

## The FIDELIS initiative: innovative strategies for increased case finding

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### SUMMARY

**SETTING:** Low-income, high tuberculosis (TB) burden countries.

**OBJECTIVE:** To compare case finding of new smear-positive pulmonary TB patients in projects funded to apply innovative approaches.

**DESIGN:** Prospective application of innovative approaches to case finding within routine services to determine the numbers of additional cases detected and the cost per additional case detected, according to the type of approach applied.

**RESULTS:** Between 2003 and 2007, 51 FIDELIS projects were implemented in 18 countries; 273 239 cases were reported, of which 85 267 were additional to the number reported in the previous year. The median cost

per additional case was US\$103. The interventions employed were: 1) social mobilisation and information, education and communication; 2) engagement of the private sector; 3) innovative approaches for microscopy services; 4) enhanced or semi-active case finding; 5) health systems strengthening; and 6) use of incentives. None of these was significantly more likely to detect additional cases or to have a lower cost per additional case than any of the others.

**CONCLUSION:** While there was a substantial increase in cases detected, at a moderate cost per additional case, we were unable to show that any single intervention had an advantage over the others.

**KEY WORDS:** tuberculosis; case finding; innovation

EARLY DETECTION and treatment of cases of tuberculosis (TB) is crucial to interrupting the chain of transmission that maintains the disease in the community, especially among those who are sputum smear-positive. Any methods that help to detect patients at an earlier stage and increase the numbers of patients who seek care should improve the epidemiological situation of the disease. Case finding in TB refers to activities aimed at identifying TB cases as early as possible after the onset of disease.<sup>1</sup> The purpose of case finding is to render infectious TB cases non-infectious through anti-tuberculosis treatment. While it is essential that cases that are detected are effectively treated,<sup>2</sup> it is also important to find the highest possible proportion of existing cases to provide them with the necessary treatment. Different approaches of TB case finding have been tested since the 1960s, with various yields depending on the strategies applied and the TB prevalence in the populations investigated.<sup>3-20</sup> Availability of resources and the prevalence of TB are two major factors that influence the choice of case finding methods.

A longstanding global target for TB control has been the detection of 70% of estimated incident new smear-positive cases.<sup>21</sup> In 2003, the global case detec-

tion rate remained well below the target, at approximately 50%,<sup>22</sup> implying that a substantial proportion of prevalent TB cases were not detected. To increase case finding globally, the Canadian International Development Agency (CIDA) provided funding for the Fund for Innovative DOTS Expansion through Local Initiatives to Stop TB (FIDELIS). The International Union Against Tuberculosis and Lung Disease (The Union) was selected to manage these 12-month projects: the first was launched in China in October 2003 and the last in Kenya in July 2006.

The guiding principle of FIDELIS was to support local initiatives of innovative approaches to detect additional new smear-positive cases (NSP), with an emphasis on patients with limited access to health services, while maintaining a high cure rate.<sup>2</sup> It was up to the applicant to propose new ideas on how to detect additional TB cases. While the proposed activities were at times innovative, the contractors often selected well-established approaches to TB control and applied them in their local settings. Implementing partners included national TB programmes (NTP), non-governmental organisations (NGOs) and academic institutions. Each patient's access to health services was assessed based on the duration of

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Article submitted 25 April 2010. Final version accepted 8 July 2010.

[A version in French of this article is available from the Editorial Office in Paris and from the Union website [www.theunion.org](http://www.theunion.org)]

symptoms before diagnosis, with a symptom period of  $\geq 12$  weeks before diagnosis suggesting limited access to health services. A basic requirement was compliance with the country's local NTP guidelines. All implementing projects were assigned external technical and financial monitors to carefully track the project.

The objective of this analysis was to compare the case finding yield and efficiency of various interventions implemented throughout the 5 years of FIDELIS implementation.

## METHODS

All FIDELIS projects were required to provide monthly reports in a standardised format, with focus on the numbers of NSP cases detected during the project and during the same month in the year preceding project implementation. The duration of each project was typically 12 months. The reports were reviewed on a monthly basis by external technical monitors, and verifications were performed during field monitoring visits.

