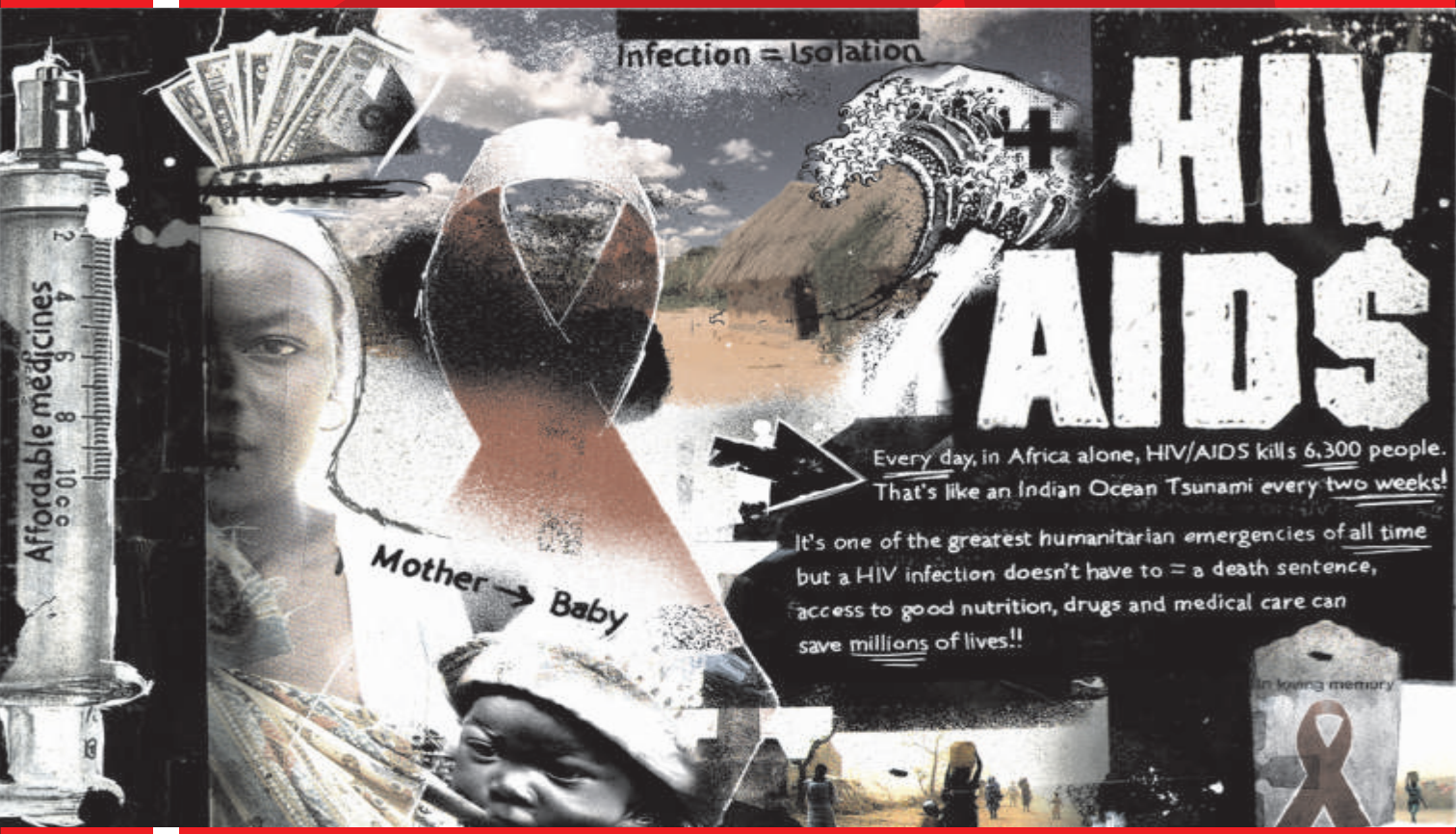
HIV AND AIDS LABORATORY CAPACITY

Where are we?

Overview of laboratory capacity in Africa

2005-2007



World Health Organization
Regional Office for Africa

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CONTENTS

FIGURES

ABBREVIATIONS

AAVP	African AIDS Vaccine Programme
AfDB	African Development Bank
AIDS	acquired immunodeficiency syndrome
APHL	Association of Public Health Laboratories
ART	antiretroviral therapy
ASCP	American Society of Clinical Pathology
ASM	American Association of Microbiology
CDC	Centers for Disease Control and Prevention
CDC-GAP	CDC Global AIDS Program
DBS	dry blood sputum
ELISA	enzyme-linked immunoassay
EQA	external quality assessment
EQAS	External Quality Assessment Scheme
EWI	early warning indicator
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	human immunodeficiency virus
HIVDR	HIV drug resistance
HIVResNet	Global HIV Drug Resistance Surveillance Network
HVI HIV	Vaccine Initiative (WHO/UNAIDS)
IAVI	International AIDS Vaccine Initiative
MOH	Ministry of Health
NGO	nongovernmental organization
NRL	National Reference Laboratories
PCR	polymerase chain reaction
PEP	post exposure prophylaxis
PLWHA	people living with HIV and AIDS
PMTCT	prevention of mother-to-child transmission
QA	quality assurance
SOP	standard operating procedure
STI	sexually transmitted infection
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV and AIDS
VAC	Vaccine Advisory Committee (WHO/UNAIDS)
VCT	voluntary counseling and testing
WB	Western blot
WHO	World Health Organization

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FOREWORD

This is the second assessment of laboratory capacity in the WHO African Region done by the Regional Office to support HIV and AIDS since "The 3 by 5 Initiative" in 2003. The first assessment was done in 2005 after a Regional Office 2003 baseline study which revealed inadequacies in national laboratory infrastructure and technical capacity to respond to the HIV and AIDS epidemic in spite of the increasing prevalence of HIV and AIDS in sub-Saharan Africa. The aim of this re-assessment was to see whether there had been an improvement in laboratory capacity and in the conduct of activities to support the access to HIV and AIDS prevention, treatment, care and support programmes.

Laboratory services are essential components among other health services that must be improved in order to support HIV and AIDS management in the African Region. Through laboratories, people get to know their HIV status, start and continue ART treatment and live positive lives. Countries get to know HIV and AIDS prevalence and access to services. Countries were therefore encouraged to support laboratory services to effectively manage HIV and AIDS.

By 2005, countries in the African Region had made significant gains in laboratory capacity with the development of national policies and plans and the decentralization of services from central to district levels. Also, the adoption and use of simple cost-effective laboratory technologies (like the simple rapid assays) as well as the initiation and monitoring of ART using essential tests like CD4 + T-cells enumeration increased during the three-year period. In spite of these gains, the laboratory still needed to improve their service capacity, hence the 2007 assessment.

The 2007 assessment showed marginal improvements in most indicators over the 2005 figures. The most significant was that by 2007, most African governments were developing their national strategic plans and mobilizing resources for laboratory services in both the private and public sectors. The availability of trained, skilled human resources was the main challenge to improving laboratory capacity. Laboratories lacked both the number of professionals required as well as those with the necessary training and skills to undertake HIV and AIDS and integrated laboratory services. Also, some countries are not complying with the Abuja Declaration of allocating 15% of their total national budgets to health, and stock-outs of supplies continue to occur in some laboratories.

The WHO Regional Office for Africa continues to play a significant role in the improvement of laboratory capacity through support visits to laboratories; provision of services and resources to Member countries; and advocacy on behalf of the African laboratory network. The most significant recommendation from this assessment is that the Regional Office should provide support and guidance for Member countries to make the development of a laboratory referral system a priority to accelerate the scaling up to universal access by 2010. Member countries should also implement the Maputo Declaration concerning the strengthening of laboratory systems.

According to the foreword of the 2005 report, "... there is no quick fix to strengthening and expanding health systems, including laboratory capacity, to meet the demands placed on countries in the WHO African Region to respond to the HIV and AIDS crisis. Rather, we must commit ourselves to a process of critical self-appraisal at the national and regional levels to identify realistic and achievable priority interventions in the years ahead."

The hope is that the intended target audience–heads of laboratories, nongovernmental and governmental agencies, organizations, donors and WHO–of this report will use it as an advocacy tool in their work to mobilize additional resources for HIV and AIDS programmes and laboratory services. Readers are free to use the findings appropriately and implement recommendations to improve laboratory capacity for reducing the HIV and AIDS epidemic.

Dr Luis Gomes Sambo
Regional Director

EXECUTIVE SUMMARY

Why laboratory capacity

According to the 2008 UNAIDS *Report on the global AIDS epidemic*, there is still unacceptably high levels of new HIV infections, even though the HIV epidemic itself is said to have stabilized. Globally, a total of 33 million people were estimated to be living with HIV and AIDS at the end of 2007, 67% of them living in sub-Saharan Africa. There was a slight drop in the estimated number of new HIV infections from 3 million in 2001 to 2.7 million in 2007, but then, 38% of all AIDS deaths were found to have occurred in the southern African subregion. Because of these high numbers, much still needs to be done to enable African countries to effectively undertake the required interventions for the prevention and control of HIV infections in order to further reduce the incidence of new HIV cases on the continent. Laboratory services form an essential component of the health services, requiring the necessary strengthening for improved testing, research and other activities.

In line with global and national commitments for strengthening control programmes, there has been a rapid scaling up of HIV and AIDS services, particularly associated with "The 3 by 5 Initiative". In 2003, the World Health Organization conducted a baseline assessment on the existing capacity of laboratories in the WHO African Region, followed by a second one in 2005. The 2003 assessment showed that the laboratories in the Region needed infrastructural and technical capacity strengthening to support HIV and AIDS programmes. The 2005 assessment showed an improvement in the formalization of laboratory operations in the Region. The current status of the laboratories in Africa and the need for their strengthening form the underlying justification for the 2007 assessment which aims to determine if some progress has been made with respect to the same parameters used in 2003 and 2005, and eventually provide an indication of how the Region should move forward.

Laboratories within the African Region need to expand in support of scaling up HIV prevention and control services; most of the laboratories are not only poorly resourced but also operate within a limited capacity. In spite of the important progress already made, improving laboratory capacity still remains a challenge that requires immediate support to meet the needs of HIV and AIDS programmes. Programmes such as voluntary counseling and testing (client-initiated or provider-initiated), follow-up of clients on antiretroviral therapy (ART), identifying pregnant women living with HIV and AIDS, measures to prevent transmission to newborns as well as surveillance processes all need laboratory back-up services for testing and therefore monitoring and controlling the disease.

This report provides comparative statistics regarding HIV laboratory capacity within the WHO African Region from 2003 to 2007, relevant trends and gaps and an assessment of the contribution of laboratories towards the universal access to HIV and AIDS management by the year 2010.

Scope and intended audience

The scope of this work was to find out and document progress made with laboratory capacity given the global commitment to the fight against the HIV epidemic. Specifically it was to:

- Provide an updated inventory of laboratory capacity and competence within the WHO African Region between 2003 and 2007;
- Provide comparative statistics for the period between 2003 and 2007;
- Identify the trends and the gaps to be filled;
- Develop a report that would be used as a basis for strategic planning.

This document is intended to serve as an advocacy tool for government representatives, nongovernmental organizations, heads of laboratories, WHO and other donors.

Summary findings

There has been some progress in 2007 for most of the parameters on laboratory activity and capacity compared to 2005, though minimal in certain cases. The strengths, weaknesses, opportunities and threats identified are summarized below.

Strengths

- Most African governments are involved in the development of national strategic laboratory plans.
- Most governments are mobilizing resources through public and private sectors.
- Technical and financial partners are present and willing to contribute to the integrated scaling up of HIV and AIDS laboratory activities towards the universal access programme.

Weaknesses

- There are inadequate human resources in terms of quantity and quality, with no career prospects or adequate financial motivation.
- Some countries do not have a designated national reference laboratory (NRL); others do not have elaborated policies and guidelines governing laboratories, and most NRLs are not given enough support to maintain their status as reference laboratories.
- National quality assurance programmes are lacking in nearly half of the respondent countries, and there are insufficient external quality assessment schemes (EQAS) for CD4+ T-cell enumeration and HIV drug resistance (HIVDR).
- Most African governments are not complying with the Abuja Declaration of allocating 15% of total national budget to health.
- There are continued occurrence of several stock-outs per year in a few laboratories.

Opportunities

- There are many technical and financial partners ready to provide funding and technical assistance.
- Vaccine development research has commenced in a few countries.

Threats

- It is difficult to sustain programmes in African countries when technical partners and stakeholders pull out.
- There are problems with monitoring and managing drug resistance due to poor drug management.
- Development of new HIV strains, currently unknown, because of the lack of research, funding and trained personnel.

Contribution of the Regional Office

The WHO HIV and AIDS Programme in the Division of AIDS, Tuberculosis and Malaria (ATM) provided technical assistance to Member States to develop HIV and AIDS policies and strengthen the health response towards universal access by 2010. The WHO Regional Office for Africa established Intercountry Support Teams (IST) situated in three locations: Ouagadougou (Burkina Faso) for West Africa; Libreville (Gabon) for Central Africa; and Harare (Zimbabwe) for Eastern and Southern Africa. The Regional Office also provided resources and did advocacy for strengthening laboratory services in the Region during the period of the review. Specific actions taken by the Regional Office include the following:

1. Conducted advocacy missions to encourage partners and national authorities to make laboratory issues a priority; and strengthened relations with regional and international media for better publicity of activities.
2. Supported 18 countries to develop action plans for resource mobilization, disbursement and service provision and incorporation into project proposals of funding partners.
3. Assisted the African laboratory network with its fourth meeting in Addis Ababa, Ethiopia, in November 2006 to finalize its action plan, and supporting participating countries to mobilize resources and implement the activities.
4. Developed a training package with CDC to improve the quality of testing in the Region; trained service providers and trainers in 15 countries on HIV rapid testing; translated a training package into French.
5. Collaborated with two national reference laboratories (NRLs) in South Africa and Senegal to initiate HIV serology external quality assessment programmes in 44 countries.
6. Jointly held a review workshop in Kampala, Uganda in May 2006 with CDC to review the performance of NAT testing for early HIV-1 diagnosis in Prevention of Mother-to-Child Transmission (PMTCT) programmes in different countries with diverse subtypes.

7. Collaborated with partners to train biologists and technicians for the *Diplôme Universitaire de Retrovirologie* at the University of Dakar, Senegal with over 15 countries participating every year.

Conclusion

Countries within the WHO African Region have made a lot of progress in developing Laboratory policies and plans that respond to HIV and AIDS needs and in the use of simple, cost-effective technologies such as simple rapid assays. This has led to successful decentralization of laboratory facilities to the district level and below to meet the challenge of universal access to HIV and AIDS prevention, treatment, care and support services by 2010.

However, findings from this work show that although some countries are on course to meet the 2010 target, a lot of work still needs to be done if the African Region is to achieve its goal. Countries that are lagging behind must quickly improve upon the gains; work on problems and deficiencies in their NRLs, quality assurance programmes, EQAS for HIV drug resistance and CD4+ T-cell enumeration; and increase the number of trained scientists and technicians. In conclusion, many Member countries in the Region need support to strengthen and accelerate their HIV response programmes in order to achieve universal access by 2010.

Recommendations

Based on the findings and conclusions above, recommendations were made to WHO Members States as well as the WHO African Regional Office. Prominent recommendations are listed below.

Recommendations for WHO Member States

Member States should endeavour to:

1. implement the Maputo Declaration on Strengthening of Laboratory Systems through the provision and standardization of laboratory services;
2. designate national reference laboratories (NRLs) based on merit; impress upon them the importance of accreditation of laboratory specialities and the necessity of maintaining the accreditations;
3. establish national quality assurance programmes at all levels of the laboratory network and assist the NRLs to provide external quality assessment for proficiency testing, supervision and monitoring;
4. encourage adaptation and use of WHO recommended testing strategies;
5. assist laboratories with continuous training in inventory control and reagent and consumable stock management to prevent recurrent stock-outs;
6. strengthen technical competency through pre- and in-service training and skills upgrading programmes that ensure retention of trained and motivated staff.

Recommendations for the WHO Regional Office for Africa

The WHO Regional Office for Africa should, among others, do the following:

1. provide support and guidance to Member States to make the development of laboratory referral systems a priority to accelerate scaling up towards universal access;
2. support countries to formally designate NRLs, go through accreditation procedures and link them with external laboratories of excellence;
3. give technical assistance and support Member States to conduct national pre- and in-service training for professional and non-professional laboratory staff and service providers to build human capacity;
4. assist countries to develop national HIV and AIDS vaccine plans and support them to include research and development in laboratory policy and planning;
5. support countries to participate in HIVDR surveillance programmes that emphasize NRLs that have the ability to establish national surveillance programmes for HIVDR; and link up intercountry, regional and international surveillance programmes;
6. provide technical assistance to countries on inventory control management to prevent stock-outs of consumables and ARVs.

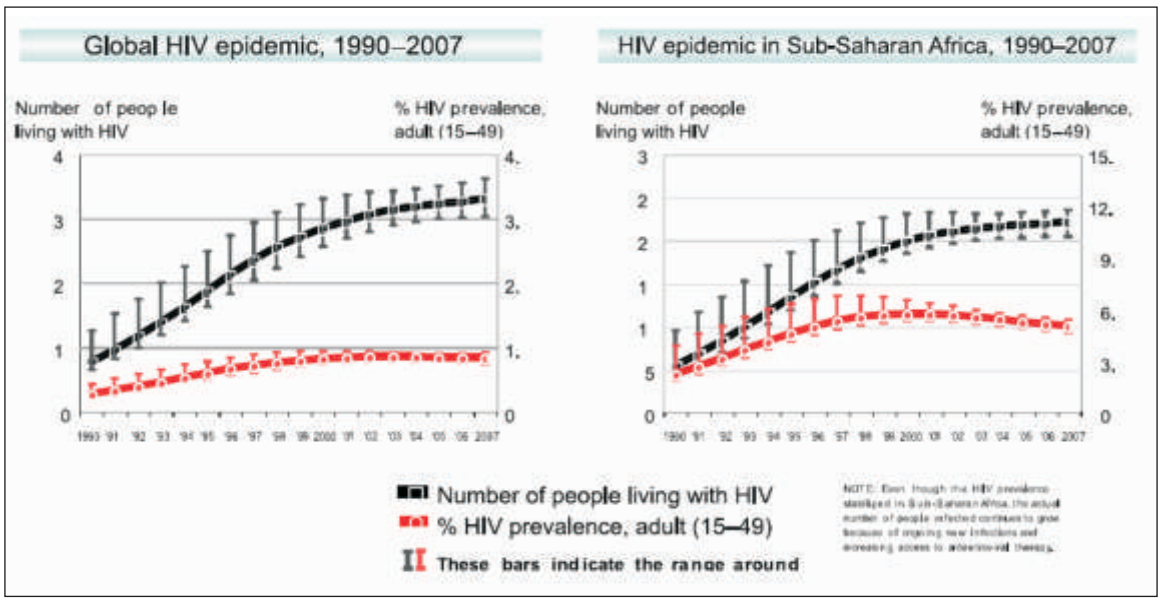
INTRODUCTION

Background

The burden of the HIV and AIDS pandemic worldwide is still very high, with sub-Saharan Africa being home to two thirds of the total number of persons living with HIV and AIDS. According to the 2008 UNAIDS *Report on the global AIDS epidemic*, the epidemic has stabilized somewhat, with an estimated 33 million PLWHA in 2007 compared to 40.3 million in 2005. However, the number of new HIV infections and AIDS deaths are still unacceptably high. The annual number of new HIV infections declined from 3 million in 2001 to 2.7 million in 2007, with 38% of AIDS death occurring in southern Africa. Consequently, there has been a huge global effort by WHO and other organizations worldwide geared at effectively addressing the AIDS pandemic, and several commitments have been made in the process; the most significant are the following:

- Millennium Development Goals 4, 5 and 6 (agreed by Member States of the United Nations in 2000) aimed at reducing child mortality; improving maternal Health; and combating HIV and AIDS, malaria and other diseases by 2015.
- The Declaration of the UN General Assembly Special Session (UNGASS) on HIV and AIDS in 2001 to reduce the proportion of infants infected with HIV by 20% by 2005 and by 50% by 2010, in countries with generalized epidemics while providing 80% coverage of appropriate interventions.
- At the Abuja (Nigeria) high-level Global Forum in December 2005 governments and leaders of the G8 countries agreed to "work with WHO, UNAIDS and other international bodies to develop and to implement a package for HIV prevention and care with universal access to treatment for those in need by the year 2010" and to "help with preventing mother-to-child transmission of the disease". UN Member States also endorsed this goal at the 2005 world summit.
- At the June 2006 high-level meeting on AIDS, UN Member States committed themselves to work towards the broad goal of "Universal Access to HIV and AIDS prevention, treatment, care and support programmes by 2010", (UNICEF/WHO, 2007).

Figure 1: Estimated number of people living with HIV and adult HIV prevalence; global HIV epidemic, 1990-2007; and HIV epidemic in sub-Saharan Africa, 1990-2007

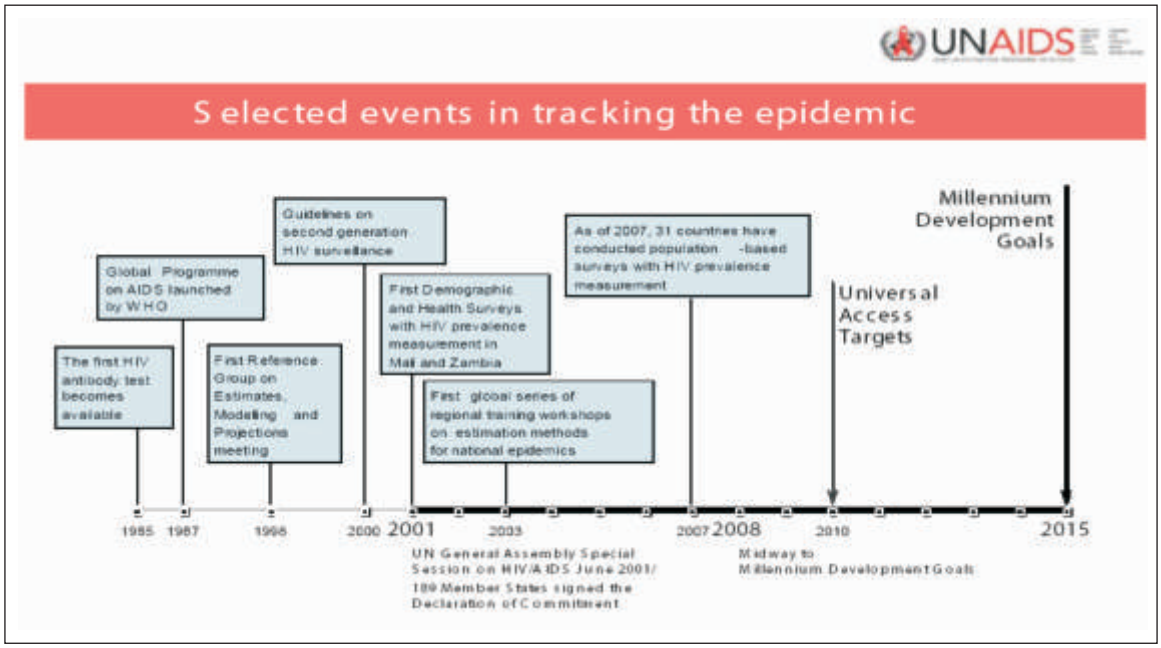


The World Health Organization (WHO) created "The 3 by 5 Initiative", endorsed by all the 192 WHO Member States, to act as a catalyst for rapid scaling up of HIV and AIDS services across the African Region from 2003 to 2005. The objective of this initiative was to provide antiretroviral therapy (ART) to 3 million eligible people in low and middle income countries by the end of 2005. This underscored the important role of laboratory support, and implied the need for strengthening the laboratories in order for them to effectively match the scaling up of activities related to prevention, diagnosis, treatment, care and support of HIV and AIDS programmes.

In March 2006, a meeting was held in Brazzaville, Republic of Congo attended by representatives from WHO Member States, nongovernmental organizations (NGOs), faith-based organizations (FBOs), civil society groups including PLWHAs, the Joint United Nations Programme on HIV and AIDS (UNAIDS), WHO and other donors to highlight the high burden of the epidemic in Africa. This meeting conceived the "Universal Commitment Towards Universal Access to HIV and AIDS Prevention, Treatment, Care and Support Activities in Africa by 2010" (hereafter referred to as "Universal Access"). This process was to build on past initiatives such as "The 3 by 5 Initiative" and to infuse existing efforts with greater momentum.

Again the role of laboratories in strengthening and expanding health services was identified in the set of priority interventions required to meet the goal of Universal Access by 2010.

Figure 2 Selected events in tracking the HIV epidemic



SCOPE AND INTENDED AUDIENCE

Given the global commitment to fight the HIV and AIDS pandemic as stated above, it was necessary to document progress made with respect to laboratory capacity since the last assessment done in 2005, in order to:

- provide a current inventory of laboratory capacity and competencies within the African Region by the end of 2007;
- provide comparative statistics on laboratories for the stated period;
- identify trends and gaps to be filled;
- produce a document that would be the basis for strategic planning.

This report therefore reflects the contribution made by laboratories in supporting HIV and AIDS control programmes in the WHO African Region and provides an inventory of HIV laboratory capacity during the period 2003-2007. It is also intended to be an advocacy tool for government representatives, NGOs, heads of laboratories, WHO and other donors.

The data collection process for this assessment reflects the diversity of the countries in the African Region and takes into account the geographic size, population and HIV prevalence of each country. Thus, the data presented in this report should be interpreted with this in mind. For example, an

indicator such as the number of specimens processed per month may have a different meaning in a small country with low prevalence than in a large country with high or low prevalence.

For easy reference and in a bid to assist comprehension, the report has been divided into four parts.

Part one examines the role of laboratories in HIV prevention, diagnosis, treatment, care and support within health-care systems in the African Region.

Part Two provides a comparative analysis of the findings regarding laboratory capacity in the African Region between 2003 and 2007.

Part Three provides an overview of the areas in which the WHO Regional Office for Africa has contributed to the development of laboratory services in support of HIV and AIDS control programmes since 2003.

Part Four provides recommendations to WHO Member States and the Regional Office for the purposes of advocacy, planning, monitoring and evaluation in the future.

PART ONE

Where we are

Even though some important progress has been made since 2003, most laboratories in the African Region remain poorly resourced and operate with very limited capacity. Achieving adequate laboratory capacity remains a challenge that requires immediate support to meet the needs of the HIV and AIDS control programmes. Services to be scaled up and therefore immediately requiring laboratory support include voluntary counseling and testing (client initiated or provider-initiated); monitoring persons on antiretroviral therapy (ART); identifying pregnant women who may be living with HIV and AIDS and instituting measures to prevent transmission to their unborn child; and surveillance.

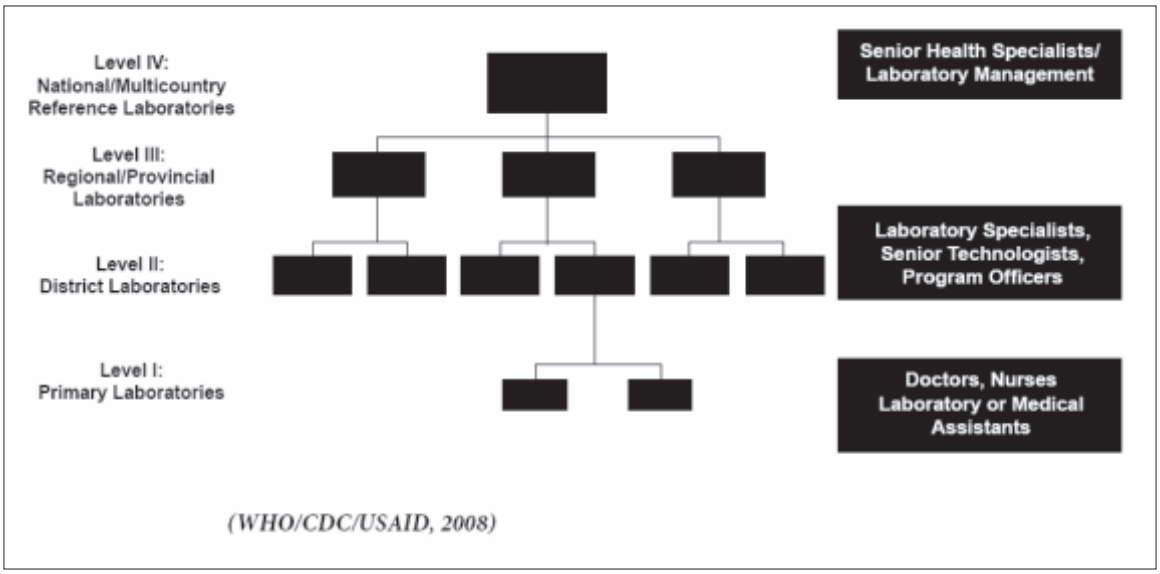
Insight into the functioning of a tiered laboratory network within a resource-limited environment is useful in understanding the role of the individual laboratory in such an arrangement.

1.1 Laboratory Network In Resource-limited Settings

In most resource-limited settings such as in developing countries, laboratory services are provided as a tiered network organized in alignment with the public health delivery network. Services are usually integrated, and clear roles and responsibilities are defined for each level of the network. Four levels are recognized in the tiered arrangement of laboratories in most countries in the African Region (Figure 3).

The services offered at each level may vary depending on the population served (e.g. infants, adults), physical infrastructure, electricity and water availability, water quality, road conditions, and the availability of trained personnel. If required testing exceeds the scope of services available from Level-I facilities, the overseer Level-II laboratories would provide a range of consultant services, including the receipt of referral specimens and patients. In many cases, such as dry blood spot (DBS) or a tuberculosis (TB) culture, the specimen may bypass a Level-II lab and go directly to the nearest performing laboratory. The functions of each level are described below.

