BEST PRACTICE

HIV-TB SERVICES IN MALAWI

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Regional office (Regional Programme on AIDS and Tuberculosis programme)
Headquarters (HIV and Tuberculosis programme)
**LIST OF ABBREVIATIONS**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>AIDS</td>
<td>Acquired immune deficiency syndrome</td>
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<tr>
<td>ART</td>
<td>Antiretroviral treatment</td>
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<td>ARV</td>
<td>Antiretroviral</td>
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<td>AZT</td>
<td>Zidovudine</td>
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<tr>
<td>CT</td>
<td>Counselling and testing</td>
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<tr>
<td>CTX</td>
<td>Cotrimoxazole</td>
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<tr>
<td>d4T</td>
<td>Stavudine</td>
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<tr>
<td>ddI</td>
<td>Didanosine</td>
</tr>
<tr>
<td>DFID</td>
<td>Department for International Development, UK</td>
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<tr>
<td>DHMT</td>
<td>District Health Management Team</td>
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<tr>
<td>DOTS</td>
<td>Directly Observed Treatment, Short Course</td>
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<td>DTO</td>
<td>District Tuberculosis Officer</td>
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<td>E</td>
<td>Ethambutol</td>
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<tr>
<td>EPTB</td>
<td>Extra-pulmonary Tuberculosis</td>
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<tr>
<td>ETV</td>
<td>Efavirenz</td>
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<tr>
<td>HIV</td>
<td>Human immunodeficiency virus</td>
</tr>
<tr>
<td>H</td>
<td>Isoniazid</td>
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<tr>
<td>KNCV</td>
<td>The Royal Netherlands Tuberculosis Association</td>
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<tr>
<td>MOH</td>
<td>Ministry of Health, Malawi</td>
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<td>MSF</td>
<td>Médecins sans Frontières</td>
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<td>NAC</td>
<td>National AIDS Commission, Malawi</td>
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<tr>
<td>NFV</td>
<td>Nelfinavir</td>
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<tr>
<td>NORAD</td>
<td>Norwegian Agency for Technical Cooperation</td>
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<td>NTP</td>
<td>National Tuberculosis Control Programme, Malawi</td>
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<tr>
<td>NVP</td>
<td>Nevirapine</td>
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<tr>
<td>PCP</td>
<td><em>Pneumocystis carinii</em> Pneumonia</td>
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<tr>
<td>PTB</td>
<td>Pulmonary Tuberculosis</td>
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<tr>
<td>R</td>
<td>Rifampicin</td>
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<tr>
<td>S</td>
<td>Streptomycin</td>
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<tr>
<td>TB</td>
<td>Tuberculosis</td>
</tr>
<tr>
<td>3TC</td>
<td>Lamivudine</td>
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<tr>
<td>UNAIDS</td>
<td>Joint United Nations Programme on HIV/AIDS</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<tr>
<td>Z</td>
<td>Pyrazinamide</td>
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INTRODUCTION

Malawi has one of the highest rates of HIV infection in the world, and it is estimated that almost one million Malawians are HIV infected (see Annex 1). The HIV epidemic explains why, despite a good national tuberculosis programme for many years, there has been an upsurge in TB notifications and TB case rates.

A strong political commitment and the dedication of health professionals have put Malawi at the forefront of joint TB/HIV work for many years.

The TB programme initially contributed to the development of TB/HIV policies, planning, and initiation of most technical aspects of HIV/AIDS care and it is now internationally recognized as a best practice.

This document describes the process and shares the tools used for TB/HIV planning, HIV counselling and testing (CT), cotrimoxazole (CTX) and ART introduction as well as standardized registration, recording and reporting. A special emphasis is placed on the contribution of the TB programme to the development of these joint approaches.
1. NATIONAL HIV-TB PLAN

The process and completion of the plan

In mid-2002, the Malawi National Tuberculosis Control Programme (NTP), in conjunction with the National AIDS Commission (NAC), began to develop a three-year plan (2003-2005) for expanding joint HIV-TB activities. The goal of this plan was to reduce the burden of ill health due to HIV-TB in the population of Malawi. The deliverable objectives are shown below in Table 1.

