

WHO MONOGRAPH ON INTEGRATED MONITORING OF TUBERCULOSIS AND HUMAN IMMUNODEFICIENCY VIRUS

A case study from Malawi



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Abbreviations

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy
CPT	co-trimoxazole preventive therapy
EPTB	extrapulmonary tuberculosis
FDC	fixed-dose combination (of medicines)
HIV	human immunodeficiency virus
IPT	isoniazid preventive therapy
РТВ	pulmonary tuberculosis
ТВ	tuberculosis
WHO	World Health Organization

Foreword

The dual epidemic of tuberculosis and human immunodeficiency virus (TB/HIV) is a major global public health challenge. WHO estimates that of the 1.4 million people living with HIV who are developing TB annually, up to 0.5 million will die of TB. Effective therapeutic interventions to reduce morbidity and mortality are available for both diseases and to achieve universal access for those in need. These interventions have to be delivered and managed in primary health-care settings using a public health approach. In addition, programmes need to prevent and treat comorbidity from TB/HIV. Ensuring the implementation of good-quality services requires effective and simple monitoring and evaluation systems for programmatic management. Examples from the field that describe in detail how such systems can work are essential.

This monograph is a case study of how integrated monitoring of treatment for HIV/ TB works in Malawi. It describes in detail the delivery of HIV treatment to a large number of people in one of the most resource challenged health systems in the world. The provision of antiretroviral therapy (ART) in Malawi has been impressive. By the end of 2008, the national HIV control programme had kept 147 479 people alive and on ART, in both the public and private sectors, representing around 75% of those who had been registered cumulatively since the start of the programme in 2003. Malawi also has a good national TB control programme, with 26 000 TB patients registered annually and a treatment success rate exceeding 75%. Both programmes have well-functioning monitoring and evaluation systems with the ability to produce national data on case-finding and treatment outcomes for TB, HIV and HIV-related TB.

The ART registers and other monitoring tools first developed in Malawi served as a prototype for the development of the WHO-recommended IMAI-HIV/AIDS monitoring and evaluation system. As part of the rapid expansion, Malawi also pioneered the public health approach to ART in the private sector and produced cutting edge TB/HIV operational research, published in peer reviewed literature, based on the national monitoring systems. Perhaps most importantly, Malawi has, and continues to demonstrate, technically sound treatment interventions for HIV/AIDS and TB. When accompanied by attention to field implementation, this can leverage limited resources to achieve remarkable results.

We commend this case study to all stakeholders in HIV and TB, be they programme managers or staff, bilateral or multilateral partners, nongovernmental organizations or civil society, or simply anyone looking to support the development of a robust country monitoring system focused on programme delivery. Indeed, for anyone wishing to know more about the practical experience of integrated TB and HIV monitoring, this monograph is essential reading!

Kevin de Cock Director WHO Department of HIV/AIDS Mario Raviglione Director WHO Stop TB Department

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Executive Summary

This monograph from Malawi provides a case study on monitoring and evaluation for TB/HIV activities. It is hoped that the lessons learnt will enable others to improve data gathering and reporting in the future.

In Malawi, a country with 13.5 million people, each year 85,000 citizens become infected with and 60,000 die of HIV. Around 48,000 people have TB, and of these 68% are related to HIV. By 2004 ART was delivered to 3000 people from 9 facilities in the public sector - the system at that time was disorganised, with different regimens being used and no data on how many patients were enrolled to treatment or on treatment outcomes. The subsequent scale-up of ART in Malawi replaced this individual medicalised model of treatment, with an approach to ART delivery that is based on the TB-DOTS management system: the system that has successfully delivered anti tuberculosis therapy to people in some of the poorest countries of the world. Standard systems of case-finding, treatment initiation, registers, recording and reporting cases, and treatment outcomes were put in place. By the end of 2007 rapid scale up of this system has placed around 150,000 people on ART in 118 public and 45 private sector sites. Quarterly monitoring reports based on a cohort approach indicate that 70 % of clients were alive and on treatment at the end of 2007. This monograph describes how the ART and the tuberculosis monitoring systems in Malawi work, and specifically addresses the monitoring and evaluation issues associated with TB/HIV.

The ART monitoring tools include tow basic elements 1) a patient treatment master card, with each follow-up card able to provide 4 years of patient follow up information, and 2) a patient register with, on the one side, patient demographic and clinical data, and on the other, dynamically up-

dated outcome data. This register provides a snapshot at any point in time of current patient status. Identity cards and stamps in health passports, patient held health information documents, are also provided. Patient monitoring is conducted monthly or less often if the patient remains healthy. Patient outcomes on the patient master-cards are up dated every three months to the registers, and these are then used for quarterly cohort analyses. Cohort analyses are carried out on those enrolled during the most recent quarter and those ever enrolled from the beginning of ART scale up. Treatment outcomes are also determined at 12, 24 and 36 months after start of ART. All staff in accredited ART sites have received a formal training on the national guidelines, and refresher trainings are carried out at regular intervals. Quarterly supervision is carried out using standard operating procedures, and checklists ensure consistency between registers and master-cards, and accuracy of cohort analyses. Good performers are rewarded with quarterly certificates of excellence. These tools and cohort analyses also provide routine data on HIV related TB. Tuberculosis data are marked on the ART master-card, and are then transferred onto the ART register. TB registers are consulted during supervisory visits, and quarterly and cumulative cohort analyses provide the proportion of those on ART who started this due to TB, as well as the proportion of all TB patients who started ART. Challenges of the current system include the fact that IPT provision is not yet captured on ART master cards, and patient TB screening, though carried out as part of routine screening, is not captured by the monitoring system.

The Tuberculosis Programme monitoring tools include master-cards providing follow-up information throughout TB treatment, TB registers providing patient and

treatment outcome data, and patient identity cards. Patient monitoring is done every two weeks for the first two months, with patient-guardians providing daily observed therapy with monthly follow-up until the end of the 8 months treatment. The TB registers are used to carry out quarterly case finding and cohort treatment outcome analyses. These provide programmatic information used in drug forecasting and monitoring of progress against targets. Quarterly supervisions using standardized supervisory tools also check the accuracy of these cohort analyses. The Tuberculosis programme captures HIV related TB data. HIV status, co-trimoxazole preventive therapy (CPT) and ART provision to tuberculosis patients is recorded on the patient's master-card, and transferred to the TB registers. HIV status assessment data from the registers is summarized on the quarterly case registration reports and HIV status, CPT and ART treatment data are summarized on the treatment outcome reports.

This monograph also addresses ideas for improving TB/HIV monitoring. Both programmes have addressed major challenges in routine reporting of TB/HIV collaborative activities. Routine TB/HIV data is collected and reported to the national level by both programmes. Reporting on TB screening, development of TB during ART provision, and IPT provision are areas on the HIV M&E side that need further development. Likewise mechanisms for ART capture/validation on tuberculosis registers need to be developed. Unlike CPT which is provided at all TB clinics, ART information for the TB register comes from the ART clinics. Thus routine cross checking of ART and TB registers is needed to update the TB registers. This could be incorporated with combined supervisory activities. Mechanisms for combined supervisions remain to be field tested under the umbrella of operational research. Challenges that impact on the programmes are reliability of supervision, use of data generated, staffing and health sector reform. Reliable planning for supervision needs to ensure that the treatment site is informed at previous supervision of the date of the forthcoming visit. This date then needs to be adhered to, in order to build up trust and credibility. The data generated from both programmes serves the purpose of giving performance feedback to peripheral sites, of drug forecasting, of operational research, of provision of information on prognosis to inform policy decisions, and provides evidence of treatment initiation, outcome and impact in support of national and international programme advocacy. Programmes are short staffed and key needs are to build up a cadre of well trained, reliable supervisors from experienced sites who, under the coordination of the central units, can reliably undertake site visits, perform supervision and collect data. In addition at the periphery the presence of a motivated hard working clerk at ART and TB sites with the duty to fill in master cards, maintain registers and take the lead with cohort analyses is crucial to the success of the programmes. There is a need for the integrity of TB and HIV programme monitoring and evaluation to be retained during the implementation of decentralization and sector wide approaches to health. Integrated health system indicators are important but insufficient for TB or ART programmes to manage themselves or to forecast drug supplies. This monograph describes the relevant programs and offers suggestions for improved integration while maintaining programmes quality.

MONITORING AND EVALUATION AT THE PERIPHERAL LEVEL



Introduction and background



I.I General statistics

Malawi is a landlocked country in central-southern Africa bordering the United Republic of Tanzania, Zambia and Mozambique. It is approximately 900 km from north to south and between 80 km and 100 km from east to west. The country is divided into three geographical regions (north, centre and south) or five zones, and 30 administrative districts. These districts are further divided into traditional authorities headed by a Chief, who plays a key role in community mobilization. Village authority is vested in a Village Headman.

The population of Malawi was estimated to be 13500000 in 2007, with an annual growth rate of approximately 3.3%. Some 14% of the population is urbanized and about 50% is aged under 15 years. There is a low literacy rate, with 23% of women and 16% of men receiving no formal education. Malawi is one of Africa's poorest countries: in 1995, the World Bank estimated per capita income at around USD \$170.

Malawi has poor health indicators. Life expectancy at birth is 43 years for men and 45 years for women. The maternal mortality rate is just below 1000 per 100000 live births, the infant mortality rate is 86 per 1000 live births and the rate of under-5 mortality is 140 per 1000 live births. The majority of the causes of disease and death are preventable or curable. Statistics indicate that 70% of deaths in hospitalized patients are attributable to nutritional deficiencies, pneumonia, anaemia, malaria, tuberculosis (TB) and acquired immuno-deficiency syndrome (AIDS).

I.2 HIV/AIDS statistics

The first case of AIDS in Malawi was reported in 1985. The human immunodeficiency virus (HIV) must therefore have entered the population in the mid-1970s; immigration and travel are thought to be the important factors in this early period of HIV transmission. Studies using sentinel surveillance among pregnant women show that HIV seroprevalence increased rapidly from the late 1980s to the early 1990s and stabilized around 1995. Since then, HIV prevalence has remained fairly constant, although there is some evidence of a recent decline among individuals aged 15-24 years attending antenatal clinic. The total number of people infected with HIV is estimated to be between 780 000 and 1 120 000, of which 69000-100000 are children. Every year, a further 85000 people are newly infected with HIV and 60000 people die of AIDS.

Studies on HIV prevalence are carried out using (i) sentinel surveillance among women attending antenatal clinics – latest report in 2007; (ii) the Demographic and Health Survey – latest report in 2004; and (iii) the country-wide situational analysis of HIV/ AIDS in Malawi – latest report in 2006. According to the various recent surveys, the rate of adult HIV prevalence nationally is 12–14%. HIV prevalence among women countrywide is about 30% higher than among men. Women become infected earlier in life than men: the prevalence among women aged 20–24 years is about three times higher than in men (13% versus 4%).

The large majority of HIV infections in Malawi are due to HIV-1. HIV-2 has occasionally been reported in districts of the Southern Region bordering Mozambique: this is thought to be due to contact with Mozambique, where HIV-2 has also been reported. HIV-1 subtype C is the predominant subtype in Malawi, which was confirmed by a recent HIV drug resistance survey in which all 47 successfully sequenced samples obtained in Lilongwe, the capital city, were HIV-1, subtype C.

