WHO/TB/97.221 Distr.: General(e) Original: English

# TUBERCULOSIS CONTROL IN REFUGEE SITUATIONS: AN INTER-AGENCY FIELD MANUAL





# GLOBAL TUBERCULOSIS PROGRAMME WORLD HEALTH ORGANIZATION

OFFICE OF THE UNITED NATIONS HIGH COMMISSIONER FOR REFUGEES

This Manual was developed by the Global Tuberculosis Programme (GTB) of the World Health Organization (WHO) and the Office of the United Nations High Commissioner for Refugees (UNHCR).

Other participating agencies were the International Committee of the Red Cross, Médecins sans Frontières, the International Federation of Red Cross and Red Crescent Societies, and the International Organization on Migration.

Acknowledgment is made to Dr. Michael Toole and Dr. Christina Drummond (International Health Unit, Macfarlane Burnet Centre for Medical Research, Melbourne, Australia), Dr. Nancy Binkin (US Centers for Disease Control and Prevention (CDC)), Dr. Jeroen van Gorkom (Koninklijke Nederlandse Centrale Vereniging tot bestrijding der Tuberculose (KNCV)), Dr. Claudia Kessler and Dr. S. B. Squire (Liverpool (UK) TB Interest Group) for their valuable comments.

## **TABLE OF CONTENTS**



	FOREWORD	5
	EXECUTIVE SUMMARY	7
	GLOSSARY	9
	ABBREVIATIONS	13
1	TURFROULOSIS (TR)	15
	TODEROOEOSIS (TD)	10
	1.2 Natural History of TB	. 15 . 15
2	IMPLEMENTATION OF TB CONTROL PROGRAMMES	19
	IN REFUGEE SITUATIONS	
	<ul> <li>2.2 Situation Analysis</li> <li>2.3 Training</li> <li>2.4 Local TB Protocol</li> <li>2.5 Supply of Drugs and Equipment</li> </ul>	20 21 22 22
3		25
	3.1 Diagnosis. 3.2 Treatment. 3.3 Treatment Regimens and Treatment Categories. 3.4 Treatment Adherence 3.5 Patient Management. 3.6 TB Treatment during Pregnancy.	. 28 . 29 . 36 . 37



4	MANAGEMENT OF TB IN REFUGEE	39
	SITUATIONS - CHILDREN	
5	PREVENTION OF TB IN REFUGEE SITUATIONS	41
	5.1 Prevention	
6	MONITORING OF TB CONTROL PROGRAMMES IN REFUGEE SITUATIONS	43
	6.1 Recording and Reporting	43 44 44
7	EVOLUTION OF TB CONTROL PROGRAMMES IN REFUGEE SITUATIONS	49
	<ul> <li>7.1 Expansion of TB Control Programmes in Refugee Situation</li> <li>7.2 Maintenance Phase of a Programme</li></ul>	49
	APPENDICES	
	1 Responsibilities of Key Agencies. 2 Job Descriptions and Responsibilities of TB Programme Sta 3 Adverse Effects of Anti-TB Drugs. 4 Estimating Drug Requirements. 5 Price List of Anti-TB Drugs. 6 Some Suppliers of Anti-TB Drugs. 7 Laboratory Requirements for Smear Examination. 8 Estimate the Quantity of Forms, Registers, and Health Education Materia.	af 55 57 59 63 67

**BIBLIOGRAPHY AND RESOURCES** 

71

#### FOREWORD



After years of neglect, tuberculosis (TB) is now acknowledged as a major global health problem. The world's growing number of refugees and displaced persons are at risk of both TB, and of inadequate TB treatment. In order to provide guidance to organizations (both government and non-government) on the implementation of effective TB control programmes in refugee situations, the World Health Organization (WHO) and the Office of the High Commissioner for Refugees (UNHCR) have collaborated to produce this Manual.

Effective TB control programmes:

- cure TB patients
- reduce the transmission of TB, and
- prevent the development of drug resistant TB organisms.

The principles of TB control presented in this document are simple. A TB control programme should be integrated into the primary health care services, and be consistent with the overall goals of relief activities, namely to:

- reduce the suffering of the affected community, and
- facilitate the resumption of normal and productive lives.

All aspects of a relief programme should adhere to the following criteria:

- foster ownership, participation, and capacities of the affected population
- contain the displacement of a population where possible
- avoid potentially harmful relief measures, such as large and unsanitary camps, inappropriate medical supplies, and culturally insensitive practices
- minimize dependency on external resources
- ensure consistent and transparent communication between relief providers and communities, and
- ensure that the needs of local communities in proximity to refugee and displaced persons camps have access to assistance programmes, when indicated.

Overcrowding in camps is undesirable and is often associated with inadequate access to water and sanitation, lack of land for farming, loss of community initiative and over-dependency, disruption to normal social patterns, and considerable psychological problems. Each one of these issues will affect a TB control programme.

In conflict settings, or famine situations communities should be held together and relief assistance should be provided directly to the village or town, whenever feasible. This may make the provision of public health services (including TB diagnosis and treatment) logistically more difficult; however, the overall benefit to the community is considerable.

When camps are unavoidable, dependency should be minimized by including refugees and displaced persons in the planning of health programmes and ensuring that community health workers play an active role in implementing the programme. Programmes for refugees and displaced persons should be designed with their eventual repatriation or resettlement in mind. Plans for eventual repatriation should be developed from the outset.

TB control should not be used as a pretext for discouraging repatriation or any other



durable solution to the plight of refugees and displaced communities. Suggestions for dealing with patients undergoing TB treatment in the event of a repatriation are presented.

In the process of developing this Manual, WHO and UNHCR held a meeting of interested parties at Alexandria, Egypt in October 1996. The following resolutions were passed:

- The meeting recognized the humanitarian and epidemiological catastrophe facing the world unless effective TB control programmes are implemented in refugee situations. Uncoordinated TB control activities will lead to the development of drug resistance. TB could then become untreatable in remote areas of the world and the risk of untreatable TB will progress beyond isolated communities.
- The meeting called on non-government organizations and private healthcare workers to stop distributing anti-TB drugs outside integrated TB control programmes.
- The meeting called for full participation of other international organizations such as the International Organization on Migration and the International Federation of Red Cross and Red Crescent Societies, and non-government organizations to assist in the full implementation of TB control programmes in refugee situations consistent with the WHO TB control strategy.

This Manual requires field testing in a number of different situations. Comments on the document are welcome and should be sent to:

Global Tuberculosis Programme World Health Organization CH-1211 Geneva 27 Switzerland

Fax: + 41 22 791 4199

#### **EXECUTIVE SUMMARY**



This Manual is intended to inform operational agencies, donor agencies and field managers of the issues related to TB control in refugee situations. The Manual will serve as a tool in the implementation, monitoring and evaluation of TB control programmes in refugee situations.

TB control is **not** a priority in the immediate emergency phase when mortality and malnutrition rates are high due to measles, diarrhoeal disease, meningitis, and malaria. The priorities during this phase are the provision of adequate food, water, shelter, sanitation, basic drugs and the control of common acute communicable diseases.

A TB control programme should not commence until death rates have been reduced to less than 1 per 10,000 population per day, basic needs are provided, and essential clinical services and supplies are available.

A TB control programme should be implemented only if the security situation is stable and the camp population are expected to remain for at least 6 months. Funding should be available for at least 12 months, along with sufficient medical supplies and trained staff.

Since TB is more common, both in countries of origin and in host countries, the involvement of the national TB programme (NTP) of the host country in the implementation of the TB programme is essential.

The priority of a TB control programme is to identify and treat infectious patients, and ensure that they become non-infectious as soon as possible. Successful cure of infectious patients will reduce transmission and prevent new patients from occurring. Patients become non-infectious within two weeks of commencing the treatment if drugs are taken regularly.

In addition to smear-positive pulmonary TB patients, severely ill patients with non-pulmonary TB are to be treated in the TB programme. Other non-infectious TB patients should not be included the TB programme until it has demonstrated that cure rates are satisfactory.

The recommended strategy for curing infectious TB patients is the WHO TB control strategy (DOTS), which is implemented by providing the correct combination of TB drugs for 6 or 8 months, and observing patients swallowing their medicines. This is especially important during the first two months of treatment.

TB patients co-infected with HIV respond well to standard TB treatment. Since TB is more common in HIV infected individuals, and because many refugees and displaced persons may come from, or seek refuge in, countries with a high prevalence of HIV infection, TB control and HIV programmes should be carefully coordinated.

TB is an energy wasting disease. Many refugees may also be suffering from malnutrition which is exacerbated by TB. TB treatment will normally lead to an increased need for calories, therefore nutritional rehabilitation may be an important component of a TB control programme in refugee situations.

TB control programmes should be integrated into the primary health care services for the refugee population; however, a TB Coordinator should be appointed for approximately every 50,000 refugees.



#### **GLOSSARY**



#### Acid-fast bacilli (AFB)

Bacteria which do not lose their stain when exposed to acid during the staining process e.g. *Mycobacterium tuberculosis* (the TB organism).

#### Active case finding

Suspects are vigorously looked for within the community.

#### Annual risk of TB infection

The chance of an uninfected person becoming infected with the TB organism in a one year period.

#### **Bacille Calmette-Guerin (BCG)**

A live vaccine against TB derived from an attenuated strain of *Mycobacterium bovis*.

#### **Bactericidal**

A drug which kills bacteria.

#### **Bacteriostatic**

A drug which stops bacteria from growing

#### **Chronic patients**

Patients who have completed a retreatment course of anti-TB medication but have failed to become cured. They are infectious to others and they may excrete drug resistant organisms.

#### **Cohort analysis**

An assessment of the treatment outcomes of a group of patients who were diagnosed, registered and planned to have the same treatment, within a defined period (usually 3 months, one year prior to analysis).

#### Continuation phase of treatment

The second period of treatment, after the initial phase, when treatment is maintained with a reduced number of drugs.

#### **Directly observed therapy**

Each dose of medication administered to the patient is observed by the health staff to ensure it is taken and swallowed.

#### Extra-pulmonary TB

TB of organs other than the lungs. This includes TB of the pleura, lymph nodes, abdomen, genito-urinary tract, skin, joints and bones, and meningitis.

#### **Haemoptysis**

Sputum containing blood.



#### Incidence

The number of new patients of a disease in a defined population during a specified period of time.

#### Initial phase of treatment

The first period of treatment when a combination of drugs are given to kill as many of the TB organism as possible, as quickly as possible, for a period of 2-3 months.

#### Mantoux test

A skin test to assess previous BCG vaccination, or infection with the TB organism.

#### Multiple drug resistant (MDR) TB

Strains of TB organism which are resistant to, at least, both isoniazid and rifampicin.

#### Mycobacterium tuberculosis

The bacteria (organism) which causes TB.

#### Passive case finding

Screening by sputum microscopy of persons presenting themselves at a health facility with respiratory symptoms (e.g. cough > 3 weeks).

#### **Pulmonary TB**

Tuberculosis affecting the lungs.

#### Short course chemotherapy (SCC)

Treatment with TB drugs for 6 or 8 months duration based on the combination of at least 3 major TB drugs: isoniazid, rifampicin and pyrazinamide.

#### Smear conversion rates

The rate at which a group of patients changes from sputum smear positive to smear negative.

