

# Providing insecticide treated bed nets in antiretroviral treatment clinics in Malawi: a pilot study

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## Summary

HIV infection and malaria, two of the most common and important health problems in sub-Saharan Africa, have been demonstrated to have interactive pathology. In Malawi, where malaria is endemic, and antiretroviral therapy (ART) delivery is scaling up, we piloted integration of long-lasting insecticide-treated bednets (ITN) provision in three ART clinics. In July 2006, 1,910 ITNs were delivered to pilot sites, and ART clinic staff personnel were briefed on ITN provision and use of a monitoring system. Sites were assessed using a structured questionnaire in December 2006. During the pilot period, 1,282 ITNs were distributed to patients. A large proportion (70%) of ART patients at these sites received pilot study ITNs. Site adherence to the monitoring system was variable. Seventeen patients were interviewed, 14 of whom were ART patients who had received ITNs; 11 of these (79%) had slept under the net the previous night. This pilot demonstrates the feasibility of ITN distribution to patients attending ART clinics in Malawi. Programmatic and policy considerations for national roll-out include the need to: 1) adopt a standardized monitoring system, 2) develop information, education, and communication materials, 3) develop in-service training for ART clinicians, and 4) identify systems for forecasting, procuring and distributing ITNs.

## Introduction

Infection with the human immunodeficiency virus (HIV) and *Plasmodium falciparum* are the two most common and important health problems in sub-Saharan Africa.<sup>1,3</sup> To the estimated 26 million adults and children already infected with HIV in this region, every year another 3 million people become newly infected and 2.5 million people die of HIV-related disease or AIDS.<sup>3</sup> In addition, there are between 300 - 500 million clinical *Plasmodium falciparum* infections every year, with more than a million malaria-associated deaths.<sup>4</sup> There is considerable geographical overlap between the two diseases, and growing evidence of interactive pathology.<sup>1,2</sup> HIV increases the risk of malaria infection and the development of clinical malaria and severe disease, while malaria induces

HIV-replication.<sup>5-13</sup> Mathematical models show that repeated malaria infections can be associated with elevated HIV viral loads, which in turn increase transmission potential and thereby amplify HIV prevalence.<sup>1</sup> Growing evidence suggests that prevention of malaria in HIV-infected persons may be a useful strategy for the prevention of HIV infection, in addition to the direct benefits of reduced malaria-related morbidity and mortality.<sup>1,2</sup> In Uganda, a strategy of cotrimoxazole prophylaxis, antiretroviral therapy (ART) and insecticide treated bednets (ITN) reduced the baseline malaria prevalence in HIV-infected persons by 95%, from 51 episodes per 100 person-years to 2 episodes per 100 person-years.<sup>14</sup> While the scale up of cotrimoxazole prophylaxis and ITNs is moving relatively slowly in sub-Saharan Africa, ART is being massively scaled up. For example, at the end of 2005 there were 810,000 people estimated to have been started on this life-saving medication in the region compared with a baseline of about 20,000 a few years earlier.<sup>15</sup>

Malawi is one of the countries in sub-Saharan Africa making good progress with ART scale up.<sup>3</sup> In January 2004, 9 facilities in the public sector were providing ART to about 4,000 patients, and by December 2006, there were 104 public sector ART facilities and 82,001 patients started on ART (source- HIV Unit, Ministry of Health, Malawi). Scale-up of cotrimoxazole prophylaxis is planned to begin in 2007, initially at facilities that provide ART.<sup>16</sup>

In Malawi, where *Plasmodium falciparum* is holoendemic, a number of efforts are underway to scale-up malaria prevention and treatment for targeted groups. ITNs have been demonstrated to reduce malaria transmission rates and malaria-associated morbidity, particularly in key risk groups such as young children and pregnant women.<sup>17-19</sup> Using funds from its Round 2 Global Fund (GFATM) Malaria Award and anticipated funding from the U.S. President's Malaria Initiative (PMI), Malawi plans to scale-up the distribution of ITNs through antenatal clinics, clinics for young children (<5 years old), immunization clinics, and community venues to increase net coverage.<sup>20-22</sup> This will be accompanied by mass media and community-based interventions to increase year-round use of ITNs.<sup>23</sup> HIV-infected patients, however, have not yet been targeted for ITN distribution at health facilities in malaria prevention efforts.

In Malawi, where ART delivery is carried out in a simple, standardised way, we believe that this system can also be used to deliver ITNs to a large number of HIV-infected persons.<sup>24-26</sup> We therefore set up a pilot project to test the feasibility of integrating ITN provision in three facilities that provide ART in the central region of Malawi.

