

**THREE YEAR DEVELOPMENT PLAN  
FOR  
THE IMPLEMENTATION  
OF  
JOINT TB AND HIV SERVICES  
IN  
MALAWI**

**Prepared by the TB-HIV Technical Working  
Group**

*July 2002*

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## **LIST OF ABBREVIATIONS**

### **Organisations, staff and policies:**

AIDS	Acquired Immuno Deficiency Syndrome
ARI	Acute Respiratory Infection
CBC	Community-based care
CHAM	Christian Health Association of Malawi
CHSU	Community Health Services Unit
CMS	Central Medical Stores
CRL	Central Reference Laboratory
CU	Central Unit of the NTP
DFID	Department for International Development, UK
DHMT	District Health Management Team
DHO	District Health Officer
DOTS	Direct Observed Treatment, Short-Course
DTO	District Tuberculosis Officer
EHP	Essential Health Package
GOM	Government of the Republic Malawi
HMIS	Health Management Information System
HSA	Health Surveillance Assistant
IUATLD	International Union Against Tuberculosis and Lung Disease
KNCV	Royal Netherlands Tuberculosis Association
MIM	Malawi Institute of Management
MO	Medical Officer
MOHP	Ministry of Health and Population of Malawi
NAC	National AIDS Commission
NGO	Non Governmental Organisation
NORAD	Norwegian Agency for Development Cooperation
NTP	National Tuberculosis Control Programme
RTO	Regional Tuberculosis Officer
SWAp	Sector wide approach to health
WHO	World Health Organization

### **Technical:**

ARV	Antiretroviral therapy
ELISA	Enzyme-Linked Immuno Sorbent Assay
EPTB	Extra-Pulmonary Tuberculosis
HIV	Human Immunodeficiency Virus
IEC	Information, Education and Communication
PTB	Pulmonary tuberculosis
QA	Quality Assurance
SCC	Short-Course Chemotherapy for Tuberculosis
SM+	Smear-positive
SM-	Smear-negative
STI	Sexually Transmitted Infections
S/V	Supervision
VCT	Voluntary Counselling and Testing

### **Financial:**

USD \$	American Dollar
MK	Malawi Kwacha

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## **EXECUTIVE SUMMARY .**

This document provides a plan for joint TB-HIV activities for a three year period, 2003- 2005. The goal is to reduce the burden of ill health due to HIV-TB in the population of Malawi. The purpose of the joint initiative is to reduce HIV-prevalence rates in TB patients, reduce case notification rates of TB and reduce TB case fatality rates. In order to achieve this purpose, a set of 9 objectives are proposed with activities directly related to each objective.

The objectives can be summarised as follows:

- To provide VCT services for TB patients and the general public
- To provide isoniazid preventive therapy for HIV+ve persons who do not have TB
- To provide cotrimoxazole preventive therapy to HIV-positive persons with TB
- To provide care and support for HIV-related illness in TB patients
- To provide secondary isoniazid preventive therapy to HIV-positive TB patients who have completed a course of anti-TB treatment
- To provide antiretroviral (ARV) therapy to HIV-positive TB patients
- To establish and maintain TB-HIV management capacity and coordination
- To establish and maintain relevant TB-HIV operational research
- To ensure TB-HIV monitoring and evaluation.

The TB-HIV activities which are described under each objective are those needed to fill a “gap” between standard TB activities (funded by the NTP through its 5-Year development plan) and HIV activities planned in the application to the GFATM (Global Fund for AIDS, tuberculosis and malaria).

The 3-year TB-HIV Plan is a plan to place TB-HIV activities in 7 districts in Malawi in the first year, followed by another 7 districts in the second year with full country coverage in the final year. With regard to ARV therapy, the plan covers implementation of this initiative in just one district during the 3-year period. The budget reflects this phased development. Moreover, within each district there will be a phasing in of different activities, with a sine qua non for implementation being provision of VCT and HIV testing.

The budget for each year and for the whole three years is shown in Tabular Form in the document, and the Annexes explain how the budget is calculated for each specific objective and activity. The TB programme has already been pledged a rolling budget for the next five years, and with the application to the GFATM funds should arrive for HIV/AIDS activities – this includes budget support for VCT, drugs for opportunistic infections and ARV therapy. A budget in this plan is calculated for specifically managing HIV+ve TB patients and bridging the gap in funds.

The 3-year expenditures in relation to each objective are as follows:-

	USD\$
VCT Services	45,400
Isoniazid Preventive therapy	32,300
Cotrimoxazole preventive therapy	0
Care and Support	80,000
Prevention of recurrent TB	160,000
ARV therapy	0
TB-HIV Management	161,600
Operational Research	180,000
Monitoring and Evaluation	200,400
<b>Total Budget</b>	<b>859,700</b>

The budget assumes that VCT services plus training (with the exception of support for the current 2 PROTEST counsellors), HIV drugs and ARV delivery with training / registers etc will be covered by GFATM funds.

The total 3-year TB-HIV budget will be USD\$859,700

The mechanisms for financial support and disbursement need to be worked out.

## TB-HIV PROGRAMME Logical Framework

<b>Project Name:</b>	TB-HIV Programme		
<b>Country:</b>	Malawi		
<b>Narrative summary</b>	<b>Objectively Verifiable Indicators (OVIs)</b>	<b>Means of Verification (MOV)</b>	<b>Assumptions</b>
<b>Goal</b>			
To reduce the burden of ill health due to HIV – tuberculosis in the population of Malawi	HIV prevalence rate in TB patients reduces TB incidence rate reduces TB mortality rate reduces	HIV surveillance NTP data	
<b>Purpose</b>			
To reduce HIV-prevalence rates	1. HIV prevalence rates in TB patients reduce (targets to be developed through operational research)	Operational research data and data from VCT sites	No decrease in financial and technical support to TB-HIV activities from Government of Malawi
To reduce case notification rates of TB and to reduce TB case fatality rates	2. Annual TB case notification rates plateau by 2005	NTP routine data collection through quarterly regional and district reports	Continued financial and technical support to TB-HIV activities from donors NTP remains a strong programme under health sector reform
	3. Mortality rates in new smear +ve PTB patients reduced from 20% to 10% by 2005	Targetted operational research studies	Districts responsive to developing implementation plans with TB-HIV Technical working group with respect to TB-HIV control activities

