



Increasing Access to Antiretroviral Care in Rural Malawi

2003–2009 programme report



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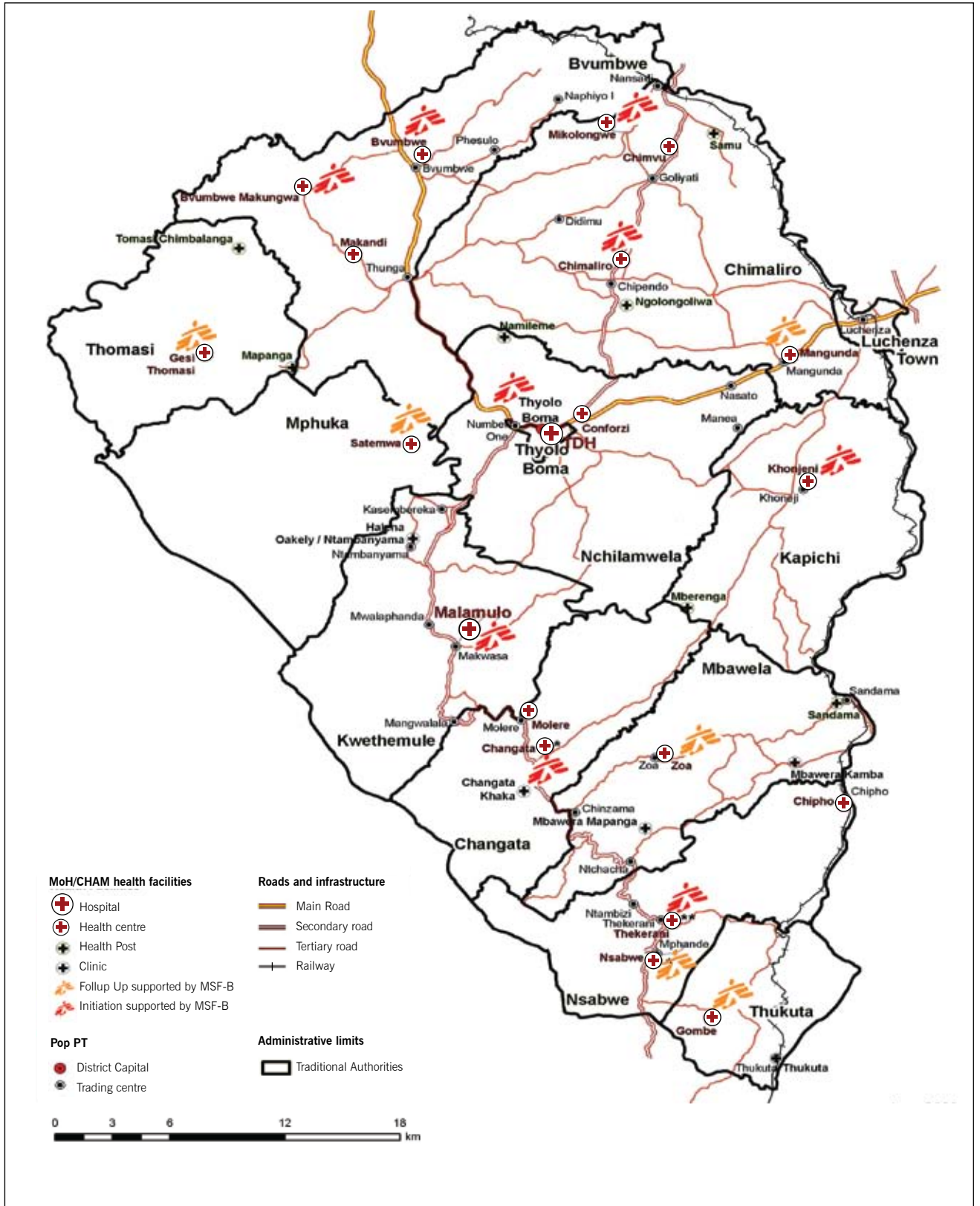
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Table of Contents

THYOLO DISTRICT HEALTH FACILITIES MAP	2
ABBREVIATIONS AND ACRONYMS	3
EXECUTIVE SUMMARY	4
INTRODUCTION	6
HIV/AIDS PROGRAMME SERVICES AND OUTCOMES	7
HIV counselling and testing	7
Management of opportunistic infections	8
Prevention of mother-to-child transmission	9
TB/HIV services	10
Targeted nutrition services	10
Antiretroviral therapy	11
INNOVATIVE APPROACHES TO SCALING UP TREATMENT	13
Simplification of care	13
Task-shifting	13
Streamlining HIV/AIDS services	14
Decentralization of care	15
Community-level services and PLWHA engagement in service delivery	16
Tackling the human resource crisis	17
Staff health services	18
HIV care and health systems strengthening	18
Operational research	19
FUTURE CHALLENGES	20
Sustaining universal access	20
Improving quality of care	20
Long-term support for ART	21
CONCLUSION	22
REFERENCES	23

Thyolo District Health Facilities



Abbreviations and Acronyms

ANC	Antenatal care
ART	Antiretroviral therapy
ARV	Antiretroviral
BEMOC	Basic emergency obstetric care
BMI	Body mass index
DBS	Dried blood spot (testing method for early infant diagnosis)
DHO	District Health Office
DNA PCR	HIV (viral) testing method by DNA
EHRP	Emergency Human Resources Plan
HSA	Health surveillance assistant
HTC	HIV testing and counselling
OI	Opportunistic infection
MoH	Ministry of Health
MSF	Médecins Sans Frontières
NAPHAM	National Association of People Living with HIV/AIDS in Malawi
NRU	Nutrition Rehabilitation Unit
PCR	Polymerase chain reaction
PLWHA	People living with HIV/AIDS
PMTCT	Prevention of mother-to-child transmission
TB	Tuberculosis
WHO	World Health Organization



Executive Summary

Background: Malawi is among the ten countries of the world with the highest prevalence of HIV. Despite a dire shortage of health workers and high levels of poverty, the Malawian government has introduced a 'public health' model of care that relies on non-physician clinicians to deliver antiretroviral drugs (ARV) and which today has enabled the country to treat more than half of the estimated 300,000 needing antiretroviral therapy (ART).

The programme: Since 1997, together with the Ministry of Health (MoH), Médecins Sans Frontières (MSF) has supported HIV/AIDS care in Malawi's southern Thyolo district, where poverty rates are more than ten percent higher than the national average and some 57,500 people are living with HIV/AIDS, including 11,500 in desperate need of ART.

In 2003, MSF and the MoH developed a feasible model of care for a rural, highly impoverished district like Thyolo. Four years later, the Thyolo programme had managed to scale up ART to provide universal access to treatment across the district. At the end of 2008, the number of people on ART had increased further, indicating that, over a year and a half later, universal access was maintained. This is a remarkable achievement in a district where health structures are poorly equipped, human resources for health are insufficient, and the majority of the population lives in remote rural villages.

This successful model of care is based on several essential elements: HIV counselling and testing (HCT); Prevention of Mother to Child Transmission (PMTCT); integrated TB diagnosis and TB/HIV care; targeted nutrition support; scaling up ARV at the primary health care level; tackling the human resource crisis through task shifting and other measures, and strengthening of HIV care and health systems.

