Focus on Sciences **Original Article**

Aug 2017, Volume 3, Issue 3

Tuberculosis Control Program in Sistan: An Eligible Model of A Tropical Area: Environmental and Epidemiological Reasons for Tuberculosis Resistance

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DOI: 10.21859/focsci-03031427

Submitted: 02.18.2017

Accepted: 06.13.2017

Keywords:
Tuberculosis
Environment
Humans
Climate

Abstract

Introduction: Tuberculosis (TB) is known as an infectious disease with high burden from a long time. Various strategies are implemented to control its spread in the world and this study is to evaluate Tuberculosis Control Program in Sistan.

Methods: For this purpose we collected data with the methods of questionnaires, checklists, interviews, documentation review and observation. Using these methods together with data collection will boost the advantages of each single method. Data analyzed by using SPSS-18 software. We considered differences as significant at the level of $P < 0.05$.

Results: Effectiveness and Cost-Benefit considered as the priorities of TCPS evaluation. Current study showed TCPS reduced delayed time between case detection and treatment initiation to less than one week. TB incidence was 96 and 107 per 100,000 of population respectively in 2011 and 2012 i.e. one year before and after TCPS implementation. It increased case detection but SPSS Kruskal Wallis test showed there was not a significant change according to TCPS implementation ($P > 0.05$). It didn't have a significant change in patient destiny after implementation. From the each dollar we spend in TCPS implementation (COST), about 0.86 dollar was saved.

Conclusions: The reason why TCPS is not fully successful is because either the TB infected contacts were not screened or due to TCPS deviation from world health organization procedures. Current study showed from the each dollar we spend in TCPS implementation, about 0.86 dollar was saved.

INTRODUCTION

Tuberculosis (TB) is one of the main reasons of human mortality to this date and is cause by acid fast bacteria called *Mycobactrium tuberculosis* [1]. It particularly infects lungs, although other organ infections are also observed. Main symptoms of Tuberculosis are continuous fever and cough for more than two weeks [2]. More than 8.5 million new cases of TB were recorded in 2010 of which more than 95% were identified in developing countries and 65% in Asia [3]. Iran with the incidence of only 21 TB patients per 100,000 of the population is better compared to many of the other developing and Asian countries but its TB mortality is higher at about 0.11 per 100,000 annually in comparison [4]. Sistan is an area located in the east of Iran near Afghanistan border with a population of about 0.4 million and belonging to the Sistan and Baloochestan Province (31°1'43" N, 61°30'4" E). In this area tuberculosis is known as sad-disease with the incidence with about 100 per year and 195 patients per 100,000 per a year in Hirmand town [5]. World health organization (WHO) introduced a six components stop TB strategy for tuberculosis prevention, diagnosis, control and treatment in order to reach at one or less TB cases per million marking by 2050 [6]. Tuberculosis control program in have goals to attain 85% case detection, 90% successful treatment, 30% decrease of prevalence and mortality [7]. Implementation of this program was not sufficient

in Sistan because the problem of TB in Sistan is much greater than the national situation. Therefore the local health system designed a seven component tuberculosis control program called Tuberculosis Control Program in Sistan area (TCPS). This program is the strategy of TB controlling in Sistan area and it is running by Zabol health center since 2012. Tuberculosis elimination rate is so slow is Sistan just like throughout the world to reach the WHO targets. In this article we tried to compare effectiveness of TCPS with directly observed therapy in short course (DOTS) as an eligible model of tropical area in south east of Iran.

METHODS

In this retrospective study we have evaluated performance of Tuberculosis control program in Sistan area. This evaluation criteria was able to assess project achievements and impact [8]. Project Performance evaluation identified the level of performance we attained. In this study we collected data with the methods of questionnaires, checklists, interviews, documentation review and observation [9]. Using these methods together with data collection boosted the advantages of each single method and created more accurate results and we have got in depth, comprehensive and historical information. Data was analyzed by using Kruskal Wallis test of SPSS-18 software. We considered differences as significant at the level of $P< 0.05$.

Effectiveness

The effectiveness criterion contained all factors that can measure the project impacts, achievements, objectives and targets. Tuberculosis control program in Sistan contained seven main objectives and in this article we determined the quantity and quality of achievement in those objectives [10-12].

Quality Achievement Procedure

We studied if all seven components of tuberculosis control program in Sistan were running or not. Gathering the percentage of components implemented to quantify the achievement towards tuberculosis control targets [13].
For qualified evaluation of tuberculosis control program in Sistan, we used checklist with the questions about numbers and rate of program performance and success (Table 1) [14-16].

