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Practice of directly observed treatment (DOT) for tuberculosis in southern Thailand: comparison between different types of DOT observers

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SUMMARY

SETTING: A government health system in southern Thailand where the directly observed treatment, short-course (DOTS) strategy has been implemented.

OBJECTIVE: To compare the practice of actual directly observed treatment (DOT) and the observer sustainability for different types of observer.

METHODS: During 1999–2000, 411 patients with new smear-positive pulmonary tuberculosis were followed up. The patients and/or their observers were interviewed about the presence of any person with the patient during drug intake and the practice of watching the patient swallowing the medicine (actual DOT). Data were recorded monthly and analysed by Cox and logistic regression models.

RESULTS: For health personnel (HP), community member (CM), and family member (FM) observers, the proportions who did not practise actual DOT were respectively 11%, 23%, and 35%, and the proportions who changed to no observer or self administration were respectively 11%, 1%, and 2%, during the first 9 months of treatment. Health personnel had the lowest risk of not practising actual DOT (odds ratio HP/FM 0.1, 95%CI 0.1–0.2; CM/FM 0.9, 95%CI 0.5–1.6) but the highest risk for change to self administration.

CONCLUSION: To increase the coverage of actual DOT, strategies are needed to maintain health personnel as the DOT observers and to promote actual DOT among family member observers.

KEY WORDS: tuberculosis; compliance; directly observed treatment; Thailand

THAILAND is one of the 22 countries that have 80% of the estimated incident cases of tuberculosis (TB) in the world,[1] and one of the 10 countries with the highest prevalence of primary multidrug resistance.[2] When the World Health Organization (WHO) reviewed Thailand's National Tuberculosis Programme (NTP) in 1995, low cure rates were found (17%–68%).[3] The NTP adopted the directly observed treatment, short course (DOTS) strategy in 1996, and full DOTS coverage of all 810 districts in the country was planned by the year 2001.[4] Training in the DOTS strategy follows the modified WHO modules of managing TB at district level,[5] and involves TB coordinators, doctors and staff members of TB clinics, laboratory technicians, and health centre staff members. The cure rate in Thailand has improved, but it is still below the WHO target of 85%.[6]

The use of directly observed treatment (DOT), one element of the DOTS strategy, has been recommended for improving patient adherence to TB treatment.[7,8] Most studies, however, focus on the effect of DOT without providing data on compliance with DOT,[9] and when available, data on compliance with the DOT principle have not been quantified.[10,11]

Three main types of DOT observer are used in Thailand: health personnel (HP: staff members of TB clinics, hospital wards and health centres), community members (CM: village health volunteers, community leaders and friends), and family members (FM: close and distant relatives). Before starting the patients on treatment, TB clinic staff members are responsible for informing them about the disease, the treatment and DOT, and for selecting a DOT observer. As the national guidelines recommend that the preferred choice of observer is HP, CM, and FM, in descending order,[12] they try to convince patients to take their drugs at a TB clinic or health centre during weekdays. However, the choice of DOT observers and places generally depends on negotiation, and the majority of assigned DOT observers are family members.[13,14] Comparative data on compliance with DOT for these three types of observer are not available.

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For these reasons, we examined the practice of DOT and compared compliance with the DOT principle between the different types of observer available for monitoring TB treatment in southern Thailand. The comparison focused on the risk of not practising actual treatment observation, and the risk of changing from having an observer to having no observer.

STUDY POPULATION AND METHODS

Study population and design

The study area covered 1.2 million people in 24 districts in southern Thailand. Through the TB Registers at the 22 TB clinics (one Zonal TB Centre, one regional hospital, three general hospitals, and 17 community hospitals), we identified and followed up all 455 patients with new smear-positive pulmonary TB according to WHO criteria,[15] who started treatment between 1 February and 30 September 1999.

Treatment

As recommended by the WHO,[15] the standard daily drug regimen consisted of a 2-month initial phase of four drugs (isoniazid, rifampicin, pyrazinamide and ethambutol) and a 4-month continuation phase of two drugs (isoniazid and rifampicin). Treatment was given three times weekly for 21 patients at the Zonal TB Centre, while the other clinics used daily regimens. If the sputum still contained acid-fast bacilli (AFB) at the end of the second month, the initial phase was extended for 1 or 2 months. For patients who could not tolerate the standard treatment, the drug regimen was changed to a 9-month regimen without pyrazinamide, or to an 18-month regimen without rifampicin or pyrazinamide.

