Responding to HIV in Malawi: towards a continuum of care
Weigel, R.

Citation for published version (APA):
Weigel, R. (2012). Responding to HIV in Malawi: towards a continuum of care

General rights
It is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), other than for strictly personal, individual use, unless the work is under an open content license (like Creative Commons).

Disclaimer/Complaints regulations
If you believe that digital publication of certain material infringes any of your rights or (privacy) interests, please let the Library know, stating your reasons. In case of a legitimate complaint, the Library will make the material inaccessible and/or remove it from the website. Please Ask the Library: http://uba.uva.nl/en/contact, or a letter to: Library of the University of Amsterdam, Secretariat, Singel 425, 1012 WP Amsterdam, The Netherlands. You will be contacted as soon as possible.
CHAPTER 1

INTRODUCTION, AIM AND OBJECTIVES
INTRODUCTION

The new century started with a number of major initiatives to fight the global spread of HIV. In July 2000, the UN Security Council dedicated for the first time in history a session to a single disease stating that HIV is a threat to the stability and security of entire regions (1). In September 2000 world leaders signed up for the Millennium Development Goals (2). Goal 6 aims to halt and begin to reverse the spread of HIV/AIDS and achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it. During a UN General Assembly Special Session (UNGASS) in June 2001 country representatives committed to “ambitious goals for reducing incidence through the expansion of prevention efforts and increasing access to care and support for all people living with HIV” (3). However, the HIV and AIDS epidemiological update released by UNAIDS in December 2002 observed insufficient progress, especially in sub-Saharan Africa.

“A tiny fraction of Africans in need of antiretroviral treatment are receiving it. Many millions are not receiving medicines to treat opportunistic infections, either. These figures reflect the world’s continues failure, despite the progress of recent years, to mount a response that matches the scale and severity of the global HIV/AIDS epidemic.”

“Treating and caring for the millions of Africans living with HIV/AIDS poses an inescapable challenge to the continent and the world at large.” (4)

Finding means to meet this challenge dominated the next decade.

Numerous barriers prevented people living with HIV (PLHIV) in sub-Saharan Africa from accessing ART. There were fears about feasibility of ART delivery in resource poor countries. Health workers were not trained in the use of antiretrovirals (ARVs). Health systems were weak with unreliable supply chains resulting in stock outs of essential medicines. Laboratory services had numerous limitations. Quality assurance systems for laboratories were frequently absent or poorly implemented. The concept of chronic, lifelong care, requiring patients to be followed up indefinitely and maintain retrievable patient records on site was largely untested. The cost of ART was high and would have allowed only a small fraction of people in need to be treated. Once patients had started on ART health systems would be committed to ensure a lifelong supply. Cost effectiveness of ART was a major concern (5).

In addition there was fear that adherence and retention would be poor such that resistant virus would spread rapidly across the continent. In the end, ART could do more harm than good and ultimately would have dangerous consequences for treatment programmes in more prosperous parts of the world. Therefore, prevention efforts took precedence over introduction of ART in sub-Saharan Africa (6).

With regards to ARVs, policymakers, researchers and clinicians faced a dilemma. The live-saving treatment was available to most adults and children in the western Europe (7), and mother to child transmission (MTCT) of
HIV was reduced dramatically (8). The situation in sub Saharan Africa was in sharp contrast. In 2002, only approximately 1% of eligible PLHIV received treatment (9). In regions with the greatest need for ART the fewest numbers of people had access (Figure 1) (10).

Figure 1: Deaths from HIV/AIDS versus people using ARV by region from (10)

However, the voices demanding access to treatment became louder (11). The Durban World AIDS conference had sent an unequivocally message: “Treatment for All, Now”. In 2001 the Indian drug company Cipla launched a fixed dose combination (FDC) tablet containing stavudine, lamivudine and nevirapine in one tablet. For the first time, highly active antiretroviral therapy (HAART) was available as a single tablet to be taken in the morning and in the evening. The price was unbeatable by Western pharmaceutical companies: 350 USD for a yearly treatment (12). Clinicians in resource poor countries split these tablets in halves and quarters to treat children as no other formulations were available to them. Within months Cipla became the largest supplier of ART for Africa, before other generic producers followed. Competition between generic providers further reduced the price.

Since the late Nineties non-governmental organisations (NGOs) started treatment programmes in Africa and Haiti and showed that ART could be delivered successfully in resource poor settings. They reported good adherence, and good virological and immunological outcomes (13;14). In 2002, the UN established the Global Fund to fight AIDS Tuberculosis and Malaria (GFATM) that required up to 10 billion USD annually from donor countries for an effective response to HIV alone. However between 2002 and 2003 the total contributions
were below 1 billion USD annually, in 2004 and 2005 approximately 1.5 billion and in 2007 slightly more than 2 billion USD annually (15).

The moral pressure of the obvious inequity in access to treatment, the threat HIV posed to the world’s stability, the fact that affordable generic ARVs that were simple to use were available, the proof of the concept that ART can be successfully delivered in resource poor settings, the advent of the GFATM—though underfunded—and, probably most important, the initiative of many African countries to apply for funds to actively fight their epidemics—finally changed the game. A general consensus emerged that ART had to be made available at a large scale in sub-Saharan Africa as soon as possible and as an emergency response.

**HIV EPIDEMIOLOGY, THE HEALTH SYSTEM AND KEY HIV SERVICES IN MALAWI**

With a gross national income (GNI) per capita of 160 USD per annum in 2000 (in 2011 the GNI has risen to 340 USD; compare UK: annual GNI of 37,780 USD per capita) Malawi is one of the poorest countries (16). Since the first patient was diagnosed with HIV in 1985 (17), the epidemic had spread unchecked throughout the general population. For example, in Blantyre the HIV prevalence among pregnant women increased continually between 1985 (2.5%) and 1996 (34%) (Figure 2) (18).

![Figure 2: HIV prevalence among antenatal care (ANC) attendees in Blantyre, Malawi by year of registration from (18)](image-url)

By 2001 the HIV prevalence among adults 15-49 year old in Malawi had reached 15% (19). Approximately 740,000 adults and 65,000 children were living with HIV. The number of orphans grew to 1.2 million (20). Between 50,000 and 70,000 Malawians died each year and the life expectancy of Malawians had dropped to 39 years against projected 54 years without the impact of the HIV/AIDS epidemic (21).
The differences of HIV prevalence among age groups and between men and women rooted in sexual behaviour and gender inequality, was fuelled by poverty, making girls and young women particularly vulnerable to contract HIV (22;23). HIV is more common in towns and cities and in the more populated southern region of Malawi. In urban settings the HIV prevalence in men and women is nearly identical (16% vs.18%) (19).

In 2004, women in Malawi had on average 6 children; in urban settings the fertility rate was lower (4.2 children per women) overall. The median age of women’s first sexual contact was 17 years and of their first marriage 18 years. (19) Though fertility is lower in women with HIV infection, the combination of high HIV prevalence in young women and high fertility has implications on the burden of HIV among children.

Malawi’s health system suffers from a severe shortage of health workers- even in comparison with its neighbouring countries. For 10.000 people there were 2.8 Malawian nurses and 0.2 doctors in 2005; the respective regional averages for these cadres were 9 and 2.2 (24;25). Compared to its neighbours, Malawi had only about a third of nurses and one tenths of doctors available for the same number of citizens. Due to the shortage of medical doctors clinical services in the country rely primarily on nurses and clinical officers. Clinical officers are health professionals with a three year practice oriented medical training. The reasons for the human resource crisis in the health sector are complex and interrelated. Poor working conditions, high workload, low motivation and burnout among health professionals, low wages, poor leadership, absenteeism due to illness and caring for others, as well as “brain drain” to the private sector, non-governmental organisations (NGOs), government and research institutions and to other countries all play a role in that health workers do not engage at the bed site (26-32).