## Methods

### Routine Patient Monitoring and Data Collection

The process of ART scale-up and delivery in Malawi in the

public sector has already been described, and only the main elements will be presented below. ART is provided free of charge in public sector facilities to HIV-infected patients who are eligible for ART.<sup>23-25</sup> HIV-positive patients are eligible for ART if they are assessed to be in WHO Clinical Stage 3 or 4, or have a CD4-lymphocyte count < 250/mm<sup>3</sup> or in the case of children have a CD4 count below the threshold value.<sup>26</sup> All ART facilities use a standard approach, which includes: a focus on the use of one generic, fixed-dose combination treatment with stavudine, lamivudine and nevirapine; a standardised system of registration, monitoring and reporting of cases and outcomes; and quarterly supervision and evaluation of all ART sites. Eligible patients are started on ART, seen two weeks later, and then monthly, with assessments and drugs being distributed from ART clinics.

When a patient is first registered for ART, he/she is given a unique ART registration number and vital data are recorded using two standardised monitoring tools: the ART patient master card and the ART register.<sup>24,25</sup> These monitoring tools are kept in the ART clinic, while the patient also keeps an ART identity card, in which is recorded the unique ART registration number and other vital information pertaining to ART. Patient details, which are entered into the master card and register, include age, sex, date and place of HIV test, reason for starting ART and the drug formulation. Every month the patient comes for review and standardised outcomes and follow-up details are recorded monthly on master cards; these master cards are used to update the follow-up status for each patient in the ART register each quarter.

The HIV Unit of the Ministry of Health, Malawi, and its partners conduct quarterly supervisory and monitoring visits to all ART public sector sites in the country. The monitoring teams check the accuracy, completeness and consistency of the register and compare master card details with entries to the register. A quarterly cohort analysis is performed on the most recent 3-month cohort of patients started on ART and the cumulative cohort of patients ever started on therapy, with outcomes censored at the end of the respective quarter.<sup>25</sup>

### **Provision of ITNs to patients attending the ART clinics in 3 pilot sites**

In early 2006, the Ministry of Health, along with key stakeholders including the National Malaria Control Program, the Centres for Disease Control and Prevention (CDC), and UNICEF initiated a pilot study. The objective was to provide long-lasting ITNs (PermaNet®; purchased with CDC funding) to the ART clinics for staff to distribute free to new patients starting ART as well as to patients alive and coming for follow-up who had not received an ITN.

Three ART facilities in the Central Region of Malawi (Dedza District Hospital, Salima District Hospital and Kamuzu Central Hospital [KCH] Paediatric Clinic) were selected for the pilot study. As medium burden (defined as starting 50 new patients on ART per month) Ministry of Health ART facilities that do not receive external assistance, these sites were selected as they were considered "typical" of other medium burden ART sites in Malawi. The geographic proximity of the sites to the capital city of Lilongwe allowed for periodic monitoring of implementation during the pilot phase.

A total of 1,910 ITNs were distributed by MOH staff directly to the ART clinic for the pilot study. ART clinic personnel were briefed by staff from the Ministry of Health and implementing partners involved with quarterly ART site supervision about how to provide ITNs and use a sticker system for tracking ITN distribution, monitoring and evaluation. ART clinic personnel were also invited to take up to two ITNs for themselves as a benefit of the program.

### **Monitoring and Evaluation System**

ITNs were distributed to the three sites between July and August 2006. An ITN sticker book was provided to each site. This book had several pages of rows of sticker numbers, starting at row 1 and continuing up to row 1,000. Each row had a unique number with five numbered stickers which were to be removed and stuck on: a) the patient's ART master card, b) the patient's row in the ART register, c) the ITN register, which included the date of provision of the ITN, the name and ART number of the patient, d) the patient's health passport, and e) a sticker to remain in the sticker book for record keeping. This system allowed the patient who had been given an ITN to be identified within the ART monitoring system.

### **Data collection and analysis**

ART site evaluation visits took place in December 2006 and, using a structured questionnaire, data were collected on a) quantitative aspects of ITN provision, b) education and information provided to patients, c) storage of ITNs, and d) qualitative aspects about provision of ITNs from patient interviews. Data was entered and analysed in an EXCEL spread sheet.

### **Ethical approval**

General measures are provided in all ART facilities to ensure patient confidentiality, consent for HIV testing, and counselling and support for those who receive a positive HIV test result. Specific data collected for this analysis did not include personal identifiers. The Malawi National Health Science Research Committee provides general oversight and approval for the collection and use of routine programmatic data for monitoring and evaluation.

