A brief history of tuberculosis control **in Kenya**

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Abbreviations

AFB
acid-fast bacilli

AIDS
acquired immunodeficiency syndrome

AMREF
African Medical and Research Foundation

ANC
antenatal clinic

ART
antiretroviral therapy

CDC
Centers for Disease Control and Prevention (United States)

CIDA
Canadian International Development Agency

CoAg
cooperative agreement

CPT
co-trimoxazole preventive therapy

CRL
central reference laboratory

DFRD
District Focus for Rural Development

DHMB
District Health Management Board

DOTS
the basic package that underpins the Stop TB Strategy

DST
drug susceptibility testing

DTLC
district TB and leprosy coordinator

EH
ethambutol and isoniazid

FDC
fixed-dose combination (tablet)

FIDELIS
Fund for Innovative DOTS Expansion Using Local Initiatives

GAP
Global AIDS Programme (of CDC)

GDF
Global Drug Facility

GLC
Green Light Committee

Global Fund
The Global Fund to Fight AIDS, Tuberculosis and Malaria

GoK
Government of Kenya

HIV
human immunodeficiency virus

ISAC
Intensified Support for Action in Countries Initiative

JSI
John Snow International

KAPTLD
Kenya Association for Prevention of Tuberculosis and Lung Disease

KEPH
Kenya Essential Package of Health

KNCV
Koninklijk Nederlandse Centrale Vereniging ter bestrijding van de Tuberculose (Royal Netherlands Tuberculosis Foundation)

MDR-TB
multidrug-resistant tuberculosis

NASCOP
national AIDS control programme

NGO
nongovernmental organization

NHSP
National Health Strategic Plan

NLP
national leprosy control programme

NLRA
Netherlands Leprosy Relief Association

NTP
national TB control programme

NLTP
national leprosy and tuberculosis control programme

NSL
Nederlandse Stichting voor Leprabestrijding

PATH
Program for Appropriate Technology in Health

PEPFAR
President's Emergency Plan for AIDS Relief (United States)

PPM
public-private mix

PTLC
provincial TB and leprosy coordinator

RH
rifampicin and isoniazid

SAIDIA
Samburu AID In Africa (a Kenyan NGO)

SNV
Netherlands Development Organization

TB
tuberculosis

USAID
United States Agency for International Development

WHO
World Health Organization

Summary

Before the advent of the human immunodeficiency virus (HIV) in 1990, notification rates of cases of tuberculosis (TB) in Kenya were falling steadily at about 4% per year. The HIV epidemic reversed this trend, and by the middle of the 1990s the case notification rate was increasing at 15% per year. People who are at high risk include those with HIV infection; those who inject drugs; and those who have resided in, volunteered, or worked in high-risk congregate settings such as prisons, nursing homes, hospitals, residential facilities for patients with AIDS or homeless shelters. In order to strengthen its national TB control programme (NTP), Kenya developed a national DOTS strategy that was finalized in 1991. Short-course chemotherapy was introduced in 1993, which aimed at reaching all districts by 1997. At least one diagnostic and treatment centre was set up in each district and sub-district hospital. Some health centres started diagnostic services, while many more initiated DOTS treatment centres. These were deemed inadequate, however, and in 2000 special steps were taken to increase the capacity of the programme. Between 1996 and 2006, the number of health units increased from 916 to 1796, the number of TB microscopy centres from 280 to 773 and the staff complement from 90 to 188, more or less doubling the overall capacity.

In 2005, Kenya adopted the policy recommended by the World Health Organization (WHO) of offering HIV testing and counselling to all TB patients. By the end of 2006, about 60% of TB patients had been counselled and tested for HIV. Those found to be HIV-positive were provided with co-trimoxazole preventive therapy (CPT) and referred to HIV care clinics for antiretroviral therapy (ART). Approximately 25% were put on antiretroviral drugs. Other new initiatives that have been introduced since 1997 include: community TB care; engaging all care providers, including public–private mix (PPM); infection control in congregate settings; strengthening the health-care delivery system through the provision of additional staff; and the introduction of additional advocacy, communication and social mobilization activities. The resources available to the NTP have increased greatly since 2000 and have come from a range of sources including the Government of Kenya, the Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund) as well as international technical partners and donors. The introduction of these initiatives and the consolidation of previous gains have served to increase TB case detection rates, to an estimated 71% in 2006. If the prevalence of HIV continues to fall, the incidence of TB will probably fall with it.

Introduction

Notification rates of cases of tuberculosis (TB) in Kenya have increased six-fold in the past 15 years, largely as a result of the impact of the human immunodeficiency virus (HIV) on the disease, presenting substantial challenges to control of the disease. During this time, the coverage and quality of the national TB control programme (NTP) greatly improved, also contributing to the increased case notification rates. This document reviews the history of TB control from the inception of the Kenyan NTP in 1956, the greatest attention is given to the period 1996–2006, with special emphasis on the impact of HIV and the subsequent responses of the NTP.

1. TB control in the context of **health system development**

The development of the Kenya health system in relation to TB control can be divided into three phases: 1980–1998; 1999–2004; and 2005–2010. To set this document in context, the main developments and reforms in these three periods are summarized below.

Phase 1 1980-1998: Establishment and consolidation of the National Leprosy and Tuberculosis Control Programme (NLTP)

The NLTP was established in 1980, with specialized staff at national, provincial and district level. The role of these staff was to provide technical guidance and supervision of TB and leprosy control activities. Then as now, TB diagnostic and treatment services were delivered within the primary health-care system, at hospital, health centre and dispensary level. Diagnostic tests and treatment were available free-of-charge in all government facilities.

The main health sector reform that affected TB control during this period was decentralization of responsibility for providing health services to the district level in 1983, through a strategy called 'District Focus for Rural Development (DFRD)'. Decentralization was accompanied by intensive training and orientation of district-level personnel.

Phase 2 1999 – 2004: the First National Health Strategic Plan

Kenya's first National Health Strategic Plan (NHSP) was developed in the late 1990s, for the period 1999-2004. During this time, major health sector reforms, principally focusing on decentralization and an essential health package, occurred. The NLTP was actively involved in these reforms, as a member of the secretariat of the national health sector reform team. The main developments relevant to TB control were as follows:

- Procurement and distribution of drugs and supplies were decentralized to the district level. However, anti-tuberculosis drugs and vaccines were identified as priority public health goods for which procurement and distribution would remain a central-level responsibility.
- The NLTP altered its planning processes, to adapt to decentralization. Planning of TB control activities was integrated in district and provincial-level planning, to ensure that TB control activities were planned as part of a district's overall activities, and that TB was a priority health concern at local level. The central unit of the NLTP made major efforts to ensure that district TB and leprosy coordinators were involved in district-level planning.
- TB diagnosis and treatment services were expanded to a broader range of health facilities (for example to a larger number of health centres and dispensaries). With an ever-expanding network of laboratories performing sputum smear microscopy, the number of facilities where smear microscopy services were available reached 776 by 2006. Microscopes purchased and provided by the NLTP helped to strengthen other diagnostic services at health centre and dispensary level, and also contributed to an increase in TB notifications.
- The NLTP contributed to human resource development, building on the decentralization process. District TB coordinators were trained annually, and in turn provided training to local health-care workers.
- All church hospitals and clinics were supplied with free anti-tuberculosis drugs and laboratory reagents through the NLTP.
- Private sector involvement in TB control was initiated in collaboration with the Kenyan Association for the Prevention of TB and Lung Disease (KAPTLD). Anti-tuberculosis drugs and laboratory supplies were provided to private sector providers collaborating with the NLTP, so that diagnosis and drugs could be provided to patients being treated by these providers free-of-charge. This initiative was particularly important in the context of an increasing trend for TB patients to seek care in the private sector.

- Financing for government health-care services was relatively stable, at around US$70 *per capita,* most of which was used to pay the salaries of health-care workers.

2005-2010: the Second National Health Strategic Plan

The second National Health Strategic Plan covers the period 2006–2010 (*1*). This plan emphasizes the importance of local ownership and community involvement in health care, with the establishment of District Health Management Boards (DHMBs) that include community representatives.

"Although the national TB programme is often called vertical, it is fully integrated in the primary health-care system where TB suspects are **selected, diagnosed and treated** by peripheral health-care workers."

In line with the second NHSP the NLTP strategic plan 2006–2010 stresses the need to strengthen the infrastructure and human resources for health. Priorities include improving outreach into urban slums and other hard-to-reach places, rolling out TB/HIV collaborative activities throughout the country, advocating for adequate funding, involving communities, creating and nurturing public–private sector partnership for better case detection, holding and reporting. In 2007 the Ministry of Health raised the status of the NLTP in the ministerial structure from programme to divisional level by creating the Division of Leprosy, TB and Lung Disease.