The majority of infections are acquired through heterosexual intercourse. Motherto-child transmission of HIV is the second commonest cause of HIV transmission in African countries, including Malawi, and is by far the largest source of HIV infection in children aged under 5 years. Infected blood transfusions and unsafe injecting practices as well as scarification may play their role in HIV transmission, although the extent of these means of transmission is unknown. In other countries, HIV can be transmitted by the sharing of needles among injecting drug users and by men who have sex with men: injecting drug use is very rare in Malawi, and the practice of men having sex with men is also thought to be highly uncommon, although there are limited data on this.

I.3 Scaling up ART

In early 2004, there were nine facilities in the public sector delivering antiretroviral therapy (ART) to approximately 3000 patients. At that time, there was no standardized system of ART delivery, no monitoring system in place and no supervision.

A two-year plan (2004–2005) laid out the principles of ART scale up. Initially, it was recognized that delivering ART using a "medicalized" model would not work and that the key to rapid and massive scale up was to keep the principles and practice of ART delivery as simple as possible. In this regard, many of the principles of "DOTS" – the system used successfully to deliver antituberculosis treatment to people in some of the poorest countries of the world – were borrowed and adapted to ART delivery. A standardized system was put in place, so that wherever one travelled in the country and wherever one accessed ART, from central hospital to health centre, the same system of finding cases, initiating treatment, and registering, recording and reporting cases and treatment outcomes were followed. Above all, the country made an important policy decision that ART in the public sector was to be free of charge for all patients. In late 2005, a further five-year plan (2006–2010) was put in place to sustain ART scale up until 2010.

An initial 60 sites in the public sector were selected. Staff were formally trained and accredited, following which they prepared their facilities for ART delivery services. These sites were inspected and accredited by the Ministry of Health and, once accredited, supplied with antiretroviral medicines. The facilities then started ART delivery to the community. All 60 sites were up and running by mid-2005 (Round 1). A further 40-50 sites were up and running by mid-206 (Round 2). At the same time, the private sector (hospitals and clinics) joined the scale-up process and followed exactly the same scheme as that adopted by the public sector. The only difference was that patients had to pay for ART in the private sector (cost approximately USD\$ 3 per patient per month). Another 54 rural health centres (Round 3) were prepared for ART delivery in 2007, with some operational by December and the remainder by early 2008.

By the end of December 2007, there were 118 facilities in the public health sector delivering ART free of charge to HIV-positive eligible patients. In the private sector, 45 facilities were also delivering subsidized treatment. By December 2007, there were just over 141 449 patients who had ever started on ART in the public and private sector, of whom 96 712 were alive and on ART in the facility where they had been registered for therapy. Table 1 shows the progress made with ART scale up in the past five years in both the public and private sectors in Malawi.

Table I

By Dec By Dec By Dec **By Dec** By Dec 2003 2004 2005 Site of ART 2006 2007 24 103 Public sector 9 60 118 New patients started ART in year No data 10 183 24 657 43 981 59 628 Cumulative patients started ART 3 000 13 183 37 840 81 821 141 449 Patients alive on ART 10 761 28 1 1 0 57 356 96712 No data 0 0 23 38 45 Private sector New patients started ART in year 0 977 2 370 2 0 6 0 0

0

0

24

10 183

13 183

10 761

977

977

83

25 634

38 817

29 087

0

0

9

No data

3 000

No data

Progress in scaling up antiretroviral therapy (ART), Malawi, 2003–2007

I.4 Delivering ART

Cumulative patients started ART

New patients started ART in year

Cumulative patients started ART

Patients alive on ART

Patients alive on ART

Public and private sectors

The principles of ART are to reduce HIVrelated morbidity and mortality including that caused by TB, to prolong good-quality life, to assist patients in returning to previous work and employment and to further prevent transmission of HIV. There are two commonly-used classes of antiretroviral medicines in Malawi: the reverse transcriptase inhibitors – divided into nucleoside, nucleotide and non-nucleoside reverse transcriptase inhibitors – and the protease inhibitors.

In order to be eligible for ART, adults and children have to be HIV-seropositive, the patient or the guardian of the child has to understand the implications of ART, and patients have to be assessed in WHO Clinical Stage 3 or 4 or be in WHO Clinical Stage 1 or 2 with a CD4-lymphocyte count below the threshold value for severe immunodeficiency (in the case of adults, this is set at 250 cells/mm3). Most ART clinics do not have a machine for measuring CD4-lymphocyte counts, and the emphasis is therefore on clinical staging, although this may change in the future. Once staged eligible for ART, patients go through a process of group counselling (where the concept of ART is explained), individual counselling and then begin treatment.

3 3 4 7

2 624

46 351

85 168

59 980

5 407

3 937

163

61 688

146 856

100 649

Malawi has focused ART scale up on the use of one generic, fixed-dose combination treatment with stavudine, lamivudine and nevirapine. Two alternative first-line regimens (for serious adverse effects) are available in all ART sites, and one second-line regimen (for drug failure) is placed strategically in central and major district hospitals around the country, and a referral system set up so that any patient in need can access appropriate therapy.

Patients begin treatment, are seen two weeks later and then followed up every four weeks for life. If after six months the patient is stable and has adhered to medication, he or she can be seen every two or three months. Monitoring for well-being, adverse effects and drug adherence are all done clinically, and in most sites there is little in the way of laboratory investigations.

1.5 Managing HIV/AIDS

The medical response to HIV/AIDS is managed by the HIV Department of the Ministry of Health. There is a Director who reports to the Secretary for Health. The HIV unit has three main divisions: antiretroviral therapy, HIV testing and counselling, and prevention of mother-to child transmission of HIV. The unit has informal linkage with the districts through five zonal offices. There are five clinical ART supervisors, who are in the process of being linked to these zonal offices, whose main role is providing clinical mentorship to all ART facilities and assisting with national monitoring and evaluation as well as data collection and collation.

I.6 Developing the national TB control programme, and TB statistics

The first case of TB in Malawi was reported in 1877. From 1877 to 1964, cases of TB were diagnosed and treated according to available resources, but no actual TB control programme existed. The National TB Control Programme commenced in 1964 when Malawi became independent. It aimed at controlling TB through active case-finding, treatment and prevention. However, each district worked independently and the programme lacked coordination. In 1984, after some other small initiatives, Malawi formed a national TB control programme (NTP), with assistance from the International Union Against Tuberculosis and Lung Disease, based on the "DOTS" model. Other donors supported the NTP with financial and technical assistance until 2003, when TB control efforts became part of the sector-wide approach to health. Drug procurement has had protected funds, although from 2008 onwards the funds for antituberculosis medicines will be allocated as part of the total funding of the health sector.

Between 1970 and 1985, the number of notified TB cases gradually increased from 3492 to 5334. From 1985 to 1999, there was an upsurge of TB notifications and TB case rates. Part of the explanation was improved case detection within a revitalized NTP and population growth. However, the most important reason was HIV infection. TB case notifications plateaued in about 2003 at 26 000-27 000 new registered cases per annum: this is thought to be a consequence of national HIV prevalence in adult plateauing about 7-8 years previously. In 1985, the HIV prevalence in TB patients was 26%, which increased and then also reached a plateau of 75% in 2000.

I.7 Controlling TB

Malawi uses the DOTS approach for national TB control, incorporating the DOTS five-point policy package into its control strategy (Box 1).

The NTP uses a system of passive casefinding. Suspected TB cases are either investigated as an out-patient or admitted to hospital for investigation. Adult patients in whom pulmonary TB (PTB) is suspected first submit three sputum specimens for smear microscopy for acid-fast bacilli (AFB). Patients who test positive for AFB from two or more sputum smear specimens are classified as smear-positive PTB and usually require no further investigations. Patients who test sputum smear-negative and who have failed to improve after a course of broad-spectrum antibiotics undergo routine chest radiography; a diagnosis of smear-negative PTB is made for those with radiographic abnormalities consistent with TB. The diagnosis of PTB in children is made on the basis of a constellation of symptoms, signs, tuberculin testing, chest radiography and history of close

Box I The DOTS approach in Malawi

Political commitment

Case-finding using sputum smear microscopy in patients presenting to health care facilities is the cornerstone of diagnosis (passive case-finding)

Standardized, short-course combination antituberculosis chemotherapy (with the rifampicin component given under direct observation by a health care worker, a member of the community or a family member)

A standardized system for monitoring and evaluation

An uninterrupted supply of medicines

contact with an adult case of PTB. Patients (adults and children) with extrapulmonary TB (EPTB) are often hospitalized for investigation, and the diagnosis of each type of EPTB is made according to clinical, radiographic or laboratory criteria. Any patient with EPTB coughing for more than three weeks is requested to submit sputum for smear examination.

Malawi uses five essential antituberculosis medicines, which are designated by the following abbreviations: isoniazid (H); rifampicin (R); pyrazinamide (Z); streptomycin (S); and ethambutol (E). The country has recently changed to a six-month rifampicin-throughout regimen for all new cases. Treatment regimens are as follows:

- 2RHZE/4RH for new smear-positive PTB and serious EPTB cases;
- 2RHZ/4RH for new smear-negative and less serious EPTB cases;
- 2SRHZ/7RH for new TB meningitis;
- 2SRHZE/1RHZE/5 R3H3Z3E3 for relapse smear-positive PTB cases.

I.8 Managing TB

The NTP is one of the disease control programmes and is housed in the Community Health Science Unit in Lilongwe. A TB reference laboratory is part of the Public Health Laboratory, which is another component of the Unit. The NTP is organized in three levels: central, zonal and district. The central and zonal levels support the district level, where activities to diagnose TB and treat patients are fully integrated with general health services. A programme director is supported at the central unit by a deputy programme director and programme officers such as research officers, logistic officers and data clerks. Zonal TB officers are based at zonal offices. Within the NTP organigram, there is a position of NTP coordinator who acts as an advocate for the NTP.

At the national level there is a position of TB/HIV officer, which is currently filled. This officer is responsible for implementing the TB/HIV activities highlighted in the national plan and in the NTP guidelines.

I.9 Delivering ART to HIV-positive TB patients

TB patients who are registered and started on antituberculosis treatment are tested for HIV and counselled, usually within two weeks of registration. Patients who test HIV-positive are started on co-trimoxazole preventive therapy (CPT) and then allowed to go home to complete the initial (or intensive) phase of antituberculosis treatment. During this time the patient attends voluntary group counselling to prepare

for ART. Once the continuation phase of treatment starts (after two months of antituberculosis treatment), the patient begins ART. This is synchronized with monthly collection of antituberculosis medicines to allow the patient to collect antituberculosis and ART medication on the same day. Unfortunately, Malawi has not worked out the best and safest way to provide a "onestop shop" where these medicines can be collected from the same office. Currently, patients have to go to the TB office to collect their antituberculosis medicines and complete their TB monitoring forms, and then attend the ART clinic to collect their antiretroviral medicines and complete their ART monitoring forms.



MINISTRY OF HEALTH AND POPULATION

ARV REGISTER BOOK

ART monitoring



2.1 Registering ART patients at the facility level

Patients who are assessed to be eligible to receive treatment with ART are registered as follows:

Unique ART registration number. All new patients are given a unique ART registration number based on a unique code for the facility and a unique number. Numbers are increased sequentially. For example, the first patient in a facility is given the number "01". The thousandth patient is given the number "1000". This number is written on the patient's ART treatment master card, the patient ART identity card and the ART Register.

