PUTTING RESEARCH INTO POLICY AND PRACTICE:
THE EXPERIENCE OF THE MALAWI NATIONAL TUBERCULOSIS PROGRAMME

THE COMMUNICABLE DISEASES CLUSTER OF THE WORLD HEALTH ORGANIZATION
Table of Contents

1 Summary

7 Background

11 TB Control in Malawi

14 HIV and Tuberculosis in Malawi

17 TB Research in Malawi

24 The Research Agenda: Putting the Results into Policy and Practice

35 Judging the Success of the Research Programme

37 Factors Contributing to the Success of the Research Programme

40 The Future
Summary  Malawi, a small, landlocked country in south-central Africa, has always placed a high priority on the prevention, control and treatment of tuberculosis. In its first year of independence from Britain in 1964, the new Malawi government established a National Tuberculosis Control Programme (NTP) to control TB through active case finding, treatment and prevention.
Today, even though its 11 million people struggle daily with poverty, disease, and a daunting lack of resources, Malawi's tuberculosis programme is seen by many as a model for sub-Saharan Africa.

"Tuberculosis is the biggest single cause of adult illness and death from communicable disease in Malawi," says National TB Programme Manager Felix Salaniponi. "We had 20,000 new TB cases last year, and about 8,000 people died from it. Many of these people are dying in their most productive years. It is an important problem."

Malawi was one of the first countries in the world to implement short-course, directly observed treatment (DOTS) for tuberculosis. In 1984, with assistance from the International Union against Tuberculosis and Lung Disease (IU- ATLID), Malawi adopted DOTS for treatment of smear-positive cases and initiated a country-wide standardized reporting and evaluation system. By 1986, DOTS was the standard of treatment for smear positive cases throughout Malawi.

"Apart from Tanzania, Malawi has been one of the pioneers in DOTS," says Salaniponi. "The whole country was covered in three years."

The results were dramatic. Cure rates in new smear-positive pulmonary TB cases rose from 74 percent in 1984 to 90 percent in 1987, and death rates decreased from eight percent to six percent. Officials were hopeful that tuberculosis would soon be controlled in Malawi.

"People saw that patients got better quite fast," says Salaniponi. "The mortality rate was going down, and the message got around—this was a treatment that worked."

But the optimism was short-lived.

In 1985, Malawi reported its first case of AIDS. A study of TB patients in 1986 found that 25 to 30 percent were HIV positive. Since then, the country has been swept by an explosive epidemic of HIV infection and AIDS. HIV-seroprevalence rates among sexually active adults in urban areas are estimated to be as high as 30 to 40 percent.

The effect of HIV on the incidence of tuberculosis in the country has been dramatic. In 1985, there were 5,334 new TB cases reported. By 1995, the number had risen to 19,155. The cure rate for TB declined to 63 percent in 1996, and the death rate climbed to 21 percent. HIV-seroprevalence among TB patients now stands at about 75 percent of new cases.

Malawi's healthcare system has strained under the load. Congestion in some TB wards in the country has reached levels of three to four patients for each bed. Small, understaffed hospital laboratories have had difficulty coping with the increased numbers of sputum specimens. Morale began to fall among TB Programme staff, and donors threatened to withdraw support unless performance improved.

In 1994, recognizing the need to analyze and address the problems facing Malawi's TB programme, the Malawi Ministry of Health and Population and WHO's Global Tuberculosis Programme asked Dr. Anthony Harries, then a Professor of Medicine at the College of Medicine in Blantyre, to serve as a technical advisor to the NTP. Harries spent the next nine months working with NTP officers at the central, regional, district and local levels and performing district assessments with the assistance of the regional TB officers.

DEFINITION OF TREATMENT OUTCOMES AT THE END OF SHORT COURSE CHEMOTHERAPY

Cured: patient who completes treatment and who is smear negative at one month prior to the completion of treatment and on at least one previous occasion.

Treatment completed (Rx.Comp): patient who completes treatment but in whom smear examination results are not available on at least two occasions prior to the completion of treatment.

Fail: patient who remains or becomes again smear-positive at 5 months or more during treatment.

Died: patient who dies during treatment regardless of cause.

Defaulted (Default): patient who at any time after registration has not collected drug for two consecutive months or longer.

Transfer out: patient who has been transferred to another unit and the treatment outcome is not known.

Source: AD Harries

In a resulting report submitted to the Ministry of Health and Population (MOHP) in 1995, the NTP was praised for what it was able to achieve under the combined constraints of a lack of resources and the burden of the TB/HIV co-epidemic. However, the report indicated that performance and outcome indicators could be improved if problems such as laboratory performance; diagnosis, treatment, and education of patients; and staff supervision, training and morale were addressed.

The report concluded that the NTP should develop operational research projects to provide data to help solve prob-
CONRAINTS ON THE MALAWI NTP IN 1995

- **Diagnosis:** A large proportion (up to 30%) of smear-positive patients in some districts diagnosed in the laboratory register who were not being registered and placed on treatment; improper use of chronic cough registers; long delays in the diagnosis of smear-positive TB patients who were admitted to hospital with risk of nosocomial transmission to health care workers; too many smear-negative TB patients related to sputum smears never being examined chest radiographs being incorrectly interpreted; in one district (Zomba) a large number of prisoners being registered and treated for PTB.

- **Treatment:** Congestion of patients in TB wards who were receiving initial phase of treatment (particularly noted in the urban hospitals); improper directly observed treatment with rifampicin; no follow-up of patients with smear-negative PTB and extrapulmonary TB; increasing numbers of private practitioners in Blantyre and Lilongwe who were diagnosing and treating TB patients.

- **Laboratories:** Irregular supply of slides; poor precautions observed by personnel when preparing smears; too little time spent examining smears; short-cuts (i.e., only one out of 3 sputum specimens from each patient actually examined); insufficient numbers of laboratory staff; poorly maintained equipment.

- **Education:** Lack of formal education sessions for patients by the district TB officers.

- **Supervision:** Lack of regular supervision by regional TB officers because of no resources; lack of supervision of health centres by district TB officers because of no motor-cycles and no fuel; lack of a unified supervisory check list.

- **Training:** No regular training seminars for health centre staff or for influential community members such as traditional healers and village headmen.

- **Communications:** Poor communication between all levels of the NTP; no computers to assist in the collating and disseminating of information.

- **Documentation:** Incomplete documentation of the laboratory and TB register.

*Source: AD Harries*

TB Ward, Queens Hospital, Blantyre

In September 1995, the NTP submitted a project proposal to the Overseas Development Administration—now called the Department for International Development (DFID)—in the UK. The proposal highlighted the problems and constraints facing the NTP and set a number of long term project goals: 1) to demonstrate at a national level that TB control could be sustained in the face of HIV infection; 2) to develop a proper career structure for NTP staff and provide NTP staff with the necessary resources to carry out their jobs; 3) to develop a comprehensive training programme, particularly at health centres and in the community and; 4) to carry out high-quality operational research and train a cadre of local medical and paramedical health personnel with the necessary technical expertise for this work.

The strategy of the research agenda was to better define— with data—the problems of TB control in Malawi and to try out interventions to solve these problems. The NTP's goal

---

The Communicable Diseases Cluster, provided financial and advisory support for several projects during the first six months of 1995. The preliminary results from these studies strengthened the proposal that was being developed for additional donor assistance.

**First Steps**

To help launch the NTP's operational research programme, WHO's Global Tuberculosis Programme, now housed in 3 COMMUNICABLE DISEASES CLUSTER
was to improve the diagnosis, care, and access for TB patients by translating the results of the research into policy and practice. This integrative approach has become central to the way Malawi's TB programme thinks about research.