#### Smear-negative pulmonary TB

either: a patient who fulfils all the following criteria:

- two sets (taken at least 2 weeks apart) of at least two sputum specimens negative for acid-fast bacilli on microscopy
- radiographic abnormalities consistent with pulmonary TB and a lack of clinical response despite one week of a broad-spectrum antibiotic, and
- a decision by a physician to treat with a full curative course of anti-TB chemotherapy.



or: a patient who fulfils all the following criteria:

- severely ill
- at least two sputum specimens negative for acid-fast bacilli by microscopy
- radiographic abnormalities consistent with extensive pulmonary TB (interstitial or miliary), and
- a decision by a physician to treat with a full curative course of anti-TB chemotherapy.

**or:** a patient whose initial sputum smears were negative, who had sputum sent for culture initially, and whose subsequent sputum culture result is positive.

#### Smear-positive pulmonary TB:

either: a patient with at least two sputum specimens positive for acid-fast bacilli by microscopy;

**or:** a patient with at least one sputum specimen positive for acid-fast bacilli by microscopy and radiographic abnormalities consistent with pulmonary TB;

**or:** a patient with at least one sputum specimen positive for acid-fast bacilli by microscopy, which is culture positive for *M. tuberculosis*.

#### Sputum smear examination

A laboratory technique where acid-fast bacilli (AFB) are stained with the Ziehl-Neelsen method, then identified by microscope.



#### **ABBREVIATIONS**



#### CHW

Community Health Worker

#### **DOTS**

Directly-observed therapy, short-course

#### GTB

Global Tuberculosis Programme

#### HIV

Human immunodeficiency virus

#### **IUATLD**

International Union Against Tuberculosis and Lung Disease

#### NGO

Non-governmental organization

#### NTF

National Tuberculosis Programme

#### ТВ

Tuberculosis

#### UNICEF

United Nations Children's Fund

#### **UNHCR**

Office of the United Nations High Commissioner for Refugees

#### **WHO**

World Health Organization





#### **TUBERCULOSIS (TB)**



#### 1.1 GLOBAL BURDEN OF TB

In 1996 there were about 9 million new cases of TB with 3 million deaths, worldwide. These deaths comprise 25% of all avoidable adult deaths in developing countries. 95% of patients, and 98% of deaths, from TB occur in developing countries. 75% of TB patients in developing countries are in the economically productive age group (15-50 years).

The increase the global burden of TB is due to a combination of:

- population growth
- rapid urbanization
- increasing poverty
- spread of HIV (in some regions of the world), and
- ineffective TB control programmes leading to the development of multiple drug resistant organisms.

#### 1.2 NATURAL HISTORY OF TB

It is estimated that up to one-third of the world's population is infected with the TB organism. Once infected, a person stays infected for many years, probably for life. The vast majority (90%) of people who are infected with the TB organism do not develop active TB disease. In these healthy, asymptomatic, but infected individuals, the only evidence of infection may be a positive tuberculin skin test.

Transmission occurs by airborne spread of infectious droplets. The source of infection is a person with TB of the lung who is coughing.

Infected persons can develop active TB disease at any time. The chance of developing TB disease is greatest shortly after infection and then steadily lessens as time goes by. Various physical or emotional stresses may trigger the progression of infection to disease. The most important trigger is weakening of immune resistance, especially by HIV infection. TB can affect most tissues and organs, but most commonly the lungs.

Without treatment, after 5 years, 50% of active pulmonary TB patients will be dead, 25% will be healthy (self-cured by a strong immune defence), and 25% will remain ill with chronic, infectious TB.

#### 1.3 TB IN REFUGEE SITUATIONS

The number of refugees, displaced persons and other persons of concern to UNHCR was estimated to be more than 26 million in 1996. Over 85% of refugees originate from, and remain within, countries with high burdens of TB.





Refugees are at particularly high risk of developing TB. Coexistent illness and the poor nutritional status of many refugees weaken their immune system and make them more vulnerable to developing TB. The crowded living conditions of most refugee camps facilitate the transmission of TB from infectious patients.

The HIV epidemic affects many countries with large refugee populations, particularly in sub-Saharan Africa. TB notifications have trebled in parts of Africa over the past decade, much of this increase being attributed to the HIV epidemic. Refugee camps in high HIV prevalence countries could be experiencing an even more dramatic rise in TB burden.

#### KENYA

The incidence of new infectious TB patients in camps was 4 times the rate in the local population.

TB is also a major cause of death in refugee situations.

#### SOMALIA

In a refugee camp in 1989, one quarter of all adult deaths were due to TB. In two camps in eastern Sudan in 1990, 38% and 50% of all adult deaths were due to TB.

#### 1.4 HIV / TB

In some countries (particularly sub-Saharan Africa), 30-70% of TB patients are infected with HIV. Compared with a non-HIV infected person, an HIV infected person is 25 times more likely to progress from infection to active disease. As well as being at greater risk of developing severe disease, HIV infected people are also at greater risk of developing serious side-effects from TB drugs.

TB is the leading cause of death amongst people infected with HIV. When a HIV / AIDS prevention programme is established in a camp or emergency setting, education on HIV prevention should be provided to TB patients through the TB clinics. TB clinics are also suitable places for the distribution of condoms.

TB patients with concurrent HIV infection respond well to TB treatment but may have more side effects from TB drugs. If a TB patient is infected with HIV, monitor for opportunistic infections, and refer to a doctor for assessment.

TB patients should not be routinely tested for HIV.

The symptoms and signs of TB in patients who are infected with HIV are the same as in non-infected individuals. Spread from the lungs to other parts of the body is common and may result in the severer forms of TB (e.g. meningitis). This is particularly so in children.

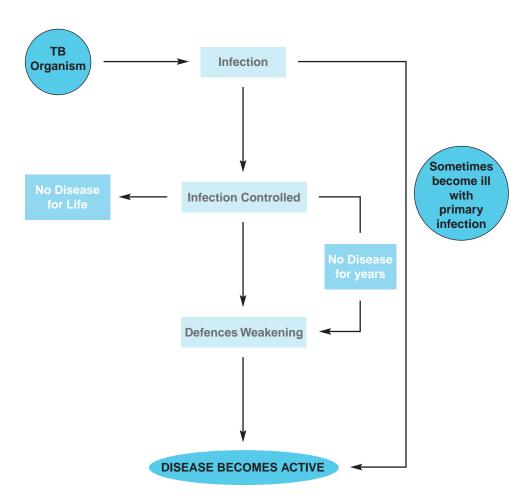


Thioacetazone should be avoided because severe, even life-threatening, reactions occur more frequently in HIV co-infected individuals. It is not recommended for use in refugee situations.

#### RESOURCES

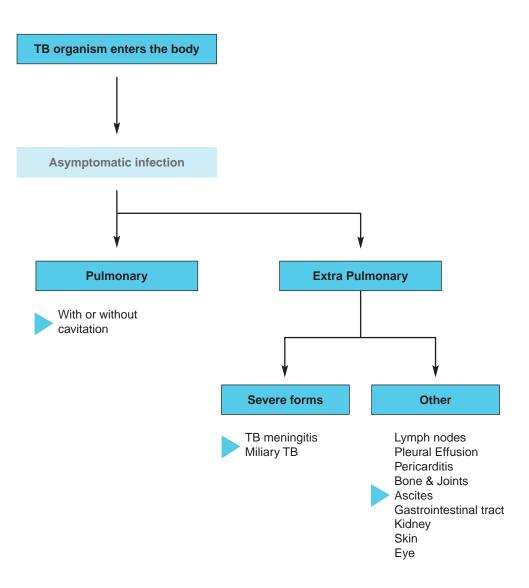
Crofton J, Horne N, Miller F. Clinical Tuberculosis, MacMillan, TALC and IUATLD,1992 Harries AD, Maher D. TB / HIV: a Clinical Manual. Geneva: WHO: 1996. WHO / TB / 96.200.

### Figure The Natural History of Tuberculosis





Classification of TB Figure 2





## IMPLEMENTATION OF TB CONTROL PROGRAMMES IN REFUGE SITUATIONS



The aim of TB control in refugee situations is to reduce the morbidity, mortality and transmission of TB.

The objectives for TB control should be to cure at least 85% of detected infectious patients and to detect at least 70% of existing cases.

#### 2.1 INITIATION

When the basic health services are able to meet the daily needs and care of all acute respiratory infections and acute respiratory symptoms (e.g. pneumonia), for both adults and children, TB services should be developed.

The following criteria are essential before a decision to implement a TB control programme is made:

- data indicate that TB is an important health problem
- the emergency phase is over (death rates < 1 per 10,000 population per day)
- basic needs of water, adequate food, shelter and sanitation are available
- essential clinical services and basic drugs are available
- security in, and stability of, the camp envisaged for at least 6 months
- sufficient funding for at least 12 months, and
- laboratory services for sputum smear microscopy will be available.

TB can be effectively treated using the WHO TB control strategy (DOTS). The essential component of the strategy is to provide TB drugs for 6 or 8 months under direct observation of healthcare workers.

The WHO TB control strategy involves:

- a commitment to TB control by authorities (at many levels)
- passive case-finding
- diagnosis by smear microscopy
- treatment by directly observed therapy, using short-course chemotherapy, and
- monitoring TB patients by a standardised recording and reporting system.

Therefore a TB control programme needs to ensure the:

- availability of adequate funds
- establishment of a system of regular drug supply
- establishment and maintenance of a sputum microscopy service
- application of the WHO recommended recording and reporting systems, and
- training health care workers in the management and application of TB control.





#### 2.2 SITUATION ANALYSIS

Once the decision to implement a TB control programme is made, an assessment of the situation should be carried out. Information which should be collected includes:

- funding available to implement a TB control programme
- demographic composition of camp population
- annual TB incidence rates in the country of origin
- TB control policies and coverage in the country of origin
- TB control policy and coverage in host country
- programme performance of both host and country of origin programmes
- TB knowledge, attitudes and practices of refugees and healthcare workers, and
- expertise amongst the NTP or NGOs in implementing TB control programmes.

Drug procurement, establishment of a laboratory and training, may take over 3 months to complete. The decision to commence a TB programme should therefore be taken as early as possible. Funding must be assured for at least 12 months of programme activity, preferably longer. There should be agreement between all partners (NTP, NGOs) on the TB control policies to be implemented.

The key steps involved in setting up a TB control programme are as follows:

- lead agency identified i.e. NGO, NTP
- budget prepared
- TB Coordinator (possibly 1 per 50,000 population) with a contract for at least 12 months appointed
- agreement with representatives of NTP of host country on:
  - integration of refugee TB control programme with NTP
  - drug regimens to be used
  - coverage of the local population in the TB control programme
  - referral of seriously-ill patients to local hospitals
  - laboratories suitable for quality control of smear examination
  - procurement of drug stocks and reagents
  - procedures for follow up of cases in repatriation phase
  - programme evaluation
- staff needs assessed, job descriptions developed, and staff recruited
- staff trained TB coordinators, nurses, community health workers, laboratory technicians
- secure storage facilities identified
- production of local TB control protocol, and
- and reporting system established.



#### KENYA

In 1992 in the north-eastern part of Kenya, an influx of refugees from Somalia attending the local TB treatment centres led to the near collapse of these services. As a result, the National Leprosy and TB Programme developed guidelines for the diagnosis and treatment of refugees with TB inside the camps based on its existing practices. Voluntary workers from the refugee community supported by staff from the Ministry of Health and *Médecins sans Frontières* supervised patients taking their drugs daily during the 7 months of treatment. UNHCR ensured that funds and drugs were continuously available.