## Outputs

1. To provide VCT services for the general public and TB patients	<p>1.1 Integrated hospital-based VCT services established in all hospitals in Malawi by 2005</p> <p>1.2 Stand-alone VCT services established in all districts in Malawi by 2005</p> <p>1.3 Quality of counselling assurance system and supervision established and running by 2005</p> <p>1.4 Quality control of HIV testing established and running by 2005</p> <p>1.5 Training system for counsellors established by 2003</p>	<p>Reports from DHMTs</p> <p>Quarterly reports from RTOs in the NTP</p>	<p>MOHP committed to establish a new cadre of health personnel "counsellors"</p> <p>Sufficient resources made available for VCT services to be sustained and expanded</p> <p>Resources for training are adequate</p> <p>Rapid HIV test kits in good supply and approved by Government</p>
2. To provide isoniazid preventive therapy to HIV-positive persons who do not have active TB.	<p>2.1 Number of stand-alone VCT centres increased to one per district by 2005</p> <p>2.2 All VCT centres using isoniazid register books to monitor adherence to INH prophylaxis</p> <p>2.3 VCT centres using isoniazid register books to report on a quarterly basis on number of persons using INH prophylaxis</p> <p>3.4. Adherence to INH prophylaxis increased to and maintained at 60% or more from 2003 onwards</p>	<p>DHMT reports</p> <p>RTO quarterly reports</p> <p>VCT-INH prophylaxis quarterly reports</p>	<p>VCT counsellors in good supply</p> <p>Good liaison between VCT centres and NTP for provision of INH</p> <p>MOHP accepts the rationale for INH prophylaxis</p>
3. To provide cotrimoxazole preventive therapy to HIV+ve TB patients	<p>3.1 90% or more of TB patients are offered VCT in each district where there is a VCT service provided</p> <p>3.2 85% or more of HIV+ve TB patients identified by VCT are offered cotrimoxazole</p> <p>3.3 80% or more of HIV+ve TB patients on cotrimoxazole adhere to cotrimoxazole during the course of anti-TB treatment</p> <p>3.4 TB-supervisory system to include checks on use of cotrimoxazole</p> <p>3.5 Each district which administers cotrimoxazole preventive therapy develops a system to ensure that cotrimoxazole can be continued after anti-TB treatment has finished</p>	<p>TB registers</p> <p>Treatment cards</p> <p>Periodic surveys of cotrimoxazole pill counts</p> <p>Established systems of communication between District Health Services and the Community</p>	<p>MOHP accepts the operational research evidence for use of cotrimoxazole prophylaxis</p> <p>Cotrimoxazole availability in districts</p> <p>Ability of districts to conduct periodic surveys</p> <p>Ability of districts and communities to establish communication and two-way referral systems</p>

<p>4. To provide care and support for HIV-related illness in TB patients and active case finding for contacts of HIV+ve smear+ve TB patients</p>	<p>4.1 Districts include weekly ward rounds for hospitalised TB pts</p> <p>4.2. Hospital pharmacy stocks of basic drugs for treating HIV-illness checked once a year</p> <p>4.3. Nutritional support for TB patients both in hospital and in the community for needy patients (targets to be defined)</p> <p>4.4. Palliative care at hospital and community level</p> <p>4.5. Two-way referral systems between hospital and community</p> <p>4.6. Active case finding mechanisms established in households of index HIV+ve smear+ve TB patients</p>	<p>DTO reports</p> <p>RTO supervisory reports</p> <p>Operational research</p>	<p>Hospitals able to purchase and maintain stocks of drugs for treating HIV-related illness and for palliation</p> <p>Nutritional support available</p> <p>Communication systems able to be established between hospital and the community,</p>
<p>5. To provide isoniazid to HIV-positive TB patients who have completed treatment to prevent a recurrent episode of TB</p>	<p>5.1 Clinical studies to determine efficacy of secondary isoniazid preventive therapy</p> <p>5.2 District feasibility and effectiveness studies of secondary isoniazid preventive</p>	<p>Results of clinical studies assessing efficacy</p> <p>Results of operational studies assessing feasibility and effectiveness</p>	<p>Clinical evidence base is small</p> <p>Efficacy studies demonstrate efficacy</p> <p>Ability of NTP to manage post-treatment isoniazid preventive therapy</p>
<p>6. To provide antiretroviral therapy (ARV) to HIV+ve TB patients in at least one district</p>	<p>6.1. 90% or more of TB patients are offered VCT</p> <p>6.2. 85% or more of HIV+ve TB patients identified by VCT are offered ARV therapy</p> <p>6.3. 90% or more of HIV+ve TB patients adhere to ARV during the course of anti-TB treatment</p> <p>6.4. TB-supervisory system includes checks on ARV drug adherence</p> <p>6.5. Each district which administers ARV therapy develops a system to ensure that ARVs can be continued after anti-TB treatment is completed</p> <p>6.6. District staff who administer ARV have completed recognised training course in ARV</p> <p>6.7. System established to ensure security of ARV drugs</p> <p>6.8. Systems established to do regular cohort analysis</p>	<p>Clinical studies</p> <p>District operational research studies</p>	<p>Exact timing of ARVs for administering to HIV+ve TB patients to be determined</p> <p>Exact ARV regimen to be determined to ensure maximum safety and efficacy</p> <p>ARVs available in the public sector</p> <p>ARV training courses in place</p>

7. To maintain and improve TB-HIV management capacity	<p>7.1 Human resources increased at all levels (National and District)</p> <p>7.2 TB-HIV Technical Working Group Meetings held every 6 – 8 weeks</p> <p>7.3 TB-HIV finance meetings held every 3 months</p> <p>7.4 NTP costed annual workplans submitted by March each year to the Steering Committee</p> <p>7.5 Districts assisted in developing TB-HIV activities into their Annual workplans, including M&amp;E</p> <p>7.6 6-monthly and annual reports submitted to Steering Committee by end August and end February each year</p> <p>7.7 Position papers written and discussed with MOHP as and when required</p>	<p>Reports on human resources on an annual basis</p> <p>Technical Working group Meeting minutes</p> <p>TB-HIV finance group minutes</p> <p>Annual Workplans delivered on time</p> <p>6-month and Annual reports delivered on time</p> <p>Position papers circulated</p>	<p>MOHP increases the necessary human resource base</p> <p>Sufficient office space provided to accommodate increased staff</p> <p>MOHP acts on recommendations made in position papers</p>
8. To perform operational research relevant to TB-HIV activities	8.1. Operational research studies implemented in accordance with annual plans, and completed studies written up and disseminated within 6 months of completion of research	NTP reports TB-HIV reports	
9. To maintain TB-HIV monitoring and evaluation	<p>9.1. Sustain routine TB-HIV monitoring and reporting systems</p> <p>9.2. Quarterly TB-HIV financial audit</p> <p>9.3. 6-monthly meetings with Steering Committee with co-opted Technical assistance as required</p> <p>9.4. Annual review meeting</p>	<p>NTP reports</p> <p>TB-HIV reports</p> <p>Reports from auditors</p> <p>Steering committee minutes</p> <p>External TA reports</p>	

## **INTRODUCTION**

### **1. HIV and AIDS.**

Malawi is badly affected by the AIDS Epidemic. Since the first reported cases in 1985, the number of cases has escalated. In 1999, it was estimated that out of approximately 10.5 million people there were 800,000 adults and children living with HIV/AIDS in Malawi (source = UNAIDS). There were 760,000 adults, aged 15 - 49, giving an adult rate of approximately 16%. An estimated 70,000 adult and child deaths were due to AIDS in 1999, and the cumulative number of orphans since the beginning of the epidemic is approximately 390,000. HIV/AIDS is now the leading cause of death in the most productive age group (20 - 49 years). It accounts for over 40% of all in-patient admissions and is likely to increase.