Some notable successes include increased HIV testing as a result of scaled-up testing services at primary health care level and in hospital wards, and improved access to diagnostic tools for children; better access for women to PMTCT services and; improved TB detection and integrated TB and HIV care through 'one-stop' health clinics; and nutrition support to reduce mortality among TB patients and other vulnerable groups.

ARV coverage was significantly improved through the scale-up of services available at primary health care level, which was made possible through five key steps:

- i) Simplifying of ARV care through adoption of the 'public health approach' which includes standardized case finding and treatment and minimized laboratory requirements;
- ii) Task-shifting, where certain medical responsibilities were delegated to less specialized health

care workers, enabling a four-fold increase in ART initiations despite the critical shortage of health workers in the country;

iii) Providing support to patients, whereby a 'multi-track' system was introduced to streamline patients according to clinical status and duration on ARVs. This led to clear service efficiency gains, including a two-fold increase in the number of patients enrolled on ART, a two third reduction in delays to starting treatment, and freeing-up specialized health workers to provide non-HIV related consultations;

iv) Decentralization of care, substantially increasing the number of sites offering ART, bringing services closer to patients' homes and thus supporting the scale-up of ARV coverage as well as reducing treatment defaulting; and

v) Providing community level services and engaging people living with HIV/AIDS in service delivery. Providing patients with community support significantly improves patient survival and retention in care. Establishing community health posts to provide a minimum package of HIV services decongests health services and increases access to a range of essential non-HIV services.

MSF also focused efforts in retaining staff through the provision of training and other non-monetary incentives, as well as dedicated staff health services and support networks for health workers reluctant to seek HIV care themselves in the same facilities where they treat patients.

Future challenges: The Thyolo model of HIV care has proven effective, yet there are clear challenges for the future. Ensuring sustained universal access

to treatment will require putting 80% of the 6,000 to 7,000 newly eligible patients on treatment each year. However, the widening gap in human resources threatens universal access and as much as innovative approaches to task shifting remain important, the number of health workers overall must increase in the district. Equally, current costs to ensure universal access are within the World Health Organization (WHO) minimal essential health care costs. However, any introduction of new drugs could threaten affordability and will require major advocacy efforts.

Another core challenge is to improve quality of care by increasing capacity to manage stable patients at the community level. Community health posts are expected to play an increasingly important role in decongesting hospitals and health centres and bringing care closer to the need. In addition, testing facilities must be improved in terms of quality and access to ensure that eligible patients are identified and put on treatment early. The standard treatment regimen provided in Thyolo shows good durability, nevertheless efforts must be made to address inevitable needs for better access to viral load and second line treatments.

Provision of support for people on ART will need to evolve over time as patients face new challenges related to long-term adherence and retention in care. In addition, community care should be developed so that ARVs fit with people's lives, rather than the other way around. Clinical challenges can also be expected to change over time, requiring strong supervision of health care provision at the peripheral level.



Introduction

Malawi (population 13 million) is a small, highly impoverished country with an HIV prevalence estimated at 12% [1], placing it among the ten highest HIV prevalence countries worldwide. Despite a dire shortage of health workers and a high level of poverty (per capita GDP is just \$US596 [2]) the government of Malawi has made tremendous efforts to scale up HIV care and treatment. The country embarked on a national scale-up of antiretroviral (ARV) care in early 2004, at a time when an estimated 170,000 people were in need of antiretroviral therapy (ART) [3]. A model of care was developed that relied on non-physician clinicians to deliver ART. Together with other innovations aimed at simplifying the delivery of ARVs as much as possible, Malawi's 'public health' approach to HIV care has today enabled around 245,255 people start on ART via 223 ART delivery points country-wide [4]. Of these, 158,138 were alive and on ART at the end of the first quarter of 2009. This represents over half the number of people currently estimated to need ART in Malawi (300,000) [1]. This approach has put Malawi ahead of many of its better-resourced neighbours in terms of ARV coverage - South Africa, Malawi's wealthiest neighbour, has a GDP per capita more than 16 times that of Malawi, yet its ART coverage is significantly lower, estimated at just 30%.

Médecins Sans Frontières (MSF) Belgium has been supporting HIV/AIDS care in Thyolo district, southern Malawi, since 1997. Thyolo district (population 587,455 [5]), is one of the country's poorest

districts: the poverty rate is more than 10% higher (64.4%) than the national average (52.4%) [6]. It also has one of the highest rates of HIV infection in the country – 23% of adult women and 18.6% of men are HIV-positive [7].

In mid 2003, MSF and the Ministry of Health (MoH) set out to develop a model of care that would be feasible in a rural, highly impoverished district like Thyolo. After two years, having demonstrated the feasibility of ART in this context, the objective evolved into ensuring district-wide access to ARTs. Based on 2006 figures, an estimated 57,500 were living with HIV/AIDS in the districtⁱ, among whom approximately 11,500 (c. 20%) were at the time in urgent need of ART. Each year 6,000 to 7,000 new patients in Thyolo are estimated to progress in their disease and require treatment.ⁱⁱ This ambitious goal was met in August 2007, when the target of over 9,000 patients alive and on ART was reached, which represents universal access according to MoH targets at the time.ⁱⁱⁱ At the end of 2008 the number of people receiving ART increased further to 16,106, indicating that universal access is being maintained.

This report outlines the main package of HIV/AIDS services, some of the achievements of the MSF/MoH programme in Thyolo, and describes the essential elements of the model of care that enabled universal access to ARVs in this rural district.

i According to an overall HIV prevalence of 10% in Thyolo District
ii Assuming that each year one eighth of Stage 1/2 patients progress to Stage 3/4
iii Universal access is defined by MoH as reaching at least 80% of the need



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HIV/AIDS programme services and outcomes

MSF provides support to HIV/AIDS care in Thyolo district via two hospitals, 29 primary care health centres, and several community health posts.^{iv} These health facilities are part of the district health network and MSF works in close collaboration with the District Health Office (DHO) of the MoH and other partners. A full package of HIV/AIDS services is provided, including HIV testing and counselling (HTC), management of opportunistic infections (OIs), prevention of mother-to-child transmission (PMTCT) services, nutritional support, integrated TB and HIV care, and ART for adults and children. Strong community links have also been developed for community-based HIV care and follow up.

HIV counselling and testing

Recognizing that HIV testing is the entry point for prevention, care, treatment and support, the government of Malawi has promoted provider-initiated HTC as national policy since 2006. This is supported by a national 'testing week' each July,

Major milestones in the evolution of Thyolo ART Programme

- 1997:** MSF support to HIV/AIDS/TB services begins
- 2002:** PMTCT begins
- 2003:** MSF/MoH starts ART in Thyolo district (April 2003)
- 2004:** National ART programme begins; delocalization of ART follow-up and care to nine peripheral sites
- 2006:** ART delivery is decentralized to health centres
- 2007:** National policy provides for nurse initiation of ART. Universal access to ART is reached
- 2008:** ART begins in community health posts (mainly refilling of ARVs under nurse supervision)

which contributes substantially to the number of people tested across the country. A five-year plan, launched in 2006, aims to ensure testing services are integrated into all health facilities and to increase the number of testing sites with the aim of testing a total of 3.8 million people by 2010 [8]. By the end of 2008, a total of 1,465,338 tests had been conducted via 677 HTC static testing sites and 248 outreach sites [9].

