Risk factors for unfavourable treatment outcome among new smear-positive pulmonary tuberculosis cases in China

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Setting: Three projects of the Fund for Innovative DOTS Expansion through Local Initiatives to Stop TB.

Objectives: To assess unfavourable treatment outcomes (UTOs), including failure, died, loss to follow-up (LTFU), transferred out and unknown outcome, and to identify risk factors associated with UTOs.

Design: This was a cross-sectional study using routine programme data.

Results: Of 30277 new smear-positive tuberculosis (TB) patients, 4261 (14.1%) had UTOs: 2048 (6.8%) LTFU, 1418 (4.7%) transferred out, 390 (1.3%) died, 340 (1.1%) failed and 65 (0.2%) had an unknown outcome. Risk factors for LTFU (including LTFU, transfer out and unknown outcome) were residing in Anhui, age > 55 years, service delay > 10 days, patient delay < 30 days, directly observed treatment (DOT) provided by a family member or others and unknown DOT provider. The outcome of 'died' was associated with residing in Shaanxi, age > 55 years, male sex, patient delay > 30 days and unknown DOT provider. 'Failed' was associated with having unlimited access to health services, patient delay of >30 days and unknown DOT provider.

Conclusion: This study highlights the predominance of lost patients among UTOs. Patients with family members or other non-medical DOT providers or unknown DOT providers had a high risk of a UTO. There is an urgent need to address these service-related factors.

Over the last 20 years, China has implemented the DOTS model for tuberculosis (TB) control and has achieved substantial reductions in its TB burden.¹ The prevalence of smear-positive pulmonary TB decreased from 134 per 100000 population in 1990 to 66/100000 in 2010.² Case detection rates have been reported to be >85% and treatment success rates in new smear-positive (NSP) pulmonary TB patients to be >90%.¹ TB nevertheless remains a major public health problem in China despite these improvements, with 0.8–1.0 million TB cases notified every year, the third largest number in the world after India and Indonesia.¹ Furthermore, multidrug-resistant TB (MDR-TB) was diagnosed among 5.7% of new TB patients and among 25.6% of previously treated patients.³

Even with a high reported treatment success rate, there is a considerable absolute number of cases each year among NSP patients with reported unfavourable treatment outcomes (UTOs): treatment failure, death, loss to follow-up (LTFU), transfer out and unknown

outcome.¹ Those with an UTO, especially failure and LTFU, are a public health concern, as they may have developed drug resistance and may remain infectious and continue to transmit the disease in the population. Furthermore, several small-scale studies have raised concern about the quality of directly observed treatment (DOT) in China, as well as problems with staff performance in patient management.^{4,5} Identifying and addressing preventable risk factors for unsuccessful treatment is therefore critical to prevent drug resistance, control infection transmission, improve national and sub-national TB control programmes, and contribute towards eliminating TB in China and worldwide.

This study aimed to determine the proportion of UTO among NSP patients, and identify the factors linked to this outcome through an analysis of routinely reported information from a large-scale intervention project across provinces. This paper reports findings among 30277 NSP patients detected in three FIDELIS (Fund for Innovative DOTS Expansion through Local Initiatives to Stop TB) projects in China from 2004 to 2008.

METHODS

The FIDELIS projects were intervention projects funded by the Canadian government that aimed to increase the NSP case detection rate in areas of poverty. Details of the design, setting, sites, patients, interventions, data collection and ethics review of the FIDELIS projects have been published elsewhere.⁶ Of the 15 FIDELIS projects in China, we report here the findings from three projects, the Anhui (middle east), Guizhou (south west) and Shaanxi (north west) projects, which were implemented from 2004 to 2008.

Tuberculosis services

TB patients were registered according to the guidelines of the China National TB Programme (NTP) and managed in public health TB dispensaries.⁷ Treatment regimens and anti-tuberculosis drug formulations were in accordance with those recommended by the World Health Organization (WHO) and the NTP guidelines.⁸ The standardised treatment regimen consisted of 2 months of thrice-weekly isoniazid, rifampicin, pyrazinamide and ethambutol, followed by 4 months of thrice-weekly isoniazid and rifampicin.

