

LIST OF ABBREVIATIONS

AIDS Acquired immunodeficiency syndrome

ART Antiretroviral treatment

ARV Antiretrovira

CD4 Cluster of differentiation 4, human immune system

CTS Community treatment supporters

DOTS Directly observed treatment, short-course

DR-TB Drug-resistant tuberculosis
DS-TB Drug-sensitive tuberculosis

DST Drug sensitivity test

EAAA Early access to ARV for adults
GDP Gross domestic product
HCWM Health care waste management
HTC HIV testing and counselling
HIV Human immunodeficiency virus
ICER Incremental cost-effectiveness ratio

MAI Integrated management of adolescent and adult illness

LTFU Lost to follow-up
MCH Mother and child health
MDR_TP Multidays resistant tubers

MDR-TB Multidrug-resistant tuberculosis

MoH Ministry of Health

MSF Médecins Sans Frontières

MSF-CH Médecins Sans Frontières Switzerland

MTB Mycobacterium tuberculosis
NGO Non-governmental organisation
NTSF National Task-Shifting Framework

OI Opportunistic infection
PDR-TB Polydrug resistant tuberculosis
PHCC Primary health care clinics
PHU Public health unit

PLWHA People living with HIV/AIDS

PMTCT Prevention of mother-to-child transmission

PMTCT B+ Prevention of mother-to-child transmission, option B+

POC Point-of-care

PTB Pulmonary tuberculosis
RIC Retention in care

SHCF Secondary health care facility
SNAP Swaziland National AIDS Programme
SRHU Sexual and reproductive health unit

TLA Thin-layer agar

UNDP United Nations Development Programme
UNAIDS Joint United Nations Programme on HIV/AIDS

VCT Voluntary counselling and testing

VL Viral load

WHO World Health Organisation

XDR-TB Extensively drug-resistant tuberculosis



MAKING A DIFFERENCE

DECENTRALISATION OF HIV/TB CARE IN SHISELWENI REGION OF SWAZILAND

Summary Evaluation Report December 2013

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Jimson Bhembe a HIV positive patient on ART referred for treatment by Traditional Healer in Mnyatsini village in the Shiselweni region, south of Swaziland.

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MSF staff addressing the community during the Dip Tank community testing campaign at Nhletsheni, in Shiselweleni region, south of Swaziland.





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1 EXECUTIVE SUMMARY

Swaziland is a small, sub-Saharan African country with a population of only 1.2 million people and one of the world's highest rates of both HIV prevalence and new TB infections. Since the early 1990's, when these two diseases took root in the country, life expectancy has plummeted by more than 11 years. To support Swaziland in responding to this dual epidemic, in 2008 MSF Switzerland (MSF-CH) launched an HIV/TB project in the rural region of Shiselweni. The project was based on a strategy of decentralising care to the primary facility and community levels by building local clinical and laboratory capacity, and expanding human capacity by shifting the provision of care to lower cadres of health workers.

In early 2013, MSF conducted a retrospective assessment of the first five years of the Shiselweni HIV/TB programme. The evaluation involved reviewing patient outcomes, infrastructure and human resource development, costeffectivness, advocacy efforts, and perceptions of the various local and national stakeholders. In this report we present the results of our assessment and describe the lessons learned—including successes and failures—to the entire MSF movement, to local actors in Shiselweni, to Swaziland's national authorities, and to the international community.

Overall, this evaluation found that decentralisation of activities to the primary health care clinic and community levels greatly improved access to diagnostic and treatment services for HIV and TB patients. By 2012, Shiselweni had reached universal ART coverage (as defined by WHO)—a major increase relative to the baseline of only 17% coverage in 2006, before decentralisation was implemented.

This expanded access was associated with a steady improvement of treatment effectiveness over the five-year period. ART outcomes for the region improved consistently at every follow-up time point assessed (6, 12, 18 and 24 months), with a trend towards better coverage and long-term retention at primary health care clinics compared with secondary health care facilities. TB treatment shifted to primary care clinics also showed a clear trend towards better treatment outcomes among drug-sensitive TB patients at both health care levels. A steady decrease in the burden of TB and other HIV-related opportunistic infections (the main health risk for Swaziland's HIVpositive population) over the period of 2008-2012 correlated well with the reduction of crude mortality in Shiselweni during this time.

The example of Shiselweni thus demonstrates that, in a context of high HIV and TB prevalence and limited resources, decentralisation of care from regional and district hospitals to primary health care clinics and communities is a highly effective way to improve the quality of care and the efficiency of service delivery. It also improves patient satisfaction and acceptance of health service providers by direct beneficiaries and the wider community. A separate analysis of costs found that decentralisation is highly cost-effective from the service provider perspective and allows for a better use of resources than do centralised care strategies. The key to successful decentralisation of HIV and TB services in the Shiselweni project was strengthening human capacity for providing care, via a strong, well-implemented task-shifting component. Inclusion of lay people as service providers, in particular people living with HIV/AIDS and TB, improved the acceptance of medical services by affected populations. It also decreased stigma, a crucial barrier to accessing care, and improved both the self-esteem of affected populations and their acceptance by the community. Other key ingredients of success for the Shiselweni decentralisation model included implementation of more robust infection control measures, adaptation of laboratory services to the needs of an expanded, low-resource health care system, and advocacy to ensure strong commitment from all stakeholders in terms of supportive policies, best practices, and effective funding mechanisms.

In conclusion, decentralised health care with task-shifting in Shiselweni resulted in improved patient access to care and better treatment outcomes. It also strengthened human resources in health care and empowered PLWHA and the wider community. Through lowered burden of opportunistic infections it also most likely contributed to the overall reduction of mortality in the region. During the next phase of the programme, which will incorporate "treatment as prevention" strategies, this now-established model of care has the potential to accelerate the gains achieved and thus begin to turn back the HIV and TB epidemics that have cost tens of thousands of lives in Swaziland.

1 80% of population in need of ART treatment, based on having a CD4 count < 350 (WHO definition).

MSF Expert Client during a pre HIV test counselling session with a local youth at MSF Dipping Tank community testing campaign at Nhletsheni, in Shiselweleni region, south of Swaziland.

² INTRODUCTION

HIV/AIDS and tuberculosis (TB) continue to pose major challenges to socioeconomic development in Swaziland. It is widely recognised that reversing the country's high HIV/TB burden and meeting the demand for equity of care requires scale-up and decentralisation of HIV and TB services to the community level. This approach has proven its effectiveness in many contexts worldwide (MSF 2010, 2011). Beyond the obvious impact of ART on saving lives and alleviating suffering, recent evidence demonstrates unequivocally that treatment also works as prevention, which in turn can slow the epidemic's spread (Cohen et al, 2011). The decentralisation approach to delivering HIV services has been broadened to integrate HIV and TB care, especially in resource-limited settings (Fraser 2007).

The challenges associated with decentralisation have also been documented. They include: increased demand for already limited resources (e.g., quantity and quality of human resources; laboratory capacity), financial burden and lack of accountability, lack of community engagement in some settings, political conflict between different levels of the health care system, and long-term sustainability (Rasson et al, 2011).