A situational analysis of HIV and TB services in major public sector health facilities in Malawi found that in 2002 70 sites performed HIV testing and counselling (HTC) (33). A total of 149,540 tests were carried out, among them only 5059 in pregnant women in the context of PMTCT. These tests were performed by 456 trained counsellors using different types of whole blood rapid tests (WBRT). Three hospital offered ART (Kamuzu Central Hospital in Lilongwe through Lighthouse Trust and Queens Elizabeth Central Hospital in Blantyre provided ART at cost through an revolving fund; and the MSF- supported District Hospital in Chiradzulu in the southern region free of charge), all but one hospital had an AIDS coordinator and most districts had AIDS coordinating committees. A basic supply of medicines for the management of HIV related diseases was available in most hospitals. The three ART sites had started approximately 1300 patients on ART. The 44 HCT sites that were found at District hospitals were able to refer HIV infected people for screening or for services to other sites- 3 HTC sites referred to TB clinics, 22 to STI clinics, 6 to HIV&AIDS clinics (3 provided ART), 7 to PMTCT services, and 33 to community home based care clinics. Clearly, more HTC sites with more referral opportunities, more clinics and better linkages had to be established to scale up access to services.
In 2002, the impact of AIDS dominated daily life throughout Malawi. People did not complete their regular tasks because they took care for family members, attended funerals or were sick themselves and unable to work. The health system was hit hard. In Blantyre, 70% of patients admitted to medical wards were HIV infected and 68% of deaths were related to AIDS and TB (34). Nurses and clinical officers frequently re-admitted patients who suffered from severe and recurrent opportunistic infections. Effective treatment was not available. Health workers were affected too—deaths related to AIDS and TB were high among them (35;36). They were at risk for burn out and unsurprisingly left the public sector for better remunerated jobs and working conditions (30;37).

In 2002 the destructive combination of food shortage and HIV and AIDS became visible (38). Most Malawian households depend on subsistence farming. The inability to work or working less effectively on the farm because of illness or the need to look after ill family members had a direct impact on food security. Political mismanagement and a severe draught further aggravated the situation. The price for fertilizer increased. In order to meet their needs households had to sell their commodities or “bread winners” left the villages and abandoned their field to make small scale business in towns and cities. HIV and hunger had formed a vicious cycle; dragging families further into poverty.

Women carry multiple burdens and are at particular risk to contract HIV. Women do fieldwork, look after the household and raise the children. When they needed to care for their sick family members or fell ill themselves they struggled to cope. Search for food and money made them vulnerable to engage in risky behaviour, to engage in transactional sexual relationships exposing them to HIV (39). Children of mothers with HIV infection were more likely to become sick or die, whether or not HIV infected (40), requiring more attention and resources from their parents.

The HIV epidemic affects children in Malawi in many ways. As the weakest members of the society, they depend on its support and the support by the family. First, many HIV infected children had died. The HIV prevalence among pregnant women in 2003 was 19.8% (18). In a cohort of 190 children infected through MTCT of HIV followed up from birth, 89% had died by age of 3 years (41). AIDS became the most common cause of death in adults (42) and had a major impact on under 5 mortality (40). Second, children dropped out of school in order to work and contribute to the family income. Girls may be forced into early marriage, early sexual debut and pregnancy exposing them to an increased risk of HIV infection. Among young people 20-24 year old the HIV prevalence in women was more than three times higher than in men (13.2% vs. 3.9%) (Figure 3) (19).
THE IMPACT OF HIV

In 2002, the impact of AIDS dominated daily life throughout Malawi. People did not complete their regular tasks because they took care for family members, attended funerals or were sick themselves and unable to work. The health system was hit hard. In Blantyre, 70% of patients admitted to medical wards were HIV infected and 68% of deaths were related to AIDS and TB (34). Nurses and clinical officers frequently readmitted patients who suffered from severe and recurrent opportunistic infections. Effective treatment was not available. Health workers were affected too—deaths related to AIDS and TB were high among them (35;36). They were at risk for burn out and unsurprisingly left the public sector for better remunerated jobs and working conditions (30;37).

In 2002 the destructive combination of food shortage and HIV and AIDS became visible (38). Most Malawian households depend on subsistence farming. The inability to work or working less effectively on the farm because of illness or the need to look after ill family members had a direct impact on food security. Political mismanagement and a severe drought further aggravated the situation. The price for fertilizer increased. In order to meet their needs households had to sell their commodities or "bread winners" left the villages and abandoned their field to make small scale business in towns and cities. HIV and hunger had formed a vicious cycle; dragging families further into poverty.

Women carry multiple burdens and are at particular risk to contract HIV. Women do fieldwork, look after the household and raise the children. When they needed to care for their sick family members or fell ill themselves they struggled to cope. Search for food and money made them vulnerable to engage in risky behaviour, to engage in transactional sexual relationships exposing them to HIV (39). Children of mothers with HIV infection were more likely to become sick or die, whether or not HIV infected (40), requiring more attention and resources from their parents.