Patient management

Patients were requested to return monthly to evaluate their response to treatment and to collect their an-

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ti-tuberculosis drugs. DOT was provided by rural doctors/other medical staff, family members or others who were members of the same community; neighbours, for example, or someone assigned by the village head, but not family members or relatives, according to local practice. Sputum smear status was reassessed at the follow-up visits, which took place at months 2, 3, 5 and 6 of treatment. Because the patients were managed within FIDELIS, which aimed to improve treatment outcomes among people with limited access to health services (PWLHAHS), a specially designed information form was completed for the purpose of the project.

Definitions

New smear-positive (NSP): a smear-positive patient who had never had treatment for TB for longer than 1 month in the past. Treatment success: bacteriologically confirmed cure or a completed course of treatment without bacteriological proof of cure. UTO includes those reported as failure, death and loss (LTFU, transfer out and unknown outcome). On the pre-testing evaluation, of 19 patients classified as transferred out, only one arrived and was registered in the assigned TB dispensary. We therefore classified those reported as transferred out and those with unknown treatment outcomes in the UTO category. PWLAHS: the project used a specifically designed questionnaire to evaluate the time interval from the earliest symptom onset to initiation of TB treatment and the type of health care providers visited. If the total value of the score in either section was 13 points or higher, the patient was classified as PWLAHS.⁶

Study measures

Treatment outcome is a time-related sequence. Ideally, anti-tuberculosis treatment outcomes would be analysed using a survival analysis which necessitates the availability of dates when certain events have taken place. In this study, it was unfortunately not possible to carry out a survival analysis. We consequently chose to analyse the data in a step-wise fashion that we considered logical in terms of the treatment process. We analysed each succeeding outcome, excluding those earlier in the list. For example, an analysis of 'failed' was a comparison of those recorded as failed compared with all other outcomes, excluding died, lost to follow-up, transferred and unknown outcome.

Data analysis and statistics

Patient data were double-entered into an EpiData v. 3.1 database (EpiData Association, Odense, Denmark) without names, addresses or any other personal identifiers. Categorical variables were analysed using the χ^2 test. Stepwise logistic regression models were constructed to assess factors associated with specific UTOs. Where outcomes were unknown, for example, we compared the unknown outcome with all known outcomes prior to comparing the presence and absence of the factor, excluding the unknown. The data were cross-tabulated and 95% confidence intervals (CI) were determined. $P < 0.05$ was considered statistically significant.

RESULTS

The records of 30304 NSP patients were obtained, of which 27 were excluded because anti-tuberculosis treatment was incomplete. A final total of 30277 NSP patients were included in the study.

Table 1 provides a description of the demographic and service-related characteristics of the NSP patients. There was a predominance of male sex, younger age and rural residence. The ma-

TABLE 1 Demographic and service-related characteristics of new smear-positive pulmonary TB patients in the three FIDELIS projects in China

	Total <i>n</i> = 30 304 <i>n</i> (%)	Cohort <i>n</i> = 30 277 <i>n</i> (%)	On treatment <i>n</i> = 27 <i>n</i> (%)
Age group, years			
0–54	19 185 (63.3)	19 167 (63.3)	18 (66.7)
≥55	11 119 (36.7)	11 110 (36.7)	9 (33.3)
Sex			
Female	9 074 (29.9)	9 060 (29.9)	14 (51.9)
Male	21 230 (70.1)	21 217 (70.1)	13 (48.1)
Residence			
Rural	25 876 (85.4)	25 856 (85.4)	20 (74.1)
Urban	4 428 (14.6)	4 421 (14.6)	7 (25.9)
Access to health services			
Limited	20 783 (68.6)	20 758 (68.6)	25 (92.6)
Not limited	9 407 (31.0)	9 407 (31.1)	0
Unknown	114 (0.4)	112 (0.3)	2 (7.4)
Patient delay, days			
0–30	8 183 (27.0)	8 180 (27.0)	3 (11.1)
>30	22 121 (73.0)	22 097 (73.0)	24 (88.9)
Diagnosis level			
Specialist	26 767 (88.3)	26 766 (88.4)	1 (3.7)
County	2 158 (7.2)	2 134 (7.1)	24 (88.9)
Township	945 (3.1)	944 (3.1)	1 (3.7)
Others	434 (1.4)	433 (1.4)	1 (3.7)
Service delay, days			
0–10	25 140 (83.0)	25 117 (83.0)	23 (85.2)
>10	5 164 (17.0)	5 160 (17.0)	4 (14.8)
2-month smear			
Negative	26 131 (86.2)	26 112 (86.2)	19 (70.4)
Positive	1 639 (5.4)	1 638 (5.4)	1 (3.7)
Not done	2 477 (8.2)	2 470 (8.2)	7 (25.9)
Unknown	57 (0.2)	57 (0.2)	
DOT			
Health staff	18 248 (60.2)	18 248 (60.3)	0
Others	2 119 (7.0)	2 119 (7.00)	0
Unknown	9 937 (32.8)	9 910 (32.7)	27 (100.0)

TB = tuberculosis; FIDELIS = Fund for Innovative DOTS Expansion through Local Initiatives to Stop TB; DOT = directly observed treatment.

majority of the patients (20 758, 68.6%) were judged to be PWLAHS, 22 097 (73.0%) had delays of >30 days in seeking care after the onset of symptoms and 26 766 (88.4%) were diagnosed in specialist care facilities. There was one important difference among the three project sites in terms of the number of patients regarded as PWLAHS: the proportion of PWLAHS in Anhui was 49.5%, while it was 80.1% in Guizhou and 94.2% in Shaanxi ($P < 0.001$).

Of the 30 277 NSP patients, the majority of the records (24 136, 79.7%) indicated bacteriologically confirmed cure, with 4 261 (14.1%) having a UTO (Table 2).

Of the various UTOs, 82.9% were lost (LTFU, transferred out or unknown outcome); the association of risk factors is presented in Table 3. Risk factors for losing a patient were living in Anhui province, age ≥ 55 years, a service delay of >10 days, a patient delay of <30 days and those with DOT provided by a family member or other non-medical staff or an unknown DOT provider.

Among other UTOs, after adjusting for possible confounding factors the outcome 'died' was more frequently associated with

TABLE 2 Treatment outcome by project, three FIDELIS projects in China, 2004–2008

							Transferred out n (%)	Unknown outcome n (%)	
Anhu	14 343	10 255 (71.5)	1 153 (8.0)	169 (1.2)	107 (0.8)	1 377 (9.6)	1 282 (8.9)	0	<0.001
Guizhou	9 512	7 948 (83.5)	492 (5.2)	157 (1.6)	217 (2.3)	569 (6.0)	64 (0.7)	65 (0.7)	
Shaanxi	6 422	5 933 (92.4)	235 (3.7)	14 (0.2)	66 (1.0)	102 (1.6)	72 (1.1)	0	
Total	30 277	24 136 (79.7)	1 880 (6.2)	340 (1.1)	390 (1.3)	2 048 (6.8)	1 418 (4.7)	65 (0.2)	

*The χ^2 test was used for comparison of the difference in each specific treatment outcome among sites.

FIDELIS = Fund for Innovative DOTS Expansion through Local Initiatives to Stop Tuberculosis; LTFU = loss to follow-up.

TABLE 3 Univariate and multivariate analysis of risk factors associated with lost to follow-up treatment outcome*

	Total n†	Other n	Lost* n (%)	Unadjusted OR (95%CI)	Adjusted OR (95%CI)
Total	30 277	26 746	3 531 (11.7)		
Site			0		
Anhui	14 343	11 684	2 659 (18.5)	1	
Guizhou	9 512	8 814	698 (7.3)	0.348 (0.319–0.380)	0.094 (0.076–0.117)
Shaanxi	6 422	6 248	174 (2.7)	0.122 (0.105–0.143)	0.154 (0.131–0.182)
Age group, years					
0–54	19 167	17 435	1 732 (9.0)	1	
≥55	11 110	9 311	1 799 (16.2)	1.945 (1.812–2.087)	1.498 (1.387–1.619)
Sex					
Female	9 060	8 062	998 (11.0)	1	
Male	21 217	18 684	2 533 (11.9)	1.095 (1.013–1.184)e	
Residence					
Rural	25 856	22 779	3 077 (11.9)	1	
Urban	4 421	3 967	454 (10.3)	0.847 (0.763–0.940)	
Access to health services					
Limited	20 758	18 559	2 199 (10.6)	1	
Not limited	9 407	8 091	1 316 (14.0)	1.373 (1.276–1.477)	0.553 (0.503–0.609)
Unknown	112	96	16 (14.3)	1.407 (0.827–2.392)	1.611 (0.936–2.773)
Patient delay, days					
0–30	8 180	7 116	1 064 (13.0)	1	
>30	22 097	19 630	2 467 (11.2)	0.841 (0.778–0.908)	0.848 (0.769–0.936)
Diagnosis level					
Specialist	26 766	23 629	3 137 (11.7)	1	
Other	3 511	3 117	394 (11.2)	0.952 (0.852–1.064)	
Service delay, days					
0–10	25 117	22 252	2 865 (11.4)	1	
>10	5 160	4 494	666 (12.9)	1.151 (1.052–1.260)	1.359 (1.201–1.492)
DOT provider					
Medical staff	18 248	16 524	1 724 (9.5)	1	
Other	2 119	1 186	933 (44.0)	7.540 (6.829–8.325)	6.428 (5.773–7.157)
Unknown	9 910	9 036	874 (8.8)	0.927 (0.851–1.010)	5.586 (4.535–6.880)

*LTFU, transferred out and unknown vs. other treatment outcomes.

†Cohort total, not including the 27 patients who were still on treatment.

LTFU = loss to follow-up; OR = odds ratio; CI = confidence interval; DOT = directly observed treatment

living in Shaanxi province (odds ratio [OR] 1.71, 95%CI 1.23–2.37), age ≥ 55 years (OR 3.92, 95%CI 3.17–4.84), male sex (OR 1.31, 95%CI 1.03–1.65), patient delay > 30 days (OR 1.47, 95%CI 1.12–1.91) and unknown DOT provider (OR 9.87, 95%CI 5.56–17.56).

The risk factors associated with the outcome ‘failed’ were being non-PWLAHS (OR 1.51, 95%CI 1.18–1.94), patient delay > 30 days (OR 2.15, 95%CI 1.59–2.91) and unknown DOT provider (OR 2.27, 95%CI 1.05–4.91), but were less likely to be associated

with living in Shaanxi (OR 0.16, 95%CI 0.09–0.28) and having DOT provided by a family member or others (OR 0.33, 95%CI 0.15–0.70).

DISCUSSION

To our knowledge, this is the first in-depth analysis on UTO from a routine programme setting. We recruited all of the NSP patients detected from the FIDELIS intervention projects to avoid any se-

lection bias. The large sample size and the fact that individual patient data rather than aggregate data were analysed are particular strengths of this study.

The main finding of this study was that DOT provided by persons other than medical/health staff or unknown DOT providers were independently confirmed as being risk factors for LTFU. Furthermore, 'unknown DOT provider' was strongly associated with death and treatment failure. As successful treatment for TB depends not only on a standardised treatment regimen, but also on good patient adherence and patient support during the 6-month course of anti-tuberculosis treatment, this finding suggests scope for further improvement in treatment outcomes among NSP patients; national and sub-national TB programmes need to pay more attention to this factor.

Our study confirmed a high rate of treatment success among NSP patients, indicating achievement of the WHO treatment target.¹ Anhui had a significantly higher risk of LTFU than Guizhou and Shaanxi. Anhui, a large province situated close to the east coast, was the first province to introduce rural reform, which boosted migration. It had a higher proportion of LTFU and transfer-out than the other projects, which might be partially due to population migration.

Our finding of inaccuracies in the recording of patients who were transferred out led us to classify this factor as a UTO. Similar challenges have been highlighted in other studies.¹¹ Several studies in China have identified that migrants had long delays in accessing health services and had poor treatment outcomes after being diagnosed with TB.^{12,13}

One study in India reported that older TB patients had a 38% higher risk of UTO compared to other TB patients.¹⁴ This was similar to our findings. Delay in accessing health services has been reported to be significantly associated with increased age, and has been highlighted in other research.⁶

The longer patient delays associated with treatment failure and death should be addressed as a priority by the national and sub-national TB programmes by enhancing patient support and community service. The association of short patient delays (0–30 days) with LTFU needs to be further investigated, as this was highlighted as a risk factor in this study. Speculative reasons for this association could be a combination of many social factors, such as the possibility that short patient delay may represent a better economic situation and these patients may not perceive free treatment as an important opportunity for their health. A 5-year study in Uzbekistan reported that the urban population was at risk for treatment failure and LTFU.¹⁵ Potential reasons could include MDR-TB, which could be more frequent among urban than rural TB patients, and is associated with more medical resources in urban areas, which may lead to incomplete treatment.^{3,16}

We found that those with an unknown DOT provider were more likely to be lost to follow-up, die or have a failed treatment outcome. The lack of information concerning DOT may reflect limited medical resources, a long history of illness among the patients or social disadvantages.

Previous research has reported on the performance of TB control in the context of projects.^{5,17} Where the information was available, the majority of the patients had been assigned a DOT provider, and most of them were managed by medical staff (mainly rural doctors). A study in China revealed that DOT provided by family members led to less frequent interruption in the treatment of MDR-TB than among patients whose treatment was supported by village doctors.⁴ We found that patients with a

non-medical DOT provider were more likely to be lost to follow-up but less likely to have treatment failure. It is possible that the lower frequency of treatment failure might be explained by LTFU.

A study in Kenya reported that male patients had a 1.6 times higher risk of LTFU than female patients.¹⁸ Our study did not confirm this finding; older age, short patient delay, non-medical DOT provider and unknown DOT provider were factors associated with LTFU. A low literacy rate or social disadvantages in older patients could possibly contribute to this finding. The same study in Kenya indicated that more than 94% of TB patients received family-based DOT and were more likely to be lost to follow-up than those who received DOT from health care workers,¹⁸ which is similar to our findings.

The study has several limitations. It used routinely collected data that may have been subject to reporting errors depending on the quality of the TB programme. There were 0.2% of patients with unclear treatment outcomes, whose real status was unknown. We were unable to determine treatment outcomes in relation to patients' economic status and co-morbidities. Furthermore, we did not collect data on what kinds of patients visited the different types of health facilities. Other studies have reported that socially disadvantaged patients, such as the unemployed, urban migrant workers, and those lacking insurance, were more likely to visit a low-level health care provider, leading to long patient delay and worse TB disease.^{21,22}

CONCLUSION

Although UTO was relatively uncommon, this study has highlighted the profile of patients who may not complete their anti-tuberculosis treatment successfully and who may benefit from strengthening the TB programme and community support. The predominance of LTFU among the various types of UTOs should draw government attention, as partially treated patients may continue transmitting TB bacilli in the community. The patients with family member or other non-medical DOT providers or unknown DOT providers had a high risk for UTO. There is an urgent need to address these service-related factors, particularly those that can be addressed by NTPs. China has one of the highest TB burdens in the world, and there are substantial public health benefits to be had if the NTP strengthens treatment outcomes and ensures that outcome data are analysed regularly to identify necessary remedial action.

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Contexte : Trois projets du Fund for Innovative DOTS Expansion through Local Initiatives to Stop TB (FIDELIS).

Objectifs : Evaluer les résultats défavorables du traitement (UTO) incluant l'échec, le décès, les pertes de vue, les transferts et les résultats inconnus, et identifier les facteurs de risque associés aux UTO.

Schéma : Une étude transversale basée sur des données de routine du programme.

Résultats : De 30 277 nouveaux patients TB à frottis positif, 4261 (14,1%) ont eu un UTO : perdus de vue (2048 ; 6,8%), transférés (1418 ; 4,7%), décédés (390 ; 1,3%), en échec (340 ; 1,1%) ou inconnus (65 ; 0,2%). Les facteurs de risque de perte d'un patient (incluant les patients perdus de vue, transférés et inconnus) ont été le

fait de vivre à Anhui, l'âge > 55 ans, un délai du service > 10 jours, un retard du patient < 30 jours et le traitement directement observé (DOT) fourni par un membre de la famille ou d'autres personnes ou un prestataire de DOT inconnu. Le résultat « décès » a été associé avec le fait de vivre à Shaanxi, l'âge > 55 ans, le sexe masculin, un retard du patient > 30 jours et un prestataire de DOT inconnu. Un « échec » a été associé avec un accès non limité aux services de santé, un retard du patient > 30 jours et un prestataire de DOT inconnu.

Conclusion : L'étude a mis en lumière la prédominance de pertes de vue parmi les UTO. Les patients ayant comme prestataire de DOT un membre de la famille ou un autre prestataire non médical ou inconnu ont eu un risque élevé d'UTO. Il y a un besoin urgent d'aborder ces facteurs liés au service.

Marco de referencia: Tres proyectos del Fondo de Estrategias Innovadoras de Ampliación de DOTS mediante Iniciativas Locales para Detener la Tuberculosis (FIDELIS).

Objetivos: Evaluar los desenlaces terapéuticos desfavorables (UTO) que incluyen el fracaso terapéutico, la muerte, la pérdida durante el seguimiento, la transferencia a otro centro y el desenlace desconocido y definir los factores de riesgo que se asocian con estos resultados.

Método: Un estudio transversal a partir de los datos corrientes del programa.

Resultados: Se incluyeron en el estudio 30 277 casos nuevos de tuberculosis (TB) con baciloscopia positiva. De estos pacientes, 4261 tuvieron UTO (14,1%), a saber: perdidos durante el seguimiento (2048; 6,8%), transferidos a otro centro (1418; 4,7%), fallecidos (390; 1,3%), fracasos (340; 1,1%) o desenlaces desconocidos (65; 0,2%). En Anhui, los factores de riesgo de pérdida durante el seguimiento (incluidas las pérdidas, las transferencias a otro centro y los desenlaces desconocidos) fueron la edad > 55 años, un retraso

dependiente del servicio > 10 días, un retraso dependiente del paciente < 30 días y el tratamiento bajo observación directa (DOT) suministrado por miembros de la familia u otras personas y un dispensador de DOT desconocido. En Shaanxi, el desenlace 'fallecido' se asoció con la edad > 55 años, el sexo masculino, un retraso dependiente del paciente > 30 días y un dispensador de DOT desconocido. El 'fracaso' se asoció con el hecho de no pertenecer a la categoría de acceso limitado a los servicios de salud, el retraso dependiente del paciente > 30 días y un dispensador de DOT desconocido.

Conclusión: El estudio puso de manifiesto el predominio de la pérdida durante el seguimiento en los desenlaces desfavorables del tratamiento antituberculoso. Los pacientes que recibían el DOT por parte de un miembro de la familia o de otra persona diferente a un profesional de salud o cuyo dispensador de DOT se desconocía presentaron un alto riesgo de UTO. Es urgente abordar estos factores que dependen de los servicios de salud.