ART patient treatment master cards. Every patient has a patient treatment master card: one card for new patients (lasts for 12 months) and then follow-up cards (each card lasts for four years). The ART Treatment Master Card for new patients (Annex 1) records all registration data at the time of their enrolment on ART. This includes: ART registration number, name, address, age, sex, weight, height, whether the patient is a "transfer in" from another treatment unit, name of identifiable guardian, reason for starting ART, date of starting first-line ART, whether the patient has previously been exposed to ART, initial outcome status and concomitant use of CPT.

The address is very important for followup purposes. Wherever possible, the address recorded should be a postal address and include a phone number. At the end of the address row, a "yes/no box" should be ticked in which the patient agrees to be followed-up in the community in the event of not appearing at the clinic at or near to the scheduled appointment. Patient treatment master cards are placed in a polythene sleeve (for protection during storage and to allow additional cards to be added in the years to come) and filed sequentially. It is vital that these master cards are kept in an ordered sequence in the arch-back files. It is recommended that 50 master cards in their polythene sleeves be kept in one arch-back file. The files are kept in strict order according to ART numbers and thus can be easily retrieved.

All follow-up data are also recorded in the master card. At the end of the first year, an ART Treatment Master Card for follow-up patients (*Annex 2*) is given to the patient and filed away in the same polythene sleeve as the first master card.

ART patient register. Every facility has its own unique ART Patient Register (Annex 3). The register has a left-hand page and a right-hand page. The left-hand page records case registration data, including: ART number, year of registration, quarter, date of registration, name, age, sex, address, reason for ART, date of starting ART, name of guardian and treatment unit. The right-hand page records patient treatment outcomes. At the end of each page is a column to record the patient's occupation and remarks. Both left-hand and right-hand pages are completed at the time of registration, when patients are registered as "Alive" and on "Start".

ART patient identity card. The ART Patient Identity Card contains the same basic information as the ART treatment master card but in a smaller format (Annex 4). The information includes: ART registration number, name, address, age, sex, weight, whether the patient is a "transfer in" from another treatment unit, name of identifiable guardian, the reason for starting ART, the date of starting first-line ART, the date of starting substitution or second-line ART and the reason. Patients are given their own ART identity cards, which serve as a reference for all follow-up visits and record if and when patients become ill and are admitted to another facility for treatment.

Patient stamps in health passports. An alternative identity reference is a stamp placed in the health passport. Every health facility has a small wooden device into which the identity card details are imprinted. The device is dipped in ink and a stamp is made in the health passport. The patient details, and especially the ART and registration number, are written into this template in the health passport.

Transfer-in patients. Patients who transfer in from another site or reporting facility are registered as follows. A transfer-in patient always brings the ART patient master card from the referring facility. At the new facility the new ART number assigned to the patient replaces the previous number on the master card and the patient is indicated on the master card as a "transfer-in". In the ART register the transfer-in patient is recorded on the next available row with the new number and demographic and clinical details. The date of registration (the same date as the transfer-in) is recorded in the appropriate column. The date first started on ART is the date the patient was first started on ART in the previous facility. Under reason for ART, the staging condition by which the patient started ART at the previous facility is recorded and the patient is also indicated in this column as a "transfer-in".

2.2 Monitoring the response to ART at the facility level

Patient visits. Patients are seen at the clinic two weeks after starting ART and thereafter every four weeks. If after six months the patient is stable and adherent and has attended another formal group counselling session, he or she can be reviewed once every two months, and sometimes every three months. During follow-up visits, patients are weighed, assessed clinically, educated about adherence to treatment and given pill bottles of ART and CPT.

Standardized treatment outcomes. Standardized outcomes of treatment are monitored at every follow-up visit. Table 2 defines the five primary outcomes of ART.

Table 2Treatment outcomes for patients receiving
antiretroviral therapy (ART)

Outcome of treatment	Definition	
Alive and on ART (A) [note 1]	Patient who is alive, on ART at the facility where he or she is registered, and has collected his or her own supply of medicines	
Dead (D)	Patient who has died for any reason while being registered on ARV therapy	
Defaulted (DF) [note 2]	Patient who is not seen at all during a period of three months	
Stopped (Stop) [note 3]	Patient who has stopped treatment completely either because of adverse effects or for other reasons	
Transferred-out (TO) [note 4]	Patient who has transferred out permanently to another treatment unit	

Note 1. A patient who is alive is further categorized according to the type of ART treatment regimen he or she is taking: *start* – on a first-line regimen; *substituted* (Sbs) – on an alternative first-line regimen as a result of side-effects; *switch* – on a second-line regimen because of first-line treatment failure.

Note 2. A patient is declared defaulted if he or she has not appeared at the clinic two months after the next appointed date. The date of default is the date at which the default classification is made.

Note 3. A patient may stop or be withdrawn from treatment because of (i) severe adverse effects despite substituting an alternative first-line regimen, (ii) poor adherence to medication, or (iii) other reasons, such as discontinuing ART.

Note 4. If a patient transfers permanently out of a district to another ARV treatment facility, this is recorded in the patient master card and also in the ART register. The patient takes that master card to the new district, where it is indicated that he or she is a transfer-in. The patient is given a new ARV registration number and is placed in the cohort of the new district at the time that the patient registers in the new district. The ARV programme realizes that this patient is counted twice in terms of case-finding.

Secondary treatment outcomes are recorded for patients who are alive and on ART: ambulatory status; ability to work status; side-effects experienced in the last month of the quarter; pill counts based on remaining pills in bottles and used to assess drug adherence. From 2008, CPT (in the form of tins of 120 standard tablets that last an adult for two months) has been distributed to all ART sites, and clinic staff personnel are mandated to record in the ART master card and register whether a patient is on CPT or not. Recording standardized treatment outcomes. The standardized outcomes of treatment and the patient's weight, with the date of the visit, are recorded in the appropriate row in the treatment master card every time the patient reports to the clinic. If the patient's outcome changes from "Alive" and from "Start", this is recorded in the master card and also in the ART Register with the **date or month** of the change. The date of default is the date that the decision was made to register the patient as defaulted.

Outcomes are dynamic. If a patient is recorded as "defaulted" and the outcome is subsequently discovered to be "dead" or "transferred-out", then the outcome is changed to "dead" or "transferred-out" with the date or month of this outcome.

If the patient transfers out to another district and sometime in the future transfers back to the first district where he or she was registered, the patient maintains the original ART number and the outcome is changed back from "transfer out" to "alive and on ART".

2.3 Conducting ART cohort analyses at the facility level

At the end of every quarter, the ART clinic team is expected to cross-check the records, in particular to check that treatment outcomes in the master card have been accurately recorded in the register, and perform cohort analysis of cases and end-of-quarter outcomes with events censored at the end of that particular quarter. There are three types of cohort analysis: (i) a quarterly analysis of new patients started on ART in the latest three-month period; (ii) a cumulative analysis of all patients ever started on ART and (iii) a group cohort treatment outcome analysis related to set time periods. ART Quarterly Cohort Analysis. The updated quarterly information for the most recent quarterly cohort of patients started on ART is entered into the data set (Annex 5). Details are cross-checked during supervisory visits.

ART Cumulative Quarterly Analysis. This data set is completed every quarter. It represents a cumulative analysis of case-finding data and treatment outcome data on all patients ever started on ART (Annex 5). Details are cross-checked during supervisory visits.

Group cohort treatment outcomes. 12-monthly, 24-monthly and 36-monthly treatment outcomes are determined based on the quarterly cohorts placed on therapy, the quarterly cohorts selected according to the censor date of the quarter and cumulative analysis. For example, if the censor date is 31 December 2007, the 12-month treatment outcomes are determined for those patients who started ART between 1 October and 31 December 2006; the 24-month treatment outcomes are determined for patients who started ART between 1 October and 31 December 2005; and the 36-month treatment outcomes are determined for patients who started ART between 1 October and 31 December 2004.

Notes on completing the cohort analysis. Annex 6 is a sample cumulative cohort analysis, with explanations given below.

Case-finding data

For the number of patients registered in the quarter and in the cumulative cohort:

- males and females must add up to the total number;
- adults and children must add up to the total number;
- occupation details must add up to the total number;
- number with Stage 1 + 2 (i.e. CD4 count) + Stage 3 + Stage 4 must add up to the total.

Treatment outcomes data

Outcomes are censored on the last day of the quarter in question. Thus, in the quarterly analysis from October to December and cumulative analysis up to December, the last day of census is 31 December. Also, outcomes such as ambulatory, at work, side-effects and pill counts are done for the last month of the quarter.

For the number of patients registered in the quarter and in the cumulative cohort,

• the number alive on ART + dead + defaulted + stopped + transferred-out must add up to the total number registered.

For patients alive and on ART,

• the number on start + substitute + switch must add up to the number alive.

Value of cohort analyses. Quarterly cohort analysis provides data on the number of new patients started on ART in the previous quarter, enabling the facility to check whether it is meeting targets. Cumulative cohort analysis provides data on the number of patients ever started on ART, particularly the number (broken down to adults and children and broken down to regimen) retained alive on therapy. All these data, along with a record of ART drug stocks in the pharmacy, help with drug quantifications and procurement.

2.4 Training for ART delivery, and monitoring of cases and treatment outcomes

Doctors, clinical officers, medical assistants and nurses who are selected from hospitals or health centre facilities to run ART clinics must participate in formal, standardized ART training, consisting of classroom training (five days), an end of course examination for competence (which has to be passed with a mark of 70% or above) and a clinical and nursing attachment at an established ART site (two weeks). The training focuses on: recognition of HIV-related diseases; WHO clinical staging and eligibility for ART; initiation of ART; clinical monitoring and management of sideeffects; and registration and monitoring of patients and conducting cohort analysis. For every new site that has been accredited for ART, the team of clinician, nurse and clerk is also invited to a refresher ART training (one-day) just before the antiretroviral medicines arrive, at which the details of registration, monitoring and cohort analysis are discussed and refreshed with the participants. Established staff members working at ART clinics attend a refresher ART training (two days) every year, and again monitoring and cohort analysis are always part of the training time table.

2.5 External supervision and monitoring of ART sites

Every three months the HIV unit of the Ministry of Health (the ART officers) and its partners conduct supervisory and monitoring visits to all ART sites in the country. Partners consist of the ART clinical supervisors, and clinicians and nurses from well-performing ART sites. Currently, there is no established linkage with the newly created zonal officers (who are too few in number) to undertake these supervisory activities, although these linkages are being discussed.

Standard operating procedures guide the planning and implementation of supervision. The purpose of supervisory visits is to ensure adherence to guidelines and standards, to check that registers and treat-

ment master cards are correctly completed, to collect data for national reporting, to provide encouragement and support (and sometimes admonishment if performance is poor) and to obtain drug stock levels to help with drug procurement. During these visits, the supervising teams give each ART site a copy of the latest national report. The schedule for the next ART supervisory visit is also left with the clinic personnel. Thus, the HIV unit has to prepare these schedules six months in advance. Leaving a schedule at the time of the visit obviates the need for posting dates of next visit or having to contact sites to advise them of a supervisory visit.

A standard supervision and monitoring tool – an ART Supervision and Monitoring Checklist – is used for these visits (Annex 7). If the qualitative assessment of the Register and Treatment Master Card is good, and if the cohort analyses have been performed and are correct, a certificate of excellence (Figure 1) is awarded to the site. An ART site can be awarded a certificate of excellence every quarter if its performance is satisfactory.

