

Scaling Up Antiretroviral Therapy in Malawi—Implications for Managing Other Chronic Diseases in Resource-Limited Countries

Anthony D. Harries, MD, FRCP,* Rony Zachariah, MB, PhD,† Andreas Jahn, MD, PhD,‡
Erik J. Schouten, MD,‡ and Kelita Kamoto, MB, BS‡

Abstract: The national scale-up of antiretroviral therapy (ART) in Malawi is based on the public health approach, with principles and practices borrowed from the successful DOTS (directly observed treatment, short course) tuberculosis control framework. The key principles include political commitment, free care, and standardized systems for case finding, treatment, recording and reporting, and drug procurement. Scale-up of ART started in June 2004, and by December 2008, 223,437 patients were registered for treatment within a health system that is severely underresourced. The Malawi model for delivering lifelong ART can be adapted and used for managing patients with chronic noncommunicable diseases, the burden of which is already high and continues to grow in low-income and middle-income countries. This article discusses how the principles behind the successful Malawi model of ART delivery can be applied to the management of other chronic diseases in resource-limited settings and how this paradigm can be used for health systems strengthening.

Key Words: ART, DOTS, health systems, HIV/AIDS, Malawi, noncommunicable diseases, tuberculosis

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A very poor landlocked country in southern Africa, Malawi, has a per capita gross domestic product of less than US \$200 per year, a population of 13 million¹, and a dire HIV epidemic. In 2004, when antiretroviral therapy (ART) was being introduced at national scale, approximately 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

National scale-up of ART commenced in June 2004, with financial support from the Global Fund to Fight AIDS, Tuberculosis and Malaria. At that time, 9 health facilities in the public sector delivered ART to about 3000 patients. ART delivery was unstructured, very few health care workers had

been formally trained for the activity, and national systems of monitoring or reporting did not exist. In short, what might be called “ART anarchy” prevailed.

With the assistance of a well thought out national plan, explicit national guidelines for the management and monitoring of ART, and a standardized process for training health care workers and preparing facilities for ART, this life-saving treatment was scaled up rapidly and efficiently in both public and private sectors. By December 31, 2008 (4½ years after the start of scale-up), 170 health facilities in the public health sector had registered 215,449 adults and children on ART, and 51 health facilities in the private sector registered 7988 adults and children on ART.³ Both public and private health sectors use the same standardized systems of delivering and monitoring treatment. By December 31, 2008, of the 223,437 patients ever registered in both public and private sectors, 147 479 (66%) were known to be alive and on ART, 23,699 (11%) were dead, 24,409 (11%) were lost to follow-up, 27,069 (12%) had transferred out to another treatment facility, and 781 patients were known to have stopped treatment. The number of new patients registered increased year by year, from 10,183 in 2004 to 76,581 in 2008.³ Although technical and operational challenges remain in abundance, this growth has been, and continues to be, an immense achievement for Malawi and an oft-cited example internationally. ART has already begun to reduce adult mortality at the population level.⁴

This article discusses how the principles behind the successful Malawi model of scaling up ART can be applied to the management of other chronic diseases in resource-limited settings and how this paradigm can be used for health systems strengthening.

PRINCIPLES OF ART SCALE-UP IN MALAWI AND REASONS FOR SUCCESS

Right from the start it was recognized that ART delivery in Malawi using a “medicalized” model would not work and that the key to rapid and massive scale-up was to keep the principles and practices of ART delivery as simple as possible. In this regard, many of the principles of DOTS (directly observed treatment, short course)—the system used to successfully deliver tuberculosis (TB) treatment to people in some of the world’s poorest countries⁵—were borrowed and adapted to ART delivery and could be similarly adapted for other chronic diseases (Box 1). A standardized system

From the *International Union against Tuberculosis and Lung Disease, Paris, France; †Medical Department, Médecins sans Frontières, Brussels Operational Centre, Brussels, Belgium; and ‡HIV Department, Ministry of Health, Lilongwe, Malawi.

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Correspondence to: Anthony D. Harries, MD, FRCP, Professor, Old Inn Cottage, Vears Lane, Colden Common, Winchester SO21 1TQ, United Kingdom (e-mail: adharries@theunion.org).

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BOX 1. Principles of TB Control

