Did FIDELIS projects contribute to the detection of new smear-positive pulmonary tuberculosis cases in China?

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Setting: The first phase of the Fund for Innovative DOTS Expansion through Local Initiatives to Stop TB (FIDELIS) projects in China started in 2003.

Objective: To determine whether the FIDELIS projects contributed to the increased case detection rate for new smear-positive pulmonary tuberculosis (PTB) in China.

Methods: We compared the case notification rates (CNRs) in the intervention year with those of the previous year in the FIDELIS areas, then compared the difference between the CNRs of the intervention year and the previous year in the FIDELIS areas with those in the non-FIDELIS areas within the province.

Results: There was an increase in the CNR in the intervention year compared with the previous year for all the project sites. The differences between the CNR in the intervention year and the previous year ranged from 6.4 to 31.1 per 100 000 population in the FIDELIS areas and from 2.9 to 20.4/100 000 in the non-FIDELIS areas. Differences-in-differences analysis shows that the differences in the CNRs in the FIDELIS areas were not statistically significantly different from those in the non-FIDELIS areas ($P = 0.393$).

Conclusion: The FIDELIS projects may have contributed to the increase in case detection of new smear-positive PTB in China, but the level of evidence is low.

In the global strategy for tuberculosis (TB) control, targets were set for the year 2005 for successful treatment among registered TB cases and for case-finding activities to identify other existing cases.¹ The data indicated that case finding was obviously lagging, and it was thought to be impossible to reach the target rate without scaling up activities.²

In response, the Canadian International Development Agency (CIDA, Ottawa, ON, Canada) created the Fund for Innovative DOTS Expansion through Local Initiatives to Stop TB (FIDELIS), selecting the International Union Against Tuberculosis and Lung Disease (The Union, Paris, France) to manage the project.³ FIDELIS was developed to support innovative approaches by local groups to increase detection of new smear-positive TB cases, focusing on communities with limited access to health services. Successful candidates were selected from among applicants responding to a series of requests for proposals for innovative ideas to be implemented and evaluated over a 12-month period that were posted on the internet.

Among the 51 proposals that received initial phase funding, 15 were from China, for areas with limited

resources where case detection was lagging. China had implemented the World Bank loan project for tuberculosis control (known as the Health V Project) in 1990s, but the estimated tuberculosis case detection rate remained low. The distribution of the FIDELIS-funded provinces in China is shown in Figure 1. The median per capita gross domestic product in 2003 for the provinces with the FIDELIS projects was RMB 5847 (US\$1 = 8.2 RMB in 2003) vs. RMB 7962 for provinces without FIDELIS projects.⁴

The FIDELIS-funded projects have been reported in detail elsewhere.⁵ The estimated case-detection rate in China during the implementation period of the FIDELIS project rose from 43% in 2003 to 79% in 2006.^{6,7} This analysis was undertaken to determine to what extent the 15 FIDELIS projects in China might have contributed to the increase in detection of new sputum smear-positive pulmonary TB (PTB) cases.

STUDY POPULATION, DESIGN AND METHODS

All of the FIDELIS projects were required to report the number of new sputum smear-positive PTB cases detected in the areas supported by the grants on a monthly reporting form, along with the number of new cases detected during the same period and in the same location 1 year previously. These reports were verified by external monitors who visited the sites on a routine basis and also reviewed the site's records, compared them with sputum smear examination results, cross-checked the laboratory register with the TB treatment register, reviewed randomly selected positive smears and interviewed randomly selected patients. A separate team of experts, the Independent Results Assessment Group (IRAG), who were independent of the routine FIDELIS operations, reviewed the projects and obtained information on case finding in comparable areas outside the project sites for comparison.

For the purposes of this study, four sources of information were consulted. First, to compare the TB burdens in the various provinces, data from the national TB prevalence survey undertaken in 1990 were used.⁸ As the data from subsequent surveys did not provide province-specific data, they could not be used for this purpose.