DFID approved the proposal and support for the NTP commenced in September 1996.

Results

The ultimate test of the effectiveness of Malawi's operational research programme is in the improved performance of its National Tuberculosis Programme. Research is only useful if it delivers practical results that can be measured by programme performance and patient outcomes.

By 1997, many of the problems related to case finding in Malawi had been defined and measures put in place to counter some of the substandard practices at the local and district level.

Today, Malawi has begun to see a leveling off in case notifications after 10 years of steady increases. In 1995 and 1996, case notifications were 19,155 and 20,630 respectively. In 1997, case notifications reached 20,676.

In 1998, case notifications increased to 22,674 total cases, of which 8,765 (39%) were smear-positive cases. In 1998, considerable efforts were made by the NTP to improve case finding, especially of smear-positive PTB cases, by educating up to 1600 traditional healers in TB case finding, supporting health centre training, supporting health centre supervision by district TB officers, and by supporting RTO supervision of districts.

As a result of improved case finding and diagnosis, smear-positive cases exceeded smear-negative cases for the first time in nearly ten years. In 1997, there were 7,587 notified cases of smear-positive PTB and 7,481 cases of smear-negative PTB. The proportion of cases due to extrapulmonary TB also decreased from 27 percent in 1995 to 25 percent in 1997. These are encouraging trends and probably reflect the efforts of the NTP in motivating personnel and staff to adhere to TB control guidelines.

The national cure rate in smear-positive TB cases has begun to inch up from 63 percent in 1992 to 65 percent in 1995. However, this cure rate is severely affected by the very high death rate—12 percent in 1992, 19 percent in 1995, and 21 percent in 1996—which is largely attributable to HIV. Operational research in Malawi has also led to policy changes within the NTP.

### Costs for Some TB Research Activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>Cost: US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence of Tuberculosis in Zomba Prison</td>
<td>700</td>
</tr>
<tr>
<td>Testing different strategies for diagnosis of pulmonary TB suspects</td>
<td>4000</td>
</tr>
<tr>
<td>Assessment of urban decentralization in Blantyre</td>
<td>400</td>
</tr>
<tr>
<td>Prevalence of sexually transmitted diseases in TB patients and controls</td>
<td>60</td>
</tr>
<tr>
<td>District operational research 1997:</td>
<td>7500</td>
</tr>
<tr>
<td>- accuracy of chest x-ray diagnosis</td>
<td></td>
</tr>
<tr>
<td>- profile of laboratories</td>
<td></td>
</tr>
<tr>
<td>- risk of TB in health care workers</td>
<td></td>
</tr>
<tr>
<td>- health centre sputum service</td>
<td></td>
</tr>
<tr>
<td>- registration of smear-positive PTB</td>
<td></td>
</tr>
<tr>
<td>Assessment of true defaulter status in Blantyre district</td>
<td>2000</td>
</tr>
</tbody>
</table>

Source: AD Harries
One recent development is the decentralization of Malawi's DOTS programme. Supervised TB treatment is now being decentralized from the hospital to the local level, with local healthcare workers and family members—known as "guardians"—responsible for treatment supervision. Guardian-based treatment is still being evaluated in 5 pilot districts in Malawi, but it looks to be a very promising community-based approach.

In 1997, the NTP produced a three-year development plan that defined certain targets to be reached by the year 2000: 1) an increase in the cure rate of smear-positive PTB cases from 65 percent to 75 percent; 2) registration and treatment of more than 95 percent of smear-positive PTB cases that are diagnosed and recorded in the laboratory register; 3) an increase in the percent of newly detected cases of smear-positive PTB as a proportion of all PTB cases from 46 percent to more than 55 percent; 4) a decrease in the percent of cases with extrapulmonary TB from 27 percent to less than 25 percent; 5) a treatment completion rate of 70 percent for smear-negative patients.

**Factors Influencing Success**

The effectiveness of Malawi's TB research programme can be attributed to the combined influence of several factors:

**A strong National TB Control Programme:** The Government of Malawi has made a strong commitment to a well-structured National Tuberculosis Control Programme. The NTP, supported for many years by the IUATLD, is a strong programme with standardized practices, diagnosis and treatment outcomes. Staff from the central unit to the regional and district levels are well trained in TB control activities, and this enables reasonably accurate data to be collected on case finding and case treatment.

**Advocacy:** The Controller of Preventive Services, the TB Programme Coordinator, and the TB Programme Manager have been strong advocates for incorporation and integration of operational research into the overall TB programme. This advocacy has been an important factor in motivating MOHP and NTP staff to accept research as an established part of the NTP.

**Incorporation into the NTP of a senior medical doctor with research experience:** The presence of a senior medical doctor with 15 years of experience in clinical research has helped the NTP develop research ideas and translate these ideas into protocols that can be implemented in the field. His experience in writing proposals has been particularly useful in preparing an operational support and research proposal for a major international donor.

**Financial support:** The major capital outlay incurred in setting up a research programme is the establishment of a central base equipped with furniture, office equipment, computers, software, transport capability, and supplies. Initial funding for this was provided to the College of Medicine in 1994 by the WHO Global Tuberculosis Programme. The cost was approximately USD$ 25,000.

In 1996, DFID also provided funds for setting up the central and regional units with office equipment and transport. Motorcycles and bicycles—of great assistance in the implementation of many operational research initiatives—were also given to districts for TB supervision. The budget for four Landrovers, 35 motorcycles, 100 bicycles, five computers, software, one photocopy machine, one overhead projector, and supplies was approximately USD$ 250,000.

The research activities themselves are relatively inexpensive to carry out.

**Technical support:** Technical support and research advice from international organizations such as IUATLD and WHO has been invaluable in helping the NTP to develop research ideas, plan studies, analyse results and write research papers.

**Recruitment of good local staff:** Initiative, drive, integrity and a love of hard work are important qualities in a good research officer. Two clinical research officers were selected for the initial WHO-supported research studies carried out in the medical school in Blantyre. Similarly, appointment of a national TB officer at the central unit and a clinical research officer for one district in each region assisted in expanding the research base.
The extra funding provided for operational research has made it possible to give allowances to NTP staff who assist in collecting data. In a country where monthly salaries are low, financial incentives for extra work that is done well—without neglecting routine duties—can be an important motivation. These allowances are presented in the form of awards at national meetings or workshops.

However, the availability of local human resources remains a concern. The NTP hopes to provide further in-country training for TB officers who have performed well in small, operational research projects so that they can develop their skills further.

The Future

The MOHP has recently developed a strategic health plan in which the NTP has set out its policies and objectives for the next five years. (Table 25) Donors have been approached for resources needed to carry out some of the research, and support has come from the Department for International Development (DFID) in the UK, the Royal Dutch TB Association (KNCV), and the Norwegian Agency for Development Cooperation (NORAD).

Malawi’s NTP Programme representatives feel hopeful about the continued effectiveness and success of the operational research programme. They feel, too, that the programme can serve as a useful model for other national TB programmes, as well as for other disease control programmes in Malawi.

“We are one of a few countries in Africa whose programme has matured,” says NTP Programme Manager Salaniponi. “We bring a lot of experience, and we hope to contribute to a new regional effort at TB control. I think we can assist other countries by saying, ‘This is what we did when we had this problem.’”

“You have to remember that Malawi is one of the poorest countries in the world. We have enormous problems—and a big burden of disease—all reasons why people should say, ‘It won’t work in Malawi.’

“But our programme works well, and we have been able to demonstrate to the international community that it works. So, if this works in Malawi—and we have all these problems like HIV and a scarcity of funds—then countries that are better off than us should find it feasible to do. The same methods should work anywhere in sub-Saharan Africa.”
Background  Malawi—"the warm heart of Africa"—is a small, landlocked country that lies between Tanzania, Zambia and Mozambique in south-central Africa. About 900 kilometers (kms) from north to south and 80 to 100 kms from east to west, Malawi occupies a narrow, elongated plateau on the edge of the Great Rift Valley. Lake Malawi, the third largest lake in Africa, comprises one-fifth of Malawi's 120,000 sq. kms.
A poor and crowded country whose 11 million people struggle daily with poverty, disease, and a daunting lack of resources, Malawi ranks 157th out of 174 in the UNDP human development rank index, a compound indicator that considers economic as well as social parameters.

There are nine main ethnic groups in Malawi, complemented by a small but economically important Indian community and an even smaller European community, most of whom are involved in diplomatic, missionary, volunteer or agricultural work.

Malawi’s population—fifty percent of whom are under 15 years of age—is growing at an annual rate of 3.3 percent. The literacy rate is 54.7 percent, although the rate for women is substantially lower.

Malawi’s staple food—and most important agricultural product—is maize.

**Economy**

Almost 90 percent of Malawi’s population live in rural areas and work mainly as subsistence farmers. Of an estimated workforce of three million, less than half are in paid employment. The average monthly salary of an employed worker is US$35.

According to the 1996 UNDP Human Development Report, the gross domestic product for Malawi was US$210 per annum, 2.9 percent of which was spent on public services. Agriculture accounts for 40 percent of GDP and 90 percent of export revenues.

Malawi suffered a severe economic slump in the 1980s that has been partially reversed by structural adjustments in the economy. However, the resulting growth has done little to reduce poverty, and half of the population still lives below the poverty line.

### SELECTED HEALTH INDICATORS FOR MALAWI: 1993

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Figure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Crude death rate</td>
<td>21 per 1000 person years</td>
</tr>
<tr>
<td>Crude birth rate</td>
<td>55 per 1000 person years</td>
</tr>
<tr>
<td>Total fertility rate</td>
<td>7.6</td>
</tr>
<tr>
<td>Contraception prevalence rate</td>
<td>13</td>
</tr>
<tr>
<td>Infant mortality rate</td>
<td>134 per 1000 live births</td>
</tr>
<tr>
<td>Child mortality rate</td>
<td>234 per 1000 live births</td>
</tr>
<tr>
<td>Maternal mortality rate</td>
<td>170 per 100,000 live births</td>
</tr>
<tr>
<td>Life expectancy at birth (yrs)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>41.4</td>
</tr>
<tr>
<td>Female</td>
<td>44.6</td>
</tr>
<tr>
<td>Government expenditure on health (per annum)</td>
<td></td>
</tr>
<tr>
<td>% of total budget allocation US$ per person</td>
<td>70.44</td>
</tr>
</tbody>
</table>

Source: AD Harries
Humanitarian aid and donor support for Malawi were resumed following the 1994 multi-party elections. However, the economy has remained unstable, with an inflation rate of 37.6 percent for 1996. The price of food and fuel rose sharply in 1998 following a currency devaluation.

**Administration**

Malawi is divided into three separate regions—north, central and south—and twenty-six districts—five in the north, nine in the center and twelve in the south.

Malawi’s capital, Lilongwe, is also the administrative center for the central region and the national headquarters of government departments. Blantyre, the largest city in the country, is the capital of the southern region. Muzu is the administrative center of the northern region.

The central government administration oversees the regional centers, which in turn oversee the districts. Within each district there are varying numbers of traditional authorities administered by traditional chiefs. The smallest administrative unit is the village, which has a headman appointed by the community.

**Health Services in Malawi**

By any standard, Malawi has very poor health indicators. Health care is primarily provided through the Ministry of Health and Population (MOHP), Ministry of Local Government, or nongovernment—primarily Christian mission—health facilities. In addition, some government departments, companies and estates maintain clinics for employees and their families. Malawi also has an extensive network of traditional medical practitioners, often the first stop in the healthcare system for Malawians.

The MOHP has the same administrative structure as other government departments, with central, regional and district administrative levels. Each level reports to the level directly above.

Malawi adopted a primary health care approach in 1979, and there is an extensive integration of health service delivery following the primary health care model.

There are three tertiary referral hospitals—one in each of the urban centers of Blantyre, Lilongwe and Zomba—that also serve as district hospitals for their respective districts. The other 23 districts have Ministry of Health district hospitals in the major town of the district.

In the rural areas, there is an extensive system of government-run health clinics that are administered by the Ministry of Health or by the local government. The Ministry of Health clinics offer all services free of charge, while there is a nominal fee for services at local government facilities. The primary clinical staff at these facilities are paramedical clinical officers and medical assistants who are supported by both state-registered and enrolled midwife nurses. A growing number of national medical officers complement a dwindling cadre of expatriate doctors.

Staff at technical assistant grade provide most of the support services, including running the pharmacy. Environmental staff—health inspectors, health assistants, community health nurses and health surveillance assistants—are represented at all levels of the system. Civil service regulations provide for staffing positions by specific categories.

The Christian Health Association of Malawi (CHAM)—responsible for nearly 40 percent of health service delivery in Malawi—is the umbrella organization for most of the nongovernmental organizations involved in the health sector. Most CHAM institutions—district-level hospitals, smaller hospitals and health centers—are located in rural areas. All charge fees for services, although some services, including tuberculosis treatment, are offered free of charge.

Traditional healers play an important role in health delivery because of their geographic and cultural accessibility and historic role. Most people use the traditional sector and the allopath-
ic sector simultaneously or consecutively, and they are often perceived to complement each other. Very few attempts have been made to bridge the traditional sector with the allopathic sector. There are several types of traditional healers, including traditional birth attendants and sin'gana (traditional healers), who are required to be licensed by the government.

**Structure of the Malawi National TB Control Programme (NTP)**

Malawi’s Ministry of Health and Population (MOHP) is headed by a Principal Secretary, with an administrative wing headed by a Principal Secretary (administration) and a technical wing headed by the Chief of Health Services.

The NTP is one of the technical programs of the Community Health Science Unit (CHSU) under the Controller of Preventive Services. A TB reference laboratory is part of the Public Health Laboratory which is another component of CHSU. Both the TB laboratory and the NTP are part of the same unit, CHSU, and this allows an easy and direct collaboration.

The NTP is organised on a three-tier system: central, regional and district. (Figure 4) Central and regional levels support the district level, where TB activities are fully integrated.

Until 1996, the NTP’s central level was staffed by a programme manager assisted by a clerk and supported by CHSU general office staff. There is also a position of NTP Coordinator, a senior MOHP doctor who previously directed the TB programme and acts as an advocate and an adviser to the NTP.

Both the programme manager and the NTP Coordinator fall under the umbrella of the Controller of Preventive Services.

The TB programme manager and all his regional TB staff are clinical officers — paramedical officers with four years of training. The district TB officers come from the health assistant level, i.e., two years of training, primarily in public health.

---

**Central TB Unit**
- reference laboratory
- evaluation, coordination, supervision and training
- drugs and supplies

**Regional TB Officers (RTO)**
- evaluation, supervision and training
- regional drugs and supplies

**District TB Officers (DTO)**
- registration
- case holding and cure
- district drugs and supplies
- recording and reporting
- supervising health centre staff

**Multidisciplinary Health Centre Staff**
- sending TB suspects or their sputum for investigation
- provision of treatment services
- tracing defaulters
- keeping patient records for the DTO
- health education

*Source: AD Harries*
TB control in Malawi  History of Tuberculosis Control in Malawi. Malawi has always placed a high priority on the prevention, control and treatment of tuberculosis. Malawi's National Tuberculosis Control Programme (NTP) was established in 1964, shortly after the country's independence. The University of North Carolina provided assistance in the form of drugs, equipment, and transport. The goal of the programme was to control tuberculosis (TB) through active case finding, treatment and prevention. However, because each district operated independently, the programme lacked coordination.
In 1969, a tuberculosis control unit and central registry were established at the MOHP headquarters. The goals of this unit were to coordinate activities in the districts and provide on-going analysis of TB cases in the country. The TB Control Unit was directed by a newly appointed TB Control Officer and was strengthened by the appointment of regional TB officers to supervise and coordinate activities in the districts.

Malawi was one of the first countries in the world to implement short-course, directly observed treatment (DOT) for tuberculosis.

In 1984, the International Union against Tuberculosis and Lung Disease (IUATLD) provided drugs for short-course chemotherapy of smear-positive TB cases and established a standardized reporting and evaluation system in all districts of the country. IUATLD continued to provide technical advice until the end of 1998, and continues today through different organizations.

By 1986, DOTS was the standard of treatment for smear-positive cases throughout Malawi.

The results were dramatic. Cure rates in new smear-positive pulmonary TB cases rose from 74 percent in 1984 to 90 percent in 1987, and death rates decreased from eight percent to six percent.

But in 1985, Malawi reported its first case of AIDS. A study of TB patients in 1986 found that 25 to 30 percent were HIV positive. Since then, the country has been swept by an explosive epidemic of HIV infection and AIDS. HIV seroprevalence rates among sexually active adults in urban areas are estimated to be as high as 30 to 40 percent.

The effect of HIV on the incidence of tuberculosis in the country has been dramatic. In 1985, there were 5,334 new TB cases reported. By 1995, the number had risen to 19,155. The cure rate for TB declined to 63 percent in 1996, and the death rate climbed to 21 percent. HIV-seroprevalence among TB patients now stands at about 75 percent of new cases.

Malawi's healthcare system has been severely strained under the load. Congestion in some TB wards in the country reached levels of three to four patients for each bed. Small, understaffed hospital laboratories had difficulty coping with the increased numbers of sputum specimens.

Diagnosis and Registration of TB Cases

The NTP uses a system of passive case finding. TB suspects are either screened in an out-patient setting or are admitted to hospital for investigation. Adult pulmonary tuberculosis (PTB) suspects submit three sputum specimens for smear microscopy for acid-fast bacilli (AFB). Patients who are sputum smear-positive for AFB are classified as smear-positive PTB and, in most cases, no further investigations are carried out.

In patients who are sputum smear-negative, routine chest radiography is performed and a diagnosis of smear-negative PTB is made on 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 contact with an adult case of PTB.

Patients (adults and children) with extrapulmonary TB (EPTB) are usually admitted to hospital for investigation.

Malawi's TB registration and recording system is centered around district tuberculosis registers. The registers—generally well kept and accurate—are maintained by District Tuberculosis Officers (DTOs). For each TB patient, the DTO records the date of diagnosis, the name, age, sex, address, type of tuberculosis and category (i.e., new case, relapse, transferred in from another district). Each patient is given a unique TB registration number. Only one type of TB is recorded for each patient, and, if the patient has a combination of pulmonary and extrapulmonary TB, the patient is recorded as having pulmonary TB.

### NEW NOTIFIED TUBERCULOSIS CASES IN MALAWI: 1975 - 1985

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of New TB Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>1970</td>
<td>3492</td>
</tr>
<tr>
<td>1973</td>
<td>3651</td>
</tr>
<tr>
<td>1975</td>
<td>3925</td>
</tr>
<tr>
<td>1977</td>
<td>4296</td>
</tr>
<tr>
<td>1979</td>
<td>4115</td>
</tr>
<tr>
<td>1981</td>
<td>4365</td>
</tr>
<tr>
<td>1983</td>
<td>9824</td>
</tr>
<tr>
<td>1985</td>
<td>5334</td>
</tr>
</tbody>
</table>

*Source: AD Harries*
Treatment
Malawi uses five essential anti-tuberculosis drugs that are designated by the following abbreviations: isoniazid = H; rifampicin = R; pyrazinamide = Z; streptomycin = S; ethambutol = E. Up until 1997, thiacetazone was included, but, because of an unacceptable rate of side effects, it was removed from the essential drug list.

The notation of regimens is as follows: numbers preceding the abbreviations indicate months of treatment; if there is no subscript following the abbreviation the treatment is daily, otherwise the subscript indicates the number of doses per week.

The treatment regimen for new smear-positive PTB patients and patients with severe extra-pulmonary TB—miliary disease, pericardial disease, spinal disease with neurological involvement and meningitis—is eight months of short-course chemotherapy. This includes two months of hospitalization during which patients receive daily, supervised, intensive therapy with streptomycin, rifampicin, isoniazid and pyrazinamide, followed by six months of maintenance treatment at home with isoniazid and ethambutol. The regimen is 2SRHZ / 6HE.

The 12-month standard treatment regimen for new smear-negative PTB and forms of extra-pulmonary TB (EPTB) not mentioned above is one month of hospitalisation during which patients receive daily treatment with streptomycin, isoniazid and ethambutol, followed by 11 months of isoniazid and ethambutol at home. The regimen is 1SHE / 11 HE. Relapse smear-positive PTB cases receive the retreatment regimen recommended by WHO.

Monitoring and Follow-up
Patients with smear-positive pulmonary tuberculosis have sputum smears examined at two months, five months and eight months of treatment, and the outcome is recorded at the end of treatment, i.e. eight months. All smear-positive patients who are registered during a quarter have their eight-month treatment outcome evaluation performed 15 months after closure of the quarter in question to allow time to obtain sputum results and treatment outcome information from health centres and other districts.

Follow-up and recording is not performed on patients with smear-negative PTB or EPTB.

---

### ALL NOTIFIED TUBERCULOSIS CASES IN MALAWI: 1986 – 1995

<table>
<thead>
<tr>
<th>Year</th>
<th># of TB Cases</th>
<th>TB case rate/100,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>1986</td>
<td>6301</td>
<td>82.8</td>
</tr>
<tr>
<td>1987</td>
<td>7581</td>
<td>94.5</td>
</tr>
<tr>
<td>1988</td>
<td>8247</td>
<td>97.3</td>
</tr>
<tr>
<td>1989</td>
<td>943</td>
<td>105.6</td>
</tr>
<tr>
<td>1990</td>
<td>12364</td>
<td>132.0</td>
</tr>
<tr>
<td>1991</td>
<td>14443</td>
<td>146.5</td>
</tr>
<tr>
<td>1992</td>
<td>15183</td>
<td>149.4</td>
</tr>
<tr>
<td>1993</td>
<td>17105</td>
<td>162.6</td>
</tr>
<tr>
<td>1994</td>
<td>19496</td>
<td>179.8</td>
</tr>
<tr>
<td>1995</td>
<td>19155</td>
<td>172.1</td>
</tr>
</tbody>
</table>

Source: AD Harries
HIV and Tuberculosis in Malawi

Human Immunodeficiency Virus (HIV) Infection. In 1985, Malawi reported its first case of AIDS. In the same year, an HIV-seroprevalence study carried out among pregnant women attending an antenatal clinic in Queen Elizabeth Central Hospital in Blantyre found an HIV-infection rate of two percent. Since then, the country has been affected by an explosive epidemic of AIDS and HIV infection.
HIV-seroprevalence rates in TB patients in Malawi.

<table>
<thead>
<tr>
<th>Year of Study</th>
<th>Site</th>
<th>No. TB patients</th>
<th>% HIV-positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>1986</td>
<td>Zomba</td>
<td>125</td>
<td>26</td>
</tr>
<tr>
<td>1989</td>
<td>Makwasa</td>
<td>152</td>
<td>52</td>
</tr>
<tr>
<td>1993</td>
<td>Mzuzu</td>
<td>167</td>
<td>67</td>
</tr>
<tr>
<td>1994</td>
<td>Blantyre</td>
<td>665</td>
<td>75</td>
</tr>
<tr>
<td>1995</td>
<td>Zomba</td>
<td>793</td>
<td>77</td>
</tr>
</tbody>
</table>

Source: AD Harries

HIV seroprevalence rates in pregnant women in the antenatal clinic in Queen Elizabeth Hospital rose from 8.2 percent in 1987 to 21.9 percent in 1990, 30.2 percent in 1993 and 34 percent in 1996. In 1996, the HIV-seroprevalence rates in pregnant women attending antenatal clinics in urban sites in Malawi was 27 percent, in semiurban sites 18 percent, and, in rural sites, 10 percent.

The national prevalence rate in adults aged 15 to 49 years has been estimated at 13.2 percent, or about 600,000 young and middle-aged Malawians. HIV seroprevalence rates among sexually active adults in urban areas are estimated to be as high as 30 to 40 percent.

As of mid-1997, about 50,000 AIDS cases had been reported to the National AIDS Control Programme. However, this is probably a gross underestimate of the true magnitude of the actual number of cases, which may be on the order of 10 to 20 times the reported figure.

**Tuberculosis and HIV**

Between 1970 and 1985, there was a small, gradual increase in notified TB cases in Malawi. From 1985 to 1995 there was an upsurge of TB notifications and TB case rates in the country. In 1985, there were 5,334 new TB cases reported. By 1995, the number had risen to 19,155.

Part of this increase can be attributed to population growth and improved case detection within a revitalized TB control programme. However, the most important reason has undoubtedly been the concomitant HIV epidemic. HIV-seroprevalence rates in TB patients in the country have risen dramatically in the last ten years to 75 percent of new cases.

**Consequences of HIV Interaction with Tuberculosis**

The first few years of the IUATLD-supported TB programme in Malawi were quite successful under the leadership of Dr. D.S. Nyangulu who has continued to support the programme actively and in an advisory role as TB Programme Coordinator. From 1984 to 1987, case numbers rose—but not excessively—and the proportion of smear-positive PTB cases to smear-negative PTB cases grew to greater than 50 percent, a sign that laboratories were working well and that clinicians were relying on those results. Cure rates in new...
<table>
<thead>
<tr>
<th>Year</th>
<th>Total Evaluated</th>
<th>% Cured</th>
<th>% Died</th>
</tr>
</thead>
<tbody>
<tr>
<td>1987</td>
<td>1959</td>
<td>90</td>
<td>6</td>
</tr>
<tr>
<td>1988</td>
<td>2720</td>
<td>80</td>
<td>8</td>
</tr>
<tr>
<td>1989</td>
<td>3312</td>
<td>75</td>
<td>10</td>
</tr>
<tr>
<td>1990</td>
<td>4355</td>
<td>67</td>
<td>10</td>
</tr>
<tr>
<td>1991</td>
<td>4071</td>
<td>67</td>
<td>11</td>
</tr>
<tr>
<td>1992</td>
<td>5366</td>
<td>63</td>
<td>12</td>
</tr>
<tr>
<td>1993</td>
<td>5462</td>
<td>68</td>
<td>16</td>
</tr>
<tr>
<td>1994</td>
<td>6285</td>
<td>68</td>
<td>16</td>
</tr>
<tr>
<td>1995</td>
<td>6278</td>
<td>65</td>
<td>19</td>
</tr>
<tr>
<td>1996</td>
<td>6702</td>
<td>63</td>
<td>21</td>
</tr>
</tbody>
</table>

Source: AD Harries

smear-positive PTB cases rose from 74 percent in 1984 to 90 percent in 1987, and death rates decreased from 8 percent to 6 percent.

But the good news was not to last.

From 1988 onwards, the effects of HIV infection became increasingly apparent in all health-related areas, and the TB programme started to strain under the load.

TB case numbers increased dramatically and the pattern of the disease began to change. Smear-negative PTB cases exceeded smear-positive PTB cases, reaching a zenith in 1991 when there were 3,944 notified smear-positive PTB cases against 7,293 notified smear-negative PTB cases. In 1994 there were 5,988 notified smear-positive PTB cases against 8,958 notified smear-negative PTB cases.

The proportion of TB cases with extrapulmonary disease began to rise from 11 percent in 1987 to 27 percent in 1995.

The effects of increased case notifications were most apparent in the urban areas of Blantyre, Zomba and Lilongwe, where congestion of TB wards reached levels of three to four patients for each bed. Laboratories had difficulty coping with the increased numbers of sputum specimens, and procedures became lax.

Clinicians also noticed an increased HIV-related morbidity amongst TB patients during treatment. Drug reactions—especially due to thiacetazone—were reported and became an increasing problem. Cure rates fell and mortality rates increased.

Morale began to fall among TB programme staff, and donors threatened to withdraw support unless performance improved.

“When I first came to Malawi in 1986, the TB programme was really functioning very well,” says Dr. Anthony Harries, who was then Head of the Department of Medicine at the College of Medicine in Blantyre. “Lots of smear positive cases, very good cure rates. From my perspective, during the years 1986, 1987, and 1988, the TB programme was great. A model programme, just like Tanzania.

“But this was before HIV had really hit us. I remember that in 1986 a small HIV study of TB patients was done and 25 to 30 percent were found to be HIV positive.

“Then I left for three years, and, when I came back in 1991, the programme was not working properly. HIV had pushed up the cases. There had been a change in leadership, and some new people had come in who were trying hard to grapple with the deteriorating situation. Resources for training and supervision had dwindled and there was a general lack of discipline around the country in following guidelines. We began to try to put things right, but didn’t do very well. Cases continued to go up, and we know all the problems that causes.

“That’s why we started this research program. People were asking questions, but the answers were based on assumptions. Why did we have such a high mortality rate? What was happening to smear negative patients? Were healthcare workers following guidelines? We needed a framework to answer these questions, and research provided the data to do that.”
TB RESEARCH IN MALAWI Early Research Initiatives. Between 1985 and 1993, there were a number of research projects undertaken in Malawi, most of them stimulated by the special interests of individual researchers. The majority of the studies were clinical and were based in the central hospitals in Lilongwe and Blantyre.¹¹³ Resource personnel included medical students, government medical officers, medical specialists and, on occasion, TB programme staff.
The study findings were presented at twice-yearly Malawi Medical Association meetings and published in the local Malawi Medical Journal or a peer-reviewed international journal.

Development of a Research Programme

The First Steps

In 1994, recognizing the need to analyse and address the problems facing Malawi’s TB programme, the Malawi Ministry of Health and Population and the former WHO Global Tuberculosis Programme asked Dr. Anthony Harries, then a Professor of Medicine at the College of Medicine, to serve as a technical advisor to assess the problems and constraints faced by the National Tuberculosis Programme. The terms of reference for his appointment were drawn up by the Ministry of Health and Population and were confirmed at the end of 1994.

Harries spent the first three months of his appointment consulting with and assisting officers of the NTP at the central, regional, district and health centre levels and becoming familiar with the overall programme, the registration books, and the cards. He also assisted the regional TB officers in district TB supervisions, assessed problems in the field by visiting all district and CHAM hospitals, and helped develop a structured checklist to record information on laboratory performance, case finding and treatment outcome.

In a resulting report submitted to the Ministry of Health and Population in mid-1995, the NTP was praised for what it was able to achieve under the combined constraints of a lack of resources and the burden of the TB/HIV co-epidemic. However, the report stated that performance and outcomes could be improved if problems such as laboratory performance, diagnosis, treatment, patient education, staff supervision, training and morale were addressed.

The report concluded that the NTP should conduct operational research to provide data that would help solve problems related to the diagnosis and treatment of patients.

Initial Support by WHO’s Global TB Programme

Beginning in 1995, WHO’s Global TB Programme – now housed in the Communicable Diseases Cluster – began providing strategic advice and financial support to the NTP to stimulate TB research.

A large project evaluating an unsupervised ambulatory treatment regimen for smear-negative PTB in Blantyre and Zomba was begun in April. Two clinical research officers were recruited for this exercise, and WHO provided assistance with a vehicle and a driver.

Studies also began that focused on delay in diagnosis and risk of nosocomial transmission, screening strategies for diagnosis of pulmonary TB, case finding for PTB in outpatient settings, and TB prevalence in prisons.
Preliminary results from these studies helped strengthen the proposal that was being developed for extra donor assistance to the NTP.

"For a small amount of money—about $5000—we were able to identify some problems and say that we needed additional money to solve those problems in order to benefit the programme," says Harries. "And getting this research done—identifying problems and proposing solutions to those problems—enabled the NTP, with help from WHO, to put together a project proposal."

**Development of a Project Proposal**

With assistance from WHO's Global TB Programme, the NTP Programme manager and the technical advisor developed a project proposal for submission to the Overseas Development Administration—now called the Department for International Development (DFID)—of the United Kingdom.

Submitted in September 1995, the proposal highlighted the problems and constraints of the NTP and set some long-term project goals: 1) to demonstrate at a national level that TB control could be sustained in the face of HIV infection; 2) to develop a formal career structure for NTP staff and the provide staff with the necessary resources to carry out their jobs; 3) to develop a comprehensive training programme, particularly at health centres and in the community; and 4) to carry out high-quality operational research and train a cadre of local health personnel (medical and paramedical) with the necessary technical expertise.

At the same time, the NTP manager and technical advisor met with the local donor community to present a case for further support to the NTP. In October 1995, the NTP also met with senior officials of the MOHP and IUATLD to discuss how the DFID support could be integrated with the programme support currently provided by Holland, Norway and Malawi.

The NTP proposal was accepted by DFID and support commenced in September, 1996.

---

**Prisoners' ACCESS TO CARE**

Health officials suspected that tuberculosis was highly prevalent in the prison populations in Malawi, but there was no data to confirm the problem. In 1996, NTP investigators conducted an active case-finding study in Zomba Prison, the largest prison in the country, and found that 5 percent of the prisoners had pulmonary TB. Almost all of them had contracted it in prison.

"One of our concerns is equal access to TB care," says TB Programme Manager Felix Salaniponi. "Is there a specific group of the population that has no access to care? So we looked at prisoners—a group that is confined—and found that they had one of the highest risks for TB in the country."

After discussing the results of the study with prison officials, the NTP was given approval to implement a program of improved diagnosis and treatment within the prison system.

"We set up a system where every prisoner is tested for TB when they enter prison," says Salaniponi. "They are monitored throughout their stay, and, if they have a persistent cough, they give a sputum sample. Once someone is diagnosed with TB, they are registered in our system and receive monitored treatment.

"We also meet with the health workers in the prisons every quarter. As part of our goal of cooperating with other public health programs, we have even extended beyond TB to look at other diseases in the prison, like scabies and HIV."

The NTP held workshops with prison clinical staff in 1997, and later that year initiated interventions in eight of the largest prisons in the country. The interventions include collection of data on general prisoner health, including TB; education of prison clinical staff about TB; simple health checks on all prisoners on entry into prison and collection of sputum specimens from those with a cough of one week or longer; and collection of sputum specimens from those already in prison who have a cough of longer than three weeks.

"The last time we met with the prison clinical staff, they had screened about 1000 prisoners for cough, and 60 had smear positive TB," says TB Programme Advisor Dr. Anthony Harries. "That's good. But we have 21 prisons in this country, and only eight have medical staff. We're now considering what to do with the prisons where there is no medical staff."
Traditional Healers

Traditional healers—sin’gana—play an important role in Malawi’s healthcare system and are often the first stop for Malawians seeking care. Traditional healers in a district probably see as many patients per month as the regular district health services.

A 1996 study in Blantyre showed that more than one-third of all sputum smear-positive TB patients had visited a traditional healer before seeking regular medical care. Patients spent about four weeks visiting the traditional healer and, during that time, the majority either did not improve or continued to deteriorate. None of the patients were referred to government medical services by the healers.

“One of the policies that has come out of our operational research is an understanding that traditional healers are an important factor in TB control,” says TB Programme Manager Felix Salaniponi. “Within our culture, most patients will use the traditional healer first, before coming to us. As a program, we need to open a dialogue and cooperate with them. If we know what they are doing, perhaps we can influence them.”

Delay in receiving medical treatment for tuberculosis because of time spent with a traditional healer has important consequences. The patient may present in an advanced state of disease, which can contribute to the high, early mortality seen in smear-positive TB patients in Malawi. Also, the smear-positive patient is the “transmitter of infection in the community” who poses a considerable public health risk until he or she is started on adequate anti-TB treatment.

As a result of its research, the NTP is trying to involve traditional healers in case finding. In 1997, a series of meetings was held to persuade traditional healers to refer TB suspects for early diagnosis and treatment.

“We try to involve them and teach them the basics.” says Salaniponi. “When we go to certain districts where there are very powerful traditional healers, we go and shake hands with them and chat with them. We tell them that TB is an infectious disease, it is not caused by spirits. It is caused by germs that can move from one patient to another through the air. And there is medicine for it. If you delay, the patient can die. In the meantime he is infecting other people.

“Now the traditional healers are starting to refer patients. They actually write: ‘I don’t think this patient has been bewitched. He has been coughing for three weeks, I think he has a natural disease, possibly TB. So I am sending him to you for treatment.’”

Integration of Research into the TB Control Programme

Philosophy of Integration

The initial research agenda submitted to DFID was based on an assessment of the problems and constraints faced by the NTP. This integrative approach has become central to the way the NTP thinks about research. Research is to be conducted in order to better define—with data—the problems of TB control in Malawi and to test interventions to solve those problems. The NTP believes in getting the results of research into policy and practice, and, in this way, be able to influence and improve the care of TB patients. The research outputs ultimately must have measurable benefit, direct or indirect, for TB control.

“When we first proposed an operational research programme, it just related to the immediate things we were interested in,” says Harries. “But what has evolved, now that we’ve been two or three years in the programme, is that we have clarified our research objectives so that they fit into the overall objectives of the programme.”

“Our research objectives have a purpose—to improve diagnosis, care, and access for TB patients. All of our objectives relate to that. For example, we want to ensure that there is equity and equal access in TB care. We know that prisoners don’t get very good access to care, and perhaps women don’t have very good access. So we have two research objectives: to find out more about what happens to prisoners and to women. Then we take it from there.

