

12-Year Treatment Outcomes of Tuberculosis Patients: A Full-Scale Non-Family DOT Model in Thailand

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Abstract

A descriptive study of a non-family DOT (Directly-Observed Treatment) model in the Muang District of Nakhon Si Thammarat Province in Thailand was conducted, with the aim of reviewing the 12-year treatment outcomes under the full-scale non-family DOT model, in order to demonstrate the possibility and feasibility of DOT in Thailand. Four hundred and fifty four new smear-positive pulmonary TB patients, registered during the fiscal year 2001 - 2012, were evaluated for treatment outcomes. The overall cure rate and treatment success were 81.1 and 84.0 %, respectively. The proportion of the TB patients under the model that received DOT by health staff was as high as 95.0 %, even in the urban setting. We have concluded that a non-family DOT service for new smear-positive TB patients is possible and feasible in Thailand, even in an urban setting.

Keywords: Tuberculosis, TB, DOT, non-family, DOTS

Introduction

Thailand is one of the 22 highest tuberculosis (TB)-burdened countries in the world [1]. Contributing factors which make TB a major public health problem in Thailand include the Human Immunodeficiency Virus (HIV) epidemic, urbanization, mobile populations, and so on. However, the most important factor is poor TB treatment outcome due to a superficial understanding of Directly-Observed Treatment (DOT), which leads to a less effective application of real field practice. Family-based DOT was first founded in Thailand in 1992 [2]; since 1994, nearly all Zonal TB Centers (ZTCs) in Thailand have conducted DOT by family member. Following the first external review for the Thai National TB Programme (NTP) by a joint effort between the World Health Organization (WHO) and the Thai Ministry of Public Health (MoPH) in 1995, Directly-Observed Treatment, Short-course (DOTS) has been recommended for implementation in Thailand to combat TB [3]. DOT, as one of the essential elements of DOTS, requires another person - a so called observer - to watch the TB patient while swallowing TB drugs. However, since the early stage of DOTS implementation, most DOT observers in Thailand have been family members [4,5]. The number of reported TB cases in Thailand has remained on the rise [6], and this has possibly resulted from the family DOT. From our experiences in the early stage of DOTS implementation, it has seemed that family members are unreliable DOT observers, and are unable to make the DOTS program sustainable. Therefore, the recommendations of the Center for Disease Control and Prevention (CDC) [7] and WHO [8] have been reviewed, and have suggested that family members should not be DOT observers. A non-family DOT model for TB patients registered at Zonal TB Center 11, Nakhon Si Thammarat (ZTC 11) was developed in 1999 [9]. The TB patients who

lived outside our catchment area were referred to community hospitals near their home to facilitate DOT [10]. ZTC 11 was previously under the jurisdiction of the Department of Communicable Disease Control, MoPH, and was collapsed to become a TB Clinic under the 11th Regional Office of Disease Prevention and Control, Nakhon Si Thammarat (DPC 11), Department of Disease Control (DDC), MoPH, since 2003. The responsible area covers 7 provinces of upper-southern Thailand, a population of about 4 millions. The main responsibilities are the development of operational models of disease control, training, and the conduction of supervision, monitoring and evaluation, mainly for the provincial sector. To treat TB patients under the model in the catchment area, many other organizations have cooperated, especially the health centers under Nakhon Si Thammarat's Muang District Health Office (DHO) of the provincial sector, a City Hospital of the municipality, and Wachirawut Hospital, a military hospital in the Muang District of Nakhon Si Thammarat. After getting TB diagnoses, the patients were asked to receive DOT service at health centers or other hospitals near their homes. In addition, the nurses of the municipality hospital provided DOT to the majority of TB cases at their homes in the municipality area; some of them who stayed near the municipality hospital needed to visit the hospital every day to receive DOT. The full-scale non-family DOT model has been conducted since 2001, after a transitional period in 1999 - 2000 [9].

Our objective of this descriptive study is to review the 12-year treatment outcomes under the full-scale non-family DOT model, in order to demonstrate the possibility and feasibility of DOT in Thailand; the model is very different from other previous reported studies, which included very high proportions of family members. Our model is expected to be able to strengthen district TB control activities, to effectively reverse the increasing trend in Thailand.