Table 1: Deliverable objectives of the Malawi HIV-TB Plan (2003-2005)

- To increase the number and quality of voluntary counselling and HIV testing services for TB patients and the general public
- To provide isoniazid preventive therapy for HIV-infected persons who do not have tuberculosis to reduce the incidence of TB
- To give cotrimoxazole preventive therapy to HIV-positive persons with TB to reduce the frequency of opportunistic infections and case fatality rates
- To improve care and support for HIV-related illnesses
- To provide secondary isoniazid preventive therapy to HIV-positive TB patients who have completed a course of anti-TB treatment to reduce recurrent rates of TB
- To provide antiretroviral therapy to patients with AIDS, including those with HIV-related TB

The HIV-TB plan was completed in September 2002. It was approved by the TB Programme Steering Group (chaired by the Principal Secretary of Health and comprising senior Ministry of Health representatives and members of the donor community) at the end of October.

It was recommended that the joint HIV-TB plan be incorporated within the TB Programme’s five-year Development Plan (2002-2006). This allowed certain HIV-TB budget lines to be supported by the TB programme’s traditional donors – the Department for International Development (DFID, UK); the Norwegian Agency for Technical Cooperation (NORAD) and the Royal Dutch TB Association (KNCV). WHO and USAID provided additional financial support to fill the gaps.

It was agreed that the structures for managing the expansion of joint HIV-TB activities were to be subsumed within those of the NTP. Consumables for CT would continue to be the responsibility of MOH, NAC and the district health offices, but the NTP would provide cotrimoxazole (CTX) for the period of anti-TB treatment.
Continuation of CTX after anti-TB treatment would be the responsibility of the
district health services.

**Implementation of the plan**

The three-year plan was approved in late 2002, and activities started in January 2003. Each year, the annual plan for activities was developed by officers entrusted with HIV-TB activities, and approved by the National TB programme director.

This best practice paper focuses on Malawi’s progress and success in implementing two of the major components of the plan: (1) scaling up routine counselling, HIV testing and CTX preventive therapy for TB patients; and (2) scaling up antiretroviral treatment (ART) for HIV-positive patients who are eligible for such treatment, including those with TB.
2. SCALING UP ROUTINE HIV COUNSELLING AND TESTING (CT) AND COTRIMOXAZOLE (CTX) FOR TB PATIENTS

The basis for using CTX in HIV-positive persons

In 1999, the World Health Organization (WHO) and UNAIDS issued provisional recommendations that CTX be given to all patients in Africa living with AIDS, including HIV-positive patients with TB.

Since then, CTX is widely used as a prophylaxis against *Pneumocystis jiroveci* pneumonia (PCP), and is recommended for asymptomatic HIV-positive persons with a CD4-lymphocyte count of < 200/ul or a history of oral candidiasis.

National policy endorsement on CT and CTX in TB patients in Malawi

In 2000, the Malawi Ministry of Health (MOH) decided that the WHO/UNAIDS recommendations could not be adopted without more national evidence of effectiveness because:

- The pattern of HIV-related disease seemed to be different in East and Southern Africa compared with West Africa;
- Resistance profiles of commonly occurring pathogens to CTX were also different, low levels of resistance being found in Cote d'Ivoire and high levels being found in Malawi.

The country therefore embarked on a controlled trial of CTX in HIV-positive patients with TB, but the WHO/UNAIDS recommendations made it difficult at the time to ethically justify the continuation of this trial, and the trial was terminated. The MOH therefore endorsed the implementation of operational research studies in two rural districts (Thyolo and Karonga) and in one urban district (Blantyre). These studies were completed in 2002. In Thyolo district, it was found that counselling and HIV testing (CT) was feasible in the routine setting with a high uptake from patients, and that the package of CT and CTX for those who were HIV-positive resulted in a significant reduction in mortality. Similar results were found in Karonga and in Blantyre.