Figure 3 The Tiered Integrated Laboratory Network



Level-I Primary

Health post and health centre laboratories primarily serve outpatients and may also serve as a peripheral branch of a laboratory at the next higher level of the network. Clean water and electricity may not be regularly available, and a laboratory assistant or nurse is often the only one providing services. The responsibilities of laboratories at this level are listed below.

Level-I: Responsibilities of Health Centres/Health Post laboratories Undertake routine laboratory basic tests for:

1. clinical diagnosis and public health e.g. DBS, rapid/dipstick tests, certain automated chemistry tests required for ART monitoring in sites with reliable electricity and water supply;
2. Refer samples to Level-II;
3. Provide the system of information of the health centre/health post;
4. Participate in the management of reagents and consumables;
5. Implement quality assurance activities, quality control and basic record keeping, adequate specimen collection and basic reagent use. Same day delivery of results to patients in order to provide immediate counseling, treatment and regimen modification;

Level-II District

Laboratories in intermediate referral facilities (e.g. district hospitals) serve inpatients and individuals/specimens referred from Level-I facilities. Such laboratories should have a consistent source of reagent grade water, reliable electricity supply and formally trained personnel of whom one member would serve as the senior or supervisory technologist. Their functions are listed below.

Level-II: District/Rural Hospital Laboratories

1. Act as Reference Laboratory in the district;
2. Refer samples to Level-III;
3. Accomplish routine basic laboratory analysis for diagnosis and health programme monitoring
4. Support implementation of quality assurance systems in the district, including but not limited to QC, QI, EQA/PT, on-site quality assessment visits, periodic review of QC and safety procedures, annual review of SOPs and policies to ensure alignment with current practices;
5. Supervise the laboratories at the health centres;
6. Participate in training programmes, performance management, competency assessment, staff development and re-training;
7. Plan and budget laboratory activities;
8. Maintain laboratory information system (results, reporting and record retention);
9. Participate in the management of reagents and consumables;
10. Manage the maintenance of equipment and infrastructure; and review of maintenance logs;
11. Conduct follow-up of laboratory incident and accident reports;
12. Coordinate courier/transport services.

Level-III Regional/Provincial

These are laboratories in a regional/provincial referral hospital that may be part of a regional or provincial health bureau and support Level I and II laboratories. Although a biosafety Level III designated area would be desirable, the minimum requirement is that of a Level II. Reagent grade water is required. They must be headed by a seasoned technologist who has managerial skills.

Level-III: Provincial /Regional/Hospital Laboratory

1. Act as laboratory reference in their service area;
2. Forward reference samples to the central or designated reference laboratories;
3. Accomplish routine laboratory and specialized analysis with a more comprehensive test menu than that provided at Level-II;
4. Support the implementation of QA system in the province, through laboratory performance assessments and evaluation of the QA data from laboratories in the Region;
5. Provide logistic support to their service areas;

6. Participate in the development of training programmes and coordination of continuing education;
7. Plan and budget for laboratory activities;
8. Assure adequate requisition and reporting mechanisms, and record retention procedures;
9. Standardize methodologies, units and reference ranges based on national reference laboratory recommendations;
10. Participate in the management of reagents and consumables;
11. Manage the maintenance of equipment and infrastructure.

Level-IV National/Reference/Central Laboratory

The National/Reference Laboratory is at the apex of the national network, with senior laboratory scientists and technologists. It also has the infrastructure, equipment, information system and logistic capabilities required for it to function as a national reference laboratory as well as support the laboratories at lower levels with training, quality control and logistics. These laboratories may provide a linkage with research laboratories, academic institutions and other public health laboratories, forming a network that can provide assistance in clinical trials, evaluation of new technologies and surveillance. These and other responsibilities are listed below.

Level-IV: National/Reference /Central Hospital Laboratories

1. Offer reference and diagnostic services using special tests such as nucleic acid assays, HIVDR studies;
2. Serve as the national coordination for HIV programmes;
3. Establish standards for quality management and assist with policy and procedure development;
4. Plan and budget for laboratory activities;
5. Define sensitivity and specificity requirements in order to select methods for evaluation using a validation plan;
6. Select and evaluate diagnostic tests;
7. Provide assistance for reference ranges; validate and develop national reference ranges specific to equipment/methods used;
8. Develop and implement testing algorithms;
9. Introduce and implement new technologies, appropriate for each level, to reflect current best practices;
10. Develop and/or adopt laboratory standards (ISO 15189) and processes for laboratory accreditation;
11. Support the implementation of quality assurance systems in the nation, participate in international EQA programmes and develop/oversee national EQA programmes;
12. Coordinate the collection of surveillance data to obtain and monitor statistics nationwide;
13. Develop monitoring and evaluation activities for laboratories;

14. Assure training programmes;
15. Develop operational research;
16. Maintain the information systems and determine information needs per test result that would lead to a good interpretation of results;
17. Participate in the management of reagents and consumables;
18. Manage national database of equipment and infrastructure maintenance;
19. Provide courier and logistics management support for the nation.

1.2 Laboratory Capacity In Resource-limited Settings

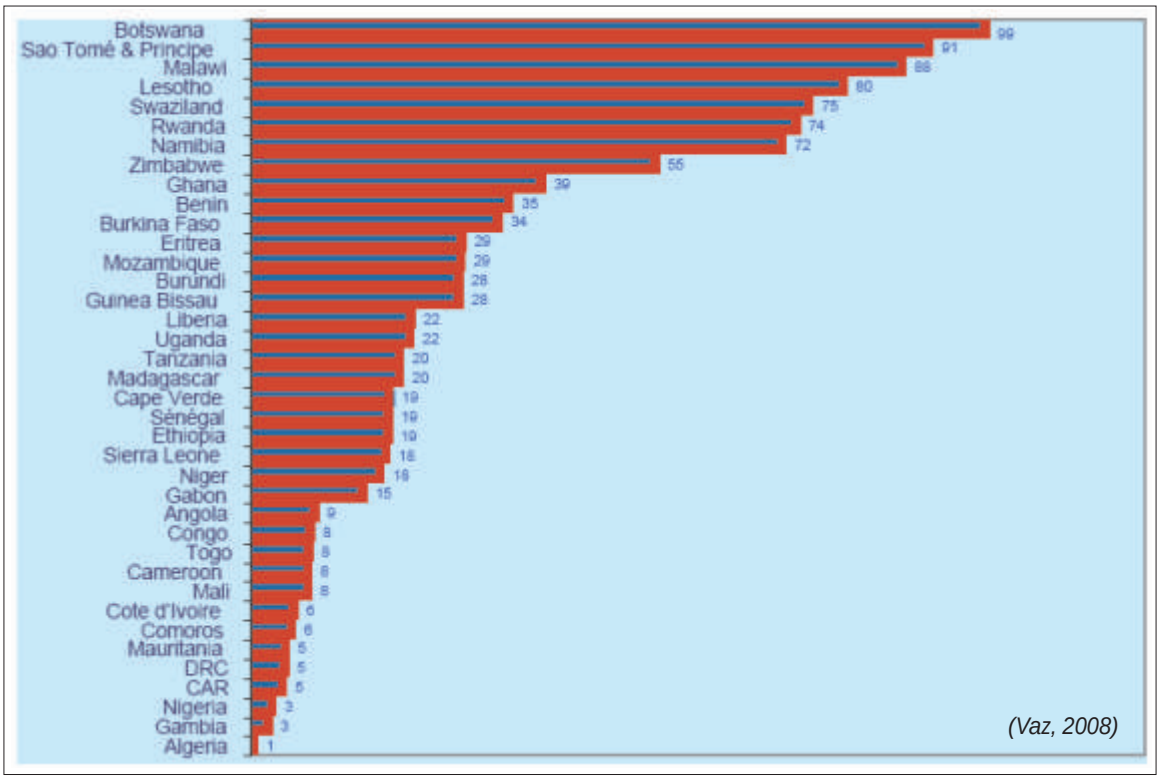
Sub-Saharan Africa is home to over 60% of all PLWHA in the world. This high prevalence creates a demand for laboratory services that must be satisfied for HIV and AIDS management to be effective. HIV testing and counseling is an important ingredient in the implementation of prevention strategies, offering individuals the opportunity to know their HIV status and thus facilitate their entry into treatment and care programmes. The ability of countries in the Region to maintain momentum towards full coverage of laboratory services including testing and counseling (availability, affordability, acceptability) over the next two years will be crucial for the success of Universal Access by the year 2010. The laboratory is indispensable for making decisions on initiation of antiretroviral therapy, for monitoring the efficacy of treatment, as well as for the diagnosis of sexually transmitted infections (STIs) and opportunistic infections. The role of the laboratories in supporting the collection of data for second generation surveillance is the key in monitoring the overall progress in HIV and AIDS control interventions.

HIV Testing and Counseling

Effective prevention of HIV and AIDS is at the core of controlling the HIV and AIDS Epidemic, and the prevention of new infections is the only way to ensure a reduction in the number of people capable of further transmission of the virus and also requiring treatment. Testing and counseling constitute pillars in the implementation of all prevention strategies. However, success requires effective protection from stigma and discrimination as well as assured access to integrated prevention, treatment and care services.

The proportion of public service facilities in the African Region offering voluntary testing and counseling ranges from 99% in Botswana to only 1% in Algeria (Vaz, 2008), as illustrated in Fig 4.

Figure 4 Proportion of public services offering voluntary testing and counseling in 38 countries of the African Region, December 2007



Such services are now based on updated guidelines released by WHO and in line with the WHO/UNAIDS Policy Statement on HIV Testing. It was reiterated that the "three C's"–informed consent, counseling, and confidentiality–irrespective of the circumstances, should accompany any HIV testing and counseling. WHO recommends the following methods of HIV testing and counseling:

Client-initiated testing and counseling: Often referred to as voluntary counseling and testing or VCT, where the individual specifically goes to the testing site or laboratory or health-care provider and requests an HIV test;

Provider-initiated testing and counseling (PITC): Where the health provider offers (initiates) HIV testing to all patients seeking services as a standard component of care including those seeking assessment or treatment for STIs, those seen in the context of pregnancy, those seen in clinical and community-based health services where HIV is prevalent and people who are asymptomatic. Under PITC, informed consent must be obtained and patients provided with the option to accept (opt in), or to refuse (opt out) of having an HIV test;

Mandatory HIV screening: Mandatory screening for HIV and other blood-borne viruses in all blood, blood products, organs/tissues destined for transfusion or transplantation. Mandatory testing should not be conducted on public health grounds for any other reason.

Tables showing the recommended test menu to support diagnosis and monitoring of treatment for HIV and AIDS at each level of the tiered laboratory network in resource limited settings are presented in Annex 1.

Prevention Strategies

Every country in the African Region has to define a national prevention strategy by taking into account the environment and behavioural issues as well as the prevalence of HIV in that setting. Certain key populations at higher risk of HIV exposure may exist in both high and low prevalence countries including those considered to be having concentrated epidemics.

Prevention of Mother-to-child Transmission (PMTCT)

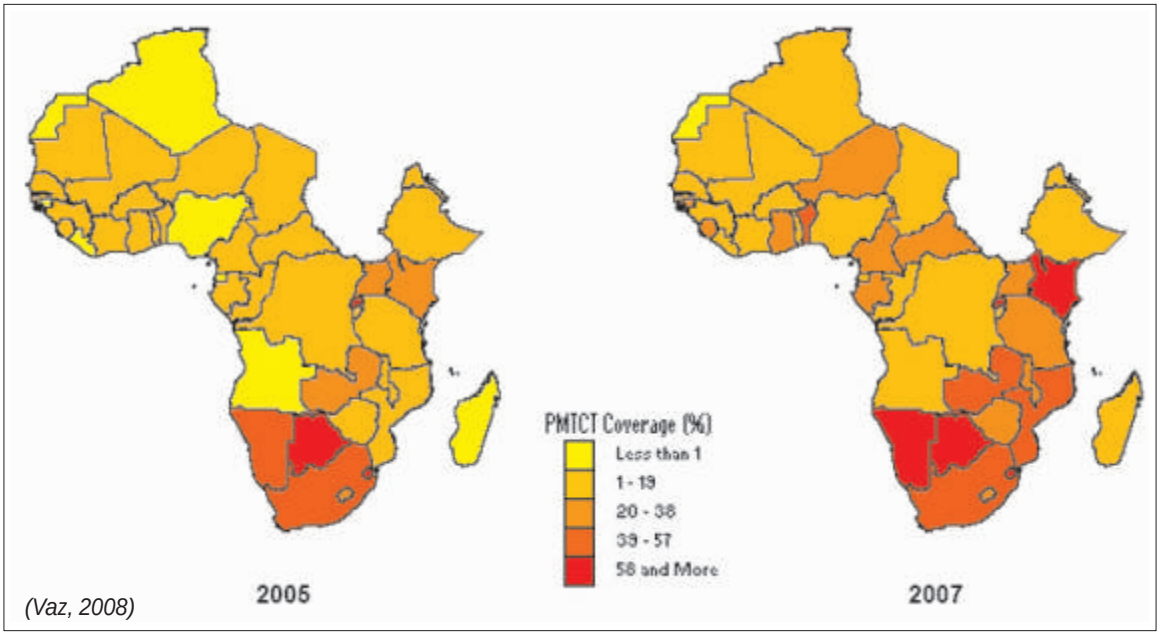
In 2007, some 2.1 million children aged less than 15 years old were living with HIV, and an estimated 420 000 children were newly infected with HIV. It is estimated that 90% of these infections occurred through mother-to-child transmission (MTCT) leading to approximately 270 000 AIDS deaths in that same year. Most of the deaths were in sub-Saharan Africa, (UNAIDS, 2008). In most heavily affected countries, such as Botswana and Zimbabwe, HIV is the underlying reason for more than a third of all deaths of children less than five years of age (Mason, 2006). Women continue to be affected by the HIV epidemic, and in some countries, the proportion of infections among women is increasing. In the African Region, only 34% of pregnant women received ART treatment in 2007 before childbirth to prevent HIV transmission (Vaz, 2008). However, they do not continue to receive ART post-natally (Figure 6). Thus, it is of utmost importance to scale up preventive measures in order to protect their unborn children.

Infection may occur pre- or post-natally at any stage: during pregnancy (estimated transmission rate 5-10%), during labour and delivery (10-20%) or post-natally through breastfeeding (5-20%) (UNICEF/WHO, 2007). The daily infection rate of children less than 11 years of age is estimated at 1400 children daily (UNICEF/WHO, 2007). MTCT is almost entirely preventable through ART and other interventions. However, the coverage levels of such services is remarkably low in most resource-limited countries resulting in HIV and AIDS being a leading cause of illness and death among the reproductive age group, especially in countries with high burdens of HIV infection.

Services for PMTCT require a comprehensive approach that includes a set of key interventions to be implemented as part of maternal, newborn and child health care services. These interventions include:

- Preventing primary HIV infection in women,
- Preventing unintended pregnancies in women with HIV infection,
- Preventing transmission of HIV from HIV-infected pregnant women to their infants,
- Providing care, treatment and support, including ART to HIV-infected women and their families.

Figure 5. Estimation of the percentage of HIV positive women in the WHO African Region receiving ART for PMTCT in 2005 and 2007



Note: This report refers to 46 countries of the WHO African Region. Algeria is the only country of Northen Africa that responded to the questionnaire. The other northern countries are not part of this study.

Prevention of HIV Transmission in the Health-Care Setting

There are two groups of essential elements of HIV prevention in health-care settings: primary prevention procedures or measures and secondary prevention procedures (WHO, 2007).

The primary prevention procedures include:

- blood/transplantation safety to prevent transmission through contaminated blood and blood products and transplanted organs, and tissues;
- prevention of unsafe injections and unsafe injecting practices with assistance of the Safe Injection Global Network (SIGN);
- emergency and essential surgical care to improve the quality and safety of services provided at the primary health level;

- standard precautions to minimize the potential for transmission of HIV and other blood and airborne infections through safe and appropriate practices for any interventions associated with body fluids including basic hygiene, protective equipment, appropriate waste disposal and decontamination procedures;
- effective occupational health and safety education programmes to identify and remove hazards that may place workers at higher risk of HIV infection in the workplace;
- safe waste disposal including provision of safe disposal of contaminated sharps including needles and syringes to prevent HIV transmission.

Secondary prevention measures, on the other hand, are applicable when primary prevention has failed. An important element of such measures is post-exposure prophylaxis (PEP) and is applicable in situations such as when a health-care worker or patient has been exposed to the risk of HIV transmission. PEP for HIV refers to a set of comprehensive services to prevent infection developing in the HIV-exposed person. These services include first aid care; counseling and risk assessment; HIV testing based on informed consent dependent on risk assessment; and the provision of short term (28 days) ART, with follow-up and support.

Tuberculosis (TB) is a common opportunistic disease associated with HIV infection with up to 50% of persons living with HIV and AIDS eventually developing TB. Effective preventive measures should be implemented to limit transmission of TB where possible including clear operational guidelines on biosafety within laboratories to limit infection of laboratory workers. For instance due consideration should be given to appropriate areas for sputum collection (WHO, 2004).

Laboratories in the Region require support and guidance in ensuring the existence of standard operating procedures (SOPs), manuals of methods, safety guidelines, adequate safety equipment and infectious waste disposal guidelines, as well as in the training of all laboratory staff in the use of such guidelines. There should be operating guidelines for comprehensive national quality assurance programmes, including consistent supervisory visits at the national level to guarantee the quality of laboratory services as well as the proper execution of operational guidelines for specimen handling. It is through such means that laboratories in the Region can participate in minimizing the risk of exposure to HIV and other infectious diseases and therefore in reducing the transmission of HIV in health-care settings.

Blood Safety

The transfusion of contaminated blood is the most assured way of transmission of HIV compared to other means of acquiring the infection (WHO, 2007). African women and their children are disproportionately vulnerable as a result of conditions requiring blood transfusion. Such conditions include severe anaemia following obstetrical complications, malaria and helminth infections, malnutrition and sickle-cell disease.

Only 40 countries in the Region had achieved 100% voluntary blood donations in 2006 (WHO, 2007). Of the 2.7 million units of blood collected in 40 sub-Saharan countries in 2004, 88.5% of

them were not tested for HIV in a quality-assured manner (WHO, 2007). More than 20 years after sensitive screening testing systems became available, failure to screen all donated blood for HIV in accordance with the minimum quality standards is a matter of great concern, as is the issue of availability of blood. Effective screening of donated blood for HIV before transfusion is a highly cost-effective strategy to prevent HIV transmission.

Countries in the Region therefore need clear policies and regulations, good organization of blood transfusion services, adequate funding and human resource to improve on the efficiency and safety of their blood transfusion services. Additional efforts are also needed to reduce unnecessary blood transfusions through the establishment of a national blood transfusion service that participates in quality assurance programmes and functions according to strict operational guidelines for the safe collection, screening, handling and use of blood products.

Research on new prevention technologies

The annual rate of new HIV infections continues to rise (4.3%) every year despite worldwide efforts to prevent them. In the African Region, the majority of the new infections are acquired through unprotected heterosexual contact and MTCT whilst elsewhere it is through sex between men and injecting drug use. However, it has been observed that HIV prevalence is generally lower in populations that practise male circumcision than in populations where men are uncircumcised. Randomized clinical trials between 2005 and 2006 confirmed a 60% reduction in transmission of HIV from women to uncircumcised men compared to circumcised men (CDC, 2008). However, it should be noted that for this effect to occur, circumcision must be associated with other preventive measures such as:

- correct and consistent condom use,
- delayed sexual debut,
- reduced number of sexual partners,
- avoidance of penetrative sex,
- voluntary HIV testing and counseling.

Studies on the use of microbicides, gels and foams as preventive measures are ongoing. Post-exposure prevention (PEP) is currently the only prophylactic option. Prophylaxis following occupational exposure to HIV is considered standard in other countries including the USA, and also encouraged in sub-Saharan Africa.

Although treatment and care are very important initiatives for African countries, the only realistic hope for future control of HIV globally will be the development, equitable distribution and use of an effective HIV and AIDS vaccine. The development of such a vaccine has been fraught with a number of scientific, technological, financial and logistic challenges. These include the poor understanding of the genetic diversity of the virus, lack of an ideal animal model, extensive genetic variability of the virus which occurs as a result of its high mutation rate, etc. Various African countries are currently involved in HIV and AIDS vaccine trials or are actively preparing for such trials. Among them is

Uganda, where the first trials led by national scientists started in 1999. Since then Botswana, Cameroon, Ethiopia, Kenya, Malawi, Niger, Rwanda, Senegal, South Africa, Tanzania, and others have been involved in vaccine trials. The development of an effective HIV and AIDS vaccine is a critical issue for African countries and consequently African countries are playing a critical role in its development.

The development of a safe and efficacious vaccine by itself does not constitute the perfect solution and cannot immediately control or eliminate HIV infection and its associated morbidity and mortality. Other control strategies for prevention and control such as the practice of safe sex through the use of condoms, the treatment of STIs and effective ART programmes are also essential in rapidly achieving the goals of HIV and AIDS control programmes.

Antiretroviral Therapy

In 2007, approximately 3 million individuals worldwide were on ART (UNAIDS, 2008). Of these, 2.3 million were living in sub-Saharan Africa. The WHO "3 by 5 Initiative" was widely credited with establishing a global commitment to ensuring access to ART for individuals living with HIV.

The rapid expansion of treatment access in resource-limited settings has been shown to prolong life expectancy; improve quality of life; and contribute to the economic and social rejuvenation of households, communities and entire societies. The scaling up of ART can be attributed to ART delivery systems that are now better adapted to each country context. The WHO public health approach to scaling up emphasizes, among others, simplified and standardized drug regimens, decentralized services and judicious use of personnel and laboratory infrastructure for HIV diagnosis, initiation, ART adherence monitoring effectiveness and toxicity, HIV drug resistance and surveillance. The ART delivery system must be equipped with the following to make it effective:

- HIV counseling and testing and follow-up counseling services to ensure psychosocial support and adherence to treatment regimes;
- capacity to appropriately manage HIV related illness and opportunistic infections;
- a laboratory that provides tests for monitoring treatment regimes;
- continuous supply of antiretroviral drugs and medicines for the treatment of opportunistic infections and other HIV related illnesses;
- reliable regulatory mechanisms.

With the provision of antiretroviral treatment on such a large scale, the emergence of HIV drug resistance (HIVDR) is also anticipated. HIVDR is the ability of the human immunodeficiency virus to reproduce itself in the presence of anti-HIV drugs. The emergence and transmission of HIVDR poses a significant public health threat because the virus quickly mutates in its host T-cells. Also, clients need ART treatment for the rest of their life.

WHO recommends that as part of the planning for scaling up ART, Member countries should put in place systems to assess ART programme factors that may be associated with preventing the

emergence of HIVDR. They are called early warning indicators (EWI). WHO recommends the following EWI:

- prescribing practices,
- percentage of patients lost to follow-up,
- patient retention on first line ART,
- ARV drug pick-up,
- ART appointment-picking,
- pill count/adherence,
- drug supply continuity,
- proportion of individuals starting ART whose viral load is less than 1000 copies per ml after 12 months.

Countries should begin by evaluating which of the WHO listed EWI can be captured from current ART medical records systems or ART cards at all sites used in the country, or from a subset of sites. WHO also recommends that countries collect EWI that are readily available from data currently recorded routinely at sites and that are most useful for programme assessment. Countries need not collect all the information required for calculating the indicators. Indicators should not be reported if the appropriate data are not available (WHO, 2007).

The Global HIV Drug Resistance Surveillance Network (HIVResNet) that has indicated willingness to provide assistance has developed a strategy to implement and coordinate HIVDR surveillance, monitoring, analysis and information dissemination activities; and to produce evidence-based public health recommendations and actions that enhance efforts to scale up ART. This network includes more than 50 experts from organizations and institutions prominent in HIVDR research and public health work. Another group, the WHO HIVResLab, a criteria-based HIVDR genotyping network of national, regional and specialist laboratories, has been formed to provide quality-assured laboratory results for HIVDR surveillance and monitoring laboratories in the Region.

Surveillance

Together with UNAIDS, WHO recommends the use of second generation HIV surveillance to improve collection, analysis and use of data essential to HIV and AIDS control programmes. The use of second generation surveillance is also promoted to help national and international institutions monitor the epidemic and their response to it. Second generation surveillance relies on data collected from two main sources:

1. Biological surveillance/sero surveillance—STI prevalence, TB prevalence, number of adult AIDS cases, number of paediatric AIDS cases;
2. Behaviour surveillance—sex with a non-regular partner in the last 12 months, no condom use at last sex with a non-regular partner, age at first sex in youths, report sharing of unclean injections among drug users, reported number of clients in last week for sex workers.

The aim is to improve the integration of data from these sources; support continuous research into new epidemiological tools; obtain improved methods for producing estimates for modelling the epidemic; and develop better ways for using data for advocacy, planning, monitoring and evaluation.

In order to describe the situation of the disease within a given country, the HIV epidemic can be divided into three epidemic states. Each state is dependent on the underlying HIV prevalence in certain groups: low-level epidemic, concentrated epidemic or generalized epidemic (UNAIDS/WHO, 2000).

Low-level epidemic

The epidemic state in which HIV has never spread to significant levels in any subpopulation, although HIV infection may have existed for many years. (Numerical proxy: HIV prevalence has not consistently exceeded 5% in any defined subpopulation).

Concentrated epidemic

The epidemic state in which HIV has spread rapidly in a defined subpopulation but is not well established in the general population. (Numerical proxy: HIV prevalence is consistently >5% in at least one defined subpopulation and is <1% in pregnant women in urban areas, (WHO, 2009 *in press*).

Generalized epidemic

The epidemic state in which HIV is firmly established in the general population. (Numerical proxy: HIV prevalence is consistently >1% in pregnant women).

A second generation surveillance system should:

- be appropriate to the epidemic state or level,
- use resources where they will generate the most useful information,
- compare biological and behavioural data for maximum explanatory power,
- integrate information from other sources.

HIV testing can be conducted for surveillance, diagnosis and blood screening (UNAIDS/WHO, 1998). In developing countries, most HIV testing for surveillance purposes is conducted as part of the sero-prevalence surveys among population groups such as women attending antenatal clinics, individuals presenting for treatment and care of STIs, female sex workers, and injecting drug users. In addition, the results of testing for diagnostic purposes and for blood screening can provide additional data for surveillance purposes but should be interpreted with caution due to inherent biases. Surveillance data that provide accurate information on the national and regional status of the HIV and AIDS epidemic are crucial for planning, programming and evaluation.

PART TWO

How Far We Have Come—Findings

2.1 Assessment Justification

After two years of implementation of the Universal Access goal, it was deemed necessary to do a mid-term assessment of the progress made in laboratory services in order to take stock of achievements, identify existing competencies and gaps, and provide recommendations on priority areas for building laboratory capacity in the Region to support HIV and AIDS programmes. In addition, these results could be used as a strategic advocacy tool for mobilizing further support to strengthen the capacity of the laboratories in the African Region.

The assessment process was guided by the following objectives:

- To provide an inventory of laboratory capacity and competencies available in the African Region between the years 2003 and 2007;
- To provide comparative statistics for that period;
- To identify the trends and the gaps to fill;
- To develop a document that can be used as an advocacy tool for resource mobilization.

Similar assessments were undertaken in 2003 and 2005 by the WHO Regional Office for Africa, providing a basis for comparison of the achievements and challenges over time.

2.2 Assessment Methods

The methodology and questionnaire formats used in this assessment were the same as those used for both the 2003 and 2005 assessments. The questionnaire was sent to 46 focal points of National Reference Laboratories for HIV and AIDS in the African Region. A total of 45 laboratories responded, giving a response rate of 98%. The list of respondent countries for the 2007 assessment is in Annex 2 and the questionnaire is reproduced in Annex 5.

The data were analyzed using the Epi Info™ software version 3.2.2 at the WHO Regional Office for Africa. All figures were rounded up to whole numbers with no decimals. The denominator was determined from the number of countries that responded and percentages calculated. Results were reviewed and categorized according to their strengths, weaknesses, opportunities and threats.

2.3 Assessment Findings

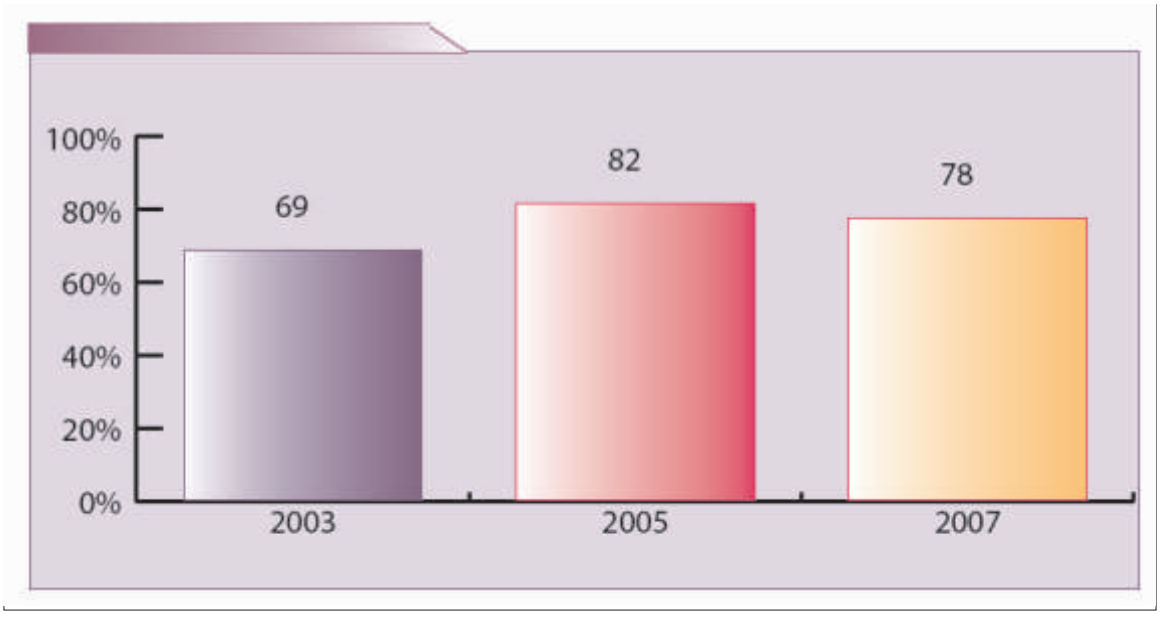
Policy and planning

Effective policy and planning of HIV laboratory services guide the design, implementation of programmes and government involvement in policy development and planning. They help with setting specific national targets and time-lines for increasing laboratory capacity to meet the goals for testing coverage. Some key actions that countries need to undertake to successfully implement national policies include:

- engaging a variety of national and local stakeholders in the development and implementation of plans;
- increasing the skills and number of trained management personnel particularly for policy and planning;
- integrating inter-related laboratory services – (HIV, tuberculosis and malaria) among migrant, urban and rural populations through policy and planning outcomes.