2.6 Collating facility-level data with national data

An EXCEL spreadsheet reflects the supervision and monitoring tool. Data from each facility are entered into this spreadsheet following a supervisory visit. The spreadsheet is set up to calculate regional as well as national totals and to recognize and check key punching (data transfer) errors. Once data are entered for the whole country, these are used to write the quarterly report. THE ART REGISTER



ART monitoring and integration of TB-related data

3.1 ART Treatment Master Card

The back of the master card for new patients (*Annex 1*) lists the WHO clinical stages and their associated disease conditions. Patients with active PTB or a previous history of PTB will have these conditions circled under the WHO Stage 3 column, while those with EPTB will have those conditions circled under the WHO Stage 4 column. The front of the master card has a special box to indicate that the patient has either PTB or EPTB. This is one of the areas specially marked for checking during routine ART supervision.

3.2 ART Register

The ART Register records in the column for "Reasons for ART" the patient's WHO clinical stage and whether or not the patient has PTB or EPTB. The correct transfer of information on TB from the master card to the register is one of the special items checked by supervisors during ART supervision.

3.3 Quarterly and cumulative cohort analysis, and Quarterly ART Report

In both the quarterly and cumulative cohort analysis, the number of patients started on ART due to PTB and EPTB is added and recorded in the structured supervision forms.

In addition, during the supervision process itself, the number of patients with active TB registered and started on antituberculosis treatment is obtained from the facility TB register. These data are aggregated for the country and reported in the quarterly reports on ART scale up for the country. The following information is thus reported:

- the number of patients in the quarter started on ART due to TB, broken down to PTB and EPTB [numerator] compared with the total number of patients started on ART due to all reasons [denominator];
- the number of patients with TB started on ART in the quarter [numerator] compared with the total number of patients registered for TB in that quarter [denominator];
- the number of patients ever started on ART due to TB, broken down to PTB and EPTB [numerator] compared with the total number of patients ever started on ART due to all reasons [denominator].

3.4 Shortfalls with the recording and reporting processes

There are a number of shortfalls with the current method of reporting TB data from the ART monitoring tools.

- Patients with PTB are not usually disaggregated into those with active and previous TB, making it difficult to know how many patients with active PTB were actually placed on ART.
- Because of the two-month delay between starting antituberculosis treatment and commencing ART, the ratio of patients with TB starting ART during a quarter compared with the number of TB patients starting antituberculosis treatment in a quarter is not a valid comparison given the different time periods.

Moreover, it is only the HIV-positive TB patients who are eligible for ART and these data are not captured in the supervision and monitoring exercise.

- The reports provide no disaggregated outcome data in relation to the diagnosis of TB, although the data are available in master cards and ART registers and could be collected through special surveys.
- At present adjunctive activities such as CPT and post-treatment isoniazid preventive therapy are not recorded in registers or treatment master cards.



TB monitoring



Systems for monitoring TB follow closely those for ART; in fact, the systems used to monitor and evaluate ART borrow heavily from those for TB. District TB officers are responsible for completing the TB monitoring forms.

4.1 Registering TB patients at the facility level

TB registration number. Every new patient is given a unique TB registration number based on a unique code for the facility and a unique number. Numbers are increased sequentially throughout the year, but in contrast to the ART programme, the numbers for TB patients start again from "01" at the start of a new year. This is because treatment is time-limited (six months) rather than lifelong as is required for ART. The TB registration number is written on the TB treatment master card, the TB identity card and the TB Register.

TB treatment master cards. A TB treatment master card is completed at the time of registration. It records clinical and demographic details, including date of diagnosis, name, age, sex, address, and type and category of TB case (i.e. new, relapse, transfer in). The rows for the initial phase and the continuation phase of treatment are completed in much the same way as the ART treatment master cards.

TB register. Every TB patient has a record made of the diagnosis date, name, age, sex, address, and type and category of TB. The patient is given a unique TB registration number. Only one type of TB is recorded for each patient. Where a combination of PTB and EPTB is present, the patient is recorded as having PTB. EPTB is divided into three categories: (i) serious cases, including pericardial TB, miliary TB and spinal TB; (ii) TB meningitis, and (iii) less serious cases that encompass all the other types.

TB identity card. TB identity cards are very similar to the ART identity cards and contain the same basic information as the TB treatment master cards: TB registration number, name, address, age, sex, weight, type of TB and case category, and rows for dates and other variables to be recorded at each visit.

"TB transfer-in patients". Patients who transfer in from another site are registered and managed in a different way from ART patients. A transfer-in patient brings the TB patient treatment master card from the previous facility. At the new facility, the patient retains the old TB registration number from the previous facility and is clearly indicated as a TRANSFER-IN. He or she remains a part of the cohort from the previous site and not of the new site. The final treatment outcomes are recorded in the previous site's treatment outcome analysis. It is thus necessary for the original TB registration site to follow up the outcomes of its transfer-out patients.

4.2 Monitoring the response to antituberculosis treatment at the facility level

Smear-positive PTB. Patients with smearpositive PTB have their sputum smears examined at 2 months (3 months in relapse cases), 5 months and at the end of treatment (8 months), when the final treatment outcome is recorded.

Smear-negative PTB and EPTB. Sputum smears are not performed during follow up, and therefore there are no outcomes of "cure" or "fail".

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Follow up of patients. Patients are followed up at monthly intervals. During the first two months these visits are often at twoweekly intervals. The important principle is that the rifampicin component of treatment is directly observed. In the continuation phase, visits are monthly, and medication is dispensed from TB offices in the same way as for ART. The fixed-dose RH is given by DOT through guardians at home.

TB treatment outcomes. The definition of TB treatment outcomes are similar to those used in ART but take into account the results of sputum smears at 5 months and beyond. Table 3 defines the six outcomes of antituberculosis treatment.

Table 3 Treatment outcomes for patients receiving antituberculosis treatment

Outcome of treatment	Definition	
Cured	A patient who completes treatment and who is smear-negative at one month prior to the end of treatment and on at least one previous occasion.	
Completed treatment	A patient who completes treatment but in whom smear examination results are not available at the end of treatment.	
Failed treatment	A patient who remains or becomes again smear-positive at five months or beyond during treatment.	
Died	A patient who dies during treatment, regardless of cause.	
Defaulted	A patient who has not collected his or her medication for two consecutive months or longer.	
Transferred out	A patient who is transferred to another registration unit and for whom the treatment outcome is not known.	

4.3 Conducting TB cohort analyses at the facility level

There are two main types of cohort analysis: quarterly analysis of case-finding and quarterly analysis of treatment outcomes.

Quarterly analysis of case-finding. The total number of cases registered for TB treatment in a quarter is recorded and broken down by type and category of TB and, for smear-positive TB patients, by age and sex.

Quarterly analysis of treatment outcomes. The treatment outcomes of the cohort on case-finding are analysed and reported 12 months after the cohort started therapy. This allows time for final treatment outcomes and results of sputum smears to be collected and entered into registers.

Value of cohort analyses. The quarterly cohort analysis provides data on the number of TB patients started on TB treatment in the previous quarter. This allows the NTP to see whether it is meeting the targets set for case detection and treatment success (set globally at 85% for smear-positive PTB cases). These data, along with a record of TB drug stocks in the pharmacy, help with drug forecasting.

4.4 External supervision and monitoring of TB registration sites

Every three months the central unit of the TB control programme and the zonal TB officers conduct supervisory and monitoring visits to all TB registration facilities in the country. The purpose of these visits is to ensure that guidelines and standards are being followed, to collect data for national reporting and to obtain drug stock levels to help with drug procurement. A standard supervision tool is used, very similar to that used for ART supervision. Visits are made to hospitals, health centres and prisons where the programme conducts TB control activities. Zonal TB officers are accompanied by regional laboratory supervisors who supervise the performance of hospital laboratories. District TB officers visit health centres once a month. Each level of supervision uses a structured checklist. As with ART supervision, there is currently no integration of supervisory visits with zonal office activities. This matter is under discussion.

4.5 Collating facility-level data with national data

Zonal officers collect and collate the data for their zonal area of responsibility. Every quarter, there is a central-zonal officer meeting at which data are pooled and collated for national reporting, and these are then used to write the quarterly report.

Visits are made to hospitals, health centres and prisons where the NTP operates. Zonal TB officers are accompanied by zonal laboratory supervisors who supervise hospital laboratory performance. District TB officers visit health centres once a month. Each level of supervision uses a structured checklist.

4.6 Shortfalls with the monitoring and evaluation system for HIV parameters

The established system for monitoring and evaluating TB focuses solely on TB parameters, and there are no routine standard recording and reporting mechanisms for HIV parameters. TB/HIV registration books have been initiated in TB registration offices to capture the number of TB patients referred for HIV testing, the number who test HIV-positive and the number placed on CPT. However, these registering systems were not always filled in properly and the data were not therefore reflected in quarterly reports.

Given the need to capture HIV parameters in a more formal and reliable way, TB monitoring and evaluating tools have been adapted to enable more user-friendly and reliable reporting (see also section 5 below). <form>

Adapting TB monitoring tools to capture HIV parameters

5.I TB/HIV Treatment Master Card

The Malawi TB Treatment Master Card was modified to accommodate HIV parameters and to ensure that HIV testing, CPT and ART are recorded (*Figure 2*).

The main changes to the front and back pages are highlighted below.

• Front page

A box has been added indicating the Start Date for ART, the ART Number and the ART status as well as the Start Date for CPT. The ART status is defined as: (i) started ART before TB treatment; (ii) started ART while on antituberculosis treatment; and (iii) ART not started by the time of discharge from antituberculosis treatment.

A box has been added indicating the documented HIV history according to date of initiation of antituberculosis treatment, the 2–3 month sputum-smear date, the 5-month sputum smear date and finally the 8-month sputum smear date. There are four main results: recent negative HIV test, past positive HIV test, new recommended HIV test that is negative, positive or not tested, and HIV test unknown.

A small box has been added reminding the district TB officer to refer for start of ART at 2 months if the patient is HIVpositive.

• Back page.

A box has been added for the TB Officer to indicate the documented HIVtest history.

5.2 TB/HIV Register

The Malawi TB Register was modified to accommodate HIV parameters and to ensure that HIV testing, CPT and ART are recorded (*Figure 3*).

The main changes concerned the righthand page and are highlighted below.

New column to indicate HIV status (negative, positive or unknown, and with the HTC serial number in case the result needs to be checked).

New column to indicate ARV status (A, B, C) with A=started ART before starting TB treatment, B=started ART while on TB treatment and C=ART not started by the time of discharge from TB treatment.

New column to indicate CPT status, particularly whether CPT was started or not and the date of starting CPT.

5.3 TB/HIV Cohort Reporting Form

The Malawi TB quarterly reports on case registration and TB treatment outcome were modified to accommodate HIV parameters (*Figure 4*). The case registration reports reflect the numbers tested for HIV and those who tested HIV-positive. Treatment outcome reports reflect the numbers HIV-positive, started on CPT and started on ART. Annex 8 shows an example of how these two data sets might look.

FILES CONTAINING ART TREATMENT MASTER CARDS



Improving TB/HIV monitoring



Monitoring of the TB and HIV control programmes could be improved to report on TB/HIV data. This section describes how this could be done.

6.1 Improving capture of TB data in the ART programme

Capturing in the ART Register the number of patients with active TB who have started on ART would greatly improve the monitoring of TB and HIV. This relatively straightforward task, which is already done by some facilities, involves staff writing in the reasons for starting ART column - active PTB, active EPTB and previous history of PTB. Making this a standard reporting field in the ART supervision form would ensure the task is done nationally. Given the increasing case-loads with ART, there is a need for an electronic data system that disaggregates the outcomes of TB-ART patients from the total treatment outcomes.