The HIV epidemic affects children in Malawi in many ways. As the weakest members of the society, they depend on its support and the support by the family. First, many HIV infected children had died. The HIV prevalence among pregnant women in 2003 was 19.8% (18). In a cohort of 190 children infected through MTCT of HIV followed up from birth, 89% had died by age of 3 years (41). AIDS became the most common cause of death in adults (42) and had a major impact on under 5 mortality (40). Second, children dropped out of school in order to work and contribute to the family income. Girls may be forced into early marriage, early sexual debut and pregnancy exposing them to an increased risk of HIV infection. Among young people 20-24 year old the HIV prevalence in women was more than three times higher than in men (13.2% vs. 3.9%) (Figure 3) (19).

Third, it is hard to imagine what the losses within the family had meant to surviving children. To some extent the sense of despair and breakdown of relations might have been mitigated by the “extended family”. Aunties, Uncles, older brothers and sisters and grandparents stepped in to look after the orphaned children, brought them to the clinic, provided shelter and food. But even these safety nets reach their capacity (43).

At the World AIDS conference 2002 in Barcelona Justin Malewezi, the Vice President of Malawi summarized the impact of the HIV epidemic on his country as follows:

“AIDS in Malawi is devastating our economy. It is destroying the very fabric of our society. It is not only taking away our present, it is taking away our future and the future of our children.” (44)

MALAWI’S RESPONSE TO HIV: THE PUBLIC HEALTH APPROACH TO FIGHT HIV

After the 2000 World AIDS conference in Durban the Malawi Government had formed a working group and developed a proposal to the GFATM. This proposal was built on the “Strategic Framework for AIDS prevention and care 2000-2004” (45). Dr. Kamuzu Banda, who ruled the country until 1994, did not allow a public debate about HIV/AIDS and sexuality. The new government’s HIV response focussed initially on blood screening policies, public education on HIV/AIDS, programmes for orphans and home based care and the development of a seroprevalence surveillance system. The 2000-2004 framework had a more holistic approach by identifying areas of concern and prioritizing interventions through policy development, strengthening of institutions, service delivery and research. For example, to reduce the transmission of HIV it proposed to develop policies to mitigate gender inequity and to develop PMTCT guidelines. In 2001, the National AIDS Commission replaced National AIDS control programme (NACP) that had been established in 1989, to better coordinate HIV...
activities. After several revisions Malawi’s GFATM proposal was finally approved in August 2002 and the country received 196 Million USD to roll out HIV services (10).

Malawi’s National TB control programme (NTP) groaned under the rising numbers of patients with HIV associated TB. It had successfully introduced WHO’s DOTS strategy among the first in the world. The treatment was delivered by paramedics (TB officers) using “simple, standardised methods of case finding, standardised treatment using free drugs, standardised system of monitoring and procurement” (46). This system became the blueprint of Malawi’s national ART programme (47). The vision of such an approach was debated already in 2001 (48-50) and contributed to what became WHO’s strategy to scale up ART services in resource poor settings, the “public health approach” (Box 1) (51). This approach formed the basis of WHO’s future initiatives such as “3by5” (52), “Treatment 2.0” (53) and the UN’s 2006 General Assembly Declaration on “Universal access” (54).

The main elements of the public health approach are:

- Standardised regimens and simplified formularies
- Simplified clinical decision-making and standardised monitoring of ART response
- Standardised toxicity and drug-drug interaction management
- Sentinel surveillance of HIV drug-resistance

This approach will be implemented through:

- Decentralised, integrated delivery of care
- Task shifting and specialist support
- ART free at the point of delivery
- Reliable procurement and supply management
- Tracking progress through an robust Monitoring and Evaluation (M&E) system

Box 1: Elements of the public health approach to ART in resource limited settings from (51)

It allowed the development of 1st edition of Malawi’s national ART guidelines (21) that had built on the 2002 WHO ART guidelines (55). Malawi developed them further by providing suitable and pragmatic recommendations for paediatric ART: weight band based dosage tables for split adult generic ART. At the same time, operations research was launched to examine safety and effectiveness of these regimens (56-60). The HIV unit developed a two year rapid scale up plan (61) detailing the plans for training of health workers in ART
management and rapid roll out that was successfully implemented. By June 2004, through global funding, the first free ARVs in the country arrived at the Lighthouse pharmacy. By December 2005, 37,840 patients had started ART in 60 facilities throughout Malawi (62).