In October 2002, a meeting was held between MOH and key stakeholders on the way forward. The MOH endorsed a policy that all TB patients in Malawi would be offered CT and adjunctive CTX would be given to those who were HIV-positive, and that this package should be implemented country-wide in a phased approach over three years. It was further endorsed that this intervention be a key component of the HIV-TB plan of work. As there was no strong and convincing evidence in Malawi, or in other parts of Africa, to suggest benefit of CTX in HIV-positive persons without TB, the recommendations applied to TB patients only.
Countrywide situational assessment

In January 2003, the NTP and members of the National AIDS Commission implemented the first of what were to become annual events; countrywide situational analysis. The purpose was to (1) assess the state of HIV/AIDS and joint HIV-TB services delivered in hospitals, health centres and clinics in the country; (2) collect data on counselling and HIV testing for the previous year and (3) decide which hospitals could, with a reasonable degree of success, start to implement routine counselling and HIV testing for TB patients and CT, with administration of CTX to HIV-positive TB patients. Visits were made to all treatment facilities in Malawi between January and March 2003, and an assessment was conducted using a structured questionnaire form. In April, a detailed report on the findings and recommendations was finalised by staff from the NTP, NAC and MOH.

Choosing sites for Routine CT and CTX for TB patients

During the situational analysis, the decision about whether a hospital should be selected for support in expanding joint HIV-TB activities was made as follows:

*CT/HIV services were assessed in relation to:* number of clients/patients tested in 2002; presence of a dedicated CT room; presence of full-time counsellors or a regular full-time service using a system of rotating part-time counsellors; well kept CT registers and/or laboratory registers; and a supportive District Health Management Team (DHMT).

*TB control services were assessed in relation to:* the organization of the TB office; an up-to-date TB register; a return rate of treatment cards of 60% or higher from health centres to the TB office; and a cure rate of over 65% in new smear-positive patients registered in the fourth quarter of 2001.

Based on these criteria, in 2003 15 hospitals were selected for supported expansion of joint HIV-TB activities. In three of these hospitals, HIV-TB activities were already developed. In the other 12 hospitals, it was agreed with the DHMT that all TB patients would be routinely offered CT using the “opt out” strategy, with HIV-positive patients being started on adjunctive CTX as soon as possible after the results of HIV testing were known.

Developing national guidelines for CT and CTX for TB patients

In May 2003, two meetings were held with representatives from the NTP, NAC and DHMT from the 15 hospitals, which had been selected for the CT and CTX initiative. National guidelines of how to implement this intervention in a standardised manner were agreed upon and circulated in June.

The guidelines provided specific details of how patients registered with TB would be counselled and HIV tested and how CTX would be started and continued during the course of anti-TB treatment (see Table 4, page 11). The guidelines also included the format to be used for the registers (see Table 3, page 10), contra-indications to CTX,
dosages for adults and children, management of adverse effects, and logistics of the provision of CTX. It was agreed that implementation would commence on 1 July 2003, the start of the third quarter of the year.

<table>
<thead>
<tr>
<th>TABLE 3: THE DTO-CTX REGISTER FOR DATA ENTRY IN THE TB OFFICE</th>
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<tr>
<td>TB Registration Number</td>
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**Preparedness for implementation of CT and CTX for TB patients**

Following the development of guidelines, the registers for CT and CTX were prepared and printed. Enough CTX was ordered for TB patients for nine months based on the previous year’s registration figures and assuming an HIV-infection rate of 75%. The first consignment of cotrimoxazole tablets was delivered directly to individual hospitals by the National TB Control Programme. Subsequent orders for additional cotrimoxazole tablets were made using the standardized drug-ordering mechanism through central medical stores, based on the previous quarter’s consumption. The 15 hospitals were asked to submit proposals and budgets to the NTP so that hospital and health centre staff could be briefed about the new initiative. The TB-HIV officer and other NTP colleagues visited the hospitals in June to provide the registers and check that the staff understood the interventions.

**Supervision of the 15 hospitals starting CT and CTX in the first year**

**First year**

All 15 hospitals were visited within the first six months of starting the new intervention. At the end of each hospital visit, a meeting was held with representatives of the hospital management team to discuss the findings, implications and solutions to problems. The TB-specific registers in the CT units and the DTO-CTX registers in the TB offices were being used and data was being entered on a regular basis. HIV counselling and testing was offered to known TB patients and the ones found to be HIV-positive were offered CTX. Patients diagnosed with TB after they already knew their HIV status were requested to bring a proof of their HIV status before they were offered CTX.

