Responding to HIV in Malawi: towards a continuum of care

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CHAPTER 9

DISCUSSION
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The research described in previous chapters was conducted between 2002 and 2010 and aimed at improving services based on the local context and international recommendations. HIV services expanded massively during this period in Malawi and in sub-Saharan Africa as a whole. Drivers for this progress were: (a) leadership through WHO, UNAIDS and UNICEF; (b) increased funding through PEPFAR, GFATM and others donors; and − most importantly- (c) the efforts of countries, their health workers, community volunteers, programme managers and policy makers in adopting and implementing the international guidelines and making best use of resources. Operations research is an essential part of these efforts.

Operations research findings guide the implementation of international recommendations at the national level. Global guidelines require adaptation to the local situation. For example, WHO’s 2002 ART guidelines did not recommend split adult ARV tablets for the treatment of HIV infected children. However, the first edition of the Malawi ART guidelines recommended treating children using these formulations as no other alternative was available. Similarly, the Malawi 2011 Integrated HIV guidelines recommended treating HIV infected pregnant women with lifelong ART regardless of their clinical or immunological stage, though this wasn’t mentioned in the 2010 WHO PMTCT guidelines. Local policies should consider the context in which services are provided, including the epidemiological situation, infrastructure and human resources. To conduct meaningful operations research a thorough understanding of the international recommendations and the local circumstances is therefore needed.

The research presented here reflects also the changing and developing focus of the global and local HIV response. For example, the first study was conducted between 2002 and 2004 describes barriers to successful ART in children such as high costs related to drugs, transport and absence from work. Health workers and policy makers in Malawi had very little knowledge and skills in paediatric ART management and little understanding of perceptions of caregivers. Less than 500 children had started ART in the country. Therefore, we conducted a formative research using qualitative and quantitative methods to gain more insight. The last study was completed in 2010 and examined nurses’ capabilities to manage stable children on ART to inform policy about safety when tasks are shifted from clinical officers to nurses. By then, the number of children ever started on ART had risen to more than 34,000.

The next section briefly illustrates the changes in the HIV landscape in sub-Saharan Africa in general and in Malawi in particular. Giving this context allows a better understanding of rationales, objectives and meanings of the studies presented in Chapters 2 to 8. The section leads to a framework focussing on access to and retention in ART services that will guide us through the rest of the discussion.

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TOWARDS A CONTINUUM OF CARE

An increase of funding from 1.6 billion in 2001 to 15.9 billion USD in 2009 fuelled the 3by5 and Universal access initiatives (1). The 3by5 targets were achieved by 2007 but in 2010 only few countries had achieved the universal access targets. UNAIDS’ Treatment 2.0 initiative (1) supports the universal access targets by prioritizing (among others) the adaptation of service delivery methods through further expansion of ART access, task-shifting and retention in care. To guide governments on HIV diagnosis, treatment and care WHO launched a new strategy recently (2) outlining 5 directions. One focuses on the use of ART. New ART recommendations are expected in 2013 that will include guidance on integration of services (e.g. TB and HIV, HIV and Maternal and Child Health) and retention in care, representing a shift in approaches from rapid scale up to chronic care management.

These ambitious initiatives and strategies aim to change the current epidemiological situation. However, many countries have not yet fully implemented the WHO 2010 recommendations, despite progress over the last years. According to the latest report (3) the majority of people in sub Saharan Africa do not know their HIV status. Monitoring testing rates is difficult as countries use different denominators and may not control for people who tested repeatedly. However, overall, the number of testing facilities and tests per population in need is increasing (the median number of tests per 1000 adults rose from 47 to 55 globally between 2009 and 2010). More context specific testing and counselling methods will increase uptake among specific underserved groups further (e.g. home testing for couples, testing at the workplace for men, mobile testing in schools for young people, provider initiated testing at health facilities, ANC and TB clinics).

WHO and UNAIDS increasingly relate numbers of patients on treatment to the estimated need and report coverage. Coverage with ART in eastern and southern Africa has reached 62% in adults but is only 26% in children <15 years. Coverage among women (62%) is better than among men (48%) (3). Few countries report on retention in ART care. Globally, retention dropped to 81%, 75% and 67% after 1, 2 and 3 years on ART. However, the value of these data is limited because only a fraction of countries are reporting and major differences between countries exist (3).