Financing of the Kenya Essential Package of Health (KEPH) proposed in the second NHSP is expected to be provided by the Government of Kenya, the private sector, grants from development partners, the Global Fund and a national social health insurance fund. The plan envisages a phased introduction of a national social health insurance fund that will give universal free health care to all Kenyans. Funding for health from the Government of Kenya is expected to rise from 5.6% to 12% of GDP by 2010.

2. TB control before 1990

The early history of TB control in Kenya is closely linked to the history of leprosy control. Before the Second World War, leprosy patients in Kenya were maintained in small "leper settlements" in Kakamega, Lamu, Malindi and Tumbe (*2*). In 1948, the first attempts were made to treat leprosy systematically using dapsone monotherapy (*2*). Between 1951 and 1957, the Alupe Leprosarium was built in Busia District in Western Province to manage up to 300 patients. In 1956, the NTP was created (*2*), providing control activities that included diagnosis, treatment and occasional mass campaigns using miniature chest X-rays.

In 1973, the Ministry of Health issued a circular that described TB diagnostic procedures, chemotherapy, case-holding, bacteriological monitoring, and recording and reporting systems to be implemented in all districts (*3*). By the end of the 1970s, the incidence of TB disease was declining in most countries of the world, and interest in TB waned. Leprosy, on the other hand, was still prevalent in some areas and continued to receive attention. In the early 1970s, the Government of Kenya with the assistance of the Netherlands Leprosy Relief Association (NLRA) initiated a number of separate leprosy control projects, including the West Kenya Leprosy Control Scheme, the Meru and Kitui Leprosy Projects

"...in 1980
the Government of Kenya
launched the
National Leprosy and
Tuberculosis Programme (NLTP)..."

and the Coast Leprosy Control Scheme. In 1976, these projects were brought together in the national leprosy control programme (NLP).

Interest in controlling TB was revived in the late 1970s with the recognition of the need to strengthen control of the disease in developing countries. In many countries,

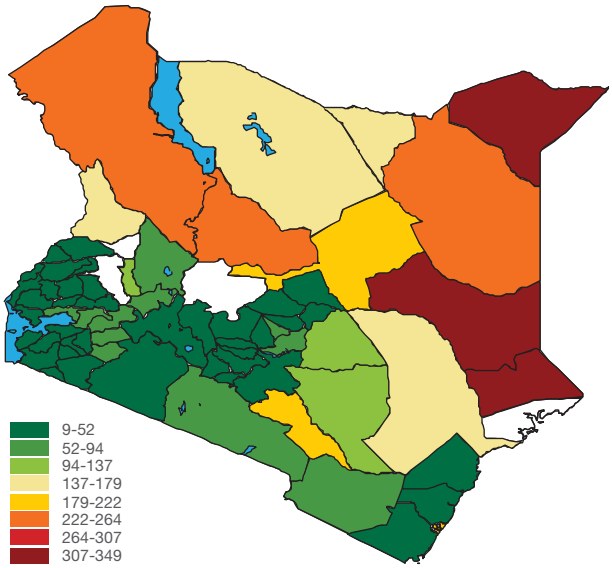

Figure 1. TB Case notification rates per 100k population, Kenya, 1990 (NLTP database; Nairobi)

the control of TB was carried out by the NLP, which already had strong organizational structures. In 1980, the Government of Kenya launched the national leprosy and TB control programme, or NLTP (*2*) in which the existing TB control activities were combined with the activities of the NLP (*4*).

During the 1980s, further steps were taken to improve the quality of TB control, initially by getting provincial leprosy coordinators, many of whom were expatriate staff from the Netherlands, to take on some of the work of TB control. Recognizing the need for dedicated TB staff, the Government of Kenya established a course on chest and skin diseases for clinical officers at the Medical Training College in Nairobi. This course continues to provide training for clinical officers from Kenya and other countries in the region on lung and skin diseases. Most of the Kenyan nationals who are trained go on to become

district TB and leprosy coordinators (DTLCs) responsible for the implementation of TB and leprosy control activities at district and peripheral levels.

It was already apparent, as shown in Figure 1, that the incidence of TB was particularly high in the pastoralist districts of North-Eastern Province (Garissa, Mandera and Wajir), the northern districts of Eastern Province (Isiolo and Marsabit) and in Rift Valley Province (Elgeiyo Marakwet, Samburu, Turkana and West Pokot). In the remoter pastoralist districts, compliance with treatment was poor and up to 70% of patients defaulted. In order to control the disease in these mobile populations, TB patients were admitted into newly constructed small villages, or manyattas, adjacent to a health-care facility, such as a health centre or hospital, for four months.

"In order to control TB...
patients with TB
were admitted
into newly constructed small villages
for four months."

The concept of the 'TB manyatta' was started by Dr Tonelli, a Catholic Sister, who in 1976 persuaded nomads in Wajir District with TB to construct their dwellings next to her health centre to make it possible to receive supervised drug administration. Patients were admitted for four months and a family member was allowed to stay with the patient in order to provide support. The Wajir manyatta received drugs and medical support from the NLTP, and between 1984 and 1986, the Kenyan Government, in collaboration with the Royal Netherlands Tuberculosis Foundation (KNCV), the Netherlands Development Organization (SNV) and the Foundation of Swiss Civil Servants, started TB manyattas at district hospitals first in Lodwar and later in Garissa, Hola, Kajiado, Laisamis, Loitokitok, Marsabit, Moyale, North Horr and Wajir. The manyattas became very popular; only one (Laisamis) failed and was abandoned.

Treatment in the manyattas was observed directly every day, with rifampicin included during the first four months of treatment; this was the start of directly-observed treatment using short-course chemotherapy in Kenya. After four months of treatment, patients were given a three-month supply of Thiazina (thioacetazone and isoniazid) for self-administration and discharged.

Treatment compliance improved greatly, and TB manyattas have since been established in most of the remote and hard-to-reach nomadic districts in Kenya. In the rest of Kenya, the standard 12-month regimen with streptomycin, isoniazid and thioacetazone continued until 1993.

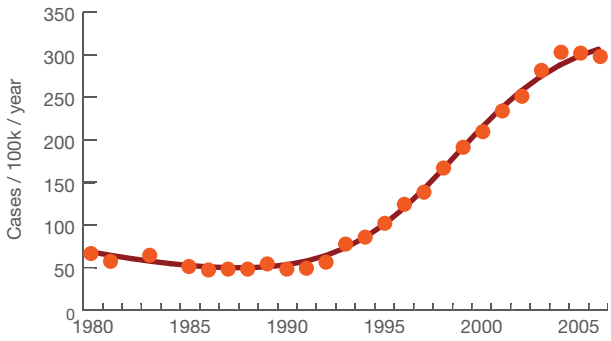

Figure 2. TB case notification rates from 1980 to 2006

Data on TB case notifications are available from 1980 (5), although the systematic recording of TB notification rates according to the type of TB and treatment outcomes only started in 1987. As TB control improved in the1980s, the per capita case notification rates fell by 3.8% per year (Figure 2); if this trend had continued, the notification rate would now be 26 cases per 100k/year instead of 300 cases per 100k/year. However, in 1984 the first case of AIDS was diagnosed in Kenya (*6*) and in 1987 the Government of Kenya set up the national AIDS control programme (NASCOP) to address the HIV epidemic.

3. Short-course chemotherapy 1991–1995

In 1991, the Governments of Kenya and the Netherlands signed a formal agreement to provide financial and technical support to the NLTP for the implementation of short-course chemotherapy for TB and multi-drug therapy for leprosy. The Government of the Netherlands agreed to provide financial support while the Ministry of Health agreed to provide the infrastructure and staff and to procure some of the anti-TB drugs. KNCV and the Netherlands Leprosy Relief Association (NSL) were contracted by the Ministry of Foreign Affairs and Development Co-operation of the Netherlands to help and advise the Kenyan Ministry of Health in the implementation of the plan and to administer the support provided by the Government of the Netherlands. A key component of the plan was the expansion to all districts of short-course chemotherapy, with daily observation, during the initial phase of treatment. In 1991 and 1992, seven Kenyan doctors were reassigned to the NLTP, trained and deployed as provincial TB/leprosy coordinators to take over the work of expatriate staff who had been responsible for implementing programme activities. The team was also strengthened in 1994 with two more staff in the central unit.

> **"In 1991**
> the Governments of Kenya
> and the Netherlands
> signed a formal agreement..."

In 1993, WHO launched the DOTS strategy for controlling TB; in March of that year, a pilot programme using an eight-month regimen (2SRHZE/6TH) for smear-positive TB patients and a 12-month regimen (2STH/10TH) for smear-negative and extrapulmonary TB patients. The standard WHO re-treatment regimen was also adopted.

Implementation of short-course chemotherapy was slow, as each province was obliged to show that acceptable smear conversion rates could be achieved at two months before expanding activities to other districts.

> **"By the mid-1990s**
> it was clear that
> the prevalence of HIV
> was high in Kenya..."