From the findings in Figure 6, the percentage of countries with HIV and AIDS action plans for laboratories rose from 69% (2003), to 82% (2005) and then fell to 78% (2007).

Fig 6. Proportion of Countries that have an HIV and AIDS Action Plan for Laboratories (2003–2007)



The increase in the number of plans in 2005 was attributed to WHO initiatives in collaboration with the United States Centers for Disease Control and Prevention (CDC) during which technical support was provided to national authorities to develop realistic plans based on national needs. The drop in the number of countries that had plans in 2007 could be attributed to the expiration of some laboratory plans, and readjustments and revision of certain others to span a longer period of time, for example five years.

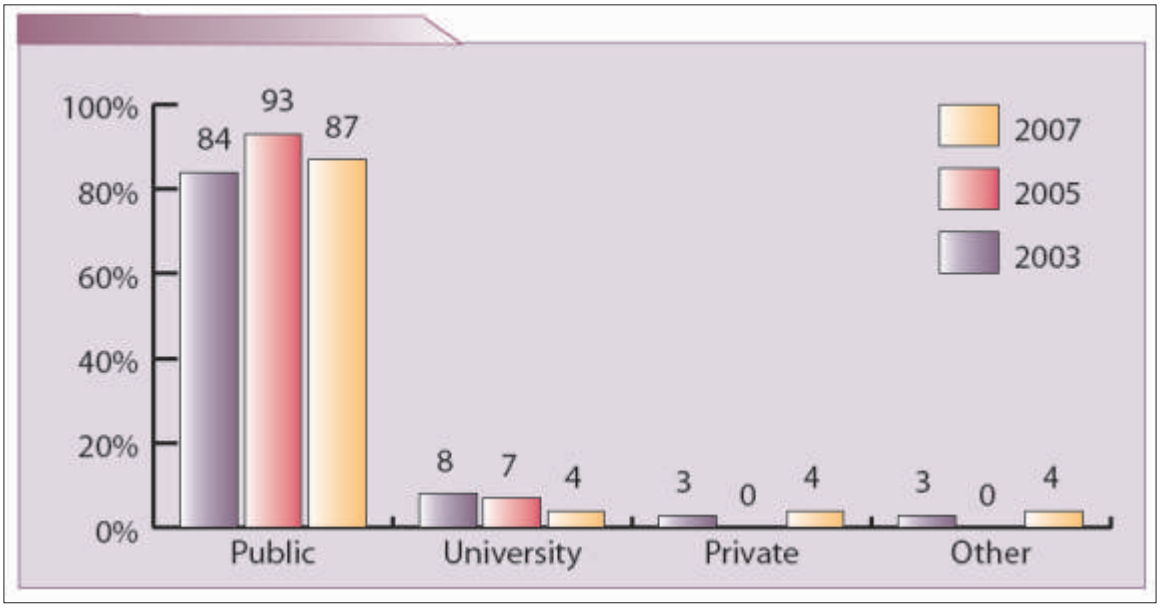
There is need to do more to transform the plans into tangible practical actions, and these plans must also meet the needs identified by each country. Such actions will result in high quality laboratory services in Africa by the year 2010.

National Reference Laboratory

The National Reference Laboratory (NRL) plays a central role in establishing testing policies and protocols within each country and in line with local experience and conditions. The NRL should act as the information hub of all laboratory activities in both the public and private sectors within a country, and should also provide a supportive framework for ensuring quality assurance and staff development.

Affiliation of NRLs with the public sector dropped from 93% in 2005 to 87% in 2007, and a similar pattern is observed within the academic sector (from 7% to 4%) during the same period. Some problems associated with the mobilization of funds donated by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and a lack of coordination in the utilization of resources from other NGOs by government may have contributed to the decline in government affiliation. This observation is however offset by an increased affiliation to the private sector, from 0% in 2005 to 4% in 2007. In recent years, the NRLs have increased their affiliation with some private institutions probably due to the support provided by the United States President's Emergency Plan for AIDS Relief (PEPFAR) (Fig. 7).

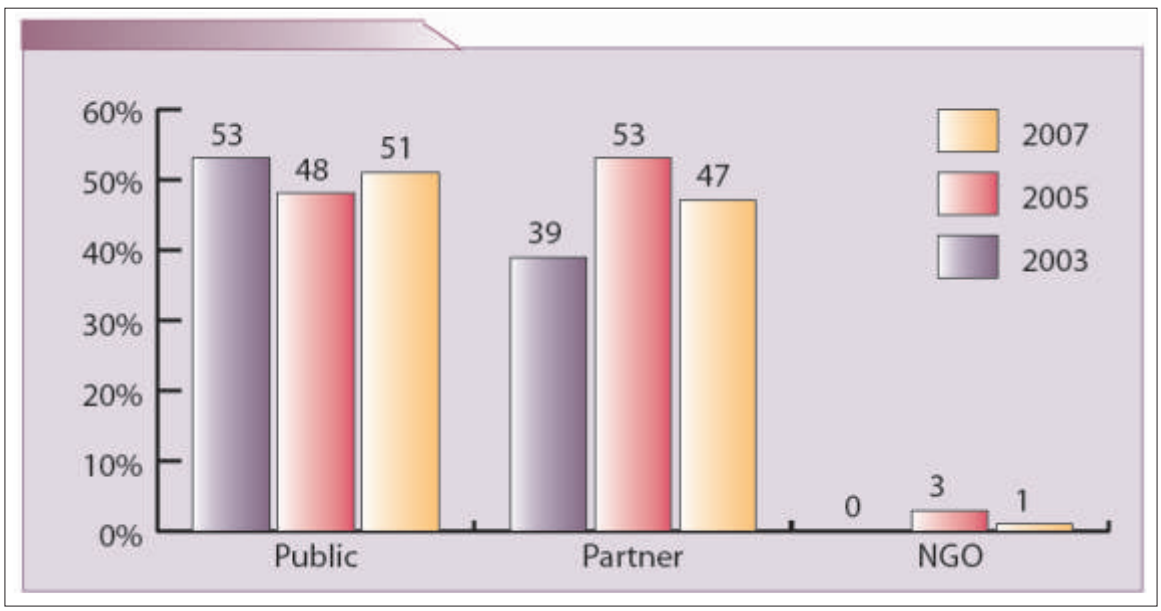
Fig 7. Affiliation of National Reference Laboratories (2003–2005–2007)



Funding

The increase in funding for HIV and AIDS activities in low and middle income countries during this decade is beginning to yield fruit. There are signs of progress in HIV health response demonstrated by the drop in the annual number of AIDS-related deaths, from an average of 2.2 million in 2005 to 2 million in 2007. In spite of this, long-term political commitment is required for the continuity of laboratory supplies, staff loyalty and annual strategic reviews. Figures 8 and 9 show that funding from the public sector for NRLs increased slightly from 48% to 51% between 2005 and 2007, suggesting greater government involvement during the period.

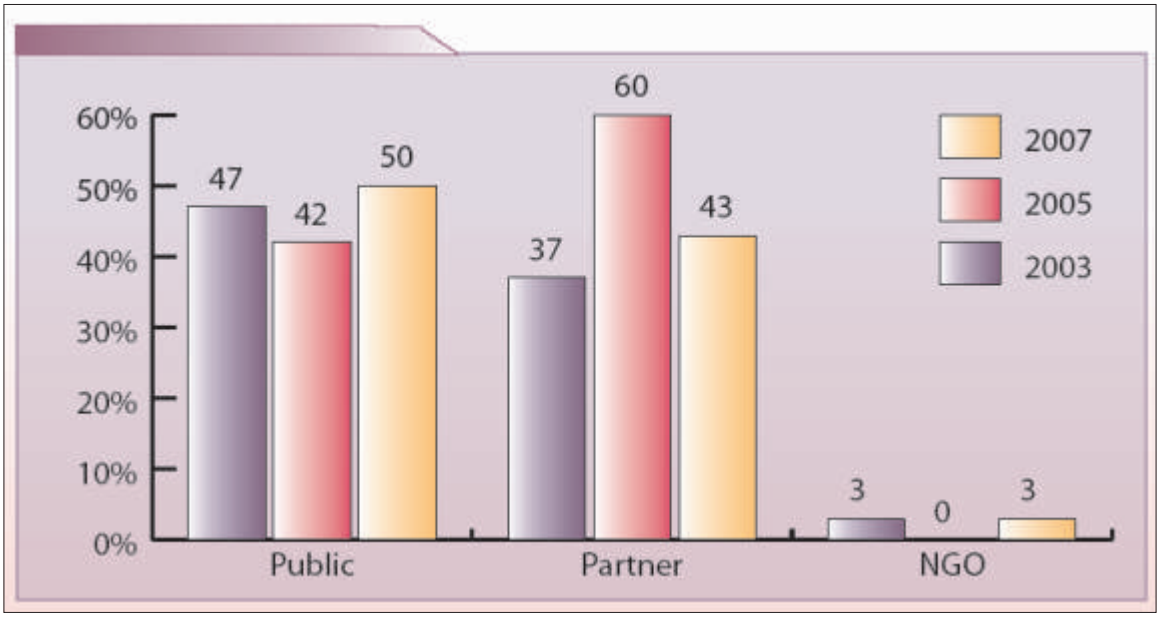
Fig 8. Level of Funding by Sector for National Reference Laboratories (2003–2005–2007)



Funding from partners dropped from 53% (2005) to 47% (2007). Most external funds were from the Global Fund which relies on local ownership, planning and expertise for its work; thus, most funds were channelled through governments. The GFATM strategy enables countries to design and implement their own programmes, on condition that funds are distributed only on the basis of proven efficiency. In the case of the GFATM-funded programmes, governments maintain ownership which allows countries to decide on how to use the funds in order to ensure the sustainability of programmes. Countries must ensure that budget allocations are realistic, covering not only the purchase of equipment and reagents but also transport, data entry, training, maintenance and quality assurance aspects of the testing process.

The level of funding from public and partner sources for activities of the public health laboratories within the tiered laboratory network is almost equal as illustrated in Fig. 9.

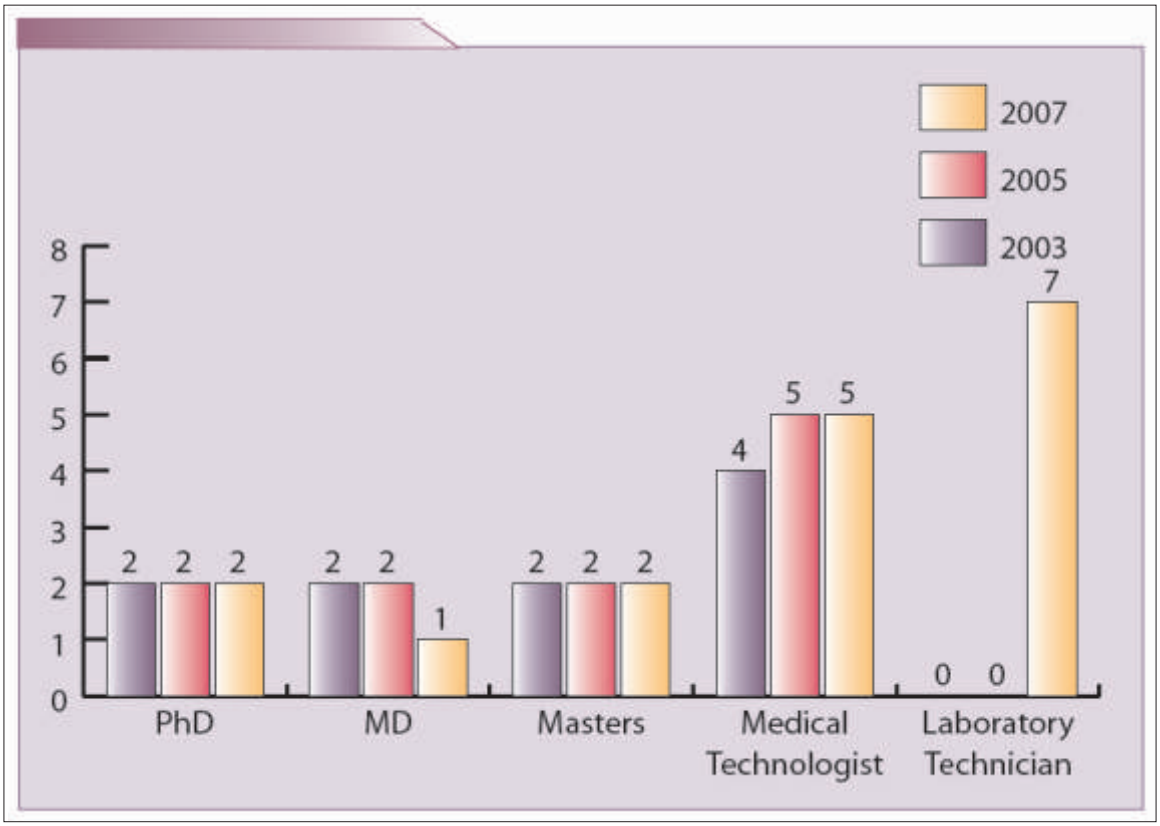
Fig 9. Level of Funding of HIV Public Health Laboratories by Sector (2003–2005–2007)



Personnel Training

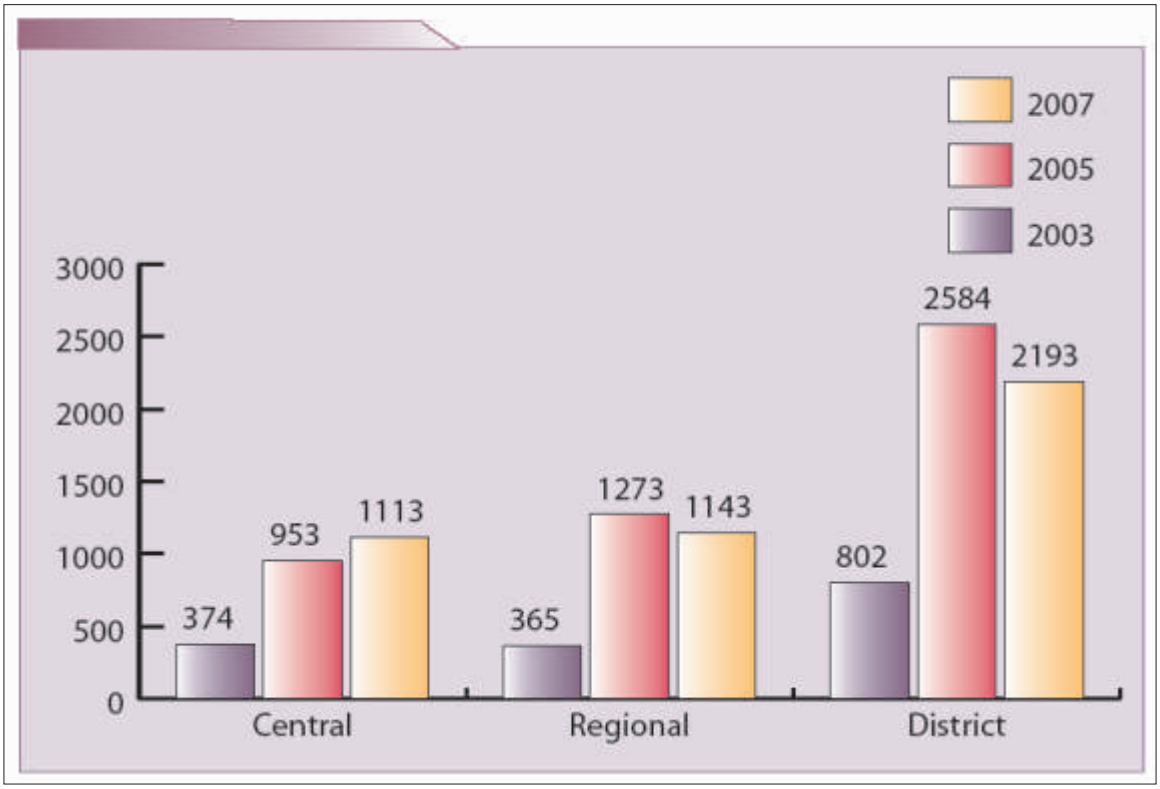
Human resources with the appropriate professional capacity represent the most urgent and most severe operational constraint facing the scaling up of services for prevention, treatment and care of HIV and AIDS in the Region. The loss of trained staff to the private sector, developed countries, and to illness and death from the epidemic itself is increasingly eroding the skills base of laboratories in the Region. The retention of skilled laboratory staff remains a critical component of quality assurance programmes. On average, two laboratory staff per facility hold a PhD, MD or Masters certification at NRL level in the 2007 assessment, and this has remained relatively stable since 2003 (Fig. 10). These statistics show the need to plan and implement policies regarding the recruitment and retention of qualified staff.

Fig 10. Average Number of Trained Laboratory Staff at NRLs



On the average, there were four to five medical technologists per facility working at NRLs in 2007, but the number of laboratory technicians has greatly increased since 2005. The average NRL has a total of 17 staff compared to 10 total staff in 2003. As the push towards decentralization of laboratory facilities heightens, the recruitment and retention of laboratory staff with all levels of education cannot be overemphasized.

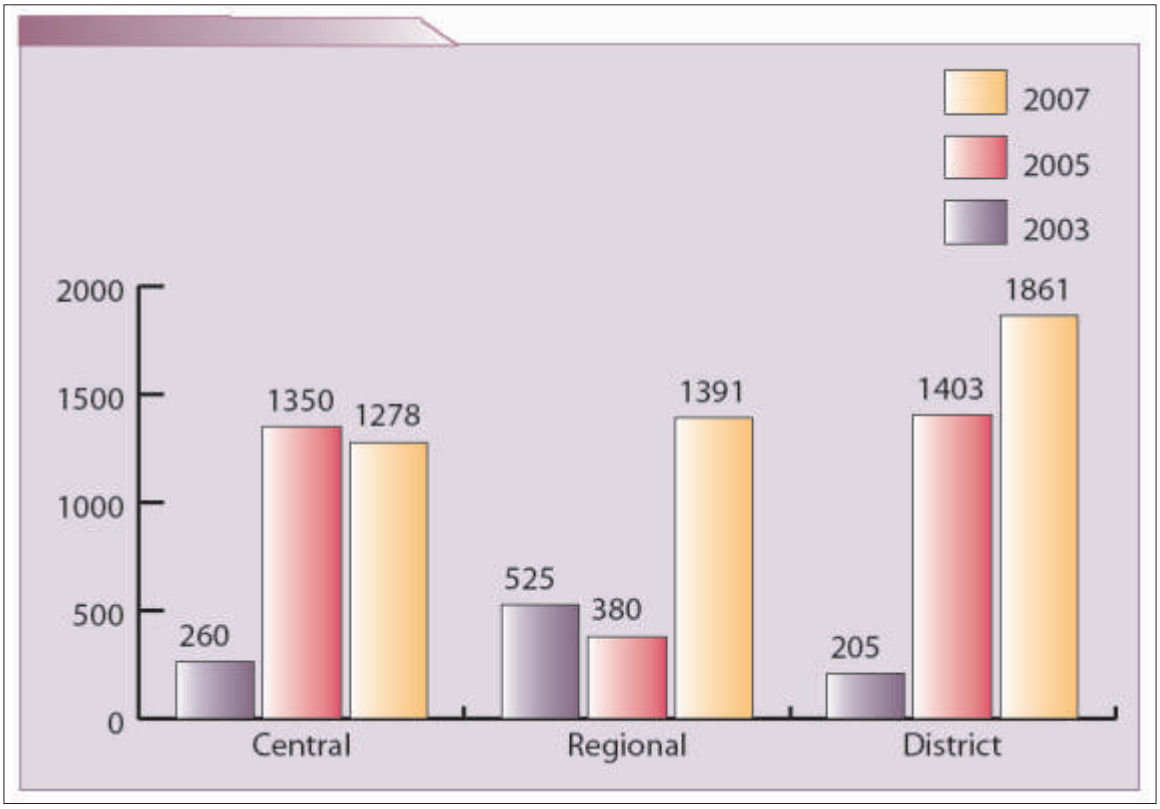
Fig 11. Laboratory Staff Trained in HIV Laboratory Techniques (2003–2005–2007)



The training of non-laboratory staff in HIV laboratory techniques is a key strategy for meeting the human resources shortfall for laboratory services (called "task-shifting"), particularly at district level and at primary health centres. Assays that do not require sophisticated laboratory equipment or technical expertise can be conducted at district level and primary health centres by existing health personnel. However, these people should be trained in testing procedures, proper collection and handling of specimens, and referrals to the higher level laboratories at the regional and central levels for more complex analyses. The clear establishment of standard operating procedures (SOPs) and the training of non-laboratory staff in quality assurance programmes is essential for ensuring that the quality of service is not compromised. Attention must be paid to both initial and on-going training of such staff to meet capacity needs in response to the increasing demand for laboratory facilities because of the rapid scaling up. Figure 12 gives the numbers of non-laboratory personnel trained over the past two years.

The Ministry of Health (MOH) in each country would do well to develop a standardized and certified training programme for both laboratory and non-laboratory staff in collaboration with training institutions.

Fig 12. Non-Laboratory Staff Trained in HIV Laboratory Techniques (2003–2005–2007)



Such training must be certificated and must include written examinations and a required demonstration of competency for laboratory techniques conducted by non-laboratory staff. Control systems should be put in place for continuous on-site monitoring of the competency of trained laboratory and non-laboratory staff in the use of SOPs, specimen handling and transport, interpretation of results based on national protocols and record keeping.

Countries should encourage personal capacity development of all staff through:

Training – Make training of medical and laboratory technicians a top priority within HIV and AIDS action plans for laboratories, workplans and budgets. Support basic training institutions, strengthen continuing education (in-service, refresher, and up-grading of skills) and support supervision;

Upgrading skills – There is a need to task-shift and upgrade the skills of nurses and other health professionals to conduct basic laboratory techniques, particularly at district level and primary health centres;
Widen the provider network – Harness existing resources of qualified personnel within non-state sectors, the private for-profit and not-for-profit sectors at the regional and district levels;
Adequate wages and benefits – Address issues of conditions of service, remuneration, performance based incentives and benefits, and physical working conditions for retention of qualified staff;
Workplace HIV and AIDS policies – Institute workplace HIV and AIDS policies; develop and implement occupational health policies that ensure comprehensive protection of laboratory staff and promote measures to reduce risk factors.

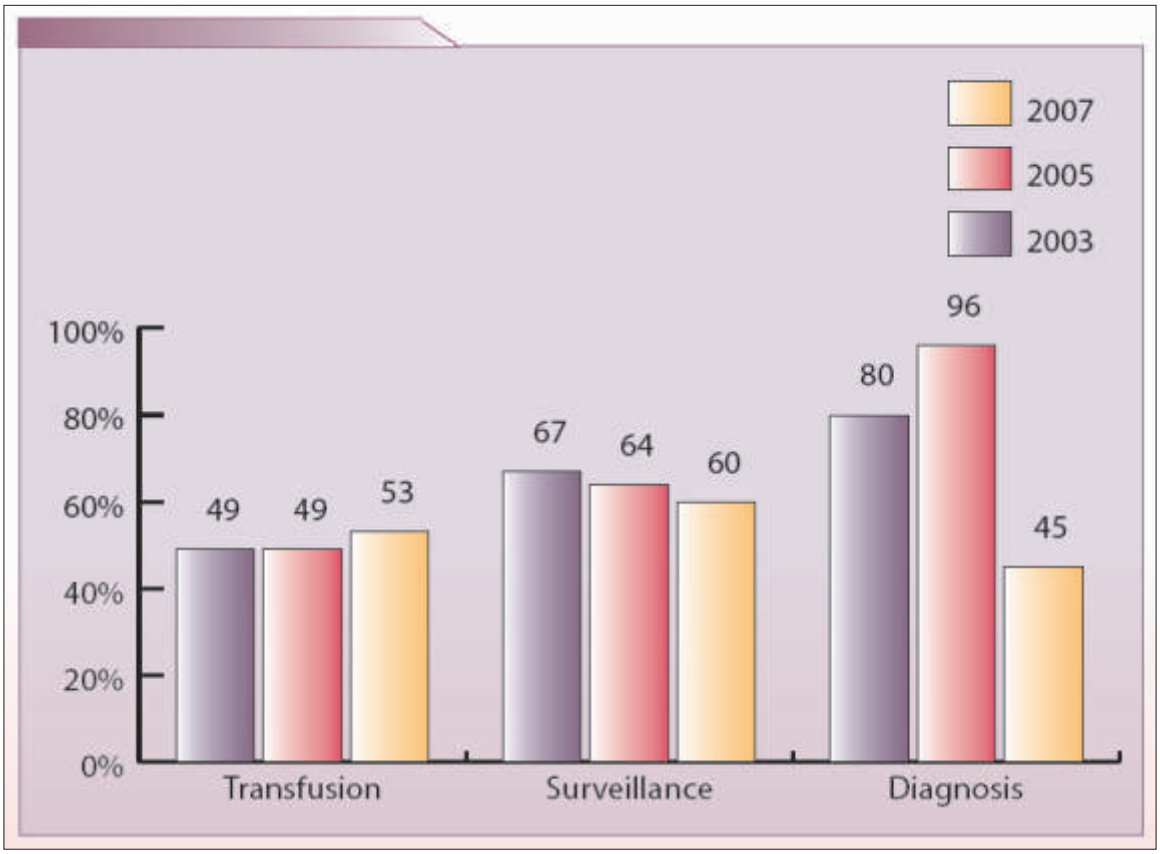
2.4 Laboratory Services

Testing strategies

Antibody assays for HIV testing were first recommended by WHO in 1992 and revised in 1997 (WHO, 1992, 1997). Choosing the most appropriate testing strategy at any time depends on the objective of testing (blood safety, surveillance, diagnosis) and the HIV prevalence in the population to be tested. The new developments in HIV testing technologies, the scaling up of HIV testing in support of Universal Access and the trend towards HIV testing outside traditional laboratory settings (in primary health centres) have necessitated a review of the WHO/UNAIDS HIV testing strategies. In addition, available data confirmed a 50% decrease in the use of WHO recommended testing strategies for diagnosis from 96% (2005) to 45% (2007) (Fig. 14). This may have arisen because many countries have not developed the recommended testing strategies to suit their environment. A lack of confidence in the testing strategies may have also led to unnecessary testing. This review was being done at the time of the publication of this report and is scheduled for release in 2009.

A lot of effort must be put into sensitizing governments on the development and use of national testing strategies adequate for country-specific environments. The use of recommended WHO testing strategies for transfusion activities increased from 49% to 53% but dropped slightly from 64% to 60% for surveillance activities (Fig. 13).

Fig 13. Proportion of Countries Using Appropriate WHO Testing Strategies (2003–2007)



Parallel or serial testing strategies are also methods that can be used to confirm HIV detection. For parallel testing, the same specimen is tested simultaneously on two different assays and the results, if found to be concordant, are reported. If found to be discordant, however, further testing is required. Serial testing refers to a specimen being tested using a highly sensitive assay and if found to be reactive, the specimen is further tested using a second highly specific assay. If the results are found to be concordant, they may be reported. If they are found to be discordant, further testing is required. It is readily accepted that serial testing is the most cost-effective manner to perform testing and particularly in the periphery i.e. primary health centres. Parallel testing may be used in certain situations, such as during labour and delivery, where time needed to produce results is critical to save a life.

HIV serological diagnosis

Testing is one entry point for accessing services and support for HIV prevention and PMTCT in particular. It is also useful for effective diagnosis and treatment of opportunistic infections, initiation of ART and ensuring blood safety. Serological tests for detecting HIV antibodies are generally classified into three formats: enzyme immunoassays (EIAs) or enzyme-linked immunoassays (ELISAs), simple/rapid assays and confirmatory assays (such as Western blot and line immunoblots). HIV testing plays a significant role in ensuring Universal Access to treatment and care.