Following the completion of all FIDELIS projects, the technical staff responsible for monitoring the initiative classified all FIDELIS activities into six groups of interventions. Each project was assessed as to whether or not it employed each specific intervention; a project could be classified as having none, one or multiple interventions.

Data on NSP case detection during the project and during the same month in the year prior to project implementation were collected from routine project reports between 2003 and 2007. 'Additional' case finding during the project period is the difference between the number of cases detected during the FIDELIS initiative and that detected during the same period in the previous year in the same location. Data on actual expenditures for each project were obtained to calculate a cost per additional case detected, defined as the total cost expenditures of a project divided by the number of additional NSP cases detected.

Data on NSP case detection and project expenditures were double-entered into EpiData software (EpiData Association, Odense, Denmark), validated, corrected and exported into SPSS (Statistical Package for the Social Sciences, SPSS Inc, Chicago, IL, USA) for analysis. Because there were few projects and due to the non-normal distribution of both additional case finding and cost per additional case detected, the median was calculated for both additional case finding and cost per additional case detected, and a non-parametric test (the Mann-Whitney test) was applied for comparison by type of intervention. Statistical significance was defined as  $P < 0.05$ .

This analysis used only aggregate, routinely collected programme data with no personal identifiers, and therefore did not require ethical approval.

## RESULTS

Between 2003 and 2007, 51 FIDELIS projects were implemented in 18 countries. Each of the projects was evaluated as to whether any of six strategies were employed (Table 1), and classified as having none, one or

**Table 1** All projects in the FIDELIS initiative, showing additional case finding, cost per additional case and strategies involved

Country	Additional case finding	Cost per additional case, US\$	Strategies employed
1 China <sup>23</sup>	5640	44	HSS+Incent
2 China <sup>24</sup>	4052	61	HSS+Incent
3 China	3878	64	IEC+Micro+ACF+HSS+Incent
4 Pakistan	971	34	HSS
5 China	2975	84	IEC+HSS+Incent
6 Kenya	15	10619	IEC+Incent
7 Pakistan	2415	103	HSS
8 Sudan	261	631	HSS
9 China	4030	58	IEC+ACF+HSS+Incent
10 Indonesia <sup>25</sup>	529	299	Priv
11 Tajikistan	418	552	Incent
12 Bangladesh	2900	67	Priv
13 Tanzania	1027	127	None
14 Pakistan	2059	101	IEC
15 Kenya	916	116	IEC+Priv+Micro+ACF
16 Indonesia	2236	60	IEC+ACF+Incent
17 China	2510	100	IEC+HSS+Incent
18 Nigeria	0		IEC+Priv
19 China	6278	31	IEC+HSS+Incent
20 China	3307	67	IEC+HSS+Incent
21 Madagascar	410	200	Micro
22 Tanzania	402	395	None
23 Uganda	659	301	None
24 Somalia	0		Priv
25 Bangladesh <sup>26</sup>	2282	73	Priv+Micro
26 Pakistan	3363	59	IEC+Micro
27 Sri Lanka	118	1390	IEC+Priv+ACF
28 Pakistan	567	193	None
29 China <sup>27</sup>	2631	95	IEC+HSS+Incent
30 China	2044	74	IEC+HSS+Incent
31 China	2273	94	IEC+HSS+Incent
32 China	1602	125	IEC+HSS+Incent
33 China	2936	84	IEC+HSS+Incent
34 Indonesia	775	216	Priv
35 Sierra Leone	1043	166	IEC+Micro
36 Eritrea	46	717	None
37 Uganda	101	1626	ACF
38 Afghanistan	1889	77	ACF+Incent
39 Myanmar	1041	211	IEC+ACF+Incent
40 Kenya	2640	61	Priv
41 China	1207	100	IEC+HSS+Incent
42 Ethiopia	5	28825	IEC+HSS
43 Tanzania	421	483	None
44 Kenya	1265	148	IEC+ACF
45 Pakistan	39	3001	IEC+Priv
46 Pakistan	586	260	IEC+Incent
47 Pakistan	1752	92	IEC+Micro+HSS
48 Kenya	1194	108	IEC+Priv+ACF
49 Tanzania	157	1020	Priv
50 China	3680	58	ACF+Incent
51 Pakistan	1722	95	IEC+Priv+HSS