Assigned DOT observer, practical observer and actual DOT

Assigned DOT observers were chosen by the TB clinic staff members on the first day of treatment. In practice, the person who actually stays with the patient during drug intake, defined as a 'practical observer', may or may not be the same as the assigned observer. The practical observer may change over time, or may stop observing, which is equal to treatment with no observer. When more than one type of observer was involved during a given month, the one with the highest frequency of being the observer in that month was used in the analyses. For each dose of drug intake, DOT was considered to be 'actual DOT' only if the practical observer watched the patient swallow the drugs. Other practices, such as staying with the patient during drug intake, preparing the drugs for patients, or reminding patients about drug intake without watching, were classified as 'actual non-DOT'.

Data collection

The patient records and registers relevant to TB were reviewed. In addition, the patients and/or their observers were interviewed by the first author (PP) and/or one of 24 health professionals working in the study TB clinics. There were two planned interviews per patient, at least one month after starting the treatment and at the end of treatment. Data on the practical observer and actual DOT practice were recorded for each month until the end of treatment (data shown only for the first 9 months).

Data management and statistical analysis

Compliance with the DOT principle and sustainability of observer were our two outcome variables; the unit of analysis was patient-month. For the compliance with the DOT principle, an odds ratio (OR) of no practice divided by practice of actual DOT for any dose during each month was compared between the different types of practical observer. As the compliance each month varied over time in the same patient, logistic regression with population-average model and exchangeable intra-subject correlation was used to deal with the repeated measures.[16,17]

For the observer sustainability, the outcome of interest was a change from having an observer to having no observer. Time to outcome (change to self administration) was estimated, and the hazard ratio (HR) was computed between the different types of practical observer in a Cox proportional hazard model.[18] Censoring occurred at the time of death, treatment interruption, transfer to another area, end of treatment, or end of follow-up (31 July 2000), whichever came first.

The main predictors were the types of practical observer: health professional, community member, or family member. A number of covariates were considered as potential confounders and divided into three groups: 1) demographic and socio-economic characteristics (sex, age, marital status, ethnic group, formal education, understanding of Thai language, income, ability to take time out of work/study, number of living places, and independent means of travel), 2) health services (type of TB clinic, use of fixed-dose combinations, and initial DOT assignment), and 3) disease condition (initial weight, initial AFB result, initial drug resistance, human immunodeficiency virus (HIV)/acquired immune-deficiency syndrome (AIDS) status, and other co-morbidity, including heart disease, hypertension, cerebrovascular accident, diabetes mellitus, psychosis, alcoholic consumption, liver cirrhosis, drug abuse and imprisonment).

We identified associations between two variables by cross-tabulation and by using Pearson's χ^2 test. Variables that were associated with the specific outcome ($P < 0.05$) were selected for testing in the models. Four specific models of increasing numbers of covariates were applied to determine the association between the exposure and the outcome, 1) without covariates, 2) with inclusion of the first group of covariates, 3) with inclusion of the first and second

Table 1 Type of DOT observer during treatment

Month*	A	0	1	2	3	4	5	6	7	8	9	End
Number of patients being treated	411	411	402	391	375	366	353	61	23	9	5	411
Observer type												
Health personnel	177	94	74	52	38	29	25	3	0	0	0	28
Community member	21	31	30	32	32	30	28	6	2	1	1	30
Family member	181	210	219	225	217	210	203	36	16	4	2	233
Self administration	32	76	79	82	88	97	97	16	5	4	2	120

* Month: A = initially assigned observer (data from the records); 0-End = practical observer (data from the interviews): 0 = at the start of treatment, 1–9 = at the end of that month, End = at the end of the final month which varied according to the different periods of received treatment (standard regimen: 6 months; extended or changed regimen: 7–18 months; incomplete treatment: death, interruption, transfer to another area, or failure.). Five patients who received long-course chemotherapy were still on treatment after 9 months.
DOT = directly observed treatment.

groups of covariates, and 4) with inclusion of all three groups of covariates. At each step at which additional covariates were incorporated, only those that fulfilled the following criteria were retained: 1) having a significant association with the outcome (Wald test, $P < 0.05$) or 2) being associated with the outcome ($P < 0.1$) and leading to a change of more than 15% of OR or HR for any observers in the larger model, if removed.