Principles of TB Control	Delivery of ART	Application to Care of Chronic Diseases, (eg, DM)*
Standardized diagnosis and case finding based on:		
<ul style="list-style-type: none"> • Smear microscopy • Different categories of TB (smear-positive and smear-negative pulmonary TB and extra pulmonary TB) 	<ul style="list-style-type: none"> • Positive HIV test result • Different WHO clinical stages (stage 3 or 4) or a low CD4-lymphocyte count 	<ul style="list-style-type: none"> • Blood glucose levels • Different categories of DM (type 1 or type 2)
Standardized treatment based on:		
<ul style="list-style-type: none"> • Treatment regimen for new cases of TB • Re-treatment regimen for patients who fail, relapse, or return after default 	<ul style="list-style-type: none"> • First-line ART regimen for new cases • Second-line ART regimen for failure 	<ul style="list-style-type: none"> • Oral hypoglycemic drugs • Parenteral insulin • Dietary regimens
Standardized recording and reporting based on:		
<ul style="list-style-type: none"> • TB patient treatment cards • TB patient registers • TB patient identity cards • TB cohort analysis forms 	<ul style="list-style-type: none"> • ART patient treatment cards • ART patient registers • ART patient identity cards • ART cohort analysis forms 	<ul style="list-style-type: none"> • DM patient treatment cards • DM patient registers • DM patient identity cards • DM cohort analysis forms
Standardized system of procurement based on:		
<ul style="list-style-type: none"> • Forecasting of new TB patients starting treatment • Taking into account old drug stocks 	<ul style="list-style-type: none"> • Forecasting of new patients starting ART • Forecasting cumulative number of patients retained on ART • Taking into account old drug stocks 	<ul style="list-style-type: none"> • Forecasting of new patients starting treatment • Forecasting cumulative number of patients retained on treatment • Taking into account old drug stocks
Management by paramedical officers	Management by paramedical officers	Management by paramedical officers†
Free drugs for patients in public sector	Free drugs for patients in public sector	Free drugs for patients in the public sector

*This example could similarly apply to other chronic diseases, such as hypertension, epilepsy, and mental illness.
 †Where there are shortages of highly qualified human resources.
 DM, diabetes mellitus.

was put in place so that the same system of assessing patients for ART eligibility, initiating treatment, and registering and reporting cases and outcomes was followed wherever ART was being delivered from central hospital to health center and from public health facility to private clinic. An important policy decision was made that ART in the public sector was to be free to all patients and subsidized for patients in the private sector.

Of the number of factors responsible for the success of Malawi's ART scale-up, the most important were:

- The clear lead taken by the Ministry of Health in assuming responsibility for national scale-up and a desire by all implementing partners to work with the Ministry of Health and use nationally standardized systems.
- A focus on scaling up using a single first-line fixed-dose combination regimen, a focus that was made possible by the fact that Malawi's sole ART funding source was the Global Fund.
- The existence of clear national ART guidelines, with an emphasis also placed on the system of registration, monitoring, and recording of results.^{6,7}
- An intensive training schedule focused particularly on clinical officers and nurses learning ART guidelines and undertaking practical attachments at experienced ART sites.
- A structured system of accrediting ART sites before they were permitted to deliver treatment to patients.
- Quarterly supervision and monitoring and reporting for all ART delivery sites by the HIV Unit of the Ministry of Health and its partners.
- An absence of ARV drug stockouts.

Because of this simplified and highly standardized delivery model, an average of approximately 1 clinician and 1 nurse were able to manage 1000 patients on ART by the end of 2008.³

ADAPTING THE ANTIRETROVIRAL DELIVERY MODEL TO MANAGEMENT OF OTHER CHRONIC DISEASES

The prevalence and incidence of noncommunicable diseases (NCDs) such as hypertension, diabetes mellitus, cardiovascular disease, obstructive airways disease, and asthma grow inexorably each year and increasingly affect patients and communities in resource-poor settings.⁸ For example, diabetes mellitus was estimated to affect 246 million people globally in 2007, with 6 million new cases and 3.5 million deaths; 70% of this burden was in developing countries.⁹ Similar numbers pertain to asthma: 300 million patients are estimated to be living with the disease, with 250,000 deaths annually—the majority in developing countries.¹⁰ Even in rural communities in southern Africa, racked by chronic infectious diseases such as HIV/AIDS and TB, the burden and mortality of chronic NCDs such as cardiovascular disease, diabetes, and malignancy increases year by year.¹¹ Although patients with these NCDs usually need chronic care and treatment over their lifetimes, it is simply not provided in most resource-poor countries outside a few centers of excellence, and there are no systems to monitor patient access or outcomes.

The system put in place in Malawi to facilitate the management and monitoring of lifelong ART can also be used for patients with NCDs.¹² Simple diagnostic and treatment protocols would be helpful for patients in chronic structured care to ensure that standard quality treatment is maintained at all levels of the health care system. Primary outcomes—alive, dead, stopped therapy, lost to follow-up, and transferred out to another treatment facility—apply to all NCDs. Quarterly collation of data would allow regular updating of the denominator (how many patients have started on therapy in a facility) and the key numerator (how many patients are retained on therapy in that facility at the end of every quarter). The number of patients alive and on treatment can be further subdivided into those on particular types of medication and those with complications of the disease. The number alive and on treatment is a vital piece of strategic information, which provides at any set moment in time the prevalent number of cases and thus the current burden of disease. If measured regularly and accurately, this information would be vital for rational drug forecasting and planning of logistics and staffing.