HSS = health systems strengthening; IEC = information, education, communication; Micro = innovative microscopy services; ACF = active or semi-active case finding; Incent = incentives; Priv = involving private sector.

multiple interventions. The following interventions were identified:

- 1 Social mobilisation and information, education and communication (IEC; used in 28 projects), included many methods of communicating TB messages, such as loudspeakers, posters and school information.
- 2 Engagement of the private sector (PPM; used in 13 projects) included involving primary care practitioners in TB control activities such as referral of suspects or diagnosis, or involving private facilities in diagnosis and follow-up.
- 3 Innovative approaches for microscopy services (used in 7 projects) included activities such as sputum collection and preparation in peripheral locations and transport of samples to a central laboratory.
- 4 Enhanced or semi-active case finding (ACF; used in 11 projects) involved activities where risk groups were encouraged or helped to provide sputum for examination.
- 5 Health systems strengthening (HSS; used in 20 projects) aimed at strengthening the DOTS strategy in general and expanding DOTS services to more areas through activities such as improving referral routines, more focused tracing of latecomers and new microscopy centres.
- 6 Use of incentives (used in 21 projects) included activities where health workers received an incentive for identifying cases or ensuring treatment completion, or where patients received incentives for treatment completion.

On review, it was felt that some projects had no major new interventions beyond routine activities within the DOTS strategy; these were classified as 'no intervention' for the purposes of the analysis. Each project was assessed with respect to each of the above types of intervention; 13 were determined to include one focal intervention, 13 incorporated two interventions and 19 used three or more interventions. Six of the projects had no clear focal intervention.

Thirty-one projects were implemented by institutions such as NTPs and those with similar responsibilities, whereas NGOs implemented 20 projects. The majority of the projects were implemented in Asia (33 projects), 15 of which were in China. The remaining 18 projects were implemented in Africa. Most projects in China employed IEC (80%), HSS (93%) and incentives (100%), and this had a significant impact on the overall analysis.

#### Case finding

A total of 273 239 NSP cases were detected by the 51 projects. The mean and median numbers of NSP cases detected per project were respectively 5358 and 3877. A total of 85 267 additional NSP cases were

**Table 2** Additional case finding according to each type of intervention ( $N = 51$ )

Intervention	<i>n</i>	Case finding median (95%CI)	<i>P</i> value
IEC	28	1737 (1043–2510)	0.164
No IEC	23	659 (410–2282)	
PPM	13	775 (39–2282)	0.057
No PPM	38	1677 (971–2415)	
Innovative micro	7	1752 (410–3878)	0.381
No innovative micro	44	1201 (586–2059)	
ACF	11	1265 (118–3878)	0.492
No ACF	40	1125 (567–2273)	
HSS	20	2463 (1722–3307)	<0.001
No HSS	31	659 (410–1194)	
Incentives	21	2510 (1602–3680)	<0.001
No incentives	30	717 (402–1194)	
No innovation	6	494 (46–1027)	0.044
All other projects	45	1722 (971–2282)	

CI = confidence interval; IEC = social mobilisation, information, education and communication; PPM = public-private mix; innovative micro = improved sputum smear microscopy services; ACF = active or semi-active case finding; HSS = health systems strengthening.

detected in all the projects, an increase of 45%. The mean and median numbers of additional cases detected per project were respectively 1672 and 1207.