#### Laboratory

The correct diagnosis and classification of TB cases depends on a reliable microscopy laboratory that can perform sputum examinations.<sup>1</sup>

#### 2.3 TRAINING

Training is a key element in a successful TB control programme. All involved in the programme require basic knowledge of TB, its diagnosis and appropriate treatment. Training must be conducted by people who are themselves well trained in TB control. The NTP, WHO and NGOs who specialize in TB control may be sources of such trainers.

Often health workers who have worked in TB control in their home country may be found amongst the refugees or displaced people. These persons may be able to provide useful background information on community knowledge, cultural beliefs, regimens, and practices used previously. They could also be employed as supervisors of treatment.

Staff training should occur locally where possible, using existing materials adapted to the local setting. The topics covered should include the following:

- transmission of TB
- clinical signs and symptoms of TB
- diagnosis of TB, including the role of the laboratory
- treatment of TB, including dosages and side-effects of drugs
- patient education and follow-up
- management of a TB clinic
- record keeping and medical supplies management
- community education, and
- monitoring and evaluation.

<sup>&</sup>lt;sup>1</sup> For details, readers are referred to Tuberculosis Guide for Low Income Countries (4th Ed, 1996). International Union Against Tuberculosis and Lung Disease.



#### 2.4 LOCAL TB PROTOCOL

A simple protocol for implementation of the TB programme at the local level should be developed through consultation with all agencies involved in TB care. It should be adapted for the local situation. Copies should be distributed to all treatment facilities.

In selecting the drug regimen, a WHO recommended short-course chemotherapeutic regimen should be used. Consideration should be given to the protocol of the host NTP, and of the country of origin of refugees.

#### 2.5 SUPPLY OF DRUGS AND EQUIPMENT

#### Required Steps:

- identify the responsible officer for procurement of drugs and materials
- identify potential suppliers and their costs
- estimate supply needs, cost of freight, insurance, customs duties / taxes
- estimate time from placing the order to arrival of drugs at central store
- prepare a budget for the cost of drugs, laboratory supplies and other requirements
- obtain a firm commitment for funding
- find suitable storage facilities.
- purchase the drugs and supplies, and
- monitor usage and inspect stores and recording periodically.

#### 2.6 FINANCIAL MANAGEMENT

The following items must be included in the budget estimates:

- health staff salaries
- drugs and other medical supplies
- laboratory equipment and reagents
- stationary and other clinic needs, and
- transport.

#### RESOURCES

World Health Organization. Framework for Effective TB Control. Geneva: WHO: 1994.

World Health Organization. Managing TB at National Level - A Training Course.

Geneva: WHO: 1996.



Figure 3

Key Steps in the Planning and Management of a TB Control Program

#### **SITUATION ANALYSIS**

#### **ASSESSMENT OF AGENCY'S CAPACITY**

## DEFINITION OF OBJECTIVES & TARGETS FOR THE TB CONTROL PROGRAM

#### **DEFINITION OF STRATEGIES, POLICIES, ACTIVITIES**

## PREPARATION OF WORKPLAN, RESOURCE NEEDS, BUDGET, PERSONNEL

#### **DESIGN OF MONITORING SYSTEM**

#### **IMPLEMENT**

- 1. Team building
- 2. Staff management
- 3. Problem solving
- 4. Resource management
- 5. Reporting

## **SUPERVISION**

#### **EVALUATE**





## MANAGEMENT OF TB IN REFUGEE SITUATIONS - ADULTS



#### 3.1 DIAGNOSIS OF TB IN ADULTS

The most important symptoms in the selection of TB suspects in adults (over 15 years of age) are the following:

- productive cough > 3 weeks, or
- haemoptysis, and
- significant weight loss.

Patients with TB may also have other symptoms (which are more common, but less suggestive) such as:

- chest pain
- breathlessness
- fever / night sweats
- tiredness, and
- loss of appetite.

In refugee situations, it is unusual to have ready access to x-ray facilities. It is the priority of the health services to detect the sources of infection by sputum-microscopy, and cure them.

Each TB suspect should have 3 sputum samples examined by light microscopy. The chances of finding TB organisms are greater with 3 sputum samples than with one or two samples. Secretions build up in the airways overnight, therefore an early morning sputum sample is more likely to contain the TB organism than a sample later in the day.

In practice a suspect provides sputum samples in the following manner:

- Day 1
   Sample 1 Suspect provides an "on the spot" sample under supervision on presentation to the health facility. Then the suspect is given a sputum container to take home for an early morning sample the following morning.
- Day 2
   Sample 2 Suspect brings an early morning sputum sample.
   Sample 3 Suspect provides another "on the spot" sample.

Smears should be stained using the Ziehl-Neelsen method. Any TB suspect with two positive smears is a TB patient, who must then be registered and commenced on anti-TB treatment.

If the initial 3 smears are negative, but pulmonary TB is still suspected because of persistent symptoms, the suspect should be given broad-spectrum antibiotics (e.g. amoxicillin or co-trimoxazole, **but not rifampicin**), treated for acute respiratory infection for at least one week, and re-examined two weeks after the first sputum examination by sputum smear microscopy. Specific anti-TB medication should not be commenced unless the presence of AFB is confirmed.

80% of all pulmonary TB cases are expected to be sputum smear positive: 60-65% are identified at the first examination, the remainder on subsequent examination. If at the second examination all specimens are negative, it is unlikely that the suspect has TB. Nevertheless, if it is possible to access x-ray facilities and / or refer to a hospital, an x-ray



compatible with TB should encourage further sputum examination. In the absence of a compatible x-ray the suspect is not a TB patient.

In exceptional circumstances, a compatible x-ray read by an experienced physician in the presence of symptoms consistent with TB will lead to the diagnosis of pulmonary TB in smear negative cases. These patients are not a priority for treatment, as they are not contagious at the time.

Additional cases of TB may be found among close contacts of known smear-positive cases, either family members or persons sleeping in the same shelter. Symptomatic contacts should be screened, using the procedures described above.

#### CRITERIA OF DIAGNOSIS OF PULMONARY TB IN ADULTS

#### Smear-positive pulmonary TB:

either: a patient with at least two sputum specimens positive for acid-fast bacilli by microscopy;

**or:** a patient with at least one sputum specimen positive for acid-fast bacilli by microscopy and radiographic abnormalities consistent with pulmonary TB;

**or:** a patient with at least one sputum specimen positive for acid-fast bacilli by microscopy, which is culture positive for *M. tuberculosis*.

#### **Smear-negative pulmonary TB:**

either: a patient who fulfils all the following criteria:

- two sets (taken at least 2 weeks apart) of at least two sputum specimens negative for acid-fast bacilli on microscopy
- radiographic abnormalities consistent with pulmonary TB and a lack of clinical response despite one week of a broad-spectrum antibiotic, and
- a decision by a physician to treat with a full curative course of anti-TB chemotherapy.

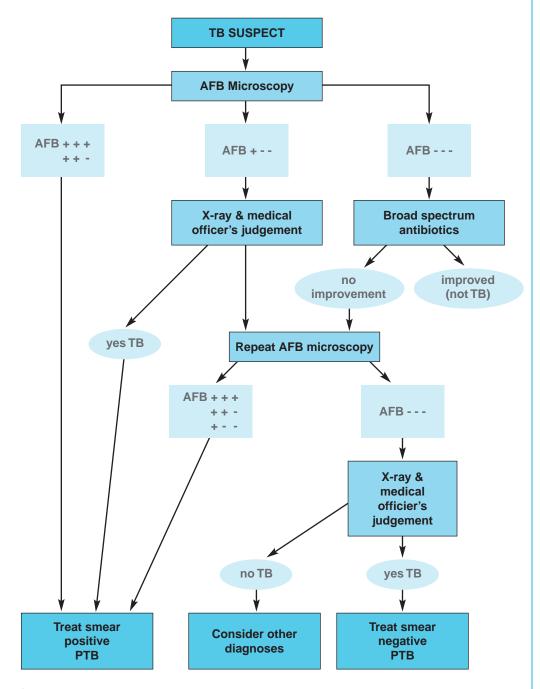
**or:** a patient who fulfils **all** the following criteria:

- severely ill
- at least two sputum specimens negative for acid-fast bacilli by microscopy
- radiographic abnormalities consistent with extensive pulmonary TB (interstitial or miliary), and
- a decision by a physician to treat with a full curative course of anti-TB chemotherapy.

**or:** a patient whose initial sputum smears were negative, who had sputum sent for culture initially, and whose subsequent sputum culture result is positive.



## Figure Standardised Management Plan for TB Patient<sup>1</sup>



<sup>&</sup>lt;sup>1</sup> From *Treatment of Tuberculosis. Guidelines for National Programmes.* Second Edition 1997. WHO

#### **ZAIRE - GOMA**

In 1994, 750,000 Rwandan refugees arrived in Goma, distributed in 4 camps in the Kivu region. With the close co-ordination of the Zairean NTP, 538 TB cases were detected (1995). 430 pulmonary TB cases (390 sputum smear positive, and 40 sputum smear negative) and 108 extra-pulmonary TB cases were registered. Smear positive cases represented 91% of pulmonary TB cases, and 72% of all TB cases. These results illustrate that high quality diagnosis, high quality laboratory services, and prioritisation of the programme are achievable under difficult circumstances even in a population where estimated HIV prevalence was 60%.

Extrapulmonary TB should not be neglected in the refugee situation, especially in young adults and children.

Some cases will be easy to diagnose:

- peripheral lymphadenitis, with swelling of cervical or axillary lymph nodes, chronic evolution with sinus and production of caseous discharge, and
- ascites due to TB peritonitis, without liver disease, or other symptoms of cirrhosis, with lymphocytes and protein in the fluid extracted by puncture.

Other cases will be suspected, but should be referred to a hospital:

- for assessment and definitive diagnosis (severe, life-threatening forms, with dyspnoea, coma or other neurological symptoms (miliary TB, TB meningitis)), or
- for x-ray, in case of suspected TB pericarditis, TB arthritis, osteomyelitis (including Pott's disease (vertebral TB)).

#### 3.2 TREATMENT

Once diagnosis is made, and before beginning treatment, every patient must be questioned carefully as to whether or not they have ever taken anti-TB drugs before.

The patient should be classified according to the following criteria:

- site of disease (pulmonary or extra-pulmonary)
- severity of disease
- bacteriological status (assessed by sputum microscopy), and
- history of anti-TB treatment (new or previously treated).

**New case** - a patient who has never had treatment for TB or who has taken anti-TB drugs for less than four weeks:

- sputum smear positive pulmonary TB
- sputum smear negative pulmonary TB, and
- extra-pulmonary TB.

Previously treated case - a patient who has ever received anti-TB treatment for more than



one month.

This group of patients comprises:

- return after interruption (common among recent refugees)
- failure a patient who while on treatment remained, or became again, smear-positive five months, or later after commencing treatment. It is also a patient who was initially smear-negative before starting treatment and became smear-positive after the second month of treatment
- relapse a patient who has been declared cured of TB in the past by a physician, after one full course of chemotherapy, and has become sputum smear-positive
- **chronic** a very small number of previously treated cases are (a patient who remained or became again smear-positive after completing a fully supervised, standardised retreatment regimen).