## **Results**

### **Receipt, distribution and storage of ITNs**

Data on the number of ITNs received and distributed, the remaining stock, the number unaccounted for and the number of patients alive and on ART as of September 30<sup>th</sup> 2006 are shown in Table 1. Using the ITN Register as the gold standard, there were 1,282 ITNs distributed to patients from July 2006 until the time of the visit. The total number of patients alive and on ART at these sites by end of September 2006 was 1,821, so a good proportion (70.4%) of these received ITNs. An additional 35 bed nets were recorded to have been distributed to the health care workers at the facilities.

In terms of monitoring the distribution of ITNs, some variance was observed in sites' adherence to the monitoring system. In Dedza District Hospital there was 100% concurrence with stickers placed on all monitoring tools. However, distribution of ITNs to health care workers was recorded in a separate book, and there were 20 (4%) ITNs

*Table 1: Receipt, distribution and stocks of insecticide treated bed nets (ITN) in three antiretroviral treatment (ART) clinics in Malawi*

	Dedza DH	Salima DH	KCH Paediatrics	Total
Number ITN bed nets received (Bulk store record)	505	505	900	1910
Number ITN bed nets given to patients (ITN Register)	466	316	500	1282
Number ITN bednets given to health care workers (separate record)	18	17	0	35
Number ITN bed nets in stock	1	172	391	564
Number ITN bednets unaccounted	20	0	9	29
Comparison of Number ITN bednets given to patients ( by source information)				
Number ITN bednets given to patients (ITN Register)	466	316	500	1282
Number ITN bednets given to patients (ART Mastercards)	466	316	no record	
Number ITN bednets given to patients (ART Register)	466	306	no record	
Number ITN bednets given to patients (ITN sticker books)	466	324	500	1290
Number ART patients alive on ART by Sep 30, 2006	541	829	451	1821

KCH = Kamuzu Central Hospital

DH = District Hospital

ITN = Insecticide treated bed net

ART = antiretroviral therapy

*Table 2: Patients perspectives on insecticide treated bed nets*

	Number of patients interviewed	Number (%) with parameter
Patient monitoring tools (i.e. health passports) with ITN stickers in place	10	9 (90%)
Patients who slept under the ITN the previous night	15	11 (73%)
Number of persons sleeping in the same room or under the ITN	11	26 people (average 2.4 people per net)

not accounted for. In Salima District Hospital there was concurrence between stickers placed in the ITN Register and in master cards, but there was a smaller number of stickers placed in the ART register due to the ART clerk forgetting to do this. All ITNs were accounted for at the Salima District Hospital site. In KCH Paediatric Clinic, ITNs were given to any HIV-infected person attending the clinic and not just ART patients. ITN sticker numbers had not been placed in the ART Register or the ART Patient master card, but instead had been placed in a separate patient filing system used by a non-governmental organization (NGO) that works in the clinic and it was therefore impossible to know how many ART patients had received bed nets. Record keeping was further compromised by the use of a parallel identity system making it difficult to link patients in the ITN register

(which listed IDs from the parallel ID system) with records of ART patients in the patient master cards and register (that are based on the national ART ID system). There was no record of ITNs being given to health care workers. There were 9 ITNs (1%) not accounted for.

In the two district hospitals, the ITNs were stored in the hospital bulk stores room, while in KCH they were stored in the pharmacy. All ITNs were distributed from sub-stocks in the ART clinics. None of the hospitals had any formal written material on use of ITNs, and the education provided to patients was of a verbal nature usually given during group counselling ART sessions and individual counselling at the start of ART. All of the ART staff welcomed the introduction of ITNs in the clinic. Although they initially found it additional work, they adjusted to the use of stickers, they felt they were offering an additional and welcome service for their patients, and the patients were very positive about receiving free ITNs.

### Patients' perspectives on ITNs

A convenience sample of 17 patients was interviewed in the sites. Of the 17 patients, 15 had received ITNs, and 14 were patients on ART. Details about interviews with the 15 patients are shown in Table 2. There were 4 patients who did not sleep under the ITN the previous night, the reasons reported being: the ITN had been burnt (2), the ITN had been stolen (1) and the ITN had been used by a family member other than the patient (1). The 11 patients who had slept under the net the previous night also reported that a total of 26 individuals (11 ART patients and an additional 15 family members) had slept under the same net the previous night, suggesting an added protective benefit to family members against malaria.

