

Why Did the Scale-up of HIV Treatment Work?: A Case Example From Malawi

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Abstract: The national scale-up of antiretroviral therapy (ART) in Malawi is based on a public health approach, with principles and practices borrowed from the successful DOTS (directly observed treatment short course—the system used to successfully deliver antituberculosis treatment to people in some of the poorest countries of the world) tuberculosis control framework. During the first 6 years, the number of patients registered on treatment increased from 3000 to >350,000 in both the public and private sectors. The most important reasons for this success have been strong international and national leadership combined with adequate funds, a standardized approach to ART with practical guidelines, an approved national scale-up plan with clear, time-bound milestones; investment in an intensive program of training and accreditation of ART sites, quarterly supervision and monitoring of ART and operational research, rational drug forecasting and no stock-outs of drugs during the first few years, and involvement of the private sector. The looming challenges of human resources, guaranteed financial support, better but also more expensive ART regimens, use of electronic medical records to monitor response to therapy, and attention to HIV prevention need to be met head-on and solved if the momentum of the earlier years is to be maintained.

Key Words: HIV, antiretroviral therapy, Malawi, Africa, health systems

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SCALE-UP OF ANTIRETROVIRAL THERAPY IN MALAWI

Malawi is a poor, land-locked country in Southern Africa with a population of 13 million and a per capita gross domestic product of <US \$200 per year.¹ The HIV epidemic is dire: When antiretroviral therapy (ART) was being introduced at national scale in 2004, ~930,000 people were thought to be HIV-infected, with another 100,000 new HIV infections

occurring annually, and 170,000 people were estimated to be in immediate need of ART.²

In January 2004, before the national scale-up of ART started, there were 9 facilities in the public sector delivering ART to ~ 3000 patients. ART delivery was unstructured, many patients had to pay for medication, very few health care workers had been formally trained, and there were no national systems of monitoring or reporting. In short, there was “ART anarchy.” By June 2004, ART was being delivered at health facilities within the public sector, with this life-saving treatment rapidly brought to scale in both public and private sectors in the subsequent years. By June 30, 2010 (6 years after the start of scale-up), there were 396 clinics (290 static and 106 outreach) in the public and private sector that had registered 359,771 patients on ART.³ Both the public and private health sectors implement the same standardized systems of delivering and monitoring treatment. By June 2010, a total of 225,010 patients were alive (see Table 1), the majority of whom would have died within 1–2 years of diagnosis without such therapy.⁴ Despite the technical and operational challenges, this has been an immense achievement for the country and a well-quoted example internationally. At the population level, ART has already begun to have an effect in reducing adult mortality.^{5,6}

This article examines the reasons that underpinned this successful endeavor and discusses briefly the challenges that lie ahead.

REASONS FOR ANTIRETROVIRAL THERAPY SCALE-UP SUCCESS

International Leadership and Funding

In 2003, the World Health Organization (WHO) and the joint United Nations Program on HIV/AIDS launched the “3 by 5” initiative, with an ambitious goal of having 3 million people in developing countries on ART by the end of 2005.⁷ Dr Jong-Wook Lee, then director-general of WHO, led the clarion call exhorting member states to recognize the catastrophe being wrought by HIV/AIDS, to plan bold measures for scaling up treatment, to be prepared to take risks, and above all to get started.⁸ Fortunately, this call to arms was accompanied by a huge injection of funds for HIV/AIDS programs through the Global Fund to fight AIDS, Tuberculosis and Malaria, the U.S. President’s Emergency Plan for AIDS Relief, and the World Bank.

Malawi accepted the ART scale-up targets that were stipulated by WHO, even though the country realized from the

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TABLE 1. Characteristics and Outcomes of Patients Ever Started on ART in Malawi up to June 30, 2010