At the time of the visit, 2,397 TB patients had been offered HIV testing, of whom 1,404 (59%) had accepted. Reasons for not accepting and undergoing HIV testing were not documented in the registers, but discussions with TB officers and hospital staff indicated that the main reasons were:
• TB officers failing to send patients to VCT
• Counsellors not being available
• HIV test kits being out of stock
• Patients refusing to be tested for HIV
• Patients being very ill and dying before counselling took place
• Lack of a dedicated counselling and testing room
• Counsellors not trained to perform whole blood rapid tests for HIV

Altogether, 68% of TB patients tested were HIV-positive, and 97% of those were started on CTX, most within seven days of registration for TB treatment, which is very effective in preventing early morbidity and mortality. Monitoring of TB patients accessing counselling and HIV testing, TB patients testing HIV positive and those offered CTX was routinely incorporated in the quarterly supervision of TB control activities by regional TB officers.

Subsequent years

In 2004, another countrywide situational analysis was carried out using the same process as in 2003, and a further 19 hospitals were selected for expansion of CT and CTX activities. During the year, it was also decided to speed up expansion to the remaining hospitals. These were visited in September and October, and the hospital staffed were trained and prepared for the intervention by the end of the year. By January 2005, all 44 hospitals providing anti-TB treatment in the country were offering routine CT and CTX to their patients. Results for 2002 and 2003 are shown in Table 4. It is too early to determine whether this countrywide provision of CTX to HIV-positive TB patients will reduce the TB case fatality rates.

<table>
<thead>
<tr>
<th>TABLE 4: CT and CTX for TB patients in Malawi in 2002 and 2003</th>
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<tr>
<td><strong>In the Public Health sector</strong></td>
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<tr>
<td></td>
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<tr>
<td>TB patients registered in the year</td>
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<tr>
<td>HIV-tested patients</td>
</tr>
<tr>
<td>HIV-positive patients</td>
</tr>
<tr>
<td>Patients given CTX</td>
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</tbody>
</table>
Reasons for successful implementation of CT and CTX in TB patients

The whole process of developing the three-year HIV-TB plan and the subsequent annual plan for 2003, carrying out the country-wide situational assessment, producing CT and CTX guidelines and enabling the 15 hospitals to prepare for VCT and CTX moved fairly rapidly. This was a result of several factors:

- Adequate funding from bilateral donors, USAID and WHO
- A functioning organization within the NTP to plan and organize the logistics of training and delivery
- Motivated personnel at both the NTP and the district hospitals who wanted to implement what they believed to be a useful intervention package to reduce morbidity and mortality in TB patients
- A concrete plan with a timeframe and measurable targets to be achieved
- Recruitment of a dedicated national TB/HIV coordinator who was technically supported by both the NTP and HIV/AIDS Programme

In general, the registration, recording and implementation of VCT and CTX worked well, although fewer patients accepted CT compared with the observations made during operational research studies in Thyolo district. Some of the reasons for this lower uptake were apparent during supervisory visits, and were addressed during the meetings with representatives of the DHMT.

A review of the first three months’ activities was carried out, and was useful in three ways: Firstly, it provided support for staff in the field, and operational questions could be discussed and potentially solved on the spot. Secondly, it demonstrated to staff the importance of this HIV-TB intervention to the NTP. Thirdly, it was apparent in some sites that counsellors were not always completing their TB-specific registers, and the importance of this exercise was pointed out. CT counsellors based in the NTP are now working with the HIV unit to conduct quarterly monitoring and supervision of CT activities.

The successful implementation in the first year paved the way for scaling up activities in the second and third years, and speeded up the process of getting all TB treatment facilities to offer CT and CTX by the end of 2004. Good progress was made in providing routine CT to patients, and efforts are now being made to screen all clients and patients who access CT and ART services for active TB.

The way forward and challenges with CT and CTX

Good progress has been made with CT and CTX preventive therapy in TB patients and scaling up ART.

It will be important to determine whether this intervention in the routine setting is associated with a reduction in TB case fatality rates. In the clinical and operational research setting, good results were seen, but, if in the routine setting CT uptake is low and patient adherence to CTX is poor, then less demonstrable effects may be seen.