Second, to compare trends during the period of FIDELIS implementation, the annual number of new smear-positive TB cases notified and the calculated case notification rates (CNRs) within the province

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KEY WORDS

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FIDELIS provinces and non-FIDELIS provinces

FIGURE 1 The FIDELIS provinces and non-FIDELIS provinces in China. FIDELIS = Fund for Innovative DOTS Expansion through Local Initiatives to Stop TB; TB = tuberculosis.

were considered separately for the FIDELIS and the non-FIDELIS provinces. The CNR was obtained from the total number of new smear-positive cases notified within the given year for the whole province, divided by the province population. Data providing the total number of new smear-positive cases notified within the given year were obtained from the National TB Control Centre of the Chinese Center for Disease Control and Prevention, Beijing, China. Data describing the population of the whole province were available publicly. Notification numbers and rates were compared for the entire province, and not only for the areas specific to the projects.

Third, all routinely reported data from the FIDELIS monthly reports were double-entered, checked and verified in an electronic database without personal identifiers. To compare the FIDELIS CNRs with those of the previous year, the numbers of cases notified in the report forms were used.

Finally, for comparison of the FIDELIS and non-FIDELIS areas within a specific province where FIDELIS was implemented in part of the province, the numbers of cases detected in the year of the project and the previous year for both the FIDELIS and non-FIDELIS areas within the province were obtained from the IRAG reports.

STATA v.12.0 (StataCorp, College Station, TX, USA) was used for statistical analysis. First, the median prevalence of TB in 1990 in FIDELIS provinces was compared with that of non-FIDELIS provinces using the Kruskal-Wallis test. Second, we calculated the average annual change in the notification of new smear-positive TB cases in the FIDELIS and non-FIDELIS provinces, and the difference in these changes between the FIDELIS and non-FIDELIS provinces. Third, we calculated the ratio of the CNRs during the intervention period over that of the previous year in the FIDELIS areas. Meta-analysis was applied to estimate the pooled ratio of the CNRs of the FIDELIS intervention year and the previous year, and meta-regression was applied to assess whether the ratio of the CNRs varied between the provinces with the World Bank Loan Project and the provinces without. Fourth, the difference between the CNRs in the year of the project and the previous year was calculated separately for the FIDELIS and non-FIDELIS areas within a specific province where FIDELIS was implemented in part of the province; a differences-in-differences analysis was then performed to assess whether the difference in CNR in the year of the project

and the previous year in the FIDELIS areas was statistically significantly different from that in the non-FIDELIS areas. $P < 0.05$ was considered statistically significant.

Ethics

The study used non-identifiable data collected as part of a routine programme activity that was publicly available and analysed retrospectively. Patient information was handled only by those providing care for the patients. No individual identifiers were provided to anyone outside the health services. The project was therefore not considered to require specific consent or review by an ethics committee.

RESULTS

Tuberculosis prevalence in 1990

For the FIDELIS project provinces, median TB prevalence was 110 cases per 100 000 population compared to 98/100 000 for the non-FIDELIS provinces. The slightly higher median prevalence of TB in 1990 in the FIDELIS provinces compared to non-FIDELIS provinces was not statistically significant ($P > 0.05$) by the Kruskal-Wallis test.

Trend during the FIDELIS period

The total population in 2003 was 657.4 million in the FIDELIS provinces and 624.5 million in the non-FIDELIS provinces. The number of cases notified in the FIDELIS provinces rose from 84 524 in 2002 to 259 953 in 2006, an average annual increase of 47 522 (95% confidence interval [CI] 20 962–74 081, $P = 0.011$). In the non-FIDELIS provinces, the number of cases increased from 110 448 in 2002 to 208 338 in 2006, with an average annual increase of 27 673 (95%CI 14 564–40 782, $P = 0.007$). Figure 2 shows the trend in CNRs over the period in which the FIDELIS projects were in operation for the provinces with and those without the projects. The provinces with the projects started the period with lower CNRs than those without the projects, but over the period the CNR rose more steeply in the provinces with projects. The overall CNR in the FIDELIS provinces was 12.6/100 000 in 2002 and increased to 38.9/100 000 in 2006, with an annual increase of 7.1/100 000 (95%CI 3.2–11.1, $P = 0.011$). The overall CNR in the provinces without FIDELIS was 18.8/100 000 in 2002 and in-

FIGURE 2 Trend in annual CNR per 100 000 population of new sputum smear-positive cases of TB in China among provinces with and without the FIDELIS projects, 2002–2006. CNR = case notification rate; TB = tuberculosis; FIDELIS = Fund for Innovative DOTS Expansion through Local Initiatives to Stop TB.