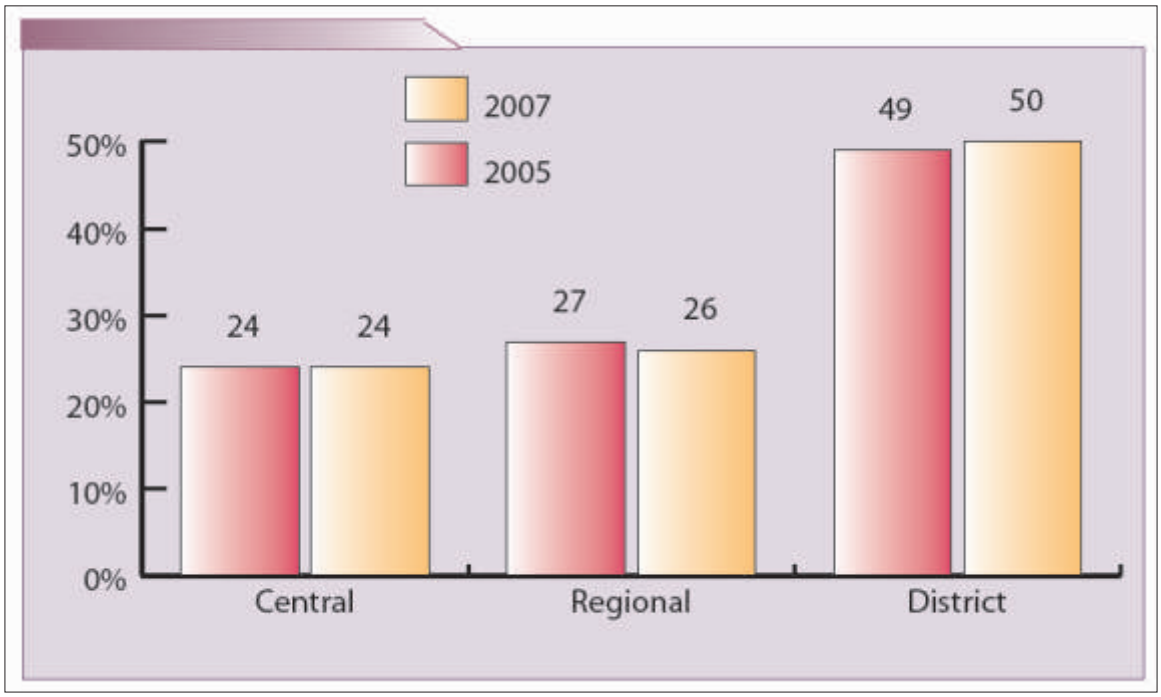
In the African Region, the success of managing HIV and AIDS strategies will largely depend on well-organized decentralized HIV testing services. Some suggested tasks that national laboratory managers need to perform for the appropriate management of district and health centres are the following:

- establish systematic planning and information management systems, including financial planning, forecasting for procurement and supply chain management;
- create public awareness and use of client- and provider-initiated tests and counseling services, while employing social marketing approaches, community participation and the involvement of PLWHA;
- ensure quality assurance on simple/rapid assays at all levels for all service providers and training all staff;
- apply supplies management skills to assist countries and suppliers to adequately forecast and procure testing supplies based on lead times and population needs;
- institute realistic testing policies and the use of WHO recommended testing strategies at national, regional and district levels;
- provide technical support at all decentralized levels;
- institute national listing of all stakeholders and sectors (public, private, NGOs) involved with HIV testing and streamline their respective procurement policies and activities;
- find out pricing and policy from manufacturer, pricing information available to countries and bulk purchasing capacities (national and international).

In resource limited settings, the tiered laboratory network is recommended in addition to certain test menus and capabilities necessary for the diagnosis and treatment of HIV and AIDS. These capabilities are developed and updated regularly by WHO. Also, WHO advocates that HIV antibody testing be available at all levels of care in each country.

Findings from the assessment show that district level laboratory HIV antibody testing is twice as frequent as that of regional level laboratories (Fig. 14). This indicates that decentralization of testing services is useful and should be sustained. Thus properly functioning HIV laboratory networks that operate efficient referral systems should be priorities in the decentralization process that is currently taking place in laboratory services in the African Region.

Fig 14. Proportion of HIV-antibody screening activity by level of laboratory (2005–2007)



Enzyme-linked immunoassay (ELISA)

ELISA tests are the most widely used HIV screening assays worldwide, but they are best suited for analyzing large numbers of specimens on a daily basis, as with blood transfusion screening services. The correct use and interpretation of these tests depend on the availability of adequate laboratory equipment, an adequate cold chain system and skilled technicians. Unfortunately, these tests do not currently constitute a viable serological screening method for laboratories below the central and regional levels because of the resource inputs required. What would be useful at this stage of Universal Access is the decentralization of laboratory services and development of instrument-free testing alternatives that will increase accessibility and affordability of HIV testing at all levels.

In 2005, 28% of public laboratories (26 countries) used ELISA in more than 50% of laboratories in the public sector. The percentage dropped from 28% to 17% in 2007 (Fig. 15).

Fig 15. Proportion of Countries with >50% of Laboratories Using ELISA Across Sector (2003–2007)

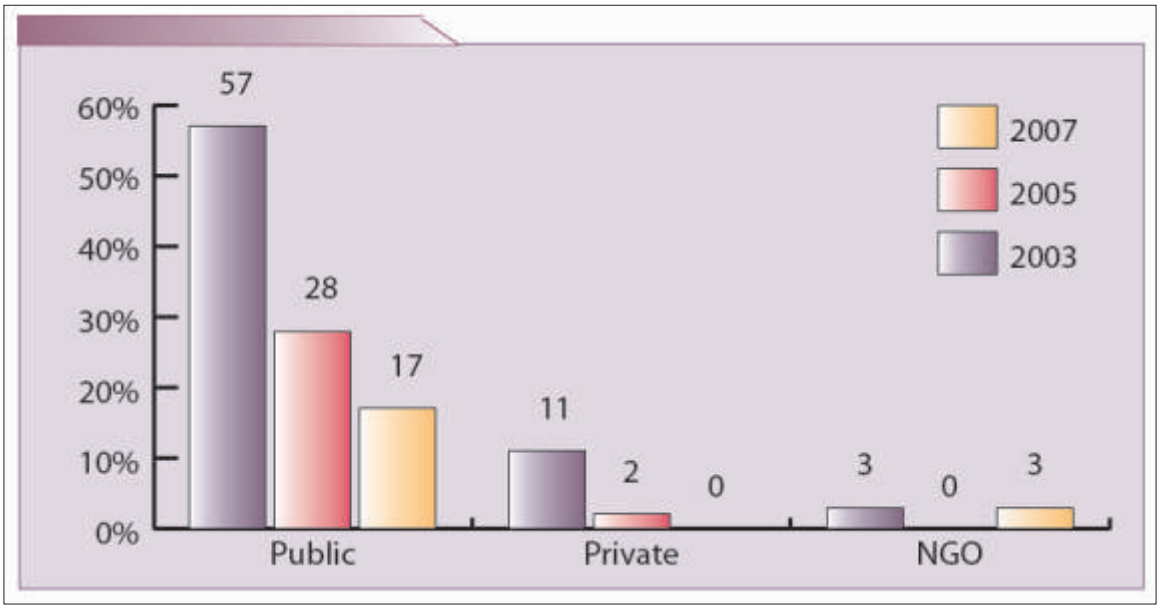
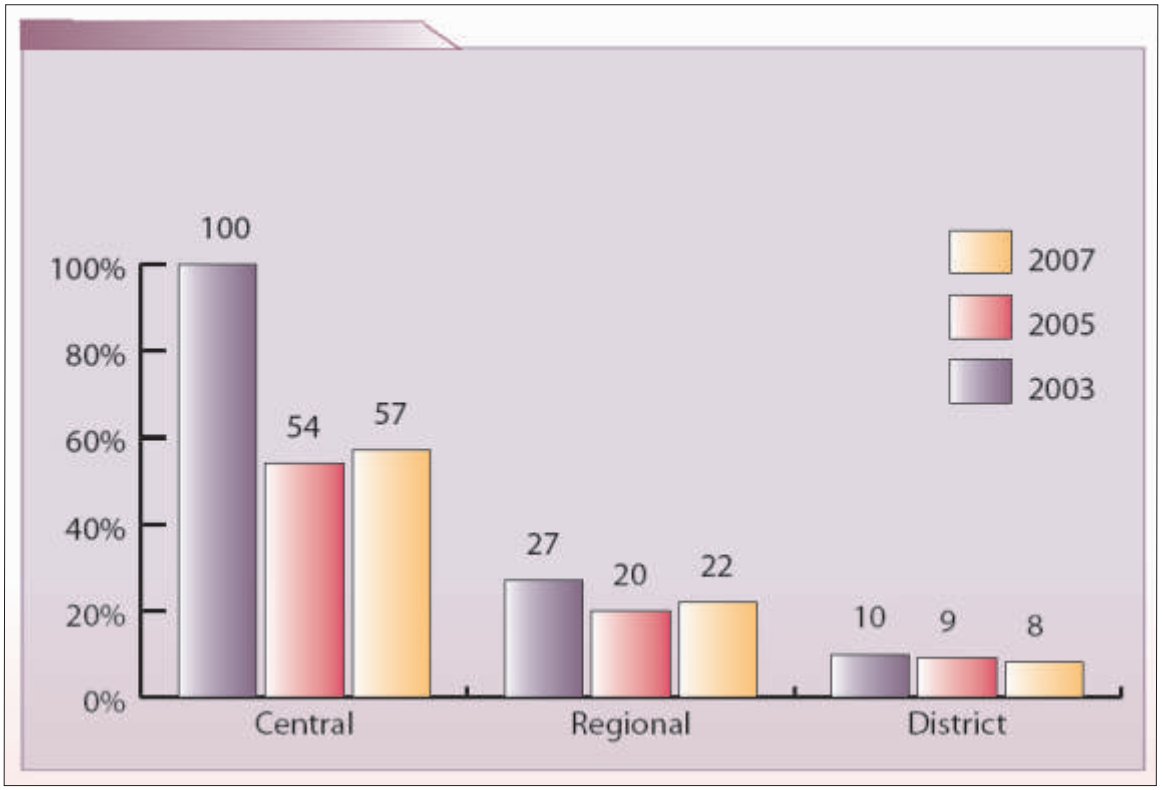


Figure 16 shows that very few ELISA tests (8%) were conducted at district compared to central (57%) and regional (22%) laboratories. Also a few more ELISA tests were used for HIV testing in 2007, both at central (3% more) and regional level (2% more) than in 2005. The reason is that most district laboratories use simple/rapid assays for their work and not ELISA.

Fig 16. Use of ELISA Test by laboratories Health Care Level (2003–2005–2007)



Simple/rapid assay

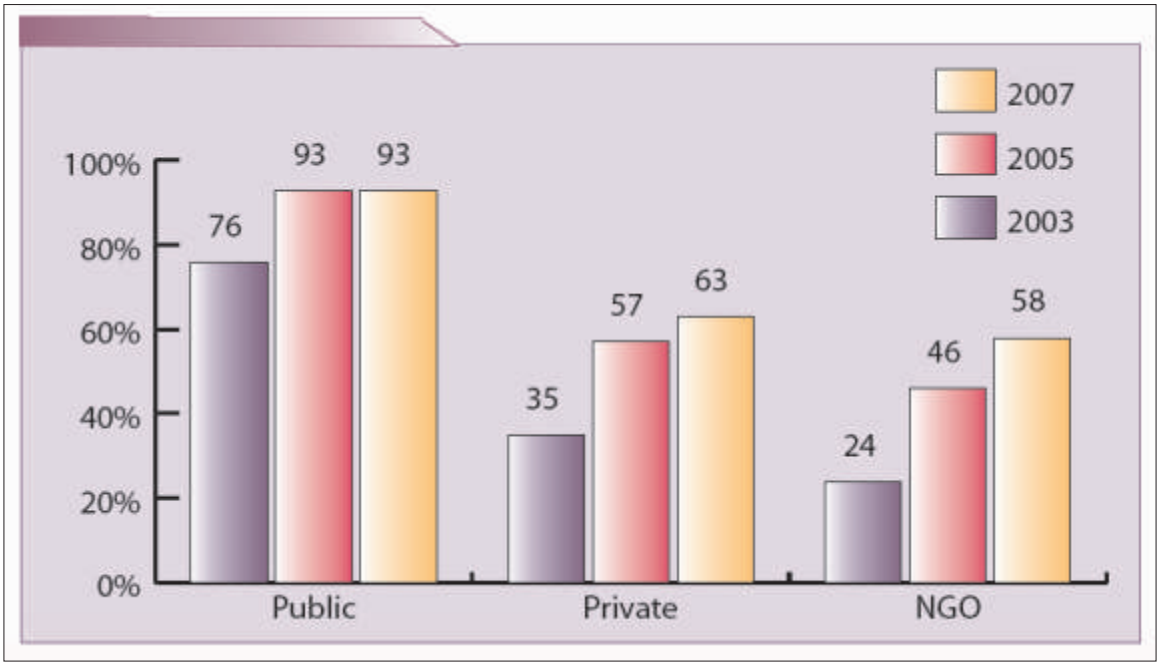
The simple/rapid assays are instrument-free tests that employ single-use, disposable devices that may be used for directly testing whole blood specimens, serum, plasma or oral fluids for antibody to HIV. Simple/rapid assays can be performed by non-technical laboratory staff and do not require complex equipment. They are considered resource-effective methods for HIV testing at community level such as Primary Health Care (PHC) centres.

Figure 17 shows an increase in the proportion of countries using rapid assays for HIV testing in more than 50% of their laboratories in all the sectors. In 2003, 76% of laboratories used simple/rapid assays compared to 93% in 2005 and 2007. One can infer that the simple technology employed for simple/rapid assays and ease in training staff to perform tests may have accounted for the increase.

This correlates with data from Figure 12 on the large number of non-laboratory staff trained to perform tests at the district level. It may also be because of the reduction in the number of trained laboratory staff as well as material resources needed to conduct laboratory-based assays.

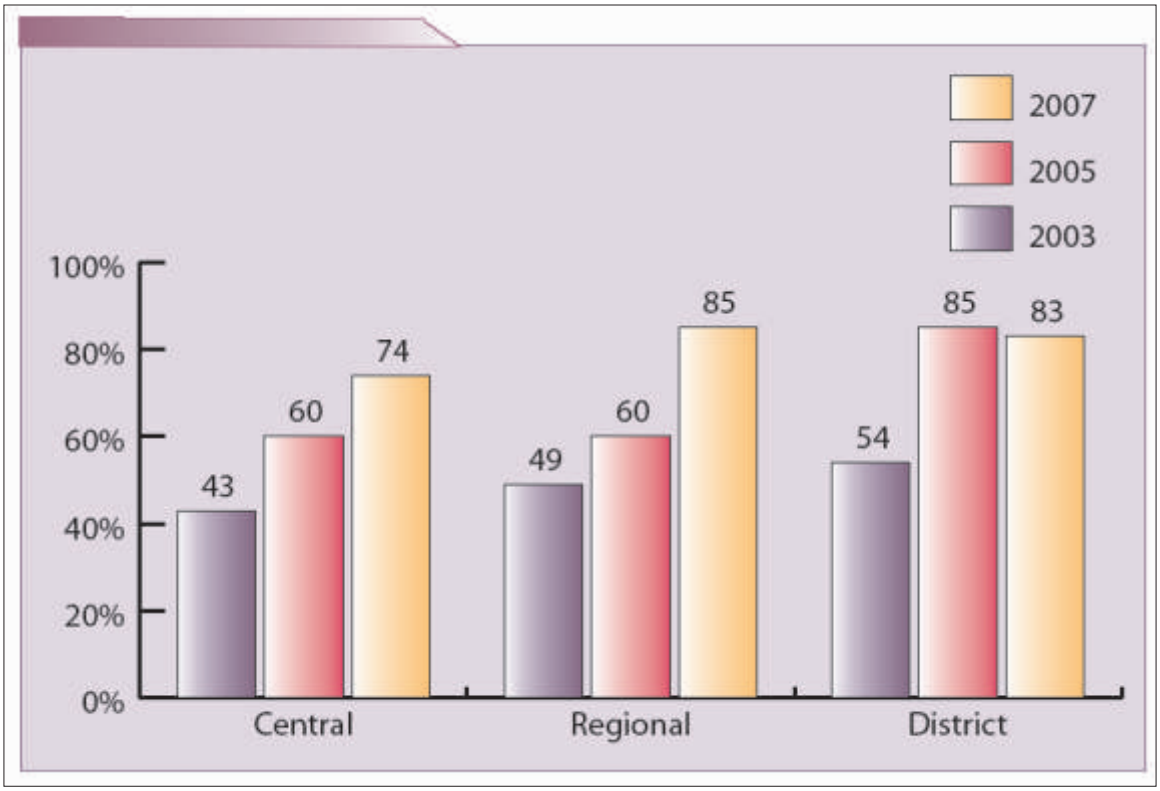
There were slight increases in the use of simple/rapid assays for serological diagnosis of HIV in the NGO and private sectors, but the public sector percentage (93%) remained the same in 2005 and 2007 (Fig. 17).

Fig. 17. Proportion of Countries with >50% of laboratories Using Rapid Assays Across Sectors (2003–2005–2007)



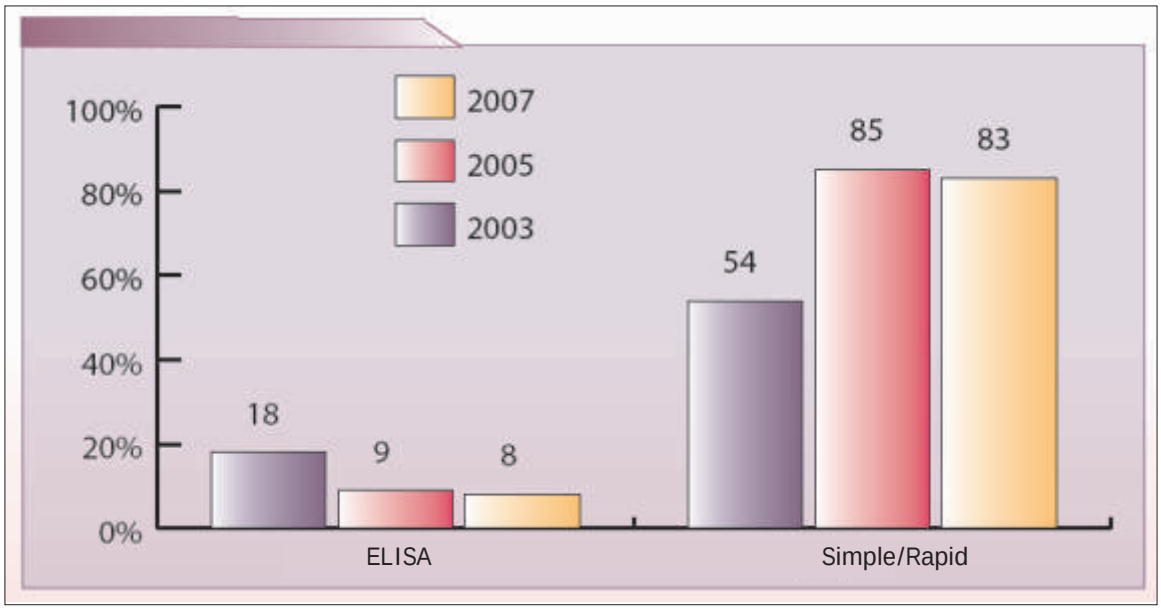
There were increases in the use of simple/rapid assays at the central level (Fig. 18) but a 2% decrease at the district level. This suggests that governments and partners in the sector are making use of more cost-effective and less resource-intensive serological tests for rapid scaling up towards Universal Access.

Fig 18. Use of Rapid Test by laboratories at various levels (2003–2005–2007)



These findings reveal that the use of simple/rapid assays has gone up while use of ELISA has decreased in the African Region in all three sectors in the five-year period. The marked increase in the use of simple/rapid assays between 2003 and 2007, especially when compared to the decrease in the use of ELISA, suggests that communities had greater access to HIV testing services in the African Region during this period. This is a positive finding in the scenario depicting decentralization of laboratory services required for Universal Access to HIV and AIDS in the African Region.

Fig 19. Percentage Level of Testing Methods used at District Level (2003–2005–2007)



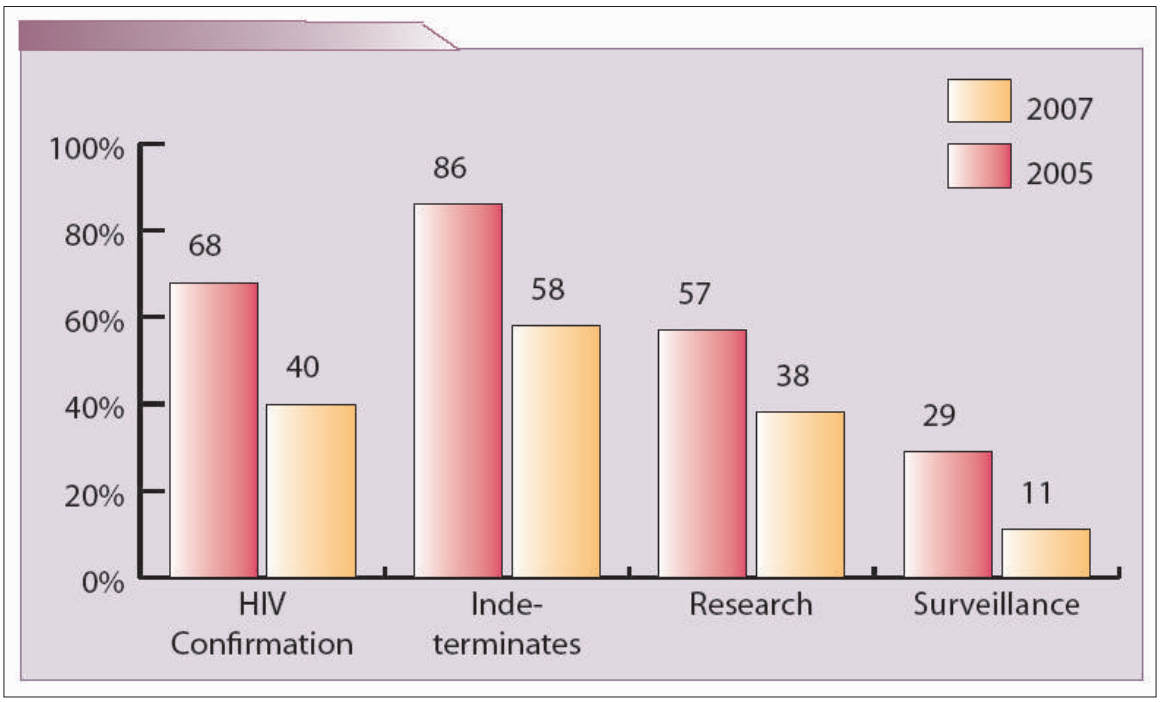
Confirmatory assay

The conventional algorithm for diagnosing HIV involves screening tests like the simple/rapid assay or ELISA with reactive ones being confirmed with more specific assay tests such as a Western blot (WB) or line immunoblot. However, the limitations of the confirmatory assay have become obvious with advances in serological diagnostic technology. The main limitations are:

- The WB is expensive and requires technical expertise.
- The WB could yield indeterminate results with certain types of specimens resulting in uncertain diagnostic significance.
- Both ELISA and WB are time-consuming and require well-equipped laboratory facilities.

Alternative screening algorithms are now being used instead of the confirmatory tests. The trend is to use a combination of simple/rapid assays or a combination of simple/rapid assay and ELISA tests. The findings in Figure 20 show a decrease of 28% (68% to 40%) in the proportion of countries using the WB confirmatory assay for HIV in the two years.

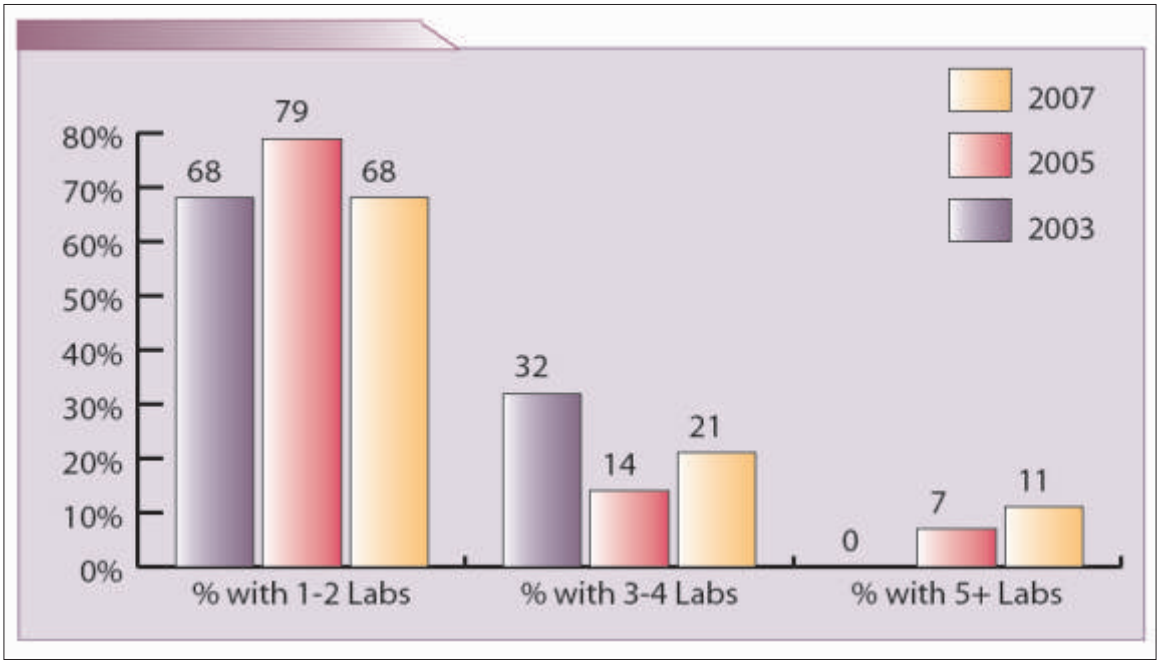
Fig 20. Percentage of Countries using WB test by circumstance (2005–2007)



P24 antigen testing

P24 is a soluble antigen produced by HIV that is important in resolving HIV indeterminate specimens and in the diagnosis of HIV in infants under 18 months (when an immune complex dissociation [ICD] step is incorporated). The assay is an instrument-based EIA that requires cold chain storage for reagents. For this reason, P24 testing is a useful diagnostic tool at regional and central level laboratories but not at district level or lower. Figure 21 shows the percentage of laboratories that conducted P24 testing during the period. A lot of effort has been put into raising the capacity of laboratories to conduct P24 antigen testing from 2003 to 2007. The percentage of laboratories that conduct P24 testing has increased from 0% to 11% in countries that have more than five laboratories.

Fig 21. Proportion of laboratories Conducting P24 Test (2003–2005–2007)



Immunological testing

The need for appropriate cost-effective laboratory monitoring of HIV infection and the efficacy of ART regimens is an ever-present challenge in all strategies used in managing HIV and AIDS. One of the biggest challenges facing national laboratory programmes has been the ability to process large volumes for CD4+ T-cell enumeration. For instance, the South African national programme had to expand the number of laboratories capable of performing CD4+ cell enumeration in less than one year from 3 to 22 to meet this need. This was done during the scaling up of the national programme in response to "The 3 by 5 Initiative". CD 4+ T-cell enumeration is a useful tool for:

- determining when to put an individual on ART in the absence of AIDS-defining clinical illness/syndrome signs;
- assessing the degree of immune deterioration and speed of progression towards AIDS;
- deciding the timing of prophylaxis for opportunistic infections;
- monitoring the effectiveness of treatment regimens and candidate vaccines.

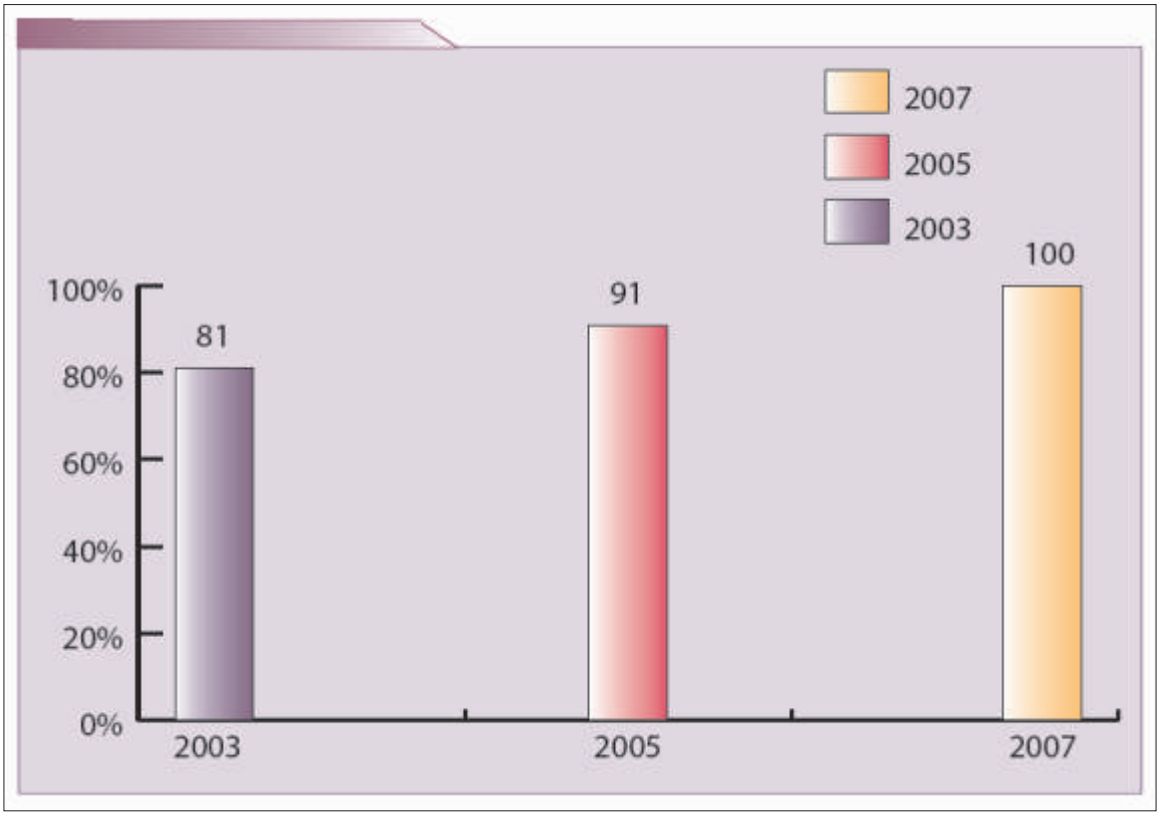
When planning for appropriate technologies to use for HIV testing, countries should take into consideration the following factors:

- targeted population that need to be monitored with CD4+ T-cell analysis (adults versus children);
- current and future estimated number of specimens to be processed daily;
- laboratory infrastructure at each level;
- capacity of laboratory staff;
- cost and availability of technical support and maintenance.