6.2 Improving capture of HIV data in the TB control programme

Developing new TB/HIV treatment master cards, TB/HIV registers and TB/HIV cohort analysis forms is a major step towards improving capture of data. At the time of writing, these new tools have not been widely distributed in Malawi and are not widely used. Distribution of these tools will help to ensure that data are collected, provided that supervisors insist on data collection during supervision and monitoring and evaluation visits.

The HIV data and CPT data are controlled by the TB control programme, and diligent TB officers will be able to fairly easily collect and input this information into the TB treatment cards and registers. ART data are more difficult.

For ART data, the TB officers will have to visit the ART clinic on a regular monthly basis to update their registers. They will need to take their TB registers and, using a list of HIV-positive PTB patients registered in the previous quarter, determine which patients have started on ART. If patients have been placed on ART from another facility clinic, these data will be difficult to obtain.

6.3 Supervision, monitoring and evaluation, and reporting

Supervision carried out on a quarterly basis and using structured forms is essential for sustaining timely, accurate data collection and analysis. How this is best done needs to be worked out. The advantages and disadvantages of independent or combined supervision are shown in Table 4 below. Combined supervision is a new venture and could be tested out under the umbrella of operational research.

Table 4

Independent or combined supervision and monitoring and evaluation (M&E): advantages and disadvantages

Type of supervision	Advantages and disadvantages	
Independent supervision and M&E by ART and TB control programme	Programmes can plan their activities according to their own agendas. However, this is expensive in terms of finances and human resources.	
Combined supervision and M&E by ART and TB con- trol programme	The two programmes need to plan together and programme officers need to work together. All TB registration sites will have ART sites, but there are many ART sites with no TB registration facilities.	

If combined supervision is successful, a combined supervision form is warranted. This would lead to a combined national data repository and a combined national quarterly report on TB and HIV-ART.

In Malawi, one of the potential complications to merging with TB is the pressure to integrate HIV testing and counselling, supervision of prevention of mother-to-child transmission and monitoring and evaluation with that of ART. Adding TB to this large scope of work may be difficult.



Miscellaneous issues



33 WHO MONOGRAPH ON INTEGRATED MONITORING OF TUBERCULOSIS AND HUMAN IMMUNODEFICIENCY VIRUS

7.1 Planning and implementing national supervision

The ART programme uses a manual on standard operating procedures to ensure that in each quarter the supervision of all sites takes place (*Annex 9*). One of the most important activities is to inform sites of the date of the forthcoming visit, so that the supervising team does not arrive at an empty clinic. This prior information is best done by planning in advance, and at the time of supervision visit, to give the site the schedule for the next quarter. It is vital then that these schedules are adhered to in order to build trust and credibility between peripheral sites and the supervision teams.

7.2 Using data for feedback, drug forecasting, operational research, policy guidance and advocacy

Once collected and collated, data from the ART programme are used to prepare a quarterly ART report. These data and the report serve several purposes:

- Feedback to peripheral sites. ART reports with site-specific data are fed back by hard copy and electronic mail to every ART site on a quarterly basis. This enables sites to measure their performance against other sites as well as against national data. The reports are also posted on the HIV unit web site.
- Quantification of antiretroviral medicines. Each site uses variables to forecast its needs for antiretrovirals in the next 9–12 months:

numbers of patients started on treatment each quarter, numbers alive and on treatment, numbers alive and on different ART regimens and levels of drug stock.

- Operational research. Reliable and verified data can be used for national operational research, for example for assessing access to and outcomes of ART by certain sectors of the population (health workers, teachers, armed forces) or reasons for default and loss to follow-up.
- *Policy guidance.* Data and ART reports with quarterly and cumulative outcomes can guide policy decisions on eligibility for ART, different ART regimens and adjunctive therapies that might improve prognosis.
- *Advocacy.* Regular, timely and reliable data produced nationally every quarter are useful for advocacy purposes, particularly in demonstrating nationally and internationally that large number of patients are being started on and ultimately retained on ART. These data, combined with operational research, can also be used to examine the impact of ART scale up on reducing death rates and contributing to improvement in the economy and fabric of society.

7.3 Staffing peripheral sites and central units for highquality data collection

Peripheral sites. Health-care workers in Malawi are in short supply, and most district or mission ART sites that are not supported by nongovernmental organizations run an ART clinic with one clinician, one nurse and one clerk. The number of days in a week
that the clinic operates and the number of staff who run the services in this clinic are recorded every quarter during supervision. For national purposes, the number of fulltime equivalent clinicians, nurses and clerks to run the ART programme is calculated each quarter. These data are important to regularly review the human resource input needed to run the ART programme.

The experience with ART scale up in Malawi is that the presence of a motivated, hard-working clerk at an ART site with a duty to fill in master cards, maintain registers and take the lead with cohort analyses is crucial to the success or otherwise of the ART clinic. Thus, every ART site should have a good-quality clerk. This principle probably applies to TB clinics and offices as well, particularly if TB/HIV activities are to be integrated.

An unproven but potentially useful strategy would be to equip clerks with cell phones and airtime so that they can communicate with other sites about transfer-in and transfer-out patients and cross-check within districts for HIV-positive TB patients receiving ART at another site. Cell phones and airtime could be assessed each month based on performance, and ways to minimize abuse could be worked out.

Central and provincial sites. Currently, there are too few staff working at TB and ART programmes at the central unit level for the job at hand. The TB control programme in Malawi managed to maintain its cadre of zonal TB officers throughout the process of health-sector reform, and these personnel currently play an invaluable role in supervision and monitoring and evaluation. What is needed is to build up a cadre of well-trained, reliable supervisors from experienced sites (this is done in the ART programme) who, under the coordination of the central units, can reliably undertake site visits, perform supervision and collect data.

7.4 Incentives for good performance

Running busy clinics for ART and TB/ HIV is demanding work. Incentives of some sort are needed to motivate staff to perform to their highest standards. Some of the incentives proven to work in the ART programme include:

- regular supervisory visits that are always conducted according to schedule;
- certificates of excellence for well-performing ART sites;
- invitations each year to attend regular refresher trainings;
- feedback of reports, including comparison of district data, to sites;

7.5 Collecting data using computerized versus manual systems

The ever-increasing number of patients recruited to lifelong therapy in the ART programme warrants the need for computerized systems. Manual registers and treatment cards can be used with patient numbers up to 3000, but beyond this the workload and organization of files become a huge task. Well-used registers tend to wear out, and vital pages on case-finding and treatment outcomes may become torn or lost from the register itself. With TB patients, where the number of patients nationally registered and treated each year has remained at 25 000-28 000 for the past five years, the pressure to move to computerized systems is not so intense or immediate. Entering back data is tedious and in busy clinics will likely not be done. Thus, real-time, dedicated touch-screen computers offer the best alternative to the manual system, although they have to be robust to cope with power outages and power fluctuations. In Malawi, through the Baobab initiative, such computers are already in use and are being pilot tested in district hospitals.

Computerized systems have the advantage that cohort analysis is done at the push of a button, and it is relatively easy to provide disaggregated data sets and match these to treatment outcomes.

With most sites having started with manual systems, the big challenge is how to move to a computerized system and whether to maintain or phase-out the manual system of registers and treatment master cards. The answers to these questions are not yet known.

7.6 Incorporating new indicators in the future

As TB and HIV/ART programmes evolve, monitoring systems need to be flexible enough to incorporate the introduction of new parameters. These would include robust, simple laboratory technology such as point-of-care CD4-lymphocyte counts or viral loads measured through dipsticks, or simpler second-line regimens for patients who have failed the first-line regimen. Measuring these parameters may be important for future reporting and planning.

7.7 Health sector reform, decentralization and SWaPs

So-called "vertical programmes" such as those for TB and ART have to operate within the context of the health sector, and in the case of Malawi this means within the context of health sector reform, the philosophy of decentralization and the sectorwide approach (SWaP) to health. The TB control programme in Malawi is currently being integrated into a SWaP, and moves are currently taking place to integrate HIV services supported by the Global Fund to Fight AIDS, Tuberculosis and Malaria, including ART, into SWaPs as well.

In Malawi, there are 65 SWaP indicators to monitor the inputs and outputs of the health sector, three of which relate explicitly to TB and ART: (i) case detection rates of TB, measured every 10 years; (ii) cure rates for TB patients, measured every year; and (iii) the number of patients alive and retained on ART, measured every year. While these are important and key indicators, individually they are insufficient for TB or ART programmes to manage themselves or, most importantly, for such programmes to forecast and procure their drug supplies. More detailed data are needed for these programmes and also for international donors such as the Global Fund¹ and PEPFAR².

The detailed data needed for planning and monitoring progress in the ART programme are shown below.

The Global Fund to Fight AIDS, Tuberculosis and Malaria (http://www.theglobalfund.org/en/).

The United States President's Emergency Plan for AIDS Relief (http://www.pepfar.gov/).

- Number of patients starting on ART in a quarter broken down by adults and children. These data provide a yardstick for planning the number of medicines needed for new patients every 6 months and, as regimen formulations are different between adults and children, the age breakdown, which is vital.
- Number of patients retained alive and on ART – broken down by adults and children and by type of regimen. These data are vital for planning the number of medicines needed for patients alive and on therapy. To know the number of patients retained alive and on therapy it is vital to know, out of the total number of patients ever started on treatment, those who have died, defaulted, stopped therapy and transferred out.

These data, combined with the recording of regular drug stock levels in pharmacies, are essential for rational drug forecasting. This is an essential activity if drug stockouts are to be avoided – and they must be avoided – to prevent the emergence of drug resistance.

SWaPs frameworks for monitoring and evaluation need to take these factors into account. The frameworks can maintain their core set of TB and HIV indicators, but there should be an insistence from ministries of health on collecting and reporting on additional essential pieces of data in order to keep programmes on track and to determine how the nation is progressing against agreed global targets. Table 5 lists the important TB, ART and TB/HIV indicators to be included in a SWaPs framework for monitoring and evaluation.

Table 5Proposed indicators and rationalefor monitoring and evaluation of TB, ARTand TB/HIV using a SWaPs framework

TB control programme	Rationale
Number of TB patients registered each year	Needed for knowing the extent of the epidemic in the country
Number of smear-positive PTB patients registered each year	One of the Stop TB Partnership targets is to detect 70% of the estimated smear-positive PTB cases, and hence the need for the numerator in the left-hand column
Number of smear-positive PTB patients registered and successfully completing treatment	One of the Stop TB Partnership targets is to cure 85% of detected smear-positive PTB cases
ART programme	Rationale
Number of patients enrolled for ART each quarter and each year	Needed for knowing the coverage of ART provision against targets such as Universal Access
Number of patients cumulatively retained on ART	Needed for knowing about the success or otherwise of ART delivery and for national planning of medicines
TB/HIV programme	Rationale
Number of TB patients tested for HIV each year	Global Plan to Stop TB target
Number of HIV-positive TB patients identified each year	Needed for planning the management of HIV-related disease in TB patients at the national level
Number of HIV-positive TB patients who were on CPT by the time TB treatment was completed	Needed for knowing whether this important compo- nent of HIV-related adjunctive care is being provided
Number of HIV-positive TB patients who were on ART by the time TB treatment was completed	Needed for knowing how good the access is of HIV- infected TB patients to ART

A WORN-OUT PAGE OF THE ART REGISTER



Conclusion



The Global Plan to Stop TB³ set the ambitious target of halving the prevalence of TB and deaths from the disease by the year 2015 compared with 1990 levels. In sub-Saharan Africa, this goal cannot be achieved without addressing HIV-TB. Within the 10-year plan, an important component for controlling the burden of HIV-TB includes the provision of HIV care for coinfected TB patients. The gateway to this care is HIV testing, and then offering CPT and ART to those TB patients who are HIVpositive.