The National AIDS Control Programme (NACP) carries out regular surveys of women attending antenatal clinics. In 1999, the overall HIV-seroprevalence in 6885 adult women, aged 15 - 49 years, was 24%, with rates of 26% in urban areas, 27% in semi-urban areas and 12% in rural areas.

### **2. Tuberculosis.**

#### **2.1. TB Case notifications**

Between 1970 and 1985 there was a small gradual increase in notified TB cases in the country from 3492 to 5334. From 1985 to 2001 there has been an upsurge of TB notifications and TB case rates. Part of the explanation in the mid-1980s was improved case detection within a revitalised TB control programme and population growth. However, the most important reason is HIV infection.

Table: TB case notification rates between 1987 and 2001

Year	No. TB cases	TB cases/100,000 population
1987	7,581	95
1989	9,431	140
1991	14,443	155
1993	17,105	172
1995	19,155	180
1997	20,676	181
1999	24,396	211
2001	27,672	265

#### **2.2. TB Treatment.**

Malawi has currently moved to an ambulatory, fully oral initial phase of treatment for all new patients with TB. Treatment for recurrent TB continues as previously. The regimens are shown in **Annex 1**.

### 2.3. TB Treatment outcome.

Treatment outcome has been monitored in patients (new and relapse) with smear-positive PTB since 1984. Initially cure rates were high (between 85 – 90%), and then began to decrease in the 1990s. In the last ten years, cure rates have remained between 63 - 69%, and have not reached the 85% cure rates demanded by WHO. The NTP has tightened up its performance so that treatment completion, default and transfer out rates have been kept low (10% or less). The main reason for low cure rates is the high death rate which has risen from 10% in 1990 to above 20% from 1996 onwards. Treatment failure rates have remained low at 1%, signifying a low rate of drug-resistant TB. For more details of treatment outcome in patients with new smear-positive Pulmonary Tuberculosis, please refer to the TB 5-Year Development Plan.

## **3. HIV infection and TB**

### 3.1. HIV-seroprevalence rates in TB patients.

There has been a steady increase in HIV-seroprevalence in TB patients in Malawi since the start of the HIV epidemic. Studies carried out in different sites in the country have found an HIV-seroprevalence rate of :- 26% in Zomba in 1986, 52% in Makwasa, Thyolo, in 1988, 67% in Mzuzu in 1991, 75% in Blantyre in 1993 and 77% in Zomba in 1995.

A country-wide study in 1993 of 358 patients from 16 hospitals showed an HIV-seroprevalence rate of 63%. Another country-wide study carried out in 482 patients in 13 hospitals in the country in 2000 showed an HIV-seroprevalence rate of 77%. In Lilongwe and Blantyre and certain other districts, HIV rates were above 80%. HIV-seroprevalence did not differ between men and women, and according to age groups the highest rate was in patients aged 25 - 34 years. According to types of TB, HIV-seroprevalence rates were 67% in smear-positive PTB, 77% in extrapulmonary TB and 87% in smear-negative PTB.

### 3.2. Implications of the high HIV-infection rate.

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

1. The general public has increasingly begun to associate TB with AIDS, and positive ways of dealing with this stigmatising association need to be found. The TB Equity study has examined this association, and the IEC strategy of the NTP plans to address it
2. Early identification of TB cases is important, not only to reduce TB transmission in the community but also to improve the chances of a good outcome with anti-TB treatment. Delays in diagnosis as a result of stigma makes early identification of cases difficult
3. High HIV rates mean high rates of smear-negative PTB and EPTB, and ways to improve the diagnosis of these difficult conditions need to be found
4. HIV care issues, such as good quality HIV voluntary counselling and testing (VCT) or screening and treating patients for common HIV-related diseases, are currently not well addressed in Malawi. These care issues should be incorporated into the diagnosis and management of TB. The lessons being learnt by the ProTEST project in Lilongwe need to be taken up by the policy makers, who will also need to identify the most appropriate implementing bodies for the HIV/AIDS care-related activities
5. High case fatality rates in TB patients are a result of the strong link with HIV, and interventions to reduce this death rate need to be found. Such interventions include the diagnosis and treatment of HIV-related diseases, prevention of opportunistic infections using adjunctive cotrimoxazole and restoration of immunity using antiretroviral (ARV) therapy
6. The risk of developing TB or getting recurrent TB is increased in HIV-positive people, and the NTP will need to consider whether it should be trying to prevent the development of TB in HIV-positive persons and prevent recurrent disease in those who have had TB and have completed treatment.

#### **4. Integrating and engaging with Malawi's Health Sector Policies**

#### 4.1. Health sector policies

There are three important health sector policies which will impact on any plan aiming to deliver HIV-TB activities on the ground.

The MOHP is engaged with the donor community in designing and ultimately delivering a sector wide approach to health (SWAp). This is a process with two main objectives: a) the development of a coherent sector policy as the basis for concerted action and b) a donor coordination mechanism to promote joint implementation.

The Essential Health Package (EHP) is considered essential to the SWAp process. The EHP provides essential health services centred around Malawi's burden of disease. It is a package of priority health services, provided at a given level of the health care system, supported by the necessary administrative, logistics and management systems. The priority conditions include TB and HIV/AIDS.

A National Decentralisation Policy provides districts with more autonomy and responsibility for the conduct of their affairs. The District Assemblies and their District Health Management Teams will have the responsibility for delivering the components of the EHP on the ground. Districts for the last two years have been developing Annual District Implementation Plans, in which all activities including TB and HIV/AIDS activities are costed and planned for the forthcoming financial year. Mechanisms for supervising these activities and obtaining annual reports have yet to be established.