The confounders for the effect of the practical observer on each outcome were controlled by multivariate analysis. The results were presented as OR and HR with 95% confidence interval (95%CI) of no practice over practice of actual DOT and change to self administration, respectively. Hosmer-Lemeshow statistic was used to check the fit of the logistic regression models.[19] Likelihood ratio tests were used to determine the significance of the presence of covariates in the Cox regression models. A *P* value of less than 0.05 was considered statistically significant. All analyses were done using STATA.[20]

RESULTS

Of the 455 patients enrolled, 44 were excluded because the interviewer was unable to establish contact with them or their DOT observers. Compared with the remaining patients, the excluded patients were younger (median age 31 vs. 42 years), more likely to have HIV/AIDS (27% vs. 11%), and more often treated at a general or regional hospital (48% vs. 29%).

The remaining 411 patients were 6 to 86 years of age (mean 44, SD [standard deviation] 17), and 75% were male. Of the 323 patients with data available on income, 76% earned less than the official minimal daily wage in the study area (about 3.5 US$).

Initially assigned observer vs. practical observer

The distribution of patients by type of initially assigned and practical observer is shown in Table 1. The numbers decreased markedly by the end of the sixth month, as 71% of 411 patients reached cure or treatment completion. Of 379 patients assigned to an observer, 212 (56%) changed their initially assigned observers during the treatment period, and 130 did so on the day of assignment. Of 177 patients assigned to health personnel, 84 changed on the day of assignment. Most changes during treatment (84%) were toward a less preferred category according to the national guidelines.

No practice of actual DOT

During the first 5 months of treatment, the proportions of patients who practised no actual DOT were between 7%–15% among HP, 20%–26% among CM, and 32%–38% among FM observers (Table 2). The adjusted OR of no practice over practice of actual DOT was similar between CM and FM, but was only about 1/8 among HP over FM (Model 4 in Table 3). The OR in non-FM (CM+HP) compared with FM was 0.3 (95%CI 0.2–0.5).

The odds of no practice of actual DOT were higher among patients who had no formal education, who had a higher income, who were treated at a general or regional hospital, or who had no other co-morbidity.

Change to no observer

During the first 5 months of treatment, between 10%–16% of patients with HP observers changed to

Table 2 No practice of actual DOT during the first 9 months of treatment by type of observer

Type of practical observer	Month of treatment*								
	1	2	3	4	5	6	7	8	9
Family member	72/223	78/234	80/224	76/213	79/207	77/202	6/32	3/15	0/5
Community member	8/31	8/32	7/32	7/31	6/30	6/26	1/5	0/1	—
Health personnel	5/75	7/52	6/39	4/30	3/26	3/24	0/3	—	—

* No. of patients with no practice of actual DOT/No. of patients analysed in that month.
DOT = directly observed treatment.

Table 3 Odds ratios of not practising actual DOT: crude and adjusted analyses

Included variable	Actual DOT* No	Actual DOT* Yes	Odds ratios (95% confidence interval)† Crude Model 1	Adjusted analyses Model 2	Model 3	Model 4
Practical observer						
Health personnel	28	221	0.13 (0.07–0.24)‡	0.12 (0.06–0.21)‡	0.14 (0.07–0.26)‡	0.13 (0.07–0.24)‡
Community member	43	145	0.64 (0.39–1.05)	0.63 (0.38–1.04)	0.88 (0.50–1.53)	0.90 (0.51–1.58)
Family member	471	884	1	1	1	1
Formal education						
Educated	396	1018	—	0.54 (0.36–0.82)‡	0.55 (0.36–0.84)‡	0.57 (0.37–0.87)‡
None	147	232	—	1	1	1
Minimal income						
>Minimal daily wage	122	209	—	2.31 (1.48–3.62)‡	2.40 (1.51–3.81)‡	2.38 (1.49–3.80)‡
<Minimal daily wage	293	810	—	1	1	1
No information	128	231	—	1.88 (1.23–2.87)‡	2.42 (1.53–3.81)‡	2.73 (1.71–4.34)‡
Independent travel						
Travel alone	368	780	—	1.48 (1.03–2.12)‡	1.36 (0.94–1.98)	1.31 (0.90–1.91)
Travel with other	175	470	—	1	1	1
TB clinic						
Community hospital	329	736	—	—	0.62 (0.42–0.90)‡	0.58 (0.39–0.86)‡
General/regional hospital	183	291	—	—	1	1
Zonal TB centre	31	223	—	—	0.18 (0.09–0.39)‡	0.23 (0.11–0.49)‡
Co-morbidity						
Yes	73	329	—	—	—	0.41 (0.25–0.65)‡
No	470	921	—	—	—	1

* Number of patient-months with actual DOT: No = no practice of actual DOT; DOT = practice of actual DOT for any dose.
† Model 1 = crude analysis; Model 2 = Model 1 + demographic and socio-economic covariates; Model 3 = Model 2 + covariates related to health services; Model 4 = Model 3 + covariates related to disease condition.
‡ $P < 0.05$.
DOT = directly observed treatment.

self administration, compared to 0%–3% with CM and 0.5%–4% with FM observers (Table 4). The risk of change to self administration was four-fold higher among HP over FM, but was only about a half among CM compared with FM (Model 2 in Table 5, Figure). The relative risk for change in the non-FM compared with the FM group was 2.6 (95%CI 1.5–4.5).

Change to self administration was about two-fold more likely among patients who had no living partner than those with a living partner, and about 2.6-fold more likely among patients who lived in more than one place than those who lived in only one place during treatment.

DISCUSSION

Compliance with the DOT principle was poor. HP observers practised actual DOT more often than CM or FM observers. However, changing from HP observer to self administration occurred more frequently than changing from other types of observer to self administration.

DOT has been recommended for all patients with TB because of the expected difficulties in predicting whether a patient will adhere to treatment.[7,8] However, in practice, the reality is different. The proportion of patients with no observer assignment was high (34%) in a previous study in north-eastern Thailand,[14] compared with 8% in our study. A higher proportion of patients with observer assignment may suggest greater agreement with DOT among service providers. The remaining non-assignment was claimed to be due to a lack of suitable observers in this study. This challenges the feasibility of trying to implement DOT for all.[21,22]

The national guidelines recommend HP as the first choice of observer, but HPs are not always available or accepted by the patients. A study from India

Table 4 Changing to no observer during the first 9 months of treatment by type of observer

Type of practical observer	Month of treatment* 1	2	3	4	5	6	7	8	9
Family member	4/219	10/225	7/217	3/210	1/203	0/36	1/16	0/4	—
Community member	0/30	1/32	1/32	0/30	0/28	0/6	0/2	0/1	—
Health personnel	8/74	5/52	6/38	3/29	3/25	0/3	—	—	—

* No. of patients with change to self administration/No. of patients analysed in that month.

Table 5 Hazard ratios of changing to no observer: crude and adjusted analyses

Included variable	Change to SA* Yes	Change to SA* No	Hazard ratio (95% confidence interval)† Crude Model 1	Adjusted analyses Model 2	Adjusted analyses Model 3	Adjusted analyses Model 4
Practical observer						
Health personnel	25	196	4.98 (2.85–8.68)‡	4.19 (2.38–7.36)‡	4.66 (2.51–8.64)‡	4.54 (2.43–8.49)‡
Community member	2	159	0.53 (0.13–2.22)	0.46 (0.11–1.93)	0.53 (0.12–2.27)	0.54 (0.13–2.34)
Family member	26	1104	1	1	1	1
Living partner						
Having no partner	28	415	—	2.16 (1.25–3.74)‡	2.18 (1.26–3.79)‡	2.16 (1.25–3.75)‡
Having partner	25	1044	—	1	1	1
Living place						
Only one	23	419	—	0.39 (0.23–0.67)‡	0.38 (0.22–0.66)‡	0.38 (0.22–0.67)‡
More than one	23	1040	—	1	1	1
TB clinic						
Community hospital	21	875	—	—	0.55 (0.29–1.02)	0.53 (0.28–1.00)‡
General/regional hospital	19	381	—	—	1	1
Zonal TB centre	13	203	—	—	0.53 (0.24–1.14)	0.51 (0.23–1.11)
HIV/AIDS						
Yes	10	136	—	—	—	1.27 (0.62–2.60)
No	43	1323	—	—	—	1
Log likelihood			−284.90	−274.55	−272.47	−272.27
Degrees of freedom			2	4	6	7