### Discussion

This pilot study shows that it is feasible to distribute ITNs to patients attending ART clinics, that this intervention did not disrupt primary service delivery, and was welcomed by patients, who in general used the ITNs according to education by care providers. However, there were some important lessons learnt in the pilot that will need to be incorporated into practice and policy:

- During initial scale-up, policy must be clarified to ensure that in ART clinics, ITNs are for ART patients only and not for other HIV-infected persons currently ineligible for ART. Eventually, provision of ITNs may be extended to include other HIV-infected individuals; however those with advanced clinical stage and/or CD4 cell count <250 should be prioritized. In the future, in order to establish a system of ITN distribution to prioritized groups of HIV patients not yet eligible for ART, a system for distributing ITNs (e.g in outpatient clinics), as well as tools for monitoring ITN distribution, would need to be developed. Expansion of the program to include pre-ART HIV patients, such as those attending VCT sites, and especially inclusion in home-based care kits, should be considered following the national roll-out of ITNs to ART patients.
- A standardized monitoring system needs to be adopted by ART clinics and ITN distribution monitored during routine supervisory visits. Specifically,
  - a) ITN stickers must be placed on all national

*Table 3: Key components for national roll-out of ITNs in ART clinics*

- Knowledge of the number of ART clinics and the number of patients alive and on ART at each of these clinics at the end of 2006 (data obtained from national quarterly ART reports)
- Knowledge of the number of patients to be started on ART during the year 2007 (data obtained from disease burden classification of ART sites)
- Printing of stationery for ITN stickers and ITN Registers to complement the ART monitoring tools already in use in the clinics
- Development of a short training module on distribution and monitoring of ITNs to be used during ART refresher training
- Development and printing of IEC materials for health workers and patients on the value of ITNs
- Budget with timeline for ITN roll-out
- Identification of system for ITN forecasting, procurement, and distribution

standardised monitoring tools (ITN registers, ART registers and ART master cards), and this must be checked during routine supervisory visits

- Parallel recording systems with different numbers to the ART register and patient master card should be discouraged
  - ITN registers must record all persons (ART patients and health care workers) who receive an ITN in order to reduce the number of ITNs that are not accounted for
  - The cumulative numbers of patients given ITN stickers should be recorded at each routine quarterly ART supervision and monitoring visit carried out by the HIV Unit and its partners.
- Formal information education and communication (IEC) materials on malaria and use of ITNs should be produced for ART clinic staff and for ART patients
  - A formal in-service training module should be developed for ITNs, that is used for ART clinic staff during the annual ART refresher trainings
  - Logistical issues for ITN procurement, distribution and storage on a national level will need to be addressed. ART drugs in Malawi are distributed through a parallel system to assure consistent availability of ART, and to date, Malawi has not experienced a stock-out of ART drugs. Decisions on how ITNs are procured and distributed will need to be reached in order to potentiate national scale-up for HIV-infected individuals, ideally leveraging procurement and supply chain systems developed for GFATM- and PMI-supported ITN distribution programs as much as possible.

Having shown that ITN distribution from ART clinics is feasible, it is now imperative to undertake national roll-out of the initiative. The key components for national roll-out are shown in Table 3. As of the end of 2006, we expect about 60,000 patients to be alive and taking ART at 104 public sector health facilities in the country, and during 2007 an additional 45,000 patients are expected to start ART. Thus, in planning the first year of national roll-out, a program budget will have to be made for 105,000 – 115,000 patients. At a unit cost of about \$4.50 per long-lasting ITN, this would amount to \$450,000 - \$495,000. These funds have not been budgeted in existing malaria funds for malaria, including

the U.S. President's Malaria Initiative and Malawi's funding from Global Fund against AIDS, TB and Malaria for HIV services.<sup>19,20</sup> An ongoing source of funding will need to be identified.

ITNs are especially important for children and pregnant women in malaria endemic areas, and their use by all of those at risk of malaria will contribute to community-wide effects when high coverage is achieved.<sup>17</sup> For the reasons already discussed, ITNs may have an additional important role to play in HIV-infected persons in preventing severe malaria disease and in mitigating the course and transmission of HIV.<sup>1</sup> Targeting of ITNs to HIV-infected persons through ART clinics allows a structured delivery of this intervention and, because patient outcomes are monitored every quarter, it also allows a way to monitor the effectiveness of such an intervention.

In resource-constrained environments such as Malawi, provision of comprehensive HIV care is being rolled out through an incremental approach. Non-ART interventions such as cotrimoxazole prophylaxis and ITNs, making use of existing program infrastructure, are feasible, will likely reduce morbidity and mortality, and may augment broader HIV prevention efforts.

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