WHO updated their guidelines in 2003, 2006 and 2010 and increased the pool of eligible patients by constantly lowering the threshold for ART eligibility. Now, WHO recommends lifelong ART regardless of CD4 count and HIV associated signs and symptoms for PLHIV who are partners in sero-discordant couples (4), pregnant women (5), patients with TB or Hepatitis B (6) and children under 2 years of age (7). The world moves towards a “test and treat” approach (8), driven by the understanding of “treatment as prevention” (TasP) (9). Improving access to and retention in ART care are prerequisites for TasP to work on a large scale and scale up of TasP combined with other prevention strategies brings the elimination of HIV transmission on the agenda.
Children and women might be the first beneficiaries, if the targets for pregnant women with HIV infection can be reached by 2015. The HIV department in Malawi updated its guidelines in 2004, 2006 and 2011, keeping pace with the global recommendations. The 2011 guidelines went beyond the WHO 2010 guidelines by recommending ART for all HIV infected pregnant women for life. They integrate guidance for adults and children on HTC, pre-ART, ART, PMTCT and Sexually transmitted infections (STI) in one document. Quarterly reports holding on to a robust M&E system provide national HIV service data, quality assured through structured supervisions.

By implementing and following the public health approach access to HTC, PMTCT and ART has increased steadily in Malawi. Since July 2007, about 1/3 of the entire population has been tested (3,783,813 people were tested). Of the 155,802 pregnant women that registered at ANC between January and March 2012, 76% (128,959 women) had their HIV status ascertained. By March 2012 in the 595 public sector ART sites, 477,022 patients had ever started on ART and of those 73% were retained alive and on ART, 11% had died, 16% were lost to follow up and <1% had stopped ART. Between December 2004 and June 2011 the overall ART coverage has increased from 3% to 67% (based on CD4 threshold of <250/µl). However, coverage differed notably between adults and children (76% vs. 32%) (14). Seventy-six percent of HIV infected pregnant women received ARVs (including a small proportion still receiving single dose NVP) for PMTCT at ANC representing approximately a 46% coverage of all HIV infected pregnant women in need for ARV prophylaxis during Quarter 1, 2012. Internationally and in Malawi understanding emerges, that scale up of a combination of interventions, utilizing synergies, is needed to control the spread of HIV. ART has a central role in this.

**A FRAMEWORK FOR THE “TEST, TREAT AND RETAIN “ APPROACH**

Improved access to and retention in the continuum of care are key to achieving the ambitious global targets. TasP as a strategy for elimination of HIV at the population level will only come into play if access is massively scaled up and those who access treatment are then retained. Better retention requires higher standards of care within the continuum. The scheme below (Figure 4) acts as a framework for the discussion of the individual studies in the following paragraphs. They focus on increasing access to services, concentrating on children and women enrolled into care at different points, and retention. I aimed to identify gaps and missed opportunities along the “test, treat and retain” continuum of care (CoC) and proposed and evaluated interventions designed to address these limitations.

For each paper I will now briefly give rationale, summarize the results and critically explore what has changed in practice locally (at Lighthouse or Malawi) or what the studies have added to the general understanding of the subject.
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Figure 4: “Test, treat and retain”- continuum of care (CoC): Outcomes and interventions to improve access to and retention in ART services for PLHIV, adapted from (8;15). Steps 1 to 5 represent periods PLHIV can stay in for different durations. For example, a pregnant woman can be tested and found HIV infected (step 1), enrol, found eligible and start ART (step 5) within one day. At each step, interventions can improve access and retention (top boxes) and patients have outcomes that are known (if retained in care) or unknown (if lost to follow up). PITC: provider initiated testing and counselling; CTX: Cotrimoxazole; INH: Isoniacid; NCD: non-communicable diseases; ITN- insecticide treated bed nets; PoC: Point of care; FDC: Fixed dose combination.
Chapter 2 explores step 5 in the CoC framework during a time when ART was at cost (2002-2004), using qualitative and quantitative methods. It describes characteristics and outcomes of some of the first children that started ART in Malawi and the first at Lighthouse. Just when ART became free, we conducted interviews and focussed group discussions with caregivers about their knowledge, attitudes and perceptions of HIV, ART and services at Lighthouse.

During the course of the study we developed a structured approach to ART management for children that did not exist before: an initiation schedule with structured education sessions prior to initiation, paediatric visit (initial and follow up) forms, an initiation checklist, information, education and communication (IEC) materials, an appointment schedule, dosage guidelines (weight band based) and a revolving fund for paediatric ART (similar to the one for adults). We were able to show that ART delivery to children is possible at Lighthouse using these structures.