#### 3.3 TREATMENT REGIMENS

The chemotherapeutic regimes are based on standardized combinations of 5 essential anti-TB drugs:

- rifampicin (R)
- isoniazid (H)
- pyrazinamide (P)
- ethambutol (E), and
- streptomycin (S).<sup>2</sup>

Each of the standardized chemotherapeutic regimens consists of 2 phases:

- initial (intensive) 2-3 months, with 3-5 drugs given daily under direct observation, to maximally reduce the number of TB organism.
   The number of drugs used relates to the risk of failure of treatment due to bacterial resistance; and
- continuation 4-6 months, with 2-3 drugs given 3 times a week under direct observation, or in some cases (e.g. during repatriation of refugees) 2 drugs for 6 months given daily unsupervised, but in fixed-dose combination form.

All doses of rifampicin containing regimens are observed by staff. Actual swallowing of medication must be checked.

<sup>&</sup>lt;sup>2</sup> Regimens are written in short form with the number of months the medication is to be given in front of the letter and the doses per week written after the letter. If there is no number after the letter, a daily dosage is given. The symbol "/" separates the different phases of the therapy, e.g. 2 RHZE / 4 H3R3 means that for the first 2 months of treatment, rifampicin, isoniazid, pyrazinamide and ethambutol are given daily. This is followed by 4 months of rifampicin and isoniazid given regularly but each only given 3 times per week.

#### **Treatment Categories**

Treatment categories are essential for prioritisation of TB treatment according to public health risk - Category I is the highest priority, Category III the lowest.

#### Category I

These patients are:

- smear-positive persons who have never previously been treated or have only received treatment for less than one month
- severely ill patients with other forms of TB (new smear-negative pulmonary TB with extensive parenchymal involvement, and new cases of severe forms of TB³), and
- children with a score of 7 or more on the score chart (See TB in Children
   Chapter 4).

The recommended regime is for 6 months. For the first 2 months of treatment (initial (intensive) phase), rifampicin, isoniazid, pyrazinamide and ethambutol under direct supervision are given daily, or three times a week (streptomycin can replace ethambutol). At the end of the second month, most patients will have a negative result on sputum microscopy - they can then progress to the second stage of treatment - the continuation phase. This phase lasts for 4 months, with rifampicin and isoniazid given 3 times per week, under direct supervision.<sup>4</sup>

Whatever the reason, if the sputum smear examination is positive at the end of the second month, the initial phase is prolonged for a third month. The patient then starts the continuation phase. If the sputum smears are still positive at the end of the fifth month, this patient is classified a **treatment failure**. The patient is re-registered, and commences a full course of the retreatment regimen as a Category II patient.

Drug dose is adjusted for weight gain at the end of the initial phase (2nd or 3rd month).

#### Category II

Patient who were previously treated and are now sputum-smear positive, include:

- treatment after interruption
- treatment failure, and
- relapse after treatment.

These patients should receive a standardized retreatment regimen, fully supervised throughout both phases of treatment.

For the first 3 months of treatment (initial phase), rifampicin, isoniazid, pyrazinamide and ethambutol are given daily. This regimen is supplemented by streptomycin daily for the first 2 months. The continuation phase of this regimen is followed by 5 months of rifampicin, isoniazid and ethambutol given 3 times per week.

<sup>&</sup>lt;sup>3</sup> This category includes patients with TB meningitis, disseminated TB, pericarditis, peritonitis, bilateral or extensive pleurisy, vertebral disease with neurological complications, and intestinal and genitourinary disease.

<sup>&</sup>lt;sup>4</sup> Daily self-administered ethambutol and isoniazid may be used in the continuation phase for 6 months, so this treatment regime takes a total of 8 months.



Sputum-smear examination is performed at the end of the initial phase of treatment (at the end of three months), during the continuation phase of treatment (at the end of the fifth month) and at the end of treatment (at the end of the eighth month). If the patient is sputum-smear positive at the end of the third month, the initial phase of treatment is extended for one more month. Patients who are still positive at the end of the fourth month, progress to the continuation phase, regardless.

#### Category III

These patients are:

- smear-negative pulmonary patients (with limited parenchymal involvement), and
- non-serious extra-pulmonary disease in adults and children (including symptomatic primary disease).

All Category III patients should receive two months of rifampicin, isoniazid and pyrazinamide daily, followed by four months of alternate day isoniazid and rifampicin (if it is decided that treatment is to be commenced). These patients are not high priority, and should not be treated in the initial stages of the TB programme, or if resources are scarce.

## Essential anti-TB Drugs - Recommended Dosage (optimal and range)

	DAILY ADMINISTRATION (mg / kg)	3X PER WEEK (mg/kg)	
Н	5 (4-6)	10 (8-12)	
R	10 (8-12)	10 (8-12)	
Z	25 (20-30)	35 (30-40)	
S	15 (12-18)	Not Recommended	
Е	15 (15-20)	30 (25-35)	



# Recommended Treatment Regimen for Each Treatment Category 5

Treatment Category	Patients	Initial (Intensive) Phase	Continuation Phase
I	New smear-positive pulmonary TB; new smear- negative pulmonary TB with extensive parenchymal involvement; new cases of severe forms	2 EHRZ (2 SHRZ) or 2 E <sub>3</sub> H <sub>3</sub> R <sub>3</sub> Z <sub>3</sub> (2 S <sub>3</sub> H <sub>3</sub> R <sub>3</sub> Z <sub>3</sub> )	4 H₃ R₃ (6 HE)
	of extra-pulmonary TB.	(2 <b>3</b> 3 H3 K3 Z3)	
II	Sputum smear-positive; relapse; treatment failure; treatment after interruption.	2 SHRZE / 1 HRZE	5 H₃ R₃ E₃
III	New smear-negative pulmonary TB (other than	2 HRZ	4 H₃R₃
	in Category I); new less severe forms of extra-	or	(6 HE)
	pulmonary TB.	2 H <sub>3</sub> R <sub>3</sub> Z <sub>3</sub>	

N.B. Some authorities recommend a 7 month continuation phase with daily isoniazid and rifampicin (7 HR) for Category I patients with serious forms of disease: TB meningitis, miliary TB, spinal TB with neurological signs.

<sup>&</sup>lt;sup>5</sup> Adapted from *Treatment of Tuberculosis*. Guidelines for National Programmes. Second Edition 1997. WHO / TB / 97.220.

Pretreatment Body Weight (kg)	Initial (intensive) Phase			Continuation Phase			
	2 Months (daily)			4 Months (3 x per week)		6 Months (daily)	
	Isoniazid + Rifampicin (100mg+150mg tablet, or 150mg+300mg tablet)	Pyrazinamide (400mg or 500mg tablet)	Ethambutol (400mg tablet)	Streptomycin (1g base powder, for injection)	Isoniazid + Rifampicin (100mg+150mg tablet) *	Isoniazid (300mg tablet)	Ethambutol + Isoniazid (400mg+150mg tablet)
<33	2 (100mg+ 150mg tablet)	2	2	500mg	2	1	11/2
33-50	3 (100mg 150mg tablet)	3	2	750mg	3	1	2
>50	2 (150mg+ 300mg tablet)	4	3	1g (750mg for persons >5 years)	4	1	2

<sup>\*</sup> When Isoniazid + Rifampicin is given daily in the Continuation Phase, the doses given are the same as in the initial phase.





#### Pretreatment Continuation Phase Initial (intensive) Phase Body Weight (kg) 3 Months (daily) 5 Months (3 x per week) Isoniazid + Pyrazinamide Ethambutol Streptomycin Isoniazid + Isoniazid Ethambutol Rifampicin (400mg or (400mg tablet) 1g base powder, Rifampicin (300mg tablet) (400mg tablet) (100mg+150mg 500mg tablet) for injection) \*\* (100mg+150mg tablet, or tablet) \* 150mg+300mg tablet) <33 2 (100mg+ 2 2 500mg 2 2 1 150mg tablet) 33-50 3 (100mg+ 3 2 750mg 2 3 1 150mg tablet) >50 2 (150mg+ 4 3 1g 4 1 3 (750mg 300mg tablet) for persons >50 years)



<sup>\*</sup> When Isoniazid + Rifampicin is given daily in the Continuation Phase, the doses given are the same as in the initial phase.

<sup>\*\*</sup> Streptomycin is only given for the first 2 months of the initial (intensive) phase.

Recommended Treatment Regimens for Category III Patients

MANAGEMENT OF TB IN REFUGEE SITUATIONS - ADULTS

Pretreatment Body Weight (kg)	Initial (inten	Continuation Phase			
	2 Month	4 Months (3 x per week)		6 Months (daily)	
	Isoniazid + Rifampicin (100mg+150mg tablet, or 150mg+300mg tablet)	Pyrazinamide (400mg or 500mg tablet)	Isoniazid + Rifampicin (100mg+150mg tablet) *	Isoniazid (300mg tablet)	Ethambutol + Isoniazid (400mg+150mg tablet)
<33	2 (100mg+150mg tablet)	2	2	1	12
33-50	3 (100mg+150mg tablet)	3	3	1	2
>50	2 (150mg+300mg tablet)	4	4	1	2

<sup>\*</sup> When Isoniazid + Rifampicin is given daily in the Continuation Phase, the doses given are the same as in the initial phase.









#### 3.4 TREATMENT ADHERENCE

Ensuring patient adherence is mandatory to ensure the cure of the patient and the success of the programme. Conditions for producing adherence include:

- directly observation of treatment
- home visits to trace non-compliers and patients who interrupt their treatment (defaulters)
- good relationship between staff and patient
- continuing education programme for staff, patients and families, and the community, and
- clinic setting acceptable to patients and staff.

Active follow-up of defaulters by the healthcare worker responsible for that patient must be in place. All TB patients should be followed-up, even after missing one attendance.

TB control programmes operating within the refugee camps in 1995, covering a population of 750,000 recruited 357 new smear positive TB patients; the cured + treatment-completed rate was 71%, 13% died, 8% defaulted and 6% transferred out. The high death rate was related to the high prevalence of HIV.

#### I - CAMBODIAN BORDER

A programme tailored for the Khmer refugees in the camps achieved an excellent adherence rate. After their sputum was found to be positive for the TB organism, each patient was required to attend a 4 day course for 1 hour per day. This course covered most aspects of TB, its spread and its treatment. A housemate was chosen to help take responsibility for the TB patient receiving their course of treatment. Patients were required to teach their housemate what had been taught at the course. A home visit was made by members of the TB staff, including the health worker who would follow the patients throughout their course of treatment. The visit was to evaluate household contacts for symptoms of TB and to assess how much the housemate had learnt from the patient. Multiple interviews occurred prior to acceptance into the programme. It was felt necessary that patients had a stable residence, were not looking for missing family members and thus likely to leave, and had a regular source of food (to ensure they stayed for the duration of treatment). If the staff agreed to take the patient into the programme, a contract was signed by all the parties before treatment could begin. The refugee was required to commit himself to attend the clinic regularly for the entire duration of the treatment.

Food incentives have been successfully used is some programmes but their use is controversial. Extra food may help the nutritional state of patients, and may act as a powerful incentive to attend for treatment. The use of **material** incentives is discouraged.



### SOMALIA

A successful TB programme was established despite the security problems in the country. Here excellent adherence rates were achieved and new patients were attracted from other areas as word spread of the programme's success.