#### 4.2. Engaging with health sector policies

In the NTP's 5 Year Development plan mechanisms to engage actively with the health sector policies are described. For further information, consult the 5-Year Development Plan.

## **POLICIES FOR JOINT TB – HIV ACTIVITIES**

The policies are shown in the TB-HIV Log Frame, and are explained in narrative form below.

### **Goal.**

The goal is to reduce the burden of ill health due to HIV-TB in the population of Malawi.

Measurable outcomes will include:-

- a) HIV incidence rates, measured in sentinel populations
- b) TB case notification rates measured within the NTP,
- c) TB mortality rates measured within the NTP

### **Purpose.**

The purpose of the joint initiative is to reduce HIV prevalence rates, reduce case notification rates of TB and reduce TB case fatality rates.

Objective verifiable indicators and targets have been developed. HIV prevalence rates in TB patients will be measured – this is usually done every 5 years, with the next survey planned for 2005 (year three of the TB-HIV plan). It is difficult to know what will happen with annual TB case notification rates, but with the interventions in place the aim is to achieve a plateau in TB case notifications by the end of the three years. The target for case fatality in smear-positive PTB patients is a decrease from 20% to 10% by 2005.

A plateau in TB case notification rates implies that a significant number of HIV-positive persons are started on and adhere to isoniazid preventive therapy to prevent first ever episodes of TB or to prevent recurrent TB after completing treatment for a first episode. Case notification rates will be measured within the NTP. Mortality rates will be measured in new smear-positive PTB cases by collecting treatment outcome data within the NTP. Smear-positive cases are those who are microbiologically proven to have TB, in contrast to patients with smear-negative TB where the diagnosis is sometimes difficult and in doubt. A decrease in mortality reflects both extent of coverage and quality of delivery of a) care of HIV-related disease, b) preventive therapy for opportunistic infection and c) use of anti-retroviral therapy.

## **Objectives.**

### 1. To provide VCT services for TB patients and for the general public.

VCT services need to be set up in hospitals in order to provide for the sick and at stand-alone sites in order to provide for the “worried well”. Current demands on health care staff preclude them also being trained and used as VCT counsellors. Another cadre of staff – trained dedicated counsellors – needs to be trained and employed within the health service. VCT services require personnel, rapid HIV testing kits and office space. When they are set up there also needs to be a quality of counselling assurance system and a quality control system of HIV testing in order to ensure that quality services are being offered to the public: this means supervision from a level higher than the district. The target is for each district to have one hospital-based VCT and one stand-alone VCT centre by end of 2005.

### 2. To provide isoniazid preventive therapy to HIV-positive persons who do not have TB.

Stand-alone VCT centres will act as the main service point for these activities. These VCT centres will offer isoniazid preventive therapy to HIV-positive persons who do not have TB. Register books need to be kept to record the number of clients each quarter who start on isoniazid and the number who complete a full 6-month course. VCT centres need to link with the NTP for provision of isoniazid, and be accountable in terms of the amount of isoniazid used each quarter. The assumption with this objective is that the MOHP will accept the use of isoniazid preventive therapy.

### 3. To provide cotrimoxazole preventive therapy to HIV-positive patients with TB.

Hospital-based VCT centres will act as the main service points for these activities. These VCT centres will offer cotrimoxazole preventive therapy to HIV-positive patients with all types of TB who are registered within the NTP. In order for this intervention to be effective, a high percentage of TB patients need to be counselled and tested for HIV, a high percentage of HIV-positive TB patients need to start on cotrimoxazole as soon as possible after registration, and adherence to cotrimoxazole during anti-TB treatment must be high. Targets for these measurable outcomes have been developed based on the successful operational research studies conducted in Thyolo and Karonga. At the end of anti-TB treatment cotrimoxazole needs to be continued, and systems need to be set up to ensure that patients can continue to access the medication and be monitored. The assumption is that the MOHP will accept the use of cotrimoxazole preventive therapy for HIV-positive TB patients.

4. To provide care and support for HIV-related illness in TB patients.

Objective indicators to monitor this objective would include – weekly ward rounds for TB patients (at present irregular), hospital pharmacies being stocked with drugs for treating HIV-related disease (at present there are regular stock-outs), the provision of nutritional support for TB patients both in hospital and at home, the opportunity for palliative care both at hospital and in the community for the terminally ill and finally a functioning two-way referral system for HIV-TB patients between hospital / health centres and the community. Operational research has shown a higher rate of TB in household contacts of index TB patients. Active case finding in households of HIV+ve smear-positive TB patients will be established.

5. To provide secondary isoniazid preventive therapy to HIV-positive TB patients who have completed a course of anti-TB treatment.

The evidence base for this activity is at present small (one randomised controlled study in Haiti). Nevertheless, in nearly 10% of all patients registered nationally for TB the patients have experienced a previous episode of TB. Clinical studies will need to be conducted to determine the efficacy of isoniazid in preventing a recurrent episode of TB, followed by feasibility studies to work out how the system can work.

6. To provide antiretroviral (ARV) therapy to HIV-positive TB patients.

Hospital-based VCT centres will act as the main service points for this activity. These VCT centres will offer ARV therapy to HIV-positive patients with all types of TB who are registered within the NTP. In order for this intervention to be effective, a high percentage of TB patients need to be counselled and tested for HIV, a high percentage of HIV-positive TB patients need to start on ARV therapy as soon as possible after registration, and adherence to ARVs during anti-TB treatment must be high. Targets for these measurable outcomes have been developed. At the end of anti-TB treatment ARV therapy needs to be continued, and systems need to be set up to ensure that patients can continue to access the medication and be monitored. A large number of operational issues need to be addressed.

#### 7. To establish and maintain TB-HIV management capacity

For HIV-TB activities to be established in districts and to be monitored by MOHP there needs to be an increase in the human resource pool. The TB HIV Technical Working Group will meet regularly with minutes circulated promptly. Good financial management systems will be established and maintained. Annual costed workplans will be produced by the Technical Working group, and districts need to be assisted in incorporating TB-HIV activities into their District Implementation Plans. 6-monthly and annual reports will be written for presentation to the Steering Committee according to pre-set deadlines. Position papers need to be written and discussed with the Steering Committee and MOHP as and when required.

#### 8. To establish and maintain relevant TB-HIV operational research

There will be different ways of approaching each of the service related objectives, and operational research should be conducted which will be relevant and helpful to implementation of service delivery.

#### 9. TB-HIV monitoring and evaluation

Routine TB-HIV monitoring and reporting systems will be established, a quarterly financial audit set up and 6-monthly meetings with the Technical Working Group reporting to the Steering Committee. There will need to be an annual review meeting to discuss and review progress.