Table 1: The Effectiveness Criteria

Criterion	Indicator	Results
Timely Reporting	Proportions of TB cases reported to local health center within 1 working day	Duration between case detection and report less than 24 h Duration between case detection and definitely diagnosis less than 72 h Duration between diagnosis and treatment initiation less that 24 h
Program Capacity	Demonstrated ability (i.e., organization, staffing, resources and facilities) to carry out the core components of a TB control program.	Existing facilities and health center staffs were included into TCPS By public education, public reporting was added into reporting program
TB Case Rate	Number of TB cases identified per 100,000 people.	From 96 per 1 lakh in 2011 increased to 107 per 1 lakh in 2012
Complete Reporting	Proportion of cases with complete data on key variables (i.e., homelessness, injecting drug use, non-injecting drug use, excess alcohol use)	Patients variables such as home location, family members and material abuse were recorded for all patients
Culture Identification	Proportion of pulmonary or laryngeal TB patients > 12 years of age with sputum culture obtained.	All TB suspected patients' sputum smear were obtained. Tuberculosis diagnosis was confirmed with microscopy not by culture.
Recommended Initial Therapy	Proportion of TB patients started on the recommended 4-drug regimen.	All patients (positive or MDR) had received world health organization recommended treatment in DOTS protocol.
Timely Treatment	Proportion of sputum smear-positive pulmonary or laryngeal TB patients initiating treatment in < 7 days of specimen collection.	Duration between diagnosis and treatment initiation decreased less that 24 h Diagnosis average delay decreased from 70 days in 2011 to 50 days in 2012
Culture Conversion	Proportion of sputum culture-positive TB patients with documented conversion to sputum culture-negative after initiation of treatment.	This item is not implemented by TCPS
Appropriate directly observed therapy (DOT)	Proportion of TB patients for whom DOT is recommended and who receive DOT throughout the course of treatment.	All patients received direct observed therapy
Inappropriate Self Administered Therapy (SAT)	Proportion of TB patients for whom DOT is recommended but who received inappropriate SAT throughout the course of treatment.	No patient
Timely Completion of Therapy	Proportion of TB patients who complete treatment in < 12 months.	242 (56.5%) of successful treatment completed in less than 12 months
Default From Treatment	Proportion of TB patients who default prior to completing treatment.	21 (4.9%) treatment interruption 2 (0.5%) stopped of treatment midway
Contact Identification	Proportion of sputum smear-positive cases with at least one contact identified.	This criteria is not evaluated in TCPS
Contact Evaluation	Proportion of identified contacts to smear-positive cases who complete evaluation for TB infection or disease.	This criteria is not evaluated in TCPS
Contact Treatment Initiation	Proportion of infected contacts to pulmonary cases who started treatment for LTBI.	This criteria is not evaluated in TCPS
Contact Treatment Completion	Proportion of infected contacts to pulmonary cases who have started on treatment for LTBI complete treatment.	This criteria is not evaluated in TCPS
Pediatric TB Cases	Number of TB cases in children 0-4 years old.	They were 9 cases before and 8 cases after TCPS implementation in 2011 and 2012 respectively.
TB Deaths	Number of persons who die of TB.	26 (6.1%) deaths

Cost-Benefit

With the use of checklist, and documented bill study, cost of all seven strategies estimated and compared with total strategy benefit to calculate benefit-cost ratio (BCR) [17-23].

$$BCR=(\sum_{r}^{r}=1\ B_t/(1+\&r)^t)/(\sum_{r}^{r}=1\ B_t/(1+r)^t) \quad (1)$$

Benefit

As no certain benefit was defined for each component of TCPS, total benefit (B) of whole program that is TB burden decline is considered. The number of morbidity and mortality decreased in one year after implementing program in comparison with one year before, demonstrated how much effective it was. For calculating the benefit of this program we considered decrease of disability-adjusted life year (DALY) and its influence on gross domestic production (GDP). GDP per capita in Iran is about 7,228 USD.

$$B=DALY\times GDP \quad (2)$$

DALY is equal summation of 2 components called years of life lost (YLL) and years lived with disability (YLD).

$$DALY=YLL+YLD \quad (3)$$

YLL was calculated from multiplying years of life expectancy by number of death in a period of time corresponding to gender. Years of life expectancy is 74 years in Iran.

$$YLL=N\times L \quad (4)$$

In YLD equation, I refers to the incidence, d refers to the duration and DW refers to the disability weight. Tuberculosis weight was estimated about 0.271 and TB incidence in area in one year period considered.

$$YLD=\sum I\times d\times DW \quad (5)$$

Cost

The summation of S1-7 costs demonstrated total program cost (Table 2).