The frequency distribution for 'additional case finding' is skewed to the right. A non-parametric test (Mann-Whitney test) was used to compare the additional case finding in the various strategies (Table 2). Two of the strategies were associated with statistically significantly higher additional case finding. Projects using HSS strategies had a higher median additional case detection rate of 2463 NSP cases (95% confidence interval [CI] 1722–3307) than projects without HSS (median 659, 95%CI 410–1194,  $P < 0.001$ ). Projects using incentives as a strategy had a higher median additional case finding rate of 2510 NSP cases (95%CI 1602–3680) than projects without this intervention (median 717, 95%CI 402–1194,  $P < 0.001$ ). Projects using no additional intervention reported significantly fewer additional NSP cases (median 494, 95%CI 46–1027) than all other projects with an intervention identified (median 1722, 95%CI 971–2282,  $P = 0.044$ ).

Projects in China had a higher median additional case finding rate (median 2975 cases, 95%CI 2273–4030) than projects in other countries (median 717 cases, 95%CI 410–1194); as a result, a stratified analysis of additional case finding was performed for China/other than China (Table 3). Projects in China generally performed well, and no individual intervention was particularly prominent in identifying more additional cases. In other projects excluding China, projects with 'innovative microscopy services' identified a higher median of additional NSP cases (1398, 95%CI 410–3363) than projects without this intervention (median 577, 95%CI 261–1041); the difference was not statistically significant ( $P = 0.08$ ). There

**Table 3** Additional case finding by intervention, excluding projects in China ( $n = 36$ )

Intervention	$n$	Additional case finding median (95%CI)	Mann-Whitney test $P$ value
IEC	16	1042 (39–1752)	0.691
No IEC	20	548 (402–1027)	
PPM	13	775 (39–2282)	0.780
No PPM	23	659 (410–1265)	
Innovative micro	6	1398 (410–3363)	0.082
No innovative micro	30	577 (261–1041)	
ACF	8	1118 (101–2236)	0.424
No ACF	28	577 (402–1043)	
HSS	6	1347 (5–2415)	0.641
No HSS	30	623 (410–1043)	
Incentives	6	814 (15–2236)	0.799
No incentives	30	717 (402–1194)	
No innovation	6	494 (46–1027)	0.308
All other projects	30	944 (410–1722)	

CI = confidence interval; IEC = social mobilisation, information, education and communication; PPM = public-private mix; innovative micro = improved sputum smear microscopy services; ACF = active or semi-active case finding; HSS = health systems strengthening.

were too few projects to compare strategies by type of contractor.

### Cost

For all projects, the total mean and median cost per additional case was US\$1094 and US\$103, respectively, per additional case. As expected, the distribution was again skewed to the right, and non-parametric tests were applied. Table 4 shows a comparison of the cost per additional case, by intervention. For the analysis of cost per additional case two projects where case finding was lower than the previous year were excluded. Projects using HSS had a significantly lower median cost per additional case (US\$88 per case) than projects

**Table 4** Median cost per additional case by type of intervention ( $n = 49$ )

Intervention	$n$	Median cost per additional case US\$ (95%CI)	Mann-Whitney test $P$ value
IEC	27	100 (84–148)	0.421
No IEC	22	197 (67–483)	
PPM	11	116 (67–1390)	0.350
No PPM	38	101 (84–193)	
Innovative micro	7	103 (59–200)	0.304
No innovative micro	42	105 (94–216)	
ACF	11	108 (58–1390)	0.533
No ACF	38	102 (92–216)	
HSS	20	88 (64–100)	0.003
No HSS	29	200 (108–395)	
Incentives	21	84 (61–100)	0.004
No incentives	28	180 (103–395)	
No innovation	6	348 (127–717)	0.029
All other projects	43	100 (77–148)	

CI = confidence interval; IEC = social mobilisation, information, education and communication; PPM = public-private mix; innovative micro = improved sputum smear microscopy services; ACF = active or semi-active case finding; HSS = health systems strengthening.