* Number of patient-months with change to no observer or self-administration.
† Model 1 = crude analysis; Model 2 = Model 1 + demographic and socio-economic covariates; Model 3 = Model 2 + covariates related to health services; Model 4 = Model 3 + covariates related to disease condition.
‡ $P < 0.05$.
SA = self administration; HIV = human immunodeficiency virus; AIDS = acquired immune-deficiency syndrome.

showed that HPs were assigned to all patients but without an alternative, and that 27% of 200 patients did not or could not attend the clinic as scheduled.[23] Outreach approaches have been used in New York City to solve the problem of low accessibility of HP-DOT, but this requires more staff and supervision.[24] In our setting, with its financial limitations, incentives or outreach approaches were rarely used, and patients had to bear all the costs of travel. For patients with limited income or with limited options for transport, it was clearly not feasible to assign HP-DOT without an alternative. As about half of the HP observer assignments were immediately rejected, acceptability may be an additional obstacle to accessibility.

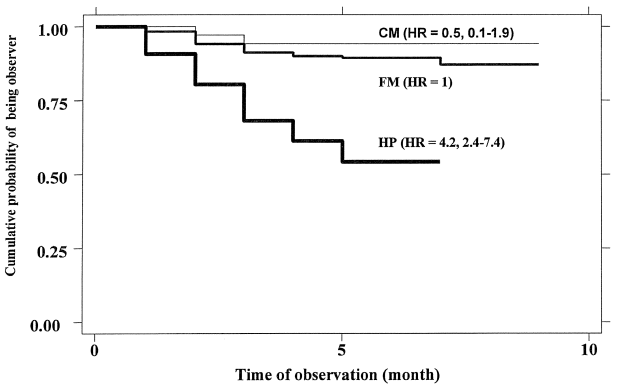

Figure Survival curve for each type of observer during 9 months of treatment. HR = hazard ratio of changing to having no observer adjusted for having/not having a living partner, number of living places, type of TB clinic, and HIV/AIDS status. CM = community member; FM = family member; HP = health personnel.

As in the study from India,[23] modification of HP-DOT occurred. Some patients met their health workers once or twice weekly or monthly because they were unable, or unwilling, to visit the hospital or health centre every day. In other cases, assigned health personnel transferred their observer role to community and/or family members. Applying an intermittent regimen apparently improved the sustainability of HP-DOT, but the benefit was not statistically significant (data not shown). Sustaining HP observers was not only a result of the patients' accessibility and willingness to accept a HP observer, but it was also associated with monitoring the DOT observer in practice and the providers' ability to counteract non-compliance.

Using community members is a promising alternative because good outcomes have been reported,[25–27] although there are no data available on actual DOT. In our setting, CM observation changed to self administration less often than non-CM, and CMs complied with the DOT principle better than FMs. However, CMs were less often assigned. The sustainability of increasing assignment to this group may need further exploration.

The Centers for Disease Control and Prevention in

the United States suggest that family members may not make good observers due to emotional ties.[7,15] Family bonds in our setting may, however, have more advantages than disadvantages with regard to general care and psychological support. The reason for not practising actual DOT was not family bonds but a lack of perceived need, and FM observation may be the only remaining option for the patients with poor performance status. Supervision of FM observers, with staff members of TB clinics or health centres making unannounced home visits, has been applied in Thailand, but the effectiveness of this activity has not yet been reported.