THE ROLE OF OPERATIONS RESEARCH

To a degree the first few years of the rapid scale up resembled a journey to the unknown. A reliable M&E system was essential to know where the programme stood and where to go. Health workers in the ART clinics routinely documented case finding and outcome data that the HIV department reviewed and collected during regular quarterly supervision visits to all clinics in the country (63). Many operational questions could be answered by analysing the routinely collected data only; others couldn’t and required additional efforts (57;64-76). Operations research that fills “the gap between what we know from research and what we do with that knowledge- the so called know-do gap, or implementation gap” (77) is instrumental to answer within weeks or months questions that aim at service improvements without needing large budgets. Commonly, these questions were raised by health workers or clinic managers working on the ground, who had a vested interest in improved services and the outcomes of this type research (78).

THE LIGHTHOUSE TRUST: SETTING AND ROLE

Lighthouse has its roots in the community and is driven and owned by Malawian health workers (79). Its director, along with a few other staff members, works for Lighthouse since its beginnings in 1997. At the time a small group of clinical officers and nurses from the medical ward at Kamuzu Central Hospital (KCH) volunteered to follow up chronically ill patients discharged from the ward and provided them with basic support in their homes. This home based care initiative expanded slowly, but added HTC services and a clinic to provide basic prophylaxis and treatment of opportunistic infections over the following years. Using the first major funding received in 2000 guardian shelters at KCH were renovated and the three functional arms (HTC, clinical and home based care) that still form the backbone of Lighthouse’ services today, found a new home. A Malawian Board of Trustees was established in 2002 that included Ministry of Health officials and the KCH director. Lighthouse was officially opened in July 2002 by the Vice President of Malawi, Justin Malewezi.

Lighthouse functions as an outpatient department of KCH, is part of the public sector with a mission “to fight against HIV and AIDS in Malawi by providing a continuum of quality care and support and by building capacity in the health sector” (80). When Lighthouse opened sceptics wondered whether the clinic will take off. People would be afraid and fear stigma when disclosing their status to other attendants when coming to a clinic dedicated to HIV care. Ten years later, Lighthouse provides on average 3500 HTC sessions each month. By the end of June 2012, Lighthouse Trust had started 34,272 patients on ART. A total of 18, 940 (55.3%) ART patients
are under active Lighthouse follow up, 7,277 (21.2%) have been transferred out to other ART clinics, 2434 (7.1%) patients have died, and for 4949 (14.4%) the outcome is unknown (80).

**AIMS AND OBJECTIVES**

Lighthouse, because of its long experience in ART management, its close following of the national guidelines and its robust M&E system using touch screens and real time data collection (81), is suited to conduct operations research on behalf of the Ministry of Health. Lighthouse’ findings are likely to be applicable to other clinics in Malawi. It is therefore always seen as the “flagship” clinic for operations research and piloting new interventions.

Using operations research we aimed to identify gaps and missed opportunities in the delivery of HIV services and to propose and evaluate interventions that address them.

The specific objectives were:

1. To assess children’s adherence to ART and explore the knowledge, perceptions and attitudes of caregivers towards their children’s treatment
2. To investigate the effect of establishing HIV testing and counselling and ART services for paediatric inpatients on uptake of these services by children
3. To examine growth response to ART among HIV infected children
4. To determine true outcomes of adults and children lost to follow up from ART and identify risk factors associated with successful tracing and death
5. To analyse mortality, loss to follow up and retention in the first year of ART among adults and children enrolled in the national programme
6. To describe and evaluate measures to increase uptake of ART among eligible HIV infected pregnant women
7. To compare ART prescribing practices between nurses and clinical officers

The studies took place at the Lighthouse Trust clinics in Lilongwe (Lighthouse at KCH and Martin Preuss Centre at Bwaila District Hospital) between 2002 and 2010. One study (Chapter 6) includes data of the entire national programme. Colleagues of five countries belonging to nine different institutions, most of them have worked or working still at the Lighthouse, have contributed to these studies, reflecting the collaborative and international aspect of its working climate. Things are done better together. Hence, tasks were shared. Though I took key responsibility for design, implementation and write up of the studies presented, parts of the analysis of some studies were led by others whose work is acknowledged in the papers. Many staff members at Lighthouse
Trust contributed to data collection, but all were involved in one or the other way be it receptionists, clinic aides or security guards. All studies required none or little additional funding. They were part of the routine services. All but one study were presented and discussed at a national forum, the annual National AIDS Research Dissemination conference in Lilongwe and, subsequently, at international conferences.
Reference List


20


