THE LIGHTHOUSE
A centre for comprehensive HIV/AIDS treatment and care in Malawi

CASE STUDY

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Perspectives and Practice in Antiretroviral Treatment

Background

The Lighthouse Trust was established in 2001 to provide a continuum of quality care and counselling as well as to improve the quality of life of people infected and affected by HIV/AIDS, including the terminally ill, in Lilongwe.

The Lighthouse evolved in response to the impact of HIV/AIDS in the medical wards at the Lilongwe Central Hospital (LCH), which reflects the countrywide dimension of the epidemic. In September 1997, independent initiatives were set up by staff members of the Medical Department, who saw the need for HIV/AIDS care and support, in both hospital patients and in their own communities. In Lilongwe district alone, there are over 90,000 HIV-infected individuals of whom about 15% would be eligible for ARV therapy.

What is known today as the Lighthouse began in September 1997. With an estimated national HIV prevalence rate of 8.4%, Malawi is one of the most severely affected countries in the world. The dilemma is further illustrated by the fact that about 15% of those aged 15–49 years are infected with the virus causing AIDS, making it the leading cause of death in the most productive age group (20–49 years). The National AIDS Commission (NAC) estimated that in 2001 there were about 1 million adults and children with HIV in Malawi, resulting in about 50,000 to 70,000 deaths annually. There is an urgent need for quality HIV care and support, including palliative care for people living with HIV/AIDS, to reduce individual suffering and to dispel the fear, despair and hopelessness that surround HIV/AIDS in Malawi.

At the same time, Malawi’s poor health infrastructure is already overburdened and faces a severe human resource crisis with lack of trained personnel in various cadres. For example, the Ministry of Health and Population (MoHP) can currently fill less than 50% of established posts in some key cadres such as clinical officers and registered nurses. Positions that are filled are inequitably distributed and show a clear disadvantage for rural health facilities. Many health centres have one or even no nurse on staff. In addition, staff morale is often low and productivity poor.

A study on patients suspected of smear negative tuberculosis (TB) which included counselling and testing, demonstrated that voluntary counselling and testing should be part of the services the hospital provided. The research team also acknowledged the need for continuing care for study patients found to be HIV-infected, and the element of clinical care gradually evolved.

In 1998, the idea was conceived of integrating existing services and initiatives into one centre, marking the inception of the Lighthouse concept. This idea received strong backup through the Pro Test TB/HIV co-infection initiative. In that same year, a building that could potentially host the proposed centre was identified and the required funds for refurbishing a dilapidated guardian shelter into a functional, friendly care centre were awarded two years later.

Malawi’s Vice President officially opened the Lighthouse Centre on 26 July 2002, demonstrating political commitment to the battle against HIV/AIDS. The provision of antiretroviral therapy (ART), previously provided at cost at a specialist-paying clinic at LCH, was integrated into the Lighthouse services in the same year.

The Lighthouse was registered as a Trust to secure independent funding and to function as an integral partner in Malawi’s public health system. Today, the Lighthouse is the first specialist centre in Malawi for the care and support of people living with HIV and AIDS, providing a comprehensive range of services for patients infected with HIV. This study describes Lighthouse’s progress up to early 2004.
OBJECTIVE
As defined in its mission statement, “the Lighthouse exists to provide a continuum of quality care and support to people infected and affected by HIV/AIDS and to the terminally ill in Lilongwe”.

The Lighthouse set out to achieve this mission by:

◗ bringing together innovative initiatives as an integrated service within a single centre;

◗ complementing those services offered by the Lilongwe Central Hospital; and

◗ integrating the main hospital’s services such as human resources, laboratory, radiology and pharmacy in order to strengthen the Lighthouse.

With its strategy, the Lighthouse also aims to support the efforts of the MoHP to introduce ART while at the same time strengthening the broader health sector.

DESCRIPTION OF THE PROGRAMME

Services provided:
The Lighthouse offers the following key services to its patients: Voluntary Counselling and Testing, clinical services including ART and palliative care, and community home-based care (Table 1).

Table 1. Services provided at the Lighthouse in 2003

<table>
<thead>
<tr>
<th>Key elements of service and components</th>
<th>Staff as of 3 November 2003</th>
<th>Number of patients per month</th>
</tr>
</thead>
</table>
| **Voluntary confidential counselling and testing**
  - Pre-test counselling
  - Testing using rapid-test
  - Post-test counselling including supportive and risk-reduction strategies | Team of trained counsellors | > 700 |
| **Clinical care**
  - Quality care for opportunistic infections
  - Antiretroviral treatment
  - Palliative care
  - Paediatric treatment
  - Day ward for stabilization of patients requiring admission or directed treatment | Potentially, 10 Malawian medical/clinical officers to run the clinic; Four clinicians are available daily, with at least one physician | > 1800 patient reviews and about 750 patients on ART |
| **Community home-based care (CHBC)**
  - Care to the sick at their homes | Nurses and community care supporters | About 150 clients/patients |
Management:
The Lighthouse exercises a participatory management style, which has its root in the self-organization of volunteers. However, the growing organization requires clear structures and decision-making processes, which are defined in the organizational chart (Figure 1).