In Thyolo, as elsewhere, HIV testing is mainly accessed via health services. Provider-initiated HTC has been gradually introduced in the health centres since 2003, and the number of testing sites has increased steadily over the years, from two in 2003 to 31 in 2008. Today, health centres are the main access point for testing, with over three-quarters (77%) of all tests done in health centres in 2008. There are plans to further expand availability of testing to 13 community health posts in 2009. HTC is also provided at a number of tea estates in the district, an important strategy to provide an entry point to care for labourers, including high-risk migrant workers.

A key policy that has supported the rapid expansion of HIV testing at the primary health centre level is the deployment of Health Surveillance Assistants (HSAs) – an official MoH health worker cadre who are generally community health workers – to do HIV testing and counselling. This is in contrast to other countries in the region where testing is limited by policies that only allow nurses or higher cadres to draw blood for HIV testing. Thanks to this approach, a cumulative total of 311,337 tests have been done in Thyolo over the last 10 years, over a quarter of which (85,000) were done in 2008.

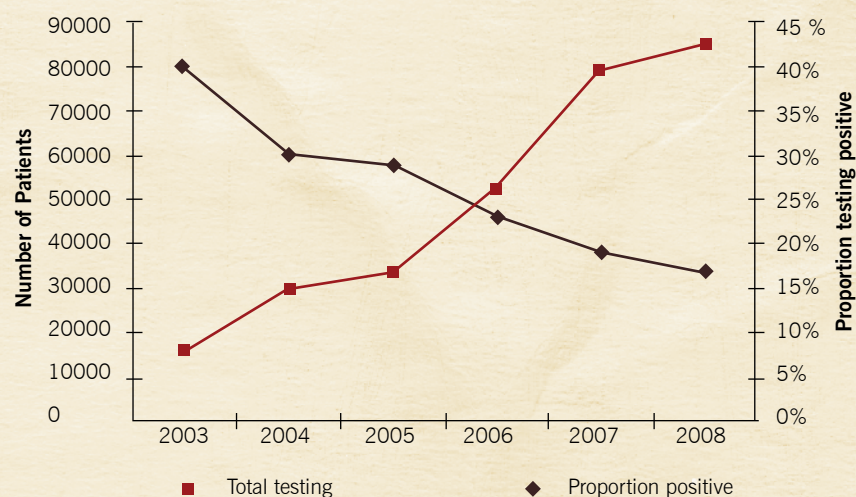
In 2007, early DNA PCR using dried blood spot (DBS) for sample collection was introduced to support the diagnosis of children under 18 months. At the district hospital, HTC is carried out in different wards (paediatric, NRU, TB, Male & Female, and maternity) contributing greatly to the identification and enrolment of people into HIV care.

Figure 1 shows the increase in testing over the last five years. The fact that the proportion of people testing HIV positive is falling indicates an increase in acceptability of HIV testing among the general population: more people who are HIV negative are testing, which is an important part of HIV prevention.

Management of opportunistic infections

All individuals who are found to be HIV positive undergo systematic screening for opportunistic infections and are then classified into different WHO clinical stages (a proxy for the severity of HIV/AIDS disease). Clinical staff have undergone specific training to be able to recognize and manage common opportunistic infections and know when to refer patients to a higher level. Drugs for clinical management of specific infections as well as cotrimoxazole preventive prophylaxis are routinely provided in all health facilities and through community sites according to national guidelines. Former studies conducted in Thyolo and in Karonga districts have shown that cotrimoxazole prophylaxis is a simple, safe and effective adjunctive intervention associated with a 19% reduction in death rates (compared to historical controls). The number needed to treat to prevent one death in both district-based studies was 12 patients [10,11].

Figure 1. Increase in testing and proportion testing positive, 2003-2008



Prevention of mother-to-child transmission

Together with the MoH, MSF started Prevention of mother-to-child transmission (PMTCT) activities in 2002 in Thyolo's two district hospitals. Around 14% of mothers attending antenatal care services in Thyolo district test HIV positive today (Figure 2). Given an average of 34,500 pregnancies per year, this translates into an estimated 4,830 HIV-positive mothers giving birth in the district each year.

A study done in Thyolo district between March 2002 and September 2003 found that while more than nine in ten mothers attending antenatal care (ANC) services accept provider-initiated counselling and testing, over three-quarters of the HIV-positive mothers had defaulted PMTCT by the six-month postnatal visit [12]. The main reason for this was considered to be that limiting PMTCT provision to the hospital setting limits access, particularly for women living in remote areas.

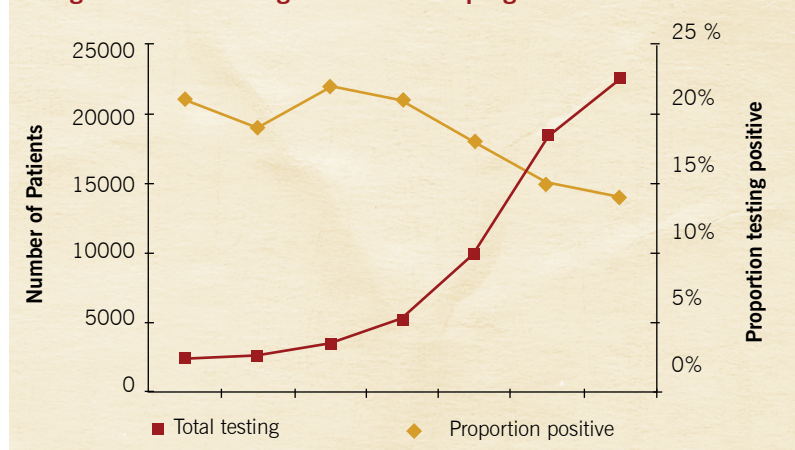
Several strategies were developed to improve the programme uptake and reduce loss to follow-up, including: introducing early infant diagnosis by PCR-DNA using DBS at hospital level (in August 2007; to be introduced at health centre level in 2009); decentralization of services to increase access to care in the community; the provision of post-delivery kits for pregnant women attending the ANC (since 2008) and nutrition supplements as incentives to encourage positive PMTCT seeking behavior and retention in care. Finally, a mentor programme is being introduced in 2009, through which experienced mothers who have gone through PMTCT, mentor new mothers, to improve the follow-up of the full package of PMTCT services for one year.

A major limitation to PMTCT coverage is the fact that more than half of births in Thyolo district take place outside of health facilities [13]. The availability of PMTCT services closer to the community has therefore been an essential strategy to enrolling mothers into care. From 2006 onwards, PMTCT activities were decentralized to health centre level to reduce defaulting and expand access to services, and today PMTCT care is available across 20 sites in the district. More than 100 trained traditional birth attendants across the district were also supported to promote PMTCT and bicycle ambulances were distributed to facilitate referral of deliveries to the health centres. MSF also supported the development of maternity waiting homes and (basic emergency



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Figure 2. HIV testing in the PMTCT programme



obstetric care) BEMOC sites in order to further encourage uptake of PMTCT services, in particular safe deliveries at clinic level.