The qualitative methods allowed different insights. Caregivers were extremely committed to the care of their children. They understood well how HIV can be transmitted to children, the need of good adherence with medication based on knowledge of the basic functioning of HIV and its effects on human defence mechanisms. They highlighted the circumstances in which they failed to adhere, what motivated them to continue and reasons for not attending the clinic. These findings informed the first edition of the national ART- guidelines: a special section in the guidelines dealt only with measures to improve adherence in children (16). The study also developed our understanding of the needs of children in a public health approach, such as ARVs free at the point of delivery, a clear and simple monitoring system and fixed dose combination tablets (instead of syrups). As a result, the health education unit at the Ministry of Health developed special paediatric IEC materials (flipchart and a calendar booklet) to support adherence that were distributed countrywide. It also brought the need for training of health workers in paediatric ART management to light. In response, Lighthouse conducted several training sessions that informed Lighthouse staff and the national training materials when ART guidelines were developed in 2003/2004. Overall, the research helped to “demystify” paediatric HIV diagnosis and management for patients, health workers and policymakers.

The results of Chapter 2 and the development of national guidelines that included paediatric HIV and ART (including weight band based doing tables) provided the foundation and rationale for the study presented in Chapter 3. We had shown that paediatric ART can be delivered in a resource poor setting following the public health approach. The next phase of research covered the period of 2003 to 2006 and focussed on improving access to ART through expanding HTC opportunities for children and families and linking them to ART. In the CoC framework the study covers therefore steps 1 to 4.

Availability of free ART in June 2004 created an enormous demand literally overnight. The waiting list to start ART increased to 3 months. Adults outnumbered children by far and results from HTC and ART registers
showed that coverage of children was low. New ways that would enable children to access HTC and ART had to be found. The research describes the introduction of provider initiated testing and counselling (PITC) at the paediatric ward at KCH and the linkage to a newly established ART clinic at the paediatric department run by paediatricians. It examines uptake of HTC and ART of children by comparing the proportion of children receiving HTC and ART before and after introduction of these new services in Quarter 4, 2004.

Most of the systems that were set up during the study are still in operation. Lighthouse HTC team worked closely with staff at the paediatric ward. A nurse and a counsellor were sent to Uganda to attend a paediatric HTC course. The paediatric department refurbished a room for HTC. Lighthouse and the paediatric department developed a rota for 7 day a week 9am -5pm counselling sessions and several lessons plans on topics related to HIV and children and HIV and ART in general. Counsellors delivered these sessions to caregivers 3 times a week at different paediatric wards including the under 5 clinic. A special checklist with questions for the counsellors during the pre-testing session was developed and briefings with staff at the wards were held. Caregivers had the opportunity for testing (and referral to Lighthouse if found positive). In addition Lighthouse helped setting up the paediatric HIV clinic by providing the visit forms. Adherence counselling (the paediatric ART clinic became soon too busy and so this task was shifted to counsellors) was introduced as a “by-product”.

Our results show that the introduction of PITC and the linkage to care was associated with an increase in proportion of children enrolled in HTC and ART services. The research developed staff’s understanding of the needs of HIV infected families. Our work helped informing the development of the national HTC guidelines and resulted- in the long term- in specific guidelines for HTC in adolescents and children (17). All these services were imperfect and were evolving with many limitations. However, future projects addressed these limitations, especially the limited uptake of PITC services (18-20).

Chapter 4 covers steps 3 to 5 in the CoC framework (HIV infected children enrolled at the clinic, ART initiation and follow up). We examined a cohort of children that started ART between 2001 and 2006 and investigated their growth over a 3 year period before and after they had started ART.

In many resource limited settings means to monitor children’s response to ART are very limited. At Lighthouse, viral load tests and CD4 count measurements were not regularly available. However, weight and height was monitored and our impression was that weight gain was a strong positive incentive and reinforcement for caregivers to adhere (results from Chapter 2). But what were the actual growth gains across the entire cohort? How long was the response sustained? To what extent were children catching up and does that affect both weight and height? Was the response equal among all children or dependant on other parameters?

Prior to the study clinicians used growth monitoring to identify eligibility for ready to use therapeutic feeding (RTUF) rather than for identifying ART eligibility and monitoring of ART response. Conducting research in growth and focussing on growth monitoring could impact on clinicians’ and nurses’ awareness on growth and improve the accuracy of measurements during routine services. We found that children did respond to ART and were catching up in both their weight and height, but without reaching normal values. Interestingly and
partly conversely with findings from others, children with poorer baseline growth caught up best. Other factors, such as age, sex, immunological and clinical status seemed not to influence their growth response. Unfortunately we were unable to correlate the growth response with immunological or virological parameters of HIV infection.