RESULTS

Tuberculosis control program in Sistan area contained 7 strategies shown with the abbreviations of S1-S7. This strategy's main target was to increase TB case detection and successful treatment (Table 3). The TCPS plan was to provide more facilities for efficient prevention, case detection, diagnosis and treatment such as new laboratory tools, transportation vehicles, new workers, medicine carriers and storage. Implementation of TCPS starts with about 50% of estimated needs to be fulfilled with existing facilities in the beginning of 2012.

Table 2: The Tuberculosis Control Program in Sistan Financial Table

Component	Cost Area	Cost
S 1	Workshops Face to face training Poster, pamphlet, television program	31,00
S2	Active case finding SS+: 3 sputum samples + sample carrier + transportation + health provider SS-: 6 sputum samples + sample carrier+ CXR+ ESAB (expanded spectrum antibiotics) transportation+ health provider PTC (pediatric TB case) Forms and cards	5,100
S3	Medicine + transportation + health provider	750 (The medicine is provided with no cost for Sistan Health Center)
S4	Health provider's income	30,330
S5	TB in charge physician for each of three town health centers, Slid smear quality control, encouragement prize for each TB detected case, forms and bags	16,500
S6	Didn't start yet	0
S7	Health provider's income, forms	130
Total		83,910

Abbreviation: S, strategy.

Table 3: The Tuberculosis Control Program in Sistan Components and Programs Achievements

Component	Targets and Programs	Results
S1 (Education and information)		
	Education needs evaluation and define training priorities	Implemented
	Society needs evaluation	Implemented
	Empowering with knowledge, attitude and performance in ordinary people, health providers and health center (TCPS) doctors in Sistan area.	Implemented
S2 (Active case finding)		
	In the infected families, TB suspected case's sputum has to be examined.	Implemented
	The status of TB suspected patient who had 3 negative sputum smear result should be identified.	Implemented
S3 (Direct observed treatment)		
	All diagnosed patient (pulmonary TB smear positive, pulmonary TB smear negative and extra pulmonary tuberculosis) should receive correct treatment.	Implemented
	All Multi drug resistant tuberculosis (MDR-TB) patients should receive standard treatment. (proper national recommended drug regimen)	Implemented
	All the TB patients (smear positive and MDR-TB specially) receive treatment of WHO DOTS procedure.	Implemented
S4 (Epidemiologic care)		
	Creation of information gathering forms required for the project	Implemented
	Giving health cards to families after filing their information.	Implemented
	Determining epidemiologic conditions in the area.	Implemented
	Determining hotspots of the area.	Implemented
	Determining week areas of the diagnosis and treatment aspect.	Implemented
	Determination of high risk groups.	Implemented
	All data have to be collected and analyzed.	Implemented
S5 (Support and empower basis of screening, training and treatment)		
	Management (managing and monitoring) structure should be build and it should remain till end of the project.	Implemented
	Provide for project needs and facilities.	Implemented
S6 (Research)		
	Research about TB disease during the project and about the project outcomes.	Not Implemented
S7 (Monitoring and evaluation)		
	Project performance evaluation during and after project.	Initiated
	Providing evaluation checklists	Not Implemented

.Abbreviation: S, strategy

Effectiveness

Quantity Achievement Procedure

In the first year of implementation they could run about 17 programs (85%) quantitatively. The Implemented programs are declared in Table 3.

In the first year, five professional and public workshops and training courses held by TCSP center in the aim of increasing total awareness about TB. TCPS reduce the period between case detection and report less than 24 h, time of case detection until diagnosis by less than 72 hours, decrease period between diagnosis and treatment initiation by less than 24 hours, increase new case findings to 44 more patients. Diagnosis average delay decreased from 70 days in 2011 to 50 days in 2012. No culture obtained of the patient's sputum and diagnosis approved by sputum smear microscopy. TB incidence was 96 and 107 per 100,000 of population respectively in 2011 and 2012 i.e. one year before and after TCPS

implementation. As one new TB case is reported, TB infected contact started by monitoring all family member symptoms. Friends and colleagues weren't considered as contact in this program. The TB suspected contacts treatment initiated as a normal TB suspected cases. All of the TB infected patient's treatment was observed by TCPS center. All patients receive recommended 4 drug regimen except sensitive groups containing children under six years old, patients with drug induced hepatitis and patient with weight less than 30 kg. For the last sensitive group exact needed dosage of each medicine out of four calculated and prescribed by TCPS center physicians. All of the patients reported from private clinics or TCPS center, got direct observed therapy (DOT) from TCPS center. All of them followed from treatment initiation until treatment termination, except who traveled out of Zabol or missed without report, for example afghan refugees who return back to their country.