By the end of 1995, 36 out of 39 non-nomadic districts in the country were using the new regimen. Nairobi was among the three districts that were still not using short-course chemotherapy, and only 51% of eligible pulmonary smear-positive cases were being treated with eight months of short-course chemotherapy. The use of rifampicin in the short-course regimen led to concerns that drug resistance would emerge, but a survey carried out in 1994 by the NLTP and KNCV, with the support of WHO, found no evidence for this (*7, 8*).

By the mid-1990s, it was clear that the prevalence of HIV was high in Kenya, especially in the western districts bordering Lake Victoria. It was also known that HIV infection was an important risk factor for TB disease (*9-11*). In 1994, a survey of HIV infection in smear-positive TB patients was carried out; in a sample of 1364 TB patients from 17 districts, the median prevalence of HIV was 36% (26–45%; interquartile range), but in some districts in Western Kenya, up to 80% of TB patients were HIV-positive (*12*). In the same year, 8% of a sample of women attending antenatal clinics tested positive for HIV (*13*). It became increasingly clear that the epidemic of HIV threatened to undermine the improvements made in TB control over the preceding years.

4. Strengthening the National Leprosy and TB Control Programme 1996–2000

The agreement between the governments of Kenya and the Netherlands signed in 1991 concerning short-course chemotherapy (see section 3 above) was evaluated in March 1995. This led to a second agreement for the period 1996–2000 (*2*). The Government of the Netherlands agreed to cover approximately half of the cost of technical assistance, supervision, training, and

"In 1997
short-course chemotherapy
for new smear-positive pulmonary TB patients
was extended to
the whole country..."

laboratory equipment and supplies. Drug costs were divided equally between the two governments, while the Government of Kenya paid salaries for programme staff and provided staff and clinics for diagnosis and treatment at peripheral health units in the public sector. Figure 3 shows the financial contributions to the programme from different sources. In the period up to 2001, the most important external funding was provided by the Government of the Netherlands through KNCV.

Many changes were introduced into the programme. Between 1996 and 2000, the number of diagnostic units was increased by 15% (from 281 to 319), while the number of health units providing anti-TB treatment was increased by 12% (from 976 to 1022), keeping pace with the 12% increase in the total population. The core staff complement remained steady, between 90 and 92 people, up to 1999. In 1997, short-course chemotherapy for new smear-positive pulmonary TB patients was extended to the whole country; Thiazina was removed from the regimen because of severe adverse effects, including Stevens-Johnson syndrome in HIV-positive TB patients. Ethambutol and isoniazid were introduced in combination tablets for the continuation phase of treatment.

"In 1998
short-course chemotherapy
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new smear-negative and
extra-pulmonary cases..."

In 1998, short-course chemotherapy was introduced for new smear-negative and extrapulmonary cases

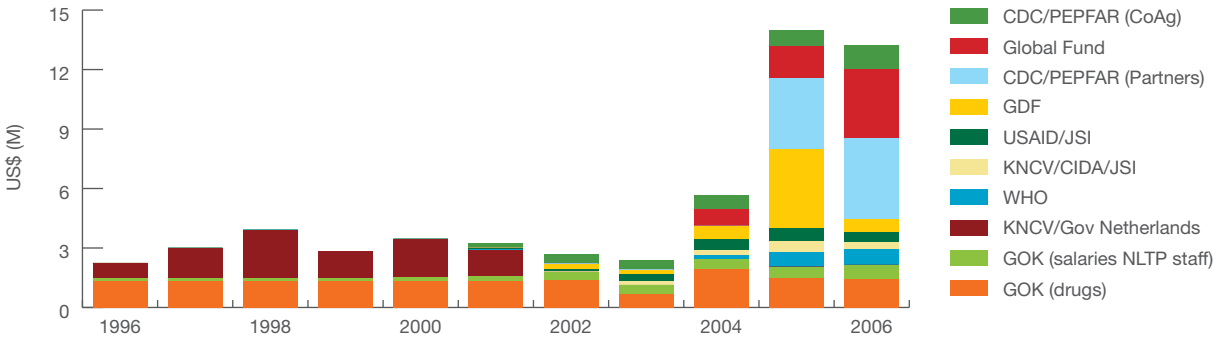

Figure 3. Funding to support the national leprosy and TB control programme in Kenya. Excludes government funding for infrastructure and for staff time used for TB control from those who are not employed exclusively by TB control. (Abbreviations are listed at the front of the document.)

using rifampicin, isoniazid and pyrazinamide during the two-month initial phase and ethambutol and isoniazid in the continuation phase. Full national coverage of short-course chemotherapy for smear-negative and extrapulmonary cases, which was achieved by the end of 1998, was made possible by the experience gained earlier with the implementation of short-course chemotherapy for smear-positive patients. To avoid the risk of spreading HIV-infection through the use of contaminated needles, streptomycin was replaced by the oral drug ethambutol in 1998 during the initial phase of treatment for new smear-positive TB cases, but not for re-treatment cases. Also in 1998, fixed-dose combination tablets (FDCs) were introduced to improve adherence to treatment. The initial-phase regimen consisted of rifampicin, pyrazinamide and isoniazid given as an FDC for smear-negative and extrapulmonary patients with the addition of ethambutol for smear-positive pulmonary TB patients.

> "With the introduction of a **fully oral regimen,** therapy could be observed daily by people in the local community…"

These changes had important implications for directly-observed treatment. Previously, most pulmonary smear-positive patients were either hospitalized or received daily injections of streptomycin at a health facility. With the introduction of a fully oral regimen, therapy could be observed daily by people in the local community or by members of the patient's family. Ambulatory TB treatment also helped to reduce the congestion in TB wards and eliminate queues of patients waiting for their injections in health units. Patients would come once a week to collect their drugs and take the first dose for each week under the supervision of a health worker. As these changes were implemented, it became apparent to the NLTP that TB diagnostic and treatment services needed to be made more accessible by providing them closer to patients' homes, by increasing and decentralizing the number of diagnostic and treatment units and by training peripheral-level health staff.

Case notification rates continued to increase between 1996 and 2000 (Figure 2). Although most of the increase can be attributed to the impact of the HIV epidemic, some of it may have been the result of improved case-finding, and recording and reporting; but it is difficult to separate the impact of HIV and the impact of the programme. The precise trend in HIV prevalence over this period is not certain, but it is likely that the prevalence of HIV peaked about 1997 (*14*). The risk of developing TB increases with time since infection with HIV (*15*) and people with TB present with a median CD4 cell count of about 200/μL, which suggests an average time between infection with HIV and the development of TB of about eight years. The increase in TB, resulting from the spread of HIV, is expected to continue for several years after the prevalence of HIV has reached its peak.

In 1998 a meeting of the NLTP, NASCOP and representatives of private and public health-care providers was held under the auspices of WHO to map out strategies for combating TB and HIV. A multisectoral committee was formed to draft guidelines for collaborative TB/HIV activities, but this task was not completed. In 1999, the Government of Kenya brought NASCOP and the NLTP into the same division within the Ministry of Health in order to strengthen collaboration between the two programmes. In 1999, the Government of the Netherlands decided to consolidate its bilateral country support by reducing the number of countries it was supporting from 109 to about 20, and the NLTP financial support from the Dutch ended in December 2000. The NLTP was, however, given a no-cost extension to enable it to use the remaining funds up to mid-2001 (Figure 3).

5. Challenges and progress 2001–2006

5.1 Funding

The gap in funding and technical support following the withdrawal of support by the Government of the Netherlands was partly filled by the United States Centers for Disease Control and Prevention (CDC) through a cooperative agreement signed between the CDC/Global AIDS Programme (GAP) and the NASCOP/NLTP Division of the Ministry of Health. From 2002 to 2006, the USAID country office provided further funding for TB control activities to the NLTP through John Snow International (JSI), an American nongovernmental organization (NGO) that was distributing drugs and other items for the Kenyan Ministry of Health. The Canadian International Development Agency (CIDA) provided additional support through KNCV, which was administrated locally by JSI. At the end of 2004, the United States President's Emergency Plan for AIDS Relief (PEPFAR) began to operate in Kenya, following which all of the funding provided by the United States Government for any

> **"In 2001**
> a grant agreement was signed between
> the Government of Kenya
> and the newly-formed
> Global Drug Facility (GDF)..."

programmes related to HIV/AIDS, including the CDC/GAP funding for TB/HIV, was taken over by PEPFAR. In 2005 and 2006, PEPFAR provided about US$4 million for TB control (Figure 3), but only some amount of this was used to support the Division of NASCOP/NLTP directly. Most of the funding was disbursed to American NGOs and their national counterparts who were working with the NLTP in Kenya. The Global Fund gave money in 2004 and 2005 from its Round 2 grants, and again in 2006 from its Round 5 grants.