In resource-limited settings, WHO recommends that CD4+ T-cells counts should be conducted upon seropositive diagnosis of HIV (at baseline) and every six months thereafter. For this to be achieved, appropriate technologies must be identified for CD4+ T-cell enumeration at central, regional and district levels.

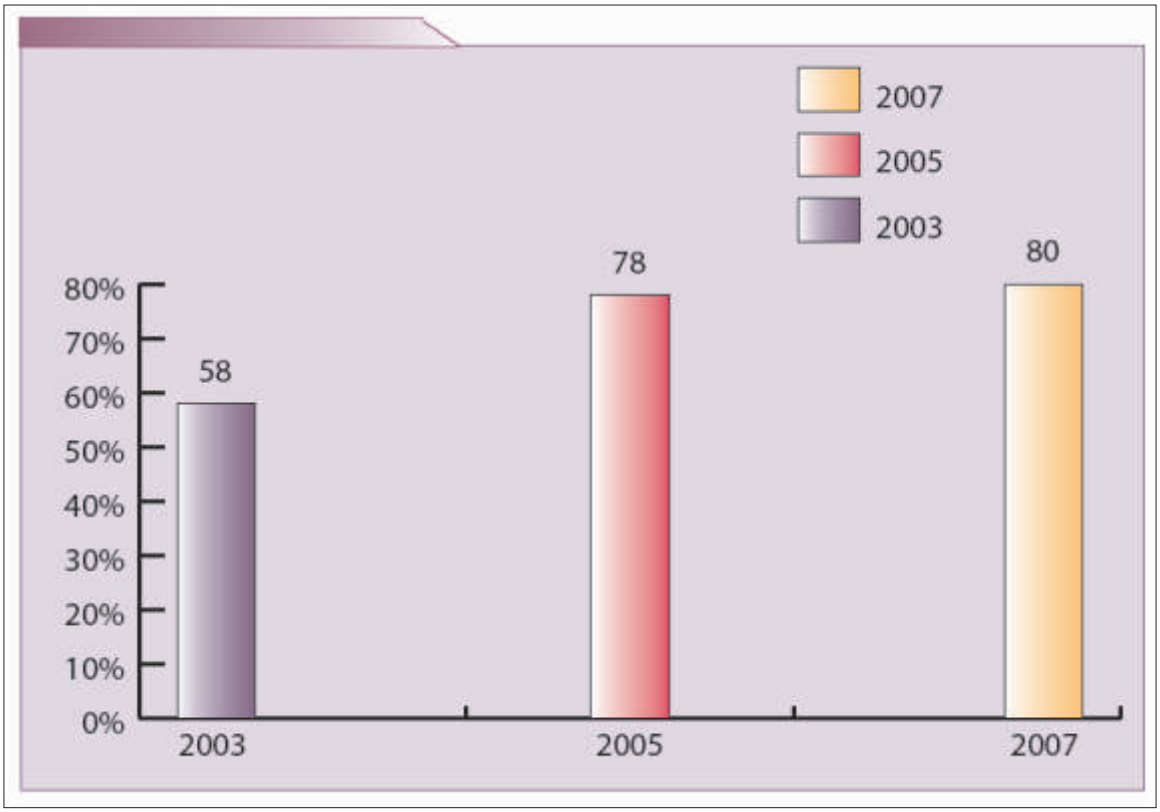
With the assessment, all the respondent countries reported that they are now able to perform CD4+ T-cell enumeration. This is shown by the steady increase in the number of countries that performed it from 81% in 2003 to 91% in 2005 and 100% in 2007 (Fig. 22).

Fig 22. Percentage of Countries Performing CD4 Counts (2003–2005–2007)



Secondly, on average, 80% of countries performed more than 100 tests per month in 2007, a slight improvement over the 2005 figure of 78% (Fig. 23).

Fig 23. Proportion of Countries Performing More than 100 CD4 cell Counts Per Month (2003–2005–2007)



Even though it appears that most laboratories performing CD4+ T-cell count were at the regional level in 2005 (Fig. 24), there has been a significant increase (14%) in the number of district laboratories performing the test. This could be attributed to an increase in the capacity of staff and the number of district facilities that perform the test.

The majority of laboratories conducting CD4+ T-cell counts currently operate within the public sector. The apparently large number of laboratories performing this test reflects the large number of health facilities at the district level compared to the regional/provincial level. The 14% increase in the number of district laboratories conducting these tests is a very important achievement in the scaling up process as it implies that the community level also has access to CD4+ T-cell enumeration services and therefore the monitoring of ART.

Fig 24. Proportion of Laboratories Performing CD4 Counts by Health Care Level (2005–2007)

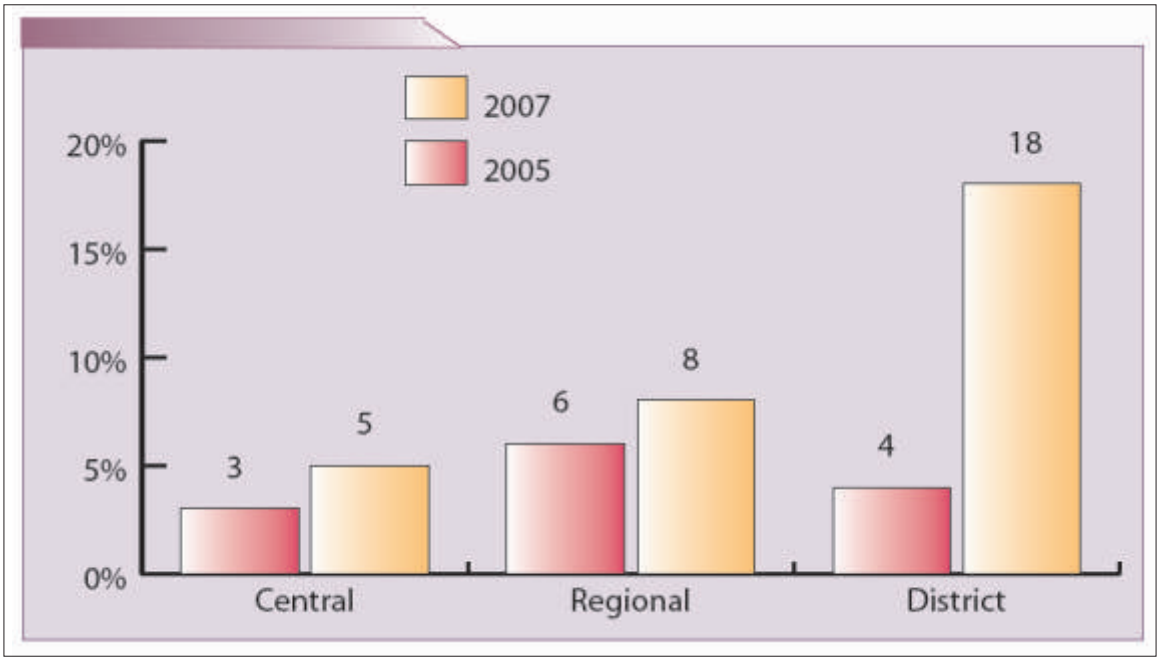
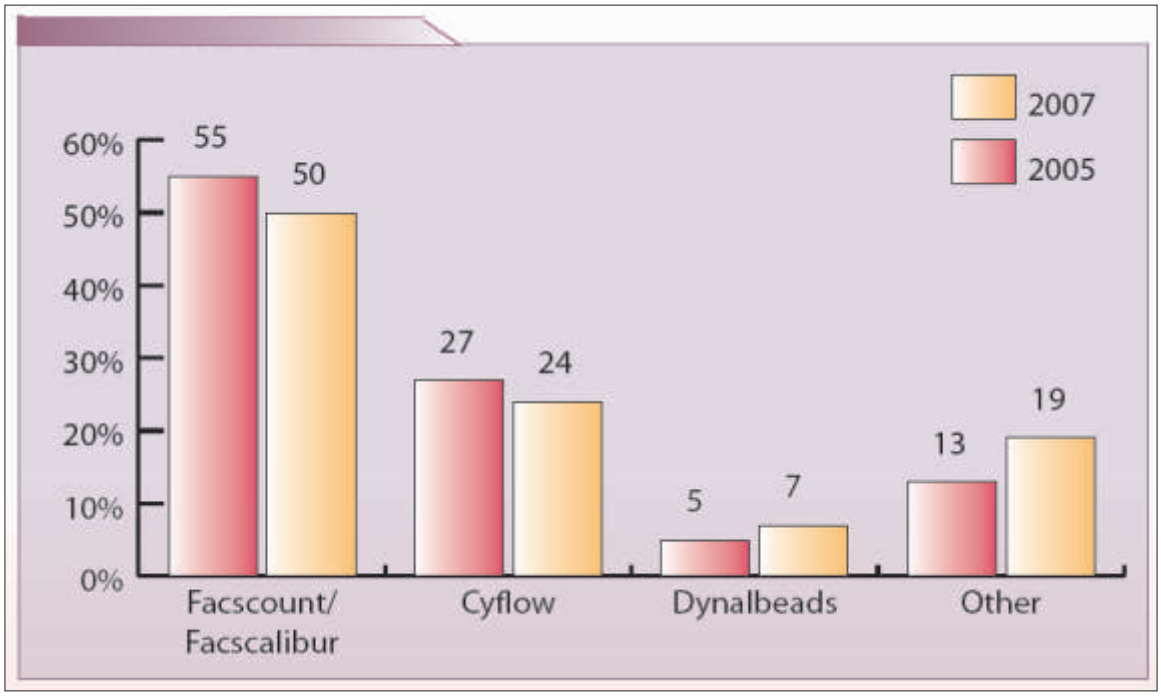


Figure 25 shows the availability of laboratory equipment by type used in performing the CD4+ T-cell counts. It shows that the majority (74%) of laboratories are currently using automated equipment for conducting CD4+ T-cell counts, such as dedicated flow cytometers (FACS Count, FACSCalibur and Cyflow). Only about a fourth (26%) of the laboratories use manual methods that require the use of a microscope or other equipment (such as Dynalbeads).

Fig 25. Percentage Type of Equipment used for CD4 Counts (2005–2007)



The Facscount/Facscalibur testing systems continued to be the equipment most frequently available for use. This may be because the system is designed and manufactured to automatically detect and flag error conditions and undertake all instrument checks; it also needs very little skill to operate.

HIV molecular methods

Molecular methods play an important role in HIV testing both in the diagnosis of HIV infection and in monitoring HIV infection in individuals using the quantitative determination of HIV viral load. Determination of viral load is useful in taking decisions on when to initiate ART and to assess treatment failure when it occurs.

Qualitative nucleic acid testing

The polymerase chain reaction (PCR) assay can be used qualitatively in diagnosing HIV through DNA and/or RNA detection. Diagnostic PCR is most useful in diagnosing HIV in infants as the presence of DNA/RNA can be detected at a time when the presence of maternal antibodies will render serological methods unsuitable. The proportion of countries performing diagnostic PCR assays increased slightly by 7% in the public sector and remained almost the same in the private sector over the two-year period (Fig. 26).

Fig 26. HIV PCR Diagnostic Services Available by Sector (2003–2005–2007)

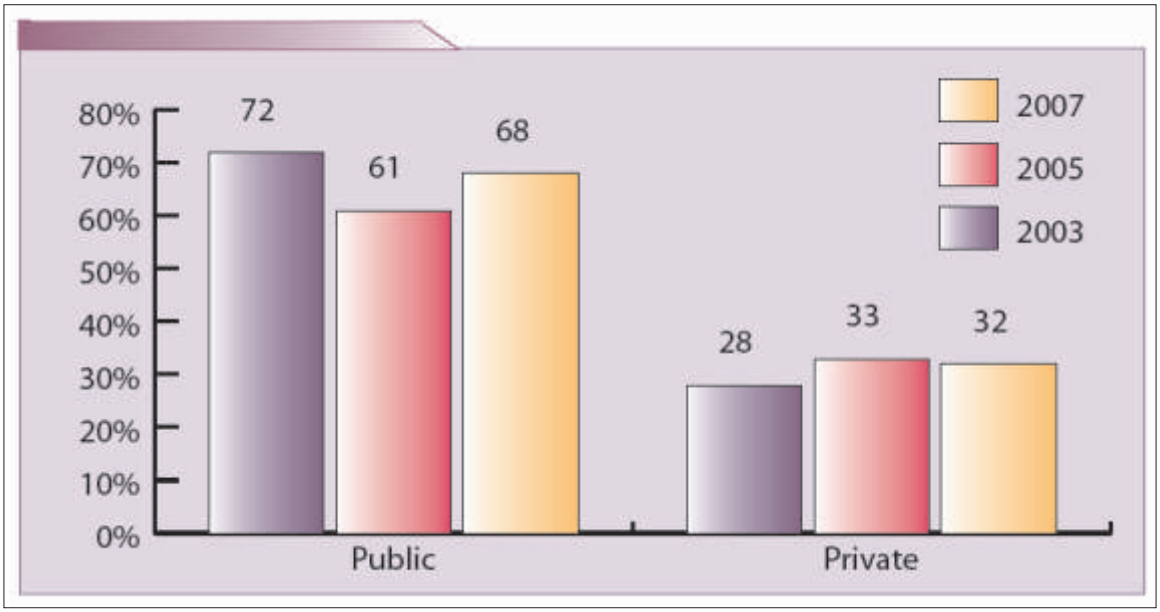
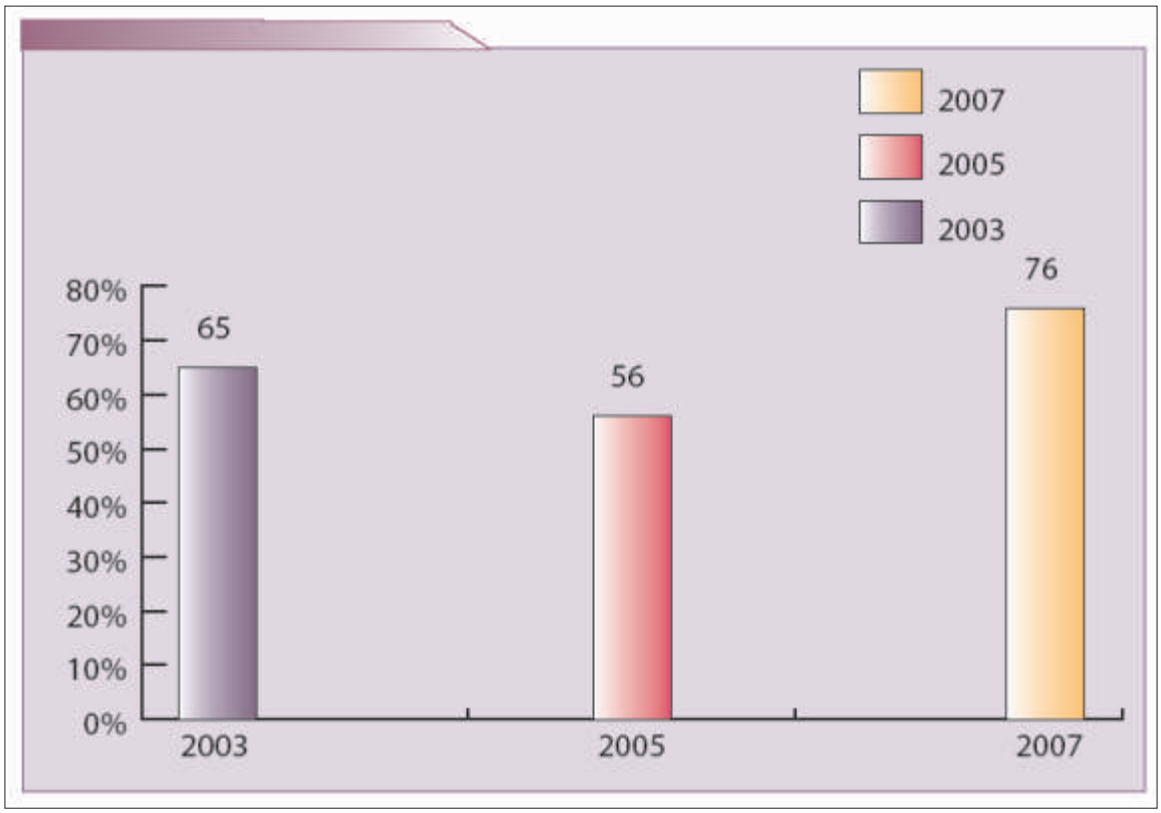


Figure 26 also shows that over two-thirds of the diagnostic PCR services are provided by the public sector and this has varied only slightly since 2003.

Also, the number of countries with adequate facilities required for PCR diagnosis has fluctuated between 2003 and 2007 (Fig. 27).

Fig 27. Proportion of Countries with Facilities for PCR Diagnosis (2003–2005–2007)

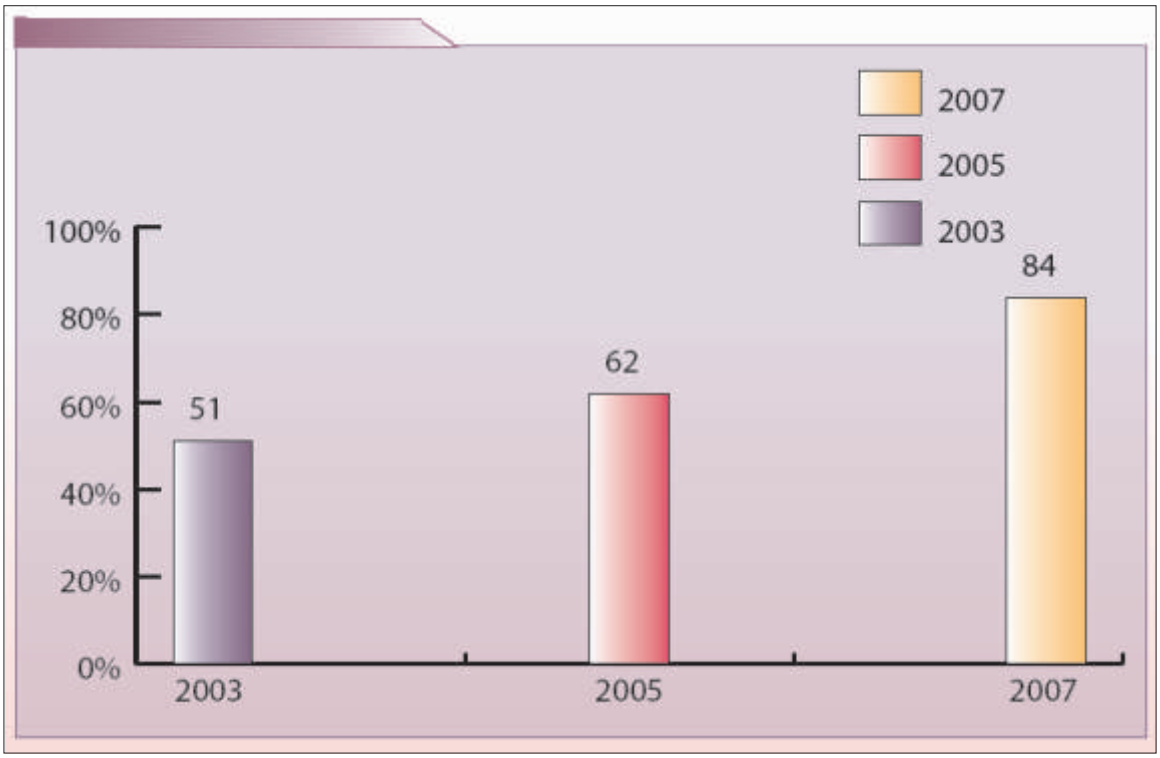


Quantitative nucleic acid testing

Viral load testing is a quantitative measure that shows how much HIV virus is present in the blood of infected individuals. In resource-limited settings, it may not be required by WHO as a criteria for initiating and monitoring of ART (WHO, 2004).

There has been a progressive increase in the number of countries performing this test (Fig. 28), from 51% in 2003 to 62% in 2005 and 84% in 2007; the increase mostly occurred at the central/regional level.

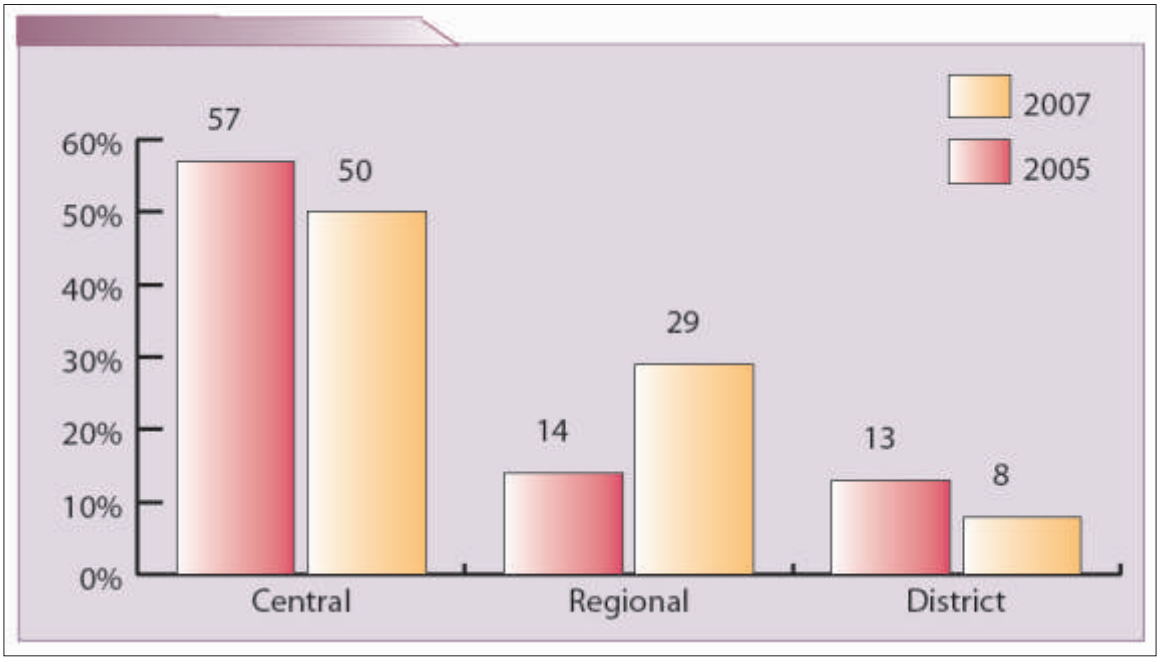
Fig 28. Proportion of Countries Performing Viral Load Test in 2003, 2005 and 2007



The number of laboratories per region/province that are able to perform viral load testing has increased by 22% (Fig. 29), with a corresponding reduction at the district level from 13% to 8%. Half (50%) of all the laboratories that undertake viral load testing are located at the central levels; 29% and 8% are located at the regional and district levels, respectively (Fig. 30). The regional level increase may be due to the fact that regional laboratories are the collecting points for all specimens from various districts. It is also likely that the lack of highly skilled staff and sophisticated equipment and infrastructure needed to perform the test may have caused some of the laboratories in the districts to stop using this method.

Given the required inputs, it is recommended that the test be limited to central level and regional laboratories only.

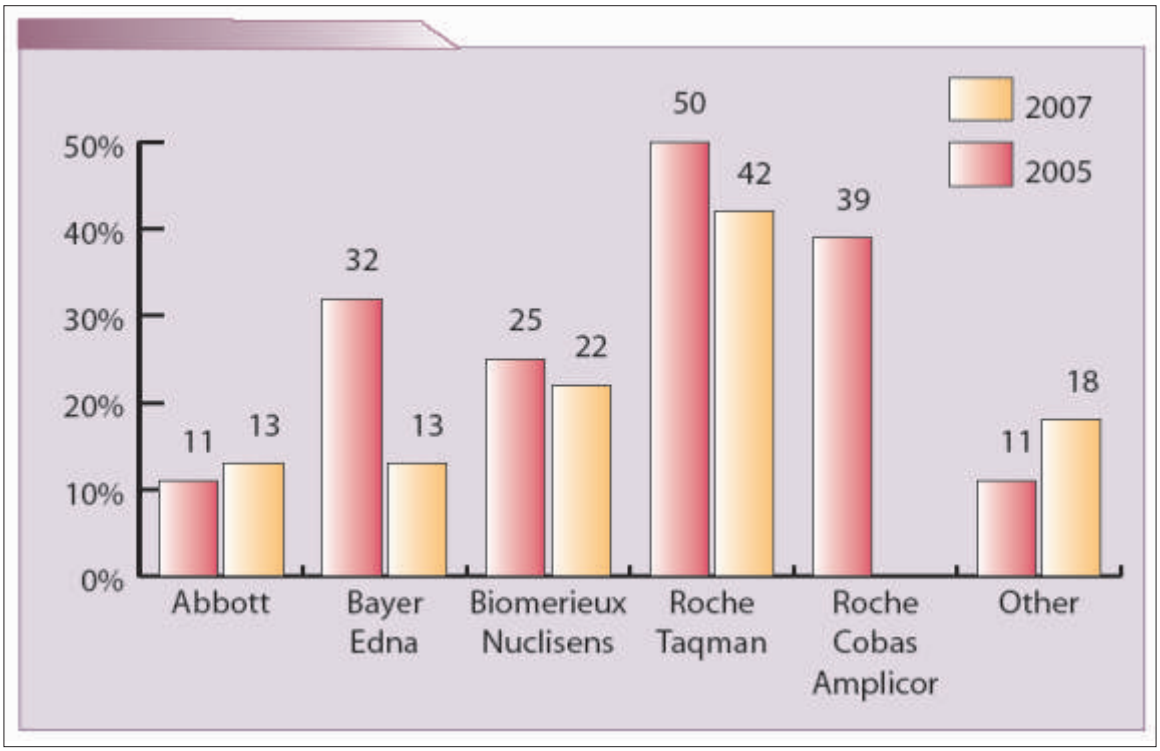
Fig 29. Proportion of Laboratories Conducting Viral Load Testing by Sector (2005–2007)



However, with the increasing numbers of individuals receiving ART, these complementary testing technologies will be needed at the regional and district levels in order to assess disease progression, determine when to initiate ART and monitor patients on ART.

Figure 30 shows that the most frequently used viral load assay in 2007 according to respondent countries was the Roche COBAS® TaqMan®. It represented 42% of all the kits used and was followed by the bioMerieux NucliSENS® assay with 22%. The Roche COBAS® AMPLICOR has recently been superseded by the Roche COBAS® TaqMan® system.

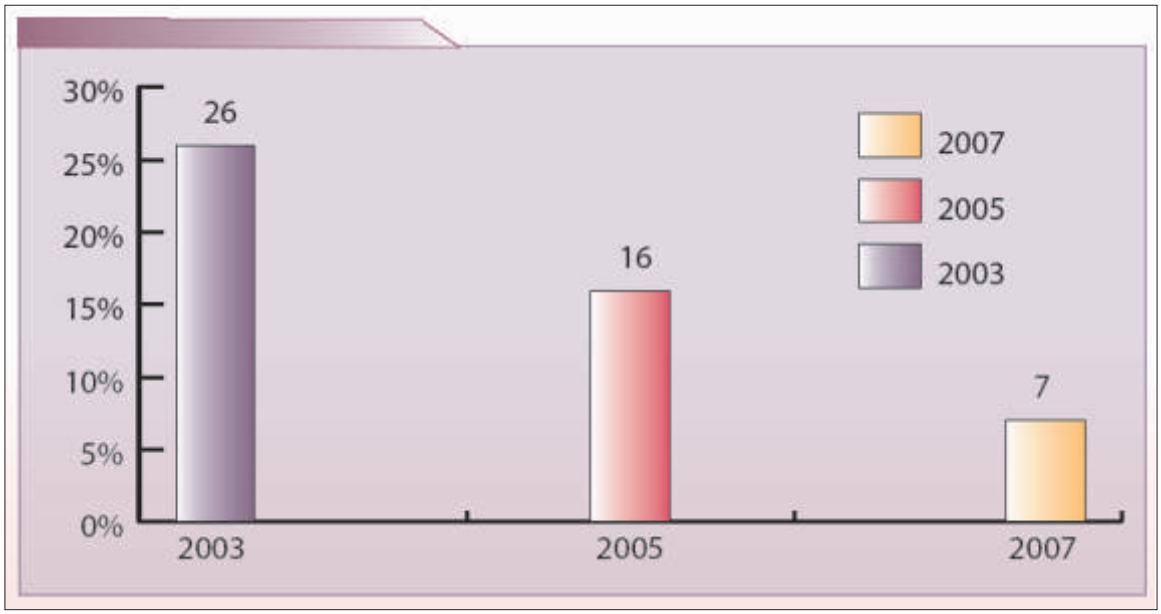
Fig 30. Frequency Distribution of HIV Viral Load Assays (2005–2007)



Heteroduplex mobility assay (HMA)

Heteroduplux mobility assay (HMA) testing is primarily used for vaccine research; it is costly and resource-intensive. The proportion of countries performing HMA has declined in the past five years, from 26% in 2003 to 7% in 2007 (Fig. 31). Because of its usefulness, it will be expedient for countries to mobilize resources to operate the HMA testing for vaccine research purposes as well as for the expansion of HIV prevention programmes.