TABLE 1 Annual case detection and notification rate of new smear-positive PTB in the provinces of China engaged with the projects and that of the year prior to the project

Province	Counties/ districts <i>n</i>	FIDELIS counties/ districts <i>n</i>	Project start year	Case detection in previous year <i>n</i>	Case detection in project year <i>n</i>	CNR in previous year /100 000	CNR in previous year /100 000
Hunan*	122	40	2003	4 887	12 494	7.3	18.7
Hubei 1*	97	40	2003	8 112	12 193	34.1	51.3
Gansu*	87	51	2003	4 242	8 121	16.3	31.0
Hebei*	172	45	2004	5 907	8 882	8.7	13.0
Anhui	105	24	2004	1 432	5 462	2.2	8.5
Shanxi	118	50	2004	4 521	7 736	13.6	23.2
Hubei 2	57	30	2004	8 784	12 091	36.3	49.9
Guizhou*	88	88	2004	6 200	12 478	16.0	32.0
Sichuan	181	50	2004	11 160	13 474	12.8	15.4
Shaanxi 1*	19	19	2004	1 154	3 198	13.9	38.3
Jilin*	60	30	2006	6 996	9 269	25.8	34.0
Jiangxi*	99	64	2006	13 707	15 309	31.8	35.3
Shaanxi 2*	88	65	2006	4 032	6 968	10.8	18.7
Chongqing*	40	21	2006	7 400	8 607	26.4	30.7
Shandong	140	33	2007	3 412	7 092	3.7	7.6
Total	1 473	650	–	91 946	143 374	–	–

*Provinces with the World Bank Loan Project.

PTB = pulmonary tuberculosis; FIDELIS = Fund for Innovative DOTS Expansion through Local Initiatives to Stop TB; CNR = case notification rate.

creased to 35.5/100 000 in 2006, with an annual increase of 4.7/100 000 (95%CI 2.5–6.9, $P = 0.007$). As the 95%CIs of the average annual change in the CNR of the FIDELIS areas and those of the non-FIDELIS areas overlap, the difference in the trend was not statistically significant ($P = 0.298$).

Comparison of case detection during the project year with that of the previous year in the FIDELIS areas

There was an increase in the numbers of new smear-positive cases reported and the CNRs in the intervention year compared with the previous year for all of the project sites (Table 1). The difference in the number of cases detected ranged from 1207 to 7607 (mean 3429, 95%CI 2494–4364), and the ratio of the case detection in the intervention year to that in the previous year ranged from 1.12 to 3.81 (mean 1.85, 95%CI 1.4–2.3). The ratio of the CNR during the intervention year to the previous year ranged from 1.1 (95%CI 1.08–1.14) to 3.78 (95%CI 3.57–4.01) (Figure 3). Meta-regression shows no significant difference between the provinces with and those without the World Bank Loan Project ($P = 0.237$). Pooling the notification rate ratio across the FIDELIS provinces may not be meaningful due to substantial heterogeneity (heterogeneity $\chi^2 P < 0.001$; $I^2 = 99.7\%$), and the estimated predictive interval is wide (Figure 3).

Comparison of the FIDELIS and non-FIDELIS areas

Seven of the projects in which FIDELIS was implemented in only part of the province were reviewed by the IRAG (Table 2). There was an increase in smear-positive TB CNRs in the intervention year as compared with the previous year for all sites in both the FIDELIS and non-FIDELIS areas. The differences in CNR between the intervention year and the previous year ranged from 6.4 to 31.1/100 000 in the FIDELIS areas and from 2.9 to 20.4/100 000 in the non-FIDELIS areas (Table 2). In five of the seven provinces, the increase in the smear-positive TB CNR in the intervention year compared with the previous year was statistically significantly higher in the FIDELIS areas than in the non-FIDELIS areas. However, overall differences-in-differences analysis showed that the difference in CNR in the FIDELIS areas and in the non-FI-

DELIS areas was not statistically significant (differences-in-differences 8.5/100 000, 95%CI –11.7 to 28.8, $P = 0.393$).