The funding provided by PEPFAR and the Global Fund has been of help to the national programme, but the disbursement of funds, especially from the Global Fund, has not been without problems. Because the accounting requirements of the Global Fund were initially not well understood, the disbursement of funds and the implementation of activities were delayed, and in 2004 only 30% of the funds for TB control from the Global Fund were spent by the NLTP. For this reason, funding for Round 2 was reduced by US$6 million. Between 2002 and 2006, an additional US$ 3.5 million was provided by CIDA and managed by KNCV, for the NLTP to support laboratory microscopy services for the detection of acid-fast bacilli (AFB) and cover operational costs, supervision and human resource development.

In 2001, a grant agreement was signed between the Government of Kenya and the newly formed Global Drug Facility (GDF) to support the provision of high-q uality anti-TB drugs for three years. This was renewed for another three years in 2003 and again in 2005. In 2003, the Ministry of Health failed to procure anti-TB drugs (Figure 3), and in 2003 and 2004 the buffer stock was exhausted leading to a crisis in the procurement of drugs. In response, the GDF provided enough money to procure drugs for 2005 and to build up a one-year buffer stock (Figure 3). This crisis and its resolution illustrate the importance both of partner agencies responding to emergency situations and of good forward planning by governments.

5.2 Diagnostic and treatment facilities

As case notification rates continued to increase (Figure 2), partly as a result of improved programme performance but mainly as a result of the increasing prevalence of HIV, the Kenyan Government further strengthened both the TB and HIV control programmes as well as their joint activities. Figure 4 shows the number of diagnostic units per person, which increased by 50% between 2000 and 2002 (11 to 16 per million people) and more than doubled by 2006 (to 23 per million people); the number of health units per person increased by 28% between 2000 and 2003 (34 to 44 per million people) and by 83% in 2006 (to 52 per million people).

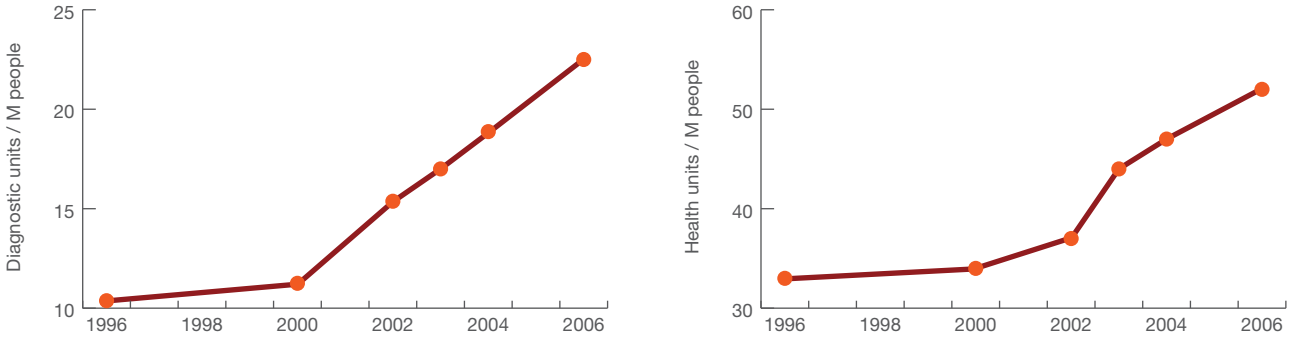

Figure 4. Number of diagnostic units (left) and health units (right) per million people in the population

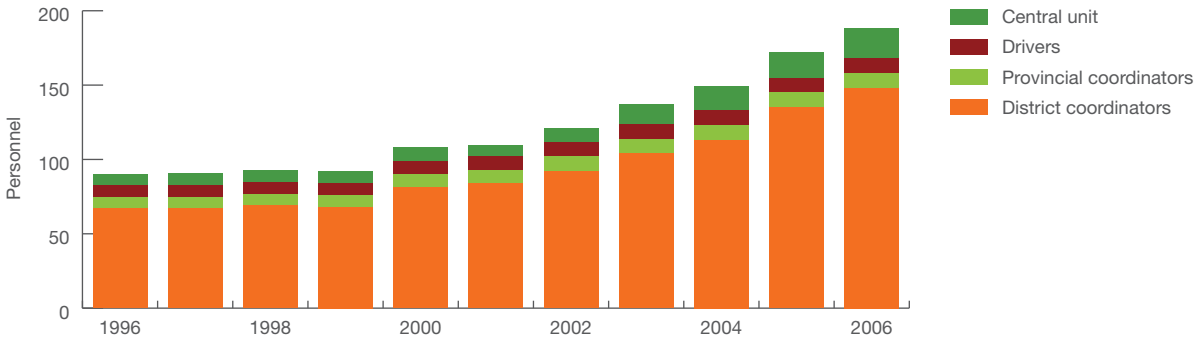

Figure 5. Staff complement of the national leprosy and TB control programme

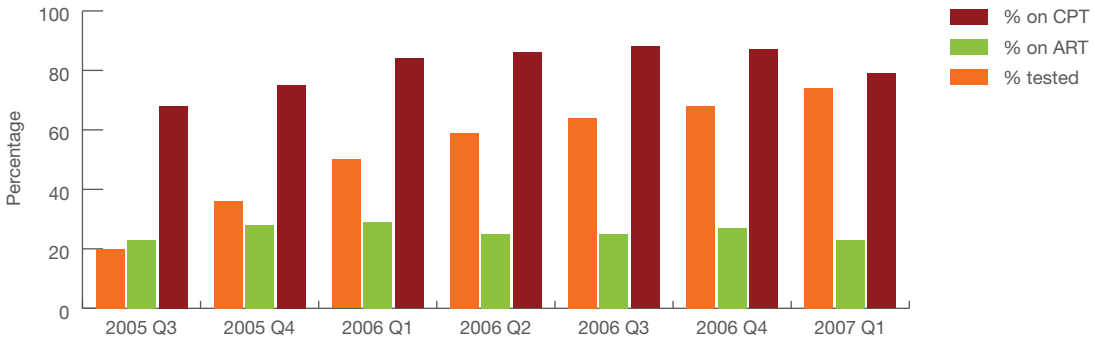

Figure 6. Percentage of patients tested for HIV and, of those who tested positive, percentage starting antiretroviral therapy and co-trimoxazole preventive therapy

5.3 Staffing

TB control is managed and carried out by full-time TB staff in the central unit, the provinces and the districts. The core staff, dedicated to TB control, ensure that activities are implemented according to current policies and that there is coordination with the various partners. Between 1999 and 2006, the staff complement in the NLTP almost doubled (Figure 5); most of the increase was at the district level.

With the increase in staffing, the responsibilities of staff members were redefined and new opportunities for training were provided. At the national level, specific officers were given responsibility for particular initiatives such as collaborative TB/HIV activities, community involvement in TB/HIV care, public–public and public–private partnerships to ensure that all care providers are fully engaged, management of multidrug resistance, infection control, TB control in nomadic communities, TB in congregate settings (prisons and slums), and monitoring and evaluation. Various donors, including CIDA through the Intensified Support for Action in Countries Initiative (ISAC), the Italian Government through WHO, and PEPFAR through PATH, provided support to recruit and pay the salaries of an additional six assistant provincial TB and leprosy coordinators (PTLCs), 30 assistant district TB and leprosy coordinators (DTLCs) and a programme biostatistician for a one- or two-year period.

5.4 Collaborative TB/HIV activities

In 2001, WHO organized a meeting in Nairobi to launch collaborative TB/HIV activities in East and southern Africa, and the first draft of a TB/HIV strategic plan for Kenya was formulated. However, it took another three years before significant progress was made. In 2003, the national TB/HIV steering committee, with a multisectoral membership chaired by the national TB/HIV coordinator, was constituted by the Kenyan Government. At the end of 2004, the Ministry of Health published a policy paper on HIV testing in clinical settings, and provider-initiated counselling and testing of patients with suspected HIV-related diseases, including TB, was introduced and rapidly gained widespread acceptance. The NLTP strongly supported the government policy by developing and implementing a national TB/HIV training curriculum, in collaboration with CDC, WHO and other partners, including guidelines for HIV testing, provision of co-trimoxazole preventive therapy (CPT) and antiretroviral therapy (ART) for HIV-positive TB patients. In 2005, the NLTP data recording and reporting system was adapted to include additional HIV-related information and was introduced in the second half of that year. WHO's "3 by 5" initiative (*16*) helped to increase awareness of the need to provide ART on a wide scale, including among TB patients. HIV testing and the provision of CPT and ART were

> "the proportion of TB patients that were tested for HIV **increased to 74%** in the first quarter of 2007..."

further encouraged by donors such as PEPFAR and the Global Fund, which linked their funding to the provision of collaborative TB/HIV activities. As a result of these decisions and activities, the proportion of TB patients who were tested for HIV increased from 20% in the third quarter of 2005 to 74% in the first quarter of 2007 (Figure 6), when 50% of those tested were HIV-positive. The number of patients starting ART increased roughly in proportion to the number tested, so that the proportion of those who were HIV-positive and started on ART remained more or less constant at about 23%. The actual number provided with ART may be rather higher, as the current recording and reporting system does not capture patients who start ART after the third month of treatment.