Each position has a clear job description, including reporting lines to the respective line manager. Staff meetings are held on a regular basis. Recruitment procedures as well as terms and conditions for staff members are transparent and range from annual performance reviews to regulations for grievances. The management team makes important strategic decisions, which are endorsed by the board of trustees. Last year the first management retreat weekend for strategic planning took place, which proved very useful for team-building and planning and hence will become a regular event.

Staffing at Lighthouse clinic:
Over the last year improved funding and a growing demand enabled the Lighthouse to expand its staff tremendously. Whereas it mainly recruits its own administrative staff, counsellors and support staff, the HBC and Clinic teams rely primarily on MoHP staff.

The Lighthouse works with a team of 13 clinicians, but none of them is assigned full time to clinical duties and half of them come in only one day a week. Staffing has included three expatriate clinicians (a paediatrician, a specialist in internal medicine and an infectious disease specialist/clinical researcher). Potentially, six Malawian medical officers, and four Malawian clinical officers are able to run the clinic (Table 1). These clinicians are drawn from the Lighthouse, LCH, University of North Carolina (UNC) and the Malawi army.

Currently, the Lighthouse opens five days a week from 8:00 until 16:00. However, the four clinic rooms are seldom all operational at the same time because of the clinicians’ other duties. When seeing patients, each clinician reviews about 30 patients a day.

The prescribing privilege has been limited to the team of clinicians in an effort to a) ensure that only well-trained individuals are prescribing and b) to monitor the use of ARV prescriptions.
In light of the precarious human resources situation in the Malawian health sector, it is difficult to foresee whether the scale-up of ART will provide a satisfying response to the demand for health care services. ART is a new and labour-intensive service, backed by strong advocacy and donor funding, and services like those at the Lighthouse have the potential to draw staff away from the periphery to central locations. Thus, primary health care and health services for the rural poor may be further weakened. A key challenge is to leverage the support and funding flowing into Malawi to support ART so that it also strengthens the broader health sector.

The Lighthouse’s strategy is designed to support MoHP in its efforts to meet this challenge. It is the Ministry’s responsibility to allocate resources rationally to provide health care equitably for the people of Malawi. Through the health sector-wide approach, the MoHP is developing the strategies it needs to control and direct nongovernmental organizations (NGOs) and other providers, for example, by insisting on service-level agreements that define and limit what services NGOs should provide, and how and where they are provided.

However, resource constraints make this difficult to achieve. The MoHP cannot hope to compete for staff with NGOs, research organizations, or the private sector, where salaries are higher and working conditions often better. Therefore, many NGOs still have carte blanche to recruit clinical staff on the open market, which generally means from the Ministry. On the downside, this makes scaling up services slow and difficult. The Lighthouse must negotiate with the Ministry for additional staff, and justify it against the demands of, for example, rural district hospitals running with only a couple of clinical officers.

Nevertheless, this rationale informs the wider Lighthouse strategy. It does not intend to scale up its services beyond its current capacity, because to do so would inevitably mean drawing more staff into Lilongwe Central Hospital. Rather, by focusing on developing a capacity-building role and implementation of models at a district-hospital or health-centre level, the Lighthouse hopes to be part of the solution to the human resources crisis, instead part of the problem.

Box 1. Lighthouse and the Malawi health sector human resources

Facility:
The Lighthouse is situated on the campus of the Lilongwe Central Hospital, one of the major referral hospitals in Malawi serving the central region. When the Lighthouse moved into the new location close to the main hospital in May 2002, the initial concern was that this easily identified “HIV/AIDS clinic” would prevent people from using the facility. While this fear proved unfounded, the location’s most obvious disadvantage is its difficult access, particularly by public transport.

The building facilities at the Lighthouse include all the rooms necessary to run the centre efficiently, including a small pharmacy and a store (Box 2). Given its rapid growth over the last two years, there is already a need for more space, particularly for teaching purposes and an improved patient flow.
Diagnostic services:
For its routine operations the Lighthouse uses the central hospital laboratory facilities, which on the one hand saves space and staff, but on the other makes the Lighthouse vulnerable to shortages or breakdown of equipment in the same way as other hospital departments. Routine laboratory investigations are kept to a minimum, and clinically indicated tests include:

- Full blood count
- Liver and kidney function tests
- Blood tests for malaria parasites
- Analysis of other body fluids, e.g. cerebrospinal fluid,\(^1\) ascites\(^2\) or pleural effusions.\(^3\)

For patients being evaluated for ART, CD4+ cell count is available through the UNC Project on the LCH campus at a current cost of MWK 1500 (about US$ 15) to be paid by the patient.