The study made staff aware of the quality of their services that could strengthen the CoC. We realized for the first time the extent of chronic malnutrition in our cohort - much higher than in the in the “normal” under 5 population in Lilongwe. Nearly 70% of our children were stunted (<-2z scores height for age). We also noticed the huge proportion of loss to follow up (LTFU) after clinic enrolment (step 3) and before starting ART (step 5) during the pre-eligibility and pre-ART periods. Forty-seven percent of children were not seen at the clinic more than 3 months after their last visit until the closing date of the cohort in March 2008. There were gaps in weight and height measurements and the lack of young children and infants in the cohort raised questions about effectiveness of diagnosis and referrals from mother and child health programmes and PMTCT.

Overall, this was one of the first papers looking at growth responses to ART in low resource settings over a longer period of time. It stimulated further research, combining findings from other countries, extending the age groups and correlating it with immunological and virological responses (21). The research highlighted also the need for high quality data collection during routine services and application of sound statistical methods that is fostered by working with international collaborators.

Chapter 5 further investigates LTFU of patients that had started on ART- it examines step 5 in the framework (Figure 4), but results indirectly informed policies of prior steps. It directly addresses LTFU through tracing, highlighting that unknown outcomes can be changed through tracing.

During the “paying period” (before June 2004) many patients did not continue to come to the clinic after initiation and this was attributed to the high cost of treatment (22). However, LTFU remained high at Lighthouse even after introduction of free ART. What happened to patients that missed their appointments? What were their true outcomes? What made patients likely to become LTFU and how could we find them? Can tracing work? Answers to these questions were not only interesting to Lighthouse but also of major interest to the national programme as lost patients could be a source of drug resistant HIV due to the risk of interrupted medication intake and poor adherence (23). Unknown outcomes cause inaccurate reporting. Tracing patients LTFU is the first step to find out about reasons for becoming LTFU.

Only a small proportion of LTFU patients could be traced in our study because contact information was missing or incomplete- a major lesson for future tracing. Accurate and regularly updated contact information is essential. However, among those with contact information tracing produced useful information. Forty-one percent of successfully traced individuals had died and 53% were still alive, getting ART either at our clinic-documentation had to improve to avoid unnecessary tracing- or silently moved to another ART site. This affected adults and children, though the small number of children limited the analysis. A number of deaths could be retrieved from central hospital records- better linkages between clinics could ease tracing and
reporting. Adult patients had a higher risk of death when LTFU occurred earlier after ART start and within 3 months after becoming LTFU. Therefore tracing efforts should start soon after becoming LTFU. The high early mortality due to late presentation observed in the cohort seemed to be reflected among the LTFUs too. So the main task was to enrol patients earlier into care. In addition, the risk of death was higher for patients starting during the paying period, underscoring the importance of free services in this population (24). Phone tracing was particular effective in identifying outcomes of patients LTFU. At the back of the study we conducted also qualitative research on reasons of adult patients to become LTFU (25).

Once more, the research informed and shaped our routine services. The systems set up were later adopted for the routine tracing operations, called Back to care programme (B2C). It included a dedicated tracing team consisting of phone and field tracers (using motorbikes), procedures for identifying patients with missed appointments through the electronic data system (EDS) and confirming their LTFU status by reviewing the files, the protocol how to approach guardians or patients in the field and by the phone, and how to get around in the community searching for missing patients. The B2C programme contributed to further research reporting on the proportion of patients returning and the effects on refining programme outcomes (26), on virological status and the resistance patterns of patients LTFU who returned (23) and risk factors of LTFU in children and their true outcomes after tracing (27). The national programme now strongly encourages tracing for all clinics. With its tracing dataset Lighthouse helped a frequently cited systematic review and meta-analysis (28) and the development of a formula to correct mortality for LTFU in sub Saharan ART programmes enhancing quality of national and international reporting (29).

The M&E system of Malawi’s ART programme is robust and produces aggregated data of high quality through quarterly structured supervision and data collection (30;31), supporting the country’s public health approach (32). Operations research built on that has informed national and international policy (33-39). However, aggregated data don’t allow breakdown of outcomes for patients of different ages and calculation of rates for example. A new method of making photographs of paper ART registers (M&E tools are the same across the country) on site and entering case finding data and outcomes from these photographs into a database off site allowed capturing of nearly complete data of all individuals that started ART in Malawi’s national programme between 2004 and 2007 and their 12 months outcomes. The study analysing these data in Chapter 6 relates to step 5 of the framework.