DISCUSSION

During the years immediately preceding 2005, a great deal of attention was paid to improving the case detection of TB, as this was the year for which case-finding targets had been set.^{9,10} Consequently, a number of investments were made to improve case finding in the provinces where the FIDELIS projects were undertaken, including substantial investments from the World Bank Loan Project¹¹ and the Global Fund to Fight AIDS, Tuberculosis and Malaria. The FIDELIS projects, by their very nature, were not

FIGURE 3 Forest plot of the ratio of new smear-positive TB CNR in the FIDELIS intervention year and in the previous year in provinces engaged in the FIDELIS projects in China. RR = rate ratio; CI = confidence interval; TB = tuberculosis; CNR = case notification rate; FIDELIS = Fund for Innovative DOTS Expansion through Local Initiatives to Stop TB.

TABLE 2 Comparison of the CNR ratio between the FIDELIS project areas and the non-project control areas in the year prior to the project and during the year of the project in selected provinces of China in which the projects did not cover all counties of the province, reviewed by the Independent Results Assessment Group, 2002–2006

Province	Project	CNR previous year /100 000	CNR project year /100 000	Difference in notification rate /100 000	Differences-in- differences	95%CI
Hubei	Yes	33.9	50.0	16.1	–2.2	–3.7 to –0.7
	No	31.4	49.7	18.3		
Hunan	Yes	27.5	58.6	31.1	26.5	25.0 to 28.0
	No	25.0	29.6	4.6		
Anhui	Yes	10.3	26.7	16.4	7.8	6.7 to 8.9
	No	8.9	17.5	8.6		
Gansu	Yes	24.6	46.9	22.3	1.9	–0.2 to 4.0
	No	21.0	41.4	20.4		
Hebei	Yes	36.9	55.2	18.3	15.3	13.7 to 16.9
	No	28.9	31.9	3		
Shaanxi	Yes	5.9	16.2	10.3	6.9	6.0 to 7.8
	No	7.2	10.6	3.4		
Sichuan	Yes	28.8	35.2	6.4	3.5	2.4 to 4.6
	No	33.1	36.0	2.9		

CNR = case notification rate; FIDELIS = Fund for Innovative DOTS Expansion through Local Initiatives to Stop TB; CI = confidence interval.

established as research projects. In this situation, it was a challenge to demonstrate that the case-finding results could be attributed to the projects themselves. Evidence to suggest any specific effect of these projects would have to include an effect in the areas where the projects were undertaken in addition to those observed in other, similar areas. The present analysis was designed to attempt this exercise.

The provinces in which the FIDELIS projects were implemented had a lower socio-economic level. Although the provincial TB prevalence estimates obtained from the 1990 national TB prevalence survey may not accurately reflect the provincial TB prevalence in 2003, when FIDELIS was launched in China, it is possible that these provinces still had a slightly higher TB burden prior to the project period.¹² This is not particularly surprising, as that was why these provinces were selected for the projects. However, the CNR for TB was lower in these provinces prior to the project period, even though the burden of disease was higher, indicating a lower case-finding rate among existing cases. This was also expected, as FIDELIS was targeting areas of suboptimal case detection.

Despite the fact that the provinces in which the FIDELIS projects were implemented had a higher burden of disease with a lower number of cases notified prior to the project period, by the end of the project period the number of cases notified in these provinces was higher than in the non-project provinces. The difference in the trends of the CNR of the FIDELIS areas and non-FIDELIS areas was not statistically significant, however. We were therefore unable to definitely conclude that the FIDELIS projects had an independent effect on increased case finding.

A substantially higher number of cases was notified during the project year compared with the previous year in all of the project areas. This finding is in agreement with previous publications,^{13,14} and is consistent with the possibility that the projects might have had an effect in improving case detection. Trends in case finding over this period are further complicated, however, by the internal migration of people from poorer counties and provinces seeking work in richer provinces.¹⁵ This migration might have had a number of effects on trends, such as increasing the numbers of cases in some provinces while reducing them in others. It was not

possible to address this question within the current analysis. In addition, we did not analyse the long-term case-finding trends after the FIDELIS projects ended, as the time period was beyond the scope of this study.

The comparison of case finding from project areas with selected similar areas in which there was no project (but in which other investments were being made, such as government-supported small-scale projects) showed bigger increases in CNRs in five of the seven project areas, consistent with a possible effect of the projects in improving case detection. The effect was heterogeneous, however, and the overall differences-in-differences analysis was not statistically significant. Again, the observational and retrospective nature of the IRAG analyses limits the certainty with which this comparison can be assessed, and selection bias cannot be excluded.