5.5 HIV in pregnant women and TB patients

Widespread testing of women attending antenatal clinics and of TB patients made it possible, for the first time, to determine with confidence the relationship between the prevalence of HIV in these two groups (Figure 7) as well as the geographical distribution of HIV infection (Figure 8).

The log-odds ratio for the prevalence of HIV infection in male and female TB patients is 0.69 ± 0.08, which is close to the value usually found in surveys of adults in the general population, indicating that male TB patients are significantly less likely to be infected with HIV than are female TB patients. The odds ratio for the prevalence of HIV infection in TB patients and women attending antenatal clinics is, however, somewhat higher than the value of 8.3 (6.1–10.8) that has been found elsewhere (*17*), with a value of 10.8 ± 1.5 for female and 15.6 ± 1.9 for male TB patients. This may reflect a general decline in the prevalence of HIV, which would be associated with a high proportion of people in the later stages of HIV infection.

Figure 8 shows the geographical distribution of HIV infection in women attending antenatal clinics and in male and female TB patients. The proportion of TB patients who are HIV-positive exceeds 30% in most districts and is greater than 80% in some. For all three groups of people, the prevalence is highest in the districts bordering Lake Victoria. The top-left figure shows the distribution in women attending antenatal clinics in more detail. In eight districts that border the lake, the prevalence of HIV is between 17% and 26%. These data show that while TB patients are likely to be infected with HIV, the problem is particularly severe in the districts surrounding Lake Victoria, and particular efforts need to be made to ensure the smooth functioning of collaborative TB/HIV activities in these districts. From 2002 onwards, the funding provided by the Government of Kenya and international donors such as USAID, the Global Fund, CIDA (through KNCV), the Italian Government (through WHO) and others increased steadily (Figure 3). The contribution of the government was mainly in providing additional staff, expanding infrastructure and providing TB consumables. Partners including CDC, WHO and KNCV increased their technical support. Funding from PEPFAR and the Global Fund increased very substantially in 2005, and the total amount of funding available for TB and TB/HIV control activities more than doubled in that year (Figure 3).

> "Funding from PEPFAR
> and the Global Fund
> increased very substantially
> **in 2005..."**

This rapid increase in funding attracted many new NGOs; PEPFAR alone disburses funds to 14 different NGOs that are involved in the implementation of collaborative TB/HIV activities in Kenya. Using CIDA funding for an initiative called FIDELIS (Fund for Innovative DOTS Expansion Using Local Initiatives), the International Union Against Tuberculosis and Lung Disease supported a TB control project in the Kibera district of Nairobi that was implemented by the International Medical Corps, as well as a community TB control project in the Rift Valley Province managed by the Academic Model for Prevention and Treatment of HIV/AIDS that is run by staff of Moi University, Kenya and Brown University, USA. Many other international NGOs are contributing to TB control in Kenya, including the Program for Appropriate Technology in Health, Family Health International, Malteser (a German NGO), the African Medical and Research Foundation and Médecin Sans Frontières.

The private sector contribution to TB control has increased over the years through expansion of a PPM-DOTS initiative that was developed jointly by the Kenya Association for Prevention of Tuberculosis (KAPTLD) and the NLTP and which had expanded to five large urban centres (Eldoret, Kisumu, Mombasa, Nairobi and Nakuru) by the end of 2006. FIDELIS also provided support to KAPTLD, which initiated public-private mix (PPM) activities in 20 rural districts in 2006. Faith-based organizations work closely with the NTP and receive support for the training, consumables and general supplies that are needed to implement TB control activities.

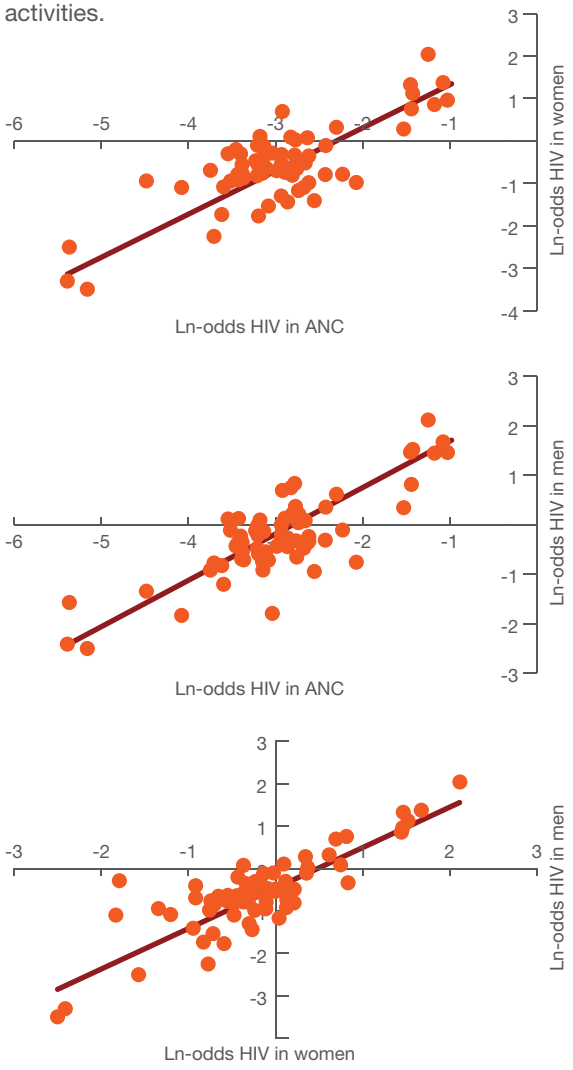

Figure 7. Ln-odds for the prevalence of HIV in women attending antenatal clinics (ANC women) and of female and male TB patients. Odds ratios: a) female TB patients and ANC women: 10.8 ± 1.5; b) male TB patients and ANC women: 15.6 ± 1.9; c) male and female TB patients: 0.69 ± 0.08