In the last two years, new research from Africa – including countries with a high degree of resistance to CTX – has shown that CTX reduces mortality in HIV-positive
adults and children with and without TB. This evidence, combined with the good results achieved with scaling up CT and CTX in TB patients in the country, persuaded the MOH to hold a consultative meeting of national experts to review the current policy on CTX preventive therapy. A decision was made in February 2005 to provide CTX to all HIV-positive symptomatic adults and all HIV-positive children as an intervention package. Stakeholders and implementers must now try and ensure that the policy gets turned into action on the ground. The added benefits of CTX given to patients taking ARV drugs remain unclear.
3. TB EXPERIENCE SUPPORTING SCALING UP ANTIRETROVIRAL THERAPY

The process of developing the ARV Scale up plan

The key processes that took place enabling the scale up of ART at a national level are shown in Table 5.

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>2001</td>
<td>Concept of DOTS to deliver ARV therapy</td>
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<tr>
<td>2003</td>
<td>National ARV Treatment Guidelines, first edition</td>
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<tr>
<td>2004</td>
<td>National ARV Scale up Plan</td>
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</table>

The important principles of the DOTS system, so successfully used to deliver anti-TB treatment over a period of eight months, were used to frame the way in which ART could be delivered on a large national scale, yet delivered within a structured, controlled and safe way. With the concept accepted, and incorporated into Malawi’s successful application for support from the Global Fund, a group of about 30 people (comprising MOH, NAC, NTP, non-governmental organizations and front-line workers) met several times during 2003 to develop the National ART Guidelines. These were finalized in October 2003.

In January 2004, through a similar consultative process to the national ART Guidelines, a two-year national ARV scale up plan (2004-2005) was developed. The plan was finalized in mid-February 2004. The main elements of the national scale up plan are:

- 59 hospitals and clinics in the public health sector are selected for ARV scale up, providing broad geographical coverage throughout Malawi;
- ARV drugs are provided free of charge in the public sector;
- Scale up in new facilities involves the use of the first line ARV regimen only, although alternative first line and second line therapy are provided once capacity to deliver first line treatment has been shown (see below);
- Facilities are only provided with ARV drugs if the HIV Unit of the Ministry of Health has assessed them as being ready to deliver ARV therapy.

At the beginning of 2004, only 4,000 patients in nine public health facilities were accessing ARV drugs. However, an important principle was that scaling up of ARV therapy should not be at the expense of general health service delivery and should not detract from other important public health programmes such as safe motherhood or the expanded programme on immunization.
Promoting drug adherence

Good drug adherence to treatment schedules is an essential component of successful therapy with either anti-TB drugs or ART. In Malawi, guardians within the family are used to support patients in adhering to TB treatment, and there is evidence that this works. The same principles in Malawi are being applied to the delivery of ART. At the first group counselling session, patients are encouraged to bring a guardian with them to be briefed about ARV therapy, and to return the following week with the same guardian for starting on treatment. The guardian is there to support the patient in taking what is essentially life-long treatment for an otherwise fatal disease.

A similar system to that used in the NTP has been developed for ARV monitoring. The tools for monitoring ART include:

- ARV Patient Master Card, with the front of the form used for case registration and monthly outcomes and the back used for recording the indicator diseases by which the patient is staged (see Annex 3);
- ARV Patient Register, with the left hand page for case registration and the right hand adjacent page for outcome data;
- ARV quarterly cohort analysis form and the ARV cumulative quarterly cohort analysis form.

The registers, cards and forms are kept in the ARV clinic, with the patient master cards and the cohort analysis forms being kept in an ordered sequence within polypropylene sheet protectors in hard arch-back files. The patient keeps an ARV Identity Card (see Annex 2), in which is recorded the unique ARV registration number and other vital information pertaining to ART. Patient details, which are entered into the ARV Patient Master Card and ARV Register, include age, sex, date and place of HIV test, reason for starting ART and the drug formulation.

Each month, the patient comes for review and the patient master card is completed. Standardized treatment outcomes (alive, dead, defaulted, stopped treatment and transferred out to another treatment site) are recorded as well as ambulatory status, work status, side effects of drugs, and pill counts to determine drug adherence. At the start of every new quarter, the patient master cards are inspected and the data from the last month of the previous quarter are used to update the ARV Patient Register. Once the ARV Patient Register is updated, this is then used to conduct quarterly and cumulative cohort analysis.