Materials and methods

From October 1st, 2000 to September 30th, 2012 (the fiscal year 2001 to 2012), 454 new smear-positive pulmonary TB patients (consistent with the definitions by WHO) were registered at the former ZTC 11, which later became the TB Clinic under DPC 11, and started treatment with 2HRZE/4HR: the daily regimen of the 2-month initial intensive phase of isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E), followed by a 4-month continuation phase of isoniazid and rifampicin. If the sputum examination at the end of second month was still positive, one additional month of HRZE was provided. All the TB patients in prisons were excluded from the report, because the nature of the patients, the method of conducting DOT, and the factors affecting TB treatment outcomes are very different from the non-incarcerated patients. In addition, all prisons in Thailand have treated TB patients under the National Health Security Scheme by collaboration with government hospitals since 2002; TB patients from prisons have not been treated in this setting since 2006. The treatment outcomes were collected year by year to determine the trend of numbers of registered patients and the distribution of age groups. The treatment outcomes were also tabulated by observer type, to determine the differences in each group. The descriptive statistics, i.e., ratio and proportion, were used for presentation and analysis. The study proposal was approved by the Ethical Review Board of Walailak University (Ethical clearance No.041/Year 2013: Date of approval 24 September 2013).

Results

Four hundred and fifty-four new smear-positive TB patients were registered at DPC 11 over 12 years, from the fiscal year 2001 to 2012. The majority of cases were in the younger age group, 25 - 34 and 35 - 44 age groups (**Table 1**). The male to female ratio was 357:97, or 3.68:1. The numbers of registered patients have been decreasing year by year, and only a few cases were registered annually in 2010 - 2012 (**Table 2**). The majority of patients received DOT by health center staff under the provincial sector, the DPC 11 staff and the municipality staff, in the proportions of 44.3, 34.8 and 15.0 %, respectively. Only 4.2 % of the patients were provided DOT by village health volunteers (VHV). The overall proportion of DOT by health staff was 95.0 %. Only one new smear-positive TB patient in 2002 did not return to get diagnosis and start treatment, and, even though many attempts were made to trace

him, he was not found. Thus, he was finally declared as a primary defaulter after two months of registration.

The overall 12-year cure rate was 81.1 % (**Table 3**), while the completion rate, the failure rate, the death rate, the default rate, and the transfer-out rate were 2.9, 2.4, 5.3, 5.1 and 2.2 %, respectively. The treatment success (the combination of cure rate and completion rate) was 84.0 %. The combined default and transfer-out rates were 7.3 %. Among the 3 main DOT groups (DPC 11 staff, municipality staff, and health center staff), the highest cure rate of 86.1 % was DOT by the DPC 11 staff, which was able to meet the WHO's global target of 85 %. The cure rate of health-center-staff group was relatively low (75.6 %), because of high death rate (7.5 %) and high default rate (7.5 %).

Table 1 Number of new smear-positive TB patients registered at TB clinic of DPC 11* by age group and sex, the fiscal year 2001 - 2012.

	Age groups of new smear-positive TB patients (years)														Total	Total		
	0 - 14		15 - 24		25 - 34		35 - 44		45 - 54		55 - 64		65+				Total	
	M	F	M	F	M	F	M	F	M	F	M	F	M	F			M	F
Number	0	0	24	14	72	24	86	19	71	9	47	14	57	17	357	97	454	
Total	0		38		96		105		80		61		74		454			
%	0		8.4		21.1		23.1		17.6		13.4		16.3		100.0			

Remark: M = male, F = female

*DPC 11 = 11th Regional Office of Disease Prevention and Control, Nakhon Si Thammarat, Department of Disease Control, Ministry of Public Health, Thailand

Table 2 Numbers of new smear-positive TB patients registered at TB clinic of DPC 11¹ by DOT observer type, the fiscal year 2001 - 2012.