Thanks to these initiatives the number of women followed by health centres has almost doubled from 22% to 41%. A total of 51,006 pregnant women were counselled and tested through ANC services between 2006 and 2008 and uptake of PMTCT services has increased progressively as a result. In 2006, only 59% (1,017) of pregnant mothers testing positive were enrolled in the PMTCT programme; this increased to 104% (2,927) in 2007 and 111% (3,502) in 2008 (figures exceed 100% as some clients enrolled in the PMTCT programme were tested elsewhere so already knew their status). Similarly, there has been a progressive increase in the number of pregnant women started on ART, from 111 in 2006 to 186 in 2007 and 316 in 2008. While a positive trend, this is below the annual target for the district of 372 new initiations per year. The rate of increase is mainly limited by the poor availability of CD4 testing, particularly in remote health centres. Uptake of ARV prophylaxis is high, with 96% (2,363/2,473) of children born to HIV-positive mothers receiving full ARV prophylaxis in 2008.^v

^v Single doses of Nevirapine at birth and more than 4 days of AZT according to national protocol.

TB/HIV services

TB is the leading cause of HIV/AIDS mortality in Thyolo and Malawi as a whole and strategies to improve TB diagnosis and treatment have been a priority. Initially, access to TB diagnosis in Thyolo district was limited by the fact that this could only be done at the hospital. Data from 2008 show that over three-quarters (79.6%) of new admissions to the TB ward were HIV-positive; 675 (40%) of all new TB cases were smear positive. Almost a quarter (23%) of the total TB and HIV-positive patients (386/1,677) were already on ART upon admission while 382 (23%) started ART whilst in the ward after testing positive for HIV.

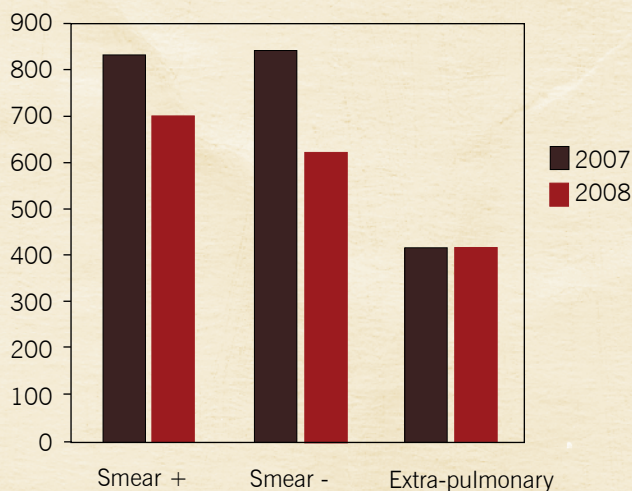
From 2005, with MSF support, the DHO increased the availability of microscopy at health centre level. Microscopy is performed by HSAs who have received specialised training and a rigorous quality control mechanism has been put in place, involving a systematic random sampling of sputum samples, following an approach recommended by the National TB control programme. Other improvements included the introduction of fluorescence microscopy in Thyolo hospital laboratory, the piloting of community sputum collection sites (sputum is collected in sputum containers and transported to smearing and fixation sites at the hospital or health centre) and the integration of HIV and TB services by means of a 'one-stop' clinic for ARV review, management of opportunistic infections, and TB treatment (available at three health centres so far). Finally, a project is underway in 2009 to assess the

feasibility of TB culture in the Thyolo district hospital to improve the diagnosis of sputum negative and extra-pulmonary TB.

In the last few years the detection rate of TB cases has increased, which is mainly due to the increase in the diagnostic capacity in the health centres as sputum collection sites. Active case finding has been introduced in all health centres and some tea estates since 2006. Five sputum smear fixation sites have been established in health centres, where sputum samples from the other sites are smeared and fixed, then transported to microscopy sites. This has contributed to a decrease in the absolute number of TB cases in the district in 2008 (see Figure 3).



Figure 3. Number of TB cases in Thyolo, Malawi



Targeted nutrition services

Food insecurity and stunting are common in Malawi and strongly associated with increased mortality in HIV/AIDS patients. A study done by MSF in Thyolo found that early mortality (first 3 months) was 3.9% in patients with normal nutrition compared with 26.2% in those with severe malnutrition [14]. Similarly, patients presenting with TB were found to have almost twice the risk of early mortality if they were moderately or severely malnourished. This is of particular concern given that over a third of TB patients present with moderate or severe malnutrition [15]. Nutritional support is provided to selected groups – children, adults with a low body mass index (BMI < 17) and all mothers enrolled in the PMTCT programme. In 2008, 556 people received nutritional support (Plumpynut) via hospital programmes (three sites) and a further 1,324 via an outpatient therapeutic programme (12 sites). At the community level adults and adolescents were enrolled and managed in 23 sites whilst orphans were managed in 12 sites.

Antiretroviral therapy

In many southern African countries, the initiation and management of ART is done by medical doctors. In Thyolo, where there are just three doctors for the whole district, task-shifting has been promoted whereby the majority of routine clinical tasks related to ARV delivery have been shifted to lower health worker cadres, in particular medical assistants. Thanks to this approach, over 16,000 people had been initiated on ART by the end of 2008.

Figure 4 shows the cumulative outcomes for the Thyolo programme since the beginning of ARV care in 2003 to the end of 2008. Overall 80% of patients ever initiated on ARVs are still alive and in care which compares favourably with other ART programmes in southern Africa [16]. The different causes of attrition – death and defaulting – are strongly associated with facility type, with significantly more patients defaulting from hospital-based care [17]. This is discussed in more detail below.

Data from Thyolo District Hospital show that people are enrolled into care when they are less sick and put on treatment more quickly than before: the mean CD4 at treatment initiation has risen from 175 in 2003 to 234 in 2008. Over the same period, the mean delay to initiation has fallen from 98 to 38 days (see Figure 5). These data provide a reassuring indication of improved access to care (rising CD4 count) and service efficiency (reduced time to initiation), which can be expected to have a favorable impact on early mortality.

Particular attention has been paid to paediatric care. At the beginning of the ART programme the enrollment of children into ART care was limited by a lack of feasible HIV diagnostic tools and paediatric drug formulations. MSF, together with other international actors (notably the Clinton Foundation) supported the introduction of improved diagnostic tools and medicines for children in Malawi. Early infant diagnosis (DBS-PCR) was introduced in mid-2007. As of June 2009, 597 children have been tested, among which 7% have tested positive. Treatment was improved through the introduction of paediatric fixed-dose combinations since 2007 (previously guardians were instructed to break up adult pills).