This unique dataset offered a wealth of information and extended a previous analysis (32). Early mortality and LTFU was a major feature of the early ART scale up in Malawi, in line with findings from other studies (24;40;41). However, early mortality is now declining steadily in parallel with patients who start with WHO stage 4 disease (13). We showed that mortality and LTFU was highest among children who started under 1 year of age ART and young people 14- 25 years. From age 20, men were at higher risk of death than women and between 2004 and 2007 mortality decreased but LTFU increased- keeping overall retention in the programme stable. However, outcomes prior to initiation of ART were not available. Exclusion of patients who started in the private sector or transferred in from other facilities was also a limitation. Nevertheless, the study
created a digital repository of the paper records and the findings pushed the needs of specific patient groups on the agenda. The national routine reporting of aggregated data now includes 12 months outcomes of children and the number of children starting at age < 2 years. Men and young people need more attention in research and programme implementation. Overall, evidence based methods to mitigate LTFU, such as active tracing (26), service integration (42;43) and improving quality of services (44) need scaling up. Finally, the plausible and consistent results of the study confirmed the good quality of data on paper and proved the validity of the new method applied.

Chapter 7 follows a cohort of pregnant women with HIV infection that were identified at ANC between 2006 and 2009 with CD4 counts less than 250/μl through the cascade from identification of eligibility until 6 months after starting of ART. The study relates to steps 4 and 5, the last two steps of the continuum of care in Figure 4.

Over the study period we implemented a series of interventions at ANC and the ART clinic and monitored their effect on referral completion and ART initiation. Linkage of eligible pregnant women to ART was a high priority nationally and internationally, as it is most effective to prevent MTCT of HIV during pregnancy, delivery and breastfeeding and improves maternal health. However, across programmes and countries, women found it challenging to navigate through the different services. As a result, LTFU along the “PMTCT cascade” was high (3). We wanted to ensure that women knew where they could access ART services and why they needed them. We tried to offer services as close and user friendly as possible. However, qualitative research shows (45) that causes for LTFU are more complex and are not limited to knowledge, simplification of procedures and physical distance. It was therefore not surprising that overall only 47% of eligible pregnant women started ART while pregnant. However, retention improved over the 3 year period in our setting. Referrals between different services caused most losses. LTFU was lower for services within the same facilities, e.g. HTC and CD4 result collection within ANC or registration (enrolment) and initiation of ART within the ART clinic. Interestingly, in 2009 those who were referred successfully from ANC to ART mostly started the same day on ART (as recommended in our policy). Delays occurred mainly between CD4 blood draw and referral. We concluded that ART initiation could be done at the ANC to prevent LTFU and CD4 testing through Point of Care (PoC) CD4 tests, giving results within minutes. The Government of Malawi has decided to address these delays by implementing option B plus - all pregnant and lactating women with HIV, irrespective of their CD4 count, are eligible and start at ANC (12;46) and WHO adopted this strategy (5).

LTFU of HIV exposed infants was also high during the study period (47) - they were referred to a specialist paediatric clinic in Lilongwe- this setup needs revision. We only looked at 6 months ART outcomes of women who started while pregnant. There is need for longer follow up to examine if their outcomes are poorer than in the general cohort. Pregnancy among ART patients is as common as in the general population in Lilongwe (48). What happened to the women and children that were lost in the PMTCT cascade? This is an important question for further research.

The study presented in Chapter 8 (similarly to the one in Chapter 4) is interested in the quality of ART services. Good quality is a prerequisite for good retention. The study relates to step 5 in the CoC framework. In Western
countries, paediatricians care for HIV infected children. In Malawi, a country with few specialists, clinical officers and nurses replace them. Adult ART services are mostly nurse-led, a strategy that is promoted by WHO (49). At Lighthouse, clinical officers traditionally manage children on ART. They use an electronic data system (EDS) to calculate dosage based on body weight, adherence based on prior supplies, observed and reported pill counts and next appointments based on available pills and new standard supplies. Accuracy in ART prescribing practices is essential for good paediatric ART management, not only at Lighthouse where the EDS is available, but also in other clinics throughout Malawi. Can nurses achieve similar results than clinical officers using just pen and paper? To answer this question we compared nurses and clinical officer results and measured agreement. The results encouraged us to shift the task of management of stable children on ART to nurses. Children and their HIV infected caregivers could be seen by the same cadre during the same visit. This could be attractive for families as it could save time and transport money. However, we did not examine the quality of clinical services of nurses nor patients’ satisfaction. In addition, nurses can reach their capacity depending on staffing levels and patient numbers. The study also showcases the use of the EDS (that is already rolled out to 24 high-burden [>2000 patients] ART sites in Malawi) as an innovation in itself (50-52). It has the potential to enforce good standards across different cadres by following a checklist approach in patient management and reduces workload for M&E by computing cohort analyses.
Reference List


