays are available at district level (>90%) although they are also performed at regional and central levels. Western Blot facilities are available at central level in 85.7% of the facilities and 57.1% of the countries perform p24 antigen testing.

Although mechanisms for defining the HIV testing algorithm exist in 85.7% of the countries 33.4%, 42.9%, and 57.1% do not conform to the WHO testing strategy for transfusion, diagnosis, and surveillance respectively.

PCR and viral load assays are available in only two countries (28.6%). All of them perform less than 25 assays per week using both amplicor monitor and BDNA. Heteroduplex Mobility Assays are not available in the region. However 14.3% of the countries have capacity for HIV culture.

Many of the countries (71.4%) have facilities for CD4 enumeration at central level.

The majority of the countries (85.7%) do not have a National Quality Assurance Programme but all of them participate in the WHO supported External Quality Assessment Scheme.

8.3 East Africa

All the countries have either an officially designated (71.4%) or a functional (28.6%) National Reference Laboratory. Only 50% of the laboratories dedicate at least 50% or more of their time to offering diagnostic support to the country. At least 57.2% of the laboratories receive more than 50% of their financial support from the public sector. While 85.7% of the countries have a policy guiding laboratory services only 71.4% have an HIV action plan.

Laboratory Facilities.

ELISA facilities are available at central level (70%), at regional level (25%), and at district level (5%). Rapid assays are performed at district level (90%) although they are also available at regional and central level. Western Blot facilities are available in 83.3% of the countries while only 50% perform p24 antigen testing.

Although the mechanism for defining the HIV testing algorithm exists in all countries, only 80%, 50%, and 33.3% follow the WHO testing strategy for transfusion, diagnosis, and surveillance respectively.

PCR and viral load assays are available in 71.4% of the countries using commercial (83.3%) and in-house (16.7%) kits. Most of the countries (75%) perform more than 25 viral load assays per week employing the amplicor monitor technique (66.6%).

Heteroduplex Mobility Assays are available in two countries (33.3%). None of the countries has sequenced the full genome.

All the countries have CD4 enumeration facilities at central level, 66.7% of these perform more than 100 enumerations per month.

All the countries in the region have a National Quality Assurance plan and all of them participate in an External Quality Assessment Scheme, 83.3% of which are supported by WHO.

8.4 Southern Africa

All the countries of the region have either an officially designated (63.6%) or a functional (36.4%) National HIV Reference Laboratory. Over 90% of the reference laboratories devote 50% or more of their time to providing diagnostic support. The majority of the laboratories (87.25%) receive 50% or more of their funding from the public sector with 72.7% and 70% of the countries having a policy guiding laboratory services and an HIV action plan respectively.

Laboratory Facilities.

ELISA facilities are available at central level (80%), at regional level (10%), and at district level (5%), in a third of the countries ELISA facilities are not available at district level. Rapid assays are performed at district level (70%) although they are also available at regional and central levels. Western Blot facilities are available at central level in 72.7% of the countries while only 36.4% perform p24 antigen testing.

Although mechanisms for defining HIV testing algorithms exist in all the countries, only 30%, 60%, and 60% conform to the WHO HIV testing strategy for transfusion, diagnosis, and surveillance respectively.

PCR and viral load assays are available in 70% of the countries. Over 80% of the countries perform over 25 assays per week. However, only 27.3% of the countries have facilities for HIV culture with capacity for less than 10 tests per week.

Heteroduplex Mobility Assays are available in only 30% of the countries. Three of the countries have sequenced the full genome.

Facilities for CD4 enumeration are available centrally in 81.8% 0f the countries with 77.8% of them able to perform more than 100 tests per month.

Only 40% of the countries have a National Quality Assurance Programme although 90.9% of the reference laboratories participate in the External Quality Assessment Schemes, 70% of which are supported by WHO.