The total new TB cases were 384 one year before TCPS implementation and 428 one year after TCPS implementation. Treatment result and patient destiny reported in 7 groups contained of 242 (56.5%) of successful treatment completed in less than 12 months, 136 (31.8%) unsuccessful treatment, 26 (6.1%) deaths, 21 (4.9%) treatment interruption, 2 (0.5%) stopped of treatment midway, 1 (0.2%) transported inside or outside country and 0 (0%) were reported others in 2012 in comparison with 217 (56.5%), 130 (33.8%), 20 (5.2%), 12 (3.1%), 4 (1.1%), 1 (0.3%), 0 (0%) respectively in 2011 (Fig 1).

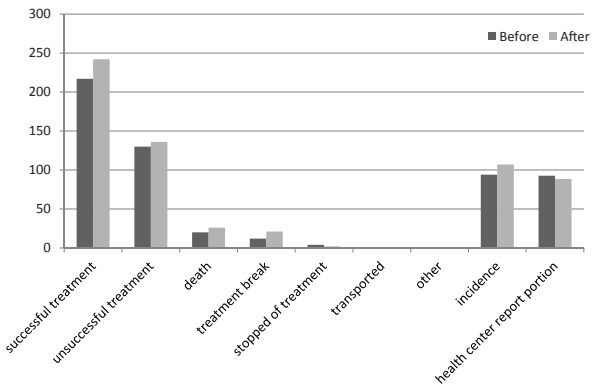

Figure 1. Tuberculosis Situation Before and After TCPS Implementation

The TCSP center reported 92.6% and 88.4% of new TB cases in 2011 and 2012 respectively. Therefore the real number of new TB cases detected by TCPS center were 355 one year before TCPS implementation and 378 one year after TCPS implementation. The pediatrics cases patients who aged between 1-4 years old were 9 in 2011 8 and in 2012.

Explaining in detail the figures of the TCPS role in patient destiny in 2011 and 2012 i.e. before and after TCPS implementation is as follows. Increase in successful treatment cases from 201 to 214, death cases from 18 to 23, treatment interruption cases from 11 to 19 and transported cases inside or outside country from 1 to 2. Decrease in treatment stop cases from 4 to 2. No change in figures of other conditions i.e. constant at 1 and unsuccessful treatment cases constant at 120 (Fig 2).

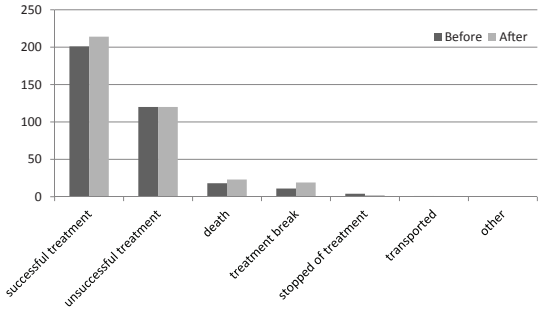

Figure 2. Health Center Rule in TB New Case Detection

Although the TB close contacts' sputum were obtained for laboratory diagnoses, but the close contact was considered as a TB suspected case. Therefore no data was recorded about contacts and infected contacts with positive laboratory results were treated without prejudice.

The Kruskal Wallis test done using SPSS18 software showed there were no significant difference in total new TB cases numbers and destiny in 2012 in comparison with 2011 (P value > 0.05). The Kruskal Wallis test done using SPSS 18 software showed there was no significant difference in number and destiny of new TB cases detected by TCPS center in 2012 in comparison with 2011 (P value > 0.05).

Cost-Benefit

Current study showed from the each dollar we spend in TCPS implementation (COST), about 0.86 dollar was saved (BENEFIT).

Benefit

Case detection was more accurate after TCPS implementation therefore in one year of TCPS, 44 more cases were detected which is preventing severe complication and mortality in unknown TB cases group. Thus 10 years were saved from disability in total. Mortality rate was decreased from 20 before program implementation to 26 after it which is a sign of increased severity, complication and obviously deaths. Therefore no benefit in saving lives was achieved. The total benefit is raised from summation of YLL and YLD which was equal 10 years and worth 72,280 USD.

Cost: The TCPS cost is the money which was spent for program strategies enrollment. Totally 83,910 USD was spent in one year TCPS implementation. The cost areas description is provided in Table 2.