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Figure 4. Cumulative ART treatment outcomes in Thyolo, Malawi, 2003-2008

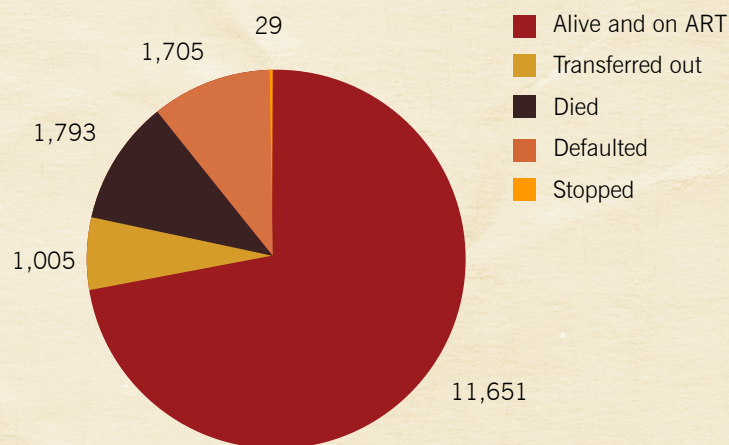
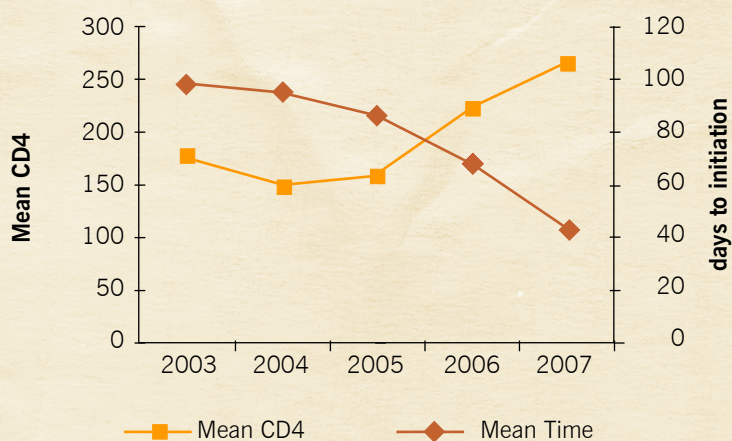


Figure 5. Mean CD4 count at ART initiation and time to ART initiation





Overall, 1,370 children have been initiated on ARVs as of the end of 2008, representing 9% of the overall cohort. Annual enrollment almost doubled between 2006 (264) and 2008 (415), reflecting an increase in confidence and skill of the medical assistants and clinical officers to initiate treatment in children. The plan for 2009 is to decentralize initiation of children to health centres (see Table 1).

Table 1. Treatment outcomes of children initiated on ART in 2008

Patients	Hospitals	Health Centres	Total
Initiated	312	103	415
Alive & on ART	226 (72%)	87 (84%)	313 (75%)
Defaulted	46 (15%)	3 (3%)	49 (12%)
Died	12 (4%)	11 (10%)	23 (6%)
Transferred Out	28 (9%)	2 (2%)	30 (7%)



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Innovative approaches to scaling up treatment

In just four years, the Thyolo programme has managed to scale-up ARV care to provide universal access to treatment across the district. This is a remarkable achievement in a district where health structures are poorly equipped, human resources for health are insufficient, and the majority of the population lives in remote rural villages. A number of innovative approaches enabled this rapid scale-up, including simplification of protocols for testing and treatment; task shifting to increase the number of health workers engaged in HIV care and improve efficiency; decentralization of care to health centres and community sites to spread the workload across multiple sites and increase access; and community engagement to increase capacity and ensure sustainability. These different approaches are outlined below.

Simplification of ARV care

The national scale-up plan launched in 2004 was founded on a public health approach to ARV delivery, simplifying as much as possible the laboratory and drug regimens for HIV care. This approach was first implemented in the Thyolo programme, where a

standard system of case finding, free standardized treatment, and quarterly, paper-based monitoring with standard treatment outcomes were established for all ARV sites. Laboratory requirements were minimized, with initiation based largely on clinical criteria (CD4 tests are not mandatory) and a standardized treatment regimen was adopted, based on a generic fixed-dose combination of stavudine, lamivudine, and nevirapine (Triomune, Cipla,). To date, the vast majority (over 95%) of patients in Thyolo district still receive this standard first-line regimen.

Task-shifting

Task shifting involves the delegation of certain medical responsibilities to less specialized health workers [18]. Given the acute shortage of doctors in the country a number of other cadres to support health services have been established by the MoH over the years to support health services, including clinical officers (four years training), medical assistants (three years training) and Health Surveillance Assistants (HSA) (ten weeks training).

Scaling up ART could only happen through a model of delivery involving non-physician clinicians as the central providers of ARV care. At the start of the programme in 2003, ART initiation and follow-up was done by doctors, but from 2005 clinical officers and medical assistants were permitted to initiate and follow-up treatment. This resulted in an increase in the number of new inclusions from 103 to 379 per month in the district [19]. With strong support from the DHO, follow-up treatment was further delegated to HSAs under nurse supervision, enabling initiations to increase to over 400 per month. In all, task-shifting has allowed for a four-fold increase in ART initiations. The effectiveness of such task-shifting has since been supported by a number of studies from Malawi [20] and elsewhere in southern Africa [21-23]. The Malawi experience has also contributed to WHO recommendations on task-shifting, released at the end of 2007 [24].

Despite these achievements, the human resource crisis remains critical in Thyolo district, and it is clear that further task shifting options will need to be explored as the current model will be unable to sustain ART coverage in terms of an ever increasing case load and quality of care. Future innovations include the full engagement of medical assistants and nurses in ART initiation (currently limited by the number of nurses), and the delegation of more tasks to HSAs and community groups (see Table 2).

Streamlining HIV/AIDS services

In addition to expanding capacity, the allocation of different tasks according to patient needs has led to clear service efficiency gains. At Thyolo District Hospital patients are directed to health providers according to their clinical status and duration on ART. Patients with clinical complications enter the 'slow track' and receive a comprehensive examination and follow-up by a clinician (medical or clinical officer); new patients and those with mild problems are managed by a clinical officer in the 'medium track'; stable patients (on ART for more than two months and with no clinical complications) are put on the 'fast track', overseen by a nurse. The average number of consultations per health care provider is 210/month for the slow track, 680/month for the medium track, and 2,100/month for the fast track. Thanks to these service adaptations the number of patients enrolled onto ART treatment doubled from 130 to 250 patients/month in the hospital; and the median delay in starting ARTs for eligible patients has reduced, from 98 days in 2003 to 38 days in 2008. In addition, streamlining has enabled health staff to devote considerably more time to non-ARV consultations – between 2003 and 2008 the total number of HIV consultations increased almost nine-fold while the number of staff remained the same (see Figure 6).

Table 2. Allocation of key tasks among health staff

Task	Past	Current	Future
Hospital			
HIV testing & counselling	Nurse	HSA/Lay counsellor	
ART/OI care	Doctor	Clinical officer	Clinical officer & Medical Assistant
Dispensing ART/drugs	Pharmacist	Nurse	Nurse & HSA
Ward rounds	Doctor	Clinical officer	
Complicated cases & treatment failure, 2 nd line	Doctor		
Health Centre			
HIV testing & counselling	Nurse	HSA/Lay counsellor	PLWHA
ART initiation	Doctor	Clinical officer & Medical Assistant	Medical Assistant & nurse
Follow up & OI management	Medical Assistant	Nurse	
ART dispensing	Medical Assistant & nurse	Nurse & HSA	HSA
Community			
WHO clinical staging	Clinical officer	Nurse	
Group counselling	Nurse	Nurse	Lay counselor & PLWHA
Screening & OI management	Medical Assistant	Nurse	
Support & defaulter tracing	Nurse	Nurse & PLWHA	PLWHA
Support group activities	Nurse	Nurse & PLWHA	PLWHA

In the health centres, a similar model of patient management applies. All patients starting ART enter the 'slow-track' where they are overseen by a medical assistant or nurse and after two months, provided there are no complications, they then enter the 'fast-track' where they are overseen by HSAs.