Every three months, the ART delivery sites perform cohort analysis. The quarterly cohort analysis is performed on all new patients registered for treatment in the previous three months. The cumulative cohort analysis is performed in a similar way, but includes all patients ever started on ART and assessed up to the end of the previous quarter.
**TB Contribution to the National Collection of ART data:**

Sites are visited and data is collected in conjunction with the peripheral staff. Although labour intensive, this system has the advantage of making central unit staff get out to peripheral sites, ensures that data is double-checked for accuracy and finally allows supervision to be conducted at the same time.

In the first year, there was no established, workable or reliable system for regularly collecting national HIV/AIDS data, so it was agreed with the National TB Programme to utilize their regional structure of district quarterly supervisory visits and piggy-back HIV/AIDS data collection onto TB data collection. During the second year of ART scale up – with more detailed data needing to be collected – the HIV Unit took over this task with its partners, and now performs the quarterly supervisions and monitoring visits using the TB programme model of reporting and recording outcomes of patients on ART.

The most recent quarterly and cumulative data sets collected nationally for patients starting on ART are shown in **Annex 4**.

**TB patients accessing ART**

Among the patients started on ART, a small but growing number have TB as the reason for starting ART. In the quarterly analysis, 13% of new patients were started on ART because of TB, and in the cumulative analysis 11% had been started because of TB. There may be several reasons for the low number of patients going onto ART:

- Poor recording practices, where peripheral staff are indicating the patients in Stage III and Stage IV, without specifying the reason being TB;
- The difficulties with placing patients who are taking rifampicin onto an ART regimen which includes nevirapine, which interacts with rifampicin;
- The fact that ART is mainly delivered from a hospital base while most TB patients go home to access their therapy in the continuation phase from health centres in the community;
- Different clinics for ART and TB within the same hospital.

**Additional references and reading materials are available at Annex 5**
Annex 1

Background

HIV/AIDS in Malawi:

Malawi has one of the highest levels of HIV infection in the world. Since the first reported cases of AIDS in 1985, the number of cases has escalated with AIDS now the leading cause of death among 15-49 year-old people. In 2003, it was estimated that out of approximately 10.5 million people there were 900,000 adults and children living with HIV/AIDS. The estimated HIV/AIDS prevalence in adults (15-49 years) was 14.4%. This level of HIV infection in the adult population has remained constant in the last seven years. Every year, about 85,000 people in Malawi die from AIDS and another 110,000 new infections occur, most of these among young people. At the current time about 170,000 patients are thought to be in need of antiretroviral therapy (ART).

The Malawi government’s HIV/AIDS Policy is available at http://www.who.int/hiv/Malawi-HIVAIDS-Policy.pdf

Tuberculosis in Malawi

TB case notifications

Malawi has had a good national tuberculosis programme (NTP) for many years. Between 1970 and 1985 there was a small gradual increase in notified TB cases in the country from 3492 to 5334. From 1985 up to 2004, there has been an upsurge of TB notifications and TB case rates. In 2004, there were 28,500 notified cases with a case rate of 265/100,000 per year. Part of the explanation in the mid-1980s was improved case detection within a revitalised TB control programme and population growth. However, the most significant reason is HIV infection.

TB Treatment

Malawi has for several years now used an ambulatory, fully oral initial phase of treatment for all new patients with TB. TB treatment is offered to patients free of charge throughout the country in 44 hospitals (4 central, 22 district and 18 mission).

TB Treatment outcome

Treatment outcome has been monitored in patients with new and relapse smear-positive pulmonary TB since 1984. Initially, cure rates were high (between 85-90%), and then began to decrease in the 1990s. In the last ten years, cure rates have remained between 63-69%, and have not reached the 85% cure rates demanded by the World Health Organization (WHO). The NTP has tightened up its performance so that treatment completion, default and transfer-out rates have been kept low (10% or less). The main reason for low cure rates is the high death rate, which has risen from 10% in 1990 to above 20% from 1996 onwards. Treatment failure rates have remained low at 1%, signifying a low rate of drug-resistant TB.
HIV infection and TB

HIV-seroprevalence rates in TB patients

There has been a steady increase in HIV-seroprevalence in TB patients in Malawi since the start of the HIV epidemic. A country-wide study carried out in 482 patients in 13 hospitals in the country in 2000 showed an HIV-seroprevalence rate of 77%. HIV-seroprevalence rates were 67% in smear-positive pulmonary tuberculosis (PTB), 77% in extrapulmonary TB (EPTB) and 87% in smear-negative PTB. Beginning from 2003, routine data for TB patients accessing counselling and testing have been collected. In 2004 a total of 27,000 TB patients were registered for anti-TB treatment of whom 6,681 were tested for HIV and 72% were HIV-positive.