| | Public Sector | Private Sector | Total |
|---|---------------|----------------|--------------|
| Number ever started on ART | 345,765 | 14,006 | 359,771 |
| Number (%) males | 133,802 (39) | 6781 (48) | 140,583 (39) |
| Number (%) females | 212,963 (61) | 7225 (52) | 219,188 (61) |
| Number (%) adults | 314,638 (91) | 13,389 (96) | 328,027 (91) |
| Number (%) children (below 15 yrs) | 31,127 (9) | 617 (4) | 31,744 (9) |
| Number (%) on ART | | | |
| Due to WHO Clinical Stage 3 | 205,380 (59) | 6187 (44) | 211,567 (59) |
| Due to WHO Clinical Stage 4 | 51,958 (15) | 2324 (16) | 54,282 (15) |
| Due to WHO Stage 1 and 2 with low CD4 | 82,216 (24) | 5307 (38) | 87,523 (24) |
| Due to other reasons (infants with presumed severe HIV, confirmed HIV in infants, low TLC, unspecified) | 6211 (2) | 188 (2) | 6399 (2) |
| Number (%) on ART due to active or previous tuberculosis | 38,838 (11) | 1059 (8) | 39,897 (11) |
| Treatment outcomes by June 30, 2010* | | | |
| Number (%) alive and on ART | 216,712 (63) | 8298 (59) | 225,010 (63) |
| Number (%) dead | 34,904 (10) | 1165 (8) | 36,069 (10) |
| Number (%) lost to follow-up | 43,150 (12) | 2400 (17) | 45,550 (13) |
| Number (%) stopped treatment | 1129 (<1) | 45 (<1) | 1174 (<1) |
| Number (%) transferred out† | 52,414 (15) | 3032 (16) | 55,446 (14) |
| Of those alive and on ART‡ | | | |
| Number (%) on first-line regimen | 197,357 (92) | 6025 (82) | 203,382 (92) |
| Number (%) on alternative regimen | 13,866 (6) | 1108 (15) | 14,974 (7) |
| Number (%) on second-line regimen | 857 (<1) | 129 (2) | 986 (<1) |
| Other/nonstandard regimen (%) | 2088 (1) | 102 (1) | 2190 (1) |

*Includes 3478 patients in transit (transferred out but not yet transferred in at the new site).

†Indicates that a patient is permanently transferred from one ART facility to another.

‡Excludes patients in transit.

TLC, total lymphocyte count.

start that the targets were not achievable in the short time frame. Nevertheless, the attempt to reach the targets galvanized action. Malawi was not a U.S. President's Emergency Plan for AIDS Relief-supported country, and the financial support for ART scale-up was from 1 source only—the Global Fund to fight AIDS, Tuberculosis and Malaria. Although this meant less overall funding, there were also no competing interests and this made it easier for the country to develop, articulate, and implement a uniform direction for scale-up.

National Leadership

A clear lead was taken by the Malawi Ministry of Health (MoH), which assumed responsibility for national scale-up. The rationale was articulated as follows: (1) there was a strong moral imperative to save lives; (2) there was the principle of equity to ensure that fair geographical access to ART was established as rapidly as possible throughout the country; (3) there was understanding at the highest levels that preventing AIDS deaths would lead to national political and economic stability; and (4) ART would allow HIV-infected health care workers to return to work thereby strengthening the general health system. In response to this strong leadership, there was a desire by all implementing partners to work together with the MoH and use 1 national standardized system to deliver and monitor ART. Occasionally a new nongovernmental organization would come into the country wanting to set up its own ART clinic. However,

the MoH would insist that the national guidelines be adhered to, and that the sites be part of the national supervision schedules. In return, stationary for ART monitoring, training, and drugs would all be supplied by the MoH.

Standardized Approach to Antiretroviral Therapy With Clear, Practical Guidelines

From the start it was realized that the key to rapid and massive scale-up in a resource-poor country like Malawi where there was a severe shortage of skilled health workers and poor laboratory infrastructure was to keep the principles and practices of ART delivery as simple as possible. In this regard, the principles of “DOTS” (directly observed treatment short course—the system used to successfully deliver antituberculosis treatment to people in some of the poorest countries of the world) were borrowed and adapted to ART delivery.⁹ Standardized systems were instituted, so that at whatever level of the health service ART was being delivered, the same methods of assessing patients for ART eligibility, initiating treatment, and registering and reporting cases and outcomes was followed. These were spelled out in national ART Guidelines, that were updated on a 2- to 3-year basis whenever the need dictated.^{10,11} Malawi focused on the use of 1 generic, fixed-dose combination treatment containing stavudine, lamivudine, and nevirapine, with 2 alternative first-line regimens and 1 second-line regimen for serious adverse drug reactions and ART failure, respectively. An

important policy decision was made that ART in the public sector was to be free of charge for all patients and subsidized for patients attending the private sector. All sites were responsible for quarterly and cumulative cohort reporting of cases registered and treatment outcomes, using ART patient treatment cards and ART patient registers.