Fig 31. Proportion of countries with HMA Testing Capabilities (2003–2005–2007)



2.5 Research and Development

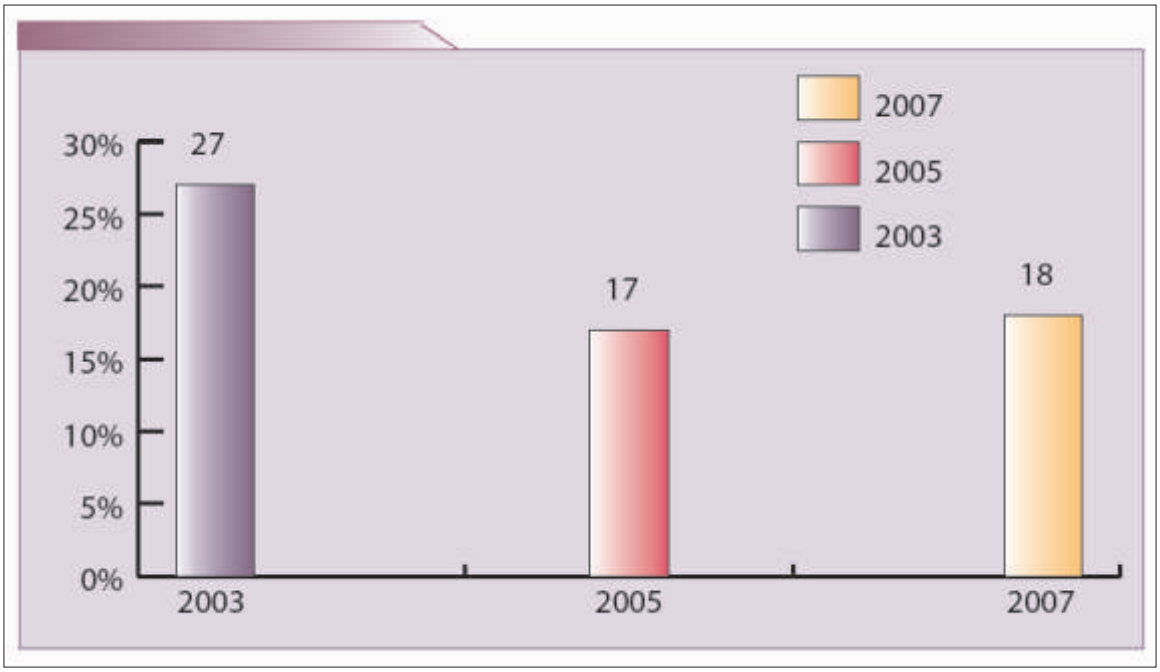
Research and development are critical in monitoring the progress of the HIV epidemic; in designing appropriate prevention, care and treatment programmes; and in the development of HIV vaccines. This section looks at what countries have done in HIV research and development.

HIV virus isolation and characterization

HIV virus isolation and characterization are research methods that have both immediate and future impact on the HIV epidemic. HIV viral culture may be used for isolating variants of HIV that may contribute to HIV drug resistance as well as for identifying variants within different geographical regions or demographic groups.

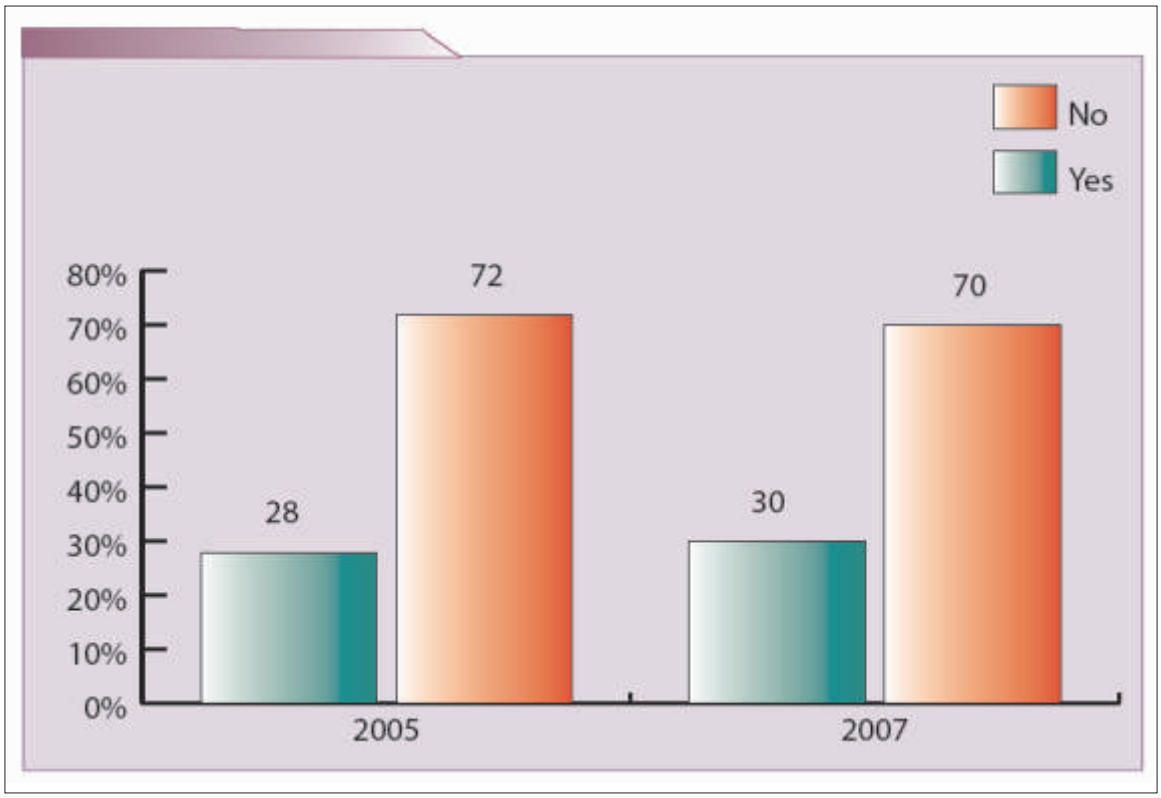
The proportion of countries performing HIV viral culture has decreased from 27% in 2003 to 18% in 2007 (Fig. 32).

Fig 32. Proportion of Countries Performing HIV Viral Culture (2003–2005–2007)



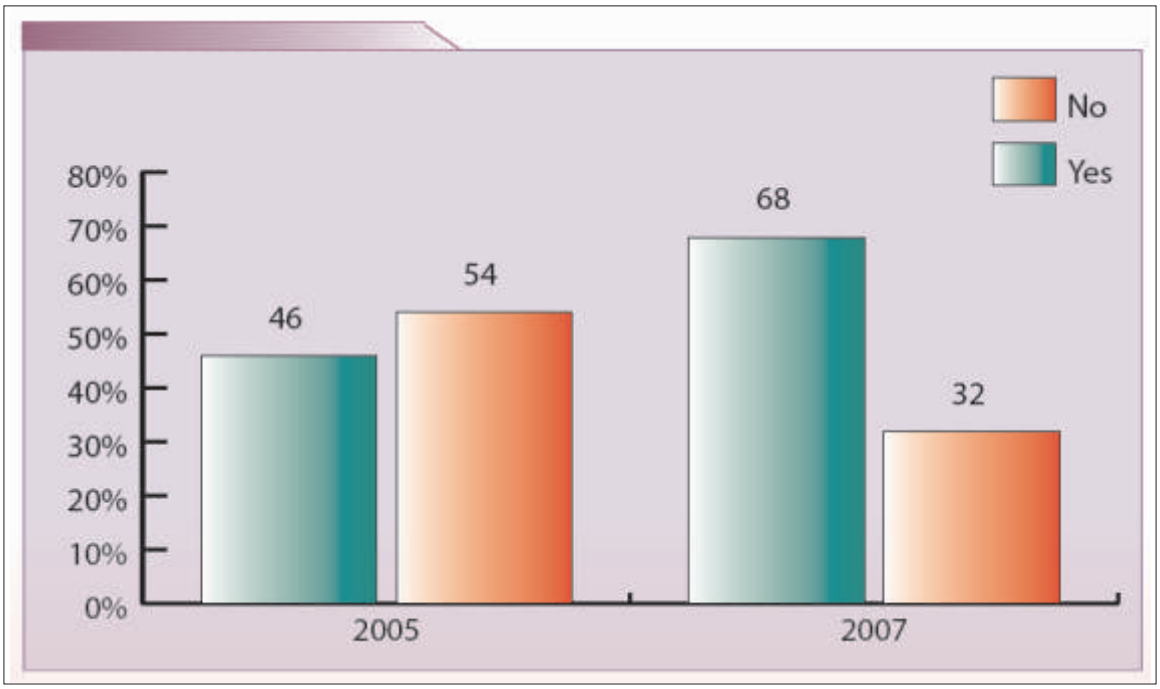
Assays for genotyping HIV are necessary components in HIV drug resistance monitoring. In the African Region, 14 (3%) countries reported that they were performing genotyping for HIV drug resistance (Fig. 33). The change of 2% between 2005 and 2007 is insignificant.

Fig 33. Proportion of Countries Performing Genotyping for HIVDR (2005–2007)



Of those countries that were not performing genotyping for HIVDR, 68% had plans to do so. The responses are shown in Figure 34.

Fig 34. Proportion of Countries Planning to Perform Genotyping for HIVDR (2005–2007)



The small number of countries that were employing these techniques may be attributed to the complex equipment and infrastructure as well as skilled personnel required for such assays. However, as access to ART increases in the Region, drug-resistant HIV strains may also emerge, thus threatening the effectiveness of treatment programmes. African countries therefore need the genotyping techniques for identification and isolation of drug-resistant HIV strains, in addition to the laboratory capacity to monitor CD4+ T-cells. Countries will also need national policies and plans to monitor drug resistance and genotyping for all institutions that will be performing the tests.

As a short-term measure, and given the complexity and resource-intensive nature of the required inputs, WHO and partners have helped to raise the capacity of one country in each subregion to carry out these tests. HIV viral isolation and characterization will become increasingly important at country level as scaling up continues and the number of individuals on ART increases. Therefore, countries will need to do human and laboratory capacity-building and establish partnerships and networks to support the use of these new complex technologies.

HIV Vaccine research, development and evaluation

Current HIV prevention and control programmes targeting affected populations may not be adequate and sustainable without due consideration being given to the development of research towards effective HIV prevention. A long-term goal would be the development of a safe and effective vaccine against HIV infection. Prominent among ongoing efforts in HIV vaccine research, development and evaluation are the WHO UNAIDS HIV Vaccine Initiative (HVI) and the African AIDS Vaccine Programme (AAVP).

It is vital for countries to develop a national plan for conducting and implementing HIV and AIDS vaccine research, development and clinical trials for the reasons listed below:

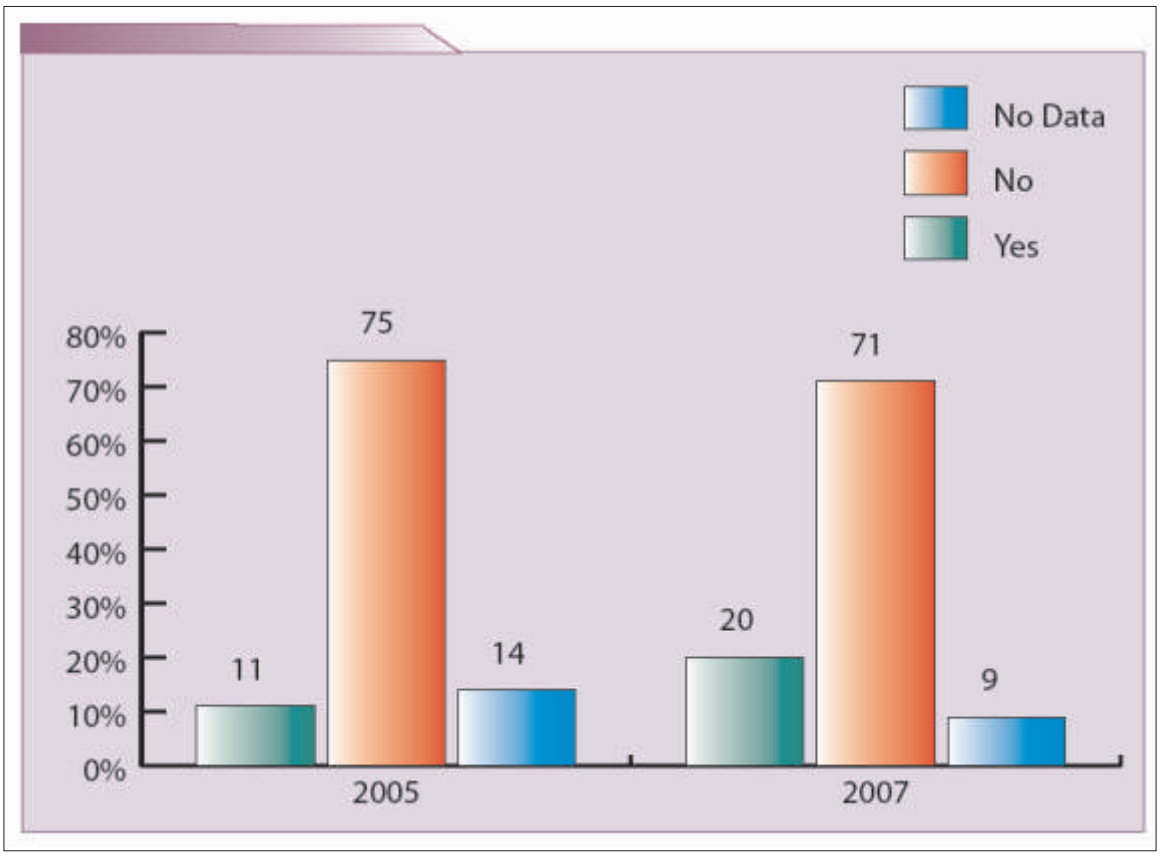
- National plans provide an opportunity to build consensus on a country's strategies for scientific, ethical, legal and regulatory frameworks in support of HIV vaccine research and development. Such frameworks are useful in future planning in accordance with international standards, and in the involvement of all stakeholders, including community participation.

- The development and existence of a national plan for HIV and AIDS vaccine research and development are likely to attract vaccine manufacturers, research collaborators and funding agencies that may wish to contribute by providing candidate vaccines, building local infrastructure, and transferring knowledge and technology to improve country capacity.

HIV vaccine trials are currently being conducted in seven (16%) of the 46 respondent countries in the Region: Botswana, Kenya, Nigeria, Senegal, Tanzania, Uganda and Zambia. In 2007, 20% of the countries were planning to conduct HIV vaccine research compared to 11% in 2005 (Fig. 35).

The greatest priority at present is the need for countries to develop national plans for HIV and AIDS vaccine research and development, which will provide the framework and necessary guidance for resource allocation as well as determine the feasibility of future initiatives.

Fig 35. Proportion of Countries Planning to Conduct Vaccine Trials (2005–2007)



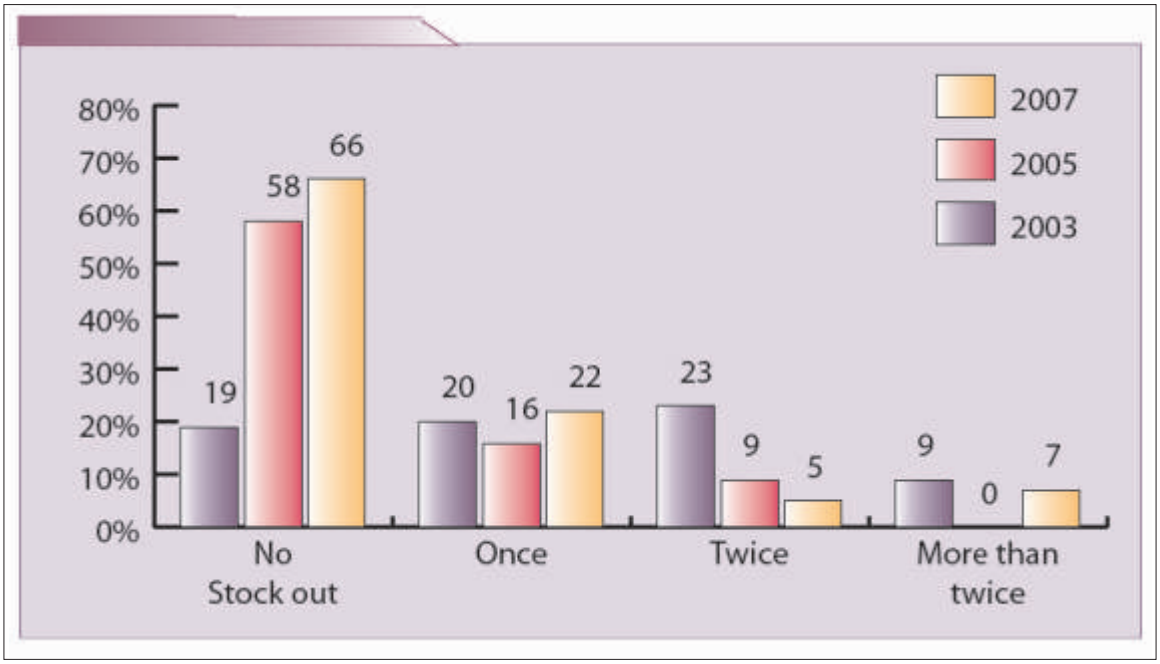
2.6 Laboratory Logistics

Reagent supply

Interruption in the reagent supply chain remains a constant threat to the provision of effective and high-quality services in the Region. The decentralization of laboratory facilities implies the need for scaling up reagent supply systems. It is encouraging that there is a steady decrease in HIV reagent supply interruptions over the past five years (Fig. 36). In 2003, 23% of countries reported at least two interruptions, with this number falling to 9% in 2005 and 5% in 2007.

No interruptions were experienced by 66% of countries in 2007, representing a significant improvement from 2003 when only 19% of countries reported no stock-outs. This is suggestive of better reagent management though some supply problems still exist in some centers (Fig. 36). This shift may be attributed to the increased awareness and involvement of stakeholders in the WHO HIV Test Kit Bulk Procurement Scheme. Initiated in 1989, the WHO Bulk Procurement Scheme aims to assist countries to access high-quality reagents at low cost through an easy purchase procedure that tends to minimize supply interruptions.

Fig 36. Proportion of Countries that experienced Reagent Stockouts (2003–2007)

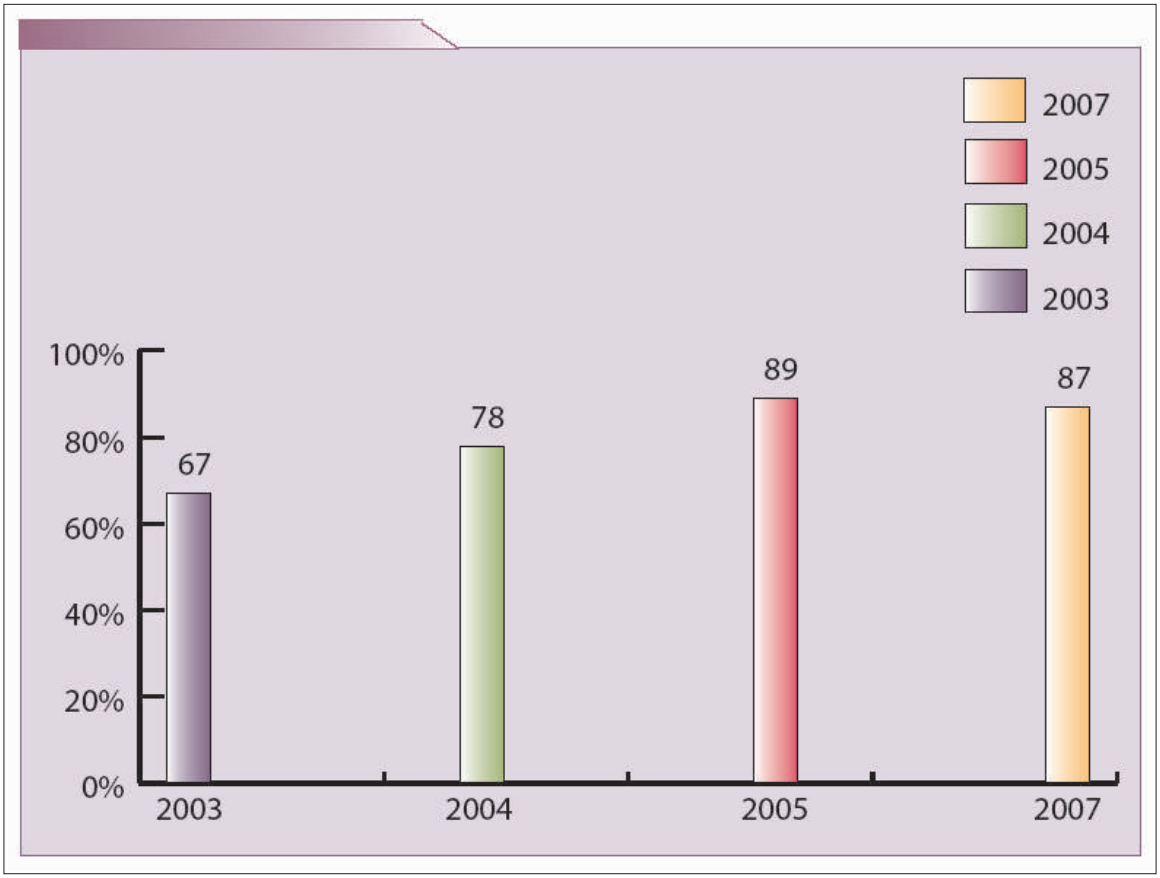


Additional procurement services offered through the United Nations Children's Fund (UNICEF), other UN agencies, commercial procurement agencies and GFATM have assisted countries to facilitate the consistent and well-planned supply of HIV reagents.

One other factor that may contribute to a drop in supply interruptions is the experience laboratory managers have gained in procuring reagents with the scaling up of activities.

When national testing algorithms are defined, the management of reagents can be more efficient. Figure 37 shows a progressive decrease in reagents stock-out among countries in which the NRL has a defined national testing algorithm. In 2003, 67% of countries had defined an algorithm for national needs and subsequently had less than two stock-outs. In 2007, 87% of respondent countries had less than two stock-outs in the presence of a national testing algorithm. The steady rise in effective procurement indicates that countries which define their national testing algorithm are becoming increasingly efficient at using it as a strategic tool for practical planning and commodity procurement.

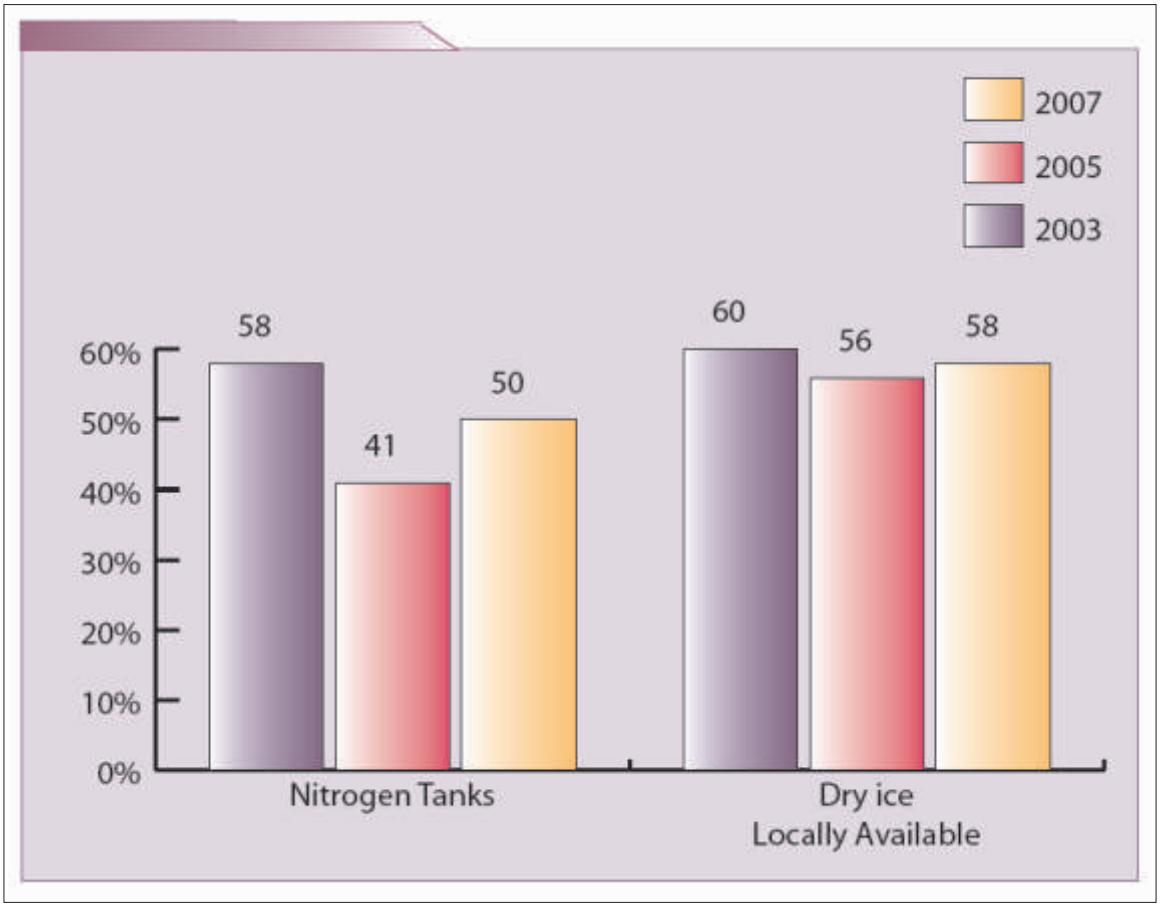
Fig 37. Proportion of NRLs Defining Algorithm of Screening for National Needs that Experienced < 2 Reagent Stock Outs (2003–2004–2005–2007)



Storage

The rapid expansion of testing services to the periphery of many countries necessitates the provision of storage facilities for specimens requiring more complex testing procedures that are not available at district level and below. The existence of adequate storage facilities is indispensable for maintaining the integrity of specimens until they can be sent via the referral mechanism to a higher level laboratory for testing.

Fig 38. Availability of Storage Facilities (2003–2005–2007)



The availability of locally available dry ice and nitrogen tanks during the past three years (Fig. 38) has stayed relatively stable. It is vital that this capacity be increased and sustained in order to improve the efficiency of the referral mechanisms within the laboratory network.

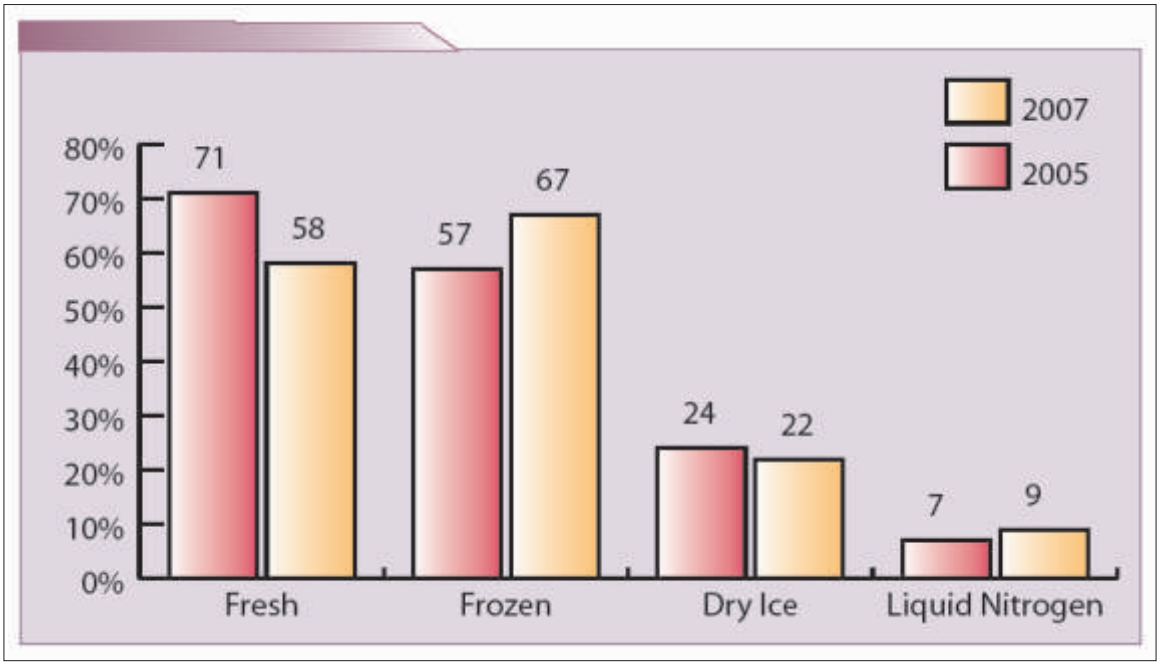
Transportation and shipment of samples

Given the ever-increasing capacity for diagnosis and monitoring services at district and lower levels, the ability to adequately store specimens and transport them in an efficient manner cannot be overemphasized.

Transportation of samples within country

The manner of transporting specimens within the Region has remained almost the same since the commencement of data collection in 2003, with the majority transported as fresh or frozen specimens, followed to a lesser extent by dry ice and liquid nitrogen (Fig. 39). What is not captured by these data are the reliability and integrity of the system for transporting the specimens as they are dependent on a number of factors. These factors include the accessibility of road networks during all seasons, the organization and dependability of the system of transport (i.e. number/type of vehicles in operation) and training of transport staff in maintaining timeliness and conditions for transporting specimens.