**Table 5** Median cost per additional cases by intervention, excluding projects in China ( $n = 34$ )

Intervention	$n$	Median cost per additional case US\$ (95%CI)	Mann-Whitney test $P$ value
IEC	15	148 (95–1390)	0.849
No IEC	19	216 (77–552)	
PPM	11	116 (67–1390)	0.699
No PPM	23	200 (103–483)	
Innovative micro	6	104 (59–200)	0.058
No innovative micro	28	238 (108–552)	
ACF	8	132 (60–1626)	0.685
No CF	26	208 (101–483)	
HSS	6	99 (34–28825)	0.498
No HSS	28	205 (116–395)	
Incentives	6	235 (60–10619)	0.857
No incentives	28	180 (103–395)	
No innovation	6	348 (127–716)	0.240
All other projects	28	157 (95–299)	

CI = confidence interval; IEC = activities of social mobilisation, information, education and communication; PPM = engaging the private sector; innovative micro = improved sputum smear microscopy services; ACF = active or semi-active case finding; HSS = health systems strengthening.

without HSS (US\$200/case), and projects using incentives had a significantly lower median cost per additional case (US\$84/case) than projects without incentives (US\$180/case). Projects with no intervention identified showed a significantly higher median cost per additional case (US\$348/case) than projects with one or more interventions identified (US\$100/case).

The cost per additional case detected in projects based in China was lower than for all the other projects (median US\$74 vs. US\$197/case,  $P < 0.01$ ); as a result, a stratified analysis for China and other than China was performed. In China no intervention had a significantly different cost per additional case detected. In projects outside China, 'innovative microscopy services' had a lower cost per additional case (US\$104, 95%CI 59–200) than the other interventions (US\$238, 95%CI 108–552), but the difference was not statistically significant (Table 5).

## DISCUSSION

While the projects supported under the FIDELIS initiative demonstrated a substantial increase in numbers of cases reported compared to the previous year, we were unable to relate this to any specific group of interventions used within the projects. Analysing all projects together, HSS and incentive-based interventions resulted in significantly higher additional case finding. However, when the analysis was performed separately for China and other locations, this result disappeared, indicating that the overall analysis was confounded by the high case finding in China.

These projects were implemented in the context of a rapid increase in case finding globally, associated with targets set by the World Health Organization for the year 2005,<sup>28</sup> the period over which these projects

were undertaken. This was particularly marked in China,<sup>23,24,27</sup> where the projects demonstrated the greatest increase in case finding.

While the data set is large in terms of numbers of individual cases, the number of projects is small when analysing the strategies, which greatly limits the statistical power of the analysis, and particularly the subanalysis. Although the relative merits of the various strategies were identified, the framework was not sufficiently powerful to draw firm conclusions. Several other limitations exist. First, classification of the strategies was done post hoc by external monitors based on their impression of the projects, and was therefore heavily subjective. Second, the number of projects with each type of intervention was frequently small, and negative findings should be interpreted with caution, particularly the subanalysis. Furthermore, as FIDELIS was conceived and implemented as a series of programmatic activities within existing TB control services, and not as a research project, the data were abstracted from routine services rather than from a rigorous research setting. Another natural consequence of this was that many projects used several interventions to maximise case finding, rather than carefully evaluating a single strategy.

An interesting finding was that HSS was less costly per case than many other interventions. This suggests that investing in the health system may be more beneficial to resolve public health problems than potential quick remedies.

The policy implications of these results should be considered with care, and a substantial impact on public health was not expected in the short term.<sup>29</sup> The projects clearly demonstrate the usefulness of standardised recording and reporting in TB control. Many projects were specific to their local setting, and cannot be easily replicated in other locations; nevertheless, the ideas can be shared. Some of the projects were shown to be efficient in terms of achieving the targets, and were scaled up in that country. Examples of scaled-up approaches include the creation of microscopy centres in township hospitals in China, use of a district laboratory supervisor in Pakistan, and various community mobilisation activities in Bangladesh.<sup>26</sup>

Several other lessons emerged from the FIDELIS projects. An independent results assessment group visited selected projects to reflect on lessons learnt and sustainability of the interventions. One of the lessons in several locations was that regular supervision of activities, including analysis of routine programme data, may greatly improve case management. In this regard, a project using a district laboratory supervisor to help and support laboratory technicians in adjoining districts led to a marked improvement in slide quality and reading in Pakistan. The use of school-children to report TB suspects at home was one of the most innovative interventions, and was shown to be a cost-effective method of increasing the number of

suspects presenting for smear examination in China. In China the benefits of strengthening the referral routines for TB suspects was also shown.<sup>23,24</sup> A useful lesson that indicated only marginal effect was a project where the intervention was the involvement of the private sector.<sup>25</sup>

In summary, FIDELIS support of enhanced programme activities within routine TB control services resulted in a large number of additional cases detected within the project sites. Analysis of routine programme data provides some insight into the relative merit of the individual approaches and strategies. However, the small absolute number of projects and the non-standardised setting of the projects limits the conclusions that can be drawn as regards 'successful' and 'unsuccessful' interventions.