National Scale-up Plan with Practical, Time-Bound Milestones

Six weeks from the political demand to scale-up ART nationally, the MoH had a 2-year scale-up plan that had been discussed and approved by all stakeholders, implementers, and donors. The plan was based on the national guidelines with clear objectives, activities, and timelines for scale-up and details about the 60 health facilities that were selected as ART delivery sites during the first 2 years.

Training and Accreditation of Antiretroviral Therapy Sites

An intensive training schedule took place between February and June 2004, focused particularly on clinical officers and nurses learning the ART guidelines and undertaking practical attachments at experienced ART sites. Novel training methods at that time for Malawi included reading guideline sections in class, an examination which had to be passed at the end of the 5-day classroom training, and a practical attachment with milestones that had to be achieved and signed off by a mentor. Trained staff returned to their facilities where they debriefed the medical officer and nurse in charge, trained an ART clerk, trained HIV counselors, and briefed the district assembly and the neighboring health centers about ART. The MoH HIV Unit then carried out a formal accreditation of the ART facility using a structured questionnaire. Once accredited, the public was informed through announcements in national newspapers, and ART drugs (ordered some months before in good faith that the site would pass its assessment) were distributed and ART delivery commenced.

Supervision and Monitoring of Antiretroviral Therapy and Operational Research

Every quarter, the HIV Unit and its partners conducted supervisory and monitoring visits to all ART sites in the country.¹² The purpose was to ensure adherence to guidelines and standards, to collect and check data for national reporting, to provide encouragement and support (and sometimes admonish if performance is poor), and to record drug stock levels to facilitate drug forecasting. Each quarter, facilities were awarded a certificate of excellence if the register and treatment cards were completed according to national guidelines and if the cohort analyses had been accurately performed. Piggybacked onto supervision was the undertaking of operational research, asking questions relevant to program needs such as (1) confirmation of the need for supervision to ensure data quality,¹³ (2) evidence to show that the number of clinicians and nurses working in ART clinics was matched by a similar number alive and well on ART,¹⁴ and (3) the use of cotrimoxazole prophylaxis with ART significantly reducing early ART mortality.¹⁵

Uninterrupted Drug Supplies

In the first few years of ART scale-up, Malawi developed a rather unique system of drug forecasting and procurement based on a “push system” with facilities graded according to burden of disease; forecasting based on new patients enrolled each quarter, cumulative numbers alive on ART, and drug stock levels; a prepacked kit system with starter packs (for the first 2 weeks of treatment) and continuation packs; and drugs delivered directly to ART sites every 6 months by the procurement agent (UNICEF). During site supervision every 3 months, the drugs stocks in facilities were documented, and the HIV Department would direct that those facilities with high stock levels transfer drugs to those with low stock levels to ensure that sites did not run out. Some large nongovernmental organizations such as Medecins Sans Frontieres (MSF) would also procure their own drugs to act as a buffer in case of site-specific stock-outs. During this period, no stock-outs were encountered nationally or at individual sites.¹⁶

Involvement of the Private Sector

Within 6 months of ART scale-up in the public sector, the private sector came on board as willing participants. They agreed to follow national systems, to undertake a modified weekend ART training course with an examination of competence, and to be accredited in the same way as the public sector. Private facilities received ART drugs free of charge, but charged patients for the drugs at a subsidized fee (US \$3.5 per course of treatment per month), some of which they were allowed to keep as part-payment for dispensing costs.

THE FUTURE

Malawi has done very well in the last 6 years, but now risks becoming a victim of its own success unless it can deal effectively with the challenges ahead. Ongoing financial support is an absolute necessity. The dire human resource shortages that occur not only in Malawi but also in sub-Saharan Africa need to be tackled, probably through task shifting.¹⁷ First-line ART regimens need to be changed so that they can be simpler, safer, and easier to take. The current low national level of switching from first-line to second-line ART regimens reflects the lack of capacity in the country to reliably diagnose treatment failure,¹⁸ and this would be helped by development of simple to use, point-of-care viral load tests. The small proportion of HIV-infected patients with tuberculosis who are accessing ART is a problem that pervades sub-Saharan Africa and is not just confined to Malawi. Nevertheless, this issue needs addressing by ensuring that centers for tuberculosis diagnosis and treatment and for HIV care and treatment are located together, integrated, or better matched quantitatively and geographically.¹⁹ Monitoring and supervision must continue, but increasing use must be made of electronic records to handle the growing number of patients on therapy.²⁰ Drug procurement processes need rigorous attention so that drug supplies remain uninterrupted. Finally, HIV prevention methods, established and new,²¹ need to be scaled-up.

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