Fig 39. Conditions for Transporting in-Country Samples (2005–2007)

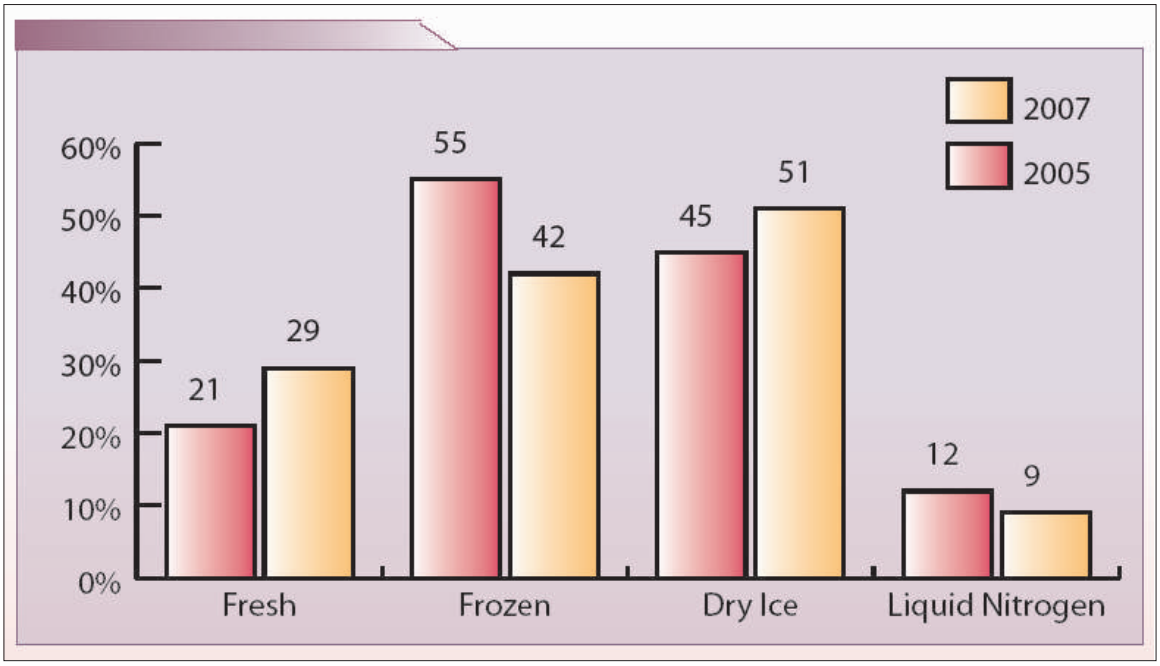


The data may indicate that in most countries, adequate storage facilities are available at the higher level testing facilities; however, with decentralization of testing, creation of storage facilities has not occurred at the same pace.

Transportation of samples out of the country

The conditions under which specimens are transported out of a country for further testing have remained almost the same for dry ice but have fallen slightly compared to other conservation methods.

Fig 40. Conditions for Transporting Samples Outside Country (2005–2007)



In line with standard procedures, specimens sent outside of the country are more likely to be transported on dry ice, or in a frozen state, rather than fresh. This assessment was not able to determine the effectiveness of these transport conditions. There is lesser capacity to send specimens within country than outside country, and efforts should be made to improve the overall transport mechanisms to ensure the effectiveness of referral mechanisms.

2.7 Quality Assurance

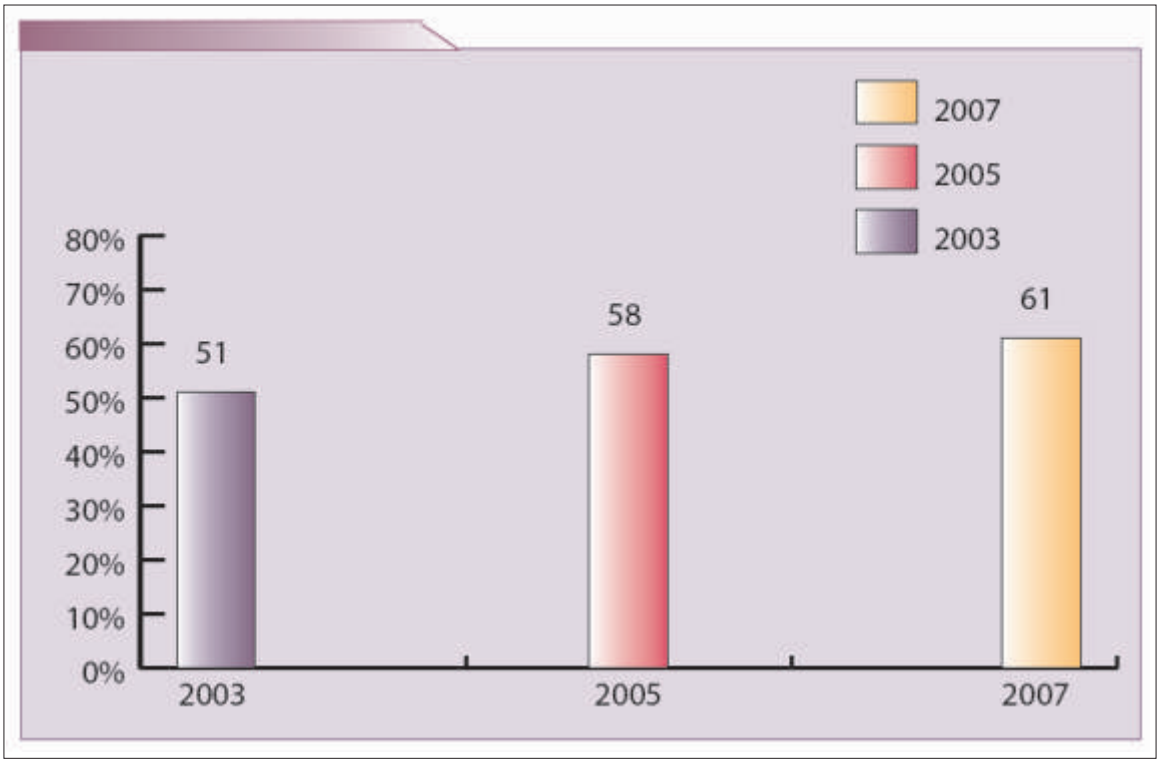
Quality assurance (QA) is the total process that guarantees that results reported by a laboratory are as accurate and reliable as possible. This involves the inspection of specimens upon receipt, using the most reliable and accurate assays, reviewing measures to prevent transcription errors, and verifying final results and reports. Therefore, QA involves the protection of health-care consumers by the Ministry of Health through measures that ensure high-quality laboratory services in all sectors.

QA is important in laboratory testing and is necessary to:

- meet consumer expectations for high standards of quality;
- define testing parameters and standard operating procedures;
- set quality goals for laboratory performance and monitoring;
- assist in the evaluation and improvement of laboratory systems;
- assure reliability and comparability of results;
- provide savings in direct costs of laboratory testing by making systems more efficient.

Regional health programmes aimed at effectively increasing access to HIV prevention, treatment, care and support services rely heavily on the existence of accurate results generated through laboratory testing. A national QA programme will ensure that SOPs exist for all testing procedures and are used appropriately, thereby increasing confidence in laboratory operations. A system of external quality assessment (EQA) can provide external support for ensuring that international and regional guidelines for laboratory procedures are being used appropriately.

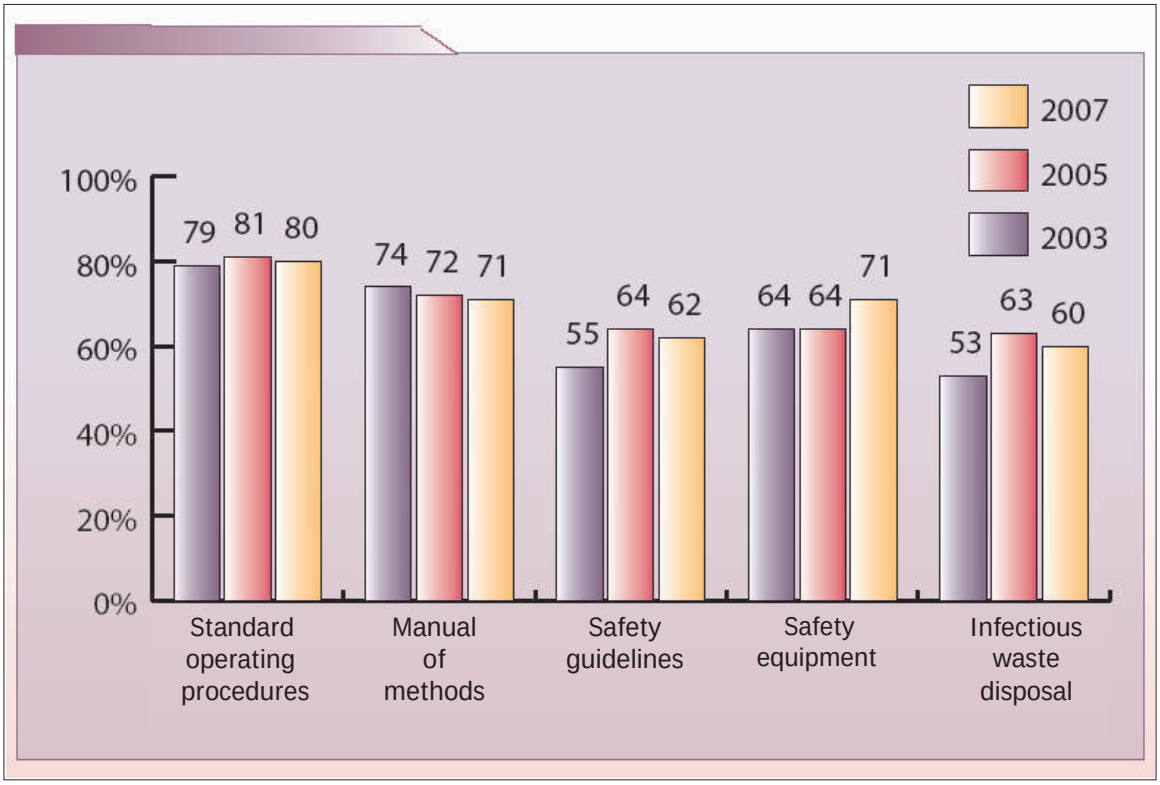
Fig 41. Proportion of Countries with National Quality Assurance Programme (2003–2005–2007)



The proportion of countries with a national QA programme for HIV has increased from 51% in 2003 to 61% in 2007 (Fig. 41); the improvement has been gradual but constant. The challenge however is to ensure that the QA programme fulfils its objective of assuring the quality of testing within the country.

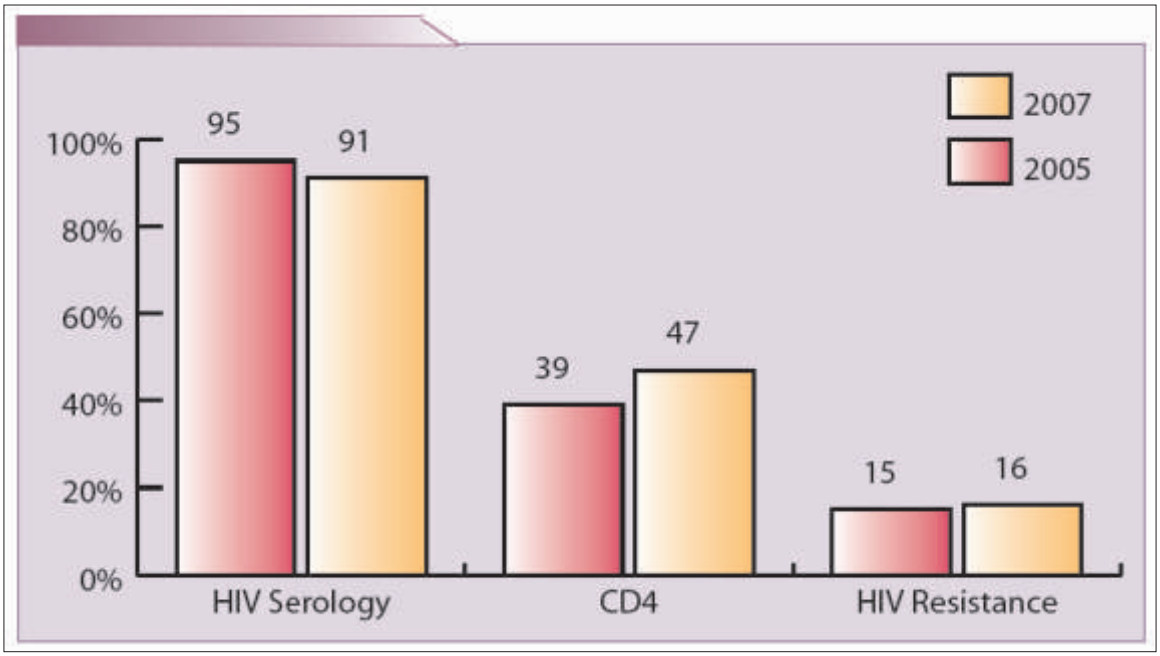
The availability of operational guidelines for use within NRLs has remained relatively stable since commencement of data collection in 2003 (Fig. 42).

Fig 42. Availability of Operational Guidelines for NRL (2003–2005–2007)



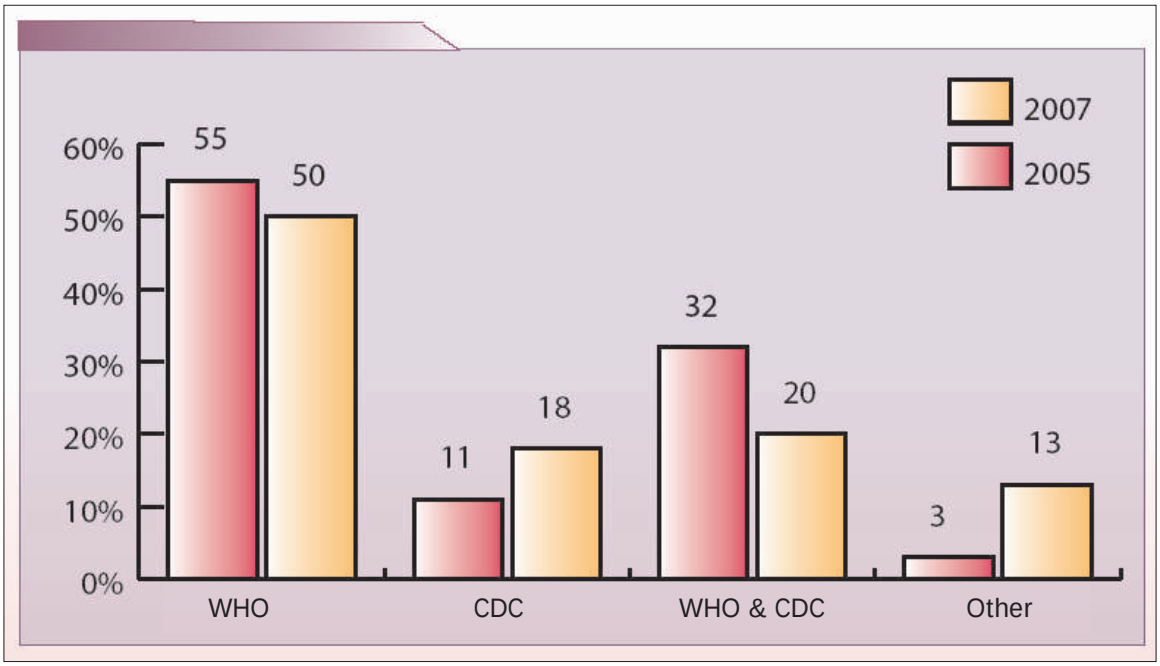
A large majority of countries (91%) participate in an HIV serology EQAS programme (Fig. 43); 47% of the countries do so for CD4+ T-cell enumeration, but only 16% do so for HIVDR. The need now is to increase the coverage of EQAS programmes.

Fig 43. Frequency of Country Participation in various EQA Programmes (2005–2007)



Over 50% of countries are involved in the WHO HIV serology EQAS programme (Fig. 44), 20% are involved in a joint WHO/CDC EQAS programme, 18% are involved in the CDC EQAS, and 13% are participating in EQA programmes of other providers.

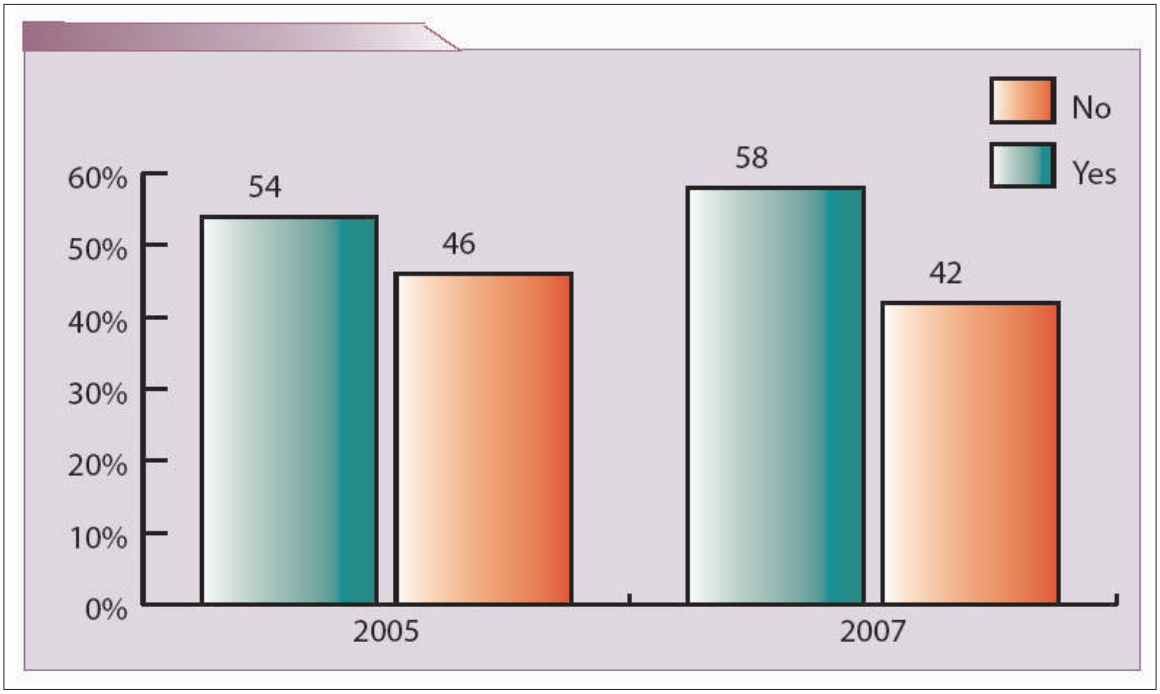
Fig 44. Proportion of countries by Institutional Link for HIV Serology EQA Programme (2005–2007)



2.8 Information and Communication

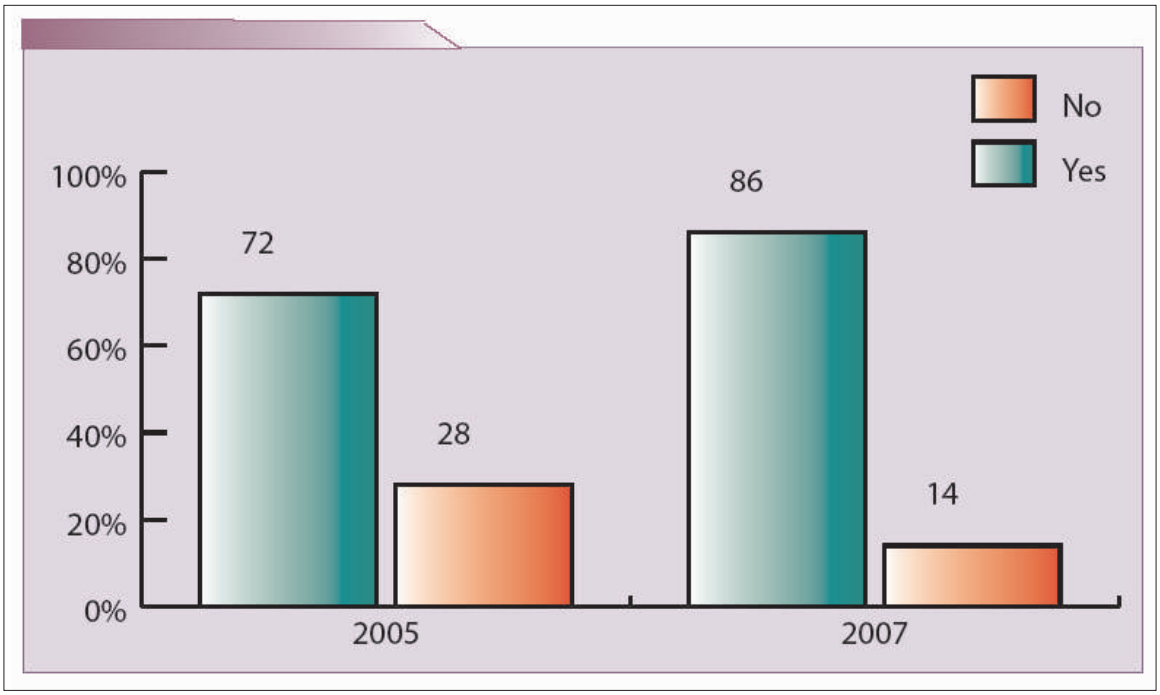
The information systems and communication networks of laboratories in the Region can always be improved as continuous developments are made within the communications sector to improve internet connectivity in-country. The proportion of countries with an established laboratory information system rose slightly from 54% in 2005 to 58% in 2007 (Fig. 45). Similarly, NRL access to the internet increased from 72% to 86% during the same period (Fig. 46). The lack of a functioning and efficient in-country laboratory information system poses a significant barrier to countries seeking to maintain QA and adherence to national policy and protocol while scaling up laboratory capacity through decentralization.

Fig 45. Proportion of Countries with Established Laboratory Information System at NRL (2005–2007)



Although a functional laboratory network can exist in the absence of internet connectivity, it is not an ideal situation because communication with external and peripheral laboratories is difficult, especially for proficiency testing and email communications.

Fig 46. Proportion of Countries in which NRLs have Internet Access (2005–2007)



Countries with NRLs that do not have established information systems require support to prioritize the development of information systems that would standardize the process of collecting and disseminating information on laboratory activities. Such systems will assist countries to identify gaps and create targeted policies and plans to improve the overall efficiency of laboratory operations at country level.

2.9 Summary of Analysis

In summary, the strengths, weaknesses, opportunities and threats identified from the findings are listed below.

Strengths

The following strengths are outstanding:

- Most African countries are involved in scaling up laboratory activities through developed national strategic laboratory plans.
- There is global involvement in the HIV and AIDS pandemic.
- Most governments are mobilizing resources for HIV and AIDS laboratory management through the public and private sectors.
- Technical and financial partners are willing to contribute to the integrated scaling up of HIV and AIDS laboratory activities necessary for prevention, diagnosis, treatment and care programmes and subsequently towards Universal Access.

Weaknesses

The following weaknesses must be addressed:

- Inadequate human resources, both in number and in quality, with inadequate financial motivation and carrier profile;
- Lack of policies and guidelines governing laboratories in some African countries;
- Low levels of inter-laboratory networking in the African Region;
  Absence of a national quality assurance programme in nearly half of the respondent countries;
- Insufficient EQAS for CD4+ T-cell enumeration and HIV drug resistance monitoring;
- Absence of designated NRL in some countries;
- Most African governments not complying with the Abuja Declaration of allocating 15% of total national budget to health issues;
- Some responding countries not using the WHO/UNAIDS testing strategy or any other strategy in their work;
- Lack of action plans for HIVDR or policies surrounding vaccine development in most countries;
- Inadequate support to assist NRLs to maintain their reference laboratory status (including accreditation, SOPs, guidelines, formalized supervisory visits);
- Continued occurrence of several stock-outs per year in a few laboratories;
  Lack of government capacity in some countries to mobilize GFATM financing;
- Inconsistencies in the use of referral mechanisms for ensuring that test results reach patients.

Opportunities

- Many technical and financial partners are ready and willing to provide funding and technical assistance.
- Research on vaccine development has commenced in a few countries.

Threats

The following threats exist:

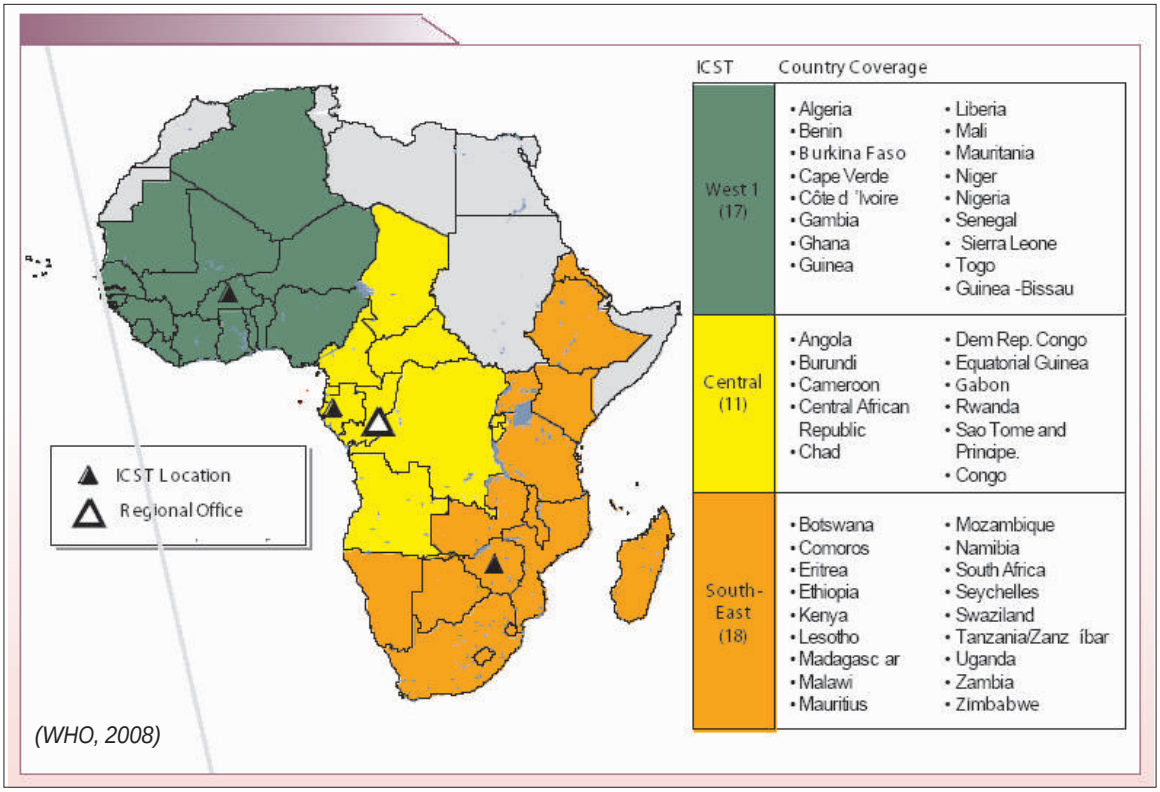
- Sustainability of programmes in African countries when technical partners, stakeholders and funding agencies pull out;
- Development of drug resistance following ruptures due to poor drug management;
- Lack of ability to detect (or late detection) of the development of new HIV strains, currently unknown, because of the lack of research funding and skilled human resources.

PART THREE

WHO Contributions to Laboratory Services

The general objective of the WHO HIV and AIDS programme is to support Member States to develop HIV and AIDS policies and strengthen health response towards Universal Access by 2010. A regional programme on HIV and AIDS was created within the Division of AIDS, Tuberculosis and Malaria (ATM) of the Regional Office for Africa to provide technical assistance to countries. To further assist countries, the Regional Office established the Intercountry Support Teams (IST) in three locations: Ouagadougou (Burkina Faso) for West Africa, Libreville (Gabon) for Central Africa and Harare (Zimbabwe) for Eastern and Southern Africa (Fig. 47). Priority programmes such as HIV and AIDS, communicable diseases surveillance and response, health systems strengthening, emergency and humanitarian action, among others, are represented in each IST by a group of technical experts. The task of these experts is to provide high quality and timely support to countries and partners to implement, monitor and evaluate programmes. HIV and AIDS national programme managers also collaborate with IST coordinators and WHO Representatives at subregional and country levels to develop and implement national plans and programmes.

Fig 47. IST Country coverage



This new arrangement in providing closer technical support to countries is one of the most profound changes in the work of the Secretariat in the WHO African Region in recent years. The contributions of the Regional Office to country efforts towards Universal Access are listed below.

3.1 Advocacy

1. Advocacy missions were undertaken in various countries. These led to countries and partners prioritizing laboratory issues in their action plans.
2. Partnerships were strengthened with regional and international media organizations in 2006 and 2007 resulting in more publicity regarding activities, meetings and workshops.
3. Collaboration with key laboratory partners was established and strengthened, e.g., American Society of Clinical Pathology (ASCP), American Society of Microbiology (ASM), Association of Public Health Laboratories (APHL), CDC and the West African Health Organisation (WAHO).

3.2 Technical Assistance

1. Support was provided to 18 countries during the two-year period to strengthen their laboratory services. Their action plans were used as resource mobilization and disbursement tools as well as to map out service provision strategies. The plans have been integrated into project proposals submitted to certain agencies for funding. These include GFATM, World Bank Multi-Country HIV/AIDS Program (MAP) and African Development Bank (AfDB) projects.
2. With WHO technical support, 18 countries developed HIV laboratory plans which were funded through GFATM and MAP.

3.3 Regional HIV and AIDS Public Health Laboratory Network

1. The African Regional HIV and AIDS Public Health Laboratory Network made the quality of laboratory testing its main focus during the period of expansion of prevention, treatment and care programmes.
2. The network promoted the validation of new testing algorithms, laboratory safety and national QA programmes for laboratories to improve the quality of the testing in the context of Universal Access.
3. The fourth laboratory network meeting was held in Addis Ababa, Ethiopia from 7-9 November 2006, with 42 country representatives from the Region participating. Participants included directors of National HIV Reference Laboratories and representatives from WHO, CDC, APHL,

ASCP, ASM, UNAIDS, AAVP and the Bill and Melinda Gates Foundation. The action plan from this meeting has been finalized and countries which needed help have been supported to mobilize resources and implement activities.