Other diagnostic procedures such as radiographic exams or ultrasonography are also performed at the LCH facilities, with the possibility of a wide range of referrals to specialists. Computer tomography is only available in Blantyre, which is some 300 kilometres from Lilongwe.

Drugs and consumables:
Drugs and medical consumables are procured through the government Central Medical Stores (CMS). Patients receive most of their medications through the Lighthouse’s own small pharmacy, which in turn takes an appropriate stock from the hospital’s main pharmacy. In order to secure uninterrupted supply, an independently funded system of buffer stock-keeping has been introduced, e.g. for drugs in the treatment of opportunistic infections or palliative care. Through these efforts the Lighthouse also succeeded in introducing oral morphine solution into the government supply system.

Antiretroviral drugs have been purchased following a different mechanism (Box 3).

Box 3. A revolving fund for procurement of ARV drugs to ensure uninterrupted supply
Money paid by patients for their ARVs goes directly into a separate hospital account for the sole purpose of purchasing ARVs. The CMS buys these drugs through the local sales agent of a pharmaceutical company.

This mechanism has worked well with simple drug regimens (one fixed drug combination). With the introduction of more complex treatment regimens, an additional backup system was required. Based on this experience, the Lighthouse learned that any scale-up strategy must give the issues of drug procurement, supply and distribution very careful consideration.

Funding:
The Lighthouse started with almost nothing but the overtime commitment of Malawian LCH staff members and some expatriates. Personal initiative, strong performance and a wider range of available funding sources have now helped the Lighthouse to secure a better funding situation. Staff allocation by the MoHP/LCH and secondment of core staff members by different donors were key in the establishment phase of the Lighthouse. To date, various donors and partners support different areas, and some of these are illustrated in Table 2.
Table 2. Services provided at the Lighthouse

<table>
<thead>
<tr>
<th>Area of support</th>
<th>Donors / Partners</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Staff secondment/ deployment</strong></td>
<td>◗ MoHP Malawi&lt;br&gt; ◗ Centre for International Migration and Development (CIM), Germany&lt;br&gt; ◗ University of North Carolina, Lilongwe Project, United States of America</td>
</tr>
<tr>
<td><strong>Testing and counselling</strong></td>
<td>◗ Centers for Disease Control (CDC), United States of America&lt;br&gt; ◗ Catholic Agency for Overseas Development (CAFOD), United Kingdom</td>
</tr>
<tr>
<td><strong>Community home-based care</strong></td>
<td>◗ Family Health International (FHI), United States of America&lt;br&gt; ◗ Diana Princess of Wales Memorial Fund (DPWMF), United Kingdom</td>
</tr>
<tr>
<td><strong>Clinic</strong></td>
<td>◗ Deutsche Gesellschaft fuer Technische Zusammenarbeit, Backup Initiative, (GTZ), Germany</td>
</tr>
<tr>
<td><strong>Institutional development</strong></td>
<td>◗ Press Trust, Malawi&lt;br&gt; ◗ European Union&lt;br&gt; ◗ Heinz -Ansmann -Stiftung, Germany&lt;br&gt; ◗ Lions Club, Seesen, Germany&lt;br&gt; ◗ Umoyo Network, Malawi</td>
</tr>
<tr>
<td><strong>Clinical research, laboratory and personnel back-up &amp; Backup system for ARV drug supply</strong></td>
<td>◗ University of North Carolina project (UNC)&lt;br&gt;Benefits were observed for both the Lighthouse and UNC in working towards the common goals of effective management and control of HIV/AIDS and Sexually Transmitted Diseases (STDs) as well as improving clinical services and infrastructure.</td>
</tr>
<tr>
<td><strong>Qualitative research: attitudes towards ART</strong></td>
<td>◗ Liverpool School of Tropical Medicine/TB Equity Programme</td>
</tr>
</tbody>
</table>