USING CHRONIC DISEASE MANAGEMENT PARADIGMS FOR STRENGTHENING HEALTH SYSTEMS

Implementation of any system that seeks to provide and monitor special quality care for patients with chronic infectious and noninfectious diseases on a large scale must be sensitive to the needs of the general health sector, as otherwise there is a risk of setting up multiple parallel, or “vertical,” programs. This being said, many urban hospitals in developing countries already run special clinics for patients with diabetes mellitus, hypertension, or asthma. Consideration could be given to merging these into single clinics for chronic diseases as in hospitals and health centers in Cambodia,¹³ where ART, diabetes, and hypertension have been successfully managed together, and in rural centers in Ethiopia,¹⁴ where diabetes and epilepsy are managed together. Moreover, efforts to reduce mother-to-child transmission of HIV should be seen not as stand-alone interventions but rather as an integral component of maternal and child health.

For all clinics serving special populations, regular structured supervision is needed to ensure that monitoring systems are of good quality, but these supervisory activities can be developed and expanded to benefit the wider health sector and chronic diseases. There is a growing conviction that vertical programs can be adapted to drive improvements throughout the health system, particularly in hitherto weak areas such as laboratory infrastructure and service delivery, monitoring, supervision, quality assurance, and rational drug forecasting and procurement.¹⁵ Any attempt to better the management and monitoring of special diseases must include a vision of how the work will improve the health sector and health care delivery as a whole.

CONCLUSIONS

The provision and monitoring of ART to thousands of patients living in resource-poor countries like Malawi, based on the DOTS framework for TB control developed during the mid-1990s,⁵ can serve as a model for managing and monitoring the growing burden of NCDs. Malawi's ART scale-up was based on a strategy, guidelines, and a well thought out plan, but the implementation was all about learning while doing. The same principles can be applied to the management of NCDs, with a vision and a strategy about how to move forward and operational research used to work out and refine the all-important details.

REFERENCES

1. *Population and Housing Census 2008: Preliminary Report*. Zomba, Malawi: National Statistics Office; 2008.
2. National AIDS Commission. *National Estimates of HIV/AIDS in Malawi*. Lilongwe, Malawi: National AIDS Commission; 2005.
3. *Quarterly Report of the Antiretroviral Treatment Programme in Malawi, With Results up to 31 December 2008*. Lilongwe, Malawi: Department of HIV and AIDS, Ministry of Health; 2008.
4. Jahn A, Floyd S, Crampin AC, et al. Population level-effect of HIV on adult mortality and early evidence of reversal following roll-out of antiretroviral therapy in Malawi. *Lancet*. 2008;371:1603–1611.
5. World Health Organization Tuberculosis Programme. *WHO Tuberculosis Programme: Framework for Effective Tuberculosis Control*. Geneva, Switzerland: World Health Organization; 1994.
6. Ministry of Health, Malawi. *Treatment of AIDS. Guidelines for the Use of Antiretroviral Therapy in Malawi*. 1st ed. Lilongwe, Malawi: Ministry of Health; 2003.
7. Ministry of Health, Malawi. *Treatment of AIDS. Guidelines for the Use of Antiretroviral Therapy in Malawi*. 2nd ed. Lilongwe, Malawi: Ministry of Health; 2006.
8. Lopez AD, Mathers CD, Ezzati M, et al. *Global Burden of Disease and Risk Factors*. Washington, DC: The World Bank and Oxford University Press; 2006. Available at: <http://www.dcp2.org/pubs/GBD>. Accessed March 1, 2009.
9. World Diabetes Foundation. Diabetes facts [Web page]. Available at: <http://www.worlddiabetesfoundation.org/composite-35.htm>. Accessed March 1, 2008.
10. Masoli M, Fabian D, Holt S, et al. *Global Burden of Asthma. Developed for The Global Initiative for Asthma (GINA)*. Wellington, New Zealand: Medical Research Institute of New Zealand and Southampton, UK: University of Southampton; 2004. Available at: <http://www.ginasthma.com>. Accessed March 1, 2009.
11. Tollman SM, Kahn K, Sartorius B, et al. Implications of mortality transition for primary health care in rural South Africa: a population-based surveillance study. *Lancet*. 2008;372:893–901.
12. Harries AD, Jahn A, Zachariah R, et al. Adapting the DOTS framework for tuberculosis control to the management of non-communicable diseases in sub-Saharan Africa. *PLoS Med*. 2008;5:e124. doi:10.1371/journal.pmed.0050124.
13. Janssens B, Van Damme W, Raleigh B, et al. Offering integrated care for HIV/AIDS, diabetes and hypertension within chronic disease clinics in Cambodia. *Bull World Health Organ*. 2007;85:880–885.
14. Mamo Y, Seid E, Adams S, et al. A primary healthcare approach to the management of chronic disease in Ethiopia: an example for other countries. *Clin Med*. 2007;7:228–231.
15. Ooms G, Van Damme W, Baker BK, et al. The “diagonal” approach to Global Fund financing: a cure for the broader malaise of health systems? *Global Health*. 2008;4:6.