Swaziland, with a population of 1.2 million people (SPP 2007), is a small, mountainous country, landlocked by South Africa and Mozambique, and is one of three remaining monarchies in Africa. The Kingdom is in 142nd place on the human development index of 2012 (also 142nd in 2007), with an estimated 40.6 % of its population living on less than US\$ 1.25 per day—62.9 % in 2007—(UNDP 2009, 2013). The country has the highest HIV prevalence in the world among adults aged 15 to 49 years: 26.5 % in 2012, slightly higher than 25.9 % in 2007 (SDHS 2007, UNAIDS 2012) and one of the highest rates of new TB infections, estimated at 1,349 new cases/100,000 population/year (WHO 2013). The dual epidemic of HIV and TB has contributed substantially to a significant reduction of life expectancy over the past two decades—from 60 years in the early 1990s to 48.9 in 2012 (UNDP 2013).

Against this context, a decentralisation project was initiated in 2007 in Shiselweni, the region of Swaziland with the least health care infrastructure and poorest overall health outcomes. Following a four-month assessment, MSF-CH signed a memorandum of understanding with the Ministry of Health to provide care throughout the Shiselweni region for people with HIV and TB, including drug-resistant TB (DR-TB).

The 2007 assessment identified several key problems the programme needed to address immediately: chronic shortages of health care staff, absence of integrated HIV/TB services, and limited access to care, due to highly centralised services and inadequate capacity to extend HIV/TB care into primary clinics. Over the next five years, MSF and its local partners implemented a plan that integrated and shifted HIV and TB care to 22 local clinics, where approximately 15,500 HIV patients and 10,500 TB patients have been treated as of the end of 2012.

At the end of five years, i.e., in early 2013, MSF conducted a comprehensive evaluation of the project in Shiselweni. The main objective was to evaluate the appropriateness, effectiveness and efficiency of the decentralised HIV/AIDS & TB care model over the period from 2008 to 2012. The evaluation was conducted as a series of independent studies. These were:

- Literature research on decentralisation models and on-the-ground experience in resource-limited African contexts.
- Study of perceptions about the programme among different stakeholders—MSF, health care staff, national authorities, international actors, patients and the wider community.
- Description of the decentralisation model adapted in Shiselweni region, and analysis of the programme outcomes in the wider public health context of Swaziland.
- Cost-effectiveness analysis of HIV service provision in primary health care clinics (PHCC) versus secondary health care facilities (SHCF).
- · Analysis of the implementation of innovative and decentralised laboratory services.
- Analysis on infrastructure development and infection control strategies.

The detailed methodologies of these studies are described in separate reports. This report summarises and discusses the implications of the key findings that emerged from these individual studies.



³DESIGN & IMPLEMENTATION OF THE HIV/TB SHISELWENI PROJECT

3.1 OVERVIEW OF THE DECENTRALISATION MODEL

In 2008 when MSF started its intervention in Swaziland, only 24 sites in the whole country (3 in Shiselweni) provided ART. Task-shifting was just beginning, with nurses to expert patients ² being the only shift slowly implemented.

To achieve the specific objective of the project—i.e., improved prevention, diagnosis and treatment of HIV and TB—MSF proposed to the Ministry of Health (MoH) a decentralised care approach that incorporated the following strategies:

- Providing HIV and TB diagnosis and treatment at both the SHCF and PHCC levels;
- Implementing HIV viral load monitoring and TB sensitivity testing (for both diagnosis & monitoring) at region level;
- Implementing HIV diagnosis and HIV/TB follow-up at the community level;
- Reinforcing patient support, education and counselling, led by expert patients³;
- Adopting effective task-shifting strategies, including nurse-led ART and TB care at all health facilities;
- Decentralising laboratory capacity and introducing new point-of-care technologies to increase PHCC diagnostic and monitoring capacity;
- Improving the infrastructure to facilitate patient-flow and accommodate increased workload;
- Improving infection control measures in PHCC and at the community level;
- Establishing effective referral system of patients and laboratory samples between the different levels of care;
- Supervising staff performance at every PHCC;
- Engaging with communities, to ensure effective linkage with health facilities;
- Incorporating innovation and conducting operational research, in order to apply
 the latest evidence to the specific context and needs of Shiselweni, and to facilitate the uptake of effective new policies.

Additionally, MSF presented the Ministry of Health (MoH) with a specific proposal to tackle TB (including DR-TB) in Shiselweni region:

- Constructing a TB Ward in Nhlangano (completed in 2011);
- Initiating a decentralised DR-TB community treatment programme;
- Updating national TB guidelines, based on results of the National TB DST Survey conducted by MSF and Epicentre in 2010;
- · Improving diagnostic laboratory services; and
- Introducing second-line TB drugs throughout the region through a Green Light Committee mechanism.

Implementation of this plan required efforts on many fronts, described elsewhere in this document. These included: rolling out a well-designed strategy of task-shifting to nurses and to newly-created health worker cadres (see section 3.2); creating a supportive policy environment through engagement with the Ministry of Health and advocacy with other actors, both in-country and external (see section 3.3); developing the necessary infrastructure in the health facilities and ensuring their capacity to implement adequate infection control (see section 3.5); and improving diagnostic capacity at both the primary and secondary facility levels (see section 3.6).

- 2 Also known in Swaziland as Expert Clients—HIV-positive patients who have disclosed their status and work in HIV care, mainly to provide HIV counselling and patient support.
- 3 Greater Involvement of People living with HIV/AIDS: translated through patient treatment literacy and patient empowerment toward the disease.



Map of Swaziland

FIGURE 1

DECEMBER 2012

Full implementation & integration of HIV/TB services in 22 clinics at PHCC level. The use of Viral Load is decentralised from central level (Mbabane) to district level (Nhlangano).



NOVEMBER 2010

Patients are initiated on antiretrovirals at CD4 count of 350.



Inauguration of the Nhlangano TB ward.



JULY 2009

Integration of TB & HIV services at PHCC level.





MARCH 2010

Mini laboratories are launched in clinics.





SEPTEMBER 2009

Task-shifting is used when initiating patients on antiretrovirals.



Nurses initiate patients on ART.







JUNE 2008

Task-shifting for antiretroviral therapy (ART) follow up. **Expert Patients begin working** at PHCC level and through community outreach activities.

Start of community Drug Resistant Tuberculosis (DR-TB) treatment.







DECEMBER 2007

MSF starts the implementation of the decentralised model of care in the region of Shiselweni.

3.2 DEVELOPING AND TASK-SHIFTING HUMAN RESOURCES FOR HEALTH CARE

Task-shifting was implemented in Shiselweni using a step-by-step approach (see figure 2), with three levels of decentralising HIV/TB care from SHCF to the 22 PHCC of Shiselweni region:

- · Doctors to nurses;
- Nurses to HIV/TB patients (expert patients); and
- Nurses to community members.

Doctors to nurses: At the start of the programme, only doctors were authorised to prescribe and follow up HIV and TB patients, while nurses focused on HIV testing and counselling. The initial tasks shifted from doctors to nurses were ART refill and patient follow-up, followed by ART initiation and then TB initiation, DS-TB management and OI management (Integrated Management of Adolescent and Adult illness, IMAI WHO training course). Today, all nurses have the authority and skills to fully manage ART and DS-TB at PHCC level, from detection and diagnosis to treatment and follow-up.

Nurses to HIV/TB patients (expert patients) and community members: At the beginning of Swaziland's HIV/TB epidemic, clinic nurses found themselves overloaded and inadequately equipped to effectively support growing numbers of patients. Task-shifting from nurses to lay people was initiated to help meet this challenge, with expert patients deployed first in the clinics and later in the community. Over time, additional tasks were successfully shifted from nurses to phlebotomists (laboratory assistants), pharmacy assistants and Community Treatment Supporters (CTS). People Living with HIV/AIDS (PLWHA) were prioritised in the selection of lay cadres, since their involvement in delivering care helps support their personal empowerment, build links to the community, and reduce stigma.