Community involvement:
One of the Lighthouse’s most valuable assets is its strong link with the community, especially in some of the poorer areas of Lilongwe. This link is best illustrated by the fact that some 200 community volunteers—while not equally and continually active—can be mobilized. Community volunteers can refer patients directly to the Lighthouse Clinic, and there are regular meetings with the Lighthouse Community and home-based care (CHBC) nurses and the liaison, the “community-care supporter”. Annual get-togethers, exchange visits to other programmes, token gifts like T-shirts, invitations to celebrate the official opening of the Lighthouse or to commemorate World AIDS Day as well as refresher training courses in CHBC all help to create some kind of corporate identity while increasing or sustaining motivation. As of 2003, no specific community involvement related to ARVs has been implemented.
However, since Malawi has been awarded funds from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), community involvement has become a critical component in identifying patients for ART. As the proposal to the GFATM foresees treating 25,000 to 50,000 people—a small proportion of those requiring treatment—the issues of equity and access to antiretroviral therapy must be socially and culturally acceptable. In discussions with patients, during clinics and IEC sessions as well as in letters to the Lighthouse’s suggestion box, clients have already shown good understanding of this problem.

In addition, it is important that civic education addresses the fact that not all HIV-positive patients require treatment. Over time, the Lighthouse will include this component of education in its services. The well-established home-based care operations of the Lighthouse will provide a forum for that. The National AIDS Commission in collaboration with the HIV Unit at the MoHP is preparing a strategy on community mobilization to address issues of equity and access to ART in Malawi in which the Lighthouse will participate.

ANTIRETROVIRAL TREATMENT

Following an implementation phase the Lighthouse developed a more systematic, programmatic approach to providing ARV treatment, and many of the features were eventually integrated into the national treatment guidelines. The new national guidelines reflect a public health approach with standardization for eligibility, treatment regimen and monitoring delivered by certified providers (Box 4). They have been developed in a wider consultative process using experienced clinicians in HIV care, drawing on the experiences of the Lighthouse and other providers of ART such as Médecins Sans Frontières (MSF) France and Luxembourg in Chiradzulu and Thyolo, Southern Malawi, respectively.

The national guidelines incorporate the same medications that have been used by the Lighthouse as well as additional alternative options for failing patients or those intolerant to recommended first-line therapy. The first edition of the guidelines, which has benefited from contributions from the World Health Organization (WHO) and other international experts, was completed in October 2003. As a result, a wider range of treatment alternatives should be available soon.

The Lighthouse has not been independent in providing ARV drugs and has observed the conditions and regulations, including drug prices, defined by the MoHP for this particular treatment.

| Box 4. Malawi’s national antiretroviral treatment guidelines demonstrate government commitment to ARV delivery |
| ▶ Standardized combination ARV therapy to HIV-seropositive eligible patients under proper case management conditions with high levels of drug adherence |
| ▶ Regular, secure and uninterrupted supply of ARV drugs to units that are administering ARV treatment |
| ▶ Monitoring system for supervision of ARV therapy, effective patient tracing and follow-up as well as regular evaluation |

Clients served:

Since the initiation of the antiretroviral programme, a growing number of patients have sought testing and counselling services at the Lighthouse. While growing awareness and improved services are in part responsible, access to ART and primary care has likely been a contributing factor. Likewise, the number of clinic patients has dramatically increased on a monthly basis. Since the beginning of the dual therapy combination regimen in early 2000, some 1500 patients have been evaluated for ARV therapy up to July 2003 (Figure 2).

Patients come from Lilongwe and its neighbouring towns within the district. However, increasingly patients travel long distances from the northern parts of the country to receive treatment. This is not only inconvenient and expensive for them but also increases the risk of poor adherence and compromised results in follow-up, such as late discovery of adverse effects. So far, little influx from patients from neighbouring countries has been observed.
Selection of people for therapy:

The Lighthouse clinic, which has open access, works on a first-come-first-served basis with no particular group targeted to benefit from the Lighthouse ART programme. However, since the cost of ARVs (direct, indirect and opportunity cost) is still a major obstacle to access, it is very likely that the wealthier, more educated, urban population of Lilongwe with greater awareness of HIV, are the main beneficiaries.

Since the Lighthouse is committed to also providing the poor with the best available primary care, half of the Lighthouse clinic’s capacity will be reserved for those patients lacking financial means for antiretroviral drugs.

However, the Lighthouse has limited the number of patients it is accepting for treatment. This decision is based on an assessment of its capacity to provide an adequate level of quality treatment and the aim to focus more on capacity-building at other sites rather than on a maximum intake at its own site. That being said, this has resulted in a waiting list of up to eight weeks for patients and frequent attempts to bypass the waiting list using personal relationships.

The ratio between male and female patients receiving ARVs is balanced, and their average age is around 39 years. The majority of them have advanced AIDS with a history of weight loss and various opportunistic infections, notably TB and oral candidiasis. Based on retrospective data collection, the median CD4+ count was as low as 70 cells, and more than 10% of patients also present with Kaposi’s sarcoma. However, these data need to be interpreted with caution.