#### Acknowledgements

Funding for the FIDELIS initiative was provided by the government of Canada through the Canadian International Development Agency. The analysis component was also supported by a research grant from the World Lung Foundation.

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## R É S U M É

**CONTEXTE :** Des pays à fardeau élevé de tuberculose (TB) et à faibles revenus.

**OBJECTIF :** Comparer le dépistage des nouveaux cas de TB pulmonaire à bacilloscopie positive des frottis dans les projets financièrement soutenus en vue de l'application d'approches novatrices.

**SCHEMA :** Application prospective d'approches novatrices au dépistage au sein des services de routine pour déterminer le nombre de cas supplémentaires détectés et le coût par cas supplémentaire détecté au sein des services de routine en fonction du type d'approche appliquée au projet.

**RÉSULTATS :** Entre 2003 et 2007, 51 projets FIDELIS ont été mis en œuvre dans 18 pays ; ceux-ci ont signalé 273 239 cas, parmi lesquels 85 267 étaient en surcroît par rapport au nombre signalé l'année précédente. Le

coût moyen par cas additionnel est de 103 US\$. Les interventions utilisées ont été : 1) mobilisation et information sociales, éducation et communication ; 2) engagement du secteur privé ; 3) approches novatrices pour les services de microscopie ; 4) renforcement du dépistage ou dépistage semi-actif ; 5) renforcement des systèmes de santé ; et 6) utilisation d'incitants. Aucun de ceux-ci n'était significativement plus susceptible de détecter des cas additionnels ou d'avoir un coût plus faible par cas additionnel que n'importe lequel des autres.

**CONCLUSION :** Alors qu'on a noté une augmentation substantielle du nombre de cas détectés, à un coût modéré par cas supplémentaire, nous n'avons pas été en mesure de démontrer qu'une intervention individuelle quelconque présente un avantage sur les autres.

## R E S U M E N

**MARCO DE REFERENCIA:** Los países de bajos ingresos con alta carga de morbilidad por tuberculosis (TB).

**OBJETIVO:** Evaluar la búsqueda de casos nuevos de TB pulmonar con baciloscopia positiva en los proyectos financiados con el propósito de ejecutar enfoques innovadores.

**MÉTODO:** Se estudió la aplicación prospectiva de enfoques innovadores de búsqueda de casos de TB en los servicios ordinarios, con el fin de determinar el número de casos adicionales detectados y el costo por caso adicional, en función del enfoque aplicado en el proyecto.

**RESULTADOS:** Se ejecutaron 51 proyectos FIDELIS en 18 países entre el 2003 y el 2007, los cuales notificaron 273 239 casos, de los cuales 85 267 estaban en exceso con respecto al número comunicado el año anterior. La mediana del costo por caso adicional fue 103 dólares.

Las intervenciones aplicadas fueron: 1) las campañas de movilización social mediante la información, la educación y la comunicación; 2) el estímulo a la participación del sector privado; 3) la introducción de enfoques innovadores en los servicios de microscopía; 4) la intensificación o búsqueda semiactiva de casos; 5) el fortalecimiento de los servicios de salud; y 6) el uso de incentivos. Ninguna de estas estrategias presentó una probabilidad significativamente mayor de detectar casos adicionales ni tuvo costos más bajos por caso adicional detectado que las demás.

**CONCLUSIÓN:** Si bien se observó un aumento considerable en los casos detectados con un moderado costo adicional por caso, no se puso en evidencia la superioridad de ninguna de las intervenciones utilizadas.