Decentralization of care

The very few doctors who work in Thyolo district are, as in the rest of Malawi, concentrated in hospitals. Task shifting has enabled the decentralization of ARV services from hospital to health-centre level. This approach, promoted as government policy since 2006, has allowed for a substantial increase in the number of sites offering ARV care and at the same time decreased the overall health care burden on tertiary facilities. As of March 2009, Thyolo district had successfully decentralized ART initiation to seven peripheral health centres with the furthest over 60 km away from the Thyolo district hospital. In addition, there are a further 16 ART follow-up sites across Thyolo district, to which patients initiated at hospital or health centre level can be referred. Services are now closer to the patients' homes and ART coverage has increased (see Figure 7).



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Over the last three years the number of people followed up at hospital level has steadily decreased as capacity at the health centres has increased. 631 patients were down-referred to health centres in 2006, 770 in 2007 and 552 in 2008. During the same period there was a substantial increase in the number of patients initiated at health centre level, from 496 (14% of all patients initiated in Thyolo district) in 2006 to 1,366 (32%) in 2007 and 1,866 (42%) in 2008. By the end of 2008, around 40% of patients were being initiated in health centres ; 61%

Figure 6. Number of consultations (total and ART) in Thyolo District Hospital

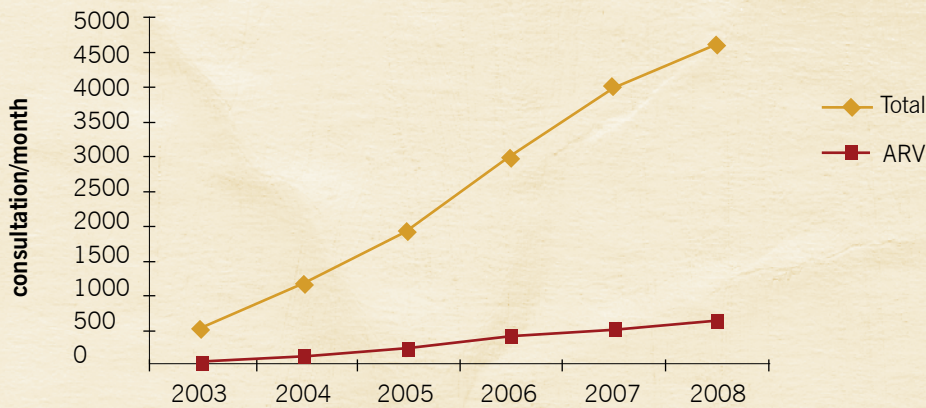
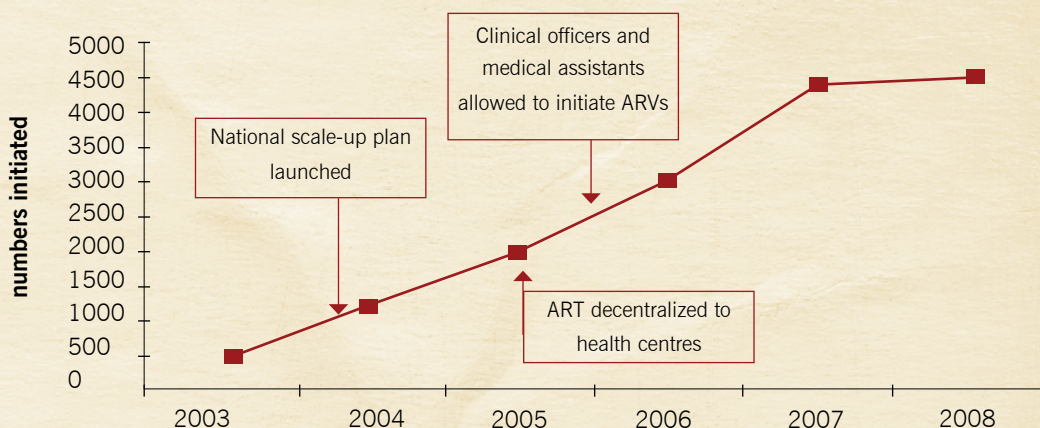


Figure 7. Decentralisation of ART services in Thyolo, Malawi





of patients already initiated were being followed-up at the health centre level.

By bringing care closer to people's homes, the decentralization of ART care has reduced the rate of treatment defaulting. An operational research study done in 2006 to 2007 found that the loss to follow-up rate was significantly higher at the hospital level (9.9%) than at the health centre level (1.5%); overall, there was a 77% absolute risk reduction in loss to follow-up in patients who started ART at health centres compared with the district hospital [17]. Mortality was higher at the health centres, possibly due to weaker ascertainment of deaths among patients lost to follow-up at the hospital level: tracing studies in Malawi have found that around half of all patients lost-to-follow-up have in fact died [25]. This is expected to improve over time.

These outcomes, together with the practical need to expand entry points to care (there are only two hospitals in Thyolo district compared with 29 health centres) support the expansion of ART care at health centre level. The objective is to have 60% of patients followed-up at health centres by the end of 2009.

Community-level services and PLWHA engagement in service delivery

Community groups play an essential supportive role for people with HIV/AIDS. Prior to the introduction of ART in 2003, considerable numbers of patients were bedridden and community home-based carers (nurses and volunteers) provided palliative care and other basic support that allowed people to maintain

their dignity. Community efforts also focused on increasing HIV/AIDS awareness and prevention activities such as condom distribution.

The contribution of these community groups became even more important with the introduction of ART. The groups encourage early treatment seeking and provide support to encourage long-term adherence. Studies have shown that community support can lead to better adherence [26] and retention in care [27]. A study done by MSF/DHO in Thyolo district, found that patients who were offered community support had significantly better survival and retention-in-care rates compared to patients who did not receive such support [28]. As of the end of 2008 over 9,000 patients – 67% of the total ART cohort – were registered within the community home-based carer network. Further efforts will be made during 2009 to find ways to maintain and increase the number of patients supported by community groups.

Community-based care is further expanding through the establishment of 13 community health posts that provide a minimum package of HIV services, including HTC, basic Opportunistic Infection care, blood-taking for CD4 count, health promotion, counselling, and referral for ART initiation. It is also envisaged that these community health posts will be able to provide ARV refills dispensed by HSAs under nurse supervision in the community. This is currently being piloted in one health post, with plans to increase to five posts during 2009. As well as removing the need for stable patients to go to health centres when they have no clinical need, this strategy is expected to contribute substantially to decongesting health centres.

In addition, a range of essential non-HIV services will be provided, including care and treatment for prevalent chronic diseases (epilepsy, diabetes, and hypertension), malaria diagnosis and treatment (during the rainy season), family planning, nutrition support and health promotion. All these services have been provided with strong support and coordination of the DHO. Each health post will be overseen by one community nurse and two to three HSAs. As of the end of 2008, six health posts were already functioning. The plan for 2009 is to add an additional seven health posts, prioritizing areas of low health service coverage. The health posts will be established in areas that are located more than 10km from existing health centres and will each serve a catchment population of 5,000 to 15,000. By managing stable patients and providing care to people with HIV/AIDS who are not yet eligible for ART, these sites are expected to contribute

substantially to supporting retention in care. At these sites, nurses also provide HIV nutrition services at community sites for eligible HIV-positive adults and children (adults with BMI <17 and children with MUAC less than 110).

A core partner for community-based HIV care is the National Association of People Living with HIV/AIDS in Malawi (NAPHAM). NAPHAM listed more than 8,000 members in Thyolo as of the end of 2008 (up from 1,000 in 2003). They form 85 community support groups, spread across Thyolo district, which meet about twice monthly for peer support sessions and ART adherence discussions, overseen by group leaders who receive training from MSF. NAPHAM also organizes outreach activities (where 30 members trained by MSF do health promotion group talks in health centres, schools, and community gatherings), and one-to-one supportive counselling sessions (where 64 members trained by the project's HTC team promote testing and ART awareness in communities).

As the programme matures, the issues facing NAPHAM members have evolved, with a shift in focus from treatment and medical problems towards economic and social issues. Income-generating activities are being piloted by NAPHAM. Community based programmes (previously mainly home-based care activities) are being re-oriented to form a community safety network supported by over 1,554 volunteers covering over 90% of the district, organized into 85 peer support groups, 45 of which are currently overseen by NAPHAM. Parallel to this, a specific support network is engaged in programme support activities, including defaulter tracing (for both HIV and TB treatment), long-term treatment adherence and treatment literacy supported by the 85 peer support groups. However, community resources are not unlimited and although there is considerable potential it will be important to ensure that adequate support is provided as responsibilities increase. The community should also not be perceived as a group for simple relegation of activities (a dumping ground for responsibilities) that ought to remain within the mandate of government. Although the experience so far has been very encouraging, there is no evidence to show that volunteerism can be sustained in the long term and introducing proper monetary or other forms of remuneration might ultimately be necessary [27].

Tackling the human resource crisis

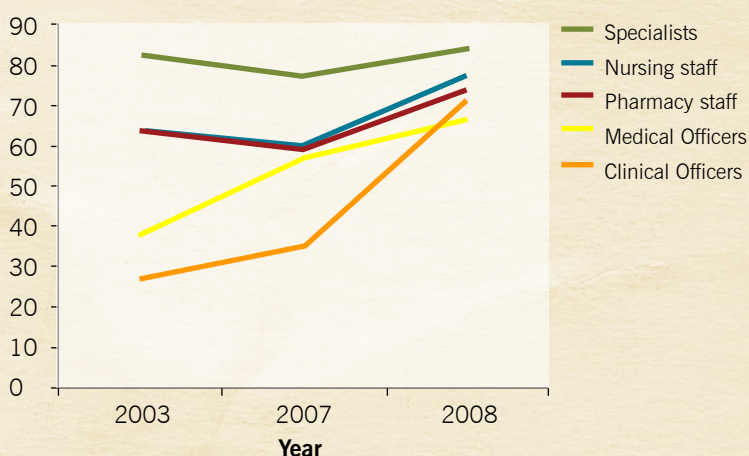
Malawi faces a severe shortage of human resources for health. According to a health employee census done at the end of 2008²⁹ there were just 135 doctors in the whole country – ten times lower than

the recommended minimum. [30] Of these, over half (72) are based in the two largest cities, Lilongwe and Blantyre. This acute shortage of health workers is due to a number of factors including inadequate salaries (many nurses only earn around \$US6 per day) and allowances, poor housing, limited prospects for training and career advancement, inadequate supervision, difficult working environment, and limited involvement in decision making [31-35].

Malawi's shortage of health workers was officially declared a crisis in June 2004. That year, the government launched a six-year 'Emergency Human Resources Plan' (EHRP), with support from a number of international donors, in particular the UK government and the Global Fund [29]. To support this plan the government reached a special agreement with the International Monetary Fund (IMF) to allow salary increases for health workers.

The EHRP has implemented a wide range of measures to support the production and retention of health staff, including: a 52% increase in health worker salaries; actively recruiting retired health workers and health workers who had left to work overseas; raising the retirement age from 55 to 60; expanding training capacity through infrastructure improvement and a tutor incentive programme; recruiting nurse tutors, doctors, specialists, and management support from overseas; and improving human resource management in the MoH. These measures have led to visible improvements: the absolute number of health workers has increased (although not at a level to match increased need), as has the number of health workers in training (all cadres). Despite these efforts, overall vacancy rates are greater than before (see Figure 8), mainly

**Figure 8. Available staff positions and vacancies
Thyolo, Malawi**



reflecting an increased number of positions that have been established to respond to growing health needs. In 2008 vacancy rates exceeded 70% across all health cadres, with the gap widening most rapidly for clinical officers and medical assistants [36]. Although the programme had planned to improve living conditions and provision of hardship packages for health staff in rural areas, building of staff houses has been delayed and the MoH has not yet been able to find sufficient funding. Health staff are still unevenly distributed over the country, with 35% of the nurses serving 80% of the population in the rural areas [36].

The main reasons for the limited impact of the EHRP to date relate to administrative obstacles to implementation (e.g. contracts and payments for previously retired staff) and insufficient knowledge of the benefits available.

Sustaining universal access to treatment in Thyolo district means putting an average of 80% of the 6,000 to 7,000 newly eligible patients on treatment each year. The number of health staff in Thyolo district will therefore have to increase proportionally to this increased patient load. According to government estimates the number of clinicians working in Thyolo district will have to more than double in the next five years (from 14 to 33) while the number of nurses will have to increase almost three-fold (from 12 to 29) to be able to respond to HIV needs alone. However, current trends are running in the opposite direction. In 2008 the number of MoH staff working in Thyolo district has not increased significantly. As a consequence, those that remain are increasingly overwhelmed: medical assistants deal with an

extremely high workload of 150 to 200 general consultations per day in the health centres.

In collaboration with the DHO, MSF is engaged in a number of activities to encourage staff retention, including a range of non-monetary incentives based on team performance (such as awards) and increased supervision and ongoing training.

Staff shortages are most acute in rural areas, and therefore the focus has been on reinforcing staff in the health centres in these areas. To increase capacity, further opportunities for task-shifting are being explored, including increasing the responsibilities of HSAs, one of the few cadres that has increased in number. The emphasis on community engagement is also helping to relieve the strain on health services. A major concern, however, is that funding for additional HSAs, currently supported by the Global Fund, could end in 2010.

Staff health services

The main cause of attrition among health staff (44%) is illness and death, often HIV-related. Health workers are reluctant to seek medical care in the same facilities as their patients and this particular stigma contributes to the high mortality rates among staff. In 2006, MSF and the DHO established a dedicated clinic within the Thyolo District Hospital where staff can access care. In its first year, almost 1,400 consultations were carried out and almost 50 staff were enrolled in ARV care. Similarly, a health worker peer support group has been established. Thanks to this service, increasing numbers of health staff have accessed HIV care. In October 2007, MSF organized a conference to raise awareness and stimulate more action to address HR shortages in the country, with a focus on the influence of human resources and on HIV/AIDS services [37]. In 2008, MSF initiated the establishment of the Nurses' HRH Action Platform to exchange information and identify areas for advocacy. Several research projects are being conducted to gather more evidence on the effectiveness of various approaches, including task shifting, the staff clinic, and the impact of an incentive system based on team performance (STAR awards).

HIV care and health systems strengthening

The high prevalence of HIV/AIDS in Thyolo district has led to substantial mortality and morbidity justifying a massive effort to scale up HIV/AIDS care. At the same time, the unmet health needs in Thyolo



are vast and range from seasonal infectious diseases like malaria and cholera to chronic diseases such as epilepsy, hypertension and diabetes. As ARV services have been rolled out across primary care services, together with the DHO, MSF has made substantial efforts to ensure that the quality and availability of all basic services are improved. Improvements have been made in terms of laboratory capacity, rationalizing drug supply management, renovating clinical and staff housing, and reinforcing the referral system for acute care.

All health centres have benefited from an increase in laboratory capability. Haemocue machines were installed in all health centres for monitoring of PMTCT mothers and people on AZT. Sputum samples can now be examined at 5 health centres with 4 other sites being able to perform the full preparation (smearing and fixation) for reading. In all, 14 HSAs and several medical assistants have been trained in these laboratory techniques. CD4 sample collection is now done at four community health posts, all health centre ART initiation sites (7) and all PMTCT sites (29), with samples transferred to Thyolo District Hospital for analysis. Rapid diagnostic tests for malaria (Paracheck) have also been made available at all health centres. Finally, a laboratory quality control team was established that provides supervision and mentoring for various aspects of techniques and safety.

In terms of rationalizing drug supply management, dispensers were recruited and trained in drug dispensing, allowing medical assistants who were formerly responsible for this task to focus on clinical duties. Consumption and ordering systems have been reinforced through regular supervision activities and the establishment of consumption reports in collaboration with the DHO pharmacist.

MSF supported renovations/extensions in nine health centres while three new outpatient department structures have been built including four maternity waiting areas in BEMOC sites. Staff houses have been renovated at two health centres, and new houses will be built at another five health centres in 2009. A further six staff houses will be built or renovated at the community health posts. Furthermore, five



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cholera camps have been erected in five health centres with 13 waste zones in 13 health centres.

Finally, to reinforce the referral system for acute care, transport for patients in need of emergency care has been provided, and a paper-based referral and counter referral system was established to monitor the quality of referrals and provide feedback to the health centres.

Operational research

Malawi has been an exceptional example in the developing world of successfully integrating an operational research agenda that is guided by the MoH in collaboration with national and international partners. Capacity to coordinate and lead such research has been built at both national and district levels and strongly influences national policy and practice.

This approach has brought with it a strong culture of scientific reasoning and reporting which guides programme orientation over time. Over the years, Thyolo district has significantly contributed to the scientific literature with involvement in close to 50 peer reviewed scientific papers



Future Challenges

The outcomes presented here provide reassuring evidence that the model of care elaborated in Thyolo district is thus far effective. There are, nevertheless, a number of clear challenges for the future. Chief among these are the need to ensure sustained universal access to treatment, to improve the quality of care, and to provide meaningful long-term support for patients.

Sustaining universal access

A 2005 costing analysis found that the average annual recurrent costs for direct care per patient on ART were US\$237. Most of the money went on ARVs (67%) and other essential drugs (14%); laboratory costs accounted for only 6%. Overall, the average annual cost for achieving universal access to ART is US\$3.2 per inhabitant, which is well within the minimal basic health package costs estimated by WHO, though not yet within the national health expenditure per capita. Clearly, the greatest threat to affordability will be the introduction of new drugs – to improve first line drug therapy and expand access

to second line therapy – and this is where major increase in donor support will be needed.

Another important consideration for the sustainability of care provision is the widening gap in human resources. Together with the MoH, MSF will continue to support innovative approaches to task shifting and decentralization, but this will not overcome the need for a significant addition of human resources, in particular clinical officers and nurses.

Improving quality of care

The main challenge for improving quality of care is to increase capacity to manage stable patients at the community level. Still today too many people are required to travel long distances to access health services, which results in delayed access to care, and avoidable mortality and attrition. The community health posts are expected to play a critical role in decongesting hospitals and health centres, bringing care closer to the need, and supporting retention in care.

Efforts are needed to increase access to laboratory investigations, in particular CD4 and viral load. Work has been done in recent years to improve access to CD4 as discrepancies were found between clinical staging and CD4 criteria for initiation: an internal study found that almost a quarter (23%) of patients who were clinically staged as being in stages 1 and 2, and thus not in clinical need for ART, had a CD4 count less than 200, meaning they were in fact eligible according to immunological criteria. As a result of this finding, CD4 counts are now done routinely at the hospital and in several community sites. Capacity will need to be expanded to ensure that CD4 counts are available at the community level for all those in need. This will be piloted in five community health posts in 2009.

The standard treatment regimen provided in Thyolo district shows good durability, with only 13 patients on second line treatment today. The low development of treatment failure was confirmed by a cross-sectional study which found that only three of 53 randomly sampled patients had a detectable viral load (VL >1000 copies/ml). Nevertheless, the need for improved first line and better access to viral load and second-line treatments will inevitably be of increasing concern and efforts must be made to ensure broader availability and affordability.

Long-term support for ART

The provision of support for people on ART will need to evolve over time as patients face new challenges related to long-term adherence and retention in care. Models of support will need to be elaborated at the community level to ensure as much as possible that ARVs are made to fit into people's lives, rather than requiring people to fit their lives around ARVs. Clinical challenges can also be expected to change over time (e.g. development of non-AIDS defining illnesses, long-term toxicities, drug resistance) that will require strong supervision of health care provision at the peripheral level.

Ensuring long-term support means ensuring sustainable financing for treatment. Currently, all funding for first- and second-line drugs for adults is provided by the Global Fund, while all paediatric drugs are provided by the Clinton Foundation. Such external support will need to be sustained for some time to come.

Finally, the work of the community support groups will be essential for providing patient support over time. Their work will need to be adequately compensated if it is to be sustained.



Conclusion

The Thyolo programme has demonstrated the feasibility of scaling up ART to the district level, even in rural areas where human resources for health care delivery are severely limited. Outcomes over time are satisfactory and show that quality of care can be sustained.

A number of challenges have been highlighted in this report to ensure that universal access is sustained, quality of care is continually improved, and people on ART are supported over the long-term to ensure they maintain good adherence and receive a continuity of safe and effective treatment.

The initial aim of the Thyolo programme was to demonstrate feasibility, and this has been achieved. The challenge for Malawi as a whole lies in replicating the positive lessons of the Thyolo programme and other successful ART programmes in Malawi in other districts. Still today, access to ART remains highly heterogeneous in the country.

This is a challenge that the government of Malawi cannot face alone. As across southern Africa, HIV/AIDS remains a major cause of mortality in Malawi and will only be confronted with substantial and sustained support of international donors.

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