9.0 RECOMMENDATIONS.

Recommendations to WHO

1. WHO/AFRO to put in place systems to assist member countries develop appropriate Plans of Action for HIV/AIDS Laboratories that can be translated into the delivery of accessible and quality laboratory services to support HIV/AIDS Prevention and Care Programmes.
2. WHO/AFRO to support member countries in advocating for support and mobilizing resources to strengthen laboratory capacity and service delivery.
3. In view of the influx of many untried simple/rapid HIV assays into the African countries, WHO should continue promoting the use of the Bulk Procurement Scheme to ensure that countries have access to quality HIV test kits.
4. WHO to identify and strengthen existing Regional HIV laboratory capacities that could offer support to neighbouring countries especially in ARV drug resistance monitoring.
5. Considering that the majority of the member states depend on the WHO run Regional External Quality Assessment Scheme (REQAS) as their only means of quality assessment, WHO/AFRO is requested to sustain and expand the scope of the current REQAS.
6. In view of the difficulties in early diagnosis of HIV in children in Africa, WHO is requested to facilitate a multicentre study to validate the use of the p24 Antigen Assay as a tool for HIV diagnosis in infants and children in Africa.

Recommendations to member states;

1. Recognising the need for adequately trained health personnel in Africa, countries are encouraged to put in place systems for health personnel development by increasing output from training institutions and retraining existing staff in order to build a critical mass of appropriately trained personnel to support HIV/AIDS Prevention and Care Programmes.
2. Considering the many advantages of the Simple/Rapid HIV Assays and recognising that the laboratory infrastructure in many countries remains weak, member states are advised to develop HIV testing strategies and algorithms that make use of the simple/rapid assays.
3. Countries are advised to develop a National Quality Assurance Programme and to put in place mechanisms for its implementation
4. Countries should establish a clearly defined National HIV Reference Laboratory with adequate personnel and resources to support the country in HIV test kit validation and managing the National Quality Assurance Programme.

10.0 CONCLUSION

This assessment report supports the observations made at the second meeting of the HIV/AIDS Laboratory Network of the WHO Africa Region in Accra, Ghana, 20-22 November, 2002. The WHO Laboratory Network had anticipated these findings and had made specific recommendations on the way forward. In particular the Network recommended assistance for countries in the development of appropriate action plans for the laboratory, development of National Quality Assurance Programmes and the strengthening of the WHO-EQAS, training of laboratory personnel and development of a questionnaire for the assessment of laboratories in countries.

It is clear from the assessment that many countries in Africa do not have the required laboratory capacity to effectively support HIV/AIDS programmes. The WHO/AFRO HIV/AIDS Strategy in the African Region policy guidelines give priority to country focused programmes and activities in collaboration with all partners. The strategy recognizes the need to mobilize and optimally use the available resources. In order to stem the spread of the epidemic, the strategy recommends scaling up of the current prevention and care activities. This will require laboratory back up and support. There is, therefore, urgent need for African countries to put in place mechanisms to strengthen national laboratory infrastructure and technical capacity. Where countries may not have the capacity to do this, opportunities exist for them to tap into the resources now made available through such initiatives like the Global Fund and MAP. Countries may also need to develop linkages with existing national university and research institute laboratories and other laboratories within the region in order to effectively maximize on existing competencies.

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LIST OF COUNTRIES THAT RESPONDED

1) Senegal
2) Algeria
3) Benin
4) Burkina Faso
5) Cote d'Ivoire
6) Gambia
7) Ghana
8) Guinea
9) Mauritania
10) Niger
11) Nigeria
12) Mali
13) Togo
14) Gabon
15) Cameroon
16) Comoros
17) Congo
18) Democratic Republic of Congo
19) Tchad
20) Centrafrique
21) Ethiopia
22) Eritrea
23) Kenya
24) Uganda
25) Tanzania
26) Rwanda
27) Burundi
28) Lesotho
29) Madagascar
30) Malawi
31) Botswana
32) Namibia
33) Swaziland
34) Zambia
35) Mozambique
36) Zimbabwe
37) Seychelles
38) South Africa