Specific objectives of the meeting were to:

- review the status of implementing the 2004 recommendations of the HIV Laboratory Network;
- review the current status and management of HIV laboratory services;
- propose ways of maintaining timely and reliable diagnostic support for HIV programmes;
- finalize an action plan for the Laboratory Network for 2007-2008.

3.4 Development of Training Manual

1. Collaboration with CDC led to the development of a training package to help improve the quality of laboratory testing in the Region.
2. The use of simple/rapid assays also contributed to the development of laboratory capacity as the demand for HIV testing increases, while the laboratories also need to ensure that test results are rapid, reliable and accurate.
3. Support was provided to 15 countries to train trainers and service providers as part of the expansion of HIV rapid testing.
4. A briefing was organized for participants in the *Diplôme Universitaire de Rétrovirologie* in Dakar, Senegal from 1–27 March 2007.
5. The training package has been translated into French and is being used in 13 countries in the Region.

3.5 Regional Quality Assurance Programme

1. In collaboration with two NRLs in South Africa and Senegal, HIV serology EQA programmes were initiated in 44 countries. Results from these countries show improvement in the quality of data collected and test results from the reference laboratories. Reports from the two EQAS have provided information to the Regional Office about countries whose HIV testing quality assurance programmes need to be strengthened.
2. In collaboration with NRLs, an EQA assessment was done to assist countries that had participated in drug resistance monitoring between 2003 and 2006.
3. Technical assistance was provided to more than ten countries to establish national QA programmes for HIV laboratories.
4. Collaboration with CDC reviewed the performance of nucleic acid testing for early HIV-1 diagnosis in PMTCT programmes in different countries with diverse subtypes in Kampala,

Uganda, 9-11 May 2006. More than ten countries and several partners (such as UNICEF and the Institute of Tropical Medicine, Antwerp) participated in the review. The report from this review has been published.

5. With collaboration from partners biologists and technicians were trained for the *Diplôme Universitaire de Rétrovirologie*, University of Dakar.
6. Collaboration with UNICEF led to the development of a programme framework for scaling up HIV-related prevention, diagnosis, care and treatment for infants and children in 2008.

3.6 ARV Resistance Monitoring

1. A workshop was held in Windhoek, Namibia in December 2007 to review the progress made in surveillance and monitoring of HIVDR. There were participants from 18 countries in the Region, including directors of NRLs and epidemiologists. The workshop was organized in collaboration with CDC, *Agence Nationale de la Recherche sur le SIDA* (ANRS) and Pharm Access.
2. Technical assistance was provided for laboratory accreditation visits, development of the laboratory strategy and prioritization of operational research.
3. Technical assistance was also provided to countries to develop national HIVDR strategies and adapt generic protocols to local needs.
4. In order to improve surveillance and monitoring of HIV drug resistance in the Region, two training workshops were held to develop staff capacity. The result is that 30 countries have implemented the WHO package for HIVDR monitoring.

PART FOUR

Where We Want To Be: Recommendations

4.1 Conclusion

Countries within the African Region have made substantial progress in the development of policies and plans to address the needs of laboratories to respond to HIV and AIDS problems. They have also made progress in the use of cost-effective technologies such as simple/rapid assays. This has led to successful decentralization of laboratory facilities to the district level towards the challenge of Universal Access to HIV and AIDS prevention, treatment, care and support services by 2010.

However, the assessment shows that, although some countries are on course towards the 2010 Universal Access target, the African Region as a whole needs to put in a lot more effort to achieve this goal. Those countries found to be lagging behind will have to quickly strengthen their NRLs; improve on QA insufficiencies; establish and improve on EQA for HIVDR and CD4+ T-cell enumeration; and recruit and train the required number of qualified laboratory scientists and technicians to do the work. In conclusion, many countries have to strengthen and accelerate response to the HIV epidemic to achieve Universal Access by 2010 if the African Region is to contribute to the reversion of HIV infection worldwide by 2015.

The recommendations below are based on the findings in the assessment done in 2007.

4.2 Recommendations

Recommendations to WHO Member States

WHO Member countries should endeavour to do the following:

1. implement the Maputo Declaration on Strengthening Laboratory Systems by harmonizing and standardizing the provision of laboratory services;
2. designate NRLs based on merit, acquire accreditation for various laboratory specialities, and endeavour to maintain these accreditations;
3. collect and strategically disseminate information; link NRLs to other country and regional laboratories for proficiency testing and mentorship; and use the information generated from these linkages for programme monitoring and evaluation, planning and execution of operational research, and documentation;

4. establish the national QA programme at all levels of the intra-country laboratory network and support NRLs to provide EQA for proficiency testing, supervision and monitoring;
5. participate in EQAS for CD4+ cell counts and HIV drug resistance monitoring, and sustain participation in EQAS for HIV serology;
6. encourage adaptation of recommended WHO testing strategies in countries;
7. assist laboratories in the management of reagents/consumables so as to avoid recurrent stock-outs through continuous staff training;
8. strengthen technical competency of staff through pre- and in-service training curricula and skills upgrading programmes that ensure the retention of trained and motivated staff;
9. effectively mobilize and allocate resources in line with the Abuja Declaration to commit 15% of national budgets to health, including HIV and AIDS, to maintain and expand existing laboratory capacity based on national needs.

Recommendations to WHO Regional Office for Africa

The Regional Office should:

1. provide support and guidance to WHO Member States to help them prioritize the development of a functional referral system for laboratories towards Universal Access;
2. provide technical support for countries to develop, update, adapt and implement evidence-based policies and guidelines in order to reverse the HIV and AIDS epidemic;
3. support countries in the Region to formally designate NRLs, assist them through accreditation procedures and link them with laboratories of excellence outside of the Region;
4. assist national health authorities and governments to mobilize and effectively allocate resources up to 2015 and beyond to ensure continued laboratory supply and services;
5. provide technical assistance and support to countries to conduct national pre- and in-service training for both laboratory staff and non-professional laboratory service providers as part of the human resources development programme;
6. advise countries to adapt existing national testing algorithms to conform to recommended WHO testing strategies to improve practical planning and commodity procurement;
7. assist countries to develop national HIV and AIDS vaccine plans, and support them to include research and development in laboratory policy and planning;
8. provide assistance to countries to participate in HIVDR surveillance programmes and emphasize the ability of NRLs to act as links between laboratories to establish surveillance programmes at national and international levels;
9. provide technical assistance to support countries with stock management and inventory control to avoid stock-outs of consumables and ARV.

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Annex 1

Laboratory capacity table

Table 1: Recommended tiered laboratory capabilities for diagnosis and treatment of HIV and AIDS in resource-limited settings (WHO/CDC/USAID, 2008)

Table 1: Recommended tiered laboratory capabilities for diagnosis and treatment of HIV & AIDS in resource-limited settings (WHO/CDC/USAID, 2008)

Laboratory testing for diagnosis and monitoring	Primary Level-I	Primary Level-I	District Level-II	District Level-II	Regional / Provincial Level-III	Regional / Provincial Level-III	National / Multi Country Level-IV
	Send out	On site	Send out	On site	Send out	On site	On site
HIV antibody testing							
ELISA	X			X		X	X
Rapid assay 1		X		X		X	X
Rapid assay 2		X		X		X	X
Rapid assay 3		X		X		X	X
HIV virological testing							
Qualitative RNA	X		X			X	X
Qualitative DNA	X		X			X	X
Ultra sensitive p24 antigen EIA	X		X		X		X
Quantitative RNA	X		X			X	X
Haematology assays							
Haemoglobinometer such as Haemocue		X		X		X	X
WHO Haemoglobin Colour Scale		X					

Laboratory testing for diagnosis and monitoring	Primary Level-I	Primary Level-I	District Level-II	District Level-II	Regional / Provincial Level-III	Regional / Provincial Level-III	National / Multi Country Level-IV
Full blood count and differential	X			X		X	X
CD4+ T-cell testing							
Absolute count	X			X		X	X
% desirable if available	X			X		X	X
HIV resistance testing							
HIV genotyping assay					X		X
Pregnancy testing							
Urine rapid test		X		X		X	X
Chemistry assays							
Liver function tests		X (if power)		X		X	X
Whole blood glucose (glucometer)		X		X		X	X
Serum glucose				X		X	X
Serum electrolytes	X			X		X	X
Renal function tests		X (if power)		X		X	X
Lipids				X		X	X
Amylase				X		X	X
Lactate				X		X	X
Urine analysis							
Urine dipstick		X		X		X	X
Urine dipstick with microscopy				X		X	X
Tuberculosis testing							

Laboratory testing for diagnosis and monitoring	Primary Level-I	Primary Level-I	District Level-II	District Level-II	Regional / Provincial Level-III	Regional / Provincial Level-III	National / Multi Country Level-IV
Microscopy							
Light		X		X		X	X
Fluorescence		X (if high vol)		X		X	X
Culture and ID							
Solid medium	X		X			X	X
Liquid medium	X		X			X	X
Drug susceptibility test							
First line			X			X	X
Second line			X		X		X
Malaria testing							
Rapid test for malaria		X		X		X	X
Microscopy for malaria (thick & thin)		X		X		X	X
Microbiology testing							
Gram stain				X		X	X
Microbiology culture & identification			X			X	X
Blood culture			X			X	X
Microbiology susceptibilities			X			X	X
Wet mounts/preps		X		X		X	
Cerebrospinal fluid (CSF) testing							

Laboratory testing for diagnosis and monitoring	Primary Level-I	Primary Level-I	District Level-II	District Level-II	Regional / Provincial Level-III	Regional / Provincial Level-III	National / Multi Country Level-IV
Microscopy including cell count, India Ink, Gram stain, Acid Fast Bacilli (AFB) stain				x		x	x
CSF glucose			x			x	x
Cryptococcal antigen (serum or CSF)				x		x	x
Syphilis testing							
Treponemal-specific rapid assays		x		x		x	x
Non-treponemal: Rapid Plasma Reagin (RPR) or VDRL Treponemol-specific: Treponema pallidium particle agglutination assay (TPHA) or FTA-ABS				x		x	x
Hepatitis testing							
Hepatitis B by EIA				x		x	x
Hepatitis C by EIA				x at high prev		x	x

Send out: refers to not having the testing capability on site; so specimens and/or individuals are sent to another site for tests to be performed.

Annex 2

Respondent Countries

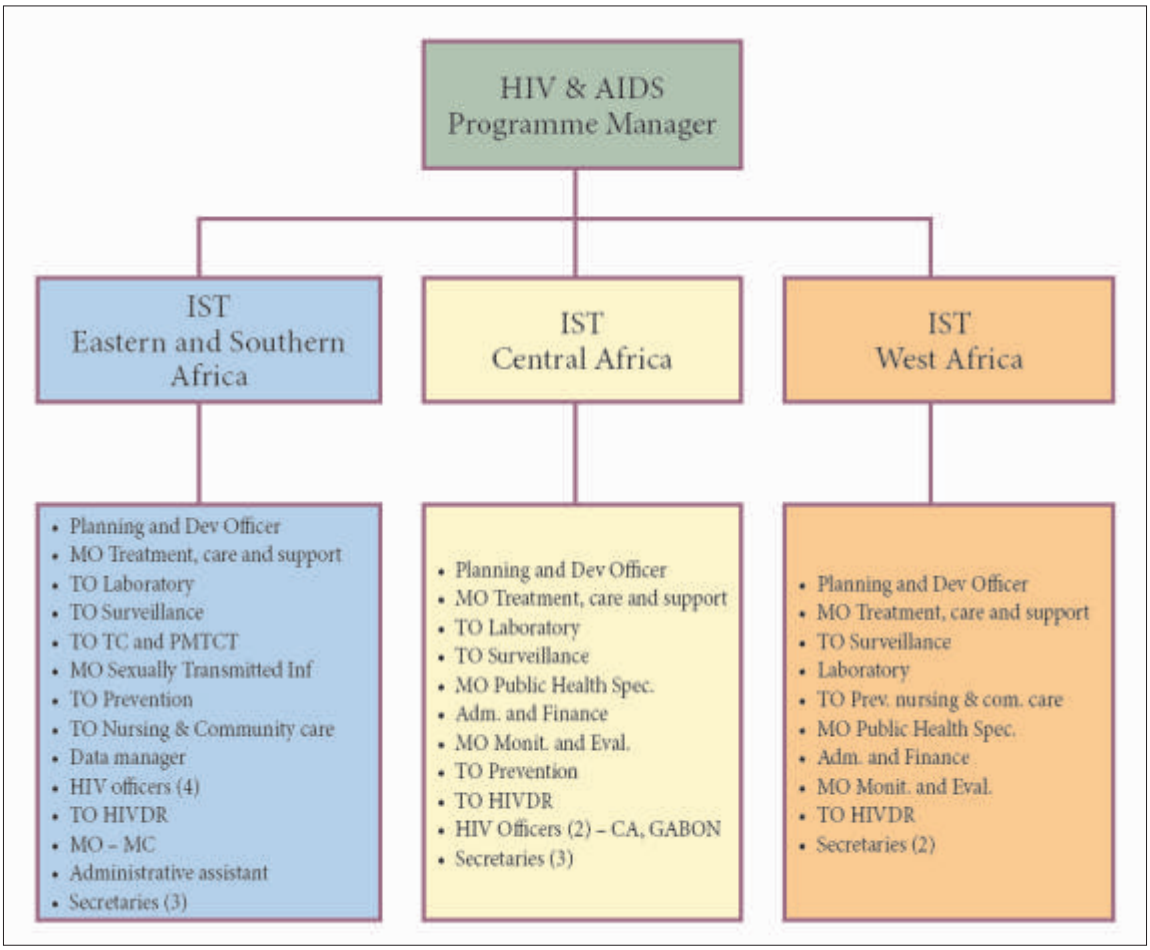
1. Algeria
2. Angola
3. Benin
4. Botswana
5. Burkina Faso
6. Burundi
7. Cameroon
8. Cape Verde
9. Central African Republic
10. Chad
11. Comoros
12. Republic of Congo
13. Cote d'Ivoire
14. Democratic Republic of Congo
15. Equatorial Guinea
16. Eritrea
17. Ethiopia
18. Gabon
19. Gambia
20. Ghana
21. Guinea
22. Guinea-Bissau
23. Kenya
24. Lesotho
25. Liberia

26. Madagascar
27. Mali
28. Mauritiana
29. Mauritius
30. Namibia
31. Niger
32. Nigeria
33. Rwanda
34. Sao Tome and Principe
35. Senegal
36. Seychelles
37. Sierra Leone
38. South Africa
39. Swaziland
40. Togo
41. Uganda
42. United Republic of Tanzania
43. Zambia
44. Zimbabwe

Annex 3

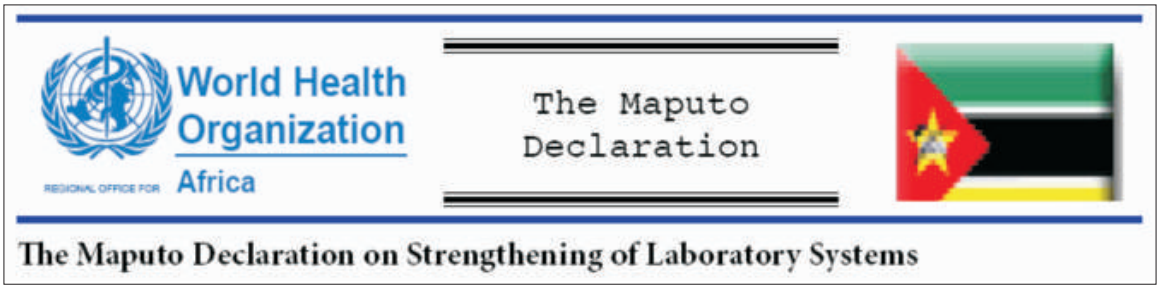
Intercountry Support Teams

Regional Office for Africa



Annex 4

Maputo Declaration



We, representatives of governments, multilateral agencies, development partners, professional associations, and academic institutions, participated in a Consensus Meeting on Clinical Laboratory Testing Harmonization and Standardization in Maputo, Mozambique, on 22nd-24th January 2008. The meeting sought to address laboratory challenges that limit the scaling-up of services for tuberculosis, malaria and HIV diagnosis and care.

The objectives of the Maputo meeting were:

- To review and agree on a list of supplies and tests needed at each level of an integrated tiered laboratory network;
- To develop a consensus to guide standardization of laboratory equipment at each level of the laboratory network;
- To develop a consensus on key considerations to guide maintenance and service contracts for equipment at various levels of the laboratory network.

Recognize the burden of the priority diseases HIV, malaria and tuberculosis. Globally, some 33.2 million individuals are living with HIV but of those just 10% are aware of their sero-status.[1] In spite of efforts to limit transmission, the incidence of HIV infection remains high. Similarly, 8.8 million new cases of tuberculosis occur annually while the prevalence of multi- and extensively-drug resistant tuberculosis continues to increase with only a fraction of cases being detected.[2] Co-infection with HIV and tuberculosis remains a difficult clinical challenge in many settings. In many countries, malaria remains the largest contributor to mortality primarily among infants and children, with about 1 million deaths per year.[3]

1 Joint United Nations Program on HIV AND AIDS (UNAIDS) and World Health Organization (WHO) *2007 AIDS Epidemic Update.* Accessed at http://data.unaids.org/pub/EPISlides/2007/071119_epi_pressrelease_en.pdf on 24 January 2008.
2 WHO factsheet no. 104 – Tuberculosis Accessed at http://www.who.int/mediacentre/factsheets/fs104/en/index.html on 24 January 2008.
3 WHO/GMP frequently asked questions Accessed at http://www.who.int/malaria/faq.html on 24 January 2008.

Recognize the need to expand and further develop quality-assured laboratory services as part of a greater framework of health system strengthening within resource-limited settings. Increasingly, countries and implementing partners have identified that limited laboratory capacity represents a major barrier to implementation and sustainability of prevention, treatment and care programmes for HIV, malaria and tuberculosis.
Recognize that in resource-limited settings, several challenges have resulted in inadequate laboratory systems to support the scaling-up of programmes. These include a lack of leadership and advocacy, human resources, career path and retention of staff, national laboratory policy, strategic planning (budgetary concerns), insufficient physical infrastructure, supply chain management, and quality management systems (quality assurance).

Note that there has been a substantial increase in funding to fight HIV, tuberculosis, and malaria. For instance, a total contribution of US$ 10 billion per annum has been secured from donors towards prevention, treatment and care programmes for the three diseases through funding bodies such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, The US Presidents Emergency Plan for AIDS Relief, US President's Malaria Initiative, the World Bank, and the Bill and Melinda Gates Foundation. This represents a significant increase on previous commitments that totaled US$ 1 billion in 2001 for disease control programmes for high burden diseases in resource-limited settings.

Recognize that in order to improve and sustain access to laboratory services, there must be an integration of laboratory support for tuberculosis, malaria and HIV disease programmes. The aim of this effort should be to sustain any improvements made to a laboratory as part of the greater health system from a public health perspective.

Call on national governments to support laboratory systems as a priority by developing a national laboratory policy within the national health development plan that will guide the implementation of a national strategic laboratory plan. Governments should establish a department of laboratory systems within the Ministry of Health.

Call on national governments with support of their donors and partners in resource-limited settings to develop national strategic laboratory plans that integrate laboratory support for the major diseases of public health importance including HIV, tuberculosis, and malaria.

Call on donors and implementing partners to ensure that in supporting laboratory strengthening that proper consideration is given to fostering national ownership.

Call on countries and all partners to urgently address the broader laboratory human resources agenda for laboratory strengthening including training, recruitment and retention of laboratory workers and their adequate financing.

Call on donors and development partners to commit to work collaboratively with each other and with coordination from the national governments to support strengthening of laboratory systems in order to create one unified, integrated national laboratory network. These laboratory strengthening efforts should seek to build public private partnerships.

Call on academic institutions and research funders to accelerate efforts to develop new diagnostic tools applicable to resourced-limited settings

Done in Maputo, Mozambique on 24 January 2008

Annex 5

Questionnaire

Assessment of HIV Laboratories in the WHO Africa Region

I. General Information

Contact Country

1. Is there an officially designated National HIV Reference Laboratory?
   Yes ❑ No ❑

   If no, is there a laboratory that performs the functions of an HIV reference laboratory
   Yes ❑ No ❑

2. What is the name, address and contact person of the HIV reference laborator or the laboratory performing the function of HIV reference laboratory.

   Contact name: _____
   Name of Laboratory: _____
   Address: _____
   Telephone: _____
   Fax: _____
   Email: _____

3. What is the affiliation of the HIV reference laboratory?
   Public: ❑ NGO: ❑ University: ❑ Private: ❑
   Other (please specify): _____

4. Where do the laboratory services sit within the Ministry of Health organogram? _____

5. Is there a written policy that guides laboratory services including testing?

Yes ❑ No ❑

6. Indicate the percentage of time the laboratory dedicates to:

Diagnostic services: 100% ❑ 75% ❑ 50% ❑ 25% ❑

Research: 100% ❑ 75% ❑ 50% ❑ 25% ❑

Teaching/Training: 100 % ❑ 75% ❑ 50% ❑ 25% ❑

7. How many laboratories can screen for HIV/AIDS antibodies in your country?

Central level: _____ %

Regional/provincial level: _____ %

District level: _____ %

Public: _____ % Private: _____ %

8. Is there a laboratory which makes selection and validation of tests at the national level?

Yes ❑ No ❑

9. Is there an HIV laboratory network in your country?

Yes ❑ No ❑

A. Plan

10. Is there an HIV/AIDS action plan for laboratories?

Yes ❑ No ❑

11. Is the plan included in the national HIV/AIDS health sector plan of the country?

Yes ❑ No ❑

B. Financing

12. What is the source of funding of the reference laboratory?

Through public/government: _____ %
Through partners/external donors: _____ %
Through NGO: _____ %

13. Who is funding the HIV activities of the public sector laboratories in the country?

Through public/government: _____ %
Through partners/external donors: _____ %
Through NGO: _____ %

C. Personnel

14. Number of laboratory staff at National HIV Reference Laboratory

PhD _____ MD _____ Master's _____
Medical Technologist _____ Lab Technician _____

II. Laboratory Facilities, Equipment and Expertise

A. HIV serological diagnosis

15. What percentage of HIV laboratories performs the ELISA test?

In the Public sector: _____ %
Among NGOs: _____ %
In the Private sector: _____ %
At central level: _____ %
At regional/provincial level: _____ %
At district level: _____ %

16. What percentage of HIV laboratories performs HIV testing using Rapid test?

In the Public sector: _____ %
Among NGOs: _____ %
In the Private sector: _____ %

At central level: _____ %
At regional/provincial level: _____ %
At district level: _____ %

17. How many times did you run out of HIV reagents?

During the year 2006: _____
During the year 2007: _____

18. Does the national reference laboratory define the algorithm of screening for the national needs?

Yes ❑ No ❑

B. Western Blot (HIV confirmatory testing)

19. Does the National Reference Laboratory perform the Western blot test?

Yes ❑ No ❑

19.1 If yes, under which circumstances is the test performed?

HIV confirmation ❑ Research ❑ In indeterminants ❑ Surveillance ❑

C. Testing Strategy

20. In your national algorithm, how many tests are performed for

Transfusion ❑	1 test ❑	2 tests ❑	3 tests ❑	4 tests ❑
Diagnosis ❑	1 test ❑	2 tests ❑	3 tests ❑	4 tests ❑
Surveillance ❑	1 test ❑	2 tests ❑	3 tests ❑	4 tests ❑

21. What is the adult HIV prevalence in your country? _____
State the year _____

D. P24 testing

22. Is P24 antigen testing performed at the HIV reference laboratory?

Yes ❑ No ❑

23. How many laboratories in your country perform P24 antigen testing?
Number: _____
Public sector: _____ Private Sector: _____
Central level: _____ Regional level: _____
District level: _____

E. HIV Molecular Methods

24. How many laboratories perform diagnostic PCR in your country?
Public: _____ Private: _____
At central level: _____ Atregionallevel: _____
At district level: _____

24.1 If yes, which type of diagnostic PCR is used?
In-house: ❑ Commercial kit: ❑

25. Number of PCR tests performed per month in your country?
Less than 50: ❑ 50 or more: ❑

26. How many laboratories perform viral load assays in your country?
Public _____ Private _____
At central level: _____ At regional level: _____ At district level: _____

26.1 If yes, which type of HIV viral load assays is used?
Roche TaqMan ❑
Bayer bDNA ❑
BioMérieux Nuclisens ❑
Abbott LCx ❑
Other (please specify) _____

27. Number of tests performed per week:
Less than 25 ❑ 25 or more ❑

F. Test of Heteroduplex Mobility Assay (HMA)

28. Are HMA assays conducted in your country?
Yes ❑ No ❑

29. In what type of facilities are the HMA done? Public ❑ Private ❑

29.1 If yes, number of laboratories Public _____
Private _____

30. Number of sequences performed per week:
Less than 25 ❑ 25 or more ❑

31. Which regions are sequenced?
Full genome ❑ gag ❑ pol ❑ env ❑ Others (please specify) _____

G. Immunology

32. Is testing for CD4 done in your country?

Yes ❑ No ❑

32.1 What type of equipment is used for CD4 testing? _____

32.2 If CD4 testing is done, how many tests are performed per month?

Less than 100 ❑
Between 100 and 199 ❑
Between 200 and 499 ❑
500 and more ❑

33. How many laboratories perform the CD4 test in the country?

Public _____ Private _____

At central level: _____
At regional level: _____
At district level: _____

H. HIV Vaccine Research, Development and Evaluation

34. Are there HIV vaccine trials ongoing in your country?

Yes ❑ No ❑

35. Are any HIV vaccine trials planned to be conducted in your country?

Yes ❑ No ❑

36. Is Intracellular Cytokine Staining (ICS) performed in your country?

Yes ❑ No ❑

36.1 If yes, how many tests are performed per month?

Less than 100 ❑ 100 or more ❑

I. HIV Virus Isolation and Characterisation

37. Is viral culture for HIV done in your country?

Yes ❑ No ❑

37.1 If yes, what number of laboratories is doing the culture?

Public _____ Private _____

38. What number of viral cultures is performed per week?

Less than 10 ❑ 10 or more ❑

39. Is biological phenotyping done within in your country?

Yes ❑ No ❑

39.1 If yes, which one?

NSI, SI ❑ Co-receptor use (R5, X4CCR2 etc) ❑

40. Is genotyping for drug resistance performed within the country?

Yes ❑ No ❑

40.1 If yes, how many samples are processed per year?

Less than 100 ❑
Between 100 and 199 ❑
Between 200 and 499 ❑
500 and more ❑

40.2 Are there plans to perform genotyping for drug resistance within the country?

Yes ❑ No ❑

41. Are neutralizing antibody assays performed within the country?

Yes ❑ No ❑

III. Training

42. How many **laboratory** staff has been trained in HIV laboratory techniques from 2006 to end of 2007?

Level	2006	2007
Central level		
Regional level		
District level		

43. How many **non-laboratory** staff has been trained in HIV laboratory techniques from 2004 to end of 2007?

Level	2006	2007
Central level		
Regional level		
District level		

IV. Storage

44. Do you have nitrogen tanks for laboratory use in the country?

Yes ❑ No ❑

44.1 If yes, what proportion of laboratories has nitrogen tanks in the country? _____%

45. What proportion of laboratories has -70°C freezers in the country?

_____ %

46. What proportion of laboratories has -20°C freezers in the country?

_____ %

47. Is dry ice locally available?

Yes ❑ No ❑

V. Transportation and shipment of samples within and outside the country

48. What method is used for transporting samples within the country?

Road ❑ rail ❑ air ❑ none ❑

49. What are the conditions for transporting the samples?

Fresh ❑ frozen ❑ dry ice ❑ liquid nitrogen ❑

50. What are the methods for shipping the samples outside the country?

Road ❑ rail ❑ Air ❑ Other ❑

51. What are the conditions for shipment?

Fresh ❑ Frozen ❑ Dry ice ❑ Liquid nitrogen ❑

52. Is there any regulatory requirement for transporting/shipping samples?

Yes ❑ No ❑

53. If yes, please specify the current regulation _____

VI. Quality Assurance

54. Is there a national quality assurance programme for HIV?

Yes ❑ No ❑

54.1. If yes, what percentage of laboratories is involved in the programme?

Public _____ % Private _____ %

55. What is the periodicity of proficiency testing?

Once/year ❑ Twice/year

56. What percentage of laboratories responded to the proficiency testing?

_____ %

57. Is your country participating in an HIV serology external quality assurance programme? Yes ❑ No ❑

57.1 If yes, with which institution?
WHO ❑ CDC ❑ Other ❑ please specify _____

58. Is your country participating in a CD4 external quality assurance programme?
Yes ❑ No ❑

58.1 If yes, with which institution? _____

59. Is your country participating in an HIV resistance external quality assurance programme? Yes ❑ No ❑

59.1 If yes, with which institution?
WHO/AFRO ❑ Other ❑ please specify _____

60. Are supervisory visits conducted at national level? Yes ❑ No ❑

61. Does the HIV reference laboratory have?

	Yes	No
Standard operating procedures:	❑	❑
Manual of methods:	❑	❑
Safety guidelines:	❑	❑
Safety equipment:	❑	❑
Infectious waste disposal guidelines:	❑	❑

VII. Information and Communication Systems

62. Is there an established laboratory information system at the reference laboratory? Yes ❑ No ❑

63. Does the reference laboratory have access to the Internet?
Yes ❑ No ❑

World Health Organization

Regional Office for Africa