## **THE STRATEGY FOR JOINT TB / HIV ACTIVITIES.**

### **1. Working within health sector reform.**

The TB-HIV Technical Working group will keep itself briefed and up to date with the development of the Essential Health Care Package and the SWAp approach. It will also contribute to the current efforts of refining the EHP in terms of quantifying and costing the direct and indirect inputs with regard to TB and HIV activities.

### **2. Working with District Health Management Teams.**

The TB-HIV Technical Working Group has representatives from district health management teams. It will be necessary to work with districts to assist the District Health Management team plan and cost forthcoming TB – HIV activities. It will also be necessary to monitor these district activities and the use of funds to assess whether activities have been carried out and money correctly used and accounted for.

The ultimate aim is to firmly embed the concept of TB- HIV control at district level, with the district taking responsibility for its own TB – HIV activities. This cannot be done country-wide all at once because of limited capacity in the districts to carry out activities and to account financially for funds. A phased and monitored approach is therefore necessary.

Districts will take the lead role in implementing joint HIV-TB activities. The DHMT, accountable to the MOHP, shall have a clear overall co-ordinating and leadership role, and shall involve government and CHAM facilities and other NGOs who may want to play a role in implementation.

### **3. Phased approach for country-wide implementation.**

The phased strategy is to implement TB-HIV activities in 7 districts in Malawi in the first year, followed by another 7 districts the following year with a target of full country coverage in the final year. The provision of ARV therapy is more difficult and requires careful piloting at one district to learn the lessons before this intervention can be reasonably rolled out to other districts. If the district feasibility study proceeds well, then it may be possible to expand to other districts before the end of the 3-year period.

The National AIDS Commission, with funds from the GFATM, has a plan for expanding VCT services to districts over the next three years. The TB-HIV Technical Working Group will be opportunistic in this regard, and chose districts where VCT services have been set up and are working.

#### 4. Phased approach within each district.

Not all activities will be implemented in each district all at once. Thus, there will be a phased approach to delivery of services within each district.

- a) The first and essential step to implementing joint TB/HIV activities is to set up a VCT site integrated within the general health service. This is the entry point to all joint interventions. No activities can start without VCT services.
- b) The second step would be to administer adjunctive cotrimoxazole prophylaxis to HIV-positive patients with TB, and at the same time improve the standard of care for HIV-illness in the hospital and the community, improve nutrition, and set up a two-way referral system between health services and the community.
- c) The third step, would be to start active case finding activities within the households of smear-positive index cases. Household contacts would be screened for TB and HIV. Those found to have TB would be treated according to standard guidelines and those willing to have VCT and found HIV-positive would be offered isoniazid preventive therapy.
- d) The fourth step would be to investigate the use of secondary isoniazid preventive therapy for HIV-positive TB patients who have completed antituberculosis treatment. This will require both operational studies and clinical studies, because the evidence base for such an intervention is not strong.
- e) The fifth step is the administration of antiretroviral therapy for HIV-positive patients with TB. This will be done initially just in one district. However, if the lessons are learnt quickly and other districts are in a position to introduce ARV therapy this can be undertaken.

A costed annual workplan will be produced before each year of the plan. This will be based on the current proposal, but will be more explicit in terms of details and the specific districts targeted for implementation activities.

## **TB-HIV ACTIVITIES**

### ***Introduction.***

The TB-HIV activities which are described are those which are needed to fill a “gap” between standard TB activities and HIV activities planned in the application to the GFATM (Global Fund for AIDS, tuberculosis and malaria).

The TB Programme is funded for another 5 years (2002 – 2006) by a consortium of donors (DFID, NORAD and KNCV) working in partnership with GOM. Where there is overlap between standard TB control activities and the activities described in this document this will be made explicit : no extra funding will be requested so that there is no duplication of funding.

A large proposal was submitted to the GFATM, with a request for funding for AIDS care and prevention and malaria control. The current status is as follows. The malaria component was rejected by the Technical Review Panel. The HIV/AIDS component was returned to Malawi for revision. The revision is now complete and the revised proposal was resubmitted to the GFATM in early July. In brief, for the first three years sums of USD\$ 12 million, USD\$ 30 million and USD\$ 44 million have been requested. These amounts cover Voluntary counselling and HIV testing, management of opportunistic infections and use of antiretroviral drugs, and community home-base care and treatment. If the proposal is funded (as seems probable) then funds will be available for these important HIV-TB activities. In the 3-year TB-HIV plan funding will not be requested for these line activities unless explicitly stated.

There are 27 districts in Malawi. The 3-year development plan is a plan to place TB-HIV activities in 7 districts in Malawi in the first year, followed by another 7 districts in the second year with full country coverage in the final year. Because of the complexity of TB-ARV administration, this plan describes the setting up of ARV therapy in one district only. The budget reflects this phased development.

The activities are described in narrative form below. They are also presented in a tabular form after the narrative. The tabular form shows responsibilities, frequency, duration and the source of financing. After the table of activities, the budget is given in tabular form. Each objective with its activities and costing is further described in the Appendices.

### **1. VCT Services for TB Patients and the General Public (Annex 2)**

### 1.1. Integrated hospital-based VCT services in all hospitals

Each hospital will establish a VCT centre with services for ill patients, blood donors, women wanting MTCT services and TB patients. TB patients upon registration will be offered the opportunity for VCT. The resources and costs for VCT services and HIV test kits will be provided by the NAC using GFATM funds.

### 1.2. Stand-alone VCT services in all districts.

Stand-alone VCT sites, situated away from health facilities, will provide entry to VCT and HIV/AIDS services for people who are generally well. This will allow the opportunity for isoniazid preventive therapy if indicated (see below).

### 1.3. Quality of VCT assurance system and supervision.

VCT centres must be able to offer quality assured, confidential HIV counselling and testing services, working according to recognised standards, using rapid HIV testing strategies and staffed by full-time counsellors. Details of how the assurance system will be established are in the country's application to the GFATM. In brief, a national body should become the regulatory body for counsellors, for setting standards and for accreditation. In the three-year plan, provision is made to support two experienced VCT counsellors who have been working in the Lilongwe PROTEST project – these personnel could be used as supervisors in the setting-up of the phased system.

### 1.4. Quality control of HIV testing.

It is essential that HIV test results are highly sensitive and specific, especially as the consequences of a wrong test result for the individual are enormous. QC of HIV testing is also part of the application to the GFATM

### 1.5. Training system for counsellors

Scaling up VCT services will require a great expansion in the number of trained counsellors. The training of VCT counsellors will be institutionalised through a Malawian training institution, such as the Malawi Institute of Management. The VCT sub-group of NAC is taking the lead in this initiative. USAID / CDC is likely to be a key partner taking the lead with MOHP in this area. The MOHP will need to consider whether a new cadre of MOHP staff is required to provide full-time counselling in these services. From experience, the training of existing health care providers has not lead to expansion of VCT services within the MOHP due to the existing workload of these cadres. The extra personnel to be trained through GFATM funds include site counsellors, community based counsellors, VCT supervisors, VCT trainers and whole blood rapid testing personnel.

## **2. Isoniazid Preventive therapy to HIV+ve persons without TB (Annex 3).**

Isoniazid will be offered to people who test HIV-positive provided that TB has been excluded. WHO guidelines will be followed. In brief, isoniazid will be given at a dose of 5mg/kg to a maximum of 300 mg daily for 6 months. The experience gained by the PROTEST project in Lilongwe will be invaluable in planning how this activity should be implemented. There is need for a briefing pack for persons who test HIV-positive who want to take isoniazid prophylaxis.

#### 2.1. Isoniazid provision to stand-alone clinics.

Isoniazid will be procured with other anti-TB drugs on a 6-monthly basis. The amount needed will be based on a situational analysis of the stand-alone MACRO VCT centre in Lilongwe

#### 2.2. Register books to monitor adherence to isoniazid prophylaxis.

Each VCT centre will need a register to record the number of people who have started isoniazid prophylaxis and to follow adherence to the 6-month course of isoniazid. Registers will need to be developed, but again the experience of PROTEST will be invaluable.

#### 2.3. Quarterly reports on persons using isoniazid prophylaxis.

Each VCT site will provide a quarterly report on a) the number of persons accepting isoniazid prophylaxis during three months and b) a report on the course-outcome of persons who were registered for isoniazid 9 months previously. A system of supervision from the NTP to check on reports needs to be set up.

### **3. Cotrimoxazole preventive therapy to HIV-positive TB patients (Annex 4)**

If the MOHP agrees to the principle that all HIV-positive TB patients will be given cotrimoxazole for the duration of anti-TB treatment, then this intervention will be introduced in a step-wise manner to all treatment units. At each treatment unit, a TB patient upon registration will be referred for VCT. If the patient tests HIV-seropositive, this patient will be offered cotrimoxazole provided there are no contraindications. For adults the dose is one tablet twice a day for the duration of anti-TB treatment (ie 8 months). Cotrimoxazole will be provided for one month at a time. Decisions about the continuation of cotrimoxazole after completion of anti-TB treatment await the results of operational research and a decision by the MOHP.

#### 3.1. Procurement of cotrimoxazole

Funds for the phased implementation of cotrimoxazole are already included in the TB 5Year Development Plan. No extra funds will be required

#### 3.2. Storage, transportation and distribution of cotrimoxazole

This is the responsibility of Central Medical Stores and the District Health offices.

### **4. Care and Support for HIV and TB (Annex 5).**

#### 4.1. Identification and Treatment of HIV-related illnesses

Hospitalised TB patients, who are usually those most sick with HIV-related illness, must receive regular weekly ward rounds. HIV-related illnesses should be identified and treated. Health care staff (in particularly 'focal TB' clinical officers and nurses attached to the TB wards) need to be regularly trained in recognition and treatment of HIV-related illness, and their performance in this field needs to be assessed. Training sessions in the diagnosis and management of HIV-related diseases is funded by the NTP under their 5-Year Development Plan. As a result of decentralisation of the initial phase of TB treatment country-wide, health centre staff also need be trained to recognise and manage HIV-related complications in TB patients. The National Unit of the NTP will assist district health offices to include in their Annual Workplans the activity of weekly ward rounds for hospitalised patients as well as up to date training in clinical management.

#### 4.2 Hospital pharmacies with stocks of drugs to treat HIV-diseases

It is essential that the essential basic drugs for managing non-TB, HIV-related complications (for example, pyridoxine, nystatin, codeine phosphate) are available in all hospital pharmacies and DOT centres. These drugs should be available throughout the country as they are all on the Malawi Essential Drugs list, but are frequently out-of-stock in both hospital and health centre pharmacies. In addition, some of the drugs frequently required at health centres (e.g. codeine phosphate, pyridoxine) are currently not recommended by the Pharmacy Board for use at health centres. The aim of this plan is to review and strengthen the provision of these drugs through the Essential Health Package. This requires linking with and supporting the activities to develop the Essential Health Package. The responsibility for purchasing and distributing the drugs remains with MOHP – if funding materialises from the GFATM then part of this will be used for the purchase of drugs. A regular audit will be carried out by the RTOs of the hospital and health centre pharmacies to check on the availability of these drugs, so that the NTP and its collaborators are kept informed.

#### 4.3. Nutritional support for TB patients.

Previously, TB patients would receive enhanced nutritional support while receiving the initial phase of treatment in hospital. Because of economic difficulties, this support has long since stopped. Nevertheless, for the ill TB patient there is often considerable malnutrition, and nutritional support is advocated for those who have to remain in hospital or who want to return to their homes. Funds for nutritional support for people living with AIDS are being requested from the GFATM. However, the TB-HIV plan would particularly like to target TB patients during the initial phase of treatment when patients have their highest levels of malnutrition. Food supplements in the form of high energy milk and Likuni Phala/oil/sugar will be provided – experience in the delivery of food supplements has already been gained in Thyolo District. The TB-HIV Technical Working Group will work closely in this field with the Nutrition Society of Malawi.

#### 4.4. Palliative care for HIV+ve TB patients.

Palliative care may be required for terminally ill patients, and provision for pain-killing drugs will come from GFATM funds.

#### 4.5. Two-way referral systems between hospital and the community.

Home based (HBC) or community based care (CBC) services are important in caring for patients with HIV/AIDS. This applies to HIV-positive patients with TB, where community services may also facilitate the DOT component of anti-TB treatment and ARV treatment. HBC and CBC will be established and strengthened in all districts as part of a continuum of care. The VCT site may serve as the focal point for the link with community volunteers and CBCs. Training materials will be developed, resources made available and volunteers will be trained and supported. Clear referral systems between community and health facilities will be established. Funds for this are being requested from GFATM.

#### 4.6. Active case finding.

Evidence is accumulating both in Malawi and in other countries that household TB transmission occurs with higher rates of TB in household contacts of index TB patients compared with households with no such index case. HIV-positive household members will be at most risk. Operational research will be needed to explore the most efficient ways of providing household contact screening and the interventions which most help household contacts in terms of early diagnosis and treatment of TB and prevention of TB with the use of isoniazid preventive therapy.

### **5. Isoniazid to HIV-positive TB patients to prevent recurrent TB (Annex 6)**

#### 5.1. Clinical studies to determine efficacy.

Efficacy of this approach has only been demonstrated in Haiti. Nevertheless, recurrent TB constitutes 10% of the case load in Malawi and ways to reduce this problem need to be found. Isoniazid preventive therapy is one possible solution. With external collaborators, appropriate clinical studies will be designed and implemented to explore the efficacy of giving isoniazid to HIV-positive patients for a period of time after completion of anti-TB treatment.

#### 5.2. District feasibility and effectiveness studies.

Discussions will need to be held with interested stakeholders about the need to concurrently proceed with feasibility and effectiveness studies at district level. A district which already has a well functioning TB Programme, has an established VCT service with links to the community will be considered.

### **6. Anti-retroviral (ARV) therapy to HIV-positive TB Patients (Annex 7)**

ARV therapy is the intervention most likely to have an impact in reducing morbidity and mortality in HIV-positive patients. Funding for ARVs has been requested as part of the application to the GFATM. ARV therapy will only be implemented in a district which has VCT services set up and a package of care which includes prevention and treatment of HIV-related diseases, links with HBC and CBC, nutritional support etc. Initially one district only will be piloted.

VCT with a positive HIV-serology test is an essential entry point to ARV therapy. The system may work like this. HIV+ve TB patients will take cotrimoxazole and return home for the initial phase of anti-TB treatment. No ARV drugs will be given at this stage. At two months, the patient returns to the hospital and sees the focal TB clinical officer on the TB ward. Smear+ve patients submit 2-month sputums at this stage. The patient is assessed and changed to continuation therapy by the focal TB officer, who has TB treatment cards. The patient is given one month supply of anti-TB drugs. The patient is assessed for ARV drugs. Details are entered to the TB-ARV register and the patient is given one month supply of ARV drugs. The patient goes home and returns every month to the TB ward to collect anti-TB drugs and ARV drugs. At the end of anti-TB treatment, the TB treatment card is returned to the TB office and the patient is referred to the general ARV clinic to continue ARV therapy.

The main problem with this approach is that it is hospital-centred. However, plans will be looked at for putting ARVs into health centres once the hospital system is up and running.

#### 6.1. Procurement of ARVs.

The following principles can be adopted. The regimen should be triple therapy, given preferably once a day and be associated with the least number of side effects. It might be sensible to include a drug with a high resistance threshold, for example didanosine (ddl), although this would require further discussion. Protease inhibitors are associated with a multitude of side effects, and because of interactions with anti-TB drugs, are best avoided in Malawi with a high HIV-TB burden. The likelihood is that the regimen will consist of 2 nucleoside reverse transcriptase inhibitors (NRTI) and one non-nucleoside reverse transcriptase inhibitor (NNRTI). The best regimen has yet to be decided.

Consideration must be given to the management of HIV-positive patients with TB: NNRTIs being contraindicated with rifampicin. It is likely that dual ARV therapy with two NRTIs will be given during the initial phase of anti-TB treatment, which includes rifampicin, and triple therapy will be re-introduced in the continuation phase of anti-TB treatment when just isoniazid and ethambutol are given. All TB patients would be eligible for ARV therapy; the main question would be the optimal time to introduce this adjunctive treatment.

A second line regimen must be drawn up at this stage for two reasons. First, in case patients develop anaemia, pancreatitis, hepatitis etc which prevents them

from taking the first line regimen. Second, a regimen is needed in case of ARV drug failure.

A plan of how to manage side effects, how to recognise treatment failure, and when to change from the first line regimen to a second line regimen must be developed.

The regimens must be standardised. If patients are unable to take both the first line and second line regimen because of adverse effects, then they are not suitable for ARV therapy.

ARV therapy in HIV-positive TB patients: Due to the complexities surrounding ARV therapy, initially one district would pilot the administration of ARV to TB patients and the expansion of this intervention would move at a slower pace than other interventions. In the pilot district, the approach would be to a) assess patients on clinical grounds for their suitability for starting ARV therapy and b) monitor side effects on clinical grounds. Sophisticated laboratory monitoring using CD4-lymphocyte counts and viral RNA levels would be beyond the capabilities of districts. Monitoring of liver function tests would also be beyond district capabilities. HIV-positive TB patients are already by definition in the WHO-AIDS category Stage 3 or 4, and this is already acceptable for starting ARV therapy according to WHO guidelines (Scaling up antiretroviral therapy in resource-limited settings – Guidelines for a public health approach. WHO, April 2002). Guidelines will be followed – for example, minimum laboratory tests required before initiating ARV therapy are an HIV-antibody test and a Haemoglobin level.

#### 6.2. / 6.3. Clearing / storage / transport and distribution of ARVs.

It is will be essential to put in place appropriate measures to assure safe procurement, clearing/ handling, storage, transportation and distribution of ARVs to the appropriate treatment units. Drug security will be an important issue and will need to be monitored

#### 6.4. Delivering ARVs to patients.

HIV-positive patients with TB will be eligible for ARV therapy. The optimal timing of when to start ARVs will be determined by discussion with experts and operational research. Once patients have started on ARVs, this therapy will be for life. In this plan, ARV drugs will be given to patients after the end of the initial phase of treatment.

#### 6.5. Recording and monitoring ARVs.

At the time of starting ARVs, all relevant patient details will be entered into specially designed registers. Patients will be given 30 day supplies of ARVs and

will be followed up every month. At each follow-up visit, there will be a clinical assessment, measurements of weight, a provision of another 30 days supply of drugs and a mechanism put in place for tracing defaulters. CD4 counts and viral load measurements are too difficult and expensive to set up at district level. The details of how this system will run need to be worked out. A system of monitoring drug use in relation to the number of patients on therapy is also essential in order to safeguard ARVs and prevent abuse of the system. An effective system will be developed for ARVs.

#### 6.6. Training courses on ARV use.

A package of training materials will need to be developed for health care staff involved in ARV and AIDS care. External technical assistance may be required for this. Training will be linked to an examination system, and staff will not be allowed the responsibility of managing ARV drugs unless they have satisfactorily passed an examination.

## 7. TB-HIV Management (Annex 8)

### 7.1. Human resources increased at all levels.

If TB-HIV activities are to be developed and implemented, and especially if VCT services are to be expanded new and increased numbers of staff will be required.

A TB-HIV officer will be needed in the NTP to provide the necessary collaboration with NAC – a position has already been requested in the 5-Year Development Plan. However, there is no guarantee that this position will be funded. The officer is absolutely essential in order to provide leadership and co-ordination of TB-HIV activities on the ground. There is also the need for secretarial and data management support. It is proposed that at the end of the project that the TB/HIV officer undertakes a masters course.

Technical assistance may also be required for advising on and implementing activities on the ground, especially in the field of implementation research.

A new cadre of counsellors will be needed, and a cadre of experienced counsellors to provide training and supervision. The two experienced counsellors, who are currently working with the PROTEST project in Lilongwe, will be needed for then first three years of this TB-HIV plan. For quality control of HIV testing and monitoring of ARV drug resistance, the CHSU laboratory unit should be the focal point. CDC are interested in supporting this initiative.

The terms of reference for each of these staff members are in **Annex 8**.

### 7.2. TB-HIV Technical Working Group.

The TOR for the TB-HIV Technical Working Group are shown in **Annex 9** . The chairman of this group will be the director or a senior member of the Department of Clinical Services, MOHP. This group will meet every 8 weeks to discuss all the ongoing activities of the TB-HIV plan according to its terms of reference. Minutes will be made and distributed to interested parties.

Provision will be made for members of the Technical Working Group to attend conferences (2 pax per year), for local training courses for secretarial and data management training and for attending relevant courses (2 pax per year) for implementing TB-HIV activities ( eg, management of ARV therapy).

### 7.3. TB-HIV Finance Meetings.

Core members of the TB-HIV Technical Working Group will meet every quarter in the first week of every quarter to review the financial ledgers of the TB-HIV programme plan and to determine inputs, expenditures and balances. A report will be circulated to interested parties. In line with the system in the NTP, public auditors (KPMG) will provide a quarterly audit of accounts. The finance group will work with KPMG towards developing targets for good financial management.

### 7.4. Costed Annual Workplans.

Before each financial year, the TB-HIV Technical Working Group will meet to prepare and agree an annual costed workplan based on the TB-HIV 3-year plan. This annual plan will be submitted to the Steering Group for approval. Amendments , additions and subtractions will be incorporated into the plan, which will be ready for implementation before the financial year begins. The system will be planned so that it fits in with the Malawi Financial Year, which runs from July to June. The workplan will be developed in March or April, and submitted to the Steering Group in May. An amended workplan will be produced within three weeks of the Steering Group, ready for implementation in July.

### 7.5. District Implementation Plans

It is essential that TB-HIV activities are included in the DIPs of each district. These plans are also developed in March or April of each year. Practical modalities will be worked out for ensuring that this process is functional and that districts which are nominated in each phased introduction of TB/HIV activities are including costed TB-HIV activities. Monitoring and evaluating mechanisms need to be built into these DIPs.

### 7.6. 6-monthly and annual reports.

Reports shall be written every 6 months. The 6-monthly report will be ready by end of February, and submitted to the Steering Group for their meeting in April/ May. The annual report will be ready by end of August, and submitted to the Steering Group for their meeting in October. The production of the report is the responsibility of the TB-HIV Technical Working group.

#### 7.7. Position papers.

From time to time the TB-HIV Technical Working group will take the initiative and write position papers on issues relating to TB-HIV. This will extend to results of operational research which influence policy and practice. These are to be discussed with senior MOHP officials.

### **8. Operational Research (Annex 10)**

Operational research has become integrated into the NTP, and such research will also become integrated into the TB-HIV 3 year plan. Research is carried out in relation to objectives of the programme, and as such much of the research output can be fed into policy and practice. Care will be taken to ensure that TB-HIV activities are integrated into the routine services, with no special research inputs with regard to actual delivery of the services. The research component will require additional resources for monitoring and properly evaluating the outputs of the interventions.

Operational research requires experience in both disease control and research methodology. A technical advisor (see above) would provide an important role in this regard.

*Surveys:* During the 3-year period, it is likely that the NTP will carry out another country-wide survey assessing HIV-seroprevalence of TB patients (the most recent survey was carried out in 2000).

*Operational Research:* An operational research agenda will be developed into the workplan for each year, based on constraints and problems that have arisen during the implementation of TB-HIV activities. A key area, identified by the NTP in its 5 year development plan, includes reducing case fatality rates with adjunctive treatments and reducing the rate of recurrent TB.

## **9. Monitoring and Evaluation (Annex 11)**

### 9.1. Routine TB-HIV monitoring and reporting systems.

The routine systems used by the NTP will be further developed for TB-HIV activities. Supervision is a crucial factor in ensuring quality of performance, and ways of linking NTP supervision systems with those proposed for the Comprehensive AIDS Care Programme need to be worked out. Supervision will be needed around the country. A vehicle with driver and costs for maintenance and fuel will be needed.

### 9.2. Financial Audit.

Every quarter a public auditing company (KPMG) will audit the TB-HIV accounts. The system used by the NTP will be followed. NTP provides a financial quarterly report of incoming funds, expenditure and balance of funds to KPMG one week after the quarter has finished. This report is accompanied by a financial request to the donors for funding of the quarter which is starting 3 months ahead. KPMG audit the accounts and report back to NTP with comments and queries. Once these comments or queries have been dealt with satisfactorily, the documents are signed off at MOHP and forwarded to the donors.

### 9.3. Steering Committee Meetings.

The TB-HIV Steering Committee will meet twice a year to monitor and evaluate the reports submitted by the TB-HIV Technical Working Group. The composition and function of the Steering Group, along with the terms of reference have been drawn up (see **Annex 12**).

### 9.4. Annual review meeting.

At the end of each year there will be an annual review meeting of 2 days to discuss and review progress.

## **BUDGET**

### **1. Budget Plan for the years 2003-2005**

The budget for each year and for the whole three years is shown in Tabular Form on pages 39 - 44. The Annexes explain how the budget is calculated for each specific objective and activity. The TB programme has already been pledged a rolling budget for the next five years, and with the application to the GFATM funds should arrive for HIV/AIDS activities. However, a budget is calculated for specifically managing HIV+ve TB patients.

### **2. Budget details.**

The 3-year expenditures in relation to each objective and set of activities is as follows:-

	USD\$
VCT Services	45,400
Isoniazid Preventive therapy	32,300
Cotrimoxazole preventive therapy	0
Care and Support	80,000
Prevention of recurrent TB	160,000
ARV therapy	0
TB-HIV Management	161,600
Operational Research	180,000
Monitoring and Evaluation	200,400
<b>Total Budget</b>	<b>859,700</b>

The budget assumes that VCT services plus training (with the exception of the two counsellors currently supported under PROTEST), HIV drugs and ARV delivery with training/ registers etc will be covered with GFATM funds.

The total 3-year TB-HIV budget will be USD\$859,700.