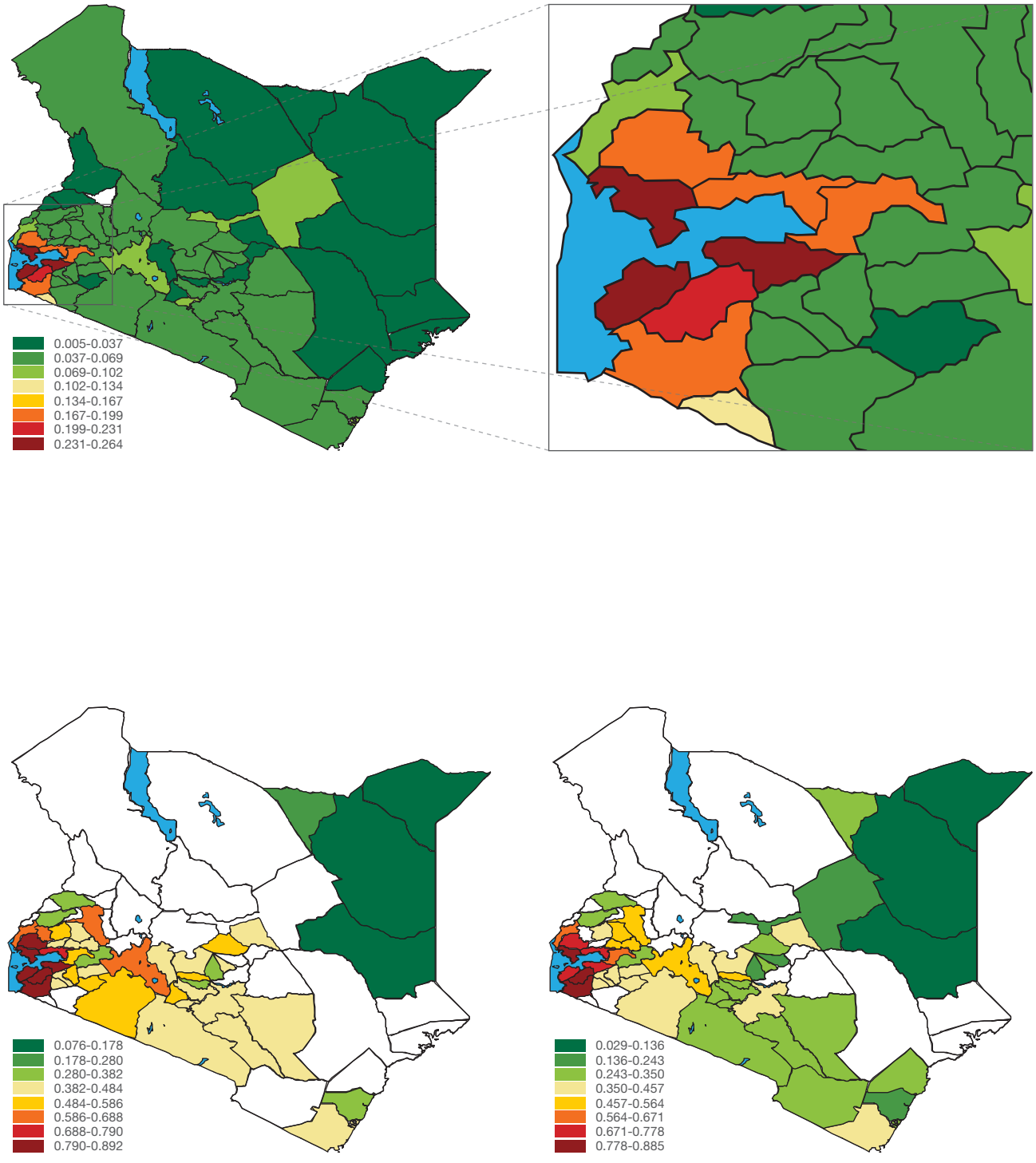

Figure 8. Prevalence of HIV in women attending antenatal clinics (top left) and expanded (top right), and in female and male smear-positive TB patients (bottom left and right). (White areas excluded as sample size was <50.) The districts with a high prevalence of HIV are Bondo, Homa Bay, Kisumu, Migori, Nyando, Rachuonyo, Siaya and Suba.

6. The impact of TB Control

Case notification rates for all forms of TB (smear-positive, smear-negative and extrapulmonary) increased steadily after 1996; but in 2005 and 2006, the smear-positive notification rate began to fall while the smear-negative and extrapulmonary notification rates continued to rise (Figure 9).

Given that the number of diagnostic units, health units and district-level programme staff more than doubled between 2001 and 2006 (Figure 4 and Figure 5), it is almost certain that the case detection rate increased over this period. Firstly, favourable treatment outcomes were maintained and even improved over this period (Figure 10). The treatment completion rates for new patients rose from 77% to 82%, while mortality on treatment fell from 9% to 5%, the proportion that defaulted remained at about 9%, while the proportion that transferred out fell from 7% to 5%. Outcomes for re-treatment cases were not quite as good. Completion rates averaged about 76% and death rates levelled off at about 10%. For smear-negative and extrapulmonary cases, cure rates increased to 79%, while death rates were steady at about 8%.

> "The treatment completion rates for new patients **rose from 77% to 82%** while mortality on treatment **fell from 9% to 5%...**"

Figure 11 shows that over this period, the number of smear-positive cases per diagnostic unit, the number of TB cases of all forms per health unit and the number of smear-positive cases per TB suspect all increased between 1996 and 2000 but started to fall between 2000 and 2004, even as the total number of diagnostic and health units and suspects continued to increase. This suggests that the increasing effort was yielding diminishing returns and that case detection rates must have been high.

	ANC	95% CL	TB patients	95% CL
High HIV	21.6	2.7	76.1	5.1
Low HIV	5.7	1.1	41.0	8.7
Odds ratio	4.56	1.44	4.58	2.91

Table 1. Prevalence of HIV among women attending antenatal clinics (ANC) and among TB patients being tested for prevention of mother-to-child transmission in two groups of districts

In order to explore the relationship between HIV and the increased TB case notification rates further, we compared the notification rates and treatment outcomes in the high HIV-prevalence districts bordering Lake Victoria and in the low HIV-prevalence districts that border these districts (Figure 12). The prevalence of HIV among women attending antenatal clinics and in TB patients was much higher both in the districts bordering the lake and in the districts bordering these districts (Table 1). In both sets of districts, the sputum smear-positive rate started to level off in 2002, increased in 2003 and 2004 and either declined slightly or levelled off after that. This increase coincides with the substantial increase in the number of diagnostic units in 2002, health units dealing with TB patients in 2003 and in the number of district-level staff employed by the NTP over the whole period (Figure 4 and Figure 5).

The same arguments might be used to explain the continuing increase in smear-negative pulmonary and in extrapulmonary TB. However, in both instances there is no sign that the notification rates are levelling off. It is likely that the intense pressure to find more TB cases in Kenya has led to an over-diagnosis of both of these forms of TB. It is unlikely that the proportion of smear-negative pulmonary TB patients is increasing because patients are being found earlier.

Figure 13 shows the trend in the proportion of smear-positive pulmonary TB patients. In the absence of HIV,

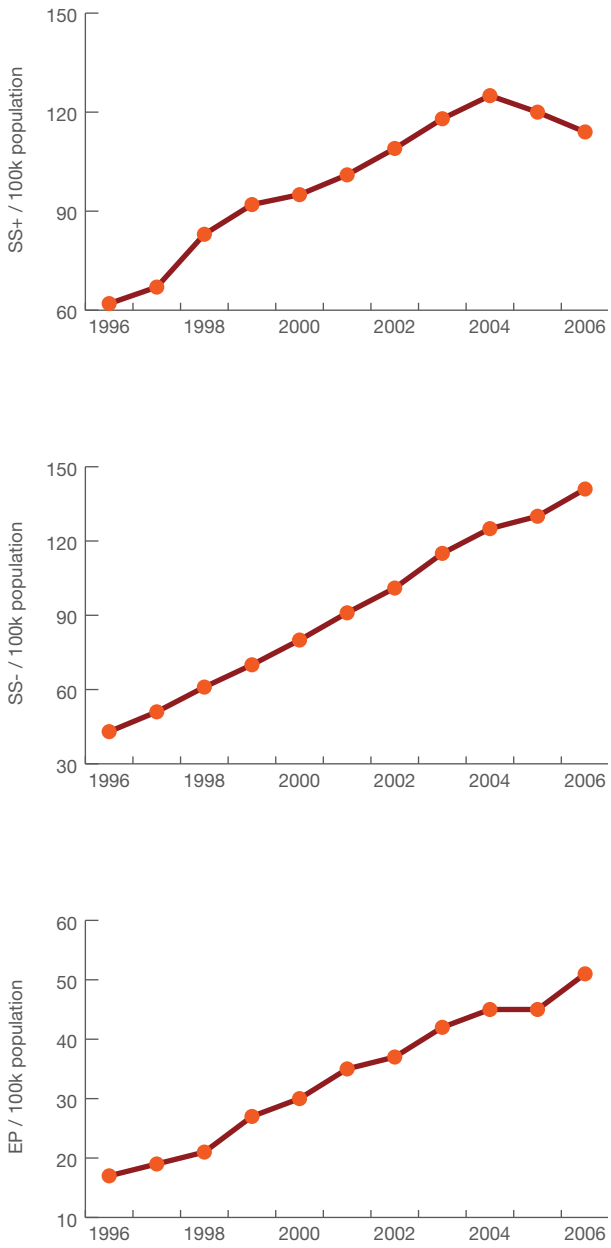

Figure 9. Cases of smear-positive, smear-negative and extrapulmonary TB per 100k total population, 1996–2006

about 60% of pulmonary TB patients are usually smear-positive. In the presence of HIV, this falls to about 50%. In Kenya, the proportion of smear-positive pulmonary patients fell to just over 50% in 2000 and has continued to decline since then, to 44% in 2006. In a small study of data provided by the Central TB Reference Laboratory in 2006, a total of 912 smear-positive and 981 smear-negative relapse patients were investigated. Of the smear-positive cases who relapsed, 25% were culture-negative; of the smear-negative cases who relapsed, 88% were culture-negative, suggesting considerable over-diagnosis, especially among the smear-negative relapse cases.

Figure 14 compares the treatment outcomes for the same two sets of districts. More people did not have smears done in the high-HIV prevalence areas. In both areas, only 0.3% of patients tested smear-positive at the end of treatment; grouping those who were not smear-tested with those who were smear-negative produces almost identical treatment outcomes in the two groups of patients. It appears that the much higher prevalence of HIV in the districts bordering the lake did not compromise the quality of treatment.

"...the case detection rate in Kenya has increased from 57% in 1996 **to 71% in 2006...**"

A recent attempt to re-estimate the case detection rate for smear-positive TB in Kenya, using three different approaches but all drawing on the relationship between TB and HIV in different ways, suggests that the case detection rate in Kenya has increased from 57% in 1996 to 71% in 2006 (*18*).