A cohort of 30 children under the age of 13 years currently also benefit from ARVs. Efforts are underway to improve HIV-related services, including drug delivery for this age group. Furthermore, the Lighthouse recently decided to deliver free ARVs to its employees and their spouses.

Eligibility for ART is determined by clinical and immunological criteria as well as treatment readiness. Each week, 15 to 20 patients are evaluated for treatment and given an appointment for a Thursday ART education session and blood test for CD4+ count (at cost). Five days later, based on the lab results, a final decision is made on the enrolment in the programme, and a starter pack of drugs for two weeks dispensed (Box 5).
The Lighthouse has also made efforts to standardize eligibility criteria: Patients meeting WHO AIDS Classification Stage 3 and 4, regardless of CD4+ count, and all patients with CD4+ counts less than 200 cells/mm3 are eligible for therapy. For patients receiving anti-tuberculosis medication and taking Rifampicin at that time, ART is deferred until completion of the intensive TB treatment phase.

Box 5. Key elements of ARV treatment at the Lighthouse

- HIV counselling and testing
- Patient registration with a unique number
- Comprehensive clinical review
- Evaluation of patient for ARV:
  - Advanced WHO stage 3 disease or WHO stage 4 (regardless of CD4+ count)
  - WHO stage 2 with CD4+ count <200 or TLC <1200
  - Exclusion of medical contra-indications
  - Evaluation of ability to continuously pay for treatment
  - Readiness
  - Guardian support
- Compulsory group education session on HIV/AIDS and ART
- Individual counselling as required
- Induction of treatment
  - 14 days D4T/3TC/NVP in the morning and D4T/3TC in the evening
  - After 2 weeks: review for early toxicity
- Continuation therapy: D4T/3TC/NVP
- Monthly checklist-based review for toxicity, illness, adherence, or other problems
- Supportive treatment for adverse effects/ alternative first-line treatment
- Switch to bi-monthly review if stable
- CD4+ count every 6 months, if possible
- Evaluation for immunological or clinical failure/ second line treatment

Note: D4T = stavudine; 3TC = lamivudine; NVP = nevirapine

ARV regimens used:
The choice of ART has largely been restricted by cost. Since the initiation of the ART component at the Lighthouse in May 2000, a number of different drug combinations have been used (Table 3).

Once patients initiate therapy, they are seen monthly for refills. Patients travelling from long distances and stable on therapy are granted two-month prescriptions, if requested. For reasons of drug security, all prescriptions carry the patient’s unique registration number. The refill procedure comprises a short clinical review, questions on adverse effects, occurring infections and adherence.
Table 3. Drugs used in the Lighthouse ART programme

<table>
<thead>
<tr>
<th>Date</th>
<th>Drug combinations</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2000</td>
<td>ZDV/3TC (brand-name), fixed-dose combination</td>
</tr>
<tr>
<td>End 2000</td>
<td>ZDV/3TC (generic, fixed dose combination) at reduced cost</td>
</tr>
<tr>
<td>October 2001</td>
<td>D4T/3TC/NVP (generic), triple therapy fixed-dose combination</td>
</tr>
<tr>
<td>January 2003</td>
<td>“Starter Pack”: one tablet D4T/3TC/NVP in the morning and one tablet D4T/3TC in the evening of (Cipla)</td>
</tr>
<tr>
<td></td>
<td>Due to arrangements with the local supplier for the pharmaceutical company, the UNC project and the Lighthouse pharmacy buy medications so that the Starter Pack could be made available to all patients.</td>
</tr>
<tr>
<td>July 2003</td>
<td>ZDV (donation from pharmaceutical company), 3TC and NVP, alternative first-line regimen for patients with D4T-associated neuropathy</td>
</tr>
<tr>
<td>Currently</td>
<td>D4T/3TC/ NVP</td>
</tr>
<tr>
<td></td>
<td>Fixed combination for first-line treatment</td>
</tr>
<tr>
<td></td>
<td>D4T/3TC</td>
</tr>
<tr>
<td></td>
<td>Induction phase</td>
</tr>
<tr>
<td></td>
<td>ZDV/3TC and NVP</td>
</tr>
<tr>
<td></td>
<td>Alternative first-line treatment in the case of d4T neuropathy</td>
</tr>
<tr>
<td></td>
<td>ZDV/3TC</td>
</tr>
<tr>
<td></td>
<td>Post Exposure Prophylaxis</td>
</tr>
<tr>
<td></td>
<td>NVP</td>
</tr>
<tr>
<td></td>
<td>Prevention of maternal to child transmission of HIV</td>
</tr>
</tbody>
</table>

Note: ZDV= zidovudine

Adherence support strategies:

Long-term adherence is crucial for the success of an ART programme. That is why the Lighthouse emphasizes the importance of patients’ understanding of the treatment implications. The Lighthouse developed its IEC programme based on experience with other chronic diseases that require the patient’s self-management, e.g. diabetes, and with regard for the patient’s personal dignity and responsibility.