“In the area of treatment, we have done quite a bit of research to show that the outcome for smear-negative TB is appalling, particularly within the routine treatment system. One quarter of the people are lost to treatment, and we don’t know what happens to them. That has made us open our eyes. So we have made that a research objective—to provide effective treatment for all TB patients, including smear negative. We will also try some interventions to improve death rates.

“So it has been a process of evolution—from small studies looking at various aspects of the programme, to studies integrated much more into the needs of the programme.”
Formation of the TB Programme Management Group (PMG) and the TB Programme Steering Group (PSG)

In November 1996, Harries left the College of Medicine and formally joined the NTP as a full-time TB advisor. Harries and TB Programme Manager Felix Salaniponi then formed a project management group to meet monthly on issues related to DFID support to the NTP.

At the suggestion of DFID, a project steering group—composed of senior MOHP officials and representatives from WHO, DFID, and IUATLD—was set up to oversee the project. The project steering group became the Programme Steering Group (PSG) in April 1997.

In May 1997, following advice from the Programme Steering Group, the project management group became the Programme Management Group (PMG), chaired by the TB Programme Manager. Under terms of reference developed with the PSG, the PMG assumed collective responsibility for operation and strategic planning of the National TB Control Programme. The PMG reports to the PSG at six-month intervals.

In addition to the TB Programme Manager and TB Advisor, members of the PMG include the head of the Depart-
ORGANIZATION OF RESEARCH WITHIN NTP

<table>
<thead>
<tr>
<th>INTERNATIONAL EXPERTISE</th>
<th>NTP</th>
<th>MALAWI NATIONAL INSTITUTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO – GTB</td>
<td></td>
<td>College of Medicine</td>
</tr>
<tr>
<td>IUATLD</td>
<td></td>
<td>AIDS Control Programme</td>
</tr>
<tr>
<td>Liverpool School of Tropical Medicine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RESEARCH IDEAS

- Approval of Research Ideas
- Development of Protocols
- Planning Financial Resources

IMPLEMENTATION OF RESEARCH

<table>
<thead>
<tr>
<th>Liv.Sch.Trop.Med</th>
<th>NTP</th>
<th>College of Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>DTOs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical TB research staff</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Central Unit staff</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WHO-supported research staff</td>
</tr>
</tbody>
</table>

Source: AD Harries

The PMG prepares an annual workplan and submits it to the PSG in early September. The workplan covers a calendar year and includes proposals for TB research. The PSG meets about one month later, allowing time for comments on the workplan to be considered before work commences in the next calendar year.

“We also have to do six-month reports to the PSG, and they are fairly demanding on financial accountability,” says Harries. “Sometimes I think our donors are too demanding in terms of what they want from us. They want first-world workplans and first-world reports, but we’re not the first world, we’re the third world.”

“For example, our Steering Group insists that we incorporate timeframes into our workplans, which is fine, but things often happen to make it unrealistic. Let’s say we want to conduct health center training. We send letters out to all the district hospitals. A third of those letters get lost in the mail. So we send out more letters. Then the proposals come back. One-third of those letters get lost. Half of the proposals are unacceptable, so you have to send them back again. It’s a process that goes on and on. Eventually you agree on the money, and then that money has to get to the district hospital. Then they do their training, and you report that. So I think we do very well if, in 12 months, we get 25 districts to do all their health centre training. To say that we are going to do four by the end of January, six by the end of February—which is what our Steering Group would like—is not achievable.”

An important component of the PMG is the programme finance committee which oversees all funds and expenditures of the NTP. This committee—made up of PMG members and the NTP accountant—meets two weeks after PMG meetings. Its mandate is to ensure that funds and expenditures related to DFID support are in line with operational support and operational research proposals. Financial reports are prepared on a regular basis for the Steering Group.

**Linkages with other Programmes and Research Groups in Malawi**

In 1998, the PMG began to form linkages with other interested groups. A regular meeting was set up with the national AIDS Control Programme, and the PMG agreed to share the minutes of meetings. A few joint initiatives have begun,
such as conducting HIV-surveillance in TB patients and using the same facilities for health education materials.

Another group, the TB Research Study Group, operates under the auspices of the London School of Hygiene and Tropical Medicine and is based in Karonga, in the northern region of the country. They also conduct TB research, although it is focused more on basic science than improving programme performance. Research currently being conducted includes trials of Mycobacterium vaccae for therapy of tuberculosis, relationship between human and bovine tuberculosis, risk factors for tuberculosis infection and disease, correlates of natural and BCG vaccine derived immunity, genetic determinants of delayed hypersensitivity responsiveness and of susceptibility to mycobacterial diseases, and treatment compliance.

The PMG receives an update on their research progress every three months, and the PMG, in turn, sends a copy of their minutes to Karonga. The study group assists in carrying out NTP activities within the district of Karonga, and a visit to the study site is conducted by the Regional TB officer once a quarter and by the PMG twice a year.

**Organization of Research within the NTP**

The process by which ideas for research are developed and implemented within the NTP is outlined in figure. These ideas, based on problems and constraints within the NTP, are part of the operational research workplan that is supported by DFID.

To provide some flexibility in the workplan, one research budget line is for district operational research, which allows projects to be developed each year and conducted on a countrywide basis. Another research budget line is for miscellaneous projects, which allows support for small projects that develop during the year.

Support for miscellaneous projects is particularly important for research ideas that come from the NTP itself, at either RTO or DTO level. Ideas are also fed to the PMG from national institutions, such as the medical school, and from international institutions such as WHO, the IUATLD and the Liverpool School of Tropical Medicine.

At its monthly meetings, the PMG reviews research proposals, grants approvals, assists in the study planning, and allocates financial resources according to its operational research budget lines.

Research is implemented in several ways: through the NTP itself—i.e., DTOs, clinical research officers and the TB Adviser and National TB Officer in the central unit—through staff of the Liverpool School of Tropical Medicine working in collaboration with the NTP and Malawian health care staff, and through WHO-supported staff at the College of Medicine.

During implementation of the research, the NTP’s central unit provides supervision, receives the data, checks the data at the source, enters the data—usually through an EPIINFO software package—performs analysis, and writes up the papers along with the other collaborators.

PMG reviews all written papers and decides where papers should be submitted and where research findings should be disseminated (i.e., in-country and out-of-country).
The Research Agenda:

PUTTING THE RESULTS INTO POLICY AND PRACTICE Resource Capacity for Research. The TB adviser and the national TB officer comprise the research staff at the central NTP level. The District Health Officer and the Head of the Department of Medicine, College of Medicine, strengthen the research capacity. It has always been understood that, while the TB Programme Manager should be fully aware of the research activities being carried out and be involved with vetting written papers, his main priority is to run the NTP programme. The PMG has always abided by this understanding.
TB RESEARCH AGENDA: CASE DETECTION

1. **Difficulties faced by TB suspects using present case detection system**
   - role of traditional healers in case detection
   - gender determinants

2. **Inefficiencies within the passive case finding system**
   - health centre and outpatient performance in dealing with patients with cough and TB suspects
   - delays between sputum submission and smear examination
   - sputum storage and smear/culture viability
   - reasons for diagnostic delay

3. **Laboratory performance**
   - knowledge and practice of recommended laboratory procedures
   - improvement of smear sensitivity
   - assessment of safety procedures

4. **Diagnosis of Pulmonary TB:**
   - assessing different strategies for screening TB suspects
   - % of smear-positive patients who do not get registered or treated
   - % of smear-negative PTB patients with no smears done with false positive smears
   - with another diagnosis and with genuine TB
   - accuracy of chest radiograph diagnosis

5. **Paediatric TB**
   - improved diagnosis

6. **High risk groups**
   - prevalence of TB in prisoners
   - prevalence of TB in health care workers
   - prevalence of TB in secondary school children

Source: AD Harries

At the regional level, the three clinical research officers were appointed for each region of the country to work under the PMG to carry out operational research. Based at a district hospital in each of the regions, the clinical research officers report to the PMG through their district health officers and hold meetings every six months at the central headquarters in Lilongwe.