A previous publication comparing the specific types of innovation employed throughout the FIDELIS projects across the globe was unable to demonstrate a significant effect of the specific interventions, including health systems strengthening, improved diagnostic services, active case finding, information/education/communication, engaging all partners and incentives/enablers,⁵ suggesting that the increased priority given to case finding and the improved investment were likely to be more important than the particular type of intervention in improving case detection.

While the analysis undertaken suggests the possibility that the FIDELIS projects might have had a measurable effect in improving case detection, the evidence is not conclusive. The project areas were not entirely comparable with the non-project areas, as they were selected as particularly needy areas from an economic and health services perspective. Furthermore, it was not possible to evaluate the simultaneous effects of other possible targeted interventions for the project areas, which makes a valid comparison difficult. It also underscores the fact that these projects were not designed as research studies, in which it would have been possible to take measures to ensure better comparability between the intervention and non-intervention groups. This markedly limits the types of conclusions that can be drawn from this health services evaluation.

CONCLUSIONS

Our analysis of the FIDELIS project data in China provides limited evidence that the project might have had a role in contributing to the increase in rates of detection of new sputum smear-positive cases of TB in certain project areas in China. In future these types of projects should perhaps be designed in such a way that evaluation of the projects' impact would be simpler and more reliable, for example, by using a step-wedge design.

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Objectif : Déterminer si les projets de la « Fund for Innovative DOTS Expansion through Local Initiatives to Stop TB » (FIDELIS), commencés en 2003, ont contribué à une augmentation de la détection des cas de tuberculose pulmonaire (TBP) à frottis positif en Chine.

Méthodes : Nous avons comparé le taux de notification des cas (CNR) pendant l'année d'intervention avec celui de l'année précédente dans les zones FIDELIS. Nous avons également comparé la différence du CNR de l'année d'intervention et de l'année précédente dans les zones FIDELIS et les zones non FIDELIS à l'intérieur de la province.

Marco de referencia: La primera fase de ejecución del Fondo para la Expansión Innovadora de DOTS mediante Iniciativas Locales para Detener la Tuberculosis (FIDELIS, por su acrónimo en inglés), en la China, comenzó en 2003.

Objetivo: Determinar si los proyectos de la iniciativa FIDELIS contribuían a aumentar la detección de casos nuevos de tuberculosis pulmonar (TBP) con baciloscopia positiva en la China.

Métodos: Se comparó la tasa de notificación de casos (CNR) durante el año de la intervención, con la tasa del año anterior en las zonas vinculadas con el proyecto FIDELIS, y se examinó además la diferencia de la CNR durante el año de la intervención y el año anterior en zonas de la provincia que no participaron en el proyecto.

Resultados: Durante el año de la intervención, se observó un

Résultats : Il y a eu une augmentation du CNR pendant l'année d'intervention comparée à l'année précédente dans tous les sites du projet. Cette différence de CNR entre l'année d'intervention et l'année précédente allait de 6,4 à 31,1 par 100 000 habitants dans les zones FIDELIS et de 2,9 à 20,4/100 000 dans les zones non FIDELIS. L'analyse des écarts dans les différences a montré que les différences de CNR dans les zones FIDELIS n'étaient pas statistiquement significatives par rapport à aux zones non FIDELIS ($P = 0,393$).

Conclusions : Les projets FIDELIS pourraient avoir contribué à l'augmentation de la détection des cas nouveaux de TBP à frottis positif en Chine, mais le niveau de preuves reste faible.

aumento de la CNR con respecto al año anterior en todos los centros del proyecto. Las diferencias de la CNR en ambos períodos en las zonas que participaron en el proyecto FIDELIS oscilaron entre 6,4 y 31,1 por 100 000 habitantes; en las zonas donde no hubo intervención las diferencias de la tasa de notificación oscilaron entre 2,9 y 20,4/100 000. Al comparar estos resultados, no se puso en evidencia una diferencia significativa en las CNR al comparar las zonas que practicaron la intervención y las zonas fuera del proyecto FIDELIS ($P = 0,393$).

Conclusión: Es posible que los proyectos FIDELIS hayan contribuido a mejorar la tasa de detección de casos nuevos de TBP con baciloscopia positiva en la China, pero la fuerza demostrativa de las pruebas científicas es escasa.