The overall aim of this programme is to inform, encourage and empower people infected and affected by HIV/AIDS to cope with the disease and related problems and to live positively. Strategies currently used include daily group discussion, individual counselling, leaflets and a suggestion box.

With respect to ART, the Lighthouse uses the principles of empowerment of patients and the reinforcement of key messages. Patients are asked to identify a guardian or relative to support them in following treatment. This may or may not include directly observed therapy. This approach is now termed “guardian supported treatment” or “empowered reinforced therapy”.

The overall aim of this programme is to inform, encourage and empower people infected and affected by HIV/AIDS to cope with the disease and related problems and to live positively. Strategies currently used include daily group discussion, individual counselling, leaflets and a suggestion box.

Note: ZDV= zidovudine
Prior to the initiation of treatment, all patients and guardians are required to attend an education session on antiretroviral therapy. This session touches on the natural history of HIV and AIDS, including opportunistic infections, the role of CD4+ and its estimation, the treatment process at the Lighthouse, messages on healthy, positive living, including partner notification/disclosure, and finally ARVs, their mode of action and potential toxic/adverse effects. The group session is well accepted by patients and guardians, and there are clear indications that this contributes to decreased stigma and increased understanding.

In the early part of the programme, there was no formal assessment of adherence but a considerable dropout rate was noted among clinic attendees (Box 6).

As the programme continued, follow-up visits included questions related to the number of missed doses per month and the number of tablets remaining in the bottle as well as reasons for missing doses. In a recent survey among 122 ART patients, over 92% reported greater than 95% adherence to the medications, after an average of seven months on treatment. The most common reason for missing doses was insufficient funds to purchase medication.

In response to adherence issues, the Lighthouse collaborated on the Equi-TB Knowledge Programme with the Liverpool School of Tropical Medicine. The study used focus groups discussions and in-depth interviews to explore patient understanding of and adherence to antiretroviral therapy. Results are pending and shall be integrated into the patient communication strategy used at the Lighthouse. Early analysis confirms the important role that lacking funds plays in discontinuing treatment.

Box 6. Lighthouse clinic patients evaluated for ART from 1 July 2002 to 31 December 2002, including further evaluation until 30 June 2003: a follow up

A survey of 482 patients evaluated at the Lighthouse for ART between July and December 2002 found that approximately 80% of patients started treatment and more than half of them remained in treatment and responded well to drugs. Among these, the vast majority of patients achieved an adherence of at least 95%. The remaining 20% of those being evaluated for treatment did not start it due to a lack of financial resources, death, an intensive phase of TB treatment or a CD4+ count > 200 cells.

However, the study confirmed that overall retention in the programme had been low. If patients did not attend the clinic for more than 90 days, they were counted as “lost to follow-up”. This was the case in about 40% of patients who initiated treatment, and in the majority of these cases the reasons remain unknown. However, there are indications that lack of funds and death may have prevented patients from adhering to therapy. Most of the loss to follow-up occurred within the first month of treatment; hence patients received only one prescription.
Clinical outcomes:
Within the same survey that is discussed in Box 6, 215 patients received at least six months of antiretroviral therapy. Tests were obtained when clinical symptoms suggested that possible toxicity and routine monitoring was needed. In general, very positive clinical outcomes were observed and include a robust and considerable increase in body weight, less or no subjective symptoms like fatigue, loss of appetite, as well as a reduced number of fever episodes. Many of the patients are back to work or pursue their usual tasks.

Adverse effects:
- Neuropathy was by far the most common, with some 40% of the patients experiencing some degree of symptoms suggesting neuropathy. The Lighthouse since has developed an algorithm for managing drug-induced neuropathy.
- Hepatitis, diagnosed with jaundice and elevated liver function tests, occurred in around 1% of patients.
- Pancreatitis and a suspected case of lactic acidosis occurred in only very few patients.
- Rash, to some extent, is a more frequent problem, leading to discontinuation of treatment in around 12% of all patients with a rash.