Our study may be subject to information bias. Misclassification of observers was often inevitable when there was more than one observer in a month. DOT practice could be overstated in the interviews because patients and observers considered the interviewers as health personnel. The 'practice of actual DOT' group included patients who practised actual DOT for any doses, and it may have included undisclosed 'no practice of actual DOT', which would bias our estimates. Furthermore, data were missing for 44 cases who were more often assigned to HP (60% vs. 43%) and more often assigned to CM (11% vs. 5%) than the patients included in the analyses. If the non-FM group maintained the observer status but did not practise actual DOT, we may have overestimated the compliance with the DOT principle among non-FM compared with FM groups.

CONCLUSIONS

Actual DOT practice was quite different from the initial assignment. Actual DOT was more often reported for health personnel than for other types of observer, but it was more difficult to maintain health personnel as observers. To improve the coverage of actual DOT, strategies to enhance the sustainability of health personnel observers and the practice of actual DOT among family member observers are needed.

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RÉSUMÉ

CONTEXTE : Le système de santé gouvernemental en Thaïlande du Sud avec la mise en œuvre d'une stratégie de traitement directement observé et de courte durée.
OBJECTIF : Comparer les pratiques réelles du traitement directement observé (TDO) et la possibilité de maintenir un observateur selon les différents types d'observateurs.
MÉTHODES : Ont été suivis en 1999 et 2000, 411 nouveaux patients atteints d'une tuberculose pulmonaire à bacilloscopie positive. Les patients et/ou leurs observateurs ont été interviewés au sujet de la présence d'une personne quelconque à côté du patient au cours de la prise du médicament et au sujet des pratiques de surveillance de la déglution du médicament par le patient (TDO réel). Les données ont été enregistrées mensuellement et analysées par les modèles de Cox et de régression logistique.
RÉSULTATS : Au cours des 9 premiers mois de traitement, les proportions de sujets ne pratiquant pas un TDO réel ont été respectivement de 11%, de 23% et de 35% pour le personnel de santé (HP), les membres de la collectivité (CM) et les membres de la famille (FM) ; la proportion de sujets qui sont passés à une administration sans observateur ou à une auto-administration a été respectivement de 11%, de 1% et de 2%. C'est le personnel de santé qui avait le risque le plus faible de ne pas recourir à un TDO réel (odds ratio HP/FM 0,1 ; IC95% 0,1–0,2 ; CM/FM 0,9 ; IC95% 0,5–1,6), mais le risque le plus élevé de passer à l'auto-administration.
CONCLUSION : Pour augmenter la couverture par un TDO réel, des stratégies s'imposent pour maintenir le personnel de santé comme observateur du TDO et pour pousser à un TDO réel les observateurs familiaux.

RESUMEN

MARCO DE REFERENCIA : El sistema de salud gubernamental de Tailandia del Sur, con la implementación de una estrategia de tratamiento directamente observado de corta duración (DOTS).
OBJETIVO : Comparar la práctica del tratamiento directamente observado (TDO) real y la permanencia del observador junto al paciente a lo largo del tratamiento, según los diferentes tipos de observadores.
MÉTODO : Se practicó el seguimiento de 411 pacientes nuevos con tuberculosis pulmonar con baciloscopia positiva, en 1999–2000. Se entrevistaron a los pacientes y/o a sus observadores acerca de la presencia de cualquier persona que hubiera permanecido con el paciente durante la toma de los medicamentos y acerca de la práctica de supervisión de la deglutición de los medicamentos (TDO real). Los datos fueron registrados mensualmente y analizados por los modelos de Cox y de regresión logística.
RESULTADOS : Durante los primeros 9 meses de tratamiento, se constató que la proporción de observadores que no realizaban el TDO real era de 11% para el personal de salud (HP), 23% para los miembros de la comunidad (CM) y de 35% para los miembros de la familia (FM) ; la proporción de sujetos que pasan a un tratamiento sin observador o a una autoadministración era de 11%, 1% y 2%, respectivamente. El personal de salud tenía el riesgo más bajo de no practicar el TDO real (odds ratio : HP/FM 0,1 ; IC95% 0,1–0,2 ; CM/FM 0,9 ; IC95% 0,5–1,6), pero el riesgo más alto para cambiar a la autoadministración.
CONCLUSIÓN : Se necesitan estrategias para mantener el personal de salud como observadores del TDO y promover el TDO real entre los observadores familiares, a fin de aumentar la cobertura del TDO real.