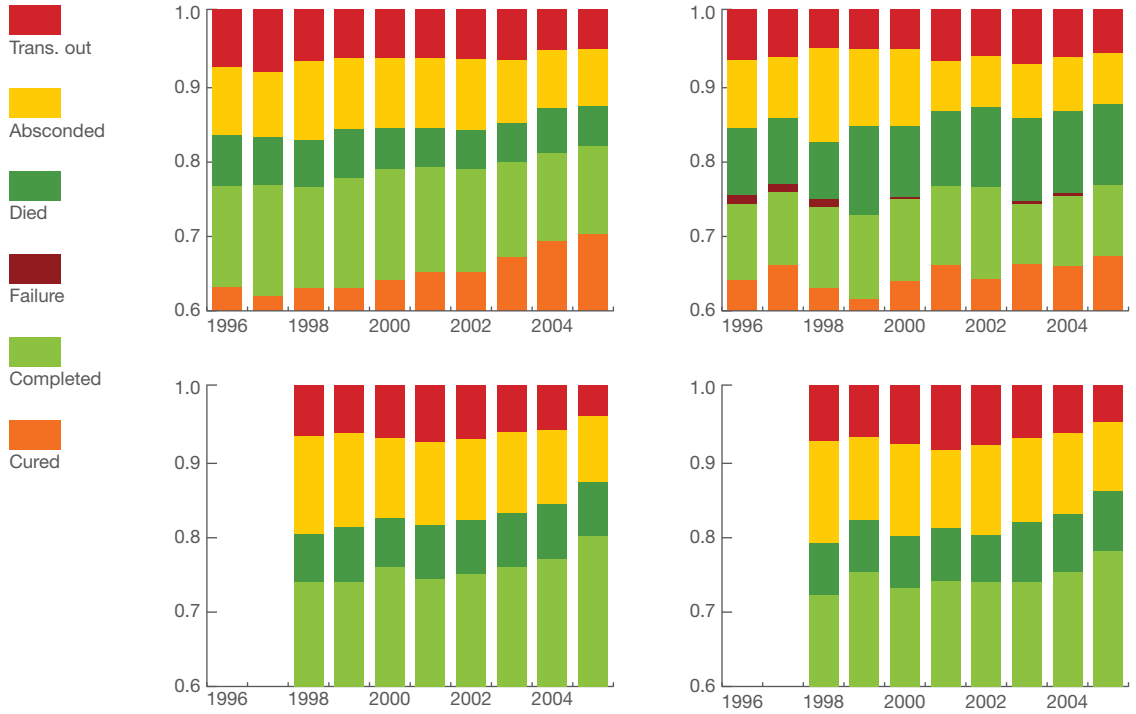

Figure 10. Treatment outcomes for new smear-positive, re-treatment, new smear-negative and new extrapulmonary patients, 1996–2005

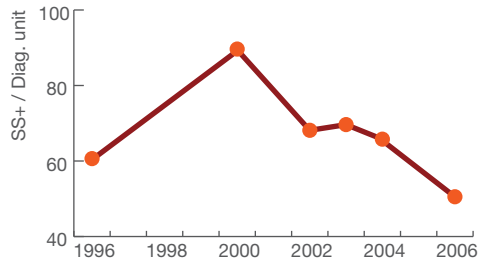

Figure 11. a) The number of smear-positive TB cases per diagnostic unit

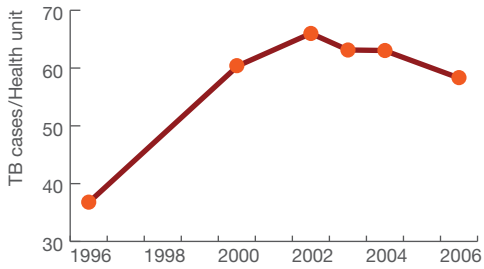

Figure 11. b) TB cases (all forms) per health unit

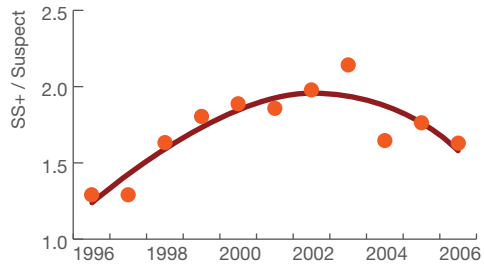

Figure 11. c) Smear-positive cases found for each 10 suspects examined

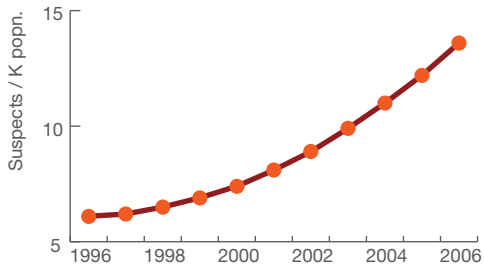

Figure 11. d) TB suspects examined per 1000 population. The data in the bottom-right plot are smoothed estimates because data were available from different districts in different periods of time. The variability around the trend line was about ± 3/k.

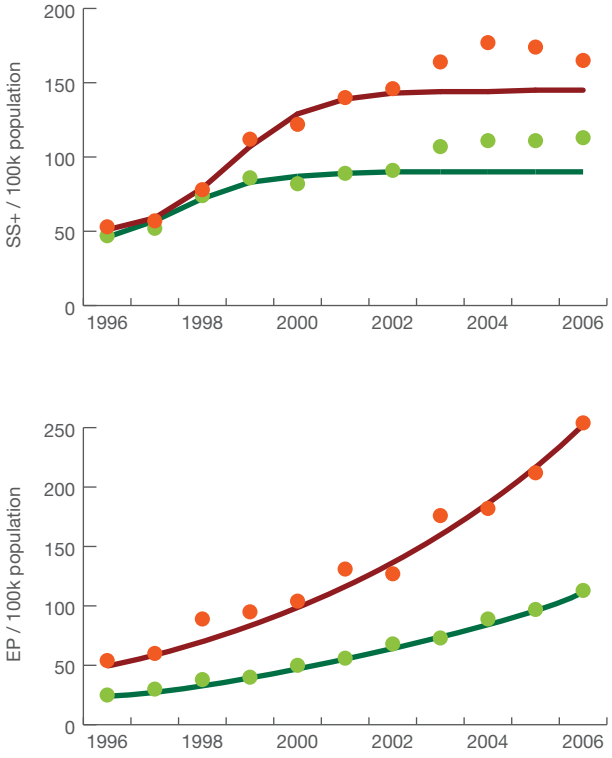

Figure 12. Cases of smear-positive, smear-negative and extrapulmonary TB per 100k population in districts with high and low HIV prevalence bordering Lake Victoria (high, brown lines; low, green lines)

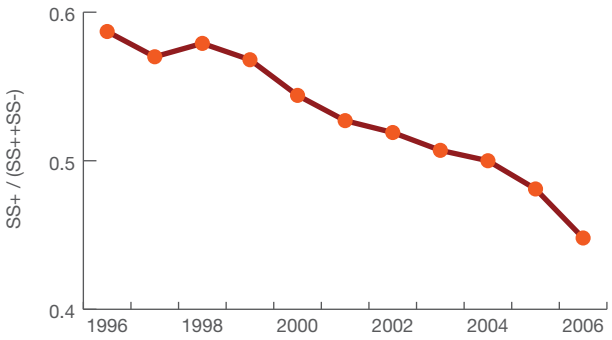

Figure 13. Proportion of smear-positive pulmonary TB cases

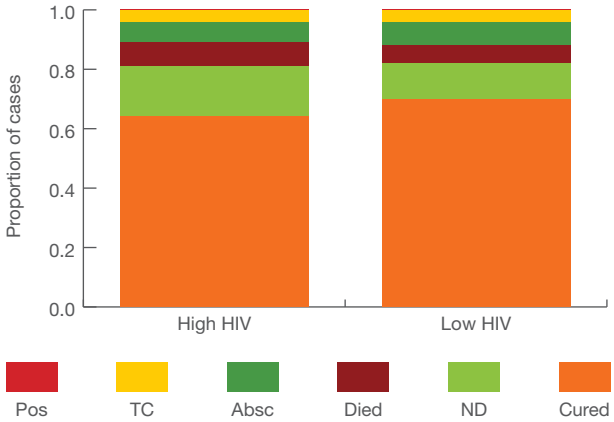

Figure 14. Proportion of initially smear-positive patients who at the end of treatment were classified as cured, not smear-tested (ND), died, transferred or absconded (Absc), completed treatment (TC) or remained smear-positive (Pos), for districts with high and low HIV prevalence (High HIV; Low HIV), Kenya

7. The way forward 2006–2010

Plans for the control of TB in Kenya are presented in the NLTP Strategic Plan 2006–2010, developed in 2005 and 2006. The intention is to consolidate gains from the previous strategic plan that ended in 2005. The development of the new strategic plan was led by the NLTP, supported by a consultant funded by WHO; other stakeholders were invited to participate and contribute. The new strategic plan builds on the achievements of the programme and responds to the new emerging challenges to TB control in line with the Global Plan to Stop TB 2006–2015 (*19*) and the related Regional Plan for Africa developed by the WHO Regional Office for Africa.