DISCUSSION

Tuberculosis control program in Sistan (TCPS) was introduced to control and eliminate tuberculosis from a tropical area located in the SouthEast of Iran. After one year, 85% of TCPS was enrolled. The main achievements were reduction the time duration between case detection and diagnosis to 72 hours and from diagnosis till treatment to 24 hours. Unexpectedly the mortality and treatment interruption had increased after program implementation. Moreover the project

was not beneficial financially. Although the total TB reported cases increased in 2012 in comparison with 2011 but there was no significant change for TB patient destiny and incidence after TCPS implementation so we can conclude active case detection was not successful in improving the situations. Moreover we observed that mortality rate which is a good sign of disease severity had increased therefore along with increased incidence we assumed that the disease severity had increased. Thus, although TCPS didn't mitigate TB but still it kept the epidemiologic situation stable.

An epidemiological study of Yang et al. showed the tuberculosis incidence and related burden was decreased in wenchuan earthquake-stricken area from 2004-2012 [24]. Lin et al. in a study on TB mortal cases showed that patients with inappropriate organ function were in the risk of septicemia and fatality [25]. The Human Immunodeficiency Virus infection is another [26] related risk factor. The tuberculosis mortality rate is different from 7-35% in the world therefore Sistan had a good situation in this aspect [26]. Hamusse et al. showed 214 people per lakh had confirmed TB in Ethiopia which is two times more than Sistan situation. Moreover close contact exposure especially in family was introduced as a major risk factor [27]. The contacts are the main carriers of *Mycobactrium tuberculosis* and hence we didn't start treating them, we have to expect TB spread in the area. Our study showed that NTCP focus is just on TB case detection and patient treatment and there is no significant program for TB infected contact screen in Sistan. Therefore the main way of TB transmission remained untreated. The secondary attack rate is one of the main criteria showing disease spread, but its evaluation was not considered in the TCPS. According to this problem, increased TB cases could be related to infected contacts and related disease transmission in 2012.

The total TB cases increase could be a sign of total TB growth and spread of TB in the area or It could be related to TB social awareness and increase in case detection at private clinics. The percentage of new TB cases reported by the TCPS center decreased after TCPS implementation in 2012 in comparison with one year before. It could be the result of awareness in society about TB caused by the TCPS training strategy. But it shows the TB suspected cases were seeking treatment from private clinics; so it shows that patients did not trust on the TCPS system. This is because there is no strategy or effort in TCPS to encourage people to trust TCPS system. In the current situation the patient will be confused between different health care providers. This will result in loss of time and money for the patient and put a burden on the society. Most of patients who are villagers and don't want to be identified and labeled as "INFECTED" in their small society, so they try to hide from TCPS which lacks certain level of discreteness in terms of patient's privacy. This is another reason we observe why patients tend towards private clinics.

During document study and interview with TCPS workers, we observed that the term DOTS is knows only as direct observation of treatment in short course chemotherapy, while DOTS is the first component of a six component strategy called the stop TB strategy introduced by world health organization. Despite DOTS is not implemented properly, but the main priority of DOTS i.e. direct observation of treatment is implemented as the main targets of TCPS. This could be one of the reasons of TCPS progress. The access of TB care providers to international TB programs in their local language could remove extra cost in the fields of trial and error and planning alternative programs [28].

The TCPS screened whole Sistan area except Zabol city (the biggest city of this area) and it could be one of TB spread causes. The only new cases reported from Zabol city was from private clinics. Therefore the new cases real number should be more than what we reported, and we are expecting incidence increase after Zabol city program.

In this project we evaluated the TCPS only in one year period. Perhaps it could be effective in a long term period. But time and energy will be wasted in this way. We are suggesting TB screen in the societies with high TB burden and low population in order to effective disease elimination.

Declaration of Conflicting Interests: Authors declare no potential conflicts of interest.

ACKNOWLEDGMENTS

The authors would like to thank all who participated in this study and especially tuberculosis centers of Zabol, Hirmand and Hamoun.

ETHICAL STATEMENT

Patient documents remained secure in this study according to the Zabol University of Medical Sciences ethical laws.

CONFLICTS OF INTEREST

Authors' declare that there is no conflicts of interest for the present study.

FINACIAL

Authors declare they have no funding resource.

AUTHORS' CONTRIBUTION

Atefeh Sargazi presented the study idea. She collaborated in study design with Zahra Sepehri and Prigil Kumar Nadakkavukaran Jim. Aliyeh Sargazi collected data and Prigil Kumar Nadakkavukaran Jim wrote the manuscript.

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