Much has to be done to ensure that these services are delivered to patients in need. However, a vital part of this work is a reliable and timely monitoring and evaluation system so that the TB and HIV programmes and the country know what is happening. These data allow the programmes to judge their progress, respond to activities that are lagging behind and, importantly, to plan for necessary resources.

This monograph from Malawi provides a case study about current resources available to address the monitoring and evaluating issues associated with TB/HIV and needs for the future to improve data gathering and reporting.

³ Stop TB Partnership and World Health Organization. The Global Plan to Stop TB, 2006–2015: actions for life towards a world free of tuberculosis. Geneva, World Health Organization, 2006 (WHO/HTM/ STB/2006.35).

CERTIFICATE OF EXCELLENCE FOR ART CLINIC



Suggested reading



Co-trimoxazole preventive therapy for HIVpositive persons in Malawi [policy document]. Malawi, Ministry of Health, 2005.

Guidelines for TB control in Malawi, 6th ed. Malawi, Ministry of Health, 2007.

HIV/AIDS counselling and HIV testing: guidelines for Malawi, 2nd ed. Malawi, Ministry of Health, 2004.

Treatment of AIDS: guidelines for the use of antiretroviral therapy in Malawi, 3rd ed. Malawi, Ministry of Health, April 2008.

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ANNEX I: NEW PATIENT MASTER CARD FOR ART [front]:

ART N	Imbel									Yea												
Name									▼	ge Ge	Sex			Mt (Kg)		Initial	Ht (cm		Transf	er-In ()	(N)	
Address (s	treet ac	dress a	hd bh	one)												Follo	w-up ag	reement (- (N/λ			
Name of i	Jentifiat	ıle guaı	⁺dian								Dat	e and pl	ace of p	ositive H	V test_							
Date of st	urting l [±]	⁺ line A	RT reg	gimer	_					Rea	son for AR	T: Stage			; PTB_		EPTB	Ÿ	S	-M	LCT	
Date of st	ırting al	ternati	ve I st	ine A	RT r	egime	an (spe	cify) _					Date of	starting 2	Ind line A	.RT regi	men (sl	becify)				
Month	Date	Kg Kg	Ht cm		Ō	utcom	e statu:	6		Of those	alive	Ambu	latory	Work	chool	Side ef	fects	No. Pills in Bottle	AR Gi	En en	CPT	Other
				۷	۵	Ы	Stop	10	Start	Sbs	Switch	Amb	Bed	Yes	No	۲	z		٩	υ		
Jan																						
Feb																						
Mar																						
Apr																						
May																						
Jun																						
٦																						
Aug																						
Sep																						
Oct																						
Νον																						
Dec																						

Specify reason for ART (Stage 3, Stage 4, Stage 1 and 2 with CD4 < 250, PTB, EPTB, KS, PMTCT, Transfer-in)

Of those alive: Start=alive and on first line regimen; Sbs=alive and substituted to alternative first line regimen; Switch=alive and switched to a second line regimen Outcome status: A =alive; D=dead; DF=defaulted and not seen for 3 months; Stop=stopped medication; TO=transferred out to another unit because of failure of first line regimen

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

Adverse effects: If Yes, specify – PN= peripheral neuropathy; HP=hepatitis; SK=skin rash; LA = lactic acidosis; LD=lipodystrophy; AN = anaemia

No. Pills in bottle: if patient comes at 4 weeks count number of pills in bottle (8 pills or less = 95% adherent)

ART given **P** = patient; **G** = guardian. Indicate the number of tins of ART given to patient or guardian

CPT: indicate if patient on co-trimoxazole preventive therapy: **Blank column for remarks**

	ow what disease(s) the patients has by plac	ing a ring around the bullet point next to t	he disease or clinical problem
WHO Clinical Stage I	WHO Clinical Stage 2	WHO Clinical Stage 3	WHO Clinical Stage 4
For adults and children	For adults	For adults and children	For adults and children
 Asymptomatic Persistent Generalised lymphadenopathy 	 Unintentional weight loss< 10% of body weight in the absence of concurrent illness Minor mucocutaneous manifestations (seborrheic dermatitis, prurigo, fungal nail infections, recurrent oral ulcerations, angular chelitis) Herpes zoster Recurrent upper respiratory tract infections (i.e. bacterial sinusitis) For children Unexplained persistent hepatomegaly and splenomegaly Papular itchy skin eruptions Extensive wart virus infection Extensive molluscum contagiosum Recurrent oral ulcerations Unexplained persistent parotid gland enlargement Lineal gingival erythema Herpes zoster Recurrent or chronic respiratory tract infections (sinusitis, otorrhoea, tonsillitis, otitis media) 	 Oral candidiasis Oral hairy leukoplakia Unintentional weight loss > 10% of body weight in the absence of concurrent illness Chronic diarrhoea > 1 month Prolonged fever (intermittent or constant) > 1 month Active Pulmonary Tuberculosis PTB within the past 2 years Severe bacterial infections (e.g. pneumonia, pyomyositis, sepsis) Acute ulcerative mouth infections or thrombocytopenia Additional for children Moderate unexplained malnutrition TB lymphadenopathy Severe recurrent bacterial pneumonia, symptomatic lymphoid interstitial pneumonia Moderate unexplained malnutrition TB lymphadenopathy Severe recurrent bacterial pneumonia bronchiectasis HIV-associated cardiomyopathy HIV-associated nephropathy 	 HIV wasting syndrome (weight loss > 10% of body weight and either chronic fever or diarrhoea in the absence of concurrent illness) Pneumocystis carinii pneumonia Toxoplasmosis of the brain Cryptosporidiosis or Isosporiasis Recurrent severe presumed pneumonia Cryptosporidiosis or losoporiasis Recurrent severe presumed pneumonia Cryptococcosis, extrapulmonary Cryptosporidiosis or losoporiasis Recurrent severe presumed pneumonia Cryptosporidiosis or losoporiasis Recurrent severe presumed pneumonia Cryptococcosis, extrapulmonary Cryptosporidiosis or losophagus/trachea/bronchus Any disseminated endemic mycosis Candidiasis of oesophagus/trachea/bronchus Atypical mycobacteriosis, disseminated or lung Recurrent bacteraemia or sepsis with NTS Extrapulmonary tuberculosis (EPTB) Lymphoma (cerebral or B-cell Non Hodgkin) Kaposi's sarcoma HIV encephalopathy Other (Cancer cervix, visceral leishmaniasis) HIV-associated nephropathy (adults only) HIV-associated nephropathy

ANNEX 2: FOLLOW UP PATIENT MASTER CARD FOR ART [front and back are similar]:

Name

ART Number_

Year

Month	Date	kg Kg	Ht cm		ō	utcom	e status		0)f those a	live	Ambulat	ory	Work/sch	loo	Side effects		No. Pills in Bottle	ART Given	CPT
)		٩	۵	ц	Stop	5	Start	Sbs	Switch	Amb	Bed	Yes	٩	≻	z		U d	
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Mar																				
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donth	Date	٧t	Ht cm		0	Jutcon	re statu:	7.4		Of those	alive	Ambula	tory	Work/sch	loo	Side		No. Pills in	ART		СРТ
		Kg														effect	Ņ	Bottle	Give	L	
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	ART treatment uni								
	Name and address of guardian								
	Reason for starting ART								
l age	Date first started ART								
-hand pa	Address								
[lef1	Age								
ER	Sex								
T REGIST	Name								
NT AR	Date of registration								
ATIE	Quarter								
3. F	Year								
ANNEX	ART registration number								

Reason for starting ART: Stage 3, Stage4, CD4 count < 250/mm³, Stage 2 with TLC < 1200/mm³ Also indicate under Reasons for ART - PTB, EPTB, KS and Transfer In (TI) Quarters: 1 = January to March: 2 = April to June: 3 = July to September: 4 = October - December

ANNEX 3: PATIENT ART REGISTER [right-hand page]

Outcome (prc	wide date v	when chang(e from alive)		Of those al cha	live (provide inge from sta	date when rt)	Ambi	ulant	At wor children)	k or (in at school	Remarks (including occupation, BMI, ITN)
Alive	Dead	Default	Stop	Transfer	Start	Substitute	Switch	Yes	No	Yes	No	

Alive - alive and on ARV drugs: Dead - whatever the cause: Default - not seen in three months: Stop - stopped treatment due to side effects/other: Transfer - transfer-out to another ART treatment unit

Start - on first line regimen: Substitute - changed to alternative first line regimen: Switch - changed to second line regimen Ambulant - yes/no: At work or school - at previous or new employment for adults

ANNEX 4: ART PATIENT IDENTITY CARD

ANNEX 5: COHORT ANALYSIS FORM [same data for quarterly and cumulative]

Case Data:

Number of patients started on ART in the last quar	ter [or cumulatively]	
Number of men started	Number of women started	
Number of adults (15 and above)	Number of children (14 and bel	ow)
Occupation: Housewives Farmers	_ Soldiers/Police	Teachers
Business Health care workers	Students/school	_ Other
Reasons for starting: Stage III Stage IV _	CD4 count	
Indicate number started because of TB	(PTB EPTB	Not known)
Indicate number of pregnant women started on AR	T from PMTCT	

Outcome Data:

Number alive and on ART _				
(Number alive and on first lin	1e regimen (Start))		
(Number alive and on alterna	tive first line regimen (Substituted))		
(Number alive and on second	line regimen (Switch))		
Number who have died				
Number who have defaulted	[no defaults in a quarterly analysis]			
Number who have stopped _				
Number who have transferred	d out			
Of the number alive and on AR	T:			
Number who are ambulatory				
Number who are at work				
Number who have side effects				
Number adults on 1 st line regimen with pill count done in last month of quarter				
Number with the pill count i	n the last month of the quarter at 8	or less		
Of those who died:	Number in month 1	Number in month 2		
	Number in Month 3	Number after month 3		

ANNEX 6: CUMULATIVE ANALYSIS – AN EXAMPLE

Case Data:

Total number of patients ever started on ART 200 Number of men started 50 Number of women started 150 Number of adults (15 and above) 180 Number of children (14 and below) 20 Occupation: Housewives 40 Farmers 50 Soldiers/Police 2 Teachers 10 Business 30 Health care workers 3 Students/school 10 Other 55 Reasons for starting: Stage III 140 Stage IV 50 CD4 count 10 Indicate number started because of TB 35 (PTB 30 EPTB 5 Not known 0) Indicate number of pregnant women started on ART from PMTCT 5

Outcome Data:

Number alive and on ART 140 (Number alive and on first line regimen (Start) 130 (Number alive and on alternative first line regimen (Substituted) 10 (Number alive and on second line regimen (Switch) **0** Number who have died **30** Number who have defaulted **20** Number who have stopped 5 Number who have transferred out 5 Of the total number alive and on ARV therapy (140) Number who are ambulatory **135** Number who are at work **I30** Number who have adverse effects 25 Number adults on 1st line regimen with pill count done in last month of quarter 100 Number with the pill count in the last month of the quarter at 8 or less 90 Of those who died: Number in month 1 (**15**) Number in month 2 (**5**) Number in Month 3 (**5**) Number after month 3 (**5**)