Observer type	The fiscal year												Total	%
	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012		
DPC 11 ¹ staff	30	30	23	20	10	12	9	4	9	3	4	4	158	34.8
Municipality staff	14	17	16	10	5	6	0	0	0	0	0	0	68	15.0
Health center staff	42	34	50	32	24	12	3	1	3	0	0	0	201	44.3
Military nurse ²	1	1	0	0	1	1	0	0	0	0	0	0	4	0.9
VHV ³	5	6	6	2	0	0	0	0	0	0	0	0	19	4.2
Others ⁴	0	0	2	1	0	0	0	0	0	0	0	0	3	0.7
No observer ⁵	0	1	0	0	0	0	0	0	0	0	0	0	1	0.2
Total	92	89	97	65	40	31	12	5	12	3	4	4	454	100.0

Remarks: ¹DPC 11 = 11th Regional Office of Disease Prevention and Control, Nakhon Si Thammarat, Department of Disease Control, Ministry of Public Health, Thailand

²The nurses of Wachirawut Hospital, a military hospital in Muang district, Nakhon Si Thammarat, Thailand

³VHV = Village health volunteer

⁴Village leaders for two cases, and a member of a local government administration for one case.

⁵A primary defaulter did not return to get diagnosis and treatment even after many attempts to trace him were made.

Table 3 Treatment outcomes of new smear-positive TB patients registered at TB clinic of DPC 11¹ by DOT observer type, the fiscal year 2001 - 2012.

Observer type	Cured		Completed		Failure		Died		Defaulted		TO ²		Diagnosis changed ³		Total	
	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
DPC 11 ¹ staff	136	86.1	2	1.3	5	3.2	6	3.8	3	1.9	2	1.3	4	2.5	158	100.0
Municipality staff	57	83.8	1	1.5	1	1.5	3	4.4	3	4.4	3	4.4	0	0.0	68	100.0
Health center staff	152	75.6	8	4.0	5	2.5	15	7.5	15	7.5	5	2.5	1	0.5	201	100.0
Military nurse ⁴	3	75.0	1	25.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	100.0
VHV ⁵	17	89.5	1	5.3	0	0.0	0	0.0	1	5.3	0	0.0	0	0.0	19	100.0
Others	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	100.0
No observer	0	0.0	0	0.0	0	0.0	0	0.0	1 ⁶	100.0	0	0.0	0	0.0	1	100.0
Total	368	81.1	13	2.9	11	2.4	24	5.3	23	5.1	10	2.2	5	1.1	454	100.0

Remarks: ¹DPC 11 = 11th Regional Office of Disease Prevention and Control, Nakhon Si Thammarat, Department of Disease Control, Ministry of Public Health, Thailand

²TO = Transferred out

³4 cases = Non-tuberculous mycobacteria (NTM), 1 case = Non-TB infection

⁴VHV = Village health volunteer

⁵The nurses of Wachirawut Hospital, a military hospital in Muang district, Nakhon Si Thammarat, Thailand

⁶A primary defaulter

Discussion

The National TB Programme (NTB) of Thailand introduced rifampicin-containing short-course chemotherapy for TB patients in 1985 [11], but did not implement DOT. The first AIDS case in Thailand was reported in 1984 [6], which started to have a huge impact on the TB situation. The number of reported TB cases in Thailand slightly increased from 1988, and dramatically increased from 1996 [12]. In 1994, nearly all former ZTCs, or, later, TB clinics under DPC, introduced DOT by family member. The first external NTP review by the WHO and MoPH joint effort was conducted in 1995, and DOTS has since been recommended to combat TB in Thailand. Since the beginning of DOTS implementation, DOT in Thailand has been conducted by family members in most area. In addition to the recommendations of WHO and CDC that DOT observers should not be family members, our own experiences have also shown that almost all family members are unreliable as DOT observers, and are unable to produce a sustainable program. Therefore, a “non-family DOT model” has been developed since 1999 by collaborating with other organizations, such as provincial sectors and local municipalities. A one day training course for the staff of health centers has been conducted, and the model has then been implemented.

Even though the majority of the treated patients were in the younger age groups, highly possibly due to the impact of HIV epidemics and many other contributing factors, this figure could not reflect TB epidemiology in our catchment area, because there are many hospitals, both government and non-government, which also provided TB diagnosis and treatment. The numbers of patients registered at the TB clinic of DPC 11 decreased year by year due to the launching of the National Health Security Scheme (NHSS) in Thailand in 2002 [13] and the upgrading of the City Hospital, under the municipality, located near to our TB clinic, in 2004. Therefore, most suspected TB patients received medical services at the City Hospital and the Regional Hospital under the NHSS. However, services for suspected TB cases have still been promoted in the catchment area of Nakhon Si Thammarat Province’s Muang District in order to maintain the model and to demonstrate the case management of TB training courses conducted for health personnel involved in the NTP every year.

Even though the overall cure rate of 81.1 % could not meet the WHO target of 85 %, the DOT by DPC 11 staff could produce a high cure rate of 86.1 %. The overall completion rate was very low, and the failure rate was under 4 %, which was considered acceptable [8]. The death rate was 5.3 %, which was quite high; some of these deaths might be associated with HIV, and should be further investigated. The combination of default rate and transfer-out rate was 7.3 %, and was acceptable, because it was less than 10 % [14]. Therefore, the most unfavorable outcome that should be taken into account was the high death rate. Currently, according to the WHO recommendations [15], all TB patients registered at the TB clinic of DPC 11 receive voluntary counseling and testing for HIV infection (VCT), in order to find out whether they have a co-HIV infection which requires further comprehensive HIV care.

The proportion of the patients receiving DOT by all-type health staff (DPC11 staff, municipality staff, health center staff, and military nurses) was very high, 95.0 %, even in the urban setting. As a result, DOT service by health staff has been demonstrated to be possible and feasible in Thailand, including an urban setting. The key to success is the understanding of the health staff themselves of why they actually need to conduct DOT for TB patients [16]. Furthermore, good coordination among health service units is also necessary. However, our settings may differ from hospital settings, because our internal coordination is far less difficult than in hospitals. In addition, our TB patients were non-severe and non-complicated cases. Therefore, hospitals need to set up intensive internal coordination so that TB patients receive non-family DOT service at health centers near the patients' homes.

Moreover, the principles of TB control should be of concern while providing TB treatment [17]. For instance, DOT is a standard of care [7], and the health system is fully responsible for the patient cure - not the patient [18]; whenever the TB patients take rifampicin, they need to receive DOT [19]. Another key activity is that sufficient information is provided for TB patients to make them accept our DOT service. About half to 1 h of talking and negotiating may be required to convince the patients to agree. Important information that should be provided includes the severe side effects that may occur during the treatment course, and the highest chance of being cured with first-line TB drugs if they receive DOT. The patients and their relatives have been provided the opportunity to plan for intensive TB case management. All essential information should be asked for, such as their home mapping and telephone number. The DOT service has been provided, particularly in our clinic, everyday, including at weekends. The staff members of the health centers, the municipality, and the military hospital have been coordinated, in the event that patients need to receive DOT there. TB drugs are delivered to the appointed health service units as soon as possible, and TB patients themselves are not allowed to carry the TB drugs. The staff members of the municipality, health centers and the military hospital have also been encouraged to provide DOT service at weekends. A suitable DOT corner at our clinic has been set up for demonstration, and all the hospitals and health centers have been encouraged to set up DOT corners in order to facilitate DOT service. Patient appointments have been made for necessary sputum examinations throughout the treatment course. The monthly TB drug supply has been delivered to the health service units. If any TB patients get severe side effects, they will be referred to see the medical doctor to solve their problems. At the end of the treatment course, the patients have a chest x-ray and sputum examination, to evaluate the treatment.

From 2004 to 2008, the budgets supported by the Global Fund to fight AIDS, TB and Malaria (GFATM) - Round 1 - were allocated separately from the regular government budgets, and this encouraged us to develop our own practice guidelines for local health center staff [20], conduct additional necessary training courses, and strengthen supervision and DOTS meetings. In addition, financial supports were provided for some TB patients who actually needed it.

Thus, as long as rifampicin-containing short-course chemotherapy is necessary to treat TB patients, good program management is needed. This includes collaboration and coordination, particularly at the district level, to provide non-family DOT service, and to effectively cure TB patients, instead of conducting any more controlled trials for DOTS implementation.

In addition, the Department of CDC, MoPH of Thailand, needs to maintain and strengthen its own health services as it has the responsibility, not only for TB patients but also for all patients with significant communicable diseases, to demonstrate feasibility of implementation, and to let the department's manpower gain knowledge and experience to further support the provincial sectors.

Conclusions

The full-scale non-family DOT model has been developed since 2001 and demonstrated that the overall cure rate was 81.1 %. The proportion of the patients that received DOT by health staff was 95.0 %, even in the urban setting. The non-family DOT service has been demonstrated to be possible and feasible in Thailand. The key to success of conducting DOT service is the understanding of the staff.

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