The impact of the high burden of the dual HIV-TB epidemic

The strong link between HIV and TB in Malawi has several implications for TB control other than increased case numbers. These are summarized below:

- The general public has increasingly begun to associate TB with AIDS, and positive ways of dealing with this stigmatising association need to be found;

- Early identification of TB cases is important, not only to reduce TB transmission in the community but also to improve the chances of a good treatment outcome with anti-TB treatment. Delays in diagnosis as a result of stigma makes early identification of cases difficult;

- As a result of the poor immune status, there are high rates of smear-negative PTB and EPTB: ways to improve the diagnosis of these difficult conditions need to be found;

- HIV care issues, such as good quality HIV counselling and testing (CT) or screening and treating patients for common HIV-related diseases, were not well addressed in Malawi. These care issues should be incorporated into the diagnosis and management of TB;

- High case fatality rates in TB patients are a result of the strong link with HIV, and interventions to reduce this death rate need to be found. Such interventions include the diagnosis and treatment of HIV-related diseases, prevention of opportunistic infections using adjunctive cotrimoxazole (CTX) and restoration of immunity using antiretroviral therapy (ART);

- The risk of developing TB or getting recurrent TB is increased in HIV-positive people, and consideration should be given to try and prevent the development of TB in HIV-positive persons and prevent recurrent disease in those who have had TB and have completed treatment;

- TB is a major cause of morbidity and mortality in HIV-infected persons.
Annex 2
ARV identity card

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<tr>
<th>ARV IDENTITY CARD</th>
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<tr>
<td>Current Treatment Unit: <strong>Chikwawa DH</strong></td>
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<td>Name of Patient: <strong>Mr Joshua Phiri</strong></td>
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<tr>
<td>Unique ARV Number: <strong>CKW/01</strong></td>
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<tr>
<td>Age: 34</td>
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<tr>
<td>Start 1&lt;sup&gt;st&lt;/sup&gt; line ARV therapy (date): <strong>14 July 2004</strong></td>
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<tr>
<td>Reason for ARV therapy: <strong>Stage III (Pneumonia)</strong></td>
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<tr>
<td>Start alternative 1&lt;sup&gt;st&lt;/sup&gt; line ARV therapy (date) ____</td>
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<tr>
<td>Start 2&lt;sup&gt;nd&lt;/sup&gt; line ARV therapy (date) ___________</td>
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</table>
Annex 3:  PATIENT MASTER RECORD CARD FOR ARV [front]:  Unique ARV Number__________________________      Year__________

Name________________________________________        Age ______      Sex_______       Initial Wt (Kg)_______    Transfer-In (Y/N)_______________

Address (physical / PO Box)_______________________________________________________________________________________________________

Name of identifiable guardian____________________________________________            Date and place of positive HIV test________________________

Date of starting 1\textsuperscript{st} line ARV regimen (specify d4t/3TC/NVP formulation) ________            Reason for ARV (specify Stage):  _________________________

Date of starting alternative 1\textsuperscript{st} line ARV regimen (specify) _____________________            Date of starting 2\textsuperscript{nd} line ARV regimen (specify)______________________________