ANNEX 7: ART SUPERVISION AND MONITORING CHECKLIST

Hospital	Date				
Year	Quarter evaluated				
ARV Clinic (orderly and tidy)					
ARV Filing system in place					
ARV Register:					
Registration numbers are correct and match the mas	ter card numbers				
Transfer-in patients are registered with the next site	registration number				
Patient registration is a continuous process and not c	ne month per page				
All columns are filled in (age, sex, reason for ART,	ambulatory, work)				
Transfer-in patients recorded under "Reason for AR	T"				
Dates of outcomes are properly recorded under outc	ome columns				
Patients' occupation is recorded in "Remarks"					
If patient is pregnant and referred from PMTCT this	is indicated in "Remarks"				
TB is indicated under "Reason for ART" – also PTI	3 and EPTB				
All ARV outcomes are updated every three months					
ARV Register is up to date and in line with Master	Cards				

ARV Master Cards:

The case finding data is properly completed on each Patient Master Card
TB indicated "PTB or EPTB" under reason for ART next to Stage
The 2-week visit after the start of ART is written at the bottom of the card
Regular record of Weight done at every visit
Each monthly visit has all columns completed
Pill counts done according to previous directives
Back of master card is completed

ARV Drug Register

Being used _____

ART Cohort Analysis:

Cohort analysis done for the quarter ______ Cohort analysis done for the cumulative number on ART ______ Cohort outcomes are correct for quarter and cumulative analysis ______

ART Clinic Days: Total number of days per week for ART clinic _____

New patient days]	Follow-up patient days	
Group Counselling (and check the time between	n GC and start of ART)	
On a clinic day, number clinicians	number nurses	number clerks

VCT Register

Properly completed and monthly summaries done properly _____

Number tested in the quarter ______ Number HIV positive in the quarter _____

Number of people referred to ART in the quarter _____

Pharmacy:

ARV medicines	Tins in Last order	Number of tins in stock
D4T/3TC (D4T-30mg) [15 tablets]		
D4T/3TC (D4T-40mg) [15 tablets]		
D4T/3TC/NVP (D4T-30mg) [I5 tablets]		
D4T/3TC/NVP (D4T-40mg) [I5 tablets]		
D4T/3TC/NVP (D4T-30mg) [60 tablets]		
D4T/3TC/NVP (D4T-40mg) [60 tablets]		
"Duovir" for PEP		
AZT/3TC [60 tablets] – Alternative/2 nd line		
Nevirapine [60 tablets]		
D4T/3TC-30/40 [60 tablets] –Alternative		D4T30= /d4T40=
Efavirenz [30 tablets] – Alternative		
Tenofovir [30 tablets]-2 nd line		
Kaletra [180 capsules] 2 nd line		
CPT (tins of 120 tablets)		
CTX (tins of 1000 or 500 tablets)		
OI medicines		Number Tablets in stock
Fluconazole (Diflucan programme)		
Acyclovir		
Ceftriaxone		
Ciprofloxacin		
Vincristine		
Morphine		
Amitryptiline		

Laboratory:

CD4 Machine installed (specify yes/no and type)

Quarterly ART Assessment: (assess for the quarter being evaluated) ______

Case Data:

Number of patients started on ART in the last quarter			
Number of females started			
Number of adults (15 and above) Number of children (14 and below)			
Soldiers/Police Teachers			
Students/school Other			
e IV CD4 count			
TB EPTB Not known)			
Indicate number of pregnant women started on ART from PMTCT			

Outcome Data:

Number alive and on ART _		
(Number alive and on first lin	ne regimen (Start))
(Number alive and on alterna	ative first line regimen (Substituted))
(Number alive and on second	line regimen (Switch))
Number who have died		
Number who have defaulted		
Number who have stopped _		
Number who have transferre	d out	
Of the number alive and on AR	V therapy:	
Number who are ambulatory	7	
Number who are at work		
Number who have side effect	S	
Number adults on 1 st line reg	gimen with pill count done in last m	onth of quarter
Number with the pill count in the last month of the quarter at 8 or less		
Of those who died:	Number in month 1	_ Number in month 2
	Number in Month 3	_ Number after month 3

Cumulative ART assessment: for patients registered up to _____

Case Data:

Total number of patients ever started on Al	RT		
Number of males	Number	of females started	
Number of adults (15 and above)	Number	of children (14 an	d below)
Occupation: Housewives Farme	ers So	oldiers/Police	Teachers
Business Health care workers	Students/	school Ot	ther
Reasons for starting: Stage III	Stage IV	CD4 count	
Indicate number started because of TB	(PTB	EPTB	Not known
Indicate number of pregnant women started	d on ART from F	PMTCT	

Outcome Data:

Number alive and on ART	
(Number alive and on first line regimen (Start))
(Number alive and on alternative first line regimen (Substituted))
(Number alive and on second line regimen (Switch))
Number who have died	
Number who have defaulted	
Number who have stopped	
Number who have transferred out	

Of the total number alive and on ARV therapy:

Number who are ambulator	У		
Number who are at work			
Number who have side effect	ts		
Number adults on 1st line r	egimen with pill count done in	last month of quarter	
Number with the pill count	in the last month of the quarte	er at 8 or less	
Of those who died:	Number in month 1	Number in month 2	
	Number in Month 3	Number after month 3	
36-month survival: out	comes by end of December	2007	
New patients registered for	ART between October and De	cember 2004:	
Number Alive and on ART			
Number Dead			
Number Defaulted			
Number Stopped Treatmen	:		
Number Transferred Out			
24-month survival: outcomes by end of December 2007			
New patients registered for ART between October and December 2005:			
Number Alive and on ART			
Number Dead			
Number Defaulted			
Number Stopped Treatment			
Number Transferred Out			
12-month survival: outcomes by end of December 2007			
New patients registered for ART between October and December 2006:			
Number Alive and an ADT			

Number Alive and on ART	
Number Dead	
Number Defaulted	
Number Stopped Treatment	

Number Transferred Out _____

Number of HIV-related diseases diagnosed in quarter: Specify			
TB patients registered in TB Register			
Kaposi's Sarcoma patients			
Cryptococcal meningitis patients in Diflucan Register			
Oesophageal candida patients in Diflucan Register			
Number of persons given post-exposure prophylaxis in the quarter:			
СРТ:			
Has your site ever provided CPT to ART patients: YES NO			
If YES,			
Has the site provided CPT to:	100% of patients		
	50% of patients		
	25% of patients		
Post-exposure prophylaxis (PEP)			
Number of persons provided PEP for occupational injuries:			
Number of persons provided PEP for rape/sexual assault:			

ANNEX 8: EXAMPLE OF TB/HIV COHORT REPORTING

I. Quarterly analysis of case-finding: January-March 2007

Number of registered TB cases	150
Number of registered sm+PTB cases	75
Number of registered sm-ve PTB cases	50
Number of registered EPTB cases	25
Number of TB cases HIV tested	120
Number of TB cases HIV-positive	75
Number of HIV+ve sm+ve PTB cases	35
Number of HIV+ve sm-ve PTB cases	25
Number of HIV+ve EPTB cases	15

2. Quarterly analysis of treatment outcomes, January–March 2007 cohort

[analysis performed in January to March 2008]

Number of registered TB cases	150
Number TB cases HIV tested	130
	(10 additional cases HIV tested later
	on during TB treatment)
Number TB cases HIV positive	80
Number TB cases started CPT	78
Number TB cases on ART	50
TB cases on ART:	
Started ART before TB treatment	5
Started ART after TB Treatment	45

ANNEX 9: STANDARD OPERATING PROCEDURES FOR ART SUPERVISION

I. Getting Ready:

Preparing the Stationery:

- Prepare in the first week of the new quarter
- Print out the facility schedule for the coming quarter
- Prepare the facility schedule for the next quarter which takes place three months later, and print it out
- Print out the previous quarter ART report and the annexes of facilities
- Prepare a new supervision check list and particularly update the 6-month, 12-month, 18-month and 24-month group outcome analyses
- Prepare the phoned report form and update this so that facilities can phone the number of patients ever started on ART at the end of the current quarter
- There should now be five files for photocopying: 1) the current supervision schedule; 2) the next quarter supervision schedule; 3) the previous quarter ART report; 4) the new supervision check list; and 5) the phoned report form
- Get these photocopied with 10 spare copies: if there are 150 facilities there is a need for 160 copies of each file with the exception of:- a) the current supervision schedule of which there is a need for about 20 copies only and b) the new supervision check list of which there should be 320 copies (one for the ART supervision team and one for the facility for the next supervision)
- Ask the secretary to pack these into hard back folders: into each folder there is placed 1) one copy of the next supervision schedule; 2) one copy of previous ART report; 3) one copy of phoned report form; 4) two copies of the supervision check list
- Get the ART certificates awarded in the last supervision printed and keep these and the above files in HIV Unit

Preparing the budget and the teams:

- For 2008 there will need to be three supervision teams (each team with two supervisors plus a driver) for each region
- The schedules are one week in North (including a visit to Likoma Island at the weekend), two weeks in Central, and two weeks in South
- Budgets need to be prepared for fuel, for allowances, for accommodation and for stationary for the end of the quarter

2. The actual supervision and monitoring:

- Prepare the master card arch back files in order (e.g. 1 1000). It is recommended that sites should file master cards in batches of 50 (and not batches for each quarter, etc.). This helps retrieval of cards and prevents polythene sleeves from tearing out due to overcrowding.
- collect the ART patient register and the ART drug register
- Ask for the cohort analysis from the facilities. Sites should have prepared a cohort analysis for the most recent quarter and a cumulative analysis
- Follow the schema of the supervision check list. The qualitative assessment on the first page should be filled at the end of the visit after the documentation has been thoroughly reviewed
- Quarterly cohort:
 - check the sequence of ARV numbers of patients registered in the last quarter: there should be no numbers skipped or duplicated
 - calculate the number of patients registered in the quarter by subtracting the ARV number of the last patient in the previous quarter from the ARV number of the last patient registered in the quarter evaluated.
 - count the number of males in the quarter evaluated
 - count the number of children in the quarter evaluated
 - calculate the number of females and the number of adults by subtraction from the total number of
 patients registered in the respective quarter
 - check that the number of different occupations adds up to the total number of patients registered in the quarter evaluated (use the cohort analysis prepared by the site)
- Reconciliation / updating of Register and Master cards for the quarter evaluated (this should have been done by the site and there should be no differences between Register and Master cards):
 - one supervisor checks the register and the other checks the master cards
 - compare: Reason for ART, PTB, EPTB, KS, PMTCT and the primary outcomes (death, default, stop, transfer out) with dates
 - Best to have the Register supervisor call out the ART numbers and reasons/outcomes with dates and the Master card supervisor to check
- Once these are checked, then tally for reason for ART, PTB, EPTB, KS, PMTCT. The tally again for primary outcomes and regimens- best for the ART register supervisor to go from column to column as this is easier for the tallyer
- <u>Cumulative cohort</u>: take the previous ART report in the folder and add to the counts from the case finding data (sex, age groups, occupations, reasons for starting) from the previous cumulative totals the most recent quarter. This should give the cumulative case finding data and this should be the same as the cohort prepared by the facility
- For the cumulative, then check primary outcomes between Register and Master cards. Again, best to have the Register supervisor call out the ART numbers and the outcomes with dates and the Master card supervisor to check
- Once these are checked, then tally for primary outcomes and regimens- best for the ART register supervisor to go from column to column as this is easier for the tallyer. Note: Do NOT count outcomes that have occurred after the end of the quarter evaluated.
- Secondary outcomes (pill counts, side effects, 'walking', 'working') are too time consuming to check and the data are just accepted from the site
- <u>Qualitative assessment</u>: Once the quarterly and cumulative analyses are completed, perform qualitative assessment of register, master cards, ART drug register and cohort analysis: - if everything done well and cohorts are correct then write: 'award certificate of excellence' on the top of the first page of the report form. Explicitly write: 'not for certificate' on the report otherwise