CD4+ counts:
CD4+ counts are recommended every six months. However, due to the cost of the test, in general less than 10% of the patients receive follow-up CD4+ counts. Although the low number of patients receiving repeat CD4+ counts (approximately 25% among the survey patients) makes assessment of immunologic response extremely limited, a mean increase of 120 cells was observed in this group of patients. However, these data need to be seen in the light of non-systematic retrospective data collection and therefore should be interpreted with caution.

\begin{table}
\centering
\begin{tikzpicture}
\node (start) {Patients evaluated for ART 482};
\node (ART) [below of=start, anchor=north] {\begin{itemize}
\item Started ART 384 (80%)
\item Did not start ART 98 (20%)
\end{itemize}};
\node (Lost) [below of=ART, anchor=north] {\begin{itemize}
\item Lost 168 (44%)
\item Confirmed deaths: 28
\item Transfers to other units: 9
\item Unknown: 131
\end{itemize}};
\node (Retained) [below of=Lost] {\begin{itemize}
\item Retained in Care 215 (56%)
\item Lost 73 (74%)
\end{itemize}};
\node (Confirmed) [below of=Retained, anchor=north] {\begin{itemize}
\item Confirmed deaths: 3
\end{itemize}};
\node (Adherence) [below of=Retained, anchor=north] {\begin{itemize}
\item Adherence of \( \geq 95\% \)
\item 194 (90\%)
\end{itemize}};
\draw[->] (start) -- (ART);
\draw[->] (ART) -- (Lost);\draw[->] (ART) -- (Retained);
\draw[->] (Lost) -- (Confirmed);
\draw[->] (Retained) -- (Adherence);
\end{tikzpicture}
\end{table}

"Each time I come into the commercial bank and get teller services from one of my patients, I feel that providing ARV to patients is one of the most rewarding therapies that I have delivered. This Lighthouse patient, a single mother with one child, had suffered within an eight-month period from TB and PCP, complicated by a pneumothorax. She had then developed Cryptococcal meningitis but could not afford ARV treatment. Then she came down with CMV retinitis but eventually managed to get support to buy the drugs. Although she is blind in one eye now, she is back at work. Not only has a life been saved, but a mother avoids leaving behind an orphan!"

A Lighthouse clinician
Currently, the Lighthouse and University of North Carolina Project collaborate on a safety and efficacy study (SAFEST) to determine patients’ immunologic and virologic response to the recommended first-line treatment. Results are pending and more robust data can be expected soon.

**Added improvements:**

At the outset of the programme, no national guidelines for the monitoring of ART existed. Despite personal efforts to guarantee a minimum of standardized data collection, the overall documentation has been relatively poor. Nevertheless, monitoring and evaluation has been acknowledged as a crucial part of a successful programme. The University of North Carolina Project facilitated the development of a standardized data extraction form to collect key information from the records of patients seen to date. Subsequently, new patients have been added to the database as they present for evaluation. For patients presenting for follow-up visits, records have been updated for attendance, clinical outcomes, adverse events, and new laboratory results. Periodic reviews of the database yield key information such as the number of monthly visits for new patients and follow-up, retention rates and toxicity data.

Modification of the database occurs in response to changes in clinical practices or anticipating national reporting requirements. Such information has been invaluable in guiding the development of the national antiretroviral treatment guidelines.

Since April 2003 all follow-up visits of patients on ART are uniformly documented using a check list of questions for symptoms as well as for indicators of adherence and consequent action by the reviewing nurse or clinician. Currently, the University of North Carolina Project has managed database development and modification, data entry and statistical analysis. However, such intensive database management with manual data entry requires a fair amount of human resources. One full-time data manager and one part-time data clerk are needed to maintain timely records and ensure data quality.

**Added improvements:**

*Electronic patient registration system (EPRS):* In collaboration with the Baobab Health Partnership which is a Health Management Information System Project at LCH’s paediatric department achieved together with the University of Pittsburgh, the Lighthouse works on providing a computerized system utilizing touch-pad entry in the clinic rooms and registration area. Apart from patient registration, paper documentation (reports and lab requests) can be generated as well. The same system has been in operation in the paediatrics inpatient department of LCH since 2000 and has been well accepted in this setting. It is expected that this new efficiency will promote better documentation and consequently care while reducing the workload related to monitoring and evaluation of patient care, in particular of the antiretroviral programme. The system will incorporate the requirements of the national guidelines for antiretroviral treatment and is expected to be operational in mid-2004.

**Fast track review:** While maintaining quality care, the increased workload in patient care has required changes in documentation procedures. In light of the staff shortages and the long waiting hours, patients stable on ARV therapy may not require clinician assessment for refills. Therefore, standardized forms were designed to assist the care provider in evaluating patients on ART. Trained nurses may well be the appropriate cadre to perform a “fast track” review and refer patients for a clinician’s review in the event of special indications. These indications for referral have been defined using an algorithm, which was developed in conjunction with the review forms. Following a pilot-run with clinicians, these forms have been tested with a nurse acting as the provider. Non-clinician providers will likely be needed for bringing ART to national scale in Malawi and standardized assessments are likely to facilitate this effort.