All patients received treatment in accordance with the WHO TB control strategy. In addition to the medications they were provided with 3 meals per day, lodging for themselves and their family if they were not from the local area, and education for their children. A mosque was provided in the premises for use by patients and their families. A contract was signed by the patient, their supporter and the TB staff prior to the commencement of therapy.

Initially, TB was a stigmatized disease in the area and many patients avoided medical assistance for fear of being labeled. This is changing as more patients are being cured.

## 3.5 PATIENT MANAGEMENT

The majority of TB patients can be treated on an outpatient basis, unless they are severely ill. They do not require isolation. Outpatient treatment is given daily or three times a week by the nurse or the health worker responsible for the health facility in the camp. These services should be fully integrated into the general health services for that population.

Indications for hospitalization are:

- severe disease (e.g. meningitis requiring high quality diagnosis, nursing care and regular observation)
- serious complications of treatment (e.g. severe skin reactions, hypersensitivity, jaundice)
- other concomitant diseases with potential deleterious impact on treatment (e.g. malaria, diabetes, hepatic insufficiency, renal insufficiency), and
- logistical difficulties (e.g. providing treatment for a sick patient from a remote village who can't walk to receive treatment).

In hospital, TB patients recently started on treatment should be separated from other patients (especially those infected with HIV) in a well ventilated area. Each patient should have a covered container for sputum and the contents must be disposed of in a safe manner. The patients and their families should receive regular education on preventive measures such as covering the mouth when coughing.

Refugees may be at risk of malnutrition. Nutritional rehabilitation is important in the treatment of TB in refugee situations. TB causes severe weight loss, even in people with adequate nutritional intake. Nutritional supplements during the intensive phase should be given, if possible, and continued in the continuation phase if signs of malnutrition persist.



## TB TREATMENT DURING PREGNANCY

Pregnant women are treated with the same regimens as others but streptomycin must not be given. All other drugs are safe in pregnancy and lactation. Ethambutol may be substituted for streptomycin.

All women should be asked if they are pregnant before commencing treatment. They should be asked to notify the TB clinic if they become pregnant during the course of TB treatment.

## RESOURCES

World Health Organization. Framework for Effective TB Control. Geneva: WHO: 1994.

World Health Organization. Treatment of Tuberculosis - Guidelines for National Programmes. Second Edition Geneva: WHO: 1997.



## MANAGEMENT OF TB IN REFUGEE SITUATIONS - CHILDREN



Cases of TB in children usually represent about 10% of all TB patients. The source of transmission of TB is usually an adult, often a family member with smear positive TB. TB in children is a general disease which may affect any part of the body. Children rarely have smear positive TB, so they are rarely infectious.

In refugee situations with a large number of children, extra-pulmonary forms of TB should be suspected, diagnosed and treated appropriately. Often, this requires referral to a hospital for x-ray and special examinations (e.g. lumbar puncture).

Children with headache, change of temperament, recent squint or ocular muscle paralysis or dyspnoea should be suspected of meningitis. TB is one, although rare, cause of meningitis (meningococcal meningitis is a more common cause in the refugee setting). Definitive diagnosis requires hospital referral.

Children with high fevers, dyspnoea, gastro-intestinal symptoms, confusion (i.e. those with suspicion of acute miliary tuberculosis) must also be referred to hospital for assessment and diagnosis.

Suspected bone and joint TB, or pleural effusions also requires referral.

Commoner forms of extra-pulmonary disease can be diagnosed and treated in a camp situation (e.g. cervical or auxiliary lymphadenitis, peritonitis with ascites).

The diagnosis of TB in children should be carefully considered in a child if there is:

- an illness lasting for more than 10 days
- a history of close contact with a TB patient
- a poor response to antibiotic therapy
- a poor response to one month of nutritional rehabilitation
- weight loss or abnormally slow growth
- loss of energy, or
- increasing irritability and drowsiness over 2 weeks.

The drug regimens used for children are the same as for adults with the exception that streptomycin should be avoided. Drug dosages must be calculated using the child's weight. Adjustments may have to be made during the course of the treatment as the child may rapidly regain lost weight.

For infants of newly diagnosed smear-positive mothers, breast-feeding should continue. The infant should not be separated from the mother. Transmission is likely to have occurred already and the infant is at greater risk of dying from other causes if breast-feeding is stopped. If the infant is well, s/he should be given isoniazid as prophylaxis for 6 months. BCG should be given one week after ceasing the isoniazid. If the infant becomes unwell, TB should be suspected.



## Score Chart<sup>6</sup>

A score sheet has been developed to improve the diagnosis of childhood TB. A score of 7 is considered suggestive of TB and treatment is recommended. If the score for the child is 6 or less, a 7 day course of antibiotics should be given and repeated if there is no clinical improvement. The response is again assessed after the second week. If there has been no improvement, anti-TB treatment is recommended.

Nutritional rehabilitation should be given to a child suspect for at least one month.

## To be used after 1 month of Nutritional Rehabilitation

FEATURE	0	1	3	SCORE
LENGTH OF ILLNESS	LESS THAN 2 WEEKS	2-4 WEEKS	MORE THAN 4 WEEKS	
NUTRITION (WEIGHT)	ABOVE 80% FOR AGE	BETWEEN 60% AND 80%	LESS THAN 60%	
FAMILY TUBERCULOSIS PAST OR PRESENT	NONE	REPORTED BY FAMILY	PROVED SPUTUM POSITIVE	

## Score for other Features if Present

Positive tuberculin test (3 points)  Large painless lymph nodes, firm, soft, sinus in neck, axilla, groin (3 points)  Unexplained fever, night sweats, no response to malaria treatment (2 points)  Malnutrition, not improving after 4 weeks (3 points)  Angle deformity of spine (4 points)  Joint swelling, bone swelling or sinuses (3 points)  Unexplained abdominal mass or ascites (3 points)	
Unexplained abdominal mass or ascites (3 points) Central nervous system signs (change in temperament, fits or coma) (3 points)	
TOTAL SCORE	

When score is 7 or more, treat for TB.

<sup>&</sup>lt;sup>6</sup> Adapted from, Crofton J, Horne N, Miller F. Clinical Tuberculosis, MacMillan, TALC and IUATLD,1992 (Courtesy Dr. Keith Edwards, University of Papua New Guinea).



### PREVENTION OF TB IN REFUGEE SITUATIONS



## 5.1 PREVENTION

The diagnosis and cure of infectious cases of TB is the most effective method of preventing the transmission of TB.

BCG has been shown to be effective in preventing severe forms of TB such as meningitis in children. As overcrowding and malnutrition are common in many refugee situations, the risk of TB transmission to children is increased. BCG is strongly recommended for all newborn children in refugee situations and any children up to the age of 5 years who have not already received it. The vaccination of newborns should be incorporated into the immunization programme for all children. Re-vaccination is not recommended.

Other methods of preventing TB transmission include ensuring good ventilation and reducing crowding in health clinics, and ensuring hospitalised patients are kept in a separate ward for the first two weeks of treatment. Particular care must be made to separate infectious TB patients from HIV positive individuals.

Isoniazid prophylaxis is not recommended in refugee situations, except for children being breast-fed by smear positive mothers. If the child is well, BCG vaccination should be postponed and isoniazid should be given to the child for 6 months. In the event of a sudden disruption to the programme, isoniazid may be stopped, and BCG should be given before the child leaves the refugee camp (preferrably after a one week interval).

## 5.2 HEALTH EDUCATION

Key elements of community education are:

- removal of stigmatization of TB
- early (self) referral of TB suspects, and
- the importance of adherence to treatment.

The most important messages to teach are:

- coughing spreads diseases including TB
- TB is curable
- good treatment is the best prevention
- anyone may contract TB
- early diagnosis and treatment stops TB spreading and cures the patient quickest
- all patients must take the full course of treatment.
- TB can cause a cough lasting more than 3 weeks, chest pain, shortness of breath and fevers or sweats
- treatment makes patients non-infectious in two weeks, but cure takes 6 or 8 months.
- incomplete treatment contributes to spreading disease
- treatment must be completed even when the patient feels better, and
- controlling TB is a community responsibility.



- covering the mouth whenever coughing or sneezing to prevent the spread of lung diseases
- all patients should be treated sympathetically and with respect
- early treatment is important for best results and to prevent spread, especially to family members
- children are especially at risk if not treated and may develop severe, even fatal disease
- treatment is necessary for at least 6 months although the patient feels better much sooner
- failure to complete the treatment may result in a recurrence which may be impossible to treat and spread of serious disease to others, especially children.

Diagrams should be used as much as possible - a high literacy rate should not be assumed.

Cured patients are often helpful teachers and supporters of new patients.



## MONITORING OF TB CONTROL PROGRAMMES IN REFUGEE SITUATIONS



## 6.1 RECORDING AND REPORTING

Good record keeping is an essential requirement for a successful programme. Because the treatment is long, and adherence is essential for a successful outcome (cure), the individual patient must be closely followed.

It is important to assess the overall progress and success rate of the programme. This requires detailed information about the patients' progress even if they have not yet completed the course of therapy.

Key requirements are:

- accurate record keeping
- regular reporting
- regular analysis, and
- regular feedback to all staff involved.

Records<sup>7</sup> which must be kept are:

- Suspects Register
- Laboratory Register
- Individual Patient's Record, and
- Central TB Register.

It is essential for an orderly referral process to be in place. The critical link is between the Laboratory Register and the Central TB Register. The TB co-ordinator must check that all patients with positive sputum results are entered in the Central TB Register in a timely manner. If the laboratory is situated near the clinic, this person should check the laboratory register daily. If daily review is not practical, twice weekly is suggested. The same staff member must also be responsible for contacting the relevant clinic so the patient can commence treatment promptly. Follow-up to ensure the patient has actually commenced the treatment is essential. Close supervision to ensure these crucial links are made is of vital importance.

## 6.2 EVALUATION OF THE PATIENT

If possible, patients should be reviewed by a doctor weekly for the first month, then every 2 weeks during the second month, and monthly for the duration of their treatment.

Essential indicators to measure individual patient progress are:

- sputum-smear result after 2 months of treatment
- if positive at 2 months, sputum microscopy to be repeated at 3 months after an additional month of intensive phase therapy;
- sputum-smear result after 4 months (5 months for Category II) of therapy, and
- sputum-smear result at the completion of the 6 months (8 months for Category II) of therapy.

<sup>&</sup>lt;sup>7</sup> Examples of recommended forms can be found in *International Union Against Tuberculosis and Lung Disease (IUATLD) Tuberculosis Guide for Low Income Countries. 4th ed. 1996.* 

Also World Health Organization, Managing Tuberculosis at District Level. Registering Cases, Quaterly Reporting on Case Finding, Quarterly Reporting on Treatment Results. 1994.



Two smears must be negative before a patient can be declared cured. The laboratory must examine all specimens, even if the specimen, after treatment, is non-purulent.

## 6.3 OUTCOME DEFINITIONS

At the end of the treatment course for each patient, the TB Coordinator should record the treatment outcome as follows:

### Cure

patient who is smear negative at (or one month prior to) the completion of treatment and on at least one previous occasion

## Treatment completed

patient who has completed treatment but in whom smear results are not available on at least 2 occasions prior to the completion of treatment

## Treatment failure

patient who remains or becomes again smear positive at 5 months or later, after starting treatment

### Died

patient who dies for any reason during the course of chemotherapy

## Treatment after interruption (default)

patient whose treatment has been interrupted for more than 2 consecutive months before the end of course of treatment, or

### Transferred out

patient who has been transferred to another treatment centre and whose treatment results are not known.

## 6.4 EVALUATION OF THE LABORATORY

The following information should be routinely reported by the laboratory:

- number of sputum samples examined and percentage positive
- number of new smear-positive sputum patients diagnosed
- number of extra-pulmonary patients diagnosed
- result of quality assurance tests, and
- · regular review of records.

All smears must be reported as being saliva or sputum.

## 6.5 EVALUATION OF TB PROGRAMME PERFORMANCE

A monthly health center report should be prepared and be integrated with the health information system in the region. In the refugee situation, UNHCR or UNICEF usually has



such a system in operation to monitor diseases which are known to be a problem. The TB section of this report merely includes the number of new TB patients diagnosed (smear-positive and extra-pulmonary) by age (under 5, and over 5 years) and the number of TB patients whose treatment is completed and are cured. **These figures are not sufficient to evaluate a TB programme.** 

Evaluation of TB programme occurs in 3 stages:

- case finding
- early treatment result (smear conversion by 2-3 months) 8, and
- cohort analysis for treatment outcome (12-15 months after registration).

## **Case Finding**

The number of:

- new patients, who were sputum smear positive
- elapse patients, who were sputum smear positive, and
- other patients being treated (e.g. extra-pulmonary)

should be reported every 3 months from each diagnosis and treatment centre.

## Early Treatment Result (Smear Conversion by 2-3 Months)

In order to anticipate the result of treatment (which would otherwise not be available for another 12-15 months) it is essential to monitor the sputum smear conversion rates achieved at the end of 2 and / or 3 months of treatment.

The expected smear conversion rate, even in refugee situations, should be higher than 80%. If a programme is achieving conversion rates of 80% or less, it should be reviewed immediately - there is either:

- misclassification of patients
- DOT is not being properly applied, or
- patient follow-up is poor.

Corrective measures should be devised and applied.

Evaluation of smear conversion by 2-3 months can be reported independently of the reporting forms, or assessed by the TB Coordinator during supervisory visits to the laboratory.

## **Cohort Analysis**

A cohort consists of patients who were diagnosed, registered and planned to have the same treatment within a defined period (12-15 months prior to analysis).

Evaluation of outcome of treatment is based on the analysis of two groups of patients:

- new sputum smear positive pulmonary cases receiving Category I regimen, and
- retreatment sputum smear positive pulmonary cases receiving Category II regimen.

<sup>&</sup>lt;sup>8</sup> The analysis of the 3 month smear conversion rate is not done until 3 months after the end of the quarter during which the cohort was registered.





## **Quarterly Report on New Cases and Relapses of Tuberculosis**

This report complies with the epidemiological and administrative requirements for the notification of new and relapse cases diagnosed in the previous 3 months. The report includes the total number of pulmonary smear positive cases (divided into new and relapses), pulmonary smear negative and extrapulmonary cases which were diagnosed and registered during a quarter. The failure, chronic and return after interruption cases are not included in this report; they are not notifiable cases. The new pulmonary smear positive cases are classified by age and sex; all the other types of patients are classified only by sex

The report is prepared by the TB Coordinator based on the information entered into the Central TB Register. The report is submitted to the NTP.

## RESOURCES

International Union Against Tuberculosis and Lung Disease (IUATLD)
Tuberculosis Guide for Low Income Countries, 4th ed. 1996

Technical Guide for Sputum Examination for Tuberculosis by Direct Microscopy.

Bulletin of the International Union Against TB. 1978. Suppl. No. 2.

World Health Organization. Managing TB at National Level - A Training Course. Geneva: WHO: 1996.

World Health Organization. Managing TB at District Level - A Training Course. Geneva: WHO: 1994.

World Health Organization. Treatment of Tuberculosis - Guidelines for National Programmes. Second Edition Geneva: WHO: 1997.



## Possible causes, and solutions, for poor treatment outcomes

If there were too many	And the cause was	Then the possible solutions are		
	High prevalence of HIV	Multiple interventions to minimize HIV transmission		
Deaths	Tuberculosis was diagnosed late	Make sure health workers properly assess symptoms in tuberculosis suspects and send sputum for examination.		
		Identify any impediments to access to health facilities, and correct them.		
	Trading in drugs and materials	Investigate thoroughly, and take appropriate action.		
	Poor quality medications may be being used.	Review the tendering and procurement procedures		
Failures	A low smear conversion rate at 2 (3) months	Make sure that there is 100% supervision		
	Patients do not take all the medications.	of dose administration.		
	Primary resistance to both Rifampicin and Isoniazid	Devise local protocol - initiate all previously treated patients (irrespective of duration of previous treatment) on Category II treatment.		
	Inappropriate regimen for the specific situation, for example: retreatment patients given a regimen for new patients	Improve supervision of the health facility		
	Prescription of an inappropriate regimen for smear-positive Patients previously treated with anti-tuberculosis medications	Ask the clinic supervisor to make sure staff knows which regimen to prescribe to each type of Patient according to the NTP. Check the regimen prescribed in the Register and on the tuberculosis Treatment Card.		
		Are medications being traded?		

continued overleaf





#### /... (continued) Possible causes, and solutions, for poor treatment outcomes

If there were too many	And the cause was	Then the possible solutions are
Defaulters	Patients were not given proper health education	Make sure that proper health education is provided to Patients on a continuous basis, and in a way that they can understand it.
		Help authorities to understand the importance of the diagnosis of tuberculosis.
	Patients were not given proper health education. Unfriendly behavior of the health staff	Pay attention to staff morale and
	Slow delivery of medications at the health unit.	enhance training.
	Non-compliers and defaulters were not followed up	Make sure health workers understand the importance of tracing Patients. Arrange tracing of Patients who disappear, especially those who are smear positive.
	Patients are released, and not follow-up, or not transferred correctly.	Increase supervision; review arrangements between NTP and community health services
Transferred out	Patients who were erroneously considered "transferred out" when they had the intensive phase and the continuation phase treated in different districts	Patients should be registered in the place where they are receiving treatment.  In well established programmes or area tuberculosis coordinator should trace Patients who transfer/move to the region and find out their treatment outcomes.



# EVOLUTION OF TB CONTROL PROGRAMMES IN REFUGEE SITUATIONS



# 7.1 EXPANSION OF TB CONTROL PROGRAMMES IN REFUGEE SITUATIONS

If the TB control programme achieves conversion rates of at least 85% at 2 (3) months of treatment in new smear-positive and relapse cases, in at least one clinic, this implies that the TB control policies can be implemented effectively. At this stage, expansion from that clinic can occur. The clinic should be designated a 'Demonstration and Training Centre'.

Expansion should be gradual. Many staff will need to be trained effectively. Higher level supervisors will need to assist as trainers, as the ongoing operations of the Demonstration and Training Centre must not be neglected.

Training should include the health staff at peripheral health facilities who have responsibilities of case-finding and treatment of TB patients. Laboratory staff must also be trained before expansion can proceed.

## 7.2 MAINTENANCE PHASE OF A PROGRAMME

Most patients are expected to complete their treatment at the site in which they was originally begun; however, a plan should be devised to deal with patients who transfer into or out of the programme.

Transfers into a programme should be treated as follows:

- if patients are smear positive and have been treated for more than one month, commence on Category II regimen, or
- if patients are smear negative, consider the duration and quality of the initial phase treatment, and apply either full continuation phase (if treated more than 2 months), or commence on Category III regimen.

Patients who transfer-in, and have documentation of an incomplete course of continuation therapy, but have two negative smear examinations, should complete the continuation phase (as *per* documentation).

Although these patients are registered, their outcome is usually not evaluated with the 'transfer-in' register. All patients previously treated, who transfer-in **and** are still sputum smear positive, should be registered as 'Return after interruption' or as 'Failure' and the outcome of their treatment should be evaluated with the cohort of retreatment cases.

Lower rates require careful review to determine why results are inadequate and serious attempts should be made to improve them.

<sup>&</sup>lt;sup>9</sup> Ideally a programmes should aim for cure rates of 85%. However, in the refugee situation the other outcome measures such as patient fatality rate may be high because of concomitant disease, malnutrition and HIV; treatment interruption and transfer-out rates can be high because of instability, either population or political. In these circumstances cure rates of 75-80% are reasonable.



## 7.3 REPATRIATION AND TRANSFERS OUT OF THE PROGRAMME

Repatriation or transfer may occur during the course of treatment if:

- the health services in the area to which the patient is transferring are functioning and are able to cope with additional patients, and
- satisfactory liaison between the 2 programmes is possible to avoid interruption of treatment.

It is very important that continuity of treatment occurs even during transfer. Contact with the new treatment center should be made by the clinic staff if possible prior to transfer. Forward planning and liaison between staff is particularly desirable if a large population is returning home.

All patients should have:

- their personal record card up to date and with the treatment plan for the rest of the course detailed (a copy of the card should be sent ahead of the patient to the new treatment center if possible)
- adequate drugs to enable them to travel to their new residence and for a short period upon arrival to enable them to establish contact with another clinic, and
- a letter detailing previous treatment, drug doses, adherence etc. which
  may also be useful if the patient treatment card is lost. A standard
  template may be made, especially if transfers are common.

In the Central TB register, patients are recorded as transferred out. However, every effort should be made to determine the final outcome and the register updated so that the outcome may be included in the statistics for the relevant cohort.

If the health services in the area to which the patient is transferring into are not functioning or able to cope with extra patients or satisfactory liaison cannot be made to avoid the interruption of treatment, it is preferable for the patients to remain in the camp or present treatment center until treatment can be completed. Many people repatriate to areas where no medical care is available and any further treatment will be impossible. The patients and their families should be counseled regarding the advantages, disadvantages and risks associated with transfer - the risks of delayed repatriation must be balanced with the specific risks of the individual's treatment.

The intensive phase of treatment is crucial in the treatment course. Repatriation or transfer should be delayed until at least this phase has been completed and 2 sputum examinations a month apart are negative (at 2 and 3 months of treatment).



# 7.4 PHASING DOWN OF TB CONTROL PROGRAMMES IN REFUGEE SITUATIONS

The programme must include contingency planning for unstable situations in the area, within the camp, or forced relocation of the refugees. If the situation appears imminent it may be useful to distribute a small supply of drugs to each patient - 3 days for example. These reserve supplies should be prepared when each patient enters the programme but only distributed if needed so as to avoid the sale of the drugs on the black market. No new cases should be recruited during this period. Suspects should be registered, for follow-up at a later date.

The TB control programme should be phased down if:

- population displacement or closure of the camp will be occurring in the next 3 months
- funding is no longer available, or
- security problems are severely interfering with the programme efficiency;
   e.g. making regular supply of drugs impossible.

Admission of new patients to the TB programme should be discontinued a few months before there is likely closure of the camp or movement of displaced persons.

It is usually unreasonable to expect patients to be able to continue treatment if repatriation is intended. The home country is unlikely to have a functioning programme and refugees will have many other priorities when they first return. Patients should not be started on treatment if they are unlikely to be able to complete it.