<table>
<thead>
<tr>
<th>Year</th>
<th>Month</th>
<th>Date</th>
<th>Wt</th>
<th>Outcome status</th>
<th>Of those alive</th>
<th>Ambulatory</th>
<th>Work/school</th>
<th>Side effects</th>
<th>No. Pills in Bottle</th>
<th>ARV Given</th>
<th>ARV not given</th>
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Outcome status:  A = alive;  D=dead;  DF=defaulted and not seen for 3 months; Stop=stopped medication; TO=transferred out to another unit
Of those alive:  Start=first line regimen; Sbs=substituted to alternative first line regimen; Switch=switched to second line regimen because of treatment failure
Ambulatory:  Amb=able to walk to/at treatment unit and walks at home unaided;  Bed=most of time in bed at home
Work/school:  Yes=engaged in previous work / employment or at school; No=not engaged in previous work / employment or not at school
Side effects:  If Yes, specify – YES-PN= peripheral neuropathy;  YES-HP=hepatitis;  YES-SK=skin rash
Number of Pills in bottle: if patient comes at 4 weeks count number of pills in bottle (8 pills or less = 95% adherent)
ARV given / not given: tick whether ARV therapy given in the appropriate column P = patient, G = Guardian; if no ARV, then indicate why
Annex 4
Data on patients started on ART up to 31 December 2004

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>New patients started on ART between October and December 2004 “Quarterly analysis”</th>
<th>All patients who ever started on ART up to December, 2004 “Cumulative analysis”</th>
</tr>
</thead>
</table>

### Case Registration

<p>| | | |</p>
<table>
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<tbody>
<tr>
<td>Number of patients</td>
<td>3,261</td>
<td>13,183</td>
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<tr>
<td>Number (% of males)</td>
<td>1,266 (39%)</td>
<td>5,274 (40%)</td>
</tr>
<tr>
<td>Number (% of females)</td>
<td>1,995 (61%)</td>
<td>7,909 (60%)</td>
</tr>
<tr>
<td>Number (% of adults aged 13 years or more)</td>
<td>3,080 (94%)</td>
<td>12,527 (95%)</td>
</tr>
<tr>
<td>Number (% of children aged 12 year or less)</td>
<td>181 (6%)</td>
<td>656 (5%)</td>
</tr>
</tbody>
</table>

### Reason for starting ART:

- WHO Clinical Stage III: 1,919 (59%)
- WHO Clinical Stage IV: 828 (25%)
- Low CD4 count: 510 (16%)
- Reason not given: 4

| Number (% started on ART due to tuberculosis) | 351 (13%) | 1,468 (11%) |

### Main Treatment Outcomes:

- Number (% alive and on ART): 3,117 (96%) 10,761 (82%)
- Number (% dead): 117 (4%) 1,026 (8%)
- Number (% who are lost to follow-up): 2 (<1%) 1,039 (8%)
- Number (% who have stopped ART): 14 (<1%) 106 (<1%)
- Number (% who have permanently transferred out to another treatment facility): 11 (<1%) 251 (2%)
Annex 5
Useful references and reading materials

*Web links for documents referenced in this paper*

Page 6, Three-year development plan for TB-HIV in Malawi, July 2002
http://www.who.int/hiv/3yr-development-plan.pdf

Page 8, Policy statement agreed at meeting on the use of VCT plus CTX
http://www.who.int/hiv/CTX-MOHP-policy.pdf

Page 9, Country-wide situational assessment findings and recommendations
http://www.who.int/hiv/Situational-analysis-05.pdf

Page 9, National guidelines on CT and CTX for TB patients

Page 14, National ARV Treatment guidelines
http://www.who.int/hiv/ARV-guidelines.pdf

Page 14, National ARV scale up plan
http://www.who.int/hiv/Malawi-ARV-ScaleUp-Plan.pdf

Page 17, Malawi government HIV/AIDS Policy
http://www.who.int/hiv/Malawi-HIVAIDS-Policy.pdf

*Counselling and HIV Testing and CTX Preventive therapy*

*General:*


*Lancet* 2004; 364: 1865-1871


Malawi-specific:


*Int Journal Tuberculosis and Lung Disease* 2001; 5: 843-846


*Int Journal Tuberculosis and Lung Disease* 2004;8: 579-585

Chimzizi RB, Harries AD, Manda E, Khonyongwa A, Salaniponi FM. Counselling, HIV testing and adjunctive cotrimoxazole for TB patients in Malawi: from research to routine implementation. 
*Int Journal Tuberculosis and Lung Disease* 2004;8: 579-585

**Scaling up Antiretroviral Therapy**

**General:**

*Geneva, WHO, 2003. (Revision).*

Malawi –specific:


