Operational Research on Tuberculosis Control Program

In East Timor:

Transdisciplinary Research Documenting the Introduction of the DOTS Strategy and Investigating Factors Contributing to Patient’s Adherence to Tuberculosis Treatment

PhD Thesis

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Declaration

“I hereby declare that the work herein, now submitted as a thesis for degree of Doctor of Philosophy by research through Charles Darwin University, is the result of my own investigations. All references to ideas and work of other researchers have been specifically acknowledged. I hereby certify that the work embodied in this thesis has not already been accepted in substance for any other degree”.

Signature,

Date, 30th September 2006
Acknowledgements

Eight years of experiencing working in the field of tuberculosis; as a physician, manager, consultant and researcher brought my admiration to many TB experts for continuing their effort to fight TB and to helping a young and a new scientist in the field of tuberculosis. This thesis would not have come into reality, if there was no chance of meeting A/Prof. Paul Kelly soon after the political violence in September 1999. Paul has been one of the key persons in the process of re-establishing TB control after the conflict, and I was very privileged to work and learn from him, both as a consultant and a supervisor. I especially thank my supervisors A/ Professor Paul Kelly, Dr Jocelyn Grace and Dr Peter Morris for all the opportunities, encouragement, motivation and their willingness to transfer some of their knowledge to me.

During the time working in the field of tuberculosis, I was fortunate to meet, work with and learn from many brilliant people. My high appreciation goes to Fr.Barreto, Dr.Rui Araujo, Dr Einar Heldal;, Mr.Basil, Sister Filomena, Dr.Jaime Sarmento, Gil, Augusto, Filomeno, Jose Lima, Costa, Cesaria, Pascoal, Tio Manuel (Caritas team). Doddy, Amanu, Iza, Melanya, Agustinho, Aje, Ze-Bernardo, Casilda, (FITTCET Dili Staff). ; Dr Jim Tulloch, Dr Rui Paulo, Dr. Sergio Lobo, Dr. Avelino Gutterres (IHA team). Professor Anthony Zwi, Professor Asma El-sony, Dr. Thurridur Arnadottir and Dr.Liisa Parkkali (International consultants).
This thesis would not be written without permission given by these great peoples to conduct the research activities in their places. Thank you to Minister of Health, Director of NTP, Dean of the Faculty of Public Health-Unpaz, the director of Motael Clinic, manager of Becora clinic, Dr Dan Murphy. I also, thank the head of the villages, community leaders, health directors, and TB nurses, staff working the clinics, and for all participants who agree to involve in these studies.

My high appreciation also goes to all Menzies staff who always helping me. To Catherine, Steve, Sue, Richard, Nick, Bart, Kayli, and Yvette. Special thanks also goes to the staff village accommodation manager (Mano Jose L Valadares ) who always keen in providing accommodation during my short staying in Darwin. Caritas Dili (formerly Caritas East Timor), Caritas Norway, the Ministry of Health of the Democratic Republic of Timor-Leste, the Northern Territory Department of Health and Community Services (Australia), WHO , AusAid for their contribution in the establishment of East Timor National Tuberculosis Control Program. This work will be impossible without the funding that made available through UNICEF/UNDP/World Bank/WHO Special Program for Research and Training in Tropical Diseases (TDR). National Health and Medical Research Council (Australia), and MSHR. Special thanks to the directors of MSHR for allowing me to work in the very supportive working environment at their institution.
Finally, the findings of this thesis has been very important in documenting works, commitments, struggles and perseverance, I personally commit as a means of liberating Maubere people from the morbidity and mortality caused by tuberculosis. I thank God, my ancestors and my late father for the spiritual support. To my mum, sisters, brothers, and all Martins’ and Carvalhos’ family, for their moral support. Their warm, love and caring means a lot when facing difficulties during the political instability and during the performance of research field work.

The last but not the least, I conclude this acknowledgment with speech I made for my wife in our wedding day, to show how much important her contribution to this work;

“A long time ago “Mussolini said “the masses love a strong man, but the woman that the strong man loves may be his greatest weakness”. Today, I would say “no great man goes alone”. The strong man will become stronger and wise with the support from the woman he loves. My wife has been an inspiration for my works, friend for my loneliness, strength for my weaknesses and motivator for my uncertainty. Thank You, Ana”

Dasilaku Ran Moruk
Executive Summary

Globally, the number of tuberculosis (TB) cases continues to rise and to cause more deaths, especially in resource poor countries. The World Health Organization (WHO) strategy known as Directly Observed Treatment Short-course (DOTS) strategy has been recommended to be adopted as the gold standard health system response to fight TB in these settings, but it has faced huge constraints in its implementation because of the lack of both financial and human resources. There remains a tendency for a one size fits all, with little scope for adaptation to find local solutions to local problems.

The DOTS strategy was introduced to East Timor in 1995. The nature of the culture, geography and political history of the country and its people combined with the very high burden of TB (see Chapter 1) offers an interesting opportunity for a series of inter-linked case studies examining TB control issues. These include the nature of TB control programs during the conflict and post-conflict situations and the cultural and health system barriers and enabling factors for treatment compliance in this setting. This operational research study was conducted to explore these issues and to answer some of the key research questions identified by the National TB Control Program. This thesis was based on: i). An extensive review of the literature on the issues of TB, post-conflict health service reconstruction and East Timor; ii). The findings from two qualitative research studies; and iii). The findings from two quantitative studies. The aims of the study and methodology used are discussed in greater detail in Chapter-2.
East Timor was as sovereign nation prior to the arrival of Europeans in the 16th Century. The country was colonized by the Portuguese for more than 450 years and was under Indonesian occupation for 24 years from 1975, finally gaining its full independence in May 2002. Tuberculosis has been recognized as a problem and claimed many lives during the time of colonial and foreign occupation. It was not until 1995, however, that the local authorities and local leaders, and was called for more serious intervention. The response was positive with the establishment of DOTS pilot in some government clinics and the establishment church based TB control program. But, the programs were destroyed following the September 1999 violence by pro-Jakarta militia. Soon after that, a comprehensive national TB program was established. The history, politics, health system and TB issues in East Timor are comprehensively discussed in Chapter-3.

Figure-1. The Launch of the first Randomized Control Trial (FITTCET) study in Dili, East Timor. Motael Clinic, 16th of March, 2005

Back: from the left. Melanya (Research Assistant); Dody (Office Manager); Agusto Pinto (Deputy Director of NTP); Dominggos (TB nurse); Mr Soares (food supplier); Agustinho (Research Assistant). Front: from the left : Dr Nelson Martins (Principal Researcher); A/Prof Paul M Kelly (Supervisor); Irman Julya (Manager of Motael Clinic); Dr Joao Martins (Dean of Faculty of Public Health, UnPaz).
Study–I (Chapter 4) is a descriptive epidemiological study which discusses how tuberculosis control has flourished despite chronic low tension conflict (1995-99), a brief but intense high level conflict (1999) and post-conflict reconstruction (2000-2004). The study found that, before 1999, a non-government TB control program was established in several districts and showed optimistic results. External donor funds, technical assistance and the local strategies for TB treatment compliance were key components. In 1999, conflict led to complete disruption of the program. Within four months a National TB Control Program (NTP) was established from the non-government program in collaboration with other partners. The notification rate of 108 sputum smear positive pulmonary TB cases per 100,000 populations in 2004 was the highest in the region and reflects high population coverage. The cure rate of 81% is close to achieving the WHO target. Key components of the NTP-TL which contributed to this success are: i) the inclusive nature of involving various parties in one unifying TB programs, ii) the ongoing assistance from international consultants; iii) constant training and supervision; iv) commitment from local staff.

Study-II (Chapter 5) is a stakeholder analysis designed to examine in greater detail the reasons for the successful re-establishment of the NTP during the emergency period which followed the violent of political conflict of September 1999. Twenty four participants who are currently or were previously involved in the TB program were interviewed for this study. These include TB nurses, international consultants, NTP directors, head of WHO, and senior minister of health staff. The existing local structure
and experience, the commitment to establish an effective program and the willingness of international advisers and local counterparts to be flexible in their approach, were important factors. The major impediments, including mass population displacement, lack of infrastructure, and the competing interests of organisations working in the health sector were addressed through a cooperation, coordination and collaboration between local and international partners. The TB Program continues to operate in all districts with high notification rates, although a lack of ownership by government health workers, low compliance and high default rate remain challenges.

Study-III (Chapter 6) discussed the finding of the first ethnographic study employed in the field of TB control in East Timor. Following on from the key issues identified in the two previous studies, this study was designed to understand the reason behind high default rates in an urban and a rural district. Semi structured interviews were conducted with 28 participants (22 patients and six TB nurses) and Focus Group Discussion (FGD) were conduct with community members in seven villages (three urban and four rural). The findings reveal the nurses have good knowledge about TB and high commitment to the DOTS strategy. In contrast, defaulter patients and community members possess a low level of knowledge and awareness of TB. Having good knowledge of the disease, the right interpretation of cure, and the provision of food incentives were important factors for patients to complete TB treatment. Obstacles for TB treatment completion included a preference for traditional medicine, economic difficulties and geographic remoteness.
Study-IV (Chapter 7) present the finding from the first randomized control trial conducted in East Timor. The study was designed to assess the effectiveness of food incentives to enhance TB treatment compliance. Newly diagnosed adult TB patients were randomly assigned into two groups. One group (intervention: N=139) received food and the second group (N=131) received nutritional advice (placebo). An interim analysis on 168 patients (Intervention N=83; Control N=85) is presented here. The study found; the majority of TB patients have lower socio-economic status, but have good access to TB services. The baseline Body Mass Index (BMI) was 16.8 before and 18.5 after the provision of food and anti TB treatment. The provision of anti-TB drugs has significantly alleviation most TB symptoms. Treatment success rate was 81% in the intervention group compared to 78% in the Control group [Differences: 95% CI: 3 (-9, 15)]. The food intervention however showed no impact in improvement clinical symptom, treatment outcome and treatment compliance. There are possible several explanations for the negative results for food in this study. Firstly: due to the strict selection of participants for the study, we might have ruled out most patients with certain attitudes for non-compliance with the treatment. Secondly, measurement bias might also contribute to this negative result. Perhaps the true impact of food on treatment outcome and compliance should be measured differently. We lacked the required equipment on site to measure potential immunological or biological determinants of an effect of the food intervention. Lastly, the data presented in this paper is not the complete sample enrolled in the study, according to our sample size calculation. It is possible therefore that it does not have sufficient power to represent the true finding from the study.
The thesis concludes with overall conclusion and recommendations arising from this body of work aimed at strengthening TB control in East Timor and those TB programs operating in similar settings in other countries (Chapter 8). The key conclusions are:

1. DOTS programs, with slight modification to fit local conditions, can be successfully introduced during low tension conflict and post conflict situations;

2. Coordination, cooperation, collaboration and flexibility are key components for a successful re-establishment of TB services after major conflict;

3. TB program understanding of community perceptions of curability of TB and the provision of acceptable incentives can be key elements for patients to complete their TB treatment. Strong belief in traditional medicine and geographical remoteness can lead patients to default from their TB treatment.

4. Food incentives showed no impact in improvement treatment outcome, clinical outcome and treatment compliance in lower socio-economic class with good access to TB services in one urban setting. Repeat clinical trials in other settings, are needed to examine the impact of food to improve clinical outcome for undernourished TB patients. Alternative study designs may be more appropriate to examine the impact of food incentives in the context of the TB program management.
Summary of Research Outputs From This Thesis

**Peer reviewed journal articles**


**Published Abstracts**


**Conference presentations by N. Martins**


2. Invited speaker to the Post-Conflict Conflict Symposium in NSW-University. Title presented: The establishment of TB services after major conflict of East Timor (a preliminary research finding), Little Bay Campus, the University of New South Wales, Sydney, NSW, **Australia**, August, 2004.


Articles in preparation


3. **Martins N**, Grace J, Soares A, Melanya J, Borromeu I, Kelly P. Patients’ perception on the introduction of additional services of providing the food supplementation to the routine TB control management in Dili, East Timor.


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CHAPTER –I

THESIS STRUCTURE, STUDY AIMS AND METHODOLOGY
Chapter I: Thesis structure, aims & methods

Thesis structure and authors contribution

This thesis includes two introductory chapters and a series of four inter-related papers for publication. This structure is somewhat different to a conventional PhD thesis but was chosen to allow rapid publication of the research findings. With this style of thesis, a certain amount of repetition, particularly in the introduction section of each paper is unavoidable. Also, due to space restrictions imposed by journals, some important details have been omitted in the body of each chapter, but may be found in the appendices. PDF copies of the papers already published at the time of submission of this thesis can also be found in the appendices.

The research studies described in this thesis represent a major breakthrough in health research in East Timor for the following reasons. Firstly, there was no history of medical research with rigorous methodology (RCT) conducted by the East Timorese researcher. Second, the study was starting from scratch with no infrastructure and logistic support for the research activities. Lastly, there were no local research assistant and administration support staff available to work for the medical research activities.

The success of this research relied on the author renting a small house and equipping it with computers and other equipment to make it as an office for coordinating research activities. A few local staff were recruited and trained as administrator and research assistants. The Author conducted or supervised all of the field work, administrative work and other research activities during the 3.3 years of this study.
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Study Aims

The overall aims of this study were to examine and test the important hypotheses for the NTP:

1. What are the socio-cultural barriers to and enabling factors for the successful implementation of Tuberculosis Control Programs? How can better information on these issues be used to modify the WHO DOTS strategy to suit local conditions, health beliefs and health system management?

2. Are food supplements cost-effective in improving compliance with TB treatment?

Specific aims were to:

1. Document the introduction DOTS strategy during the low intensity conflict, a brief high intensity conflict, and the post conflict period in East Timor (Chapter 4).

2. Examine in more detail the barriers and enabling factors to the successful re-establishment of tuberculosis control program during the post-conflict emergency situation (Chapter 5).

3. Explore socio-cultural barriers to the successful implementation of DOTS in East Timor, with a particular focus on factors which assist improved TB treatment compliance (Chapter 6)

4. Test the effectiveness of a food intervention in promoting TB treatment adherence (Chapter 7).
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Methodology

This thesis used transdisciplinary research methodology to capture the comprehensive issues related to tuberculosis control in East Timor.

Definitions & Basic Principles

The definition of transdisciplinary is referred to the article-3 of the “Charter of Transdisciplinarity” adopted at the first world congress of transdisciplinarity in Portugal, November 1994, as follows:

*Transdisciplinarity complements disciplinary approaches. It occasions the emergence of new data and new interactions from out of the encounter between disciplines. It offers us a new vision of nature and reality. Transdisciplinarity does not strive for mastery of several disciplines but aims to open all disciplines to that which they share and to that which lies beyond them.*

Transdisciplinary research methods conform to Baker et al (2003) argument from their tobacco study where they state that “Transdisciplinary research” involves the integration of measures and methods across diverse response systems and levels of analysis, with that integration occurring via a synthesis of theories and models of different scientific disciplines.

Use of transdisciplinary research methods in this study:

To facilitate the comprehensive understanding of the problems that’s goes beyond the health care providers, donors, and policy makers’ understanding, and also to identify and include the contribution that patients and community members can offer to the enhancement of the Tuberculosis Control Program in East Timor.
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Disciplines chosen for this study:
A rich combination of quantitative and qualitative methodology experts were selected from different fields of expertise, each contributing their disciplinary knowledge and world experience. These fields included epidemiology, public health, clinical infectious diseases, biostatistics, anthropology, health economics, policy analysis, TB consultancy, health services management and randomized clinical trials. The author (NM) added extensive experience and background as an East Timorese citizen, manager, clinician and TB program implementer.

Method of discipline selection
The author identified the study aims, study questions and study types to be conducted and consulted the principal supervisor. Together, they identified associate supervisors who have different expertise to complement the expertise of principal investigators. The author and principal supervisor decided that this PhD work would be based on four different studies and the thesis will be written as a series of articles for publication. During the design of the study and the writing of the research proposal, as well as during data analysis and article preparation, a number of experts were invited and consulted to become co-author for the articles produced under this PhD project. This process has enabled the author (NM) to gain routine access and consultation with supervisors and other co-authors for the articles and working with them in various locations around Australia, East Timor, and Norway. The supervisors and co-authors were routinely updated by NM on the progress of the study through teleconference, email and face-to-face
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meetings and for NM to have a quick feedback to improve research program in the field. All these processes were routinely conducted and will continue until the final article arising from this substantial body of work is produced and published.

Research methods utilised for this study

The combination of quantitative and qualitative methods was chosen to address the main operational research questions identified by the East Timor NTP. A summary of the methods used in each of the inter-linked studies is given below, with further details in the relevant chapters.

**Quantitative Study:**

1. Ten years (1996-2004) of routinely collected data contributed to the descriptive epidemiological study design which was utilized to assist study aim 1 (chapter 4). Data was collected from a variety of sources. Key TB program indicators were examined and analysed with reference to WHO targets to assess the performance of the three TB control programs that operated during the study period.

2. A Randomized Control Trial was conducted in three TB clinics in Dili to assist the study aims 4 (Chapter 7). The study participants systematically allocated to the intervention group (receive supplementary food) and control group (nutritional advice only). Two main outcome measures of treatment outcome and compliance rate were assessed for both groups.
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Qualitative Study:

1. A review of the published literature on post-conflict health systems development, a review of documents and reports from the time-period 1999-2003 relating to East Timor, interview of key informants with knowledge of the TB program and its development over this time period and critical reflection of the experience two key stakeholders and authors (NM and PK), were used to assist study aim 2 (Chapter 5). All stakeholders and influential individuals currently and/or previously involved in the setting up and administration of the TB Program between 1999 and 2003 were identified and contacted with a request to interview them. An in-depth interview with semi-structured questionnaires were employed to allow the collection of rich data, while maintaining the participants focus on the main theme defined for this study.

2. An ethnographic study was conducted in Dili and Ermera districts to assist study aim 3 (chapter 6). A series of semi-structured interviews were conducted with TB patients both default and completed TB treatment, and TB health workers. Focus Group Discussions were conducted with community members in eight villages. An observation and author personal reflection were also conducted as part of this study.
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CHAPTER II

INTRODUCTION TO TUBERCULOSIS

This chapter will introduce readers to the definition, epidemiology and the global control of tuberculosis (TB) disease.
History of Tuberculosis

Tuberculosis (TB) is an ancient disease that was known for its existence during the prehistoric time of approximately 4000 BC. Tuberculosis was recognised by Hippocrates as a clinical entity in the early nineteenth century but was not determined to be an infectious disease until 1882 when Robert Koch identified *Mycobacterium tuberculosis* (*MTB*).

Diagnosis and Treatment of Tuberculosis

Tuberculosis infection occurs when a person inhales a small, moist, expectorated droplet containing MTB from smear positive TB patients who coughs, laughs or speaks. These droplets will lodge in the alveoli to form a Ghon Focus, and together with lymphadenopathy, this is termed the primary complex. In about 95% of infected persons, the primary complex resolves spontaneously. In the other 5% of cases will develop various form of tuberculosis whether through post-primary endogenous reactivation or exogenous re-infection. Tuberculosis disease, by convention, is classified as pulmonary TB (TB in the lung) and extra-pulmonary TB (TB infected other organs)

*Pulmonary Tuberculosis*

Pulmonary tuberculosis refers to disease affecting the lung parenchyma, which is the most common form of the disease, occurring in more than 80% of TB cases. General symptoms include tiredness, a feeling of malaise, anorexia, pyrexia, amenorrhea in females, weight loss, and night sweats. Cough is the most common symptom of
pulmonary TB and present in 95% of the smear positive cases. The sputum is typically mucoid or purulent, and may be accompanied by haemoptysis. Chest pain is less common but when present may be dull or pleuritic. As lung damage (and in some cases pleural effusion) progresses, breathlessness of effort, which is related to the extent of disease, may developed and may be associated with anaemia. On clinical examination, the signs of respiratory tuberculosis can be non-specific or respiratory. Some of the signs include pallor, splenomegaly, hepatomegaly, fever or evidence of weight loss, clubbing, upper zone crackles and signs of lung consolidation. Localized wheeze may be present because of bronchial narrowing. In chronic tuberculosis the trachea may deviate to side of greatest lung destruction (fibrosis).

Extra-Pulmonary tuberculosis:

Extra pulmonary tuberculosis may effect any organ other than the lungs including lymph nodes, pleura, bones and joints, meningies and the peritoneum and abdominal organs.

Diagnosis of Tuberculosis

Tuberculosis shall be suspected from someone who show clinical illness with signs and symptoms related to TB; has a positive contact with smear positive TB patients, and show abnormalities form of TB from the chest X-ray. However, the diagnosis of tuberculosis ultimately relies on the detection of MTB, either by microscopy or culture of the appropriate body fluid or tissue. The MTB, is a slow-growing aerobic bacterium with generation times ranging from 12 to 24 hours.
technique (the Ziehl-Neelsen stain), MTB bacilli appears as red, beaded rods, 2-4 µm long and 0.2-0.5 µm wide. X-ray and tuberculin skin test are important for the diagnosis of TB in Children, extra pulmonary TB, and TB with sputum smear negative. Other rapid laboratory techniques such as rapid radiometric system, nucleic acid amplification, polymerase chain reaction and various serologist test are also utilised in some settings to diagnose TB, though are unavailable in most countries with a high burden of TB, including East Timor.

*Treatment of Tuberculosis*

Bed rest, plenty of food, fresh air and sunshine in sanatoria built on hillsides used to be the only ways to treat TB. Chemotherapy for TB started after streptomycin (S) was discovered in the 1940s. Since then more anti-TB drugs were discovered with different potency and working mechanism for killing TB bacilli. Isoniazid (INH) is a very potent bactericidal drug and can kill 90% of the total population of bacilli during the first few days of chemotherapy. Rifampicin (RIF) kills semi-dormant bacilli that isoniazid can not. Pyrazinamide (PZA) kills bacilli in an acid environment inside cells. Streptomycin, Ethambutol, PAS and Thiacetazone are bacteriostatic.

There is an increasing potency for killing TB bacilli when more than two anti-TB drugs are combined in one treatment regimen. The sterilizing potency and efficacy of regimens containing isoniazid, rifampicin, and pyrazinamide alone, can achieve over 90% sputum conversion in two months, and a more than 90% cure rate with a relapse rate less than 5%. Accordingly, WHO had developed various treatment regimens and have proposed
Chapter II. Introduction to TB

that they be adopted in TB control program globally, as part of the strategy known as DOTS.\textsuperscript{3,5} However, due to the inadequate management of TB cases, the emergence of multi drug resistant TB (MDR-TB) has become one of the main threats to TB control worldwide.\textsuperscript{10} A few new drugs are currently under trial and could significantly reduce the duration of TB treatment and be used to treat MDR -TB.\textsuperscript{11}

**Epidemiology & Global Control of Tuberculosis**

To the present TB remains the leading infectious cause of morbidity and mortality in humans. The global incidence rate of TB is still in rising of 0.1% per year, with 8.8 million of new cases occurring globally and estimated 1.7 million people died from TB in 2003.\textsuperscript{10} Several inter-linked factors contribute to the progress of this deadly disease such as the spread of Human Immunodeficiency Virus (HIV) /Acquired Immunodeficiency Syndrome (AIDS), poverty and the widening gap between rich and poor, the difficulties of case detection and the rising incidence of multidrug resistance.\textsuperscript{11,12} The overwhelming burden of TB, over 80% of the 4.4 million cases of tuberculosis notified to the World Health Organization (WHO) in 2003, lies in developing countries, and from that, almost 60% of the cases were notified from Asian or Pacific countries.\textsuperscript{10} In the South East Asian Region, TB accounts for three million cases and three quarter of a million deaths each year. The incidence of this disease is highest in the productive age between 20-45 year age group which predicted to seriously affecting economic development.\textsuperscript{13}
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In 1993, WHO declared TB a global emergency and formulated a “5 point plan” known as the DOTS (Directly Observed Treatment Short-Course) strategy to fight the disease. It comprises: political commitment, case detection using sputum microscopy, standardized short course chemotherapy under proper case-management conditions including directly observed treatment, a regular drug supply, and a standardized recording and reporting system that allows assessment of individual patients as well as overall program performance. Huge strides have been made in DOTS implementation during the past decade. However, the results have been patchy, with most countries embracing the strategy in principle although fewer than half of the estimated global cases of TB are actually being treated under DOTS.

In recent years, some have questioned the efficacy of a “one-size-fits-all” DOTS strategy and directly observed therapy in particular. The WHO are revising the strategy, and have called for the use of locally based operational research to guide policy and take account of local circumstances.

The Challenges of DOTS in Developing Countries, Conflict and Post-Conflict Settings.

To date, DOTS strategy still relies on passive case finding to screen the infectious TB cases in the community and on DOT to ensure high cure rates. The assumption behind DOTS programs is that high rates of case detection and treatment will lead to a reduction of TB prevalence, TB mortality and the rate of TB transmission. However,
Chapter II. Introduction to TB

there is still a big challenge for many NTPs to ensure a high detection of active TB cases in the community and to achieve a high cure rate for those were under TB treatment.

A significant challenge for DOTS programs in many developing countries is ensuring the DOT occurs.\textsuperscript{20} Although it has its critics, it is generally accepted that the direct observation of treatment, adapted to patients’ needs and to the availability of trained health workers, is the best method of avoiding treatment interruption\textsuperscript{21}. However, treatment completion continues to be one of the greatest challenges in TB control worldwide.\textsuperscript{20} The issue of poor compliance from both patients and health workers remain a main threat for treatment failure in many NTPs. Various reasons were documented for patients who do not adhere to the TB treatment. These includes the concerns of side effects, the cost of transportation, physical fatigue, low family support, dissatisfaction with the treatment program, feeling cured, and poor experience with the attitude of health workers.\textsuperscript{22-24} On the other hand, high workload, lack of training on the DOTS strategy, lack of understanding of patients’ socio-cultural definition of disease, and low awareness of patients were identified as contributing factors to health workers’ inability or unwillingness to adhere to national TB treatment protocols.\textsuperscript{25,26}

Establishment of TB control in conflict and post-conflict settings faces enormous challenges. A stable population and an adequate infra-structure within a well functioning health system have been argued to be fundamental requirements for the successful implementation of DOTS strategy.\textsuperscript{27} Studies have revealed that by using various local TB treatment strategies in conflict situations it is possible to attain the WHO target for cure
rate. The reported strategies include strong community support, utilization of outreach workers from different ethnic groups, the use of directly observed treatment three times a week, and modified treatment regimens.\textsuperscript{28-30} Sudan has shown good progress in DOTS implementation despite the ongoing civil war in that country.\textsuperscript{31} Similarly, Mozambique managed to implement the DOTS strategy during their civil war and achieve a good cure rate.\textsuperscript{32}
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CHAPTER III
HISTORY, HEALTH PROFILE, AND TUBERCULOSIS IN EAST TIMOR

This chapter will discuss the nature of the culture, the geography and political history of the country (including unrest and violent conflict), health system development (in an historical context), and the very high burden of TB. It will also present a brief introduction of the history of political violence and the TB situation in East Timor. The unique history of East Timor and the magnitude of TB problem in the country are the rationale for the series of inter-linked studies which are reported on in subsequent chapters in this thesis.
Chapter III. Introduction to East Timor

History and Political Systems

East Timor located northeast of Australia in the Lesser Sunda Islands at the eastern end of the Indonesian archipelago. The wide of the country are 14,610 sq km, the terrain is mountainous and the climate is tropical with distinct rainy and dry seasons. The country is divided into 13 districts, 67 subdistricts, 498 villages and 2,336 hamlets.

Pre Colonial History

The earliest known cultural influences on Timor was the first migration of Malay people around 3000 BC, who established themselves on Timor’s central north coastal area near Belu, and were later known as Belunese. The arrival of Belunese people encountered some resistance from the previous inhabitants known as the Atoni Pah Meto or Mambaian. The Mambai people are sometimes referred to as the “real” Timorese because they are the earliest known inhabitants of the Island. Prior the arrival of the Portuguese in Timor (between 1512-1520), Timor had enjoyed its peaceful life as a nation under the Wehale (Belunese) Empire, using Tetun as a lingua franca and sandalwood to finance its activities. Small tribal kingdoms were conquered and gradually developing a unified political system in Timor. Daily lives were strongly influenced by traditional practices laid down by ancestors. Violation of ancestral custom threatened the whole community with sickness and famine. At this time, the tribal chief was a dominant figure, both as a ruler and as a priest. The priests maintained contact with and interpreted the desires of ancestors and provided explanations on sacred matters. Today, there are 37
recognisably distinct languages spoken in East Timor, with Tetun, spoken by about half of those in the territory, and understood by a further quarter of the population.\textsuperscript{3; 6}

**Colonisation and Struggle Independence**

Prior to the Indonesian annexation, East Timor was colonized by Portugal and by Japan for 450 and 2 years, respectively. Following the flower revolution in Portugal on the 25\textsuperscript{th} of April 1974, the chance for independence was finally emerges in East Timor. Five main Parties; FRETELIN, UDT, APODET, KOTA and TRABALHISTA (Labour Party) were formed and contested for political support.\textsuperscript{5} On 11\textsuperscript{th} August 1975, with the support of the Police force, the UDT launched a coup from the Portugal administration and ended the coalition formerly formed by UDT and FRETELIN. Many FRETELIN supporters were taken to jail, and a few others were killed. FRETELIN retreated and organised a counterattack nine days later, in 20\textsuperscript{th} August 1975. The attack forced many UDT supporter’s to become refugees in West Timor, which is Indonesian territory.\textsuperscript{3} Others including political officials and supporters of APODETI, TRABALHISTA, KOTA and UDT were taken into prison. Many of them were later murdered when FRETELIN forces retreated to the mountains facing Indonesia invasion.

On 28\textsuperscript{th} November, 1975, the FRETELIN unilaterally proclaimed the independence of the Democratic Republic of Timor Leste. In concordance with its plan to integrate East Timor into the Republic of Indonesia, as well as concern that Republic Democratic of Timor Leste would become a communist country in the region, the Indonesian
Chapter III. Introduction to East Timor

Government used the political refugees seeking protection in the West Timor as leverage to pursue international support for an invasion of East Timor. 3 Gaining support from regional neighbours and the United State of America, on 7th December 1975, Indonesia launched a large scale land, air and sea invasion. The new government was formed and the territory was incorporated into the Indonesian Republic on 17th July 1976, and became the 27th province of Indonesia. The invasion forced the FRETELIN army to retreat to the mountains and start a guerrilla war, which lasted for 24 years, at the cost of the loss of the lives of more than one third of the East Timorese population. 6

Eleven years later, in 1987 the FRETELIN force (FALINTIL) commander, Xanana Gusmao declared FALINTIL a national liberation army, and called for national unity to fight foreign occupation. Many youths answered the call and started to organise themselves in small cells (caicha) to support the independence movement. Others simply went to the mountains to become FALINTIL soldiers. Those who pursued study in other parts of Indonesia organised themselves under student organisations for East Timor independence, such as RENETIL with a strong base in Bali, Malang and Yogyakarta; AST in Surabaya; and the Independent Group in Bandung. Dewan Solidaritas, Fitun, OJelatil and OJetil were formed inside East Timor. The main role was to alert the world about East Timor’s struggle for independence. 7 With the spirit of national unity, the National Council of Timorese Resistance was formed in 1998 by the various pro-independence groups and the five main political parties which had been established in 1975, and elected Xanana Gusmao as President. 8
The Republic Democratic of Timor – Leste

On 30th August 1999, in an United Nations (UN)-supervised popular referendum, the overwhelming majority of East Timorese voted for independence from Indonesia. Four days later, anti-independence militias supported by the Indonesian military commenced a large-scale violent conflict, which killed approximately 1,400 Timorese and forcibly evicted 300,000 people into West Timor as refugees. The majority of the country's infrastructure, including homes, irrigation systems, water supply systems, and schools, and nearly 100% of the country's electrical grid were destroyed. On 20th September 1999 the Australian-led peacekeeping troops of the International Force for East Timor deployed to the country and brought the violence to an end. The UN took over the administration of the country in the lead up to elections for a constituent assembly in 30th of August, 2001 and the transition to independence. On 20th May 2002, East Timor was internationally recognized as an independent state and became the world's newest country.

Political and Legal systems

The Democratic Republic of Timor – Leste (RDTL) has a legal system which is based on Indonesian law but will be replaced by civil and penal codes based on Portuguese law in 2006. The Head of State is the President who plays a largely symbolic role but is able to veto legislation, dissolve parliament, and call national elections. The Head of the Government is the Prime Minister and the Council of Ministers are the cabinet who assist the Prime Minister in running the government and proposing legislation. National
Parliament is comprised of between 52 to 65 members. The territory was divided into 13 administrative districts; Aileu, Ainaro, Baucau, Bobonaro (Maliana), Cova-Lima (Suai), Dili, Ermera, Lautem (Los Palos), Liquica, Manatuto, Manufahi (Same), Oecussi (Ambeno) and Viqueque. More than 17 political parties are currently registered in East Timor, with a few more expected to emerge before the May 2007 general parliamentary election.

**Population and Economy**

The population of East Timor is currently 924,642 and increasing rapidly. Approximately 90% of the East Timorese population lives in the rural area and living on a traditional small farm. The population of East Timor is young with 48.1% under the age of 17 years, 17% under five years and the mean life expectancy at birth is male: 63.96 years and female: 68.67 years. Illiteracy is a major problem with more than 60% of population not able to read and write. East Timor is one of the least developed countries measured by both income and broader human development indicators. Incomes are low with per capita Gross Domestic Product estimated at only US$478. Unemployment rate is an estimated 50%. The Government revenue was US$107.7 million in 2004.
Health Problems and the Health Care System

**The situation pre-1999**

Pre-1999, the health services was primarily carried-out under the Indonesia Ministry Of Health, under the Dinas Kesehatan Timor-timur (provisional health department). The health system was like other provinces, with 3 tiers of administration (National, Regional and District). There were eleven modern hospitals, 60 Community health centres (CHCs), and approximately 200 health posts staffed by MoH employers. However, this health care system has many limitations including public health services such as water and sanitation. There were twenty four catholic clinics and one church based hospital operating in the territory mainly providing general consultation. The Caritas TB program with its central unit located in Dili, was implementing their activities through these clinics. The Catholic clinic was important to local people because of its quality of services and its neutral role in serving patients who were seeking for health assistance. This network gained trust from pro-independence groups.

**The Situation at Independence**

Following the post-referendum violence in September 1999, which resulted in the destruction of almost all of the country’s health system; the priority was to address immediate health needs and resource inequities, and to coordinate external assistance to
health services. The East Timorese Health Professional Working Group (ETHPWG) was formed by local health staff to contribute to the development of a sustainable health sector, and to work together with international health professionals to provide short term emergency assistance. The ETHPWG with the assistance of WHO and UNICEF put together a plan for the future East Timor health care system. This lead to the establishment of the Interim Health Authority, which operated through out the ‘interim’ period leading up to the official formation of the Ministry of Health.  

**Health problems and related health policy**

Current health problems for the Ministry of Health include:

1. high infant and maternal mortality rates;
2. low immunization coverage;
3. high prevalence of infectious disease including malaria, tuberculosis, skin and intestinal parasite infection;
4. high proportion of undernourished children;
5. lack of sufficient human resources, particularly at middle management level and medical specialists;
6. under-developed health promotion activity;
7. inadequate functioning of laboratory services;
8. limited access to safe drinking water and sanitary facilities of the majority population.
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Plans to improve the health of East Timorese are encapsulated in the vision of Minister of Health, so as to achieve healthy East Timorese living in a healthy East Timor. The Government of East Timor gave the highest priority to health in the National Development Plan, which was developed to deal with the current health issues. Specific high burden diseases like malaria, TB, diarrhoeal diseases, respiratory infections, leprosy or mental health, and reproductive health, including high maternal mortality were given high priority in the health agenda. Diseases with high risk like HIV/AIDS also have been given high priority by the Ministry of Health.

Structure and Organisation

The executive work is currently organised by Ministry of Health and its thirteen district health departments. Health services are provided by six hospitals, 67 community health centres, 174 health posts and 87 mobile clinics. The Ministry of Health consists of: Minister for Health, Vice-Minister for Health, Director-General of Health, and four main Directorates:

- Health Services Delivery
- Administration, Finance, and Logistics Services
- Health Policy and Planning and
- District Health Services.
In addition the Director-General also oversees the following functions directly:

- District Liaison Services,
- Legal Office,
- Office of Protocol and Communication,
- National Hospital and Referral Hospitals,
- National Laboratory,
- National Centre for Health Education and Training (NCHET) and
- Centre for Drugs Supply and Medical Equipment.  

**Human Resources**

The health sector like others in East Timor in general has a shortage of middle managers and practitioners with specialised skills. The health department is currently still relying on expatriate specialists, doctors and advisers to run the country’s health system. There are currently only 11 Timorese with postgraduate qualifications working in the health sector (a specialist and 10 public health professionals). There are 52 doctors, eight of them overseas undertaking specialist training, two dentist and seven public health personnel. There are 530 midwives, 264 of whom are civil servants, 46 pharmacy assistants, 70 laboratory assistants, and 160 sanitary inspectors.
Health Financing

Public expenditure in East Timor comprises several components. These include:

1. the Government budget or from the Consolidated Fund for East Timor (CFET);
2. the Trust Fund for East Timor (TFET);
3. bilateral and multilateral donors including the UN agencies, programs and funds;
4. the United Nations; and
5. international Non Governmental Organisations (NGOs).

The health sector budget consumes 10.7% of the total government budget for the country, with 60% of the expenditures going to basic health care delivery (See table-1).

Table-1. The budget Health Department for the Six Financial Years (2001-2007).

<table>
<thead>
<tr>
<th>Fiscal year</th>
<th>Budget allocation (in million)</th>
<th>Percentage from state budget</th>
<th>State budget (in million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2001-2002</td>
<td>6.0</td>
<td>9.37 %</td>
<td>64.0</td>
</tr>
<tr>
<td>2002-2003</td>
<td>7.1</td>
<td>9.53%</td>
<td>74.3</td>
</tr>
<tr>
<td>2003-2004</td>
<td>9.1</td>
<td>11.46%</td>
<td>79.1</td>
</tr>
<tr>
<td>2004-2005</td>
<td>9.7</td>
<td>12.94%</td>
<td>75.1</td>
</tr>
<tr>
<td>2005-2006</td>
<td>16.9</td>
<td>12.76%</td>
<td>132.3</td>
</tr>
<tr>
<td>2006-2007</td>
<td>25.7</td>
<td>8.16%</td>
<td>315.1</td>
</tr>
</tbody>
</table>

Sources: Dr Rui M Araujo, Minister for Health RDTL; Personal Communication
Chapter III. Introduction to East Timor

Tuberculosis Control Program

Tuberculosis has been a major public health problem and was concerned many Timorese leaders for many years. The Indonesian government estimated the prevalence to be 707 per 100,000 populations in 1995 and expanded TB control into East Timor as part of the national program. In 1996, the Catholic Bishop of Dili, Bishop Belo visited Oslo to receive his Nobel Peace Prize, and asked the Norwegian government to help control TB in East Timor. This resulted in the establishment of a non-government TB program operated by the Catholic Church (Caritas East Timor) in 1997 which operated in parallel to the government. The program followed the International Union Against Tuberculosis and Lung Disease (IUATLD)/WHO recommendations but used different treatment regimens, a separate stock distribution system, training, supervision and recording and reporting mechanisms than the Indonesian TB program. Following the political unrest in 1999, TB services were severely disrupted throughout the country. In January 2000, less than four months after the short but intense conflict of September 1999 NTP was established with Caritas East Timor as the lead agency. The NTP-TL based on the existing Caritas structure and incorporated all organizations working in TB control into a DOTS program using an eight month regimen (2RHZE/6HE). The re-treatment regimen was 2SRHZE/1RHZE/5R3H3E3 (See appendix-3).
The Current Structure and Function of NTP-TL

In East Timor the tuberculosis control programme has central and district management and is implemented at health facility levels where the programme is integrated with the general health services. The current structure of NTP places it under the Division of Communicable diseases in the Directorate of Health Services Delivery (see figure-1). The NTP manager is assisted by four regional supervisors, one office assistant and one database expert. At the District level, TB activity is coordinated by a district TB coordinator (DTC) or a DPHO (District Public Health Officer) responsible for communicable diseases. In the subdistrict or Community health centre (CHC) level, the program is coordinated by a TB nurse. While, motivators responsible for supervision of TB treatment, conduct default tracing together with TB nurse and filled patients’ treatment card. The NGOs involves in TB services through various steps, includes from the very top of management level such as the role of Caritas East Timor or more in the implementation in the clinical levels. The private practitioners are directly involve in the TB management activities to refer all suspect TB or TB patients to TB centres for Treatment.
Chapter III. Introduction to East Timor

**Sources of Financing for TB control**

The MoH is committed to TB control and continues to increase the annual financial commitment to the NTP. By the end of 2005, all NTP positions at central and district level were MoH employees. All the essential elements of the NTP are funded by the MoH from 2006. East Timor has received a grant for USD 2,299,659 over five years to fund the NTP activities from the Global Fund for AIDS, TB and Malaria. Since 1999, other sources of funds have included AusAID (1999-2001), CAFOD and WHO. Caritas Norway has been a primary donor for TB Control pre-1999 and post 1999 to 2004. Since 2004, first line anti-TB drugs have been procured from the Global Drug Facility and from 2005 as a grant.

**Current and Future Challenges for Tuberculosis Control**

The recent handing over of the TB program to the MOH allows the opportunity for the development of an integrated response to the TB epidemic in East Timor and for the implementation of interventions from the National to the village level. The expanded sources of funding including from the Global Fund, drugs from the GDF and the successful submission of a proposal to Green Light Committee to treat MDR-TB patients reveal the promising future opportunities. However, the hand over also means that the MoH now must deal with certain managerial issues in the NTP central unit, and ensure adherence to the DOTS strategy at the implementation level.
Chapter III. Introduction to East Timor

Other challenges include:

- high default rate and low compliance rate;
- under reporting of smear positive cases;
- a lack of physical accessibility to TB services for rural and remote communities;
- strong belief and practices traditional medicine in rural and remote areas
- widespread poor nutrition resulting in difficulties recovering from TB;
- under-developed TB health promotion and prevention activities;
- the emergence of drug resistance and HIV/AIDS and
- poor housing and other environmental conditions which facilitate disease transmission.

The availability of the funding from the Global Fund to ensure the availability of consultants (Local and International) and embracing operational research to inform DOTS policy development are important elements to deal with the some of the above problems and to strengthen the DOTS program in East Timor.
Chapter III. Introduction to East Timor

Figure-1. Structure of East Timor National TB Control Program
Chapter III. Introduction to East Timor

References


Chapter III. Introduction to East Timor


Chapter-IV

THE DEVELOPMENT OF DOTS PROGRAMS IN CONFLICT-AFFECTED EAST TIMOR, 1996-2004

This chapter will present and discuss the challenges and achievements of DOTS in the conflict and post-conflict country of East Timor. It will examine the strategies, achievement and challenges faced by the three different TB control programs that were established under the difficult circumstances of conflict and post-conflict. This chapter has been published in the International Journal of Tuberculosis and Lung Disease (see appendix- I).
Chapter IV. DOTS in East Timor, 1996-2004

Summary

SETTING: East Timor has undergone major political changes in the past 10 years. Tuberculosis (TB) control has flourished despite chronic low tension conflict, a brief but intense high level conflict and post-conflict reconstruction.

OBJECTIVE: To assess the operation of a DOTS in East Timor from 1996-2004

METHODS: Data was collected from a variety of sources. Key TB program indicators were examined and analysed with reference to WHO targets to assess the performance of the three TB control programs that operated during the study period.

RESULTS: Before 1999, a non-government TB control program was established in several districts and showed optimistic results. External donor funds, technical assistance and the local strategies for TB treatment compliance were key components. In 1999, conflict led to complete disruption of the program. Within four months a National TB Control Program was established from the non-government program in collaboration with other partners. The notification rate is 108/100,000 (sputum positive cases), is the highest in the region and reflects high population coverage. The cure rate of 81% is close to achieving the WHO target.

CONCLUSION: The implementation of DOTS in conflict settings showed optimistic results. A relatively high detection rate, and a success rate which is not far from the target set by WHO, have been attained.
Chapter IV. DOTS in East Timor, 1996-2004

BACKGROUND

Tuberculosis remains the most important fatal infection of human beings, causing around 8 million cases and 2 million deaths each year.\(^1,2\) Conflict and post-conflict reconstruction of health services make TB control problematic for a number of reasons.\(^3\) A stable population and an adequate infra-structure within a well functioning health system have been argued to be fundamental requirements for the successful implementation of World Health Organisation’s (WHO’s) five component strategy known as DOTS. The essential elements of DOTS are political commitment, case detection through quality assured bacteriology, standardised treatment with supervision and patient support, an effective drug supply, and a management, monitoring and evaluation system.\(^1,4\) These conditions are problematic in conflict and post conflict settings. Strong community support, utilization of outreach workers from different ethnic groups, the use of directly observed treatment three times a week, and modified treatment regimens.\(^5,7\) Sudan and Mozambique implemented successful DOTS programmes despite the ongoing civil wars.\(^8,9\)
Chapter IV. DOTS in East Timor, 1996-2004

The objective of this study is to assess and document the experience of the introduction of DOTS during a chronic low level conflict and its rapid re-establishment and expansion in post-conflict East Timor. Through an analysis of reports, cohort analysis of patients and other TB data, we will examine key indicators such as program coverage, success rate, TB notification rate, laboratory performance and DOT activities in order to assess program performance and draw conclusions about the effectiveness of the NTP in East Timor during the period 1996-2004.
STUDY SETTING AND METHODS

Setting

East Timor lies to the east of the Indonesian archipelago, is divided into 13 districts, 67 sub-districts and 498 villages and 2,336 hamlets and has a population of 924,642. The country was colonised for 450 years by Portuguese and by Indonesia for 25 years. During the period of Indonesian rule, East Timor experienced “ongoing low level tension”, resulting in the loss of more than one third of its population. On 30 August 1999 the Timorese people voted overwhelmingly to become an independent nation. In September 1999, East Timor erupted in a wave of violence and destruction which devastated up to 70% of infrastructure in almost every town and village in the country.

The Territory was subsequently placed under United Nations (UN) administration in October 1999. In May 2002, East Timor became the world's newest independent state.

Tuberculosis has been a major public health problem in East Timor for many years. The Indonesian government estimated the prevalence to be 707 per 100,000 population in 1995 and expanded TB control into East Timor as part of the national program. In 1996, the Catholic Bishop of Dili, Bishop Belo visited Oslo to receive his Nobel Peace Prize, and asked the Norwegian government to help control TB in East Timor. This resulted in the establishment of a non government TB program operated by the Catholic Church (Caritas East Timor) in 1997 which operated in parallel to the government. The program followed the IUATLD/WHO recommendations but used different treatment regimens, a separate stock distribution system, training, supervision and recording and reporting mechanisms than the Indonesian TB program. Following the political unrest in 1999, TB
services were severely disrupted throughout the country. In January 2000, less than four months after the short but intense conflict of September 1999, a National Tuberculosis Control Program was established with Caritas East Timor as the lead agency.¹⁵

Methods

We collected data from the East Timorese NTP, government records, reports and other sources such as WHO, consultant reports and review documents. We examined key TB program indicators to assess the performance of the three TB control programs that operated during the study period: the Indonesian Ministry of Health (NTP-INO) (years 1996-1999), the Caritas East Timor (CTP) (1997-99) and the National TB Control Program of Timor-Leste (NTP-TL) (2000-2004). With reference to WHO targets, and performance indicators from other countries in the region, we drew conclusions about the effectiveness of TB control during the study period. For a list of definitions and abbreviations used in this paper, see table – 1.
### Diagnostic categories and program performance indicators definitions

<table>
<thead>
<tr>
<th>I</th>
<th>Diagnostic Categories</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>New</td>
<td>A patient who has definitely never taken anti TB drugs or who has taken anti TB drugs less than one month.</td>
<td></td>
</tr>
<tr>
<td>Relapse</td>
<td>A TB patient who previously received treatment and was declared cured or treatment completed; and has once again developed bacteriologically positive (by smear or culture) TB</td>
<td></td>
</tr>
<tr>
<td>Treatment After Default</td>
<td>A TB patient who return to treatment, bacteriologically positive, following interruption of treatment for 2 months or more.</td>
<td></td>
</tr>
<tr>
<td>Failure</td>
<td>A patient who, while on treatment, remained or became again smear positive five month 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.</td>
<td></td>
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</tbody>
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<tr>
<th>II</th>
<th>Outcome Categories</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Success</td>
<td>is the sum of patients cured and those who have completed treatment.</td>
<td></td>
</tr>
<tr>
<td>Cure</td>
<td>patient who is sputum smear smear negative in the last month of treatment and on at least one previous occasion</td>
<td></td>
</tr>
<tr>
<td>Treatment Completed</td>
<td>patient who has completed treatment but does not meet the criteria to be classified as a cure or a failure</td>
<td></td>
</tr>
<tr>
<td>Treatment Failure</td>
<td>patient who is sputum smear –positive at 5 months or later during treatment</td>
<td></td>
</tr>
<tr>
<td>Died</td>
<td>A patient who dies for any reason during the course of TB treatment</td>
<td></td>
</tr>
<tr>
<td>Defaulted</td>
<td>patient whose treatment was interrupted for 2 consecutive months or more.</td>
<td></td>
</tr>
<tr>
<td>Transfer out</td>
<td>patient who has been transferred to another recording and reporting unit and for whom the treatment outcome is not known</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>III</th>
<th>Definition of Program Performance</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>District Coverage</td>
<td>The TB program has formally commenced and is functioning in one or more clinics in the district. The clinic should perform TB diagnosis, including sputum smear microscopy, directly observed treatment, default tracing, recording and reporting</td>
<td></td>
</tr>
<tr>
<td>Subdistrict Coverage</td>
<td>Same as for district coverage but within the subdistrict</td>
<td></td>
</tr>
<tr>
<td>Notification rate</td>
<td>The number of TB patients registered for TB treatment during a particular time period (typically a year) divided by estimated total population of a particular geographic area (e.g. district or subdistrict)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>IV</th>
<th>WHO Target</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Case Finding :</td>
<td>To detect 70 % of existing cases of smear positive TB</td>
<td></td>
</tr>
<tr>
<td>Cure rate :</td>
<td>To cure 85 % of detected new cases of sputum smear positive TB.</td>
<td></td>
</tr>
<tr>
<td>Proportion of smear positive pulmonary TB (new and relapse)</td>
<td>Greater than 65%</td>
<td></td>
</tr>
<tr>
<td>Default rate :</td>
<td>Should be less than 10%</td>
<td></td>
</tr>
<tr>
<td>Failure rate :</td>
<td>Should be less than 4%</td>
<td></td>
</tr>
</tbody>
</table>
The authors were unable to collect detailed information on the TB program under NTP-INO, due to the destruction of health documents during the civil conflict of 1999. Information recorded here was obtained from personal accounts from the authors or secondary sources such as consultant reports.

Data analysis

Patients cohort data were compiled and tables and graphs generated in MS Excel. Statistical analysis was performed using STATA\textsuperscript{tm} (version 7, STATA Corporation, College Station, Texas, USA). Exact Ninety five percent confidence intervals for proportion were calculated using Poisson distribution. Differences in point estimates were calculated using Fishers exact P-test. Maps were produced using MapInfo Professional version 5.5 (MapInfo Corporation, New York, NY, USA, 1999).

Ethical clearance was obtained from the Human Research Ethics Committee of the Menzies School of Health Research and the Charles Darwin University in Darwin, Australia. Permission to conduct this study was also given by the Minister of Health of East Timor and the NTP director.
RESULTS

Three TB control programs

*TB Control Program under the Indonesian Health System (NTP-INO)*

The program was based on the DOTS strategy and used a six month Rifampicin based regimen (2RHZE/4RH). The TB control program used pre-packaged blister packs of TB drugs known as *com bipacks* for individualised treatment courses. Most health centres were not conducting cohort analysis [only pilot areas were using the standardised recording and reporting system]. There was a laboratory network, but with inadequate training and supervision of clinic staff and poor quality control of microscopy. Although some *com bipacks* were found in most government health centres, very few TB patients were actually treated. Directly observed therapy was not standard, with most patients receiving a weekly supply. External donor assistance to the program had not been established prior to the breakdown of health services 1999. The NTP-INO was destroyed by the conflict in 1999, with the loss of facilities, drug stocks and displacements of staff.

*Caritas TB Control Programme (CTP)*

The CTP was established through Catholic clinics based on the IUATLD/WHO DOTS strategy. Caritas Norway was the main source of funding and technical expertise. The central unit of the TB program included a Timorese director and four regional supervisors. An eight month treatment regimen (2RHEZ/6HE) was introduced with the aim of preventing Rifampicin resistance and reducing daily direct supervision to the two
month intensive phase. A number of strategies were developed to assist this aim, such as the creation of *alberugues* (temporary housing) for patients from remote areas during the intensive phase, the establishment of community based treatment observers (known as *motivators*), and the provision of supplementary food and transport costs for some patients. A laboratory network was established with TB microscopy in each clinic. To allow rapid expansion, a three month “on-the-job” training was established at the best performing clinic laboratory in Dili. Reporting and recording was strengthened through regular supervision, evaluation and training activities. Tuberculosis drugs were obtained from reputable international sources and sufficient stock for six months was kept in Dili and for three months at clinics.\textsuperscript{18} The instability of 1999 severely disrupted the CTP with all patients discontinuing treatment in the last quarter. However, most of the staff, many of the facilities and some of the equipment survived the conflict.

*The National Tuberculosis Control Programme (NTP-TL)*

The aim of the NTP-TL was to establish a control programme based on international best practice, adapting where necessary to local circumstances, which was inclusive of all health care providers in East Timor. The local TB control experience of Caritas East Timor, the financial assistance of Caritas Norway and targeted additional external technical assistance were vital elements which allowed the rapid establishment of the NTP.\textsuperscript{15}
Chapter IV. DOTS in East Timor, 1996-2004

In the early stage, the NTP-TL was established mainly through Catholic clinics and, throughout 2000, expanded to international NGO administered clinics. Caritas Dili (formally known as Caritas East Timor) was appointed as the leading implementing agency and a series of Memoranda of Understanding (MoU) were negotiated between the UN administration, Caritas Dili, and other partners. By late 2001, after the withdrawal of International NGOs, the TB program was well established through the government health structure.

The main components of DOTS were well implemented in the NTP-TL. The local strategies that had been established by the CTP were expanded throughout the country in the NTP-TL and some new strategies were adopted as required. The DOTS program is integrated with the general health services at implementation level and includes government, non-government and private clinics. The general NTP activities were organized through the Central Unit placed at the office of Caritas Dili.
TB program performance

DOTS Coverage

DOTS coverage and district level TB notification rates are shown in Figures 1 to 3. In 1996, only six (46%) of districts in East Timor had adopted DOTS under the NTP-INOT.14 By 1997, the CTP covered ten (77%) of districts and fourteen (21%) of subdistricts (figure-1). In many cases, government and Caritas clinics were situated in close proximity and shared the same population base. In many subdistricts plus some districts, there was no TB program at all.

By the end of 2004, the NTP-TL was formally operating in all 13 (100%) districts and 56 (84%) of subdistricts. (See Figure-3). This high coverage figure resulted from the inclusive nature of the NTP-TL which has adopted a unified recording and reporting mechanism.

Case finding

A laboratory and TB program manual were produced for both the CTP and NTP-TL. The CTP network of microscopy operated in 13 clinics. Utilizing similar approaches, the NTP-TL microscopy network was established in community health centres, Catholic clinics and some private clinics. In collaboration with the national reference laboratory, both CTP & NTP-TL routinely conducted laboratory quality assurance using standard WHO/IUATLD methods (Table-2). The ongoing quality assurance has been useful for detecting and correcting major error in a few clinics. The high error rate in 2001 was
almost entirely due one clinic (error rate 88%). On review, the technician at that laboratory was found to be colour blind and was replaced.

Case finding is summarized in Table 3: 183 new sputum smear positive cases registered in the NTP-INO 1996. There are no data to assess trends in subsequent years. In 1997, the CTP 1,016 cases registered over 1,000 patients. Case finding decreased from 1997 to 1999. In its first year (2000), the NTP-TL registered and treated over 4,000 patients. A relative low proportion of sputum smear positive cases were detected during the initial period of both CTP and the NTP-TL.

In 2004, 3724 TB cases were registered and treated under the NTP-TL (Table-3). The TB case notification rate was 403/100,000 and for new smear positive cases it was 108. Interestingly, the majority of cases were reporting from one urban district (see Figure-3). The proportion of infectious cases has decreased significantly from 31.4% in year 2000 to 26.9% in year 2004 (Fisher exact P-value<0.001). The proportion of retreatment cases continuously decreased. In all but one year, extra-pulmonary and sputum smear negative cases dominate the notification rate with up to 72% of cases (2004) in these categories.
Case holding

In 1996, the success rate for sputum smear positive cases was around 45% under NTP-INO. The success rate for sputum smear positive newly diagnosed TB patient improved during 1997. The CTP success rate for new smear positive cases in 1997 was low (50%) mainly due to a very high default rate (42%) (figure-4). Similarly, the success rate of the NTP-TL was only 65% with a high default rate in 2000. The success rate has continuously increased to over 80% and the default rate has steadily decreased to 10% by the end 2003, highly statistically significant improvements (Fisher exact P-value both <0.001).
Chapter IV. DOTS in East Timor, 1996-2004

**Figure-1.** TB clinic affiliation and location and district level notification rates, East Timor, 1997. White box with black cross = NGO clinic.
Figure-2. TB clinic affiliation and location and district level notification rates, East Timor, 2001. White box with black cross = government clinic; Black box with white cross = NGO clinic.
Figure-3. TB clinic affiliation and location and district level notification rates, East Timor, 2004 White box with black cross = government clinic; Black box with white cross = NGO clinic

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Clinics</th>
<th>Slide Results</th>
<th>False</th>
<th>% Error rate (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Positive</td>
<td>Negative</td>
<td>Total</td>
</tr>
<tr>
<td>1998*</td>
<td>13</td>
<td>859</td>
<td>48</td>
<td>48</td>
</tr>
<tr>
<td>2001</td>
<td>12</td>
<td>406</td>
<td>235</td>
<td>641</td>
</tr>
<tr>
<td>2002</td>
<td>20</td>
<td>388</td>
<td>109</td>
<td>497</td>
</tr>
<tr>
<td>2003</td>
<td>20</td>
<td>397</td>
<td>215</td>
<td>612</td>
</tr>
</tbody>
</table>

* Number of ‘smear positive’ and ‘smear negative’ slides not recorded in 1998.

Figure 4 Treatment outcomes for sputum smear-positive patients treated under the CTP (1997) and the NTP-TL (2000–2003). Data for 1998 and 1999 were missing due to the destruction of the Caritas Office and documents in September 1999.

<table>
<thead>
<tr>
<th>Year</th>
<th>Smear Positive</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>EPTB</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>New</td>
<td>Relapse</td>
<td>Failure</td>
<td>RAD</td>
<td>&lt;15</td>
<td>&gt;15</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>1997</td>
<td>381</td>
<td>37.5</td>
<td>7</td>
<td>0.7</td>
<td>10</td>
<td>1.0</td>
<td>21</td>
</tr>
<tr>
<td>1998*</td>
<td>281</td>
<td>34.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1999</td>
<td>204</td>
<td>55.7</td>
<td>6</td>
<td>1.6</td>
<td>3</td>
<td>0.8</td>
<td>4</td>
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<tr>
<td>2000</td>
<td>1,347</td>
<td>31.4</td>
<td>51</td>
<td>1.2</td>
<td>20</td>
<td>0.5</td>
<td>64</td>
</tr>
<tr>
<td>2001</td>
<td>1,288</td>
<td>35.1</td>
<td>27</td>
<td>0.7</td>
<td>15</td>
<td>0.4</td>
<td>47</td>
</tr>
<tr>
<td>2002</td>
<td>1,091</td>
<td>39.5</td>
<td>27</td>
<td>1.0</td>
<td>22</td>
<td>0.8</td>
<td>20</td>
</tr>
<tr>
<td>2003</td>
<td>1,026</td>
<td>37.1</td>
<td>20</td>
<td>0.7</td>
<td>8</td>
<td>0.3</td>
<td>18</td>
</tr>
<tr>
<td>2004</td>
<td>1,000</td>
<td>26.9</td>
<td>18</td>
<td>0.5</td>
<td>9</td>
<td>0.2</td>
<td>13</td>
</tr>
</tbody>
</table>

* Data for other categories of TB patients for 1998 was missing due to the destruction of Caritas TB document in 1999.
RAD = Return after default; EPTB = Extrapulmonary TB
Chapter IV. DOTS in East Timor, 1996-2004

DISCUSSION

We have documented the three different TB control program operating in two different situations in East Timor. There are main results from this study. Firstly, a non-government DOTS program was established during a low-level chronic conflict in East Timor, and although coverage was limited and initial default rates were very high, it showed promising improvements before intense conflict disrupted the program. Second, a unified National TB Control Program based on the previous NGO program was rapidly scaled up after an escalation in the conflict in 1999, and has achieved impressive and sustained results. Finally, both programs utilized similar locally produced modifications to DOTS, the main difference being the wider coverage and inclusive nature of the post-conflict program. Whilst the notification and cure rates are high, the program still faces problems with a low percentage of infectious cases and incomplete coverage in rural sub-districts.

The DOTS strategy was successfully introduced during and after the conflict of East Timor, despite facing lots of difficulties. Prior to 1999, the existence of parallel systems and the chronically precarious security situations hampered supervision and the distribution of supplies in both CTP and the NTP-INO. After the conflict, a highly mobile population, lack of infrastructure, lack of trained staff and the lack of financial support were reported as the main obstacles for re-estabilishment of DOTS.15
Due to its inclusive nature, the NTP-TL has flourished and is currently serving the majority of the Timorese population. The NTP-TL is a good example of public-private mix with cooperation between government and NGOs. The TB case notification rate under NTP-TL is much higher than the combined notification rate of the TB programs operating prior to 1999, partly because of the centralized and uniform recording and reporting system, and partly due to the higher population coverage. As Kelly et al. reported high rates of TB among East Timorese refugees arriving in Darwin in 1999, this notification rate could reflect the true TB prevalence in East Timor.

The NTP-TL reported a high number of TB cases at earlier stage of its establishment. This may be explained by poor screening processes, resulting in high recruitment of smear negative cases. Alternatively, it might be a true due to the potential for increasing numbers of TB cases during the emergency period. It is further possible that health professionals were more likely to diagnose TB because the availability of TB drugs where other treatments were lacking. Training of health staff on diagnostic pathways in 2000 may have contributed to the increased proportion of smear positive cases from 2001 to 2003. The reason for a lower proportion of smear-positive diagnoses from 2004 requires further evaluation.
Despite the potential for over diagnosis of TB, the high TB case notification also reflects the expansion of the program throughout most of the country. It will require further attention from all stakeholders to advocate for resources to reach Timor Leste’s Millennium Development Goal targets.\textsuperscript{22} The fewer infectious cases over the last 3 years under the NTP-TL might reflect decreasing TB transmission; however, it is unfortunately more likely to reflect diagnostic inaccuracies. The continuous reduction in retreatment cases probably reflects good treatment adherence and a low rate of drug resistance in this country\textsuperscript{23}, although the unusually low level of retreatment cases raises the question of under-reporting.

The success rate under the CTP was unacceptably low in the first year, but was consistently increasing every quarter up to early 1999. The success rate of 81\% under NTP-TL is close to the WHO global target of 85\%.\textsuperscript{2} It is noteworthy that these results were achieved so quickly. Most countries that have adopted DOTS l struggle to achieve the target even after 15 years.\textsuperscript{1} Local solutions to local problems have been shown to be important contributors in other countries, including those affected by conflict.\textsuperscript{5,6,6,24-28} Ongoing studies of Timorese strategies will further examine their role in improving treatment adherence.
Study limitations

The lack of systematically collected data from NTP-INO and some missing data from the CTP is a weakness of this study, but a common problem in conflict-affected situations. Some of our conclusions may have been different if complete data had been available. The retrospective nature of the data collection may have also affected the analysis in the different time periods. Despite this, we are confident that the data presented and the analysis which we have undertaken is a true reflection of the experience of the introduction of DOTS in conflict and post-conflict settings in East Timor.

CONCLUSION

The DOTS strategy was successfully introduced in East Timor during and after the cessation of conflict. In the East Timor context, the causes of a low proportion of smear positive cases requires further research so that interventions can be designed and evaluated. Research is needed to further examine the important elements for rapid and sustainable development of TB programs in other conflict and post conflict settings.
Chapter IV. DOTS in East Timor, 1996-2004

References


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CHAPTER-V

RECONSTRUCTING TUBERCULOSIS SERVICE AFTER MAJOR CONFLICT:

EXPERIENCES AND LESSONS LEARNED IN EAST TIMOR

Soon after the high tension conflict of political violence in September 1999, the Unified National Tuberculosis Control Program was established under a local faith NGOs. The successful re-establishment of this program was due to the contribution of many people from many different organisations. In this chapter we examined the factors that contribute to the successful establishment of NTP and barriers that were overcome during the emergency period. This chapter has now been published in the open access Journal, PLOS Medicine (see appendix-II).
Chapter V. Post-conflict TB service reconstruction

SUMMARY

Background

Tuberculosis (TB) is a major public health problem in developing countries. Following the disruption to health services in East Timor due to violent political conflict in 1999, the National Tuberculosis Control Program was established, with a local non-government organisation as the lead agency. Within a few months, the TB program was operational in all districts.

Methods and Findings

Using the East Timor TB program as a case study, we have examined the enabling factors for the implementation of this type of communicable disease control program in a post-conflict setting. Stakeholder analysis was undertaken, and semi-structured interviews were conducted in 2003 with 24 key local and international stakeholders. Coordination, cooperation, and collaboration were identified as major contributors to the success of the TB program. The existing local structure and experience of the local non-government organisation, the commitment among local personnel and international advisors to establishing an effective program, and the willingness of international advisers and local counterparts to be flexible in their approach were also important factors. This success was achieved despite major impediments, including mass population displacement, lack of infrastructure, and the competing interests of organisations working in the health sector.
Chapter V. Post-conflict TB service reconstruction

Conclusions

Five years after the conflict, the TB program continues to operate in all districts with high notification rates, although the lack of a feeling of ownership by government health workers remains a challenge. Lessons learned in East Timor may be applicable to other post-conflict settings where TB is highly prevalent, and may have relevance to other disease control programs.
INTRODUCTION

Tuberculosis (TB) infection and disease is intertwined with poverty.\(^1\) The overwhelming burden of TB, over 80% of the 4.4 million cases of tuberculosis notified to the World Health Organization (WHO) in 2003, lies in developing countries.\(^2\) Almost 60% of the cases were notified from Asian or Pacific countries.\(^2\)

In 1993, WHO declared TB a global emergency and formulated a “5 point plan” known as the DOTS (Directly Observed Treatment Short-Course) strategy to fight the disease. It comprises: political commitment, case detection using sputum microscopy, standardized short course chemotherapy under proper case-management conditions including directly observed treatment, a regular drug supply, and a standardized recording and reporting system that allows assessment of individual patients as well as overall program performance.\(^3\) Huge strides have been made in DOTS implementation during the past decade. There is a need for research to address the applicability of the DOTS strategy in post-conflict settings because of the often extra-ordinary circumstances present.\(^1\) East Timor shares a border with Indonesia and lies 800 km to the northwest of Australia. It is one of the poorest countries in the Asia-Pacific. The population of 924,642 are predominantly subsistence farmers; their families live in rural areas.\(^4\) After 450 years as a colony of Portugal, Indonesia annexed East Timor in 1975 and for the following 24 years it was considered a province of Indonesia. In 1999 the country was torn apart by political violence led by groups who opposed the outcome of a referendum in favour of East Timorese independence. Militia systematically ransacked, looted and destroyed up to 70% of infrastructure in almost every town and
village, with government buildings, including health facilities, being major targets. The health care system collapsed. United Nations peacekeeping troops intervened and stabilised the country under United Nations administration for two years before gaining independence in May 2002 (Table 1).
**Table 1.** Timeline of key political and tuberculosis control developments in East Timor.

<table>
<thead>
<tr>
<th>Date</th>
<th>Political developments</th>
<th>Tuberculosis control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior to 1974</td>
<td>Portuguese colonization</td>
<td></td>
</tr>
<tr>
<td>1975 to 1999</td>
<td>Indonesian occupation</td>
<td>• Indonesian NTP¹ (1996-99)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Caritas East Timor TB control program (1997-99)</td>
</tr>
<tr>
<td>May 1999</td>
<td>Referendum announcement; UNAMET² arrives to oversee democratic process</td>
<td></td>
</tr>
<tr>
<td>May to August 1999</td>
<td>Increasing militia activity disrupting health services throughout East Timor</td>
<td>TB control also severely affected</td>
</tr>
<tr>
<td>30 August 1999</td>
<td>78.5 % of East Timorese vote for independence</td>
<td></td>
</tr>
<tr>
<td>1- 19 September, 1999</td>
<td>Post-referendum period; anti-independence militia destroy East Timor; mass refugee movements.</td>
<td></td>
</tr>
<tr>
<td>20 September, 1999</td>
<td>First INTERFET³ troops arrive.</td>
<td></td>
</tr>
<tr>
<td>September 1999 to February 2000</td>
<td>Emergency period.</td>
<td>• 26-28 October 1999: WHO TB assessment mission to East Timor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 26 November 1999: 1st meeting of National TB Committee</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 21 January 2000: NTP established &amp; commenced operations in 3 districts</td>
</tr>
<tr>
<td>16 February, 2000</td>
<td>Formation of the IHA⁴ under UNTAET⁵ by 8 international and 16 Timorese health professionals.</td>
<td></td>
</tr>
<tr>
<td>March 2000 to May, 2002</td>
<td>Transition to independence</td>
<td>October 2000: NTP operating in all 13 districts with NGOs⁶ as main implementing partners in early period then IHA in later period</td>
</tr>
<tr>
<td>20 May 2002</td>
<td>East Timor independence day</td>
<td>By end of 2002:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Population coverage: 79%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 10,722 patients treated (2000-02)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Treatment success: 81%</td>
</tr>
</tbody>
</table>

¹ NTP = National TB Control Program; ² UNAMET = United Nations Assistance Mission for East Timor; ³ INTERFET = International (Peace enforcement) Force for East Timor; ⁴ IHA = Interim Health Authority (nascent Ministry of Health); ⁵ UNTAET = United Nations Transitional Authority for East Timor; ⁶ NGO = non-government organisation
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The international humanitarian response to the complex emergency in 1999 was swift: within a week of internationally sanctioned UN peace enforcement mission (INTERFET) in September, several UN agencies (including WHO) had arrived. Within a month, around 100 international NGOs, many with health components to their work, were present in the country. The lack of government structures, the absence of many community leaders, the mass displacement of the population and a perceived reluctance on the part of East Timorese leaders to make decisions in these circumstances, made dealing with the situation from a development perspective difficult. In the emergency phase, health services were mainly delivered by international NGOs with church run clinics and some not-for-profit private practices providing important additional coverage. In the transition to independence, NGO-run health services were progressively handed over to the nascent Ministry for Health (the Interim Health Authority) under the UN administration. (Table 1)

Tuberculosis had, for many years, been identified as a major public health problem in East Timor. From 1996, two TB programs operated in parallel: the Indonesian Ministry of Health and an externally funded church-based organisation. Following the referendum and associated violence, many health staff left East Timor or were unable to continue working and TB services were severely disrupted. The magnitude of the TB epidemic in East Timor is believed to have increased in 1999. Within a few months of the September events, people from many different organisations contributed to the establishment of a National Tuberculosis Control Program which conformed to WHO’s DOTS strategy (Figure 1). In its first five years, the TB Program diagnosed and
Chapter V. Post-conflict TB service reconstruction

commenced treatment on 17,210 patients. In 2001 the notification rate was 446 per 100,000 populations for all forms of TB and 154 per 100,000 population for new smear positive pulmonary cases. These are the highest rates in the South East Asian and Western Pacific Regions. This reflects both the high burden of disease and the effective case-finding system which has been developed and sustained in East Timor since 1999. There has been gradual progress in DOTS expansion, with the TB Program functioning in all 13 districts and accessible to 79% of the population of East Timor. Treatment results have improved and the treatment success rate is now consistently over 80%.

This paper aims to identify the key factors which enabled the establishment of a successful TB Program in East Timor, while attempts to develop other sustainable programs in the post-conflict period have struggled. We document, analyse and reflect on this set of experiences and place them in the public domain for critique and lesson-learning.
Figure 1. Structure of the National Tuberculosis Control Program in East Timor, 1999–2002

1Minister of Health includes earlier health leaders, including the co-chair of the Interim Health Authority of the United Nations Transitional Administration in East Timor (UNTAET) and later Head of the Division of Health Services in the East Timorese Transitional Authority (ETTA).

2MoH, Ministry of Health.

3NTP, National Tuberculosis Control Program.

4Caritas, Caritas East Timor, a Timorese church-based NGO.

5iNGO, international NGO.
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METHODS

The methods employed included: review of the published literature on post-conflict health systems development; review of documents and reports from the time-period 1999-2003 relating to East Timor; interview of key informants with knowledge of the TB program and its development over this time period; and critical reflection of the experience of two key stakeholders and authors (NM and PK).

All stakeholders and influential individuals currently and/or previously involved in the setting up and administration of the TB Program between 1999 and 2003 were identified and contacted with a request to interview them. Of the thirty people identified, twenty-four were available for interview. No stakeholder refused participation and the six who did not participate were either non-contactable or were otherwise unavailable for interview. Stakeholders who were not interviewed were represented in the interviewed group by others who held closely related posts during the time period of the study. Those who participated in this study included government officials (Minister of Health and other high ranking staff), local and international health professionals, staff of local and international NGOs involved in health services delivery, private practitioners, local politicians, church leaders, current and previous TB Program directors and staff, the current and previous WHO Representatives in East Timor, donor representatives and TB consultants.
Semi-structured interviews were conducted by the principal author (NM), either face-to-face (N=16) or via email (N=8). Open-ended questions were employed in order to gain as much qualitative information as possible about the participants’ views on the process of establishing the TB Program. Participants were also asked to comment on the effectiveness of the TB Program, and the current and future challenges it faces. The interviews were recorded in handwritten notes, tape recordings and e-mail messages in response to the interviewer’s written questions. After each interview a summary transcript was prepared and participants were offered the opportunity to read and check these for accuracy. Where required, follow-up interviews were undertaken to clarify particular comments and issues. From these interviews we were able to identify, through the perspectives of these stakeholders, the factors that were perceived to contribute to the success of the East Timor TB Program, and the challenges it faces in the future. Three authors (NM, AZ and JG) contributed to the stakeholder analysis, drawing on the methods described by Varvasovszky and Brugha. Two of the authors (AZ and JG) were not directly involved with the events reported in this paper and acted as independent external observers within the team. (See Box-1)

Ethical approval for the study was obtained from the Human Research Ethics Committees of the Menzies School of Health Research, and the Charles Darwin University, Darwin, Australia. In the absence of a local Ethics Committee, written permission to carry out the study was obtained from the Minister for Health of the Democratic Republic of East Timor.
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Box 1. Insider and Outsider Perspective in Qualitative Research

An important feature of the work undertaken and presented here was the involvement of two of the authors in the events described in this paper. These insider-outsider perspectives are contentious, but we believe add considerable strength to the insights able to be derived through such work: they offer an opportunity to tell the story of the TB program through the words of both the authors and the range of informants consulted, and they demand reference back to the real constraints and opportunities operating in such environments. They add to the reflections of others to develop a rich insight into the perspectives of the stakeholders involved at the time, and their voices, heard through this paper.

The boundary between researcher and researched frequently blurs in qualitative studies. The nature of the involvement of two of the authors (NM, the founding director of the TB Program and PK, an international TB consultant) were key participants in the processes and events described in this paper. Power relationships are always problematic in research, in particular in qualitative research. We were acutely aware of this during the planning phase, the research itself, the analysis of the data and in the writing up of our findings. The Principal author (NM) was the key to access in this study, and we feel that this unique access to such a wide variety of opinions outweighs the potential bias which his previous position may have bought to the study findings. It should be noted that NM was not in a position of power when the interviews took place (he had resigned as TB Director some 3 years previously). In Timorese society, it is true that social hierarchy can lead to those perceived as “inferiors” being reticent to criticise their “superiors”. However, peers and those in socially superior positions are typically frank with their opinions, as evidenced by the dissenting and critical statements included in the article. The same experience is demonstrated by dissenting views from foreigners. Thus, we are confident that we have addressed this important issue, and acknowledged potential bias in our conclusions.

The positioning of two of the authors as “insiders”, particularly in combination with two “outsider” authors, adds strength, but also has some limitations. The limitations include whether too strong a voice is given to the particular perspectives of two of the players, whether their involvement in conduct and analysis of interviews undermines objective assessment. The involvement of the two authors not involved in the TB program development offers an opportunity to engage with some of the material through review of the interview data, and to test out some of the ideas and the analysis.

As stated by Merriam and colleagues, “the insider’s strengths become the outsider’s weaknesses and vice-versa” and that “this multiplicity of perspectives” enhances rather than detracts from the validity of observations made. Developing an insider-outsider team helps establish balance. What is presented can perhaps be described as the perspectives and critical insights of key players in the establishment of the TB Program at a crucial time in its history. The benefit is that unique insights are documented, analysed and presented for further critique and analysis: no attempt is made here to state that the insights presented in this paper are neutral or not coloured by the involvement of two key players. Rather we argue that this history provides additional depth and richness, available for others to build upon.
RESULTS

The key barriers to establishing a TB control Program are summarised in Table 2. These included population mobility; lack of health infrastructure, supplies, equipment and trained staff; transport and communication difficulties; and a scarcity of financial, technical and political will to address TB in the emergency phase.

Most participants expressed concern about the increased number of TB cases during the emergency period, most likely due to the massive displacement of people, malnutrition, sanitation and shelter problems, and the disruption of the previous TB programs. The World Health Organization reported that there had been no TB treatment program for several months in late 1999, therefore there was a “backlog” of patients requiring treatment. The displacement of the majority of the country’s population was another major problem in the implementation of an effective TB treatment program. It was reported that there was a large population drift to Dili during the first few months of the emergency period, for security, food, shelter and the possibility of gaining employment. This situation greatly concerned some of the participants in this study, who during the first TB Program co-ordination meeting predicted future constraints to the successful completion of TB treatment when these people returned to their villages after having begun treatment in Dili.
Table 2. The major impediments to the establishment of a National TB Control Program in East Timor, the solutions identified and the agencies responsible for their implementation.

<table>
<thead>
<tr>
<th>Major impediments</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly mobile population</td>
<td>• Suspect register</td>
</tr>
<tr>
<td></td>
<td>• Albuergue</td>
</tr>
<tr>
<td></td>
<td>• Rapid roll-out of program to rural areas</td>
</tr>
<tr>
<td></td>
<td>• Communication mechanisms</td>
</tr>
<tr>
<td>Infrastructure destroyed</td>
<td>• Use of undamaged Catholic Clinics</td>
</tr>
<tr>
<td></td>
<td>• Use of alternative buildings (eg church halls)</td>
</tr>
<tr>
<td></td>
<td>• Rebuilding of clinics (not in emergency phase)</td>
</tr>
<tr>
<td>Lack of co-ordination of interest in TB treatment</td>
<td>• Early regular coordination meetings open to all</td>
</tr>
<tr>
<td></td>
<td>• Appointment of lead agency</td>
</tr>
<tr>
<td></td>
<td>• National guidelines developed</td>
</tr>
<tr>
<td></td>
<td>• Political support ensured</td>
</tr>
<tr>
<td></td>
<td>• MOUs developed &amp; signed</td>
</tr>
<tr>
<td>Human resources scarce</td>
<td>• Utilisation of local capacity</td>
</tr>
<tr>
<td></td>
<td>• High motivation &amp; work ethic of central unit staff</td>
</tr>
<tr>
<td></td>
<td>• Adaptation of Training materials for clinicians, TB nurses &amp; lab staff</td>
</tr>
<tr>
<td></td>
<td>• Rapid implementation of training courses to TB staff (open to all organisations who had signed MOU)</td>
</tr>
<tr>
<td>Transport/communication difficulties</td>
<td>• Coordination with UN agencies</td>
</tr>
<tr>
<td></td>
<td>• Use of vehicles, police radio</td>
</tr>
<tr>
<td>Drugs and other supplies unavailable</td>
<td>• Use of available data for planning</td>
</tr>
<tr>
<td></td>
<td>• Rapid procurement from international sources</td>
</tr>
<tr>
<td>Limited financial resources</td>
<td>• Rapid scale up from current donor</td>
</tr>
<tr>
<td></td>
<td>• Extra sources of support</td>
</tr>
<tr>
<td>Increased requirement for technical support</td>
<td>• Rapid deployment and frequent repeat visits of international consultants</td>
</tr>
<tr>
<td></td>
<td>• Continuation of long-term technical assistance</td>
</tr>
<tr>
<td></td>
<td>• Rapid expansion of NTP supervision to all health units with TB program</td>
</tr>
</tbody>
</table>

Notes for Table 2.
MOU = Memoranda of Understanding; NTP = National TB Control Program; TB = tuberculosis; UN = United Nations
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There were also a number of factors that delayed the process of establishing the TB Program. Lack of money, drugs, infrastructure and transportation characterised all sectors in East Timor in the early emergency period. It was very difficult to get from one place to another in order to coordinate the work without regular and reliable transport and amidst security concerns in some areas. There were many times when TB Program staff had to rely on the United Nations (UN) and NGOs for transportation. In the early stage of the TB Program, the TB program was mainly run through the Catholic Church clinics because many of these had not been totally destroyed, unlike government clinics.

The main enabling factors for success of the TB Program are also summarised in Table 2. The findings of this study suggest that at the centre of the successful development of East Timor’s TB Program were coordination, cooperation and collaboration between local and international agencies, TB experts and staff. These were brought about by, and resulted in, a willingness to take into account and adapt to local contextual factors (flexibility), and the strong commitment and high level of motivation on the part of key stakeholders.

Co-ordination and Co-operation

By coordination, we mean a sharing of responsibilities to prevent a duplication of effort. Cooperation is a closely related concept referred to hear as a sense of common purpose, using common methods to work together to achieve something.

Most participants in this study considered coordination to be a major factor in the successful establishment of a national TB program, while acknowledging that it was very
difficult to achieve given the conditions of the early emergency phase. The competing interests of local and international health professionals, NGO, UN agencies and military forces mitigated against it.

In the early phase of the emergency more than fifteen NGOs plus the International Committee of the Red Cross (ICRC) and the INTERFET Military Health team arrived to give assistance, each of them making claims to develop activities in a particular geographic region or in relation to a particular component of health policy and system development. WHO attempted to act as a coordinating body for health but experienced a number of constraints. Some of those interviewed argued that budget limitations had prevented WHO from functioning as effectively as had been hoped for. At that time services including health were highly centralised, and health service teams were sent out from Dili to different parts of the country in the company of the security forces. Neither capacity building nor institutional development occurred.

Soon after the conflict in 1999, TB was regarded as a relatively minor and non-urgent issue when compared to diseases with high outbreak potential such as cholera, dysentery, dengue fever and measles. Most of the international NGOs chose not to include TB in their treatment procedures. As one participant explained:
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*The international NGOs had their own mission, and they focused more on acute or emergency cases. Although, they were aware of the increasing number of TB cases, they did nothing because there was no mechanism through which they could do so.*

*Sr. TB Program official*

The Caritas TB program was reported to be still functioning in some places at this time, and there were also some uncoordinated and inappropriate TB treatments being provided by local health professionals who administered single drug treatment to TB patients. These local professionals had obtained the drugs they used from government health centres before they were destroyed by militia during the period of violence. It was difficult for the TB program to convince these local professionals to follow international best practice in treating TB patients because they had been following a different treatment regime for a long time. Some international medical practitioners also followed sub-optimal treatment regimens.

*During the emergency period, there was a vacuum. There was no coordination. Everybody felt they had the right to treat TB patients, without follow-up because they had no capacity to follow up the patient. There wasn’t good coordination.*

*Founding member of the Interim Health Authority*

Of those NGOs treating people for TB, not all followed the WHO recommended treatment schedule. International NGOs and certain “independent” international staff worked to their own agendas. On the one hand, they insisted on their own procedures for
TB control, and their “right” to diagnose and treat TB patients without follow-up in many cases. On the other hand, some refused to diagnose and treat TB, stating that it was not a priority in a complex emergency situation, and their organisations’ mandates precluded them from doing so.

*Barriers to implement [the TB Program] were obviously plenty, but what struck me most was the difficulty in coordinating health professionals, particularly to make them adhere to the Manual or Standard Protocol. This is particularly so in the case of medical doctors who came from a wide gamut of countries in the world, bringing their own preferences and practices while ignoring the international standards of DOTS adopted by the TB Program*

*Senior Ministry of Health Official*

In establishing a policy framework for the provision of general health services to the population, many interviewees reported that, at least in the emergency period (see table 1), there were major difficulties in coordination between WHO, UNICEF, NGOs, local professionals, the East Timorese Interim Health Authority and bilateral and multi-lateral donors at the highest level. Key barriers to coordination were competition (between organisations and individuals) and differences of opinion on priorities. This included competition for resources (financial and local personnel), legitimacy and leadership. For example, some donors and some NGOs wanted to introduce their own style of TB control without reference to the local situation.
Despite this there was intensive negotiation in an effort to coordinate the work for the establishment of an effective TB program. There was strong commitment to preventing the re-establishment of parallel TB programs. Experience from the Indonesian period demonstrated that a coordinated approach was crucial.

The experiences of TB treatment during the Indonesian period inspired us to strengthen the coordination and control of the treatment strategy. We [the Interim Health Authority] appointed Caritas as the sole implementer of the TB program in East Timor, with the authority to ban private practitioners or NGOs from treating TB cases and importing TB drugs without their permission.

Founding member of the Interim Health Authority

Caritas East Timor began holding weekly coordination meetings to accelerate the establishment of the TB Program in late 1999. Local and international professionals, local and international NGOs working in health, clinicians, donor representatives, other UN agencies such as the World Food Program (WFP) and UNICEF, and large NGOs such as the International Organisation for Migration (IOM), ICRC and Oxfam were among those who routinely attended. These meetings led to a high degree of cooperation from the organisations involved. Senior staff made a commitment to come to these meetings that was vitally important for the planning process. Continuity and consistency of decision-making and the ability to carry this back to the field was also important. A similar phenomenon was observed outside of Dili as the TB program rolled out to the rural districts. The agreements on roles and responsibilities formulated in these
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Early coordination meetings eventually resulted in a series of Memoranda of Understanding (MOU) between the TB program and the implementing partners which codified the responsibilities of the agencies involved in the implementation of the TB program in the emergency and early transition period. These MOUs were crucial in enforcing a standardised national approach to TB control, particularly in the absence of any legislative framework.

Cooperation between international TB consultants and their Timorese colleagues as characterised by the willingness to adapt to local circumstances was an important factor in the establishment of a sustainable TB program in East Timor. The international consultants involved did not see East Timor as a “blank slate” upon which their public health plans could be written without reference to local conditions. The previous TB control structures and the experience and expertise of local partners were acknowledged and became central to the establishment of the TB Program. From the outset, the opinions of local TB control staff were sought before any decisions were made on technical and operational aspects. At their second meeting, the TB coordinating committee appointed a Timorese doctor (NM) as the national TB coordinator who chaired all subsequent meetings and became the founding TB Program director.
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_We had the money and expertise; we could easily have built a sophisticated, though unsustainable TB program in East Timor. However, we did not do it because we did not want to be involved in the same mistakes as has occurred in Kosovo and Cambodia._

*International TB Consultant*

In East Timor, money and drugs became readily available due to the prompt response to the crisis by donors, including the long-term donor to the NGO program. This continuity of financial and technical support, together with additional support from other sources in the emergency period, was identified as one of the most important factors in accelerating the process of developing the TB Program.

**Collaboration**

Collaboration is a concept that is deeper than cooperation and represents a shared vision for the future and not merely the absence of competition. Partnership, shared understanding, open communication, tolerance of difference and trust are key components of a collaborative approach. In the case of the TB Program in East Timor, successful implementation depended on the readiness of local staff to trust their international counterparts, to learn from them and to adopt the international best practice standard. At the time many East Timorese were experiencing intense feelings of distrust following the deeply disturbing and destructive events of September 1999. The broken promises of the UN Assistance Mission (UNAMET), which had fled the country instead of staying to fulfil its commitment to protect ordinary people after the referendum,
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reflected badly on international staff. Many members of the latter were surprised to experience rejection from their East Timorese colleagues. The lack of trust needed to be managed sensitively and sincerely. Sergio Lobo – the Interim Health Authority Co-Chair at the time – coined the term “One Table Two Chairs” to encapsulate the expectation that local and international counterparts would sit and work together, to develop ideas and make decisions. This was central throughout the process of developing the TB Program.

*Well, I think it is because there was a willingness to work together between local and international expertise. But it depends on the international expertise or counterpart to transfer the knowledge and provide a motivation. On the other hand, the willingness of local professionals to accept the opportunity, to learn, and to work based on the international best practice standard.*

*Senior TB Program Official*

Throughout there was also strong commitment from TB Program consultants and staff to incorporate international best practice guidelines at the local level. This was covered in a MoU signed by the main stakeholders in early 2000 (Table 3).

One strength of the collaboration at that time was the ability of international experts to recognise the importance of the National Council of East Timorese Resistance (CNRT) as the only representative political organisation in East Timor.
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\textit{At my first attendance as CNRT representative to the health coordination meeting organized by WHO and UNICEF, I realized that the meeting was to coordinate the work of the International NGOs and agencies. Later on, I was told that the UN and most of International agencies have a mandate or regulation that prevents them to work with any political party. CNRT has been regarded as a political party.}

\textit{CNRT Health Spokesman}

There were strong links between the CNRT and Caritas East Timor during the Indonesian period. This internal political profile, its track record in TB control and the recommendations of the October 1999 WHO assessment mission prompted the Interim Health Authority to appoint Caritas East Timor as the lead agency in the new National TB control program.\textsuperscript{13} This decision was crucial to establishing a sustainable TB program.

\textit{The government [Interim Health Authority] made a decision to have only one TB program and appointed Caritas East Timor as the implementing agency. That decision was based on: firstly because the fact that the Catholic clinics structure was there. Secondly, Caritas East Timor has experienced staff who were willing to run and manage the program. And lastly, the government didn’t yet have the structure to manage and run the program.}

\textit{Founding member of the Interim Health Authority}
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East Timorese sovereignty over the TB program was maintained throughout the establishment and expansion of the TB Program. This ensured a rapid response by the TB Program leadership, with the assistance of international consultants, to feedback from the field, and to the analysis of quantitative data available from the program.

Most of the participants in this study felt that staff motivation was also a key factor in the success of the TB program. This was a difficult time for the staff in the early stage, with most directly or indirectly affected by the post-referendum violence. Despite this, most TB control staff remained highly motivated and committed. The Christian ethos of the NGO staff was an important factor, and staff drew strength from their Christian beliefs to serve those in need. The strong Timorese leadership was also an important motivating factor. There was the previous experience from the NGO TB program pre-independence, there was also a certain amount of euphoria about finally becoming independent which led to many extra-ordinary things. Nation building, contributing from one’s own expertise, coming together to assist fellow-Timorese, these were all elements which led to health workers working for no pay, or only minimal pay during the emergency and even well into the post-emergency phase.

In January 2000, less than two months after the first coordination meeting, the TB Program was launched. This occurred one month prior to the establishment of the Interim Health Authority. Five months after the first meeting, one co-chair of the Interim Health Authority referred to the TB Program as the “shining-light” in the reconstruction process of East Timor, a view supported by many interviewees.
It [the TB Program] was the first program to develop a memorandum of understanding... In that sense it was a model of collaboration in which all of the partners had clearly defined roles. The links with the church run health services was a great asset in re-establishing the Program as well as the continuous commitment of Caritas Norway. The proximity of the technical assistance in Darwin was obviously helpful.

*Founding member of the Interim Health Authority*
Table 3. Main points included in the Memorandum of Understanding between collaborating partners in the establishment and implementation of the TB Program (NTP) in East Timor, 2000.

<table>
<thead>
<tr>
<th>Partner</th>
<th>Main roles</th>
</tr>
</thead>
<tbody>
<tr>
<td>NGO (Lead Agency)</td>
<td>1. Implementation of TB control</td>
</tr>
<tr>
<td></td>
<td>2. Choose and employ the NTP Director and central unit staff</td>
</tr>
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<td></td>
<td>3. Be responsible for supply and distribution of drugs and other supplies,</td>
</tr>
<tr>
<td></td>
<td>writing TB manual and other materials</td>
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<tr>
<td></td>
<td>4. Report (at least quarterly) on the progress of the NTP to the</td>
</tr>
<tr>
<td></td>
<td>Interim Health Authority</td>
</tr>
<tr>
<td></td>
<td>5. Ensure regular supervision to all regions and districts</td>
</tr>
<tr>
<td></td>
<td>6. Take a leading role in the planning and conduct of training courses</td>
</tr>
<tr>
<td>Interim Health Authority (nascent MoH)</td>
<td>1. Ensure that the activities of the NTP are in accordance with East Timor’s national health policies and plans</td>
</tr>
<tr>
<td></td>
<td>2. Facilitate and ensure the full participation of suitable and interested health service providers</td>
</tr>
<tr>
<td></td>
<td>3. Oversee the coordination of the parties involved with the NTP</td>
</tr>
<tr>
<td>External donors</td>
<td>1. Be the main donor for the NTP</td>
</tr>
<tr>
<td></td>
<td>2. Periodical monitoring of the progress of the NTP</td>
</tr>
<tr>
<td>External technical advisors</td>
<td>1. Provide external technical assistance to Lead Agency in the planning and implementation of the NTP</td>
</tr>
<tr>
<td></td>
<td>2. Participate in capability building of East Timorese health workers through formal and on-the-job training</td>
</tr>
<tr>
<td></td>
<td>3. Participate in the periodical monitoring of the NTP progress</td>
</tr>
<tr>
<td></td>
<td>4. Participate in planned reviews and evaluations of the NTP</td>
</tr>
<tr>
<td>World Health Organization</td>
<td>1. Participate in planned reviews and evaluations of the NTP</td>
</tr>
<tr>
<td></td>
<td>2. Assist the NTP with the planning and conduct of training courses, and human resource development</td>
</tr>
</tbody>
</table>

Notes for table 3:

In 1999-2001, actual implementation of NTP at District, subdistrict and clinic level relied heavily on cooperation with many other partners in Government and Non-government health care providers. This was a dynamic situation with increasing Interim Health Authority responsibility as the recruitment of government staff was finalised (see figure 1). NTP=National TB Control Program; MoH=Ministry of Health
Chapter V. Post-conflict TB service reconstruction

Four years on: current challenges for the TB Program in East Timor

Tuberculosis control remains a public health priority for the new East Timorese administration. Participants in this study are aware of many problems which might affect the program’s future effectiveness and sustainability.

Indeed, the TB Program probably facing the same constraints that TB Programs everywhere in less developed countries are facing: personnel issues, supervision, quality control, etc.

Founding member of the Interim Health Authority

The lack of a sense of ownership of the program by government health staff has been noted since the TB Program launch. Some staff of government clinics still regard the TB Program as a non-government program and refuse to commit their time. The perception that the TB Program is the responsibility of Caritas has begun to change since the Minister of Health wrote a letter to staff directing them to cooperate with the TB Program as part of the core business of the Government Health Service. However, this needs further consolidation through the involvement of sub-districts and health posts in all TB Program activities.7

There has been a feeling of job insecurity and dissatisfaction among TB Program staff due to the fact that many were on short-term contracts with NGOs. In some cases, those with previous experience in TB have been recruited by the government but have staff...
placed in other positions in the health department, leaving their positions in the TB Program vacant. Consequently the government has had to recruit staff that have no previous TB program experience to key roles within the TB Program. This has necessitated retraining in many cases.

_The government has been recruiting the experienced staff to work in the TB program, however, because of their competency they are often promoted to higher level positions, leaving their posts empty to be filled by those who lack TB experience._

_Senior Ministry of Health Official_

Some participants felt there is a need to change the government recruitment procedure so as to keep the current TB Program structure under Caritas. Given continuing capacity gaps in the government health service, they felt that Caritas is the best organisation to continue to manage the TB Program. However, there is a recognised need for the government to take over some coordination and financial responsibility so as to gain a greater sense of ownership of the program. Resolving this challenging period of handover from NGO to government sensitively and constructively is key to the long-term sustainability of most, if not all, emergency-introduced health programs.

There was also concern expressed about the low level of community awareness of TB in East Timor, and some argued that unless this issue is addressed TB will always be a problem. Some informants suggested that this problem could be overcome by conducting
Chapter V. Post-conflict TB service reconstruction

a promotional campaign on TB to increase patient and community awareness. It is a challenge not only to explain what the TB Program strategy involves but also to help patients understand the rationale behind the strategy. As one participant argued:

There is a need to allocate more time and resources to conduct nation-wide health education campaign in the country. This will reduce stigma and improve the patient’s knowledge on TB.

International TB Consultant

Major challenges remain in determining the appropriate balance between different components of TB programs and recognising the limitations of each component in achieving long-term sustainable health outcomes.
DISCUSSION

There have been consistent calls for a more reflective approach to the evaluation of health care interventions in conflict-affected settings, leading to policies and guidelines better informed by evidence if we are to improve the international response. An examination of several recent high-profile complex emergencies – Mozambique, Cambodia, Kosovo, East Timor, Afghanistan and Iraq – demonstrate that post-conflict situations, and the response to them, as well as the response required, have changed in a number of important ways. TB control in these settings is particularly interesting and illustrative.

The geographic distribution of TB and that of political conflict overlap. Of the 22 high TB burden countries which account for 80% of all cases of TB in the world, seven have a history of significant conflict and/or complex emergency situations in recent years. During the 1980s and 90s high rates of TB disease and TB mortality were reported in refugee camps in Africa and Asia. Social and political disruption fuels TB epidemics and disrupts the delivery of TB control services, resulting in increased numbers of cases and, due to incomplete treatment, heightens the possibility of multiple drug resistant TB (MDR-TB).

This global epidemiology reinforces the need to improve TB control in these complex settings, both for the benefit of the people affected by the conflict, but also for neighbouring nations, including those who receive refugees for temporary or permanent re-settlement. This was dramatically demonstrated by the high rate of TB documented in
participants of the “safe haven” exercise in East Timor in 1999. East Timorese arriving in Darwin during September 1999 represented less than 0.01% of the Australian population, but accounted for six percent of all TB cases diagnosed in Australia in that year.

Continuity of health systems in periods of transition from pre- to during emergency to post-emergency and ultimately to sustainable Programs are an important component of international responses to emergencies, but is rarely achieved. Co-ordination, cooperation, and collaboration were key components to achieving this aim in relation to TB control in East Timor.

**Co-ordination**

Poor coordination is a well established problem in the response to complex emergencies. As was the case in Kosovo, WHO’s ambition to become the implementing agency for certain programs meant that they were at risk of being seen as a competitor with other implementing agencies. Constrained organisational mandates have been described elsewhere as a potential impediment to comprehensive care and services. It can be argued that this is a reasonable and perhaps responsible attitude for agencies with short-term commitments and a lack of expertise in TB. However, in the context in East Timor in 1999, many of the usual public health and clinical concerns of emergency situations were not present whilst TB was so prominent. It was thus appropriate that the health sector did treat TB as a priority issue in the early emergency phase.
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Caritas East Timor was appointed as the lead agency and successfully acted as the coordinating body. The role of faith-based NGOs is increasingly recognised as important, but not without complexity and contradictions, in international development settings. One of the negative aspects of NGO leadership is their lack of legislative authority. Hence cooperation with the government is crucial. For example, in East Timor, the TB Program required the Interim Health Authority to take a policy decision to stop the private sector from importing TB drugs or treating TB independent of the TB control Program.

Co-operation

The emergency period is critical. The rapid injection of money, expertise and technology makes the recipient countries vulnerable to the development of sophisticated programs which they will not be able to sustain. It takes good planning with extensive knowledge of the local situation to establish a cost-effective and sustainable program for a country under these circumstances, and co-operation, particularly with local counterparts is a key component for facilitating this desirable outcome. The inclusive approach taken during the establishment of the TB program in East Timor was in contrast to some other programs introduced in the emergency period by specific donors and/or international NGOs. The Roll Back Malaria campaign and oral health lacked the same level of cooperation with local partners and these programs have been less successfully sustained in the longer term. In Cambodia the UN took control of the TB Control Program in 1989 and sidelined local expertise for political reasons, allowing state-based structures and
services to be unwound. The result of this was limited short-term success, but an unsustainable program in the long term.

**Collaboration**

The truly collaborative approach used in the establishment of the TB control Program in East Timor was built on mutual trust and flexibility. Key to the development of these was a recognition of the political context of East Timor by international TB advisors.

In contrast with other political emergencies, for example, Kosovo and Cambodia, where competing political interests were prominent and contestation the norm, the CNRT was the single, uncontested political authority in post-conflict East Timor. While CNRT was the umbrella organisation for all political parties and groups that fought for independence, in the early phase of the emergency period most of the NGOs and UN agencies refused to work with them as they were bound by their mandate not to deal with political parties. This created a sense of exclusion among the Timorese. WHO was the exception, and considered the CNRT a valuable partner in health system development.

International technical advisors truly listened to local experience and accepted that this experience was valid in the local context of East Timor. Local solutions, not just the uncritical adoption of international standard solutions, were key components. This flexible approach was more about the maintenance of Timorese sovereignty and the legitimisation of the local political context rather than radical changes to internationally
recognised best practice guidelines. All of the essential elements of DOTS were maintained, with the adoption of some local adaptations (e.g., use of hospices in intensive phase of treatment, a network of satellite clinics in churches and other public buildings and the use of incentives to ensure treatment compliance).\(^7\) Trust is increasingly being described as a key issue in the re-establishment of services in the aftermath of conflict.\(^{33}\)

For Timorese health workers, the mixture of feelings of euphoria, pride and distrust might have prevented them from accepting and cooperating with the international staff in the initial post-conflict period. Importantly, local TB health workers trusted their international advisors and heeded their advice concerning, for example, the need for an inclusive approach and the use of MoUs. Thus, flexibility, built on trust was a crucial two way process in the TB control Program establishment.
CONCLUSION

During the year 2000 a sustainable National Tuberculosis Control Program was established in East Timor in a post-conflict setting, despite the many difficulties encountered. Coordination, cooperation and collaboration were the keys to this success, achieved through the high level of commitment of those involved, and the willingness of international experts and agencies to acknowledge local expertise and adapt to local circumstances. The latter was most evident in the early appointment of a local NGO to manage and implement the program. The utilisation of an existing local structure drawing on local expertise and experienced staff was essential to the program’s success. The East Timorese TB Program continues to function well and to improve the breadth and quality of its interventions. The government’s commitment to, and sense of ownership of the national TB Program will be important to its continued performance improvement, and ensuring its long-term sustainability. It is acknowledged that certain contextual issues, including the relatively small size of the country, the presence of charismatic Timorese leadership and the presence of ongoing external financial and technical support, have also contributed to the establishment of the TB program. Despite this, the East Timorese experience holds useful lessons for international donors and aid agencies, with these findings providing valuable lessons for those establishing TB control programs in other complex emergency situations in the future.
References


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Chapter-VI

SOCIO-CULTURAL BARRIERS AND ENABLING FACTORS TO THE IMPLEMENTATION OF THE DOTS STRATEGY IN EAST TIMOR

An Ethnographic Study

The findings from chapter IV and V suggest that an effective TB control program has been established during the emergency period and continues to show optimistic results. Despite this, the problems of low compliance to TB treatment and high default rate have been ongoing problems for the NTP. This chapter will present the finding from an ethnographic study from the one urban and one rural district in East Timor about the socio-cultural barriers and enabling factors in relation to the treatment compliance in East Timor.
Chapter VI. Cultural barriers to DOTS implementation

Summary

Setting: A rural and an urban district in East Timor where adherence to tuberculosis (TB) treatment remain a challenge.

Objective: To identify socio-cultural barriers to and enabling factors for the successful implementation of the TB control strategy known as DOTS in East Timor.

Method: Semi-structured interviews and Focus Group Discussions were conducted with patients, health workers and community members in eight villages.

Results: Nurses have good knowledge of TB and high commitment for implementing the DOTS strategy. Defaulter patients and community members have a low level of knowledge and awareness of TB. Having good knowledge of the disease, the right interpretation of cure, and the provision of food incentives were important factors in assisting patients to complete TB treatment. Obstacles to TB treatment completion were; preference for traditional medicine, economic difficulties and geographic remoteness.
Chapter VI. Cultural barriers to DOTS implementation

Conclusions: This is the first ethnographic study in the field of TB control in East Timor. This study has assisted the TB control program to identify the barriers that prevented patients to complete their treatment and factors that could be used to strengthen the TB program in the two districts. Modification of health beliefs will be targeted through health promotion campaigns. Locally developed TB strategies to deal with economic and geographical difficulties, such as the provision of supplementary food, may be examined with an appropriate study.
Chapter VI. Cultural barriers to DOTS implementation

INTRODUCTION

Tuberculosis as a global public health problem

Presently tuberculosis (TB) remains the leading infectious cause of morbidity and mortality in humans. The global incidence rate of TB is still rising at a rate of 0.6% per year.\(^1\) This deadly disease is a growing problem in many parts of the world because of the combination of poverty, inadequate TB control measures, multidrug resistance (MDR-TB) and the HIV/AIDS epidemic.\(^2\) \(^3\) In 1993 the World Health Organization (WHO) declared the incidence of TB a global public health emergency and introduced the strategy known as Directly Observed Treatment Short-Course (DOTS) strategy to fight the disease. DOTS comprises of: political commitment, case detection using sputum microscopy, standardized short course chemotherapy, a regular drugs supply and a standardized recording and reporting system.\(^4\)\(^5\) The World Bank regards DOTS as one of most cost-effective of all health interventions and recommends it as a part of the essential clinical services package for Primary Health Care.\(^5\) Following its successful introduction in China, WHO called for more countries to adopt the DOTS strategy.\(^6\) By the end of 2004, 183 of 210 countries were implementing DOTS strategy, covering a total of 83% of the world’s population.\(^1\)
Chapter VI. Cultural barriers to DOTS implementation

The Constraints of WHO DOTS Strategy to Fight TB in Developing Countries

To date the DOTS strategy relies on passive case finding to identify the infectious TB cases in the community and on directly observed treatment (DOT) to ensure high cure rates.\(^6\)\(^7\) The assumption behind DOTS programs is that high rates of case detection and treatment will lead to a reduction in the incidence of new cases. However, there is still a big challenge for many national tuberculosis programs (NTPs) to ensure high rates of detection of active TB cases, and to achieve a high cure rate for those undergoing TB treatment.\(^8\) There are other significant challenges for DOTS programs in many developing countries in ensuring that daily supervision of treatment (DOT) occurs.\(^9\) Although it has its critics, it is generally accepted that DOT, adapted to patients’ needs and to the availability of trained health workers, is the best method of avoiding treatment interruption.\(^10\) However, treatment completion continues to be one of the greatest challenges in TB control worldwide.\(^9\) The issue of poor compliance by patients and the lack of adherence to treatment guidelines by health workers remain major threats for treatment failure in many NTPs.

There have been a considerable number of studies which have reported on the various reasons for patient non-adherence with TB treatment. These reasons include concerns about side effects, the cost of transportation, physical fatigue caused by the disease, lack of family support, dissatisfaction with the treatment regimen, feeling cured (prematurely), and negative experiences with health workers.\(^11\)\(^12\)\(^13\) On the other hand, high workload, lack of training on the DOTS strategy, lack of understanding of patients’ socio-cultural
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understanding of disease, and low awareness among patients of the symptoms or risk of TB were identified as contributing factors to health workers’ inability or unwillingness to adhere to national TB treatment protocols.\textsuperscript{14,15}

It is important for tuberculosis programmes to perform locally-based studies to investigate possible impediments to treatment completion and to find the local solutions to improve DOTS performance.\textsuperscript{4,12} To date, there have been few studies that have used ethnographic methods to identify socio-cultural barriers and enabling factors for the successful implementation of Tuberculosis Control Programs, and in particular have explored the role of the health service personnel who deliver DOTS.\textsuperscript{16,17} We followed the qualitative approach advocated by Ogden and colleagues to examine the central issue of treatment adherence.\textsuperscript{17,18} This paper will examine these issues from the perspective of the key players in tuberculosis control in East Timor including patients, community members (include community leaders) and health care workers. The study findings will be used to suggest steps to improve the practice of TB control in the local setting of East Timor.
STUDY SETTING AND METHODS

Setting

East Timor is a newly independent country with a population of 926,642, divided into 13 districts, 67 subdistricts and 498 villages. Tuberculosis has been a public health problem for many years. The NTP was established in February 2000 and rapidly expanded to cover all districts. In the three years between the commencement of the program and the study reported here, 10,723 patients were registered and treated under the NTP. The program has covered 78% of subdistrict health facilities with the success rate reaching 81% by the end of 2002. However, the low detection rate, low compliance and high default rate remain the main challenges for the NTP. It is important to find the answer to the current challenges through proper research methodology in order to improve the management of TB services. Anthropologic research was employed with two objectives: firstly, to identify the socio-cultural barriers to adherence to TB treatment and secondly, to identify enabling factors that assist in the implementation of the DOTS program. These issues were explored from the perspective of patients, community members and health workers.

This study was conducted in Dili (urban) and Ermera (rural), the two districts with the highest TB notification rate reported under the TB control program. Dili, the capital city of East Timor, has a multi-ethnic population and the largest district population in the country (137,959 persons) as well as the highest population density. At the time of the study, there were four TB diagnostic and treatment centres, and five TB satellite
clinics providing DOT services to the Dili population. Ermera is located in the west-central part of the country with an area of 746 km², lies 58 km southwest of Dili and has a population of 103,169. Ermera is mainly inhabited by Mambae people (also known as the Atoni people), the indigenous people of the area with very strong traditional beliefs. There are two other minority ethnic groups, Kemak and Bunag, which are living mainly close to border of Bobonaro district in the west. There is one TB diagnostic and treatment centre in the district capital (Gleno), and six DOT centres located in each subdistrict to allow daily supervision of treatment for patients. A system of trained community voluntary health workers known as motivators was also developed in one of the Ermera subdistricts (Lete-Foho) to supervise TB treatment.

Methods:

The study began with a review of the literature on the various issues surrounding default, compliance and the challenges faced by TB Control Programs in developing countries. The East Timor TB Control Program’s epidemiological information was then examined to assess the magnitude of the default rate. The sites for the study were selected on the basis of the following criteria: firstly, those districts with the highest TB notification rate, secondly, the TB diagnostic and treatment centres with the highest default rate, and thirdly, the villages in those districts from where the highest number of defaulter patients originated. In these selected sites, all TB nurses working in TB centres, and a random selection of the defaulter patients registered in the clinic, and of patients who had completed TB treatment during the same time period as those who had defaulted, were
invited to participate in this study, and were interviewed. Other community members, comprised of members of youth and women’s groups, traditional leaders and village heads, were also randomly selected and invited to take part in focus group discussions. In addition, the author (NM) and two Timorese research assistants conducted participant observation in the TB clinics, patients’ houses, and at sacred traditional places where traditional ritual activities were taking place.

The fieldwork for this study took place over a three months period (April to June 2004) in the selected sites of Ermera and Dili districts, and the methods used to collect the qualitative data required included participants observation, in-depth interviews and focus group discussions. The author (NM) is indigenous to the district of Ermera, and has lived the majority of his life in Dili, and so is fluent in the local languages, and a functioning member of the community who engages in local traditional ceremonies and other activities. In addition, he was the founding director of East Timor TB program, and for eight years worked as a TB physician, and so has strong professional, social and cultural ties in both districts chosen for this study. Two local research assistants, one from Dili and the other originally from Ermera, with previous experience in qualitative research methods and fluent in their local dialect, were recruited and trained to assist in conducting in-depth interview.
Standardised, open-ended interview schedules were developed for the in-depth interviews and focus group discussions. Written consent was obtained from the participants prior to interviews being conducted, and the findings were clarified with participants after each interview. On some occasions, interview participants were asked to listen to the tape recorder together with the research assistant so the participant had an opportunity to revise his/her comments if they wished. The principal researcher and research assistants usually used an opportunity during an informal ‘snack time’ which followed each of the focus groups to clarify issues with participants. Each in-depth interview was conducted by two researchers who both made handwritten notes and compared their notes after each interview.

Data Analysis

Interview results were transcribed by each of the research assistants, and the transcripts were compared and found to have consistent meaning. The interviews conducted by the author (NM) were transcribed by himself. If any inconsistencies occurred, the principal investigator and the research assistants utilized the handwritten notes and listened to the tape recorder in order to capture the correct meaning. The data was coded by the author (NM), and was then interpreted and analysed. Content analysis was utilized to analyse data through the following process. Firstly, categories were established prior to searching them in the data and the data was read and re-read to search for the established categories. Secondly, selected samples was categorised and the categories which occurred were counted and recorded. The category that occurred most frequently was classified as
Chapter VI. Cultural barriers to DOTS implementation

the main reason, second highest classified as second, and so on. Thirdly, coding was focussed at finding more general categories and developing connections between them; Finally, the preliminary results were shared with the two independent authors PK (TB expert) and JG (Anthropologist) for first proof reading and critical analysis of the findings. Recommendations derived from the external authors were utilized as guide to revisit the data and to improve the presentation of study finding.
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RESULTS

We have successfully conducted twenty-eight in-depth interviews with patients and community health workers, and seven focus group discussions with community members, on average twelve participants attended each FGD interview (see Table1). The main findings of this study can be classified into three main categories. Firstly, the reason for non adherence to TB treatment among default patients. Secondly, the knowledge and perception of tuberculosis among patients, TB nurses and community members. Thirdly, the acceptability of the current TB strategy to health service personnel and general community members. The findings suggest that nurses have a high level of adherence to, and good knowledge of the DOTS strategy. Among patients and community members in general, there is a fairly good level of knowledge of TB. Despite the majority of patients and nurses being satisfied with current TB activities, those community members interviewed suggested that health education about TB could be improved, and that the delivery of DOTS should be made physically closer to where patients live. The perception of symptomatic improvement and the need to continue treatment among patients who completed treatment and those who defaulted was markedly different.
Chapter VI. Cultural barriers to DOTS implementation

Table 1. Participants Interviewed.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Dili District</th>
<th>Ermera District</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-depth Interview</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurses</td>
<td>3</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Completed patients</td>
<td>3</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>Default patients</td>
<td>5</td>
<td>9</td>
<td>14</td>
</tr>
<tr>
<td>Focus Group Discussion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FGD</td>
<td>Community Members (12 people per FGD)</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
ADHERENCE TO TB TREATMENT

Barriers for Patients to Complete their Treatment

The main barriers for patients to complete their TB treatment could be summarised into five categories.

Rapid symptomatic improvement

Many of the patients who default explained that they stop the treatment because they felt well after taking the drugs for a few weeks. This symptomatic improvement is interpreted as “cure” and therefore causes reluctance on the part of patients to continue their treatment, as expressed by a default patient.

*I no longer go to the hospital for taking drugs because I feel well.*

*When I returned here (to the village), I felt a little bit well and was able to do light activities such as weaving (suku tais).*

*Default TB Patient, Ermera*
Chapter VI. Cultural barriers to DOTS implementation

The nurses also agreed that patient mis-interpretation of symptomatic improvement, which they attributed to a low level of understanding of TB treatment, is one of the main reasons for patients to stop attending their clinics.

Economic and geographical difficulties

Transport cost were a major concern for many defaulting patients in both Ermera and Dili districts. It has been a frustrating issue for TB health workers, and was raised by community members during focus group discussions, who explained the difficulties for patients who live far from the clinic to attend daily for treatment.

_We think, when we look at the main reason for default here, it is because of a lack of transportation. We said transportation because each time patients visit the clinic, they have to pay a return cost for transportation and when they get there, they are only allowed to swallow drugs in front of the nurse. And then, the patient was asked to return the next day for the same reason._

_Community members, Eraulo Village Ermera_
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Use and belief in traditional medicine

Traditional medicine emerged as the second main reasons for TB patients to default in Ermera district. One default patient, who claimed no improvement of his condition during treatment with anti-TB drugs, had turned to traditional medicine. The use of traditional treatment was widely reported by community members in both Dili and Ermera districts. This was supported by the nurses interviewed, who argued that this was the case because some patients, and community members in general, are unaware about the fatality of TB infection.

Firstly, when I got this disease I went to the clinic for treatment and after two weeks I realized my condition did not improve. Then the nurse asked me to stay there for eight months and I refused. I have a cousin who had previously suffered from the same disease and recovered well by taking traditional medicine.

Default patient, Ermera
Worsening of Patient condition

A few default patients from Dili and Ermera were forced to drop-out of TB treatment because they could not walk, and so were unable to visit the clinic daily because their condition had deteriorated. In some cases, the TB health workers rarely visit their homes to deliver treatment. However, the nurses argue that it would be difficult to visit patients who default because most of them do not provide them with correct addresses, or are simply living too far away from the clinic. This may well be the case, as in the early establishment of National TB program in East Timor many of the TB patients came from rural areas to be treated in the district capitals.

When patients failed to come to clinic, we searched for them from the addresses provided. However, when we arrived at that address usually the patient was not there. They provided us with wrong address or they just simply went back to their places of origin, which was far away.

TB Nurse, Dili.
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*Busy with other competing activities*

Being involved in activities, such as attending school or working, was another reason patients gave for defaulting on their treatment. The restricted hours of the clinic, and the long wait to receive treatment once there, has been an obstacle to completion of TB treatment for some patients.

*Table-2. Barriers and Enabling factors to completion of TB treatment*

<table>
<thead>
<tr>
<th>Reasons For</th>
<th>Dili-Urban</th>
<th>Ermera - Rural</th>
<th>Main Categories for Both areas</th>
</tr>
</thead>
</table>
| Default     | *Feel Improved*  
*Transport costs*  
*Disease became severe*  
*Busy with school*  |  
*Feel Improved*  
*Taking Traditional Medicine*  
*Living far from TB centre*  
*Transport costs*  
*Could not walk*  
*Busy with work*  
*No symptomatic improvement*  |  
1. Symptomatic improvement  
2. Economic and geographical barriers  
3. Worsening of Patients condition  
4. Busy with competing activities |
| Complete    | *Aware of the disease and strong willingness to be cured.*  
*Symptomatic improvement*  
*Satisfaction with services*  |  
*Aware of the disease and strong willingness to be cured.*  
*Received food supplement*  
*Followed nurse’s instruction*  
*Satisfied with clinical services*  
*Symptomatic improvement*  |  
1. Previous knowledge of TB  
2. Receiving food supplement  
3. Symptomatic improvement  
4. Good Clinical TB management |
Factors which Assist Patients to Complete TB Treatment:

Previous knowledge on TB

In general, patients who completed treatment have a good understanding of what they suffered from and wanted to be cured. Despite not possessing an understanding of the biomedical definition of TB, they expressed knowledge that their symptoms required medical intervention.

*What I got first was a cough, then coughing blood and chest pain. That’s why I went to the hospital. They gave me a cup to collect my sputum. I did collect my sputum three times and after that the nurse said I had TB and asked me to start treatment for eight months. The nurse asked me to stay in hospital but I didn’t want. I took seven pills daily for two months. When I completed the first two months, I felt well and the nurse gave me more drugs for another six months.*

*Completed patient, Dili*

Receiving supplementary food

A few of the completed patients said that the provision of beans, milk and oil in addition to the anti-TB drugs encouraged them to visit the TB clinic regularly. The nurses argue that the provision of supplementary food is an important element in treating TB patients.
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Most of the community members regarded supplementary food as a means to compensate for the economic difficulties faced by most of TB patients in their area.

*Our approach to TB control will not be maximal if we only provide the drugs to patients without sufficient food consumption for these patients. I think tuberculosis patients needs milk, green bean and fish to enhance their nutritional status.*

_Nurse, Hatolia, Ermera_

Given the importance of the food mentioned in this study, the author further expanded the question to capture the right message behind the reason of why food is so important for TB patients. Once asked about the number of meals that participants normally consumed each day; the answer was “three times a day”. This is in line with the number of meals consumed by ordinary Timorese living in Dili, and includes breakfast, lunch and dinner. In general, for an ordinary Timorese family the daily menu will consist of; i) bread or cassava or sweet potato with a cup of coffee or tea for breakfast; ii) rice, vegetables, beans and meat or fish (occasionally) for lunch, and a similar menu at dinner. The reported menu from Ermera district was different. The majority of TB patients reported having only one or two types of food for breakfast, lunch and dinner, which mostly consisted of carbohydrate staples, such as cassava, rice, sweet potato and corn.
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Symptomatic improvement

As an interesting counterpoint to defaulters for whom this phenomenon was a barrier to completing treatment, for those who successfully completed treatment, symptomatic improvement encouraged them to continue taking their anti-TB drugs.

*I take drugs from this clinic because I got Tuberculosis. After taking the drugs for the first time I felt nothing, second time also the same and the third time I felt the drugs run through all my blood and body, and I felt well. I could eat, sit and walk as usual. Since then, I kept taking the drug regularly and completed the treatment for eight months.*

*Cured TB patient, Dili*

Satisfaction with the services and following nurses’ instructions

Satisfaction with services provided in the TB treatment centre was another reason mentioned by patients for completing TB treatment. This was reported both Ermera and Dili districts. Despite this, some of community members argued that TB nurses in some TB centres were not polite and are not doing their jobs properly, and that is another reason for patient to dropout from treatment.
KNOWLEDGE AND PERCEPTION ON TB

The majority of TB nurses interviewed for this study have good knowledge of TB and of the DOTS strategy. They also have a high commitment to their work. In general, completed patients have a good understanding of what they suffered from and want to be cured. However, there was a quite low level of understanding about tuberculosis among defaulter patients and community members. A few community members still regard TB as an inherited disease, and there is a lot of stigma attached to contracting the disease. A few terms emerged from the interviewed participants regarding tuberculosis and their understanding of the disease, its symptoms and the cause (summarized in Table 3).

Many patients and community members associated TB with “Mear” or “Muta Ran” which refers to haemoptysis (coughing blood). They regard this symptom as denoting a very serious condition which needs urgent intervention, but have different perceptions of the cause and the appropriate way of treating this condition. Despite the fact that the majority of people prefer the biomedical explanation of the causation of TB, and modern medicine to treat this condition, a few regard “Mear Ran” as an inherited disease which they believe occurs because there was killing inside their family trees. Those interviewed in Ermera, believe that modern medicine doesn’t work unless the ritual ceremony named “sakit ain iha mota” has been performed by a traditional priest (kuku).
For example, there is a killing inside the family, even though it is in the war when we killed one of our relatives such as uncle, brother or sister, etc... we will get the blood (mutah ran) one day in our life. This might not directly affect the murderer, but for sure it will happen to one of his/her descendents, could be her/his children, grand children or others inside their family tree.

Community members Talimoro, Ermera.
Table-3. Local terms associated with TB symptoms

<table>
<thead>
<tr>
<th>Local symptoms definition</th>
<th>Modern term</th>
<th>Causes</th>
<th>Treatment Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mear Mutin</td>
<td>Dry cough</td>
<td>To much cigarettes smoking</td>
<td>cough medicine or traditional remedies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Germ</td>
<td></td>
</tr>
<tr>
<td>Mear Tasak</td>
<td>Cough with sputum</td>
<td>To much cigarettes smoking</td>
<td>Cough medicine or traditional remedies</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Germ</td>
<td></td>
</tr>
<tr>
<td>Mear/muta Ran</td>
<td>Haemoptysis</td>
<td>Family sins</td>
<td>Traditional ceremony (sakit ain)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Germ</td>
<td>Modern Treatment</td>
</tr>
<tr>
<td>Paru-paru basah</td>
<td>Pleural effusion</td>
<td>Sleep on wet floor/humid</td>
<td>Modern treatment</td>
</tr>
<tr>
<td>Hirus matan moras</td>
<td>Chest pain</td>
<td>Lifting a heavy weight/ heavy work</td>
<td>Modern medicine or Traditional remedies</td>
</tr>
</tbody>
</table>
CURRENT TB MANAGEMENT STRATEGY

Most of the TB nurses and patients interviewed for this study have a high regard for the current TB strategy as sufficient and effective to cure TB. Default patients argued that it was their choice to stop TB treatment, and they did so for their own reasons and did not blame the clinic staff. However, the majority of community members argue that there is a need to improve TB health education, in order to help patients and community members understand TB.

*To date, we never heard anyone conducting a TB campaign in our place, I think the messages broadcasting through radio and television will not reach most of the population living in remote area. People living here are too poor to buy a radio. What we need is the doctors or nurses to visit us in this remote area in order to convey TB messages to us directly.*

*Community members, Eraulo, Ermera*

On the other hand, the nurses argue that they always spend time providing instructions to patients. The majority of TB patients that complied with treatment supported this statement. At the same time, the nurses agree that they have not been involved in promotional activities such as health education campaign outside their clinic because of their workloads, and because there has been no funding for such activities.
DISCUSSION

This is the first ethnographic study conducted in the field of TB control in East Timor to seek the explanation on the unusually high default rate in an urban and a rural district. Our finding may suggest some complementary steps toward the comprehensive approaches to improve the DOTS program in these two districts. The discussion for this finding will be directed to examine the following arguments. Firstly, the socio-cultural barriers identified in this study should be managed properly in order to reduce default rate. Similarly, the identified enabling factors for improving compliance should be maintained and strengthened in order to improve treatment outcome. Secondly, local knowledge on TB symptoms should be considered and specifically targeted for a community based TB promotional campaign in order to improve case detection. Thirdly, the strong and widespread community support for the TB program is worthy of follow-up so as to engage more community members in the management of DOTS activities in their local area.

Barriers to the compliance with TB treatment

Patients’ non compliance with TB treatment has been an ongoing problem facing by TB control programs world-wide. There were a considerable number of studies which have reported on the various reasons for patient non-adherence with TB treatment. In a recent ethnographic study of non-compliance with TB treatment among the indigenous Aymara residents of the city of La Paz in Bolivia, it was found that patients
Chapter VI. Cultural barriers to DOTS implementation

overwhelmingly cited hidden costs of treatment, poor access to care, ethnic discrimination, and prior maltreatment by health care services as the major reasons for non-compliance. In this study, we found that the socio-cultural definitions of TB, self-perception of curability, and economic and geographical difficulties were the reasons for defaulting. An interesting phenomenon observed here was that many of those who stop treatment do so intentionally due to the false perception that they have been cured. This behaviour was considered as an unacceptable attitude by nurses, who believe non-compliance to be simply due to patients being unaware of the danger of TB disease. However, in her study about health seeking behaviour in Lombok (an Indonesian island not too far from East Timor), Grace found that treatment seeking behaviour in general may be related to distance to the facility, knowledge and trust of the practitioner, and belief in traditional medicine, or feeling “cocok” (appropriate). In the case of East Timor, the health workers need to be aware that patients weigh up the cost and benefits of continuing drug treatment within the context and constraints of their daily lives, which is consistent with observations made by Donovan and Blake in a very different context.

Since there is no single “magic bullet” to fix the problem of non-compliance, findings from local studies need to be managed wisely. It requires creativity of local TB managers to utilize the study findings and develop the local solution for dealing with the issue of non compliance. Local solutions to local problems proved to be effective in improving DOTS performance in Malawi. In the case of East Timor, the issues of economic difficulties and geographical remoteness may be resolved by revisiting, expanding and strengthening some of the previous local strategies which were
specifically design to deal with these issues; such as albergues (hostels), satellite clinics, community volunteer treatment observers, the provision of transport costs and food supplementation for patients. But, it would much better, if these local solution and local strategies be formally evaluated before being adopted as national strategies.

**Strengthening treatment compliance through maintaining or introducing recognised enabling factors**

Assuring adherence to tuberculosis treatment is essential for reducing transmission, preventing developing of drug resistance, and curing patients. In order to deal with patient non-compliance there are an increasing number of recommendations from clinical trial studies from various settings to introduce incentives in an effort to improve program performance. These include the provision of monetary and other non monetary incentives such as a food vouchers, a reminding phone call, education and intensive counselling. This study found that the provision of supplementary food acts as one of the enablers factors that assist patients to complete their treatment. Despite the importance of the provision of incentive to improve treatment compliance, incentives alone may not be sufficient for patients with multiple risk factors for non-adherence. Other enabling factors found in this study may be strengthened to further improve treatment compliance. These include: possessing a good understanding of TB prior to treatment; satisfaction with TB services; and symptomatic improvement. Equipped with good knowledge about TB, and their health status, will not only help patients to comply with TB treatment, but will also help them to make a quick decision to visit a clinic for diagnosis and treatment.
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The satisfaction with TB services needs to be sincerely manage because patients who report that they are unsatisfied with treatment may be more likely to default, as has been observed in Pakistan. In the East Timor context, ongoing on the job training and supervision of TB program staff in clinics may contribute to the improvement of health services, which may in turn affect patients’ satisfaction. To be fully effective, however, these training activities need to be expanded to other health staff working in hospital or community health centres. This will allow them to recognise TB symptoms, to earlier commence TB treatment, and to provide precise TB messages to patients.

The provision of supplementary food as previously implemented under TB Program in East Timor should be revisited because of its contribution in improving TB treatment compliance as found in this study. However, the question is whether food supplementation should be used as an incentive to improve treatment compliance? Or the food should be used adjunct therapy to compensate the undernourish TB patients? Unfortunately, there have been contradictory results of the relationship between the uses of micronutrients supplement in clinical outcome from randomized trial studies in various settings. In addition, food is expensive and its distribution had logistic challenges. Thereby, despite the strong agreement from participants in our study supporting the importance of food for TB patients, formal evaluation with rigorous methodology is needed before adopting food supplement as a national strategy.
Local knowledge on TB and targeted TB health promotion campaigns

Informants understood the biomedical description of tuberculosis and recognised the importance of receiving tuberculosis treatment by biomedical doctors, while at the same time holding their own indigenous understandings and ways of treating the disease. The similar findings have been reporting from other countries,\(^{23,32}\) and its may convey some important messages to improve tuberculosis program management. Scholars from Vietnam have counselled TB Program staff in that country to acknowledge that patients have choices other than the NTP.\(^{33}\) This does not mean that patients should be leave to make decisions which might result in their deaths. But, rather the health professionals need to be creative in finding solutions to deal with a variety of problems within TB control programs. Understanding patients’ perceptions and definitions for various terms frequently used in western bio-medical circles is very helpful in finding appropriate mechanisms to overcome factors which deter patients from seeking and completing TB treatment.

The belief that certain types of TB (\textit{mutah ran}) was inherited and was handed down by blood poses stigma to the population, especially in Ermera district, and presumably more widely in East Timor. The issues and consequences of stigma have been well discussed elsewhere.\(^{7}\) A belief in hereditary TB was also discovered with the local term “\textit{lao truyen}” in Vietnam.\(^{32}\) Contrasting to the finding from Vietnam, Timorese believe that this disease can be cured by the combination of traditional ritual and modern treatment. Significantly, there is a widely held belief that the appropriate traditional
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ritual must be performed by a traditional healer (Kuku) before seeking modern treatment. This phenomenon could affect both treatment delay and treatment interruption. The kuku poses special supernatural power that allows him to communicate with the ancestors. Quite similar beliefs and practice have also been reported from Bolivia. In contrast, Farmer argues that patients’ etiologic belief did not predict their compliance with chemotherapy for patient from Haiti. Greene suggests that non-compliance was not due to culturally determined barriers or culturally inappropriate communication between doctors and patients, and stresses the importance of exploring the social dimensions of health care delivery rather than overemphasising cultural difference in investigating non-compliance in marginalised populations.

Study from Malawi suggest the importance to address local beliefs in health education and possibly find ways of involving healers in supervision of treatment. However, for East Timor it may be important to include traditional healers in the TB programs management, especially for referral and treatment supervision. Traditional healers might make good DOT supervisors, as they are, by nature of their chosen professions, concerned with the health of their communities. From the study of Gambia Harper et al reveal that with proper training the traditional healer can play positive role in tuberculosis control. An encouraging pilot study from South Africa revealed convincing results that DOT supervised by the traditional healers shows no difference in treatment outcome than DOT supervised by other categories of health workers. Further examination of this approach is required in different settings, including East Timor. This Operational research should be done within the context of a national disease control
Chapter VI. Cultural barriers to DOTS implementation

programme to allow rapid adoption of the findings as what has been reported from Malawi

The Implementation of DOTS strategy in the primary health care clinic and community level

Recently, there is increasingly reporting of the effectiveness of integrating TB control activities into the primary health care activities. WHO highlight the importance to decentralise TB diagnostic and treatment services to improve access to all patients, especially for the poorest.1 The studies of decentralisation of TB control activities to the public health clinic in peripheral levels showing good results from some of the African countries.39-41 From the study of Nepal, Wares and colleagues called for more decentralisation of treatment delivery to the lowest health service level to improve accessibility.13 However, it may well aware that the integration of TB services into the primary health care clinics, normally brought with them a financial burden and workload to the clinic, which may already be under resourced. The high workload and lack of training on the DOTS strategy have been reporting as factors that preventing many health workers working in the primary health care clinic to follow DOTS strategy.14,15 In this study, we found that the lack of financial resources prevented TB nurses to effectively perform all DOTS activities, despite being well trained and highly motivated. The lack of financial and human resources has also been reported from the neighbouring country of Indonesia.15 Without proper measurement and appropriate remediation, in the long run this issue will endanger the TB services in the clinics. Khan
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argues that many of the problems encountered by Pakistani TB patients trying to obtain good tuberculosis treatment were caused by poor services provision. Wares and colleagues highlight the importance of strengthening health systems include buildings, supplies, reporting systems, staff motivation and capacity in relation to treatment adherence in Nepal.

The finding from this study suggests a high satisfaction with the current TB management among community members, patients and the nurses. WHO recognised the approach taken by the NTPs to involve NGO and community groups so as to improve awareness of, and access of TB services. Thereby, it is important for the NTP to direct more resources to the clinic to allow the TB workers perform some of their activities outside the clinic, and to engage local communities in TB control activities. There is growing concern on the lack of TB information among the patients and community members, as found in this study. The high demand for TB information was also reporting from Malaysian TB patients in order to comply with the treatment. Locally produced health promotion messages are required to combat stigma, increase community awareness and to prevent misconceptions about TB. However, it is still important to ensure that the TB services are highly accessible to the community. Greene argues that if this population understood the disease process but were not in a position to access treatment, the dissemination of educational materials was not likely to help patients overcome the barriers for comply with the treatment. In East Timor, the involvement of the community in a participative dialogue with health workers is one
possible alternative approach to gain political commitment at the grassroots level, in order to bring TB treatment closer to the poorest and most disadvantaged people.

**Study limitations**

Selection bias may occur in this study because difficulties encountered in tracing registered default patients. Many patients gave false addresses to the TB centres for unknown reason and others were reported to have died. Similar problems have been encountered in other countries.  However, we argue that the current sample size is sufficient for us to generate a valid data presenting in this study. The data saturation method was employed and we did indeed reach a saturation point before the end of our study. The study may not be generalizable to the whole of East Timor or to other countries because of the different ethnic and geographic background. However, a number of findings from this study are similar to those found elsewhere and point to a number of common themes which need to be taken into account by TB control programs.

*Time frame and Investigator role in the Ethnographic study*

Three months fieldwork would not normally be considered long enough to constitute an ethnographic study. The qualitative methods employed in this study are those used in ethnography – participant observation, in-depth interviews and focus group discussions.
However, the first is the cornerstone of ethnography, and has usually required researcher spending years rather than months in the field before they develop the necessary language skills and understanding of the local social norms and culture, for it to be effective. In this study, the author (NM) did not require this preparatory phase in order make an in-depth exploration of the subject of study given his knowledge and familiarity with the local culture, and the national TB program.

The involvement of author (NM) may raise the issues of power relationship that are always problematic especially in the qualitative research. The limitations include whether too strong a voice is given to the particular perspectives, however, the involvement of two external authors (PK TB expert) and JG (Anthropologist, qualitative research expert) enriched the study finding and ensured NM’s role to become more as researcher than researched, which frequently blurs in qualitative study.\textsuperscript{44} NM and his research assistants, by virtue of being able to speak local dialects, and being immersed in the local culture and society, had the necessary knowledge and skills to undertake a rapid ethnography, albeit limited to a specific, focussed topic, in this case compliance with TB treatment. It has been argued that since the ethnographer is interested in understanding and describing a social and cultural scene from the emic (an insider’s) perspective, he or she is both storyteller and scientist, and this was certainly the case in this study.\textsuperscript{45}
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Chapter VII

THE EXAMINATION OF

FOOD INCENTIVES TO IMPROVE TREATMENT

COMPLIANCE IN EAST TIMOR (FITTCET STUDY)

A Randomized Clinical Trial in three TB clinics,

Dili, East Timor

Food supplementation was regarded by most participants in the ethnography study (chapter VI) as one of the main reasons that enabled TB patients to comply with treatment. Food was also seen by TB nurses and community members as an important element in the management of tuberculosis program to compensate the undernourished and underprivileged TB patients. This chapter will present the findings from the first randomised control trial study to look at using food supplementation as an incentive to improve treatment outcome and treatment compliance in Dili, East Timor. This is the first Randomized Control Trial (RCT) ever performed in East Timor and, as far as we are aware, the first RCT to ever examine the effectiveness of food incentives to promote TB treatment compliance anywhere in the world.
Chapter VII. The FITCET study

Summary

**Background:** The external review of East Timor TB control program in March 2003 recommended the conduct of operational research to inform policy. Food supplement has been used in the East Timor NTP, but has not been formally evaluated. Despite being used by TB control programs in several countries, there have been no randomised controlled trials looking at food incentives to improve treatment outcomes.

**Objective:** Our objective was to test the hypothesis that nutritional supplementation is a cost-effective adjunctive therapy to enhance TB treatment compliance in East Timor. It compared a culturally appropriate dietary intervention (daily meal at the clinic in the first two months of intensive treatment and then fortnightly food packages in the six month continuation phase) versus nutritional advice. The primary outcome measure was treatment success and secondary outcome measures were the treatment compliance, sputum conversion rate and weight gain.

**Design:** This community based randomised control trial was conducted in the three busiest TB clinics in Dili. Between 16th March to 9th November 2005, newly diagnosed adult TB patients were randomly assigned into two groups. An intervention group (N=139) received food and a control group (N=131) received nutritional advice. Both groups received tuberculosis treatment according to the Timorese DOTS strategy guidelines. Clinical examination and anthropometric measurement were performed before and each week after the provision of anti TB treatment. The daily compliance and
the drugs adverse effect were also recorded. Outcomes were assessed remotely, blinded to allocation status.

**Results:** Due to time constraints related to PhD submission, the analysis was limited to the 168 patients who had completed follow-up by 10\textsuperscript{th} May 2006. The majority of TB patients were from the socio-economically disadvantaged population and lived close to the TB clinics. The food intervention showed no impact in improvement of either treatment outcome or compliance. The mean baseline BMI was 16.8 before and 18.5 kg/m\textsuperscript{2} after the provision of food and anti-TB treatment. This improvement was not significantly different in the intervention group. The provision of anti-TB drugs commonly caused minor side-effects with itch significantly more common in the intervention group [(34\% vs 14\%; mean difference 20\% (95\% CI: 7,32)]

**Conclusion:** The provision of food supplementation shows no impact in a variety of measures in this disadvantaged population with easy access to TB services in Dili population. Possible causes of this negative result could be limitations of this study related to selection and measurement biases, confounding and the current political and social conflicts in Dili which disrupted the study before it could be concluded. Further studies in different settings and measuring different outcomes are required to confirm this finding.
Chapter VII. The FITTCET study

INTRODUCTION

Tuberculosis (TB) is a significant cause of morbidity and mortality for people around the world. The latest WHO report shows the incidence of TB is still rising and now causing an estimated nine million cases and two million deaths annually.\(^1\) Several inter-linked factors contribute to the progress of this disease including the spread of HIV/AIDS, poverty, the difficulties of case detection; and the rising incidence of multidrug resistance.\(^2\) The adoption of the WHO Directly Observed Treatment Short-course (DOTS) strategy to fight TB continues to increase in developing countries. By the end of 2004, 83\% of the world’s population were covered by a DOTS program.\(^1\)

However, recently some have questioned the effectiveness of directly observed treatment (DOT), which has been promoted as the centrepiece of the DOTS strategy.\(^3\) A recent Cochrane review concluded that randomised trials provided no evidence that directly observed therapy in low and middle income country settings improves cure or treatment completion rates in patients with tuberculosis.\(^4\) WHO has called for more operational research on TB control, with a particular focus on health systems and economic analysis.\(^5,6\) A systematic review of strategies to promote adherence to treatment for tuberculosis concluded that further innovations were needed to help find specific approaches that will be useful in low income countries.\(^7\) The provision of monetary and other incentives to improve TB treatment compliance have been tried and have been found to be effective in some settings. These incentives include the provision of cash payment, food vouchers, a reminding phone call, education and intensive counselling.\(^8-10\)
Prior to the antibiotic era, nutrition was a centrepiece of therapy for tuberculosis. Its contribution has been superseded by the overwhelming importance of chemotherapy and health service management approaches to diagnosis and treatment. There is a well recognised link between adult malnutrition and tuberculosis, with malnourished adults more likely to develop active tuberculosis disease and active tuberculosis causing weight loss. The extent of malnutrition is strongly associated with severity of lung disease in adult pulmonary tuberculosis. An Indonesian study showed that TB patients are protein, vitamin A and zinc deficient at diagnosis compared with a control group. Patients from Jakarta treated with vitamin A and zinc supplements in a randomised controlled trial showed improved microbiological and radiological outcomes and serum retinol concentration after two months of TB treatment.

Despite some studies which suggest the effectiveness of using incentives to improve treatment outcome, there have been no randomized control trials examining the effectiveness of food incentives to improve treatment outcome. Food supplements for TB patients have previously been used in East Timor for two reasons. Firstly, to compensate for the under-nourishment of TB patients, and secondly, to encourage compliance with TB treatment. The strategy has not been formally evaluated, and was discontinued because of both logistic difficulties and a lack of funding. An external review of the East Timor National TB Control Program in March 2003 included recommendations to conduct operational research to examine the issues of high default rate, low treatment compliance, low case detection rate and drug resistance, and to provide recommendations to guide the DOTS policy in East Timor.
Chapter VII. The FITCET study

required to test the hypothesis that the provision of nutritional supplementation is a cost-effective adjunctive therapy to enhance Tuberculosis treatment compliance in East Timor. This study will provide new insight for decision making for using food as part of TB control program in East Timor, and possible in other resources poor countries.

The objective of this study was to test the hypothesis that nutritional supplementation is an effective adjunctive therapy to enhance TB treatment compliance in East Timor. It compared a culturally appropriate dietary intervention with nutritional advice using treatment success (cure) as the main outcome measure. Secondary outcome measures were treatment compliance, sputum conversion rate (at two months), weight gain and symptomatic improvement.
METHODS

PARTICIPANTS

The study was conducted in three busy community health clinics which function as the main out-patient TB treatment centres in the East Timorese capital, Dili. These were: a private not-for-profit clinic located in South-Central Dili which covers the population from the South and South West of the city; a church clinic, located in the North-Central Dili which covers the population from the North and North-West; and a government clinic, located in the East of the city which covered the population from that area. The study commenced in March 2005 and was scheduled to be completed by the end of July 2006. The participants were selected on the basis of the following criteria: i) age 18 years of age or older; ii) diagnosed to have pulmonary tuberculosis (sputum smear positive or smear negative TB) using standard National Tuberculosis Control Program protocols; iii) agreement to continue to receive TB treatment at the diagnosing clinic for the full eight months of treatment; iv) agreement to participate in the study. Exclusion criteria were: i) pregnancy; ii) previous treatment of TB for more than one month.

This study was approved by the Charles Darwin University Ethics Committee, Menzies School of Health Research Human Research Ethics Committee, Northern Territory, Australia and the WHO Ethics Committee for Biomedical Research Involving Human Subjects, Geneva. The permission for conducting this study was given by the Minister of Health, East Timor.
Chapter VII. The FITTCET study

**Study Design**

This was an operational study within the National TB Control Program and all participants enrolled in this study were receiving the routine standard of care including drugs, default tracing and clinical monitoring according to national guidelines. The study was a community-based randomised controlled trial of food supplementation with study participants randomly allocated to an intervention (patients who receive supplementary food) or a control group (patient who receive nutritional advice, but do not receive supplementary food).

Recruitment:

The TB nurse in the three clinics provided verbal information with the written information sheets about the study to all new adult TB patients, who agreed to speak with the research assistant (RA). The RA then provided the patients with further information about the study and asked them to sign the consent form. Once patients commenced treatment, they were followed-up until the end of their treatment. Patients enrolled were randomised to receive either the food intervention or nutritional advice. Research assistants supervised the food allocation, performed nutritional measurement and assessed compliance for both groups.
Chapter VII. The FITCET study

Those patients randomised to nutritional advice (control group) were given verbal and written advice concerning the types of locally available food which would constitute a balanced diet likely to assist in cure from tuberculosis (high protein diet rich in vitamins A and C and in zinc). These patients received routine care and were asked to attend the clinic according to routine practice (five morning per week in the private and the government clinic or six mornings per week in the church clinic) to receive directly observed therapy for TB in appropriate doses, according to the normal National TB Control Program protocol.18

Those randomised to receive food supplementation (intervention group) were asked to attend the clinic in the mid-day. In addition to normal TB treatment, in appropriate doses, they also received food on every attendance at the clinic. Two related interventions were conducted for this group. The first was the preparation of a meal during the intensive phase of treatment, one bowl of *feijuada*: a meat and vegetable stew with rice was prepared for administration daily during the first two months of the intensive phase at the health centre of enrolment, see table-1. During the continuation phase of treatment, patients in the intervention group were given a small food parcel containing unprepared food to take home (red kidney beans, rice and oil).
Randomisation and Blinding

The random allocation sequence was computer-generated (Stata Version 8.0) and prepared at the Menzies School and Health Research in Darwin. Block randomisation (randomly varying block sizes) was used to maintain similar numbers of participants in both groups and to minimise the potential influence of time of enrolment. The random allocation sequence was concealed from all investigators throughout the study. Allocation was stratified by community health clinic and by TB patient diagnosis (sputum smear positive and sputum smear negative). At each clinic, after the RA received the signed consent form; he/she took the next opaque sealed envelope from the appropriate set of envelopes (sputum positive or negative). The envelope was then opened by the RA witnessed by the patient. The patient was assigned to the group as indicated by the information contained inside the envelope. With an RCT of this nature, it is clearly impossible to use a “double blind” design. Both participants and treatment providers were aware of individual allocation status after randomisation. However, the primary outcome (treatment success) was determined by an independent observer (based in Darwin) who was blinded to the intervention received by the patients.
Chapter VII. The FITCET study

Food Supplementation

The local acceptability and availability of ingredients for *feijuada* lead to this being chosen as the supplement used in this study. We cooked this local Timorese food and served it together with rice at each clinic. This meal is a rich source of carbohydrates, protein, fat, minerals, micronutrient and vitamins. See table-1.

Table-1. Composition of meal nutrients for patients.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Kidney Beans</td>
<td>19.4 gr</td>
</tr>
<tr>
<td>Meat</td>
<td>30 gr</td>
</tr>
<tr>
<td>Green Vegetables</td>
<td>10 gr</td>
</tr>
<tr>
<td>Oil</td>
<td>2.5 gr</td>
</tr>
<tr>
<td>Salt</td>
<td>0.1gr</td>
</tr>
<tr>
<td>Potatoes</td>
<td>20 gr</td>
</tr>
<tr>
<td>Flavours</td>
<td>0.10 gr</td>
</tr>
<tr>
<td>Tomato</td>
<td>0.20 gr</td>
</tr>
<tr>
<td>Onion</td>
<td>0.20gr</td>
</tr>
<tr>
<td>Carrots</td>
<td>5 gr</td>
</tr>
<tr>
<td>Rice</td>
<td>200 gr</td>
</tr>
</tbody>
</table>
Table 1a. Nutrient composition of the intervention meal.

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Quantity</th>
<th>%RDI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy</td>
<td>1800 kJ</td>
<td></td>
</tr>
<tr>
<td>Protein</td>
<td>18.4g</td>
<td>34</td>
</tr>
<tr>
<td>Carbohydrate</td>
<td>55.6g</td>
<td></td>
</tr>
<tr>
<td>Vitamin C</td>
<td>24.2mg</td>
<td>60</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>363mcg</td>
<td>48</td>
</tr>
<tr>
<td>Iron</td>
<td>3.1mg</td>
<td>44</td>
</tr>
<tr>
<td>Zinc</td>
<td>3mg</td>
<td>25</td>
</tr>
<tr>
<td>Folate</td>
<td>60mcg</td>
<td>30</td>
</tr>
</tbody>
</table>

%RDI = recommended daily allowance (Australian values).

The ingredients were purchased from local suppliers with fresh produce purchased on the day of consumption and other produce purchased in bulk as required. A research team employee was responsible for purchasing food ingredients and preparing food parcels for the continuation phase of treatment. One person was employed as a cook in each clinic. The food was given by the cook to patients in the clinic before the patient consumed their TB medication. Food intake in the intensive phase of treatment was directly observed by a research assistant.
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Safety

A data safety monitoring committee was established to monitor the study and had the power to discontinue the study if adverse events related to the intervention occurred. The quality and quantity of produce was checked at random intervals during the study period by the author and his supervisor. An independent assessment was carried-out to ensure the safe preparation and administration of the food (Appendix-12).

Anti-Tuberculosis Drugs

The anti-tuberculosis therapy was according to the standard National TB Control Program (table-2). Treatment was directly observed by health care workers during the intensive phase and then fortnightly in the continuation phase.\textsuperscript{18}

Outcomes assessment

The outcome assessment was determined by an independent observer blinded to the allocation and situated remotely from the study site. See box-1 for outcome definitions.

The primary outcome measure was treatment success. This was defined as the clearance of Acid Fast Bacilli from the sputum after treatment (for patients with sputum smear positive for Acid Fast Bacilli at diagnosis), and/or the completion of eight months of TB treatment. This was measured by recording attendance at the clinic, the collection of prescribed medication and laboratory sputum examination.
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Secondary outcome measures were treatment compliance, clinical improvement and adverse events. Treatment compliance was measured by recording clinic attendance and directly observed therapy (daily in the intensive phase and twice a month for the continuation phase); counting the empty pill blisters; and interview with patient or relatives about the TB pills that patient brought to their house (continuation phase). Clinical improvement was measured by recorded clinical symptoms and weight gain. Adverse events were recorded using a standardised questionnaire and included all common side-effects of TB treatment.
Box-1. The definition of treatment outcome categories

<table>
<thead>
<tr>
<th>OUTCOME CATEGORIES</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PRIMARY OUTCOME</strong></td>
<td></td>
</tr>
<tr>
<td>Treatment Success</td>
<td>Is the sum of patients cured and those who have completed treatment.</td>
</tr>
<tr>
<td>Cured</td>
<td>Patient who become sputum smear negative in the last month of treatment and on at least one previous occasion.</td>
</tr>
<tr>
<td>Completed</td>
<td>Patient who has completed the course of treatment but does not meet the criteria to be classified as a cure or a failure.</td>
</tr>
<tr>
<td>Treatment Not Success</td>
<td>Is the sum of patients default, failure, died</td>
</tr>
<tr>
<td>Default</td>
<td>Patient whose treatment was interrupted for two consecutive months or more.</td>
</tr>
<tr>
<td>Failure</td>
<td>Patient who is sputum smear –positive five months or later after commencing TB treatment.</td>
</tr>
<tr>
<td>Died</td>
<td>Patient who dies for any reason during the course of TB treatment.</td>
</tr>
<tr>
<td>Transfer-out</td>
<td>Patient who has been officially transferred to another DOTS centre and for whom the treatment outcome is not known.</td>
</tr>
<tr>
<td><strong>SECONDARY OUTCOME</strong></td>
<td></td>
</tr>
<tr>
<td>Compliance</td>
<td>The observed number of visits to the clinic to receive TB treatment divided by the expected number. The gold standard is 100% compliance.</td>
</tr>
<tr>
<td>Clinical Improvement</td>
<td>Weight gain and decreased frequency or severity of a range of symptoms commonly associated with TB illness</td>
</tr>
<tr>
<td>Side-effects</td>
<td>Unintended and undesirable effect of TB treatment.</td>
</tr>
</tbody>
</table>
Chapter VII. The FITT CET study

Table 2. TB treatment regimen for the East Timor TB control program.

<table>
<thead>
<tr>
<th>Body Weight (kg)</th>
<th>Initial (intensive) Phase</th>
<th>Continuation Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2 Months (daily)</td>
<td>6 Months (daily)</td>
</tr>
<tr>
<td></td>
<td>Rifampicin + Isoniazid (RH) (150mg + 100mg tablet)</td>
<td>Pyrazinamide (Z) (500mg tablet)</td>
</tr>
<tr>
<td>&lt;33</td>
<td>2</td>
<td>1,5</td>
</tr>
<tr>
<td>33-50</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>&gt;50</td>
<td>4</td>
<td>3</td>
</tr>
</tbody>
</table>

Chapter VII. The FITCET study

**CLINICAL AND LABORATORY ASSESSMENT**

Outpatients were examined by a nurse or physician when visiting the clinic for the first time. When the patient revealed symptoms such as cough for more than 3 weeks, haemoptysis, weight loss, night sweats, fever and chest pain, had a positive history of close contact with a smear positive TB patient, he/she was referred to the TB nurse specialist for further examination. The specialist TB nurse examined the patients and ordered three sputum examinations using the spot-morning-spot method. The first spot sputum was collected immediately on the day patient was sent to the laboratory for examination. Each patient was asked to take one small container to collect his/her early morning sputum the following day and to bring it back to the clinic. The next day the third sputum specimen was collected when the patient returned to the clinic. The Ziel Nielsen (ZN) staining method was used and a trained laboratory technician was stationed in each TB diagnostic centre. In collaboration with the national reference laboratory and supranational WHO reference laboratory in Adelaide, Australia NTP-TL routinely conducted laboratory quality assurance using standard WHO/IUATLD methods. All sputum smear positive TB slides and ten percent of sputum smear negative slides were sent to WHO supranational reference laboratory in Adelaide for quality assurance.

A chest X-ray was requested for sputum smear negative patients who continued to experience symptoms suggestive of TB after receiving a fourteen day course of a broad-spectrum antibiotic thus conforming to the national guidelines for the diagnosis of smear negative pulmonary TB. Once diagnosed with TB, newly diagnosed adult patients were asked to participate in the study. If they agreed, they were referred to research assistants.
for interview and the informed consent process. The patient was then randomly assigned to the intervention or control group and further anthropometric measurement was carried out by the RA. A blood sample was taken by a trained laboratory technician for eligible sputum smear positive patients for future measurement of nutritional markers which are not reported in this thesis.

Anthropometric measurement

Height in centimetres was measured without shoes on equipment provided by the clinic. The tragus was ensured level with the eyes. Weight in kilograms was measured without shoes, using standard bathroom scales which were routinely available in each clinic. Body Mass Index was calculated \( \text{(weight (kg)} / \text{height (m)}^2 \). All measurements were made at weekly during the intensive phase of treatment and then at each clinic visit (fortnightly) during the continuation phase of treatment using the same equipment on each occasion.
Chapter VII. The FITCET study

**Statistical Methods**

Sample size calculation

Based on existing default rates of 13%, we enrolled 270 patients (135 in each arm) to detect a reduction in the primary outcome (default rate) to an acceptable 3%, with 80% power and an alpha of 0.05. For the secondary outcome (daily compliance), 64 patients were required in each arm to detect a 10% improvement in the mean number of days attending for treatment with SD: 20%, 80% power and an alpha of 0.05.

Statistical analysis

All continuous variables were summarised using mean, median, standard deviation (SD) and Interquartile range (IQR), and categorical variables using frequency and percentages. Independent t-tests were used to compare the difference between groups for normally distributed variables. Two-sample Wilcoxon rank-sum (Mann-Whitney) tests were used to compare the non-normally distributed variables. Pearson chi² test was used to compare the association between treatment group and various categorical variables. Statistical significance was based on a two-tailed P value < 0.05. Statistical analyses were performed using STATA™ (version 8, STATA Corporation, College Station, Texas, USA). The data were compiled in MS Access and MS Excel was also used to generate tables and graphs.
Chapter VII. The FITCET study

Figure-1. Participants’ enrolment flow diagram

Assessed for eligibility (n=843)

Excluded (n=573)
- Not meeting inclusion criteria (n=505)
- Refused to participate (n=68)

Randomised (n=270)

Allocated to Intervention Food (n=139)
- Received allocated intervention (n=139)

Allocated to non food (n=131)
- Received allocated intervention (n=131)

Finished study by 10th May, 2006 (83)
- Include in this preliminary analysis (n=83)

Loss of Follow-up
- Transfer out: 1
- Cure: 17
- Complete: 50
- Default: 14
- Failure: 0
- Died: 1

Finished Study by 10th May, 2006 (85)
- Include in this preliminary Analysis (n=85)

Loss of Follow-up:
- Transfer-out: 4
- Cure: 20
- Complete: 46
- Default: 14
- Failure: 1
- Died: 0
Chapter VII. The FITCET study

RESULTS

Eight hundred forty three TB patients were registered in the three clinics in Dili during the study enrolment period (16th March to 9th November 2005). Five hundred and seventy three were excluded from the study because they were ineligible or refused to participate. The main reasons for refusing to participate in the study were: busy with other activities and unwilling to come to the clinic; preference to visit the clinic at anytime and not able to commit to come at lunchtime (if randomised to the food intervention); severe disease and unable to walk to the clinic; and treatment observers were available to supervise the treatment in patient’s house (table-3).

Two hundred seventy (270) TB patients were recruited into the study. The study commenced on 16th March 2005 and final follow-up was scheduled to be completed by 31st July 2006. Sixty two percent (168/270) of patients who enrolled into the study had completed follow-up by 10th May and were included in this preliminary analysis (figure-1). The analysed group consisted of 61% (83/139) of the intervention group and 65% (85/131) of the control group. This preliminary analysis was done with patients who completed their treatment up to 10th of May, 2006 because of the financial restriction for NM to continue his PhD study. The remainder of the patients will be followed-up and data analysed in planned post-doctoral work.
Demography, socio-economic status and history of illness

Overall, there were no statistically significant demographic differences between the three clinics nor between the intervention and control groups. Sixty six percent of study participants were male and the participants have an age average of 30 years. Eighty percent of the study participants claim to have no formal income, but only 48% regarded themselves as unemployed. The majority of participants lived close to the clinic with 77% living within a distance of three kilometres and 90% within 30 minutes travel time from the clinic (table-4).

<table>
<thead>
<tr>
<th>Reason for excluding</th>
<th>Motael Clinic</th>
<th>Bairro-pite Clinic</th>
<th>Becora Clinic</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Eligible</td>
<td>73</td>
<td>330</td>
<td>102</td>
<td>505</td>
</tr>
<tr>
<td>Transferred-out</td>
<td>2</td>
<td>157</td>
<td>51</td>
<td>210</td>
</tr>
<tr>
<td>Less than 18 years old</td>
<td>43</td>
<td>95</td>
<td>38</td>
<td>176</td>
</tr>
<tr>
<td>Previously treated TB Patients</td>
<td>22</td>
<td>28</td>
<td>12</td>
<td>62</td>
</tr>
<tr>
<td>There are Family members or motivators living close to supervise the treatment</td>
<td>0</td>
<td>27</td>
<td>0</td>
<td>27</td>
</tr>
<tr>
<td>Transferred- in</td>
<td>1</td>
<td>8</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Pregnant</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Reluctant to continue daily treatment in these clinics.</td>
<td>0</td>
<td>7</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Missing after diagnosed</td>
<td>0</td>
<td>5</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Died before enrolling into the study</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Refuse</td>
<td>40</td>
<td>18</td>
<td>10</td>
<td>68</td>
</tr>
<tr>
<td>Busy with activities (school and works)</td>
<td>11</td>
<td>8</td>
<td>3</td>
<td>22</td>
</tr>
<tr>
<td>Require time flexibility to visit clinic (want to visit clinic at any time)</td>
<td>9</td>
<td>6</td>
<td>2</td>
<td>17</td>
</tr>
<tr>
<td>Want motivators (include family members) supervising their treatment</td>
<td>13</td>
<td>0</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td>Disease became to severe to visit clinic daily</td>
<td>7</td>
<td>0</td>
<td>2</td>
<td>9</td>
</tr>
<tr>
<td>Reluctant to eat in the clinic</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Want to have treatment in the DOTS centre close to patients home</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
## Table 4. Demographic and socioeconomic summary of participants

<table>
<thead>
<tr>
<th></th>
<th>Treatment Group</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention N=83</td>
<td>Control N=85</td>
<td>Total N=168</td>
<td></td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>34.7 (15.1)</td>
<td>34.0 (13.1)</td>
<td>34.3 (14.1)</td>
<td></td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>29 (22 – 45)</td>
<td>30 (24 – 45)</td>
<td>30 (23 – 45)</td>
<td></td>
</tr>
<tr>
<td>Min – Max</td>
<td>18 – 78</td>
<td>18 – 67</td>
<td>18 – 78</td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male N (%)</td>
<td>55 (67%)</td>
<td>55 (65%)</td>
<td>110 (66 %)</td>
<td></td>
</tr>
<tr>
<td><strong>Education N (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Education</td>
<td>27 (33%)</td>
<td>31 (36%)</td>
<td>59 (35%)</td>
<td></td>
</tr>
<tr>
<td>1 - 6 years</td>
<td>14 (17%)</td>
<td>16 (19%)</td>
<td>30 (18%)</td>
<td></td>
</tr>
<tr>
<td>7-9 years</td>
<td>9 (11%)</td>
<td>7 (8%)</td>
<td>17 (10%)</td>
<td></td>
</tr>
<tr>
<td>10-12 years</td>
<td>23 (27%)</td>
<td>22 (26%)</td>
<td>43 (26%)</td>
<td></td>
</tr>
<tr>
<td>&gt; 12 years</td>
<td>10 (12%)</td>
<td>9 (11%)</td>
<td>18 (11%)</td>
<td></td>
</tr>
<tr>
<td><strong>Income N (%) $ US</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No Income</td>
<td>67 (81%)</td>
<td>73 (85%)</td>
<td>140 (83%)</td>
<td></td>
</tr>
<tr>
<td>≤ 50</td>
<td>8 (9%)</td>
<td>3 (4%)</td>
<td>10 (6%)</td>
<td></td>
</tr>
<tr>
<td>50.5 - 100</td>
<td>5 (6%)</td>
<td>5 (6%)</td>
<td>10 (6%)</td>
<td></td>
</tr>
<tr>
<td>&gt; 100</td>
<td>3 (4%)</td>
<td>4 (5%)</td>
<td>8(5%)</td>
<td></td>
</tr>
<tr>
<td><strong>Occupation N (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Farmer</td>
<td>5 (6%)</td>
<td>6 (7%)</td>
<td>12 (7%)</td>
<td></td>
</tr>
<tr>
<td>Civil Servants</td>
<td>1 (1%)</td>
<td>5 (6%)</td>
<td>7 (4%)</td>
<td></td>
</tr>
<tr>
<td>Private Employee</td>
<td>14 (17%)</td>
<td>5 (6%)</td>
<td>18 (11%)</td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>37 (45%)</td>
<td>45 (53%)</td>
<td>80 (48%)</td>
<td></td>
</tr>
<tr>
<td>Housewife</td>
<td>13 (16%)</td>
<td>11 (13%)</td>
<td>24 (14%)</td>
<td></td>
</tr>
<tr>
<td>Student</td>
<td>12 (14%)</td>
<td>11 (13%)</td>
<td>24 (14%)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1(1%)</td>
<td>2 (2%)</td>
<td>3 (2%)</td>
<td></td>
</tr>
<tr>
<td><strong>Distance to Clinic N (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 3 KM</td>
<td>65 (78%)</td>
<td>65 (76%)</td>
<td>129 (77%)</td>
<td></td>
</tr>
<tr>
<td>&gt; 3</td>
<td>12 (15%)</td>
<td>16(19%)</td>
<td>29 (17%)</td>
<td></td>
</tr>
<tr>
<td>Not recorded</td>
<td>6 (7%)</td>
<td>4 (5%)</td>
<td>10 (6%)</td>
<td></td>
</tr>
<tr>
<td><strong>Travel Time N (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 30 minutes</td>
<td>74 (89%)</td>
<td>77 (90%)</td>
<td>151 (90%)</td>
<td></td>
</tr>
<tr>
<td>&gt; 30 minutes</td>
<td>9 (11%)</td>
<td>8 (10 %)</td>
<td>17 (10%)</td>
<td></td>
</tr>
</tbody>
</table>
Chapter VII. The FITT CET study

Tuberculosis patients from both groups recalled quite similar symptoms when visiting clinics for the first time. The common symptoms included: cough (92% in the intervention group vs 96% in the control group); weight loss (95% vs 98%), chest pain (89% vs 85%), lethargy (84% vs 91%), night sweat (76% vs 75%), anorexia (58% vs 52%), fever (61% vs 58%). Haemoptysis was quite commonly observed in both groups (49% vs 44%). There were no differences in the frequency of symptoms between intervention and control group.

The majority of TB patients from intervention group had experienced TB symptoms for approximately two months before they were diagnosed, which was similar for the control group. The majority of patients from both groups had visited a health clinic during their illness. There were no differences observed between intervention and control group regarding the history of illness, health seeking behaviour or history of cigarette smoking (table-5).
Chapter VII. The FITCET study

Table- 5. History of illness, health seeking behaviour and smoking habits

<table>
<thead>
<tr>
<th></th>
<th>Intervention N=83</th>
<th>Control N=85</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td><strong>Duration of illness</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median weeks (IQR)</td>
<td>8 (4 - 20)</td>
<td>8 (4 - 44)</td>
</tr>
<tr>
<td><strong>Treatment Seeking Behaviour</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health clinic</td>
<td>70 (84)</td>
<td>86(73)</td>
</tr>
<tr>
<td>Private practice</td>
<td>12 (14)</td>
<td>11(9)</td>
</tr>
<tr>
<td>Traditional healer</td>
<td>8 (7)</td>
<td>5(4)</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>5 (4)</td>
<td>7(6)</td>
</tr>
<tr>
<td>Other</td>
<td>7 (6)</td>
<td>7(6)</td>
</tr>
<tr>
<td><strong>History of Cigarettes Smoking</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>41(34)</td>
<td>34 (29)</td>
</tr>
<tr>
<td>Number cigarettes per day * (Median : IQR)</td>
<td>10 (5.5 - 12)</td>
<td>10 (5.5 - 14)</td>
</tr>
<tr>
<td>Years smoking* (Median : IQR)</td>
<td>5 ( 3 - 10)</td>
<td>5 ( 3 - 9)</td>
</tr>
</tbody>
</table>

* only includes smokers (n=63)

**Primary Outcome Assessment**

No statistically significant difference in treatment success was observed between the intervention and control groups. The default rate remained high in both groups at 17% in the intervention group and 16% in the control group (Table-6). When patients who transferred-out to another clinic and with unknown treatment outcome were classified as defaulters, there was a small but not statistically significant difference in default rate between the intervention group (18%) compared to the control group (21%).
Table 6. Summary of treatment outcome by treatment group

<table>
<thead>
<tr>
<th>TREATMENT OUTCOME CATEGORY</th>
<th>INTERVENTION N=85</th>
<th>CONTROL N=85</th>
<th>% Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success rate (%)</td>
<td>67 (81)</td>
<td>66 (78)</td>
<td>3 (-9, 15)</td>
</tr>
<tr>
<td>Cure rate (%)</td>
<td>17 (20)</td>
<td>20 (24)</td>
<td>-3 (-16, 9)</td>
</tr>
<tr>
<td>Completed rate (%)</td>
<td>50 (60)</td>
<td>46 (54)</td>
<td>6 (-9, 21)</td>
</tr>
<tr>
<td>Default rate (%)</td>
<td>14 (17)</td>
<td>14 (16)</td>
<td>1 (-11, 12)</td>
</tr>
<tr>
<td>Failure rate (%)</td>
<td>0 (0)</td>
<td>1 (1)</td>
<td>-1 (-3, 1)</td>
</tr>
<tr>
<td>Died (%)</td>
<td>1 (1)</td>
<td>0 (0)</td>
<td>1 (-1, 4)</td>
</tr>
<tr>
<td>Transfer out (%)</td>
<td>1 (1)</td>
<td>4 (5)</td>
<td>-4 (-9, 1)</td>
</tr>
</tbody>
</table>

**Secondary Outcomes:**

Treatment Compliance:

During the intensive phase (week 1-8), the mean daily compliance was high in both groups and dropped slightly during the eight week course of treatment (see figure-2). The mean compliance rate was statistically significantly higher in the control group in this period (P = 0.04).
During the continuation phase, patient only requires to visit clinic twice a month. In the continuation phase of treatment (week 9-32), compliance remained high. In contrast to the intensive phase, the intervention group performed slightly better, but this difference was not statistically significant (P = 0.34, figure-3).
Symptomatic improvement and weight gain

The provision of anti TB treatment rapidly alleviated or significantly reduced most of the baseline symptoms. Haemoptysis and fever virtually disappeared during the first two months of treatment. Cough remained a problem for 35% of patients after eight weeks and 15% of patients were still coughing at the end of the eight month treatment course (figure-4). There is no evidence that the intervention group perform better than control group in regard to symptomatic improvement. Body Mass Index (BMI) was low at diagnosis in both groups: 16.8 kg /m$^2$ in the intervention and 17.0 kg /m$^2$ in the control group. With the provision of anti TB treatment, the BMI gradually increased over 8
months to reach 18.4 kg/m$^2$ in control and 18.6 kg/m$^2$ in intervention arm (figure-5a). Similar improvement was observed for weight gain (figure-5b). There is no statistically significant difference observed between intervention and control groups regarding weight gain and BMI improvement (table-7).

Table-7. Comparison between Week 4, 8 and Week 28 for patients with BMI & Weight data at each visit.

<table>
<thead>
<tr>
<th></th>
<th>WEEK 0 – 4</th>
<th>WEEK 0 – 8</th>
<th>WEEK 0 – 28</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BMI</strong> (mean, 95 % CI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>0.54 (0.25, 0.83)</td>
<td>1.14 (0.80, 1.47)</td>
<td>1.80 (1.44, 2.17)</td>
</tr>
<tr>
<td>Control</td>
<td>0.63 (0.29, 0.97)</td>
<td>0.83 (0.45, 1.20)</td>
<td>1.43 (1.07, 1.78)</td>
</tr>
<tr>
<td>Difference</td>
<td>-0.09 (-0.53, 0.36)</td>
<td>0.31 (-0.19, 0.80)</td>
<td>0.38 (-0.13, 0.89)</td>
</tr>
<tr>
<td><strong>WEIGHT</strong> (mean, 95 % CI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention</td>
<td>1.02 (0.41, 1.64)</td>
<td>2.53 (1.81, 3.25)</td>
<td>4.38 (3.48, 5.28)</td>
</tr>
<tr>
<td>Control</td>
<td>1.46 (0.63, 2.29)</td>
<td>2.02 (1.05, 2.98)</td>
<td>3.52 (2.60, 4.45)</td>
</tr>
<tr>
<td>Difference</td>
<td>-0.43 (-1.45, 0.59)</td>
<td>0.52 (-0.67, 1.70)</td>
<td>0.86 (-0.42, 2.13)</td>
</tr>
</tbody>
</table>
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Figure-4. Symptomatic improvement of TB patients on TB treatment.

Figure-5a. Change in BMI by treatment week and group
Adverse events

The adverse events presented here were from the full 270 participants enrolled in this study. We are able to present the data here for all participants because almost all adverse events occurred during the first weeks of the enrollment. At the time of this preliminary analysis, all of the participants had completed the intensive phase of the treatment (2 months treatment). Approximately, 55% (149/270) of the participants’ complained about side effects during the course of treatment. This consists of 71 from control group and 78 from Intervention group. These were minor adverse events which occurred mostly during the first week of TB treatment and resolved with symptomatic treatment. No patients required the cessation of TB treatment. Influenza syndrome, itch and nausea dominated the complaints.
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In contrast, itch was more than twice as likely to occur in the intervention group, and this was a statistically significant difference when compared with the control group (table-8). This unusual presentation requires further attention given the fact that this might be related to the some substances contained in the food intervention used in this study.

Table-8. Side Effects of Anti TB drugs reporting from both groups

<table>
<thead>
<tr>
<th>ADVERSE EVENTS</th>
<th>INTERVENTION (N=83) N (%)</th>
<th>CONTROL (N = 85) N (%)</th>
<th>TOTAL (N = 168) N (%)</th>
<th>% DIFF (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Minor Side-effect</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influenza syndrome</td>
<td>21 (25)</td>
<td>25 (29)</td>
<td>46 (27)</td>
<td>-4 (-18, 9)</td>
</tr>
<tr>
<td>Itch</td>
<td>28 (34)</td>
<td>12 (14)</td>
<td>40 (24)</td>
<td>20 (7, 32)</td>
</tr>
<tr>
<td>Nausea</td>
<td>13 (16)</td>
<td>13 (15)</td>
<td>26 (15)</td>
<td>0 (-11, 11)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>8 (10)</td>
<td>10 (12)</td>
<td>18 (11)</td>
<td>-2 (-11, 7)</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>8 (10)</td>
<td>7 (8)</td>
<td>15 (9)</td>
<td>1 (-7, 10)</td>
</tr>
<tr>
<td>Rash</td>
<td>9 (11)</td>
<td>5 (6)</td>
<td>14 (8)</td>
<td>5 (-3, 13)</td>
</tr>
<tr>
<td>Joint Pain</td>
<td>7 (8)</td>
<td>4 (5)</td>
<td>11 (7)</td>
<td>4 (-4, 11)</td>
</tr>
<tr>
<td>Numbness in feet and hand</td>
<td>6 (7)</td>
<td>5 (6)</td>
<td>11 (7)</td>
<td>1 (-6, 9)</td>
</tr>
<tr>
<td>Anorexia</td>
<td>3 (4)</td>
<td>1 (1)</td>
<td>4 (2)</td>
<td>2 (-2, 7)</td>
</tr>
<tr>
<td><strong>Major Side Effect</strong>*</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* Sufficient to stop TB treatment
Chapter VII. The FITCET study

Subgroup analysis

All important variables such as sputum results, clinic type, sex, education, occupation, income, distance, travel time were included in an analysis to assess potential effect modification but no statistically significant differences were found (table-9).

Table-9. Effect Modifiers

<table>
<thead>
<tr>
<th>Variable</th>
<th>Success (%)</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diagnosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smear negative</td>
<td>90/112 (80)</td>
<td>P=0.591</td>
</tr>
<tr>
<td>Smear positive</td>
<td>43/56 (77)</td>
<td></td>
</tr>
<tr>
<td><strong>Clinic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>36/45 (80)</td>
<td>P=0.832</td>
</tr>
<tr>
<td>2</td>
<td>62/77 (81)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>35/46 (76)</td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>48/56 (86)</td>
<td>P=0.132</td>
</tr>
<tr>
<td>Male</td>
<td>84/111 (76)</td>
<td></td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No education</td>
<td>46/58 (79)</td>
<td>P=0.950</td>
</tr>
<tr>
<td>Some education</td>
<td>86/109 (79)</td>
<td></td>
</tr>
<tr>
<td><strong>Occupation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>66/81 (81)</td>
<td>P=0.476</td>
</tr>
<tr>
<td>Employed</td>
<td>67/87 (77)</td>
<td></td>
</tr>
<tr>
<td><strong>Income</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No income</td>
<td>111/139 (80)</td>
<td>P=0.630</td>
</tr>
<tr>
<td>Income</td>
<td>22/29 (76)</td>
<td></td>
</tr>
<tr>
<td><strong>Distance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=2km</td>
<td>68/91 (75)</td>
<td>P=0.271</td>
</tr>
<tr>
<td>&gt; 2km</td>
<td>55/67 (82)</td>
<td></td>
</tr>
<tr>
<td><strong>Travel Time</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=15min</td>
<td>37/50 (74)</td>
<td>P=0.308</td>
</tr>
<tr>
<td>&gt; 15 min</td>
<td>94/116 (81)</td>
<td></td>
</tr>
</tbody>
</table>
DISCUSSION

This study is the first randomized control trial to examine the utility of using food as a non-monetary incentive to improve TB treatment outcome in developing countries. This study is also the first ever randomized control trial study conducted in the health field in East Timor. The preliminary analysis presented here was conducted on 168 participants, who had completed their treatment by the 10th of May, 2006. In TB patients enrolled in this study in Dili, the main findings were; i) patients had low socioeconomic status, but with no geographical limitation to access TB services; ii) the provision of tuberculosis treatment, especially during the first two months has major impact in alleviating most TB symptoms and increasing patient weight; iii) food supplementation has no impact on treatment outcome or compliance rate; iv) minor drug related side-effects occurred very commonly. When speculating on the reasons why no effect was found from the food intervention, it could be due to limitations of this study related to the selection and measurement biases, confounding and the current political and social conflicts in Dili which disrupted the study before it could be concluded.

East Timor is categorised as one of the poorest countries; with more than 40% of the population living below the poverty line of US$0.55 per day. This was confirmed by the majority of tuberculosis patients in this study, which reported having no daily income. In general, TB patients found in studies from other countries were poorer than the general population. The overwhelming poverty found in this study may contribute to widespread poor nutrition among TB patients and result in difficulties recovering from TB. This may be the case because the majority of TB patients in intervention group
were very skinny with an average BMI of 16.5 kg/m² which is below the WHO classification of undernourished (moderate thinness). Studies from other countries also revealed that on average TB patients were undernourished compared with healthy controls. The relationship between nutritious food and TB has been well described elsewhere. It was expected that the provision of food supplementation in addition to the anti-TB treatment would increase body weight and thus improve BMI. The evidence of a study from Tanzania revealed increased weight gain with the provision of multi-micronutrient supplements. However, our study shows no evidence that the provision of a whole food supplementation increased body weight or BMI. This finding correlated with the finding from Indonesia but the small sample size in the analysed group may have prevented us to demonstrate the impact of food in improving body weight and BMI.

Delayed diagnosis and treatment of tuberculosis results in severe disease and a higher mortality. The delay in accessing health services is substantially influenced by both patient and health service delays. The reasons for delaying were well examined in studies from other countries. In this study we found that despite living close to the clinic, the majority of TB patients still experience major diagnostic delay. A study from Southern Thailand showed an average delay of six weeks and it was more associated with health system delays. In this study, the delay was probably due to the health system delays as most patients had presented to clinics during their illness. The failure of clinic staff to recognise TB symptoms may be explained by the rapid turnover of physicians with short-term contracts with the Timorese Ministry of Health who mostly do not consult the National TB Control Program guidelines. In other countries, doctors are not
even familiar with guidelines and TB Control Programs rely on nurses and technical personnel to succeed in the DOTS program implementation.\textsuperscript{30}

The provision of tuberculosis treatment, especially during the first two months has a significant impact by killing active bacilli and this will result in the rapid symptomatic improvement.\textsuperscript{31} It is possible that, by improving the immune response, the provision of food supplementation may contribute to the effectiveness of anti TB treatment in this period. An Indonesian study suggests that the provision of micronutrient supplements improved the effectiveness of anti TB treatment, especially in the first two months.\textsuperscript{15} On the contrary, a study from Tanzania revealed no evidence that the provision of multi-micronutrient supplementation had a significant effect on culture conversion at two months.\textsuperscript{32} Our study was not specifically designed to assess this association. However, no significant improvement in symptoms or sputum clearance rate was observed with our intervention.

The provision of both cash and non-cash incentives have been reported to effectively improve treatment compliance.\textsuperscript{8-10} Our study failed to prove that the provision of food supplementation is an effective incentive. It is interesting to see the control group were more motivated to attend the clinic than intervention group during the intensive phase. This may be due to the fact that most of the eligible patients who agreed to be enrolled in this study were living close to the clinic and appeared to be a highly compliant group. Moreover, it is interesting to see the unexpected feature of lower treatment compliance in the intervention arm during the intensive phase. The availability of research assistants to
receive complaints and provide information might indirectly increase motivation of those in the control arm. Experience from Pakistan reveals that routine counselling has a significant impact on treatment adherence.\textsuperscript{10} It can be assumed that the availability of research assistants had a similar effect on patients in the intervention arm and yet their compliance was lower in the intensive treatment period. Other factors might be responsible for this phenomenon. The qualitative data derived from participants in the intervention group suggests that, despite the overwhelming acceptability of the meal, a few of the participants expressed a feeling of shyness about eating at the clinic, while others required time flexibility to attend the clinic. Time flexibility was argued as factors that may influence TB treatment results when implementing directly observed therapy.\textsuperscript{3} Nevertheless the 81\% treatment success in the intervention groups suggests a good program performance and that the WHO target of 85\% is achievable. This finding is correlated to the treatment success rate reported in 2004.\textsuperscript{16} However, further attention is needed to focus on reducing the default rate to acceptable level of less than 10\%.\textsuperscript{31;33}

Major adverse reactions to antituberculosis drugs can cause significant morbidity, and compromise treatment regimens for TB\textsuperscript{34}. The consequences of these adverse events included hospitalizations, prolonged therapy, and more clinic and home visits.\textsuperscript{34}. Studies from developing countries suggest that the drugs side effect was one the reasons for patients to default from their treatment.\textsuperscript{35;36} In this study we recorded an unusually high percentage of adverse events and this may be because we more actively recorded side-effects and report to nurse or doctors to take immediate action conforming to the national TB protocol.\textsuperscript{18} The side effects found in this study were categorized as a minor side-
effect and can be controlled with anti-symptomatic treatments. The unusual presentation of itch in the intervention group has rise concern, but, the symptom was quickly resolved with the provision of anti histamine drugs. Abdominal pain, only represented 11% of the complaints. The influenza syndrome, nausea, dizziness and abdominal pain were less often observed in the intervention group, but the difference was not statistically significant. The NTP needs to give more attention to the management of side-effects. The proper management of side effects could lead to better compliance with treatment and in turn improvement of treatment outcome.

The Limitations of the study

The nature of a Randomised Controlled Trial minimises confounding and maximises study validity. It is possible, however, that due to the strict selection of participants for this study, we might have ruled out most patients with certain attitudes for non-compliance with the treatment. Our study finding will be different if we included, for example, those patients who were admitted to albuergues (hostels) and therefore made ineligible by our strict selection criteria. In Dili, albuergues were designed to host patients with certain characteristics, including non-compliance. However, because this study is a community based randomized trial in an out-patients clinic, we believe the result presented here reflects the real situation on the ground for the majority of patients. Measurement bias might also contribute to this negative result. Perhaps the true impact of food on treatment outcome and compliance should be measured differently. We lacked the required funding and equipment on site to measure potential immunological or
biological determinants of an effect of the food intervention. Additionally, rather than concentrate on individual treatment outcome or compliance, the impact of a food incentive could be measured in the context of the TB program management. Perhaps the wider influence on the reputation of the clinics might lead to a greater willingness to come for both diagnosis and remain on treatment. This study has successfully presented the preliminary data to provoke further investigation of these issues.

The data presented in this paper is not the complete sample enrolled in the study, according to our sample size calculation. It is possible therefore that it does not have sufficient power to represent the true finding from the study. The current violent conflict in East Timor has prevented us to assess the treatment outcome from all patients enrolled. It has also prevented us from gathering information on the treatment outcome of those who were excluded from this study and who we believe to have a different treatment outcome experience from the study participants. Both of these deficiencies will be addressed in the coming months as the security situation allows, but due to time constraints, cannot be included in this thesis.
Chapter VII. The FITTCET study

Conclusion

The first randomized control trial of using food incentive to improve treatment outcome was successfully conducted in East Timor. The study shows no evidence that food supplementation improved treatment compliance and treatment outcome in this setting. Further studies with a larger sample size and a wider patient selection in different settings will be required to confirm this finding. The impact of food supplementation as a strategy to improve TB program management more widely and on the biological and immunological determinants of TB treatment response should also be performed.
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References


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29 Chiang CY, Chang CT, Chang RE, Li CT, Huang RM. Patient and health system delays in the diagnosis and treatment of tuberculosis in Southern Taiwan. INT J TUBERC LUNG DIS 2005; 9(9):1006-1012.


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A Transdiciplinary approach was taken in this investigation of TB control in East Timor, drawing on different fields of expertise in order to understand and identify important factors and issues which impact on its effectiveness. This was done by integrating the measures, methods, and the levels of analysis that developed via a synthesis of theories from different scientific disciplines.1 This approach was used at every stage of the research process, from the design and implementation of the study to the analysis of findings and preparing manuscripts for peer reviewed articles (chapter).

The use of both descriptive epidemiology and the qualitative technique of stakeholder analysis allowed me to fulfil study aim one, that is, the documentation of the introduction of DOTS and the reconstruction of TB services during and after the conflict in East Timor in 1999. Data from the epidemiology study demonstrated promising programmatic achievement during the conflict and a great improvement after the conflict. The series of in-depth interviews with stakeholders further explained the reasons behind this success and on the measures utilised at this time.
Chapter VIII. Conclusion and Recommendations

Using the same combination of qualitative and quantitative studies, I have successfully examined the issue of treatment compliance (study aim-2) and have provided an answer to the contentious issue of food supplementation under the NTP strategy in East Timor. An ethnographic study explored the issue of compliance and possible mechanisms for improvement in the default rate amongst TB patients. While, various reasons were documented for default and for non compliance, food supplementation seems to be the common possible solution proposed in this study. However, unfortunately, the RCT study employed later to test the effectiveness food revealed no effect in improving treatment outcome, at least amongst patients attending urban clinics in Dili.

1.1 Policy Implications

Globally, the findings from the epidemiology study support those of studies from other conflict zones\(^2,3\) and contribute to informing global TB policy on the modification of the DOTS strategy to suit local conditions when introducing or rebuilding TB control programs in conflict and other unstable conditions. The findings from chapter V provide a positive example, informing global TB control policy by emphasizing the need for strengthening coordination and involving local expertise in re-establishing of TB control programs during emergency periods. The ethnographic study undertaken here may have less policy implication globally than locally, given the fact that it applies to a specific region. However, the broader implications are that local beliefs and practices need to be taken into consideration by NTP managers, and appropriate measure taken to address them. International best practice guidelines might include the importance of designing
local health promotion materials to address local perceptions of TB that have a negative impact on presentation and treatment compliance rates. Food has been used widely to support TB control, particularly in post-conflict settings, but has rarely been formally evaluated. The findings from chapter VII will make an important contribution to the policy debate.

For East Timor, the findings from chapter IV may assist the NTP-TL to develop policies that strengthen district and subdistrict level strategies to improve case findings (especially smear positive cases) and to enhance treatment outcome by reducing default rates. The study findings from Chapter V have already informed policy and decision makers and encouraged them to maintain coordination and to strengthen collaboration with implementing partners to assist the successful decentralisation of DOTS in line with the National Tuberculosis Strategy. The findings from chapter V provide the basis for modifying the current TB strategy to include community and patients’ perspectives, and to increase their participation in program planning. The findings from the RCT study have already influenced the decision of GFATM to re-visit their policy of including food as an incentive for TB patients as part of NTP activities in East Timor.
Chapter VIII. Conclusion and Recommendations

1.2 Research Implication

Globally, chapter IV supports previous studies on the feasibility of introducing TB control in conflict zones.\textsuperscript{2,3} The main findings from chapter-V support conventional wisdom that coordination, coordination and collaboration are successful factors for re-introduction of health systems after major conflict. The contrast with the overwhelming documentation of poor coordination in the response to complex emergencies\textsuperscript{5-7}, because of competition\textsuperscript{5} and the lack of an organisational mandate.\textsuperscript{8} How to achieve this coordinated approach in TB control will require further research in different settings. While focusing on a small sample of the population in East Timor, chapter-VI contributes to the increasing body of literature on socio-cultural understandings of TB, which are likely to be of particular relevance in the South East Asia region. Chapter VII is the first randomised trial to test the effectiveness of using food as an incentive to improve TB treatment compliance. The findings provide some major implications to research on this important topic and will provide guidance for future research studies in different settings.\textsuperscript{9}

Locally, these studies have made a major contribution to the enhancement of knowledge and skills of the researchers and the generation of new evidence based data to guide TB policy. The findings from these studies may become the basis for further qualitative and quantitative research to be conducted in East Timor, as outlined below.
2.1. Policy Recommendations:

Global Context:

1. Tuberculosis treatment can and should be introduced at an early stage of the emergency response to complex emergencies occurring in countries with a high pre-conflict burden of TB. The DOTS strategy needs to be modified to suit the local conditions, but should be adopted to control TB in these settings.

2. Non-government organisations with experience in TB control program should be allowed to lead the implementation of DOTS strategies during conflict and post-conflict situations. However, coordination by the government authority (Ministry of Health or equivalent) should be strong to allow rapid expansion to all health service providers and a feeling of the ownership of government staff toward the program.

3. Coordination, co-operation and collaboration should be strengthening in the reconstruction of health services after the conflict to allow rapid establishment of TB programs and possibly other health programs.

4. Recognition of local knowledge and expertise is important and early involvement of local experts in the reconstruction process allows rapid establishment of more sustainable TB programs after complex emergencies.
Chapter VIII. Conclusion and Recommendations

5. Using food as an incentive to improve treatment outcome should be carefully considered in an urban context with easy access to clinics, and a relatively high cure rate.

6. Side-effects of TB treatment may occur more commonly than is thought to be the case in high-burden settings and this needs to be documented as part of routine data collection. The proper management of side effects needs to be included in TB program guidelines.

Local Context (East Timor)

1. The local strategies need to be strengthened to improve TB program performance and to assist the decentralisation of DOTS. The utilisation of *albuergue*, satellite and motivators should be continued and strengthened. The provision of incentives such as transport costs and food supplements require careful evaluation and will depend upon local geographical and economic conditions.

2. The unified TB control program with one central management unit needs to be maintained in East Timor. There is need for MOH to increase its financial contribution and management control for TB-CMU to improve the ownership and facilitate further decentralisation of TB services to the reach remote areas.

3. Ongoing training and supervision is important to enhance the skills of TB health staff working in the peripheral TB centres.
4. Lessons learned during the experience of reconstruction of the TB Control Program during the 1999 conflict should be included in both the national TB strategy and the national disaster plan so as to encourage TB control during conflict and natural disasters.

5. To developed locally acceptable mechanisms to involve community members in TB control management in the village level. This will allow more referral of TB patients from the community and ensure high rates of TB treatment completion.

6. To incorporate local knowledge and practices in developing local TB promotion materials to improve people knowledge on TB, prevent misconception and reduce stigma related to TB in East Timor.

7. The NTP should revisit its current strategy to provide supplementary as part of TB control activities, especially for Dili population. This could be substituted by the provision of routine nutritional advice.

8. The NTP should improve the information and management of drugs side effect in the TB clinic. TB patients should receive information regarding their disease and side effects of treatment at the time of diagnosis and frequently during their treatment.
2.2. Research Recommendations

Global Context:

1. To further document the experience of the introduction of DOTS in other conflict and post conflict settings. The research is needed to document the experiences and to produce the guidelines for introduction DOTS in long and ongoing conflict areas.

2. To conduct methodologically rigorous research, even in the most under-resourced settings and in post conflict situations to inform policy development of TB control strategies.

3. To examine the effectiveness of micronutrient supplementation and/or food to improve clinical outcome, especially for under-nourished TB patients in settings of food shortage and where treatment compliance is sub-optimal.
Local Context

1. To evaluate the effectiveness of satellite clinics, *albuergue* and TB motivators in improving treatment outcome in East Timor.