“We have got a lot of good people involved in research who wouldn’t have come into TB if we didn’t have a research agenda,” says Harries. “They are proud of the programme and proud of the operational research. A lot of them have contributed to the thoughts behind the research. They are not just rubber stamps.”

“We have a very good team spirit and we try to make it a bit competitive. Tanzania has always had the best programme in Africa, so we say ‘Guys, we want to be number one.’ This programme is owned by the Malawians, so people work to be number one. Not just for themselves, but for the patients. They are doing a good job, and I think it is reflected in patient care.”

The strategy of the NTP’s research agenda is to better define—with data—the problems of TB control and to try out interventions to solve those problems. The goal is to improve the diagnosis, care, and access for TB patients by translating the results of that research into policy and practice. Malawi’s TB research programme—centered around the cardinal activities of case finding and case holding and treatment—has influenced both policy and practice.

**Case Finding**

**Involving Traditional Healers in Case Finding Activities**

**Problem:** Traditional healers play an important role in Malawi’s healthcare system, yet there is only anecdotal information about the attitudes and role of traditional healers in the management of tuberculosis. Several research studies have been conducted to address this.

**Research findings:** In Blantyre, operational research showed that more than one third of sputum smear-positive TB patients had visited a traditional healer before seeking regular medical care. 14
A Strong National TB Control Programme

The Government of Malawi has made a strong commitment to a well-structured National Tuberculosis Programme. The NTP, supported for many years by the IUATLD, has developed a strong tradition of standardized practice, diagnosis and treatment outcomes. Staff throughout the system are well-trained in TB control procedures, enabling collection of reasonably accurate data on case finding and case treatment activities.

Advocacy

The TB Programme Coordinator and the Programme Manager are strong advocates for incorporation and integration of operational research into the TB programme. This has been an important factor in convincing MOHP and NTP staff to accept research as an established part of the NTP.

Incorporation of a Senior Medical Doctor with Research Experience into the NTP

A senior medical doctor with a 15-year background in clinical research helped the NTP develop ideas for research and incorporate them into protocols that could be implemented in the field. His experience in writing proposals proved to be extremely useful in preparing a funding proposal for a major international donor.

Financial Support

Setting up a research base requires capital for office set-up, computers and software, office supplies and transportation. Initial funding for this—approximately USD$25,000—was provided to the College of Medicine by the WHO Global Tuberculosis Programme in 1994.

In 1996, the British Department for Overseas Development provided funds to the central and regional units for office equipment and transport. They also provided motorcycles and bicycles to the districts for TB supervision. This support facilitated the implementation of many operational research initiatives. The budget for four Landrovers, 35 motorcycles, 100 bicycles, five computers with software, one photocopy machine, and one overhead projector was approximately USD$250,000. Technical assistance was provided by DFID out of a different budget line.

The actual research activities are reasonably cheap to carry out. However, it is unlikely that government ministries of health will be able find the funds to support such activities, and, therefore, donor support will often be necessary.

The extra funding provided for operational research has made it possible to give allowances to NTP staff who assist in collecting data. In a country where monthly salaries are low, financial incentives for extra work done well are an important motivation. These allowances are presented in the form of awards at national meetings or workshops.

Technical Support

Technical support and advice from international organizations, such as IUATLD and WHO-GTB, have been invaluable in developing research ideas, planning studies, assisting with analysis and writing research papers.

Recruitment of Good Local Staff

Initiative, drive, integrity and hard work are important characteristics of good research officers. Two clinical research officers were selected for the initial WHO-supported research studies that were carried out in the medical school in Blantyre. Appointment of a national TB officer at the central unit and a clinical research officer for one district in each region greatly assisted in expanding the research base.

Problems and constraints

Lack of Research Personnel

There is a lack of support staff and research personnel. At the central unit, there is no secretarial or data entry support, which means many tedious tasks must be carried out by relatively senior staff members. There is also a lack of staff in the field. However, there is a great shortage of staff at all levels of the health service in Malawi, and the NTP and its research unit know that recruiting more research staff means withdrawing staff from other areas of the healthcare system.

Poor Quality of Data Collected by Peripheral NTP Staff

Early in the research programme, DTOs and laboratory assistants were asked to collect simple data on various TB control activities in their respective districts. When the data was checked, it was apparent that there were many errors. In some instances, the research had to be repeated on-site by central unit staff. To remedy this, central unit staff now help peripheral NTP staff collect simple research data in the hope that regional and local staff will begin to appreciate the importance of collecting correct, quality data. Beginning in 1999, an annual training workshop will be held for district and mission TB officers to review the essential elements of operational research and assist officers in preparing simple research protocols and collecting accurate data.

Publication Difficulties

While the research programme has had some success in publishing operational research papers in international journals, it is a difficult process. Editorial boards fail to ap-
preciate the problems inherent in carrying out research under difficult conditions and sometimes overlook the importance of simple research for TB programmes. Unreasonable demands from editorial boards and repeated rejections of papers that authors consider important result in a lowering of morale.

**Duration of Donor Support**

At the present time, donor support for the TB research programme is for a three-year period. This timeframe is too short. It takes time to collect, analyze and publish data. A short funding period prompts investigators to go for “quick and dirty” research. While this can be useful and can quickly produce the results necessary to justify the research investment, some issues require a longer timeframe. This is particularly true for household or community behavioural studies.

**Poor Infrastructure**

Irregular electricity, poor postal and telephone service, lack of good communications facilities, and difficulties with transportation add layers of frustration to the research process. It is ironic that operational research programmes are needed most in poorer countries that lack infrastructure.

**Feelings of Isolation**

Lack of finances for purchase of journals and an absence of colleagues with whom one can discuss programme issues and research ideas can lead to a feeling of isolation. Regular meetings of the PMG and e-mail connections with the outside world are useful countermeasures.

**Interference of Research with Programme Activities**

This has been a rare phenomenon thus far. However, in one district (Ntcheu) some research proposals were put on hold by the District Health Officer because he felt that general TB programme activities were being neglected. A good balance must be struck between enthusiasm for research and performance of routine duties. A cardinal principle held by the PMG is that research must not interfere with the NTP activities, and, if there is any conflict, research must take second place.
AUTHORS AND INSTITUTIONS:

National Tuberculosis Control
Programme, Malawi
Felix Salaniponi
Anthony Harries
Thomas Nyirenda
Anshu Banerjee
Martin Boeree
Daniel Nyangulu

International Union against Tuberculosis and Lung Disease
Tone Ringdal
Jerome van Gorkum
Jaap Veen

Department for International Development, UK
Jenny Allan
Stewart Tyson

Global Tuberculosis Programme, World Health Organization
Peter Godfrey-Faussett
Dermot Maher
Paul Nunn

Writer/Editor/Photography:
James Mullins

This document is not a formal publication of the World Health Organization (WHO) and all rights are reserved by the organization. The document may, however, be freely reviewed, abstracted, reproduced, or translated, in part or in whole, but not for sale nor for use in conjunction with commercial purposes. © 1999 World Health Organization