7.1 Diagnosis

Kenya has an extensive laboratory network that coordinates services for AFB microscopy. There are now 777 diagnostic centres. The central reference laboratory (CRL) has been strengthened by refurbishing the building, procuring new equipment and increasing the staff complement. It coordinates sputum culture and drug susceptibility testing (DST) for all re-treatment cases and carries out surveillance for drug resistance. Efforts at improving the quality of smear microscopy have been initiated and will be strengthened to include better control of the quality of reagents and regular re-testing of slides at the district, provincial and central laboratories. The CRL, which uses both the Lowenstein-Jensen and the MGIT960 system, will continue to culture specimens for surveillance of resistance to first-line drugs. Promising new rapid methods to test drug susceptibility, such as the Hain Genotype MTBDR plus assay, are being validated with the existing methods at CRL. Second-line drug testing will continue to be done by the supranational reference laboratory in Brisbane, Australia.

7.2 Changes in drug regimens

In 2007, EH (ethambutol and isonazid) was replaced by RH (rifampicin and isoniazid) in the continuation phase of treatment. Full coverage is expected by the end of 2008, reducing the period of treatment from 8 to 6 months. It will be important to monitor the development of resistance to isoniazid and rifampicin.

7.3 Drug supply and quality

The NLTP will work closely with the pharmacy and prisons board, the Kenya Medical Supplies Agency, the Pharmaceutical Society of Kenya, the private health-care sector and the national quality control laboratory to ensure that only high-quality anti-TB drugs are in circulation in Kenya, including in the private health sector. The drug supply will continue to be carefully safeguarded by improving procurement procedures, forecasting drug needs and by strengthening the logistic management information system.

7.4 Monitoring and evaluation systems

Traditionally, the NTP has collected TB data from services delivery points, which will now be further strengthened. The use of personal data assistants for data collection has been piloted in Nairobi and Nyanza provinces. The intention is to introduce electronic recording and reporting throughout the country, making the capture of data faster and more reliable and making it easier to access and analyse individual patient data. A central data bank will make it possible to access data rapidly in order to facilitate planning. Impact studies will be conducted regularly.

To improve the quality of diagnosis and ensure that standard methods are used, the CRL started a programme of external quality assessment, covering all hospitals, in 2003. By 2007, with the support of grants from the Italian government, this had been expanded to cover 30 districts. The intention is to carry out external quality assessment in all districts by the end of 2008.

7.5 Community involvement

A pilot study of community involvement in TB control was carried out in Machakos District in 2004 (*20, 21*) and

found to be both feasible and cost effective. Community-based DOTS will be scaled up from 45 districts to cover the whole country in line with the Ministry of Health's community strategy.

7.6 Engaging all care providers (PPM)

The PPM initiative that was piloted in Nairobi in 1999 and now covers five large urban centres will gradually be scaled up to cover all urban centres. In addition, the PPM activities that were introduced in 20 rural districts with funding from FIDELIS will be strengthened and scaled up to cover the entire country. The intention is to engage all care providers, taking particular care to engage providers who serve the poor in urban slums and in the rural areas. The PPM effort will also include linkage of private sector laboratories to the national external quality assurance system. Other PPM initiatives that are planned include working with the corporate sector and the pharmaceutical retail industry to speed up referral of relevant patients for TB screening.

7.7 Congregate settings

Prisons in Kenya are congested, living conditions are poor and health-care services are weak. The NLTP, in collaboration with the Kenyan Medical Research Institute and CDC, has initiated demonstration TB control projects at both the Kamiti and Kodiaga prisons. By the end of 2008, the lessons learnt in these projects will be used to expand these initiatives to all prisons. The key interventions will include the screening of all new inmates for TB on admittance. Cell mates of index cases of pulmonary TB will be screened for TB. HIV testing services will be made available in all prisons. Attention will also be given to other congregate populations including the police, army and schools.

7.8 Nomadic areas

Much of Kenya is arid or semi-arid and is sparsely populated by nomadic people living far from, and with limited access to, social amenities such as schools and health-care facilities. In these areas, the incidence of TB is high and TB services are limited. The Manyatta strategy – developed specifically for such people – needs to be reviewed. A standing committee has been formed to develop appropriate strategies for the control of TB in remote areas. This committee draws membership from individuals from the programme and NGOs, including African Medical and Research Foundation (AMREF) and Samburu AID In Africa (SAIDIA), who have extensive experience with health service delivery in these areas as well as other relevant players.

7.9 Drug resistance

The most effective way of minimizing the development of resistance to anti-TB drugs is to maintain high cure rates among susceptible patients. In addition, a good surveillance system is needed to identify and manage patients who develop drug-resistant TB. By the end of 2006, only 24% of patients initiating re-treatment for smear-positive pulmonary TB, all of whom should have had sputum samples submitted to the CRL for TB culture and DST, had their sputum samples reaching the CRL. The immediate plan is to increase the proportion of patients eligible for routine drug resistance surveillance through sputum culture and DST to at least 80%.

A national drug resistance survey will be carried out in 2008. An MDR-TB project has already been designed and a proposal for doing this work has been approved by the Green Light Committee (GLC) for the first 40 patients. Drugs provided by the Global Fund were delivered in February 2008. A centre for treating MDR-TB has been set up at Kenyatta National Hospital and the doctors, nurses and an engineer have been trained in Latvia. A country training workshop took place in August 2007 and the initiative is now ready to be rolled out. The intention is to set up a similar centre at the Moi Teaching Hospital in Eldoret.

In January 2008, 40 patients started MDR treatment following approval by the Global Fund (Round 5) of a grant to the NLTP. By the end of 2006, 202 MDR-TB cases had been recorded from the sputum samples submitted to the CRL since 2003. From 2008, the government will provide medicines and diagnostic consumables to all sectors, including the private sector, on the condition that patients have access to these services at no cost.

"...national drug resistance survey will be carried out **in 2008"**

7.10 Funding needs

Using the planning and budgeting tool developed by WHO (*22*), the NLTP will develop a budget for the strategic plan to control TB 2006–2010 and a fact sheet explaining in more detail the funding requirements for TB control in Kenya. In summary, US$ 156 million is required for the five-year period 2006–2010 (about US$ 31 million per year). The largest components of the budget are for DOTS, ACSM (advocacy, communication and social mobilization) and collaborative TB/HIV activities. The needs for DOTS include first-line anti-TB drugs, dedicated NTP staff, programme management, supervision activities and human resource development (including training). Although funding has improved in recent years, mainly as a result of funding from United States Agency for International Development (USAID) and PEPFAR, a funding gap of US$ 64 million for the five-year period remains.

8. Conclusion

The control of TB in Kenya has a long history, starting soon after the Second World War but gaining momentum after independence from Britain. The cumulative experience of dealing with TB over so many years has provided a sound basis for building a strong NTP and in particular for countering the impact of HIV, which has dramatically increased the incidence of TB. Since 1990, the TB notification rate has increased by a factor of six, mainly as a result of HIV. Despite the increased burden of disease, the NTP has been strengthened, cure rates have improved and rates of case detection have increased. Kenya has reached the 2005 targets for both case detection and cure.

"...Kenya has reached **the 2005 targets** for both case-detection and cure."

Starting in the 1970s, but continuing in the 1980s, the NTP developed a solid public health approach to TB control, initially focussing on nomadic communities who were hard to reach and among whom the burden of TB was particularly high. In the 1990s, as the impact of the HIV epidemic became increasingly evident, the NTP introduced short-course chemotherapy and embraced the DOTS strategy. But at each stage, new methods were tried and tested and only rolled out as they were shown to be effective and as the staff were trained and able to apply them.

As the notification rates continued to climb in the 1990s, the Government of Kenya sought and received support from various international partners, both from the KNCV Tuberculosis Foundation and the Government of the Netherlands in particular. With the commitment of the Government of Kenya and the support from the Netherlands, it was possible to expand significantly the number of health units, treatment units and the staff complement in the NTP between 2000 and 2006. This period was not without difficulties. After the Ministry of Health failed to procure anti-TB drugs in 2003, the buffer stock was exhausted but the GDF was able to fill the gap.

Starting at the end of 2005, the NTP rapidly expanded testing of TB patients for HIV and provided TB patients with CPT and ART as appropriate. As the epidemic of HIV recedes, it is likely that the incidence of TB will also begin to fall. However, the prevalence of HIV among TB patients will remain high for many years, and it will be important to ensure that they are provided with access to ART.

There are now plans in place to continue to improve the quality of programme data through the use of electronic reporting and recording systems, to strengthen community involvement in TB control, to engage all health service providers in the control of TB, to strengthen TB control in congregate settings, to re-examine the control of TB in nomadic areas, and finally to strengthen the control and treatment of drug-resistant TB.

Between 1996 and 2003, an average of about US$ 3 million was spent each year for TB control; in 2005 and 2006, this had increased to about US$ 13 million per year. It will be important to examine and to understand the impact of increased funding on TB control over the next few years.

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