Every effort should be made to complete treatment for existing patients, even if new patients are not registered. **Incomplete treatment is worse than no treatment.**Once treatment has commenced, the TB programme has a commitment to the patient to provide a complete course of treatment.

Following closure of a TB programme in an area, the TB register should be sent to the NTP so that enrolled patients may be followed-up to completion of treatment.





### **RESPONSIBILITIES OF KEY AGENCIES**



In order to implement an effective TB control programme, it should be planned and operationalised at several levels:

## National level

- where there is an effective NTP, the NTP will be the lead agency, assisted by WHO, UNHCR and NGOs operating in the country, or
- where the NTP is not functional, the WHO Representative will be the lead officer to assist in the development of a TB control programme in close collaboration with appropriate national agencies, assisted by UNHCR and NGOs operating in the country. In this situation, efforts are to be made to develop an effective NTP.

**Inter-country level** - especially during the repatriation phase and at other periods of mass population movement.

NTP Managers of the host country, the recipient country and any third country (e.g. during transit), assisted by appropriate NGOs - this process will be assisted by various mechanisms:

- WHO Regional participation
- UNHCR participation, and
- inter-country (border) committees.

Where the NTP uses WHO / IUATLD endorsed regimens, then the regimen used in the programme should be that used by the NTP. If the NTP is using some other protocol, then advice should be sought from the WHO representative in consultation with the NTP manager. When there is inconsistency between the host country and the country of origin, the decision on drug regime should be referred to an inter-country (border) committee.

## **Key Agencies**

## National TB Programme

- responsibility for all TB control activities in the country
- delegation of TB control activities to recognized organizations, as appropriate
- planning, implementing and evaluating the TB control activities in refugee and displaced populations
- coordinating government, international and non-government organizations funding
- drug procurement and distribution
- training
- supervision of TB control activities for refugees and displaced populations, and
- establishment of inter-country (border) committees to coordinate TB control activities in border areas.

## World Health Organization

- provide technical support, such as development of guidelines and human resource development
- advise on when to commence, and when not to commence, a TB control programme



- assist in the development of a quality control system for drugs
- assist in the arrangements for drug procurement
- assist in advocacy and fund-raising, and
- take the lead role, in the absence of an effective NTP.

## Office of the United Nations High Commission for Refugees

- secure the camp or emergency setting situation to a point where planning a TB control programme can commence
- support NTP / WHO in planning a TB control programme as a component of general health services
- assist in procurement of TB drugs, and
- support planning, especially in anticipation of, and during, repatriation and mass population movement.

## Non-government organizations

- operate during the non-secure phases of an emergency limited relevance to TB control
- monitor health, security and human rights within refugee and displaced populations
- organize health facilities
- implement TB control activities
- recognize the supervisory and coordination functions of the NTP / WHO, and
- provide resources for training, programme management, laboratory, drugs and health promotion.



# JOB DESCRIPTIONS AND RESPONSIBILITIES OF TB PROGRAMME STAFF



The number of personnel required and their job descriptions will depend on the local situation. Factors such as the number of refugees or people requiring care in the emergency situation, the site and how spread out the population is will help to determine staffing needs. In large areas, where the affected population is dispersed in a number of different camps or villages, local area coordinators may be required in addition to the overall TB coordinator.

## Lead Agency

- Ensure adequate funding is available for the programme
- Appoint a suitable TB Coordinator
- Assist with the training of personnel, especially laboratory technicians, and
- Liaise with national authorities, donors and international agencies involved in refugee care

## TB Coordinator10

- Liaise with National TB Programme
- Provide leadership, encouragement and advice for problem solving to all staff members
- Responsible for the production of TB protocol for the camp or emergency settings and their distribution to each treatment post
- Responsible for the training of camp or local area coordinators
- Responsible for setting up the programme in all the camps (and any sites for Internally Displaced Persons)
- Coordinate training of programme staff including 2 laboratory technicians for each laboratory
- Supervise overall functioning of the programme
- Ensure quality control of all aspects of the programme including the laboratory
- Ensure adequate stocks are available at all times
- Ensure continuing education programmes for staff and the community
- Visit the laboratory regularly and record all new patients in the central register
- Maintain the Central TB register up-to-date
- Ensure follow-up all patients, especially transfers and difficult patients, and
- Coordinate management of all TB-related information.

## Health Workers

- Liaise with laboratory to ensure all sputum positive patients are followed up
- Ensure all records are kept up-to-date and are accurate
- Ensure all follow-up sputum tests are performed as required and results recorded
- Provide feedback of clinic results to CHWs and other staff
- Ensure all patients are treated with respect and compassion by clinic staff

<sup>&</sup>lt;sup>10</sup> This is the only position dedicated to TB control



- Ensure clinic hours are suitable for the patients and long waits are not encountered
- Ensure incentives are distributed appropriately
- Implement continuing education programmes in the clinic
- Ensure all who fail to attend for treatment are followed up
- Check supplies are adequate (including emergency stock) and orders placed in a timely manner
- Liaise with camp or emergency setting coordinator, and
- Provide continuing education programmes for staff and the community.

## Community Health Workers

- Refer anyone with symptoms suspicious of TB to the clinic
- Educate community, patients and relatives re TB and its management
- Supervise directly observed therapy administration to patients for whom they are responsible
- Record all treatments given in clinic records and on patient's record card
- Identify defaulters, 'returnees' and 'missing', and
- Follow up non-compliers and defaulters.

## Laboratory Technician

- Examine all smears sent for AFB examination and accurately report the findings. Reports should include whether the sample was saliva or sputum, whether AFBs were seen and if so in what numbers (e.g. scale from ++++ to +)
- Supply regular written reports to the clinic supervisor of all smear results, both positive and negative, and
- Keep a list of all new smear positive patients, the date of diagnosis, when and who notified.



## **ADVERSE EFFECTS OF ANTI-TB DRUGS**



Adverse effects are classified as minor or major. In general, a patient who develops minor adverse effects should continue the anti-TB treatment, usually at the same dose but sometimes at a reduced dose. The patient also receives symptomatic treatment. If a patient develops a major side effect, the treatment or the offending drug is stopped. Patients with major adverse reactions should be managed in a hospital.

Side Effects	Drug(s) probably responsible	Management
MINOR		
Anorexia, nausea, abdominal pain	Rifampicin	Give drugs last thing at night
Joint pains	Pyrazinamide	Aspirin
Burning sensation in the feet	Isoniazid	Pyridoxine 100 mg daily
Orange / red urine	Rifampicin	Reassurance
MAJOR		
Itching of skin, skin rash	Streptomycin	Stop anti-TB drugs
Deafness	Streptomycin	Stop streptomycin use ethambutol
Dizziness     (vertigo and nystagmus)	Streptomycin	Stop streptomycin use ethambutol
Jaundice     (other causes excluded)	Most anti-TB drugs (especially isoniazid, pyrazinamide and rifampicin)	Stop anti-TB drugs
Vomiting and confusion (suspect drug-induced acute liver failure)	Most anti-TB drugs	Stop anti-TB drugs.
Visual impairment (other causes excluded)	Ethambutol	Stop ethambutol
Shock, purpura, acute renal failure	Rifampicin	Stop rifampicin

Management of a cutaneous reaction - the recommended approach is to try symptomatic treatment with anti-histamines, continue anti-TB treatment, and observe the patient closely. However, if a skin rash develops then all anti-TB drugs must be stopped.





### **ESTIMATING DRUG REQUIREMENTS**



## **Drug Requirements**

To estimate the requirements of an initial order of drugs for the first year, follow these steps:

- Define the treatment regimens to be adopted, then define the drugs to be used for each category of patient, the number of weight groups to be differentiated, and the dosages for each
- Calculate the drug requirement per patient for each category (see table)
- Estimate the number of smear-positive cases based on epidemiological data (e.g. Africa and Asia 100 per 100,000; Latin America and the former USSR 50 per 100,000)
- Estimate the number of adult patients in each category to be treated.
   When a large population is displaced, the proportion of patients whose treatment has been interrupted is high during the first year. For example, with Rwandan refugees (October, 1994), the estimate for each 100,000 population was:
  - 50 Category I patients (new smear positive cases with 10% severe smear-negative)
  - 20 Category II patients (failures, relapses, and smear-positive cases after interruption of treatment), and
  - 30 Category III patients.
- Calculate total estimated drug requirements for adults
- Add 10% to the quantity of each drug (or combination drug) to provide for children and some wastage, and then
- Add 50% for reserve stock to the first purchase

For planning purposes, add an additional 50% to costs, to cover transportation and distribution.

Review drug usage after the first three months and, based on consumption during that period, recalculate requirements for the rest of the year. Place orders well in advance to ensure continuity in supply. Note that requirements may increase if treatment is seen to be successful, as more suspected cases will be encouraged to come forward.

The drug cost (FOB) of a full course of treatment in 1997 is approximately \$26 per new patient (Category I); \$61 for retreatment (Category II); \$20 per new patient (Category III).

Distributing and administering four separate drugs simultaneously — and ensuring that all are available and taken together every time — poses considerable logistic and supervisory problems.

Combination tablets (i.e. isoniazid + rifampicin, or isoniazid + ethambutol) can simplify matters (and could even make self-administration a possibility in certain cases).

Some countries with large TB programmes, special "blister packs" are produced in which three or four tablets, corresponding to the daily requirement for the particular treatment regime adopted, are packaged together. These packs should be used wherever they are already being produced, and made available for a national programme.



## Examples of Treatment Regimens and Drug Requirements<sup>11</sup>

		HR 100mg + 150mg	Z 400mg or 500mg	E 400mg	S 1gm	H 300mg
Cat I	1st 2 months then next 4 months	4 daily 4,3x per week	4 daily -	3 daily -	-	- 1,3x per week
Cat II	1st 3 months then next 5 months	4 daily 4,3x per week	4 daily -	3 daily 4,3x per week	1 daily (for 2 months)	- 1,3x per week
Cat III	1st 2 months then next 4 months	4 daily 4,3x per week	4 daily -	-	-	- 1,3x per week

## Total requirements / patient (initial and continuation phases)

	HR 100mg + 150mg	Z 400mg or 500mg	E 400mg	S 1gm *	H 300mg	EH 400mg + 150mg
Cat I	470	250	180	-	50	360
Cat II	620	360	530	60	70	-
Cat III	470	250	-	-	-	360

<sup>\*</sup> plus water for injection (5ml), a disposable syringe and a needle

<sup>&</sup>lt;sup>11</sup> These dosages are appropriate for persons >50kg in weight.



## Programmes using fixed-dose combinations

		HR	EH	E	S
		100mg + 150 mg	400mg + 150mg	400mg	1gm
Cat I	1st 2 months then next		-	3 daily	-
	4 months or next	3,3x per week	-	-	-
	6 months	-	2 daily	-	-
Cat II	1st 3 months then	-	-	3 daily	1gm per day (for 2 months
	5 months	3,3x per week		4, 3x per week	only)
Cat III		-	-	-	-
	then next 4 months or next	3, 3x per week	-	-	-
	6 months	-	2 daily	-	-

Programmes using fixed-dose combinations - total requirements / patient (initial and continuation phases)

		HR	EH	Е	S
		100mg + 150 mg	400mg + 150mg	400mg	1gm*
Cat I	6 month regimen 8 month regimen	160 -	- 360	180 180	- -
Cat II	8 month regimen	180	-	240	60
Cat III	6 month regimen 8 month regimen	160 -	- 360	1 1	-

<sup>\*</sup> plus water for injection (5ml), a disposable syringe and a needle





## PRICE LIST OF ANTI-TB DRUGS



Drug	Dosage Form	Dosage Strength	Quantity	UNICEF price <sup>12</sup> (US Dollars)	Lowest price obtainable <sup>13</sup> (US Dollars)
Н	Tablet	100 mg 300 mg	1000 1000	2.90 8.32	2.30 5.80
R	Capsule or Tablet	150 mg 300 mg	1000 1000	38.7 55.4	25.7 46.5
Z	Tablet	500 mg	1000	34.20	31.5
E	Tablet	400 mg	1000	25.10	18.3
S	Powder for injection	1g base in vial	100	23.84	7.3
<ul><li>water</li><li>disposable syringe and needle</li></ul>	vial unit	5 ml	100 100	1.56 -	2.67 2.8
EH	Tablet	400 mg + 150 mg	1000	-	22
RH	Tablet	150 mg +100 mg 300 mg +150 mg	1000 1000	-	24 55

<sup>&</sup>lt;sup>12</sup> The free on board (FOB) price of purchases ordered through UNICEF is calculated by adding 6% to the price indicated in: UNICEF, Essential drugs price list, January - June 1997 [Address - Supply Division, UNICEF PLADS, Free port, DK 2100 Copenhagen, DENMARK. Fax (+45) 3526.94.21]

<sup>&</sup>lt;sup>13</sup> Usually FOB price (including handling charges, excluding insurance and freight): special tariff 1996 (except as otherwise indicated) applied to international aid organizations for national programmes. See other prices in: International drug price indicator guide, Management Sciences for Health, 1995 [address - MSH, Drug Management Programme, 1655 North Fort Drive, Suite 920, Arlington, VA 22209-3108, USA. Fax (703) 524-7898].





## SOME SUPPLIERS OF ANTI-TB DRUGS



Action Medeor Deutches Medikamenten-Hifswerk St Töniser Strasse 21 D-4154 Toenisvörst 2, Germany

Fax: (49-21-56) 80632

ECHO (ECHO International Health Services Limited)

**Ullswater Crescent** 

Coulsdon, Surrey CR5 2HR, United Kingdom

Fax: (44-181) 6680751

IAPS (International Association for Procurement and Supply)

Rode Kruisstraat 20 PO Box 37 030

1030 AA Amsterdam, The Netherlands

Fax: (31-20) 6343401

IDA (International Dispensary Association)

PO Box 37098

1030 AB Amsterdam, The Netherlands

Fax: (31-20) 4031854

KCR International 45, rue de la Libération 78350 Jouy-en-Josas, France

Fax: (33-1) 39565355

Orbi-Pharma Van Trierstraat 40 B 2018 Antwerp, Belgium

Fax: (32-3) 2169897

## For a recent copy of the UNICEF Essential Drugs Price List, write to:

UNICEF Unicef Plads Freeport DK-2100 Copenhagen Denmark

Fax: (45) 269421

## For the International Drug Price Indicator Guide, write to:

Management Sciences for Health Drug Management Programme 1655 North Fort Myer Drive Suite 920 Arlington, VA 22209 USA





# LABORATORY REQUIREMENTS FOR SMEAR EXAMINATION



## Microscopy examination for 2000 specimens

<u>Binocular microscopy</u> for use in daylight and electric power, with oil immersion objective (x 100), eye-pieces (x8 or x10) and spare bulbs for microscope. In hot and humid climate, warm cupboard heated by 1 or 2 light bulbs (40 Watts) is also needed.

Equipment	Number
Plastic, disposable sputum containers, 45 to 50 ml	3000
Slides for microscope, 25 x 75, 1.1 - 1.3 mm thick	3000
Applicators, wooden or Nickel-chrome wire, 1 mm diameter	3000 50 cm
Loop holder	2
Slide holder made of metal (12 to 25 slides), 40 cm x 5 cm	2
Bunsen burner for use with butane gas with Butane gas cylinders or, Spirit lamp, cotton wool plug or metal wire	2 2 1
Glass marker, diamond point	2
Timer, 0-60 minutes, with alarm	1
Forceps, stainless steel for slides, 15 cm	2
Scissors, stainless, 25 cm	1
Slides rack made of plastic for 12-25 slides	2
Slides boxes for 100 slides	2
Funnel glass, 45 mm or 60 mm diameter	4
Funnel glass, 90 or 125 mm diameter	4
Drop bottles, glass, 100 ml	4
Bottles, brown glass, 100 ml	4
Flasks, glass or pyres, 500 ml	3
Flasks, brown glass, 1000 ml	2
Bowl made of plastic, 50 x 30 cm	2
Wash bottles, made of plastic, 500 ml	2
Drop plastic bottles, 10 ml for immersion oil	2
Bucket, plastic, 12 ml	2



Reagents	Number
Acid-ethanol for Ziehl-Neelsen staining	3 litres
Carbon fuchsin for Ziehl-Neelsen staining	6 litres
Aqueous methylene blue	4 litres
Immersion oil	200 ml
Xylene or toluene	200 ml

Laboratory records, reports, miscellaneous	Number
Laboratory request forms	3000
Laboratory register for TB	1
Pens, ball point, black or blue ink	2
Pens, ball point, red ink	2
Adhesive labels for sputum containers	3000
Lens paper	2 rolls
Ball of white absorbent cotton	500 gm
Filter paper, 15 cm diameter, no. 1	4 boxes
Toilet tissues	2 rolls
Pressure cooker	1
Still (apparatus for distilled water)	1
Towel and clean rags	as needed
Masks and overall	as needed
Sodium hypochlorite	10 litres
Methylated Spirit	2 litres



# ESTIMATE THE QUANTITY OF FORMS, REGISTERS AND HEALTH EDUCATION MATERIALS



Estimate the quantity of TB forms, registers, and education materials needed during the first year. They will need to be ordered and distributed on a yearly basis.<sup>14</sup>

# Determine the minimum quantity of forms, registers, and health education materials needed for the year.

Refer to the table below that lists the recommended quantity of forms and registers. Your country may need additional forms.

Name of forms an Registers	Quantity Needed for Each NDT Discrict	
Tuberculosis Treatment Card	1 per patient	
Tuberculosis Identity Card	1 per patient	
District Tuberculosis Register	1 per year	
Tuberculosis Laboratory Register	1 per year	
TB Laboratory Form Request for Sputum Examination	13 for every new pulmonary smear-positive case	
Tuberculosis Culture / Sensitivity Test Request / Report Form	country specific	
Quarterly Report on New Cases and Relapses of Tuberculosis	12 per year (3 copies x 4 quarters)	
Quarterly Report on the Results of Treatment of Pulmonary Tuberculosis Patients Registered 12-15 Months Earlier	12 per year (3 copies x 4 quarters)	
Tuberculosis Referral / Transfer Form	Based on proportion of patients who transferred out of the district during the previous year	

# Add an additional 20% to the quantity of forms, registers, and education materials needed.

To account for the increase of tuberculosis patients and lost forms, add 20% to the quantity of forms, registers, and educational materials needed. (You do not have to make this calculation for the registers because one of each register book should be sufficient for 1 year).

Also World Health Organization, Managing Tuberculosis at District Level. 1994.

<sup>&</sup>lt;sup>14</sup> Examples of recommended forms can be found in International Union Against Tuberculosis and Lung Disease (IUATLD) Tuberculosis Guide for Low Income Countries. 4th ed. 1996.



## **BIBLIOGRAPHY AND RESOURCES**



Bigot A, Varaine F. Programmes de lutte contra la tuberculose. 2nd Ed. MSF 1996.

Crofton J, Horne N, Miller F. Clinical Tuberculosis, MacMillan, TALC and IUATLD, 1992.

Centers for Disease Control and Prevention (CDC) MMWR Famine - Affected, Refugee, and Displaced Populations: Recommendations for Public Health Issues. July 24, 1992: 41; No. RR-13

Harries AD, Maher D. TB / HIV: a Clinical Manual. Geneva: WHO: 1996. WHO / TB / 96.200.

International Union Against Tuberculosis and Lung Disease (IUATLD) Tuberculosis Guide for Low Income Countries, 4th ed. 1996

Kessler C. Tuberculosis Control in Refugees A Focus on Developing Countries. Dissertation, London School of Hygiene and Tropical Medicine, 1995.

Mears C, Chowdhury S. Health Care for Refugees and Displaced People. Oxfam Practical Health Guide No. 9 1994.

Médecins sans Frontières. Clinical Guidelines Diagnostic and Treatment Manual 1990

Médecins sans Frontières. MSF and Tuberculosis Policy Paper. April 1995.

Murray CJ, DeJonghe E, Chum HJ, Nyangulu DS, Salomao A, Styblo K. Cost effectiveness of chemotherapy for pulmonary tuberculosis in three sub-Saharan African countries. Lancet 1991;338: 1305-1308.

Perrin P. International Committee of the Red Cross War and Public Health 1996.

Porter J, Kessler C. Tuberculosis in refugees: a neglected dimension of the "global epidemic of TB." Trans. Royal Soc Trop. Med. Hyg 1995; 89: 241-242.

Rieder HL. Tuberculosis in an Indochinese refugee camp: epidemiology, management and therapeutic results. Tubercle 1985; 66:179-186.

Rieder HL, Snider DE, Toole MJ *et al.* Tuberculosis control in refugee settlements. Tubercle 1989: 70: 127-134.

Slutkin G. Tuberculosis in the Refugee Camps of the Hiran Region, Somalia. February 1983.

Sang RK, Varaine F. Assessment of the tuberculosis control programmes in the refugee camps of Kenya. Paris: Epicentre, 1994.

Sumatojo E. When Tuberculosis treatment fails. Am Rev Respir Dis 1993; 147: 1311-1320.

Technical Guide for Sputum Examination for Tuberculosis by Direct Microscopy. Bulletin of the International Union Against TB. 1978. Suppl. No. 2.

United Nations High Commissioner for Refugees. Geneva, Switzerland.



Essential Drugs Policy. HCR / GEN / 88 / MISC / 25.

UNHCR Handbook for Emergencies, Geneva. December 1982.

van Gorkom J. Guidelines for Tuberculosis Treatment in Refugee Camps in Kenya 3rd ed.

WFP / UMBRO Guidelines for the Management of Tuberculosis on the Thai-Kampuchean Border. July 1984.

World Health Organization. Framework for Effective Tuberculosis Control. Geneva: WHO: 1994.

World Health Organization. Managing TB at District Level - A Training Course. Geneva: WHO: 1994.

World Health Organization. Managing Tuberculosis at National Level - A Training Course. Geneva: WHO: 1996.

World Health Organization. Stop TB at the Source. WHO Report on the TB Epidemic. Geneva: WHO: 1995.

World Health Organization. TB - A Global Emergency. WHO Report on the TB Epidemic, 1994. Geneva: WHO: 1994.

World Health Organization. The New Emergency Health Kit. Geneva: WHO: 1990. WHO / DAP / 90.1

World Health Organization. Treatment of Tuberculosis - Guidelines for National Programmes. Second Edition Geneva: WHO: 1997.

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 and translated, in part or in whole, but not for sale nor for use in conjunction with commercial purposes.

The views expressed in documents by named authors are solely the responsibility of those authors.



© World Health Organization 1997