- <u>Group cohort survival analyses</u>: take the number registered in the particular quarter and tally the number of deaths, defaulters, stops and transfer outs in this cohort by the appropriate censor date. Note: Do NOT count outcomes that have occurred after the end of the censoring period
- <u>Miscellaneous activities for the supervision</u>: ask about clinic days and staff needed to run the clinics; use of CPT in ART patients; training of staff using district ART training module; CD4 machines
- <u>TB register</u>: If the visited facility is a TB registration site: visit TB office and collect number of patients started on TB treatment in most recent quarter
- <u>Pharmacy</u>: visit pharmacy and collect drug stock data on all ART drugs and signified OI drugs if recorded ART drug stocks do not make sense do a manual count. Check to make sure any new ART supplies have been added to the bin cards. Review the Diflucan Register: tally the number of NEW CASES of cryptococcal meningitis and oesophageal candidiasis in the quarter evaluated. If the site does not have a Diflucan Register, then take the data from the ART master cards.
- <u>Check on completion of ART supervision check list</u>: before leaving the site check that all parameters have been completed. Indicate if the site has been awarded a certificate
- <u>Give the necessary stationery to ART staff</u>: previous ART report, new supervision check list for the next cohort analysis, next ART schedule, phoned ART form
- <u>Inform</u> the ART staff about the next visit (with the next supervision schedule) and feed back previous site and national data (with the previous ART report)
- De-Brief with the medical officer / nursing officer in charge

3. Data entry:

- Prepare the EXCEL file for the quarter being assessed, get help if necessary from CDC M&E specialist
- Enter data as the sites are evaluated, don't leave this until the end
- Use the data accuracy checks at the end of each row to check whether the numbers for quarterly, cumulative and group cohort analyses add up correctly to the total

4. ART Certificates:

- Data entered into EXCEL include reports of sites with certificates
- Prepare the ART site certificate list and give to HEU for printing
- Remember to collect ART Certificates for next round of supervision

5. ART Report:

- Once supervision is completed and data all entered to EXCEL file, appoint a specific person with responsibility for getting the report ready
- This person must analyse the data and write the report using the same format as previously
- Once report is written it should go out to all people who assisted with the supervision for their agreement and comments, and once back (give a few days only) then finalise report. Get the finalised report approved by Secretary for Health and circulate to the group email list
- Make sure the ART report gets circulated to all national and international stakeholders before the end of the quarter

6. Start again for the next quarter:

• Once all the above is done, breathe a sigh of relief, relax for 1-2 days and then re-start at the beginning. Good Luck! **ANNEX 10: Certificate of Excellence for ART clinic**



ANNEX II: TB-HIV Treatment Master Card

INT CARD District TB No Health Unit:	Registr. Date:	Management of HIV+ Patien ARV CTX	Start Date:	ARV NO.: ARV-Status: A B C	Update ARV-Status in Register from this card: A: started ARV before starting TB treatment	 B: started ARV <u>while on</u> TB treatment C: ARV <u>not</u> started by the time when discharged from TB 	I t s Weight Documented HIV Test History (see back) (kg) Recent Past Never tested / old negative Unkn	Result Result New New New Pos. Not Test	RN PP NN NP NT U	RN PP NN NT U	RN PP NN NP NT	RN NN VP	still positive Update HIV-Status in Register from latest entry on ca RN or NN: HIV-Status Negative PP or NP: HIV-Status Positive	NT or Unk: HIV-Status Unknown	19 20 21 22 23 24 25 26 27 28 29 30 31	At 2 month	
IBERCULOSIS TREATME					ail Oth Specify other:	New case T I= Transfer In re Oth = Other	Sputum Resu	Test Date Serial No	ation smear growth	nth 2 smear	into Stitted	t nih 6/8 smear	* 3 month repeat only if 2 month smear was		9 10 11 12 13 14 15 16 17 18		
NATIONAL TUBERCULOSIS PROGRAMME TU MALAWI	Name:	Audress: (in full) Name and	address of Guardian:	Sex: M F Age:	Disease P EP New Relapse TI Def Fi	Patient P= Pulmonary TB EP= Extra-pulmonary TB New= N Category Def= Retreatment after default Fail= Treatment failur	1. INITIAL INTENSIVE PHASE	Badiman and daily docare of tablets / grams of S	Regimen 1 Regimen 2 TB Meningitis		R : ritampicin S S S Moni H : isoniazid	Z : pyrazinamide E : ethambutol S : streptomycin (S for 2 months only in Regimen 2) moni		DOT Option: Guardian Hospital HealthCentre	Month Day* 1 2 3 4 5 6 7 8 5		

ANNEX II: TB-HIV Treatment Master Card

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6		Regim			Month					* Enter)

Version 3 September 2007

Remarks:

61 WHO MONOGRAPH ON INTEGRATED MONITORING OF TUBERCULOSIS AND HUMAN IMMUNODEFICIENCY VIRUS

ANNEX 12: TB-HIV Register

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	Other	Oth		13	strict ulting re															
3)	Failure	Fail		12	n another di n after defat atment failu															
ategory ⁽	Return after default	RAD		11	t district fron atment agai ain after tree oned above															
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Name of	Treatment Unit															_			1	(3) Patient Category New: new patient; never Relap: relapse-patient; f cured but now has TB &
	Address (in full)																			(2) TB Classification P: Pulmonary TB EP: Extra-pulmonary TB
	Age																			ition Jian oital centre
	Sex	A M	M	Μ	M	R	R	Μ	M	MF	R	L M	R	R	M F	M	۲ ۳		1 2	(1) DOT Op Guar Hosp: Hosp HC: Health
	Name (in full)																	PAGE TOTALS	Field number	
Dietrict TB	Number																			January 2008
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ANNEX 12: TB-HIV Register

Remarks																			_	
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tatus ⁽⁵⁾	ARV No.																			us N <u>before</u> starting RV <u>while on</u> TB to started by the tim om TB treatment
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atment O	Tx complete (no smear)	(monito pu)																Tx compl.	15	ent failure; sn patient who l red out; patie
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amination toe: date of labo	Month 3	Smear																		ults on 2 or mo I negative smea ause whatsoeve
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	Initiat	Smear																		(4) Treatment Cure: treatme Complete: tre Died: patient k

ANNEX 13: TB-HIV Cohort Report Forms

Quarterly Report on TB Case Registration in Basic Management Unit

Patients registered during Date of completion of this form:	
Name of BMU: Name of TB Coordinator: Signature:	

Block I:All TB cases registered²

			X	S	TOT
Puln			Σ	ш	ALS
nonary sp	New	cases			
utum smear	a	Relapses			
r microscop	^o reviously t	After failure			
y positive	reated	After default			
New p smear n		0-4 yrs			
ulmonary		5-14 yrs			
sputum negative		> I5 yrs			
Pulmona microsco		0-4 yrs			
ury sputum py not dor available		5-14 yrs			
i smear 1e / not		> 15 yrs			
New ex		0-4 yrs			
trapulmo		5-14 yrs			
nary		> 15 yrs			
Other previously	treated ³				
TOTAL	All cases				

Block 2: New pulmonary sputum smear microscopy positive cases – Age group

	Sex	Σ	Ľ	
	0-4			
-	5-14			
	15-24			
	25-34			
	35-44			
-	45-54			
	55-64			
	> 65			
	Total			

Block 3: Laboratory activity – sputum smear microscopy⁴

No. of TB suspects with positive sputum smear microscopy result No. of positive cases registered for treatment	o. of TB suspects examined r diagnosis by sputum smear icroscopy	
No. of positive cases registered for treatment	o. of TB suspects with positive utum smear microscopy result	
	o. of positive cases registered r treatment	

Block 4:TB/HIV activities²

	No. of patient	s tested for HIV:	_
	Before	Cuinc turnet	
	treatment		_
Vew smear			
os TB			
All TB cases			

¹ Registration period is based on date of registration of cases in the TB Register, following the start of treatment. Q1: 1 January-31 March; Q2:1 April-30 June; Q3: 1 July-30 September; Q4:1 October-31 December.

³ Other previously treated cases include pulmonary cases with unknown history of previous treatment, previously treated sputum smear microscopy negative pulmonary cases and previously treated extrapulmonary cases. 'Transferred in' and chronic cases are excluded.

⁴ Data collected from the TB Laboratory Register based on "Date specimen received" in the laboratory during the quarter, without including patients with examination because of follow-up.

⁵ Documented evidence of HIV tests (and results) performed in any recognized facility before TB diagnosis or during TB treatment (till end of the quarter) should be reported here.

Forms
Report
Cohort
TB-HIV
X 13: 1
NNE

Quarterly Report on TB Treatment Outcome and TB/HIV Activities

Name of BMU: Name of TB Coordinator:	Facilit-y:				P ate of completion	atients registere quarter of y of this form:	d during ^l ear	
Block I:TB treatment outcon	nes ^l							
	Total annulus of			Treatment	outcomes			Total number
Type of case	patients registered during quarter *	Cure (I)	Treatment completed (2)	Died (3)	Treatment failure ² (4)	Default (5)	Transfer out (6)	evaluated for outcomes: (sum of 1 to 6)
New sputum smear microscopy positive								
Previously treated sputum smear microscopy positive (Relapses)								
Previously treated sputum smear microscopy positive (Failures , Treatment after default)								
Sputum smear negative								

*These numbers are transferred from the Quarterly Report on TB Case Registration for the above quarter. Specify any exclusion.

Other previously treated (recurrent, smear

Extra-pulmonary TB

negative and Extra-pulmonary³

Block 2:TB/HIV activities¹

All TB cases	
No HIV positive	
No. of patients on CPT ⁴	
No. of patients on ART ⁵	
- - - - -	

Quarter: This form applies to patients registered (recorded in the BMU TB Register) in the quarter that ended 9-12 months ago. For example, if completing this form at the close of the second quarter then record data on patients registered in the 2nd quarter of the previous year.

² Includes patients switched to Cat.IV because sputum sample taken at start of treatment turned out to be MDRTB.

³ Other previously treated cases include pulmonary cases with unknown history of previous treatment, previously treated sputtum smear microscopy negative pulmonary cases, and previously treated extrapulmonary cases.'Transferred in' and chronic cases are excluded.

⁴ Includes TB patients continuing on CPT started <u>before TB diagnosis</u> and those started <u>during TB treatment</u> (fill last day of TB treatment).

⁵ Includes TB patients continuing on ART started before TB diagnosis and those started during TB treatment (till last day of TB treatment).

Notes

Notes



For further information, contact: World Health Organization 20, Avenue Appia CH-1211 Geneva 27 Switzerland Stop TB Department E-mail tbdocs@who.int Web: http://www.who.int/tb/publications/2009/en/index.html Department of HIV/AIDS E-mail hiv-aids@who.int Web: http://www.who.int/hiv/pub/en/



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