Early in the programme, informal and on-the-job trainings in Shiselweni helped kick off task-shifting among the different layers of health workers. However, formal training and accreditation proved to be important for official recognition by the MoH and for future absorption of these cadres into the health care system. Our analysis indicated that supportive supervision methods, implemented mostly by MSF, were adequate and effective; however, the need to include more MoH staff in the supervisory teams was highlighted.

3.3 ADVOCATING FOR SUPPORTIVE HEALTH POLICIES AND SUFFICIENT FUNDING

Advocacy and lobbying played an important role in helping to generate awareness and support of the decentralisation strategy, and to translate it into policy. The foundation of these activities was built on evaluating patient and programmatic outcomes, which over time clearly demonstrated the success of the approach. MSF's active participation in preparing the MoH National Task-Shifting Framework, which was finalised at the end of 2011, was another key element of the advocacy strategy. All health worker cadres that had been introduced into the Shiselweni project (pharmacy assistants, lab assistants, HTC counsellors, expert patients, and health motivators in the community), were incorporated into this framework. The framework calls for measures that are now common practice throughout the country.

Another focus of policy work to support HIV/TB programmes was to provide input into the country's Global Fund applications, an effort that started soon after MSF began working in Swaziland on HIV/TB. During 2011 we contributed to the application for Round 11 funding, which was subsequently cancelled due to lack of money—a situation that triggered a series of lobbying efforts at the national level, and of public positioning at the national and southern African regional levels. At the same time MSF participated in public events (demonstrations, etc.) in South Africa to raise awareness and protest against this cancellation.

Several other advocacy efforts were undertaken along the way, as needed to support the overall programme. In 2009, MSF lobbied for a new ARV (tenofovir) to be included in first-line HIV treatment and for the country to adopt the new WHO guidelines endorsed in 2010. The following year, MSF worked to update the National DR-TB Guidelines based on our experience in Shiselweni. In 2011, MSF worked with PLWHA organisations to raise public awareness about the consequences of ARV stock-outs on the life of the patients. During 2012, MSF and collaborators worked on the Human Resources for Health Strategic Plan and also finalised the National Treatment as Prevention Framework. That same year, viral load monitoring was introduced in Shiselweni; the outcomes will be used to help shape future policies and guidelines. Innovative laboratory diagnostic methods like GeneXpert®MTB/RIF (2011) and TLA (2012) for diagnosing DR-TB were also put in place, demonstrating the feasibility of decentralising laboratory diagnostic and follow-up of patients.

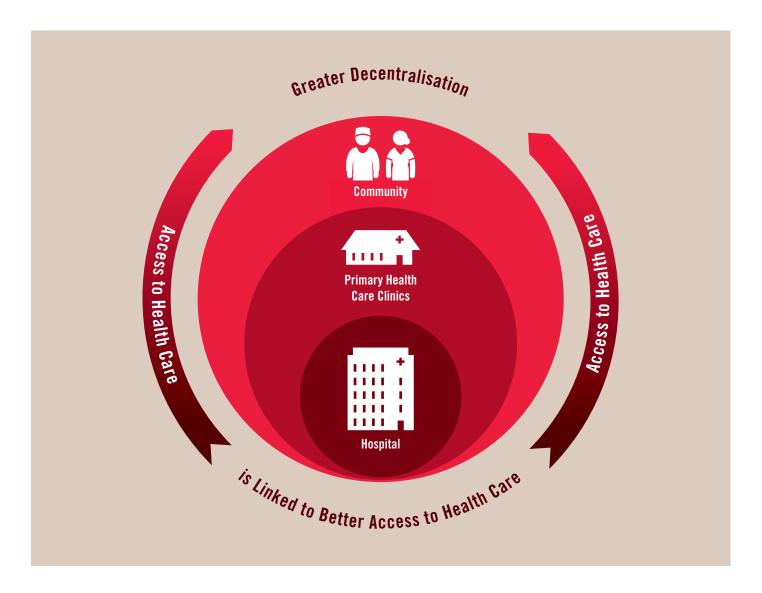


FIGURE 3

3.4 ACHIEVING DECENTRALISATION

Due to the concerted efforts of MSF and the national and regional authorities, decentralisation proceeded gradually, leading to impressive results by the end of the five years period. Treatment and care for HIV/AIDS and drug-sensitive DS-TB were fully decentralised to the region's 22 primary health care clinics. What started as two separate programmes for HIV and TB is now fully integrated into PHCC, ensuring the provision of much-needed "Point-of-Care" (POC) services for patients. Moreover, most HIV and TB follow-up services are available at the community level.

Even DR-TB diagnosis and treatment has been decentralised, improved and expanded, through building capacity of the staff, adding new infrastructure (Nhlangano TB ward) with innovative infection control measures (incorporating natural ventilation), and introducing community services to follow up patients closer to their homes. The region also developed capacity to diagnose DR-TB and to follow resistance patterns, thanks to the implementation of diagnostic technologies such as GeneXpert®MTB/RIF and TLA—making the area self-sufficient.

Laboratory service was to a large degree decentralised and integrated into the clinics via mini-labs, and linked to the SHCF through transport system for samples. Achieving continuity in drug and medical supply was another important component of decentralisation, as was equipping the medical facilities with improved infection control measure such as adequate ventilation and waste management systems, and improving space/patient flow.



3.5 IMPROVING INFRASTRUCTURE & INFECTION CONTROL

To reinforce transmission control at health facilities and within the community, the Shiselweni project put in place various infection control mechanisms. These new measures involved infrastructure improvements at all three levels of health care provision: at the secondary health care level in Nhlangano Health Centre, which houses a TB Ward for MDR and XDR-TB patients and a TB microbiology laboratory; at the primary health care level, in the clinics of Shiselweni region; and at the community level, in the homes of DR-TB patients.



The DR-TB ward (see figure 4) was built next to the existing health centre in Nhlangano. It comprises of 30 small and medium-sized rooms that encompass an inpatient department, including a unit for critical and palliative care, and an outpatient department for diagnosis and follow-up. A sustainable design integrates the exclusive use of natural cross-ventilation; for better infection control, patient flow is organised according to the transmission risk level.

PRIMARY HEALTH CARE LEVEL

Numerous infrastructure improvements in the clinics included the building of outdoor waiting areas, extra consultation rooms (equipped with accelerated air flow from outside) adjacent to the clinics, and Health Care Waste Management (HCWM) systems.

COMMUNITY LEVEL

To decrease DR-TB transmission in communities, the programme worked with community members to install windows and doors at patients' home, thereby improving ventilation, and to build separate patients rooms when needed, according to infection control rules.



FIGURE 4

The TB ward in Nhlangano health centre



FIGURE 5

Point-of-care diagnostic technologies implemented at PHCC level



Alere Pima™

Reflotron®Plus



HemoCue 201®



FIGURE 6

 $\ensuremath{\mathsf{HIV}}$ and $\ensuremath{\mathsf{TB}}$ diagnostic technologies introduced at the regional level



GeneXpert®MTB/RIF

3.6 INNOVATING AND DECENTRALISING DIAGNOSTIC TECHNOLOGIES

Strengthening laboratory services and adapting them to the low-resource environment represented another key strategy of the decentralisation programme. This strategy was implemented on two levels: ensuring that PHCC have the necessary diagnostic capacity to support HIV/TB scaleup, and reinforcing diagnostic capacity at the regional level. management systems, and improving space/patient flow.

ENSURING THE DIAGNOSTIC CAPACITY OF PHCC THROUGH "MINI-LABORATORIES"

Starting in 2010, MSF introduced several innovative diagnostic approaches to the PHCCs by introducing POC technologies that could be operated by trained lay personnel (phlebotomists) with minimum supervisory support. These POC diagnostics included (see figure 5):

- CD4 POC instrument (Alere Pima[™]) (1)
 Measures CD4 cell count from blood, information which
 both WHO and national guidelines use as a key factor in
 identifying which HIV-positive individuals should be initiated on ARV.
- Biochemistry POC (Reflotron®Plus) (2)
 Performs clinical chemistry tests (creatinine, glucose, potassium and ALAT).
- Haematology POC (HemoCue 201®) (3)
 Measures haemoglobin level using blood from a finger prick.

These selected low-complexity POC technologies could be maintained at the clinic level with only minor support, which was provided by a mobile laboratory technologist. Quality assurance was implemented by both internal and external control mechanisms. Programmatic experience with these three POC technologies has demonstrated their good performance in field conditions within the Shiselweni context, indicating the feasibility of transferring them to similar settings. Prior to a transfer, an assessment of the technical reliability of laboratories and the availability of human resources should be conducted.

IMPROVING DIAGNOSTICS AT THE REGIONAL LEVEL

In parallel to these improvements at PHCC, latest-generation technologies for early detection of MDR-TB and for monitoring HIV viral load (VL) in patients on ART were implemented at the regional level. Together with an effective sample transportation system from PHCCs to the reference laboratory, these measures meant that rural populations could have timely access to the following diagnostics:

- HIV Viral Load Test (Biocentric method)
 Suppression of VL is the key reason for using ART, and VL
 level is the best direct indicator of how well an HIV patient
 is responding to treatment. Establishment of this technology in the Nhlangano referral laboratory therefore makes a
 vitally important test available to the region's ART patients.
- GeneXpert®MTB/RIF (Cepheid®) (see figure 6) (4)
 The GeneXpert® analyser delivers a very fast and accurate diagnosis of both DS- and DR-TB (the latter by also detecting resistance to rifampicin, one of the first-line TB drugs).
 Although it has some limitations, GeneXpert® technology is a vast improvement over other TB diagnostics in terms of speed, accuracy, and reduction of clinic staff workload.
- Thin Layer Agar (TLA)
 This method, which was introduced into the Nhlangano
 TB laboratory, makes it possible to perform more rapid TB culture-based diagnoses and drug sensitivity (DS) tests (to detect resistance to TB drugs other than rifampicin) compared with most other tests. In 2013, MSF, the MoH and the Institute of Tropical Medicine (Antwerp, Belgium) began the process of validating TLA testing with second-line TB drugs (ofloxacin and kanamycin) for the rapid detection of XDR-TB.

⁴ PROGRAMME OUTCOMES

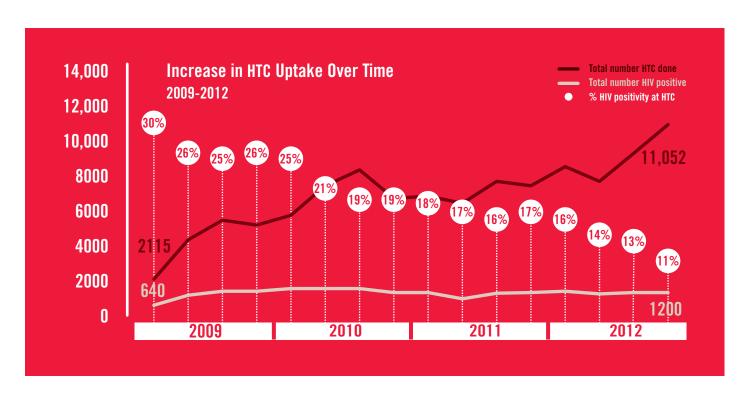


FIGURE 7

4.1 INCREASED UPTAKE OF HIV TESTING

Decentralisation of HIV services and greater focus on provider-initiated testing (vs VCT) led to an increase of more than 500% in the uptake of HIV testing and counselling (HTC4) between the beginning of 2009 to the end of 2012, as shown in figure 7. During this same time period, the proportion of HIV-positive people identified at HTC decreased from 30% to 11%, indicating that more HIV-negative people were accessing HTC. At the end of 2012, most of the HTC (70%) was performed at PHCC and community level and the remaining (30%) at SHCF.

WHO recommendations and national guidelines call for HIV-negative people to undergo HIV testing once a year (WHO 2010; MoH 2010). Coverage of annual HTC in Shiselweni was estimated at 10 % in 2009, and increased to more than 20 % in 2012. However, despite this welcome improvement, these numbers remain low and point to the need for additional strategies that reach a wider population and improve HTC uptake.

⁴ Provider-initiated testing is also known as PITC: Provider-Initiated HIV Testing & Counselling, referring to HIV testing and counselling which is routinely recommended by health care providers to persons attending health care services. Voluntary Counselling & Testing refers to HIV testing and counselling being sought by individuals on their own initiative. HTC includes both, PITC and VCT.

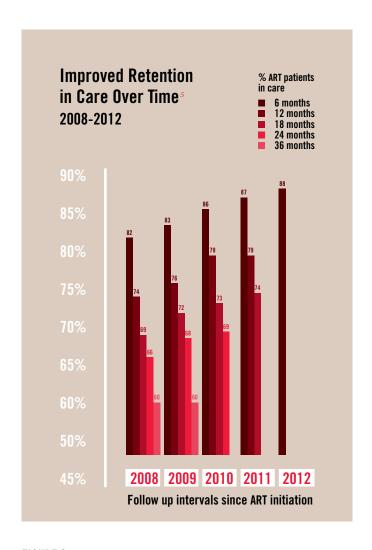
5000	New ART Initi 2008-2012	ations Over Time			
4500					
4000					
3500			0	O	
3000		0			
2500					
2000					
1500					
1000		0			0
500	2008	2009	2010	2011	2012
0	2964	3716	4328	3930	3579

FIGURE 8

4.2 INCREASED ACCESS TO ART

Improved access to HIV/TB care through rapid scale-up and decentralisation across the region (2009-2010), as well as changes in national HIV treatment guidelines (earlier ART initiation—at CD4 \leq 350 instead of 200—and ART for all TB co-infected patients, regardless of CD4 count, since 2009), were the main factors behind an increase in annual ART initiations before 2010 (see figure 8) (MoH 2010).

Estimates from Shiselweni indicate that "universal" ART coverage—defined by WHO as ART coverage that reaches > 80 % of patients in need of treatment—was achieved in 2012 (vs. 17 % in 2006). Throughout this period, the PHCC provided treatment for an increasing proportion of the region's ART cohort, managing more than half of all patients by 2012.



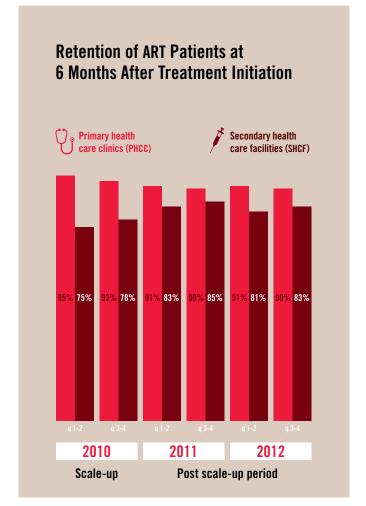


FIGURE 9 FIGURE 10

4.3 IMPROVED RETENTION IN CARE (RIC)

Retaining people on lifelong treatment for HIV is challenging in most settings around the world, and Shiselweni is no exception. Retention in Care (PHCC and SHCF combined) has consistently improved over time at every follow-up interval assessed, as shown in figure 9.

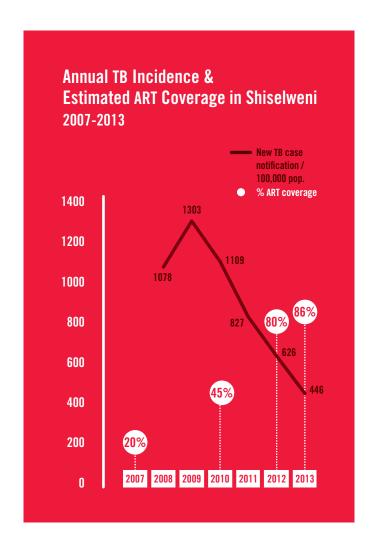
Gains in retention were also seen for HIV patients with the highest risk of death (those with CD4 counts ≤ 50), indicating a higher quality of care in later years: the combined risk of death and loss-to-follow up decreased by 14% (2009-2010) and 42% (2011-2012) compared to pre-scale-up years (2007-2008). Easier patient access to HIV/TB care (i.e. closer to patients' homes), laboratory services integrated into PHCC, enhanced patient support through a comprehensive counselling package, and increased community awareness about the importance of adherence to a long-term treatment were all key to gradually improve ART retention across the entire region.

Despite the shifting of certain tasks to new health cadres and the inclusion of lay people (including PLWHA) in providing HIV care, retention of ART patients at the PHCC level was higher than at SHCF, at least in the early phase after initiation when this indicator was assessed (see figure 10). The fact that PHCC's typically follow fewer patients than the busier SHCF's, and can therefore provide more individualised care, may help explain this trend.

However, these data also show that 6-month retention rates also improved at SHCF in 2011-2012, reaching over 80 %. This may reflect another benefit of decentralising HIV/TB services: relieving pressure on the few centralised and specialised SHCF, by distributing case load more uniformly over the region. Decongestion of SHCF, in turn, allowed clinicians to give more attention to higher-risk patients, including those with complications, resulting in better retention. This may explain why SHCF achieved high 6-month retention rates > 80 % only during the post-scale up period (see figure 10).

Better retention in treatment, together with increased ART coverage and better outreach to less sick HIV-infected people, represent important successes of the HIV/TB decentralisation programme in the Shiselweni region.

⁵ RIC is followed up per cohort. The years shown in figure 9 correspond to the years of beginning of treatment for the different cohorts.



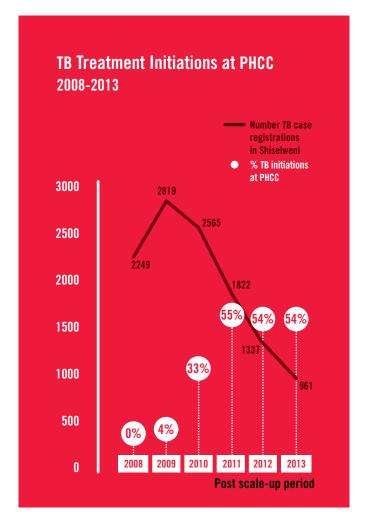


FIGURE 11 FIGURE 12

4.4 TB SPREAD & SHIFT OF TREATMENT INITIATION TO PHCC

In parallel to the devastating spread of HIV/AIDS in Swaziland, the TB burden has also increased, peaking in 2009 with 1,303 TB new cases per 100,000 people per year—the highest incidence of any region in Swaziland (see figure 11). Additionally, in Shiselweni HIV/TB care was decentralised and ART coverage increased significantly, from about 20 % in 2007 to 80 % in 2012. These factors, even alongside enhanced TB case finding throughout the country starting in 2009, led to a rapid decline of TB incidence; the downward trend was fastest in the Shiselweni region, and reached 446 new cases per 100,000 people per year in 2013.

Huge efforts in 2009 and 2010 to decentralise TB services—in particular, nurse-led TB treatment initiation and follow-up at PHCC—led to a major shift in TB care, as shown in figure 12: while in 2009 only 4% of TB treatment initiations occurred at PHCC, this number increased to 55% in 2011.

4.5 IMPROVED TREATMENT OUTCOMES FOR DS-TB PATIENTS

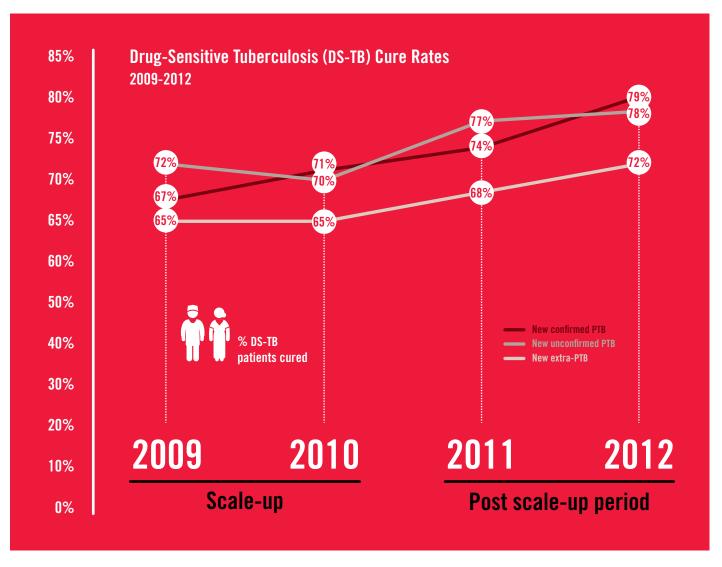
In general, the programme showed a steady and significant trend towards improved TB treatment outcomes both for bacteriologically confirmed and unconfirmed DS-TB cases at PHCC and SHCF combined, with cure rates 6 increasing from 67% in 2009 to 79% in 2012 (see figure 13).

However, TB is the main cause of mortality in HIV-infected individuals in most settings; not surprisingly, in 2012 TB mortality in Shiselweni remained high (15%), with 83% of these deaths occurring in HIV co-infected patients. Therefore, despite the overall positive trend in TB cure rates, the treatment success rate is still below the WHO target of 85%. Achieving the WHO target in this high HIV prevalence setting will require that TB co-infected patients enter treatment earlier, when better outcomes can more readily be achieved.

6 A cured patient is a patient that was initially smear-positive, completed the treatment, and was smear-negative in the last month of treatment and on at least one previous occasion.

(WHO definition, http://www.who.int/tb/publications/global_report/2007/table_5/en/index1.html)

FIGURE 13

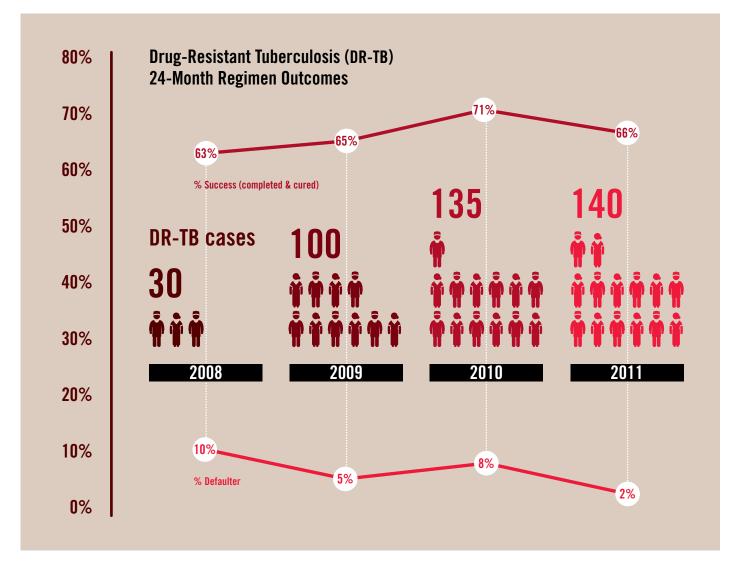


4.6 IMPROVED ACCESS TO DR-TB TREATMENT

Follow-up of DR-TB patients was first decentralised from national to regional level at SHCF, then in a second step to PHCC (2008), and, finally, to community level for patients living in remote areas. Members of the community, who became the community treatment supporters (CTS), received training about DR-TB treatment during the intensive and follow-up phases, including implementation of daily DOTS (directly observed treatment, short-course) and administration of intra-muscular injections. Through this approach, combined with active defaulter tracing, the DR-TB treatment outcomes slightly improved since the beginning of the programme. The success rates (treatment completed and patient cured) were consistently higher that the national ones (MoH 2012). The proportion of patients lost to follow-up (LTFU) during treatment decreased from 10 % in 2008 to 2 % in 2012, as shown in figure 14.

An in-depth comparison of adverse treatment outcomes (LTFU/death/failure) in patients followed at outpatient departments by health professionals versus those followed at the community level by CTS showed equivalent treatment outcomes. This finding suggests that daily support for DR-TB care through the CTS probably improved treatment adherence for patients living in most remote locations, who usually cannot access daily DR-TB at health facility level and thus are at the highest risk of defaulting and death.

FIGURE 14



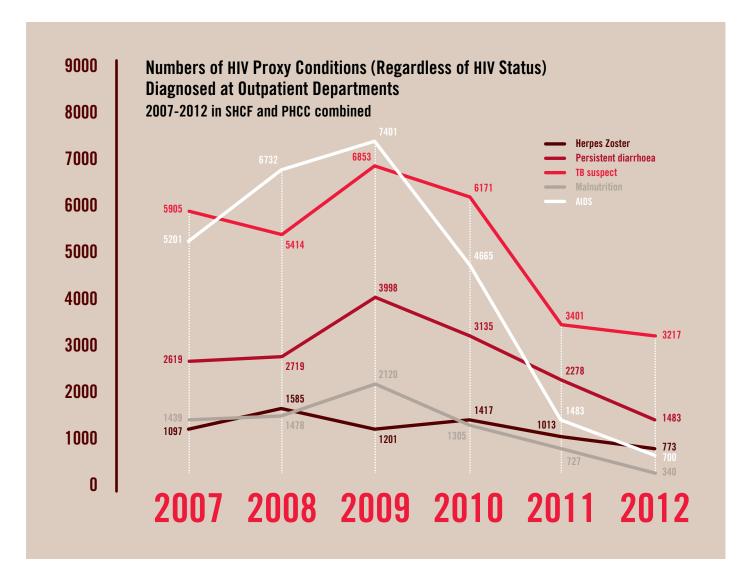


FIGURE 15

4.7 REDUCED INCIDENCE OF OPPORTUNISTIC INFECTIONS

It is well-known that ART prolongs life and prevents or mitigates opportunistic infections (OI's) and other HIV-associated conditions in PLWHA (Hogg et al, 2008). In a high HIV prevalence context such as Shiselweni, increasing ART coverage is therefore expected to reduce overall HIV-related morbidity.

As shown in figure 15, the absolute burden of typical HIV-associated conditions diagnosed (regardless of patients' HIV status) at all outpatient departments across the region followed a two-phase pattern. The annual number of new diagnoses increased during the HIV/TB programme scale-up period (2009-2010), due to expanded patient access to quality care, including nurses trained in HIV/TB and in diagnosing 0I's. Subsequently, after the scale-up period (2011-2012), the number decreased dramatically. For instance, diagnoses of AIDS and malnutrition (which in Swaziland is usually related to HIV) decreased 10- and 7-fold, respectively, between 2009 and 2012 (MoH routine data). Consequently, the rapid ART scale-up and attainment of high treatment coverage alleviated the burden on the health care system.

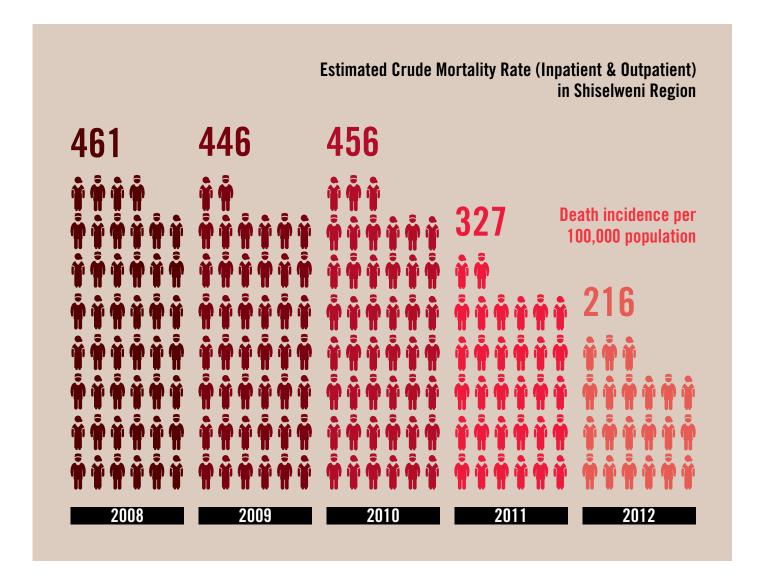


FIGURE 16

4.8 DECREASED CRUDE MORTALITY RATE

From the time HIV/AIDS hit Swaziland in the early 1990's, life expectancy declined steadily. In Shiselweni, crude mortality rate seen in inpatient and outpatient departments stabilized by 2008-2009 and then declined 2-fold in 2010-2012 (see figure 16). We presume that the high level of ART coverage and the improvement in quality of care are behind this observation (MoH routine data).



PERCEPTION & ACCEPTABILITY OF DECENTRALISED HIV/TB CARE

5.1 PERCEPTIONS OF THE MODEL & ITS IMPACT ON PATIENT CARE

The perception study was conducted through individual and group interviews, as well as focus groups discussions. Respondents included health workers, patients, community leaders, MoH, MSF staff and other national and international actors.

The results of this study identified some clear shifts in the perception and acceptability of various components of the programme over its first five years. These are summarised below.

Decentralisation was widely recognised as a success in significantly increasing access to HIV and TB services, since distance and costs for travel and lost work time are major barriers to care. For these reasons, the availability of services at the PHCC level was highly appreciated by both staff and beneficiaries. However, people living in very remote areas still face difficulties accessing care. Greater accessibility, in turn, is credited with increased coverage for early diagnosis and treatment, improved treatment outcomes and better retention in care.

There is general agreement that decentralisation of services has had a positive impact on the quality of care. Quality is perceived as very good at PHCC, but as more mixed at centralised facilities. In addition, waiting times at clinics are shorter than they were at central facilities before decentralisation. Overall acceptability of HIV/TB services at PHCC level is therefore very high.

Task-shifting is now widely accepted as feasible and indispensable to the decentralisation of HIV/TB care in Swaziland, given the country's limited human resources for health. Although there was initial resistance, it was overcome over time by demonstrations of feasibility and impact, and by the provision of training to health workers taking on new roles. On the latter point, the combination of formal staff training with mentoring and supervision was considered effective and was highly appreciated by participants. Government-certified training courses further increased acceptance and are seen as necessary for the integration of future cadres.

Advocacy by MSF together with other implementing partners was also instrumental in fostering acceptance of task-shifting. This advocacy (described in section 3.3) led, among other outcomes, to the development of the National Task-Shifting Framework (NTSF). This crucial policy document defines new roles and tasks for health cadres, as practiced under the task-shifting model.

Integration of HIV/TB care into primary health care has increased the level of privacy for patients, compared with central health facilities that provide HIV care at dedicated ART clinics—which segregate, and thereby label, HIV-positive patients.

The small user fees charged by PHCC (5 Emalangeni, equivalent to 0.30 Euros) were not seen as an obstacle to seeking care, although both higher fees at the central level and charges for non-HIV/TB care and for medicines at private clinics, seemed to deter some patients. In choosing a health facility where they will seek care, patients considered convenience (shorter distance and lower travel cost) as the number one factor. A smaller number of patients cited fear of being recognised by community members at the local clinic, or the perception that better care was available elsewhere, as reasons for selecting a more distant facility.

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An HIV positive patient on ART from Mnyatsini village in the Shiselweni region.

5.2 INCREASED MOTIVATION FOR STAFF

Medical professionals at the central level noted a decreased workload compared to earlier days of providing ART and TB treatment. Nurses at the clinics varied in their perceptions of changes to their workload, while other staff members perceived a significant decrease in overtime following decentralisation.

All cadres of health workers stated that they felt empowered by the successful outcomes of their work after decentralisation, and reported very high motivation and work satisfaction.

Clinic staff expressed confidence in their skill level, as did their supervisors from MoH and MSF, based on seeing the successful health outcomes for patients. The skills of former lay cadres were valued by their professional colleagues, who viewed them as specialists in their area—for example, expert patients who work as counsellors were described as being crucial in this role. Involving PLWHA in health care provision was seen as key to increasing the acceptability of HIV testing and treatment, improving adherence and boosting patient empowerment. Since they are viewed as role models in the community, their presence in the clinic was also perceived as encouraging the disclosure of HIV or TB status, which in turn helps reduce stigma.

Interdisciplinary team relationships after decentralisation, integration of HIV/TB services and task-shifting, were largely perceived as positive, especially at the clinic level.

Staff members also highlighted improved protection of clinic workers from the risk of HIV or TB infection—through implementing better infection control measures and making post-exposure treatment available at the workplace, as provided by MSF—as very important to their job satisfaction.

5.3 ACCEPTANCE OF COMMUNITY ACTIVITIES

Community-based activities were viewed as another strength of the Shiselweni model. Engaging through training, consultation and collaboration with village chiefs and other community leaders, traditional healers, religious leaders and rural health motivators was perceived as a very powerful strategy for promoting positive health behaviours and reducing stigma. A traditional healer taking ARVs and who disclosed his status publicly on World AIDS Day was mentioned in this context as a positive example.

MoH officials and other national and international actors expressed appreciation for the integration of TB into MSF community activities, a step they viewed as distinct from treatment practice by other organisations.

5.4 SPEED OF IMPLEMENTATION VERSUS ENGAGEMENT WITH AUTHORITIES

Study respondents expressed a range of opinions about MSF's speed of implementing new programme activities and about its hands-on approach. On one side, the rapid roll-out of decentralisation was seen as greatly benefiting patients and contributing to the demonstration that new strategies and higher standards of care are feasible in the Shiselweni setting. Many participants concluded that less would have been achieved if MSF had not put itself "in the driver's seat." On the other hand, MSF was initially perceived by MoH as using an emergency approach that was inappropriate for chronic disease control.

This latter perception, and the lack of joint planning at the regional level, contributed to initial resistance to the MSF project and delayed the development of a more productive early collaboration between MoH and MSF. However, it was also noted that a positive shift in MSF's collaboration with MoH towards increased dialogue and engagement subsequently ushered in a more fruitful partnership. Part of this engagement involved demonstrating the feasibility of proposed innovations by piloting these approaches before widescale implementation and, in parallel, encouraging operational research to improve them and assess their outcomes; the impressive results obtained helped make MoH more receptive to MSF's proposed strategies. Dialogue with national counterparts and other stakeholders was also seen as a very powerful tool in identifying priorities and communicating the lessons learned. Thus, MSF was a catalyst for change not only in the field but at a policy level.

PERCEPTION OF REMAINING CHALLENGES

Despite an overall increase in the uptake of testing and treatment services in the region, coverage of these services among men and youths is still viewed as insufficient. Low rates of testing, especially among men, also pose a challenge to improved prevention, as does inconsistent use of condoms by all groups surveyed. Other remaining challenges in the region include unsatisfactory paediatric treatment coverage and outcomes in the region, as well as proper monitoring and documentation of PMTCT programmes.

6.1 STIGMA

While stigma related to HIV/TB is widely seen to have decreased significantly in recent years—a change attributed to both improved knowledge and availability of ART—it is still considered a major barrier to disclosure of HIV status and to the management of HIV/TB care.

Disclosure is generally seen as a necessary determinant of treatment adherence and well-being of HIV-positive people. MSF expert patients typically described their disclosure experience as being relieved of a burden, and as the beginning of a new, more confident life. They also recognised that reduction of fear and stigma in the community is linked to disclosure. Unfortunately, examples of public disclosure are still extremely few in the region, and mostly limited to female community members.

While different gender norms and use of maternity care make it easier to reach women at health facilities, cultural expectations of men discourage early health-seeking behaviour. This is often compounded by men's stronger fear of HIV-related stigmatisation and by perceptions that clinics are not sufficiently male-friendly. Men and youths in Swaziland, as in many other parts of the world, are seen as hard-to-reach groups.

One potentially big opportunity for reducing stigma arises from the fact that community leaders (chiefs, traditional healers, pastors, etc.) are highly respected and influential in the rural Swazi society. Involving them is therefore perceived as an important strategy for enhancing acceptance of services and decreasing HIV- and TB-related stigma at the community level. Disclosure among community leaders or other influential people can be an especially powerful tool in the strict hierarchical society of Swaziland.

6.2 CONTINUITY

Despite the fact that some important pre-conditions for the continuity of the Shiselweni programme are met—including political will to sustain the basic decentralised HIV/TB care model, the capacity-building of staff, and effective laboratory supportthere is concern that the quality of care could deteriorate and some systems could collapse once MSF's support ends. The major barrier to continuity is seen as lack of funding, mostly for human resources but also for laboratory reagents, sample transport, drug supply and supervision, all of which are presently supported by MSF. MSF's ongoing leadership in the regional programme implementation is perceived as another barrier to greater MoH ownership.

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People living with HIV during a Support Group meeting at KaPhunga, in the Shiselweni region.





¹ COST EFFECTIVENESS

The main goal of this cost-effectiveness evaluation was to compare the decentralised approach to a centralised one from a service provider perspective. To make this comparison, the incremental cost-effectiveness ratio (ICER) of PHCC versus SHCF was calculated, and then, following WHO's criteria, compared to Swaziland's GDP (WHO 2013).

By this measure, the decentralised ART programme at PHCC in Nhlangano health zone is more cost-effective than the ART programme at SHCF. This conclusion is based on calculating an ICER of US\$ 652 per life-year saved in PHCC versus SHCF, a figure which is much less than the GDP per capita in Swaziland (US\$ 5,300).

OPPORTUNITIES FOR COST-SAVING

The cost analysis identified some opportunities for savings. Annual treatment cost (for service providers) per ART patient was slightly higher at PHCC (US\$ 311) than at SHCF (US\$ 233). This difference is mainly due to higher human resource costs, which are roughly 2-fold higher in the clinics compared to SHCF's, in terms of both supervision staff and direct staff costs for consultations with patients.

This finding is explained by comparing the ratio of consultations to staff members at the PHCC versus SHCF levels, which shows that the higher costs for PHCC are due to the lower number of patients who come to the clinic each day rather than to staff spending too much time with patients. Therefore, the same level of care could be reached with more optimised human resources.

Laboratory monitoring costs are nearly identical in primary and secondary facilities, despite the fact that the technologies used and the level of cadres performing the tests are very different. Transport costs are higher at PHCC, but the difference is not significant.

Optimising the use of human resources for health in the PHCC (direct staff and supervision) is therefore a high priority for increasing the efficiency of ART programmes in Shiselweni.

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MSF Patient Support Education and Counselling (PSEC) Community Supervisor, Sylvia Khuzwayo with Community expert patient, Busi Gumbi and HIV patient.

* RECOMMENDATIONS

8.1 AT PROJECT LEVEL

Address HIV/TB-related stigma, focusing on hard-to-reach groups.

- Expand inclusion of community leaders in planning and implementing community-based activities so that their local knowledge can enhance programmes and their influence on community members can help reduce stigma and foster acceptance of services.
- Encourage disclosure as a vehicle for reduced stigma and discrimination.
- Strengthen and adapt services for men in their local environment and workplaces, for example by using male staff, male expert patients and male health workers, and by piloting more convenient opening hours for clinics (evenings, weekends).
- Strengthen youth-friendly (outreach) services.
- When piloting new male/youth-friendly strategies, solicit regular feedback from target groups on their perceptions and acceptance of these strategies.

Increase cost-effectiveness of the decentralisation programme by rationalising human resources costs at the clinics.

Implement a community-based ARV medicines distribution model.

- Establish more ARV distribution points that are closer to remote communities. Schools and community centres could be used for this purpose.
- Pilot community ART groups, for example, small groups in remote areas.
- When piloting different community-based ARV distribution models, solicit regular feedback from target groups on their perceptions and acceptance of these approaches.

Strengthen MSF support to the regional and secondary health care facilities in Shiselweni.

- Strengthen support to the regional health authorities in terms of their management capacity and supervision of PHCC's.
- Strengthen support to the SHCF's for clinical ART management and for task-shifting and integration of TB and HIV services.

Improve continuity of the current Shiselweni HIV/TB programme.

- Ensure systematic joint programme planning, monitoring and supervision activities with the MoH, to foster MoH ownership and long-term preparation for eventual handover of programme components.
- Explore alternative funding possibilities and identify implementing agencies to take over components currently supported by MSF.
- To optimise staffing levels, systematically assess the workload at individual clinics relative to international and national standards.

8.2 AT COUNTRY LEVEL

Replicate the best practice components of HIV/TB decentralisation in Shiselweni at the national level.

- Introduce nurse-led ART and TB at all health facilities, along with well-organised task-shifting to new cadres.
- Introduce strong patient support, education and counselling by expert patients.
- Implement full integration of HIV and TB treatment, including MDR-TB, into general health care.
- Build strong community components within programmes, ensuring productive linkage between health facilities and communities.
- Decentralise laboratory services by establishing mini-laboratories at all clinics and implementing a sample transportation system to reference laboratories.

Address policy issues

 Advocate for full implementation of the National Task-Shifting Framework.

9 FUTURE PERSPECTIVES: INCORPORATING "TREATMENT AS PREVENTION" STRATEGIES

A crucial next step in the evolution of the Shiselweni decentralised programme model is to incorporate HIV "treatment as prevention" strategies into its operations, so that the high rate of new infections can be curbed and the HIV/AIDS and TB epidemics slowed.

As part of its ongoing work in decentralising HIV and TB testing and care to the community level, MSF, in collaboration with Swaziland National AIDS Programme (SNAP), proposes to pilot various test & treat strategies—first for HIV-positive pregnant women (PMTCT B+ strategy) and subsequently for HIV-positive adults. These activities aim to contribute to the reduction of HIV-and TB-related mortality, morbidity and incidence in the region while demonstrating acceptability and feasibility of these strategies.

The main components of the proposed programme are:

- Reinforcing HIV testing and retention in treatment through provider-initiated and community-based HIV testing, reinforcement of pre-ART care and community-based self-management of ART.
- Piloting PMTCT B+ (test & treat for all HIV-positive pregnant women) in the Nhlangano Health Zone, through the Mother and Child Health (MCH) services of the Public Health Unit (PHU) and Maternity of the Nhlangano Health Centre and the MCH services of the 7 PHCC's (pilot to run from early 2013 to 2016).
- Demonstrating acceptability & feasibility of Early Access to ARV for Adults (EAAA) strategy for HIV-infected adults in the Nhlangano Health Zone (pilot to run from 2014 to 2016).

This proposed programme aligns with the Swaziland Treatment as Prevention National Framework, which supports evidence-based interventions through a National Research Platform that coordinates operational research on Treatment as Prevention. If successful and adopted by the Swaziland National AIDS Programme, PMTCT B+ (and later EAAA) can then gradually be rolled out to the other two health zones in Shiselweni and the rest of the country.

Detailed implementation plans for the two pilots will be developed through discussion with the relevant departments in the MoH, including SNAP and the Sexual and Reproductive Health Unit (SRHU). All pilot activities will be carried out under normal programmatic conditions where possible. During the 4-year period of the pilot studies, MSF commits to provide all required resources (diagnostic tests, ARV medicines and additional human resources) beyond the ongoing HIV/TB services.

Accompanying qualitative and quantitative research will be carried out by an MSF research team in close collaboration with SNAP and the SRHU (for PMTCT B+). This research will include ethnographic and epidemiological studies to address feasibility, acceptability and effectiveness of the different pilot interventions. The research will also include a costing study with marginal analysis for each additional programme component and resource relative to standard programmatic conditions.

A Drug sensitive tuberculosis (DS-TB) patient from Nsalitje in Shiselweni.





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IMPRESSUM

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Patients waiting at the Zombedze clinic, where MSF has decentralised TB and HIV services, in the Shiselweni region.