The fast-track review will be accompanied by a simplified process of drug dispensing in which the role of new technology like smart cards needs to be explored. The fast-track review forms at the Lighthouse will be integrated into the EPRS and, within a newly developed operational framework, it is expected to improve the documentation while maintaining the standard of care.
Scaling up:
Through its successful proposal to the Global Fund to Fight AIDS, Tuberculosis, and Malaria Malawi has clearly demonstrated its commitment to scaling up efforts, including access to ART. The Lighthouse plays an important role within this process and the Lighthouse Trust strategy has been aligned to support the MoHP’s efforts to meet the challenge of bringing ARV treatment and care to the people of Malawi.

The strategy includes activities geared toward:
● bringing the Lighthouse services to full capacity: identifying funding and recruiting staff to achieve the defined organizational structure;
● making the Lighthouse services systematic: defining procedures and protocols;
● establishing the Lighthouse as a model that can inform the development of similar interventions elsewhere; and
● establishing the Lighthouse as a training institution for capacity-building to deliver care and support for HIV/AIDS in Malawi.

The Lighthouse has a maximum capacity of 2000 visits per month of which less than 1000 are new ARV patients. Since this capacity will be reached in the coming months, the institution will soon have to cap the number of patients seen. Increasingly, patient reviews will have to be performed at periphery health centres, making the Lighthouse centre more of a referral centre for complicated cases.

Thus the future activities of the Lighthouse will focus on preparing other sites to implement clinic activities. Currently, an in-service training module for clinicians is being developed that foresees a six-week attachment of clinicians to the Lighthouse. Furthermore, to prepare institutions prior to a clinician’s attachment to the Lighthouse, an ART implementation framework is being drafted in collaboration with the HIV unit of the MoHP and other potential partners.

Lessons learned:
● The Lighthouse, as an integral part of the health-sector response to HIV/AIDS in Malawi, faces familiar challenges. They include the urgent need for scaling up in response to the demand dictated by the epidemic, while at the same time paving the way towards an equitable access to a quality standard of care (quantity vs. quality). This is even a greater challenge in light of the precarious infrastructure and human resource constraints of the Malawian health care system.

● This challenge also needs to be considered in the Lighthouse’s rapid development over the last 18 months. Because of an imminent risk of overestimating its own capacity, phases of rapid expansion need to be followed by the time of consolidation in order to ensure the programme’s sustainability.

● The Lighthouse has taken innovative paths in its close cooperation with MoHP, while being organized as an independent trust. The Trust has been very successful in acquiring funds from various donors. The funds were awarded because of already existing activities and high personal commitment. The wide array of funding sources helps to reduce donor dependency, e.g. in the case of policy changes but at the same time creates more reporting and political obligations.
The participatory process of development and the finalization of the National Treatment Guideline for AIDS in Malawi, to which the Lighthouse and many others have provided considerable contributions, must be regarded as a very significant milestone and prerequisite for further expansion of the ART programme. The Lighthouse is prepared to continue its creative role in the scaling-up process in close cooperation with other stakeholders.

Provision of ART under circumstances like those in Malawi is necessary, feasible, rewarding and challenging. The initial steps of the Lighthouse have been difficult, but the subsequent steps will be even more demanding, since, for example, most of the second-line treatment regimen will be more complicated to deliver, not only for the individual but also for the system as a whole.

Despite patient willingness, the current paying system for ART has led to high numbers of patients lost to follow-up and carries the risk of promoting inequity and reduced adherence to treatment, which in turn will fuel the development of viral resistance. Parallel systems of paying and non-paying access to ART may make control and follow-up very difficult.

The scaling-up process is a work in progress, with little pre-existing experience. It requires critical evaluation of all steps being undertaken both within the individual institution and the health care system. The Lighthouse has already gone a long way together with its partners, the University of North Carolina in particular, to develop internal policies and quality standards that need vigorous implementation and follow-up. There is no one correct way of delivering ART in Malawi, but all should follow the framework laid out in the national treatment guidelines. There is the opportunity that large-scale provision of ART may boost the health care system in general, but there is also the threat that this might draw resources and contribute to further decline of primary health care.

Empowerment of patients, community involvement and participation of institutions in civil society will be key to a successful scaling-up strategy. At the level of the Lighthouse this means continuing the development of the IEC strategy by integrating the results of the study on patients’ understanding of and attitudes towards ART.

Keeping staff skilled and motivated requires a favourable work environment, opportunities for continuous professional training and development, and a sense of ownership within the institution. The transparent and participatory management of the Lighthouse with clear decision-making structures has, to date, been successful.

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