2. To assess the effectiveness of the current laboratory diagnostic strategy and settings to enhance the TB diagnostic procedure in East Timor.

3. To explore ways for enhancing the community contribution to the TB control program.

4. To evaluate the effectiveness current TB health promotion and design and test the effectiveness of locally based health promotion to combat stigma, reduce misconceptions and increase knowledge on TB.
Reference


4 NTP. National Tuberculosis Strategy. 1-27. 16-7-2004. Dili, Minister of Health, RDTL.


Appendices

1. Article-1. Tuberculosis Control in conflict-affected East Timor, 1996-2004 (Attach separately)

2. Article-2. Reconstructing Tuberculosis Services after Major Conflict: Experiences and Lessons Learned in East Timor (Attach separately)

3. Glossary:

1. 2RHZE/6HE means: Consume four drugs contain Rifampicin (R), Isoniazid (H), Pirazinamid (Z) and Ethambutol (E) daily during the first two months, and the continue with two drugs H and E daily during the continuation phase. The first two months should be under strict supervision by health workers.

2. 2SRHZE/1RHZE/5R$_3$H$_3$E$_3$ means the injection of Streptomycin daily in addition to the four drugs contain Rifampicin (R), Isoniazid (H), Pirazinamid (Z) and Ethambutol (E) that should be consumed daily for first two months, followed by one months daily consume of four drugs R, H, E, Z, and consume three drugs contains R, H, E three times per week for the duration of five months.
4. Questionnaires and Participants Information sheet for Study -2
(Chapter-V)

Questionnaire for TB Study 2:

A research study examining the development of the National Tuberculosis Control Program in East Timor.

Time of interview  :
Date  :
Place  :
Interviewer  :
Interviewee  :

1. What was the situation of TB disease and TB control/treatment in East Timor in the period post referendum (September 1999) and during the emergency period (October 1999-December 2000)?

2. What was done to address these issues? What were the barriers to successful implementation of the program in the emergency period? What were the factors that assisted in its implementation?

3. What was your role in these events?

4. The TB program (NTP) was regarded by the Interim Health Authority of the United Nations Transitional Authority (UNTAET) as the “shining light” in the of Health sector reconstruction process. Others have noted the spirit of cooperation, coordination and collaboration among many stakeholders. What is your opinion of these statements?

5. The recent external reviews of NTP revealed that the program, despite many constraints and challenges, has been well implemented in all thirteen districts, but not all sub-districts. In your opinion what are the current constraints and challenges, and what can (should) be done to address them?

6. With regard to your current role and responsibilities, what contributions do you feel you are making to improve the NTP performance and its sustainability into the future?

Thank you, for participating in this interview. I will assure that this information will be kept confidential and be stored in a secure place.
Tuberculosis is a major public health problem in East Timor. Following the disruption to health services in East Timor in 1999, many people from many different organisations contributed to the establishment of a National Tuberculosis Control Program (NTP). Within a few months, the program was operational in all districts in the country.

We are conducting a research study to gain a better understanding of how this program was developed. We will interview as many of the key people involved in the development of health services during the transition to independence, with a particular focus on the TB program development. With the information gained from these interviews and a thorough review of the objective performance indicators for the NTP, we will be comparing the East Timorese experience with other similar post-conflict settings. We hope that the knowledge gained by this research will help other countries faced with the reconstruction of health services after conflict.

The interview will be conducted in a place convenient to the participant and will take approximately one hour to complete. The questions are to collect information and are not a test of your knowledge. To aid in the information gathering process, your interview may be tape recorded. Participation is voluntary and does not cost you any money. All information collected is confidential and all tapes, written and electronic records will be kept in a secure place. You can withdraw from the study at any time and for any reason.

If you have any questions about the study, you can contact Dr Nelson Martins at +670 7242404. For complaints or concerns about the study you can also contact the following people who are independent from the research team:

- Local contact person: Dr Avelino Gutteres, Dean, Faculty of Public Health, University of Dili on 07234841
- In Australia: Ms Gabrielle Falls, Secretary, Top End Human Ethics Committee, Darwin on +61 (0)8 89228196
- In Australia: Ms Hemali Seneviratne, Executive Officer, Human Research Ethics Committee, Northern Territory University, Darwin on +61 (0)8 89467064
Consent Form for TB Study 2:
A research study examining the development of the National Tuberculosis Control Program in East Timor.

This form means you can say no

I have read the participant information sheet on the other side of this page and have had the details explained to me by the person whose name appears below. I understand that I will be interviewed and that the interview may be tape recorded. I understand that all information collected is confidential and that information will not be available to anyone except the study researchers. I understand that I am not required to participate in this study and can withdraw at any time.

I..................................................(print name) agree to take part in this study.

Signed........................................................  Date......................

Witness: I, ............................................................. have explained the study & information sheet:

Signed........................................................  Date............................
5. Questionnaires and Participants Information sheet for Study -3 (Chapter-VI)

Questionnaires-1

A research study examining “The Role of TB Satellites Clinics in Enhancing Accessibility to the TB Services and Promoting Program effectiveness, in East Timor”

Time of Interview : 
Date of Interview : 
Place for Interview : 
Interviewer : 
Interviewee : 

In-depth Interview : Patients

1. We’ve seen you came to this satellite clinic everyday to receive your treatment. Would you like to explain to us why we do that?

2. According to the rumours many people do not seek or continue their treatment because they live far way from the clinic. Do you think this satellite could be the option for resolve problem? Please explain to us.

3. Have you heard about the term TB? Would you like to explain to us “what is TB and what causes TB? How TB spread? and how to treat TB?”

4. Do you satisfied with what have been offered through this satellite clinic? Do you have any ideas on what this satellite clinic should be functioning?

5. Have you received a regular information about TB from this satellite clinic? Does the health officer in this provide some information to you about your disease and treatment?

Thank you, for participating in this interview. We will assure that this information will be kept confidential and be stored in a secure place.
Questionnaires-3

A research study examining tuberculosis treatment adherence in East Timor

Time of Interview :
Date of Interview :
Place for Interview :
Interviewer :
Interviewee :

Indepth Interview : Health Workers

1. We see many patient still drop-out from your clinic? Could you explain the reasons behind this drop-out?

2. Could you explain to us on the cost and consequences that the health services when one of TB patient Drop-out?.

3. What is your opinion on the current TB treatment strategy (Is the program sufficient to address TB problem in your clinic). If Not, do you think the current treatment strategy need to be improved? If, So what is your recommendations?

4. Previously, the NTP provide some food supplementary to patient who get the treatment, but current there is no more food supplementary? Do you think, the food supplementary is useful strategy to keep patient comply with the treatment?

5. It is belief that good (nutritious) food could accelerate the curative process and prevent some from having TB. What is good (nutritious) in your opinion? What should someone (you) eat for your daily meals? and how many times someone have eat each day?

6. Please explain: What will you do/ have done to ensure your diagnose for some one you suspect of having TB? And What will you do for some one with clinically and laboratory positive of having TB?
7 Have you ever heard about the TB drugs resistance in East Timor. What will you do prevent this problem and to effectively treat your patients? Please explain about the medicine (regimen) to treat malaria. Have you regularly used it to treat TB patient?

8 Please explain: on how you conduct health education campaign in your clinics. The topic you choose and the medium that you use to transfer the information.

9 What measures should be taken to ensure patient comply with treatment in your work place? What are the barriers prevent to the successful implementation of those measures?

10 With regard to your current role and what contributions do you feel you are making to improve DOTS strategy in your place? Is there any plan to include NGOs, Church, community leaders and other related sector to control TB in your place?

Thank you, for participating in this interview. We will assure that this information will be kept confidential and be stored in a secure place.
Questionnaires -3

A research study examining tuberculosis treatment adherence in East Timor

Time of Interview : 
Date of Interview : 
Place for Interview : 
Interviewer : 
Interviewee : 

In-depth Interview / FGD: Community members

1. We’ve seen many people have drop out from the TB treatment in your village? Could you explain to us what the reasons behind this?

2. Could you explain to us on the cost and consequences that your might be prevented or bearer when you decide to comply or stop the treatment?

3. What is your opinion on the current TB treatment strategy (Is the program sufficient to address problem of TB patients in your place ) ?. IF Not, do you think the current treatment strategy need to be improved? If, So what is your recommendations?

4. Previously, the clinic provides some food supplementary to patients who get the treatment, but currently there is no more food supplementary? Do you think, the food supplementary is useful strategy to help resolve some of the TB patient in village, why?

5. It is belief that good (nutritious) food could accelerate the curative process and prevent some from having TB. What is good (nutritious) in your opinion? What should someone (you) eat for your daily meals? and how many times someone have eat each day? Is it enough resources for meals that you mentioned above in your village?

6. Could you explain to us (in your opinion) on what is TB (the definition), how is transmitted, what cause TB ?.

7. Do you think TB can be cured, if so, when someone got TB where should she/he does and go?
8. Do you think there are other alternatives for TB treatment? For example, traditional medicine, etc?

9. Have you heard any messages or information on TB? What media did you get the messages?

10. In your opinion, what is the best media should be used to disseminate the TB information to the community, especial in your village?

Thank you, for participating in this interview. We will assure that this information will be kept confidential and be stored in a secure place.
How to Increase Patient’s Adherence to the Tuberculosis Treatments in East Timor.

Tuberculosis is major cause of sickness in East Timor and it can affect any part of the body. It requires 8 months to 1 year of treatment to cure Tuberculosis disease. The implementation of DOTS strategy in this centre helps overcome most of the obstacles for the TB treatment. Patient adherence to the treatment is one of the important aspects for the successful implementation of the program in order to cure TB. However, it remains the main challenges for the NTP to increase program performance. We do not know what the barriers to and enabling factors that contribute to the adherence to the treatment protocols by patient and clinic staff.

This research is looking at different opinions, perceptions, knowledge, beliefs, and attitudes of how to improve patient adherence to the treatment. We will ask participants some questions regarding tuberculosis if they want and have time to participate. This is a simple questionnaire to facilitate the collection of the data and some of the information will may tape recorder. The interview will be conducted in a place convenient to the participants. This interview is purposely used only for collecting the data, and will take on average 30 to 60 minutes. This is not a test of participants’ knowledge. If you wish to have transcription on the tape, it will be made and you are welcome to arrange a time to read it if you wish.

Participations in this study is voluntary; it does not costs you any money. All information collected is confidential. No personal identification will be revealed to persons outside the study. If you decide to participate, you can withdraw from this study at any time for any reason. For the patient, you will still receive standard treatment for tuberculosis by the staff at the health centre, regardless of you participation or refusal to participate in this setting.

If you have any questions about the study you can telephone Dr Nelson Martins at +670-7242404 at the Ermera Institute of Medical Research in Gleno, Ermera or Ms Gabrielle Falls, Secretary, Top End Human Ethics Committee in Australia on 61-8-89228196.
Study ID:……../…….. 

Consent Form

A research study of how to Increase Patient’s Adherence to the Tuberculosis Treatments in East Timor.

This form means you can say No.

I have read the patient information sheet on the other side of this page and have had the details explained to me by witness below. I understand that I will be interviewed and my information may be tape recorded. While this interview may provide some important information to others, it will not have a direct benefit to me.

I understand that all information collected is confidential and no information will be available to anyone outside the study. I understand that I am not force to participate in this study. I can withdraw from this study at any time for any reason.

I…………………………………………(print name) agree to take part in this study.

Signed…………………………………………………Date…………………………..

Witness : I, ……………………………Have explained the study & information sheet:

Signed…………………………………. Date………………………………………….
Table-10. Sputum Conversion Rate

<table>
<thead>
<tr>
<th>At least 1&quot;+&quot;</th>
<th>Week 0</th>
<th>Week 4</th>
<th>Week 8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention</td>
<td>37/83 (45%)</td>
<td>16/83 (19%)</td>
<td>15/83 (18%)</td>
</tr>
<tr>
<td>Control</td>
<td>29/85 (34%)</td>
<td>12/84 (14%)</td>
<td>12/84 (14%)</td>
</tr>
<tr>
<td>Comparison</td>
<td>$\chi^2 = 1.93, p=0.165$</td>
<td>$\chi^2 = 0.74, p=0.388$</td>
<td>$\chi^2 = 0.44, p=0.506$</td>
</tr>
</tbody>
</table>
7. Follow-Up data form for study-4 (chapter-VII/ attach different)
8. Participants' Information Sheets for study-4 (Chapter-VII)

Participant information sheet
The Food Incentives for Tuberculosis Treatment Compliance in East Timor, (FITTCET) Study

I am Dr Nelson Martins working for the Faculty of Public Health, University da Paz, Dili and studying for a PhD through the Menzies School of Health Research in Darwin. My research project is about finding better ways to treat people with tuberculosis (TB, TBC, TB paru paru).

Tuberculosis is a serious health problem in East Timor and the National Tuberculosis Control Program operates in all districts and through many health clinics to try to control the disease. One of the challenges for TB treatment is the long time it takes to achieve a cure (eight months). In East Timor, people with TB are required to come to the clinic every day during the first two months of treatment and then every two weeks for the following six months of treatment to collect the medications. Sometimes people with TB find it difficult to finish the treatment and the TB program is looking for ways to assist people to do this. It is important to finish the treatment because otherwise there is a risk that the TB illness will not be cured or the bacteria that cause TB will become resistant to the treatment.

There have been different methods tried in East Timor and other countries for encouraging people with TB to finish the course of treatment. One way is by giving food with the TB medicines. This makes sense because eating the right food in the right amounts helps the body to fight off infections like TB. Sharing a meal with other people who have a similar bad health experience like TB is probably also a supportive thing and an encouragement to come to the clinic for the medicine. However, neither the physical or mental/social benefits of food incentive has been fully studied and that is why we are doing this research.

We propose to test if providing a meal (fejuada and rice) five days per week for two months followed by a food parcel fortnightly for six months will assist people with TB to complete their treatment. This is a “randomized controlled trial” which means that, by agreeing to participate in the research study, you will have a 50% chance of receiving the food, and a 50% chance of receiving nutritional advice but no food. Everyone who joins the research study (and anyone who refuses to join it) will receive normal treatment for TB with all the usual care, medicines and follow-up examinations that usually occur now. To help us to know the true effect of the food intervention, and to remove any bias, neither the clinic staff nor the researchers will know which group you will be assigned to. Your group will be chosen from a secret envelop with a number generated at random by a computer.

If you choose to participate you will be required to undergo the following procedures which are not included in the routine care of TB patients at this clinic. These are:
1. an interview by one of the research staff and asked a series of questions about yourself, your current illness and some relevant past medical history;
2. an examination by one of the research staff including height and a weight check which will also assess the amount of fat in your body. These tests will not cause any
discomfort;
3. for some study participants (depending on the type of TB diagnosis), a blood test of 15mls (about three teaspoons) of blood taken from a vein on your arm which will be used to measure your response to infection and the levels of protein and of some vitamins and minerals in your blood. All care will be taken to make this as safe and painless as possible, but some people may feel discomfort at the time of the blood test and there is a small chance of bruising which may cause pain for some hours or days after the blood test.

The enrolment procedure will take approximately one hour to complete.

You will then be assigned to one of the two groups of the study. The “food group” will be asked to come to the clinic five days a week at midday and receive a meal with their medications, all routine care as a TB patient and a short questionnaire and physical examination. This procedure will take less than one hour. The “control group” will be asked to come to the clinic in the morning at the usual time and receive medications, all routine care as a TB patient and a short questionnaire and physical examination (same as above). This procedure will also take less than one hour. At the first visit, the “control group” will also receive detailed information to assist in receiving a balanced diet to assist healing from TB but will not receive food. Both groups will have a blood test (15 mls as described above and for the same tests to be performed) after one, two, five and seven months of treatment. In addition, a member of the research staff may visit you in your home during the TB treatment period. The purpose of this visit is to accurately assess the distance of your home from the clinic and to ask some questions about food supply in the home. You will not be required to make any extra visits to the clinic other than those required by the TB program.

We plan to use the biological specimens obtained by this research project (blood and sputum) only for the purposes described above and they will be destroyed after 5 years or earlier if the research is completed. The blood will only be used for the tests described in this sheet (that is, tests of protein vitamins and minerals in the blood and the response of the body to infection). The main risk involved with this research project is the blood test as described above. The main benefits are for the “food group” who will receive food which may help recovery from TB (you have a 50% chance to be in this group). The “control group” will receive scientific advice on the types of food which will assist you to recover from TB. All participants will have access to TB specialist doctors during their treatment.

We will inform the clinician in charge of your care of any results that would assist the clinician to give you the best care available. Otherwise, the information which we collect as part of this research will remain confidential. That is, only the research team will have access to the information provided by you. This information will be locked in a cupboard at the research office and on a computer protected by a password. Any reports on the results will refer to groups of individuals in a way which will protect your privacy.

You do not have to take part in this research project if you do not wish to do so, and refusing to take part will not mean any change in the usual treatment and care you will receive at the clinic as part of the TB program. You may also choose at anytime to stop taking part in the research project, again without influencing the normal TB treatment.
If you have any questions about the study, you can contact Dr Nelson Martins at +670 7242404. For complaints or concerns about the study you can also contact the following people who are independent from the research team:

- Local contact person: Dr Joao Martins, Dean, Faculty of Public Health, University Da PAZ on 7234841
- In Australia: Ms Linda Ward, Secretary, Top End Human Ethics Committee, Darwin on +61 (0)8 89228196

Thankyou for considering to be part of this important research project. This is for you to keep.
Consent Form
The Food Incentives For Tuberculosis Treatment Compliance in East Timor, (FITCET) Study

This form means you can say no

I have read the participant information sheet (attached) and have had the details explained to me by the person whose name appears below. I understand that I will be assigned to one of the two groups in this study by chance. I understand that due to the randomization process, I have 50% chance to be assigned in each group (whether intervention “food” or control group). If, I am assigned to the intervention group, I will receive food supplement. On the other hand, if assigned to the control group, I will not receive food supplement. I understand that I need to take anti-TB medicines regularly in order to be cured. I understand that my blood may be taken in addition to the routine sputum collection up to four times during the course of the treatment and study time. I understand that all information collected is confidential and that information will not be available to anyone except to the study researchers. I understand that I am not required to participate in this study and can withdraw at any time I want, and I will still receive all the usual care for my TB illness.

Study Participant:

I, .............................................................. (print name) agree to take part in this study.

Signed........................................................  Date....../......./....…(dd/mm/yyy)

Independent literate witness (if patient is illiterate):

I, ................................................................. (print name) confirm that the above named understands about the study and agrees to take part.

Signed........................................................  Date....../......./....…(dd/mm/yyy)

Researcher: I, .............................................................  have explained the study & information sheet:

Signed......
9. Demography Questionnaires for study-4 (Chapter-VII).

The Food Incentives For Tuberculosis Treatment Compliance in East Timor, (FITCET) Study: Enrolment questionnaire

Date : ___/___/____ (dd/mm/yyyy) Interviewer :………………………….
Study ID:…………………………………… Clinic Name:…………………………

I DEMOGRAPHY

1. First Name:__________________ 2. Surname: ___________________
3. Other Names: _______________________________
4. Age: ___________________
5. Sex: M F
6. Marital status: Single Married Divorce Widow/widower
7. Address:
Aldeia…………….Suco…………….Sub-dist rict…………District………
Street _________________________________ Location (Dili) ___________
Closest known landmark (eg church, school, market) ___________________
8. Education (Years of formal schooling): ____
9. Occupation: (circle correct answer)
   a. Farmer
   b. Civil Servant
   c. Private employee
   d. Unemployed
   e. Housewife
   f. Other (Please specify) _________________________________

10. Average Monthly Income ($US): ______

II HISTORY OF CURRENT ILLNESS

11. How long have you been sick with this current illness

During the current illness, have you ever experienced any of the following symptoms:

12. Cough : > 3 weeks Yes / No
13. Night sweats Yes / No
14. Chest Pain Yes / No
15. Weight loss Yes / No
16. Anorexia (loss of appetite) Yes / No
17. Lethargy (tire easily) Yes / No
18. Fever Yes / No
19. Haemoptysis (coughing blood) Yes / No
20. Exertional dyspnoea (shortness of breath on walking) Yes / No
21. Diarrhoea Yes / No

During the current illness, have you sought treatment from
22. A community health clinic Yes / No
23. A private practitioner Yes / No
24. A traditional healer Yes / No
25. A pharmacy Yes / No
26. Any other source Yes / No

During the current illness, have you received any of the following treatments:
27. Antibiotics Yes / No
28. Cough medicine Yes / No
29. Vitamins Yes / No
30. Injections Yes / No
31. Other (please specify) __________________________________

32. Do you have any close relatives who have been diagnosed with TB? Yes / No
33. When was the most recent diagnosis ___/__/____ (dd/mm/yyyy)
34. What clinic did they receive treatment
   (a) Motael
   (b) Becora
   (c) Bairro Pite
   (d) Other (specify) ____________________

35. Do you have any other illness Yes / No
36. If yes, please specify other illnesses
   __________________________________________________________

37. Do you smoke? Yes / No
38. If Yes, How many cigarettes do you smoke every day? _____
39. How long have you smoked? _____ years

III PATIENT COST ESTIMATES
40. How far is your house from the clinic _____ kilometres
41. How long did it take to travel to the clinic today _____ minutes
42. What form of transport did you use to come to the clinic:
   a. Walk
   b. Private vehicle (specify type: bike, motorcycle, car) ______________
   c. Public transport
   d. Taxi
   e. Other (please specify) _________________________________________

43. If you paid for transport, what was the cost? $ _____

During the current illness,
44. How much time have you spent seeking diagnosis and treatment (including doctors, clinics, traditional healers and pharmacies)? ____ hours

45. In addition to the transport cost, did you spend any money for something related to treatment? Please explain. ____________________________________________________________

46. How much money did you spend on other costs? $ ___

47. What is the labour cost per hour for your current jobs or how much money could you earn for doing an hour work? $____

IV   CLINICAL EXAMINATIONS

Physical exam: (date: ___/___/___)

BP: _____ Pulse: _____ temp: _______ RR: _______

V   ANTHROPOMETRICS MEASUREMENTS

1. Weight (kg) _______
2. Height (cm) _______
3. BMI (wt/ht^2) _______
4. Fat % _______
5. Fat mass (kg) _______
6. Free fat mass (kg) _______
7. Total body water (kg) _______

VI LABORATORY FINDINGS

I. Sputum Smear Examination Results: AFB

Clinic Lab Cross-check

Specimen 1
Specimen 2
Specimen 3

VII   X- Ray (Dr Nelson to report on any Xrays)

Chest/other X-ray: Date_________ □ Abnormal □ Normal

□ Cavitary
□ Miliary
□ Primary complex
□ Pleural Effusion
□ Infiltrate
□ other ______

Xray Score: _____
10. **Questionnaires and Participants Information sheet for Study -4 (chapter-VII) Qualitative data collection.**

Participants information sheet for TB Study 4:

Follow-up information for the (FITTCET) Study

As you know, we are conducting a randomised controlled trial of a food intervention to improve compliance in East Timor. You agreed to enrol in this study, and have been randomised to receive the intervention (meal at the clinic daily during the first two months of treatment and a food parcel fortnightly during the other six months of treatment) or standard care (nutritional advice only). You have now been chosen at random to participate in another research exercise to assist us to better understand the ways in which we can assist TB patients to complete their treatment and be cured.

In addition to the information we are already collecting with your consent, we are also interested in gathering further information about your experience of being involved in the study and of receiving TB treatment. We will conduct a series of interviews and form a number of focus groups to collect this information. Two researchers will ask a series of questions about your experience. In the focus groups, you will be sharing these experiences with a small group of other patients attending this clinic.

We will feedback the main findings to you and you will have an opportunity to correct any information which does not accurately reflect your views. All information collected is confidential and that information will not be available to anyone except the study researchers. You are not required to participate in this study and you can withdraw at any time you want. Refusal to participate will not affect your access to health care in any way.

If you have any questions about the study, you can contact Dr Nelson Martins at +670 7241615. For complaints or concerns about the study you can also contact the following people who are independent from the research team:

- **Local contact person:** Dr Avelino Guterres, Dean, Faculty of Public Health, University Da PAZ on 7234841
- **In Australia:** Ms Linda Ward, Secretary, Top End Human Ethics Committee, Darwin on +61 (0)8 89228196
Study ID: ___________

Consent Form for TB Study:
Follow-up information for the (FITTCET) Study

This form means you can say no

I have read the participant information sheet on the other side of this page and have had the details explained to me by the person whose name appears below. I understand that I have been chosen to be part of a focus group discussion/interview (delete one) to inform the FITTCET study which I am already participating in. I understand that I will be part of the focus group/interview (delete one) for up to two hours on one occasion. I understand that all information collected is confidential and that information will not be available to anyone except the study researchers. I understand that I am not required to participate in this study and can withdraw at any time I want.

I..................................................(print name) agree to take part in this study.

Signed........................................................  Date...........................................

Witness: I, ............................................................. have explained the study & information sheet:

Signed........................................................  Date...........................................
11. Adverse events collection form

Lembaran Keluhan Pasen

ID : ..................................................
Nama : ..................................................
Umur : ..................................................
Tanggal : ...........................................

Keluhan utama :

Keluhan tambahan :

- Gatal-gatal □
- Kemerahan pada kulit □
- Gangguan Gastrointestinal
  - Mual dan muntah □
  - Diare □
  - Nyeri di uluhati □
- Rasa terbakar, mati rasa pada kaki dan tangan □
- Kuning (ikterus) □
- Gangguan penglihatan □
- Nyeri, kekakuan dan pembengkakan sendi □
- Pusing-pusing atau ketulian □
- Sindroma influenza
  - Demam, nyeri otot, sakit kepala dan tidak enak badan □
- Lain-lain □
  - Uraikan: ..................................................

Dili, ……/……./200

TTD

Asisten Peneliti : ..................................................
Peneliti Lokal : ..................................................
Komentar :
12. The results of Independent Investigation of the food handling and preparation (attach separately)
Diketahui bahwa tingkat kecukupan gizi cukup baik, variasi menu cukup tetapi perlu dimodifikasi menurut TKTP lain, flavour / cita rasa makanan cukup, tingkat kematangan cara penyajian hidangan makanan cukup baik, suasana ruangan penyajian dan keadaan saniter cukup tetapi perlu ditelusuri setiap saat.

Dari hasil pemeriksaan diatas dapat disaranakan bahwa secara umum cara penyajian dan keadaan saniter ditiga (3) lokasi penelitian seperti Clinika bairopite, hotel dan CHC becora sudah cukup baik, hal ini tidak dapat berpengaruh terhadap tingkat konsumsi pasien tuberculosis (TB). Dan selama penelitian bertlangsung juga ditemukan adanya suhu hidangan pada saat penyajian masih bisa dipertahankan suhu konstan, dimana pasien menyajikan hidangan kondisi makanan masih dalam keadaan hangat. Sedangkan keadaan saniter secara umum cukup baik seperti perlindungan terhadap bahan makanan, keadaan personil atau petugas, perlengkapan peralatan makan dan memasak, kebersihan perlengkapan makan dan memasak, kebersihan tempat penyajian atau dapur, fasilitas kemudahan sanitasi dan pengawasan.

Catatan: Peringatan dan kesan; Kondisi bangunan dapur, kebersihan dapur, jarak dapur dengan ruang perawatan dan WC perlu diperhatikan (Clinika bairopite) dan juga variasi menu perlu dimodifikasi agar tidak memberi kesan atau rasa bosan terhadap pasien (untuk semua Clinika).

Dili, 02 Januari 2006
Team Pemeriksaan

Miguel Quintai, AME
NUTRITIONIST